HEALTH TECHNOLOGY ASSESSMENT

VOLUME 23 ISSUE 14 MARCH 2019
ISSN 1366-5278

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NHS
National Institute for Health Research

DOI 10.3310/hta23140

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Declared competing interests of authors: Luke Vale is a member of the National Institute for Health Research Health Technology Assessment Clinical Evaluation and Trials Board and co-ordinating editor of Cochrane Incontinence. Ash Monga was a paid speaker for Astellas Pharma (Tokyo, Japan), SEP Pharma Ltd (London, UK), Boston Scientific (Boston, MA, USA) and Atlantic Pharma Ltd (Bedford, UK). Phil Mackie is a member of the Scottish Independent Review of Transvaginal Mesh Implants.

Published March 2019
DOI: 10.3310/hta23140

This report should be referenced as follows:

Brazzelli M, Javanbakht M, Imamura M, Hudson J, Moloney E, Becker F, *et al*. Surgical treatments for women with stress urinary incontinence: the ESTER systematic review and economic evaluation. *Health Technol Assess* 2019;**23**(14).

Health Technology Assessment is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE, *Science Citation Index Expanded* (SciSearch®) and *Current Contents®*/ Clinical Medicine.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.513

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 15/09/06. The contractual start date was in August 2016. The draft report began editorial review in December 2017 and was accepted for publication in July 2018. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Surgical treatments for women with stress urinary incontinence: the ESTER systematic review and economic evaluation

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Background: Urinary incontinence in women is a distressing condition that restricts quality of life and results in a large economic burden to both the NHS and women themselves.

Objective: To evaluate the clinical effectiveness, safety and cost-effectiveness of surgical treatment for stress urinary incontinence (SUI) in women and explore women's preferences.

Design: An evidence synthesis, a discrete choice experiment (DCE) and an economic decision model, with a value-of-information (VOI) analysis. Nine surgical interventions were compared. Previous Cochrane reviews for each were identified and updated to include additional studies. Systematic review methods were applied. The outcomes of interest were 'cure' and 'improvement'. Both a pairwise and a network meta-analysis (NMA) were conducted for all available surgical comparisons. A DCE was undertaken to assess the preferences of women for treatment outcomes. An economic model assessed the cost-effectiveness of alternative surgeries and a VOI analysis was undertaken.

Results: Data from 175 studies were included in the effectiveness review. The majority of included studies were rated as being at high or unclear risk of bias across all risk-of-bias domains. The NMA, which included 120 studies that reported data on 'cure' or 'improvement', showed that retropubic mid-urethral sling (MUS), transobturator MUS, traditional sling and open colposuspension were more effective than other surgical procedures for both primary outcomes. The results for other interventions were variable. In general, rate of tape and mesh exposure was higher after transobturator MUS than after retropubic MUS or single-incision sling, whereas the rate of tape or mesh erosion/extrusion was similar between transobturator MUS and retropubic MUS. The results of the DCE, in which 789 women completed an anonymous online questionnaire, indicate that women tend to prefer surgical treatments associated with

no pain or mild chronic pain and shorter length of hospital stay as well as those treatments that have a smaller risk for urinary symptoms to reoccur after surgery. The cost-effectiveness results suggest that, over a lifetime, retropubic MUS is, on average, the least costly and most effective surgery. However, the high level of uncertainty makes robust estimates difficult to ascertain. The VOI analysis highlighted that further research around the incidence rates of complications would be of most value.

Limitations: Overall, the quality of the clinical evidence was low, with limited data available for the assessment of complications. Furthermore, there is a lack of robust evidence and significant uncertainty around some parameters in the economic modelling.

Conclusions: To our knowledge, this is the most comprehensive assessment of published evidence for the treatment of SUI. There is some evidence that retropubic MUS, transobturator MUS and traditional sling are effective in the short to medium term and that retropubic MUS is cost-effective in the medium to long term. The VOI analysis highlights the value of further research to reduce the uncertainty around the incidence rates of complications. There is a need to obtain robust clinical data in future work, particularly around long-term complication rates.

Study registration: This study is registered as PROSPERO CRD42016049339.

Funding: The National Institute for Health Research Health Technology Assessment programme.

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Report Supplementary Material 1 Direct pairwise meta-analysis results for adverse events and resource utilisation

Supplementary material can be found on the NIHR Journals Library report project page (www.journalslibrary.nihr.ac.uk/programmes/hta/150906/#/documentation).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

Glossary

Anterior vaginal repair A surgical treatment used to treat stress urinary incontinence by lifting and supporting the bladder. One or more placating sutures are used to secure the fascia, which elevates the bladder neck and urethra.

Bladder neck needle suspension A procedure usually performed on women for whom colposuspension is considered challenging, including women with limited vaginal mobility. The bladder neck is elevated with a long needle that threads sutures from the vagina to the anterior abdominal fascia.

Laparoscopic colposuspension A relatively minimally invasive surgery that requires one or more small incisions through the lower abdomen. The aim is also to lift the junction between the urethra and the bladder.

Open retropubic colposuspension A procedure during which a large incision is made in the lower abdomen to lift and stitch up the tissues near the bladder neck and urethra.

Retropubic mid-urethral sling operation Mid-urethral sling surgery during which a tape or sling is placed underneath the urethra. The surgery is retropubic as the sling incision is made through the vagina with two other incisions made through the lower abdomen.

Single-incision sling operation An operation similar to a mid-urethral sling procedure in that it supports the urethra through the use of a sling. There is a single access made through the vagina and the sling is shorter than that used in mid-urethral sling procedures, making it a less invasive procedure than other slings.

Traditional suburethral sling procedure A procedure that improves urethral support by lifting the urethra–vesical junction and supporting it with autologous or synthetic material.

Transobturator mid-urethral sling operation Mid-urethral sling surgery that is considered to be transobturator if one incision is made through the vagina and an incision is made on either inner thigh.

Urethral injection therapy (periurethral injections or injectable bulking agents) A procedure in which high-pressure devices are required to advance the agents through the bladder neck. Once this is done, the bulking agents are intended to create cushions within the urethral submucosa.

List of abbreviations

AIC	Akaike information criterion
AMND	Aberdeen Maternity and Neonatal Databank
ASC	alternative specific constant
BIC	Bayesian information criterion
BNF	*British National Formulary*
CCA	cost–consequences analysis
CEA	cost-effectiveness analysis
CEAC	cost-effectiveness acceptability curve
CENTRAL	Cochrane Central Register of Controlled Trials
CI	confidence interval
CR	ceiling ratio
CRD	Centre for Reviews and Dissemination
CrI	credible interval
CRS	Cochrane Register of Studies
CRSO	Cochrane Register of Studies Online
DCE	discrete choice experiment
EQ-5D	EuroQol-5 Dimensions
EVPI	expected value of perfect information
EVPPI	expected value of partial perfect information
GP	general practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HCHS	hospital and community health services
HES	Hospital Episode Statistics
ICER	incremental cost-effectiveness ratio
ICTRP	International Clinical Trials Registry Platform
ID	identifier
IIA	irrelevant alternatives assumption
IRR	incidence rate ratio
LR	likelihood ratio
MCMC	Markov chain Monte Carlo
MM	Markov microsimulation
MRS	marginal rates of substitution
MUI	mixed urinary incontinence
MUS	mid-urethral sling
MXL	mixed logit
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Health and Care Excellence
NMA	network meta-analysis
NMB	net monetary benefit
OR	odds ratio
PFMT	pelvic floor muscle training
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSA	probabilistic sensitivity analysis
PSS	Personal Social Services
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RR	relative risk
SA	sensitivity analysis
SD	standard deviation
SMD	standardised mean difference
SUCRA	surface under the cumulative ranking curve
SUI	stress urinary incontinence
TOT	transobturator tape

TVT	tension-free vaginal tape	UUI	urge urinary incontinence
TVT-O	tension-free vaginal tape-obturator	VOI	value of information
UI	urinary incontinence	WHO	World Health Organization
UTI	urinary tract infection	WTP	willingness to pay

Plain English summary

Urinary incontinence, defined as involuntary leakage of urine, is a common condition that varies in type and severity and can have a huge impact on the quality of life of women. The aim of this project was to summarise the evidence on the clinical effectiveness, safety and cost-effectiveness of nine surgical operations for stress urinary incontinence in women and assess the need for further research. Women's preferences for surgery were also explored. Currently there is no agreement among decision-makers, doctors and patients about which of the available surgical operations is best.

Based on previous Cochrane reviews, the effects and safety of each operation were systematically reviewed and analysed. Their cost-effectiveness and the value of conducting further research were also evaluated. To better understand the preference of women, an online survey containing a discrete choice experiment was conducted. Finally, patient representatives were consulted to help us to understand the consequences of the findings from a patient's perspective.

The evidence on surgical operations was predominantly short to medium term (up to 12 months). This analysis found that the quality of the evidence varied, with the majority of trials being subject to high or unclear risk of bias, making the conclusions that can be drawn less robust. The findings of the clinical evidence review suggest that retropubic sling procedures, transobturator sling procedures and traditional sling procedures are more effective than other surgical procedures for both 'cure' and 'improvement' of stress urinary incontinence. The results of the economic analyses support these findings, suggesting that retropubic mid-urethral sling is the most cost-effective surgical operation. However, data on complications were lacking, limiting any strong conclusions. The results suggest that there is value in undertaking further research to reduce the uncertainty around the medium- to long-term complications of all surgical treatments and this was reflected in patients' views.

Scientific summary

Background

Urinary incontinence (UI) in women is a distressing and common condition that impairs quality of life and results in a large economic burden to both the NHS and women themselves. The prevalence of UI varies during life but is high in women who have had children and in older women (20–50%). The incidence of stress urinary incontinence (SUI) increases following menopause because of lowered oestrogen levels. Many women access conservative treatment with physiotherapy to deliver pelvic floor muscle training (PFMT) and bladder training initially but, if this fails, surgery is the mainstay of treatment.

Incontinence varies in degree of severity from several drops of urine to complete bladder emptying. It may occur daily, many times a day or only occasionally, perhaps once a month or related to a certain activity. It may be predictable or very unpredictable. These different factors – severity, frequency and predictability – all play a role in evaluating the impact of incontinence on behaviour, treatment choice, quality of life and economic burden. The precise economic burden has proved difficult to calculate.

There are several surgical treatment options for the management of women with SUI, with many variations on most options, but, essentially, they fall into nine distinct categories: anterior vaginal repair; bladder neck needle suspension; open abdominal retropubic colposuspension; laparoscopic retropubic colposuspension; traditional suburethral retropubic sling procedures; mid-urethral sling (MUS) procedures, comprising two distinct categories (retropubic MUS and transobturator MUS); single-incision sling procedures (‘mini-slings’); and periurethral injection (injectable bulking agents).

The high failure rates of early surgical techniques led to the development of colposuspension, but this approach, though efficacious, was associated with greater morbidity and a longer recovery time. The development of laparoscopic colposuspension, a more minimally invasive variation of colposuspension, was considered slightly less effective than the open surgery, but reduced morbidity and length-of-stay outcomes. Innovation and unmet need led to the development of traditional suburethral sling procedures in which a piece of material, which could be biological or synthetic, is placed under the urethra and the free ends secured in one of a number of different ways. The advent of a new minimally invasive technique that enabled the sling/mesh to be placed without tension ushered in a new era of simpler, potentially effective and cheaper treatment.

The number of women having surgery has increased and the choice of operation has changed over the last decade. In 2013–14, Hospital Episode Statistics (HES) data for England show that around 12,000 women had a MUS operation, with around 500 having another type of continence procedure (colposuspension ≈300, traditional slings ≈200) and just over 700 having periurethral injections. In contrast, 10 years earlier just under 7000 women had a MUS operation and ≈1400 had a colposuspension and ≈250 had a traditional sling. Records of how many vaginal mesh implants are implanted or removed per year in women with SUI are scant. However, until recently it would appear that the trend has shifted to the majority of women having a minimally invasive MUS, which in turn has led to a substantial increase in the total number of women having continence surgery. These trends are likely to be driven, in part, by the perception of improved effectiveness and safety. However, over the past decade safety concerns raised by patients over mesh implants have been growing. These concerns led to a patients’ campaign, which was followed by a non-mandatory recommendation by the Scottish Government not to use mesh implants. An independent enquiry followed within Scotland and the suspension of use of any vaginal mesh (including MUSs) was maintained, with UK parliamentary questions, a mandatory national audit and a national campaign, Hear Our Voice, joining the discussions. The debate encompasses the wider use of vaginal mesh in conditions not being considered in this report. There remains a lot of uncertainty surrounding the optimal choice of surgery,

especially related to long-term safety, with recent news and media headlines adding to the ambiguity faced by all involved. What is unclear is the strength of evidence to support the choice of any one surgery over another.

Objectives

The aim of this project was to evaluate the clinical effectiveness, safety and cost-effectiveness of surgical treatments for SUI and stress-predominant mixed urinary incontinence (MUI) in women based on published evidence.

The key objectives were to:

- undertake an evidence synthesis using systematic review methods, including a network meta-analysis (NMA) to estimate the relative clinical effectiveness of the different types of surgery
- undertake a review of safety/adverse effects associated with each type of surgical intervention
- develop a decision model to estimate the cost-effectiveness of surgical treatments for SUI and stress-predominant MUI
- utilise the decision model to undertake a value-of-information (VOI) analysis to assess the need and focus of further primary research
- undertake a discrete choice experiment (DCE) to explore the preferences of women.

Methods of the clinical effectiveness review

A systematic review was undertaken to evaluate the effectiveness and safety of surgical treatment options for SUI. The Cochrane Incontinence Group has published eight systematic reviews assessing nine distinct surgical procedures for the treatment of SUI in women. These existing Cochrane systematic reviews form the foundation of our work and were used to identify studies that meet our prespecified inclusion criteria. An additional search of the Cochrane Incontinence Group Specialised Trials Register was performed (date of last search 8 June 2017) to identify additional trials that met our inclusion criteria but had not been included in the published Cochrane reviews.

To be eligible for inclusion, studies had to compare two or more of the surgical interventions listed above. Studies that compared a surgical intervention with PFMT were also considered suitable for inclusion. The primary effectiveness outcomes of interest were the number of women cured (defined as resolution of clinical symptoms) and the number of women improved (defined as any improvement in clinical symptoms from baseline). Standard systematic review methods were applied. Both pairwise and network meta-analyses were undertaken for the primary outcomes. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was adopted to assess the quality of evidence of the primary outcomes. A number of adverse effect outcomes were also evaluated (i.e. repeat continence surgery, de novo symptoms of urgency or urgency incontinence, bladder or urethral perforation, tape/mesh extrusion or exposure, pain, infection and death) as well as outcomes assessing use of resources (i.e. length of hospital stay and operation time). Pairwise meta-analyses were undertaken for these outcomes.

Results of the clinical effectiveness review

Data from 175 studies were included in the review; 147 were from the Cochrane reviews and 28 were from additional searches. The included studies reported 21 treatment comparisons; the majority involved MUSs (retropubic or transobturator) as part of their interventions ($n = 97$). Open colposuspension versus other surgery was another common comparison (46 studies), followed by laparoscopic colposuspension (21 studies) and traditional sling (20 studies). Only one study comparing injectable bulking agents with

traditional slings was identified. The majority of included studies had high or unclear risk of bias across all risk-of-bias domains, but most notably for allocation concealment (selection bias).

The NMA, which combined evidence from direct head-to-head comparisons and indirect comparisons, included 120 studies that reported data on 'cure' or 'improvement'. The results suggest that retropubic MUS and transobturator MUS are more effective than other surgical procedures for both primary outcomes. Direct evidence was available mainly for the comparisons involving retropubic MUS, transobturator MUS or single-incision sling. Follow-up time was generally short (median of 12 months). However, assessment of adverse events for all procedures was hampered by sparse data. Transobturator MUS had a higher rate of further SUI procedures than retropubic MUS but a lower rate compared with single-incision sling. Rate of tape and mesh exposure was higher after transobturator MUS compared with after retropubic MUS or single-incision sling, whereas the rate of tape or mesh erosion or extrusion was similar between transobturator MUS and retropubic MUS. Retropubic MUS had a higher rate of major vascular complications, voiding difficulties and bladder or urethral perforation than transobturator MUS but a lower rate of groin pain. Rate of postoperative pain was higher after retropubic than single-incision sling whereas rate of unspecified 'pain' was higher after transobturator MUS than single-incision sling. Rate of infection (including urinary tract infection, wound infection and infection related to mesh) was similar between single incision sling and transobturator MUS.

Methods of the discrete choice experiment

An online survey containing a DCE was designed to explore women's preferences for different aspects of surgical treatments. Five attributes framed the hypothetical scenarios: adverse events, chronic pain, length of hospital stay, time to return to normal activities, and risk of recurrence during 12 months after surgery. The analytic approach considered conditional and mixed logit models to account for preference heterogeneity.

Discrete choice experiment results

Responses from a general population sample of women (n = 789) were collected by means of an online survey. The sample consisted of 436 non-patients and 353 patients with one or more types of UI. Results suggest that women in general would prefer a surgical treatment over no surgery. This preference was stronger for patients but was mediated by the respondent's health status. As expected, respondents preferred shorter hospital stays and surgical treatments that were associated with a lower risk of recurrence. Whereas preferences for chronic pain did not vary between groups, patients appeared to care less about adverse events and more about a shorter period to return to normal activities. Infections and pain during intercourse were preferred to the reference category of new urinary symptoms, whereas damage to organs or nerves and voiding difficulties were less preferred.

Methods of the cost-effectiveness model

The review of cost-effectiveness studies identified 17 published modelling studies. However, none of the published models was deemed robust enough to be used within this analysis. Therefore, a new cost-effectiveness model was developed to assess the cost-effectiveness of the different surgical techniques and estimate the VOI to help inform decisions about further research. The model took a lifetime horizon and an NHS and personal social services perspective. A Markov microsimulation (MM) model, with 3-monthly cycles, was developed in TreeAge Pro® (TreeAge Software, Inc., Williamstown, MA, USA). Quality-adjusted life-years (QALYs) and costs were discounted at an annual rate of 3.5%. The model assumes that patients can receive a maximum of three surgical treatments for the treatment of SUI.

The main probabilities for the model were the success rates of the different interventions (i.e. subjective cure), rates of retreatment, complications/adverse events and mortality rates. The clinical evidence was based on the results of the systematic NMA. Long-term effectiveness estimates were extrapolated from these data. EuroQol-5 Dimensions (EQ-5D) utility estimates were derived from UK studies; however, utility decrements for complications were only available from a study based on elicitation from experts. Both deterministic and probabilistic sensitivity analyses were used to explore uncertainty surrounding estimates of cost-effectiveness.

Cost-effectiveness, expected value of perfect information and expected value of partial perfect information results

Over a lifetime time horizon, retropubic MUS is, on average, the least costly (£8099) and the most effective (24.22 QALYs) surgical treatment. With the exception of traditional sling, all other surgical treatments are dominated as they are more costly and less effective than retropubic MUS. Similarly, over a shorter time horizon (10 years), retropubic MUS remains the dominant strategy.

Over a lifetime time horizon, retropubic MUS has a > 26% probability of being cost-effective at a willingness to pay (WTP) threshold value of £20,000. Given the number of comparators, if all of the interventions were comparable we would expect each to have an 11% chance of being cost-effective. The only other strategies with reasonable size probabilities of being cost-effective are traditional sling (≈27% across all WTP values presented, suggesting little difference between retropubic MUS and traditional sling) and open colposuspension (≈14–16% across all WTP thresholds > £10,000). All other strategies have a < 10.5% probability of being cost-effective across all WTP values presented.

Seventeen individual sensitivity/scenario analyses were carried out on the base-case model results.

The expected value of perfect information (EVPI) per woman per year is £11,180. The EVPI for the population was also estimated based on an assumed 15,000 surgical interventions for SUI in the UK each year. Therefore, the population EVPI for 1 year is estimated to be £167.7M. Expected value of partial perfect information (EVPPI) analyses were conducted to estimate the value of removing uncertainty around particular parameters/groups of parameters. The largest value appears to be in removing uncertainty around the complications incidence rates, relative treatment effectiveness and health utility values.

Conclusions

The evidence for the effectiveness and safety of surgical treatments for SUI is limited, making robust conclusions difficult to draw. Overall, studies were rated as being at a high or unclear risk of bias. The NMA based on cure and improvement suggested that retropubic MUS, transobturator MUS and traditional sling were more effective, but this ranking does not consider the complication profile of these techniques. The short- to medium-term adverse event data were sparse. The DCE found that although women with a treatment history had a negative preference for surgical treatments, those with forms of UI that were extremely or moderately limiting in daily activities preferred a surgical treatment option. Further research investigating a woman's choice for or against surgery needs to explore treatment history in greater detail while considering more individual characteristics, including personal beliefs and perceptions that may act as a barrier to seeking professional advice. The economic model suggests that retropubic MUS is the most cost-effective technique based on the current evidence base, although sensitivity analysis to increase mesh complication rates and persistent pain after mesh surgery made traditional sling the more cost-effective option. The VOI analysis supports the need for further research to reduce the current uncertainty around complication rates. The wider literature and recent independent reviews have also highlighted the lack of robust adverse event long-term data.

Recommendations for research

Further robust evidence is required on long-term adverse effects and quality of life. Trials to ascertain these data may not be feasible; it would be more realistic to promote awareness as well as adequate reporting and monitoring of complications among surgeons and health professionals. In addition, more needs to be done to understand and quantify the relationship between different levels of severity of SUI and quality of life.

Most importantly, further research should focus on adverse events that, although infrequent, can have devastating impacts on women's quality of life when they occur.

Study registration

The study is registered as PROSPERO CRD42016049339.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Background

Description of underlying health problem

Urinary incontinence (UI) is defined as an involuntary loss of urine. It is a common condition that is believed to affect millions of people. There are several types of UI; the focus of this research is stress urinary incontinence (SUI). SUI is the loss of urine when coughing, laughing, sneezing or exercising. It is a common and distressing condition, greatly affecting quality of life. The prevalence of SUI varies during life but is greater in women who have had children and in older women (20–50%).[1] The physical changes resulting from pregnancy, childbirth and menopause often contribute to SUI. For many women, SUI can worsen during the week before the menstrual period. Lower oestrogen levels can lead to lower muscular pressure around the urethra, which in turn increases the chances of leakage. Many women access conservative treatment with physiotherapy to deliver pelvic floor muscle training (PFMT) and bladder training initially but, if this fails, surgery is the mainstay of treatment. Data suggest that women have a 10% lifetime risk of having continence surgery.[1]

The aim of surgery is to support or partially obstruct the bladder neck and/or urethra, thus blocking the leakage of urine on exertion or coughing. Women with mixed urinary incontinence (MUI) (a combination of SUI and urgency UI) may also be helped because they are better able to defer voiding and leakage. However, urinary urgency and urgency UI can be both caused by and made worse by SUI surgery.[1]

Incontinence varies in degree of severity from several drops of urine to complete bladder emptying. It may occur daily, many times a day or only occasionally, perhaps once a month. It may be predictable or very unpredictable. These different factors – severity, frequency and predictability – all play a role in evaluating the impact of incontinence on behaviour, treatment choice, quality of life and economic burden. The precise economic burden has proved difficult to calculate. One published UK study suggests an estimated total figure for combined health, personal and societal expenditure of £818M for SUI at 1999/2000 prices (upwards of £1.1B at 2017 prices),[2] whereas another study published in 2004 suggests a health-care cost to the UK NHS (SUI only) of £117M per year.[3]

One of the main purposes of this research is to comparatively draw together all the relevant evidence from published randomised controlled trials (RCTs), accomplished through a network meta-analysis (NMA) and associated economic model. This allows all the available surgical treatments to be simultaneously compared with each other, for what we believe to be the first time, to determine which treatments should be offered in clinical practice on the basis of being the most clinically effective, safest and most cost-effective.

Description of current service provision

Women are likely to have tried many things prior to presenting to their general practitioner (GP), including lifestyle changes, PFMT and incontinence pants or pads. Embarrassment stops many seeking help from their GP until symptoms become unmanageable or begin to have a greater impact on everyday life. The treatment offered within primary care will depend on the type and severity of incontinence. Conservative treatments are usually tried first before moving on to medication. Conservative treatments can overlap with treatments tried by women prior to presenting and may include lifestyle changes (e.g. reduced caffeine intake, adjusted fluid intake, weight loss); PFMT, which can be aided by biofeedback, vaginal cones or electrical stimulation; and bladder training.

If these treatments are unsuccessful, medication is available. For SUI only one medication is available: duloxetine. The National Institute for Health and Care Excellence (NICE) recommends (as of September 2013)

that duloxetine not be routinely offered as first-line treatment and that it be offered as second-line therapy only to women wishing to avoid other therapy (i.e. surgery). The guidelines further state that women should be counselled regarding the drug's side effects. The evidence for duloxetine is uncertain. The drug failed to receive Food and Drug Administration (FDA) approval for SUI owing to concerns over liver toxicity and suicidal events. In the UK, as mentioned previously, it is currently recommended as an add-on medication for SUI instead of surgery. Its safety and utility for SUI have been evaluated in a number of meta-analyses, the latest of which, published in 2016 and based on clinical trial reports, found that, although effective for SUI, duloxetine's associated harms were high and, when individual patient data were analysed, outweighed the benefits.[4]

There are several surgical treatment options for the management of women who have failed first-line treatment for SUI. Furthermore, there are a number of variations on most techniques, but, essentially, they fall into nine distinct categories:

- anterior vaginal repair (anterior colporrhaphy)
- bladder neck needle suspension
- open abdominal retropubic colposuspension
- laparoscopic retropubic colposuspension
- traditional suburethral retropubic sling procedures
- mid-urethral sling (MUS) procedures
    - retropubic MUS
    - transobturator MUS
- single-incision sling procedures ('mini-slings')
- periurethral injection (injectable bulking agents).

One of the earliest operations described for SUI was anterior repair with urethral buttressing sutures (Kelly sutures). Although curing over half of women, the high failure rate (and that of another operation, bladder neck needle suspension) led to the development of colposuspension, which is an open abdominal method of elevating the bladder neck. The evidence base suggested that this was more effective but with greater morbidity and a longer recovery time than the previous options. Laparoscopic colposuspension, although a minimally invasive variation of colposuspension, was considered slightly less effective than open surgery. These issues led to the development of traditional suburethral sling procedures, in which a piece of material, which could be biological (such as a rectus sheath graft) or synthetic (such as a polypropylene mesh sling), is placed under the urethra and the free ends secured in one of a number of different ways. The advent of a new minimally invasive technique that enabled the sling to be placed without tension ushered in a new era of simpler, effective and cheaper treatment. This brief summary of the evidence concurs with the conclusions of the Cochrane reviews that have collated the relevant evidence for these types of procedures.[5–12]

The number of women having surgery has been rising and the choice of operations has changed over the past decade. In 2013–14, Hospital Episode Statistics (HES) data for England show that around 12,000 women had a MUS operation, with around 500 having another type of continence procedure (colposuspension, ≈300; traditional slings, ≈200) and just over 700 having periurethral injections. In contrast, 10 years earlier just under 7000 women had a MUS operation, ≈1400 had a colposuspension and ≈250 had a traditional sling. There is no single database that records how many vaginal mesh implants are implanted or removed each year in women with SUI, making an assessment of trends difficult. However, it would appear that, until recently, there had been a shift towards minimally invasive MUS, with the majority of women choosing this procedure, which in turn led to a substantial increase in the total number of women having continence surgery. These trends are likely to have been driven, in part, by the perception of improved effectiveness and safety.

In 2014 the American Urogynecologic Society and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction published a position statement: 'The polypropylene mesh mid-urethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women'.[13] However, subsequent international media publicity regarding supposed long-term severe adverse effects from vaginal mesh procedures has caused anxiety in women, many of whom have decided, owing to high levels of uncertainty, to avoid any type of surgery involving synthetic material, including MUS, despite the lack of any robust new evidence to support this view.

Women's concerns about the safety of vaginal mesh implants led to a patients' campaign, which in turn led to an independent enquiry and the suspension of use of any vaginal mesh (including MUSs) in Scotland, UK parliamentary questions, a mandatory national audit and a national campaign, Hear Our Voice (www.scottishmeshsurvivors.com/). The debate encompasses the wider use of vaginal mesh in conditions not being considered in this report. There remains a lot of uncertainty surrounding the optimal choice of surgery, especially related to long-term safety, with recent news and media headlines adding to the ambiguity that clinicians and women face when making decisions regarding treatment options. It is likely that the trend in the use of minimally invasive MUSs has taken a downwards turn; however, what is currently unclear is the strength of evidence to support the choice of any one of the other surgery options.

Description of technologies under assessment

The technologies under assessment are the surgical techniques anterior vaginal repair (anterior colporrhaphy); bladder neck needle suspension; open abdominal retropubic colposuspension; laparoscopic retropubic colposuspension; traditional suburethral retropubic sling procedures; retropubic MUS; transobturator MUS; and single-incision sling procedures (mini-slings).

Decision problem

Currently there is no clear evidence to indicate which surgery is the best choice. It is unclear if the older operations that were previously available (such as anterior repair and colposuspension) really result in equivalent or better outcomes than the polypropylene MUS. However, the feeling of our clinical experts who used to offer colposuspension and traditional slings is that these techniques had more frequent and severe associated complications and returning to them may be detrimental to women. To enable women to make an evidence-based choice and inform practice guidelines, it is essential to collect reliable evidence in a transparent, concise manner to allow impartial counselling of women regarding the benefits and risks of the alternative surgical operations for the management of SUI.

The wide range of surgical operations available, the different techniques used to perform these operations and the lack of a consensus among surgeons make it challenging to establish which procedure is the most effective. The existing evidence base, including the Cochrane systematic reviews, has focused on discrete two-way comparisons, with no attempt being made to collate all of the evidence on the surgical options available and rank them in terms of clinical effectiveness, safety and cost-effectiveness. This has resulted in a piecemeal evidence base that is difficult for women and clinicians to interpret. This assessment includes an evidence synthesis of all available RCTs to determine the relative clinical effectiveness and safety of interventions, a discrete choice experiment (DCE) to explore women's preferences, an economic decision model to determine the most cost-effective treatment and a value-of-information (VOI) analysis to help inform the focus of further research.

Aims and objectives of the research

The aim of this project was to evaluate the clinical effectiveness, safety and cost-effectiveness of surgical treatment for SUI and stress-predominant MUI in women.

The key objectives were to:

- undertake an evidence synthesis using systematic review methods, including a NMA to estimate the relative clinical effectiveness of the different types of surgery and inform key clinical parameters for a decision model
- undertake a review of safety/adverse effects associated with each type of surgical intervention
- undertake a DCE to explore the preferences of women
- develop a decision model to estimate the cost-effectiveness of surgical treatments for SUI and stress-predominant MUI
- utilise the decision model to undertake a VOI analysis to assess the need for further primary research.

Chapter 2 Methods of clinical effectiveness review(s)

This chapter reports the methods used for conducting an objective synthesis of the current evidence for assessing the clinical effectiveness and safety of surgical interventions for the treatment of SUI or stress-predominant MUI in women. The evidence synthesis was carried out according to the general principles of the Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in health care,[14] the recommendations of the *Cochrane Handbook for Systematic Reviews of Interventions*[15] and the NICE guide to the methods of technology appraisal[16] and was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[17] The methods were prespecified in a research protocol (PROSPERO database registration number CRD42016049339).

Search strategy

Literature searching was performed in two stages. First, relevant studies were identified from the existing relevant Cochrane systematic reviews published in the Cochrane Database of Systematic Reviews. Second, the Cochrane Incontinence Group Specialised Register was searched to identify new studies added since the publication of the Cochrane systematic reviews (henceforth 'updated literature searches').

The Cochrane Incontinence Group has published eight systematic reviews assessing nine distinct surgical procedures for the treatment of SUI in women. Two Cochrane systematic reviews that were obtained through personal communication and were in the process of being updated (review on traditional suburethral slings for UI in women: Dr Lucky Saraswat, Aberdeen Royal Infirmary, 2016; review on laparoscopic colposuspension for UI in women: Dr Muhammad Imran Omar, University of Aberdeen, 2016) were also used as source data. Both reviews have currently completed the peer-review process. On approval, the final versions of these systematic reviews are expected to be published in the Cochrane Database of Systematic Reviews.

We used these Cochrane systematic reviews to identify studies that met our prespecified inclusion criteria. To avoid duplicates, the studies were taken from the reviews in the following order:

1. Lapitan *et al.*[5] – open retropubic colposuspension for UI in women
2. Ford *et al.*[8] and Ogah *et al.*[18] – MUS operations for SUI in women
3. Nambiar *et al.*[9] – single-incision sling operations for UI in women
4. Saraswat *et al.*[7] and Rehman *et al.*[19] – traditional suburethral sling operations for UI in women
5. Freites *et al.*[6] and Dean *et al.*[20] – laparoscopic colposuspension for UI in women
6. Glazener and Cooper[11] – bladder neck needle suspension for UI in women
7. Glazener and Cooper[10] – anterior vaginal repair for UI in women
8. Kirchin *et al.*[12] – urethral injection therapy for UI in women.

There was a certain degree of overlap between systematic reviews, with some primary studies included in more than one review. The additional reports of primary studies included as second/multiple publications were checked across reviews.

The Cochrane Incontinence Group Specialised Trials Register was searched (date of last search: 8 June 2017) using the terms given in *Appendix 1* to identify studies published since the conduct of the Cochrane systematic review. The Cochrane Incontinence Group Specialised Trials Register is updated regularly and contains studies from the following databases and other sources:

- Cochrane Central Register of Controlled Trials (CENTRAL) [via Cochrane Register of Studies Online (CRSO)] (inception to 15 May 2017) (searched 15 May 2017)
- MEDLINE (via OvidSP) (1946 to April week 3 2017)
- MEDLINE In-Process & Other Non-Indexed Citations (via OvidSP) (covering 28 April 2017)
- MEDLINE Epub Ahead of Print (via OvidSP) (covering 2 May 2017)
- ClinicalTrials.gov via Cochrane Register of Studies (CRS) standalone
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP)
- hand-searching of journals and conference proceedings.

EMBASE is not included in the above list because the Cochrane Centralised Search Service already searches EMBASE for identification of RCTs and adds them to CENTRAL. Details of the search methods used to build the Specialised Register are available from the group's module in The Cochrane Library.[21]

Inclusion and exclusion criteria

Types of studies

Randomised controlled trials or quasi-RCTs (using alternate allocation) were eligible for the assessment of clinical effectiveness. There was no restriction on the trials' publication status (published or unpublished) or on the year or the language in which they were reported.

Population

The type of participants considered for this assessment were adult women with SUI or stress-predominant MUI. Either a clinical or a urodynamic diagnosis of SUI was considered suitable. We accepted the diagnoses as defined by the authors of the included trials. Women who underwent continence surgery as a primary or repeated procedure, women with SUI and concomitant prolapse and women who received concomitant prolapse surgery were deemed suitable for inclusion. Studies that did not specify the type of incontinence (stress, urge, mixed) or the predominant MUI symptoms (stress or urge) were excluded.

Interventions

The interventions detailed below were deemed suitable for inclusion. There are a number of variations on most surgical techniques, but, essentially, they fall into nine distinct categories, each of which has been previously evaluated in systematic reviews published in The Cochrane Library:

1. retropubic MUS operations
2. transobturator MUS operations
3. open retropubic colposuspension
4. laparoscopic colposuspension
5. traditional suburethral sling procedures
6. single-incision sling operations
7. anterior vaginal repair
8. bladder neck needle suspension
9. urethral injection therapy (periurethral injections/injectable bulking agents).

To be eligible for inclusion, studies had to compare two or more of the surgical interventions listed above. Studies that compared a surgical intervention with PFMT were also considered suitable for inclusion as they were useful for the development of a NMA treatment diagram for assessing direct and indirect treatment comparisons. For the purpose of this assessment, we considered eligible for inclusion PFMT programmes

taught and monitored by health professionals, clinicians or instructors (defined as 'supervised PFMT').[22] PFMT programmes for which instructions were delivered using written material only (e.g. leaflets or flyers delivered to women), without any interaction or face-to-face contact with health-care professionals, were considered to be equivalent to no treatment and, therefore, excluded from this assessment.

We excluded, post hoc, studies that compared surgery with pharmacological treatments or no treatment, as they were not considered useful for the development of the treatment network diagram. We did not include studies comparing specific technical variations of the relevant surgical techniques (e.g. inside-out vs. outside-in transobturator MUS operations, or one injectable agent vs. another) as it was beyond the scope of this review to assess specific technical approaches within each surgical category.

Outcomes

The following outcome measures were considered.

Primary outcomes

- Number of women cured (defined as resolution of clinical symptoms).
- Number of women cured or improved (henceforth referred to as 'improvement').

Secondary outcomes

- Long-term data:
  - number of women having repeated continence surgery.
- Adverse events:
  - haemorrhage/major vascular complications, including haematoma
  - infection, including wound infection and urinary tract infection (UTI)
  - infection related to use of synthetic mesh
  - de novo symptoms of urgency or urgency incontinence
  - voiding difficulties including urinary retention
  - bladder or urethral perforation
  - tape/mesh/implant exposure
  - tape/mesh erosion or extrusion
  - persistent pain or discomfort, including osteitis, which is pertinent to the Marshall-Marchetti-Krantz procedure
  - dyspareunia (pain with intercourse)
  - death.
- Resource use:
  - operating time
  - length of hospital stay.

We considered outcomes measured at 12 months or the nearest time point available as well as longer-term outcomes (e.g. at 2 years or 5 years). Studies with a time point of < 2 weeks were excluded.

The measurement of these outcomes was not used as an eligibility criterion for selecting studies for inclusion in this assessment.

Primary outcomes (cure and improvement) were defined in many different ways. For example, authors of individual studies defined cure as 'no stress incontinence symptoms', 'negative testing' or subjective reports of being 'continent', 'dry', 'satisfied' or 'very much improved'. To have a more consistent definition of cure, we checked the original definitions used by the authors of each included study to ensure that 'cure' was used to refer to the resolution of SUI symptoms. We also accepted cases where authors reported resolution of 'incontinence symptoms' without specifying stress symptoms. Any indication of satisfactory improvement in SUI symptoms was defined as 'improvement'.

A variety of measures could be used to define cure or improvement in SUI symptoms, including subjective (women-reported) measures such as women's observations and objective measures such as quantification of symptoms (e.g. pad tests) and urodynamic tests. We chose to extract data based on a hierarchy of reported outcomes. For 'cure', women's self-report of cure was given priority when available. When this measure was not available, a composite measure (a combination of women-reported and objective measures) was used instead. Pad test and urodynamic test results were considered only when the previous two outcome measures were not available. For 'improvement', the women's self-report of improvement was preferred but if this was not available the women's satisfaction rate was used as a proxy. If satisfaction rate was also not available, we considered improvement rates based on pad tests and then on urodynamic tests. Cough stress tests or diaries were considered less reliable measures for the assessment of cure and improvement.

Adverse event outcomes were extracted verbatim from the relevant Cochrane systematic reviews. The classification of secondary outcomes and time points of outcome measurements were only consistent within each Cochrane systematic review, but not necessarily across different Cochrane systematic reviews. For example, in certain reviews pain outcomes were classified by time (short term and long term) whereas in others this was by location (e.g. groin or abdominal). Haematoma was reported as either a distinct outcome (haematoma) or part of a group of outcomes (e.g. perioperative complications). Though some outcomes were redefined by Cochrane authors to facilitate meta-analysis, the definitions used were not always clearly reported. No attempt was made to standardise adverse event outcomes extracted from different Cochrane systematic reviews.

The GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach,[23] which takes into account five criteria – study design (judged according to the Cochrane risk-of-bias tool), inconsistency, imprecision, indirectness and publication bias[24] – was used for rating the quality of evidence of the two primary outcomes included in the NMA (cure and improvement). The following steps were taken: (1) assess the quality of evidence of direct treatment effect (head-to-head comparison), when available; (2) assess the quality of evidence of indirect treatment effect (i.e. two pairwise comparisons contributing to the first-order loop; the lower confidence rating of the two pairwise comparisons was used to indicate the overall quality of indirect treatment effect); (3) use the higher of the two quality ratings when both direct and indirect estimates of treatment effect are available; and (4) when only a direct or indirect estimate of treatment effect is available, base the network quality on that estimate. As GRADEpro GDT (McMaster University and Evidence Prime Inc, Hamilton, ON, Canada; https://gradepro.org) is a web-based tool that does not support assessment of the quality of evidence of network meta-analyses, we used Microsoft Excel® 2013 (Microsoft Corporation, Redmond, WA, USA). There are four levels of quality of evidence: high, moderate, low or very low. 'High quality' means that the authors have a lot of confidence that the true effect lies close to that of the estimated effect. 'Moderate quality' means that the authors believe that the true effect is probably close to the estimated effect but there is a possibility that it is substantially different. 'Low quality' means that the true effect might be markedly different from the estimated effect. 'Very low quality' means that the true effect is probably markedly different from the estimated effect.

Owing to the lack of suitable data and the fact that the risk-of-bias assessment in the relevant Cochrane systematic reviews was not always provided for individual outcomes, it proved unfeasible to use the GRADE approach for grading the quality of other outcomes.

Data collection

Selection of studies

The selection of studies included in the Cochrane systematic reviews was established by one reviewer (SW) and checked by a second reviewer (MI). Screening of the titles and abstracts of all citations identified by the updated literature searches was conducted by one reviewer (SW). Full text copies of all potentially relevant reports were retrieved by the same reviewer for eligibility and checked by a second reviewer (MI or MS) to ensure that they met the prespecified inclusion criteria.

Data extraction

Studies selected from Cochrane systematic reviews

The original data extraction performed by the authors of the individual Cochrane systematic reviews was used as a basis for the assessment of clinical effectiveness. The characteristics of included studies were extracted as reported in the relevant Cochrane systematic reviews. Outcome data presented in forest plots of each Cochrane systematic review were exported using RevMan version 5.3 (Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). Of these, data for primary outcomes (cure and improvement) were cross-checked against the original study reports and supplementary information (such as definitions and time points) was extracted to enable the performance of a NMA.

Cross-checking of secondary outcome data was performed only when there was inconsistency in the extracted data or when studies were originally included as abstracts in the Cochrane systematic reviews but subsequently published in full (eight studies).[25–32] In other cases, adverse event data were accepted as reported in the Cochrane reviews.

Some Cochrane systematic review authors attempted to contact the corresponding authors of included studies to obtain key missing data or have full-text copies of non-English-language translations. Any relevant information retrieved in such a manner was included in this assessment. In some cases, reports published in languages other than English were translated by the authors of the Cochrane reviews. When a translation could not be arranged, the information used in the Cochrane reviews was limited to the content of the English abstracts.

Studies identified by the updated literature searches

For new studies identified by the updated literature searches, data extraction was carried out by one reviewer and checked by a second reviewer (MI and MS) for errors or inconsistencies. Any disagreement was resolved through consensus or arbitration by a third party. A data extraction form was designed and piloted for the purpose of this assessment (see *Appendix 2*). Details related to study design, characteristics of participants, settings, characteristics of interventions and outcome measures were recorded. Outcome data were extracted as needed to allow calculation of summary statistics and measures of variance. Numbers of events and total number of participants in each treatment group were extracted for the assessment of dichotomous outcomes, and means and standard deviations (SDs) were extracted for the assessment of continuous outcomes. Missing data were not imputed and there was no attempt to contact study authors for missing data.

Risk-of-bias assessment of included studies

Studies selected from Cochrane systematic reviews

We relied on the original risk-of-bias assessments performed by the authors of the Cochrane systematic reviews. Assessment criteria varied across different Cochrane systematic reviews, which were accepted as reported. We updated the risk-of-bias assessments using the new criteria described below only for those studies that were initially included in the Cochrane systematic reviews as abstracts but subsequently published in full (eight studies).[25–32]

Studies identified by the updated literature searches

For the studies identified by the updated literature searches, the Cochrane risk-of-bias assessment tool was used.[15] Critical judgments were made for the following domains: selection bias (random sequence generation, allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessor), attrition bias (incomplete outcome data), reporting bias (free of selective reporting) and other bias. Each included study was judged to be at 'low risk of bias', 'high risk of bias' or 'unclear risk of bias'. The assessment was conducted by one reviewer (MI or MS) and checked by a second reviewer (MI or MS). Any disagreements were resolved by consensus or arbitration with a third reviewer (MB). Studies were not included or excluded on the basis of their methodological quality.

Data analysis

Network meta-analysis

Network meta-analysis aims to synthesise all of the available evidence within a distinct framework. It enables the integration of direct evidence with indirect evidence from a network of studies involving all possible intervention comparisons. Direct evidence is obtained from all possible head-to-head comparisons between the different interventions, whereas indirect evidence is obtained from comparisons of two or more interventions that share a common comparator. For example, direct evidence from comparing intervention A with B and B with C can be combined to provide indirect evidence for intervention A versus C.

We conducted a NMA to assess the effects of the surgical interventions for SUI in terms of the number of women who were cured or experienced an improvement in their incontinence symptoms (primary outcomes). Studies that reported 100% events in all arms (all participants were cured or improved) were excluded from the analysis as they provide no evidence for the analysis. The NMA included outcomes measured at 12 months or at a time point closest to 12 months (studies with a time point of < 2 weeks or > 36 months were excluded).

Convergence was assessed using Brooks–Gelman–Rubin plots, trace plots and autocorrelation plots. The NMA analysis was undertaken within a Bayesian framework, using WinBUGS 1.4.3 (MRC Biostatistics Unit, Cambridge, UK)[33] and using code provided by Dias *et al.*[34] (see *Appendix 3*). The analysis used vague uniform prior and adjusted for multi-arm trials using conditional distributions. Consistency, which is where direct and indirect evidence are in agreement, was assessed by comparing the individual data point's posterior mean deviance contributions for the consistency and inconsistency model and node splitting analysis[35] using R 3.4.1 (R Foundation, Vienna, Austria).

In the results section, network diagrams are presented for each outcome and effect sizes are reported as posterior median odds ratios (ORs) and 95% credible intervals (CrIs). We also present rankograms for all surgical interventions, which gives probabilities of an intervention being ranked 1 (the highest) to 9 (the lowest) as well as reporting the surface under the cumulative ranking curve (SUCRA), which is a numerical presentation of the overall ranking and presents a single number associated with each intervention. SUCRA values range from 0% to 100%. The closer to 100% the SUCRA value, the more likely that an intervention is in the top rank or one of the top ranks; the closer to 0 the SUCRA value, the more likely that an intervention is in the bottom rank or one of the bottom ranks.[36]

Direct pairwise (head-to-head) meta-analyses

Adverse event outcomes as well as cure and improvement were summarised as direct head-to-head comparisons using a random effects model. Effect sizes are reported as ORs with 95% confidence intervals (CIs) for dichotomous outcomes and as mean differences with 95% CI for continuous outcomes. When data were available, meta-analyses assessing adverse events were performed at different time points (e.g. 6 months, 12 months, 24 months). Heterogeneity was assessed using the I^2 statistic. Analyses were performed using Stata version 14 (StataCorp LP, College Station, TX, USA).

Subgroup analysis

We planned to undertake subgroup analyses for the following groups: women with stress-predominant MUI versus women with SUI alone; repeated surgery (after failed previous continence surgery) versus primary procedures; women with and without coexisting vaginal prolapse/having concomitant prolapse surgery. However, these were not performed owing to the lack of available data. For example, lack of clarity in some trial reports made it difficult to decipher whether study participants had SUI, MUI or both. Moreover, outcome data for each patient subgroup were not reported separately in all trials. Owing to such inconsistencies and limited reporting of suitable data in the included studies, we were unable to perform these analyses.

Chapter 3 Results of clinical effectiveness review(s)

Number of studies identified

Studies identified from Cochrane systematic reviews

From the eight published Cochrane systematic reviews that provided data suitable for this assessment, a total of 166 studies (in 443 reports) were initially selected as potentially relevant. Of these, 147 studies (in 406 reports) were included as they met the prespecified inclusion criteria for this assessment, 17 studies were excluded and one was merged with another study.[37] The number of included studies from each Cochrane systematic review is shown in *Table 1*.

Studies identified from updated literature searches

The updated literature searches identified 591 potentially relevant titles and abstracts from which 216 reports were selected for full-text evaluation. Of these, 65 reports (describing 28 new studies) were considered suitable for inclusion. In addition, 100 reports were identified as additional references of studies already included in the relevant Cochrane systematic reviews and two reports were additional references of studies originally included in the Cochrane systematic reviews but subsequently excluded from the effectiveness and cost-effectiveness of surgical treatments for women with stress urinary incontinence (ESTER) report. A total of 26 reports of 23 ongoing trials were also identified and two further reports were included as 'awaiting assessment' and 21 reports were excluded.

In total, 175 studies were included in the assessment of clinical effectiveness. Of these, 43 studies were available only as conference abstracts.[38–80] A PRISMA flow chart summarising the study selection process is provided in *Appendix 4*. The list of included studies and associated references is reported in *Appendix 5*. Reasons for exclusion for a sample of excluded studies are described in *Appendix 6*. The list of ongoing trials is provided in *Appendix 7*.

TABLE 1 Number of studies selected from eight Cochrane systematic reviews and new studies identified by updated literature searches

Source of studies	Number of studies selected
(a) Selected from published Cochrane systematic reviews	
Lapitan *et al.*:[5] open retropubic colposuspension for UI in women	47
Ford *et al.*[8] and Ogah *et al.*:[18] MUS operations for SUI in women	68
Nambiar *et al.*:[9] single-incision sling operations for UI in women	24
Saraswat *et al.*[7] and Rehman *et al.*:[19] traditional suburethral sling operations for UI in women	6
Freites *et al.*[6] and Dean *et al.*:[20] laparoscopic colposuspension for UI in women	1
Glazener and Cooper:[11] bladder neck needle suspension for UI in women	1
Glazener and Cooper:[10] anterior vaginal repair for UI in women	0
Kirchin *et al.*:[12] urethral injection therapy for UI in women	0
Subtotal	147
(b) Identified via updated literature searches	
Subtotal	28
Total number of included studies (a + b)	175

Characteristics of included studies

The characteristics of the included studies are detailed in *Appendix 8*. The included studies involved a total of 21,598 women, with a median follow-up of 12 months, ranging from 1 month[80] to 126 months.[81] Sample size ranged from 15[70] to 655[82] participants, with a median of 91 participants per study. There were 25 studies with a sample size of ≥ 200 participants.[28,37,61,65,72,82–101] The largest study assessed 655 women treated with either open colposuspension or traditional slings.[82] The mean or median age of women ranged from 34.3[38] to 65.0[102] years.

There were 10 quasi-randomised trials (out of 175 included studies; 6%) considered to be at high risk of selection bias, as participants were allocated to treatment by alternation,[103–110] date of birth[111] or medical history numbers.[112]

The primary references of the included studies (either the first publication or the first full-text publication) were published between 1978[105] and 2016.[65,91,113–115] Around 10% (17 out of 175) of the included studies were published before 2000, 81 (46%) were published between 2000 and 2009 and 77 (44%) were published in 2010 or thereafter. All of those published before 2000 compared open colposuspension with other surgical procedures, whereas those published from 2000 onwards tended to include MUSs (retropubic or transobturator route) or single-incision slings as one of the study arms.

The number and type of intervention comparisons are shown in *Table 2*. Altogether, the included studies reported 21 treatment comparisons. The majority of included studies involved MUSs (retropubic or transobturator route) as part of their interventions. The most common intervention comparisons were between retropubic MUSs and transobturator MUSs (58 studies) and between transobturator MUS and single-incision slings (39 studies). The latter comparisons included 17 new studies, nearly two-thirds of the 28 new studies identified by the updated literature searches (17 out of 28; 61%). Another common comparison was between open colposuspension and other surgery (46 studies), followed by laparoscopic colposuspension (21 studies) and traditional slings (20 studies). Few studies were available for most other comparisons.

Six trials were based on a three-arm design.[47,49,88,116,145,188] One four-arm trial was also converted to a three-arm trial because two of the four arms compared two variations of the same treatment and were therefore combined [i.e. tension-free vaginal tape-obturator (TVT-O) and transobturator tape (TOT) were combined as transobturator MUS].[72]

Some of the three-arm trials were converted into two-arm trials because either two of the three treatment arms compared two variations of the same surgical operation,[91,92,117–119,167–169,189,200] or one of the three arms assessed a treatment that did not meet our inclusion criteria [e.g. de Olivera *et al.*[44] included pre-pubic tension-free vaginal tape (TVT) and Tapp *et al.*[78] included PFMT plus electrical stimulation].

The characteristics of the participants enrolled in the included studies are summarised in *Table 3*. The majority of studies (91 out of 175; 52%) included women with urodynamically confirmed SUI.[25,30,31,37,39,40,43,49,51,53–55,57,58,60,61,67–69,76–78,81,83,85,87–93,97,100–103,106,107,109,111,113,115,118,122–131,138,140–142,145–152,155,160–162,166,167,171,173,178,180,182,183,185,187–190,193–196,198,201–203] Eight studies included women with a clinical diagnosis based on either urodynamic tests or symptoms of SUI[27,28,120,157,165,168,172,191] and the remaining studies appeared to use a diagnosis based on symptoms of SUI.

In general, it was difficult to determine from the relevant Cochrane systematic reviews whether or not the patient populations had other specified characteristics (e.g. mixed incontinence or mixed symptoms, previous incontinence surgery, co-existing prolapse) as information on participants' characteristics was not reported consistently across reviews.

TABLE 2 Number of included studies by treatment comparison

Intervention		Number randomised	Number of studies	Number of new studies	References
1 (control)	2 (experiment)				
Retro-MUS	Transob-MUS	8876	58	4	Darabi Mahboub *et al.*,[26] Tarcan *et al.*,[31] Wang,[37] Cervigni *et al.*,[41] Choe *et al.*,[42] de Oliveira *et al.*,[44] Diab *et al.*,[45] El-Hefnawy *et al.*,[48] Elshawaf and Al bahaie,[49] Hammoud *et al.*,[56] Kamel,[58] Leanza *et al.*,[61] Mansoor *et al.*,[64] Palomba and Zullo,[70] Riva *et al.*,[71] Rudnicki *et al.*,[72] Salem *et al.*,[73] Aigmüller *et al.*,[83] Aniuliene,[84] Araco *et al.*,[86] Chen *et al.*,[90] Krofta *et al.*,[94] Laurikainen *et al.*,[96] Meschia *et al.*,[97] Rechberger *et al.*,[98] Richter *et al.*,[99] Enzelsberger *et al.*,[104] Lee *et al.*,[107] Nerli *et al.*,[110] Wang *et al.*,[116] Andonian *et al.*,[117] Chen *et al.*,[118] Scheiner *et al.*,[119] Alkady and Eid,[120] Aniuliene *et al.*,[121] Barber *et al.*,[122] Barry *et al.*,[123] David-Montefiore *et al.*,[124] deTayrac *et al.*,[125] Deffieux *et al.*,[126] El-Hefnawy *et al.*,[127] Freeman *et al.*,[128] Jakimiuk *et al.*,[129] Karateke *et al.*,[130] Kiliç *et al.*,[131] Kim *et al.*,[132] Liapis *et al.*,[133] Mehdiyev *et al.*,[134] Nyyssönen *et al.*,[135] Porena *et al.*,[136] Ross *et al.*,[137] Schierlitz *et al.*,[138] Tanuri *et al.*,[139] Teo *et al.*,[140] Wang *et al.*,[141] Wang *et al.*,[142] Zhang and Zhu[143] and Zullo *et al.*[144]
Retro-MUS	Open colpo	1240	13	0	Trabuco *et al.*,[32] Drahoradova *et al.*,[46] Elshawaf and Al bahaie[49] Halaska *et al.*,[55] Han,[57] Koelbl *et al.*,[60] O'Sullivan *et al.*,[69] Ward *et al.*,[100] Liapis *et al.*,[108] Bai *et al.*,[145] Foote *et al.*[146] and Paraiso *et al.*[147]
Retro-MUS	Lap colpo	651	8	0	Adile *et al.*,[39] Maher *et al.*,[63] Mirosh and Epp,[67] Foote *et al.*,[146] Paraiso *et al.*,[147] Persson *et al.*,[148] Ustün *et al.*[149] and Valpas *et al.*[150]
Retro-MUS	Trad sling	868	9	0	Abouhashem *et al.*,[38] Sharifiaghdas and Mortazavi,[81] Guerrero *et al.*,[92] Kondo *et al.*,[106] Bai *et al.*,[145] Amaro *et al.*,[151] Arunkalaivanan and Barrington,[152] Basok *et al.*[153] and Song *et al.*[154]
Retro-MUS	Single incision	1092	9	3	Lee *et al.*,[62] Rudnicki *et al.*,[72] Barber *et al.*,[87] Wang *et al.*,[116] Abdelwahab *et al.*,[155] Andrada Hamer *et al.*,[156] Basu and Duckett,[157] Gopinath *et al.*[158] and Ross *et al.*[159]
Retro-MUS	Ant repair	53	1	0	Wadie *et al.*[160]
Transob-MUS	Open colpo	272	4	0	El-Din Shawki *et al.*,[47] Elshawaf and Al bahaie,[49] Bandarian *et al.*[161] and Sivaslioglu *et al.*[162]
Transob-MUS	Lap colpo	35	1	0	Samiee *et al.*[163]
Transob-MUS	Trad sling	141	3	1	Al-Azzawi,[164] Silva-Filho *et al.*[165] and Tcherniakovsky *et al.*[166]

continued

TABLE 2 Number of included studies by treatment comparison (*continued*)

Intervention		Number randomised	Number of studies	Number of new studies	References
1 (control)	2 (experiment)				
Transob-MUS	Single incision	4612	39	17	Bianchi *et al.*,[25] Djehdian *et al.*,[27] Lee *et al.*,[28] Schweitzer *et al.*,[29] Smith *et al.*,[30] Dati *et al.*,[43] Enzelsberger *et al.*,[50] Fernandez *et al.*,[52] Friedman,[54] Kim *et al.*,[59] Melendez Munoz *et al.*,[65] Merali *et al.*,[66] Rudnicki *et al.*,[72] Seo *et al.*,[74] Shawky *et al.*,[75] Van Rensburg *et al.*,[79] Yoon *et al.*,[80] Gaber *et al.*,[91] Masata *et al.*,[101] Amat I Tardiu *et al.*,[112] Jurakova *et al.*,[113] Pastore *et al.*,[114] Xin *et al.*,[115] Wang *et al.*,[116] Masata *et al.*,[167] Oliveira *et al.*,[168] Sottner *et al.*,[169] Enzelsberger *et al.*,[170] Foote,[171] Hinoul *et al.*,[172] Hota *et al.*,[173] Mackintosh,[174] Maslow *et al.*,[175] Campos *et al.*,[176] Schellart and Roovers,[177] Sivaslioglu *et al.*,[178] Tang *et al.*[179] and Tommaselli *et al.*[180]
Transob-MUS	Ant repair	120	2	1	El-Din Shawki *et al.*[47] and Salari and Sohbati[181]
Transob-MUS	PFMT	460	1	1	Labrie *et al.*[95]
Open colpo	Lap colpo	1402	12	N/A	Burton *et al.*,[40] Fatthy *et al.*,[51] Morris *et al.*,[68] Stangel-Wojcikiewicz,[76] Summitt *et al.*,[77] Ankardal *et al.*,[85] Carey *et al.*,[89] Kitchener *et al.*,[93] Mak *et al.*,[182] Su *et al.*,[183] Tuygun *et al.*[184] and Ustün *et al.*[185]
Open colpo	Trad sling	922	7	N/A	Fischer *et al.*,[53] Albo *et al.*,[82] Demirci and Yucel,[103] Henriksson and Ulmsten,[105] Bai *et al.*,[145] Enzelsberger *et al.*[186] and Sand *et al.*[187]
Open colpo	Bladder neck needle	639	7	N/A	Bergman *et al.*,[88] Mundy,[109] Athanassopoulos and Barbalias,[111] Bergman *et al.*,[188] Gilja *et al.*,[189] German *et al.*[190] and Palma *et al.*[191]
Open colpo	Ant repair	690	8	N/A	El-Din Shawki *et al.*,[47] Bergman *et al.*,[88,188] Berglund and Lalos,[192] Colombo *et al.*,[193] Holmes *et al.*,[194] Kammerer-Doak *et al.*[195] and Liapis *et al.*[196]
Open colpo	PFMT	45	1	N/A	Tapp *et al.*[78]
Trad sling	Single incision	72	1	1	Sharifiaghdas *et al.*[197]
Trad sling	Injectable	45	1	N/A	Maher *et al.*[102]
Trad sling	Bladder neck needle	20	1	N/A	Hilton[198]
Bladder neck needle	Ant repair	346	3	N/A	Bergman *et al.*[88,188] and Di Palumbo[199]

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; injectable, urethral injection therapy; lap colpo, laparoscopic colposuspension; N/A, not applicable; open colpo, open colposuspension; retro-MUS, retropubic MUS; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator MUS.

Note

Study numbers do not add up to 175 as three-arm trials are shown as pairwise comparisons.

TABLE 3 Summary of patient characteristics

UI diagnosis	Number of studies
Urodynamically confirmed stress incontinence	91
Symptom diagnosis of stress incontinence	76
Either urodynamic or symptom diagnosis of stress incontinence	8
MUI	
SUI/USI only, no MUI	23
SUI/USI or MUI	53
SUI/USI, unclear if MUI is included or excluded	99
Previous UI surgery	
Excluded	81
Excluded specific surgery only	16
Included	31
Not reported	47
Co-existing prolapse at recruitment	
Excluded	11
Excluded ≥ 2 degree only	28
Excluded ≥ 3 degree only	28
Excluded 'major' or 'significant' prolapse only	11
Included	36
Not reported	61
Concomitant prolapse surgery performed	
No	39
Yes	35
Yes (hysterectomy)	6
Not reported	95

USI, urodynamic stress incontinence.

It was ascertained that, based on the reported information, 23 studies included women with SUI alone[37,60,67,78,90,91,94,104,105,108,114,118,129,139,142,143,161,162,178,179,181,192,201] as they specifically mentioned exclusion of urgency UI or MUI. A total of 53 studies included women with SUI as well as some with MUI.[26,30–32,48,52,56,72,79,81,82,85,87,89,99,101,106,107,110,112,113,115–117,119,120,122,124–128,135,136,148,153,154,156,159,160,164,167–169,173,174,176,180,187,194,198,199]

The majority of studies excluded women with any previous UI surgery (81 out of 175 studies)[29–31,38,39,43,52,58,67,69–72,78,85,86,88,89,91,92,94–97,100,101,103,104,108,113–116,118,120,126,128–130,133,136,137,140,141,143,144,147,148,155–157,159–163,165,167,168,170,172,174–178,180–185,188,192–194,196,201–204] or certain types of incontinence surgery (16 out of 175 studies).[28,65,77,83,87,93,102,119,121,122,127,135,146,150,171,173] A total of 31 studies (out of 175; 18%) included women presenting with recurrent incontinence after failed surgery.[25,27,32,37,51,56,63,79,82,84,99,106,107,109,117,123–125,138,139,142,151,152,166,186,187,190,191,195,197,198] Of these, one study included only recurrent cases.[186] The remaining studies (47 out of 175) did not indicate whether study participants had primary or recurrent incontinence, or both.

In 45% of the studies (78 out of 175) women presenting with coexisting prolapse were excluded either completely (11 studies)[60,63,86,104,105,107,113,125,129,149,203] or if they presented with moderate to severe prolapse (67 studies). Six studies included exclusively women with coexisting prolapse.[32,70,88,181,193,199] A total of 30 studies included a proportion of women with prolapse of varying degrees[28,30,37,41,48,52,61,64,79,82,87,90,91,99,108,111,112,117,119,122,123,142,154,166,173,176,184,192,194,195] and the remaining 61 studies did not specify whether women with prolapse were included or excluded.

A total of 39 studies did not allow concomitant prolapse surgery to be performed.[39,50,60,63,67,77,81,83,85,86,93,94,100–102,104,105,107,113,116,125,126,129,133,135,137,146,148–150,156,159,167,171,174,179,186,188,203] Three studies reported that prolapse surgery was performed in all included women[32,41,88] and 32 studies reported that some women received prolapse surgery.[28,30,31,37,43,48,52–54,61,79,82,87,89,99,106,112,117,119,120,122,123,127,138,160,173,176,185,187,193,195,196] Six studies explicitly reported that hysterectomy was performed.[103,147,182,183,194,199] The remaining 95 studies did not indicate whether or not concomitant prolapse surgery was performed.

The source of funding and the setting of included studies were not consistently reported in the relevant Cochrane systematic reviews. Out of the 36 studies with available information (28 studies identified by the updated searches and eight studies identified from the Cochrane systematic reviews), five studies appeared to be funded by industry[28,29,159,176,177] and seven studies were conducted in more than one clinical centre.[28,72,79,95,159,176,177]

The clinical experience of the surgeon performing the procedures was not consistently reported in the Cochrane systematic reviews. Among the 36 studies providing this information, the surgeon's clinical experience varied from 'having inserted a minimum of one sling prior to the study'[29] to 'having performed 200 surgical procedures'.[115] Five studies reported that surgeons tended to be less experienced in performing sling procedures than the comparator surgical intervention.[25,101,113,159]

Risk-of-bias assessment of included studies

There is wide variation across Cochrane systematic reviews in the number and types of criteria (domains) used to assess risk of bias. For example, the number of risk-of-bias domains was four,[7,11] five,[8,9,18] six[5] or seven[6] across reviews. The 28 new studies identified by the updated literature searches, and the eight studies originally included as abstracts in the Cochrane systematic reviews and subsequently updated based on new full-text reports, were assessed using the current version of the Cochrane risk-of-bias tool, which involved a total of nine domains. An overall assessment of risk of bias is presented in *Table 4* below. *Appendix 9* provides the risk-of-bias results for all individual studies included in this assessment.

Selection bias (adequate sequence generation/allocation concealment)

For all 175 included studies, risk of selection bias was assessed in two domains: random sequence generation and allocation concealment. A total of 43 studies (out of 175; 25%) reporting both adequate sequence generation and adequate allocation concealment were considered to have an overall low risk of selection bias.[25,27–29,32,51,63,64,83,86,87,92,93,96,97,100,101,116,120,122,124–126,128,135–137,140,144,147,148,150,157,159,160,167,174–176,182,183,185] A further six studies (out of 175; 3%) reported adequate allocation concealment but they did not describe the method used for random sequence generation.[77,85,127,156,173,199] A total of 40 studies (out of 175; 23%) reported adequate sequence generation but did not provide information on allocation concealment.[26,30,31,37,41,52,60,65,72,79,82,88,89,91,94,99,101,114,119,129,130,138,141,143,146,162,164,172,178,180,181,186–189,194–196,198,203] Two studies (out of 175; 1%) with adequate random sequence generation specifically mentioned that the treatment allocations were not concealed.[95,193]

TABLE 4 Summary of risk-of-bias assessment

Items	Risk, *n* (%)			Number of studies assessed
	Low	Unclear	High	
1. Random sequence generation (selection bias)	85 (49)	80 (46)	10 (6)	175
2. Allocation concealment (selection bias)	49 (28)	116 (66)	10 (6)	175
3. Blinding of participants and personnel (performance bias)	8 (5)	123 (73)	37 (22)	168
4a. Blinding of outcome assessment (detection bias): all outcomes	20 (15)	107 (81)	5 (4)	132
4b. Blinding of outcome assessment (detection bias): patient reported outcomes	4 (11)	17 (47)	15 (42)	36
4c. Blinding of outcome assessment (detection bias): clinician-measured outcomes	8 (22)	20 (56)	8 (22)	36
5. Blinding (performance bias and detection bias)	1 (14)	6 (86)	0 (0)	7
6a. Incomplete outcome data (attrition bias): all outcomes	54 (39)	76 (55)	9 (6)	139
6b. Incomplete outcome data (attrition bias): patient-reported outcomes	18 (50)	16 (44)	2 (6)	36
6c. Incomplete outcome data (attrition bias): clinician-measured outcomes	21 (58)	13 (36)	2 (6)	36
7. Selective reporting (reporting bias)	24 (65)	7 (19)	6 (16)	37
8. Other bias	0 (0)	82 (100)	0 (0)	82

There were eight quasi-randomised trials (out of 175 included studies; 5%) in which treatment allocation was based on a method of alternation[103–107,109,110] or on date of birth.[111] These were considered to be at high risk of selection bias in terms of both allocation sequence generation and concealment of allocation. Two further studies (out of 175; 1%) allocated participants by alternation[108] or by medical history numbers[112] and were considered to be at high risk of selection bias, although allocation concealment was considered to be at unclear (rather than high) risk of bias by the authors of the Cochrane systematic reviews.[5,9] The remaining studies (74 out of 175; 42%) did not provide this information.

Performance and detection bias (blinding)

Blinding of patients and personnel provides a safeguard against performance bias and blinding of outcome assessors protects against detection bias. It is worth noting that, owing to the nature of the interventions, blinding of participants and personnel, especially the surgeon performing the operation, is not possible. Blinding of outcome assessment for patient-reported outcomes would similarly be difficult in this clinical context (with unblinded patients being the assessors), although it should be possible to blind health-care professionals who assess clinical outcomes.

In seven studies identified from the Cochrane systematic reviews assessing traditional slings[7] and bladder neck needle suspension,[11] risk of performance bias and detection bias was assessed using a single criterion (whether or not a lack of blinding could introduce performance and detection bias). One study (out of 7; 14%) was judged to be at low risk of bias[92] and the other six studies (86%) at high or unclear risk of bias.[38,81,102,166,198,199]

Risk of performance and detection bias was assessed separately in the 168 included studies identified from sources other than the two Cochrane reviews mentioned above. With respect to the assessment of whether or not lack of blinding of patients and personnel could introduce performance bias, eight studies (out of 168; 5%) were judged to be at low risk of bias[87,89,117,128,129,151,157,191] and the other 160 studies (95%) were judged to be at high or unclear risk of bias.[25–32,37,39–80,82–86,88,90,91,93–101,103–114,116,118–127,130–150,152–156,158–165,167–190,192–197,201–203]

Risk of detection bias in the 132 studies identified from Cochrane systematic reviews on MUS,[8,18] open colposuspension,[5] laparoscopic colposuspension[6] and single-incision slings[9] was assessed in terms of whether or not lack of blinding of outcome assessors could affect results. A total of 20 studies (out of 132; 15%) were judged to be at low risk of bias[37,86,87,89,94,117,122,125,127,130,136,141,142,144,148,156,174,178,191,204] and the remaining 112 studies (85%) were judged to be at high or unclear risk of bias.[39–42,44–47,49,51,53–61,63,64,67–71,73,74,76–78,80,82–85,88,90,93,96–100,103–112,116,118–120,123,124,126,128,129,131–135,137–140,145–147,149–155,157,160–163,165,167–170,172,173,180,182–190,192–196,201–203]

Detection bias in the 36 studies identified from other sources (e.g. new studies from the update literature searches) was assessed on a per outcome basis in terms of whether or not lack of blinding of outcome assessors could affect effect estimates of patient-reported outcomes such as subjective perception of cure of UI (where outcomes are assessed directly by women) and of clinician-measured outcomes such as urodynamic tests (where outcomes are assessed by care providers). One study (out of 36; 3%) was judged to be at low risk for patient-reported outcomes,[159] five studies (14%) at low risk for clinician-measured outcomes,[25,115,143,175,181] and three studies (8%) at low risk for both patient-reported and clinician-measured outcomes.[29,32,91] The remaining 27 studies (75%) were judged to be at high or unclear risk for either outcome.[26–28,30,31,43,48,50,52,62,65,66,72,75,79,95,101,113,114,121,158,164,171,176,177,179,197]

Attrition bias (incomplete outcome data)

In 139 studies included in the relevant Cochrane systematic reviews, risk of bias was assessed for all outcomes concerned. A total of 54 were judged to be at low risk of attrition bias, with missing data either balanced between treatment groups or imputed using appropriate methods, or with no missing data;[37,40,41,54,67,81–84,88,92–94,96–98,100,102,106,116,119,120,122,123,126–128,130,133,135–137,139,141,142,144,147–150,155,157,160,162,166,168,170,174,178,184,185,193,198,199] nine were judged to be at high risk of bias;[86,87,112,140,156,172,173,180,189] and 76 were judged to be at unclear risk of bias.[38,39,42,44–47,49,51,53,55–61,63,64,68–71,73,74,76–78,80,85,89,90,99,103–105,107–111,116–118,124,125,129,131,132,134,138,145,146,151–154,161,163,165,167,169,182,183,186–188,190–192,194–196,201–203]

In 36 studies identified from other sources (e.g. new studies from the updated literature searches), risk of attrition bias was assessed on a per outcome basis in terms of patient-reported outcomes and clinician-measured outcomes. Of these, 18 studies were judged to be at low risk for both patient-reported and clinician-measured outcomes,[25,27,30,52,91,95,101,113,114,121,143,159,164,171,176,177,179,181] three studies were judged to be at low risk for clinician-measured outcomes but unclear for patient-reported outcomes,[66,72,75] two studies were judged to be at high risk for both patient-reported and clinician-measured outcomes[29,175] and the remaining 13 studies were judged to be at unclear risk of bias for both outcomes.[26,28,31,32,43,48,50,62,65,79,115,158,197]

Reporting bias (free of selective reporting)

Few of the relevant Cochrane systematic reviews assessed the risk of reporting bias. Information was available from one study identified from the Cochrane systematic review assessing laparoscopic colposuspension[6] and from 36 further studies (28 new studies and the eight studies originally included as abstracts in the Cochrane systematic reviews and subsequently published in full). Of these, 24 studies (out of 37; 65%) were judged to be at low risk of reporting bias on the basis that all outcomes specified in the methods section were reported in the results section of the study report,[25,27–32,52,62,65,79,95,101,113–115,143,159,171,175,177,179,181,197] six studies (16%) were judged to be at high risk of bias on the basis that they did not report the results for all the outcomes specified in the method section of the study report,[26,43,72,75,91,176] and the remaining seven studies (19%) did not provide sufficient information to formulate a judgement.[48,50,66,121,158,163,164]

Other sources of bias

Information on which to assess 'other sources of bias' was available for 82 of the included studies. In these studies, there was no clear evidence that other sources of bias were present.[25–32,40,43,46–53,55,57,60,62,65,66,68,69,72,75–79,82,85,88,89,91,93,95,100,101,103,105,108,109,111,113–115,121,143,145,158,159,161–164,171,175,177,179,181–195,197,200–203]

Assessment of clinical effectiveness

Network meta-analysis of primary outcomes: number of women cured and number of women who experienced an improvement in their incontinence symptoms

Technical information about the model

The NMA included eight surgical procedures for SUI:

- retropubic MUS operations
- transobturator MUS operations
- open colposuspension
- laparoscopic colposuspension
- traditional sling operations
- single-incision sling operations
- bladder neck needle suspension
- anterior vaginal repair.

The ninth procedure, urethral injection therapy, did not add any information to the network and was excluded from analysis (for the cure outcome analysis, urethral injection therapy was only connected to one intervention). Separate models were developed for the two primary outcomes: the number of women cured (defined as resolution of symptoms) and the number of women improved (defined as women experiencing an improvement in their incontinence symptoms, including cure). *Figure 1* shows the network diagrams for the number of women cured and improved, respectively. The size of the circles reflects the number of participants and the line width reflects the number of direct comparisons. *Figure 1* also includes the total number of women for each surgical intervention included in the NMA.

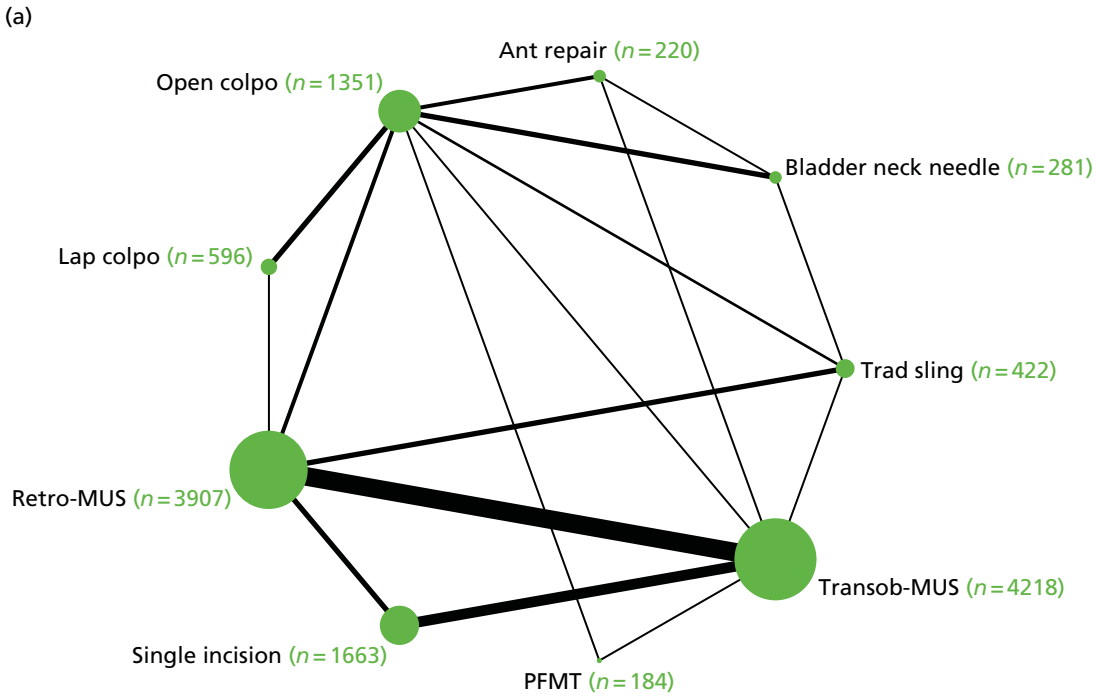

FIGURE 1 Network plot for (a) the number of women cured; and (b) the number of women improved. Note: circle size reflects the number of participants; line width reflects the number of direct comparisons. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; open colpo, open colposuspension; lap colpo, laparoscopic colposuspension; retro-MUS, retropubic MUS; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator MUS. (*continued*)

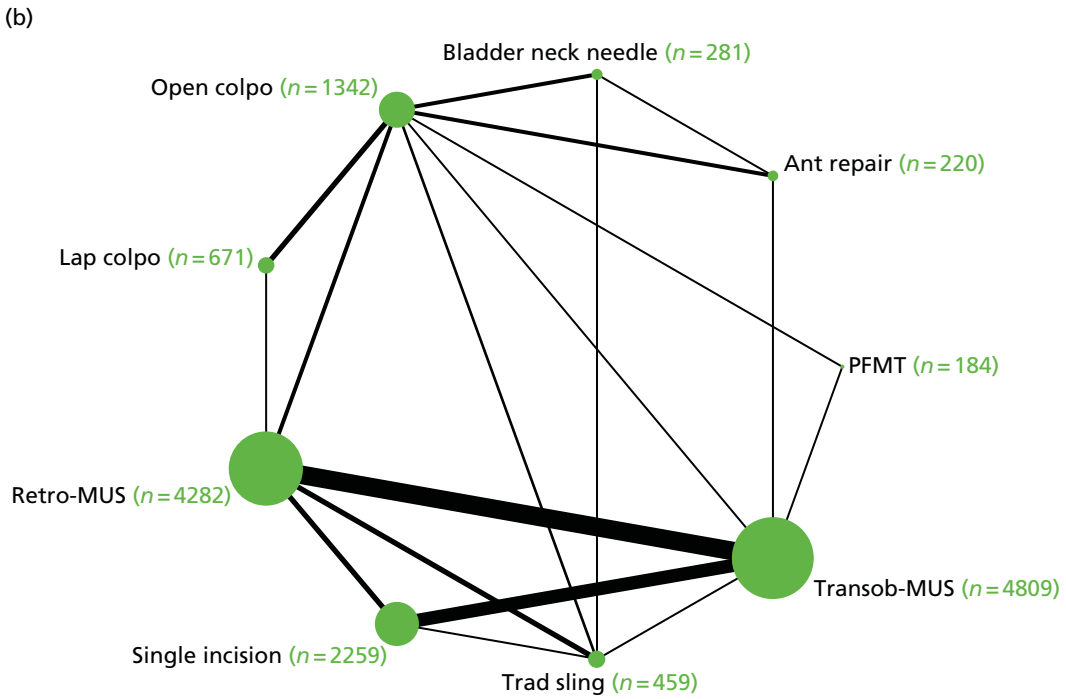

FIGURE 1 Network plot for (a) the number of women cured; and (b) the number of women improved. Note: circle size reflects the number of participants; line width reflects the number of direct comparisons. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; open colpo, open colposuspension; lap colpo, laparoscopic colposuspension; retro-MUS, retropubic MUS; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator MUS.

Cure or improvement of incontinence symptoms was assessed subjectively (by the woman), objectively (by a clinician) or by a combination of subjective and objective measures (composite measure). When more than one of these outcome measures were reported within a study, only one measure was included in the NMA. This measure was selected in the following order: women's self-report assessment was given priority and, if this was unavailable, the composite outcome measure followed by the objective outcome measure were chosen as a proxy. The NMA included outcomes measured at 12 months or at a time point closest to 12 months.

The number of studies providing direct head-to-head (pairwise) evidence for each intervention that contributed data to the NMA is shown in *Tables 5* and *6*. The searches identified 125 trials that reported cure or improvement, or both. Three trials[67,76,105] were excluded from the cure data set and four trials[67,76,105,124] from the improvement dataset because they reported '100% events' in all treatment arms (i.e. all participants in the study were cured or improved), providing no information for the NMA. Thus, 105 trials contributed to the NMA for assessing the number of women cured, and 120 trials were included in the analysis assessing the number of women improved. For 'cure', the analysis included four three-arm trials and 101 two-arm trials and generated a total of 17 direct comparisons, whereas for 'improvement' the analysis included five three-arm trials and 115 two-arm trials and generated a total of 18 direct comparisons. *Appendix 10* shows the total number of trials for each treatment comparison for the assessment of both primary outcomes.

The direct pairwise analyses showed some heterogeneity in four direct comparisons for the number of women cured (single-incision sling vs. retropubic MUS; single-incision sling vs. transobturator MUS; laparoscopic colposuspension vs. open colposuspension; and anterior vaginal repair vs. open colposuspension) and one comparison for the number of women improved (laparoscopic colposuspension vs. retropubic MUS) (see *Appendices 10* and *11*).

TABLE 5 Results for number of women cured

Treatment		Direct evidence			NMA		
1	2	Number of trials	OR[a]	95% CI	OR[a]	95% CrI	GRADE
Transob-MUS	Retro-MUS	36[b]	0.83	0.71 to 0.97	0.74	0.59 to 0.92	Moderate
Open colpo	Retro-MUS	6[b]	0.95	0.68 to 1.32	0.85	0.54 to 1.33	Low
Lap colpo	Retro-MUS	2	0.40	0.11 to 1.45	0.58	0.31 to 1.05	Low
Trad sling	Retro-MUS	6[b]	0.87	0.58 to 1.29	1.06	0.62 to 1.85	Very low
Single incision	Retro-MUS	6[b]	0.42	0.20 to 0.87	0.50	0.36 to 0.70	Low
Bladder neck needle	Retro-MUS	N/A	N/A	N/A	0.34	0.15 to 0.75	Low
Ant repair	Retro-MUS	N/A	N/A	N/A	0.22	0.10 to 0.45	Very low
PFMT	Retro-MUS	N/A	N/A	N/A	0.12	0.04 to 0.32	Low
Open colpo	Transob-MUS	1	0.90	0.30 to 2.69	1.16	0.72 to 1.86	Low
Lap colpo	Transob-MUS	N/A	N/A	N/A	0.79	0.42 to 1.46	Low
Trad sling	Transob-MUS	1	2.00	0.17 to 23.96	1.44	0.81 to 2.62	Very low
Single incision	Transob-MUS	21[b]	0.74	0.54 to 1.00	0.68	0.51 to 0.91	Low
Bladder neck needle	Transob-MUS	N/A	N/A	N/A	0.46	0.21 to 1.02	Very low
Ant repair	Transob-MUS	1	0.50	0.15 to 1.62	0.30	0.14 to 0.62	Very low
PFMT	Transob-MUS	1	0.20	0.12 to 0.33	0.16	0.06 to 0.43	Low
Lap colpo	Open colpo	9	0.74	0.43 to 1.30	0.68	0.42 to 1.08	Low
Trad sling	Open colpo	3[b]	2.47	0.73 to 8.40	1.24	0.66 to 2.45	Very low
Single incision	Open colpo	N/A	N/A	N/A	0.59	0.34 to 1.01	Low
Bladder neck needle	Open colpo	3[b]	0.41	0.25 to 0.68	0.40	0.20 to 0.78	Low
Ant repair	Open colpo	3[b]	0.20	0.07 to 0.60	0.26	0.14 to 0.48	Very low
PFMT	Open colpo	1	0.08	0.01 to 0.51	0.14	0.05 to 0.39	Low
Trad sling	Lap colpo	N/A	N/A	N/A	1.83	0.86 to 4.04	Very low
Single incision	Lap colpo	N/A	N/A	N/A	0.87	0.44 to 1.70	Low
Bladder neck needle	Lap colpo	N/A	N/A	N/A	0.59	0.26 to 1.33	Very low
Ant repair	Lap colpo	N/A	N/A	N/A	0.38	0.18 to 0.82	Very low
PFMT	Lap colpo	N/A	N/A	N/A	0.21	0.07 to 0.63	N/A
Single incision	Trad sling	N/A	N/A	N/A	0.47	0.25 to 0.88	Very low
Bladder neck needle	Trad sling	1	1.00	0.05 to 18.57	0.32	0.13 to 0.79	Very low
Ant repair	Trad sling	N/A	N/A	N/A	0.21	0.09 to 0.49	Very low
PFMT	Trad sling	N/A	N/A	N/A	0.11	0.04 to 0.34	Very low
Bladder neck needle	Single incision	N/A	N/A	N/A	0.67	0.29 to 1.56	N/A
Ant repair	Single incision	N/A	N/A	N/A	0.44	0.20 to 0.96	Very low
PFMT	Single incision	N/A	N/A	N/A	0.24	0.08 to 0.65	Low

continued

TABLE 5 Results for number of women cured (*continued*)

Treatment		Direct evidence			NMA		
1	2	Number of trials	OR[a]	95% CI	OR[a]	95% CrI	GRADE
Ant repair	Bladder neck needle	1[b]	0.92	0.55 to 1.55	0.65	0.30 to 1.36	Very low
PFMT	Bladder neck needle	N/A	N/A	N/A	0.35	0.10 to 1.17	Low
PFMT	Ant repair	N/A	N/A	N/A	0.55	0.17 to 1.77	Very low

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; injectable, urethral injection therapy; open colpo, open colposuspension; lap colpo, laparoscopic colposuspension; N/A, not applicable; retro-MUS, retropubic MUS; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator MUS.

a An OR of > 1 favours the first treatment, i.e. more events (cure) occur; an OR of < 1 favours the second treatment, i.e. fewer events occur.

b These analyses are also informed by three-arm trials, including one comparing retropubic MUS, transobturator MUS and single-incision sling, one comparing retropubic MUS, open colposuspension and traditional sling, and two comparing open colposuspension, bladder neck needle and anterior vaginal repair.

TABLE 6 Results for number of women improved

Treatment		Direct evidence			NMA		
1	2	Number of trials	OR[a]	95% CI	OR[a]	95% CrI	GRADE
Transob-MUS	Retro-MUS	40[b]	0.86	0.70 to 1.06	0.76	0.59 to 0.98	Moderate
Open colpo	Retro-MUS	6[b]	0.83	0.55 to 1.24	0.65	0.41 to 1.02	Low
Lap colpo	Retro-MUS	4	0.49	0.18 to 1.35	0.52	0.29 to 0.91	Low
Trad sling	Retro-MUS	6[b]	0.62	0.38 to 1.02	0.69	0.39 to 1.26	Low
Single incision	Retro-MUS	6[b]	0.42	0.20 to 0.89	0.50	0.35 to 0.71	Moderate
Bladder neck needle	Retro-MUS	N/A	N/A	N/A	0.25	0.11 to 0.58	Low
Ant repair	Retro-MUS	N/A	N/A	N/A	0.18	0.08 to 0.39	Very low
PFMT	Retro-MUS	N/A	N/A	N/A	0.43	0.14 to 1.37	Low
Open colpo	Transob-MUS	1	0.90	0.30 to 2.69	0.85	0.52 to 1.41	Low
Lap colpo	Transob-MUS	N/A	N/A	N/A	0.69	0.37 to 1.26	Low
Trad sling	Transob-MUS	1	2.00	0.17 to 23.96	0.91	0.49 to 1.72	Very low
Single incision	Transob-MUS	28[b]	0.74	0.57 to 0.96	0.66	0.49 to 0.89	Moderate
Bladder neck needle	Transob-MUS	N/A	N/A	N/A	0.33	0.14 to 0.79	Very low
Ant repair	Transob-MUS	1	1.00	0.26 to 3.89	0.24	0.10 to 0.53	Very low
PFMT	Transob-MUS	1	0.18	0.10 to 0.33	0.56	0.19 to 1.78	Low
Lap colpo	Open colpo	9	0.93	0.58 to 1.48	0.81	0.49 to 1.31	Low
Trad sling	Open colpo	3[b]	2.47	0.73 to 8.40	1.07	0.54 to 2.15	Low
Single incision	Open colpo	N/A	N/A	N/A	0.78	0.44 to 1.36	Low
Bladder neck needle	Open colpo	3[b]	0.38	0.22 to 0.63	0.38	0.18 to 0.81	Low
Ant repair	Open colpo	3[b]	0.20	0.07 to 0.60	0.28	0.14 to 0.55	Very low
PFMT	Open colpo	1	8.87	1.66 to 47.25	0.66	0.21 to 2.16	Low
Trad sling	Lap colpo	N/A	N/A	N/A	1.32	0.62 to 2.98	Low

TABLE 6 Results for number of women improved (*continued*)

Treatment		Direct evidence			NMA		
1	2	Number of trials	OR[a]	95% CI	OR[a]	95% CrI	GRADE
Single incision	Lap colpo	N/A	N/A	N/A	0.97	0.50 to 1.87	Low
Bladder neck needle	Lap colpo	N/A	N/A	N/A	0.47	0.20 to 1.17	Very low
Ant repair	Lap colpo	N/A	N/A	N/A	0.34	0.15 to 0.79	Very low
PFMT	Lap colpo	N/A	N/A	N/A	0.82	0.25 to 2.88	Very low
Single incision	Trad sling	1	1.92	0.65 to 5.64	0.73	0.37 to 1.39	Low
Bladder neck needle	Trad sling	1	1.00	0.05 to 18.57	0.36	0.13 to 0.95	Very low
Ant repair	Trad sling	N/A	N/A	N/A	0.26	0.10 to 0.65	Very low
PFMT	Trad sling	N/A	N/A	N/A	0.62	0.18 to 2.18	Very low
Bladder neck needle	Single incision	N/A	N/A	N/A	0.49	0.20 to 1.24	Very low
Ant repair	Single incision	N/A	N/A	N/A	0.36	0.15 to 0.82	Very low
PFMT	Single incision	N/A	N/A	N/A	0.84	0.28 to 2.78	Low
Ant repair	Bladder neck needle	1[b]	0.92	0.55 to 1.55	0.72	0.31 to 1.63	Very low
PFMT	Bladder neck needle	N/A	N/A	N/A	1.72	0.45 to 6.89	Low
PFMT	Ant repair	N/A	N/A	N/A	2.38	0.65 to 9.30	Very low

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; injectable, urethral injection therapy; open colpo, open colposuspension; lap colpo, laparoscopic colposuspension; N/A, not applicable; retro-MUS, retropubic MUS; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator MUS.

a An OR of > 1 favours the first treatment, i.e. more events (improvement) occur; an OR of < 1 favours the second treatment, i.e. fewer events occur.

b These analyses are also informed by two three-arm trials comparing retropubic MUS, transobturator MUS and single-incision sling.

Number of women cured

Table 5 shows the estimates of treatment effect from the direct pairwise meta-analyses and the NMA for the number of women cured (the direct meta-analysis results for all the included studies are presented in *Appendix 11*). The NMA showed that, on average, women who underwent a traditional sling or retropubic MUS operation were more likely to be cured compared with those who had other surgical procedures. Some of the comparisons had a limited number of studies and there is considerable uncertainty around the estimates of effect, for example for the comparison between retropubic MUS and traditional sling [OR 1.06, 95% CrI 0.62 to 1.85 (quality of evidence: very low)], between retropubic MUS and open colposuspension [OR 0.85, 95% CrI 0.54 to 1.33 (quality of evidence: very low)] and between retropubic MUS and laparoscopic colposuspension [OR 0.58, 95% CrI 0.31 to 1.05 (quality of evidence: very low)].

Number of women who experienced an improvement in their incontinence symptoms

Table 6 shows the estimates of treatment effect from the NMA and the overall estimates from the direct pairwise meta-analyses for the number of women with improvement in incontinence symptoms (the full set of direct meta-analyses results is presented in *Appendix 12*). The NMA showed that women who had retropubic MUS or transobturator MUS were more likely to experience an improvement in their incontinence symptoms. However, there is some uncertainty around the estimates of effect for some of the comparisons, for example the comparisons between retropubic MUS and open colposuspension [OR 0.65, 95% CrI 0.41 to 1.02 (quality of evidence: low)] and between retropubic MUS and traditional sling [OR 0.69, 95% CrI 0.39 to 1.26 (quality of evidence: low)].

Ranking of treatment effectiveness

Figure 2 shows the SUCRA values for all surgical interventions. The rankograms are reported in *Appendix 13*.

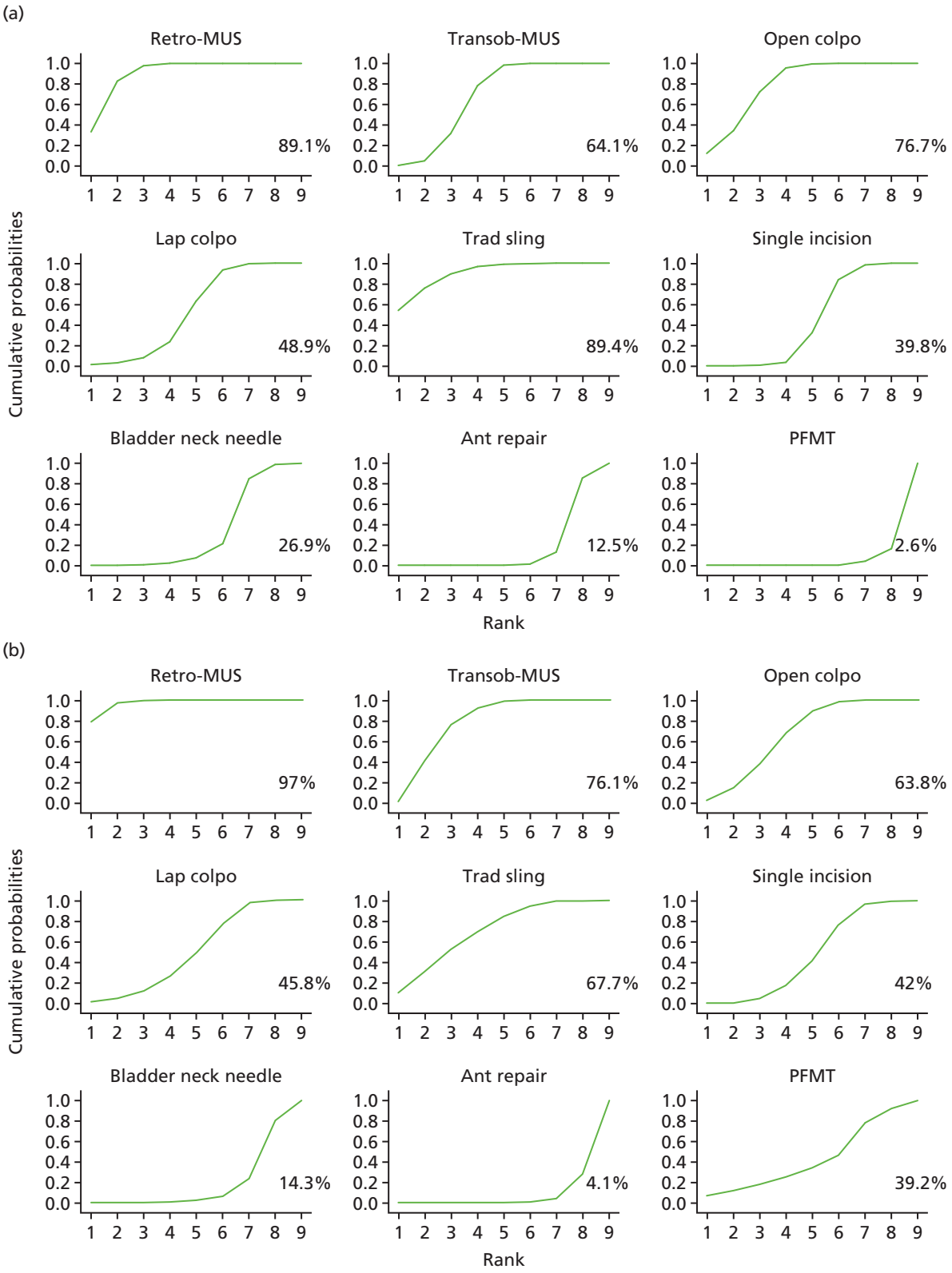

FIGURE 2 Surface under the cumulative ranking curve values for (a) the number of women cured; and (b) the number of women improved. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; open colpo, open colposuspension; lap colpo, laparoscopic colposuspension; retro-MUS, retropubic MUS; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator MUS.

Traditional sling and retropubic MUS (see *Figure 2a*) are the treatments most likely to result in the highest proportion of women cured (89.4% and 89.1%, respectively), followed by open colposuspension (76.7%), transobturator MUS (64.1%), laparoscopic colposuspension (48.9%), single-incision sling (39.8%), bladder neck needle suspension (26.9%), anterior vaginal repair (12.5%) and PFMT (2.6%). On the other hand, retropubic MUS (97.0%) and transobturator MUS (76.1%) are the most likely treatments to result in the highest proportion of women with an improvement in their incontinence symptoms (see *Figure 2b*), followed by traditional sling (67.7%), open colposuspension (63.8%), laparoscopic colposuspension (45.8%), single-incision sling (42.0%), PFMT (39.2%), bladder neck needle suspension (14.3%) and anterior repair (4.1%).

Consistency between direct and indirect evidence

In the NMA there was no evidence of inconsistency for the cure outcome (see *Appendix 14, Figure 45* and *Table 33* for full details) and some evidence of inconsistency for the improvement outcome (see *Appendix 14, Figure 46* and *Appendix 14, Table 34*). Consistency assessed using the node-splitting method (see *Appendix 14, Table 34*) showed inconsistencies for PFMT compared with transobturator MUS and for traditional sling and PFMT compared with open colposuspension. However, caution is required here, as the node splitting method can have low statistical power to detect inconsistency.

Adverse events: direct pairwise comparisons

The adverse event results are shown in *Appendix 15*. Full meta-analyses results for all included studies are available in *Report Supplementary Material 1*.

Overall, few studies reported adverse events. Numbers of events included in the analyses were generally small and, therefore, CIs were wide. It is worth noting that many of the adverse events meta-analyses were based on < 5 studies. This is mainly owing to the dearth of available data but also to the inconsistencies with regard to the type and definition of adverse events as well as to the time points at which these were measured across individual trials and across Cochrane systematic reviews. In particular, the lack of common definitions made it difficult to combine results and to incorporate data extracted from newly identified studies into the pool of data extracted from the relevant Cochrane reviews. For some of the included studies, follow-up time was unknown, as it could not be extracted from the relevant Cochrane systematic reviews. Below we summarise the most relevant meta-analyses results, focusing on comparisons for which most data were available (in terms of the number of studies and number of participants).

Repeat continence surgery

Appendix 15, Figure 47 shows a summary of the meta-analyses results (overall ORs and the 95% CI) for different treatment comparisons for repeat continence surgery based on the 30 studies that reported this outcome. The majority of studies compared retropubic MUS or transobturator MUS with other surgical procedures at different time points. In general, fewer repeat surgeries were observed after retropubic MUS compared with other interventions. However, the number of studies was generally small and CIs were wide.

For the comparison of transobturator MUS and retropubic MUS (seven studies, assessments conducted 12 months post surgery), the number of women requiring further surgery was 21 (out of 585; 3.6%) and 14 (out of 641; 2.2%), respectively. Pooled analysis of these studies showed wide CIs and considerable uncertainly around the estimated OR (seven studies, 12-month post-surgery: OR 1.37, 95% CI 0.55 to 3.46). At 12 to 60 months after the procedure, rates of repeat continence surgery were considerably higher in women undergoing transobturator MUS (32 out of 175; 18.3%) compared with retropubic MUS (1 out of 180; 0.5%), although only two studies were available for the analysis (OR 24.57, 95% CI 4.67 to 129.35). A similar trend was observed in studies with a longer follow-up period (i.e. > 60 months) but the pooled analysis of these studies showed wide CIs [five studies: 40 out of 422 (9.4%) vs. 7 out of 438 (1.5%); OR 4.06, 95% CI 0.80 to 20.74].

For the comparison of single-incision sling versus transobturator MUS (10 studies, assessments conducted 12 months post surgery), single-incision sling was associated with more repeat surgeries compared with transobturator MUS [35 out of 685 (5.1%) vs. 18 out of 614 (2.9%), respectively], but the pooled analyses showed some uncertainty around the estimated OR (OR 1.57, 95% CI 0.83 to 2.95). At > 36 months after the procedure, there were 19 (out of 185; 10.3%) versus 14 (out of 185; 7.6%) repeat surgery events, respectively (three studies: OR 1.42, 95% CI 0.68 to 2.97).

Open colposuspension was associated with fewer repeat surgeries than anterior vaginal repair, although only two studies were available for this analysis [assessments conducted 24 months post surgery: 22 out of 74 (29.7%) vs. 3 out of 129 (2.3%); OR 13.95, 95% CI 4.22 to 46.09].

Haemorrhage and major vascular complications including haematoma

Appendix 15, Figures 48–50 show a summary of the meta-analyses results for different treatment comparisons for haemorrhage, haematoma and other major vascular complications. The majority of the treatment comparisons compared retropubic MUS or transobturator MUS with other surgical interventions. Outcomes were reported using different definitions and assessed at different time points. For the comparison of transobturator MUS with retropubic MUS, the pooled analysis of 22 studies showed that major vascular complications were less likely to occur after transobturator MUS than after retropubic MUS [see *Appendix 15, Figure 49*; 10 out of 2008 (0.5%) vs. 47 out of 1966 (2.4%); OR 0.36, 95% CI 0.21 to 0.64]. Other comparisons were based on a smaller number of studies as well as a smaller number of events and were therefore insufficient to draw any meaningful conclusion.

De novo symptoms of urgency or urgency incontinence

Appendix 15, Figures 51 and *52* show the meta-analyses results for different treatment comparisons for de novo symptoms of urgency or UI and 'detrusor instability' (detrusor overactivity). The comparisons with the largest number of studies compared transobturator MUS with retropubic MUS within 12 months [see *Appendix 15*, *Figure 51*; 28 studies, within 12 months post surgery: 172 out of 2264 (7.6%) vs. 183 out of 2321 (9.5%); OR 0.93, 95% CI 0.74 to 1.17] and single-incision sling with transobturator MUS at 12 months [13 studies, 12 months post surgery: 63 out of 665 (9.5%) vs. 55 out of 597 (9.2%); OR 0.98, 95% CI 0.66 to 1.46]. The summary estimates did not favour one intervention over another. The comparison of single-incision sling with transobturator MUS at 6 months favoured transobturator MUS, even though there was considerable uncertainty around the estimate of effect [see *Appendix 15, Figure 51*; three studies, 6 months post surgery: 14 out of 118 (11.9%) vs. 4 out of 117 (3.4%); OR 3.33, CrI 1.08 to 10.23]. None of the other comparisons assessing de novo symptoms showed evidence of a difference between interventions. The incidence of detrusor instability appeared to be similar between interventions (see *Appendix 15, Figure 52*).

Voiding difficulties including urinary retention

Appendix 15, Figure 53 shows a summary of the meta-analysis for different treatment comparisons for voiding difficulties. The summary estimate of 36 studies comparing transobturator MUS with retropubic MUS favoured transobturator MUS [36 studies: 116 out of 3110 (3.7%) vs. 234 out of 3109 (7.5%); OR 0.51, 95% CI 0.40 to 0.64]. Fewer women treated with single-incision sling than women treated with transobturator MUS reported voiding difficulties during the perioperative period [23 out of 835 (2.8%) vs. 31 out of 689 (4.5%); OR 0.60, 95% 0.33 to 1.08] and at 12 months [43 out of 899 (4.8%) vs. 45 out of 802 (5.6%); OR 0.74, 95% CI 0.45 to 1.21]. Voiding difficulties appeared to be more common after laparoscopic colposuspension [12 out of 161 (7.5%) vs. 9 out of 177 (5.1%); OR 1.34, 95% CI 0.54 to 3.34] and traditional sling [40 out of 259 (15.4%) vs. 26 out of 255 (10.2%); OR 1.46, 95% CI 0.84 to 2.53] than after retropubic MUS. However, the summary estimates of these comparisons showed wide CIs indicating a certain degree of uncertainty. There was no evidence of a difference for the comparison assessing open colposuspension versus retropubic MUS [29 out of 374 (7.8%) vs. 31 out of 413 (7.5%); OR 0.87, 95% CI 0.41 to 1.82].

Bladder or urethral perforation

Appendix 15, Figure 54 shows a summary of the meta-analyses results for different treatment comparisons for bladder or urethral perforation. Compared with other surgical interventions, retropubic MUS was generally associated with a higher incidence of bladder or urethral perforation. In particular, there were more cases of bladder or urethral perforation after retropubic MUS than after transobturator MUS [38 studies: 5 out of 3161 (0.2%) vs. 157 out of 3171 (5.0%); OR 0.15, 95% CI 0.09 to 0.24], open colposuspension [six studies: 5 out of 338 (1.5%) vs. 28 out of 362 (7.7%); OR 0.23, 95% CI 0.10 to 0.55] and traditional sling [six studies: 16 out of 305 (5.2%) vs. 28 out of 276 (10.1%); OR 0.50, 95% CI 0.28 to 0.98]. Compared with open colposuspension, the rate of bladder or urethral perforation was higher for laparoscopic colposuspension [10 out of 267 (3.7%) vs. 2 out of 284 (0.7%); OR 4.65, 95% CI 1.15 to 18.75] but lower for traditional sling [2 out of 326 (0.6%) vs. 10 out of 329 (3.0%); OR 0.20, 95% CI 0.04 to 0.91].

Tape/mesh extrusion or exposure

Appendix 15, Figures 55 and *56* show a summary of the meta-analyses results for the different treatment comparisons for tape or mesh erosion or extrusion and tape or mesh exposure. It was not clear whether or not the terms 'erosion', 'extrusion' and 'exposure' were used consistently across individual studies and across Cochrane systematic reviews. The majority of the comparisons compared surgical interventions with either retropubic or transobturator MUS.

The meta-analysis results for the comparison between transobturator MUS and retropubic MUS showed similar rates of tape/mesh erosion or extrusion between the two surgical procedures [see *Appendix 15, Figure 55*; 27 studies: 53 out of 2225 (2.4%) vs. 48 out of 2298 (2.1%); OR 1.10, 95% CI 0.70 to 1.70]. The exact time points at which measurements occurred could not be derived from the Cochrane systematic reviews but most studies were reported to have a short follow-up period ($\leq$ 12 months), with only a few studies having a follow-up period of $\geq$ 2 years.

The meta-analysis results for the comparison between single-incision sling and transobturator MUS (see *Appendix 15, Figure 55*; seven studies, 12-month post-surgery assessment) showed similar rates of mesh erosion or extrusion between interventions [19 out of 399 (4.8%) vs. 13 out of 354 (3.7%), respectively; OR 1.23, 95% CI 0.57 to 2.68]. Incidence of tape/mesh erosion or extrusion was lower for open colposuspension than for retropubic MUS [see *Appendix 15, Figure 55*; three studies: 0 out of 230 (0%) vs. 9 out of 273 (3.3%); OR 0.20, 95% CI 0.03 to 1.19].

Fewer data were available for the assessment of tape or mesh exposure. This may be owing to unclear distinction between the terms ('extrusion' and 'exposure') in the studies that assessed these outcomes. Rate of tape or mesh exposure was higher after transobturator MUS than after retropubic MUS [2 studies, 60–95 months post-surgery assessment: 12 out of 140 (8.6%) vs. 4 out of 145 (2.8%); OR 3.25, 95% CI 1.02 to 10.36]. Similarly, more women treated with transobturator MUS experienced tape or mesh exposure than those treated with single-incision sling, but CIs around the summary estimate were wide [see *Appendix 15, Figure 56*; seven studies, 12 months post surgery: 25 out of 494 (5.1%) vs. 11 out of 463 (2.4%); OR 1.74, 95% CI 0.59 to 5.07].

Pain

Appendix 15, Figures 57–59 show a summary of the meta-analyses results for different treatment comparisons for outcomes related to pain. It is worth pointing out that pain was defined and measured in many different ways across individual trials and across Cochrane systematic reviews. Some pain outcomes were categorised by location (e.g. suprapubic) or time (e.g. short or long term). These discrepancies made it difficult to combine data from different studies. Data were available mainly for the comparison between retropubic MUS and transobturator MUS and other surgical procedures.

Transobturator MUS was associated with a higher rate of groin pain than retropubic MUS [see *Appendix 15, Figure 57;* 22 studies: 116 out of 1833 (6.3%) vs. 24 out of 1798 (1.3%); OR 3.80, 95% CI 2.45 to 5.89]

but with a lower rate of suprapubic pain [see *Appendix 15, Figure 58;* eight studies: 8 out of 687 (1.2%) vs. 27 out of 681 (4.0%); OR 0.37, 95% CI 0.17 to 0.84]. The time points at which measurements occurred could not be derived from the Cochrane systematic reviews, but most studies were reported to have a short follow-up period (≤ 12 months), with only a few studies having a follow-up of ≥ 2 years.

Rate of 'post-operative pain' was higher after retropubic MUS (176 out of 916, 19.2%) than after single-incision sling (64 out of 946; 6.8%) (see *Appendix 15, Figure 59;* 14 studies; OR 0.21, 95% CI 0.12 to 0.39). Rate of unspecified pain was higher after transobturator MUS than after single-incision sling both at 12 months [six studies; 4 out of 412 (1.0%) vs. 17 out of 328 (5.2%)] and at 24 months [two studies; 2 out of 138 (1.4%) vs. 13 out of 125 (10.4%)] (see *Appendix 15, Figure 59*; OR 0.24, 95% CI 0.06 to 0.92, and OR 0.16, 95% CI 0.04 to 0.62, respectively).

Dyspareunia

Limited evidence was available for the assessment of dyspareunia (see *Appendix 15, Figure 60*). In general, the number of studies included in the meta-analyses for the different treatment comparisons was small and CIs were wide.

Infection (including urinary tract infection, wound infection and infection related to mesh) and other complications

The number of available studies for the assessment of infection (see *Appendix 15, Figures 61–63*) was limited. Our meta-analyses results indicate that the rate of UTI was similar between single-incision sling and transobturator MUS [see *Appendix 15, Figure 61*; seven studies, 12 months post surgery: 36 out of 544 (6.6%) vs. 26 out of 447 (5.8%); OR 1.11, 95% CI 0.63 to 1.96]. For the other treatment comparisons the number of studies was small and CIs were wide.

Appendix 15, Figure 63 shows the summary estimate for the different treatment comparisons for the assessment of 'complications' as defined by the authors of the individual trials and of the Cochrane systematic reviewers. It is worth pointing out that perioperative complications may include outcomes such as haemorrhage, haematoma, cardiovascular events and pain as well as other unspecified outcomes. Transobturator MUS and retropubic MUS showed similar rates of perioperative complications [see *Appendix 15, Figure 63*; 15 studies: 127 out of 1084 (11.7%) vs. 150 out of 1153 (13.0%); OR 0.81, 95% CI 0.55 to 1.19].

Death

No deaths (related to surgery) were reported in any of the included studies.

Resource utilisation: pairwise comparison

Appendix 15, Figure 64 reports the meta-analyses results for the different treatment comparisons for the assessment of resource utilisation. For some comparisons only a limited number of studies were available and no firm conclusions can be drawn.

Length of hospital stay

Length of hospital stay after transobturator MUS was shorter than after retropubic MUS [17 studies: transobturator MUS vs. retropubic MUS, standardised mean difference (SMD) –0.38, 95% CI –0.70 to –0.06], open colposuspension (two studies: open colposuspension vs. transobturator MUS; SMD 1.83, 95% CI 1.36 to 2.30) and traditional sling (two studies: traditional sling vs. transobturator MUS; SMD 1.71, 95% CI 1.25 to 2.17).

Length of hospital stay after colposuspension was longer than after retropubic MUS (four studies: open colposuspension vs. retropubic MUS, SMD 2.26, 95% CI 1.98 to 2.55) or laparoscopic colposuspension (seven studies: laparoscopic colposuspension vs. open colposuspension; SMD –1.64, 95% CI –2.45 to –0.84) but shorter than after anterior repair (one study: anterior repair vs. open colposuspension; SMD 0.90, 95% CI 0.37 to 1.43).

Operation time

Operation time for transobturator MUS was shorter than that for retropubic MUS (32 studies: SMD –0.12, 95% CI –1.29 to –0.74) but longer than that for single-incision sling (18 studies: single-incision sling vs. transobturator MUS; SMD –0.53, 95% CI –0.86 to –0.19).

Summary of clinical effectiveness assessment

The systematic review of clinical effectiveness was based on data from 175 studies (21,598 women in total) comparing one surgical procedure with another for the treatment of SUI in women. The number of included studies identified from the eight published Cochrane systematic reviews was 147 (84%). A further 28 studies (16%) were identified through an updated literature search conducted in May 2017. This updated search used the same search strategy and eligibility criteria as those used for the included Cochrane systematic reviews.

A further, more recent, updated search was conducted in October 2017 and identified an additional 10 articles that appeared to meet our inclusion criteria. These studies have not been incorporated into the current assessment, but are listed, for information, in *Appendix 16*.

The majority of included studies had a high or unclear risk of bias across all risk-of-bias parameters but most notably for allocation concealment (selection bias). As blinding of participants and personnel is not feasible in trials assessing surgical interventions, protection against performance bias and detection bias was likely to be compromised in the included studies. This is a general issue with all surgical trials.

The assessment of effectiveness focused on two primary outcomes: the number of women cured from incontinence and the number of women who experienced an improvement in their incontinence symptoms. The NMA, which combined evidence from direct head-to-head comparisons and indirect comparisons, included 120 studies that reported data on cure or improvement. The NMA results indicate that retropubic MUS, transobturator MUS and traditional sling are more effective than other surgical procedures for both primary outcomes. Open colposuspension appears to be relatively effective for both outcomes (see the SUCRA ranking in *Figure 2*). For both primary outcomes, cure and improvement, the overall quality of evidence was low. As we were unable to extract study characteristics, we were unable to check the transitivity assumption (studies are similar with regard to important characteristics).

Assessment of adverse events was hampered by the dearth of available data. Direct head-to-head meta-analyses were available mainly for treatment comparisons involving retropubic MUS, transobturator MUS or single-incision sling. Follow-up time was generally short, with a median of 12 months.

Compared with retropubic MUS, transobturator MUS was associated with lower rates of major vascular complications and voiding difficulties but higher rates of repeat surgery.

For other intervention comparisons, the number of studies was generally small and the CIs wide. However, there was some evidence to suggest that bladder perforation was more likely to occur after retropubic MUS than after transobturator MUS, open colposuspension or traditional sling. Rate of tape or mesh erosion or extrusion was similar between transobturator MUS and retropubic MUS (27 studies with a total of 4523 women).

Transobturator MUS was associated with a higher rate of groin pain but a lower rate of suprapubic pain than retropubic MUS. Retropubic MUS had a higher rate of post-operative pain than single-incision sling and transobturator MUS had a higher rate of unspecified pain than single-incision sling. Studies that assessed pain had usually short follow-up periods (i.e. $\leq$ 12 months).

The main area of uncertainty for all surgical interventions relates to the lack of long-term data for the assessment of their safety.

Chapter 4 Discrete choice experiment

Introduction

To estimate women's preferences for key aspects of surgical interventions being evaluated in this research we designed and conducted a DCE. DCEs describe an intervention or service in terms of a number of characteristics or attributes (e.g. post-operative complications, post-operative pain). The extent to which an individual values an intervention is expected to depend upon the level these characteristics take (e.g. whether or not patients could experience chronic post-operative pain). In other words, DCEs explore relative preferences for treatments with differing attributes,[205] which allows an exploration of the relative importance of each attribute of a surgical treatment that may influence a patient's decision for or against surgery.

Discrete choice experiments are used regularly in health economics to elicit preferences over health-care products and programmes and in the valuation of preference for health states[206–208] and they offer an additional approach to investigate acceptability of different surgical treatments among patients. Several reviews have been conducted to compile the evidence of the use of DCEs in the health-care setting.[209–212] DCEs usually involve three inter-related components: (1) an experimental design used to implement a survey that aims to assess individual choices and generate choice data, (2) a quantitative analysis to estimate preferences from choice data and (3) the use of the estimated preferences to either derive welfare measures or construct other policy analyses.[205]

A DCE was conducted to explore women's preferences for surgical treatment options for SUI assessing differing attributes. Data were collected by means of a self-completed online survey. Best practice guidance for DCEs were followed throughout.[205,211] The DCE results provide policy-relevant information on average preferences for treatments and outcomes for women with SUI.

Aims

The DCE will answer the following research questions:

- What are the key attributes of surgical treatments for SUI as expressed by female patients?
- What are the relative preferences for different levels of these attributes among women and, more specifically, female patients?
- What trade-offs are women/female patients willing to make between the different attributes?

Methods

The methods that were employed in the DCE study were informed by the Lancsar and Louviere[205] and Ryan and Gerard[211] reviews of the applications of DCEs in health care, considered to provide best practice guidance for DCEs. The methods can be broken down into four key steps: step 1 – identification of attributes and levels; step 2 – experimental design; step 3 – data collection; and step 4 – data analysis and interpretation. Details of the four steps, with regard to the current study, are provided below.

Step 1: identification of attributes and levels

The findings from the clinical effectiveness review (section 3) were consolidated to facilitate the creation of key attributes and associated levels related to women's preferences for the different surgical treatment options. The chosen attributes and levels were plausible in both clinical and policy terms.[205] Once the attributes and levels were finalised a DCE design was generated (see *Step 2: experimental design*).

It is recognised that a reasonable number of attributes to be included within a DCE is around six, as more than this might lead to an unmanageable number of options to be meaningfully considered by the respondent.[213] The more attributes that are included in a DCE, the less likely respondents are to fully consider the pros and cons of different choices as described by differences in the attribute levels. Therefore, it may prove more difficult to identify trade-offs between attribute levels that a respondent is willing to make during the decision-making process, which is crucial when estimating marginal rates of substitution (MRS) (an estimation of the ratio between values that individuals place on different attributes, quantifying the trade-off a respondent is willing to make between two attributes). Probabilities for all adverse events included in the choice tasks were assumed to be similar and were therefore considered constant for all scenarios.

The final list of attributes and corresponding levels is reported in *Table 7*.

Step 2: experimental design

The DCE survey consisted of a number of possible clinical scenarios based on the attributes and levels identified in step 1. Each scenario was made up of all five attributes and the associated levels contained in each attribute. The combination of attributes and levels presented in *Table 7* would generate > 4000 possible scenarios [4320 (5 × 4 × 6 × 6 × 6)]. We reduced the number of scenarios to a manageable number by using a measure known as D-efficiency, which provides an efficient choice design by minimising the overlap in attribute levels between scenarios. The D-efficient design was used to reduce the number of scenarios to the minimum required to estimate all main effects and higher order interactions while still providing sufficient data to estimate preferences from responses.[205,209] We applied one restriction that implied that an adverse event of infection could only occur with a hospital stay of ≥ 2 days to mirror clinical practice in which post-operative infections extend the hospital stay.

The design for the DCE was generated using Ngene 1.1 (ChoiceMetrics, Sydney, NSW, Australia). The best design generated by Ngene was chosen with the aim of minimising standard errors. The reliability of the model parameters to be estimated can be quantified in terms of the asymptotic standard errors and covariances; thus, improvements in reliability indicate a reduction in the asymptotic standard errors (i.e. variance around preference estimates).[215] A blocked design of DCE choice sets was used to ensure greater variance in the data. We used three blocks of 12 questions to minimise respondents' burden, randomly allocating respondents to a block of DCE choices. Based on a pilot run of the DCE, we updated the design to improve the validity of the results.

An example of a pairwise choice set is shown in *Table 8*. Respondents were asked to choose their preferred scenario from each pairwise choice set. An opt-out option was given, which in this instance was defined as the choice of no treatment (i.e. 'I would choose not to undergo surgery').

The DCE survey was part of a full questionnaire that included (1) questions on basic sociodemographics (including age, ethnicity and employment status), (2) questions on potential incontinence history, (3) an introductory text explaining the DCE task and (4) the main DCE survey.

Step 3: pretesting and data collection

Pretesting

Pretesting of the DCE component of the questionnaire was conducted to (1) test the wording used to describe attributes and levels, (2) assess ease of use and (3) identify missing attributes and levels. Members of the general public ($n = 5$) and the Cochrane Consumer Network ($n = 5$) were consulted to pretest and refine the draft questionnaire using cognitive interviewing and semistructured 'think-aloud' interviews.[216]

TABLE 7 Attributes and levels of surgical treatments for use in the DCE survey

Characteristic	Available options	Comments
Adverse events	New urinary symptoms (including UUI)[a]	Need to understand women's preferences for certain types of adverse events and which adverse events are least preferred
	Infections (post-operative or urinary tract)	
	Damage to organs/nerves	
	Pain during intercourse (dyspareunia)	
	Voiding difficulties	
Chronic pain	No[a]	Need to understand women's preferences for being pain free after the operation. By definition, chronic pain refers to pain lasting for > 6 months
	Mild	
	Moderate	
	Severe	
Length of hospital stay (days)	1	The average duration for a hospital stay in the UK is ≈2.5 days.[214] We are interested if women may trade off a longer hospital stay for an improvement in other attributes, so also include longer durations
	2	
	3	
	4	
	5	
	6	
Time to return to normal activities (weeks)	2	We are interested in identifying women's preferences for recovery time and if they might be willing to trade off a longer duration for an improvement in other attributes
	4	
	6	
	8	
	10	
	12	
Risk of recurrence during 12 months after surgery (%)	0	We are interested in identifying women's preferences for the recurrence risk and if they might be willing to trade off a higher risk for an improvement in other attributes
	10	
	20	
	30	
	40	
	50	

UUI, urge urinary incontinence.
a Reference category in regression models.

TABLE 8 Illustrative scenario pair to be used in the DCE survey: question 1 – 'If you could choose only ONE out of the three options, which would you prefer?'

Attribute	Option		
	Scenario A	Scenario B	Neither – I would choose not to undergo surgery
Adverse event	Infections (post-operative or urinary tract)	New urinary symptoms	
Chronic pain	No	Moderate	
Length of hospital stay (days)	5	3	
Time until return to normal activities (weeks)	4	6	
Risk of recurrence during 12 months after surgery (%)	10	20	

Data collection

Data were collected via the online platform Qualtrics (Qualtrics, Provo, UT, USA), which is a standard provider of data collection and analysis products for academic research. The main data collection took place via an online survey and was conducted by a market research company (Research Now, Plano, TX, USA) between August and September 2017. Ethics approval for all aspects of the DCE study was granted from Newcastle University Ethics Committee (reference 11664/2016).

Participants

All participants were aged ≥ 18 years, resident in the UK and members of Research Now's online panel. As part of the data collection process (and in accordance with Research Now's procedure), participants received a small financial incentive (in the form of a voucher) to take part. Quota sampling was used to guarantee the representativeness of participants according to the age distribution of incontinence patients.

Sample size

Lancsar and Louviere[205] highlight the complexities and problems of performing sample size calculations for DCEs and stress the need for further research in this area. Based on findings from previous health-related DCEs, where robust models have been estimated from samples sizes of 50 respondents,[217] we aimed to collect data from 800 participants, which – following a rule of thumb of a minimum of 10 observations per parameter plus 50 – provided a more than sufficient sample size and allowed for some subgroup analyses.

Piloting the full questionnaire

The full questionnaire was piloted in a subset of the target population. The pilot sample size was big enough ($n = 61$) to conduct preliminary regression analyses, allowing for detection of potential inconsistencies (e.g. positive relations where negative ones were anticipated) and adjusting of the DCE design accordingly. The pilot sample was part of the main survey sample.

Step 4: data analysis and interpretation

Data were returned to the research team in an anonymised format. The research team did not receive contact details or any personal identifier information from survey participants.

Data were analysed using a random utility model framework and appropriate logistic regression techniques to estimate the mean change in utility that women place on different attribute levels compared with the reference level. This assumes that respondents choose the alternative in a choice set that gives them greatest utility out of the available options[218] and that therefore the choices individuals make in a DCE reveal the utility they place on the alternatives presented.

Analyses were undertaken on the full study sample of the general population and separately for subgroups of women with and women without any type of UI.

Analysis methods

The sociodemographic profile and characteristics of respondents in the full sample and the subgroups were calculated in the univariate descriptive analyses in which means (and SDs) and number of observations (and proportions) were calculated for continuous and categorical variables, respectively.

Using bivariate analyses, we assessed whether or not preferences were influenced by characteristics of respondents (e.g. experience of previous treatments, socioeconomic factors). The standard approach to elicit responses and analyse data from choice sets with more than two options are conditional probit or logit models. Therefore, data were analysed using a random utility model framework and conditional and mixed logistic regressions to estimate mean change in utility placed on an attribute level compared with the reference level. The initial analysis employing a conditional logit model[219] may have violated the assumption of independence compared with irrelevant alternatives assumption (IIA). This assumption requires the ratio of probabilities for any two alternatives to be independent of the attribute levels in a third alternative. To overcome this potential problem, we used a mixed logit (MXL) model that accounted for preference heterogeneity within the specified random variable. It allowed investigation of unobserved preference heterogeneity, that is, identifying if preferences for a specific attribute vary across respondents. If preference heterogeneity was present, the final coefficient for the specific attribute may have disguised the variation in preferences between respondents. The MXL model is a more general approach to a subgroup analysis because no assumptions are required regarding how individual characteristics may influence individual preferences. The alternative specific constant (ASC) variable was considered to be the random, normally distributed parameter and all other model parameters remained fixed. We used 100 Halton draws for the simulation of maximum likelihood.

Main effects parameters were estimated from the utility function (μ) (equation 1). The functional form incorporated 22 dummy attribute-level coefficients (see *Table 7*) so that:

$$\mu_{qj} = \propto + \lambda' X_{qj} + \varepsilon_{qj}, \quad (1)$$

where μ is the indirect utility function of individual q for alternative j, α is the ASC term, $\lambda' X_{qj}$ is the vector of attribute levels included in the DCE survey and ϵ_{qj} is the random element that is added to reflect the unobservable factors affecting the estimation of the indirect utility function.

Different regression models were employed to analyse the effect of attribute levels on individual preferences for different characteristics of surgical treatments. Interaction terms were included to identify if and how individual characteristics mediated choices. The chosen interaction terms were used to explore whether or not preferences differed (e.g. between women with and without UI). For those without UI, the effect of knowing someone close with UI on overall preferences was also investigated. Given the sufficiently large sample size, subgroup analyses were run to identify potential differences in preferences between the total sample and subgroups of women with any type of UI and those women who did not have UI.

An ASC for options A or B was included in the regression model to account for any latent or unobserved factors that may have been associated with choosing an alternative of surgical treatment (option A or B) compared with no treatment (opt-out option). Dummy coding was used for the attributes adverse events and chronic pain and all other attributes (length of hospital stay, time until return to normal activities, risk of recurrence) were considered continuous variables and assumed to be linear. Reference levels for the DCE attributes used in the regression models were new urinary symptoms, including urge urinary incontinence (UUI), and no pain. Length of hospital stay, time until return to normal activities and risk of recurrence were included as continuous (linear) variables.

Model goodness of fit was assessed using the likelihood ratio (LR) test statistic.

Marginal rates of substitution were calculated for all attributes included in the DCE based on average willingness to wait for a return to normal activities (i.e. how much longer an individual would be willing to wait, on average, for a change in the utility of another attribute).

This analysis enables the estimation of the trade-offs between attribute levels and the magnitude of the coefficient in the regression models to be interpreted (i.e. the willingness to wait values can be directly compared in order to determine relative strength of preference across the remaining attributes).

Predictive uptake rates were also calculated based on the best-case scenario (as observed in the DCE) versus no surgery and worst case scenario versus no surgery. The statistics are presented as percentages and compare the variation in uptake rates associated with different configurations/outcomes of surgery.

Both MRS and predictive uptake rates were based on results from the MXL model (see *Table 10*).

Results

Descriptive analysis

A total of 789 women completed the DCE. Each of the respondents provided responses for 12 choices, resulting in a total of 9468 choices that were included in the analysis. *Table 9* describes the sample population. The number of missing data for some of the characteristics describing the women responding to the survey was $\lesssim 1\%$.

TABLE 9 Descriptive statistics

Characteristic	Respondents, *n* (%)		
	All (*N* = 789)	With UI (*N* = 353; 44.7%)	Without UI (*N* = 436; 55.3%)
Age (years), mean (SD)	53.1 (12.3)	51.5 (12.1)	54.4 (12.3)
Declared, *n* (%)	786 (99.6)	352 (99.7)	434 (99.5)
Missing, *n* (%)	3 (0.4)	1 (0.3)	2 (0.5)
Country			
England	632 (80.1)	280 (79.3)	352 (80.7)
Northern Ireland	18 (2.3)	9 (2.5)	9 (2.1)
Scotland	92 (11.7)	42 (11.9)	50 (11.5)
Wales	47 (6.0)	22 (6.2)	25 (5.7)
Children			
Yes	559 (70.8)	285 (80.7)	274 (62.8)
No	223 (28.3)	66 (18.7)	157 (36.0)
Prefer not to say	5 (0.6)	2 (0.6)	3 (0.7)
Missing	2 (< 1.0)	0 (0.0)	2 (< 1.0)
Marital status			
Single	126 (16.0)	47 (13.3)	79 (18.1)
Cohabiting/married/civil partnership	537 (68.1)	251 (71.1)	286 (65.6)
Separated/divorced	93 (11.8)	41 (11.6)	52 (11.9)
Widowed	24 (3.0)	11 (3.1)	13 (3.0)
Other	1 (0.1)	1 (0.3)	0 (0.0)
Prefer not to say	5 (0.6)	1 (0.3)	4 (0.9)
Missing	3 (< 1.0)	1 (< 1.0)	2 (< 1.0)

TABLE 9 Descriptive statistics (*continued*)

Characteristic	Respondents, *n* (%)		
	All (*N* = 789)	With UI (*N* = 353; 44.7%)	Without UI (*N* = 436; 55.3%)
Employment status			
Yes (full-/part-time)	394 (49.9)	186 (52.7)	208 (47.7)
Self-employed	41 (5.2)	9 (2.5)	32 (7.3)
Retired	206 (26.1)	75 (21.2)	131 (30.0)
Unemployed	74 (9.4)	35 (9.9)	39 (8.9)
Looking after children	27 (3.4)	16 (4.5)	11 (2.5)
Other	43 (5.4)	30 (8.5)	13 (3.0)
Prefer not to say	4 (0.5)	2 (0.6)	2 (0.5)
Annual household income (£)			
< 15,000	125 (15.8)	64 (18.1)	61 (14.0)
15,000–25,999	170 (21.5)	79 (22.4)	91 (20.9)
26,000–34,999	127 (16.1)	53 (15.0)	74 (17.0)
35,000–49,999	147 (18.6)	60 (17.0)	87 (20.0)
50,000–69,999	65 (8.2)	25 (7.1)	40 (9.2)
≥ 70,000	85 (10.8)	46 (13.0)	39 (8.9)
Prefer not to say	58 (7.4)	17 (4.8)	41 (9.4)
Do not know	9 (1.1)	7 (2.0)	2 (0.5)
Missing	3 (< 1)	2 (< 1)	1 (< 1)
Highest level of education			
None	14 (1.8)	2 (0.6)	12 (2.8)
Secondary school	244 (30.9)	104 (29.5)	140 (32.1)
College	206 (26.1)	92 (26.1)	114 (26.1)
University	295 (37.4)	143 (40.5)	152 (34.9)
Other	27 (3.4)	11 (3.1)	16 (3.7)
Prefer not to say	1 (0.1)	0 (0.0)	0 (0.0)
Missing	2 (< 1.0)	1 (< 1.0)	1 (< 1.0)
Ethnicity			
White	735 (93.2)	331 (93.8)	404 (92.7)
Other	54 (6.8)	22 (6.2)	32 (7.3)
Health status			
Excellent	95 (12.0)	33 (9.3)	62 (14.2)
Good	354 (44.9)	121 (34.3)	233 (53.4)
Fair	219 (27.8)	112 (31.7)	107 (24.5)
Poor	93 (11.8)	64 (18.1)	29 (6.7)
Very poor	28 (3.5)	23 (6.5)	5 (1.1)

continued

TABLE 9 Descriptive statistics (*continued*)

Characteristic	Respondents, *n* (%)		
	All (*N* = 789)	With UI (*N* = 353; 44.7%)	Without UI (*N* = 436; 55.3%)
Type of UI			
Stress		128 (36.3)	
Urge		90 (25.5)	
Both		116 (32.9)	
Do not know		5 (1.4)	
Other		12 (3.4)	
Missing		2 (< 1.0)	
UI limiting daily activities			
Extremely		34 (9.6)	
Moderately		102 (28.9)	
Slightly		168 (47.6)	
Not at all		45 (12.7)	
Missing		4 (1.1)	
UI treatment history			
Yes		151 (42.8)	
No		202 (57.2)	
Type of previous UI treatment			
Surgical		32 (9.1)	
Non-surgical		94 (26.6)	
Both		19 (5.4)	
Do not know		5 (1.4)	
Missing		1 (< 1.0)	
SUI treatment scheduled			
Yes		51 (14.4)	
No		297 (84.1)	
Missing		5 (1.4)	
Member of incontinence support group			
Yes		25 (7.1)	
No		328 (92.9)	
Know someone close with UI (if not UI patient themselves)			
Yes			123 (28.2)
No			307 (70.4)
Missing			6 (1.4)
DCE responses (*n*)	9468	4236	5232
Option A (%)	34.4	35.5	33.5
Option B (%)	31.9	31.5	32.1
Opt-out option (no treatment) (%)	33.7	33.0	34.4

The average age was 53 years and significantly lower in the patients group than in the non-patients group. The majority of respondents lived in England (80%), followed by Scotland (12%), Wales (6%) and Northern Ireland (2%). The percentage of women with children differed significantly between both groups: 81% of women with UI reported having children, whereas only 63% of women without UI reported having children. This is intuitively sensible, as having had children is a risk factor for developing some forms of incontinence. The majority of respondents in both groups lived with their partner (with UI, 71%; without UI, 66%) and around half were in full- or part-time employment (with UI, 53%; without UI, 48%), 21–30% were retired and 3–7% were self-employed. Most respondents in either group had an annual household income of £15,000–25,999 and between 15–20% reported an annual household income of ≤ £15,000 or £26,000–34,999 and £35,000–49,999, respectively. The distribution of educational attainments was relatively even between both groups, although a higher proportion of patients had a university degree (with UI, 41%; without UI, 35%). The majority of respondents (92–93%) had a white ethnic background. Health status varied significantly between both groups. On average, women with UI reported poorer health than those without UI and around two-thirds of non-patients described their general health to be 'excellent' or 'good'.

Among women with UI, the most common type of UI was SUI (36%), followed by MUI (33%) and UUI (26%). The majority of women with UI found their incontinence to be not or only slightly limiting in their daily activities (13% and 48%, respectively), 29% reported it to be moderately limiting and 10% reported it to be extremely limiting. Around 43% had received treatment previously. However, the majority of previous treatment took the form of management of incontinence (i.e. non-surgical treatment). Out of the 128 patients with SUI, nearly half reported to have treatment scheduled and 7% reported to be a member of an incontinence support group.

Among women without UI, 28% knew someone close to them with UI.

Statistical analyses

Two-thirds of women were prepared to make a choice between surgical options and one-third of women declared that they would rather choose no surgery. Responses to the three choices were evenly split: around one-third of all responses was allocated to each of the options (A, B and the opt-out option), indicating that the majority of respondents would choose surgery (options A and B) over no surgical treatment (opt-out option).

Table 10 reports the marginal effects of each attribute on utility for the conditional models (1–7) and the MXL model (8). Conditional logistic regressions were run for all respondents (models 1–2), women with UI (models 3–6) and women without UI (model 7). Marginal utility values indicate relative preferences for levels within an attribute (for example, relative preferences against mild/moderate/severe pain compared with no pain). Positive marginal utility values indicate an attribute level is preferred to the reference level and negative marginal utility values indicate that the attribute level is valued less than the reference level. For the MXL model, means and SDs are reported for the random parameter. The sign of SDs is irrelevant; significant SDs imply preference heterogeneity among respondents for that specific attribute, suggesting that the reported coefficient may disguise differences in the underlying preferences. To identify which differences are statistically significant, *p*-values are included.

The results were found to be very similar across all models, except for the marginal effect of the ASC capturing a preference for or against surgical treatment in general. Preferences for surgical treatment varied significantly in both the significance and direction of the effect depending on model specifications. The coefficient for the ASC was only significant in some of the models for women with UI (model 4–6) and the mixed-effects model (model 8), whereas the estimations for the full sample and women without UI suggest no significant result (i.e. no preference for or against surgical treatment in general). Significant coefficients for both the mean and SD from the mixed-effects model suggest that preference heterogeneity is present among respondents.

TABLE 10 Marginal utility values from logistic regression models

	Model							
	Conditional logit							MXL
Variable	1 (all)	2 (all)	3 (patients)	4 (patients)	5 (patients)	6 (patients)	7 (non-patients)	8 (all)
ASC (option A or B)								
Mean	0.100	0.071	–0.087	0.394***	0.274***	–0.362**	0.075	1.361***
SD	N/A	N/A	N/A	N/A	N/A	N/A	N/A	4.029***
Adverse event								
New urinary symptoms[a]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Infections	0.231***	0.231***	0.244***	0.245***	0.247***	0.248***	0.213***	0.280***
Damage to organs/nerves	–0.107**	–0.106**	–0.127*	–0.151**	–0.136*	–0.140*	–0.084	–0.088*
Pain during intercourse	0.107**	0.107**	0.123*	0.142**	0.131*	0.142**	0.090	0.135***
Voiding difficulties	–0.274***	–0.274***	–0.218***	–0.217***	–0.223***	–0.219***	–0.325***	–0.278***
Chronic pain								
No[a]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Mild	–0.036	–0.036	0.034	0.044	0.037	0.036	–0.099*	–0.053
Moderate	–0.171***	–0.171***	–0.073	–0.061	–0.071	–0.057	–0.245***	–0.185***
Severe	–0.204***	–0.204***	–0.112*	–0.119**	–0.107*	–0.110*	–0.279***	–0.204***
Length of hospital stay	–0.031***	–0.031***	–0.030**	–0.030**	–0.028**	–0.032**	–0.032***	–0.030***
Time until return to normal activities	0.021***	0.021***	0.022***	0.022***	0.022***	0.022***	0.023***	0.023***
Risk of recurrence during 12 months after surgery	–0.002*	–0.002**	–0.001	–0.001	–0.001	–0.001	–0.003**	–0.002***

	Model							
	Conditional logit							MXL
Variable	1 (all)	2 (all)	3 (patients)	4 (patients)	5 (patients)	6 (patients)	7 (non-patients)	8 (all)
Interactions and additional variables								
ASC × UI patient								
Patient	N/A	0.063	N/A	N/A	N/A	N/A	N/A	N/A
ASC × UI type (reference category: mixed)								
SUI	N/A	N/A	0.348***	N/A	N/A	0.686***	N/A	N/A
UUI	N/A	N/A	0.123	N/A	N/A	0.221**	N/A	N/A
Other	N/A	N/A	0.752***	N/A	N/A	0.569***	N/A	N/A
ASC × limiting UI (reference category: extremely)								
Moderately	N/A	N/A	N/A	0.150	N/A	0.339**	N/A	N/A
Slightly	N/A	N/A	N/A	0.437***	N/A	–0.158	N/A	N/A
Not	N/A	N/A	N/A	1.303***	N/A	1.079***	N/A	N/A
ASC × treatment history								
Previous treatment	N/A	N/A	N/A	N/A	0.754***	0.690***	N/A	N/A
ASC × knowing someone with UI	N/A	N/A	N/A	N/A	N/A	N/A	0.272	N/A
Log (pseudo)likelihood	–10293.3	–10292.2	–4557.8	–4462.4	–4550.5	–4359.2	–5587.6	–7838.0

*$p < 0.1$, **$p < 0.05$, ***$p < 0.01$.
N/A, not applicable.
a Reference category.

Preferences for the different types of adverse events were relatively robust to varying model specifications. Infections and pain during intercourse were found to be associated with a utility gain and, therefore, not disliked as much as the reference category of new urinary symptoms, and damage to organs or nerves and voiding difficulties were less preferred.

The results for different levels of chronic pain were in line with expectations, describing a gradient of increasingly negative preferences with higher levels of pain. Compared with the reference level of no pain, mild chronic pain was not found to affect utility significantly across most models, whereas moderate and severe pain were associated with a greater negative preference. However, the results were mediated in models for women with UI that included interactions between the ASC and how limiting the type of UI was perceived with regard to daily activities (models 4 and 6) and between the ASC and a positive treatment history (models 5 and 6). In these models, the negative gradient could still be observed but was no longer statistically significant. Instead, if respondents had had treatment before, and the more limiting their UI, the more likely they were to choose surgery.

As expected, women would prefer not to experience longer hospital stays or a higher risk of recurrence. However, the negative preference for a higher risk of recurrence was not significant in models for women with UI (models 3–6) in which interaction terms between the ASC (and, therefore, the overall preference for surgery) and different characteristics capturing patient experiences may have dominated the impact of different levels of pain. The sample of women without UI showed the strongest gradient of negative preferences for higher levels of pain. A longer time to return to normal activities was associated with a utility gain and, therefore, described a positive preference.

Adding interactions between ASCs and additional variables improved the goodness of fit for all patient models, and model 6 was found to be the best-fitted model. Compared with patients with a mixed form of UI, those suffering from SUI were more likely to choose surgery. Similarly, patients with a positive treatment history and a more limiting form of UI gained more utility from choosing surgical treatment options.

Comparing the log LRs between model 1 (conditional logit) and model 8 (MXL) that used the same variables and same study populations showed that the MXL model provided better model estimates when accounting for preference heterogeneity around the ASC. In the non-patient model 7, knowing someone close with UI did not significantly increase the preference for surgical treatment.

Marginal rates of substitution were calculated for all attributes included in the DCE based on average willingness to wait for a return to normal activities (i.e. how much longer an individual would be willing to wait, on average, for a change in the utility of another attribute). In comparison with new urinary symptoms, individuals would, on average, be willing to wait an additional 3.8 weeks to return to normal activities to avoid damage to their nerves or organs and up to an additional 12 weeks, on average, to avoid voiding difficulties. Individuals were not willing to wait any additional time to avoid infections or pain during intercourse in comparison with new urinary symptoms.

To avoid chronic pain, individuals would, on average, be willing to wait an additional 2.3 weeks to avoid mild pain compared with no pain. Individuals would be willing to wait an additional 8 and 9 weeks, on average, to avoid moderate and severe pain, respectively.

For a one-night reduction in their hospital stay an individual would, on average, be willing to wait 1 additional week to return to normal activities. To reduce the risk of recurrence by 1%, an individual would on average be willing to wait an additional 15 hours.

Predicted uptake rates, based on a hypothetical best-case surgery (adverse event of infection, no pain, a length of stay of 2 days, 12 weeks to return to normal activities and 0% risk of recurrence) versus a no surgery option were calculated. Given this option, it is predicted that 62% of respondents would choose the surgical option over no surgery. Similarly, for the hypothetical worst-case surgery (voiding difficulties,

severe pain, length of stay of 6 days, 2 weeks to return to normal activities and 50% risk of recurrence) versus the no surgery option, the predicted uptake rates were estimated as 33% for the worst-case scenario. In this case, 67% of respondents would, on average, choose no surgery.

Discussion

Summary of results

To our knowledge, this is the first DCE to investigate differential characteristics of surgical treatment options for UI and their potential impact on women's decisions to undergo surgery. Analysis of choice set data from the DCE revealed that around two-thirds of respondents chose a treatment option over no surgery. However, we found evidence that preferences around the choice of surgical treatment may vary across individuals.

In terms of types of adverse event associated with surgical treatment, infections and pain during intercourse were preferred to the reference category of new urinary symptoms, whereas damage to organs or nerves and voiding difficulties were less preferred. These preferences were relatively robust across all models, but the results, although confirming the same trend in preferences, were not statistically significant for damage to organs or nerves and pain during intercourse in non-patient respondents. Respondents associated increasing levels of disutility (i.e. negative preference) with higher levels of chronic pain, longer durations of hospital stay and higher risk of recurrence. We also found evidence that longer durations to return to normal activities after the surgery was associated with a statistically significant, positive preference.

Interpretation of results

The heterogeneity around a general preference for or against surgical treatment may be explained by the range of surgical treatments available, their level of invasiveness and, therefore, their varying impact on some of the attributes included in the DCE. The different subgroups in our sample may have contributed to the heterogeneity around the preference for surgical treatment in general. Comparing results across all models suggests that general preferences concerning surgical treatment vary not only between patients and non-patients but also within the patient subgroup, as implied by the change in sign of the ASC coefficient between model 4 and models 5 and 6. Although the results for the full sample suggest a preference for surgery, this finding may have been driven by the majority of non-patients within the sample. We found some evidence that patients in general may associate a negative preference with surgery for UI. However, those patients with SUI, who reported their UI to be extremely limiting with regard to daily activities and who had undergone surgical treatment before were more likely to choose surgery again. This may indicate that patients who have never undergone surgery fear the surgical procedure and are more reluctant to choose surgical treatment. One reason for this finding may be that patients are more used to managing their UI and may consider non-surgical treatment as long as their condition is not experienced as limiting their daily activities too much. Interviews conducted with patients during the pretesting stage of the DCE provided further support for this finding.

Preferences around different types of adverse event following surgery were captured compared with the reference of new urinary symptoms. Our findings suggest that infections and pain during intercourse are considered to be more acceptable adverse events, whereas damage to organs or nerves and voiding difficulties were less acceptable and reduced the likelihood of respondents choosing a surgical treatment option. This is also confirmed by the MRS analysis, which showed that individuals were willing to wait longer to recover to avoid damage to organs or nerves and to avoid voiding difficulties but were not willing to wait to avoid infections or pain during intercourse.

As expected, we found evidence for higher levels of chronic pain and increased risk of recurrence to be associated with negative preferences. However, although the same trend could be observed in all models, the statistical significance varied, which may indicate the difference in importance of these attributes for patients and non-patients. When accounting for patient characteristics around their type of UI, the degree

to which it was limiting them in daily activities and their treatment history, preferences for chronic pain and risk of recurrence were less significant. Patients with SUI or UUI, extremely or moderately limiting UI and a treatment history had a stronger preference for surgery regardless of the associated level of pain or risk of recurrence.

There was a strong preference for shorter hospital stays, suggesting that the less invasive may be the preferred treatment options, with reduced risk of infections that may increase the length of hospital stay following surgery.

Other than expected, we found evidence for a preference for longer durations to return to normal activities, although the pilot data had suggested a negative preference for this attribute. A reason for this finding may be that respondents may have interpreted 'return to normal activities' as 'return to work' (assumes that they would not lose any wages). Alternatively, and especially for those who had never experienced any surgical treatment, respondents may have found the attribute levels to be unrealistic, expecting the recovery after surgery to be longer than the stated maximum of 12 weeks.

Strengths and weaknesses

A major strength of our study, which elicited preferences for different characteristics of surgical treatment options of UI is the use of a DCE in combination with an online panel. It allowed us to use a relatively large sample size and control for differences in respondent characteristics accordingly. The anonymity of the online setting may have allowed the responding UI patients to be more honest and report their problems in greater detail than they may feel comfortable to report in a health-care setting. The advantage of using a DCE for preference elicitation is that it allows consideration of real-life choice situations in which multiple factors may influence the decision-making process. The combined influence of those factors and potential trade-offs between their varying levels cannot be readily elucidated or quantified by other methods.

However, DCEs have been criticised as difficult for participants to understand. We aimed to minimise this risk by following best practice guidelines for the design and development of DCEs[205,211] and engaged members of the general public and patients in the development process to maximise internal and external validity.

We acknowledge that the sample recruited by the research company is a convenience (i.e. non-random) sample that may not be representative of the target population and did not allow us to determine response rates to the survey. Some of our analyses were aimed at identifying differences in preferences between subgroups of patients and non-patients; however, the characteristics of those subgroups may have differed by definition (e.g. see the lower average health status and higher proportion of respondents with children in the patient subgroup). Alternative methods of recruitment and data collection in the context of DCEs, such as postal or telephone surveys, have been found to achieve very low response rates, thereby potentially reducing the representativeness and validity of results.[220]

Implications of findings for research

To our knowledge, this research provides the first insights into what women (with and without) UI want their treatment options to be like and which fundamental surgical treatment characteristics they prefer. More than half of respondents had UI or knew someone close with UI. However, given the wide range of surgical treatments and significant differences between them, capturing specific influences on and preferences for or against certain treatment characteristics is a complex process. Our patient subsample was not large enough to capture sufficient variation beyond the interaction effects for patient experience already included in our analyses. More research is needed to distinguish trade-offs between different characteristics of surgical treatment options. One study found that women suffering from UI would choose the treatment with the lowest risk of recurrence.[221] Our results provide further support but suggest that this preference may be mediated by other factors such as previous treatment experience and that this finding cannot necessarily be generalised without further research.

Although UI can have a substantial impact on a woman's daily activities and quality of life, previous research suggests that women under-report their condition and manage their incontinence before seeking treatment.[222] Barriers to seeking professional help may be imposed by a lack of awareness of treatment options, by the perception that these symptoms are normal after childbirth or in older age, or by feelings of shame or embarrassment.[223,224] Considering women's preferences and trying to reduce those barriers may help to reduce the levels of unmet need for incontinence services and to improve the organisation of surgical services.

Conclusion

To our knowledge, this is the first DCE to investigate differential characteristics of surgical treatment options for UI and their potential impact on women's decisions to undergo surgery. We found that women are less likely to choose surgical treatments that are associated with longer hospital stays, higher risks of recurrence and increased levels of chronic pain. However, although women with a treatment history had a negative preference for surgical treatments, those with forms of UI that were reported to be extremely or moderately limiting in daily activities preferred the surgical treatment option to no surgery. Further research investigating a woman's choice for or against surgery needs to investigate treatment history in greater detail and consider more individual characteristics including personal beliefs and perceptions that may act as a barrier to seeking professional advice.

Chapter 5 Review of cost-effectiveness evidence

Methods

In addition to the review of the clinical effectiveness of surgical treatments for SUI, a review of full model-based economic evaluations was conducted. The purpose of the review of model-based evaluations was to identify robust models and inputs to inform the economic modelling in this study. Specifically, the objective was to perform a critique of existing economic models to identify a model suitable for augmentation or to justify the development of a new economic model. Additionally, the review would be used to identify clinical and health economic data that were used in the identified models that could also be used in a new economic model. Trial-based economic evaluations were not included in the review to minimise the time commitment required for this aspect of the work. The review work was conducted in accordance with the Centre for Reviews and Dissemination's guidance for undertaking reviews in health care.[14]

Search strategy

The search strategy is outlined in *Appendix 17*.

Data sources

The following databases were searched during the review process:

- MEDLINE (via Ovid)
- MEDLINE In-Process & Other Non-Indexed Citations (via Ovid)
- Excerpta Medica Database (EMBASE) (via Ovid)
- NHS Economic Evaluation Database (NHS EED) (via Ovid)
- Health Management Information Consortium (via Ovid)
- Cost-effectiveness Analysis (CEA) Registry.

All databases were searched using the Ovid interface, except for the CEA Registry, which was searched through the CEA Registry website (https://cevr.tuftsmedicalcenter.org/databases/cea-registry).

Study selection

Two researchers undertook the screening of titles and abstracts obtained through the search using EndNote® X7 [Clarivate Analytics (formerly Thomson Reuters), Philadelphia, PA, USA] reference management software. Prior to initial screening, deduplication of records was undertaken. After initial screening, all potentially relevant articles were obtained for further scrutiny against the full selection criteria, with any disagreements resolved by discussion. The inclusion criteria were as follows:

- Study design: full economic evaluations involving a decision model-based analysis. A full economic evaluation can be defined as a comparative study including both costs and effects.
- Population: women with SUI and stress-predominant MUI (adult women of any ethnic background).
- Intervention: any of the surgical treatments for UI being evaluated in our own study (as either a primary or a repeat surgery).
- Comparator: alternative treatment (surgical and non-surgical) or no treatment for UI.
- Outcome: cost-effectiveness, cost estimates, utilisation estimates and quality-of-life estimates.
- Language: studies with full text in English.

No restrictions were placed on the publication time frame or the study country. Modelling studies where data were imputed from multiple sources, without specific reference to the age and ethnic background of women, were included in the review. Studies comparing diagnostic/screening techniques or other non-surgical procedures without considering surgical interventions in the model pathway were excluded.

Data extraction

Relevant data were extracted into an Excel spreadsheet. Data on the following, where available, were extracted from included studies by one reviewer and checked by another:

- study characteristics, such as study question, form of economic analysis, population, interventions, comparators, perspective, time horizon and form of modelling
- clinical effectiveness and cost parameters, such as effectiveness data, health-state valuations (utilities), resource use data, unit cost data, cost year, discounting and key assumptions
- results and sensitivity analyses.

Findings

A total of 821 titles and abstracts were identified from the original search, with 732 remaining after deduplication. Following title and abstract screening, 30 studies remained. Full-text copies of these 30 studies were obtained for scrutiny against the full selection criteria and 13 were excluded. Therefore, 17 studies were included in the final review. A flow diagram presenting the process of selecting studies can be found in *Figure 3*.

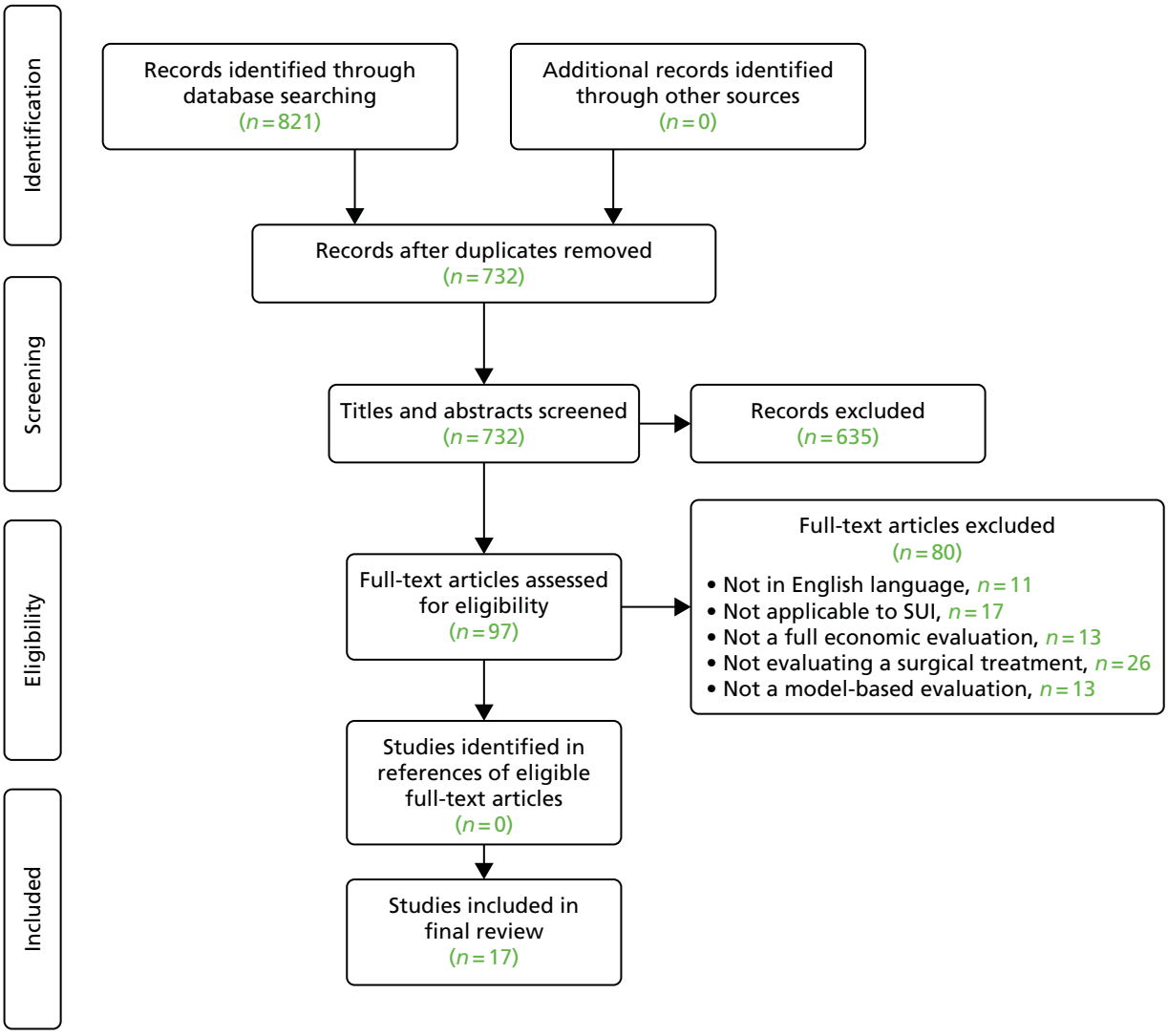

FIGURE 3 Flow diagram showing study selection for the economic evaluations review.

Summary of review data from included model-based economic evaluations

A total of 17 studies were included in the final review. An overview of the key data extracted from these studies is presented in *Table 11*. In the section that follows, a more comprehensive description of the data extracted from the included studies is presented. Finally, a descriptive quality assessment of the included studies is presented, based on the criteria defined in the Drummond checklist for economic evaluations.[242]

Comprehensive overview of data extracted from included model-based economic evaluations

Country

Nine studies were based in the USA,[225,226,230,233,235–237,239,240] four in the UK,[227–229,241] three in Canada[231,232,234] and one in the Netherlands.[238]

Cost year

The cost year of four studies was 2012,[226,233–235] of one study was 2007,[228] of one study was 2001,[229] of four studies was 1998,[231,236,239,240] of one study was 2005,[237] of one study was 2010,[232] of two studies was 2013,[225,238] of one study was 2008[241] and of two studies was not reported.[227,230]

Currency

Currency matched the country in all studies.[225–241]

Study population

All studies were conducted among a population of women with UI, SUI or MUI.[225–241]

Population age

Three studies reported a population age of 45 years, based on the age of peak incidence of SUI.[226,229,241] One study reported a population aged ≤ 65 years.[240] One study reported a population aged > 65 years, chosen because elderly patients are likely to have a greater unmet need.[238] In all other studies, population age was not reported.[225,227–237,239,241]

Analysis type

A total of 11 studies were cost–utility analyses,[225–230,233,235,237,238,241] five were cost-effectiveness analyses[231,232,234,236,240] and one was a cost–consequences analysis.[239]

Perspective

Four studies reported a societal perspective,[226,236,238,240] nine studies reported a health service perspective,[225,228,229,231,232,234,235,237,241] one study reported a third-party payer perspective[233] and three studies did not report a perspective.[227,230,239] However, on the basis of the costs included the perspective was interpreted as the health-care system for two of these studies[230,239] and societal for the third.[227]

Model structure and comparators

Model type

A total of 10 studies used a Markov model.[226–230,234,235,237,238,241] The remaining seven studies used a decision tree.[225,231–233,236,239,240]

Time horizon

One study reported a lifetime time horizon,[226] five studies reported a 10-year time horizon,[228–230,235,237] seven studies reported a 1-year time horizon,[225,231–233,236,239,240] two studies reported a 3-year time horizon,[234,238] one study reported a 2- to 5-year time horizon[227] and one study reported a 40-year time horizon.[241]

TABLE 11 Overview of included model-based economic evaluations

Number	Study	Population	Analysis type	Intervention	Comparator	Model type	Perspective	Time horizon	Time cycle	QoL measure	CE measure	Results
1	Kunkle *et al.*[225]	SUI	CUA	MUS	Urethral BA	Decision tree	Health-care system	1 year	N/A	NR	Cost/QALY	MUS compared with BA leads to an ICER of US$70,400 per utility gained
2	Von Bargen *et al.*[226]	SUI	CUA	MUS	1. Expectant management 2. PFMT 3. PFMT+ES 4. Vaginal cone/biofeedback 5. Incontinence pessary	Markov model	Societal	Lifetime	1 year	NR	Cost/QALY	Incontinence pessary was the more cost-effective option with US$11,411 cost/QALY With a WTP of US$60,000, MUS would be the most cost-effective option
3	Das Gupta *et al.*[227]	SUI	CUA	Duloxetine	1. PFMT 2. Surgery	Markov model	NR	2–5 years	3 months	NR	Cost/QALY	First-line use of duloxetine alone and in combination with PFMT is more cost-effective than standard treatment, with ICERs of £8730 and £5854, respectively Second-line use of duloxetine alone and in combination with PFMT is less costly and more effective than standard treatment
4	Jacklin *et al.*[228]	SUI	CUA	TVT	Duloxetine	Markov model	Health-care system	10 years	1 day	NR	Cost/QALY	TVT had an ICER of £7710 (US$12,651) at 10 years
5	Kilonzo *et al.*[229]	SUI	CUA	TVT	1. Open colposuspension 2. Laparoscopic colposuspension 3. Traditional suburethral sling procedures 4. Periurethral urethral injection therapy	Markov model	Health-care system	10 years	1 year	EQ-5D	Cost/QALY	TVT dominates open colposuspension (lower cost and same QALYs) within 5 years after surgery
6	Laudano *et al.*[230]	SUI	CUA	TVT	Open Burch colposuspension	Markov model	NR	10 years	NR	NR	Cost/QALY	At 10-year follow-up, TVT was more cost-effective (CE, US$1495/QALY) than BC (CE, US$1824/QALY)
7	Oremus *et al.*[231]	SUI	CEA	Collagen	1. Retropubic suspension 2. Transvaginal suspension 3. Sling procedure	Decision tree	Health-care system	1 year	N/A	N/A	Cost/treated woman	Retropubic suspension vs. collagen ICER: CA$1824 Transvaginal suspension vs. collagen ICER: CA$5151 Sling procedure vs. collagen ICER: CA$6814
8	Oremus and Tarride[232]	SUI	CEA	Collagen	1. Needle bladder neck suspension 2. Burch colposuspension 3. Slings	Decision tree	Health-care system	1 year	N/A	N/A	Cost/treated woman	ICER is CA$341.35 for Québec

Number	Study	Population	Analysis type	Intervention	Comparator	Model type	Perspective	Time horizon	Time cycle	QoL measure	CE measure	Results
9	Richardson and Sokol[233]	SUI	CUA	MUS	1. Continence pessary 2. PFMT	Decision tree	Third-party payer	1 year	N/A	HUI	Cost/QALY	MUS was the more cost-effective strategy with an ICER of US$32,132/QALY
10	Sand *et al.*[234]	SUI	CEA	Transurethral radiofrequency micro-modelling	1. TVT 2. TOT 3. Burch colposuspension 4. Traditional bladder neck autologous sling	Markov model	Health-care system	3 years	3 months	N/A	Cost	Procedure costs for RF-SUI were less than half of the cost of sling treatments and were one-fifth of the cost of Burch surgery
11	Seklehner *et al.*[235]	SUI	CUA	Retropubic MUS	Transobturator MUS	Markov model	Health-care system	10 years	NR	NR	Cost/QALY	Transobturator MUS was more cost-effective than retropubic MUS with an ICER of US$177,027/QALY
12	Weber and Walters[236]	SUI	CCA	Burch colposuspension	Sling procedure	Decision tree	NR	10 years	N/A	N/A	Costs and clinical outcomes	N/A
13	Wu *et al.*[237]	SUI	CUA	Burch colposuspension	TVT	Markov model	Health-care system	10 years	1 year	NR	Cost/QALY	The ICER was US$98,755 per QALY
14	Holtzer-Goor *et al.*[238]	UI	CUA	Global optimum continence service specification	Current care pathway for UI in the Netherlands	Markov model	Societal	3 years	3 months	EQ-5D	Cost/QALY	The PSA results show that, with 95% certainty, the new care intervention dominates current care (i.e. it is more effective and cost-saving)
15	Weber and Walters[239]	Symptomatic pelvic organ prolapse and SUI	CEA	Office evaluation and no further testing	Office evaluation and subsequent testing	Decision tree	Societal	1 year	N/A	N/A	Cost/additional cure	In the base case, the strategy of basic office evaluation was more cost-effective than the strategy of urodynamic testing. In the short model the incremental cost-effectiveness (cost per additional cure of UI) was US$55,495 for urodynamic testing relative to basic office evaluation. In the full model a single additional cure of UI was achieved by urodynamic testing at a cost of US$328,601 relative to basic office evaluation
16	Weber *et al.*[240]	SUI	CEA	Office evaluation and no further testing	Office evaluation and subsequent testing	Decision tree	Societal	1 year	N/A	N/A	Cost/additional cure	In the base case, the strategy of basic office evaluation was more cost-effective than the strategy of urodynamic testing. In the short model the incremental cost-effectiveness (cost per additional cure of UI) was US$55,495 for urodynamic testing relative to basic office evaluation. In the full model a single additional cure of UI was achieved by urodynamic testing at a cost of US$328,601 relative to basic office evaluation

continued

TABLE 11 Overview of included model-based economic evaluations (*continued*)

Number	Study	Population	Analysis type	Intervention	Comparator	Model type	Perspective	Time horizon	Time cycle	QoL measure	CE measure	Results
17	Imamura *et al.*[241]	SUI	CUA	Treatment sequence 1	Treatment sequence 2–8	Markov model	Health-care system	40 years	3 months	EQ-5D	Cost/QALY	The strategy employing lifestyle changes and PFMT with extra sessions followed by TVT surgery has a > 70% probability of being considered cost-effective for all threshold values for WTP for a QALY presented. The other five strategies each have a probability of < 20% of being considered cost-effective

BA, bulking agent; BC, Burch colposuspension; CCA, cost–consequences analysis; CE, cost-effectiveness; CUA, cost–utility analysis; EQ-5D, EuroQol-5 Dimensions; HUI, health utility index; ICER, incremental cost-effectiveness ratio; N/A, not applicable; NR, not recorded; PFMT+ES, PFMT with electrical stimulation; PSA, probabilistic sensitivity analysis; QoL, quality of life; RF-SUI, radiofrequency stress urinary incontinence; WTP, willingness to pay.

Cycle length

Three studies used a 1-year cycle length,[226,229,237] one study used a 1-day cycle length,[228] four studies used a 3-month cycle length,[227,234,238,241] two studies did not report cycle length[230,235] and for seven studies cycle length was not applicable as they adopted a decision-tree approach.[225,231–233,236,239,240]

Intervention

Three studies looked at MUS,[225,226,233] three studies looked at TVT,[228–230] one study looked at transurethral radiofrequency micro-remodelling,[234] one study looked at retropubic MUS,[235] two studies looked at Burch colposuspension,[237,239] two studies looked at collagen injection,[231,232] one study looked at duloxetine,[227] one study looked at global optimum continence service specification,[238] two studies looked at office evaluation and no further testing[236,240] and one study looked at initial treatment with conservative therapies.[241]

Comparator

One study compared the intervention with expectant management, PFMT, PFMT with electrical stimulation, vaginal cone or biofeedback and incontinence pessary,[226] one study compared the intervention with duloxetine,[228] one study compared the intervention with open colposuspension, laparoscopic colposuspension, traditional suburethral sling procedures and periurethral injectables,[229] one study compared the intervention with open Burch colposuspension,[230] one study compared the intervention with continence pessary and PFMT,[233] one study compared the intervention with TVT, retropubic mid-urethral synthetic sling procedures, TOT, transobturator mid-urethral synthetic sling procedures, Burch colposuspension surgery and traditional bladder-neck autologous sling procedures,[234] one study compared the intervention with transobturator MUS,[235] one study compared the intervention with sling procedures,[239] one study compared the intervention with TVT,[237] one study compared the intervention with bladder neck needle suspension and Burch slings,[231] one study compared the intervention with retropubic suspension, transvaginal suspension and sling procedures,[231] one study compared the intervention with urethral bulking agents,[225] one study compared the intervention with PFMT and surgery, colposuspension and traditional slings,[227] one study compared the intervention with the current care pathway for UI in the Netherlands,[238] two studies compared the intervention with office evaluation and subsequent urodynamic testing[236,240] and one study compared the intervention with initial treatment with MUS.[241]

Model inputs and analysis

Discounting

Three studies applied a 3.5% discount rate,[227,228,241] two of which[228,241] justified this rate on the basis of it being the discount rate recommended for the reference case in the NICE technical manual.[243] Two studies applied a 3% discount rate but did not justify this choice of rate.[226,237] One study applied a 4.54% discount rate based on the 10-year AAA corporate bond yield for that year.[230] One study applied a 5% discount rate but did not justify this choice of rate.[234] One study applied a 2.26% discount rate based on the 10-year AAA corporate bond yield for that year.[235] One study applied a 6% discount rate for costs and a 1.5% discount rate for quality-adjusted life years (QALYs);[229] however, these rates were not justified in the text. For six studies, a discount rate was not applicable as the time horizon of the included model was only 1 year,[225,231–233,236,240] and for two studies discounting was applicable but a discount rate was not reported.[238,239]

Clinical effectiveness measure(s)

Eight studies used cure rate (objective or subjective) only,[226,229,231,232,236,237,239,240] three studies used improvement rate (objective or subjective) only,[233–235] one study used both cure rate and improvement rate,[241] one study used the percentage of women continent,[238] one study used probability of cure, probability of retreatment and probability of cure after retreatment,[230] one study used success rate (defined as dry, which is resolution of symptoms),[225] one study used reduction in incontinence episode frequency[227] and one study used a change in incontinence episode frequency as the measure of clinical effectiveness.[228]

Quality of life measure(s)

Three studies used EuroQol-5 Dimensions (EQ-5D),[229,238,241] with one of those[229] using data derived from Manca *et al.*[244] One[238] used data derived from a cross-sectional study of quality of life in a general female population in the Netherlands aged 45–85 years, whereas another[241] used data derived from Manca *et al.*[244] and Haywood *et al.*[245] Eight studies that used quality of life estimates in their analysis did not report a quality of life measure in their study[225–228,230,233,235,237] and for six studies a quality of life measure was not applicable as they were conducted as either a CEA or a cost–consequences analysis (CCA), for which a quality of life measure is not required.[231,232,234,236,239,240]

Cost-effectiveness measure

A total of 11 studies used cost per QALY,[225–230,233,235,237,238,241] two studies reported costs and clinical outcomes in a disaggregated manner,[234,239] two studies reported cost per increased probability of successful treatment[231,232] and two studies reported cost per additional cure.[236,240]

Complications/adverse events

One study reported UTI, voiding dysfunction, mesh erosion and intra-/post-operative adverse events;[226] one study reported haematoma, urinary retention, detrusor overactivity, UTI, abscess, mesh or suture erosion, recurrent stress incontinence, pelvic organ prolapse, incisional hernia, bladder perforation and revision;[230] one study reported voiding dysfunction, wound complication, mesh exposure or erosion and recurrent cystitis;[234] one study reported mesh erosion/exposure, urinary retention, lower urinary tract symptoms, bladder perforation, infection, bleeding, neurological symptoms, catheterisation, anticholinergics, antibiotics, blood transfusion and drainage of haematoma;[235] one study reported recurrent incontinence, detrusor instability and urinary retention;[239] one study reported UTIs, fractures and skin breakdown;[238] one study reported adverse events related to drugs only;[241] one study reported mesh erosion;[237] one study reported retention, voiding, infection and haematuria;[231] one study reported immediate haemorrhage, immediate bladder injury, short-term urinary retention, short-term pain, short-term haematuria, long-term persistent urinary retention, long-term UTI, long-term mesh complication and long-term recurrent SUI; and seven studies did not report complications/adverse events.[227–229,231,233,236,240]

Mortality modelling

Two studies incorporated all-cause mortality,[226,237] one study incorporated all-cause mortality and surgery-specific mortality,[241] three studies did not incorporate all-cause mortality,[228–230] seven studies did not include mortality in their economic model,[227,234–236,238–240] and for four studies mortality was not applicable owing to the short time horizon of their model.[225,231–233]

Sensitivity analysis

One study conducted multivariable sensitivity analysis (SA),[226] seven studies conducted deterministic SA only,[228,230,231,233,234,237,239] seven studies conducted deterministic SA and probabilistic sensitivity analysis (PSA)[225,227,229,231,235,238,241] and two studies conducted deterministic SA and a threshold analysis.[236,240]

Resource use costs

Two studies used Medicare reimbursement codes to derive cost of treatment;[226,233] one study[239] collected costs using codes from Medicare diagnostic-related groups and the *International Classification of Diseases,* Ninth Edition (ICD-9); one study used a combination of literature (routine UK sources) and assumption;[228] and two studies used a combination of relevant literature, such as reports from manufacturers, and advice from experts in the field.[229,241] One study derived costs from 2003 Medicare reimbursement data and diagnosis-related group codes,[237] one study used only the Medicare fee schedule,[225] two studies used the Medicare resource-based relative value scale,[230,235] one study used a combination of Medicare and expert opinion,[234] one study used previous economic evaluations to derive cost information,[231] one study used a combination of hospital records and expert opinion,[232] one study used a combination of HES, assumptions and literature[227] and two studies[236,240] used an issue of the *Federal Register*. One study used a combination of expert opinion, reimbursement prices and previous literature.[238]

Data source for clinical effectiveness

Twelve studies used literature as a source,[225–230,234,235,237–239,241] one study used data from the ATLAS (Ambulatory Treatments for Leakage Associated with Stress Incontinence) trial,[233] one study used data from a RCT,[231] one study used data from clinical guidelines[231] and two studies used data from a combination of literature and consensus from the study team.[239,240]

Quality assessment

The completed Drummond checklist for each of the included studies is presented in *Appendix 18*.
In this section, a descriptive summary of the quality assessment of all included studies is presented.

1. Was a well-defined question posed in answerable form?

All of the included studies had a well-defined question posed in an answerable form and examined both the costs and the effects of the alternative options.[225–241] Only three of the included studies did not state a viewpoint for the analysis or place the study in any particular decision-making context.[225,230,239]

2. Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where, and how often)?

Only three of the included studies did not provide a comprehensive description of the competing alternatives or provided only a comprehensive description of the intervention without focusing sufficiently on the comparator(s).[230,232,235] Only one study did not omit important alternatives from the analysis.[241] None of the studies included a do-nothing alternative in their comparison.

3. Was the effectiveness of the programme or services established?

All of the included studies established the effectiveness of the programme or services included in the model.[225–241] Of the studies that did establish effectiveness, three determined effectiveness through a clinical RCT.[227,232,233] A total of 13 studies established effectiveness through an overview of clinical studies.[226,228–231, 233–237,239–241] Five studies used observational data or assumptions to establish effectiveness.[225,227,233,237,238]

4. Were all the important and relevant costs and consequences for each alternative identified?

All of the included studies identified the important and relevant costs and consequences for the alternatives being compared.[225–241] The range of relevant costs and consequences was wide enough for the research question at hand in all studies other than in four, in which the range was unclear.[225,226,228,238] In one study it was determined that the range was not wide enough for the research question at hand.[231] Costs and consequences were covered from all relevant viewpoints (community or social viewpoint and those of patients and third-party payers) in only five studies.[226,236,238–240] In one study, the perspective was not clear.[230] In all remaining studies, at least one perspective (primarily patient perspective) was not considered.[225,227–235,237,241] Capital costs were included in eight studies;[226–228,236,238–241] in the other nine studies, capital costs were not included.[225,229–235,237]

5. Were costs and consequences measured accurately in appropriate physical units?

All of the included studies measured costs and consequences accurately in appropriate physical units.[225–241] None of the studies omitted identified items from its analysis. Only two of the included studies encountered circumstances (joint use of resources) that made measurement of costs and consequences difficult.[225,231] These circumstances were handled appropriately in the studies.

6. Were the costs and consequences valued credibly?

All of the included studies valued costs and consequences credibly and clearly identified the sources of all values.[225–241] Only one of these studies did not clearly identify the sources of all values.[231] In only four of the included studies was the valuation of consequences not appropriate for the question posed.[231,234,236,240]

7. Were costs and consequences adjusted for differential timing?

In nine of the included studies, costs and consequences were adjusted for differential timing (and discounted).[226–230,234,235,237,241] In six studies, this was not applicable.[225,231–233,236,240] In two studies, this was not reported.[238,239] Of the studies that applied discounting, only four did not provide any justification for the discount rate used.[226,227,229,234]

8. Was an incremental analysis of costs and consequences of alternatives performed?

Only two of the included studies did not conduct an incremental analysis of the costs and consequences of alternatives.[234,236] Only one of these studies did not compare the additional costs generated by one alternative over another with the additional effects, benefits or utilities generated.[236]

9. Was allowance made for uncertainty in the estimates of costs and consequences?

Only four of the included studies did not make any allowance for uncertainty in the estimates of costs and consequences.[228,231,236,240] Eight of the included studies performed appropriate statistical analysis on stochastic data, meaning that the data incorporated in the model had a random probability distribution and an appropriate PSA was conducted.[225,227,229,230,232,235,238,241] Five studies did not perform appropriate statistical analysis on stochastic data.[228,231,233,236,240] In three studies this was not applicable as probabilistic distributions were not assigned to the model data.[234,237,239] Rather, these studies included a deterministic SA only. In one study, this was not clear.[226] Twelve studies provided justification for the range of values used in SA.[225–227,232–234,236–241] Five studies did not provide justification.[228–231,234] In 13 studies, the study results were sensitive to the change in values.[225,227–230,232,233,235–237,239–241] In three studies, study results were not sensitive to the change in values[231,234,238] and in one study this was unclear.[226]

10. Did the presentation and discussion of study results include all issues of concern to users?

Only in one of the included studies did the presentation and discussion of study results not include all issues of concern to users.[238] In 15 of the studies, the conclusions of the analysis were based on some overall index or ratio of costs to consequences. [225–233,235–238,240,241] In one study, an overall index was not presented[239] and in one study this was not applicable.[234] Only one of the included studies did not compare their results with those of others who have investigated the same question.[233] Eight studies discussed the generalisability of the results to other settings and patient/client groups.[226,231–235,237,239] In the other nine studies, the authors did not discuss the generalisability of the results.[225,227–230,236,238,240,241] Only one of the included studies alluded to, or took account of, other important factors in the choice or decision under consideration.[241] Finally, none of the included studies discussed issues of implementation, such as the feasibility of adopting the 'preferred' programme given existing financial or other constraints, or whether or not any freed resources could be redeployed to other worthwhile programmes.

Limitations of identified model-based economic evaluations in informing economic analysis

A total of 17 model-based economic evaluations were identified through the systematic review. All studies were conducted among women with SUI or stress-predominant MUI and included at least one of the surgical treatments for UI being evaluated in this study (as either a primary or a repeat surgery). However, none of the models was sufficient for the analysis required for our own study.

First, the time horizons of the models identified were generally of insufficient length, with only one of the included studies assessing costs and consequences over a lifetime time horizon.[226] One study did report a 40-year time horizon, but even this would not be of sufficient length to capture the entire lifetime of all patients being modelled in our own analysis (patient starting age, 45–55 years). The majority of studies extended to a maximum time horizon of 10 years.

Second, only 11 of the identified studies were conducted as pure cost–utility analyses.[225–230,233,235,237,238,241] Of these, only three used EQ-5D as a quality of life measure in their analysis (the measure proposed for our own analysis).[229,238,241] The other eight studies that conducted a cost–utility analysis did not report a

quality of life measure and this was noted as a generally poorly reported feature among the studies identified.[225–228,230,233,235,237]

Furthermore, very few studies had used appropriate utility weights estimated using tools like EQ-5D and the Health Utilities Index[227,229,233,235,241] for cured and incontinence health states in the economic models.[227,235] Because the intended outcome of the surgical treatments is increased quality of life, estimating effectiveness using an appropriate tool is essential for the estimation of actual treatment outcomes. Moreover, not all of the studies had included complications in the models. Complication after surgical treatment is another important factor that affects women's quality of life, which highlights the importance of including major complications in the calculations.

Finally, only one of the identified models did not omit important alternatives from their analysis.[241] As highlighted during the quality assessment, all other studies failed to include at least one important alternative.[225–240]

Given these limitations, and the information presented in this chapter, it was decided that a new economic model needed to be developed to estimate the relative cost-effectiveness of the nine surgical interventions.

Summary

A systematic review of economic studies modelling the management of women with UI was conducted. Specifically, the focus was on studies that included surgical treatments for SUI and stress-predominant MUI. In total, 17 studies were included in the final review. All data of interest were extracted from these studies, and studies were quality assessed using the Drummond checklist for economic evaluations.[242] None of the identified studies was considered suitable for use in the economic evaluation component of this study.

Chapter 6 Development of a new cost-effectiveness model

This chapter provides a detailed description of the modelling approach, the estimation of input parameters used to populate the model and the key assumptions underpinning the cost-effectiveness results. The results from the economic model are presented in two sections. In the first section, the results of the economic model are presented. In the second section, results from a VOI analysis, which can be used to aid decisions about the direction of further research, are presented (see *Chapter 5*, *Summary*). The chapter concludes with a summary of the results for all comparators and of the factors deemed to be most critical in affecting the cost-effectiveness of different surgical treatments for SUI and stress-predominant MUI.

Model overview

As seen in the review of model-based economic evaluations, no existing research has compared all the relevant comparators. Therefore, a decision-analytic model was developed to evaluate the cost-effectiveness of nine different surgical interventions for the treatment of women with SUI or stress-predominant MUI:

1. retropubic MUS
2. anterior vaginal repair
3. bladder neck needle suspension
4. open abdominal retropubic colposuspension (open colposuspension)
5. laparoscopic retropubic colposuspension (laparoscopic colposuspension)
6. traditional suburethral retropubic sling (traditional sling)
7. transobturator MUS
8. single-incision sling
9. periurethral bulking agents (urethral injection therapy).

The model is based on a hypothetical cohort of women (age range, 45–55 years) with either SUI (52%) or stress-predominant MUI (48%).[246] Health outcomes from the model were expressed in terms of QALYs, the year of the cost data is 2016 and the currency is pound sterling (GBP). The costs were estimated from a NHS and Personal Social Services (PSS) perspective. Both costs and QALYs were evaluated over 1-year, 10-year and lifetime time horizons and discounted using a 3.5% annual discount rate.[16] The expected cost and QALYs for each of the strategies were estimated and compared using incremental cost-effectiveness ratios (ICERs) where appropriate. The ICER represents the incremental cost per additional QALY associated with a more costly and effective strategy. The ICER can be compared with thresholds used by NICE to establish value for money in the NHS (i.e. £20,000–30,000 per additional QALY gained). These thresholds can be used to identify the optimal strategy in terms of cost-effectiveness considerations, based on existing evidence.

The model is probabilistic, meaning that most of the input parameters were entered into the model as probability distributions to reflect parameter uncertainty (i.e. uncertainty in the mean estimates). Monte Carlo simulation was used to address the uncertainty in input parameters in such a way that the results of the analysis can also be presented with their associated uncertainty.

Model structure

A Markov microsimulation (MM) model was developed to estimate the relative cost-effectiveness of the nine surgical interventions. The MM model is a computer modelling technique that simulates an individual's life course from initial surgical treatment until death. Within the model, each person is represented by a record containing a unique identifier and a set of associated attributes (e.g. age, disease condition). A set of rules

(transition probabilities) and state rewards (cost and health state utility) are then applied based on these characteristics. These rules may be deterministic or stochastic. The model applies all defined parameters and rules to simulate the passage of an individual through the model. This is then repeated for each individual in the cohort, thereby generating individual life histories for a specific population of women. The main reason that a microsimulation model was used as opposed to a cohort-based Markov model was to overcome the memorylessness of cohort-based Markov models. Building the MM model in TreeAge Pro® (TreeAge Software, Inc., Williamstown, MA, USA) enabled us to keep track of simulated patients about their treatment history and time since last treatment. Unfortunately, individual-level data were not available; therefore, we assumed a uniform distribution for age groups (45–55 years) and women were randomly selected and simulated within the model. In the model, 52% of the randomly selected women have SUI only, and are modelled as receiving treatments for SUI only. However, some women with SUI may experience UUI as a result of complications of surgical treatments for SUI, and these women receive UUI treatment as well. In 48% of random draws, women have MUI (SUI and UUI). Therefore, after receiving surgical treatments for SUI they would receive three lines of treatment for UUI, which could be successful or unsuccessful.

The structure of the model is shown in *Figure 4*. We assumed a 3-month cycle length. The reason for this assumption is that it will take between 3 and 6 months to determine if a procedure has worked and to decide if further treatment if required.

The MM model incorporates both the temporal and the logical sequences of treatment, including the events and complications that may happen after each procedure (e.g. pain), and the outcomes for the woman associated with each possible scenario. Hypothetical individual women pass through the model one at a time and are followed up until death. Treatment history for both SUI/stress-predominant MUI and UUI was recorded for each simulated woman and used to define the woman's transition to different health states and treatment types. For example, if a woman with MUI is being simulated and she has already received a first repeat surgery for SUI and second-line treatment for UUI, then in the event of a recurrence of SUI or UUI she may only be given second repeat surgery for SUI or third-line treatment for UUI, respectively. The model was developed in TreeAge Pro.

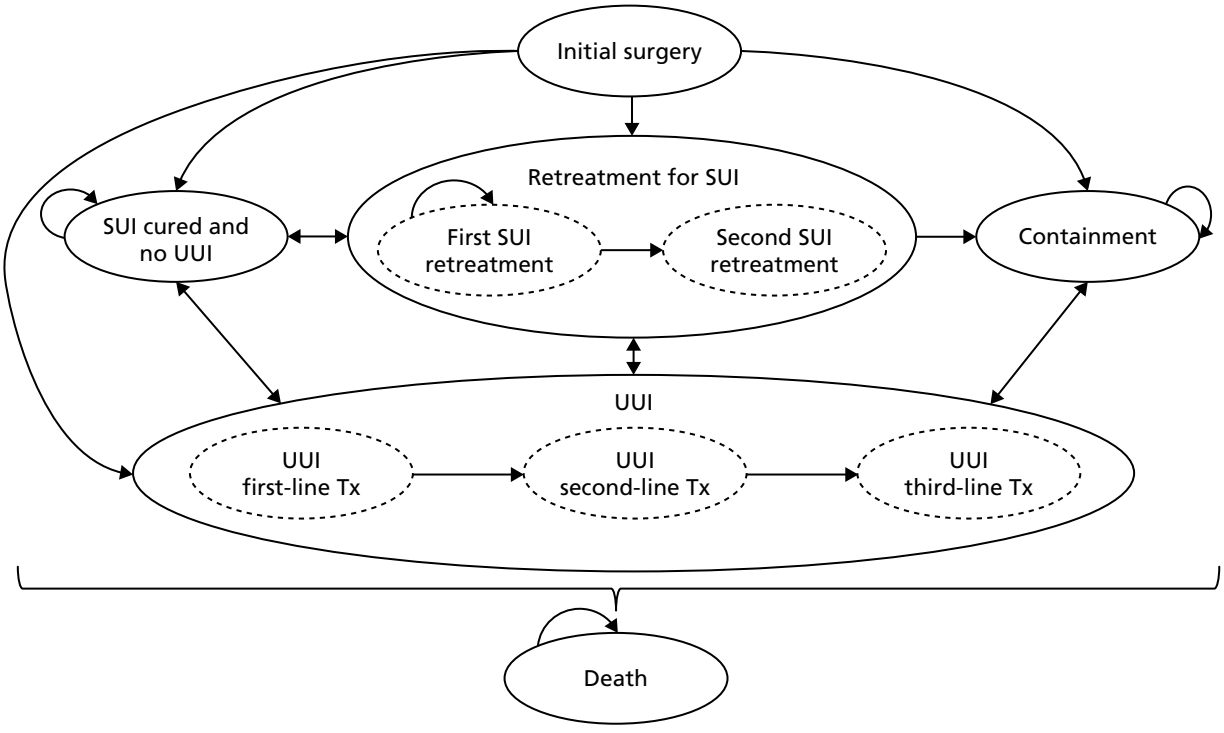

FIGURE 4 Markov model structure. Tx, treatment.

On entry into the model, a woman can have either SUI or MUI (based on the specified proportion of women with SUI or MUI). Both groups of women will initially have one of the nine surgical treatments. The surgical treatment is for SUI, but a woman may still need further treatment for symptoms of UUI, which is a component of MUI, or develop UUI as a side effect of surgical treatment of SUI or the SUI component of MUI. After initial surgery, a woman can move into one of the following five health states:

1. cured and no UUI (continent) by subjective measures
2. cured from SUI but UUI exists (UUI caused as a side effect of the initial surgery or because the woman has MUI)
3. surgery fails to resolve the SUI but the woman proceeds to retreatment (as women can be offered a second or third surgery if initial surgery fails)
4. permanent state of incontinence (containment) (e.g. resorting to containment management of their incontinence by using pads)
5. death due to all-cause mortality or operation-related mortality, which can occur when a woman is exposed to the risks of open surgery such as colposuspension or traditional sling procedures (see *Figure 4* and the detailed model structure in *Appendix 19*).

The model assumes that women can receive a maximum of three surgical treatments for treatment of SUI/MUI, which includes the initial surgery and two subsequent retreatments. If all three surgeries fail then the woman has to manage her symptoms using containment products. The model allows for individuals to elect to move to containment treatments at any point after initial failure. Women with MUI who still have UUI after successful treatment of SUI, or those who develop UUI owing to surgery, will receive three lines of treatment including first-line (bladder training), second-line (drug, i.e. oxybutynin hydrochloride) and third-line treatment (botulinum toxin type A).

Model inputs

In this section, the data required to populate the model are presented. Initially, clinical data are detailed. The main clinical data required for the model were the success rates of the different interventions (i.e. subjective cure rate), rates of retreatment and complications/adverse events and mortality rates, which were mainly sourced from the review of clinical effectiveness (see *Chapter 3*) and supplemented with UK data on mortality rates. Following on from this, information on resource use and unit costs utilised in the model are presented. These data were primarily sourced from the review of previous economic evaluation, supplemented by further information from the literature and UK databases. Finally, the utility data included in the model are presented. All the utility values were sourced from the review of economic evaluations.

Relative effectiveness of surgical treatments

The relative effectiveness of surgical treatments, in terms of subjective cure rates, were based on the results of the NMA reported in *Chapter 3*. *Table 12* describes the mean and median ORs for different surgical treatments versus retropubic MUS, which was taken to be the reference treatment. The reported values for mean and median ORs were used to define log-normal distributions in the model.

Estimation of absolute cure rates

The absolute cure rates were calculated in the model by combining the information on relative cure rates described in *Table 13* with the absolute cure rates for retropubic MUS. The absolute cure rates at 1 year for retropubic MUS were estimated to be 84%, based on a meta-analysis of retropubic MUS trials (44 studies were included).

TABLE 12 Odds ratios of cure rates for surgical interventions compared with retropubic MUS

Treatment	OR		
	Mean	Median	95% CrI
Transobturator MUS vs. retropubic MUS	0.742	0.738	0.588 to 0.923
Open colposuspension vs. retropubic MUS	0.874	0.853	0.544 to 1.325
Laparoscopic colposuspension vs. retropubic MUS	0.605	0.580	0.315 to 1.046
Traditional sling vs. retropubic MUS	1.106	1.061	0.623 to 1.846
Single-incision sling vs. retropubic MUS	0.511	0.504	0.360 to 0.699
Bladder neck needle suspension vs. retropubic MUS	0.368	0.340	0.154 to 0.745
Anterior vaginal repair vs. retropubic MUS	0.235	0.220	0.105 to 0.452

Laparoscopic colposuspension, laparoscopic retropubic colposuspension; open colposuspension, open abdominal retropubic colposuspension; traditional sling, traditional suburethral retropubic sling.

TABLE 13 Estimation of absolute cure rate after retropubic MUS at different time points: results from meta-analysis

Time (months)	Median	95% CrI	Number of	
			Studies	Participants
6	0.776	0.175 to 0.983	17	908
12	0.841	0.214 to 0.990	44	2882
24	0.784	0.454 to 0.941	6	315
36	0.341	0.001 to 0.995	5	205
60	0.329	0.005 to 0.979	3	377

To calculate the absolute probability of success for each surgical treatment, the OR of a given intervention compared with the baseline treatment (retropubic MUS) was derived from the NMA. This figure was then converted into a relative risk (RR) using the following formula:

$$\text{Absolute risk} = \text{baseline risk} \times \text{RR}, \quad (2)$$

where:

$$\text{RR} = \text{OR} / [1 - \text{baseline risk} + (\text{baseline risk} \times \text{OR})]. \quad (3)$$

The RR for each treatment was then applied to the baseline risk[247] to estimate the absolute probability of success for each surgical treatment.

Transition probabilities

Because the comparative effectiveness of surgical treatments may wane/decline over time, an additional search was conducted to identify studies on the long-term effectiveness (> 1 year) of the baseline intervention. After extensive searching, very few data were identified on the long-term effectiveness of the baseline intervention. Therefore, estimates used in the model were based on extrapolation of the available data.

Results from the review of clinical effectiveness data showed that there were six trials that had reported cure rates at 2 years after retropubic MUS and three studies that had reported cure rates at 5 years. A meta-analysis

was conducted on each set of studies. *Table 13* shows the absolute probabilities for retropubic MUS at different time points along with the number of studies and participants. The probability that participants are cured at 6, 12, 24, 36 and 60 months are 78%, 84%, 78%, 87% and 68%, respectively. For 24, 36 and 60 months, there are considerably fewer studies and participants than for the other time points.

The long-term recurrence rates after retropubic MUS were used to estimate long-term recurrence rates for surgical treatments using a parametric survival model from the data reported in *Table 14*. Parametric methods are commonly used to extrapolate survival times beyond the duration of the studies. These methods assume that recurrence rates for women follow a given theoretical distribution, such as Weibull, exponential and log-normal.

Scale and shape parameters were estimated for a Weibull distribution using the reported cure rates. This distribution was chosen because it was felt to provide a reasonable representation of the estimated long-term recurrence rates and has been used in a previous study.[241] The scale parameter (λ) describes the probability that the woman becomes incontinent during the next cycle of the model, given that she is continent during the current time period. The shape parameter (γ) describes the hazard function of the Weibull function for the survival time. The hazard function for Weibull survival time could be increasing or decreasing with time, depending on the value of the parameter. If the shape parameter is < 1, the hazard decreases with time, and if the value is > 1, the hazard rate increases with time. If the shape parameter is equal to 1, the Weibull distribution is equivalent to an exponential distribution.

To estimate alternative values to explore in SA, the long-term recurrence rates of retropubic MUS were derived using the long-term cure rates of a trial conducted in the UK comparing TVT with Burch colposuspension,[248] which provides an optimistic estimate of cure rates after retropubic MUS and has been used in a previous study, which included an economic evaluation of non-surgical and surgical treatments for SUI in the UK.[241] In the trial, the data from reported cure rates for ≤ 5 years were used to estimate longer-term recurrence rates using a Weibull survival model. In addition, we derived data from the study with the longest follow-up, which was conducted by Song *et al*,[249] in which the reported cure rates at 1 year and 13 years were 78% and 67.5%, respectively, to estimate long-term cure rates after retropubic MUS.

The following survival hazard formula was used:

$$S(t) = \exp(-\lambda t^{\gamma}), \tag{4}$$

where $S(t)$ is the probability of cure, t is time (measured in terms of the number of cycles, where each cycle is equivalent to 3 months), λ is the scale parameter (which describes the probability that the woman becomes incontinent during the next time period, given that she is continent during the current time period) and γ is the shape parameter (which describes the hazard function of the Weibull function for the survival time).

It was assumed that proportional hazards stand; therefore, the transition probabilities for other surgical treatments were estimated by combining the respective RR and long-term probabilities for retropubic MUS (*Figure 5*).

TABLE 14 Long-term cure rates after retropubic MUS used for extrapolation

				Parameter	
Scenario	Time (years)	Cure rate (%)	Source	Scale (λ)	Shape (γ)
Base-case analysis	1	84.0	Meta-analysis	0.08799444	0.4932644
	2	78.4			
Ward *et al.*[248]	1	85.0	Ward *et al.*[248]	0.1969761	0.12368398
	5	80.0			
Song *et al.*[249]	1	78.0	Ward *et al.*[248]	0.19391258	0.1788069
	13	67.5			

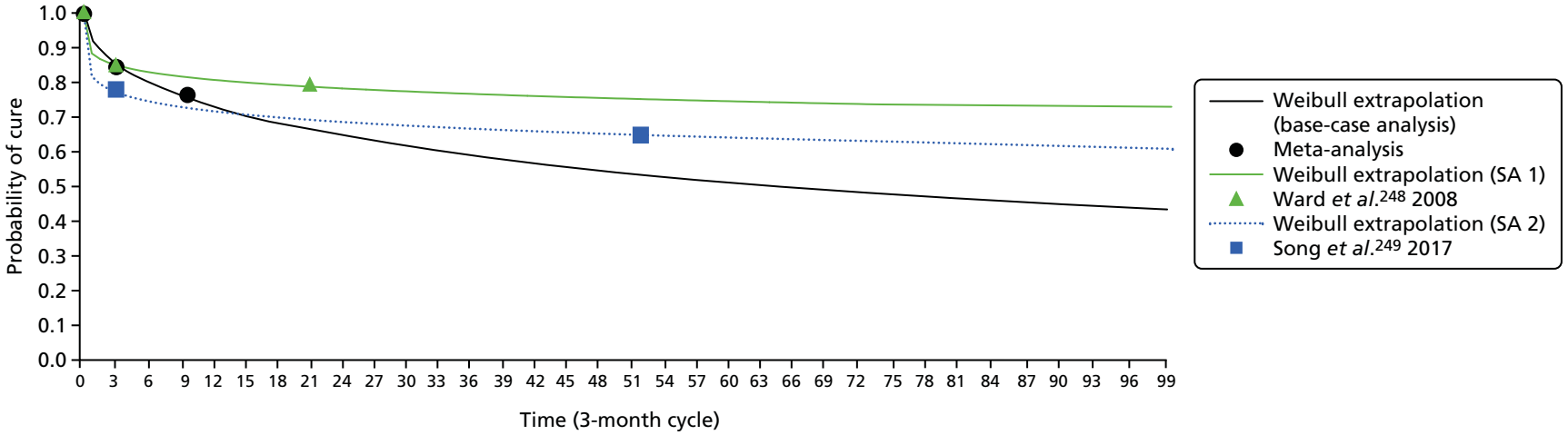

FIGURE 5 Extrapolated long-term cure rates after retropubic MUS surgery. Note that each cycle is 3 months long.

Because urethral injection therapy was not included in the NMA, the estimated short-term and long-term cure rates were obtained from a study by Ghoniem and Miller.[250] They performed a systematic review and meta-analysis to investigate the safety and effectiveness of silicon particles (Macroplastique®; Cogentix Medical, Inc, Orangeburg, NY, USA) for women with SUI (958 women from 23 cohorts were analysed). The cure rates were 43% (95% CI 33 to 54) in the short-term (< 6 months), 37% (95% CI 28 to 46) in the mid-term (6–18 months) and 36% (95% CI 27 to 46) in the long-term (> 18 months). Their meta-analysis suggested that long-term therapeutic benefit was frequently maintained. Cure rates in the short- and long-term were used to estimate longer-term success rates using Weibull survival models.[102] The parameters for the Weibull hazard functions for the cure rates are presented in *Table 15* and cure rates are presented in *Figure 6*.

Repeat surgery

Because data from HES for England in 2013–14 and data for hospital discharge in Scotland in 1996–2014 show that around 91% to 96% of SUI surgeries were for MUS (retropubic, 55%; transobturator, 45%), and given that, from a clinical point of view, MUS (either retropubic or transobturator) can be offered after all types of surgery, it was assumed that all subsequent surgeries were either retropubic MUS (55%) or transobturator MUS (45%).[251] Owing to data limitations, subgroup analysis was not conducted to explore success rates after repeat surgery (after failed previous continence surgery) versus primary procedures. Therefore, it was assumed in the model that repeated MUS surgeries after failed primary surgeries are almost as effective as primary MUS surgeries, based on the finding from Kociszewski *et al.*[252] Kociszewski *et al.*[252] showed that 96% of women after primary sling implantation, and 88.46% of women after repeated sling, were dry at 6 months. The difference in percentage of negative pad test after primary and repeated procedure was not statistically significant. However, some previous studies show a lower success rate for retreatment with the same procedure. For example, Black and Downs[253] showed that retreatment colposuspension was 78.4% less effective on average than primary colposuspension. Therefore, we tested two scenarios: in the first scenario it was assumed that subsequent surgeries (retropubic and transobturator MUS) are 90% as effective as they would have been as a primary surgery, and in the second scenario it was assumed that the subsequent surgeries are 75% as effective as primary retropubic and transobturator MUS.

Long-term repeat surgery rates estimation

To estimate the rate at which women choose to remain incontinent rather than seek retreatment in the model, individual-level data from a previous study was obtained.[254] In brief, the study used data from Aberdeen Maternity and Neonatal Databank (AMND) to estimate the lifetime risk of undergoing pelvic floor surgery in a cohort of UK parous women. The AMND stores linked information on all obstetric-related events occurring in women living in Aberdeen city and district since 1950 and currently contains data for approximately 200,000 women. Within the cohort of women, 762 (2.2%) had an operation for UI. We utilised this subset of data to estimate the risk of reoperation over time after different types of SUI surgeries. We excluded 11 women who had urogenital fistula repair surgery as it is not a SUI procedure. We analysed 751 cases that had SUI surgery. The number of women with one, two, three and four surgeries for each type of surgery are reported in *Appendix 20*. As some of the surgical treatments are no longer popular, this dataset was used because it contains data for those surgical treatments.

TABLE 15 Weibull hazard function parameters for estimation of long term cure rates after urethral injection therapy

	Cure rate		
Weibull parameters	Lower limit	Mean	Upper limit
Lambda	1.020173	0.767078	0.548895
Gamma	0.120006	0.137820	0.166837

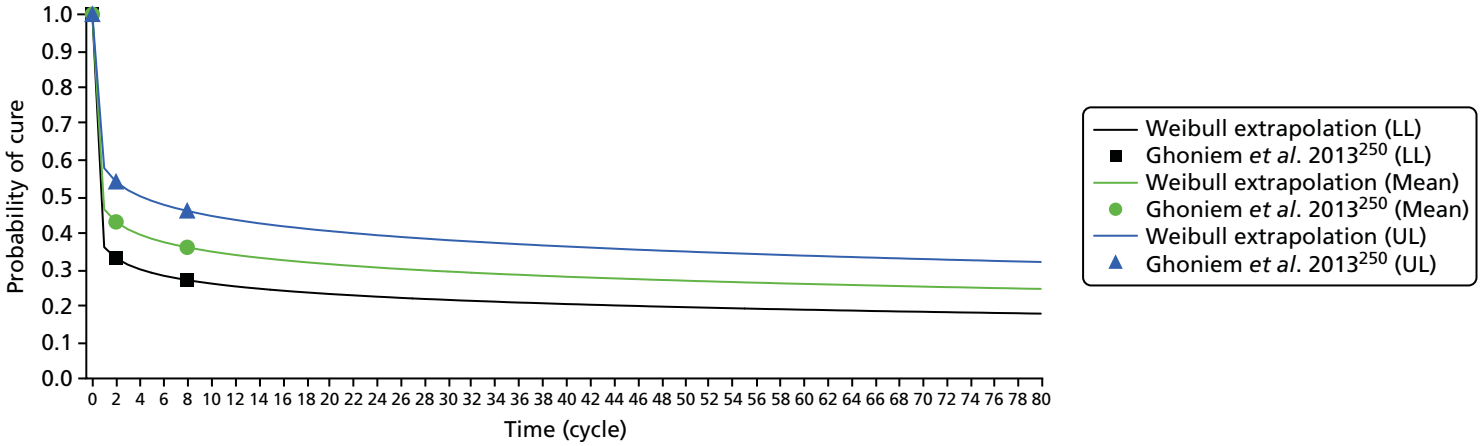

FIGURE 6 Extrapolated long-term cure rates after urethral injection therapy. Note that each cycle is 3 months long. LL, lower limit; UL, upper limit.

These data were analysed to estimate the rate at which women chose to remain incontinent rather than seek retreatment in the model. Parametric methods were used to extrapolate survival times beyond the follow-up duration in the data. We analysed the data using graphical exploration and statistical criteria of goodness of fit. First, Kaplan–Meier curves and survival, hazard and other related functions were examined graphically. The exponential, Gompertz, log-logistic, Weibull and log-normal distributions were fitted to the data and their fit was assessed visually and compared using statistical criteria based on log-likelihood, the Akaike information criterion (AIC) and the Bayesian information criterion (BIC); the model with the lowest AIC and BIC is preferred.[255] A log-normal distribution was applied to estimate the long-term rates of repeat surgery based on the AIC and BIC criteria. All fitted and observed survival data for different types of SUI surgeries are presented in *Appendix 20*.

Finally, the rate at which women choose to remain incontinent rather than seek retreatment was estimated based on the estimated cure rates and estimated repeat surgery rates at each time point. For example, if 1-year cure and repeat surgery rates after a particular surgery were 80% and 10%, respectively, the following formula was used to estimate the proportion of women who seek a second treatment following failure of the first treatment:

$$\text{Proportion} = P_{rt} / (1 - p_{cure}) = >10\% / (1–80\%) = 50\%, \quad (5)$$

where P_{rt} is the probability of having repeat surgery after a given surgery at time t and p_{cure} is the probability of a surgery still being successful at time t.

The observed repeat surgery rates were compared with data from the included RCTs and pairwise meta-analysis results for repeat surgery rates after different surgical treatments. We felt that the observed repeat surgery rates were underestimating the actual rates. For example, results from the analysis show that the rate of repeat surgery after anterior vaginal repair (colporrhaphy) in 2 years is about 3%, whereas data from two trials show that the rate is ranging from 26.0% to 37.5%.[194,196] Therefore, in the base-case analysis it was assumed that (based on the data from previous assessment of surgical treatments for SUI) 75% of women whose first treatment was not successful would seek retreatment and 30% of women whose first retreatment failed would seek second retreatment in the base-case analysis.[256] We used the results from the analysis of AMND data in the SA to inform the model in terms of the proportion of women who will seek retreatment after failure of first surgery.

Complication rates after surgical treatments

There are different types of complications that can happen after each surgical treatment. The model incorporates only severe complications/adverse events that are important in terms of their effect on women's quality of life, the cost and duration of treatments and data availability. To estimate complication incidence rates, random-effect meta-analysis models were fitted using WinBUGS software.[33] A Bayesian approach was used to combine existing knowledge with prior information based on established rules of probability. We checked the convergence of the model in different number of iterations; 50,000 Markov chain Monte Carlo iterations after a burn-in period of 20,000 iterations was chosen to get posterior distributions. The convergence was checked graphically using trace and autocorrelation plots. All the complications included in the model, and estimated incidence rates, are presented in *Table 16*. The estimated incidence rates were defined as distributions in the economic model (beta distribution). Lastly, the rates were used to estimate health-care costs and utility decrements associated with each treatment (see *Resource use and unit costs* and *Health utility* for more details).

All-cause mortality rates

In the model, women were at risk of death (from any cause) during any given cycle period. The cycle-specific risk of mortality was dependent on the simulated woman's age. The risk of mortality will therefore increase with each cycle period (the 'all-cause ageing effect'). Age-specific all-cause mortality rates were derived from general population mortality statistics reported in national life tables (Office for National Statistics).[232] The model incorporated the risk of operation-related death also. A rate of 0.0005 has been applied for open

TABLE 16 Complications incidence rates after different surgical treatments (results from random-effect meta-analysis)

	Complication (%), mean (SD)						
Surgery	Infection	De novo symptoms of urgency or UI	Voiding difficulties including urinary retention	Bladder or urethral perforation	Tape/mesh erosion/ extrusion/exposure	Short-term pain	Persistent pain or discomfort
Anterior vaginal repair	NA	15.84 (11.83)	0.01 (0.15)	NA	NA	NA	NA
Bladder neck needle suspension	NA	8.14 (4.87)	1.67 (2.61)	NA	NA	57.64 (30.08)	NA
Open colposuspension	24.33 (21.82)	5.78 (1.15)	3.00 (1.04)	1.02 (0.50)	0.0 (NA)	20.94 (25.65)	0.15 (2.58)
Laparoscopic colposuspension	NA	8.38 (3.98)	6.32 (2.35)	2.10 (1.22)	0.0 (NA)	NA	NA
Traditional sling	14.85 (12.49)	7.85 (3.23)	11.63 (3.60)	1.82 (1.11)	0.17 (0.34)	28.99 (28.12)	7.00 (8.98)
Retropubic MUS	3.91 (4.72)	4.30 (0.66)	6.75 (0.95)	4.89 (0.50)	1.40 (0.31)	4.36 (1.14)	5.09 (2.37)
Transobturator MUS	2.84 (1.03)	5.31 (0.51)	2.88 (0.44)	5.13 (0.50)	2.08 (0.26)	7.04 (2.08)	4.93 (1.22)
Single-incision sling	3.22 (1.20)	6.47 (0.81)	2.15 (0.45)	0.37 (0.18)	2.38 (0.55)	4.54 (3.21)	1.28 (1.39)
Urethral injection therapy	17.94 (24.59)	17.94 (24.59)	11.47 (20.70)	NA	NA	NA	NA

Laparoscopic colposuspension, laparoscopic retropubic colposuspension; NA, not available; open colposuspension, open abdominal retropubic colposuspension; traditional sling, traditional suburethral retropubic sling procedure.

surgeries in previous studies[241,256] based on the results from a report by Leach *et al.*[257] In addition, a recent study showed that urethral injection therapy had a higher mortality rate than open colposuspension [adjusted incidence rate ratio (IRR) 1.98, 95% CI 1.36 to 2.91]. They also showed retropubic MUS had a lower mortality rate than open colposuspension[251] (adjusted IRR 0.65, 95% CI 0.44 to 0.96).

Clinical inputs for effectiveness of urge incontinence treatments

For those women with MUI who have UUI following surgery for SUI, or those SUI women who develop de novo UUI after surgery for SUI, three lines of treatment were assumed. Although it is possible to get more than three types of treatment for UUI, to simplify the model only three types of treatment were incorporated:

1. *first-line treatment:* bladder training
2. *second-line treatment:* anticholinergics drugs (oxybutynin hydrochloride)
3. *third-line treatment:* botulinum toxin type A.

The results from a systematic review undertaken by Lee *et al.*[258] showed that the efficacy of bladder training on symptoms of urgency ranges from 12% to 90%. In the base-case analysis, a 32% cure rate after bladder training was assumed.

The results from another NMA, which was conducted recently, showed that the absolute probability of being continent at 12 weeks after oxybutynin hydrochloride treatment is 21%.[259] Oxybutynin hydrochloride (5 mg twice daily) was used as an index second-line treatment. After 3 months, probabilities were assumed to be constant, which is consistent with the evidence from a long-term study suggesting that the treatment effect of antimuscarinic therapy at 4 months is maintained to 24 months.[260] Failure rates after botulinum toxin type A treatment at different time points were obtained from a previous economic evaluation that was conducted within the development of clinical guidelines for UI.[259] It was assumed that the cure rate at 6 months using botulinum toxin type A is 36%.[259]

Resource use and unit costs

As mentioned in *Model overview*, the analysis was undertaken from a NHS and PSS perspective. Information on the precise description of resources required for each individual surgical treatment was based partially on data derived from the review of economic modelling studies, augmented where necessary by clinical experts in the study group and published economic literature. Unit costs were taken from appropriate routine sources, such as NHS Reference Costs,[261] the Personal Social Services Research Unit (PSSRU)[262] and the most recent *British National Formulary* (BNF)[263] for medication.

Surgery costs

Surgeries for SUI and stress-predominant MUI vary in terms of the complexity of the procedure and the setting in which surgery would be conducted. For women undergoing anterior vaginal repair, bladder neck needle suspension, open colposuspension, laparoscopic colposuspension and traditional sling procedures, surgery would typically be conducted in an inpatient setting, based on expert clinical input. Women undergoing retropubic MUS and transobturator MUS procedures would typically be treated in a day case setting, based on expert clinical input. Costs for each of these individual surgeries were derived from *NHS Reference Costs 2015/16*.[261] Finally, both single-incision sling procedures and urethral injection therapy would be conducted in a day case setting, on the basis of clinical advice. No appropriate NHS reference costs were identified for these procedures and, therefore, costs for both of these surgeries were derived from previous literature, with costs inflated to a 2015/16 price year using the hospital and community health services (HCHS) index listed in the *Unit Costs of Health and Social Care 2016*.[262] The cost of each surgery is presented in *Table 17*.

TABLE 17 Cost inputs

Resources	Cost (£)	Source	HRG code
Type of surgery			
Anterior vaginal repair	2236.50	*NHS Reference Costs 2015/16*[261]	MA04C/D: intermediate open lower genital tract procedures – elective inpatient
Bladder neck needle suspension	1819.72	*NHS Reference Costs 2015/16*[261]	LB26A/B: intermediate endoscopic, prostate or bladder neck procedures – elective inpatient
Open colposuspension	3909.55	*NHS Reference Costs 2015/16*[261]	LB59Z: major, open or laparoscopic bladder neck procedures – elective inpatient
Laparoscopic colposuspension	3909.55	*NHS Reference Costs 2015/16*[261]	LB59Z: major, open or laparoscopic bladder neck procedures – elective inpatient
Traditional sling	1924.32	*NHS Reference Costs 2015/16*[261]	LB51A/B: vaginal tape operations for UI – elective inpatient
Retropubic MUS	1351.10	*NHS Reference Costs 2015/16*[261]	LB51A/B: vaginal tape operations for UI – day case
Transobturator MUS	1351.10	*NHS Reference Costs 2015/16*[261]	LB51A/B: vaginal tape operations for UI – day case
Single-incision sling	1040.54	Boyers *et al.*[264]	N/A
Urethral injection therapy	1820.29	Kilonzo *et al.*[229]	N/A
Additional resource use associated with surgery			
Incontinence pads	106.20 (3-month cost estimate)	NICE guidance document[214]	N/A
Urodynamic test	155.00	*NHS Reference Costs 2015/16*[261]	N/A
Consultation pre surgery (20-minute consultation with surgical consultant)	46.00	PSSRU's *Unit Costs of Health and Social Care*, 2016[262]	N/A
Urine dipstick analysis	3.94	NICE clinical guidelines[214]	N/A
Full blood count	6.31	NICE clinical guidelines[214]	N/A
Diagnostic flexible cystoscopy	152.00	*NHS Reference Costs 2015/16*[261]	LB72A: diagnostic flexible cystoscopy
500 mg of paracetamol (AAH Pharmaceuticals Ltd) × 32	0.16 (daily cost based on a recommended dose of 4 g a day)	BNF, 2016[263]	N/A
10g/15 ml of lactulose (AAH Pharmaceuticals Ltd) × 10 sachets	0.50 (daily cost based on a recommended dose of 15 ml twice a day)	BNF, 2016[263]	N/A

TABLE 17 Cost inputs (*continued*)

Resources	Cost (£)	Source	HRG code
Urge incontinence treatment			
Bladder training	97.81 (3-month cost estimate)	Appendices of NICE guidelines[214]	N/A
Band 6 hospital-based physiotherapist consultation (1-hour consultation)	45.00	PSSRU 2016[262]	N/A
5 mg of oxybutynin hydrochloride (AAH Pharmaceuticals Ltd) × 56	0.05 (daily cost based on a recommended dose of 5 mg twice a day)	BNF 2016[263]	N/A
Consultant-led non-admitted follow-up face-to-face attendance in urology	100.00	*NHS Reference Costs 2015/16*[261]	N/A
Intermediate endoscopic bladder procedure (day case)	971.00	*NHS Reference Costs 2015/16*[261]	N/A
Botulinum toxin type A 100-unit powder for solution for injection vials (Allergan Ltd)	138.20	BNF 2016[263]	N/A
Adverse event treatment			
250/125 mg of co-amoxiclav (AAH Pharmaceuticals Ltd) × 21	0.27 (daily cost based on a recommended dose of 250/125 mg every 8 hours)	BNF 2016[263]	N/A
Attention to bladder catheter (outpatient, urology)	123.00	*NHS Reference Costs 2015/16*[261]	N/A
Self-catheterisation	6.20 (daily cost based on 4 catheters required per day)	NICE guidance document[214]	N/A
Mesh excision or repair	1316.85	*NHS Reference Costs 2015/16*[261]	MA04: intermediate open lower genital tract procedures – day case
300 mg of aspirin (AAH Pharmaceuticals Ltd) × 28	0.40 (daily cost based on a recommended dose of 300 mg every 6 hours)	BNF 2016[263]	N/A

HRG, Healthcare Resource Group; N/A, not applicable.

Additional costs associated with surgery

In addition to the cost of individual surgeries, costs associated with complementary tests, treatments and consultations that would typically be carried out in advance of, and following, each surgery were also considered. Clinical experts advised that women undergoing surgery for SUI and stress-predominant MUI would typically use incontinence pads until their condition had been resolved. The weekly cost of pads was estimated from a NICE guidance document[214] with costs based on a guidance development group opinion on estimated pad usage per week. Costs reported were inflated to the current price year and converted to a 3-monthly cost to fit the model time cycle. Clinical experts advised that a urodynamic test would be conducted in a separate consultation before each surgery, and that the woman would also have a separate 20-minute consultation before undergoing surgery with the clinician carrying out the surgery. Costs for test and consultation were derived from *NHS Reference Costs 2015/16*[261] and PSSRU 2016[262] respectively.

Clinical experts involved in the study advised that a urine dipstick analysis and full blood count would need to be taken prior to each surgery, excluding injectable agent procedures, for which only a urine dipstick analysis would be required. Costs for both were obtained from NICE clinical guidelines for routine pre-operative tests for elective surgery.[214] In addition, it was advised that a cystoscopy on the day of the procedure would be mandatory for women undergoing a retropubic MUS or transobturator MUS procedure. The cost of a diagnostic flexible cystoscopy in an outpatient setting was obtained from *NHS Reference Costs 2015/16*.[261] Finally, the cost of medication needed for pain relief post surgery (paracetamol) was considered, with the duration of pain relief required greater for inpatient procedures (7 days) than for the less invasive day case procedures (3 days). It was also advised that lactulose would be taken as pain relief for 1 day following anterior vaginal repair only. Costs of medication were obtained from the BNF 2016.[263] All additional costs are reported in *Table 17*. Omitting the cost of incontinence pads, which are used by all women with incontinence regardless of the type of initial surgery, the total additional costs associated with anterior vaginal repair, bladder neck needle suspension, open colposuspension, laparoscopic colposuspension, traditional sling, retropubic MUS, transobturator MUS, single-incision sling and urethral injection therapy were £212.87, £212.37, £212.37, £212.37, £212.37, £363.73, £363.73, £211.73 and £205.42, respectively.

Urge urinary incontinence costs

As well as the cost of surgical treatments for SUI and stress-predominant MUI, the costs associated with treatment for UUI were also considered. The NICE clinical guidelines on the management of urge incontinence recommend three broad lines of treatment for women with this type of incontinence:[214]

1. conservative measures such as bladder training
2. antimuscarinic drugs, most typically oxybutynin hydrochloride
3. invasive therapy such as botulinum toxin type A.

This treatment pathway was confirmed by clinical experts in the study team. The cost of bladder training was obtained from the appendices of a NICE draft for consultation on guidelines for UI in women.[214] Costs reported in this document were based on women being seen 5 times over a 4-month period (i.e. initial consultation and once in each of the 4 months). To estimate 3-monthly bladder training costs to fit the model time cycle, it was assumed that the woman would have an initial consultation with a band 6 hospital-based physiotherapist and would be seen for training once in each of the 3 months. The cost of a consultation was based on data obtained from PSSRU 2016.[262] The cost of consumables required during training were obtained directly from the guidelines[214] and were also included in the estimate. These costs were inflated to the current price year using the HCHS index listed in PSSRU 2016.[262]

Antimuscarinic medication taken was assumed to be oxybutynin hydrochloride, on the basis of recommendations from the clinical guidelines[214] and expert clinical advice. Appropriate costs were obtained from the BNF 2016.[263] Additionally, it was assumed that the woman would require a consultation with a specialist before beginning medication, and this cost was based on the average unit cost of a consultant-led non-admitted face-to-face follow-up attendance in urology, obtained from *NHS Reference Costs 2015/16*.[261] Cost of medication was estimated for 3 months. Finally, the cost of a botulinum toxin type A procedures was based on micro-costing details presented in a NICE draft for consultation on guidelines for UI in women.[214] Included in this overall procedure cost was the cost of an intermediate endoscopic bladder procedure (day case) and the cost of botulinum toxin type A 100-unit powder for solution for injection vials. These costs were obtained from *NHS Reference Costs 2015/16*[261] and the BNF 2016,[263] respectively. Additionally, it was assumed that the woman would require a consultation with a specialist before undergoing a botulinum toxin type A procedure, and this cost was based on the average unit cost of a consultant-led non-admitted face-to-face follow-up attendance in urology, obtained from *NHS Reference Costs 2015/16*.[261] Costs of urge incontinence treatments are reported in *Table 17*.

Adverse events treatment costs

The cost of treating complications associated with surgical treatments was also considered in the model. Typical treatments were informed by expert clinical advice and costs were obtained through routine sources. The cost of treating an infection was based on the cost (obtained from the BNF 2016[263]) of co-amoxiclav antibiotic medication over a 2-week period (advised duration of infection). It was advised that women experiencing voiding difficulties (including urinary retention), or bladder or urethral perforation, would require catheterisation. This cost was based on the cost, obtained from *NHS Reference Costs 2015/16*,[261] of a bladder catheter procedure in an out-patient setting. As voiding difficulties may impact the woman for up to 3 months, the cost of self-catheterisation over this period was also estimated. For a bladder injury the cost of a suprapubic bladder catheter procedure in an out-patient setting was applied, as well as the cost of self-catheterisation over a 12-day period (based on expert clinical advice). The cost of a single catheter was obtained from the NICE draft for consultation on guidelines for UI in women[214] and inflated to the 2016 price. It was assumed that the woman would require four catheters per day, based on data presented in the NICE guidelines.[214]

The cost of a mesh excision or repair to treat mesh erosion was based on the cost of a partial removal of TVT [HRG (Healthcare Resource Group) code MA04: intermediate open lower genital tract procedures – day case], obtained from *NHS Reference Costs 2015/16*.[261] Based on the reference cost schedule, a relatively small percentage (16%) of these procedures will be major procedures. The intermediate option was chosen, reflecting that the greatest percentage of procedures are intermediate. The cost difference between the major and intermediate procedure is in the region of £200. This was assumed to be a one-off cost. It was advised that persistent pain would typically be treated through the use of non-steroidal anti-inflammatory drugs. For the purpose of this costing, medication taken for pain was assumed to be aspirin (based on expert clinical advice) and relevant costs were obtained from the BNF 2016.[263] The estimated incidence rates for each complication were used to estimate cost associated with complications after each surgical treatment by multiplying respective incidence rates by the cost of each complication. All costs associated with treating adverse events are reported in *Table 17*.

Health utility

The identified papers from the review of economic evaluation studies were screened specifically for utility estimates for women with SUI, stress-predominant MUI and UUI. The focus of the screening was to identify studies (economic evaluations or otherwise) that included populations of these women and were conducted in the UK (or elsewhere but included a UK-based subpopulation or population that was generalisable to a UK population). The baseline value for pretreatment SUI was derived from a previous UK-based economic evaluation comparing two types of surgical intervention for this condition.[244] The utility value for a successful treatment was derived from a UK-based study exploring health outcomes in women with UI.[245] This study was also used to estimate the utility values for health states following failed surgical treatment (*Table 18*). The same data were used to inform the utility weights in two previous studies of surgical and non-surgical treatment of SUI in the UK.[85,241]

The availability of utility values for outcomes and complications of surgical treatment for SUI, stress-predominant MUI and UUI were sparse. Only one study identified through the review of economic evaluation studies had reported appropriate utility data related to adverse events, conducted by Shepherd *et al.*[265] Owing to the unavailability of utility values for complications related to surgery, values in Shepherd *et al.*'s study were assigned by an expert panel of six urogynecologists by matching complications included in the model to published data on similar conditions in different groups of women. This study was used to derive utility values for all adverse events included in the model. Utility decrements for all adverse events included in the model, as well as their duration in the economic model, are presented in *Table 18*. In the model, utility decrements were assigned only to the proportion of the woman population experiencing that complication for the duration each complication was expected to last.

TABLE 18 Utility values for different health states and utility decrement associated with complications

EQ-5D	Utility value	Source	Duration
SUI pretreatment	0.78	Manca *et al.*[244]	Variable
Mixed pretreatment	0.78	Manca *et al.*[244]	Variable
Cured from SUI and no urge UI	0.85	Haywood *et al.*[245]	Variable
UUI	0.74	Haywood *et al.*[245]	Variable
Pure SUI retreatment	0.74	Haywood *et al.*[245]	Variable
Mixed retreatment	0.74	Haywood *et al.*[245]	Variable
SUI failure of treatment (containment)	0.74	Haywood *et al.*[245]	Variable
Mixed failure of treatment (containment)	0.74	Haywood *et al.*[245]	Variable
Adverse event	**Utility decrement**	**Source**	**Duration**
Infection	–0.19	Shepherd *et al.*[265]	2 weeks
Voiding difficulties (long term)	–0.23	Shepherd *et al.*[265]	3 months
Bladder/urethral perforation	–0.08	Shepherd *et al.*[265]	2 weeks
Tape/mesh exposure/erosion	–0.25	Shepherd *et al.*[265]	3 months
Short-term pain	–0.25	Shepherd *et al.*[265]	2 weeks
Persistent pain	–0.25	Shepherd *et al.*[265]	6 months

Main modelling assumptions

- As data from HES for England in 2013–14, and data for hospital discharge in Scotland in 1996–2014, showed that around 91% and 96% of SUI surgeries were MUS procedures (retropubic MUS, 55%; transobturator MUS, 45%), and given that, from a clinical point of view, MUS can be offered after all types of surgeries, it was assumed that all subsequent surgeries are either retropubic MUS or transobturator MUS.
- No further conservative (i.e. PFMT, medication or lifestyle change) management of SUI were considered as a comparator, or within the treatment pathway, after surgery.
- It was assumed that all women in containment, retreatment and urge incontinence states will use containment products.
- For women with MUI, and those who develop UUI after surgical treatments for SUI, first-line treatment of UUI (bladder training) will be offered, and if the first line treatment fails they will be offered second-line treatment (drug, i.e. oxybutynin hydrochloride). In the event that second-line treatment fails, they will be offered third-line treatment (botulinum toxin type A) for UUI. We appreciate that there are multiple options for treating UUI, but for reasons of simplification we have used the most common treatments for UUI.
- SUI and UUI are modelled independently, meaning that any treatment that has been received for SUI will not affect the effectiveness of UUI treatment and vice versa.
- It was assumed that the time interval between initial surgery and any subsequent surgery for SUI is 1 year. The reason behind this assumption is that it will take up to 1 year to find out about results from surgical treatments and to decide if further surgery is required.
- It was assumed that the time interval between first-line treatment for UUI and any subsequent treatment is 3 months.
- The model assumes that women can receive a total of three treatments, which includes the initial surgery plus two subsequent repeat surgeries, if required.
- Utility decrements associated with complications were incorporated based on their duration, utility decrement weights and respective incidence rates.

Incremental cost-effectiveness analysis

The joint estimates of costs and effects were combined in an incremental analysis, and presented in terms of the mean ICER for each comparator. The ICERs were calculated as the difference in costs divided by the difference in effects (QALYs) between treatment options. The ICERs were calculated for each successive alternative, from the least to the most costly. To help identify the optimal approach, the net monetary benefit (NMB) framework was used, where the NMB for a given strategy is equal to the accrued QALYs multiplied by the ceiling ratio (CR) of willingness to pay (WTP) per QALY, minus the strategy costs:

$$\text{NMB} = (\text{QALYs} \times \text{CR}) - \text{costs}. \quad (6)$$

The value of £20,000, which is typically used by NICE as a threshold to inform judgements on cost-effectiveness, was placed on the CR.[16] The threshold means NICE is prepared to pay £20,000 for each extra QALY gained through different interventions. Measures of variance for the joint incremental costs and effects were obtained using Monte Carlo simulation within the PSA and presented graphically using cost-effectiveness planes and cost-effectiveness acceptability curves (CEACs).

Sensitivity analyses

Both deterministic SA and, as noted above, PSA were used to explore parameter and other forms of uncertainty surrounding estimates of cost-effectiveness. Deterministic sensitivity analyses were performed to determine the impact of changing key parameters on the model results. Therefore, many of the model parameters were subject to one- and two-way sensitivity analyses, using hypothetical increases or decreases, to determine the key drivers of the model results. Deterministic sensitivity analyses were also carried out to test for the effect of assumptions and variability. These analyses are described in this section.

When available, data were also entered into the model as distributions to fully incorporate the uncertainty around parameter values so that a PSA could be undertaken. In decision modelling, many of the parameter values are often estimated with a degree of uncertainty. The probabilistic distribution for each parameter was defined by considering the mean, standard error and anticipated shape of the distribution. The PSA was run with 10,000 simulations for each woman, and CEACs were produced to identify the probability of the different surgeries being cost-effective across a range of WTP thresholds. Estimation of costs and QALYs were calculated as the expectation over the joint distribution of the parameters. This quantification of decision uncertainty also provided the starting point for assessing the value of additional research.

This section details the technical specification of the sensitivity analyses conducted.

Applying higher incidence rates of mesh complications after mid-urethral sling procedures

As mentioned in the methods section, data from the trials were used to estimate the complications incidence rates after each surgical treatment. As some of the complications may happen over the longer term, and given that the trials are short in terms of the follow-up time, results from a very recent study on MUS were used to estimate the mesh complication incidence rates after retropubic MUS and transobturator MUS in the model. Keltie *et al.*[266] conducted a study to investigate the rate of adverse events after MUS procedures using data from the HES database. The mean follow-up time was 4.2 years (unconfounded cohort). They showed that the readmissions for further surgery after initial retropubic MUS and transobturator MUS were 3.7% [removal (2.7%), repair (1%), renewal (0%)] and 2.8% [removal (1.9%), repair (0.9%), renewal (0%)], respectively. These values were used within the SA for retropubic MUS and transobturator MUS. In addition, we explored the effect of assuming both a 10% and a 20% incidence rate of mesh complications both after retropubic MUS and after transobturator MUS on the results.

Incorporating longer duration for persistent pain complication

In the base-case analysis, it was assumed that persistent pain complication will last for, on average, 6 months. In this SA, the effect of longer-term suffering from persistent pain was explored: we tested scenarios in which women suffer for 3 years and women suffer for 5 years.

Applying higher incidence rates of persistent pain after mid-urethral sling procedures

In the base-case analysis, it was assumed that the incidence rate for persistent pain complication after retropubic MUS and transobturator MUS are 5.09% and 4.93%, respectively, based on the results from meta-analysis. In these sensitivity analyses, the effect of higher incidence rates of persistent pain (10% and 20%) after MUS procedures was explored.

Applying higher incidence rates and longer duration for persistent pain after mid-urethral sling procedures

A scenario analysis was also conducted by incorporating higher incidence rates of persistent pain after MUS procedures and longer duration. It was assumed that the incidence rates for persistent pain complication after retropubic MUS and transobturator MUS are 20% and that, on average, women with persistent pain will suffer for 5 years.

Assuming that all the women in the model have stress urinary incontinence

A SA was performed to investigate the disease type of women in the model. Owing to data limitations, it was not possible to do a full subgroup analysis and estimate different success rates for two subpopulations (i.e. women with SUI and women with MUI). In this SA it was assumed that all the women in the model have SUI and the success rates are the same as the base-case analysis.

Assuming alternative values for the proportion of women who will seek retreatment after failure of each surgical treatment

In the base-case analysis, it was assumed that 75% of women whose first treatment was not successful would seek retreatment and 30% of women whose first retreatment failed would seek second retreatment. This SA was conducted to explore results using data from the linked database (AMND) to estimate the proportion of women who will seek retreatment after failure of each surgical treatment.

As mentioned in the methods section, primary data from linked databases were analysed to estimate repeat surgery incidence rates over time and were then used to estimate the proportion of women who will seek retreatment after failure of the previous surgery. Because the linked database may not be complete, the health economists felt that the rates of repeat surgery were underestimated. In this SA, the method described in *Repeat surgery* was used to estimate the proportion of women who will seek retreatment. In addition, in this SA lower probabilities of repeat surgeries (50% and 10% for first retreatment and 20% and 0% for second retreatment) were explored.

Applying different values for short- and long-term success rates after retropubic mid-urethral sling

As indicated in the estimation of model probabilities, the short-term and long-term cure rates after retropubic MUS were estimated using a random-effects meta-analysis. There are some uncertainties associated with these estimates and it is probable that these values are either an overestimate or an underestimate because of small sample size. We have explored the effect of using two different sources of data (Ward *et al.*[248] and Song *et al.*[249]) for extrapolation of long-term success rate after retropubic MUS in this SA. The short- and long-term cure rates were used to estimate an appropriate shape and scale parameter for a Weibull hazard function, and these parameters were used to estimate failure rates at each time point after retropubic MUS, as described in *Transition probabilities*.

Applying lower success rates when repeating same surgeries

This SA was conducted to explore the effect of assuming lower cure rates when the same surgeries are being conducted for a second or third time. In the base-case analysis it was assumed that all surgical treatments have the same effectiveness as a primary procedure, whereas in this SA the subsequent treatments are assumed to have less effectiveness: 90% and 75%, respectively.

Incorporating different health utility values and effect of natural decline in health utility over time

As mentioned in *Health utility*, the same values were used for SUI and MUI women using data from Manca *et al.*[244] and Haywood *et al.*[245] in the base-case analysis. Tincello *et al.*[267] showed that MUI (EQ-5D 0.75) may have a greater impact on the EQ-5D score than SUI (EQ-5D 0.85). SA was performed by adjusting the EQ-5D scores used in the base-case analysis with lower values applied to MUI health states. EQ-5D scores used for the MUI pretreatment and MUI after failure of first/second treatment states were 0.69 and 0.65, respectively. The impact of the natural decline in health utility over time was also considered in further SA. The values for the age-related reduction were derived based on published values for age-related health utility.[268]

Results

Monte Carlo simulation was performed to obtain probabilistic estimates of the cost-effectiveness of retropubic MUS compared with all other surgical treatments. The results, in terms of total and incremental costs and effectiveness, and incremental cost per QALY, are presented in *Table 19*, and in the form of a CEAC in *Figure 7*. *Table 19* reports strategies from least to most costly; the last column reports the ICERs. Over a lifetime time horizon, retropubic MUS is on average the least costly (£8099) and the most effective (24.22 QALYs) surgical treatment. All other surgical treatments are dominated as they are more costly and less effective than retropubic MUS except for traditional sling. Over a shorter time horizon (10 years), retropubic MUS remains the dominant strategy. However, over a 1-year time horizon single-incision sling is

TABLE 19 Results of the probabilistic analysis for 1-year, 10-year and lifetime time horizons

Time horizon	Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
							20,000	30,000
1 year	Single-incision sling	1953		0.76			96.6	92.3
	Retropubic MUS	2310	357	0.75	–0.01	Dominated	2.9	5.6
	Transobturator MUS	2352	399	0.75	–0.01	Dominated	0.5	1.4
	Bladder neck needle suspension	2756	803	0.75	–0.01	Dominated	0.1	0.5
	Traditional sling	2772	819	0.72	–0.04	Dominated	0.0	0.0
	Urethral injection therapy	2848	895	0.74	–0.02	Dominated	0.0	0.1
	Anterior vaginal repair	3249	1296	0.76	0.00	Dominated	0.0	0.2
	Open colposuspension	4710	2757	0.77	0.01	233,209	0.0	0.0
	Laparoscopic colposuspension	4804	95	0.76	–0.01	Dominated	0.0	0.0

continued

TABLE 19 Results of the probabilistic analysis for 1-year, 10-year and lifetime time horizons (*continued*)

Time horizon	Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
							20,000	30,000
10 years	Retropubic MUS	4649		7.33			51.0	44.9
	Traditional sling	5235	585	7.28	–0.05	Dominated	20.4	20.5
	Single-incision sling	5274	625	7.14	–0.19	Dominated	3.7	3.5
	Transobturator MUS	5414	765	7.20	–0.13	Dominated	4.3	4.4
	Urethral injection therapy	5676	1027	7.19	–0.14	Dominated	8.8	9.5
	Bladder neck needle suspension	5958	1309	7.14	–0.19	Dominated	4.0	4.3
	Anterior vaginal repair	6655	2006	7.11	–0.22	Dominated	1.8	2.4
	Open colposuspension	7375	2725	7.29	–0.04	Dominated	4.7	8.1
	Laparoscopic colposuspension	7818	3169	7.20	–0.13	Dominated	1.3	2.5
Lifetime	Retropubic MUS	8099		24.22			25.8	24.6
	Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
	Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
	Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
	Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
	Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
	Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
	Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
	Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8

dominant compared with all other strategies except for open colposuspension. *Figure 7* shows that over a lifetime time horizon retropubic MUS has a > 26% probability of being cost-effective at a WTP threshold value of £20,000. Given the number of comparators, if the interventions were comparable we would expect an 11% chance of being cost-effective. The only other strategies with reasonably sized probabilities of being cost-effective are traditional sling (≈27% across all WTP values presented, suggesting not much difference between retropubic MUS and traditional sling) and open colposuspension (≈14–16% across all WTP thresholds > £10,000). All other strategies have a < 10.5% probability of being cost-effective across all WTP values presented.

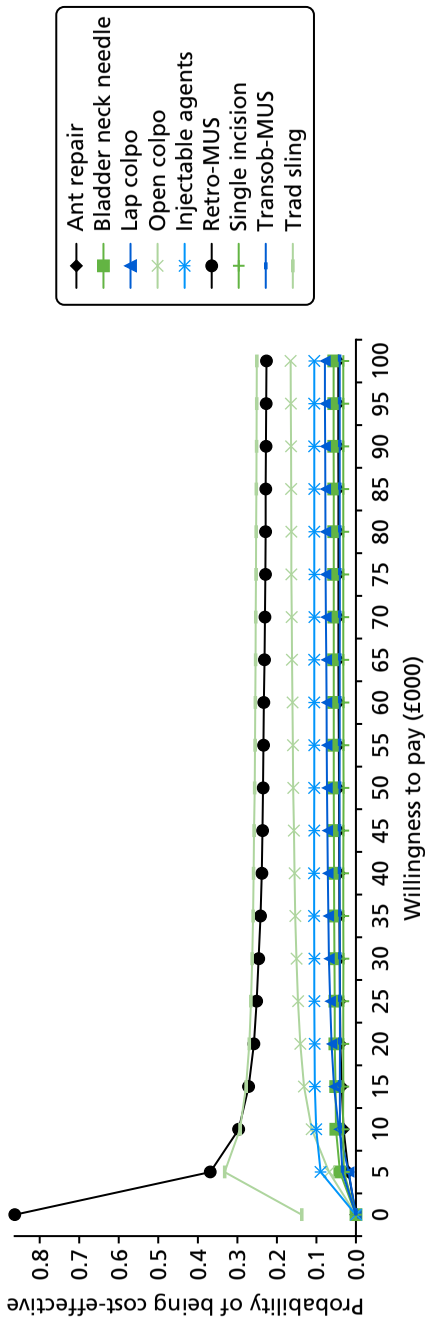

FIGURE 7 Cost-effectiveness acceptability curves for the nine surgical treatments. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; lap colpo, laparoscopic retropubic colposuspension; open colpo, open abdominal retropubic colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; transob-MUS, transobturator mid-urethral sling; trad sling, traditional suburethral retropubic sling.

Deterministic sensitivity analyses

Applying higher incidence rates for mesh complications after mid-urethral sling procedures

In this SA, results from the study by Keltie *et al.*[266] were used to inform the mesh complication incidence rate after retropubic MUS and transobturator MUS. The results from this SA show that retropubic MUS remains the least costly strategy compared with the alternative surgical interventions and is the most cost-effective option, at a WTP threshold value of £20,000 (*Table 20*). However, when 10% and 20% incidence rates are used, traditional sling is the most cost-effective option, with an ICER of < £20,000 per each QALY gained.

TABLE 20 Results from deterministic sensitivity analyses applying higher incidence rates of mesh complications after MUS procedures (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
						20,000	30,000
Base-case analysis estimating the incidence rate of mesh complications after MUS procedures based on the data from trials							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA estimating the incidence rate of mesh complications for retropubic MUS (3.7%) and transobturator MUS (2.8%) based on the data from Keltie *et al.*[266]							
Retropubic MUS	8138		24.20			24.5	23.5
Traditional sling	8530	392	24.22	0.01	26,311	27.8	26.8
Urethral injection therapy	9560	1030	23.85	–0.37	Dominated	10.7	10.7
Single-incision sling	9656	1125	23.58	–0.63	Dominated	3.3	3.2
Transobturator MUS	9683	1153	23.69	–0.53	Dominated	4.1	4.0
Bladder neck needle suspension	10,131	1601	23.67	–0.55	Dominated	5.9	6.0
Open colposuspension	10,978	2448	24.09	–0.13	Dominated	14.1	15.0
Anterior vaginal repair	11,073	2543	23.53	–0.69	Dominated	3.9	4.2
Laparoscopic colposuspension	11,805	3275	23.81	–0.41	Dominated	5.9	6.7

TABLE 20 Results from deterministic sensitivity analyses applying higher incidence rates of mesh complications after MUS procedures (lifetime time horizon) (*continued*)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
						20,000	30,000
SA assuming 10% incidence rate of mesh complications after retropubic MUS and transobturator MUS							
Retropubic MUS	8238		24.19			23.9	22.5
Traditional sling	8550	312	24.24	0.05	6631	29.1	28.1
Urethral injection therapy	9596	1045	23.86	–0.37	Dominated	11.2	11.2
Single-incision sling	9705	1155	23.58	–0.65	Dominated	3.2	3.1
Transobturator MUS	9817	1267	23.69	–0.55	Dominated	4.0	4.2
Bladder neck needle suspension	10,180	1629	23.69	–0.55	Dominated	5.8	5.9
Open colposuspension	11,010	2460	24.08	–0.16	Dominated	13.1	14.2
Anterior vaginal repair	11,120	2570	23.54	–0.70	Dominated	3.7	4.1
Laparoscopic colposuspension	11,843	3292	23.84	–0.40	Dominated	6.0	6.8
SA assuming 20% incidence rate of mesh complications after retropubic MUS and transobturator MUS							
Retropubic MUS	8381		24.17	0.00		23.6	22.4
Traditional sling	8579	198	24.21	0.04	4558	28.6	27.6
Urethral injection therapy	9644	1064	23.86	–0.35	Dominated	10.7	10.8
Single-incision sling	9766	1186	23.58	–0.64	Dominated	3.4	3.3
Transobturator MUS	9987	1407	23.66	–0.56	Dominated	3.7	3.8
Bladder neck needle suspension	10,237	1657	23.67	–0.54	Dominated	5.6	5.8
Open colposuspension	11,048	2469	24.07	–0.14	Dominated	14.1	15.0
Anterior vaginal repair	11,185	2606	23.52	–0.69	Dominated	3.6	3.8
Laparoscopic colposuspension	11,892	3312	23.82	–0.39	Dominated	6.7	7.5

Incorporating longer duration for persistent pain complication

In the base-case analysis, it was assumed that persistent pain complication will last for, on average, 6 months. In these sensitivity analyses, the effect of longer-term suffering from persistent pain was explored and it was assumed that, on average, women with persistent pain will suffer for 3 and 5 years. The results from these sensitivity analyses show that with longer duration of persistent pain, the probability of retropubic MUS being the most cost-effective option decreases and the respective probability for open colposuspension increases (*Table 21*).

Applying higher incidence rates of persistent pain after mid-urethral sling procedures

Results from these sensitivity analyses show that when a higher incidence rate (10% and 20%) of persistent pain after retropubic MUS and transobturator MUS was assumed, the probability of retropubic MUS being the most cost-effective option decreases and the respective probability for traditional sling increases (*Table 22*). The probability of retropubic MUS and traditional sling being the most cost-effective are 23–24% and 28–29%, respectively.

TABLE 21 Results from deterministic sensitivity analyses incorporating longer duration for persistent pain complication (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
						20,000	30,000
Base-case analysis assuming that persistent pain complication will last on average for 6 months							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA assuming that persistent pain complication will last on average for 36 months							
Retropubic MUS	8097		24.02			22.3	20.9
Traditional sling	8523	426	24.01	–0.01	Dominated	23.7	22.8
Urethral injection therapy	9547	1450	23.78	–0.24	Dominated	12.7	12.6
Single-incision sling	9646	1549	23.45	–0.56	Dominated	3.4	3.3
Transobturator MUS	9665	1567	23.50	–0.52	Dominated	3.2	3.3
Bladder neck needle suspension	10,126	2029	23.59	–0.43	Dominated	6.6	6.7
Open colposuspension	10,970	2872	24.02	0.00	1,134,541	17.1	18.2
Anterior vaginal repair	11,060	90	23.43	–0.59	Dominated	4.0	4.1
Laparoscopic colposuspension	11,791	821	23.75	–0.27	Dominated	7.1	8.1
SA assuming that persistent pain complication will last on average for 60 months							
Retropubic MUS	8103		23.90			20.8	19.3
Traditional sling	8524	421	23.87	–0.03	Dominated	20.7	19.9
Urethral injection therapy	9550	1447	23.74	–0.17	Dominated	13.8	13.7
Single-incision sling	9648	1545	23.38	–0.52	Dominated	3.3	3.2
Transobturator MUS	9666	1563	23.35	–0.56	Dominated	2.5	2.6
Bladder neck needle suspension	10,127	2024	23.54	–0.36	Dominated	7.1	7.3
Open colposuspension	10,976	2872	23.99	0.09	33,380	19.4	20.5
Anterior vaginal repair	11,059	83	23.38	–0.61	Dominated	4.1	4.4
Laparoscopic colposuspension	11,793	818	23.71	–0.28	Dominated	8.3	9.3

TABLE 22 Results from deterministic sensitivity analyses incorporating higher incidence rate for persistent pain complication after MUS procedures (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
						20,000	30,000
Base-case analysis assuming that incidence rate of persistent pain after retropubic MUS and transobturator MUS are 5.09% and 4.93%, respectively							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA assuming that incidence rate of persistent pain after retropubic MUS and transobturator MUS is 10%							
Retropubic MUS	8104		24.18			24.2	23.0
Traditional sling	8523	419	24.20	0.03	15,067	28.4	27.6
Urethral injection therapy	9557	1034	23.84	–0.37	Dominated	11.1	11.1
Single-incision sling	9649	1126	23.57	–0.63	Dominated	3.2	3.2
Transobturator MUS	9672	1148	23.67	–0.54	Dominated	3.8	3.8
Bladder neck needle suspension	10,128	1605	23.66	–0.54	Dominated	5.7	5.8
Open colposuspension	10,977	2454	24.07	–0.13	Dominated	13.8	14.8
Anterior vaginal repair	11,063	2540	23.51	–0.69	Dominated	3.7	3.9
Laparoscopic colposuspension	11,799	3275	23.81	–0.39	Dominated	6.2	7.0
SA assuming that incidence rate of persistent pain after retropubic MUS and transobturator MUS is 20%							
Retropubic MUS	8109		24.13			23.3	22.1
Traditional sling	8520	410	24.19	0.06	6593	28.6	27.5
Urethral injection therapy	9557	1037	23.83	–0.36	Dominated	10.8	10.9
Single-incision sling	9645	1125	23.56	–0.63	Dominated	3.5	3.5
Transobturator MUS	9677	1158	23.61	–0.58	Dominated	3.8	3.8
Bladder neck needle suspension	10,131	1612	23.65	–0.54	Dominated	6.2	6.3
Open colposuspension	10,975	2455	24.07	–0.12	Dominated	14.0	15.1
Anterior vaginal repair	11,063	2543	23.49	–0.70	Dominated	3.5	3.8
Laparoscopic colposuspension	11,796	3277	23.80	–0.39	Dominated	6.3	7.1

Applying higher incidence rates and longer duration for persistent pain after mid-urethral sling procedures

In this scenario analysis, the impact of incorporating higher incidence rates of persistent pain after MUS procedures and longer mean duration for persistent pain was tested on the base-case results. As would be expected, the probability of retropubic MUS being the most cost-effective with a £20,000 WTP decreases from 26% to 4.2% and the corresponding probability for traditional sling increases from 27% to 30.8%. The estimated ICER for traditional sling is £619 per QALY gained. Open colposuspension is not a dominated strategy and has a 25.8% probability of being cost-effective (*Table 23*).

TABLE 23 Results from deterministic sensitivity analyses applying higher incidence rates and longer duration for persistent pain after MUS procedures (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
						20,000	30,000
Base-case analysis assuming that incidence rate of persistent pain after retropubic MUS and transobturator MUS are 5.09% and 4.93%, respectively, and average duration of persistent pain is 6 months							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA assuming that incidence rate of persistent pain after retropubic MUS and transobturator MUS are 20% and average duration of persistent pain is 60 months							
Retropubic MUS	8118		22.97			4.2	3.8
Traditional sling	8527	409	23.63	0.66	619	30.8	29.5
Urethral injection therapy	9560	1033	23.37	–0.26	Dominated	17.0	16.6
Single-incision sling	9652	1125	22.90	–0.72	Dominated	2.8	2.7
Transobturator MUS	9683	1156	22.25	–1.38	Dominated	0.1	0.1
Bladder neck needle suspension	10,130	1604	23.11	–0.52	Dominated	7.0	7.0
Open colposuspension	10,978	2451	23.68	0.05	46,732	25.8	27.0
Anterior vaginal repair	11,064	86	22.89	–0.79	Dominated	3.4	3.5
Laparoscopic colposuspension	11,797	819	23.32	–0.36	Dominated	9.0	9.9

Applying different values for short- and long-term cure rates after retropubic mid-urethral sling

When data on long-term cure rates derived from the UK trial[248] comparing TVT with Burch colposuspension were applied, the results show that the effectiveness of most of the strategies increased, as women spend more time continent over the modelling time horizon and have lower costs. The probability of retropubic MUS being cost-effective also increased, compared with the base-case analysis. When the data from Song *et al.*[249] were applied, the findings are broadly similar (*Table 24*).

Detailed results from the following sensitivity analyses are reported in *Appendix 21*, assuming that all of the women in the model have SUI; alternative values for the proportion of women who will seek retreatment after failure of each surgical treatment; applying lower success rate for repeating same surgeries; and incorporating different health utility values and effect of natural decline in health utility over time.

Value-of-information analysis

In addition to assessing the relative effectiveness and cost-effectiveness of the alternative surgical treatments, the economic model was used to quantify the main uncertainties facing decision-makers and to help inform decisions about the direction of future research. This was explored through variants of VOI analysis: expected value of perfect information (EVPI) and expected value of partial perfect information (EVPPI) analysis.

Expected value of perfect information

Decision-makers are interested in understanding the amount of uncertainty associated with a decision and this can be quantified directly from the PSA results. An assessment of the significance of this uncertainty also requires consideration of the consequences associated with uncertainty, in terms of the costs or equivalent health forgone if an incorrect decision is made. The scale and magnitude of these consequences needs to be reflected in the entire population who stand to be affected by a particular decision.

Value-of-information analysis can quantify the expected gain in net benefit from obtaining further information to inform a decision. Quantifying the value of an incorrect decision, alongside the probability of making an incorrect decision, allows us to estimate EVPI. The maximum amount that policy-makers should be willing to invest to reduce uncertainty in the decision can be informed by the EVPI. If the EVPI for a decision problem exceeds the cost of future research, additional investigation may be worthwhile.

As well as determining EVPI around the decision as a whole, VOI approaches can also be used for particular elements of the decision with the purpose of focusing research in areas where the elimination of uncertainty might have the most value. Partial EVPI, or EVPPI, analysis can be used to estimate the expected value of removing uncertainty surrounding specific parameters or groups of parameters to identify where future research should focus on identifying more precise and reliable estimates of specific pieces of information, e.g. relative effectiveness, costs or utilities. EVPI places an upper value on conducting further research overall, whereas EVPPI places an upper value on conducting further research on a specific area of information. On the basis of EVPI and EVPPI calculations, the potential value of a future trial, or other research designs, can be evaluated.

Population EVPI is calculated by multiplying the individual EVPI estimate by the expected number of people who would be affected by the information over the anticipated lifetime of the technology. Population size was calculated based on previous studies. HES data for England show that in 2013–14 around 12,000 women had a MUS operation, with around 500 having another type of continence procedure (colposuspension ≈300, traditional slings ≈200), and just over 700 having periurethral injections (13,200 in total). In Scotland, the total number of surgical procedure for treatment of SUI in the same period was 929.[251] In total, it was assumed that in the UK there are 15,000 surgical treatments conducted annually for the treatment of SUI. Two-level simulations were conducted to estimate the EVPI and EVPPI. The first level occurred within the microsimulation by randomly selecting women aged 45–55 years. Each selected woman was simulated 10,000 times (PSA) and

TABLE 24 Results from deterministic sensitivity analyses applying different values for short- and long-term cure rates after retropubic MUS (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective (%) at WTP threshold (£)	
						20,000	30,000
Base-case analysis applying estimated mean values from the meta-analysis for short- and long-term cure rates after retropubic MUS							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA applying values from Ward *et al.*[248] for short- and long-term cure rates after retropubic MUS							
Retropubic MUS	7163		24.55			45.7	43.3
Traditional sling	8493	1330	24.22	–0.33	Dominated	16.6	16.7
Urethral injection therapy	9418	2255	23.89	–0.66	Dominated	8.3	8.5
Transobturator MUS	9422	2260	23.77	–0.77	Dominated	4.2	4.3
Single-incision sling	9429	2267	23.65	–0.90	Dominated	3.3	3.2
Bladder neck needle suspension	9944	2782	23.72	–0.82	Dominated	4.6	4.9
Anterior vaginal repair	10,855	3692	23.58	–0.97	Dominated	3.5	3.8
Open colposuspension	10,878	3715	24.11	–0.44	Dominated	9.0	9.9
Laparoscopic colposuspension	11,653	4490	23.86	–0.69	Dominated	4.9	5.6
SA applying data from Song *et al.*[249] for short- and long-term cure rates after retropubic MUS							
Retropubic MUS	7394		24.49			42.1	39.9
Traditional sling	8522	1128	24.22	–0.27	Dominated	19.3	19.0
Urethral injection therapy	9437	2043	23.90	–0.59	Dominated	8.1	8.3
Single-incision sling	9464	2070	23.64	–0.85	Dominated	3.1	3.2
Transobturator MUS	9475	2080	23.77	–0.72	Dominated	4.1	4.2
Bladder neck needle suspension	9979	2585	23.73	–0.76	Dominated	5.3	5.4
Anterior vaginal repair	10,881	3486	23.59	–0.90	Dominated	3.6	3.9
Open colposuspension	10,916	3522	24.11	–0.38	Dominated	9.8	10.7
Laparoscopic colposuspension	11,680	4286	23.85	–0.64	Dominated	4.6	5.3

values for the parameters were selected from the prespecified distributions. Results from the PSA were exported to Excel files and then SAVI 2.1.2 (University of Sheffield, Sheffield, UK; http://savi.shef.ac.uk/SAVI/) was used to estimate the EVPI and EVPPI.

The EVPI estimates in *Table 25* quantify the expected value to decision-makers in the UK of removing all current decision uncertainty at a threshold of £20,000 per QALY gained. This will enable a comparison to be made with previous analyses, providing an idea of the scale of decision uncertainty in this topic compared with other previous decisions. If the number of people affected by the decision per year is 15,000, then the overall EVPI per year is £167.7M for the UK.

When thinking about the overall expected value of removing decision uncertainty, one needs to consider how long the current comparison will remain relevant. If the relevant time horizon is 20 years for the decision, then the overall expected value of removing decision uncertainty for the UK would be £3.345B.

Expected value of partial perfect information results

As mentioned earlier, the value of reducing uncertainty surrounding particular input parameters in the model can also be established by estimating EVPPI. The EVPPI could be used to calculate the maximum value of reducing uncertainty around particular parameters (or groups of parameters), allowing future research to be more specifically targeted at the parameters for which more precise estimates would be most valuable. There are four groups of uncertain parameters considered in the EVPPI analysis. These relate to:

1. health utility values
2. relative treatment effectiveness (cure rates)
3. operation-related mortality rates
4. combinations of parameters associated with all the complications
5. combinations of parameters associated with short-term and persistent pain
6. combinations of parameters associated with short-term and persistent pain and mesh erosion/removal.

Table 26 reports the EVPPI for a number of groups of parameters that were considered to represent groupings that were relevant to both broader policy questions and the actual design of further research. The EVPPI associated with all the complications incidence rates, relative treatment effectiveness, short-term and persistent pain, and health utility values consistently emerge as having significant influence on overall decision uncertainty, having the highest estimate across the different groups of parameters.

TABLE 25 Results from VOI analysis

	Overall EVPI	
The expected value of removing all current decision uncertainty	£	QALY
Per person affected by the decision	11,180	0.56
Per year in UK assuming 15,000 persons affected per year	167,700,000	8385
> 5 years	838,500,000	41,930
> 10 years	1,677,000,000	83,850
> 15 years	2,516,000,000	125,800
> 20 years	3,354,000,000	167,700

TABLE 26 The EVPPI for a number of groups of parameters

Parameters	Per-person EVPPI per year (£)	EVPPI for UK (£)	
		Per year	Over 20 years
Health utility values	158	2,362,774	47,255,488
Operation related mortality rates	57	855,159	17,103,176
Relative treatment effectiveness	1315	19,717,921	394,358,420
Combinations of parameters associated with all the complications	3746	56,195,710	1,123,914,202
Combinations of parameters associated with short-term and persistent pain	405	6,068,657	121,373,135
Combinations of parameters associated with short-term and persistent pain and mesh erosion/removal	1766	26,488,639	529,772,777

Summary of cost-effectiveness and value-of-information analysis

The economic model presented in this report compared nine different strategical treatments for treatment of SUI and stress-predominant MUI. Data from network meta-analyses and standard databases were used to populate the economic model. The model compared cumulative costs and QALYs for a 1-year, 10-year and lifetime time horizon. The results suggest that retropubic MUS is less costly and more effective than all other surgical interventions over a lifetime time horizon; therefore, it is a dominant strategy. The probabilistic results show that retropubic MUS and traditional sling have the highest probabilities of being cost-effective across all WTP thresholds over a lifetime time horizon. Retropubic MUS remains dominant over a 10-year time horizon in the cure model. The only major deviation from these findings is when the time horizon is reduced to 1 year. In this scenario, the most cost-effective surgical intervention is single-incision sling.

Retropubic MUS was the least costly and a cost saving option owing in part to its lower initial cost. This is primarily because this procedure is conducted in a day case setting, and there is less chance of having retropubic MUS after repeat surgery owing to its higher cure rate than all other surgical treatments (except for traditional sling in the cure model). Results also showed that there were relatively small differences between retropubic MUS and traditional sling, in terms of total QALYs, in the cure model. Although the incremental cost-effectiveness estimates showed that retropubic MUS is less costly (£423 less than traditional sling), the probability of being cost-effective with a £20,000 WTP were 25.8% and 27.0% for retropubic MUS and traditional sling, respectively.

A total of 17 individual sensitivity/scenario analyses were carried out on the base-case model results. Traditional sling was a cost-effective option when the following scenarios were explored: assuming that all of the women in the model have SUI; using a linked database to estimate the proportion of women who will seek retreatment after failure of each surgical treatment; assuming lower cure rates when the same surgeries are being conducted for a second or third time; assuming a 10% and 20% incidence rate for mesh complications after retropubic MUS and transobturator MUS; assuming a 10% and 20% incidence rate for persistent pain complication after retropubic MUS and transobturator MUS; assuming lower health utility value for MUI health states; and assuming that the incidence rate of persistent pain after retropubic MUS and transobturator MUS is 20% and that the average duration of persistent pain is 60 months.

Value-of-information analyses were also carried out on the base-case probabilistic results. The EVPI per woman is £11,180. The population EVPI was also estimated based on an assumed 15,000 surgical interventions for SUI in the UK each year. Therefore, the population EVPI for 1 year is £167.7M. This figure increases as the time horizon (or period of time over which the information would be useful) is increased.

The cost of future research to remove uncertainty around all model parameters would need to be less than these presented amounts, otherwise it would not be considered an efficient use of resources. EVPPI analyses were also conducted to estimate the value of removing uncertainty around particular parameters/groups of parameters. The largest value appears to be in removing uncertainty around the complications incidence rates, relative treatment effectiveness and health utility values.

Chapter 7 Discussion

Stress urinary incontinence is a common condition that may cause substantial disability and reduce women's quality of life.[269] The insertion of synthetic mesh tapes has become the most common surgical procedure worldwide for the treatment of SUI in women.[266,270] Mesh tape procedures were initially adopted using a retropubic approach. A transobturator approach has been developed more recently with the aim of reducing the likelihood of damaging the bladder during the operation. A number of RCTs have assessed the use of mesh for the treatment of SUI in women. Recent trials have compared the retropubic approach with the transobturator approach to assess clinical effectiveness and complications. However, long-term data are scarce. In particular, the growing patient-led concern about the safety profile of these procedures has culminated in an international debate with a number of legal cases raised against the companies that manufacture the mesh tapes. The patients' initial campaign has led to further national campaigns against the use of mesh [e.g. the Scottish Mesh Survivors' campaign Hear Our Voice (www.scottishmeshsurvivors.com)], recent independent inquiries and an updating of existing clinical guidelines.

An independent review commissioned by the Scottish Government, which considered and analysed administrative data (routinely reported Scottish hospital inpatient data), reported that immediate complications were experienced by 3.7% of women after retropubic mesh procedures, 2.5% of women after transobturator mesh procedures, 7.1% of women after unspecified mesh procedures and 7.8% of women after open colposuspension (non-mesh open surgery).[271] Moreover, mesh procedures were reported to carry a similar risk of being readmitted for repeat surgery or for later complications compared with open colposuspension. The independent review concluded that the management of women with SUI should take place in the context of a multidisciplinary team supported by a quality assurance framework. Women must receive adequate information on all appropriate treatments (mesh and non-mesh) to make informed choices. When surgery involving the use of a synthetic mesh tape is considered, a retropubic approach should be recommended.[271] The findings of the Scottish Independent Review are in line with those of a large Scottish study published in 2017, which assessed a cohort of 13,133 women, identified in the same way as the Independent Review (i.e. from a national hospital admission database).[272] The cohort comprised women who underwent a first single incontinence surgical procedure between April 1997 and March 2016. This cohort study found that, compared with colposuspension, mesh procedures had a lower risk of immediate complications and subsequent prolapse surgery and a similar risk of further incontinence surgery and later complications.[272] The authors concluded that mesh procedures for SUI should be considered among possible surgical options and that further research on longer-term outcomes would be beneficial. Another large study of surgical mesh procedures for SUI (92,244 procedures, including 68,002 unconfounded procedures) published in 2017 investigated the rate of adverse events in NHS England over 8 years.[266] Cases were identified from the HES database. The study reported that 9.8% of women who underwent a surgical mesh procedure for SUI experienced a post-operative complication within 30 days or within 5 years. Perioperative complications and 30-day complications occurred in 2.4% and 1.7% of women, respectively. The proportion of women who required readmission for further mesh surgery within 5 years of the index procedure was 5.9%. The risk of readmission was higher during the first 2 years.

It is worth noting that the results of the two large cohort studies and the Scottish Independent Review mentioned above were all based on administrative data: routinely reported hospital inpatient data.[266,271,272] However, the rate of complications managed in outpatient or primary care settings were not captured by these reports. Moreover, the accuracy of the coding system for national databases and hospital records is known to be less than optimal owing to the lack of specific codes to identify particular complications of interest and the lag (sometimes of a few years) between the introduction of new surgical procedures (e.g. retropubic and TOT procedures) and the introduction of specific codes to identify these procedures.

The NHS England *Mesh Oversight Group Report* published in July 2017[273] concluded that mesh procedures for the treatment of women with SUI are a safe option, though a number of recommendations need to be implemented to ensure better quality of care. These recommendations included improvements to surgical practice and training, updating of clinical guidance and standards, raising awareness of possible post-operative complications among GPs and offering quicker and improved access to clinical expertise for women with post-operative complications.[273] In particular, the *Mesh Oversight Group Report* stressed the importance of better reporting of adverse events and better HES coding procedures to gain a more complete picture of the level and seriousness of complications after SUI surgery.[273]

The recent Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence[274] indicates that the use of synthetic MUS procedures for the surgical treatment of SUI has good efficacy and acceptable morbidity. Patients should be adequately informed regarding the potential success rates and the mesh-related adverse events compared with non-mesh procedures and should be engaged in the decision-making process.[274]

In general, recent cohort studies, consensus statements from clinical associations, and national inquiries seem to be in agreement that mesh procedures may be effective in the treatment of SUI, but there is uncertainty about long-term outcomes. Post-operative complications, as well as repeat SUI surgery, need to be carefully considered when weighing the benefits and risks of these interventions. In particular, it is worth mentioning that mesh implants with their anchoring system are intended to be permanent; therefore, their removal, if something goes wrong, can be extremely challenging if not impossible.

The NICE guidance on the safety of single-incision short sling mesh insertion for SUI published in October 2016[275] maintains that complications including pain, discomfort and failure of the mesh procedure are infrequent but serious. The guidance recommends that patient selection should be performed by a multidisciplinary team with experience in the management of women with SUI and the surgical insertion performed by clinicians with specific training in mesh techniques. Moreover, the NICE clinical guidance on the management of SUI (CG171, updated Nov 2015)[276] points out that 'surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders or who work within a multidisciplinary team with this training, and who regularly carry out surgery for UI in women', and again that 'when recommending optimal management the multidisciplinary team should take into account women's preference, past management, comorbidities and treatment options'. NICE is currently updating its clinical guidance on the management of SUI. The new guidance is expected to be released in early 2019.

To our knowledge, the current evidence synthesis, discrete choice experiment and economic evaluation is the most comprehensive assessment of published evidence for the treatment of SUI (a total of 175 studies were included in the effectiveness evidence synthesis). The risk of bias was high or unclear across all risk-of-bias domains in the majority of included studies. The NMA, which combined evidence from direct and indirect comparisons, included 120 studies that reported data on the two primary outcomes: the number of women 'cured' from SUI and the number of women who experienced an 'improvement' in their SUI symptoms. The NMA results suggest that retropubic MUS, transobturator MUS and traditional sling are more effective than other surgical procedures for both primary outcomes. Open colposuspension also appears relatively effective in terms of cure and improvement rates compared with other surgical procedures. Results for other surgical interventions were variable.

An adequate assessment of adverse events was hampered by the dearth of suitable data and by the inconsistency in the way adverse events were defined and reported in individual studies. Direct head-to-head meta-analyses were available mainly for the comparisons involving retropubic MUS, transobturator MUS or single-incision sling. Follow-up time was generally short (median of 12 months). Transobturator MUS had a higher rate of further SUI procedures than retropubic MUS but a lower rate than single-incision sling.

The rate of tape and mesh exposure was higher after transobturator MUS than after retropubic MUS or single-incision sling, whereas it was similar between transobturator MUS and retropubic MUS. Retropubic MUS had a higher rate of major vascular complications, voiding difficulties and bladder or urethral perforation than transobturator MUS but a lower rate of groin pain. The rate of post-operative pain was higher after retropubic than single-incision sling and the rate of unspecified pain was higher after transobturator MUS than single-incision sling. The rate of infection (including UTI, wound infection and infection related to mesh) was similar between single-incision sling and transobturator MUS.

Our economic model used data from the systematic review and other published sources but was also limited by the lack of availability of robust evidence. The model results suggest that retropubic MUS is the least costly and the most effective option. However, the results from the PSA suggest that the retropubic MUS and traditional sling have comparable probabilities of being cost-effective (26% and 27%, respectively, using a £20,000 threshold). The findings from the model are in general agreement with other published cost-effectiveness findings.

One of the strengths of our economic model is the evaluation of nine different surgical treatments in one analysis, informed by data from a network meta-analyses in which all the direct and indirect evidence (120 trials) was used to estimate the relative effectiveness of different surgical treatments in terms of cure rates. Very few studies have included complications within the cost-effectiveness analyses, despite the fact that the incidence of each complication can have an impact on women's quality of life and incur costs for the health system. Therefore, in the present study the impact of incident complications, such as infection, de novo symptoms of urgency incontinence, voiding difficulties, bladder or urethral perforation, tape/mesh erosion/extrusion/exposure, short-term pain and persistent pain, on cost and effect have been incorporated into the model and explored in SA. As about 50% of women who have SUI[246] are also suffering from UUI symptoms, and given that UUI affects women's quality of life potentially more than SUI,[267] we have incorporated treatment pathways for SUI and UUI at the same time in the model to estimate absolute QALYs more accurately. Finally, the analysis was conducted using best practice methods[277] and used a comprehensive range of sensitivity analyses to account for uncertainty. Our conclusions were broadly robust to the range of sensitivity analyses undertaken and comparable to the findings of other published evaluations.

There are a number of published cost-effectiveness analyses evaluating some of the surgeries that we have assessed, the general findings of which are presented to allow comparison. Two studies compared the single-incision sling versus MUS procedures over a 1-year time horizon, concluding that single-incision sling was less costly and of similar effectiveness.[264,278] Another compared the cost-effectiveness of TVT versus vaginoplasty, finding that TVT was a cost-effective option compared with vaginoplasty.[173] A UK study compared the cost-effectiveness of TVT versus open colposuspension, laparoscopic colposuspension, traditional sling and injectable agents, concluding that TVT dominated open colposuspension using a 5-year time horizon.[229] A US study compared the cost-effectiveness of TVT versus open Burch colposuspension, finding over a 10-year horizon that TVT was more cost-effective than open Burch colposuspension.[230] A cost–utility analysis in the UK to assess the cost-effectiveness of TVT compared with open Burch colposuspension found that TVT was less costly and more effective than open Burch colposuspension.[244] A further study to assess cost-effectiveness of TVT versus laparoscopic mesh colposuspension concluded that TVT was more cost-effective than laparoscopic mesh colposuspension over a 1-year time horizon.[279] A study based on US-based parameters compared TVT versus Burch colposuspension, finding that Burch colposuspension was more expensive than TVT but that the resulting ICER (US$98,755 per QALY gained) was above any WTP threshold used in the UK, making TVT the more cost-effective option.[237] Further analysis to assess the cost-effectiveness of collagen versus retropubic suspension, transvaginal suspension and sling procedure found that retropubic suspension was the most cost-effective option (ICER US$1824).[231] Although there are limitations with many of these studies and heterogeneity in methods, the results from all the above studies are largely in agreement with findings from our economic model, generally supporting the finding that retropubic MUS is likely to be the most cost-effective option when compared with the other types of surgeries for treatment of SUI.

However, there are some conflicting findings. Another study to evaluate the cost-effectiveness of MUS (either retropubic or transobturator) versus urethral bulking agents concluded that bulking agents are more cost-effective than MUS over a 1-year time horizon (this was in a population of SUI patients without urethral hypermobility).[225] Another examined the cost-effectiveness of retropubic MUS versus transobturator MUS over a 10-year time horizon and concluded that transobturator MUS is the cost-effective option compared with retropubic MUS.[235] A Canadian study examined the cost-effectiveness of transobturator MUS versus TVT over a 5-year time horizon, with results suggesting that transobturator MUS was more cost-effective than TVT.[137] The results from our model show that retropubic MUS has a slightly lower cost and higher effectiveness than transobturator MUS.

Three separate studies[280–282] have investigated the cost-effectiveness of laparoscopic Burch colposuspension versus open Burch colposuspension with a relatively short-term time horizon. Two of these studies[280,282] concluded that laparoscopic Burch colposuspension may be more cost-effective than open Burch colposuspension, whereas the third[281] showed that laparoscopic colposuspension is not cost-effective when compared with open colposuspension during the first 6 months following surgery, but it may be cost-effective over 24 months.

The results from our study show that open colposuspension is associated with a slightly lower cost and higher effectiveness than is laparoscopic colposuspension. The findings from the model are in general agreement with other published cost-effectiveness findings.

Uncertainty about the assessment

The majority of the evidence for the assessment of the clinical effectiveness came from trials evaluating the effects of retropubic MUS or transobturator MUS. More than half of the included studies compared transobturator MUS with retropubic MUS (58 studies), or transobturator MUS with single-incision sling (39 studies). The majority of trials identified by the updated literature searches seem to focus on transobturator MUS, which is a more recent surgical procedure than retropubic MUS, or single-incision sling. However, few studies were available for other treatment comparisons, particularly mesh versus non-mesh procedures.

The definitions and measurements of cure and improvement were not consistent across included studies. We considered women-reported outcomes to be the best outcomes on which to judge the effectiveness of surgical treatments. However, patient-reported measures were not always available. We therefore opted for proxy measures based on the quantification of symptoms derived from pad or urodynamic tests. This decision was based on the assumption that subjective and objective measures correlate sufficiently, although this assumption could not be empirically tested within the current assessment.

The NMA assessed the primary outcomes of cure and improvement at 12 months or at a time point closest to 12 months. The availability of long-term data beyond 12 months was limited.

Assessment of adverse events was hampered by the lack of suitable data and, in particular, of long-term data. The median follow-up time for all included studies was 12 months.

A further challenge was the lack of consistency in the way adverse events were defined and reported in the published Cochrane systematic reviews.[5–12,18–20] Some of these outcomes were recategorised by Cochrane authors to conduct meta-analyses but outcome definitions and exact time points at which these outcomes were measured were often not explicitly reported. Most studies were reported to have a short follow-up period (up to 12 months), with only a few studies having a follow-up of $\geq$ 2 years. Inconsistent time points and outcome categories became problematic when we had to analyse and summarise a large number of studies across different Cochrane systematic reviews.

As a result of resource constraints and the inconsistency of reporting across studies, we graded the level of evidence for the two primary outcomes, but not for adverse events.

We focused on the main mesh surgical procedures for the treatment of SUI and did not consider procedure subtypes (e.g. up-down vs. down-up retropubic mesh insertion or inside-out vs. outside-in transobturator mesh insertion). There is a large volume of published literature comparing the different techniques that are available for one type of surgery; however, this was beyond the remit of the question that our work was addressing. It should be noted, however, that there remains uncertainty about the relative effectiveness and cost-effectiveness of these subtypes. In addition, there is likely to be a lack of consistency in their use within the NHS. This decision uncertainty still needs to be addressed through robust evidence collection and analysis.

The professional experience of the surgeons performing the operations was not consistently reported in the included studies and relevant Cochrane systematic reviews. Among studies that provided this information, the surgeon's clinical experience varied from 'having inserted a minimum of one sling prior to the study'[29] to 'having performed 200 surgical procedures'.[115] A few studies reported that surgeons tended to be less experienced in performing sling procedures than the comparator surgical intervention. The current NICE guideline on the management of SUI (CG171, updated November 2015)[276] states that 'an annual workload of at least 20 cases of each primary procedure for stress UI is recommended. Surgeons undertaking fewer than 5 cases of any procedure annually should do so only with the support of their clinical governance committee'. However, from current published studies it seems that, at present, there is considerable variation in clinical practice and it is unclear whether or not (and how) the surgeons must demonstrate their ability in performing these operations.

As with all modelling studies, several limitations exist within our study that should be considered when interpreting the results. One of the main limitations of the current study is the lack of long-term data, which necessitated the extrapolation of relatively short-term data to 10 years and over the lifetime of women included in the analyses. The results achieved would only apply in a situation where relative differences in effectiveness of retropubic MUS compared with the comparators do not change with longer follow-up. The long-term incidence of complications after the surgical treatments are currently not reliably known. Therefore, all the estimated incidence rates for complications after each surgical treatment were based on the data from trials with relatively short-term follow-up times. Nevertheless, we tested the impact of possible higher incidence rates of some of the complications on the results. It should be mentioned that a clinical trial is currently being conducted to estimate the 3-year outcome after standard tension-free MUS and single-incision mini-sling procedures.[283] Another limitation of our study is that urethral injection therapy was not included in the NMA; therefore, the short-term and long-term cure rates after urethral injection therapy were obtained from a meta-analysis that reported effectiveness of silicon particles (Macroplastique) for women with SUI (958 women from 23 cohorts were included in the analysis).[250] Furthermore, the economic model has focused on costs to the NHS. It has been assumed that certain costs, such as those for containment products, may be incurred by the NHS. In practice, women may also buy different products and may well incur the costs of containment management themselves. Other costs that may be incurred by women have not been included. These include the other costs of managing symptoms, such as laundry costs, and the time and travel costs related to receiving the treatments. It might be expected that the more effective treatments would reduce the costs of managing symptoms borne by the women and their families. Therefore, we expect that including those costs would probably improve the cost-effectiveness of retropubic MUS. Finally, we had intended to use results from the DCE to inform the economic model. One potential way to have done this would have been to have included cost as an attribute in the DCE, which would have enabled a cost–benefit/net benefit analysis to have been undertaken. However, it was decided at an early stage in the DCE design process that cost would not be an appropriate attribute for inclusion given the hypothetical nature of the DCE and that we were not asking women to choose between different surgical options but rather asking for their preferences regarding outcomes of surgery.

Chapter 8 Conclusions

The following implications for practice and research are based on the results of our evidence synthesis and economic evaluation, the information collected through our DCE and the findings of recent national inquiries, reviews and consensus statements from relevant clinical associations.

Implications for practice

- The results of this evidence synthesis, although associated with some uncertainty and a lack of long-term data, indicated that cure and improvement rates were generally better for retropubic MUS, transobturator MUS and traditional sling compared with other surgical procedures. Open colposuspension appeared relatively effective in terms of cure and improvement rates compared with other interventions.
- The current evidence base on long-term safety of mesh and non-mesh procedures is inadequate in quantity and quality.
- Women should receive adequate information on the benefits and risks associated with the different types of surgical procedures for the treatment of SUI. In particular, women should be aware that mesh implants are intended to be permanent and their removal could be challenging, if not impossible.

Implications for research

- The main uncertainty relates to the long-term assessment of surgical procedures for SUI. In particular, further evidence is required on long-term adverse effects and quality of life. The long-term assessment of complications and subsequent surgery after mesh and non-mesh procedures would require a large multicentre trial with an extended follow-up period (many years). More realistic would be to promote awareness, as well as adequate reporting and monitoring, of complications among surgeons and health professionals.
- Studies of quality of life need to address the relationship between different levels of severity of SUI, quality of life and the average duration of each complication's effects, as well as investigate the multiplicative effect of different complications on quality of life.
- Further research investigating a woman's choice regarding surgery as a treatment option needs to explore treatment history in greater detail while considering more individual characteristics, including personal beliefs and perceptions that may act as a barrier to seeking professional advice.
- Although there is significant uncertainty in many of the parameters informing the modelling, the results from the VOI analysis indicate that further research should focus on adverse events that, although not very frequent, may have devastating effects on women's quality of life when they do occur (e.g. tape extrusion/exposure). In particular, information on the incidence of complications in both primary and secondary care as well as accurate measures of the spectrum of possible complications and their impact on women's quality of life would be useful.
- Future research would be of greater value if investigators could improve the quality of their study reports and agree on common definitions of outcomes and measures for recording outcomes, in accordance with the COMET (Core Outcome Measures in Effectiveness Trials) Initiative (www.comet-initiative.org).

Acknowledgement

The authors are grateful to Lara Kemp and Janice Legge for their secretarial support and patience.

Contributions of authors

Miriam Brazzelli contributed to the co-ordination of all aspects of this assessment, interpreted data, drafted the discussion and conclusions sections and took overall responsibility for the clinical sections of the report.

Mehdi Javanbakht led the review of economic evaluations and the model development, contributed to the interpretation of data and the DCE, undertook the cost-effectiveness and VOI analyses and was responsible for drafting the economic sections of the report.

Mari Imamura led the day-to-day running of the clinical effectiveness review; contributed to protocol development; performed study selection, data extraction, risk-of-bias assessment and synthesis of included studies; provided supervision to junior members of the review team; and was responsible for drafting the clinical effectiveness sections of the report.

Jemma Hudson contributed to data extraction and interpretation of results, conducted all statistical analyses and drafted the methods and results sections of the clinical effectiveness sections of the report.

Eoin Moloney undertook the review of economic evaluations and model development, cost-effectiveness and VOI analysis and contributed to drafting the economic sections of the report.

Frauke Becker led the DCE, undertook the development of the survey and the analysis of the data and was responsible for drafting the DCE section of the report.

Sheila Wallace was responsible for providing further information and details on the existing Cochrane reviews, conducted the updated literature searches, led initial study screening and selection, provided reference management for the clinical effectiveness sections of the report and drafted sections of the report related to search strategies and search results.

Muhammad Imran Omar applied the GRADE approach for evaluating the quality of evidence of the primary outcomes assessed in the NMA and drafted the relevant part of the clinical effectiveness methods section of the report.

Michael Shimonovich contributed to study selection, risk-of-bias assessment and data extraction and to drafting parts of the clinical effectiveness sections of the report.

Graeme MacLennan provided statistical support and double checked all clinical effectiveness results and statistical analyses.

Laura Ternent contributed to the development of the DCE.

Luke Vale provided advice and guidance throughout the project.

Isobel Montgomery contributed a lay perspective to all aspects of the work from proposal to final report and drafted the *Plain English summary*.

Phil Mackie provided advice and guidance throughout the project.

Lucky Saraswat provided advice and guidance throughout the project.

Ash Monga provided advice and guidance throughout the project.

Dawn Craig was the principal investigator and took overall responsibility for the project, undertook an advisory role in all aspects of the work and contributed to the writing of all sections of the report.

All authors provided comments on draft versions of the report and approved its final version.

Data-sharing statement

Most technical data are included in the report in the appendices or as supplementary material. All additional data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

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Appendix 1 Literature search strategies

To bring the searches for all reviews up to date, a search of the Cochrane Incontinence Group Specialised Trials Register was performed (date of last search: 8 June 2017) containing trials identified, at that time, from:

- CENTRAL (via CRSO) (searched 15 May 2017)
- MEDLINE (via OvidSP) (1946 to April Week 3 2017) (searched 1 May 2017)
- MEDLINE In-Process & Other Non-Indexed Citations (via OvidSP) covering 28 April 2017 (searched 1 May 2017)
- MEDLINE Epub Ahead of Print (via OvidSP) (covering 2 May 2017) (searched 3 May 2017)
- ClinicalTrials.gov via CRS standalone (searched 29 May 2017)
- WHO ICTRP (searched 6 June 2017).

Trials were identified by searching the Cochrane Incontinence Group Specialised Register using the terms given below. For each review, searches were tailored to bring the searching up to date, that is, searching was designed to retrieve any potentially relevant reports of studies added to the register since the date of the last search for each Cochrane review.

1. Lapitan *et al.*[5] – open retropubic colposuspension for UI in women
2. Ford *et al.*[8] and Ogah *et al.*[18] – MUS operations for SUI in women
3. Nambiar *et al.*[9] – single-incision sling operations for UI in women
4. Saraswat *et al.*[7] and Rehman *et al.*[19] – traditional suburethral sling operations for UI in women
5. Freites *et al.*[6] and Dean *et al.*[20] – laparoscopic colposuspension for UI in women
6. Glazener and Cooper[11] – bladder neck needle suspension for UI in women
7. Glazener and Cooper[10] – anterior vaginal repair for UI in women
8. Kirchin *et al.*[12] – urethral injection therapy for UI in women.

Search terms used for each review

All searches were of the keyword field in Reference Manager Professional Edition Version 12 (Thomson ResearchSoft, San Francisco, CA, USA) using the Cochrane Incontinence Group's own keywords.

Lapitan *et al.*:[5] open retropubic colposuspension for urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND ({intvent.surg.abdo.} OR {intvent.surg.abdo.burch.} OR {intvent.surg.abdo.colposusp.} OR {intvent.surg.abdo.mmk.} OR {intvent.surg.burch.} OR {intvent.surg.colpo*} OR {intvent.surg.endopelvicFasciaPlication.})

Freites *et al.*[6] and Dean *et al.*:[20] laparoscopic colposuspension for urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND[39]

Ford *et al.*[8] and Ogah *et al.*:[18] mid-urethral sling operations for stress urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND {INTVENT.SURG.SLIN*} OR {INTVENT.SURG.SUBURETHRAL SLING.} OR {INTVENT.SURG.ABDO.SLING.}

Saraswat *et al.*[7] and Rehman *et al.*:[19] traditional suburethral sling operations for urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND ({INTVENT.SURG.SLIN*} OR {INTVENT.SURG.SUBURETHRAL SLING.} OR {INTVENT.SURG.ABDO.SLING.})

Glazener and Cooper:[11] bladder neck needle suspension for urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND ({intvent.surg.bladnecsusp.*} OR {intvent.surg.needle.*})

Nambiar *et al.*:[9] single-incision sling operations for urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND {INTVENT.SURG.SLINGS.MINISLING*}

Glazener and Cooper:[10] anterior vaginal repair for urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND ({INTVENT.SURG.} OR {INTVENT.SURG.ABDO.*} OR {INTVENT.SURG.ASSESS.} OR {INTVENT.SURG.colpofixation.staple.} OR {INTVENT.SURG.COLPORRHAPHY.ANTERIOR.} OR {INTVENT.SURG.CYSTOPLASTY.} OR {INTVENT.SURG.DIATHERMY.} OR {intvent.surg.endopelvicFasciaPlication.} OR {INTVENT.SURG.KELLY.} OR {INTVENT.SURG.PARVAGINALdefectrepair.} OR {INTVENT.SURG.PELVICFLOORREPAIR.} OR {INTVENT.SURG.PEREYRA*} OR {INTVENT.SURG.PERINEAL*} OR {INTVENT.SURG.RAMIREZ.} OR {INTVENT.SURG.RAZ.} OR {INTVENT.SURG.STAPLING.} OR {INTVENT.SURG.SUSPENSION.URETHRAL.} OR {INTVENT.SURG.URETHROCYSTOPEXY.ABDO.} OR {INTVENT.SURG.URETHROPEXY.MODPEREYRA.} OR {INTVENT.SURG.VAGINAL/PERINEAL.} OR {INTVENT.SURG.VAGINAL/PERINEAL.ANTERIOR REPAIR} OR {INTVENT.SURG.VAGINAL/PERINEAL.COLPORRHAPHY} OR {INTVENT.SURG.VAGINAL/PERINEAL.MICROWAVE})

Kirchin *et al.*:[12] urethral injection therapy for urinary incontinence in women

Search terms used

topic.urine.incon* AND ({design.cct*} OR {design.rct*}) AND (INTVENT.SURG.INJECTIONS*)

Appendix 2 Data extraction forms

TABLE 27 Study characteristics

	Group 1	Group 2	Group 3
ID			
Source Cochrane Review			
Study name			
Abstract or full-text publication			
Study setting			
Recruitment period			
Follow-up (months)			
Funding source			
Intervention category (e.g. retropubic MUS)			
Name of surgical procedure (e.g. tension-free vaginal tape)			
Note			
Number randomised			
Number analysed			
Number and reasons for loss to follow-up			
Note			
Number of surgeons involved			
Surgeon experience			
Inclusion criteria			
Exclusion criteria			
Type of stress incontinence diagnosis (e.g. symptom based or urodynamics)			
UI status (e.g. stress-predominant MUI)			
% MUI			
Note			
Age (mean, SD)			
% women with previous UI surgery			
% women with existing POP			
% women with concurrent POP surgery			
For ongoing trials only			
Trial registration number			
Trial start date			
Trial end date			

ID, identifier; POP, pelvic organ prolapse.

TABLE 28 Cure and improvement outcome

	Group 1	Group 2	Group 3
ID			
Study name			
Intervention category			
Outcome			
Description (e.g. definition, how measured)			
Time (months)			
Event *n*			
Total *n*			

ID, identifier.

TABLE 29 Adverse event outcomes

	Group 1	Group 2	Group 3
ID			
Study name			
Intervention category			
Outcome			
Description (e.g. definition, how measured)			
Time (months)			
Event *n*			
Mean			
SD			
Total *n*			

ID, identifier.

TABLE 30 Risk-of-bias assessment

ID Study name	Judgement (low, high, unclear risk)	Support for judgement
Random sequence generation (selection bias)		
Allocation concealment (selection bias)		
Blinding of participants and personnel (performance bias)		
Blinding of outcome assessor (detection bias) (patient-reported outcomes)		
Blinding of outcome assessor (detection bias) (clinician-assessed outcomes)		
Incomplete outcome data (attrition bias) (patient-reported outcomes)		
Incomplete outcome data (attrition bias) (clinician-assessed outcomes)		
Selective outcome reporting (reporting bias)		
Other bias		

ID, identifier.

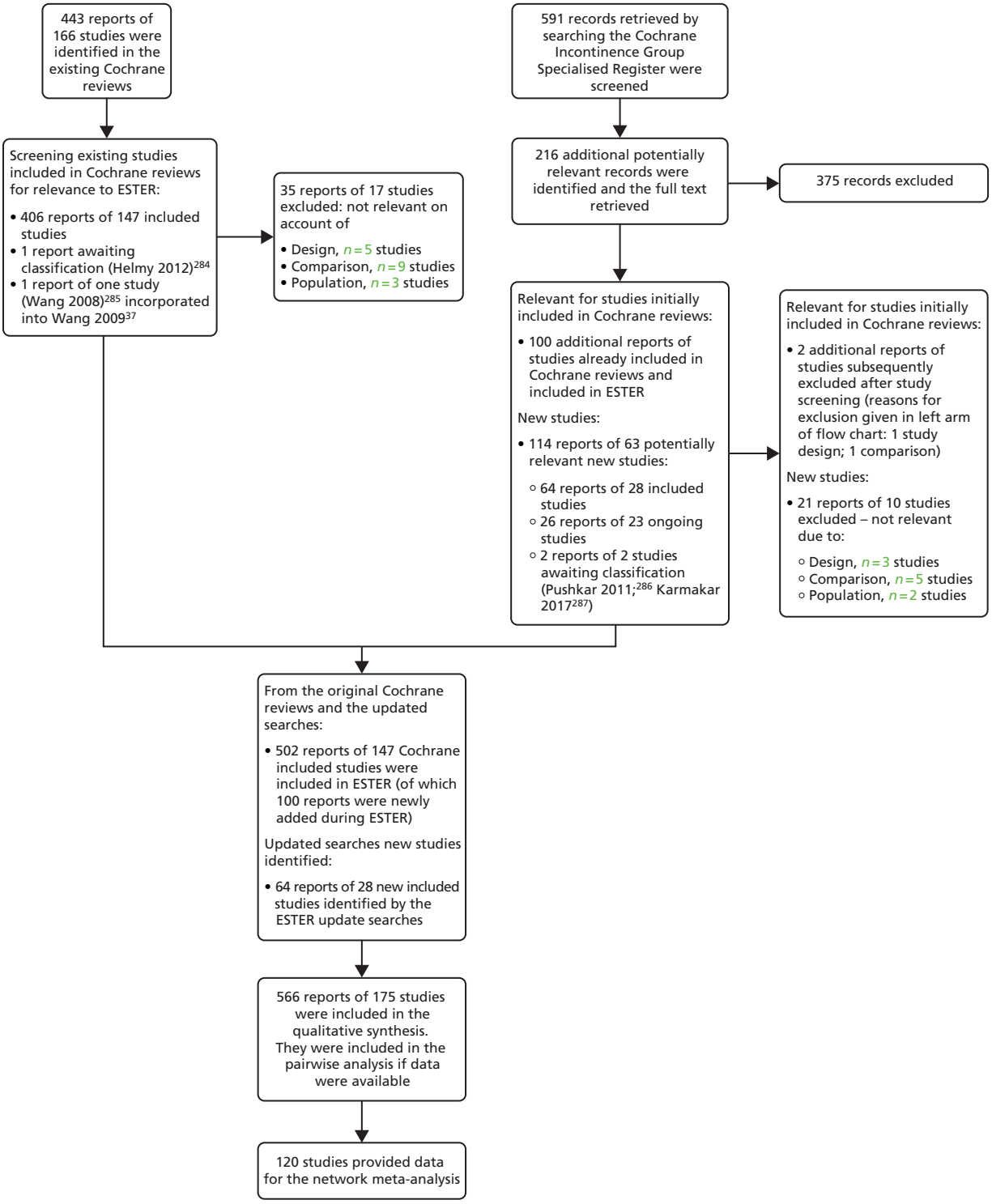
Appendix 3 WinBUGS code for network meta-analysis

```
# random effects model for multi-arm trials

model{                                                  # *** PROGRAM STARTS

for(i in 1:ns){                                         # LOOP THROUGH STUDIES

   w[i,1] <- 0                                          # adjustment for multi arm trial

   delta[i,1] <- 0                                      # treatment effect is zero for control arm

   mu[i] ~ dnorm(0,.0001)                               # vague priors for all trial baselines

   for (k in 1:na[i]) {                                 # LOOP THROUGH ARMS

      r[i,k] ~ dbin(p[i,k],n[i,k])                      # binomial likelihood

      logit(p[i,k]) <- mu[i] + delta[i,k]               # model for linear predictor

      rhat[i,k] <- p[i,k] * n[i,k]                      # expected value of the numerators

      dev[i,k] <- 2 * (r[i,k] * (log(r[i,k])-log(rhat[i,k])) +     # Deviance contribution

      (n[i,k]-r[i,k]) * (log(n[i,k]-r[i,k]) - log(n[i,k]-rhat[i,k])))

   }

 resdev[i] <- sum(dev[i,1:na                            # summed residual deviance contribution for this trial

for (k in 2:na[i]) {                                    # LOOP THROUGH ARMS

   delta[i,k] ~ dnorm(md[i,k],taud[i,k])                # trial-specific LOR distributions

   md[i,k] <- d[t[i,k]] - d[t[i,1]] + sw[i,k]           # mean of LOR distributions

   taud[i,k] <- tau *2*(k-1)/k                          #precision of LOR distributions

   w[i,k] <- (delta[i,k] - d[t[i,k]] + d[t[i,1]])       #adjustment, multi-arm RCTs

   sw[i,k] <- sum(w[i,1:k-1])/(k-1)                     # cumulative adjustment for multi-arm trials

   }

}
```

```
totresdev <- sum(resdev[])                                  #Total Residual Deviance
d[1]<- 0                                  # treatment effect is zero for reference treatment
for (k in 2:nt){
   d[k] ~ dnorm(0,.0001)
}                                                          # vague priors for treatment effects
sd ~ dunif(0,5) tau <- pow(sd,-2)
# pairwise ORs and LORs for all possible pair-wise comparisons
for (c in 1:(nt-1)){
   for (k in (c+1):nt){
   or[c,k] <- exp(d[k] - d[c])
   lor[c,k] <- (d[k]-d[c])
   }
}
# ranking on relative scale
for (k in 1:nt) {
   rk[k] <- nt+1-rank(d[],k)
   best[k] <- equals(rk[k],1)                              #calculate probability that treat k is best
   for (j in 1:nt) {
   effectiveness[k,j] <- equals(rk[k],j )
   }
}
for (k in 1:nt) {
   for (j in 1:nt) {
   cumeffectiveness[k,j] <- sum(effectiveness[k, 1:j])
   }
}
```

```
# SUCRAS

for (k in 1:nt) {

   SUCRA[k] <- sum(cumeffectiveness[k,1:(nt-1)])/(nt-1)

}

}                                                    # *** PROGRAM ENDS
```

Appendix 4 The PRISMA diagram for the clinical effectiveness assessment



Appendix 5 References to studies included in the clinical effectiveness review

This appendix includes two lists of included studies:

1. Included studies identified from the eight Cochrane systematic reviews of surgery for UI. Listed by Cochrane review in which they first appear (following the following hierarchy to avoid duplicates).

   - Lapitan *et al.*[5] – open retropubic colposuspension for UI in women
   - Ford *et al.*[8] and Ogah *et al.*[18] – MUS operations for SUI in women
   - Nambiar *et al.*[9] – single-incision sling operations for UI in women
   - Saraswat *et al.*[7] and Rehman *et al.*[19] – traditional suburethral sling operations for UI in women
   - Freites *et al.*[6] and Dean *et al.*[20] – laparoscopic colposuspension for UI in women
   - Glazener and Cooper[11] – bladder neck needle suspension for UI in women
   - Glazener and Cooper[10] – anterior vaginal repair for UI in women
   - Kirchin *et al.*[12] – urethral injection therapy for UI in women.

2. New studies from the updated searches of the Cochrane Incontinence Group Specialised Register.

Key

a Primary reference where more than one report of a study was available; this is the name given to the study as it appears in the main text of the ESTER report.

b Report from a more recent update of another of the Cochrane surgery for UI reviews.

c New further report of study found in updated search.

Note

Any relevant study and reference identifiers (IDs) are included in square brackets following each citation, e.g. [database: identifier].

Identifiers containing 'sr-incont' relate to the Cochrane Incontinence Specialised Register; 'CRSREF' identifiers refer to the Cochrane Register of Studies Web version (CRS-Web); 'other' is used to refer to either the study acronym or the trial registration number from a number of trial registries; 'Ref ID' identifiers relate to those records being processed for inclusion in the Cochrane Incontinence Specialised Register.

1. Studies identified from the eight Cochrane systematic reviews of surgery for urinary incontinence

(i) Cochrane review: Lapitan et al.[5] *– open retropubic colposuspension for UI in women*

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Appendix 6 Sample of excluded studies with reasons for exclusion

Key

a Primary reference where more than one report of a study was available; this is the name given to the study as it appears in the main text of the ESTER report.

b New further report of study found in updated search.

Note

Any relevant study and reference identifiers (IDs) are included in square brackets following each citation, e.g. [database: identifier].

Identifiers containing 'sr-incont' relate to the Cochrane Incontinence Specialised Register; 'CRSREF' identifiers refer to the Cochrane Register of Studies Web version (CRS-Web); 'other' is used to refer to either the study acronym or the trial registration number from a number of trial registries; 'Ref ID' identifiers relate to those records being processed for inclusion in the Cochrane Incontinence Specialised Register.

TABLE 31 Sample of excluded studies with reasons for exclusion

Study ID	Reason for exclusion
Studies selected from Cochrane reviews but excluded on further assessment	
Borstad 2010[288]	Not relevant comparison. TVT + concomitant prolapse surgery vs. TVT 3 months after prolapse repair
Colombo 1997[289]	Not relevant population. Includes women with severe prolapse with clinical stress UI or 'potential' stress UI
Corcos 2005[290]	Not relevant study design. Randomisation to surgery and injectable. Which type of surgery to have was decided based on surgeon's preference
Kim 2004[291]	Not relevant comparison. One type of retropubic MUS vs. another type of retropubic MUS vs. IRIS procedure (not relevant intervention)
Klarskov 1986[292]	Not relevant study design. Randomisation to surgery and PFMT. Which type of surgery to have was decided based on VCUG and anatomy
Lee 2001[293]	Not relevant comparison. Injectables vs. no treatment (placebo)
Miranda 2011[294]	Not relevant population. Study participants do not have stress UI
Okulu 2013[295]	Not relevant comparison. One type of retropubic MUS vs. another
Osman 2003[296]	Not relevant study design. Randomisation to surgery and pharmacological treatment. Which type of surgery to have was dictated by VLPP
Quadri 1985[297]	Not relevant population. Includes incontinent women with severe prolapse. Unclear if UI is predominantly stress. Available as abstracts only with insufficient details
Teixeira 2008[298]	Not relevant comparison. One type of transobturator MUS vs. another
Teleb 2011[299]	Not relevant comparison. One type of traditional sling vs. another

continued

TABLE 31 Sample of excluded studies with reasons for exclusion (*continued*)

Study ID	Reason for exclusion
ter Meulen 2009[300]	Not relevant comparison. Injectable vs. no treatment. Unsupervised PFMT (written instruction only) considered equivalent to no active treatment
Tincello 2004[301] (CARPET study)	Not relevant study design. 31 women included, of whom 4 were allocated by randomisation and 27 by preference
van der Ploeg 2013[302]	Not relevant intervention. VPR + MUS vs. VPR alone
van Leijsen 2013[303]	Not relevant study design. Diagnostic cohort study with an embedded non-inferiority RCT. Data pertinent to RCT not available
Wang 2008[285]	Duplicate. Included as part of the study with study ID Wang 2009[37]
Zargham 2013[304]	Not relevant intervention. Anterior vaginal wall sling vs. retropubic MUS. Anterior vaginal wall sling not a relevant intervention
New studies from update search	
Campeau 2007[305]	Not relevant comparison. Retropubic MUS (TVT) vs. no treatment
Caremel 2013[306]	Not relevant comparison. Transobturator MUS vs. pharmacological treatment (anticholinergics). Participants had MUI. Anticholinergics is generally for treatment of urgency UI
Choi 2006[307]	Not relevant study design. No clear evidence of randomisation. Available as abstract
Grigoriadis 2013[308]	Not relevant study design. No clear evidence of randomisation
Larsson 2014[309]	Not relevant population. Participants are patients not suitable for TVT operations. Injectable vs. no treatment
Nikas 2012[310]	Not relevant comparison. Anterior repair vs. pharmacological treatment
Rose 2012[311]	Not relevant comparison. Injectables vs. pharmacological treatment vs. no treatment
Sung 2013[312]	Not relevant population. Ongoing trial with women with MUI. Not predominantly stress UI
Tuncer 2016[313]	Not relevant study design. Not RCT
Wadie 2016[314]	Not relevant comparison. Combined MUS and anterior repair vs. MUS alone
Awaiting assessment	
Helmy 2012[284]	Awaiting classification in the open colposuspension Cochrane review.[5] Unclear if this is related to the study with study ID Albo 2007 (included study).[82] Awaiting author response
Karmakar 2017[287]	Awaiting assessment. Secondary analysis. Unclear if data are related to SIMS (single-incision mini-slings) trial (Mostafa 2013; included study)[204] or pilot of SIMS[174]
Pushkar 2011[286]	Awaiting classification in the single-incision sling Cochrane review.[9] In Russian with English abstract. Study design unclear. Single-incision (TVT-S) vs. transobturator MUS (TVT-O)

ID, identifier; IRIS, innovative replacement of incontinence surgery; VCUG, voiding cystourethrography; VLPP, Valsalva leak point pressure; VPR, vaginal prolapse repair.

References for excluded studies

(i) Studies included in Cochrane reviews but excluded from ESTER, as they did not meet the ESTER inclusion criteria

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Borstad E, Abdelnoor M, Mogimi K, Sandved M, Majida M, Western K, *et al.* Surgery for concomitant pelvic organ prolapse and urinary stress incontinence. A multicenter prospective randomized trial to compare the results of an incontinence procedure performed at the time of prolapse repair or 3 months after. *Neurourol Urodyn* 2008;**27**:713. [Other: NCT00308009; other: sr-incont29653]

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Oremus M, Tarride JE. An economic evaluation of surgery versus collagen injection for the treatment of female stress urinary incontinence. *Can J Urol* 2010;**17**:5087–93. [Other: sr-incont39605]

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Helmy H, El-Gamal S. *Three-year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence*. Proceedings of the International Continence (ICS), 42nd Annual Meeting, Beijing, 15–19 October 2012, abstract no. 589. [CRSREF: 2843756; other: sr-incont45471]

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Komesu YM, Richter HE, Dinwiddie DL, Siddiqui NY, Sung VW, Lukacz ES, *et al.* Methodology for a vaginal and urinary microbiome study in women with mixed urinary incontinence. *Int Urogynecol J* 2017;**28**:711–20. [Ref ID: 74215]

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Sung VW, Borello-France D, Dunivan G, Gantz M, Lukacz ES, Moalli P, *et al.* Methods for a multicenter randomized trial for mixed urinary incontinence: rationale and patient-centeredness of the ESTEEM trial. *Int Urogynecol J* 2016;**27**:1479–90. [Ref ID: 73960]

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Appendix 7 Ongoing trials

Key

a Primary reference where more than one report of a study was available; this is the name given to the study as it appears in the main text of the ESTER report.

Note

Any relevant study and reference identifiers (IDs) are included in square brackets following each citation, e.g. [database: identifier].

Identifiers containing 'sr-incont' relate to the Cochrane Incontinence Specialised Register; 'CRSREF' identifiers refer to the Cochrane Register of Studies Web version (CRS-Web); 'other' is used to refer to either the study acronym or the trial registration number from a number of trial registries; 'Ref ID' identifiers relate to those records being processed for inclusion in the Cochrane Incontinence Specialised Register.

TABLE 32 List of ongoing trials

Study ID	Interventions	Start date	End date	Trial registration number
Abdel-Fattah 2014[315]	RP-TVT vs. transobturator MUS (TO-TVT) vs. SIMS	1 December 2013	31 May 2019	3/069/13
Boyd 1996[316]	Open colposuspension vs. laparoscopic colposuspension	1 March 1994	28 February 1996	ISRCTN44339585
Cardozo 2002[317]	Retropubic MUS (TVT) vs. periurethral injection of collagen	1 March 2000	1 March 2002	N0116091776
Carr 2011[318]	Injectable (autologous muscle-derived cells) vs. control	December 2011	February 2016	NCT01382602
Cavkaytar 2013[319]	Retropubic MUS (TVT) vs. transobturator MUS (TOT)	1 June 2013	1 June 2014	NCT01903590
Courtney-Watson 2002[320]	Retropubic MUS (TVT) vs. injectable (Macroplastique)	1 May 1999	1 January 2002	N0280055971
Ding 2015[321]	Transobturator MUS (TVT-O) vs. TVT-O plus injectable (adipose-derived mesenchymal stem cells)	NR	NR	ChiCTR-ICR-15006045
Elsokkary 2016[322]	Transobturator MUS (TOT) vs. modified needleless SIMS	1 February 2013	2 December 2015	PACTR201607001696163
Fu 2016[323]	Transobturator MUS (inside-out TOT) vs. innovative single-incision sling (needleless)	NR	NR	ChiCTR-INR-16008068

continued

TABLE 32 List of ongoing trials (*continued*)

Study ID	Interventions	Start date	End date	Trial registration number
Hilton 2002[324]	Retropubic MUS (TVT) vs. traditional sling (fascial sling)	1 June 1998	1 November 1999	N0503016202
Innovation 2010[325]	Injectable (autologous muscle-derived cells) (ICES13; Innovacell Biotechnologie, Innsbruck, Austria) vs. placebo	18 April 2012	NR	2010–021871–10
Itkonen 2015[326]	Retropubic MUS (TVT) vs. Bulkamid® (Contura International A/S, Soeborg, Denmark) injection	1 September 2015	1 December 2022	NCT02538991
Kaufman 2013[327]	Injectable (autologous muscle-derived cells for USR) vs. placebo	1 October 2013	1 December 2018	NCT01893138
Leitch 2016[328]	Retropubic MUS vs. SIMS	21 April 2016	31 December 2017	ACTRN12616000328471
Maslow 2013[329]	Transobturator MUS (TVT-O) vs. single-incision sling (MiniArc® Precise Pro; American Medical Systems Inc., Minnetonka, MN, USA)	NR	NR	NCT01799122
Oliveira 2013[330]	Transobturator MUS vs. Ophira® (Promedon, Córdoba, Argentina) SIMS	1 January 2013	1 July 2014	NCT02540525
Reda 2014[331]	Retropubic MUS (TVT) vs. SIMS	1 November 2014	1 June 2016	NCT02263534
Saaid 2008[332]	Retropubic MUS (TVT) vs. transobturator MUS (TOT) vs. Burch colposuspension	1 October 2008	1 May 2015	NCT03085979
Shen 2015[333]	Transobturator MUS (modified TVT-O) vs. SIMS 'TVT-Adjust' [sic]	16 March 2015	16 September 2016	ChiCTR-IOR-15006140
SUITE 2009[334]	Injection (skeletal muscle-derived cells) vs. SNRI (duloxetine) vs. placebo	18 December 2009	NR	2009–011797–15
Sweed 2016[335]	Retropubic MUS (TVT) vs. transobturator MUS (TOT) vs. Burch colposuspension	1 May 2016	1 December 2018	NCT02775526
Zhu 2014[336]	Transobturator MUS (TVT-O) vs. Regen Sling® (Medprin Regenerative Medical Technologies Co., Ltd., Guangzhou, China)	1 January 2014	1 December 2015	NCT02106299
Zhu 2015[337]	Transobturator MUS (TVT-O) vs. single-incision sling (TVT-S)	NR	NR	ChiCTR-IPR-15006967

ID, identifier; NR, not recorded; RP-TVT, retropubic tension-free vaginal tape; SIMS, single-incision mini-sling; SNRI, serotonin and norepinephrine reuptake inhibitors; TVT-S, tension-free vaginal tape-secur; USR, urinary sphincter repair.

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Davidson T, McDonald A, McPherson G, Norrie J. Evaluating the use of real-time data collection using SMS texts in the SIMS study. *Trials* 2015;**16**(Suppl. 2):O65. [Ref ID: 75610]

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Boyd K. *Laparoscopic Treatment for Female Urinary Incontinence*. 2004. Trial registration number: ISRCTN44339585. URL: http://isrctn.org/ISRCTN44339585 (accessed 9 June 2004). [Other: sr-incont17206]

Cardozo 2002[317]

Cardozo L, Rufford J. *Comparative Study of the Efficacy, Acceptability, Morbidity and Cost-effectiveness of the 'Tension Free Vaginal Tape' and the Periurethral Injection of Collagen in the Management of Recurrent Stress Incontinence.* 2002. Trial registration number: N0116091776. [CRSREF: 3254222; other: sr-incont16380]

Carr 2011[318]

Carr LK , De Ridder D, Magali R, Carlson K, Quinlan D, Steele SS, *et al. A Double-blind, Randomized, Placebo-controlled Study Evaluating the Safety and Effectiveness of Cook MyoSite Incorporated AMDC in Female Patients with Stress Urinary Incontinence.* 2011. Trial registration number: NCT01382602. URL: http://clinicaltrials.gov/show/NCT01382602 (accessed 20 August 2017). [Ref ID: 49828]

Cavkaytar 2013[319]

Cavkaytar S, Aksakal SO, Kokanali MK, Topcu HO, Doganay M. *Prospective Randomized Study Comparing TVT and TOT in Female Stress Urinary Incontinence with No Intrinsic Sphincter Deficiency*. 2013. Trial registration number: NCT01903590. URL: http://clinicaltrials.gov/show/NCT01903590 (accessed 20 August 2017). [Other: srincont49363]

Courtney-Watson 2002[320]

Courtney-Watson C. *Comparison of Two Surgical Methods for Curing Stress Incontinence (Recurrent).* 2002. Trial registration number: N0280055971. [CRSREF: 3254224; other: sr-incont16382]

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Ding J, Zhu L. *Explore the Efficacy and Safety of Single-center Randomized Controlled Polypropylene Mesh Auxiliary plus Adipose-derived Mesenchymal Stem Cells in the Treatment of Pelvic Organ Prolapse*. 2015. Trial registration number: ChiCTR-ICR-15006045. URL: www.chictr.org.cn/showproj.aspx?proj=10516 (accessed 20 August 2017). [Ref ID: 67577]

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Elsokkary M. *Modified Needleless Single-incision Mini-sling Compared to Standard Trans-obturator Mid-urethral Sling in the Surgical Management of Female Stress Urinary Incontinence.* 2016. Trial registration number: PACTR201607001696163. www.pactr.org/ATMWeb/appmanager/atm/atmregistry?dar=true&tNo=PACTR201607001696163 (accessed 20 August 2017). [Ref ID: 73367]

Fu 2016[323]

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Innovation (Innovacell Biotechnologie AG). *A Multicenter, Randomized, Double-blinded, Parallel-group, Placebo Controlled Study to Assess the Efficacy and Safety of Skeletal Muscle-derived Cell Implantation in Female Patients with Stress Urinary Incontinence*. 2010. Trial registration number: EUCTR2010-021871-10-DE. URL: www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2010-021871-10 (accessed 20 August 2017). [Ref ID: 64562]

Itkonen 2015[326]

Itkonen A-M. *TVT versus Bulkamid®-Injections in Treatment of Stress Urinary Incontinence – Patient Satisfaction and Complications of the Treatment*. 2015. Trial registration number: NCT02538991/ URL: https://clinicaltrials.gov/show/NCT02538991 (accessed 20 August 2017). [Ref ID: 68788]

Kaufman 2013[327]

NCT01893138, Kaufman M. *A Double-blind, Randomized, Controlled Trial Comparing the Safety and Efficacy of AMDC-USR with Placebo in Female Subjects with Stress Urinary Incontinence*. 2013. Trial registration number: NCT01893138. URL: http://clinicaltrials.gov/show/NCT01893138 (accessed 20 August 2017). [Ref ID: 61589]

Leitch 2016[328]

Leitch A, Ow LL, Rosamilia A. *Objective Cure Rate of Mini Sling or Retropubic Sling in Women with Intrinsic Sphincter Deficiency – A RCT Study (Mini RISD).* 2016. Trial registration number: ACTRN12616000328471. URL: www.anzctr.org.au/ACTRN12616000328471.aspx (accessed 20 August 2017). [Ref ID: 71376]

Maslow 2013[329]

Maslow KD. *Randomized Clinical Trial Comparing Mini-Arc Precise Pro and the Trans Vaginal Obturator Tape for Surgical Management of Stress Urinary Incontinence.* 2013. Trial registration number: NCT01799122. URL: http://clinicaltrials.gov/show/NCT01799122 (accessed 20 August 2017). [Ref ID: 62915]

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Oliveira E. *Transobturator Sling Compared with Single-incision Mini-sling for the Treatment of Stress Urinary Incontinence: a Randomized Controlled Trial*. 2013. Trial registration number: NCT02540525. URL: https://clinicaltrials.gov/show/NCT02540525 (accessed 20 August 2017). [Ref ID: 68787]

Reda 2014[331]

Reda A, Gomaa I. *Retropubic Single Incision Minisling versus Tension Free Vaginal Tape for Management of Stress Urinary Incontinence*. 2014. Trial registration number: NCT02263534. URL: http://clinicaltrials.gov/show/NCT02263534 (accessed 20 August 2017). [Ref ID: 64746]

Saaid 2008[332]

Saaid HA. *Surgical Management of Mixed Urinary Incontinence*. 2008. Trial registration number: NCT03085979. URL: https://clinicaltrials.gov/show/NCT03085979 (accessed 20 August 2017). [Ref ID: 76076]

Shen 2015[333]

Shen W, Fu J. *Single-incision Mini-slings versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: a Prospective Randomized Controlled Trial to Evaluate the Efficacy and Safety.* 2015. Trial registration number: ChiCTR-IOR-15006140. URL: www.chictr.org.cn/showproj.aspx?proj=10638 (accessed 20 August 2017). [Ref ID: 67571]

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[a]SUITE (Innovacell Biotechnologie AG). *Skeletal Muscle-derived Cell Implantation in Female Patients with Stress Urinary Incontinence: a Multicenter, Randomized, Parallel-group, Placebo-controlled Clinical Study – SUITE Study*. 2009. Trial registration number: EUCTR 2009-011797-15-DE. URL: www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2009-011797-15 (accessed 20 August 2017). [Ref ID: 64582]

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Appendix 8 Characteristics of included studies

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
Abdelwahab 2010[155]	Nambiar	9	I. Retro-MUS	I. 30	I. 39.2	USI (DO excluded)	No	Yes (> 2 POP-Q excluded)	NR
			II. Single incision	II. 30	II. 40.2				
[b]Abouhashem 2014[38]	Saraswat	60	I. Retro-MUS	Total 56	34.3	SUI	No	NR	NR
			II. Trad sling						
[b]Adile 2003[39]	Ford	36	I. Retro-MUS	I. 67	51	USI	No	NR	No
			II. Lap colpo	II. 66					
Aigmüller 2014[83]	Ford	3	I. Retro-MUS	I. 285	I. 59.7	USI (DO or predominant OAB excluded)	No except for previous anterior repair	NR	No
			II. Transob-MUS	II. 269	II. 58.6				
Al-Azzawi 2014[164]	New	12	I. Transob-MUS	I. 40	I. 42.8	SUI, predominant SUI	NR	Yes (> 1 grade cystocele excluded)	NR
			II. Trad sling	II. 40	II. 39.2				
Albo 2007[82]	Lapitan	60	I. Open colpo	I. 329	I. 52.2	SUI, predominant SUI	Yes	Yes	Yes
			II. Trad sling	II. 326	II. 51.6				
Alkady 2009[120]	Ford	12	I. Retro-MUS	I. 15	I. 48	USI, SUI, MUI (DO excluded)	No	Yes (≥ 4 stage excluded)	Yes
			II. Transob-MUS	II. 15	II. 50				
Amaro 2007[151]	Ford	36	I. Retro-MUS	I. 20	I. 52	USI (DI excluded)	Yes	NR	NR
			II. Trad sling	II. 21	II. 49				
Amat 2011[112]	Nambiar	54	I. Transob-MUS	I. 71	I. 60.6	SUI, MUI	NR	Yes	Yes
			II. Single incision	II. 87	II. 59.9				
Andonian 2007[117]	Ford	12	I. Retro-MUS	I. 112	I. 57–61	SUI, MUI	Yes	Yes	Yes
			II. Transob-MUS	II. 78	II. 56.2				
Andrada Hamer 2011[156]	Nambiar	12	I. Retro-MUS	I. 69	I. 48	SUI, predominant SUI	No	NR	No
			II. Single incision	II. 64	II. 47				

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
Aniuliene 2009[84]	Ford	12	I. Retro-MUS	I. 114	I. 51	SUI (OAB excluded)	Yes	Yes (> 2 stage excluded)	NR
			II. Transob-MUS	II. 150	II. 49				
Aniuliene 2015[121]	New	12	I. Retro-MUS	I. 78	I. 50	SUI (predominant OAB excluded)	No previous suburethral sling	Yes (> 2 POP-Q excluded)	NR
			II. Transob-MUS	II. 76	II. 67				
Ankardal 2001[85]	Lapitan	12	I. Open colpo	I. 120	I. 42.6	USI, predominant SUI	No	NR	No
			II. Lap colpo	II. 120	II. 40.9				
Araco 2008[86]	Ford	12	I. Retro-MUS	I. 120	54	SUI (OAB excluded)	No	No	NA
			II. Transob-MUS	II. 120					
Arunkalaivanan 2003[152]	Ford	36	I. Retro-MUS	I. 68	I. 54	USI (DO excluded)	Yes	NR	NR
			II. Trad sling	II. 74	II. 53				
Athanassopoulos 1996[111]	Lapitan	8–27	I. Open colpo	I. 27	50	USI	NR	Yes	NR
			II. Bladder neck needle	II. 24					
Bai 2005[145]	Lapitan	12	I. Retro-MUS	I. 31	I. 58.2	USI (DO excluded)	NR	Yes (> 2 grade excluded)	NR
			II. Open colpo	II. 33	II. 56.5				
			III. Trad sling	III. 28	III. 56.3				
Bandarian 2011[161]	Lapitan	22	I. Transob-MUS	I. 31	I. 49.4	USI only (no MUI)	No	Yes (> 1 POP-Q stage excluded)	NR
			II. Open colpo	II. 31	II. 46.9				
Barber 2008[122]	Ford	24	I. Retro-MUS	I. 88	I. 52	USI, MUI (DO excluded)	No previous sling surgery	Yes	Yes
			II. Transob-MUS	II. 82	II. 53				
Barber 2012[87]	Nambiar	24	I. Retro-MUS	I. 127	I. 54.6	USI, MUI	No previous sling surgery	Yes	Yes
			II. Single incision	II. 136	II. 54.6				

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Barry 2008[123]	Ford	3	I. Retro-MUS	I. 107	I. 53.6	USI (some had OAB)	Yes	Yes	Yes
			II. Transob-MUS	II. 80	II. 54.2				
Basok 2008[153]	Ford	12	I. Retro-MUS	I. 72	I. 50.3	SUI, MUI	NR	Yes (excluded uterine prolapse, rectocele, enterocoele, grade III or IV cystocoele)	NR
			II. Trad sling	II. 67	II. 47.4				
Basu 2010[157]	Nambiar	36	I. Retro-MUS	I. 33	I. 48.2	USI, SUI (some had DO)	No	Yes (> 2 POP-Q excluded)	NR
			I. Single incision	II. 38	II. 49.7				
Berglund 1996[192]	Lapitan	60–84	I. Open colpo	I. 30	50	SUI only (no UUI)	No	Yes (included cystocele but excluded other gynaecological disease requiring surgery)	NR
			II. Ant repair	II. 15					
Bergman 1989a[88]	Lapitan	12	I. Open colpo	I. 101[c]	57	USI (DI excluded)	No	Yes (all)	Yes (all)
			II. Bladder neck needle	II. 98[c]					
			III. Ant repair	III. 99[c] 339 randomised					
Bergman 1989b[188]	Lapitan	60	I. Open colpo	I. 38[c]	55	USI	No	NR (excludes other gynaecological disease needing surgery)	No
			II. Bladder neck needle	II. 34[c]					
			III. Ant repair	III. 35[c] 127 randomised					
Bianchi 2012[25]	Nambiar	24	I. Transob-MUS	I. 56	I. 52.1	USI (DO excluded; some had urgency)	Yes	Yes (> 2 POP-Q excluded)	NR
			II. Single incision	II. 66	II. 54.1				
[b]Burton 1994[40]	Lapitan	60	I. Open colpo	I. 30	NR	USI	NR	NR	NR
			II. Lap colpo	II. 30					
Campos 2013[176]	New	12	I. Transob-MUS	I. 28	I. 59.1	SUI, predominant SUI	No	Yes	Yes
			II. Single incision	II. 30	II. 60.8				

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Carey 2000[89]	Lapitan	60	I. Open colpo II. Lap colpo	I. 104 II. 96	I. 52.3 II. 50.7	USI, MUI	No	Yes (but excluded major degrees of POP requiring surgery other than a simple rectocele repair)	Yes
[b]Cervigni 2006[41]	Ford	NR (in-hospital stay only?)	I. Retro-MUS II. Transob-MUS	Total 118	57.4	SUI	NR	Yes (include ≥ 2 stage)	Yes (all)
Chen 2010[118]	Ford	NR	I. Retro-MUS II. Transob-MUS	I. 77 II. 110	I. 52.2 II. 47–52	USI only (no MUI)	No	Yes (> 2 grade cystocele excluded)	NR
Chen 2012[90]	Ford	24	I. Retro-MUS II. Transob-MUS	I. 102 II. 103	NR	USI only (no MUI)	NR	Yes	NR
[b]Choe 2013[42]	Ford	NR (in-hospital stay only?)	I. Retro-MUS II. Transob-MUS	Total 41	I. 55.6 II. 53.7	SUI	NR	NR	NR
Colombo 2000[193]	Lapitan	96–204	I. Open colpo II. Ant repair	I. 37 II. 34	I. 54.9 II. 55.7	USI (DI excluded)	No	Yes (all had grade 2 or 3 cystocele)	Yes
Darabi Mahboub 2012[26]	Ford	30	I. Retro-MUS II. Transob-MUS	I. 50 II. 50	I. 52.0 II. 52.3	Predominant SUI	NR	Yes (> 2 grade excluded)	NR
[b]Dati 2012[43]	New	6	I. Transob-MUS II. Single incision	I. 58 II. 57	NR	USI	No	Yes (> 3 stage POP excluded)	Yes
David-Montefiore 2006[124]	Ford	48	I. Retro-MUS II. Transob-MUS	I. 42 II. 46	I. 56.8 II. 53.4	USI, MUI	Yes	NR	NR
[b]de Oliveira 2006[44]	Ford	12	I. Retro-MUS II. Transob-MUS	I. 41[d] II. 42[d]	52.6	SUI	NR	Yes (≥ 2 stage excluded)	NR

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de Tayrac 2004[125]	Ford	12	I. Retro-MUS	I. 31	I. 53.6	USI, predominant SUI	Yes	No	NA
			II. Transob-MUS	II. 30	II. 54.7				
Deffieux 2010[126]	Ford	24	I. Retro-MUS	I. 75	I. 54.6	USI, MUI	No	Yes (> 1 stage POP-Q excluded)	No
			II. Transob-MUS	II. 74	II. 52.8				
Demirci 2001[103]	Lapitan	12	I. Open colpo	I. 23	I. 48.1	USI (some had UUI but not DI)	No	Yes (severe POP excluded)	Yes? (hysterectomy)
			II. Trad sling	II. 23	II. 48.9				
Di Palumbo 2003[199]	Glazner 2014	48	I. Bladder neck needle	I. 28	I. 60.6	SUI, MUI, UUI, urge-predominant MUI (% not reported)	NR	Yes [all women had urethrocystocele (anterior prolapse) grade 3 or 4]	Yes? (hysterectomy)
			II. Ant repair	II. 52	II. 59.8				
[b]Diab 2012[45]	Ford	26	I. Retro-MUS	I. 32	NR	SUI	NR	NR	NR
			II. Transob-MUS	II. 31					
Djehdian 2010[27]	Nambiar	36	I. Transob-MUS	I. 61	I. 51.9	USI, SUI (DO excluded; some had urgency)	Yes	Yes (> 1 grade excluded)	NR
			II. Single incision	II. 69	II. 54.2				
[b]Drahoradova 2004[46]	Lapitan	12	I. Retro-MUS	I. 79	59	SUI	NR	NR	NR
			II. Open colpo	II. 60					
El-Barky 2005[201]	Lapitan	24	I. Retro-MUS	I. 25	I. 50	USI only (no MUI)	No	Yes (> 1 grade cystocele excluded)	NR
			II. Open colpo	II. 25	II. 50				
[b]El-Din Shawki 2012[47]	Lapitan	3	I. Transob-MUS	Total 60	NR	SUI	NR	NR	NR
			II. Open colpo						
			III. Ant repair						

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El-Hefnawy 2010[127]	Ford	24	I. Retro-MUS II. Transob-MUS	I. 45 II. 42	I. 47 II. 45	USI, predominant SUI	No pelvic or vaginal surgery within the preceding 6 months	Yes (> 2 stage excluded)	Yes
[b]El-Hefnawy 2012[127]	New	12	I. Retro-MUS II. Transob-MUS	Total 75	I. 47 II. 45	SUI, predominant SUI	NR	Yes	Yes ('grade II cystocele or rectocele were only concomitant procedure allowed per protocol')
[b]Elshawaf 2009[49]	Lapitan	6	I. Retro-MUS II. Transob-MUS	I. 25 II. 25 III. 25	NR	USI	NR	NR	NR
Enzelsberger 1996[186]	Lapitan	48	I. Open colpo II. Trad sling	I. 36 II. 36	I. 59.8 II. 56.3	SUI	Yes (all recurrent case)	Yes (grade 3 cysto- or rectocele excluded)	No
Enzelsberger 2005[104]	Ford	15	I. Retro-MUS II. Transob-MUS	I. 52 II. 53	51	SUI only (no MUI)	No	No	NA
Enzelsberger 2010[170]	Nambiar	24	I. Transob-MUS II. Single incision	I. 45 II. 45	I. 54 II. 53	SUI	No	NR	NR
[b]Enzelsberger 2011[50]	New	20	I. Transob-MUS II. Single incision	I. 25 I. 25	NR	SUI	NR	NR	No
[b]Fatthy 2001[51]	Lapitan	18	I. Open colpo II. Lap colpo	I. 40 II. 34	I. 42.9 II. 40.3	USI (DI excluded)	Yes	Yes (stage 3–4 excluded)	NR
[b]Fernandez 2015[52]	New	27	I. Transob-MUS II. Single incision	I. 98 II. 89	I. 57.8 II. 57.6	SUI, predominant SUI	No	Yes	Yes

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
[b]Fischer 2001[53]	Lapitan	6	I. Open colpo	I. 11	NR	USI	NR	NR	Yes
			II. Trad sling	II. 11					
Foote 2006[146]	Ford	28.8	I. Retro-MUS	I. 49	I. 52.4	USI (DO excluded)	No previous retropubic surgery excluded	Yes ('significant' POP excluded)	No
			II. Lap colpo	II. 48	II. 51.2				
Foote 2015[171]	New	6	I. Transob-MUS	I. 25	I. 46.2	USI	No previous retropubic UI surgery	NR	No? ('other vaginal surgical procedures being performed concurrently' excluded)
			II. Single incision	II. 25	II. 49.6				
Freeman 2011[128]	Ford	12	I. Retro-MUS	I. 92	I. 50	USI, predominant SUI	No	Yes (POP extending beyond the hymen excluded)	NR
			II. Transob-MUS	II. 100	II. 54				
[b]Friedman 2009[54]	Nambiar	12	I. Transob-MUS	I. 42	NR	USI	NR	NR	Yes
			II. Single incision	II. 42					
Gaber 2016[91]	New	12	I. Transob-MUS	I. 70	I. 44.1	USI only (no MUI)	No	Yes	NR
			II. Single incision	II. 140	II. 43–44				
German 1994[190]	Lapitan	24	I. Open colpo	I. 24	I. 50	USI	Yes	NR	NR
			II. Bladder neck needle	II. 26	II. 53				
Gilja 1998[189]	Lapitan	36	I. Open colpo	I. 56	36	USI	NR	NR	NR
			II. Bladder neck needle	II. 90					

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Gopinath 2013[158]	New	NR	I. Retro-MUS	NR	NR	NR	NR	NR	NR
[Pilot RCT was mentioned in a qualitative research paper; no further detail provided on the RCT]			II. Single incision						
Guerrero 2008[92]	Saraswat	120	I. Retro-MUS	I. 72	I. 54.3	USI (DO excluded)	No	Yes (> 2 POP-Q excluded)	NR
			II. Trad sling	II. 129	II. 52				
[b]Halaska 2001[55]	Lapitan	6	I. Retro-MUS	I. 15	I. 58.3	USI	NR	NR	NR
			II. Open colpo	II. 11	II. 53.4				
[b]Hammoud 2011[56]	Ford	NR	I. Retro-MUS	I. 60	I. 43	SUI, MUI	Yes	Yes (included cystocele grade 1–2)	NR
			II. Transob-MUS	II. 50	II. 42				
[b]Han 2001[69]	Lapitan	6	I. Retro-MUS	I. 25	NR	USI	NR	NR	NR
			II. Open colpo	II. 25					
Henriksson 1978[105]	Lapitan	3	I. Open colpo	I. 15	I. 56	SUI only (no UUI)	NR	No	NA
			II. Trad sling	II. 15	II. 50				
Hilton 1989[198]	Saraswat	24	I. Trad sling	I. 10	I. 53.7	USI, MUI	Yes	NR	NR
			II. Bladder neck needle	II. 10	II. 57.1				
Hinoul 2011[172]	Nambiar	12	I. Transob-MUS	I. 98	I. 53.2	USI, SUI (some had OAB)	No	Yes (≥ 2 stage excluded)	NR
			II. Single incision	II. 96	II. 52.3				

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Holmes 1985[194]	Lapitan	24	I. Open colpo	I. 26	I. 44.3	USI, MUI	No	Yes	Yes? (hysterectomy)
			II. Ant repair	II. 25	II. 47.1				
Hota 2012[173]	Nambiar	12	I. Transob-MUS	I. 44	I. 50.5	USI, predominant SUI	No previous suburethral sling	Yes	Yes
			II. Single incision	II. 43	II. 52				
Jakimiuk 2012[129]	Ford	6	I. Retro-MUS	I. 19	NR	USI only (no MUI)	No	No	NA
			II. Transob-MUS	II. 16					
Jurakova 2016[113]	New	13	I. Transob-MUS	I. 48	I. 64.3	USI, predominant SUI	No	No	NA
			II. Single incision	II. 45	II. 62.3				
[b]Kamel 2009[58]	Ford	NR	I. Retro-MUS	I. 60	NR	USI	No	NR	NR
			II. Transob-MUS	II. 60					
Kammerer-Doak 1999[195]	Lapitan	12	I. Open colpo	I. 19	I. 44.5	USI (DI excluded)	Yes	Yes	Yes
			II. Ant repair	II. 16	II. 53				
Karateke 2009[130]	Ford	NR	I. Retro-MUS	I. 83	I. 49.3	USI (DO/OAB excluded)	No	Yes (> 1 stage POP-Q excluded)	NR
			II. Transob-MUS	II. 84	II. 49.1				
Kiliç 2007[131]	Ford	12	I. Retro-MUS	I. 10	I. 55.8	USI	NR	NR	NR
			II. Transob-MUS	II. 10	II. 60.2				
Kim 2005[132]	Ford	3	I. Retro-MUS	I. 65	I. 45.4	SUI	NR	NR	NR
			II. Transob-MUS	II. 65	II. 45.7				
[b]Kim 2010[59]	Nambiar	NR	I. Transob-MUS	I. 20	I. 50.7	SUI	NR	NR	NR
			II. Single incision	II. 20	II. 49.6				

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Kitchener 2006[93]	Lapitan	24	I. Open colpo II. Lap colpo	I. 147 II. 144	I. 50.0 II. 50.5	USI (DO excluded)	No previous retropubic surgery but allowed for other previous UI surgery	NR	No
[b]Koelbl 2002[60]	Lapitan	NR (in-hospital stay only?)	I. Retro-MUS II. Open colpo	I. 83 II. 83	59.5	USI only (no MUI)	NR	No	NA
Kondo 2006[106]	Ford	24	I. Retro-MUS II. Trad sling	I. 32 II. 31	I. 59.1 II. 54.0	USI, MUI	Yes	NR	Yes
Krofta 2010[94]	Ford	12	I. Retro-MUS II. Transob-MUS	I. 149 II. 151	I. 57.2 II. 57.8	SUI only (no UUI)	No	Yes (≥ 2 stage POP-Q excluded)	No
Labrie 2012[95]	New	12	I. Transob-MUS II. PFMT	I. 230 II. 230	I. 50.2 II. 50.0	SUI (some had OAB)	No	Yes (≥ 2 POP-Q excluded)	NR
Laurikainen 2007[96]	Ford	60	I. Retro-MUS II. Transob-MUS	I. 136[c] II. 132[c] 273 randomised	I. 53 II. 54	SUI	No	Yes [> 2 degree (Baden-Walker) excluded]	NR
[b]Leanza 2009[61]	Ford	45	I. Retro-MUS II. Transob-MUS	I. 229 II. 211	NR	USI	NR	Yes	Yes? ('other pelvic defects were solved during the same operation for a complete repair of pelvic floor')
Lee 2007[107]	Ford	13	I. Retro-MUS II. Transob-MUS	I. 60 II. 60	I. 54.4 II. 51.1	USI, predominant SUI	Yes	No	NA

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Lee 2012[28]	Nambiar	36	I. Transob-MUS	I. 118	I. 51	USI, SUI (some had DO)	No previous MUS	Yes	Yes
			II. Single incision	II. 117	II. 52.2				
[b]Lee 2015[62]	New	12	I. Retro-MUS	Total 187	NR	SUI	NR	NR	NR
			II. Single incision						
Liapis 1996[200]	Lapitan	60	I. Open colpo	I. 105[c]	50.6	USI (DI excluded)	No	NR	Yes
			II. Ant repair	II. 50[c]					
				170 randomised					
Liapis 2002[108]	Lapitan	24	I. Retro-MUS	I. 36	I. 46.5	SUI only (no UUI)	No	Yes (included ≤ stage 1 cystocele)	NR
			II. Open colpo	II. 35	II. 48.4				
Liapis 2006[133]	Ford	12	I. Retro-MUS	I. 46	I. 53	SUI (OAB/DO excluded)	No	NR	No
			II. Transob-MUS	II. 43	II. 52				
Mackintosh 2010[174]	Nambiar	3	I. Transob-MUS	I. 15	I. 47.7	SUI, predominant SUI	No	NR	No
			II. Single incision	I. 14	II. 50.6				
[b]Maher 2004[63]	Ford	6	I. Retro-MUS	I. 40	NR	SUI	Yes	No	NA
			II. Lap colpo	II. 42					
Maher 2005[102]	Saraswat	12	I. Trad sling	I. 22	I. 63	USI (some had DI)	No previous sling surgery but allowed for other surgery	NR	No
			II. Injectable	II. 23	II. 65				
Mak 2000[182]	Lapitan	12	I. Open colpo	I. 43	I. 50.4	USI	No	NR	Yes? (hysterectomy)
			II. Lap colpo	II. 47	II. 51.1				

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[b]Mansoor 2003[64]	Ford	6	I. Retro-MUS	I. 54	NR	SUI	NR	Yes	NR
			II. Transob-MUS	II. 48					
Masata 2012[167]	Nambiar	60	I. Transob-MUS	I. 68	I. 56.6	USI, predominant SUI	No	Yes (≥ 2 stage excluded)	No
			II. Single incision	II. 129	II. 55–58				
Masata 2013[101]	New	24	I. Transob-MUS	I. 50	I. 58.9	USI, predominant SUI	No	Yes (POP > 3 excluded)	No
			II. Single incision	II. 50	II. 55.8				
Maslow 2014[175]	New	12	I. Transob-MUS	I. 50	I. 48.7	SUI (predominant OAB excluded)	No	Yes (> 1 stage POP excluded)	NR
			II. Single incision	II. 56	II. 48.8				
Mehdiyev 2010[134]	Ford	NR	I. Retro-MUS	I. 15	NR	SUI	NR	NR	NR
			II. Transob-MUS	II. 17					
[b]Melendez Munoz 2016[65]	New	6	I. Transob-MUS	I. 113	NR	SUI (some had OAB)	No previous failed suburethral tapes	NR	NR
			II. Single incision	II. 111					
[b]Merali 2012[66]	New	12	I. Transob-MUS	I. 19	NR	SUI	NR	NR	NR
			II. Single incision	II. 18					
Meschia 2007[97]	Ford	6	I. Retro-MUS	I. 114	I. 56	USI (DO excluded)	No	Yes? (POP requiring treatment excluded)	NR
			II. Transob-MUS	II. 117	II. 58				
[b]Mirosh 2005[67]	Ford	12	I. Retro-MUS	I. 16	NR	USI only (no MUI)	No	Yes (POP-Q > 2 excluded)	No
			II. Lap colpo	II. 14					
[b]Morris 2001[68]	Lapitan	72	I. Open colpo	I. 35	NR	USI	NR	NR	NR
			II. Lap colpo	II. 38					

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Mostafa 2012[204]	Nambiar	NR	I. Transob-MUS	I. 68	I. 49.4	SUI, predominant SUI	No	NR	NR
			II. Single incision	II. 69	II. 52.6				
Mundy 1983[109]	Lapitan	12	I. Open colpo	I. 26	48	USI (no DI)	Yes	NR	NR
			II. Bladder neck needle	II. 25					
Nerli 2009[110]	Ford	12	I. Retro-MUS	I. 18	I. 39.5	SUI, predominant SUI	NR	Yes (stage 3–4 excluded)	NR
			II. Transob-MUS	II. 18	II. 50.2				
Nyyssonen 2014[135]	Ford	46	I. Retro-MUS	I. 50	I. 51	SUI, predominant SUI	No previous mini-invasive operation for SUI	NR	No
			II. Transob-MUS	II. 50	II. 54				
Oliveira 2011[168]	Nambiar	24	I. Transob-MUS	I. 30	I. 52	USI, SUI, predominant SUI	No	Yes (≥ 2 POP-Q excluded)	NR
			II. Single incision	II. 60	II. 52.7				
[b]O'Sullivan 2000[69]	Lapitan	6	I. Retro-MUS	I. 11	NR	USI	No	Yes ('clinically significant' POP excluded)	NR
			II. Open colpo	II. 9					
Palma 1985[191]	Lapitan	21	I. Open colpo	I. 30	I. 46	USI, SUI	Yes	NR	NR
			II. Bladder neck needle	II. 40	II. 44				
Palomba 2008[70]	Ford	NR	I. Retro-MUS	Total 15	NR	SUI (DI excluded)	No	Yes (all had cystocele)	NR
(Trial terminated owing to poor recruitment. No results published)			II. Transob-MUS						
Paraiso 2004[147]	Ford	65	I. Retro-MUS	I. 36	I. 53.3	USI (DO excluded)	No	Yes (POP-Q > 1 excluded)	Yes? (hysterectomy and adhesiolysis)
			II. Lap colpo	II. 36	II. 54.8				

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Pastore 2016[114]	New	12	I. Transob-MUS	I. 24	I. 49.8	SUI only (no UUI)	No	NR	NR
			II. Single incision	II. 24	II. 50.2				
Persson 2002[148]	Ford	12	I. Retro-MUS	I. 38[e]	I. 48	USI, predominant SUI	No	Yes (POP-Q > 1 excluded)	No
			II. Lap colpo	II. 32[e]	II. 51				
				79 randomised					
Porena 2007[136]	Ford	99	I. Retro-MUS	I. 73	I. 61.8	SUI, predominant SUI	No	Yes (> 1 stage excluded)	NR
			II. Transob-MUS	II. 75	II. 60.6				
Rechberger 2009[98]	Ford	18	I. Retro-MUS	I. 269	I. 55.6	SUI	NR	Yes (> 1 grade POP-Q excluded)	NR
			II. Transob-MUS	II. 268	II. 55.8				
Richter 2010[99]	Ford	60	I. Retro-MUS	I. 298	I. 52.7	SUI, predominant SUI	Yes	Yes	Yes
			II. Transob-MUS	II. 299	II. 53.1				
[b]Riva 2006[71]	Ford	12	I. Retro-MUS	I. 66	NR	SUI	No	Yes (urethro-cystocele of grade 0–2)	NR
			II. Transob-MUS	II. 65					
Ross 2009[137]	Ford	60	I. Retro-MUS	I. 105	I. 51.8	SUI (UUI included; OAB excluded)	No	NR	No
			II. Transob-MUS	II. 94	II. 50.1				
Ross 2014[159]	New	12	I. Retro-MUS	I. 40	I. 47.2	SUI, MUI	No	NR	No
			II. Single incision	II. 34	II. 52.4				
[b]Rudnicki 2016[72]	New	12	I. Retro-MUS	I. 83	NR	SUI, predominant SUI	No	Yes (> 2 POP-Q excluded)	NR
			II. Transob-MUS	II. 67					
			III. Single incision	III. 155					

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
Salari 2010[127]	New	12	I. Transob-MUS	I. 30	I. 44.1	SUI only (no UUI)	No	Yes (all had stage 1 or 2 cystocele)	NR
			II. Ant repair	II. 30	II. 37.8				
[b]Salem 2014[73]	Ford	60	I. Retro-MUS	I. 39	35.3	SUI	NR	NR	NR
			II. Transob-MUS	II. 37					
Samiee 2009[163]	Freites	NR	I. Transob-MUS	I. 19	NR	SUI (DO excluded)	No	Yes (excluded severe anterior vaginal prolapse and uterine prolapse)	NR
			II. Lap colpo	II. 16					
Sand 2000[187]	Lapitan	72	I. Open colpo	I. 19	I. 61.3	USI, MUI	Yes	Yes (significant pelvic support defects excluded)	Yes
			II. Trad sling	II. 17	II. 60.4				
Scheiner 2012[119]	Ford	12	I. Retro-MUS	I. 80	I. 57.8	SUI, predominant SUI	No previous sling surgery	Yes (a symptomatic cystocele stage 2 or higher according to the POP-Q system was corrected first. Participants with concomitant sling insertion to repair prolapse were included)	Yes
			II. Transob-MUS	II. 80	II. 57–5				
Schellart 2013[177]	New	36	I. Transob-MUS	I. 96	I. 53	SUI	No	Yes (≥ 2 stage POP excluded)	NR
			II. Single incision	II. 97	II. 53				
Schierlitz 2008[138]	Ford	63	I. Retro-MUS	I. 82	I. 60	USI	Yes	NR	Yes
			II. Transob-MUS	II. 82	II. 6				
Schweitzer 2012[29]	Nambiar	12	I. Transob-MUS	I. 56	I. 48.3	SUI	No	Yes (> 1 POP-Q excluded)	NR
			II. Single incision	II. 100	II. 50.8				
[b]Seo 2011[74]	Nambiar	24	I. Transob-MUS	I. 39	I. 46.5	SUI	NR	NR	NR
			II. Single incision	II. 41	II. 46.9				

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
Sharifiaghdas 2008[81]	Saraswat	126	I. Retro-MUS	I. 48	I. 49.1	USI, MUI	NR	Yes (> 1 POP-Q excluded)	No? (gynaecological problems which need simultaneous repairs such as high-grade prolapse excluded)
			II. Trad sling	II. 52	II. 55.0				
Sharifiaghdas 2015[197]	New	13.8	I. Trad sling	Total 72	I. 52.2	SUI	Yes	Yes (≥ 3 grade cystocele excluded)	NR
			II. Single incision		II. 55.6				
[b]Shawky 2015[75]	New	12	I. Transob-MUS	I. 28	NR	SUI	NR	NR	NR
			II. Single incision	II. 30					
Silva-Filho 2006[165]	Ford	6	I. Transob-MUS	I. 10	I. 55.2	USI, SUI (DO excluded)	No	NR	NR
			II. Trad sling	II. 10	II. 49.8				
Sivaslioglu 2007[162]	Lapitan	24	I. Transob-MUS	I. 49	I. 45.4	USI only (no UUI)	No	Yes (> 1 POPQ stage excluded)	NR
			II. Open colpo	II. 51	II. 46.1				
Sivaslioglu 2012[178]	Nambiar	60	I. Transob-MUS	I. 40	I. 51.5	USI only (no UUI/MUI)	No	NR	NR
			II. Single incision	II. 40	II. 54.0				
Smith 2011[30]	Nambiar	15.3	I. Transob-MUS	I. 49	I. 48.9	USI, predominant SUI	No	Yes (median stage 3)	Yes
			II. Single incision	II. 49	II. 52.9				
Song 2004[154]	Ford	20–37	I. Retro-MUS	I. 48	I. 53	SUI, MUI	NR	Yes	NR
			II. Trad sling	II. 19	II. 71				
Sottner 2012[169]	Nambiar	NR	I. Transob-MUS	I. 12	NR	Predominant SUI	NR	NR	NR
			II. Single incision	II. 31					
[b]Stangel-Wojcikiewicz 2008[76]	Lapitan	18	I. Open colpo	I. 57	NR	USI (OAB excluded)	NR	Yes (> 2 POPQ grade excluded)	NR
			II. Lap colpo	II. 51					

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
Su 1997[183]	Lapitan	6	I. Open colpo	I. 46	I. 44.3	USI (DO excluded)	No	Yes (> 1 degree cystocele excluded)	Yes? (hysterectomy)
			II. Lap colpo	II. 46	II. 42.4				
[b]Summitt 2000[77]	Lapitan	12	I. Open colpo	I. 28[d]	NR	USI (DO excluded)	No previous retropubic urethropexy, needle suspension or suburethral sling	NR	No
			II. Lap colpo	II. 34[d]					
Tang 2014[179]	New	24	I. Transob-MUS	I. 48	I. 51.3	SUI only (no UUI)	NR	Yes (POP requiring extensive surgery excluded)	No
			II. Single incision	II. 46	II. 49.8				
Tanuri 2010[139]	Ford	12	I. Retro-MUS	I. 10	NR	SUI only	Yes	Yes (> 2 stage excluded)	NR
			II. Transob-MUS	II. 20					
[b]Tapp 1989[78]	Lapitan	6	I. Open colpo	I. 24	NR	USI only (no MUI)	No	NR	NR
			II. PFMT	II. 21					
Tarcan 2011[31]	Ford	12	I. Retro-MUS	Total 54	54	USI, predominant SUI	No	Yes (≥ 3 stage excluded)	Yes
			II. Transob-MUS						
Tcherniakovsky 2009[166]	Saraswat	12	I. Transob-MUS	I. 21	I. 46.5	USI	Yes	Yes	NR
			II. Trad sling	II. 20	II. 52.1				
Téllez Martínez-Fornés 2009[202]	Lapitan	36	I. Retro-MUS	I. 24	I. 47.13	USI (OAB excluded)	No	Yes (> I grade cystocele excluded)	NR
			II. Open colpo	II. 25	II. 50				
Teo 2011[140]	Ford	12	I. Retro-MUS	I. 66	I. 52.4	USI (DO excluded)	No	Yes (> 1 stage excluded)	NR
			II. Transob-MUS	II. 61	II. 50.9				
Tommaselli 2010[180]	Nambiar	63	I. Transob-MUS	I. 42	I. 58.2	USI, predominant SUI	No	Yes (≥ 2 POP-Q excluded)	NR
			II. Single incision	II. 42	II. 57.8				

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
Trabuco 2014[32]	Lapitan	6	I. Retro-MUS	I. 57	I. 56	SUI, predominant SUI	Yes	Yes (all; > 90% had POP-Q ≥ 2)	Yes (all)
			II. Open colpo	II. 56	II. 56				
Tuygun 2006[184]	Lapitan	38.7	I. Open colpo	I. 33	I. 53	SUI	No	Yes	NR
			II. Lap colpo	II. 27	II. 52				
Ustün 2003[149]	Ford	18	I. Retro-MUS	I. 23	I. 45.6	USI	NR	No	NA
			II. Lap colpo	II. 23	II. 45				
Ustün 2005[185]	Lapitan	14.2	I. Open colpo	I. 26	I. 42.3	USI (DI excluded)	No	NR	Yes
			II. Lap colpo	II. 26	II. 43.6				
Valpas 2004[150]	Ford	60	I. Retro-MUS	I. 70	I. 50	USI	No but allowed for previous anterior repair	NR	No
			II. Lap colpo	II. 51	II. 48				
[b]Van Rensburg 2015[79]	New	12	I. Transob-MUS	I. 41[c]	I. 55.7	SUI, MUI	Yes	Yes	Yes
			II. Single incision	II. 51[c]	II. 54.4				
Wadie 2005[160]	Ford	54	I. Retro-MUS	I. 28	I. 44.9	USI, predominant SUI	No	Yes (> 2 grade excluded)	Yes
			II. Ant repair	II. 25	II. 45.3				
Wang 2003[203]	Lapitan	22	I. Retro-MUS	I. 49	51.6	USI	No	No	NA
			II. Open colpo	II. 49					
Wang 2006[141]	Ford	9	I. Retro-MUS	I. 29	I. 51.4	USI	No	Yes (> 2 stage POP excluded)	NR
			II. Transob-MUS	II. 31	II. 50.5				
Wang 2009[37]	Ford	20	I. Retro-MUS	I. 160	I. 55	USI only (no UUI)	Yes	Yes	Yes
			II. Transob-MUS	II. 155	II. 54.8				
Wang 2010[142]	Ford	12	I. Retro-MUS	I. 70	I. 60	USI only (no UUI)	Yes	Yes	NR
			II. Transob-MUS	II. 70	II. 58				

Study ID (first author and year)	Source review[a]	Length of FU or last FU (months)	Intervention	*N* randomised	Age (mean or median)	UI diagnosis	Previous UI surgery in some or all participants	Co-existing POP in some or all participants	Concomitant POP surgery in some or all participants
Wang 2011[116]	Ford and Nambiar	12	I. Retro-MUS	I. 32[d]	I. 56.6	SUI, predominant SUI	No	NR	No
			II. Transob-MUS	II. 36[d]	II. 56.0				
			III. Single incision	III. 34[d] 108 randomised	III. 57.3				
Ward 2002[100]	Lapitan	60	I. Retro-MUS	I. 175	NR	USI (DO excluded)	No	Yes (vaginal prolapse requiring treatment excluded)	No
			II. Open colpo	II. 169					
Xin 2016[115]	New	12	I. Transob-MUS	I. 184	I. 56.5	USI, predominant SUI	No	Yes (≥ 2 POP-Q excluded)	NR
			II. Single incision	II. 184	II. 57.6				
[b]Yoon 2011[80]	Nambiar	1	I. Transob-MUS	I. 51	I. 57.0	SUI	NR	NR	NR
			II. Single incision	II. 52	II. 52.9				
Zhang 2014[143]	New	95	I. Retro-MUS	I. 70	I. 55	SUI only (no MUI)	No	Yes (> 1 stage POP excluded)	NR
			II. Transob-MUS	II. 70	II. 51				
Zullo 2007[144]	Ford	60	I. Retro-MUS	I. 35	I. 52.8	SUI (DO/OAB excluded)	No	Yes (> 1 stage excluded)	NR
			II. Transob-MUS	II. 37	II. 53.4				

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; DI, detrusor instability; DO, detrusor overactivity; FU, follow-up; ID, identifier; lap colpo, laparoscopic colposuspension; NR, not recorded; OAB, overactive bladder; open colpo, open colposuspension; POP, pelvic organ prolapse; POP-Q, pelvic organ prolapse quantification system; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling; USI, urodynamic stress incontinence.

a Source Cochrane reviews: Ford, Ford *et al.*[8] and Ogah *et al.*[18] – MUS operations for SUI in women; Lapitan, Lapitan *et al.*[5] – open retropubic colposuspension for UI in women; Freites, Freites *et al.*[6] and Dean *et al.*[20] – laparoscopic colposuspension for UI in women; Saraswat, Saraswat *et al.*[7] and Rehman *et al.*[19] – traditional suburethral sling operations for UI in women; Nambiar, Nambiar *et al.*[9] – single-incision sling operations for UI in women; Glazener, Glazener and Cooper[11] – bladder neck needle suspension for UI in women; new, studies identified by update search.

b Abstract only.

c Number analysed.

d Number followed up.

e Number receiving intervention.

Appendix 9 Risk-of-bias assessment of 175 included studies

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Ford	Aigmüller 2014[83]	Retro-MUS	Trans-MUS		L	L	H	H				L				
Ford	Alkady 2009[120]	Retro-MUS	Trans-MUS		L	L	U	U				L				
Ford	Andonian 2007[117]	Retro-MUS	Trans-MUS		U	U	L	L				U				
Ford	Aniuliene 2009[84]	Retro-MUS	Trans-MUS		U	U	U	U				L				
New	Aniuliene 2015[121]	Retro-MUS	Trans-MUS		U	U	H		H	H			L	L	U	U
Ford	Araco 2008[86]	Retro-MUS	Trans-MUS		L	L	U	L				H				
Ford	Barber 2008[122]	Retro-MUS	Trans-MUS		L	L	U	L				L				
Ford	Barry 2008[123]	Retro-MUS	Trans-MUS		U	U	U	U				L				
Ford	[c]Cervigni 2006[41]	Retro-MUS	Trans-MUS		L	U	U	U				L				
Ford	Chen 2010[118]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Chen 2012[90]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	[c]Choe 2013[42]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	[d]Darabi Mahboub 2012[26]	Retro-MUS	Trans-MUS		L	U	U		U	U			U	U	H	U
Ford	David-Montefiore 2006[124]	Retro-MUS	Trans-MUS		L	L	U	U				U				
Ford	[c]de Oliveira 2006[44]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	de Tayrac 2004[125]	Retro-MUS	Trans-MUS		L	L	U	L				U				
Ford	Deffieux 2010[126]	Retro-MUS	Trans-MUS		L	L	H	U				L				
Ford	[c]Diab 2012[45]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	El-Hefnawy 2010[127]	Retro-MUS	Trans-MUS		U	L	U	L				L				
New	[c]El-Hefnawy 2012[48]	Retro-MUS	Trans-MUS		U	U	U		U	U			U	U	U	U
Lapitan	[c]Elshawaf 2009[49]	Retro-MUS	Trans-MUS	Open colpo	U	U	U	U				U				U
Ford	Enzelsberger 2005[104]	Retro-MUS	Trans-MUS		H	H	U	U				U				
Ford	Freeman 2011[128]	Retro-MUS	Trans-MUS		L	L	L	U				L				
Ford	[c]Hammoud 2011[56]	Retro-MUS	Trans-MUS		U	U	U	U				U				

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Ford	Jakimiuk 2012[129]	Retro-MUS	Trans-MUS		L	U	L	U				U				
Ford	[c]Kamel 2009[58]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Karateke 2009[130]	Retro-MUS	Trans-MUS		L	U	U	L				L				
Ford	Kiliç 2007[131]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Kim 2005[132]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Krofta 2010[94]	Retro-MUS	Trans-MUS		L	U	H	L				L				
Ford	Laurikainen 2007[96]	Retro-MUS	Trans-MUS		L	L	U	U				L				
Ford	[c]Leanza 2009[61]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Lee 2007[107]	Retro-MUS	Trans-MUS		H	H	U	U				U				
Ford	Liapis 2006[133]	Retro-MUS	Trans-MUS		U	U	U	U				L				
Ford	[c]Mansoor 2003[64]	Retro-MUS	Trans-MUS		L	L	U	U				U				
Ford	Mehdiyev 2010[134]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Meschia 2007[97]	Retro-MUS	Trans-MUS		L	L	U	U				L				
Ford	Nerli 2009[110]	Retro-MUS	Trans-MUS		H	H	U	U				U				
Ford	Nyyssonen 2014[135]	Retro-MUS	Trans-MUS		L	L	U	U				L				
Ford	[c]Palomba 2008[70]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Porena 2007[136]	Retro-MUS	Trans-MUS		L	L	U	L				L				
Ford	Rechberger 2009[98]	Retro-MUS	Trans-MUS		U	U	U	U				L				
Ford	Richter 2010[99]	Retro-MUS	Trans-MUS		L	U	U	U				U				
Ford	[c]Riva 2006[71]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Ross 2009[137]	Retro-MUS	Trans-MUS		L	L	U	U				L				
New	[c]Rudnicki 2016[72]	Retro-MUS	Trans-MUS	Single incision	L	U	U		U	U			U	L	H	U

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Ford	[c]Salem 2014[73]	Retro-MUS	Trans-MUS		U	U	U	U				U				
Ford	Scheiner 2012[119]	Retro-MUS	Trans-MUS		L	U	U	U				L				
Ford	Schierlitz 2008[138]	Retro-MUS	Trans-MUS		L	U	U	U				U				
Ford	Tanuri 2010[139]	Retro-MUS	Trans-MUS		U	U	U	U				L				
Ford	[d]Tarcan 2011[31]	Retro-MUS	Trans-MUS		L	U	U		U	U			U	U	L	U
Ford	Teo 2011[140]	Retro-MUS	Trans-MUS		L	L	H	H				H				
Ford	Wang 2006[141]	Retro-MUS	Trans-MUS		L	U	U	L				L				
Ford	Wang 2009[37]	Retro-MUS	Trans-MUS		L	U	U	L				L				
Ford	Wang 2010[142]	Retro-MUS	Trans-MUS		U	U	H	L				L				
Ford	Wang 2011[116]	Retro-MUS	Trans-MUS	Single incision	L	L	U	U				L				
New	Zhang 2014[143]	Retro-MUS	Trans-MUS		L	U	H		H	L			L	L	L	U
Ford	Zullo 2007[144]	Retro-MUS	Trans-MUS		L	L	U	L				L				
Lapitan	Bai 2005[145]	Retro-MUS	Open colpo	Trad sling	U	U	U	U				U				U
Lapitan	[c]Drahoradova 2004[46]	Retro-MUS	Open colpo		U	U	U	H				U				U
Lapitan	El-Barky 2005[201]	Retro-MUS	Open colpo		U	U	U	U				U				U
Lapitan	[c]Halaska 2001[55]	Retro-MUS	Open colpo		U	U	U	U				U				U
Lapitan	[c]Han 2001[57]	Retro-MUS	Open colpo		U	U	U	U				U				U
Lapitan	[c]Koelbl 2002[60]	Retro-MUS	Open colpo		L	U	U	U				U				U
Lapitan	Liapis 2002[108]	Retro-MUS	Open colpo		H	U	U	U				U				U
Lapitan	[c]O'Sullivan 2000[69]	Retro-MUS	Open colpo		U	U	U	U				U				U
Lapitan	Téllez Martínez-Fornés 2009[202]	Retro-MUS	Open colpo		U	U	H	U				U				U
Lapitan	[d]Trabuco 2014[32]	Retro-MUS	Open colpo		L	L	H		L	L			U	U	L	U
Lapitan	Wang 2003[203]	Retro-MUS	Open colpo		L	U	U	U				U				U

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Lapitan	Ward 2002[100]	Retro-MUS	Open colpo		L	L	H	U				L				U
Ford	[c]Adile 2003[39]	Retro-MUS	Lap colpo		U	U	U	U				U				
Ford	Foote 2006[146]	Retro-MUS	Lap colpo		L	U	U	U				U				
Ford	[c]Maher 2004[63]	Retro-MUS	Lap colpo		L	L	U	U				U				
Ford	[c]Mirosh 2005[67]	Retro-MUS	Lap colpo		U	U	U	U				L				
Ford	Paraiso 2004[147]	Retro-MUS	Lap colpo		L	L	U	U				L				
Ford	Persson 2002[148]	Retro-MUS	Lap colpo		L	L	U	L				L				
Ford	Ustün 2003[149]	Retro-MUS	Lap colpo		U	U	U	U				L				
Ford	Valpas 2004[150]	Retro-MUS	Lap colpo		L	L	U	U				L				
Saraswat	[c]Abouhashem 2014[38]	Retro-MUS	Trad sling		U	U					U	U				
Ford	Amaro 2007[151]	Retro-MUS	Trad sling		U	U	L	U				U				
Ford	Arunkalaivanan 2003[152]	Retro-MUS	Trad sling		U	U	U	U				U				
Ford	Basok 2008[153]	Retro-MUS	Trad sling		U	U	U	U				U				
Saraswat	Guerrero 2008[92]	Retro-MUS	Trad sling		L	L					L	L				
Ford	Kondo 2006[106]	Retro-MUS	Trad sling		H	H	U	U				L				
Saraswat	Sharifiaghdas 2008[81]	Retro-MUS	Trad sling		U	U					U	L				
Ford	Song 2004[154]	Retro-MUS	Trad sling		U	U	U	U				U				
Nambiar	Abdelwahab 2010[155]	Retro-MUS	Single incision		U	U	U	U				L				
Nambiar	Andrada Hamer 2011[156]	Retro-MUS	Single incision		U	L	H	L				H				
Nambiar	Barber 2012[87]	Retro-MUS	Single incision		L	L	L	L				H				
Nambiar	Basu 2010[157]	Retro-MUS	Single incision		L	L	L	U				L				
New	Gopinath 2013[158]	Retro-MUS	Single incision		U	U	U		U	U			U	U	U	U
New	[c]Lee 2015[62]	Retro-MUS	Single incision		U	U	U		U	U			U	U	L	U
New	Ross 2014[159]	Retro-MUS	Single incision		L	L	H		L	H			L	L	L	U

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Ford	Wadie 2005[160]	Retro-MUS	Ant repair		L	L	U	U				L				
Lapitan	Bandarian 2011[161]	Trans-MUS	Open colpo		U	U	U	U				U				U
Lapitan	[c]El-Din Shawki 2012[47]	Trans-MUS	Open colpo	Ant repair	U	U	U	U				U				U
Lapitan	Sivaslioglu 2007[162]	Trans-MUS	Open colpo		L	U	H	U				L				U
Freites	Samiee 2009[163]	Trans-MUS	Lap colpo		U	U	U	U				U			U	U
New	Al-Azzawi 2014[164]	Trans-MUS	Trad sling		L	U	H		H	U			L	L	U	U
Ford	Silva-Filho 2006[165]	Trans-MUS	Trad sling		U	U	U	U				U				
Saraswat	Tcherniakovsky 2009[166]	Trans-MUS	Trad sling		U	U					U	L				
Nambiar	Amat 2011[112]	Trans-MUS	Single incision		H	U	H	U				H				
Nambiar	[d]Bianchi 2012[25]	Trans-MUS	Single incision		L	L	U		U	L			L	L	L	U
New	Campos 2013[176]	Trans-MUS	Single incision		L	L	H		H	U			L	L	H	U
New	[c]Dati 2012[43]	Trans-MUS	Single incision		U	U	U		U	U			U	U	H	U
Nambiar	[d]Djehdian 2010[27]	Trans-MUS	Single incision		L	L	H		H	U			L	L	L	U
Nambiar	Enzelsberger 2010[170]	Trans-MUS	Single incision		U	U	U	U				L				
New	[c]Enzelsberger 2011[50]	Trans-MUS	Single incision		U	U	U		U	U			U	U	U	U
New	[c]Fernandez 2015[52]	Trans-MUS	Single incision		L	U	U		H	H			L	L	L	U
New	Foote 2015[171]	Trans-MUS	Single incision		U	U	U		U	H			L	L	L	U
Nambiar	[c]Friedman 2009[54]	Trans-MUS	Single incision		U	U	U	U				L				
New	Gaber 2016[91]	Trans-MUS	Single incision		L	U	H		L	L			L	L	H	U
Nambiar	Hinoul 2011[172]	Trans-MUS	Single incision		L	U	H	U				H				
Nambiar	Hota 2012[173]	Trans-MUS	Single incision		U	L	H	U				H				
New	Jurakova 2016[113]	Trans-MUS	Single incision		U	U	H		H	H			L	L	L	U
Nambiar	[c]Kim 2010[59]	Trans-MUS	Single incision		U	U	U	U				U				
Nambiar	[d]Lee 2012[28]	Trans-MUS	Single incision		L	L	H		H	U			U	U	L	U

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Nambiar	Mackintosh 2010[174]	Trans-MUS	Single incision		L	L	H	L				L				
Nambiar	Masata 2012[167]	Trans-MUS	Single incision		L	L	H	U				U				
New	Masata 2013[101]	Trans-MUS	Single incision		L	L	H		H	U			L	L	L	U
New	Maslow 2014[175]	Trans-MUS	Single incision		L	L	H		U	L			H	H	L	U
New	[c]Melendez Munoz 2016[65]	Trans-MUS	Single incision		L	U	H		H	U			U	U	L	U
New	[c]Merali 2012[66]	Trans-MUS	Single incision		U	U	U		U	U			U	L	U	U
Nambiar	Mostafa 2012[204]	Trans-MUS	Single incision		L	L	H	L				U				
Nambiar	Oliveira 2011[168]	Trans-MUS	Single incision		U	U	U	U				L				
New	Pastore 2016[114]	Trans-MUS	Single incision		L	U	U		U	U			L	L	L	U
New	Schellart 2013[177]	Trans-MUS	Single incision		U	U	H		H	H			L	L	L	U
Nambiar	[d]Schweitzer 2012[29]	Trans-MUS	Single incision		L	L	H		L	L			H	H	L	U
Nambiar	[c]Seo 2011[74]	Trans-MUS	Single incision		U	U	U	U				U				
New	[c]Shawky 2015[75]	Trans-MUS	Single incision		U	U	U		U	U			U	L	H	U
Nambiar	Sivaslioglu 2012[178]	Trans-MUS	Single incision		L	U	U	L				L				
Nambiar	[d]Smith 2011[30]	Trans-MUS	Single incision		L	U	H		H	H			L	L	L	U
Nambiar	Sottner 2012[169]	Trans-MUS	Single incision		U	U	U	U				U				
New	Tang 2014[179]	Trans-MUS	Single incision		U	U	H		H	H			L	L	L	U
Nambiar	Tommaselli 2010[180]	Trans-MUS	Single incision		L	U	H	U				H				
New	[c]Van Rensburg 2015[79]	Trans-MUS	Single incision		L	U	H		H	U			U	U	L	U
New	Xin 2016[115]	Trans-MUS	Single incision		L	U	U		U	L			U	U	L	U
Nambiar	[c]Yoon 2011[80]	Trans-MUS	Single incision		U	U	U	U				U				
New	Salari 2010[127]	Trans-MUS	Ant repair		L	U	U		U	L			L	L	L	U
New	Labrie 2012[95]	Trans-MUS	PFMT		L	H	H		H	U			L	L	L	U
Lapitan	Ankardal 2001[85]	Open colpo	Lap colpo		U	L	U	U				U				U

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Lapitan	Burton 1994[40]	Open colpo	Lap colpo		U	U	U	U				L				U
Lapitan	Carey 2000[89]	Open colpo	Lap colpo		L	U	L	L				U				U
Lapitan	[c]Fatthy 2001[51]	Open colpo	Lap colpo		L	L	U	U				U				U
Lapitan	Kitchener 2006[93]	Open colpo	Lap colpo		L	L	H	H				L				U
Lapitan	Mak 2000[182]	Open colpo	Lap colpo		L	L	U	U				U				U
Lapitan	[c]Morris 2001[68]	Open colpo	Lap colpo		U	U	U	U				U				U
Lapitan	[c]Stangel-Wojcikiewicz 2008[76]	Open colpo	Lap colpo		U	U	U	U				U				U
Lapitan	Su 1997[183]	Open colpo	Lap colpo		L	L	U	U				U				U
Lapitan	[c]Summitt 2000[77]	Open colpo	Lap colpo		U	L	U	U				U				U
Lapitan	Tuygun 2006[184]	Open colpo	Lap colpo		U	U	U	U				L				U
Lapitan	Ustün 2005[185]	Open colpo	Lap colpo		L	L	U	U				L				U
Lapitan	Albo 2007[82]	Open colpo	Trad sling		L	U	H	H				L				U
Lapitan	Demirci 2001[103]	Open colpo	Trad sling		H	H	U	U				U				U
Lapitan	Enzelsberger 1996[186]	Open colpo	Trad sling		L	U	U	U				U				U
Lapitan	[c]Fischer 2001[53]	Open colpo	Trad sling		U	U	U	U				U				U
Lapitan	Henriksson 1978[105]	Open colpo	Trad sling		H	H	U	U				U				U
Lapitan	Sand 2000[187]	Open colpo	Trad sling		L	U	U	U				U				U
Lapitan	Athanassopoulos 1996[111]	Open colpo	Bladder neck needle		H	H	U	U				U				U
Lapitan	Bergman 1989a[88]	Open colpo	Bladder neck needle	Ant repair	L	U	U	U				L				U
Lapitan	Bergman 1989b[188]	Open colpo	Bladder neck needle	Ant repair	L	U	U	U				U				U

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Lapitan	German 1994[190]	Open colpo	Bladder neck needle		U	U	U	U				U				U
Lapitan	Gilja 1998[189]	Open colpo	Bladder neck needle		L	U	U	U				H				U
Lapitan	Mundy 1983[109]	Open colpo	Bladder neck needle		H	H	U	U				U				U
Lapitan	Palma 1985[191]	Open colpo	Bladder neck needle		U	U	L	L				U				U
Lapitan	Berglund 1996[192]	Open colpo	Ant repair		U	U	U	U				U				U
Lapitan	Colombo 2000[193]	Open colpo	Ant repair		L	H	U	U				L				U
Lapitan	Holmes 1985[194]	Open colpo	Ant repair		L	U	U	U				U				U
Lapitan	Kammerer-Doak 1999[195]	Open colpo	Ant repair		L	U	U	U				U				U
Lapitan	Liapis 1996[200]	Open colpo	Ant repair		L	U	U	U				U				U
Lapitan	[c]Tapp 1989[78]	Open colpo	PFMT		U	U	U	U				U				U
New	Sharifiaghdas 2015[197]	Trad sling	Single incision		U	U	U		U	U			U	U	L	U
Saraswat	Maher 2005[102]	Trad sling	Injectable		U	U					U	L				
Saraswat	Hilton 1989[198]	Trad sling	Bladder neck needle		L	U					U	L				
Glazener	Di Palumbo 2003[199]	Bladder neck needle	Ant repair		U	L					U	L				

Source review[a]	Study ID (first author and year)	Intervention[b]			Risk-of-bias assessment criterion[b]											
		1	2	3	1	2	3	4a	4b	4c	5	6a	6b	6c	7	8
Risk					***1***	***2***	***3***	***4a***	***4b***	***4c***	***5***	***6a***	***6b***	***6c***	***7***	***8***
Low, *n* (%)					85 (49)	49 (28)	8 (5)	20 (15)	4 (11)	8 (22)	1 (14)	54 (39)	18 (50)	21 (58)	24 (65)	0 (0)
Unclear risk, *n* (%)					80 (46)	116 (66)	123 (73)	107 (81)	17 (47)	20 (56)	6 (86)	76 (55)	16 (44)	13 (36)	7 (19)	82 (100)
High risk, *n* (%)					10 (6)	10 (6)	37 (22)	5 (4)	15 (42)	8 (22)	0 (0)	9 (6)	2 (6)	2 (6)	6 (16)	0 (0)
Total, *n*					175	175	168	132	36	36	7	139	36	36	37	82

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; H, high; injectable, urethral injection therapy; L, low; lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; trans-MUS, transobturator mid-urethral sling; U, unclear.

a Source Cochrane reviews: Ford, Ford *et al.*[8] and Ogah *et al.*[18] – MUS operations for SUI in women; Lapitan, Lapitan *et al.*[5] – open retropubic colposuspension for UI in women; Freites, Freites *et al.*[6] and Dean *et al.*[20] – laparoscopic colposuspension for UI in women; Saraswat, Saraswat *et al.*[7] and Rehman *et al.*[19] – traditional suburethral sling operations for UI in women; Nambiar, Nambiar *et al.*[9] – single-incision sling operations for UI in women; Glazener, Glazener and Cooper[11] – bladder neck needle suspension for UI in women; new, studies identified by update search.

b Assessment criteria (domain): 1, random sequence generation (selection bias); 2, allocation concealment (selection bias); 3, blinding of participants and personnel (performance bias); 4a, blinding of outcome assessment (detection bias) – all outcomes; 4b, blinding of outcome assessment (detection bias) – patient-reported outcomes; 4c, blinding of outcome assessment (detection bias) – clinician-measured outcomes; 5, blinding (performance bias and detection bias); 6a, incomplete outcome data (attrition bias) – all outcomes; 6b, incomplete outcome data (attrition bias) – patient-reported outcomes; 6c, incomplete outcome data (attrition bias) – clinician-measured outcomes; 7, selective reporting (reporting bias); 8, other bias.

c Available as abstract only.

d Risk-of-bias assessment was updated as a new full-text paper was found for the study previously available as abstract in a Cochrane review.

Appendix 10 Network meta-analysis: total number of trials included in each treatment comparison for the number of women cured or improved

Intervention comparison	Cure, *n* (%) (*N* = 105)	Improvement, *n* (%) (*N* = 120)
Transob-MUS vs. retro-MUS	36 (34.3)	40 (33.3)
Open colpo vs. retro-MUS	6 (5.7)	6 (5.0)
Lap colpo vs. retro-MUS	2 (1.9)	4 (3.3)
Trad sling vs. retro-MUS	6 (5.7)	6 (5.0)
Single incision vs. retro-MUS	6 (5.7)	6 (5.0)
Open colpo vs. transob-MUS	1 (1.0)	1 (0.8)
Trad sling vs. transob-MUS	1 (1.0)	1 (0.8)
Single incision vs. transob-MUS	21 (20.0)	28 (23.3)
Ant repair vs. transob-MUS	1 (1.0)	1 (0.8)
PFMT vs. transob-MUS	1 (1.0)	1 (0.8)
Lap colpo vs. open colpo	9 (8.6)	9 (7.5)
Trad sling vs. open colpo	3 (2.9)	3 (2.5)
Bladder neck needle vs. open colpo	3 (2.9)	3 (2.5)
Anterior repair vs. open colpo	3 (2.9)	3 (2.5)
PFMT vs. open colpo	1 (1.0)	1 (0.8)
Single incision vs. trad sling	0 (0)	1 (0.8)
Bladder neck needle vs. trad sling	1 (1.0)	1 (0.8)
Transob-MUS vs. single-incision vs. retro-MUS	1 (1.0)	2 (1.7)
Open colpo vs. trad sling vs. retro-MUS	1 (1.0)	1 (0.8)
Bladder neck needle vs. anterior repair vs. open colpo	2 (1.9)	2 (1.7)

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

Appendix 11 Meta-analyses results: number of women cured

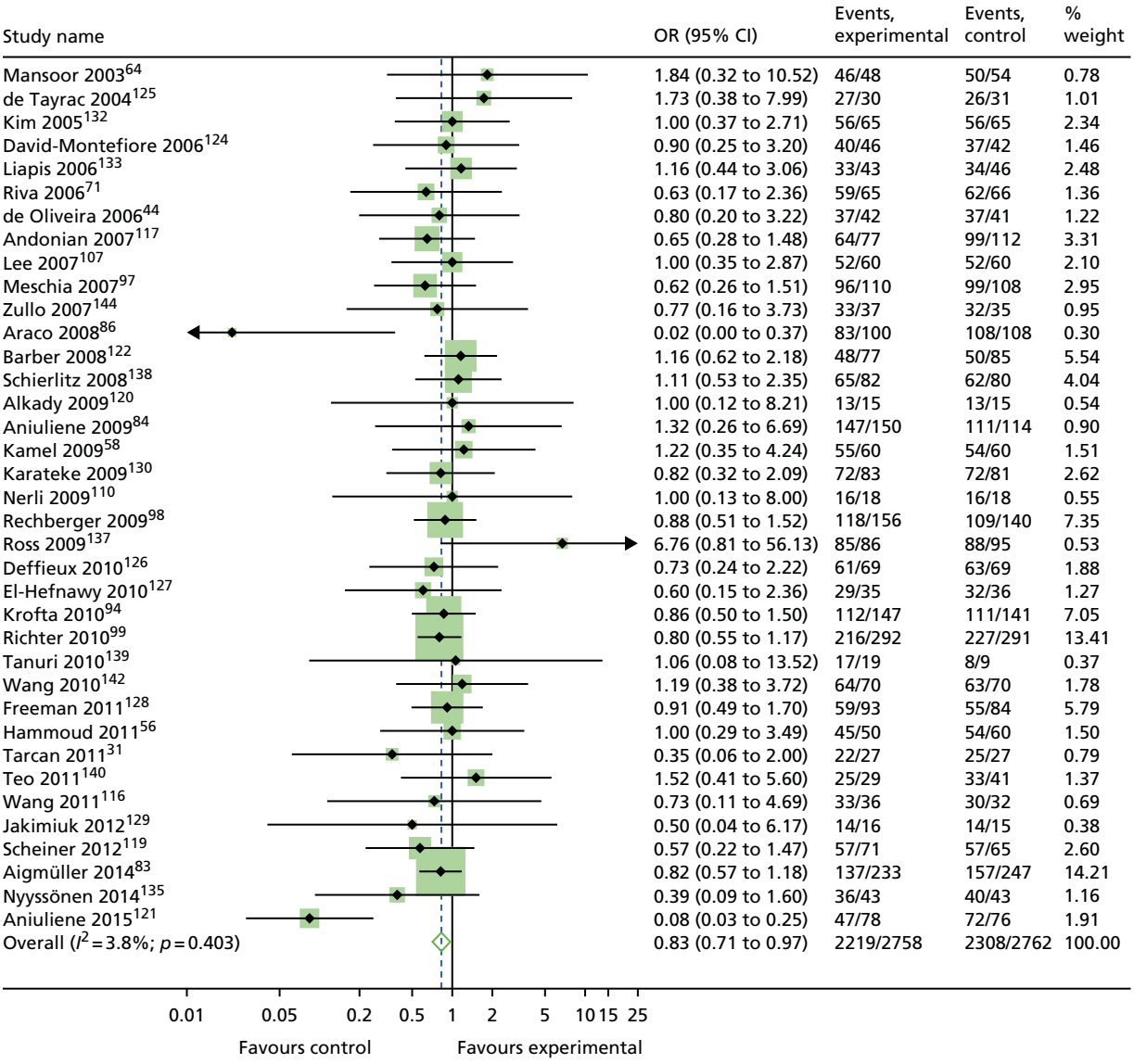

FIGURE 8 Transobturator MUS vs. retropubic MUS: cure.

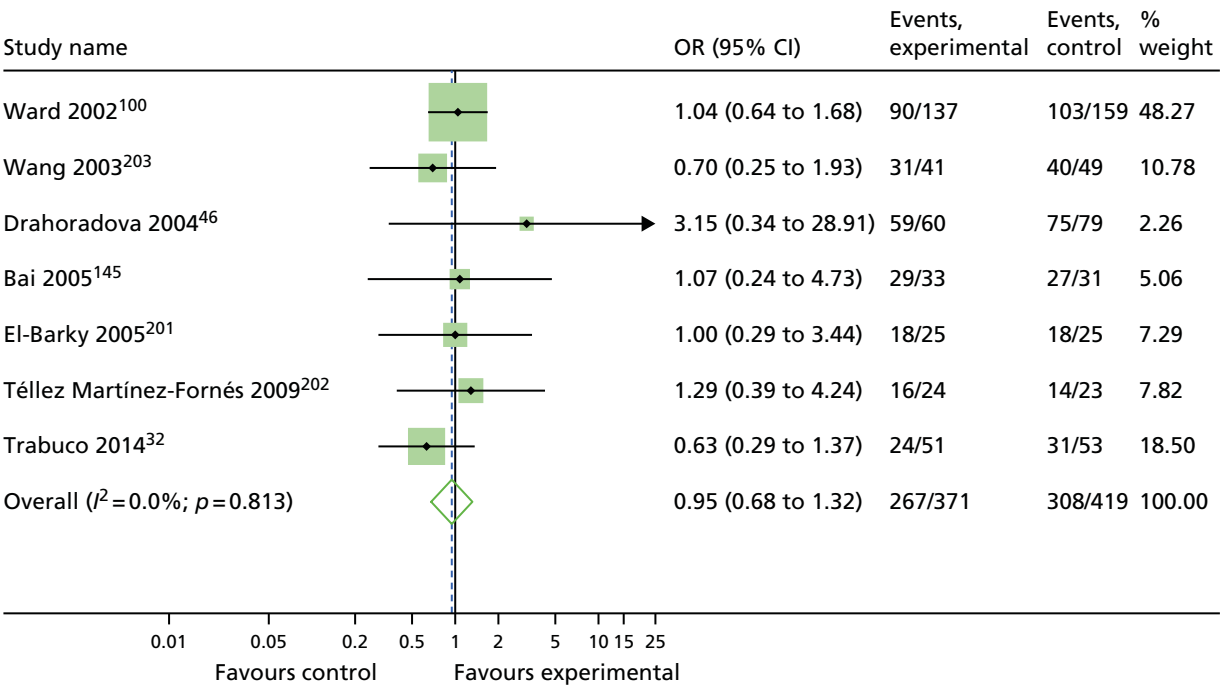

FIGURE 9 Open colposuspension vs. retropubic MUS: cure.

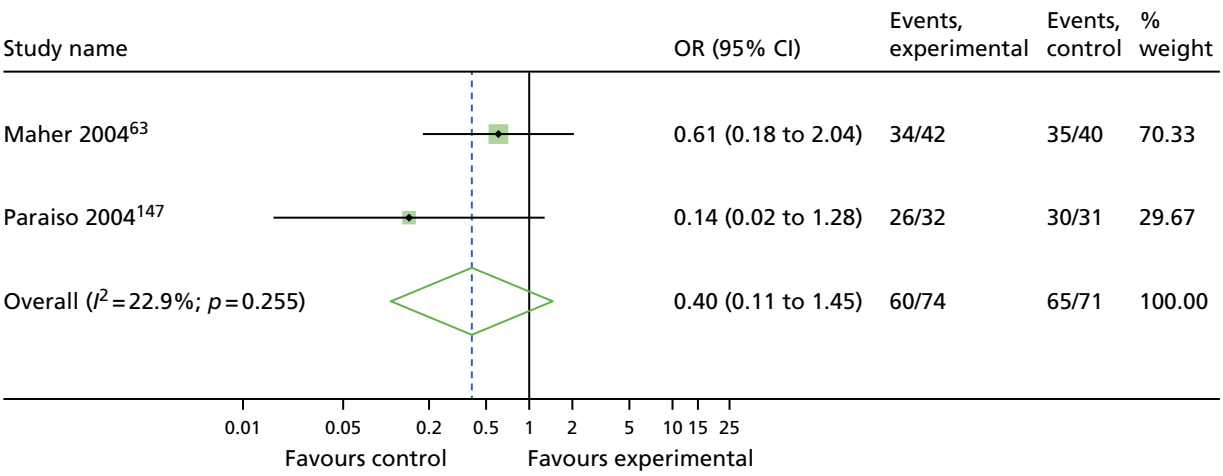

FIGURE 10 Laparoscopic colposuspension vs. retropubic MUS: cure.

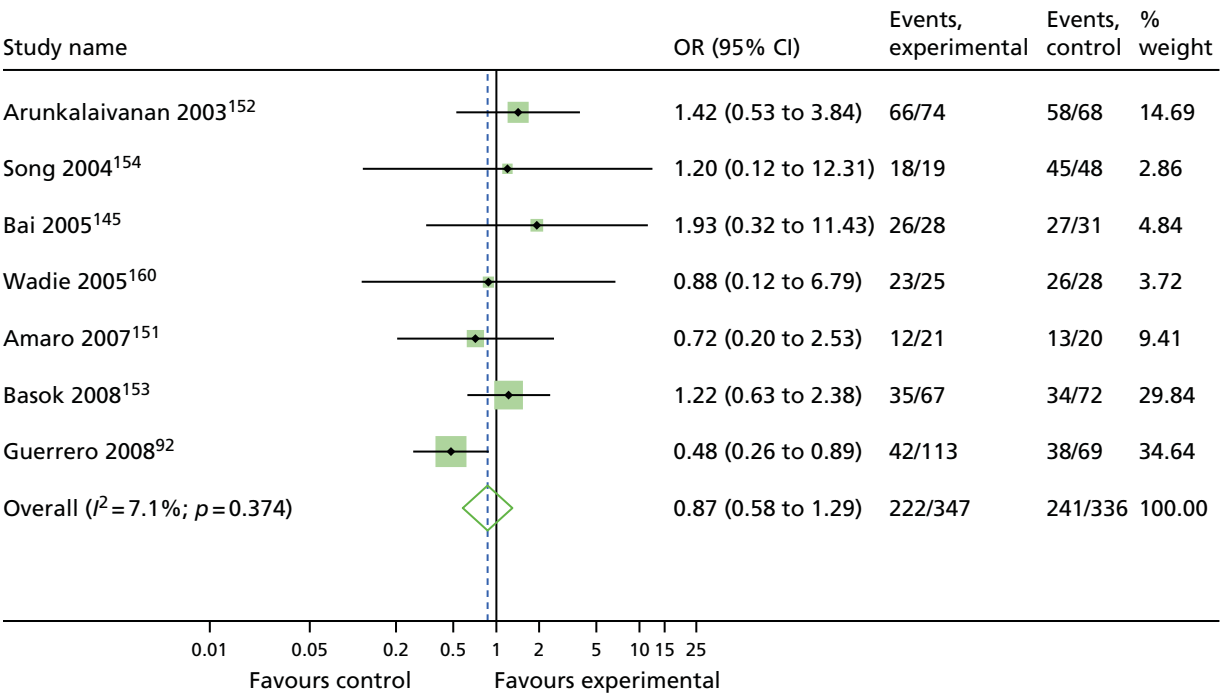

FIGURE 11 Traditional sling vs. retropubic MUS: cure.

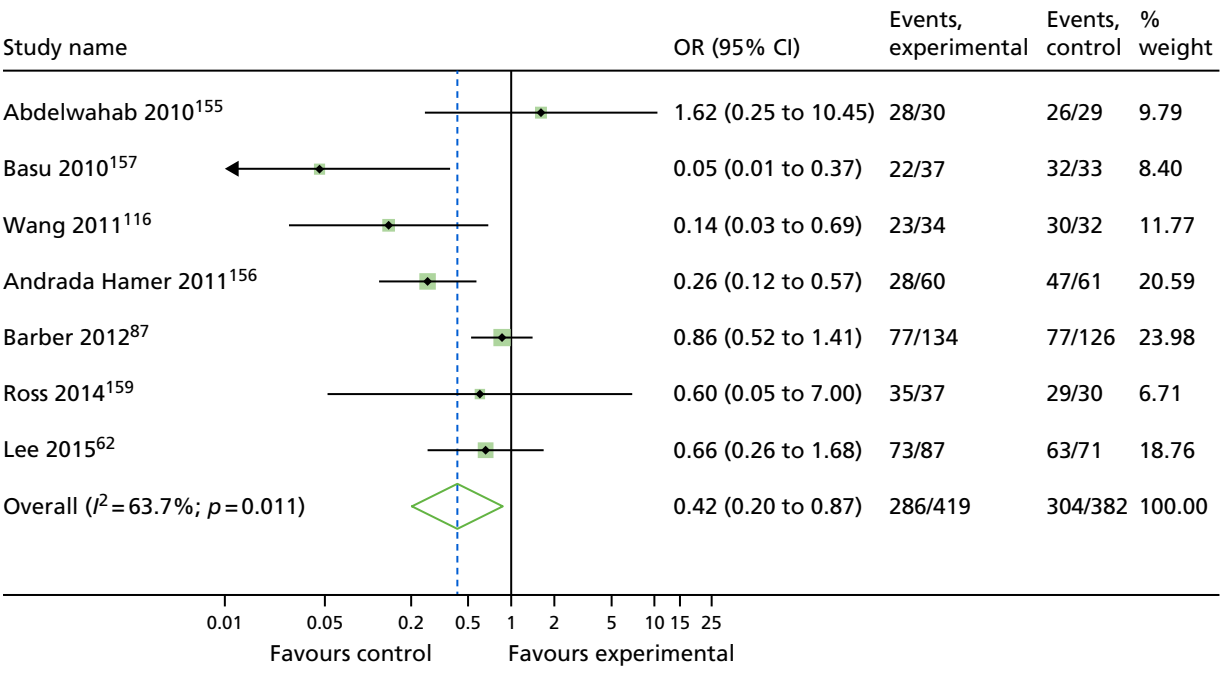

FIGURE 12 Single incision vs. retropubic MUS: cure.

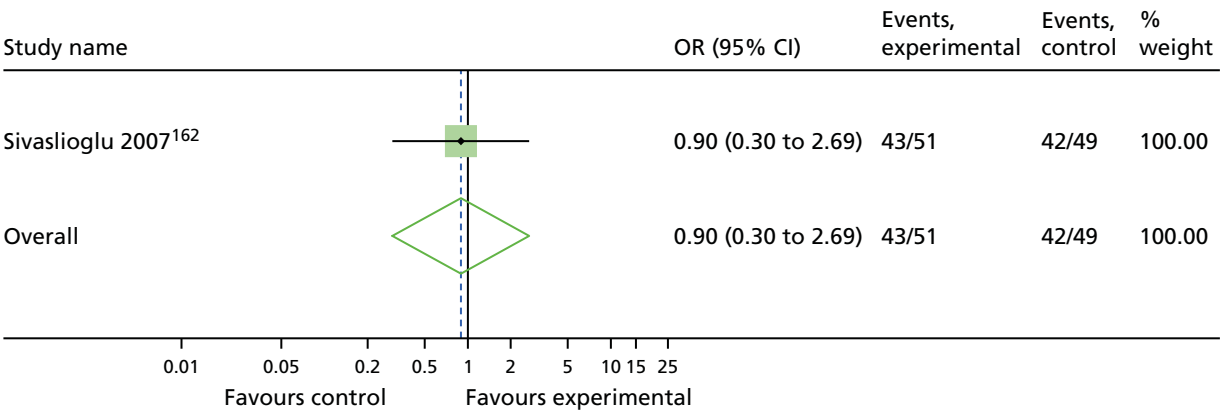

FIGURE 13 Open colposuspension vs. transobturator MUS: cure.

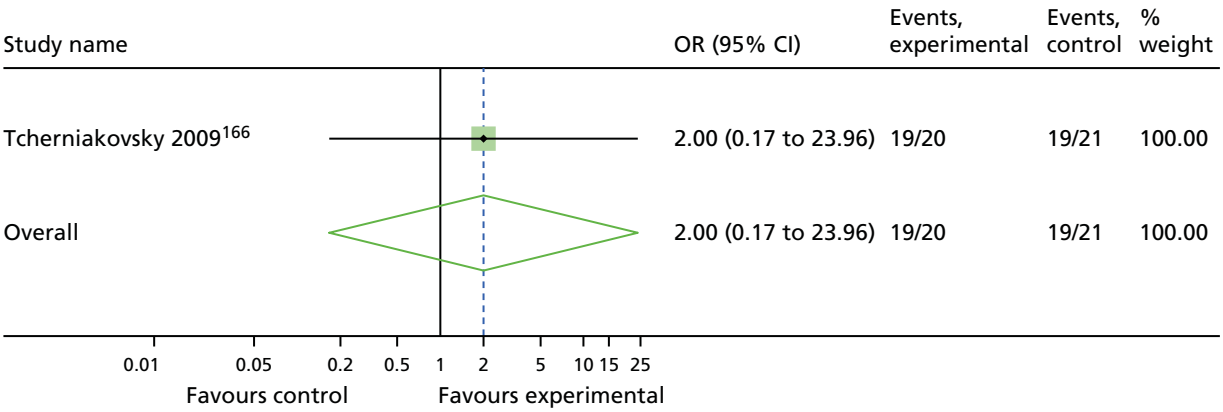

FIGURE 14 Traditional sling vs. transobturator MUS: cure.

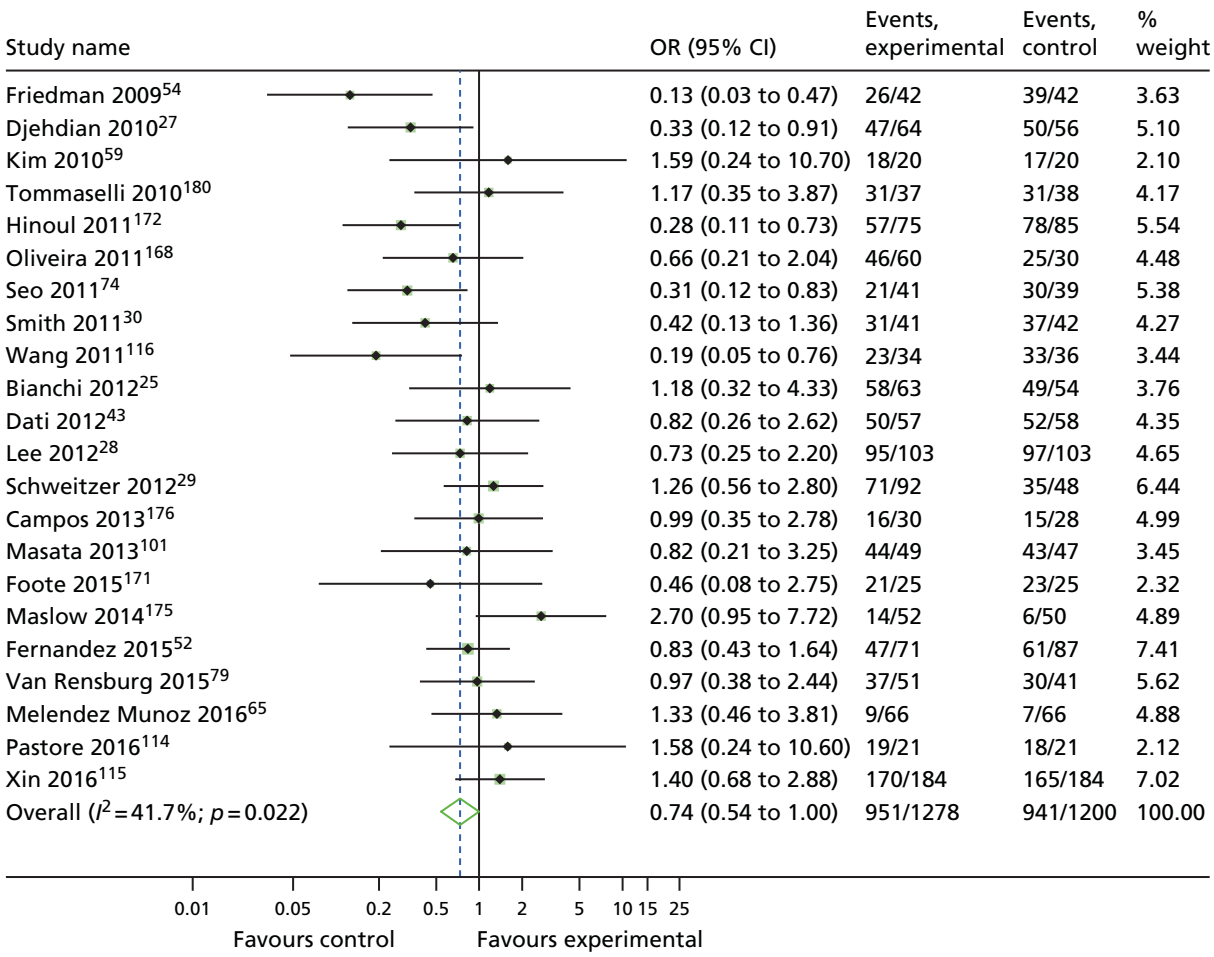

FIGURE 15 Single incision vs. transobturator MUS: cure.

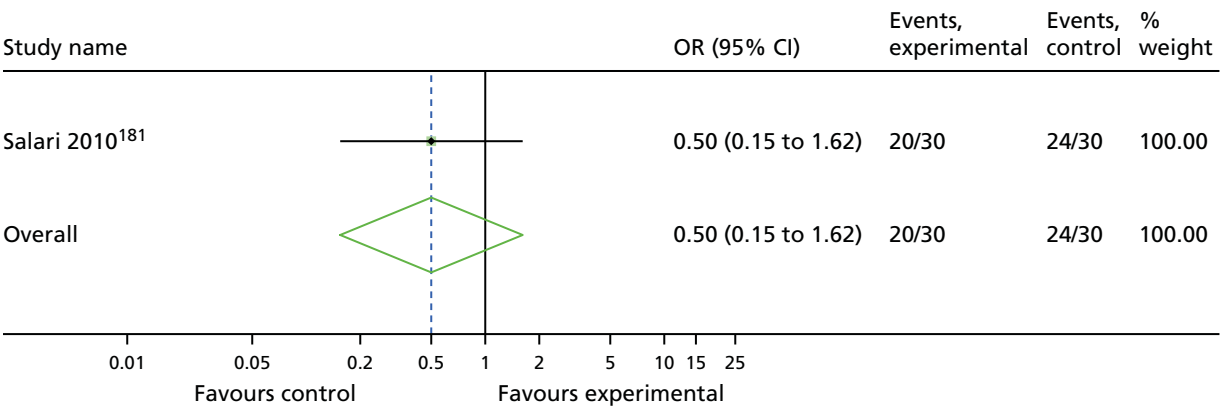

FIGURE 16 Anterior vaginal repair vs. transobturator MUS: cure.

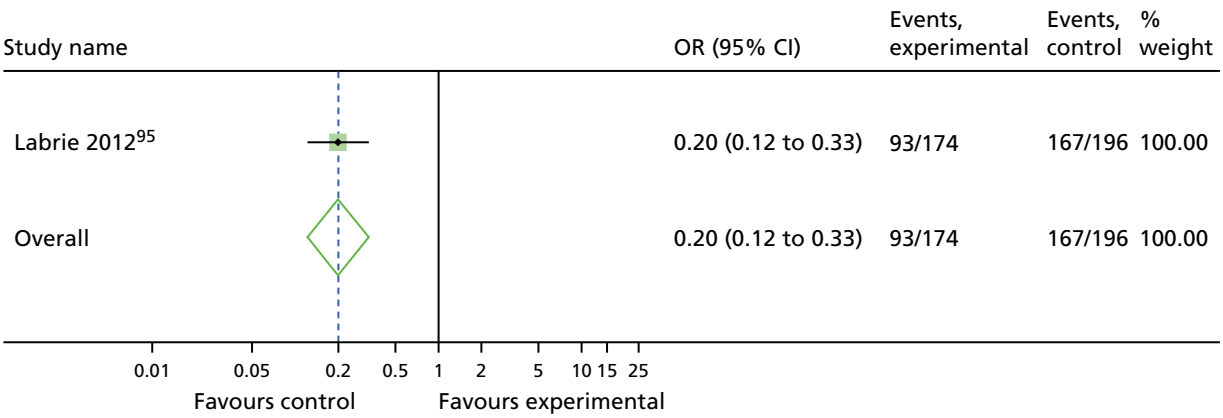

FIGURE 17 Pelvic floor muscle training vs. transobturator MUS: cure.

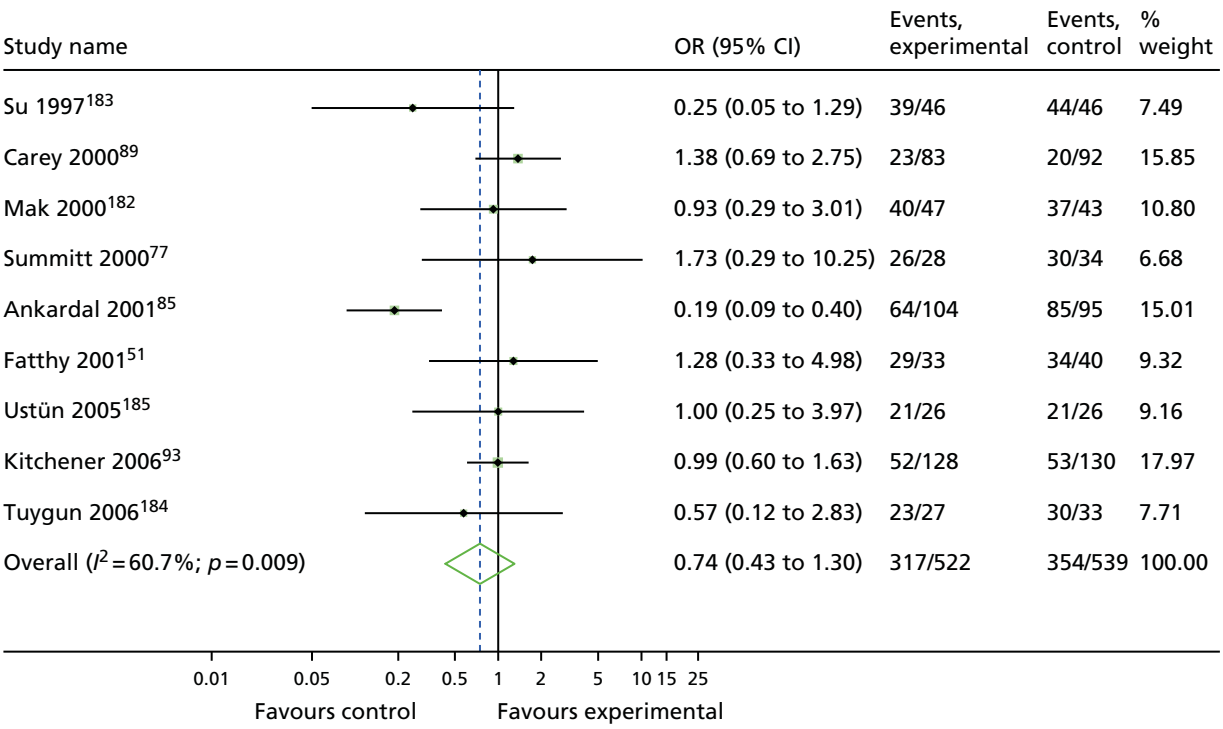

FIGURE 18 Laparoscopic colposuspension vs. open colposuspension: cure.

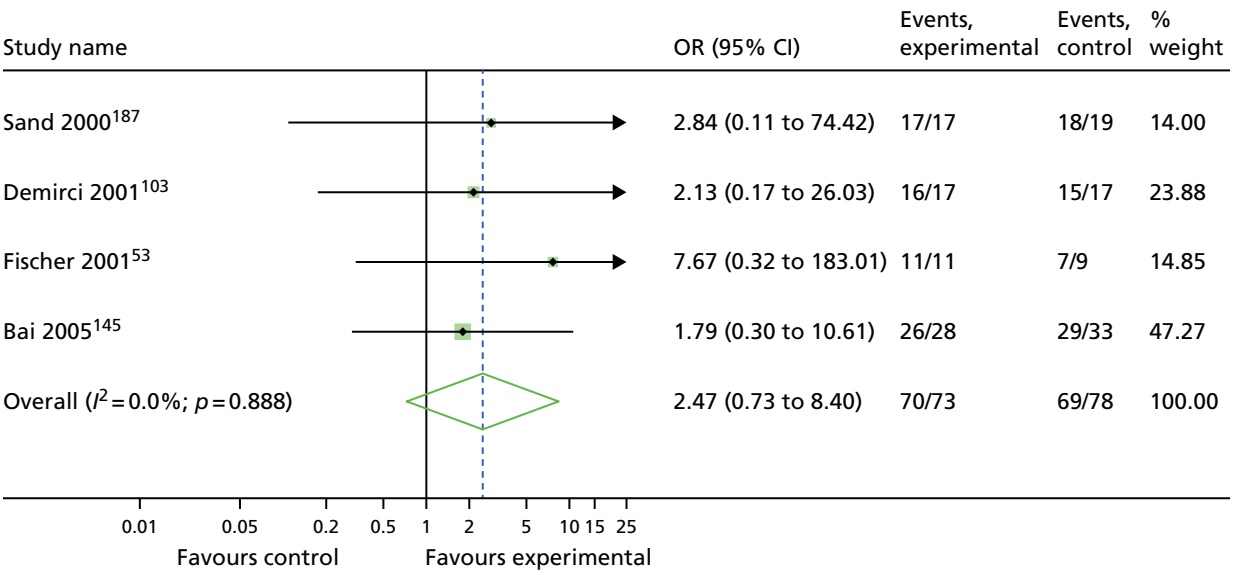

FIGURE 19 Traditional sling vs. open colposuspension: cure.

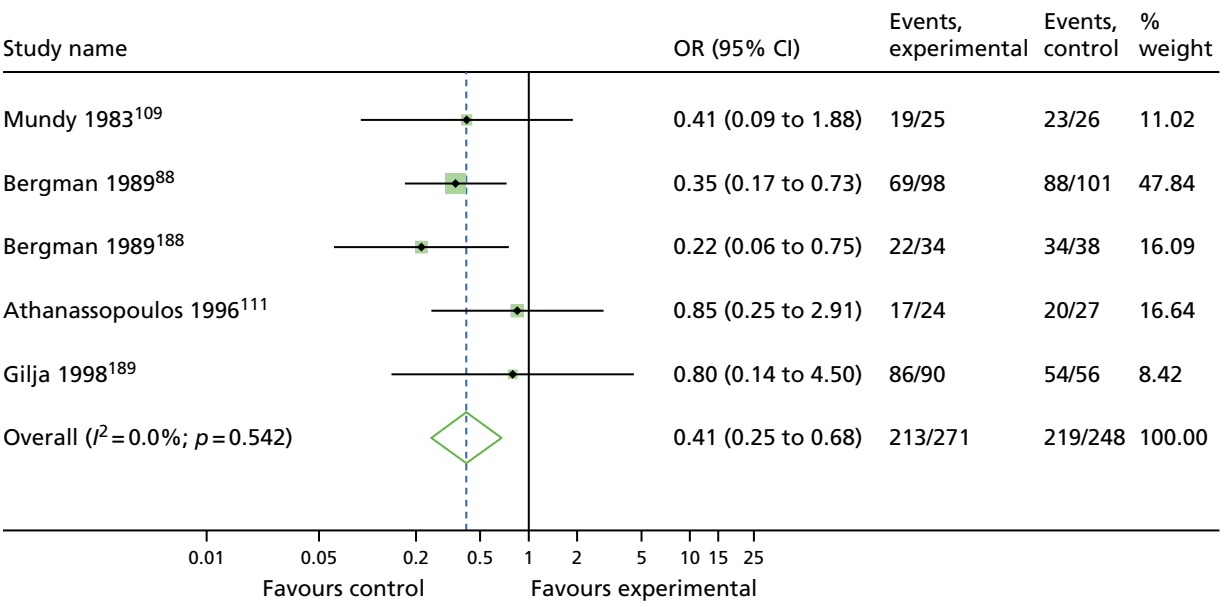

FIGURE 20 Bladder neck needle suspension vs. open colposuspension: cure.

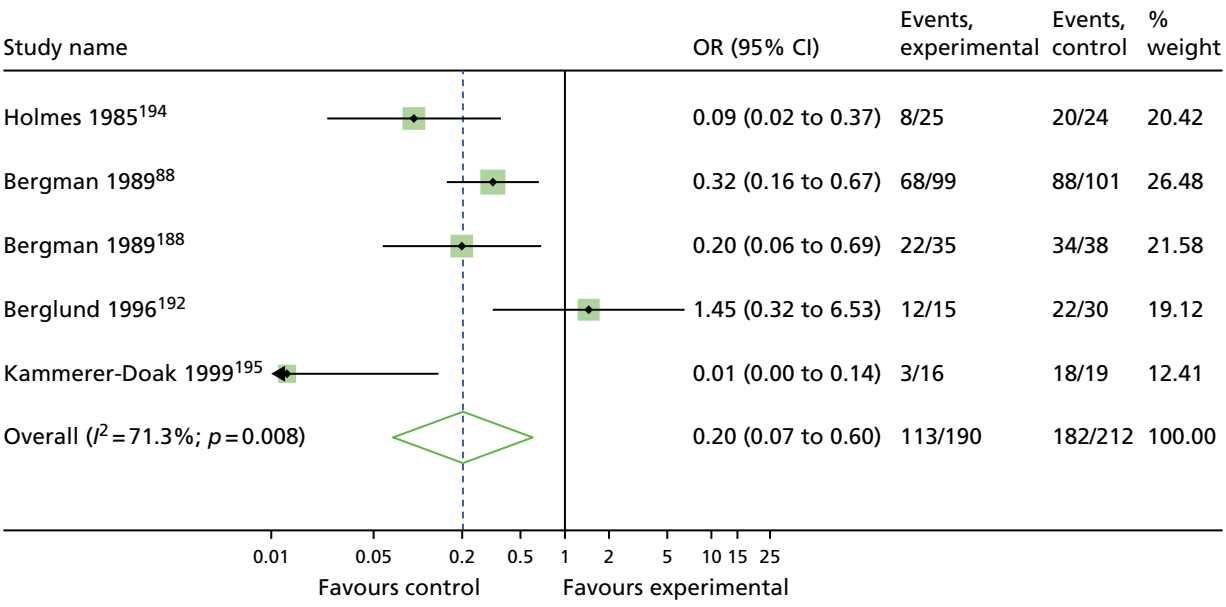

FIGURE 21 Anterior vaginal repair vs. open colposuspension: cure.

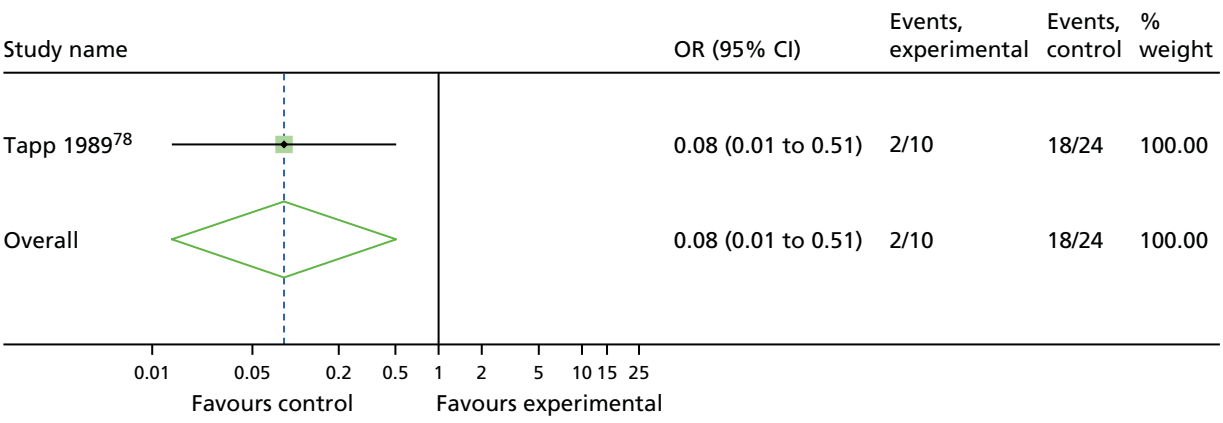

FIGURE 22 Pelvic floor muscle training vs. open colposuspension: cure.

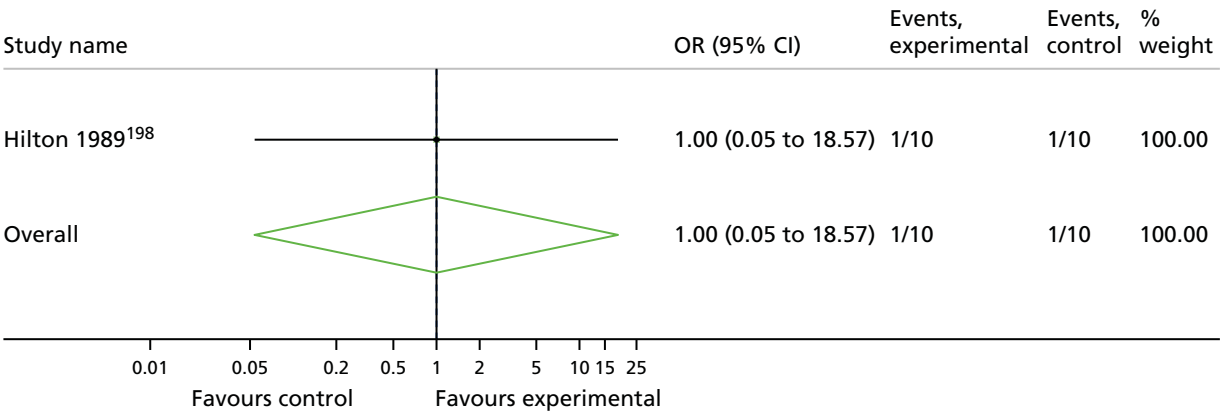

FIGURE 23 Bladder neck needle suspension vs. traditional sling: cure.

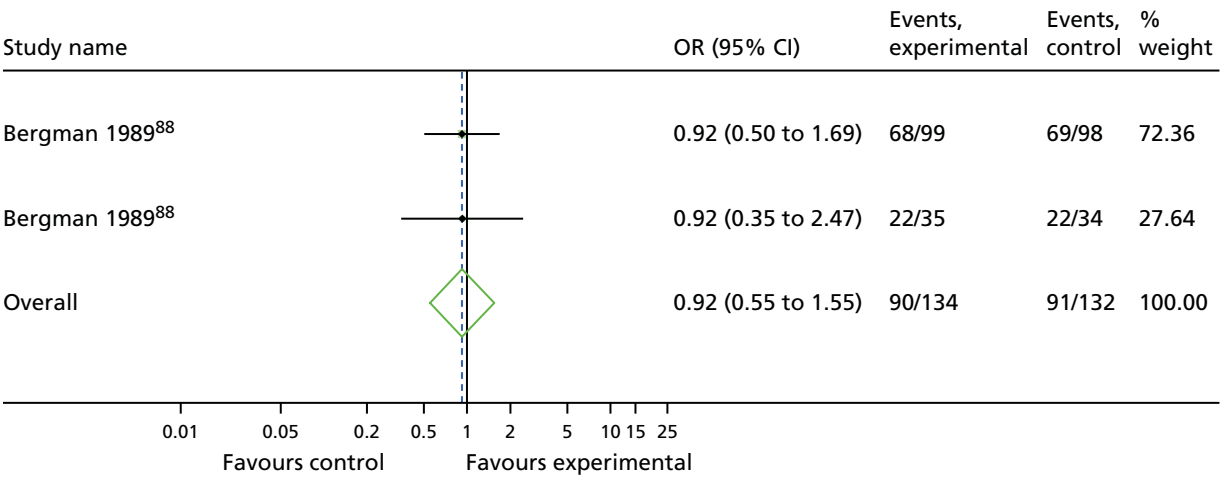

FIGURE 24 Anterior vaginal repair vs. bladder neck needle suspension: cure.

Appendix 12 Meta-analyses results: number of women improved

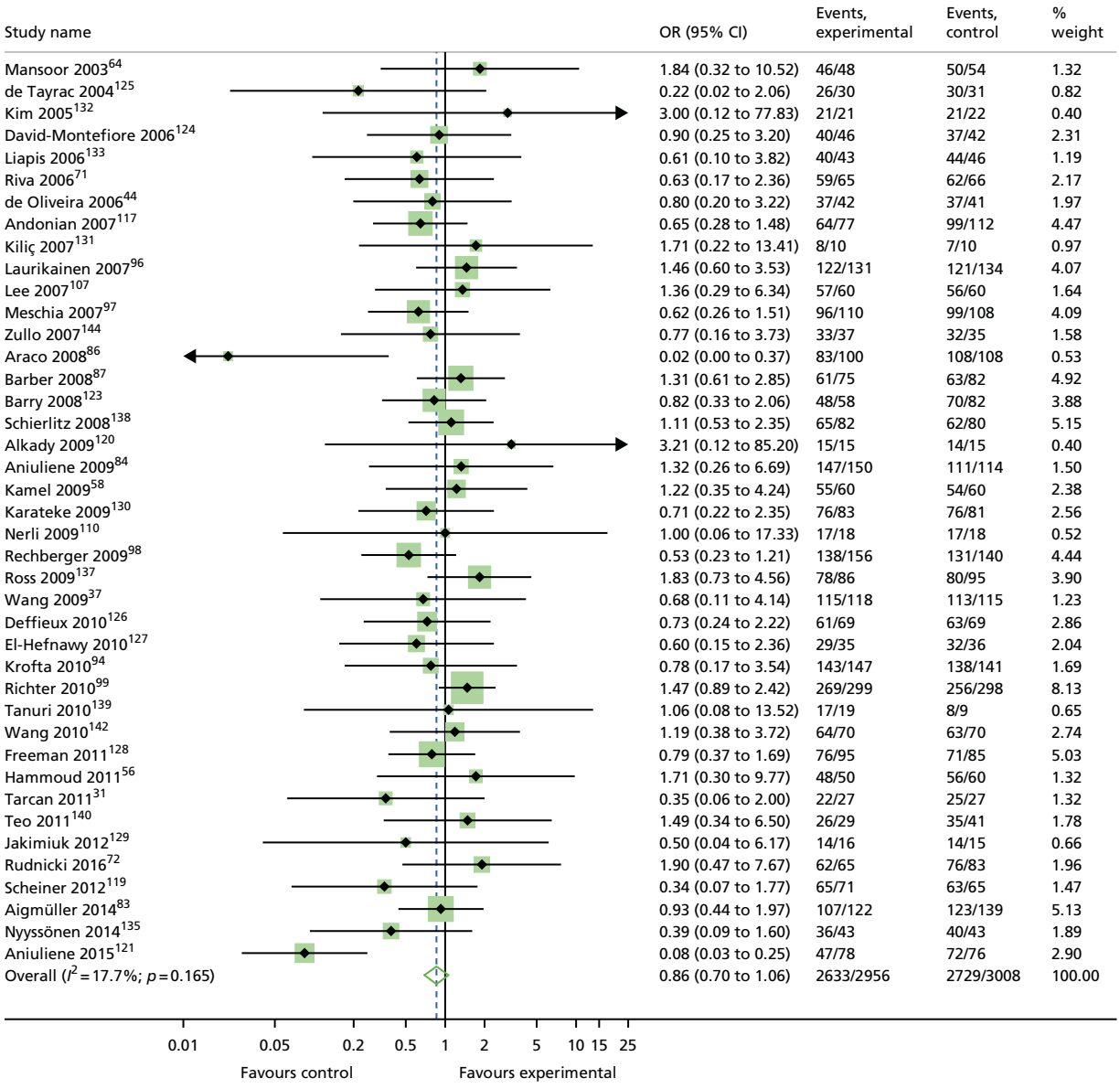

FIGURE 25 Transobturator MUS vs. retropubic MUS: improvement.

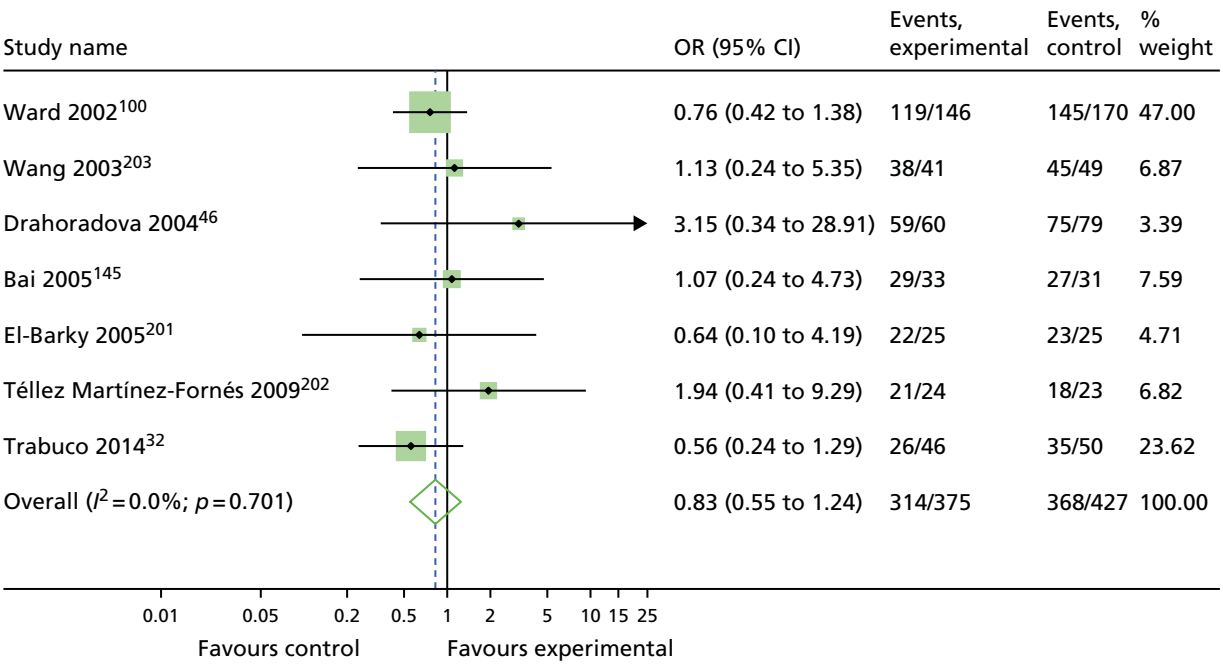

FIGURE 26 Open colposuspension vs. retropubic MUS: improvement.

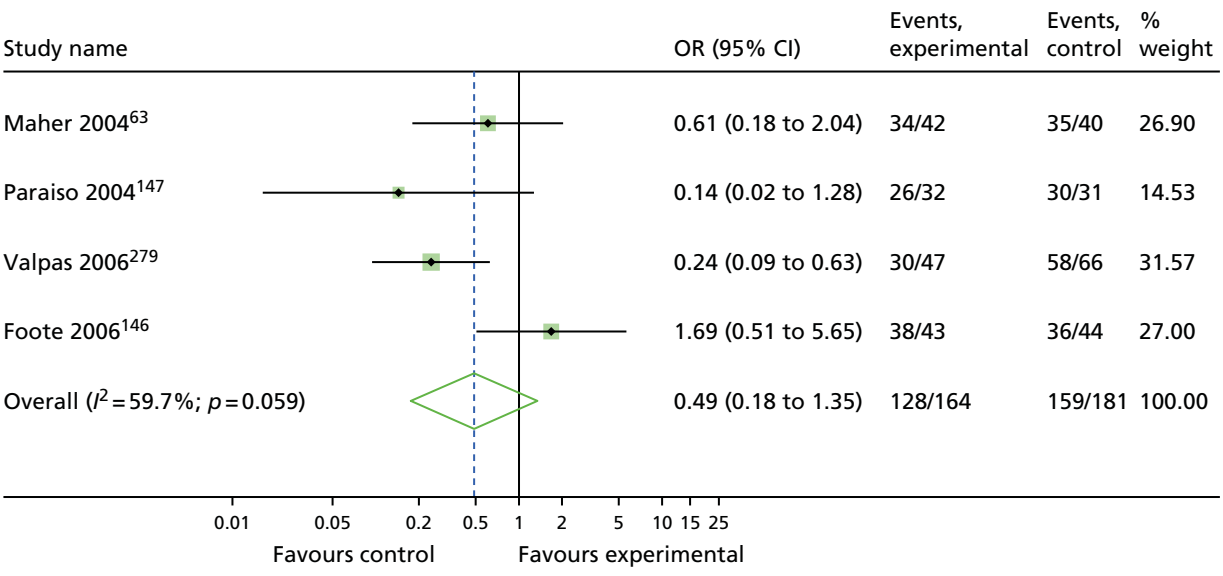

FIGURE 27 Laparoscopic colposuspension vs. retropubic MUS: improvement.

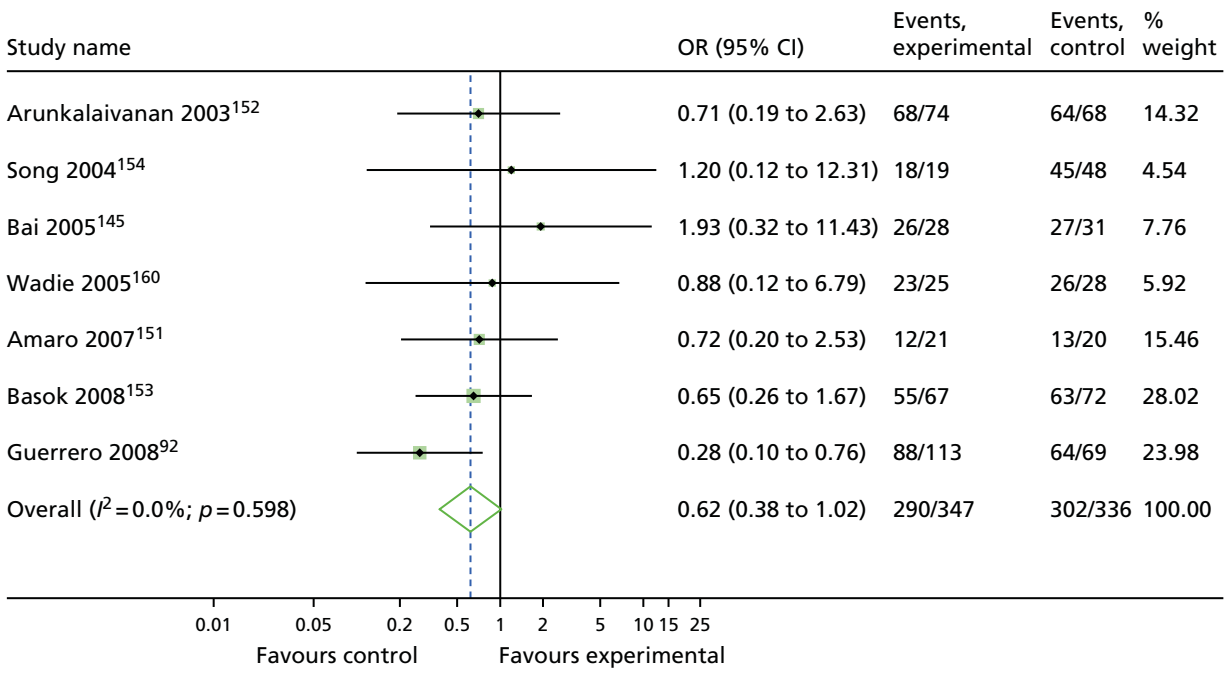

FIGURE 28 Traditional sling vs. retropubic MUS: improvement.

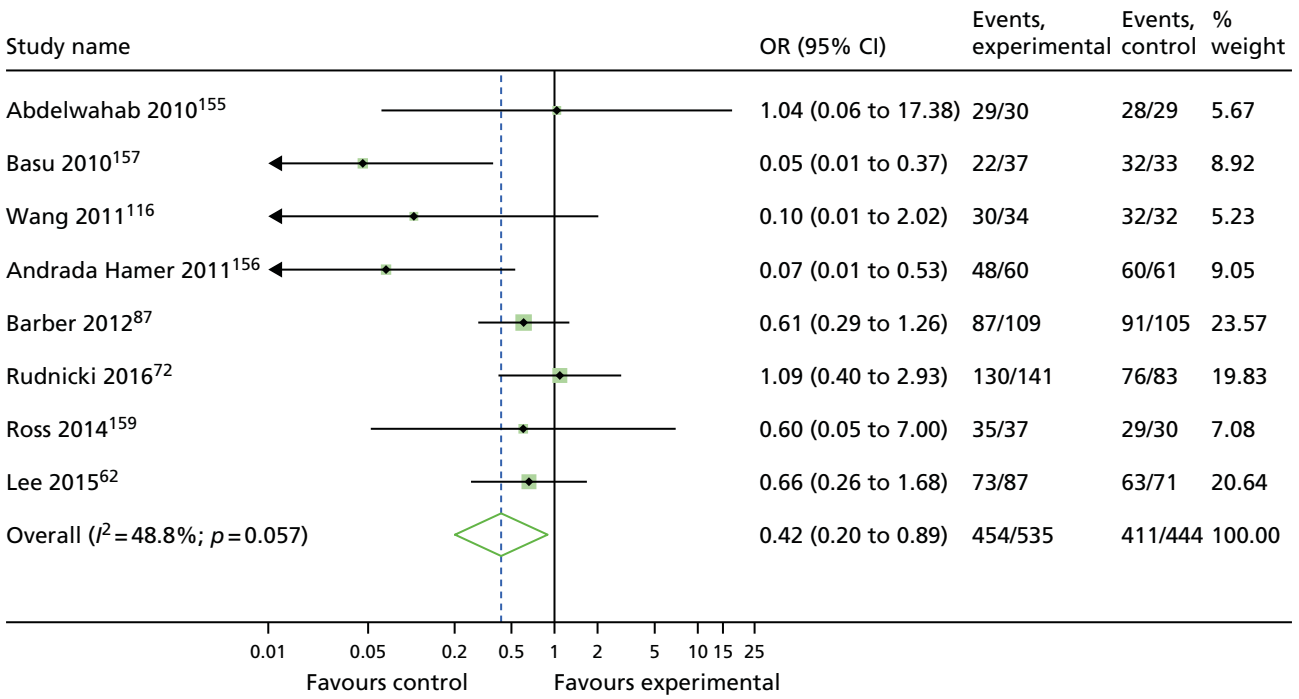

FIGURE 29 Single-incision sling vs. retropubic MUS: improvement.

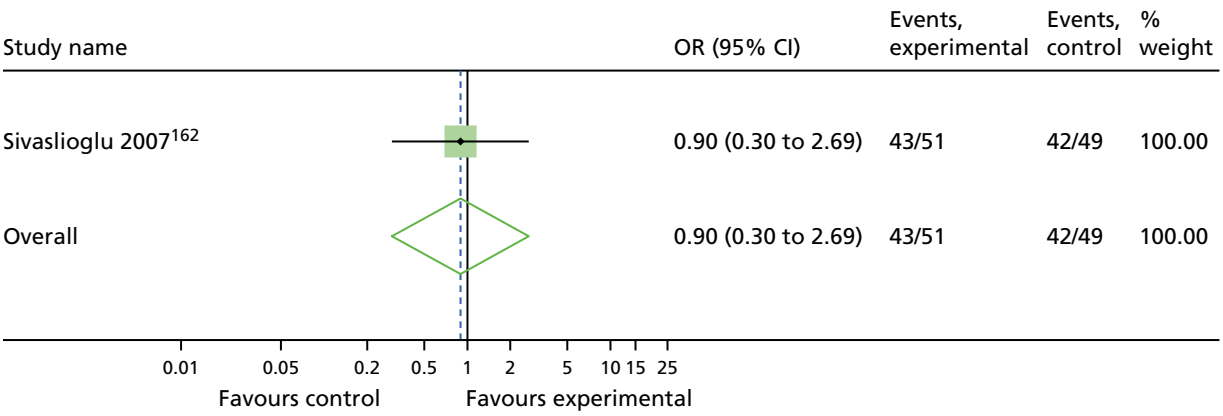

FIGURE 30 Open colposuspension vs. transobturator MUS: improvement.

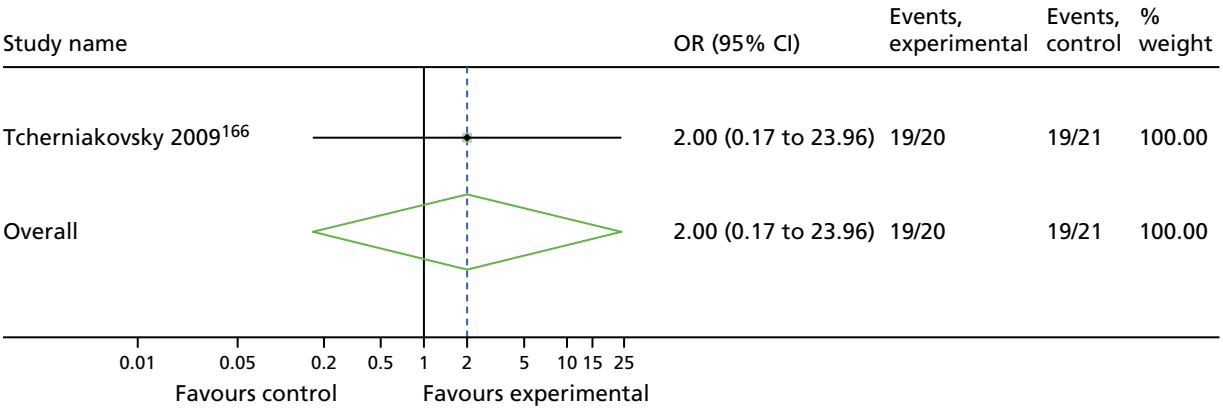

FIGURE 31 Traditional sling vs. transobturator MUS: improvement.

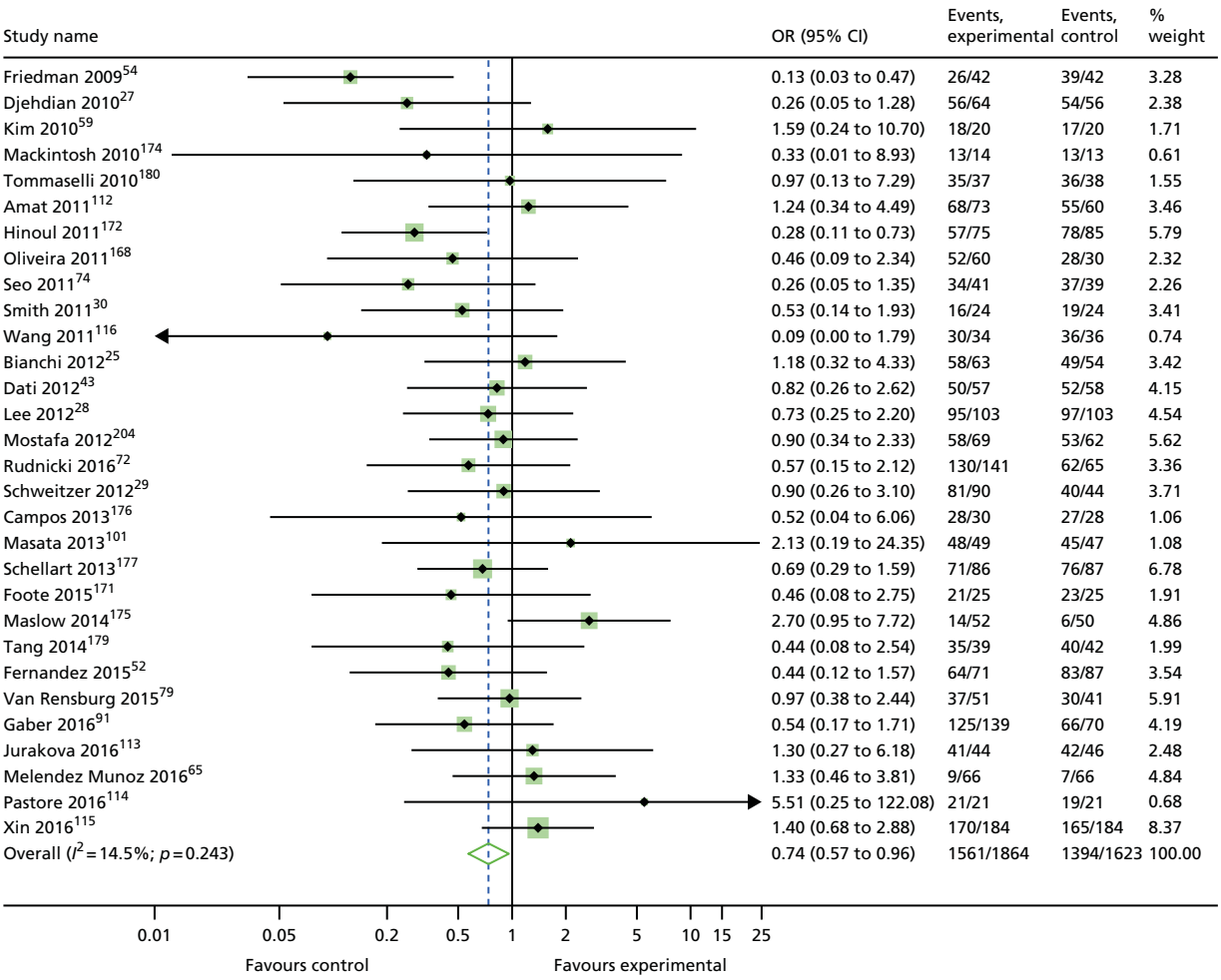

FIGURE 32 Single-incision sling vs. transobturator MUS: improvement.

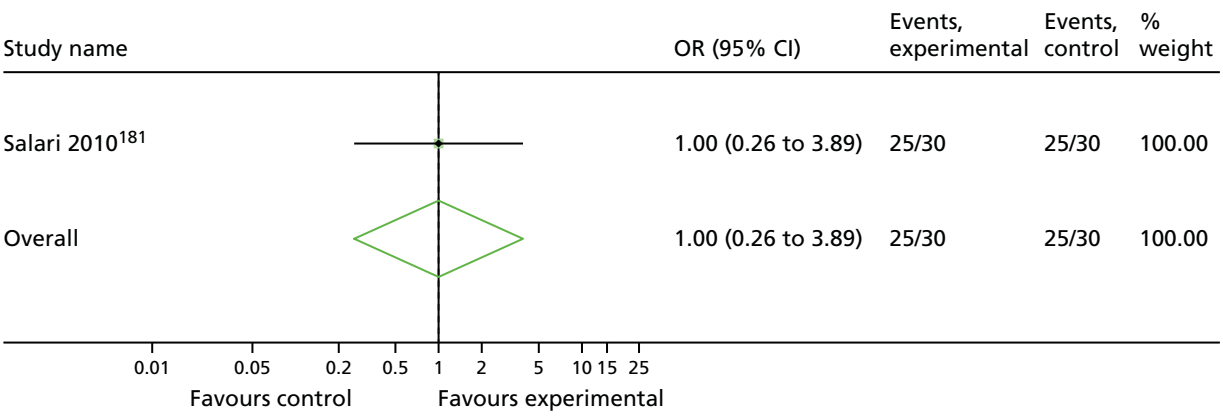

FIGURE 33 Anterior vaginal repair vs. transobturator MUS: improvement.

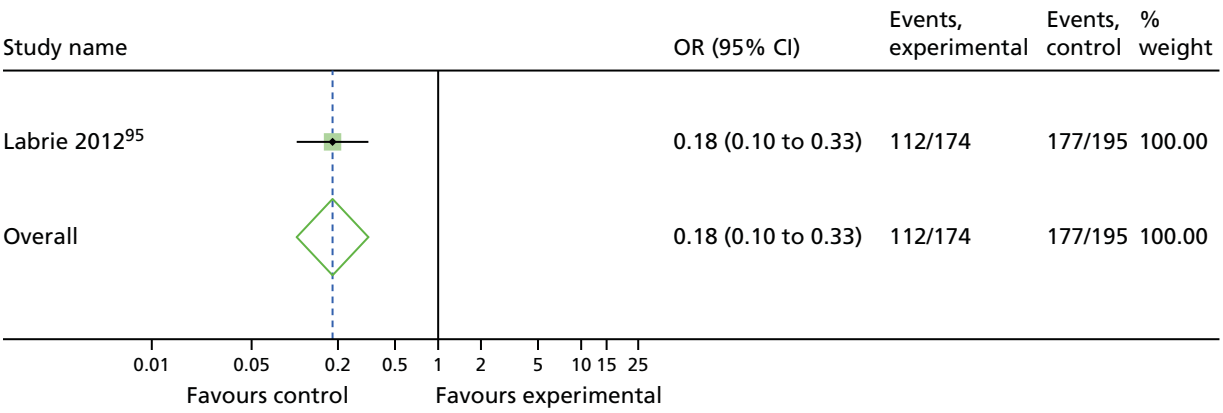

FIGURE 34 Pelvic floor muscle training vs. transobturator MUS: improvement.

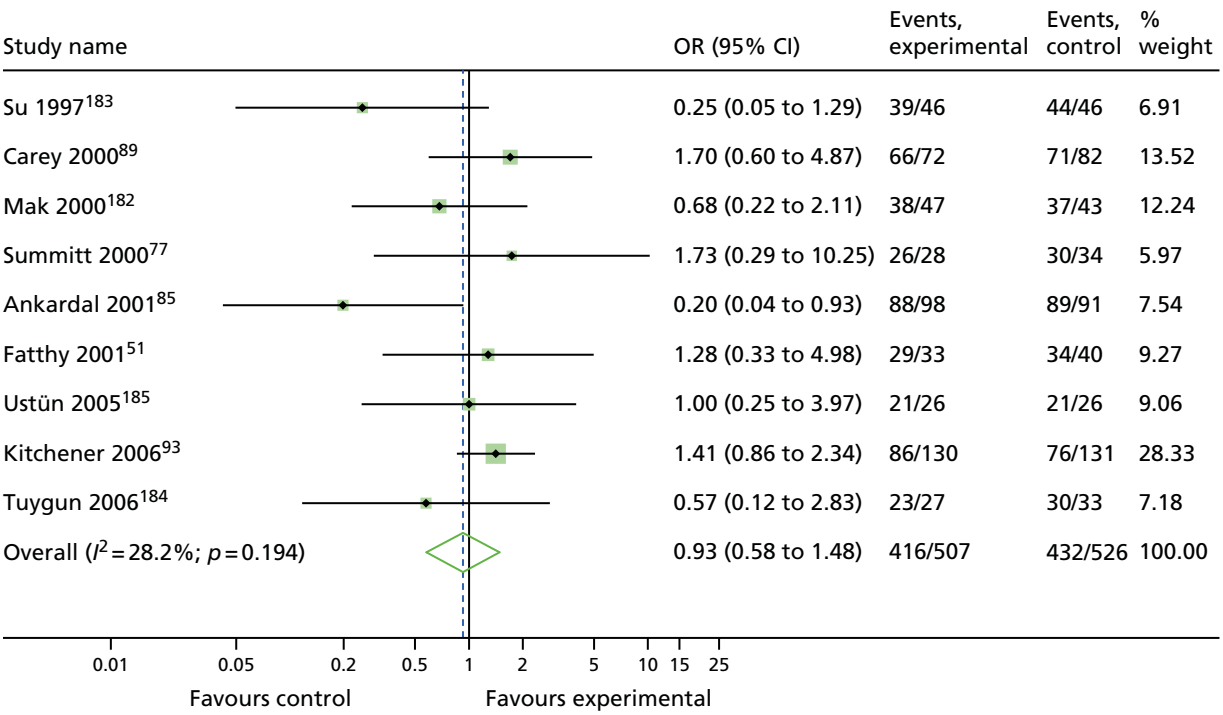

FIGURE 35 Laparoscopic colposuspension vs. open colposuspension: improvement.

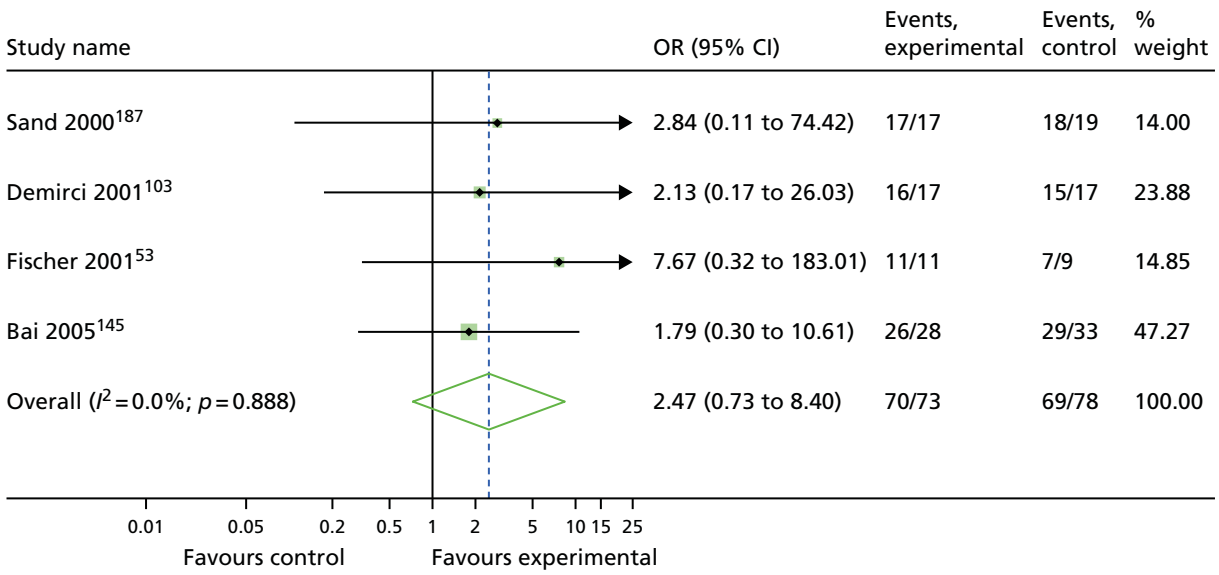

FIGURE 36 Traditional sling vs. open colposuspension: improvement.

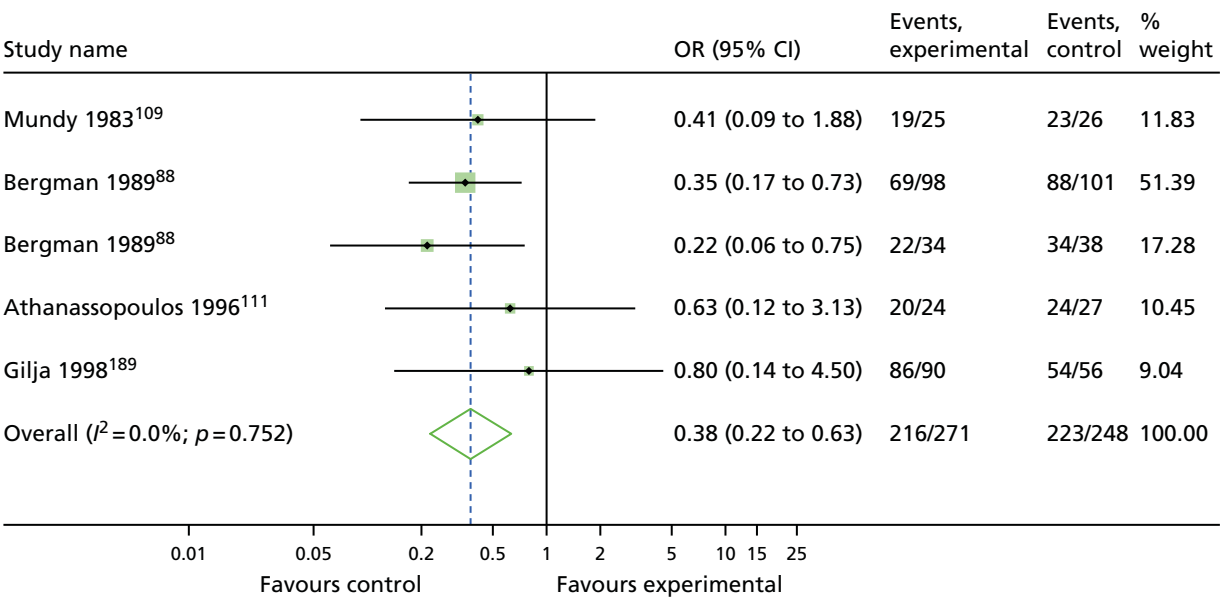

FIGURE 37 Bladder neck needle suspension vs. open colposuspension: improvement.

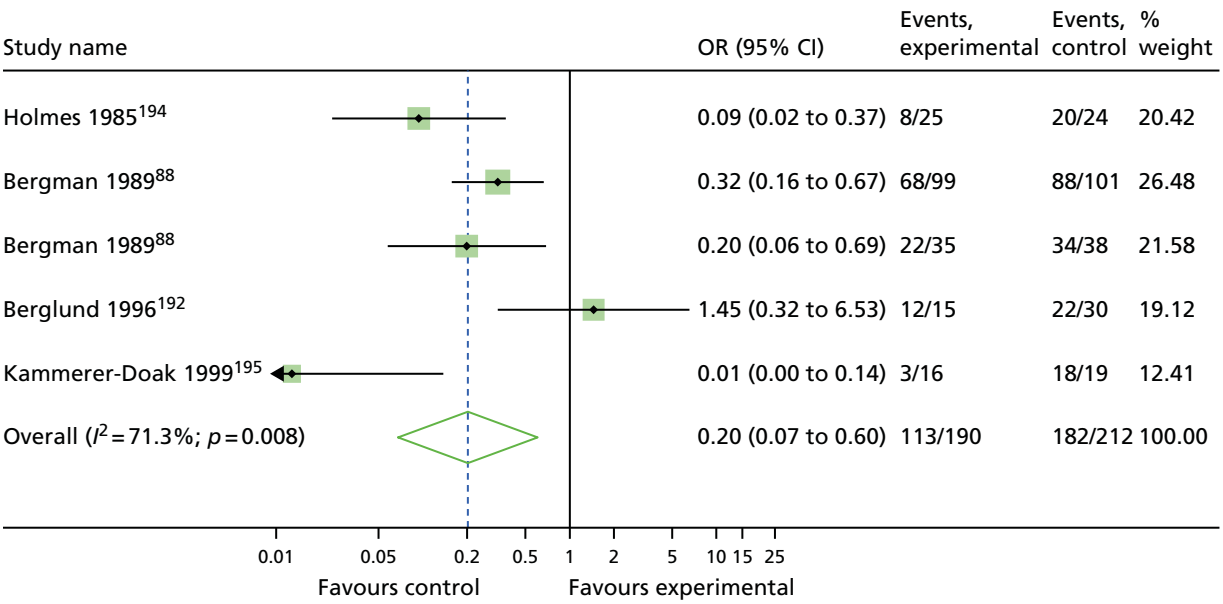

FIGURE 38 Anterior vaginal repair vs. open colposuspension: improvement.

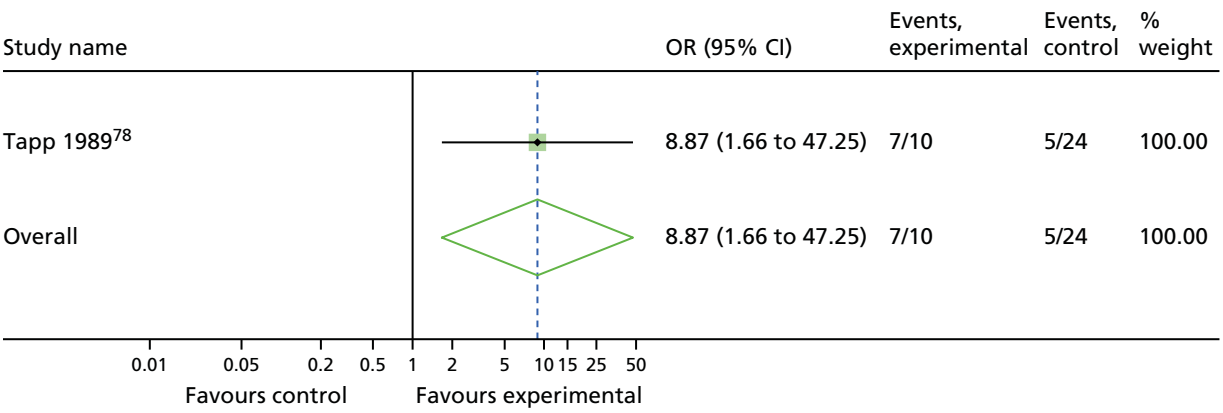

FIGURE 39 Pelvic floor muscle training vs. open colposuspension: improvement.

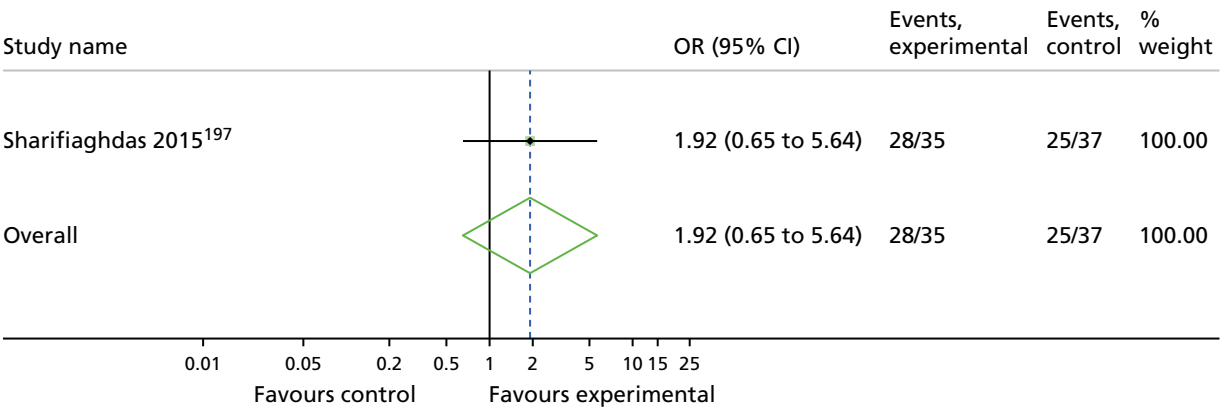

FIGURE 40 Single-incision sling vs. traditional sling: improvement.

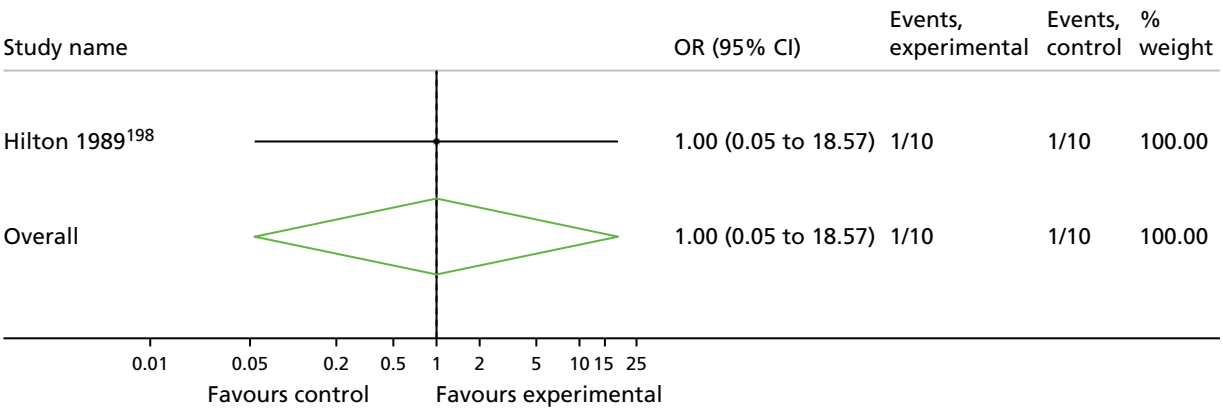

FIGURE 41 Bladder neck needle suspension vs. traditional sling: improvement.

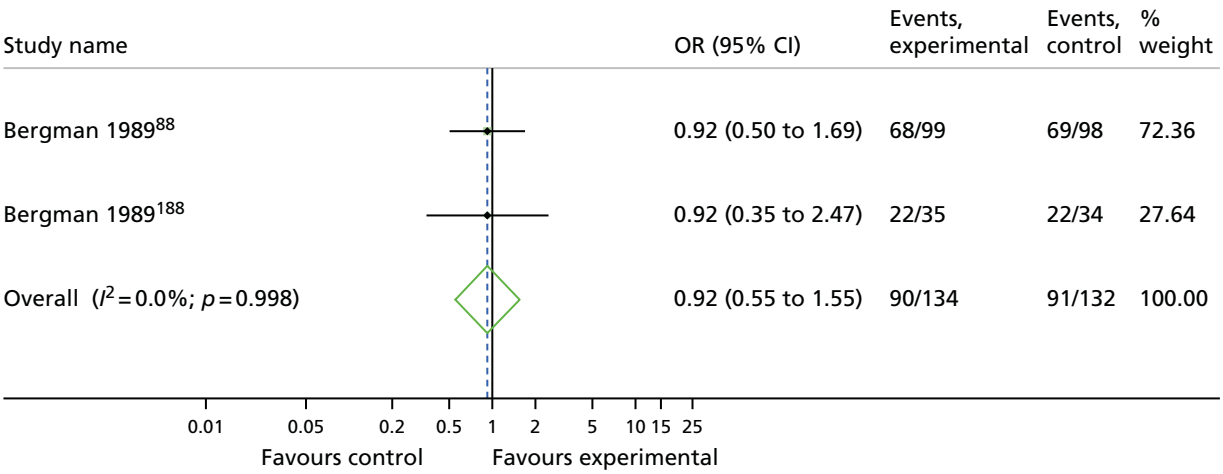

FIGURE 42 Anterior vaginal repair vs. bladder neck needle suspension: improvement.

Appendix 13 Network meta-analysis: rankogram for each intervention for the number of women cured or improved

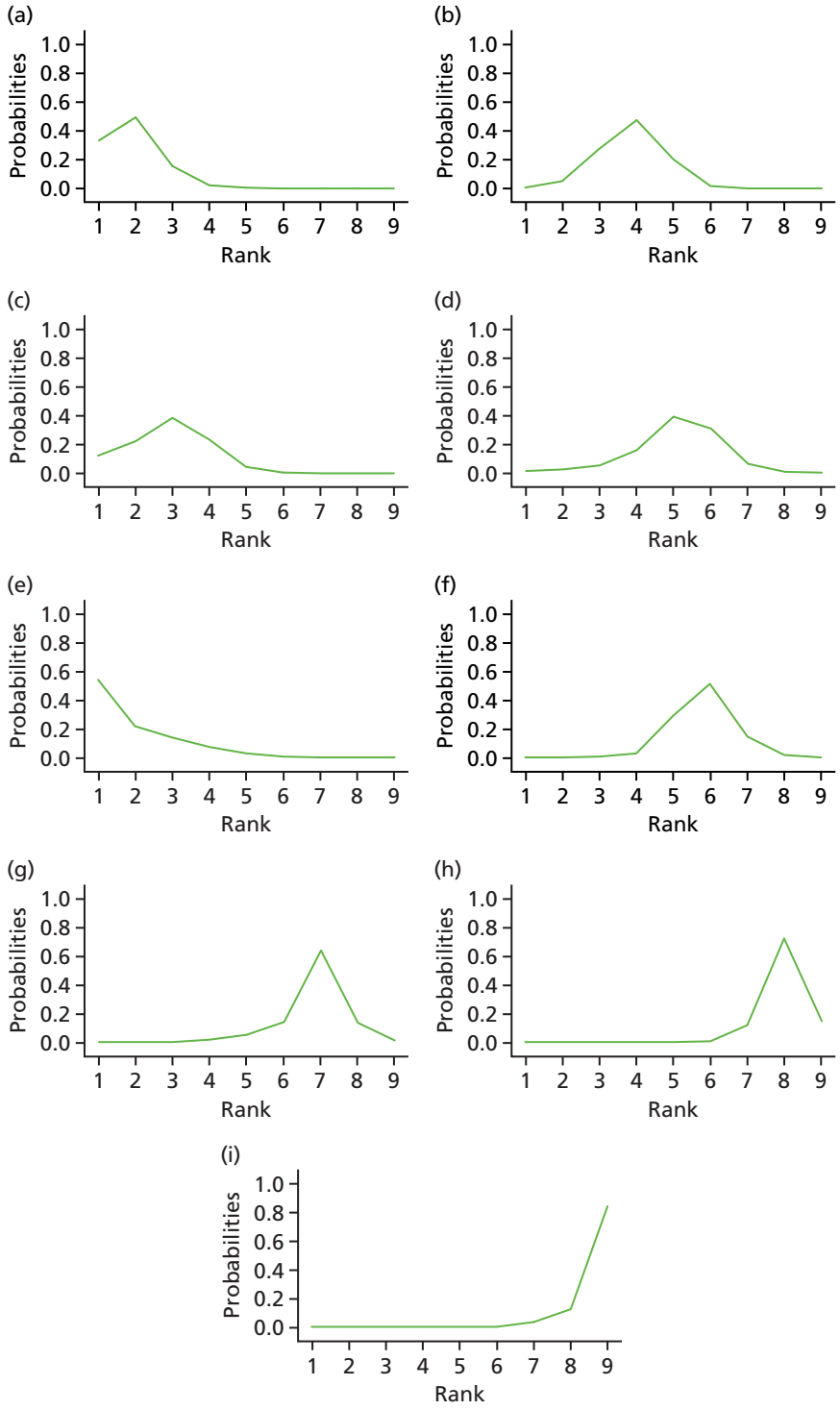

FIGURE 43 Rankograms for each intervention for number of women cured. (a) Retropubic mid-urethral sling; (b) transobturator mid-urethral sling; (c) open colposuspension; (d) laparoscopic colposuspension; (e) traditional sling; (f) single-incision sling; (g) bladder neck needle suspension; (h) anterior vaginal repair; and (i) PFMT.

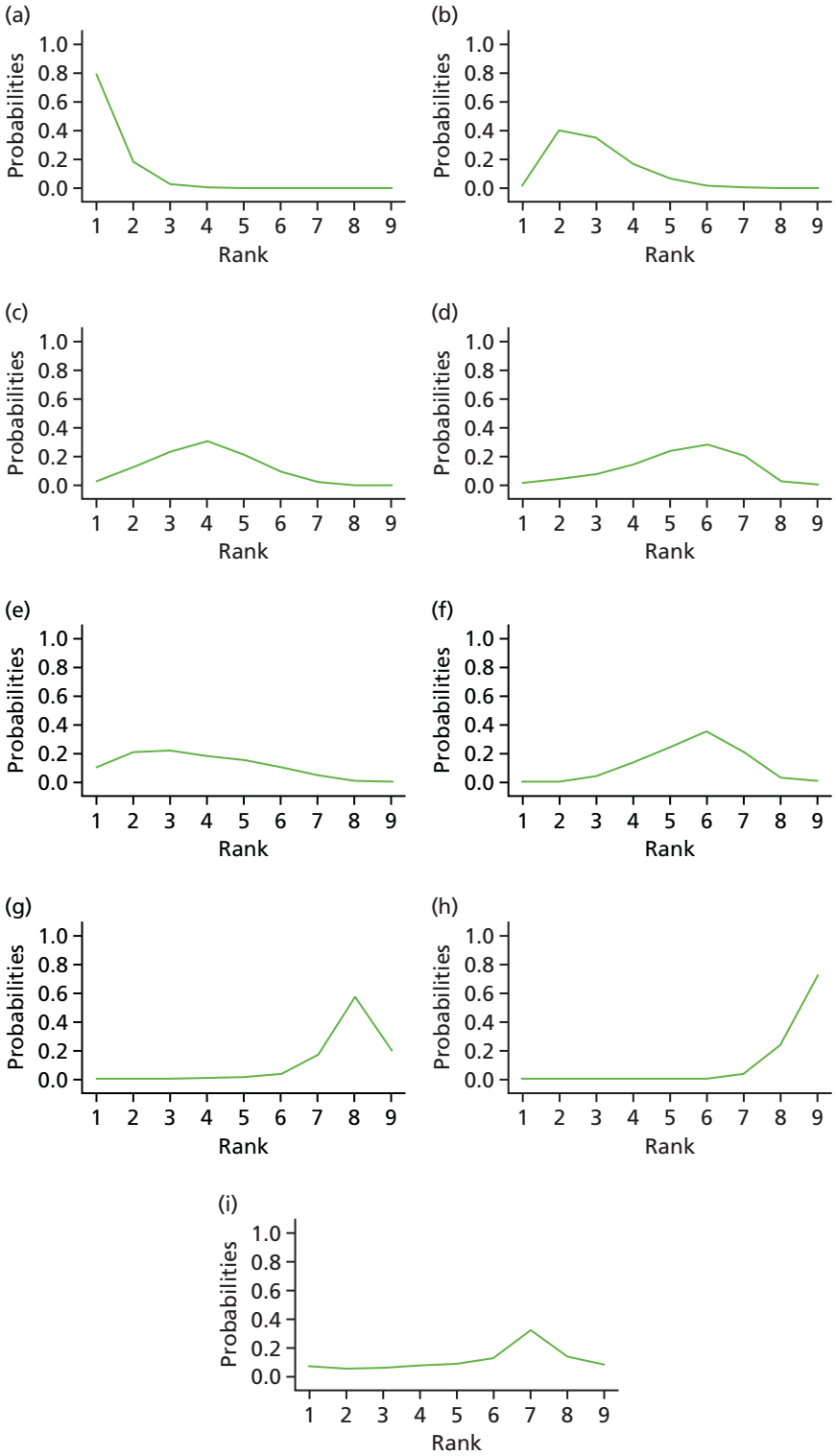

FIGURE 44 Rankograms for each intervention for number of women improved. (a) Retropubic mid-urethral sling; (b) transobturator mid-urethral sling; (c) open colposuspension; (d) laparoscopic colposuspension; (e) traditional sling; (f) single-incision sling; (g) bladder neck needle suspension; (h) anterior vaginal repair; and (i) PFMT.

Appendix 14 Network meta-analysis: inconsistency analysis and node-splitting analysis for total number of women cured or improved

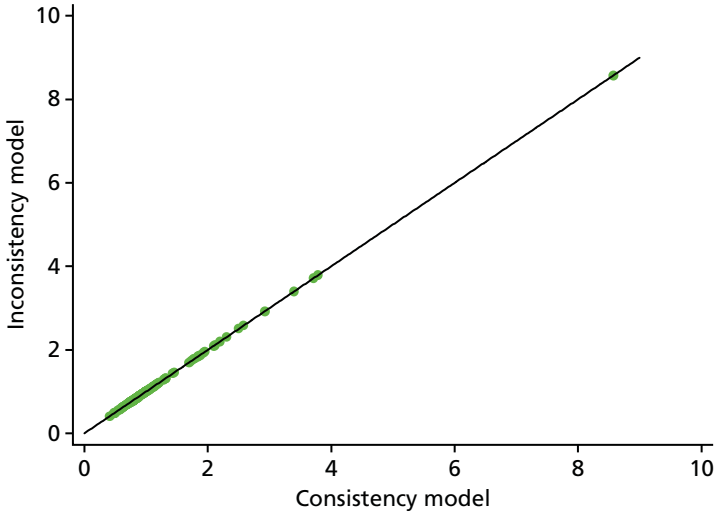

FIGURE 45 Plot of the individual data points' posterior mean deviance contributions for the consistency and inconsistency model along with the line of equality for the number of women cured.

TABLE 33 Summary of node-splitting analysis for cure of incontinence on the log scale

Intervention comparison	Analysis, median (95% CI)				Bayesian *p*-value
	NMA	Direct	Indirect	Inconsistency estimate	
Transob-MUS vs. retro-MUS	–0.304 (–0.532 to –0.080)	–0.240 (–0.485 to 0.006)	–0.658 (–1.224 to –0.102)	0.417 (–0.182 to 1.035)	0.170
Open colpo vs. retro-MUS	–0.159 (–0.609 to 0.281)	–0.036 (–0.586 to 0.522)	–0.370 (–1.134 to 0.382)	0.335 (–0.593 to 1.270)	0.476
Lap colpo vs. retro-MUS	–0.545 (–1.157 to 0.045)	–1.057 (–2.406 to 0.182)	–0.409 (–1.088 to 0.274)	–0.652 (–2.171 to 0.780)	0.370
Trad sling vs. retro-MUS	0.059 (–0.473 to 0.613)	–0.061 (–0.638 to 0.531)	0.945 (–0.574 to 2.696)	–1.007 (–2.823 to 0.630)	0.230
Single incision vs. retro-MUS	–0.686 (–1.022 to –0.358)	–0.948 (–1.534 to –0.383)	–0.543 (–0.954 to –0.145)	–0.406 (–1.109 to 0.294)	0.250
Open colpo vs. transob-MUS	0.145 (–0.332 to 0.619)	–0.127 (–1.658 to 1.371)	0.174 (–0.330 to 0.679)	–0.300 (–1.914 to 1.284)	0.708
Trad sling vs. transob-MUS	0.363 (–0.206 to 0.962)	0.901 (–1.913 to 4.506)	0.353 (–0.238 to 0.964)	0.547 (–2.333 to 4.198)	0.720
Single incision vs. transob-MUS	–0.380 (–0.672 to –0.098)	–0.343 (–0.666 to –0.023)	–0.513 (–1.191 to 0.148)	0.170 (–0.559 to 0.915)	0.652

continued

TABLE 33 Summary of node-splitting analysis for cure of incontinence on the log scale (*continued*)

Intervention comparison	Analysis, median (95% CI)				Bayesian *p*-value
	NMA	Direct	Indirect	Inconsistency estimate	
Ant repair vs. transob-MUS	–0.775 (–1.580 to 0.023)	–0.723 (–2.313 to 0.825)	–1.359 (–2.202 to –0.531)	0.634 (–1.162 to 2.412)	0.482
PFMT vs. transob-MUS	–1.211 (–1.953 to –0.473)	–1.623 (–2.756 to –0.496)	–2.610 (–5.073 to –0.546)	1.000 (–1.358 to 3.685)	0.420
Lap colpo vs. open colpo	–1.813 (–2.817 to –0.847)	–0.315 (–0.811 to 0.185)	–0.952 (–2.358 to 0.378)	0.640 (–0.779 to 2.125)	0.380
Trad sling vs. open colpo	–0.388 (–0.857 to 0.077)	1.320 (–0.088 to 2.986)	–0.060 (–0.786 to 0.665)	1.388 (–0.199 to 3.180)	0.088
Bladder neck needle vs. open colpo	0.218 (–0.420 to 0.895	–0.909 (–1.619 to –0.208)	0.264 (–3.859 to 4.079)	–1.171 (–5.064 to 3.008)	0.530
Ant repair vs. open colpo	–1.356 (–1.983 to –0.739)	–1.531 (–2.245 to –0.850)	–0.815 (–2.497 to 0.820)	–0.716 (–2.487 to 1.096)	0.424
PFMT vs. open colpo	–1.957 (–3.018 to –0.940)	–2.697 (–5.173 to –0.661)	–1.734 (–2.977 to –0.499)	–0.979 (–3.699 to 1.425)	0.434
Bladder neck needle vs. trad sling	–1.141 (–2.067 to –0.237)	0.008 (–3.834 to 3.861)	–1.239 (–2.205 to –0.316)	1.247 (–2.678 to 5.221)	0.506
Ant repair vs. bladder neck needle	–0.437 (–1.190 to 0.304)	–0.162 (–1.060 to 0.737)	–0.784 (–1.900 to 0.313)	0.621 (–0.729 to 1.992)	0.368

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

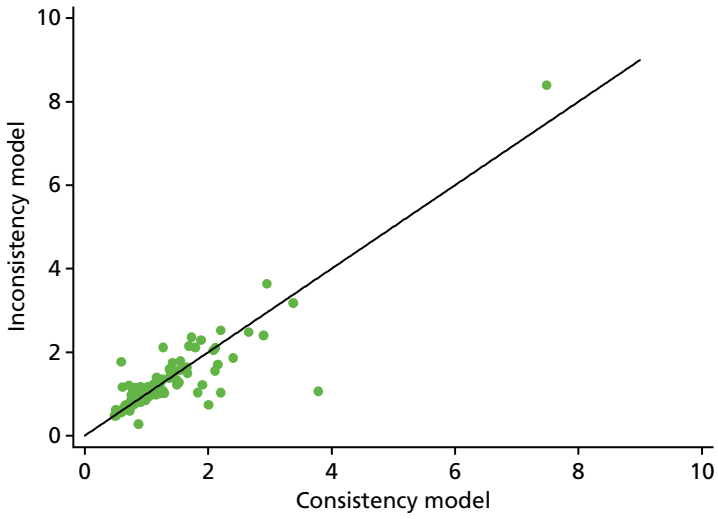

FIGURE 46 Plot of the individual data points' posterior mean deviance contributions for the consistency and inconsistency model along with the line of equality for the number of women improved.

TABLE 34 Summary of node-splitting analysis for improvement on the log scale

Intervention comparison	Analysis, median (95% CrI)				Median
	NMA	Direct	Indirect	Inconsistency estimate	
Transob-MUS vs. retro-MUS	–0.279 (–0.532 to –0.023)	–0.236 (–0.513 to 0.043)	–0.460 (1.070 to 0.134)	0.223 (–0.426 to 0.888)	0.498
Open colpo vs. retro-MUS	–0.436 (–0.894 to 0.021)	–0.152 (–0.750 to 0.464)	–0.806 (–1.536 to –0.104)	0.655 (–0.265 to 1.611)	0.160
Lap colpo vs. retro-MUS	–0.653 (–1.230 to –0.092)	–0.761 (–1.633 to 0.093)	–0.575 (–1.349 to 0.201)	–0.187 (–1.350 to 0.974)	0.750
Trad sling vs. retro-MUS	–0.372 (–0.947 to 0.230)	–0.405 (–1.101 to 0.297)	–0.265 (–1.345 to 0.867)	–0.141 (–1.466 to 1.151)	0.828
Single incision vs. retro-MUS	–0.688 (–1.050 to –0.340)	–1.118 (–1.806 to –0.456)	–0.498 (–0.921 to –0.076)	–0.618 (–1.419 to 0.155)	0.116
Open colpo vs. transob-MUS	–0.158 (–0.662 to 0.347)	–0.113 (–1.785 to 1.524)	–0.160 (–0.683 to 0.372)	0.043 (–1.697 to 1.762)	0.960
Trad sling vs. transob-MUS	–0.094 (–0.707 to 0.540)	0.924 (–2.022 to 4.706)	–0.134 (–0.761 to 0.512)	1.057 (–1.947 to 4.900)	0.498
Single incision vs. transob-MUS	–0.410 (–0.712 to –0.115)	–0.366 (–0.704 to –0.040)	–0.657 (–1.408 to 0.081)	0.290 (–0.526 to 1.101)	0.478
Ant repair vs. transob-MUS	–1.442 (–2.253 to –0.641)	–0.013 (–1.842 to 1.825)	–1.775 (–2.662 to –0.902)	1.762 (–0.283 to 3.806)	0.088
PFMT vs. transob-MUS	–0.580 (–1.662 to 0.575)	–1.712 (–2.925 to –0.506)	2.346 (0.321 to 4.583)	–4.060 (–6.629 to –1.701)	0.002
Lap colpo vs. open colpo	–0.217 (–0.722 to 0.271)	–0.174 (–0.747 to 0.392)	–0.379 (–1.391 to 0.624)	0.203 (–0.946 to 1.357)	0.728
Trad sling vs. open colpo	0.063 (–0.614 to 0.767)	1.383 (–0.094 to 3.158)	–0.318 (–1.093 to 0.455)	1.709 (0.047 to 3.611)	0.044
Bladder neck needle vs. open colpo	–0.962 (–1.697 to –0.216)	–0.971 (–1.774 to –0.190)	0.105 (–3.731 to 4.202)	–1.078 (–5.268 to 2.843)	0.566
Ant repair vs. open colpo	–1.286 (–1.976 to –0.607)	–1.571 (–2.336 to –0.841)	0.268 (–1.636 to 2.208)	–1.846 (–3.921 to 0.196)	0.076
PFMT vs. open colpo	–0.419 (–1.545 to 0.772)	2.342 (0.376 to 4.511)	–1.723 (–3.036 to –0.430)	4.080 (1.679 to 6.591)	< 0.001
Single incision vs. trad sling	–0.317 (–0.986 to 0.327)	0.676 (–0.911 to 2.298)	–0.518 (–1.247 to 0.196)	1.192 (–0.552 to 3.004)	0.178
Bladder neck needle vs. trad sling	–1.026 (–2.019 to –0.056)	–0.007 (–3.975 to 3.989)	–1.117 (–2.145 to –0.098)	1.106 (–2.974 to 5.199)	0.558
Ant repair vs. bladder neck needle	–0.322 (–1.168 to 0.489)	–0.141 (–1.156 to 0.882)	–0.482 (–1.712 to 0.736)	0.340 (–1.177 to 1.881)	0.654

Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle suspension; CrI, credible interval; lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

Appendix 15 Summary of meta-analyses of direct head-to-head comparisons for adverse events and resource use

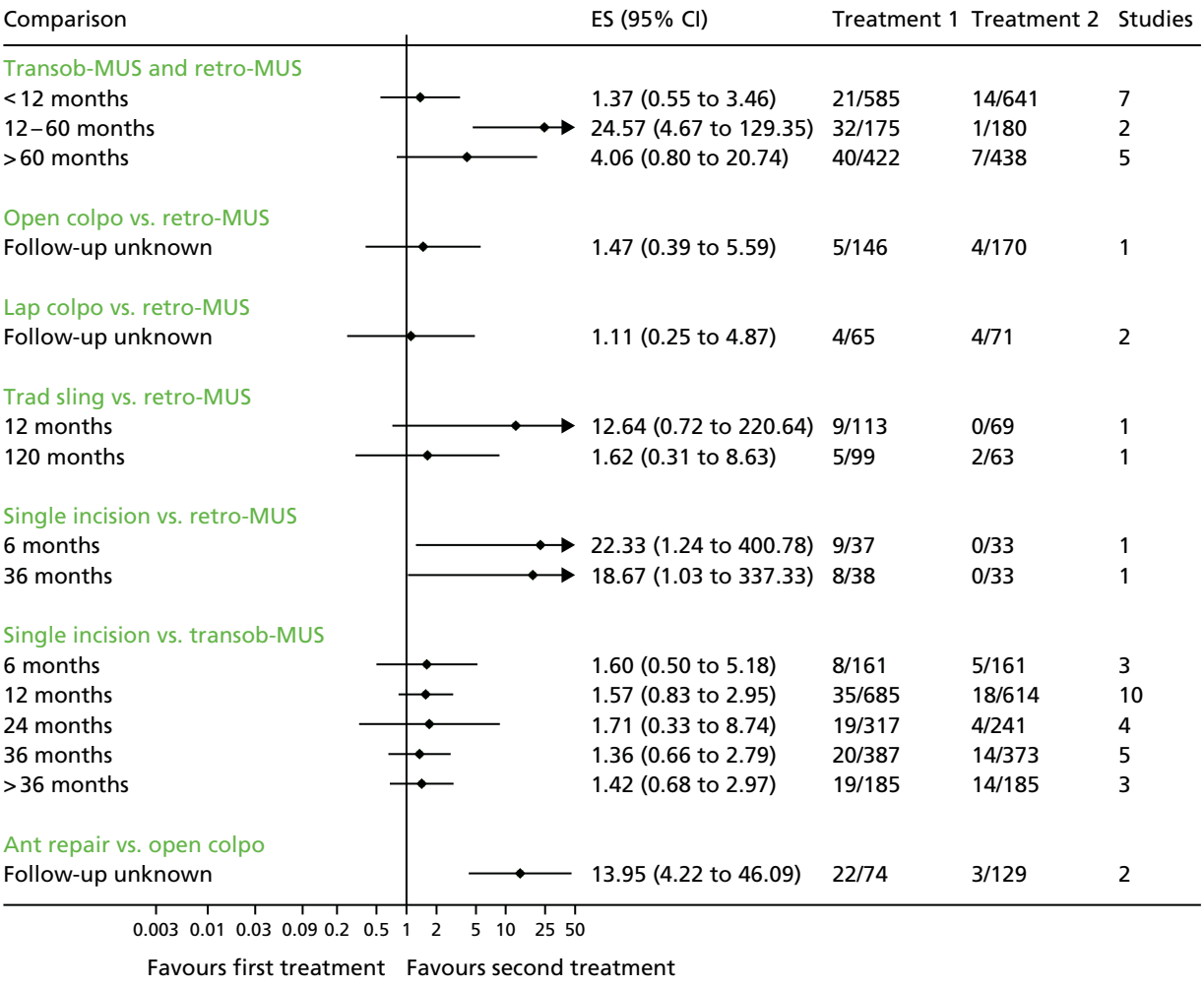

FIGURE 47 Repeat continence surgery. Ant repair, anterior vaginal repair; ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

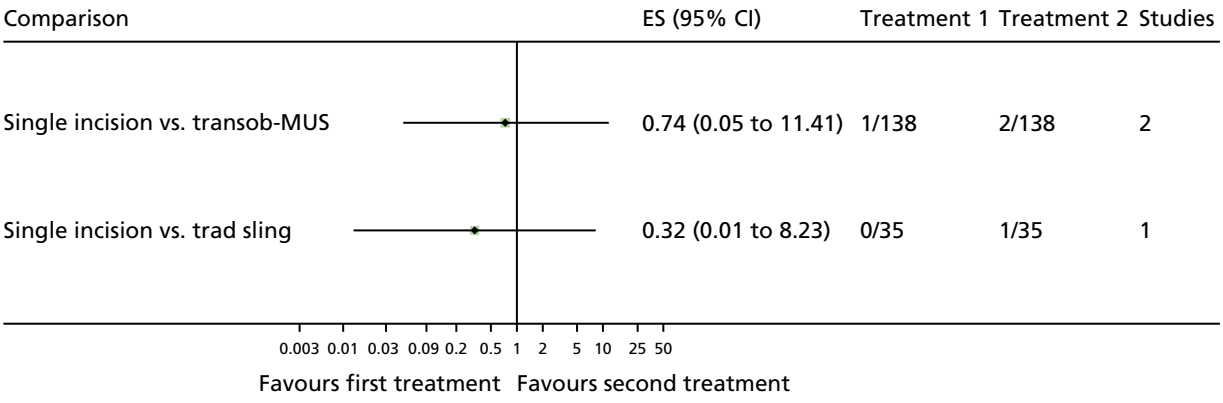

FIGURE 48 Haemorrhage. ES, effect estimate (OR); single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

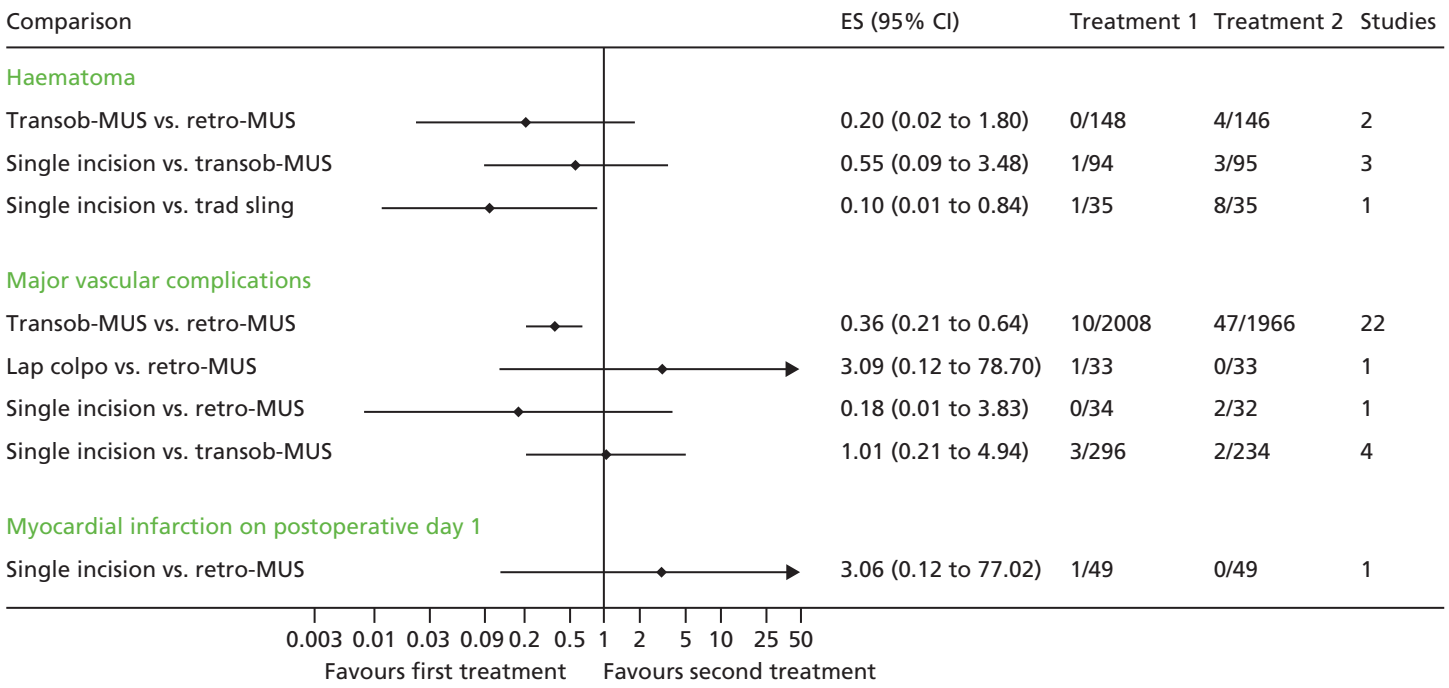

FIGURE 49 Haematoma, major vascular complications and myocardial infarction. ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

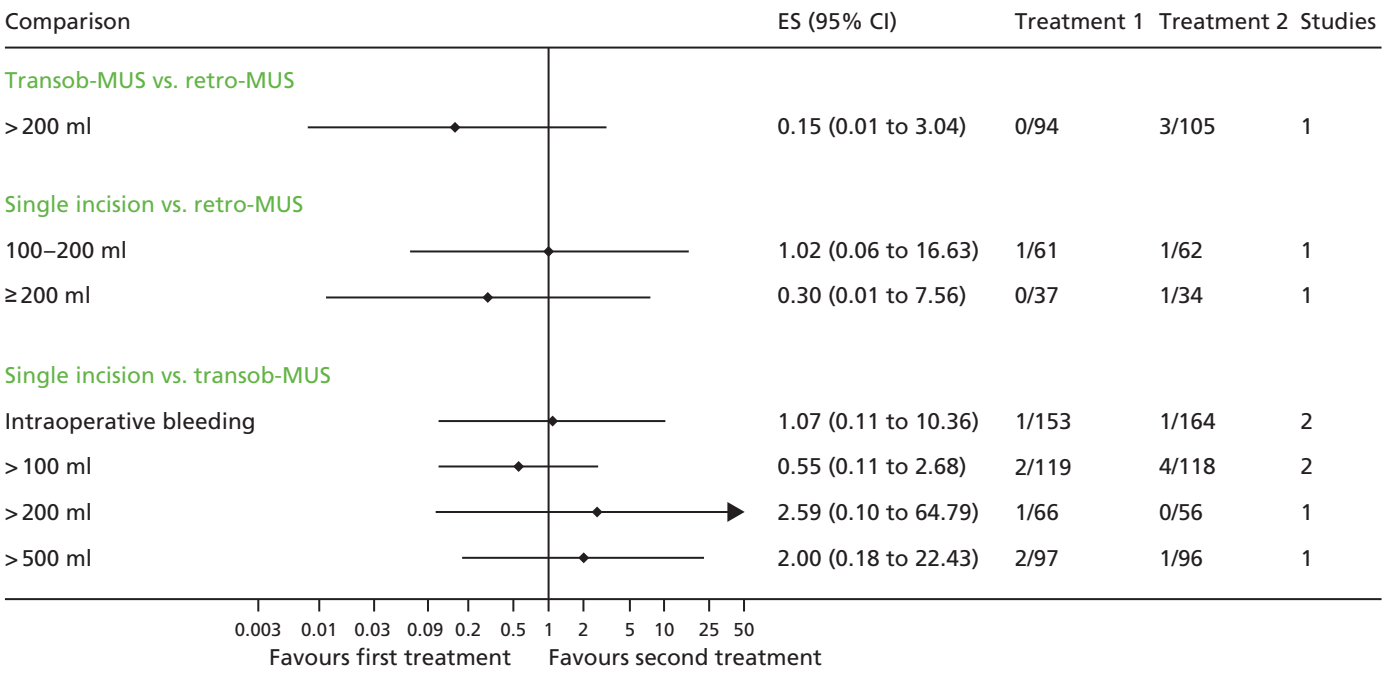

FIGURE 50 Bleeding. ES, effect estimate (OR); retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; transob-MUS, transobturator mid-urethral sling.

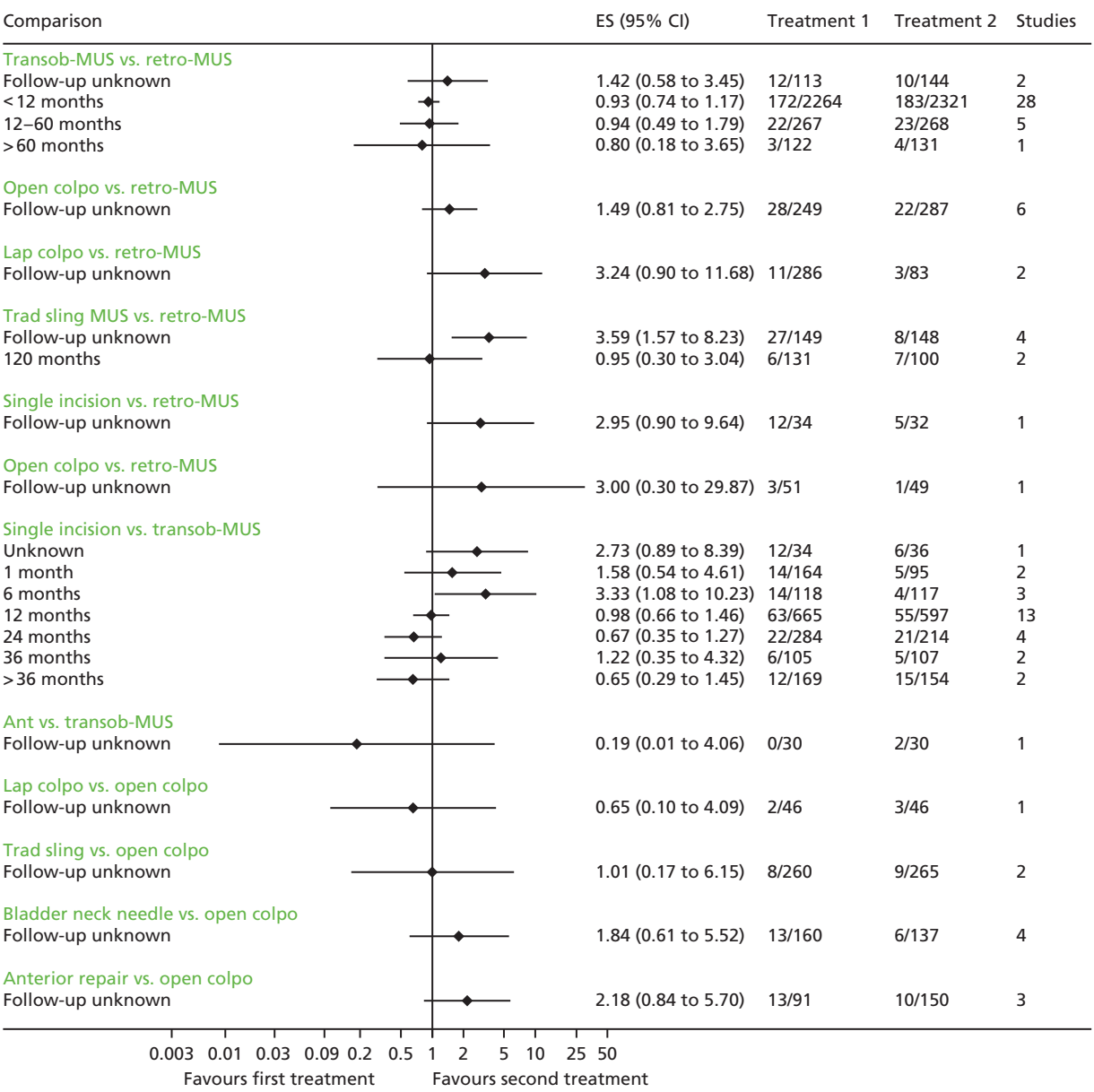

FIGURE 51 De novo symptoms of urgency or urgency incontinence. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle colposuspension; ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

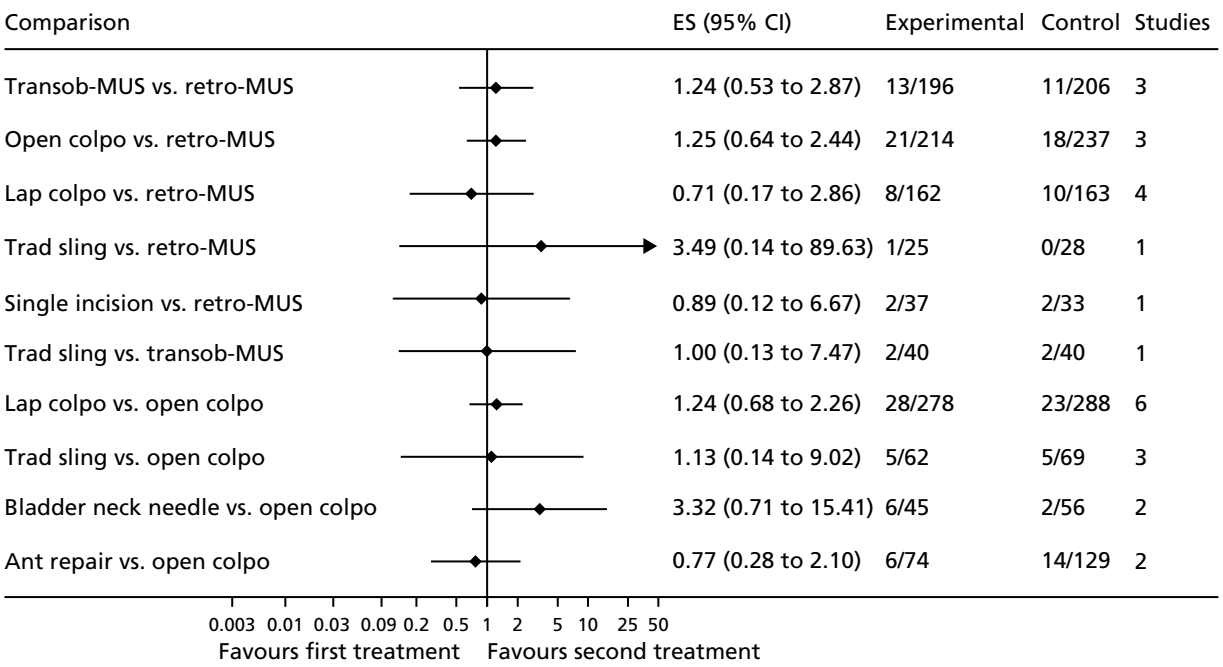

FIGURE 52 Detrusor instability. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle colposuspension; ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

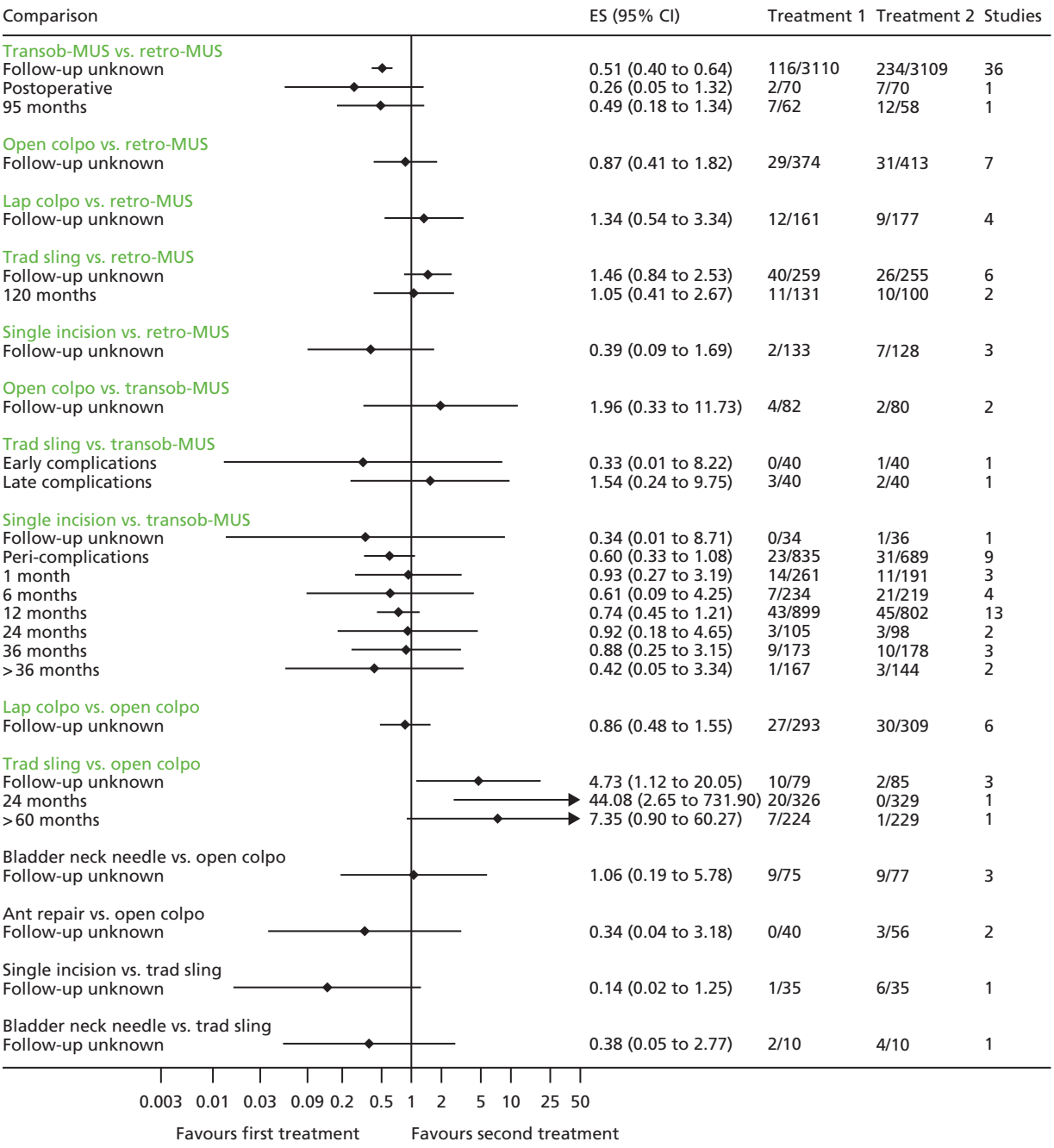

FIGURE 53 Voiding difficulty. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle colposuspension; ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

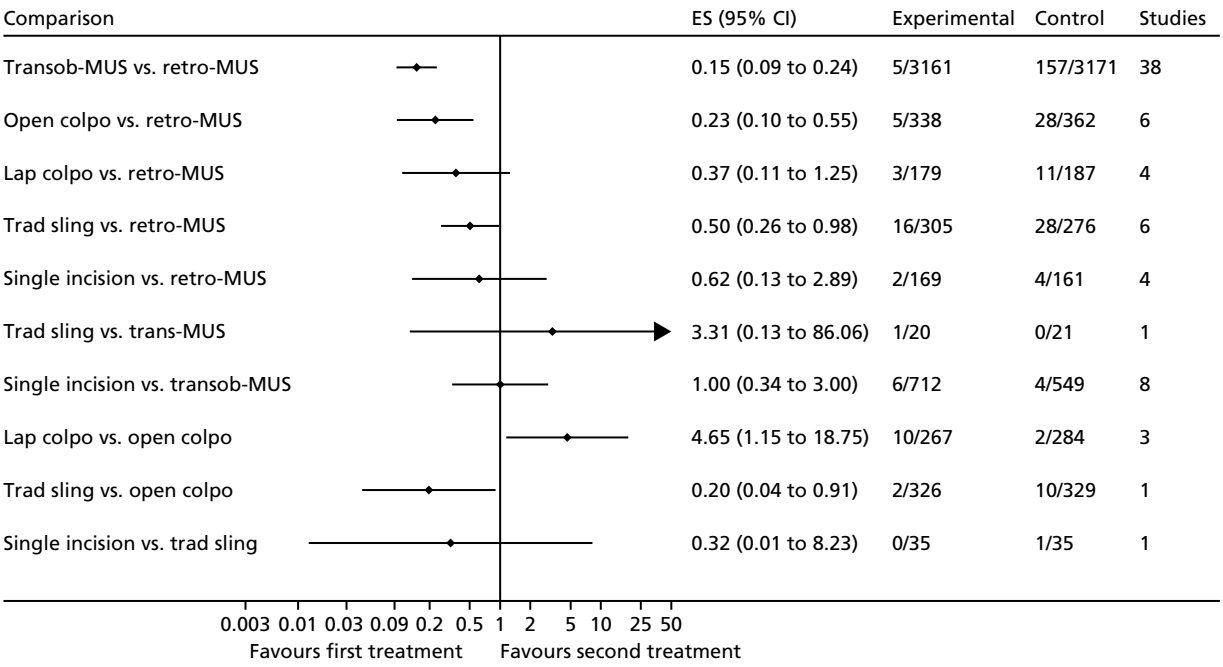

FIGURE 54 Bladder or urethral perforation. ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

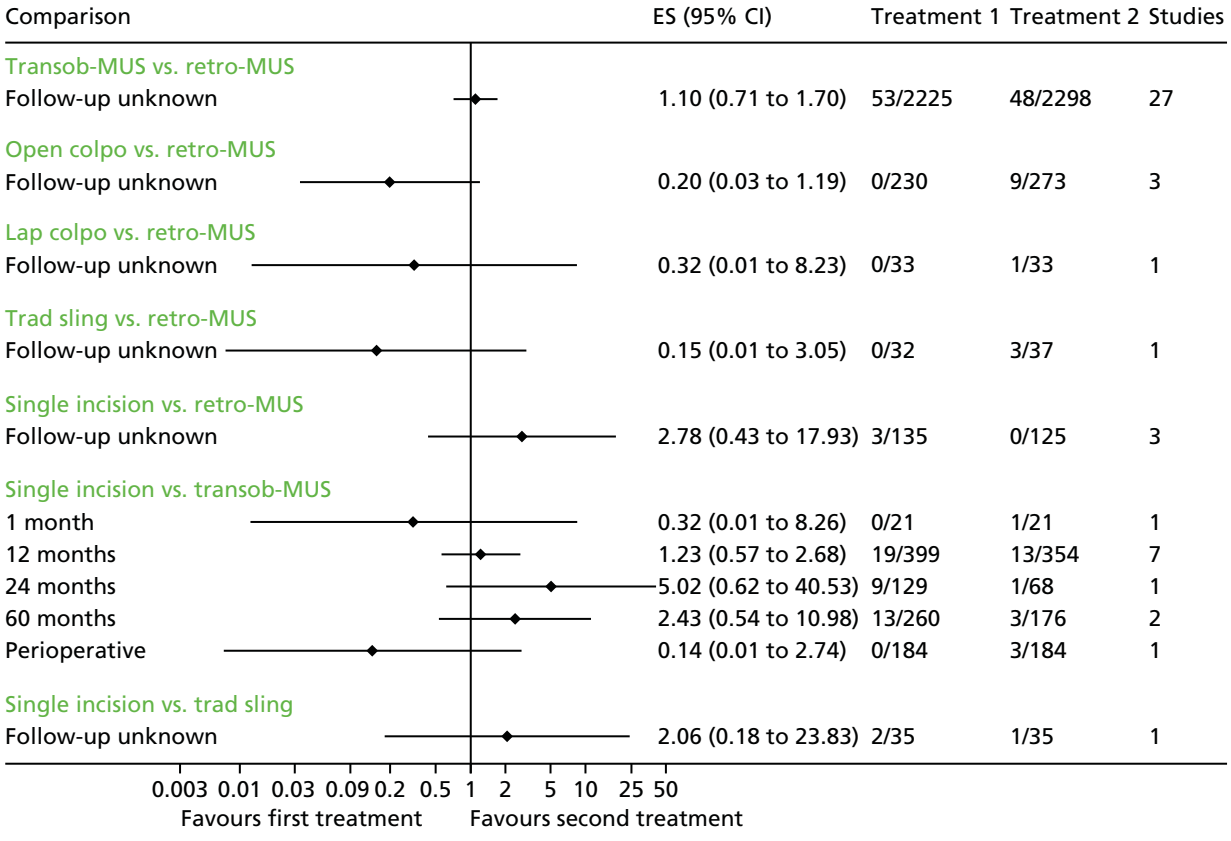

FIGURE 55 Tape/mesh erosion or extrusion. ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

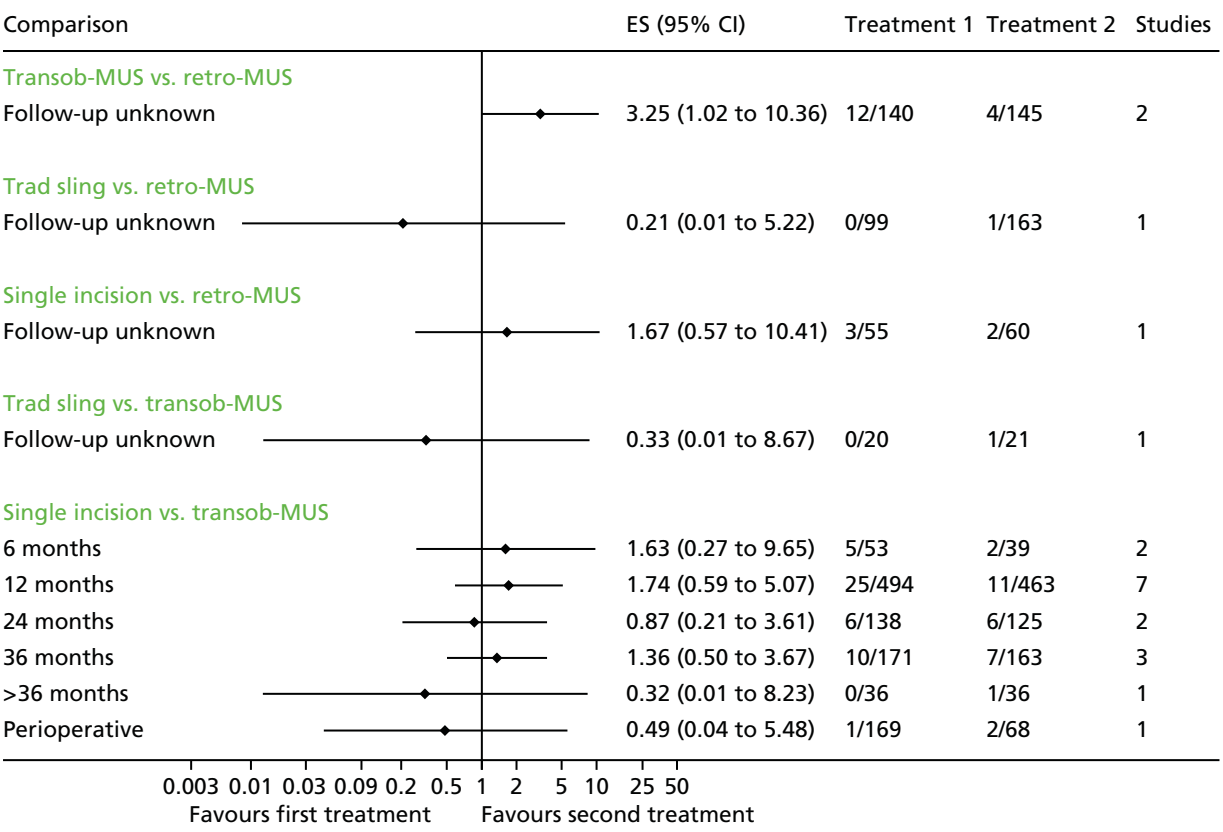

FIGURE 56 Tape/mesh/implant exposure. ES, effect estimate (OR); retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

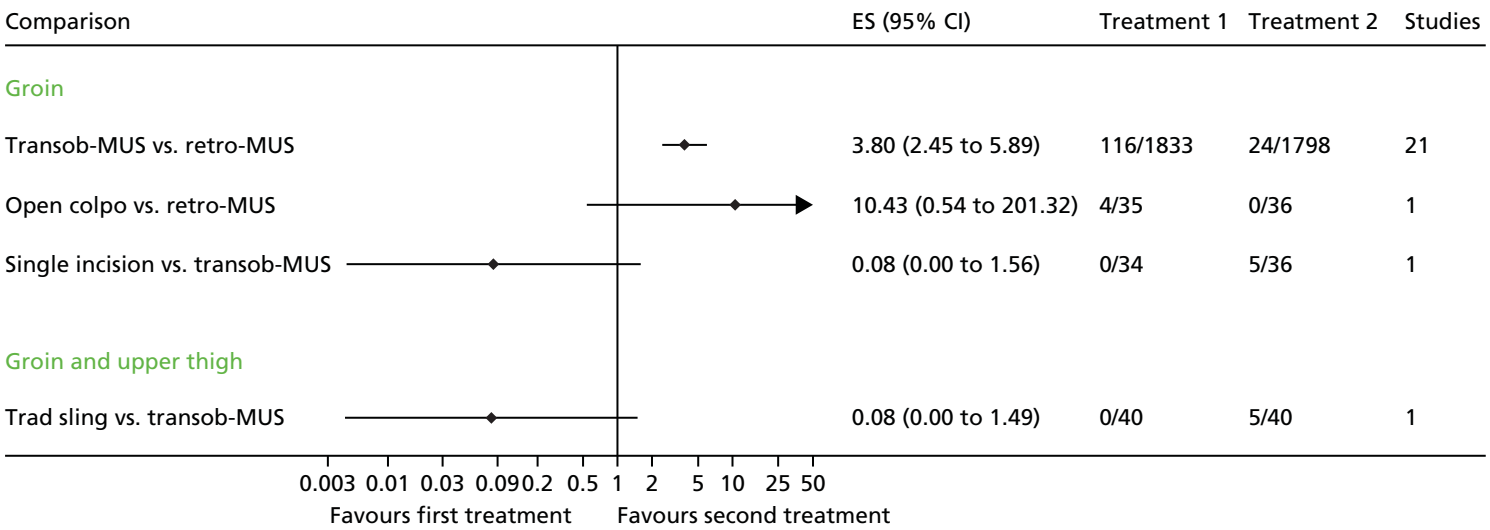

FIGURE 57 Groin pain. ES, effect estimate (OR); open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

FIGURE 58 Suprapubic pain. ES, effect estimate (OR); open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

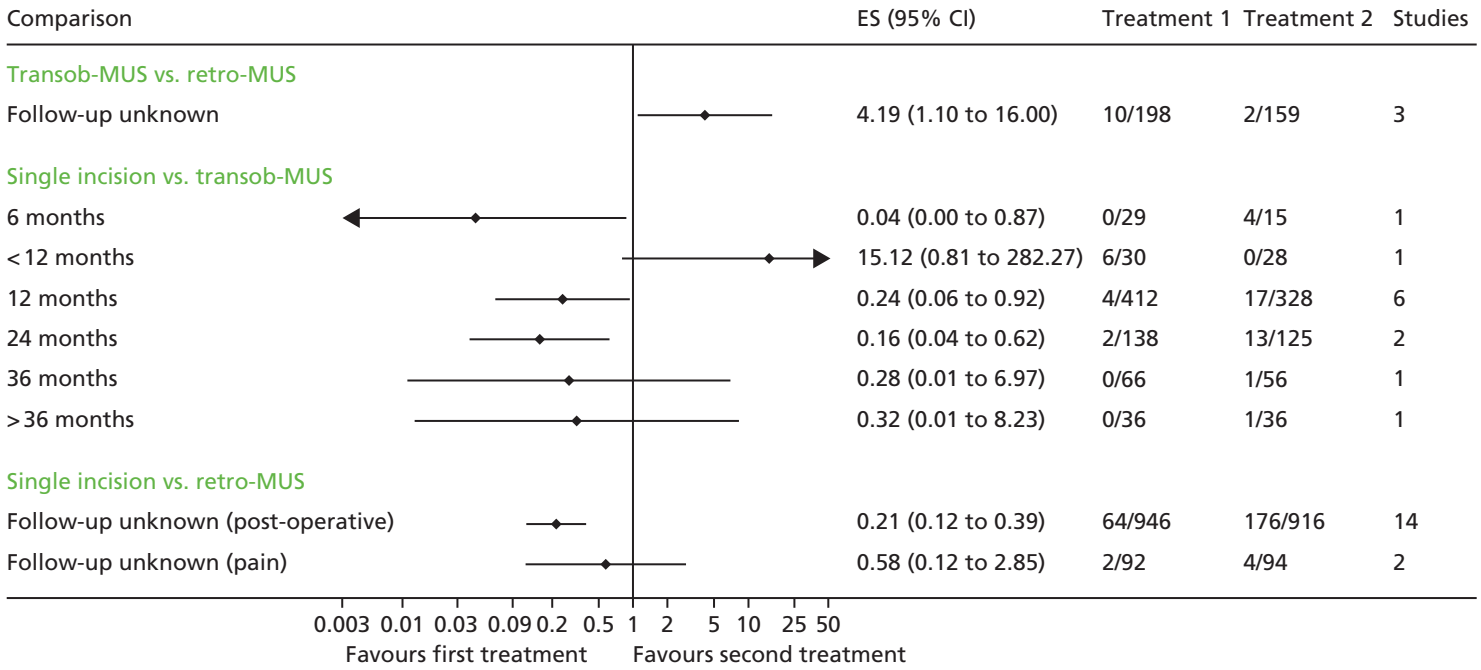

FIGURE 59 Pain. ES, effect estimate (OR); retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; transob-MUS, transobturator mid-urethral sling.

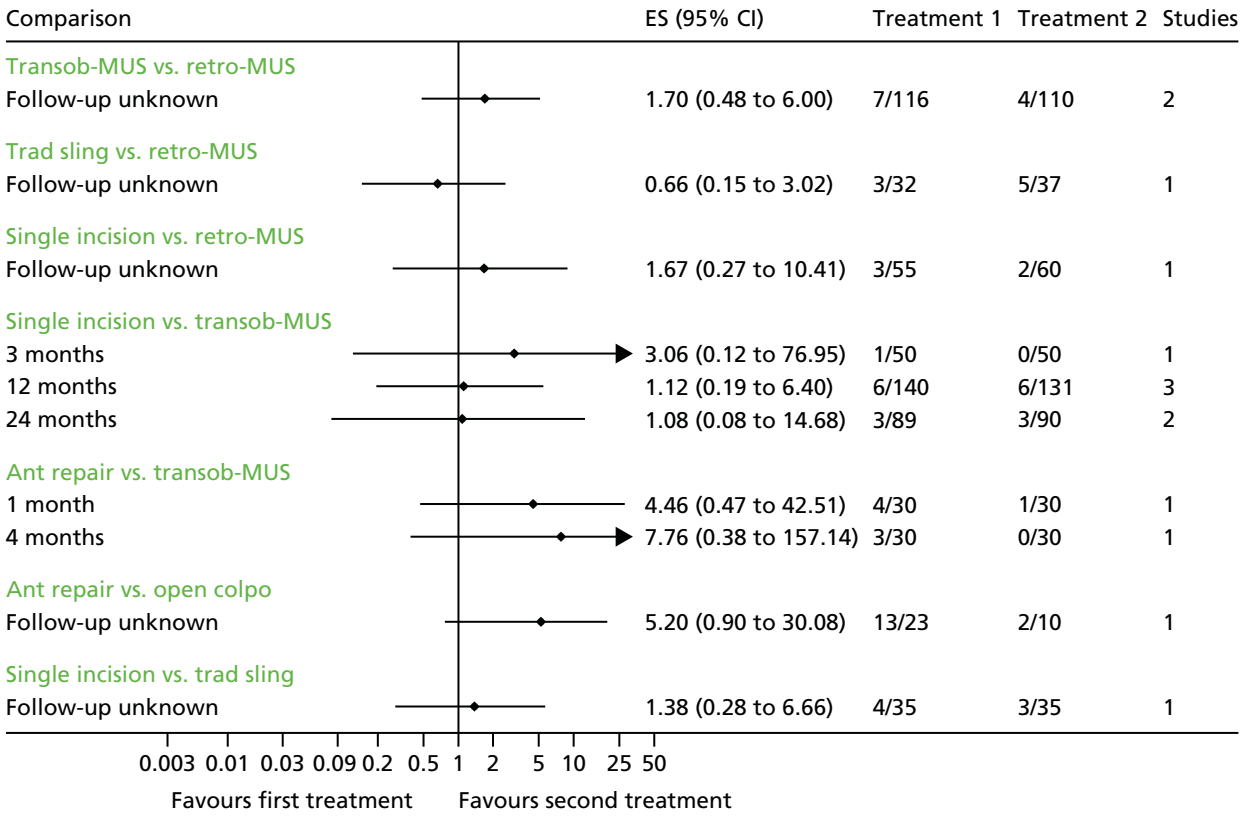

FIGURE 60 Dyspareunia. Ant repair, anterior vaginal repair; ES, effect estimate (OR); open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

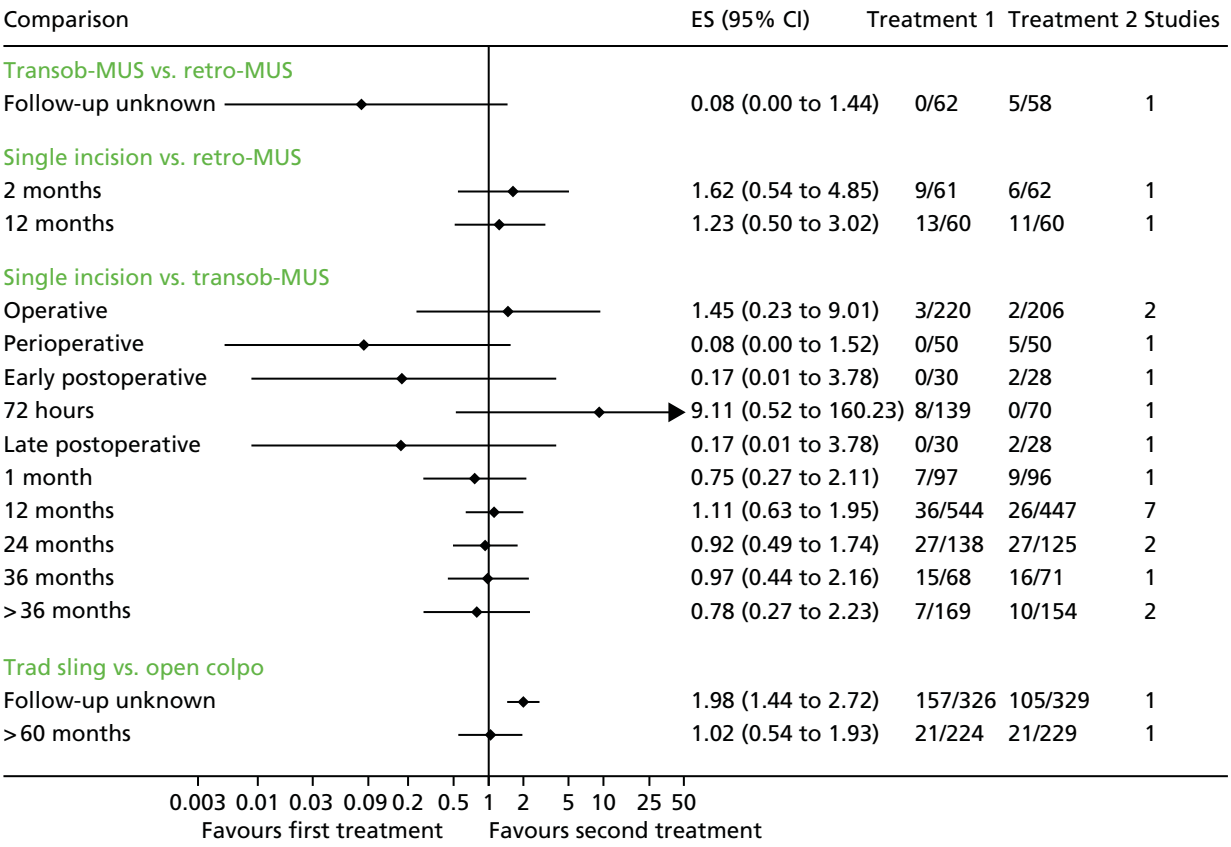

FIGURE 61 Urinary tract infection. ES, effect estimate (OR); open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

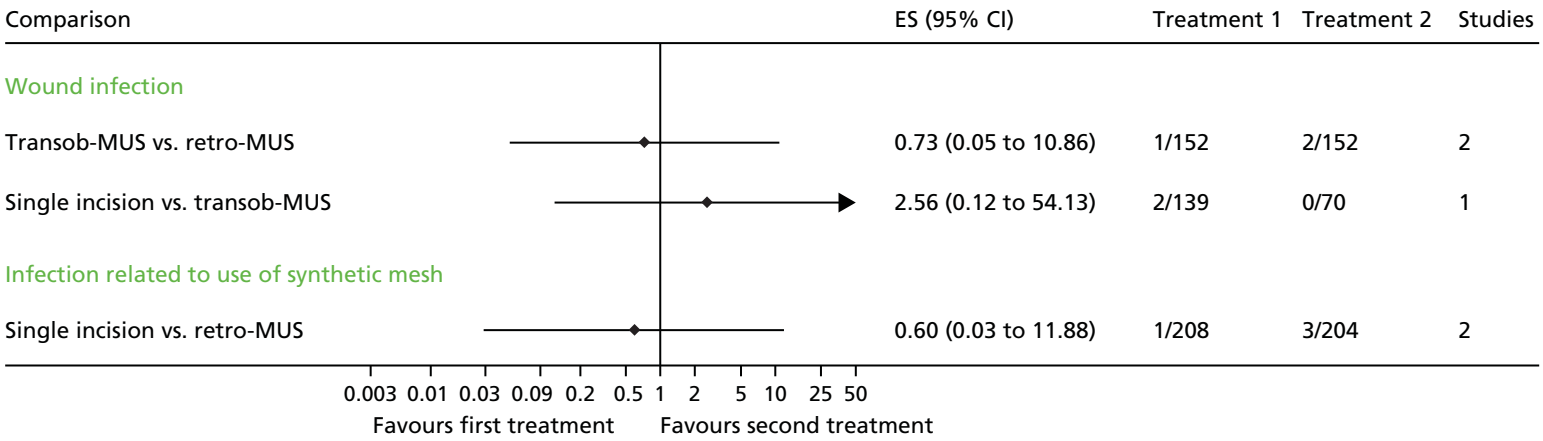

FIGURE 62 Wound infection and infection related to use of synthetic mesh. ES, effect estimate (OR); retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; transob-MUS, transobturator mid-urethral sling.

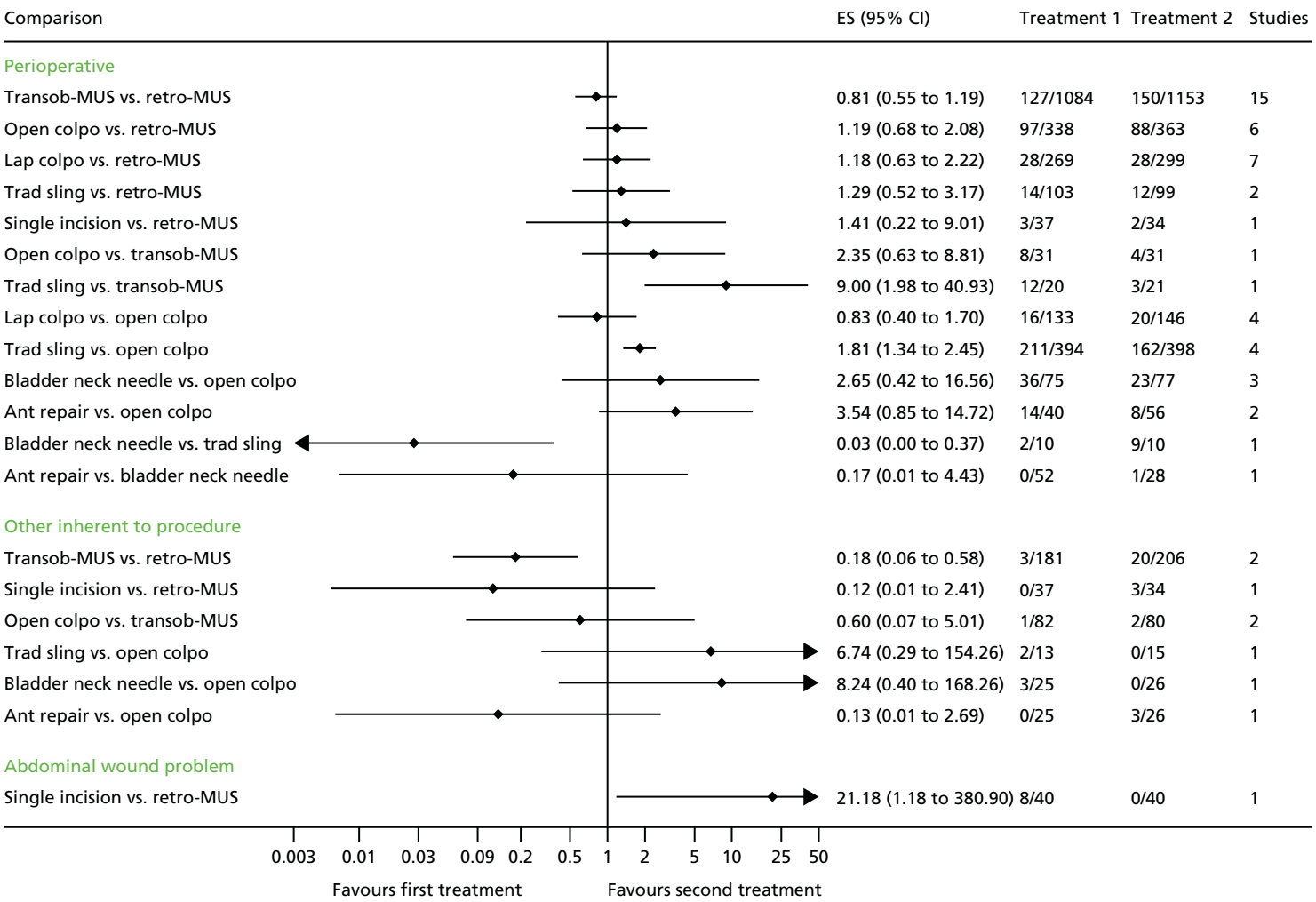

FIGURE 63 Complications. Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle colposuspension; ES, effect estimate (OR); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

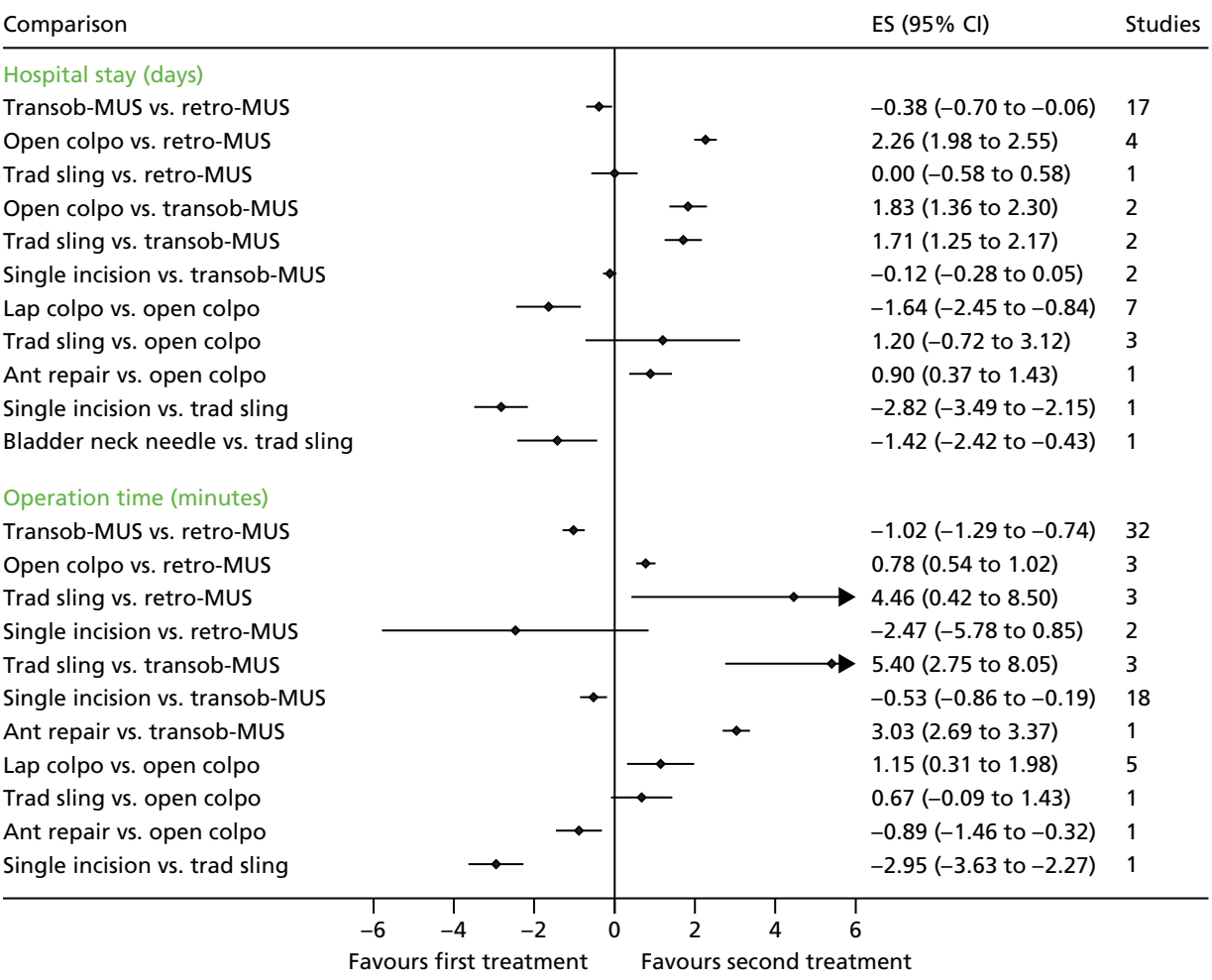

FIGURE 64 Resource utilisation (hospital stay and operation time). Ant repair, anterior vaginal repair; bladder neck needle, bladder neck needle colposuspension; ES, effect estimate (standardised mean difference); lap colpo, laparoscopic colposuspension; open colpo, open colposuspension; retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; trad sling, traditional sling; transob-MUS, transobturator mid-urethral sling.

Appendix 16 Additional reports of trials identified by an updated search of the Cochrane Incontinence Group Specialised Register on 9 October 2017

Citation for newly identified trial report	Sample size	Intervention	Notes
Extra reports of already included studies			
Richter 2010[99]			
Chai TC, Moalli PA, Richter HE, Lake AG, Kim H-Y, Nager CW, *et al.* Preoperative urodynamic parameters (Valsalva leak point pressure and maximum urethral closure pressure), urinary collagen and plasma vitamin D levels as predictors of mid urethral sling surgery outcome. *J Urol* 2016;**196**:819–23. [Ref ID: 77662]	This study report not relevant to ESTER	Retro-MUS vs. transob-MUS	Extra report of the already included study: Richter 2010 [TOMUS (Trial of Midurethral Slings)] Design: RCT Trial registration number: NCT00325039 (Not directly relevant to the ESTER project)
Thomas TN, Siff LN, Jelovsek JE, Barber M. Surgical pain after transobturator and retropubic midurethral sling placement. *Obstet Gynecol* 2017;**130**:118–25. [Ref ID: 76639]	Pain at up to 24 months. Not clear how many participants in each arm contributed data at 24 months. At 6 months: transob-MUS, *n* = 276; retropubic-MUS, *n* = 274	Retro-MUS vs. transob-MUS	Extra report of the already included study: Richter 2010 (TOMUS) Design: RCT Trial registration number: NCT00325039 'At 24 months, seven participants in the transobturator group and four participants in the retropubic group reported any pain related to the incontinence operation' Some labels missing from some of the tables, so not clear what some of the information is
Rudnicki 2016[72]			
Rudnicki M, von Bothmer-Ostling K, Holstad A, Magnusson C, Majida M, Merkel C, *et al.* Adjustable mini-sling compared with conventional mid-urethral slings in women with urinary incontinence. A randomised controlled trial. *Acta Obstet Gynecol Scand* 2017;**96**:1347–56. [Ref ID: 76834]	At 12 months: single incision, *n* = 135; MUS, *n* = 129	Single incision vs. MUS (either retro-MUS or transob-MUS)	Full report of the already included study: Rudnicki 2016 (previously only two conference abstracts and a ClinicalTrials.gov registration were available) Design: RCT Trial registration number: NCT01754558 Intervention: single incision (Ajust) vs. MUS [either retro-MUS (TVT) or transob-MUS (TVT-O or Monarc)] Length of follow-up: 12 months

Citation for newly identified trial report	Sample size	Intervention	Notes
Aigmüller 2014[83]			
Tammaa A, Aigmüller T, Hanzal E, Umek W, Kropshofer S, Lang PFJ, *et al.* Retropubic versus transobturator tension-free vaginal tape (TVT vs. TVT-O): five-year results of the Austrian randomized trial. *Neurourol Urodyn* 2018;**37**:331–8. [Ref ID: 76933]	*Overall, 331 (58%) of operated patients were available for follow-up at 5 years (331 completed questionnaires, 277 were also examined clinically)*	Retro-MUS (TVT) vs. transob-MUS (TVT-O)	Extra report of the already included study: Aigmüller 2014 (full-text report of the 5-year follow-up; previously only available as a conference abstract) Design: RCT Trial registration number: NCT00441454
Melendez Munoz 2016[65]			
Melendez MJ, Braverman M, Rosamilia A, Young N, Leitch A, Lee J. Miniarc vs. TVT abbrevo midurethral sling in women with stress urinary incontinence – an RCT-6 and 12-month follow-up. *Neurourol Urodyn* 2017;**36**(Suppl. S3):S517–S519. [Ref ID: 77508]	At 12 months: single incision, $n = 88$; transob-MUS, $n = 82$	Single incision (MiniArc) vs. transob-MUS (TVT Abbrevo)	Extra conference abstract report of the already included new study: Melendez Munoz 2016 (only conference abstract available for inclusion) includes 6- and 12-month follow-up Design: RCT Trial registration number: ACTRN12611001151921
Schellart 2013[177]			
Schellart RP, Zwolsman SE, Lucot JP, De Ridder DJMK, Dijkgraaf MGW, Roovers JWR. A randomized, nonblinded extension study of single-incision versus transobturator midurethral sling in women with stress urinary incontinence. *Int Urogynecol J* 2018;**29**:37–44. [Ref ID: 76921]	*71 patients (73%) in the MiniArc group and 74 patients (77%) in the Monarc group could be analyzed for subjective cure, and 75 (77%) and 75 (78%), respectively, for objective cure at 36 months*	Single incision (MiniArc) vs. transob-MUS (Monarc)	Extra report of the already included Schellart 2013 (full-text report of 36 months; previously only available as a conference abstract) Design: RCT Trial registration number: NTR3783

Citation for newly identified trial report	Sample size	Intervention	Notes
Extra reports of studies listed in main report as ongoing			
Abdel-Fattah 2014			
Abdel-Fattah M, MacLennan G, Kilonzo M, Assassa RP, McCormick K, Davidson T, *et al.* The SIMS trial: adjustable anchored single-incision mini-slings versus standard tension-free midurethral slings in the surgical management of female stress urinary incontinence. A study protocol for a pragmatic, multicentre, non-inferiority randomised controlled trial. *BMJ Open* 2017;**7**:e015111. [Ref ID: 76746]	Target, $n = 650$ (325 in each arm)	Single incision vs. MUS (retro-MUS or transob-MUS)	Protocol for a study listed as ongoing study in the main ESTER report: Abdel-Fattah 2014 Design: RCT Trial registration number: ISRCTN93264234 Ages: ≥ 18 years Condition: 'urodynamic stress incontinence or urodynamic MUI with predominant SUI bothering symptoms' Recruitment start date: 4 February 2014 Follow-up end date: February 2020 Place: UK, 20 research centres Funding: Health Technology Assessment (HTA) Programme
Fu 2016			
Fu Q, Lv J, Fang W, Jiang C, Gu Y, Leng J, *et al.* The clinical efficacy of needleless sling technique and TOT in the treatment of female stress urinary incontinence: a prospective randomized controlled trial. *Int J Clin Exp Med* 2017;**10**:7084–90. [Ref ID: 77232]	At 12 months, data available: single incision, $n = 78$; transob-MUS, $n = 86$	Single incision (needleless) vs. transob-MUS	Full text report for the study listed as ongoing in the main ESTER report: Fu 2016 Design: RCT Trial registration number: ChiCTR-INR-16008068 Diagnosis: USI Ages: 35–70 years Place: Shanghai, China Funding: 'SHDC1201591'

Citation for newly identified trial report	Sample size	Intervention	Notes
New ongoing studies			
Leitch A, Ow LL. Efficacy of mini sling versus retropubic sling in women with stress urinary incontinence – a RCT study (Mini Retro). 2017. Trial registration number: ACTRN12617000167369. URL: www.anzctr.org.au/ACTRN12617000167369.aspx (accessed 27 November 2017). [Ref ID: 76200]	Target sample size, *n* = 176	Single incision (Altis) vs. retro-MUS (TVT)	Design: RCT Trial registration number: ACTRN12617000167369 Recruitment start date: April 2017 Recruitment end date: April 2019 Diagnosis: USI Ages: 18–80 years Place: Monash Medical Centre, Australia Funding: Coloplast Corp.
Luo D, Shen H. Comparison of the efficacy and safety of TVT-EXACT vs. TVT-ABBREVO in the treatment of female stress urinary incontinence. 2017. Trial registration number: ChiCTR-IOR-17011788. URL: www.chictr.org.cn/showproj.aspx?proj = 20086 (accessed 27 November 2017). [Ref ID: 76204]	Target, *n* = 150 (75 each arm)	Retro-MUS (TVT-Exact) vs. transob-MUS (TVT-Abbrevo)	Design: RCT Trial registration number: ChiCTR-IOR-17011788 Recruitment start date: 1 April 2015 Recruitment end date: 31 October 2018 Ages: 40–75 years Place: Chengdu, China Funding: National Nature Science Foundation of China

Retro-MUS, retropubic mid-urethral sling; single incision, single-incision sling; transob-MUS, transobturator mid-urethral sling; USI, urodynamic stress incontinence.

Appendix 17 Economic search strategy

TABLE 35 Economic search strategy

Number	Search term	Facet	Results
MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations			
1	exp models, economic/	Economic evaluations	12,189
2	*models, theoretical/		50,817
3	*models, organizational/		5483
4	Markov chains/		11,679
5	monte carlo method/		23,376
6	exp decision theory/		10,620
7	(Markov* or monte carlo).ti,ab.		49,644
8	econom* model*.ti,ab.		2789
9	(decision* adj2 (tree* or analy* or model*)).ti,ab.		16,267
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9		145,603
11	URINARY INCONTINENCE/	Disease	19,864
12	URINARY INCONTINENCE, STRESS/		10,063
13	((stress$or mix$or urg$or urin$) adj3 incontinen$).tw.		25,719
14	colporrhaphy.tw.		519
15	colpoperineoplast$.tw.		28
16	Sling procedure$.tw.		898
17	Sling$procedure$.tw.		905
18	Bladder neck needle suspensions suspension$.tw.		7
19	Anterior vaginal repair$.tw.		45
20	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19		37,510
21	10 and 20	Final numbers	139
EMBASE			
1	URINE INCONTINENCE/	Disease	41,326
2	STRESS INCONTINENCE/		19,497
3	URGE INCONTINENCE/		6053
4	MIXED INCONTINENCE/		1624
5	((stress$or mix$or urg$or urin$) adj3 incontinen$).tw.		39,155
6	URINARY URGENCY/		5368
7	URINARY FREQUENCY/		6154
8	((urgency adj frequency) or (frequency adj urgency)).tw.		1930
9	((urinary adj frequency) or (urinary adj urgency)).tw.		3722
10	colporrhaphy.tw.		948

continued

TABLE 35 Economic search strategy (*continued*)

Number	Search term	Facet	Results
11	colposuspension$.tw.		1337
12	Sling procedure$.tw.		1554
13	Sling$procedure$.tw.		1572
14	Bladder neck needle suspensions suspension$.tw.		7
15	Anterior vaginal repair$.tw.		83
16	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15		69,648
17	statistical model/	Economic evaluations	149,789
18	exp economic aspect/		1,386,763
19	17 and 18		21,900
20	*theoretical model/		27,446
21	*nonbiological model/		4142
22	stochastic model/		9838
23	decision theory/		2696
24	decision tree/		9013
25	monte carlo method/		30,151
26	(Markov* or monte carlo).ti,ab.		52,002
27	econom* model*.ti,ab.		4018
28	(decision* adj2 (tree* or analy* or model*)).ti,ab.		22,474
29	19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28		144,098
30	16 and 29	Final numbers	269
NHS Economic Evaluation			
1	URINARY INCONTINENCE/	Disease	31
2	URINARY INCONTINENCE, STRESS/		34
3	((stress$or mix$or urg$or urin$) adj3 incontinen$).tw.		97
4	colporrhaphy.tw.		3
5	colpoperineoplast$.tw.		0
6	sling procedure$.tw.		4
7	sling$procedure$.tw.		4
8	Bladder neck needle suspensions suspension$.tw.		0
9	anterior vaginal repair$.tw.		0
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	Final numbers	100
Health Management Information Consortium			
1	URINARY INCONTINENCE/	Disease	110
2	URINARY INCONTINENCE, STRESS/		0
3	((stress$or mix$or urg$or urin$) adj3 incontinen$).tw.		174
4	colporrhaphy.tw.		0
5	colpoperineoplast$.tw.		0

TABLE 35 Economic search strategy (*continued*)

Number	Search term	Facet	Results
6	Sling procedure$.tw.		0
7	Sling$procedure$.tw.		0
8	Bladder neck needle suspensions suspension$.tw.		0
9	Anterior vaginal repair$.tw.		0
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	Final numbers	220
Cost-effectiveness Analysis Registry			
1	URINARY INCONTINENCE	Disease	32
2	STRESS URINARY INCONTINENCE		14
3	Mixed incontinence		1
4	URINARY		72
5	Incontinent		3
6	colporrhaphy		0
7	olposuspension		6
8	sling procedure		1
9	Bladder neck needle suspensions suspension		0
10	anterior vaginal repair		0
11	Sling		14
12	Incontinence		50
13	or/1–12	Final numbers	93

TABLE 36 Total number of studies retrieved by database

Database	Numbers retrieved
MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations	139
EMBASE	269
NHS Economic Evaluation Database	100
Health Management Information Consortium	220
Cost-effectiveness Analysis Registry	93
Total	821

Appendix 18 Quality assessment of economic studies

Quality assessment of the economic studies evaluating surgical treatments for SUI using the Drummond checklist.[338]

Item	Study																
	Von Bargen 2015[226]	Jacklin 2010[228]	Kilonzo 2004[229]	Laudano 2013[230]	Richardson 2014[233]	Sand 2014[234]	Seklehner 2014[235]	Weber 2000[236]	Wu 2007[237]	Oremus 2010[232]	Oremus 2003[231]	Kunkle 2015[225]	Das Gupta 2006[227]	Holtzer-Goor 2015[238]	Weber 2000[239]	Weber 2002[240]	Imamura 2010[241]
1. Was a well-defined question posed in answerable form?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1.1. Did the study examine both costs and effects of the service(s) or programme(s)?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1.2. Did the study involve a comparison of alternatives?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1.3. Was a viewpoint for the analysis stated and was the study placed in any particular decision-making context?	Yes	Yes	Yes	No	Yes	Yes	Yes	NC	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No
2. Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where and how often)?	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2.1. Were there any important alternatives omitted?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
2.2. Was (should) a do-nothing alternative be considered?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
3. Was the effectiveness of the programme or services established?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3.1. Was this done through a randomised controlled clinical trial? If so, did the trial protocol reflect what would happen in regular practice?	No	No	No	No	Yes	No	No	No	No	Yes	No	No	Yes	No	No	No	No
3.2. Was effectiveness established through an overview of clinical studies?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes
3.3. Were observational data or assumptions used to establish effectiveness? If so, what are the potential biases in results?	No	No	No	No	Yes	No	No	No	Yes	No	No	Yes	Yes	Yes	No	No	No
4. Were all the important and relevant costs and consequences for each alternative identified?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4.1. Was the range wide enough for the research question at hand?	NC	NC	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	NC	Yes	NC	Yes	Yes	Yes

Item	Study																
	Von Bargen 2015[226]	Jacklin 2010[228]	Kilonzo 2004[229]	Laudano 2013[230]	Richardson 2014[233]	Sand 2014[234]	Seklehner 2014[235]	Weber 2000[236]	Wu 2007[237]	Oremus 2010[232]	Oremus 2003[231]	Kunkle 2015[225]	Das Gupta 2006[227]	Holtzer-Goor 2015[238]	Weber 2000[239]	Weber 2002[240]	Imamura 2010[241]
4.2. Did it cover all relevant viewpoints? (Possible viewpoints include the community or social viewpoint, and those of patients and third-party payers. Other viewpoints may also be relevant depending on the particular analysis.)	Yes	No	No	NC	No	No	No	Yes	No	No	No	No	No	Yes	Yes	Yes	No
4.3. Were the capital costs, as well as operating costs, included?	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes
5. Were costs and consequences measured accurately in appropriate physical units (e.g. hours of nursing time, number of physician visits, lost work-days, gained life-years)?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.1. Were any of the identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
5.2. Were there any special circumstances (e.g. joint use of resources) that made measurement difficult? Were these circumstances handled appropriately?	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No
6. Were the cost and consequences valued credibly?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6.1. Were the sources of all values clearly identified? (Possible sources include market values, patient or client preferences and views, policy-makers' views and health professionals' judgements.)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
6.2. Were market values employed for changes involving resources gained or depleted?	N/A	N/A	No	Yes	N/A	No	Yes	Yes	Yes	Yes	No	No	No	Yes	N/A	N/A	N/A
6.3. Where market values were absent (e.g. volunteer labour), or market values did not reflect actual values (such as clinic space donated at a reduced rate), were adjustments made to approximate market values?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Item	Study																
	Von Bargen 2015[226]	Jacklin 2010[228]	Kilonzo 2004[229]	Laudano 2013[230]	Richardson 2014[233]	Sand 2014[234]	Seklehner 2014[235]	Weber 2000[236]	Wu 2007[237]	Oremus 2010[232]	Oremus 2003[231]	Kunkle 2015[225]	Das Gupta 2006[227]	Holtzer-Goor 2015[238]	Weber 2000[239]	Weber 2002[240]	Imamura 2010[241]
6.4. Was the valuation of consequences appropriate for the question posed (i.e. has the appropriate type or types of analysis – cost-effectiveness, cost–benefit, cost–utility – been selected)?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
7. Were costs and consequences adjusted for differential timing?	Yes	Yes	Yes	Yes	N/A	Yes	Yes	NC	Yes	N/A	N/A	N/A	Yes	NC	N/A	N/A	Yes
7.1. Were costs and consequences that occur in the future 'discounted' to their present values?	Yes	Yes	Yes	Yes	N/A	Yes	Yes	NC	Yes	N/A	N/A	N/A	Yes	NC	N/A	N/A	Yes
7.2. Was there any justification given for the discount rate used?	No	Yes	No	Yes	N/A	No	Yes	N/A	Yes	N/A	N/A	N/A	No	No	N/A	N/A	Yes
8. Was an incremental analysis of costs and consequences of alternatives performed?	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8.1. Were the additional (incremental) costs generated by one alternative over another compared with the additional effects, benefits or utilities generated?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9. Was allowance made for uncertainty in the estimates of costs and consequences?	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
9.1. If data on costs and consequences were stochastic (randomly determined sequence of observations), were appropriate statistical analyses performed?	NC	No	Yes	Yes	No	N/A	Yes	N/A	N/A	Yes	No	Yes	Yes	Yes	No	No	Yes
9.2. If a sensitivity analysis was employed, was justification provided for the range of values (or for key study parameters)?	Yes	No	No	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
9.3. Were the study results sensitive to changes in the values (within the assumed range for sensitivity analysis, or within the confidence interval around the ratio of costs to consequences)?	NC	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
10. Did the presentation and discussion of study results include all issues of concern to users?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes

Item	Study																
	Von Bargen 2015[226]	Jacklin 2010[228]	Kilonzo 2004[229]	Laudano 2013[230]	Richardson 2014[233]	Sand 2014[234]	Seklehner 2014[235]	Weber 2000[236]	Wu 2007[237]	Oremus 2010[232]	Oremus 2003[231]	Kunkle 2015[225]	Das Gupta 2006[227]	Holtzer-Goor 2015[238]	Weber 2000[239]	Weber 2002[240]	Imamura 2010[241]
10.1. Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g. cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion?	Yes	Yes	Yes	Yes	Yes	N/A	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10.2. Were the results compared with those of others who have investigated the same question? If so, were allowances made for potential differences in study methodology?	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10.3. Did the study discuss the generalisability of the results to other settings and patient/client groups?	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No
10.4. Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g. distribution of costs and consequences, or relevant ethics issues)?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes
10.5. Did the study discuss issues of implementation, such as the feasibility of adopting the 'preferred' programme given existing financial or other constraints, and whether or not any freed resources could be redeployed to other worthwhile programmes?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

N/A, not applicable; NC, not clear.

Appendix 19 Economic model structure

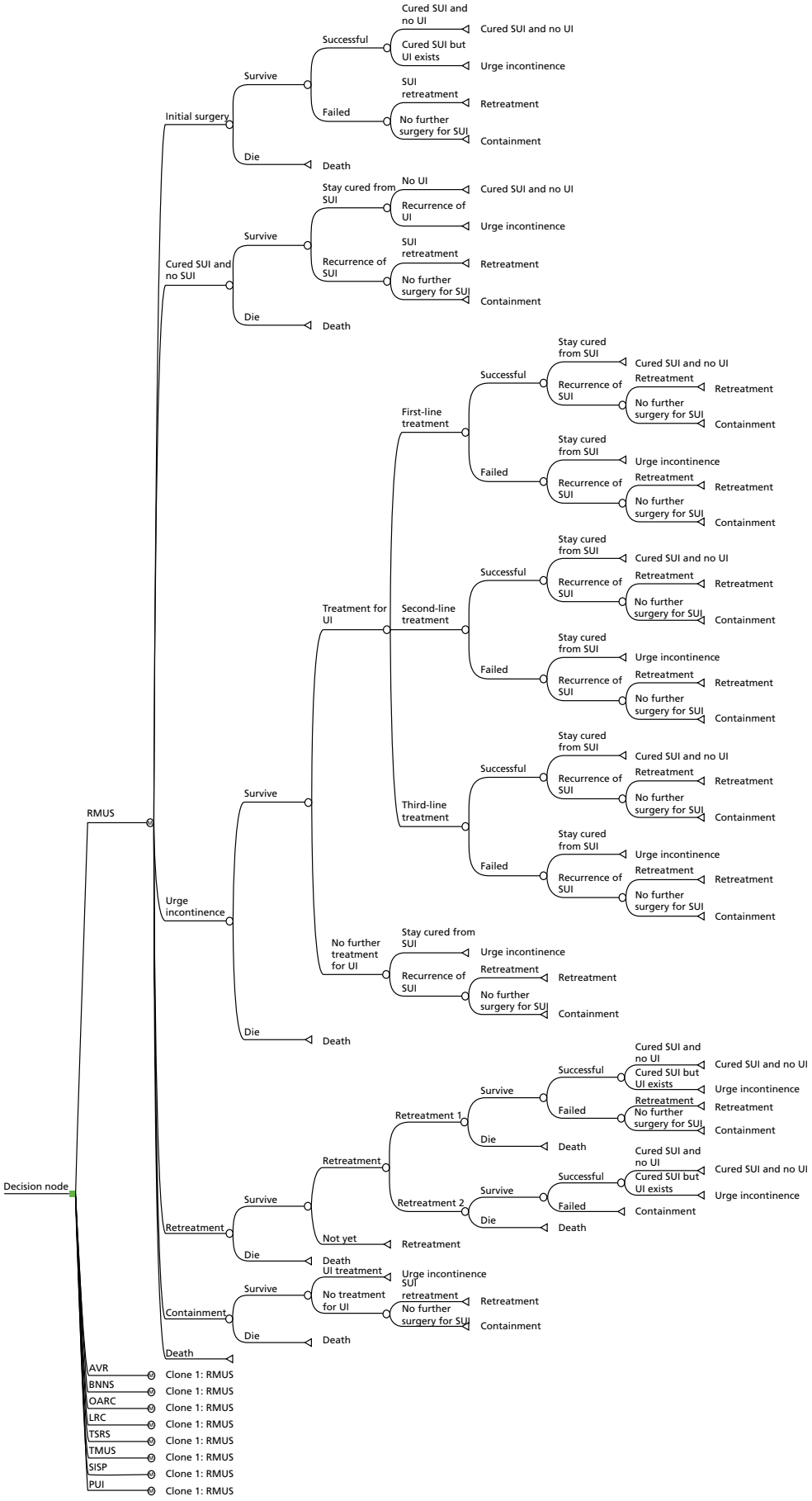
Decision node
RMUS
Initial surgery
Survive
Successful
Cured SUI and no UI
Cured SUI and no UI
Cured SUI but UI exists
Urge incontinence
Failed
SUI retreatment
Retreatment
No further surgery for SUI
Containment
Die
Death
Cured SUI and no SUI
Survive
Stay cured from SUI
No UI
Cured SUI and no UI
Recurrence of UI
Urge incontinence
Recurrence of SUI
SUI retreatment
Retreatment
No further surgery for SUI
Containment
Die
Death
Urge incontinence
Survive
Treatment for UI
First-line treatment
Successful
Stay cured from SUI
Cured SUI and no UI
Recurrence of SUI
Retreatment
Retreatment
No further surgery for SUI
Containment
Failed
Stay cured from SUI
Urge incontinence
Recurrence of SUI
Retreatment
Retreatment
No further surgery for SUI
Containment
Second-line treatment
Successful
Stay cured from SUI
Cured SUI and no UI
Recurrence of SUI
Retreatment
Retreatment
No further surgery for SUI
Containment
Failed
Stay cured from SUI
Urge incontinence
Recurrence of SUI
Retreatment
Retreatment
No further surgery for SUI
Containment
Third-line treatment
Successful
Stay cured from SUI
Cured SUI and no UI
Recurrence of SUI
Retreatment
Retreatment
No further surgery for SUI
Containment
Failed
Stay cured from SUI
Urge incontinence
Recurrence of SUI
Retreatment
Retreatment
No further surgery for SUI
Containment
No further treatment for UI
Stay cured from SUI
Urge incontinence
Recurrence of SUI
Retreatment
Retreatment
No further surgery for SUI
Containment
Die
Death
Retreatment
Survive
Retreatment
Retreatment 1
Survive
Successful
Cured SUI and no UI
Cured SUI and no UI
Cured SUI but UI exists
Urge incontinence
Failed
Retreatment
Retreatment
No further surgery for SUI
Containment
Die
Death
Retreatment 2
Survive
Successful
Cured SUI and no UI
Cured SUI and no UI
Cured SUI but UI exists
Urge incontinence
Failed
Containment
Die
Death
Not yet
Retreatment
Die
Death
Containment
Survive
UI treatment
Urge incontinence
No treatment for UI
SUI retreatment
Retreatment
No further surgery for SUI
Containment
Die
Death
Death
AVR
Clone 1: RMUS
BNNS
Clone 1: RMUS
OARC
Clone 1: RMUS
LRC
Clone 1: RMUS
TSRS
Clone 1: RMUS
TMUS
Clone 1: RMUS
SISP
Clone 1: RMUS
PUI
Clone 1: RMUS

FIGURE 65 Economic model structure. AVR, anterior vaginal repair (anterior colporrhaphy); BNNS, bladder neck needle suspension; LRC, laparoscopic retropubic colposuspension; MUS, mid-urethral sling; OARC, open abdominal retropubic colposuspension; PUI, periurethral injection (injectable bulking agents); RMUS, retropubic mid-urethral sling; TMUS, transobturator mid-urethral sling; TSRS, traditional suburethral retropubic sling procedures; SISP, single-incision sling procedure.

Appendix 20 Results of database analysis

Tables 36 and *37* and *Figure 66* provide the results from analysing data from AMND.

TABLE 37 Frequency of different SUI surgeries in the data from AMND

	Number of SUI surgery				
SUI operation	One (%)	Two (%)	Three (%)	Four (%)	Total
Abdominal retropubic procedure	285 (89.0)	28 (9.0)	5 (2.0)	1 (0.3)	319
MUS	331 (97.0)	10 (3.0)	1 (0.3)	0 (0.0)	342
Colporrhaphy	66 (83.0)	13 (16.0)	1 (1.0)	0 (0.0)	80
Urethral injection therapy	5 (5.0)	2 (20.0)	2 (20.0)	1 (10.0)	10
Total	687	53	9	2	751

TABLE 38 Different selection criteria for the different fitted hazard function forms

Model	Obs	ll (null)	ll (model)	df	AIC	BIC
Exponential	750	–302.621	–291.366	4	590.7	609.2
Gompertz	750	–298.106	–286.081	5	582.2	605.3
Log-logistic	750	–297.233	–285.114	5	580.2	603.3
Log-normal	750	–295.889	–284.734	5	579.5	602.6
Weibull	750	–297.391	–286.166	5	582.3	605.4

df, degree of freedom; obs, observations.

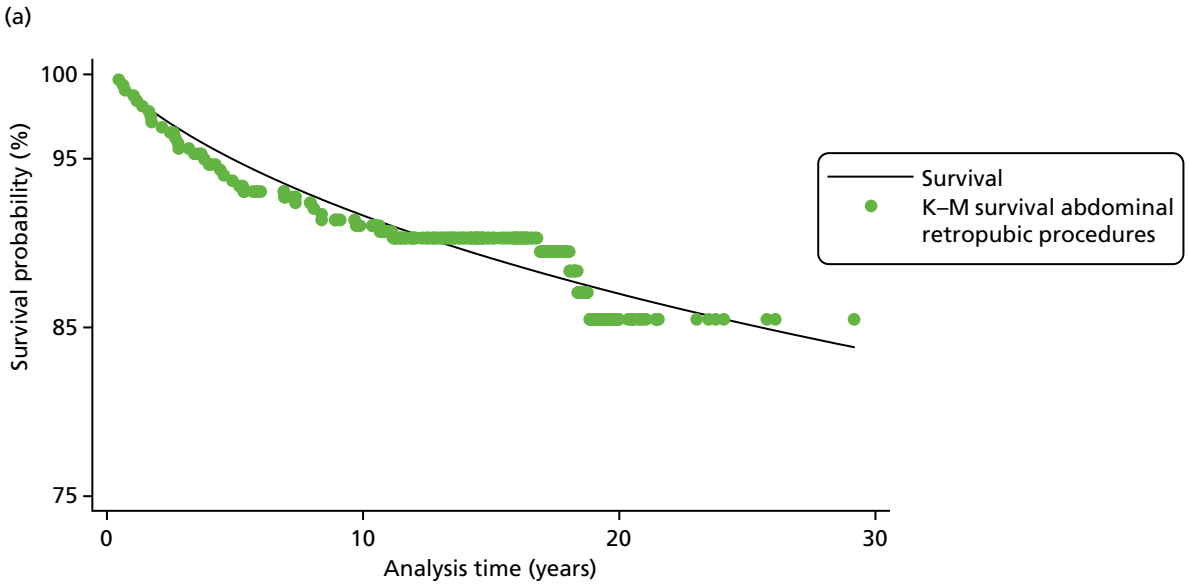

FIGURE 66 Fitted vs. observed survival in data from AMND. K–M, Kaplan–Meier. (*continued*)

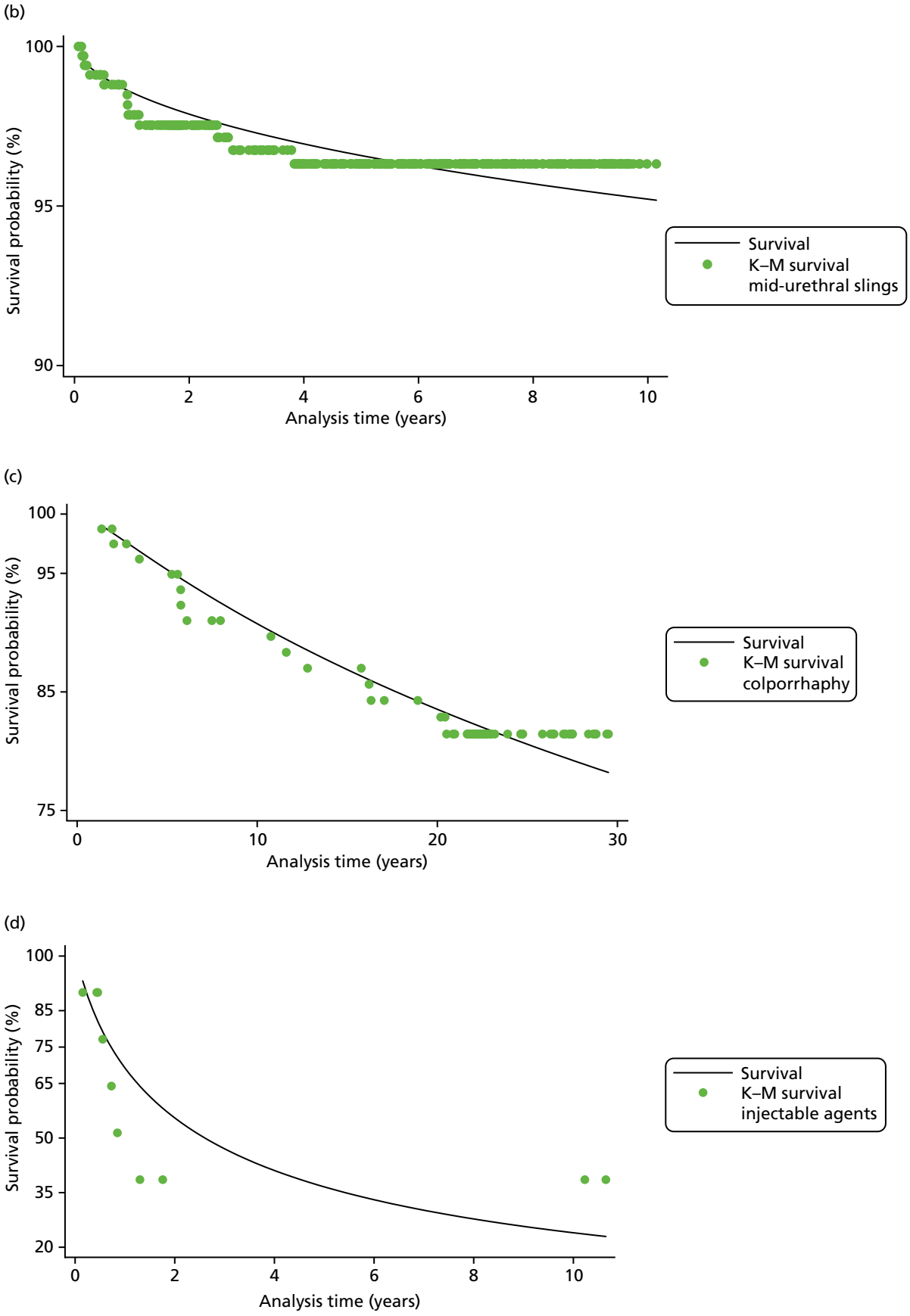

FIGURE 66 Fitted vs. observed survival in data from AMND. K–M, Kaplan–Meier.

Appendix 21 Deterministic sensitivity analyses

Assuming that all women in the model have stress urinary incontinence

The results from this SA, in which it is assumed that all women in the model have SUI, show that, compared with the base-case analysis, all strategies have a lower total cost and greater effectiveness (*Table 39*). Retropubic MUS remains the least costly strategy compared with the alternative surgical interventions but traditional sling is the most cost-effective option with an ICER of £8024 per QALY gained. *Table 40* shows that the probability of being cost-effective with a £20,000 WTP was 25.5% and 31.0% for retropubic MUS and traditional sling, respectively.

TABLE 39 Results from deterministic sensitivity analyses assuming that all women in the model have only SUI (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ΔQALY)	Probability cost-effective for different threshold (%)	
						£20,000	£30,000
Base-case analysis: 52% of the women in the model have SUI and 48% have MUI							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA assuming all women in the model have SUI							
Retropubic MUS	5282		25.11			32.1	30.5
Traditional sling	5668	385	25.16	0.05	8024	36.9	36.2
Transobturator MUS	7820	2153	24.22	–0.94	Dominated	1.9	1.9
Urethral injection therapy	7947	2280	24.34	–0.81	Dominated	5.8	6.1
Single-incision sling	8220	2553	23.94	–1.22	Dominated	1.0	1.1
Open colposuspension	8498	2831	24.87	–0.29	Dominated	14.9	16.0
Bladder neck needle suspension	8648	2980	24.09	–1.06	Dominated	2.6	2.7
Laparoscopic colposuspension	9877	4209	24.39	–0.77	Dominated	3.9	4.4
Anterior vaginal repair	9971	4303	23.80	–1.36	Dominated	1.0	1.2

TABLE 40 Results from deterministic sensitivity analyses changing the likelihood that a woman would seek retreatment if primary treatment failed (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective for different threshold (%)	
						£20,000	£30,000
Base-case analysis: 75% of women whose first treatment was not successful would seek retreatment and 30% of women whose first retreatment failed would seek second retreatment							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA using data from the linked database analysis to estimate proportion of the women who will seek retreatment after failure of each surgical treatment							
Retropubic MUS	8067		24.03			25.5	24.2
Traditional sling	8477	410	24.08	0.05	8114	31.0	30.0
Transobturator MUS	9472	995	23.48	–0.60	Dominated	3.9	4.0
Single-incision sling	9587	1110	23.28	–0.81	Dominated	1.9	1.9
Urethral injection therapy	9602	1125	23.74	–0.35	Dominated	14.4	14.7
Bladder neck needle suspension	10,134	1657	23.35	–0.73	Dominated	3.1	3.2
Open colposuspension	10,937	2460	23.89	–0.19	Dominated	13.7	14.8
Anterior vaginal repair	11,045	2568	23.18	–0.90	Dominated	1.4	1.6
Laparoscopic colposuspension	11,752	3275	23.56	–0.52	Dominated	5.0	5.6
SA assuming 50% of women whose first treatment was not successful would seek retreatment and 20% of women whose first retreatment failed would seek second retreatment							
Retropubic MUS	8061		24.14			27.0	25.6
Traditional sling	8479	418	24.15	0.01	35,896	29.0	28.3
Transobturator MUS	9551	1072	23.59	–0.57	Dominated	4.2	4.1
Urethral injection therapy	9579	1100	23.72	–0.43	Dominated	9.1	9.1
Single-incision sling	9584	1106	23.44	–0.71	Dominated	2.8	2.7
Bladder neck needle suspension	10,090	1611	23.54	–0.61	Dominated	4.8	4.9
Open colposuspension	10,930	2451	24.01	–0.15	Dominated	14.6	15.7
Anterior vaginal repair	11,003	2525	23.38	–0.78	Dominated	2.4	2.7
Laparoscopic colposuspension	11,739	3261	23.71	–0.44	Dominated	6.3	6.9

TABLE 40 Results from deterministic sensitivity analyses changing the likelihood that a woman would seek retreatment if primary treatment failed (lifetime time horizon) (*continued*)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective for different threshold (%)	
						£20,000	£30,000
SA assuming 10% of women whose first treatment was not successful would seek retreatment and 0% of women whose first retreatment failed would seek second retreatment							
Retropubic MUS	8069		24.00			29.2	27.9
Traditional sling	8482	413	24.03	0.03	14,748	33.4	32.4
Transobturator MUS	9493	1011	23.42	–0.61	Dominated	3.8	3.7
Single-incision sling	9608	1126	23.22	–0.81	Dominated	1.8	1.7
Urethral injection therapy	9693	1211	23.50	–0.53	Dominated	6.0	6.2
Bladder neck needle suspension	10,141	1659	23.32	–0.71	Dominated	3.5	3.7
Open colposuspension	10,937	2455	23.85	–0.18	Dominated	15.4	16.6
Anterior vaginal repair	11,041	2559	23.14	–0.89	Dominated	1.4	1.6
Laparoscopic colposuspension	11,752	3270	23.53	–0.50	Dominated	5.5	6.2

Assuming alternative values for the proportion of women who will seek retreatment after failure of each surgical treatment

In this SA, in which data from the linked database were applied, results show that the effectiveness of all surgical interventions is reduced slightly compared with the base-case analysis, and traditional sling, with an ICER of £8114 per QALY gained, is the most cost-effective option compared with the other surgical treatments. In the additional SA, in which it was assumed that 50% of women whose first treatment was not successful would seek retreatment and 20% of women whose first retreatment failed would seek second retreatment, total costs and effectiveness are reduced for most of the surgical interventions compared with the base-case analysis. Results from this SA show that retropubic MUS remains the least costly strategy compared with the alternative surgical interventions and is the most cost-effective option. When 10% and 0% were assumed for the rates of first and second treatments, traditional sling procedure was a cost-effective option with an ICER of £14,748, which is lower than £20,000 (*Table 40*).

Applying lower success rate for repeating same surgeries

In this SA, the effect of assuming lower cure rates (90% and 75%, respectively) when the same surgeries are being conducted for a second or third time was explored. As would be expected, the results of these sensitivity analyses show that all strategies have a higher cost and lower effectiveness. However, traditional sling is the most cost-effective option compared with other surgical treatments at a WTP threshold value of £20,000 (*Table 41*).

TABLE 41 Results from deterministic sensitivity analyses assuming lower success rate for repeating same surgeries (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective for different WTP thresholds (%)	
						£20,000	£30,000
Base-case analysis: assuming same cure rates when the same surgeries are being conducted for a second or third time							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA assuming lower cure rates (90%) when the same surgeries are being conducted for a second or third time							
Retropubic MUS	8703		24.07			27.6	26.3
Traditional sling	9079	377	24.10	0.03	12,623	31.5	30.5
Transobturator MUS	10,554	1475	23.53	–0.58	Dominated	4.3	4.4
Urethral injection therapy	10,586	1507	23.61	–0.49	Dominated	7.4	7.6
Single-incision sling	10,809	1730	23.34	–0.76	Dominated	2.3	2.3
Bladder neck needle suspension	11,252	2172	23.43	–0.67	Dominated	4.4	4.5
Open colposuspension	11,689	2610	23.95	–0.15	Dominated	15.2	16.3
Anterior vaginal repair	12,309	3229	23.27	–0.84	Dominated	2.0	2.2
Laparoscopic colposuspension	12,735	3656	23.63	–0.47	Dominated	5.4	6.0
SA assuming lower cure rates (75%) when the same surgeries are being conducted for a second or third time							
Retropubic MUS	8889		24.04			27.9	26.3
Traditional sling	9239	349	24.07	0.03	12,036	32.6	31.7
Transobturator MUS	10,846	1607	23.45	–0.61	Dominated	4.0	4.1
Urethral injection therapy	10,907	1668	23.53	–0.53	Dominated	6.6	6.8
Single-incision sling	11,160	1921	23.26	–0.81	Dominated	2.5	2.5
Bladder neck needle suspension	11,586	2347	23.36	–0.71	Dominated	3.8	4.0
Open colposuspension	11,912	2673	23.88	–0.19	Dominated	14.8	15.9
Anterior vaginal repair	12,685	3447	23.17	–0.89	Dominated	2.0	2.2
Laparoscopic colposuspension	13,023	3784	23.56	–0.51	Dominated	5.9	6.6

Incorporating different health utility values and effect of natural decline in health utility over time

In this SA, EQ-5D scores were adjusted and lower values were used for MUI health states compared with women with only SUI. The results from this SA show that traditional sling is the most cost-effective option (with an ICER of £7183 per QALY gained) compared with other surgical treatments. The impact of the natural decline in health utility over time was also considered in further SA. Results from this SA show that retropubic MUS remains the least costly strategy compared with the alternative surgical interventions and is the most cost-effective option (*Table 42*).

TABLE 42 Results from deterministic sensitivity analyses incorporating different health utility values for MUI and effect of natural decline in health utility over time (lifetime time horizon)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective for different WTP thresholds (%)	
						£20,000	£30,000
Base-case analysis assuming health states values are the same for women with SUI and MUI and fixed utility values over time							
Retropubic MUS	8099		24.22			25.8	24.6
Traditional sling	8522	423	24.22	0.01	60,863	27.0	26.2
Urethral injection therapy	9554	1032	23.86	–0.36	Dominated	10.5	10.5
Single-incision sling	9649	1127	23.59	–0.63	Dominated	3.2	3.2
Transobturator MUS	9665	1142	23.71	–0.51	Dominated	4.1	4.1
Bladder neck needle suspension	10,125	1603	23.69	–0.53	Dominated	5.4	5.4
Open colposuspension	10,977	2455	24.10	–0.12	Dominated	14.1	15.0
Anterior vaginal repair	11,057	2535	23.54	–0.69	Dominated	3.9	4.1
Laparoscopic colposuspension	11,797	3274	23.83	–0.40	Dominated	6.2	6.8
SA assuming lower health utility value for MUI health states							
Retropubic MUS	8104		23.70			30.4	29.1
Traditional sling	8526	423	23.75	0.06	7183	37.4	36.4
Urethral injection therapy	9551	1025	23.09	–0.67	Dominated	6.9	7.0
Single-incision sling	9648	1122	22.63	–1.13	Dominated	1.1	1.1
Transobturator MUS	9668	1142	22.86	–0.89	Dominated	1.9	2.0
Bladder neck needle suspension	10,125	1599	22.78	–0.98	Dominated	2.8	3.0
Open colposuspension	1097	2452	23.49	–0.26	Dominated	14.5	15.7
Anterior vaginal repair	11,057	2531	22.53	–1.23	Dominated	1.3	1.3
Laparoscopic colposuspension	11,797	3271	23.04	–0.71	Dominated	3.9	4.6

continued

TABLE 42 Results from deterministic sensitivity analyses incorporating different health utility values for MUI and effect of natural decline in health utility over time (lifetime time horizon) (*continued*)

Strategy	Cost (£)	Incremental cost (£)	QALY	Incremental QALY	ICER (£) (ΔCost/ ΔQALY)	Probability cost-effective for different WTP thresholds (%)	
						£20,000	£30,000
SA incorporating the impact of the natural decline in health utility over time							
Retropubic MUS	8096		21.81			26.9	25.4
Traditional sling	8523	427	21.79	–0.01	Dominated	27.6	26.8
Urethral injection therapy	9552	1456	21.48	–0.33	Dominated	10.6	10.6
Single-incision sling	9647	1552	21.24	–0.56	Dominated	3.5	3.4
Transobturator MUS	9666	1570	21.36	–0.45	Dominated	4.3	4.4
Bladder neck needle suspension	10,124	2028	21.33	–0.48	Dominated	5.8	6.1
Open colposuspension	10,978	2882	21.68	–0.12	Dominated	12.5	13.5
Anterior vaginal repair	11,063	2967	21.20	–0.61	Dominated	3.4	3.6
Laparoscopic colposuspension	11,798	3702	21.46	–0.35	Dominated	5.5	6.3

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