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Health Technology Assessment
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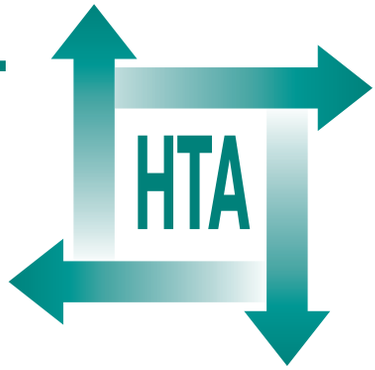

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Abstract

Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence

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Objectives: To evaluate the effectiveness and cost-effectiveness of tension-free vaginal tape (TVT) in comparison with the standard surgical interventions currently used.

Data sources: Literature searches were carried out on electronic databases and websites for data covering the period 1966–2002. Other sources included references lists of relevant articles; selected experts in the field; abstracts of a limited number of conference proceedings titles; and the Internet.

Review methods: A systematic review of studies including comparisons of TVT with any of the comparators was conducted. Alternative treatments considered were abdominal retropubic colposuspension (including both open and laparoscopic colposuspension), traditional suburethral sling procedures and injectable agents (periurethral bulking agents). The identified studies were critically appraised and their results summarised. A Markov model comparing TVT with the comparators was developed using the results of the review of effectiveness and data on resource use and costs from previously conducted studies. The Markov model was used to estimate costs and quality-adjusted life-years for up to 10 years following surgery and it incorporated a probabilistic analysis and also sensitivity analysis around key assumptions of the model.

Results: Based on limited data from direct comparisons with TVT and from systematic reviews, laparoscopic colposuspension and traditional slings have broadly similar cure rates to TVT and open colposuspension, whereas injectable agents appear to have lower cure rates. TVT is less invasive than colposuspension and traditional sling procedures, and is also usually performed under regional or local anaesthesia. The principal operative complication is bladder perforation. There are currently no randomised controlled trial (RCT) data beyond 2 years post-surgery, and long-term effects are therefore currently not known reliably. TVT was more likely to be considered cost-effective compared with the other surgical procedures. Increasing the absolute probability of cure following TVT reduced the likelihood that TVT would be considered cost-effective.

Conclusions: The long-term performance of TVT in terms of both continence and unanticipated adverse effects is not known reliably at the moment. Despite relatively few robust comparative data, it appears that in the short to medium term TVT's effectiveness approaches that of alternative procedures currently available, and is of lower cost. As TVT is a less invasive procedure, it is possible that some women who would currently be managed non-surgically will be considered eligible for TVT. Increased adoption of TVT will require additional surgeons proficient in the technique. It is likely that some of the higher rates of complications, e.g. bladder perforation, reported for TVT are associated with a 'learning curve'. Appropriate training will therefore be needed for surgeons new to the operation, in respect of both the technical aspects of the procedure and the choice of women suitable for the operation. Further research suggestions include unbiased assessments of longer term performance from follow-up of controlled trials or population-based registries; more data from methodologically sound RCTs using standard outcome measures; a surveillance system to detect longer term complications, if any, associated with the use of tape; and rigorous evaluation before extending the use of TVT to women who are currently managed non-surgically.

Contents

List of abbreviations

ACP	American College of Physicians
AMED	Allied and Complementary Medicine
B-FLUTS	Bristol Female Lower Urinary Tract Symptoms
BMI	body mass index
CCT	controlled clinical trial
CCTR	Cochrane Controlled Trials Register
CI	confidence interval
Colpo	colposuspension
ICER	incremental cost-effectiveness/utility ratio
Incon	incontinence
IQR	interquartile range
Lap	laparoscopy
LOS	length of stay
MeSH	Medical Subject Headings
MUI	mixed urinary incontinence
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
RD	risk difference
RR	relative risk
SD	standard deviation
SUI	stress urinary incontinence
TVT	tension-free vaginal tape (TVT™ is a trademark of Gynecare, UK)
USI	urodynamic stress incontinence
UTI	urinary tract infection
VAS	visual analogue scale

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Description of the service

Tension-free vaginal tape (TVT™) is a minimal access surgical sling procedure for treating stress urinary incontinence in women. The tape is passed beneath the urethra, aiming to restore the urethra to its normal position. TVT is placed with minimal tension and support is thought to be achieved by causing a tissue reaction with a subsequent collagen scar. TVT is generally reserved for women whose symptoms have not been alleviated by conservative management, such as pelvic floor muscle training.

Epidemiology and background

The prevalence of urinary incontinence is difficult to estimate owing to variations in definitions of incontinence, populations sampled and study methodologies used. It is also thought that under-reporting may mask the true magnitude of the problem. Estimates of the overall prevalence of any incontinence have varied between 10 and 52% of adult women, and of severe incontinence between 3 and 17%. A surgical intervention may be suggested where conservative interventions fail or cease to control stress urinary incontinence or in cases where they are unsuitable. The four main types of operations for female incontinence for the last 3 years in England and Wales were TVT, colposuspension, traditional suburethral sling procedures and injectable agents. In 2000–01 there were just over 8000 primary operations performed in England, with the majority being colposuspension (46%) and TVT (34%). Similar percentages were seen in Wales: colposuspension (38%) and TVT (25%).

This review assesses the effectiveness and cost-effectiveness of TVT in comparison with other surgical procedures, particularly colposuspension. The primary outcomes were subjective cure rates and quality of life, at least 24 months after the procedure. Short-term outcomes relating to the perioperative period (such as complications and resource use) were also assessed. Studies of women with symptoms of stress incontinence were considered, whether or not it had been demonstrated by urodynamics and whether or not it was combined with other symptoms such as urge incontinence. Where the data allowed, the following subgroups were considered: women undergoing a secondary intervention (after failed previous surgery), women with co-existing prolapse, and women with mixed symptoms of incontinence.

Methods

A search of electronic databases and websites between 1966 and 2002 was conducted to identify potentially relevant papers. Reference lists of relevant articles and abstracts of a limited number of conference proceedings titles were searched and selected experts in the field were contacted. Full-text papers were obtained for all potentially relevant studies and formally assessed for content relevance and methodological quality by two researchers independently. Details of study designs, participants, interventions and prespecified outcomes were recorded.

A systematic review of existing economic evaluations comparing TVT with any of the comparators was conducted. The identified studies were critically appraised and their results summarised.

A Markov model comparing TVT with the comparators was developed using the results of the review of effectiveness and data on resource use and costs from previously conducted studies. The Markov model was used to estimate costs and quality-adjusted life-years (QALYs) for up to 10 years following surgery and it incorporated a probabilistic analysis and also sensitivity analysis around key assumptions of the model.

Number and quality of studies

Eighty-two published studies related to TVT met the inclusion criteria. There were five randomised controlled trials, nine non-randomised comparative studies, two population-based registries, 17 case series with more than 2 years of follow-up and 49 case series with less than 2 years of follow-up. Additional data about the comparators were drawn from six pre-existing systematic reviews.

Summary of benefits

TVT is less invasive than colposuspension and traditional sling procedures. It is usually performed under regional or local anaesthesia rather than general anaesthesia, and is followed by a shorter stay in hospital.

The principal operative complication is bladder perforation, occurring in around one in 25 procedures. This does not appear to carry any long-term risk provided that it is recognised at the time of the operation. Other traumatic injuries, such as to a major vessel or nerve, can occur but are rare. In the longer term, the main concern is complications associated with the use of the tape, particularly erosion into the vagina or urinary tract. Current evidence suggests that these occur only rarely, but it is too soon to judge this reliably.

Most assessment has been in the form of description of case series. These show 2-year subjective 'cure' rates (variously measured) of 74–95%, with between 3 and 16% additional women improved but not cured. Only limited quality of life data are available from case series, but again they suggested significant improvement following TVT. The data from the case series must be treated with caution as bias may have been introduced because of the way in which cases were selected for inclusion and the lack of controls.

Judging how well TVT performs in comparison with other surgical procedures for stress incontinence is difficult because there are few randomised controlled trials (RCTs). Confidence intervals (CIs) around the estimates are therefore wide. In comparison with open colposuspension, at 6 months and based on one trial involving 316 women, the estimated relative cure rate is 9% lower after TVT [relative risk (RR) 0.91; 95% CI 0.78 to 1.07] with an absolute difference of –6% (95% CI –17 to 5%). **[Confidential information removed.]** Differential withdrawals and losses to follow-up in the trial that contributes most of the data complicate interpretation. The conclusions depend on what assumptions are made about these women.

Laparoscopic colposuspension and traditional slings have broadly similar cure rates to TVT and open colposuspension based on limited data from direct comparisons with TVT and from systematic reviews. Injectable agents appear to have lower cure rates.

There are currently no RCT data beyond 2 years post-surgery. Although the case series with more than 4 years of follow-up suggest sustained cure rates, there are only three such studies, and they include only around 300 women. Long-term continence rates are therefore currently not known reliably, nor are the effects of TVT on the outcome of future problems such as prolapse and recurrent stress incontinence.

Costs

Collection of cost data focused on direct health service costs, in respect of theatre costs, inpatient costs and outpatient costs. The estimated total cost of the procedures was £1114 for TVT, £1317 for colposuspension, £1340 for traditional slings, £1317 for laparoscopic colposuspension and £1305 for injectable agents. After 5 years of follow-up the cost would be £1494–1559 for TVT, £1654–1936 for colposuspension and £1626–1908 for traditional slings. Similar estimates were not derived for laparoscopic colposuspension and injectable agents.

Cost per QALY

The economic model suggested that on average TVT dominates open colposuspension: 5 years after surgery TVT was associated with a lower mean cost (£267) and the same or more QALYs (+0.00048). In the stochastic analysis, the likelihood of TVT being considered cost-effective was 100% if decision-makers were unwilling to pay for additional QALYs. If a decision-maker was prepared to pay up to £20,000 for an additional QALY, there was about a 95% chance that TVT is cost-effective; at £30,000 and £40,000 the probabilities were approximately 93% and 85%, respectively.

TVT was more likely to be considered cost-effective compared with the other surgical procedures based on the assumptions that traditional slings have the same effectiveness as open colposuspension and are also more costly; that laparoscopic colposuspension has the same or lower effectiveness as open colposuspension and similar costs; and that injectable agents are less effective than TVT but of greater cost.

Sensitivity analyses

Using plausible assumptions about the relative effectiveness of TVT compared with open colposuspension (particularly about withdrawals

from trials) and changing assumptions about retreatment rates led to a reduction in the likelihood of TVT being cost-effective: if a decision-maker was prepared to pay up to £20,000 for an additional QALY, then there is about an 88% chance that TVT is cost-effective; at £30,000 and £40,000 the probabilities are approximately 78 and 70%, respectively.

Increasing the absolute probability of cure following TVT reduced the likelihood that TVT would be considered cost-effective. This reflected the assumption that the relative risk is independent of the level of absolute risk and the absence of data to test this. Increasing the effectiveness of a secondary colposuspension increased the incremental cost per QALY and hence decreased the probability of TVT being cost-effective. Changes in the estimated costs of treatment and the probability of having a retreatment had only minor effects on the cost-effectiveness of TVT in two further sensitivity analyses.

Limitations of the calculation (assumptions made)

Varying the assumptions about withdrawals in the major trial of TVT versus open colposuspension had a large impact on estimates of relative effectiveness and cost-effectiveness. There were very few comparative studies with other operations. There were also very few data about TVT's performance after 2 years. TVT's longer term performance in respect of continence and safety is not known and the assumptions used (based on data up to 2 years) may not be reliable. Estimates of cost depend on assumptions about length of hospital stay and the costs of inpatient care.

Other important issues regarding implementation

Increased adoption of TVT will require additional surgeons proficient in the technique. Operative complications may in part reflect learning. Appropriate training will be required in both the technical aspects of the procedure and the choice of women suitable for TVT.

Notes on the generalisability of the findings

This review has only considered TVT for women whose incontinence is currently managed surgically. Its scope did not include TVT for women who at present are managed conservatively. TVT is one of a number of variants of less invasive sling procedures for urinary incontinence. No comparative data were identified that compared other variants with TVT or the other comparator operations.

Need for further research

Understanding of the place of TVT in clinical practice would be enhanced by unbiased assessments of longer term performance from follow-up of controlled trials or population-based registries; more data from methodologically sound RCTs using standard outcome measures; a surveillance system to detect longer term complications, if any, associated with the use of tape; and rigorous evaluation before extending the use of TVT to women who are currently managed non-surgically.

Chapter 1

Aim of the review

The aim of the review was to evaluate the effectiveness and cost-effectiveness of tension-free vaginal tape (TVT™, Gynecare, UK) in comparison with the standard surgical interventions currently used. The alternative treatments considered were abdominal retropubic colposuspension (including both open and laparoscopic colposuspension), traditional suburethral sling procedures and injectable agents (periurethral bulking agents). Studies that compared TVT with other types of surgical management (such as anterior vaginal repair, bladder neck or needle suspensions) were only considered if formally compared with TVT in a controlled study.

Chapter 2
Background

Description of underlying health problem

Epidemiology

Urinary incontinence is a common and potentially debilitating problem. The overall prevalence of incontinence is reported to be between 10 and 52% of adult women, and it is considered severe in about 3–17%.[1] *Table 1* summarises six of the most relevant prevalence studies.

The wide range of prevalence estimates in *Table 1* is due to variations in the definitions of incontinence used, populations sampled and study methodologies used.[9] It is believed that the true magnitude of the problem is still unknown owing to under-reporting. A cross-sectional postal survey carried out in Leicestershire in 2000[6] of 15,904 community-dwelling adults aged 40 years or over and registered with GPs revealed that 34% of the sample reported symptoms of stress incontinence.

TABLE 1 *Estimates of prevalence of female urinary incontinence*

Study	No. of women Source of data	Age group(s) (years)	Prevalence rates (%)	
Brocklehurst, 1993[2]	2124		Ever incontinent	Incontinence in previous year
	Random sample of women in the community, UK	30–49 50–59 >60	10.9 15.4 16.8	7.2 9.1 11.7
Glazener, 2001[3,4]	7879	Postnatal women	Any incontinence	Severe incontinence 16.5
	Women at 3 months after delivery, UK and New Zealand		33.4	Type of incontinence: Stress 54.1 Urge 16.4 Mixed 29.5
Jolleys, 1988[5]	807		Any incontinence	
	Women from rural GP practice, UK	25–64 >65 25+	46.4 25.4 41.1	
Perry, 2000[6]	5544	≥40	Any incontinence 20.2	Stress incontinence 34.2
	Postal survey of women in community, UK			Incontinence a bother or a problem 8.0
Thomas, 1980[7]	6476		Any incontinence	Regular incontinence
	Postal survey of women on GP practice lists, UK	25–64 >65	30.0 25.8	9.7 11.4
RCP, 1995[8]	Review of 18 epidemiological studies		Women at home	Institutions (residential, nursing, hospital)
		15–44 45–64 >65	5–7 8–15 10–20	25–70

For 7.2% of those surveyed, the symptoms were bothersome and for 2.7% socially disabling. Urinary incontinence, frequency and urgency were found to be more common in women. The prevalence of urinary incontinence in women was highest amongst those in their early 50s, lower amongst those in their 60s and then higher again amongst those aged 75 years or over.

Continence is achieved through an interplay of the normal anatomical and physiological properties of the bladder, urethra, urethral sphincter, pelvic floor and the nervous system coordinating these organs. The active relaxation of the bladder coupled with the ability of the urethra and its sphincter to contain urine within the bladder allow storage of urine until an appropriate time and place to void is reached. The role of the pelvic floor in providing support to the bladder and urethra and allowing normal abdominal pressure transmission to the proximal urethra is also considered essential in the maintenance of continence. Crucial to the healthy functioning of the bladder, urethra, urethral sphincter and pelvic floor is coordination between them, facilitated by control from an intact nervous system.

Incontinence occurs when this normal relationship between the lower urinary tract components is disrupted, for example owing to nerve damage or direct mechanical trauma to the pelvic organs. Advancing age, higher parity, vaginal delivery, obesity and menopause are associated with an increase in risk.[10]

There are three broad types of urinary incontinence: stress, urge and mixed.

Stress urinary incontinence (SUI) is the complaint (symptom) or observation (sign) of involuntary leakage of urine from the urethra on exertion or effort, straining or coughing. Urodynamic stress incontinence (USI) (formerly termed 'genuine stress incontinence') is defined as the involuntary leakage of urine during increased abdominal pressure in the absence of a detrusor contraction, noted during filling cystometry.[11] It is not clear, however, especially from the clinical management standpoint, whether a urodynamic diagnosis is imperative for successful treatment of stress urinary incontinence. For this reason, this review includes women diagnosed with either stress incontinence (symptom alone) or USI. Two sub-types of stress incontinence are recognised: one from a hypermobile but otherwise healthy urethra and the other from deficiency of the sphincter itself.[12] Urethral hypermobility is a manifestation of weakened support of the proximal urethra and sphincter deficiency is an indication of compromised ability of the urethra to act as a watertight outlet. The two types are considered as a single entity for the purpose of this review for three reasons: first, few studies have distinguished between them; second, a standardised test is not available to differentiate between them accurately; and last, there is increasing belief that more often both types co-exist although to differing degrees.

Urge urinary incontinence is the symptom of involuntary loss of urine accompanied by or immediately preceded by a sudden, strong desire to void (urgency).[11] It is a manifestation of uncontrolled bladder muscle (detrusor muscle) contraction. Detrusor overactivity may be suspected clinically from symptoms of frequency and urgency. When detected urodynamically, bladder overactivity is termed either 'neurogenic detrusor overactivity' if there is an underlying neurological pathology associated with it, or 'idiopathic detrusor overactivity' when there is no identified cause.[11] Women with urge incontinence alone were considered in this review.

Mixed urinary incontinence (MUI) is the condition of urine leakage with features of both stress and urgency. Patients may have stress incontinence with symptoms of frequency and urgency, or stress and urge incontinence (diagnosed either by symptoms alone or by urodynamics), or USI with detrusor overactivity. According to Jolleys,[5] MUI accounts for almost 50% of all cases of female urinary incontinence and women with mixed incontinence were included in this review.

Urinary incontinence, especially stress incontinence, is commonly associated with vaginal prolapse. Some degree of vaginal prolapse is common and is seen in 50% of parous women[13] and 10% of women in the community at some time undergo surgery for the management of prolapse.[14] A prolapse is herniation through a fascial defect. An anterior vaginal wall prolapse may include urethra or bladder (urethrocele and cystocele, respectively), a posterior vaginal wall prolapse may include the rectum or other parts of the gut (rectocele and enterocele, respectively) and uterine or vaginal vault prolapse occurs when the upper part of the vagina where the cervix (lower part of the uterus) opens into the vagina descends into or past the lower part of the vagina. A woman can have prolapse of one or more of these types.

The presence of vaginal prolapse is also relevant to this review. If organs surrounding the prolapse

are affected, symptoms of bladder, bowel or sexual dysfunction may be present. Bladder symptoms include incontinence, urgency or voiding dysfunction.

The management of urinary incontinence includes conservative techniques, pharmacological treatment and surgical interventions. Conservative approaches include physical therapies (e.g. pelvic floor muscle training, electrical stimulation, biofeedback and weighted vaginal cones), lifestyle modification (e.g. weight loss, regulation of fluid intake), behavioural interventions (e.g. bladder retraining, timed voiding) and mechanical devices (e.g. urethral plugs and inserts to prevent or reduce urine leakage). Drug therapies include anticholinergics and antispasmodics (for urge incontinence) and oestrogens; α-adrenergic agents are now only rarely used (for stress incontinence) because of side-effects. Conservative therapy, with or without the use of drug therapies, is generally undertaken before resorting to surgery.

Surgical procedures to treat SUI generally aim to improve the support to the urethro-vesical junction and correct deficient urethral closure. There is disagreement, however, regarding the precise mechanism by which continence is achieved with surgical manipulation. The surgeon's preference, co-existing problems, the anatomical features of the woman and her general health condition often influence the choice of procedure. Over 100 surgical procedures have been described in the literature,[15] but essentially, they fall into seven categories:

1. open abdominal retropubic colposuspension
2. laparoscopic retropubic colposuspension
3. suburethral sling procedures (the TVT operation, the subject of this review, is a new type of suburethral sling procedure)
4. bladder neck needle suspension
5. anterior vaginal repair (anterior colporrhaphy)
6. periurethral injection
7. artificial sphincter.

Artificial sphincters are not usually considered for women until all other modes of treatment including other operations have failed, and have not been considered in this review.

Significance in terms of ill-health (burden of disease)

Incontinence is a significant social and public health problem. It has been estimated that there are three million sufferers in the UK.[16] As discussed above, the true prevalence remains difficult to assess. Definitions are further complicated by the frequency of occurrence and the quantity of urine passed. In addition, some people are too embarrassed to seek help or prefer not to see it as a problem even though incontinence adversely affects many aspects of their daily life.[17] Consequently, an unidentified population of sufferers may remain untreated even though these people may be suffering a great deal.

Although many people with incontinence can be successfully cured with appropriate management, many others have persistent incontinence that can only be managed symptomatically with appliances such as pads or absorbent pants.[18,19]

Current service provision and cost

Current service provision

One study, which combined data from 18 different sources to arrive at approximate prevalence figures,[8] concluded that about 10% of women suffer from incontinence. Of the female population in England of 20,392,000 women of at least 16 years of age,[20] 2,039,200 would therefore be expected to complain of incontinence. Although this may be an underestimate, routine data sources report that 8071 women (0.004%) underwent one of the operations for incontinence as a primary procedure in the year 2000–1. In England, this would represent approximately 81 operations per year in a typical health authority of 500,000 people. In Wales there are approximately 430 of these operations per year.

Tables 2 and *3* show the use of the four main types of operations for female incontinence (TVT, colposuspension, slings and injectable agents) for the last 3 years for England and Wales, respectively. In 2000–1 approximately 8000 operations performed in England used just over 37,000 bed days (*Table 2*). In 2000–1, the majority of these were TVT (34%) and colposuspension (46%) (*Table 2*). A similar pattern of operation frequency was seen in Wales (*Table 3*).

Table 2 also shows that there are considerable differences in length of hospital stay between the four procedures. Colposuspension and traditional suburethral slings are generally performed as inpatient procedures and have comparable hospital stays: on average, women stayed for a week in hospital. One of the putative advantages of TVT is that it can be performed as a day-case procedure.

TABLE 2 *Current and recent service provision: use of NHS resources on operations for female urinary incontinence in England for 1998–2001 where data are available*[21]

Name of operation	Procedures		No. of bed days	Day cases (%)	Length of stay including day cases (mean) (days)
	No.	%			
2000–1					
TVT	2706	34	7364	5	2.9
Colposuspension	3719	46	25,923	0	7.1
Traditional slings	262	3	1804	2	7.2
Injectables	1384	17	1655	39	2.0
TOTAL	8071	100	36,746	46	
1999–2000					
TVT	715	10	1943	3	2.8
Colposuspension	4769	65	33,397	0	7.1
Traditional slings	399	5	2548	6	7.0
Injectables	1510	20	1731	41	2.0
TOTAL	7393	100	39,619	50	
1998–99					
TVT	214	3	614	0	2.9
Colposuspension	5663	72	40,888	0	7.3
Traditional slings	441	6	3000	0	7.0
Injectables	1446	19	2685	38	2.1
TOTAL	7764	100	47,187	38	

TABLE 3 *Current and recent service provision: use of NHS resources on operations for female urinary incontinence in Wales for 1998–2001 where data are available*[21]

Name of operation	Finished episodes		No. of bed days	Day cases (%)	Length of stay including day cases
	No.	%			
2000–1					
TVT	108	25	393	3	NA
Colposuspension	164	38	1321	1	NA
Traditional slings	59	13	378	0	NA
Injectables	106	24	121	40	NA
TOTAL	437	100	2213	44	
1999–2000					
TVT	30	8	135	0	NA
Colposuspension	192	51	1454	0	NA
Traditional slings	60	16	396	0	NA
Injectables	93	25	162	28	NA
TOTAL	375	100	2147	28	
1998–99					
TVT	13	3	69	0	NA
Colposuspension	202	47	1626	0	NA
Traditional slings	100	23	761	0	NA
Injectables	116	27	205	18	NA
TOTAL	431	100	2661	18	

NA, not available.

TABLE 4 *Distribution of types of operations (number of finished episodes) by women's ages in 2000–1 in England*[20,21]

Type of operation	No. of finished episodes	Mean age (years)	Age 15–59 years		Age 60–74 years		Age 75+ years	
			No.	%	No.	%	No.	%
TVT	2706	55	1784	66	735	27	187	7
Colposuspension	3719	53	2706	73	899	24	114	3
Slings	262	56	155	59	87	33	20	8
Injectables	1384	60	642	46	486	36	256	18
Total	8071		5287		2207		577	
No. of women in England (×1000)	20,392		14,627		3397		2368	

TABLE 5 *Distribution of types of operations (number of finished episodes) by women's ages in 2000–1 in Wales*[20,21]

Type of operation	No. of finished episodes	Mean age (years)	Age 15–59 years (%)[a]	Age 60–74 years (%)[a]	Age 75+ years (%)[a]
TVT	108	54	75	22	3
Colposuspension	164	51	81	17	2
Traditional slings	59	52	80	17	3
Injectables	106	57	60	32	8
Total	437				
No. of women in Wales (×1000)	1211.4		837.5	220.4	153.5

[a] Age data from Wales available only as percentages.

However, in England in 2000–1 only 5% of TVT operations were day cases. Nevertheless, the length of stay was considerably shorter (2.9 days) than the comparable figures for open colposuspension (7.1 days) and traditional slings (7.2 days). In contrast, nearly two-fifths of the injectables procedures were performed as day cases, with an average length of stay of 2 days. Length of stay information was not available for Wales.

Table 4 shows the age distribution of the women undergoing the operations. Open colposuspension was the most frequently used operation in younger women, followed by TVT. Injectable agents were most often chosen for the oldest age group (18% of all injectable operations were in women aged over 75 years). This reflects their reported usefulness in an older, frailer population, particularly if deemed unfit for an operation requiring general anaesthesia. Similarly, in Wales, the mean age of women having injectable treatment was higher than for the other three operations (*Table 5*).

Current service cost

It is estimated that incontinence currently accounts for 2% of the total annual healthcare budget of the UK.[8,17] The true cost of incontinence remains unknown in the UK as products are supplied from a variety of NHS budgets[8] and many people with incontinence choose to obtain their own products over the counter.[18] In the UK, the NHS spent £36 million in 1991 on absorbent products.[8] In the USA, it has been estimated that $16.4 billion was spent on urinary incontinence in 1994.[22] Containment of incontinence therefore represents a huge cost to the individual affected, the health service and the community.

Taking the costs of TVT to equal £1014, colposuspension and traditional slings to be £1317 (±£104) and £1340 (±£104), respectively, and injectable agents to cost £1305 (see Chapter 5 for methods of estimation), then using the data from *Tables 4* and *5*, the cost to the NHS in England is £9.8 million (£9.5–10.1 million) and in Wales is £543,000 (£526,000–555,000). Taking the activity data from *Table 4*, the cost to a standard population of 500,000 in England is £98,600 (£93,600–100,900) and to a standard population of 500,000 in Wales £92,100 (£89,200–£94,200).

Variation in services

In England, there were more operations completed (8071) for the most recent period for which data are available (2000–01) than in the two previous periods. Furthermore, there was a relative increase in the proportion of TVTs (rising from

3 to 10 to 34% of the total of the four index operations) and a fall in the proportion of colposuspensions (73 to 64 to 46%) over the same period. As the data suggest, this was mostly due to an increase in the number of TVTs performed at the expense of colposuspensions. However, there was also a disproportionate rise in the total number of TVTs, over and above that expected from a simple shift from colposuspensions to TVT, suggesting that the extra operations in the most recent period were TVTs. It appeared that in Wales the total number of operations did not increase although the proportion of TVT did increase (*Table 3*). In both England and Wales, the number of traditional sling operations also tended to fall over the same period (albeit from a relatively low level), whereas the number of injectables operations remained fairly stable.

The proportion of women undergoing day-case procedures in England and Wales did not change much over the three periods reported (*Tables 2* and *3*). It might be thought that, when TVT was first introduced in the late 1990s, surgeons might have been reluctant to perform it as a day-case procedure because they were unfamiliar with it, although one of its reported advantages was its suitability for short stays. However, as surgeons became familiar with the new TVT technique, the proportion of day cases remained low (*Tables 2* and *3*). One reason is that other procedures such as anterior vaginal repair were sometimes performed at the same time as TVT. Another is the need for prolonged bladder catheterisation, especially under regional anaesthesia. An additional possible reason is admission the day before the procedure, which may not be strictly necessary.

The proportion of injectables procedures performed as day cases remained fairly stable at around 40% in England over the three periods presented. However, in Wales a smaller proportion of women received injectable agents as day cases in 1998–99 (18%) and 1999–2000 (28%) but the proportion had risen to English levels by 2000–1 (40%, *Table 3*).

Data for laparoscopic colposuspensions as distinguished from open abdominal colposuspensions were only available for Wales (Appendix 1). The proportion of colposuspensions that were carried out by laparoscopy varied from 5 to 8% across the three periods in Wales.

Description of new intervention

TVT is a modification of the traditional suburethral sling procedures. It is a development of intravaginal slingplasty first described by Ulmsten and colleagues in the early 1990s.[23–25] The aim is to restore the patient's urethra to its normal position by placing a 'sling' of mesh tape beneath it. After surgery, the tape supports the urethra during a sudden movement, such as a cough or sneeze, allowing it to remain closed. This prevents the involuntary loss of urine. The assumption is that the tape replaces defective ligamentous and muscular structures to support the middle urethra.

The tape, covered by a plastic sheath, is introduced via a small vaginal incision over the midurethra. Regional anaesthesia is commonly used but general anaesthesia (particularly if TVT is combined with another procedure) and local anaesthesia are not uncommon. The procedure involves the insertion of two needles passed through the retropubic space blindly to the abdomen. Cystoscopy is recommended to detect any perforation of the bladder at the time of the procedure; in some centres this is performed twice (once after each passing of the needle). The TVT procedure in total takes about 45 minutes of theatre time and can be performed as a day case under local anaesthetic with intravenous sedation, although it is common for patients to have an overnight stay. Although one surgeon with one nurse can perform the procedure, it is more usual to have three nurses available. As a general rule, an anaesthetist and anaesthetic support staff are also present.

The equipment required for the procedure consists of a reusable stainless steel introducer, a reusable rigid catheter guide and the TVT device. The device is composed of a strip of polypropylene mesh, 40 cm long and 10 mm wide, covered by a plastic sheath and held between two stainless steel needles each 5 mm in diameter.[25,26] The purpose of the plastic sheath is to cover the mesh during placement of the sling to allow easy placement of the tape, which is designed to stay in place without fixation once the smooth protective cover is removed.[26] As the patient can be awake throughout the procedure, adjustment of the tape can be performed by asking the patient to cough with a full bladder to establish that continence has been achieved.

TVT, like other surgical procedures, is usually reserved for women for whom conservative therapies have failed. TVT can be used as a primary procedure or as a secondary procedure after failure of previous surgery. It has been used to treat incontinent women who have mixed

symptoms or a co-existent vaginal prolapse. TVT is not recommended for pregnant women, or women who plan to have children in the future. TVT is a less invasive surgical procedure than colposuspension or other traditional suburethral sling operations.

Description of comparators

There are six operations for which TVT could substitute. These are outlined below.

Open abdominal retropubic colposuspension

Open colposuspension is the surgical approach of lifting the tissues near the bladder neck and proximal urethra in the area of the pelvis behind the anterior pubic bones. When it is 'open', the approach is through an incision over the lower abdomen. There are generally three variations of open retropubic colposuspension. The Burch colposuspension is the elevation of the paravesical tissues towards the ileopectineal line of the pelvic side wall using two to four sutures on either side.[27] The Marshall–Marchetti–Krantz procedure is the suspension of the vesico-urethral junction (bladder neck) on to the periosteum of the symphysis pubis.[28] The paravaginal defect repair is a modification of the Burch procedure with placement of the sutures extended laterally and anchored at the obturator shelf rather than the ileopectineal line.[29] It aims to close any fascial defect rather than elevate the tissues in the paravesical area.

Laparoscopic retropubic colposuspension

In laparoscopic colposuspension, a procedure similar to a Burch colposuspension is performed, but using minimal access techniques guided by laparoscopy.

Traditional suburethral sling procedures

Traditional suburethral sling operations require a combined abdominal and vaginal approach. Strips of material are tunnelled under the urethra. They are attached to either the rectus muscle or the ileopectineal ligaments, resulting in a tightening of the sling and increased bladder support every time the woman contracts her rectus muscles. The materials that have been used for slings may be biological or synthetic. Autologous biological materials include rectus fascia, fascia lata, pubococcygeal muscle, vaginal wall and pyramidalis fascia. Exogenous biological materials include ox fascia and porcine dermis. Synthetic materials include Mersiline tape in a silicon tube, lyodura, polytetrafluoroethylene (Teflon; Gore-Tex), Marlex mesh and silastic.[30]

Periurethral injectable agents

The aim of injecting material into the periurethral space is to exert pressure on the urethra and hence its mucosa in order to maintain a higher closure pressure that will better resist raised abdominal pressure. To produce the best possible result, accurate placement of the substance is required. The material can be injected transurethrally using a cystoscope or periurethrally with a spinal needle or using a special injection device. For periurethral injection, the needle is introduced percutaneously into the subendothelial space. Manipulation is observed cystoscopically or with transvaginal ultrasound.

The injection can be carried out under local anaesthetic. This has the advantage of allowing the patient to try to cause leakage, for example by coughing, during the procedure. This means that the likely effectiveness of the treatment can be judged at the time of injection.[31] A variety of substances have been tried. They include microparticulate silicon (Macroplastique®), GAX-collagen (Contigen®) and polytetrafluoroethylene (Polytef®, Teflon).[31] GAX-collagen is formed by cross-linking bovine dermal collagen with glutaraldehyde to make it resistant to collagenase digestion and dispersing it in phosphate-buffered physiological saline.[32]

Other surgical procedures not considered further in this review

Two further surgical procedures are anterior vaginal repair and bladder neck needle suspension. There is, however, good evidence that they are less effective than open retropubic colposuspension, particularly amongst the sorts of women who might currently be considered for TVT.[33,34]

Anterior vaginal repair

Anterior vaginal repair (anterior colporrhaphy) is a surgical approach through the vagina. The vaginal mucosa below the urethra is dissected, ending just in front of the cervix. One to three sutures (often referred to as Kelly sutures) are placed in the periurethral tissue and the pubocervical fascia to support and elevate the bladder neck. Excess vaginal tissue is removed and then the dissected area is closed. A wide variety of techniques and modifications have been described, including Bologna procedure, Kelly–Kennedy,

Marion Kelly, diaphragmplasty, vaginal urethrocystopexy, cystocele repair and Kelly plication.[35]

Bladder neck needle suspension

Needle suspensions may be performed from a vaginal or an abdominal approach. A long needle is used to thread sutures from the vagina to the anterior abdominal fascia. The sutures are looped through to the para-urethral tissue on each side of the bladder neck, thereby supporting it. There are three principal types (Pereyra, Stamey and Raz) and several modifications of each, such as site of initial approach (abdominal or vaginal), type of suture, site of attachment of the sutures and the use of silastic spacers or Dacron sheaths to protect the suture from cutting through.[35] Cystoscopy (endoscopy) during or after the placement of the sutures is used to check that the bladder has not been injured. The salient features are that the passage of the needle through the retropubic space is done blindly and the support to the urethra is derived indirectly from the vaginal walls.

Chapter 3

Effectiveness

Methods for reviewing effectiveness

Search strategy

A set of TVT search terms was first developed in MEDLINE by exploring the MeSH terms, reading articles obtained from the Cochrane Incontinence Review Group, checking the MeSH terms assigned to these articles and consulting experts in the field. Textword searching (i.e. searching in titles and abstracts) was also used. In order to find all types of evidence related to TVT, a search was performed using the set of TVT terms without combining it with any other set of search terms and no limits or language restrictions were imposed. The TVT terms were then adapted for use in other databases by adjusting the syntax and the controlled vocabulary to that required by each database. Searches were conducted in the electronic bibliographic databases listed in *Table 6*.

For the comparator interventions (colposuspension, traditional slings and injectable agents), only systematic reviews were sought. The set of search terms for each comparator was developed in a similar fashion to that used for the TVT terms. The set of review terms used was based on a shortened version of the Centre for Reviews and Dissemination search strategy to locate systematic reviews.[36–38]

Searches for reviews of the comparators were performed in the following databases:

- MEDLINE (1966 to week 3, May 2002) (on OVID) (date searched for: slings 23 May 2002; injectable agents 16 May 2002; colposuspension 23 May 2002)
- EMBASE (1980 to week 19, 2002) (on OVID) (date searched for: slings 23 May 2002; injectable agents 16 May 2002; colposuspension 23 May 2002)
- DARE (Issue 2, 2002) (on OVID) (date searched for: slings 23 May 2002; injectable agents 22 May 2002; colposuspension 5 June 2002)
- Cochrane Incontinence Review Group (searched on 15 May 2002 for all three comparators).

Details of the final search strategies used can be found in Appendices 2 and 3.

Other sources of information included:

- references lists of relevant articles
- selected experts in the field
- abstracts of a limited number of conference proceedings titles (scanned for those relevant to TVT)
- the Internet (a limited search using the search engine Google was performed).

The following methods were used for handling, deduplicating and assessing the articles retrieved. All the results of the electronic bibliographic searching were imported directly into Reference Manager (version 9.5N, ISI ResearchSoft, USA) where this was possible. Where this importing was not possible, the citation details were hand keyed into the Reference Manager software. Attempts were made to remove duplicates at two stages in the search process. The first was within OVID (on Digital Island), where the search software allows the deduplication of a search across multiple databases, and this facility was used. The second was within the Reference Manager software, which performed duplicate checking when importing references.

Inclusion and exclusion criteria

The abstracts were then assessed for relevance to the review topics. Only one person assessed the TVT searches as all articles related to TVT were requested. The searches for systematic reviews of the comparators were assessed by two reviewers. Full-text copies of all potentially relevant studies were obtained and formally assessed for inclusion by two reviewers working independently. Any disagreements that could not be resolved through discussion were referred to an arbiter.

Types of studies

For TVT, studies of three types were included: randomised controlled trials (RCTs), non-randomised comparative studies and case series. The last type were categorised based on length of follow-up: at least 4 years, 3 years, 2 years and less than 2 years. Additional data describing comparators were drawn from systematic reviews.

Types of participants

The studies considered included women affected by SUI for whom non-surgical therapies, such as

TABLE 6 *Details of electronic bibliographic databases searched for TVT-related articles*

Source	Period covered by search	Date of search
Cochrane Incontinence Review Group Specialised Register of Trials	Up to March 2002	March 2002
MEDLINE	1966 to week 3, April 2002	14 May 2002
PreMEDLINE	Up to 10 May 2002	14 May 2002
EMBASE	1980 to week 19, 2002	14 May 2002
CINAHL	1982 to week 4, April 2002	14 May 2002
HealthSTAR	1975 to April 2002	14 May 2002
Cochrane Controlled Trials Register (CCTR) (on OVID)	Issue 1, 2002	28 March 2002
Cochrane Database of Systematic Reviews (CDSR) (on OVID)	Issue 1, 2002	25 April 2002
Database of Abstracts of Reviews of Effectiveness (DARE) (OVID and CRD website)	Issue 1, 2002 (web 25 April 2002)	25 April 2002
HTA database and reports (on CRD website)	Up to 25 April 2002	25 April 2002
NHS EED (on CRD website)	Up to 25 April 2002	25 April 2002
BIOSIS	1985 to 25 April 2002	25 + 29 April 2002
Science Citation Index	1981 to 20 April 2002	25 April 2002
ISI – Scientific and Technical Proceedings	1990 to 10 May 2002	13 May 2002
ZETOC	13 May 2002 and 24 May 2002	13 + 24 May 2002
ICS web-based conference abstracts (2000 and 2001)	2000 and 2001	13 May 2002
UK National Research Register	Issue 1, 2002	12 June 2002
Current controlled trials/metaRegister of Controlled Trials	Up to 12 June 2002	12 June 2002
ClinicalTrials.gov	Up to 12 June 2002	12 June 2002
CRISP (including FDA)	Up to 12 June 2002	12 June 2002
ACP Journal Club	1991 to January/February 2002	25 April 2002
AMED	1985 to April 2002	25 April 2002
SPORTDiscus	1949 to April 2002	25 April 2002

pelvic floor muscle training or oestrogens either (a) had failed or ceased to be effective or (b) are not suitable and for whom a surgical intervention was indicated.

Women with symptoms of SUI were considered, whether or not SUI had been demonstrated by urodynamics and whether or not SUI was combined with other symptoms or mixed incontinence. Women who presented with prolapse alone without overt urinary incontinence were not considered.

We aimed to identify women for whom TVT may be particularly effective (or ineffective) by studying the following sub-groups:

- women with mixed incontinence (i.e. SUI plus urge urinary incontinence or detrusor overactivity)
- women undergoing a secondary intervention (after failed previous incontinence surgery).
- women with co-existing prolapse

The assessment excluded pregnant women and those who planned to have children in the future, as TVT and other traditional sling operations are not recommended for this group.

Types of interventions

TVT was formally compared with colposuspension (including laparoscopic), traditional suburethral sling procedures and injectable agents (periurethral bulking agents). Controlled studies that had compared TVT with other types of surgical management were also sought.

Types of outcome measures

The primary outcome measures were subjective cure rates and quality of life (QoL), at least 24

months after the procedure. The analysis focused on medium- and long-term (>2 years) outcomes of clinical effectiveness (e.g. cure, improvement rates and QoL) from the women's perspective, but also assessed short-term outcomes relating to the operative procedure (e.g. surgical complications, hospital stay). Although we have reported primarily subjective cure rates, we have also reported objective rates when provided. Subjective cure or improvement is generally based on women's responses to questionnaires, whereas objective cure or improvement is based on methods for measuring urine loss such as a pad test.

Data extraction strategy

A data extraction form was developed to record details of study methods, participants, interventions, patients' characteristics and outcomes (Appendix 4). Two reviewers extracted data independently. Where a difference of opinion existed that could not be resolved through discussion, an arbiter was consulted.

Quality assessment strategy

Two reviewers working independently assessed all studies that met the selection criteria for methodological quality. Any disagreements that could not be resolved through discussion were referred to an arbiter. The assessment used a checklist developed by Downs and Black to assess the quality of studies to be included in a systematic review of surgical studies for stress incontinence (Appendix 5).[35] A quality assessment form devised specifically to assess systematic reviews was also used (Appendix 6).[39]

Methods of analysis/synthesis

Where data for a particular outcome were available from more than one RCT, the use of quantitative synthesis was considered. When this was judged appropriate the methods of the Cochrane Collaboration were used to derive summary measures of relative rates or rate differences.[40] Data for complications from case series were summarised in two ways: by deriving median values and interquartile ranges and by calculating an overall mean rate. The results from series derived from geographical registries were emphasised because they are less likely to be biased. Where quantitative synthesis was not possible, a narrative synthesis of eligible studies was undertaken. We planned to undertake secondary analyses in the following sub-groups if possible:

1. women with mixed incontinence
2. women having TVT as a secondary surgical intervention (after failed previous incontinence surgery)
3. women with co-existing vaginal prolapse.

Results

Quantity and quality of research available

Number of studies identified

The numbers of potentially relevant reports of studies as the screening process progressed are shown in *Figure 1*. Just over 2000 abstracts were identified by the literature searches and assessed

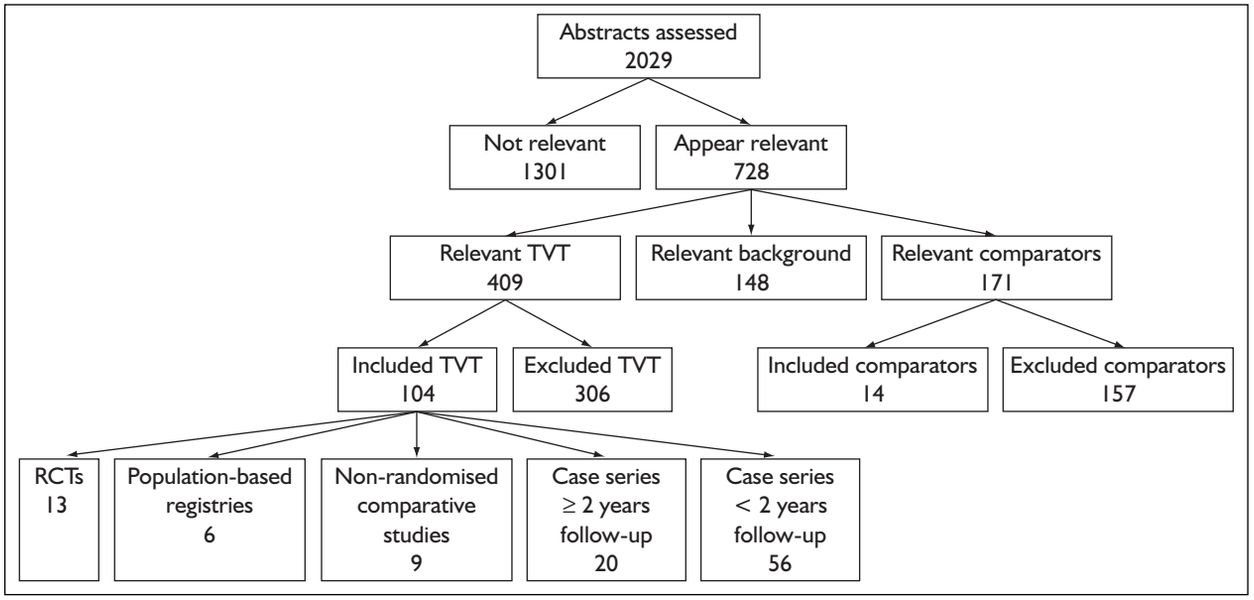

FIGURE 1 *Number of potentially relevant reports of studies as the screening of the electronic database results progressed (one study by Ulmsten and colleagues[41] has been used twice in the included studies, in the 2 years and over tables and the less than 2 years tables). NB: this figure presents numbers of reports of studies rather than numbers of studies*

TABLE 7 *Number of potentially relevant articles identified at each stage of the literature search process – TVT*

Source	No. of abstracts assessed[a]	No. of potentially relevant abstracts[b]
Electronic sources		
Cochrane Incontinence Review Group[c]	70	21
MEDLINE	215	94
PreMEDLINE	20	8
EMBASE	92	32
CINAHL	4	2
HealthSTAR	0	0
CCTR[d]	10	0
CDSR[e]	1	0
DARE[f]	0	0
HTA database	1	1
NHS EED[g]	0	0
BIOSIS	163	31
Science Citation Index	180	7
ISI – Scientific and Technical Proceedings	22	2
ZETOC	285	83
ICS web-based conference abstracts	88	34
UK National Research Register	17	9[h]
Current controlled trials	80	0
ClinicalTrials.gov	2	0
CRISP	59	0
ACP Journal Club	0	0
AMED	0	0
SPORTDiscus	0	0
Electronic sources total	1309	324
Other sources		
Reference lists	62	35
Experts in the field	43	8
Conference proceedings	72	42
Internet search	1	0
Other sources total	178	85
Total	1487	409

[a] After removal of duplicates where possible, either on OVID or using Reference Manager.
[b] Still some duplicates at this stage.
[c] The Cochrane Incontinence Review Group's specialised register of trials related to incontinence.
[d] Cochrane Controlled Trials Register.
[e] Cochrane Database of Systematic Reviews.
[f] Database of Abstracts of Reviews of Effectiveness.
[g] NHS Economic Evaluations Database.
[h] Presented in the ongoing studies (Appendix 7).

for relevance. Over 728 full-text copies of potentially relevant articles and conference abstracts were obtained and assessed independently for inclusion by two reviewers. The results of searching each source for studies related to TVT are shown in *Table 7*. The results of searching each source for systematic reviews related to the comparators are shown in *Tables 8–10*.

Number and type of studies included

In total, 80 published studies plus two population-based registries satisfied the agreed criteria and were included (*Table 11*). A further 10 ongoing comparative studies were identified and also one further comparative study planned but not yet funded. Nine of the ongoing studies are RCTs, as is the one planned study. Further details are provided in Appendix 7.

Of the 80 included studies, there were five RCTs or quasi-RCTs,[42–55] nine non-randomised comparative studies,[56–65] 17 case series with more than 2 years of follow-up[25,66–84] and 49 case series with less than 2 years of follow-up.[41,85–138] Additionally, there were six reports from two population-based registries for TVT.[139–144] Of the five RCTs

TABLE 8 *Number of potentially relevant articles identified by the literature search – reviews of retropubic colposuspension*

Source	No. of abstracts assessed[a]	No. of abstracts potentially relevant
Electronic sources		
MEDLINE	138	30
EMBASE	87	18
DARE	28	0
Cochrane Incontinence Review Group[b]	2	2
Came from other reviews	NA	15
Total	255	65

[a] After removal of duplicates where possible, either on OVID or using Reference Manager.
[b] The Cochrane Incontinence Review Group's specialised register of trials related to incontinence.

TABLE 9 *Number of potentially relevant articles identified by the literature search – reviews of injectable agents*

Source	No. of abstracts assessed[a]	No. of abstracts potentially relevant
Electronic sources		
MEDLINE	137	30
EMBASE	38	9
DARE	0	0
Cochrane Incontinence Review Group[b]	5	2
Came from other reviews	NA	19
Total	180	60

[a] After removal of duplicates where possible, either on OVID or using Reference Manager.
[b] The Cochrane Incontinence Review Group's specialised register of trials related to incontinence.

TABLE 10 *Number of potentially relevant articles identified by the literature search – reviews of traditional suburethral slings*

Source	No. of abstracts assessed[a]	No. of abstracts potentially relevant
Electronic sources		
MEDLINE	68	6
EMBASE	37	8
DARE	0	0
Cochrane Incontinence Review Group[b]	3	3
Came from other reviews	NA	29
Total	108	46

[a] After removal of duplicates where possible, either on OVID or using Reference Manager.
[b] The Cochrane Incontinence Review Group's specialised register of trials related to incontinence.

TABLE 11 *The design and numbers of TVT studies included*

Study design	TVT
Randomised/quasi-randomised controlled trials	5
Non-randomised comparative studies	9
Case series >2 years	17
Case series <2 years	49
Population-based registries	2
Total	82

included, one compared TVT with laparoscopic colposuspension[43] and the remainder with open colposuspension (including the one which formed part of the industry submission). Of the non-randomised comparative studies, three compared TVT with an open traditional suburethral sling procedure,[56,60,62] three with open colposuspension[57,59,65] and three with laparoscopic colposuspension[61,63,64] (one study had three arms which included a comparison with bladder neck

needle suspension).[63] Twelve systematic reviews were identified for the comparators, including six for open colposuspension,[35,145–151] two for laparoscopic colposuspension,[152,153] five for traditional suburethral slings[30,35,145,146,149,151,154] and three for injectable agents[149,155,156] (some reviews covered more than one comparator). Five involved the comparison of open colposuspension with traditional suburethral slings,[30,35,145,146,149–151] two compared open with laparoscopic colposuspension[152,153] and two compared open colposuspension with injectable agents.[149,150] For the purposes of this study, a further two reviews contributed data on colposuspension alone,[147,148] one on traditional suburethral slings alone[30] and two on injectable agents alone.[155,156] The patients in these studies generally had a preoperative diagnosis of USI.

The five RCTs/quasi-RCTs of TVT involved a total of 504 patients (range 26–344).[42–54] The length of follow-up ranged from 6 months to 24 months and the mean age of the patients ranged from 46.5 to 58.3 years.

However, very few usable data were available for two of these.[44,45] Both had been reported only in conference abstracts. Halaska and colleagues[44] described a sub-study on sexual function within an ongoing German–Czech multicentre trial. Han[45] reported perioperative data only. Information about the trial conducted by Cucinella and colleagues[43] also came from a conference abstract only; the limited information included some data on long-term outcome. A report of the trial performed by Liapis and colleagues[46,47] has recently been published. However, they used alternation rather than true random allocation and the trial involved only 71 women.

The larger and hence most useful trial is that coordinated by Ward and Hilton,[52] in which 344 women were recruited in 13 UK centres and one Irish centre. Multiple conference abstracts have provided limited data up to 2 years post-surgery, and a full report up to 6 months has been published in the *BMJ*. As discussed later, the usefulness of this trial is limited by failure to achieve the prestated sample size and losses to follow-up, particularly differential withdrawals from the arms of the trial between randomisation and surgery.

The nine comparative studies involved a total of 760 patients (range 16–161), for 677 of whom data were analysed. The length of follow-up ranged from 3 weeks (note: minimum reported as 3–4 weeks) to 44 months (note: one arm of study reached 44 months and the other reached 30 months) and the mean age of the patients ranged from 50 to 60.8 years.

Two population-based registries were included. One was based in Finland and included 38 Finnish hospitals (four university hospitals, 13 central hospitals and 21 local hospitals). This registry included data for 1455 women with a follow-up between 2 weeks and 2 months. The other was based in Austria and included information from 29 gynaecology units; two reports have been published. The first reported data from 806 patients and the second from 2795 patients. The mean duration of follow-up was not described in either report.

The case series with greater than 2 years of follow-up included 1369 patients (range 25–206) with a mean or median follow-up of between 24 and 60 months. The total number of patients in the case series with a mean or median of less than 2 years of follow-up was 3356 (range 9–404), for 3336 of whom data were analysed. The patients were aged between 42.7 and 80 years and the length of follow-up ranged from 7 days to 42.2 months.

It was difficult to distinguish whether the same women were being reported in duplicate in more than one study. Therefore, there is a possibility that the total number of women included is higher than it should be.

Number and type of studies excluded, with reasons for specific exclusions

A total of 306 studies were excluded from the TVT review. The main reasons for exclusion were non-English language (as resources were not available for translation at this time, although if data were reported in an English-language abstract the study was included), case reports of one patient, retrospective studies, anatomical studies or case series papers which were not obtained until after the time cut-off for reviewing of effectiveness. In all, 157 reviews on comparators were excluded as they failed the quality assessment process owing to lack of description of methods used to perform the systematic review. A list of the included studies with their associated references is given in Appendix 8.

Tabulation of quality of studies, characteristics of studies and evidence rating

Overall, the 80 primary studies were rated favourably in terms of the clarity of study question, definition of the outcome and

description of the characteristics of the patients included (Appendix 9). The descriptions of the interventions of interest were rated favourably for RCTs and case series >2 years (Appendices 10 and 11). However, this was less well rated for non-randomised comparative studies and case series <2 years, with seven (78%) out of nine and 25 (51%) out of 49, respectively, not adequately describing the procedure (Appendices 10 and 12). The main concern relating to the reporting of the studies is that only 21 (26%) out of the 80 studies clearly described the distribution of principal potential confounders in each group of subjects (RCTs three out of five; comparative studies none out of nine; case series >2 years six out of 17; case series <2 years 12 out of 31) with a further 21 (26%) studies partially describing this (RCTs one out of five; comparative studies four out of nine; case series >2 years nine out of 17; case series <2 years 24 out of 31). Only 34 (43%) out of the 80 studies provided estimates of the random variability in the data (RCTs three out of five; comparative studies three out of nine; case series >2 years 10 out of 17; case series <2 years 18 out of 31) and only 41 (51%) out of 80 described the characteristics of patients lost to follow-up (RCTs four out of five; comparative studies one out of nine; case series >2 years 10 out of 17; case series <2 years 27 out of 49).

Overall, it was difficult to determine the external validity of the studies. In particular, the assessors were unable to judge whether the women asked to participate in the study were representative of the entire population in 70% of studies. Similarly, the assessors were unable to determine whether those women prepared to participate were representative of the entire population from which they were recruited in 96% of studies or whether the staff, places and facilities where the patients were treated were representative of the treatment the majority of patients receive in 95% of studies. For 91% of studies it was unclear whether an attempt was made to blind those measuring any outcomes of the intervention. However, in almost all studies, the statistical tests used, compliance with the intervention and main outcome measures were rated favourably.

In 44% of the studies there was no information concerning the source of the patients included in the study and 43% did not specify the period over which the patients were recruited. In seven studies the patients were clearly not all recruited from the same population. Of five randomised trials, only one was considered to have adequate allocation concealment. In 54% of the studies the assessors considered the adjustment for confounding in the analyses to be inadequate and were unable to judge in a further 19%. Losses of patients to follow-up were taken into account in 54% of studies, with 25% being unclear. A statistical power calculation was provided for only two studies.

In respect of 12 included systematic reviews,[30,35,145–156] overall, the search methods used to find evidence were well reported and reasonably comprehensive. However, the criteria used for deciding which studies to include in the review were less well reported, which may have led to bias in the selection of articles. The criteria used for assessing the validity of the studies were reported in only four reviews[30,35,145,146,150,153] and although six reviews attempted to aggregate data,[30,149–153] only three conducted a formal meta-analysis.[30,150,153] Overall, the three Cochrane reviews[30,150,153] and the review by Black and Downs were considered to be methodologically the most robust.[35,145,146]

Assessment of effectiveness

The results of the individual studies are recorded in Appendices 15–19 under four headings: cure and improvement, complications, QoL and perioperative care.

Cure and improvement for TVT (RCTs and non-randomised comparative studies)

Table 12 reports the cure rates for the RCTs and non-randomised comparative studies. Only three RCTs[43,46,47,50,52] have reported cure rates. Cucinella and colleagues, who compared TVT with laparoscopic colposuspension, reported subjective cure of 100% for both TVT and laparoscopic Burch colposuspension at 3 months. This had reduced to 93% (significantly improved 5%) for TVT and and 80% (significantly improved 1.75%) for laparoscopic Burch colposuspension at follow-up of 6–24 months.[43] The small trial conducted by Liapis and colleagues had subjective cure rates of 83% for TVT and 86% for Burch colposuspension.[47] The Ward/Hilton trial measured both subjective and objective cure at 6 months, 1 year and 2 years. Subjective cure of stress incontinence amongst those assessed at 6 months was 65% for TVT and 71% for open colposuspension. A preliminary analysis reported that rates had reduced at 1 year to 50% and at 2 years to 44% when data from both procedures was combined (Hilton P, Royal Victoria Infirmary, Newcastle upon Tyne: personal communication, 2002). **[Confidential information relating to 2-year follow-up from this trial has been removed pending publication.]**

TABLE 12 *Cure rates by study design (RCTs and non-randomised comparative studies)*[a]

Study	Length of follow-up (months)	Comparator	Cure rates									
			Subjective					Objective				
			TVT		Comparator		Relative risk (95% CI)	TVT		Comparator		Relative risk (95% CI)
			No.	%	No.	%		No.	%	No.	%	
RCT or quasi-RCT												
Cucinella, 2001[43]	6–24	Lap colpo	53/57	93	45/56	80	1.16 (1.00 to 1.34)	NR		NR		NA
Halaska, 2001[44]	6	Burch colpo	NR		NR		NA	NR		NR		NA
Han, 2001[45]	6	Burch colpo	NR		NR		NA	NR		NR		NA
Liapis, 2002[47]	22	Burch colpo	30/36	83.3	30/35	85.7		NR		NR		NA
Ward, 2002[52]	6	Burch colpo	103/159	64.8	90/127	70.9	0.91 (0.78 to 1.07)	128/156	82.1	109/131	83.2	0.99 (0.89 to 1.10)
Ward, 2001[b]	12	Burch colpo	CIC	CIC	CIC	CIC	CIC	CIC	CIC	CIC	CIC	CIC
Ward, 2001[b]	24	Burch colpo	CIC	CIC	CIC	CIC	CIC	CIC	CIC	CIC	CIC	CIC
Non-randomised comparative studies												
Arunkalaivanan, 2001[56]	16.39 Min. 6	Traditional suburethral sling	54/62	87.3	46/55	83.6	1.04 (0.90 to 1.21)	NR		NR		NA
Atherton, 1999[57]	3–4 weeks	Burch colpo	8/9	88.9	7/7	100	0.89 (0.71 to 1.12)	NR		NR		NA
Atherton, 2000[58]	6	Burch colpo	NR		NR			15/20	74	14/16	88	0.86 (0.63 to 1.17)
Foote, 2001[60]	6	Traditional suburethral sling	28/34	82.4 (cure and improvement)	32/38	84.2	0.98 (0.79 to 1.20)	NR		NR		NA
Foote, 2001[61]	6	Lap colpo	28/34	82.4	64/68	94.1	0.88 (0.74 to 1.03)	NR		NR		NA

continued

TABLE 12 *Cure rates by study design (RCTs and non-randomised comparative studies)[a] (cont'd)*

Study	Length of follow-up (months)	Comparator	Cure rates								
			Subjective					Objective			
			TVT		Comparator		Relative risk (95% CI)	TVT		Comparator		Relative risk (95% CI)
			No.	%	No.	%		No.	%	No.	%	
Hung, 2001[62]	NR	Traditional suburethral sling	Unclear		Unclear			NR		NR		NA
Liang, 2001[63]	22 (12–43)[c]	Lap colpo	26/30	86.7	30/35	84.6	1.01 (0.83 to 1.23)	NR		NR		NA
		Needles			20/26	77.1	1.13 (0.87 to 1.45)	NR		NR		NA
Lukanovic, 1999[64]	4	Lap colpo	58/60	97	14/15	91	1.04 (0.90 to 1.20)	NR		NR		NA
Yalcin, 2001[65]	Max. 30 TVT Max. 44 colpo	Burch colpo	46/51	90	15/28	53.5	1.68 (1.18 to 2.4)	NR		NR		NA

[a] NR, not reported; NA, not applicable; CIC, **Confidence information pending publication**; lap, laparoscopy; colpo, colposuspension; RR, relative risk.
[b] Personal communication.
[c] Mean (range).

At 2 years, the estimated risk difference for the comparison of TVT with open colposuspension is –0.02 [95% confidence interval (CI) –0.19 to 0.14) based on data from Liapis and colleagues,[46] which indicates that there is no evidence of any difference in cure rates from this one trial. **[Confidential information relating to 2-year follow-up from the Ward trial has been removed pending publication of 6-month data.]**

Data from non-randomised comparative studies are also shown in *Table 12*. Like the RCTs, these generally suggested no clear difference between TVT and its comparator, but with wide CIs. Length of follow-up was generally short (between 3 weeks and 12 months minimum follow-up).[57,63] One study by Yalcin and colleagues[65] had a follow-up of 30 months for TVT and 44 months for open Burch colposuspension.

Three small, non-randomised comparative studies compared TVT with open Burch colposuspension.[57,59,65] In two of these, no statistically significant difference in subjective cure rates was found. This was also the case in the third study for objective cure.

Three further small comparative studies[61,63,64] compared TVT with laparoscopic Burch colposuspension. Again, there was no clear difference between the groups in any of these.

An additional three small studies[56,60,62] compared TVT with traditional suburethral slings (porcine pubovaginal, prolene, polypropylene pubovaginal). Cure rates were similar in the study groups but with wide CIs. One small study by Liang compared TVT with bladder neck needle suspension, with no apparent difference. There

TABLE 13 *Improvement rates by study design (RCTs and non-randomised comparative studies)*

Study	Length of follow-up (months)	Comparator	Additional women who reported improvement							
			Subjective				Objective			
			TVT		Comparator		TVT		Comparator	
			No.	%	No.	%	No.	%	No.	%
RCT or quasi-RCT										
Cucinella, 2001[43]	6–24	Lap colpo	3/57	5	1/56	1.8	NR		NR	
Halaska, 2001[44]	6	Burch colpo	NR		NR		NR		NR	
Han, 2001[45]	6	Burch colpo	NR		NR		NR		NR	
Liapis, 2002[47]	22 TVT 24 colpo	Burch colpo	NR		NR		NR		NR	
Ward, 2002[52]	6	Burch colpo	NR		NR		NR		NR	
Non-randomised comparative studies										
Arunkalaivanan, 2001[56]	16.39 Min. 6	Traditional suburethral sling	4/62	6.5	5/55	9.1	NR		NR	
Atherton, 1999[57]	3–4 weeks	Burch colpo	1/9	11.1	0/7	0	NR		NR	
Atherton, 2000[58]	6	Burch colpo	NR		NR		5/20	25	2/16	12
Foote, 2001[60]	6	Traditional suburethral sling	NR		NR		NR		NR	
Foote, 2001[61]	6	Lap colpo	NR		NR		NR		NR	
Hung, 2001[62]	NR	Traditional suburethral sling	NR		NR		NR		NR	
Liang, 2001[63]	22 (12–43)[a]	Lap colpo Needles	NR		NR NR		NR		NR NR	
Yalcin, 2001[65]	Max. 30 TVT Max. 44 colpo	Burch colpo	5/51	10	10/28	35.7	NR		NR	

[a] Mean (range).

was no direct comparison of TVT with injectable agents; however, a trial is ongoing (Appendix 8).

Data for additional women improved but not completely cured (*Table 13*) were available for only one RCT[43] and four non-randomised comparative studies.[56–58,65] The additional improvement ranged from 5 to 25% of women for TVT and from 1.8 to 35.7% of women for the comparators.

Cure and improvement following TVT (case series)

Data describing cure and improvement following TVT from the 17 case series of 2 years or more follow-up are summarised in *Table 14*. There was considerable variation in the way in which follow-up was reported in the literature. The median length of follow-up was chosen to categorise studies where a range was reported. The subjective cure rates were similar to those reported in the RCTs and non-randomised comparative studies (other than the Ward/Hilton trial) with rates varying between 74 and 95%. Case series data also suggested that between 3 and 16% additional women are improved but not cured. The rates for objective cure varied between 65 and 95%, and the additional proportion of women improving was between 3 and 16%.

Complications for TVT (RCT and non-randomised comparative)

Operative complications (*Table 15*)

The most commonly reported operative complication of TVT was bladder perforation. In the three randomised[43,45,52] and one non-randomised comparative studies[60] with data the rates varied between 4 and 22% for TVT. This is equivalent to one additional perforation in every eight to 25 TVT operations. Taking into account the fact that bladder perforation was also occasionally reported for comparator operations, the attributable risk (risk difference in *Table 15*) ranged from 4 to 12%. The only study showing evidence of a statistically significant increase in bladder perforations for TVT was the Ward/Hilton trial.[52] The only other complications data available from more than one comparative study related to haematoma (*Table 15*). Further data on operative and later complications have recently become available for the Ward/Hilton trial[52] (see *Table 16*). These data show significantly more episodes of

TABLE 14 *Cure and improvement rates (case series)*

Study	Length of follow-up (months)	Cure rate				Additional women who reported improvement			
		Subjective		Objective		Subjective		Objective	
		No.	%	No.	%	No.	%	No.	%
Case series ≥4 years follow-up									
Jomaa, 2001[71]	60 (48–78)[a]	59/62	95	59/62	95	2/62	3	2/62	3
Nilsson, 1998,[41] 2001[76]	56 (48–70)[a]	72/85	85	72/85	85	9/85	11	9/85	11
Nilsson, 2001[75b]	56 (48–70)[a]		86	NR			14	NR	
Rezapour, 2001[79b]	48 (36–60)[a]	36/49	74	36/49	74	6/49	12	6/49	12
Rezapour, 2001[80b]	48 (36–60)[a]	NR		68/80	85	NR		3/80	4
Rezapour, 2001[81b]	48 (36–60)[a]	28/34	82	28/34	82	3/34	9	3/34	9
Case series ≥3 years follow-up									
Jomaa, 2000[69]	36	21/25	84	21/25	84	4/25	16	4/25	16
Migliari, 1999[74b]	36	44/50	87	NR		NR		NR	
Olsson, 1999[78]	36	46/51	90	46/51	90	3/51	6	NR	
Ulmsten, 1999[84b]	24–36	NR		43/50	86	NR		NR	
Case series ≥2 years follow-up									
Bettin, 2000[66]	24	NR		19/22	86	NR		NR	
Jomaa, 2001[70]	Up to 24	30/32	94	30/32	94	1/32	3	1/32	3
Kinn, 2001[72]	24	60/75	80	NR		7/75	9	NR	
Liapis, 2001[73]	24	45/50	90	45/50	90	2/50	4	2/50	4
Ohkawa, 2001[77]	24	173/203	85	132/203	65	NR		NR	
Tunn, 1999[83]	24	NR		13/15	87	NR		2/15	13
Ulmsten, 1996[25b]	24	63/75	84	63/75	84	6/75	8	6/75	8

[a] Mean (range).
[b] One of the originators of the technique (Ulmsten) was involved in these studies.

TABLE 15 *Operative complication of TVT (RCT and non-randomised comparative studies)*

Study	Comparator	Bladder perforation					Haematoma				
		TVT		Comparator		RR[a] [RD][b]	TVT		Comparator		RR[a] [RD][b]
		No.	%	No.	%		No.	%	No.	%	
Cucinella, 2001[43]	Lap colpo	3/57	5	0/56	0	6.88 (0.36 to 130.21) [0.05 (0.01 to 0.12)]	0/57	0	2/56	4	0.20 (0.01 to 4.00) [–0.04 (–0.9 to 0.02)]
Foote, 2001[60]	Traditional sling	10/46	22	4/40	10	2.17 (0.74 to 6.4) [0.12 (–0.03 to 0.27)]	NR		NR		NR
Han, 2001[45]	Burch colpo	1/25	4	0/25	0	3 (0.13 to 70.3) [0.04 (–0.06 to 0.14)]	NR		NR		NR
Ward, 2002[52]	Burch colpo	15/170	9	3/146	2	4.29 (1.27 to 14.54) [0.07 (0.02 to 0.12)]	3/170	1.8	0/146	0	6.02 (0.31 to 115.55) [0.02 (–0.01 to 0.04)]

[a] RR, relative risk (95% CI). [b] RD, risk difference (95% CI).

TABLE 16 *Complications from the Ward/Hilton trial*[52]

Complication	TVT (*n* = 170)	Colposuspension (*n* = 146)	*p*-Value[a]
Vaginal perforation	5 (3%)	0	0.06
Wound infection	4 (2%)	10 (7%)	0.06
Fever	1 (1%)	7 (5%)	0.03
Deep vein thrombosis	0	3 (2%)	0.10
Incisional hernia	NA	3 (2%)	
Retropubic haematoma	3 (2%)	0	0.25
Vascular injury	1	0	1.0
Tape erosion	1	NA	
Urinary tract infection (in the 6 weeks following surgery)	38 (22%)	46 (32%)	0.07

[a] Fisher's exact test.

fever amongst women receiving a colposuspension. No comparative data were reported for bowel perforation or nerve injury.

Later complications (*Table 17*)
The information from comparative studies on new urge symptoms/detrusor overactivity and voiding dysfunction after 3 months is summarised in *Table 17*. The data are too few to allow reliable comparison. Postoperative pain was reported to be the same for both procedures in the one randomised trial that reported this outcome,[45] although in another trial the use of postoperative analgesia was less after TVT.[54]

Complications of TVT (case series)
The population-based registries from Austria and Finland contributed to the data on case series. As described earlier, these included data on approximately 4200 women.

Operative complications (*Table 18*)
The most commonly reported complication, as in the comparative studies, was bladder perforation. The data from the 52 studies were similar to the rates for TVT from the comparative studies, providing a median of 4.1% with an overall mean of 4.4% (equivalent to one perforation in every 24 operations). Blood loss greater than 200 ml and haematoma rates were around 2%. There were no bowel perforations reported in the three study reports that mentioned this outcome. Obturator nerve injuries were variable with a mean rate of two in 1000. However, the Industry submission by Ethicon reports 11 bowel perforations, four deaths and 32 vascular injuries from approximately 230,000 procedures [reported to Gynecare as Medical Device Reports (MDRs)] (submission to NICE from GYNECARE 27, May 2002). This is equivalent to one of these serious complications reported for every 5000 procedures.

TABLE 17 *Later complications of TVT (RCT and non-randomised comparative studies)*

Study	Comparator	New urge symptoms/detrusor overactivity					Voiding dysfunction >3 months		Postoperative pain				
		TVT		Comparator		RR[a] [RD][b]	TVT	Comparator	TVT		Comparator		RR [RD]
		No.	%	No.	%				No.	%	No.	%	
Cucinella, 2001[43]	Lap colpo	0/57		0/56		NA	0/57	0/56	NR		NR		NA
Liapis, 2002[47]	Burch colpo	6/36	17	5/35	14	1.17 (0.39 to 3.48) [0.02 (–0.14 to 0.19)]	NR	NR	NR		NR		NA
Atherton, 1999[57]	Burch colpo	1/9	11	3/7	43	0.26 (0.00 to 1.99) [–0.32 (0.74 to 0.10)]	NR	NR	NR		NR		NA
Atherton, 2000[58]	Burch colpo	3/20	15	2/16	13	1.20 (0.23 to 6.34) [0.03 (–0.20 to 0.25)]	NR	NR	NR		NR		NA
Han, 2001[45]	Burch colpo	NR		NR		NR	NR	NR	23/25	92	23/25	92	1(0.85 to 1.18) [0.00 (–0.15 to 0.15)]

[a] RR, relative risk (95% CI).
[b] RD, risk difference (95% CI).

TABLE 18 *Operative complications of TVT (case series)*

Complication	No. of studies for which relevant data are reported (no. of women studied)	Median rate (%) (IQR)[a]	Mean (%)
Bladder perforations	52 (7845)	4.1 (1.4 to 7.4)	4.4
Bowel perforation	2 (191)	0	0
Obturator nerve injury	3 (1888)	0.2 (0.2 to 1.8)	0.2
Blood loss >200 ml	14 (22,499)	1.03 (0.0 to 3.0)	2.2
Haematoma	22 (3740)	1.3 (0.8 to 2.3)	2.1

[a] IQR, interquartile range.

TABLE 19 *Later complications of TVT (case series)*

Complication	No. of studies for which relevant data are reported (no. of women studied)	Median rate (%) (IQR)[a]	Mean (%)
Sling infection	3 (225)	1.0 (0)	0
UTI[a]	19 (2601)	6.7 (3.1 to 7.9)	5.5
Defective healing	19 (2974)	0	0.5
Thrombosis[b]	3 (1795)	0.5 (0.3 to 0.6)	0.2
Postoperative pain	4 (375)	3.0 (0.9 to 5.3)	2.3
Voiding difficulty	5 (380)	1 (0 to 4.4)	8.3
New urge symptoms/detrusor overactivity	27(1644)	4.4 (1.1 to 7.2)	6.6
Voiding dysfunction	7 (402)	0 (0 to 0.4)	0
New/recurrent prolapse	3 (190)	0 (0.0 to 1.1)	1.0
Dyspareunia	3 (206)	0	0
Pain	3 (152)	4.4 (2.2 to 4.4)	2.6
Tape rejection	24 (2895)	0	0
Tape erosion	3 (278)	1 (0.5 to 1.8)	1.1
Recurrent UTI	3 (191)	1.1 (0.6 to 1.5)	1.0
Readmission	19 (4377)	2.4 (1.4 to 5.0)	2.4
Dysuria	4 (348)	7.9 (7.1 to 8.5)	7.5
Urinary retention	14 (731)	4.4 (0.4 to 9.1)	6.2
Infection	12 (2427)	0 (0 to 0.9)	0.7
Reoperation (for incontinence)	8 (3196)	1.5 (1.3 to 2.4)	1.4

[a] UTI, urinary tract infection.
[b] Two pelvic vein thrombosis, one venous thrombosis.

Later complications (*Table 19*)
Table 19 summarises data on later complications from case series. Some terms were not used consistently. There were no reported cases of tape rejection, tape infection was rare and tape erosion occurred with a mean of 1.1%, but with varying rates in individual series.

Quality of life for TVT

RCTs and non-randomised comparative studies (*Table 20*)
Only two comparative studies measured QoL. The Ward/Hilton trial used validated QoL questionnaires (SF-36, EQ-5D and B-FLUTS). At 6 months the TVT group scored significantly better for the SF-36 subscales on role limitation due to emotional problems, social functioning vitality and mental health.

Case series
Six out of the 66 studies based on case series reported some measures of QoL. These are summarised in *Table 21*. In the studies that provided pre- and postoperative scores, a consistent improvement in QoL was demonstrated.

Operative care for TVT

Data describing operative care are summarised in *Table 22* (RCTs and non-randomised comparative studies) and *Table 23* (case series).

The length of stay following TVT in the comparative studies ranged from 1 to 3 days and the case series data were consistent with this. This compared with 2.0–3.5 days for laparoscopic colposuspension and 3.4–6.5 days for open Burch colposuspension in the comparative studies.

TABLE 20 *Quality of life (RCTs and comparative studies)*

Study	Comparator	Type of measure	TVT	Comparator	Note
Ward, 2002[52] (RCT)	Burch colpo	B-FLUTS[a] (at 6 months)	No significant difference	No significant difference	
		SF-36[b] (at 6 weeks)	Better on physical function, emotional and social functioning and vitality		
		SF-36[b] (at 6 months)	Statistically significant for: Role emotional 12.1 Social functioning 11.7 Mental health 7.9 Energy/vitality 8.7	Role emotional 5.4 Social functioning 4.0 Mental health 4.7 Energy/vitality 3.6	Values are increases from baseline
Ward, 2001[51]		SF-36[b] (at 2 years)	Better for role limitation due to emotional problems, social functioning and mental health		
		EQ-5D[c] values (at 6 weeks)	Mean 0.788 (median 0.85, IQR 0.71 to 0.92)	Mean 0.754 (median 0.76, IQR 0.69 to 0.88)	
		EQ-5D[c] values (at 6 months)	Mean 0.806 (median 0.85, IQR 0.73 to 0.92)	Mean 0.794 (median 0.85, IQR 0.73 to 0.92)	
Hung, 2001[62] (non-randomised)	Sling	Urogenital Distress Inventory[d]	79.8% improved	77.8% improved	

[a] B-FLUTS (Bristol Female Lower Urinary Tract Symptoms): condition-specific QoL measure designed to quantify urinary incontinence from the patient's viewpoint, incorporating items assessing the degree of 'bother' and their impact on QoL.
[b] SF-36: standardised questionnaire (generic profile measure) to assess patient health across eight dimensions of health (physical, role physical, bodily pain, general health, vitality, social, role emotional and mental health).
[c] EQ-5D: standardised generic instrument designed to describe and value health status which is defined in terms of five dimensions (mobility, self-care, usual activities, pain or discomfort and anxiety or depression; 0 is equivalent to death and 1 is equivalent to good health).
[d] Urogenital Distress Inventory: a series of questions with scored responses to determine the effect of incontinence on the subject's social, emotional and physical health.

The average duration of operation was shorter for TVT, estimates from the comparative studies ranging from 20 to 40 minutes (mean of 30 minutes in case series) compared with 35–58 minutes for open Burch colposuspension. Laparoscopic Burch colposuspension took the longest at between 60 and 113 minutes.

There were marked variations in the anaesthesia policies adopted in the different comparative studies although general anaesthetic appeared to be infrequently used for TVT (*Table 23*). Data from case series confirmed that TVT was commonly performed under local anaesthesia.

The Ward/Hilton trial[52]

This section contains more detailed information on and analysis of the Ward/Hilton trial. Most of the data from the RCTs come from this one trial and interpretation of this study is therefore of central importance to this review.

The analyses of the Ward/Hilton trial presented in the summary tables are based on those women for whom data were available at a particular time point, with no assumptions made about those without data. *Figure 2* shows how the denominators for subjective cure rates at the three time points were derived. It should be noted first that a large number of women withdrew between randomisation and surgery, particularly in the colposuspension group (five in TVT group versus 23 in colposuspension group). Given that this study was performed within the NHS environment and TVT may only have been readily available within a trial context, it may well be that patients were prepared to be randomised and, if unsuccessful in gaining the less invasive TVT approach, may have

TABLE 21 *Quality of life for TVT (case series)*

Study	Type of measure	When measured (months)	Description	Result
Bettin, 2000[66]	VAS[a]	Unclear	Participants scored QoL; 0 rated as best. Scoring system unclear	90% scored 0–2
Haab, 2001[101]	VAS	Unclear	0–10 scale; 10 rated as best	Cured (54/62) Preop. not reported Postop. 9.3 ± 1.1 Improved (6/62) Preop. not reported Postop. 7.7 ± 2.5 Not cured (2/62). QoL not reported
Kinn, 2001[72]	B-FLUTS	24	Score from 0 to 5; 0 rated as best	Statistically significantly ($p < 0.001$) less restriction in physical activities (score change 3.5 to 2), in social life (score change 2.5 to 1.8) and depression and anxiety (score change 3 to 1.4)
Meschia, 2001[115]	VAS	21 (median)	0–10 scale; 0 rated as best	Preop. not reported Postop. score 0.7
Mukherjee, 2001[117]	King's Health Questionnaire (ver. 7)[b]	6	Scoring systems not described. Lower scores better	BMI[c] > 30 ($n = 87$) Preop. 563 Postop. 123 BMI 25–29 ($n = 98$) Preop. 409 Postop. 58 BMI < 30) ($n = 58$) Preop. 384 Postop. 78 $p < 0.001$
Rezapour, 2001[80]	VAS	48	1–100 scale; 1 rated as best	Preop. 67 Postop. 14

[a] VAS (visual analogue scales) usually range from 0 to 100, used to rate specific aspects of health, e.g. impact of urinary symptoms.
[b] King's Health Questionnaire: questionnaire including perceptions of general health, impact of urinary symptoms on health and other QoL domains and severity of urinary symptoms.
[c] BMI, body mass index.

elected to withdraw from the study. The published report mentions that the women who withdrew from the colposuspension group before surgery tended to have less severe incontinence. This differential dropout is thus likely to have introduced bias favouring TVT. Varying assumptions can be made about these withdrawals in 'modified intention to treat' analyses to explore their potential impact and these are illustrated in *Table 24*, using the data at 6 months. The report of the trial at this time point makes the assumption that all the withdrawals were 'failures' (second row of data in *Table 24*) (the analyses in the published report are based on the assumption that all withdrawals in the TVT group, both pre- and postoperatively, were failures, whereas the data in *Table 24* only consider presurgery withdrawals in this way). The modified analyses then suggest that TVT performs better than colposuspension, although not significantly so [relative risk (RR) 1.05; 95% CI 0.88 to 1.25]. Given what is said above, this seems incorrect, as it would introduce a

TABLE 22 *Operative care for TVT (RCTs and comparative studies)*

Study	Comparator	Length of stay (mean) (days)		Duration of operation (mean) (minutes)		General anaesthetic		Local anaesthetic		Spinal anaesthetic	
		TVT	Comparator	TVT	Comparator	TVT	Comparator	TVT	Comparator	TVT	Comparator
Cucinella, 2001[43]	Lap colpo	1.0	2.0	< 30	60–90	0	56/56 (100%)	0	0	56/56 (100%)	0
Han, 2001[45]	Burch colpo	1.4	3.4	23	48	NR	NR	NR	NR	NR	NR
Liapis, 2000,[46] 2002[47]	Burch colpo	Mean 2.1 (SD 1.1)	5.7 (SD 2.2)	20	58	0	0	0	0	100%	100%
Ward, 2002[52]	Burch colpo	2.2 (SD 1.9)	6.5 (SD 1.78)	40 (30 to 48)[a]	50 (35 to 60)[a]	3/170 (1.8%)	145/146 (99.3%)	164/170 (96.5%)	0	3/170 (1.8%)	1
Arunkalaivanan, 2001[56]	Sling	NR	NR	33.8	33	NR	NR	NR	NR	NR	NR
Foote, 2001[60]	Prolene sling	3.3	5.6	31.2	47.8	NR	NR	NR	NR	NR	NR
Foote, 2001[61]	Lap colpo	3.3	3.5	31.2	66.8	NR	NR	NR	NR	NR	NR
Liang, 2001[63]	Needle suspension	NR	NR	30.6 (SD 6.2)	102.2 (SD 49.5)	NR	NR	NR	NR	NR	NR
	Lap colpo				113.4 (SD 24.5)						

[a] Median and IQR.

TABLE 23 *Operative care for TVT (case series)*

	No. of studies for which relevant data are reported	Median (IQR)	Mean
Length of stay	24	2 days (1 to 2.1)	1.2 days
Duration of operation	32	30 minutes (28.0 to 39.3)	30 minutes
General anaesthetic	47	0% (0 to 5.9)	10.59%
Local anaesthetic	47	84% (32.8 to 100)	51.03%
Spinal anaesthetic	47	0.02% (0 to 50)	37.86%

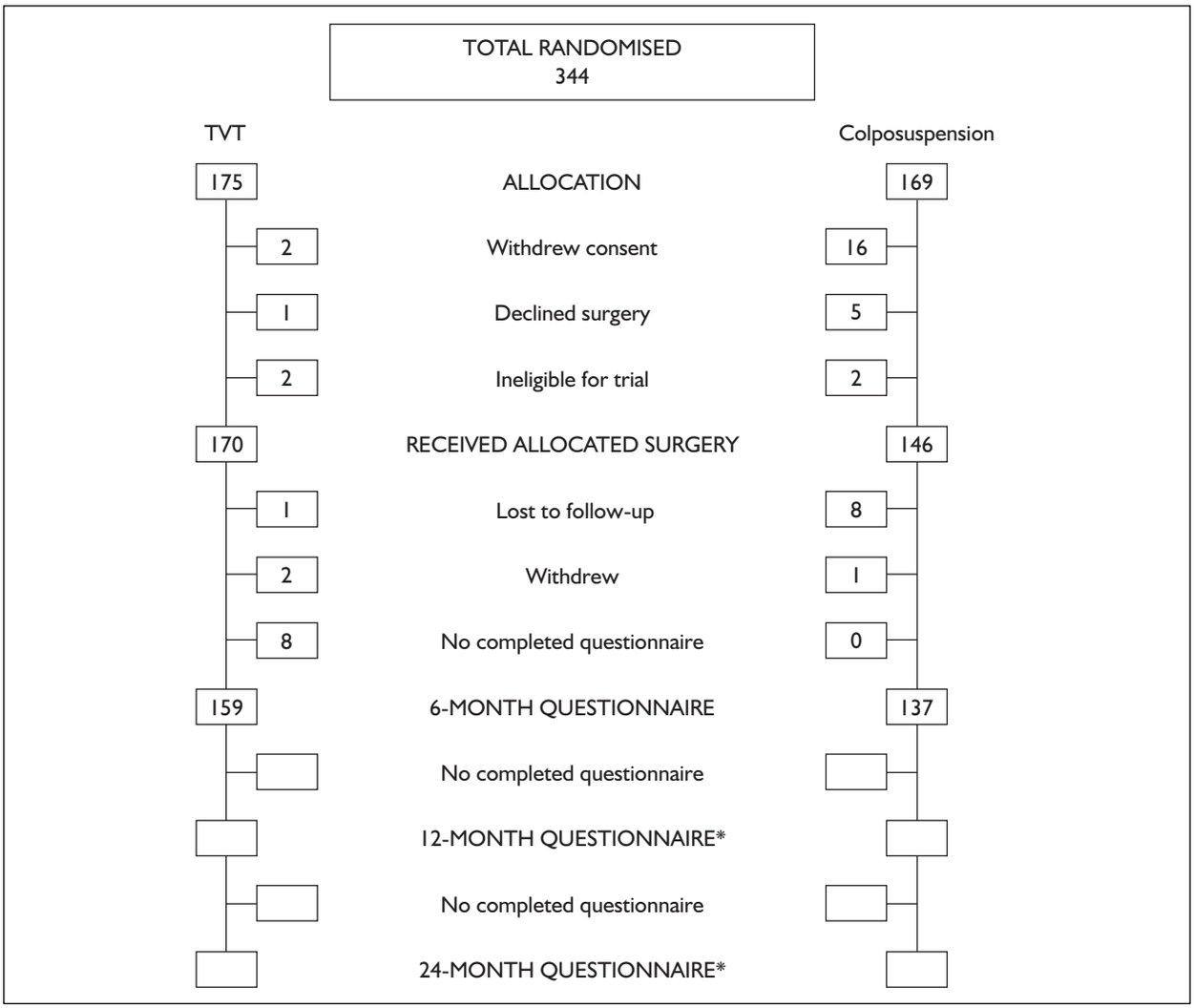

FIGURE 2 *Derivation of the study groups in the Ward/Hilton trial and reasons for losses to follow-up (for subjective outcomes). *The 12- and 24-month numbers have been removed pending publication of the data*

further bias in favour of TVT. In fact, as these women had less severe incontinence at trial entry, a more reasonable assumption would appear to be that they would all have been cured (although we recognise that this might introduce a relatively small favouring of colposuspension). The third row in *Table 24* shows that this leads to a suggestion that colposuspension performs better (RR 0.87; 95% CI 0.76 to 1.01). The most extreme types of modified intention to treat analyses are best-case and worst-case scenarios. Using a best-case scenario (assuming all pre-TVT withdrawals are successes and all pre-colposuspension withdrawals are failures) suggests better results for TVT (RR 1.1; 95% CI 0.92 to 1.30). In contrast, the worst-case scenario (assuming all pre-TVT withdrawals are failures and all pre-colposuspension withdrawals are successes) suggests significantly better outcome after colposuspension (RR 0.83; 95% CI 0.72 to 0.97).

TABLE 24 *The effects of varying assumptions on subjective cure rates in a modified intention to treat analysis in the Ward/Hilton trial*[a]

	TVT		Colposuspension		RR (95% CI)
	No.	%	No.	%	
Assumption					
Women with data available at 6 months	103/159	64.8	90/127	70.9	0.91 (0.78 to1.07)
Assuming all presurgery withdrawals failures	103/164	62.8	90/150	60.0	1.05 (0.88 to 1.25)
Assuming all presurgery withdrawals successes	108/164	65.9	113/150	75.3	0.87 (0.76 to 1.01)
Best-case scenario	108/164	65.9	90/150	60.0	1.10 (0.92 to 1.30)
Worst-case scenario	103/164	62.8	113/150	75.3	0.83 (0.72 to 0.97)

[a] From the point of the trial, it appears that for colposuspension, cure rates are based upon data from the 127 women for whom complete data were available, whereas for TVT, cure rates appear to be based on data from the 159 women who completed the B-FLUTS questionnaire rather than the 152 for whom complete data were available.

Figure 2 also shows that further women were lost to follow-up after surgery. Overall, the numbers are similar in the two groups (42 after TVT versus 44 after colposuspension at 2 years) and this is why no further analyses have been done to explore the possible implications of these. However, it is notable that the reasons for and timings of these losses to follow-up do appear to differ between the two groups and this also raises concerns about possible bias.

Additional information on comparators

A summary of findings from the systematic reviews of comparators can be found in Appendices 18 and 19.

Open abdominal retropubic colposuspension

Six systematic reviews of open abdominal retropubic colposuspension met our inclusion criteria. All described their search strategy.[35,145–151] The subjective cure rates ranged from 82 to 95% at 1 year. The lowest rates came from the Cochrane review by Lapitan and Cody which was based on randomised trials and therefore may be less likely to be biased.[150] This review reported the results for two trials with follow-ups of between 5 and a maximum of 17 years. The subjective cure rates varied for these two trials at between 82% (at 5 years) and 86% (at between 8 and 17 years). However, these data relate to a total of 68 women only. Operative outcomes were reported in four reviews.[146,147,150,151] Lapitan and Cody reported that perioperative complications occurred in 15% of cases and 3.1% were inherent to the procedure.[150] Leach and colleagues reported a rate of 2% for significant intraoperative complications and 4% for significant perioperative complications.[151] Dainer and colleagues also measured operative complications; however, the data were lumped with later complications to give an overall complication rate of 41.2%.[148] In respect of later complications, *de novo* detrusor overactivity and voiding difficulty varied between 5 and 27% and new or recurrent prolapse between 13 and 26%.

Laparoscopic retropubic colposuspension

Two reviews of laparoscopic retropubic colposuspension met the inclusion criteria.[152,153] In one, 95% CIs were reported for cure rates of between 47 and 100%.[152] In the other, which was based on RCTs only, the subjective cure rates at 18 months were reported as 94% and objective cure rates as 76%.[153] Bladder perforation, voiding dysfunction and new detrusor overactivity each occurred in approximately 5% of cases; 10% of women required repeat incontinence surgery. Lose reported that open colposuspension was statistically significantly better than laparoscopic, but this was based on a single trial.[152] The Cochrane review by Moehrer and colleagues found no difference at 18 months in subjective cure rates, but on urodynamic assessment there appeared to be a statistically significant difference in favour of open colposuspension (RR 0.89; 95% CI 0.82 to 0.98).[153] No difference was found between the rates of any other outcome, although the data were sparse.

Traditional suburethral sling procedures

Five systematic reviews[30,35,145–151,154] of traditional suburethral sling procedures met the inclusion criteria. Subjective cure rates varied between 73 and 93% in individual studies. Only Bidmead and Cardozo[154] and Lapitan and Cody[150] reported data on perioperative complications. In the former review, wound haematoma occurred at a rate of 3% and urinary tract infection (UTI) at a rate of 5%[154] and in the latter no difference in

perioperative complications was found compared with colposuspension although the 95% CIs were wide.[150] Rates for new detrusor overactivity ranged from 7 to 17% and voiding difficulties ranged between 2 and 20%. Information about new prolapse was provided by two reviews. Bezerra and Bruschini reported a rate of 2%[30] and Black and Downs commented that there were significantly more episodes of prolapse in the slings group compared with open colposuspension.[146] Bidmead and Cardozo was the only review that included data on sling erosion, which occurred at a rate of 1–23%.[154] Two systematic reviews reported information on comparative rates between open colposuspension and traditional slings.[146,150] Black and Downs reported no difference in cure rates from prospective studies.[146] Lapitan and Cody found no statistically significant differences in subjective cure rates at less than 1 year and between 1 and 5 years.[150]

Periurethral injectable agents

Three reviews of periurethral injectable agents met the inclusion criteria.[149,155,156] Subjective cure rates were reported for four different types of injectable. At up to 1 year the cure rates for autologous fat were reported as 60% in one review.[156] For collagen, two reviews reported cure rates, one of 78% and another between 40 and 60%.[155,156] The same two reviews reported cure rates for Teflon, which were 70 and 62.5%.[155,156] Silicone was reported by one review with a cure rate of between 60 and 70%.[155] Cure rates for more than 1 year were reported in one review as 63% for autologous fat[156] and in another as 33%;[155] for collagen 78%,[156] for Teflon 34%[156] and silicone 60%.[156] Duckett reported that the complication rates were generally low or the complications were not long-lasting.[155] The risk of migration, however, was believed to be highest with Teflon and silicone.[155,156] From all the reviews identified, only one small study compared surgery (principally traditional slings and open colposuspension) with injectable agents (collagen).[150] This study reported statistically significant lower cure rates with injectable agents. The RR compared with open colposuspension was 1.36 (95% CI 1.02 to 1.8), where an RR >1 indicated that open colposuspension had a higher cure rate.

Summary and conclusions of the evidence for and against the intervention

More than 230,000 TVT procedures have now been performed worldwide. Use of the operation has increased rapidly in England and Wales, suggesting growing confidence amongst urogynaecologists and urologists that it is useful, although there may be concerns that owing to lack of experience some surgeons may not adequately assess women prior to surgery.

Most assessment has been in the form of description of case series. These showed 2-year subjective 'cure' rates (variously measured) of 74–95%, with between 3 and 16% additional women improved but not cured. Only limited QoL data were available from case series, but again they suggested significant improvement following TVT. The principal operative complication is bladder perforation, occurring in around one in 25 procedures. This does not appear to carry any long-term risk provided that it is recognised at the time of the operation when it can be managed conservatively with postoperative bladder drainage. For this reason, it is now common practice to perform cystoscopy after each pass of the needle during the procedure. Other traumatic injuries, such as to a major vessel or nerve, can occur but are rare. In the longer term, the main concern is complications associated with the use of the tape. These include tape infection, tape rejection and tape erosion. Current evidence suggests that these occur only rarely, although the data about possible long-term complications associated with the tape are sparse.

As would be expected from the less invasive approach of TVT compared with colposuspension and other abdominal procedures, it is quicker to perform, can be carried out under local anaesthesia, although it is not uncommon for women to have general anaesthesia, and is followed by a shorter length of stay and more rapid return to usual activities. The main issue is how well TVT performs in the treatment of incontinence in comparison with other surgical procedures, particularly colposuspension. Case series are of limited value in this respect, particularly because of likely differences in the selection of women studied and in the definitions and measures of outcome. Non-randomised comparative studies are likely to be more reliable, but again are prone to significant selection bias. Data from RCTs are needed for a reliable assessment of the relative performance in terms of cure and improvement of incontinence and QoL. Although five RCTs were identified, the information available from these is limited. No data are currently available for two of them and one of the others has so far only been reported as a conference abstract. Furthermore, all except one

is small (and the larger one was smaller than intended) and so the RCTs give imprecise estimates of differential effects, even when data can be combined (as they can be at 2 years). Because of the sparsity of RCT data, the relatively large Ward/Hilton trial is very important in this context. Two methodological issues hamper the interpretation of this trial. The first is that, as the investigators themselves point out, the trial was underpowered. An absolute difference in cure rates between TVT and colposuspension of 10% was prespecified, and this required around 400 participants to have 80% statistical power ($p < 0.05$). Ultimately 344 women were randomised, and only 296 completed questionnaires at 6 months (*Figure 2*). For these reasons, 95% CIs around the estimates of differences tend to be wide and do not exclude a 10% absolute difference. The second is the likely bias introduced by differential withdrawals from the two randomised groups. The implications of this are discussed in the previous section. What *Table 24* makes clear is that the conclusions that might be drawn from this trial are heavily dependent on the assumptions that are made about the women who withdrew; depending on the assumption, it would be reasonable to conclude either that there is not a clinically significant difference or that colposuspension is significantly better, or that TVT is clinically better.

A key issue for TVT is its long-term performance. There are currently no RCT data beyond 2 years post-surgery. Although the case series with more than 4 years of follow-up suggest sustained cure rates, there are only three such studies, and they include only around 300 women. The management of future problems such as prolapse and treatment of recurrent SUI are currently not known.

Clinical effect size

Table 25 summarises the clinical effect sizes in terms of cure of incontinence that have been used in the economic models. Although data at 1 and 2 years were not available for the two randomised groups, pooled data (i.e. the randomised groups combined) were available from conference abstracts. These were used as best estimates of cure rates following TVT at these two periods. For similar reasons, the RR of cure at 6 months was based on the best estimate of the relative performance of the two procedures at 1 and 2 years.

The first model is based on the data actually collected (in other words, no assumption is made about withdrawals). The assumed subjective cure rate following TVT was 0.65 (65%), the RR of 0.91 (95% CI 0.78 to 1.07) giving an absolute rate difference of –0.06 (–0.17 to 0.05), compared with colposuspension.

The second estimated effect size uses the same data but adjusts for the differential presurgery withdrawals, for the reasons described above, by assuming that all were cured. This gives a slightly higher cure rate following TVT, but a lower RR and larger rate difference.

[Confidential information relating to the estimates based on information relating to the Ward/Hilton trial has been removed pending publication of the data.]

Few data were available comparing TVT directly with traditional slings or laparoscopic colposuspension and generally cure rates were similar in the study groups. There was no direct comparison with injectable agents. Because of this, data were sought comparing traditional slings,

TABLE 25 *Assumed cure rates following TVT at 1 and 2 years (based on pooled data) and assumed relative risk for TVT compared with Burch colposuspension (derived from published evidence of effectiveness at 6 months)*

Scenario		1 year	2 years
Estimates based on data actually collected (Model 1)	Assumed cure rates for TVT[a]	65% (158/245)	60% (138/230)
	Assumed RR of cure[b]	0.91 (95% CI 0.78 to 1.07)	
Adjusting for withdrawals presurgery (Model 2)	Assumed cure rates for TVT[c]	68% (186/273)	64% (166/258)
	Assumed RR of cure[b]	0.87 (95% CI 0.76 to 1.01)	

[a] Pooled estimates of TVT and open Burch colposuspension arms of Ward trial.
[b] Estimated from published 6-month data. RR < 1 favours Burch, i.e. TVT has poorer cure rates.
[c] Assuming that the 5 women in the TVT arm and the 23 in the colposuspension arm who dropped out before allocated treatment was received were cured.

TABLE 26 *Sub-group cure rates summary table (case series)*

Study	Participants	Cure rate (%)	
		Subjective	Objective
Mixed incontinence			
≥4-year follow-up:			
Rezapour, 2001[80]	80	NR	85
≥3-year follow-up:			
Jeffry, 2001[68]	24	54	83
Nilsson, 2001[125]	59	81	NR
Secondary intervention			
≥4-year follow-up:			
Rezapour, 2001[81]	34	82	82
≥2-year follow-up:			
Kinn, 2001[72]	31	NR	55
<2-year follow-up:			
Rufford, 2001[130]	23	96	81
O'Sullivan, 2000[126]	43	80	NR
Co-existing prolapse			
≥3-year follow-up:			
Liapis, 2001[73]	68	90	88
≥2-year follow-up:			
Jomaa, 2001[70]	32	94	94
<2-year follow-up:			
Lebret, 2001[108]	15	NR	60

laparoscopic colposuspension and injectable agents with open colposuspension (Appendix 19), since this is the more established procedure and most others have been compared with it. In this way, an attempt was made to compare the effectiveness of TVT with these other comparators indirectly.

Based on this, it seems reasonable to assume, first, that traditional slings would perform the same as open colposuspension when compared with TVT, second, that laparoscopic colposuspension would perform the same as open colposuspension or possibly worse when compared with TVT, and third, that injectable agents will have poorer cure rates in comparison with TVT.

Important sub-group differences

Three sub-groups were prespecified: women with mixed incontinence; where TVT was used as a secondary surgical procedure; and women with co-existing vaginal prolapse. Although women with these characteristics were included in several studies, data were rarely reported separately. The information available is summarised in *Table 26*. Cure rates were not clearly different from those in less selected populations, but these estimates were based on small numbers and so should be interpreted with caution.

Chapter 4

Systematic review of economic evidence

Methods

Search strategies

Studies that reported both costs and outcomes of TVT relative to any one of the three comparators (colposuspension, slings or injectable agents) were sought from the systematic review of the literature described in Chapter 3. In addition, the Harvard database of cost–utility analyses was searched, and industry submissions for this Technology Assessment Review were reviewed.

Inclusion and exclusion criteria

To be included, studies had to compare TVT and a comparator treatment in terms of costs and effectiveness. Studies reported in languages other than English were identified from their abstracts but were not included in the review. One reviewer assessed all abstracts for relevance. Full papers were obtained for all studies that appeared potentially relevant and were then formally assessed for relevance.

Data extraction strategy

The following data were extracted for each included study.

1. Study identification information
   (a) author and year
   (b) the intervention studied
   (c) the type of economic evaluation
   (d) the country of origin and currency reported
2. The intervention study design and main outcomes
   (a) fuller description of treatment
   (b) numbers receiving or randomised to each intervention
   (c) outcomes studied
3. Sources of data
   (a) effectiveness data
   (b) mortality and co-morbidity (if measured)
   (c) cost data
   (d) QoL (if measured)
4. Methods and study perspective
5. Results
   (a) costs
   (b) benefits
   (c) incremental cost-effectiveness/utility ratio (ICER)
   (d) sensitivity analyses
   (e) additional comments.

Quality assessment strategy

A single economist assessed included studies against the 10 components recommended by Drummond and colleagues that are commonly used for critical appraisal of economic evaluation.[157]

Data synthesis

No attempt was planned to synthesise quantitatively the studies that were identified. Data from all included studies were instead summarised and critiqued by a single economist in order to identify common results, variations and weaknesses between studies. The data were then interpreted alongside the results of the systematic review of effectiveness so that conclusions could be drawn on the relative efficiency of TVT versus the three comparator treatments for SUI.

Summary of results

The literature searches did not reveal any published economic evaluations of TVT versus any of the comparators. Several economic evaluations were identified comparing laparoscopic with open colposuspension.[158,159] Although these studies were useful for obtaining certain parameter estimates for the economic models developed in Chapter 5, they were not directly relevant to TVT. The industry submission from Ethicon Ltd contained one economic evaluation of an RCT of TVT versus open Burch colposuspension as a primary treatment for SUI (this is the Ward/Hilton trial described and discussed in Chapter 3).[48] As this evaluation was pending publication and marked 'Commercial in Confidence', the study results cannot be discussed in detail in the published version of this report. *Table 27* provides an assessment of the submission with respect to the 10 summary critical appraisal components.[157] The industry submission ranked fairly high with respect to compliance with criteria for good economic evaluation. The critique of the study provided in *Table 27* indicates that the main limitation of the study was judged to be the fact that the follow-up was limited to less than 1 year,

TABLE 27 *Quality assessment table for industry submission of economic evaluation of TVT versus open Burch colposuspension*[48]

Quality component	Assessment and comments
1. Well-defined question	Yes Economic evaluation (cost–utility analysis) of RCT of TVT versus colposuspension
2. Comprehensive description of alternatives	Yes
3. Effectiveness established	Yes
4. Relevant costs and consequences identified	Yes
5. Costs and consequences measured accurately	Yes Assessment of QALYs using EQ-5D scoring based on UK population tariffs
6. Costs and consequences valued credibly	Generally Hospital hotel cost estimate seemed low
7. Costs and consequences adjusted for differential timing	No Follow-up period was for 6 months, so discounting was not required, although it is not clear whether reusable equipment was amortised over its lifetime
8. Incremental analysis of costs and consequences	Yes Deterministic calculation of incremental cost-effectiveness ratio was not provided, but probabilistic analysis of bootstrap estimates and acceptability curves was used
9. Allowance made for uncertainty in estimates of costs and consequences	Yes Sensitivity analyses provided on differences in hospital length of stay, hospital hotel cost and methods for dealing with missing data
10. Results/discussion included all issues of concern to users	No In particular, limitation that study follow-up period was for 6 months was noted. Need for long-term follow-up emphasised. The impact on the results of the differential rate of withdrawals, after randomisation but before surgery, was not considered

and that the long-term cost–utility of TVT versus colposuspension needs to be assessed, as was acknowledged by the authors.

Review of the industry submission economic evaluation

Summary of industry submission

The industry submission contained an assessment of the cost–utility of TVT compared with open Burch colposuspension as a primary treatment for UDI.[48] The evaluation was conducted alongside the multi-centre RCT based on 344 patients discussed in Chapter 3.[50] Resource use, which was measured during surgery and for a 6-month follow-up period using UK unit costs at 1999–2000 prices, included time in theatre, hospital length of stay and complications. The EQ-5D health questionnaire was administered at baseline and at 6 months follow-up in order to estimate quality-adjusted life-years (QALYs) between these two points in time using UK population tariffs. Costs were estimated at £1014 for TVT and £1317 for open Burch colposuspension, for a mean difference of –£303 (95% CI –£407 to –£201). The study noted that although the cost of TVT tape is considerably higher than the theatre consumables used by open colposuspension, the shorter hospital length of stay required for TVT more than offsets this cost. Utility scores averaged roughly 0.78 at baseline for the two groups, with 6-month follow-up scores of 0.806 for TVT and 0.794 for colposuspension, for a mean difference in QALYs of 0.006 (bootstrapped 95% CI –0.013 to 0.024).

The analysis presented a probabilistic assessment of cost-effectiveness using 1000 bootstrap replications of the joint distribution of the mean difference in costs and effects. None of the replications indicated that the 6-month treatment costs for colposuspension would exceed 6-month treatment costs for TVT (so the authors indicated

that the probability that TVT was, on average, less costly than colposuspension was 100%). As noted by the authors, however, there was some uncertainty with respect to the mean difference in QALYs. As demonstrated by the acceptability curve provided in the paper, the probability of TVT being more cost-effective than colposuspension was 95% when the decision-maker is willing to pay at least £30,000 for an additional QALY and was 85% when the decision-maker is willing to pay at least £100,000.

Three sensitivity analyses were provided on three factors: (1) differential inpatient stay; (2) hotel cost of the hospital stay; and (3) impact of missing data. The first two analyses were related because the hospital length of stay and hotel cost comprise a substantial portion of the cost of the two procedures. The first analysis showed that TVT was still more likely to be cost saving than colposuspension as long as the hospital stay for TVT was at least 2 days shorter on average than the stay for colposuspension under the assumed hotel cost per day of £103. The sensitivity analysis of the hotel cost component had little impact on the results, showing that TVT is still cost saving for hotel cost components as low as £80 per day. The third analysis used a multivariate multiple imputation approach under the assumption that the data were missing at random rather than missing completely at random as was assumed for their base case. This sensitivity analysis also did not change the basic conclusion that there was a high probability that TVT was either cost saving or more cost-effective over a wide range of cost per QALY values. The concluding section of the report identified the key limitations of the study as the inability to blind patients and non-surgical staff to the procedure used and the limited follow-up period of only 6 months.

Critique of industry submission

As indicated in *Table 27*, the economic evaluation included in the industry submission is generally a very comprehensive and competent analysis. The analysis was based on a strong methodology (RCT) although the caveats noted in the section The Ward/Hilton trial (p. 25) also apply to the economic evaluation, and the investigators collected detailed measures of resource use. The study was the only one identified in the systematic review that provided direct measurement of QALYs. The acceptability curve approach provided concise and important information that is relevant for decision-makers.

The lower cost of TVT relative to colposuspension was a key factor in their results. Although the sensitivity analyses addressed variation in hospital length of stay and hospital hotel cost per day separately, joint variation in these two factors was not assessed. Furthermore, since TVT technically can be done as a day-case operation, it might have been useful to explore through sensitivity analysis the implications of policies to reduce the length of TVT from the value of 2.29 days that was documented in the trial. Nevertheless, a mean stay of 2.29 days may realistically reflect the longer length of stay after concurrent anterior repair for cystocele (which would not be necessary if a colposuspension was performed). The hotel cost per day, estimated at £103 per day for their base-case analysis, seems low, and a higher hotel cost per day would particularly reduce the cost advantage of TVT under a scenario of smaller differences in hospital length of stay. However, national data for the UK on the length of stay, which indicate 2.9 days for TVT and 7.1 days for colposuspension, are very close to the submission estimates of 2.29 and 6.67 days, respectively. Therefore, the evidence of a cost advantage of TVT over open Burch colposuspension seems strong. The two greatest limitations of the study are the facts that the follow-up period was limited to 6 months (this limitation is highlighted by the authors as an important issue for future research) and the problems associated with the assessment of effectiveness noted in the section Additional information on comparators (p. 29).

Chapter 5

Economic modelling results

Methods

As described in Chapter 4, economic evaluations of TVT versus comparator treatments were virtually non-existent at the time of this review. The single exception was the study of TVT versus open Burch colposuspension.[48] Even this study was limited by the fact that the follow-up period was only 6 months.

This section provides economic models of TVT versus four comparators (open Burch colposuspension, laparoscopic colposuspension, traditional slings and injectable agents) over follow-up periods of up to 10 years. The results over the extended period must be qualified by the fact that follow-up data on TVT are limited to 2 years (although not yet published) from the largest RCT identified and approximately 5 years from case-series data. The projections are therefore predicated on the assumption that TVT does not experience catastrophic failure at some future point in time. Sensitivity analyses were used to identify key parameters that may affect the cost-effectiveness of TVT over time.

The chapter starts with a description of the Markov model developed for the assessment and parameters that were common across all models. Key parameters specific to each model and results are then presented separately for each comparison. The section 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 TVT versus the comparators.

Markov model framework

Economic evaluation based on a Markov model was used to assess the cost-effectiveness of TVT relative to the standard surgical procedures currently used for SUI. The Markov model incorporated both the temporal and logical sequences of treatment, including the events that follow from the procedure and the outcomes for the patient associated with each possible scenario. The model provided estimates of total NHS costs and patient outcomes from the use of TVT and other procedures for the treatment of stress incontinence over a defined period. A probabilistic analysis using Monte Carlo simulation was used to assess the likelihood of TVT being cost-effective at various values for decision-makers' willingness to pay for an additional QALY.

Initial treatment by either TVT or one of the comparators listed below was compared within a Markov model:

- open abdominal retropubic colposuspension, the most common surgical intervention used to treat female SUI
- laparoscopic retropubic colposuspension
- traditional suburethral sling procedures
- periuretheral injectable agents.

The model was composed of defined health states between which a patient could move over specified periods. On entry into the model, all women with SUI initially had TVT or a comparison procedure. Age and disease severity were not varied within the model. After their initial surgery, patients move into one of four states:

- cured or dry (continent) by subjective measures
- failed but proceeding to retreatment (as patients can be offered a second or different type of procedure if their initial one fails)
- permanent state of incontinence (e.g. resorting to containment management of their incontinence by using pads, etc.)
- death (all-cause mortality is not included in the model as it was not expected to vary across the treatments, but a very small risk of death occurs when a patient is exposed to open surgery of colposuspension or traditional sling procedures).

Figure 3 provides a simplified summary of the model. Both permanent incontinence and death are included in the model as absorbing states. Since complications could be experienced after any procedure, the model incorporates generic complications by type of procedure to limit the number of branches in the tree. The time spent in

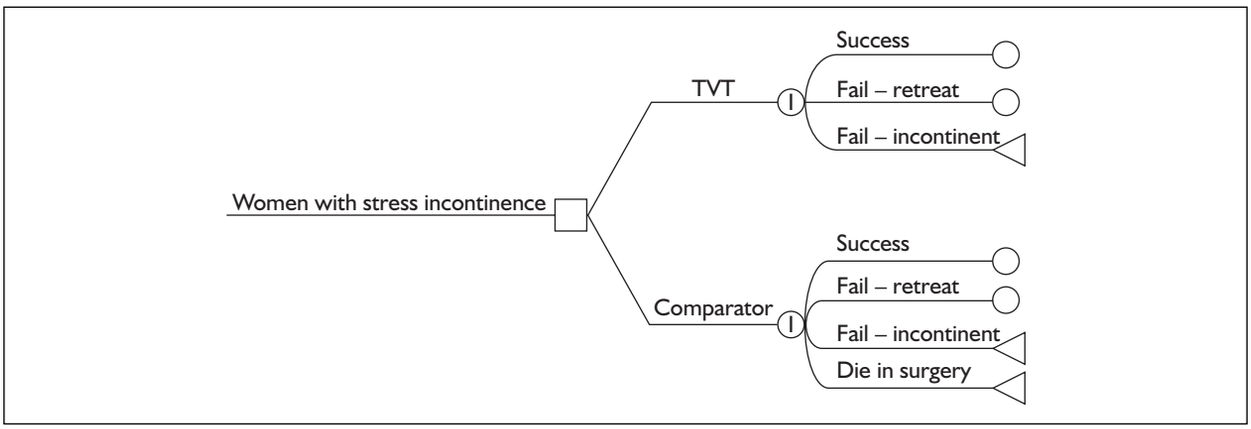

FIGURE 3 *Simplified Markov model for TVT versus comparators*

any but the absorbing states before a transition was allowed was 1 year (i.e. the cycle length was 1 year long). In the years following initial surgery and initial outcome, patients either stayed cured/dry or eventually moved to states of retreatment or permanent incontinence.

Patients who require retreatment can conceivably receive any of the procedures. To simplify the model, the most common procedure (open colposuspension) was used as the subsequent retreatment procedure. (TVT patients who required retreatment were therefore exposed to a very small risk of death during retreatment.) Alternative approaches considered but not used were to vary the retreatment procedures (e.g. use colposuspension or slings as the first retreatment and injectable agents as the second or final treatment) or to construct a composite/generic retreatment procedure that represented some average of the costs and effects of the four procedures.

The rate at which women chose to remain incontinent rather than seek retreatment was increased with each successive procedure. The model did not allow anyone to receive a total of more than three treatments (the initial surgery and two subsequent retreatments).

Data used to build the model included the success rates of the different procedures, probabilities of specific events used to estimate the cost of specified states (e.g. complications of procedures), probabilities of retreatment, QoL estimates and direct health service costs. Although in theory the model allowed for variation in the parameters of the treatment-specific Markov models between different branches of the model, in practice it was necessary to assume that many parameters were the same.

DATA 4.0 software was used to estimate deterministic versions of the model for up to 10 years and probabilistic versions of the model for varied periods. The probabilistic models are most important because current evidence suggests that there is no statistically significant difference in effectiveness between TVT and colposuspension or traditional slings. Monte Carlo cohort simulation was used for the probabilistic estimates. A detailed tree for the model comparing TVT and colposuspension is included in Appendix 22. Probabilistic estimations were done for 2 and 5 years of follow-up since the maximum follow-up period identified from the case series is approximately 5 years and it is not known with certainty what the longer term outcomes of TVT are.

Parameters used across all models

Probabilities

The main probabilities for the model were success rates of the different interventions, rates of retreatment and mortality rates. Success rates varied by procedure and were allowed to vary over time to the extent supported by the data. The estimations used fixed subjective cure rates for TVT and confidence intervals for the relative risk ratios of the effectiveness of TVT versus the comparator treatments.

As noted earlier, the costs of complications were assumed to be incorporated in the average cost of the procedures. Death rates were only incorporated for open surgery and a rate of 0.0005 was used based on evidence for colposuspension.[160] The industry submission reports four deaths out of a total of 230,000 (a rate of 0.000017). As this submission points out,

the true rate may be higher owing to under-reporting (submission to NICE from GYNECARE 27, May 2002).

The most problematic probability was the rate of retreatment. Consultation with a clinician indicated that many women try either repeat surgery or treatment with an alternative approach if their initial treatment fails, yet evidence on rates of retreatment for different procedures was not found in any of the studies or case-series data. The models were estimated with an assumption that 75% of women whose first treatment was not successful would seek retreatment, 30% of women whose first retreatment failed would seek second retreatment and no one would seek a third retreatment. Sensitivity analysis was performed on these rates given the lack of evidence. A lower success rate was used for retreatment with the same procedure (i.e. retreatment with colposuspension in these models) given evidence that retreatment colposuspension was 78.4% less effective on average than primary colposuspension.[145] Sensitivity analysis was also performed on this parameter.

Outcomes data

The short-term outcome measures included duration of operation, serious complications, time in hospital and time taken to return to normal activities. The first three of these outcomes have implications for costs to the NHS and the fourth outcome is not reflected in costs to the NHS, although it has implications for women and carers. The primary outcome measure was QALYs. As mortality effects were so small, this was largely dependent on whether the patient was continent or incontinent.

Published evidence on QoL for women with stress incontinence was extremely limited. The best source was the industry submission marked Commercial in Confidence.[48] A search of the Harvard database of cost–utility analyses (www.hsph.harvard.edu/organizations/hcra/cuadatabase/intro.html) yielded no estimates of QoL for women with stress incontinence. The industry submission had a baseline estimate of QoL of roughly 0.78 measured using the EQ-5D UK population tariffs. Following treatment, the mean QoL score rose to 0.806 and 0.794 at 6 months following surgery for TVT and colposuspension groups, respectively. If surgery failed to achieve a cure, then it was assumed that the woman would have a QoL of 0.78. The QoL associated with cure was 0.82. This value was calculated using the EQ-5D scores obtained at baseline and 6 months, along with the rates for cure at 6 months reported by the study by Manca and colleagues.[48] Values of 0.80 and 0.85 were used for incontinent and continent women, respectively, for the deterministic analysis of all the models used. Therefore, in the analysis differences in QALYs between treatments were driven solely by differences in cure rates.

Costs

Resource use data were identified from existing studies, relevant literature such as reports from manufacturers and advice from experts in this field. Cost data were extracted from the literature or from relevant sources such as manufacturer price lists and NHS reference costs. Costs were measured in pounds sterling (£) for the year 2001. As specified in the guidelines for conducting health technology assessment, discount rates of 6% were applied to costs and 1.5% per annum to QALY values.

The basic model for calculating the present value of costs was

$$PVC_A = TC_A + \sum [(P_{xt})\ (P_{yt})\ C_r] / (1 + 0.06)^n$$

for summation over $n = 1, \ldots, 10$, where

PVC_A = present value of cost of the treatment alternative A over n years ($t = 1, \ldots, n$);
TC_A = total cost of initial procedure;
P_{xt} = probability of being alive in year t;
P_{yt} = probability of receiving retreatment in year t;
C_r = cost of procedure;
6% = discount rate for healthcare costs.

Total procedure costs include operation costs, hospital ward costs and follow-up costs. The costs for every procedure included the components in *Table 28*.

Data specific to each comparison

TVT compared with open colposuspension

The cure rates for TVT and colposuspension for 1 and 2 years following surgery were derived from the systematic review of effectiveness reported in Chapter 3. The second-year rates were applied to each subsequent year in those models estimated for more than 2 years. *Table 29* (a replication of *Table 25*) provides the TVT subjective cure rates and the relative risk of cure for TVT versus open colposuspension for Model 1 and for rates adjusted for withdrawals (Model 2). As discussed earlier, in the Ward/Hilton trial more women

TABLE 28 *Cost components for stress incontinence treatments*

Costs	Relevant variables	Method of costing	Output
Hospital costs (theatre)	Consumables	Resource use of the individual, drugs and other consumables	Cost per patient
	Theatre	Based on the estimates of time procedure takes	Cost per patient
	Staff	Based on estimates of staff time in theatre	Cost per patient
Inpatient costs	Inpatient stay	PSSRU Scottish Health Service Costs	Cost per patient
	Tests and investigations	Resource use of the individual; drugs and other consumables	Cost per patient
	Medications	Resource use of the individual; drugs and other consumables	Cost per patient
	Staff	Based on estimates of staff time spent on the patient in the ward	Cost per patient
	Postoperative complications	By number of episodes and identification of the resource type used for each complication	Cost per patient
Outpatient costs	Outpatient appointments	By number of episodes and identification of the resource type used for each visit	Cost per patient
	Staff	Based on estimates of staff time in theatre	Cost per patient

TABLE 29 *Assumed cure rates following TVT at 1 and 2 years (based on pooled data) and assumed relative risk for TVT compared with Burch colposuspension (derived from published evidence of effectiveness at 6 months)*

Scenario		1 year	2 years
Estimates based on data actually collected (Model 1)	Assumed cure rates for TVT[a]	65% (158/245)	60% (138/230)
	Assumed RR of cure[b]	0.91 (95% CI 0.78 to 1.07)	
Adjusting for withdrawals presurgery (Model 2)	Assumed cure rates for TVT[c]	68% (186/273)	64% (166/258)
	Assumed RR of cure[b]	0.87 (95% CI 0.76 to 1.01)	

[a] Pooled estimates of TVT and open Burch colposuspension arms of Ward trial.
[b] Estimated from published 6-month data. RR < 1 favours Burch, i.e. TVT has poorer cure rates.
[c] Assuming that the 5 women in the TVT arm and the 23 in the colposuspension arm who dropped out before allocated treatment was received were cured.

withdrew from the colposuspension group than the TVT group, and evidence indicates that women with less severe incontinence problems may have been more likely to withdraw once they knew they were randomised to colposuspension.

[Confidential information relating to models based on 12- and 24-month efficacy data has been removed.]

The TVT cure rates for the model using rates adjusted for withdrawal (Model 2) were slightly higher than baseline rates (Model 1). The greatest difference between the two models (baseline versus adjusted for withdrawals) is that the relative risk of cure for TVT is considerably lower (i.e. colposuspension is relatively more successful than TVT) in the model adjusted for withdrawals than in the baseline model. Permission was obtained from the authors of the study that formed part of industry submission to use their estimated costs.[48] Their estimates indicated total 6-month costs which were assumed to reflect full-year costs as most treatment in the first year would occur within this time. The cost of TVT was £1014 and that of colposuspension was £1317.

TVT versus traditional open slings

The data reported in the section Additional information on comparators (p. 29) and summarised in the section Summary and conclusions of the evidence for and against the intervention (p. 30) suggest that the effectiveness of traditional slings would be the same as open colposuspension. Therefore, in the comparison with TVT, the data reported in *Table 29* were used.

There were no cost data from studies comparing traditional open slings with TVT, but three studies were identified that compared traditional open sling with open colposuspension. The cost of a sling procedure was calculated by using published estimates of average length of stay and the operation time of the traditional open sling procedure as they were not similar to those of open colposuspension. The operation time for traditional slings on average was 46 minutes and the average length of stay was 7.2 days. This was based on the results of the systematic review that indicated that the time in theatre for slings was 6 minutes less than that of open colposuspension (Appendix 18). The length of stay was based on the Hospital Episode Statistics data for England. Using these data in place of length of stay and operation time, the estimated cost of a traditional sling procedure was £1340. This cost was higher than that of TVT and that of open colposuspension.

TVT versus laparoscopic colposuspension

In the section Additional information on comparators (p. 29), data were reported that suggested that laparoscopic colposuspension had cure rates the same as or lower than open colposuspension. Therefore, it was assumed that in comparison with TVT, laparoscopic colposuspension would have the same effectiveness either as TVT or open colposuspension (*Table 29*).

Owing to the paucity of published cost data for laparoscopic colposuspension, calculations were carried out to establish estimates of costs based on the available information. Data on length of stay were available from Wales (Appendix 1b). However, they related to a small number of cases and it was believed that the results were not representative of normal conditions. The three identified studies all gave different results, with the most recently published one indicating that the costs of laparoscopic colposuspension were significantly higher owing to expenses associated with increased operative time and use of laparoscopic equipment.[161] All the studies supported this conclusion. Based on Foote,[61] laparoscopic colposuspension length of stay is 1.06 times that of TVT. The average costs of equipment used in open colposuspension were 38% of those of laparoscopic colposuspension. Estimates of costs were therefore derived using data from the systematic review and the assumption that the length of stay of laparoscopic was typically less than that of open colposuspension but more than that of TVT. The cost of laparoscopic colposuspension was estimated as £1317. This cost, however, did not take into account the additional cost of theatre equipment for laparoscopic surgery, which several studies have indicated is significantly more than that of open colposuspension. Kung and colleagues reported that the equipment costs of laparoscopic colposuspension without laser were 2.58 times those of the open procedure.[159]

TVT versus injectable agents

The effectiveness of injectable agents was based on that reported in the section Additional information on comparators (p. 29). These data suggested that injectable agents would have a poorer cure rate than open colposuspension (RR 1.36, 95% CI 1.02 to 1.8). It was assumed that injectable agents would have similar poorer relative cure rates than TVT.

Although the data in Chapter 2 indicated that injectable agents have the highest number of day cases, patients were also seen as inpatients (*Tables 2* and *3*). The average length of stay was 2.0 days and the length of time spent in the theatre was 20 minutes where the surgeon was experienced.[162] The cost of injectable agents was derived from a published review by weighting results of several studies to establish the total volume of injectable material used in millilitres and the average number of injections that patients received. The average volume of injectable materials used, estimated from the studies, was approximately 7 ml and the number of injections received was approximately two. However, the authors of the review indicated that the average volume of material that was needed was 5 ml, and the large volumes of materials used in the studies were attributable to inexperienced surgeons carrying out the procedures. The average cost of 2.5 ml of injectable material was £325. The total cost estimate of injectables treatment was £1305. This is a conservative estimate as it does not include theatre costs.

Sensitivity analysis

Sensitivity analysis was conducted by varying several assumptions or parameters in the model comparing TVT and open colposuspension. One of the parameters that was varied was the cost of the different procedures. Revised new estimates were derived by using the average of theatre time derived from Chapter 3 and the hospital length of stay in England and Wales (*Tables 2* and *3*). The average length of stay for England for the year 2000–1 was 2.9 days for TVT, 7.1 days for open colposuspension and 7.2 days for traditional slings.

Theatre time for TVT was identified from the systematic review of effectiveness using case-series studies, which gave an average theatre time of 30 minutes (*Table 23*). For open colposuspension, time in theatre was derived by using the weighted (by size of study) average of the three identified RCTs (*Table 22*). The results indicated that the average operation time was 52 minutes.

The cure rate was varied by using a higher rate than that reported in the Ward/Hilton trial.[50,52] This rate was identified from the systematic review of effectiveness (*Table 14*) and a cure rate of 90% was used. Also varied was the probability of having retreatment following treatment failure. In the sensitivity analysis lower (60% for first retreatment and 20% for second retreatment) and higher (85% for first retreatment and 40% for second retreatment) probabilities were used.

The sensitivity analysis carried out took into account the confidence intervals of both the costs and QALYs based on calculated differences in the data from the industry submission. As the data in the report covered the 6-month period of the study, assumptions were made to derive the QALY for 1 year as the treatment cycles were considered to cover 1 year. A triangular distribution was used in the analysis to incorporate the minimum, the mean and the maximum point of the distribution. The cost confidence intervals ranged from a minimum of £224 to £328 as the mid rate and £432 as the maximum rate. The QALY 95% CI for 1 year ranged between 0.78 as a minimum, 0.82 as the mean and 0.869 as the maximum.

Results for TVT versus open colposuspension

Deterministic results

Table 30 provides the full deterministic results for Models 1 and 2. For all follow-up periods (1–10 years), the cumulative costs of TVT were less than the cumulative costs of colposuspension. Using mean estimates of cure, TVT was initially less effective than colposuspension in terms of QALYs (given the initial cure rates used), and over time the cumulative QALYs from TVT in all models apart from Model 2 exceeded the cumulative QALYs from colposuspension for each model, making TVT dominant.

It is important to note that the dominance of TVT ultimately occurs because of the assumption that retreatment colposuspension is not as effective as primary colposuspension. If retreatment colposuspension is assumed to have cure rates equal to primary colposuspension, then dominance of TVT over colposuspension does not occur in the deterministic models as shown in the last column in *Table 30*.

Also shown in *Table 30* is the range in the incremental cost per QALY for Model 1 obtained when the upper and lower bounds of the 95% CI for relative cure rates of TVT were compared with open colposuspension (*Table 29*). As these estimates show, there is considerable variation in the cost per QALY and hence in the conclusion that would be drawn. The appropriate way to represent this sampling variation is using a stochastic analysis, as is reported in the next sub-section.

Stochastic results

All models were also run using Monte Carlo simulation to obtain probabilistic estimates of the cost–utility of TVT versus open colposuspension. The results in terms of incremental cost per QALY are shown as cost-effectiveness acceptability curves. Estimations were made for both 2- and 5-year follow-up periods to reflect the limited length of follow-up data after TVT from the existing RCTs and case-series studies.

Figure 4 presents the Monte Carlo cohort simulation results (for 1000 samples) for Model 1 in the four-quadrant cost-effectiveness plane. All the estimates for Model 1 indicate that TVT is expected to cost less than open colposuspension. *Tables 31* and *32* summarise the distribution of the simulation sample in the cost-effectiveness plane for each model at 2 and 5 years, respectively. The last column in the tables emphasises the fact that the cumulative costs for TVT are always less than for colposuspension for the follow-ups considered. Furthermore, consistent with the deterministic results, TVT is more likely to dominate colposuspension for the baseline models than for the models adjusted for withdrawals (which have higher cure rates for colposuspension). **[Confidential information relating to alternative models based on effectiveness data has been removed.]**

The estimates for costs, QALYs and differences in costs and QALYs are presented in *Table 33* and the incremental costs per QALY are presented as a series of cost-effectiveness acceptability curves in *Figure 5*. The acceptability curves were drawn in the same manner as the acceptability curve presented in the Commercial in Confidence submission to facilitate comparison, although the presentation is essentially the inverse from the usual presentation[163] since so many of the estimates fall

TABLE 30 *Deterministic analysis of TVT versus open colposuspension for Models 1 and 2*[a]

Years after initial surgery[b]	Strategy	Cost (£)	Incremental cost (£)	QALYs	Incremental QALYs	ICER[c] (£)		ICER Model 1 (£) sensitivity colposuspension[d]
						Model 1	Model 2	
1	TVT	1345	–243	0.819951	–0.002748	88,450	35,446	88,450
	Colpo	1588	(–342 to –133)	0.822699	(–0.0086 to 0.0025)	(–138,237 to 15,524)		
2	TVT	1412	–254	1.634642	–0.001986	127,753	36,849	67,125
	Colpo	1666	(–357 to –143)	1.636628	(–0.0098 to 0.0057)	(–62,282 to 14,635)		
3	TVT	1454	–258	2.436397	–0.001255	205,532	37,712	56,496
	Colpo	1712	(–356 to –153)	2.437652	(–0.0109 to 0.00867)	(–40,996 to 14,007)		
4	TVT	1492	–261	3.224982	–0.000428	611,087	39,334	48,842
	Colpo	1753	(–354 to –162)	3.225410	(–0.012 to 0.01162)	(–30,470 to 13,528)		
5	TVT	1526	–267	4.000629	0.00048	–554,277	41,770	43,095
	Colpo	1790	(–352 to –170)	4.000152	(–0.0129 to 0.01455)	(–24,225 to 13,150)		
6	TVT	1556	–271	4.76357	0.00144	–185,017	45,178	38,641
	Colpo	1823	(–351 to –176)	4.762127	(–0.01373 to 0.01746)	(–20,109 to 12,847)		
8	TVT	1606	–273	6.25225	0.00351	–77,217	56,321	32,237
	Colpo	1877	(–349 to –187)	6.248739	(–0.01511 to 0.02315)	(–15,056 to 12,395)		
10	TVT	1645	–274	7.692829	0.00569	–48,215	79,284	27,903
	Colpo	1920	(–346 to –196)	7.687143	(–0.01619 to 0.02862)	(–12,103 to 12,087)		

[a] Information relating to Commercial in Confidence effectiveness data has been removed from this table.
[b] Results from years 7 and 9 not shown.
[c] 95% CI for the incremental cost per QALY only shown for Model 1.
[d] Retreatment colposuspension assumed to have cure rates equal to primary colposuspension.

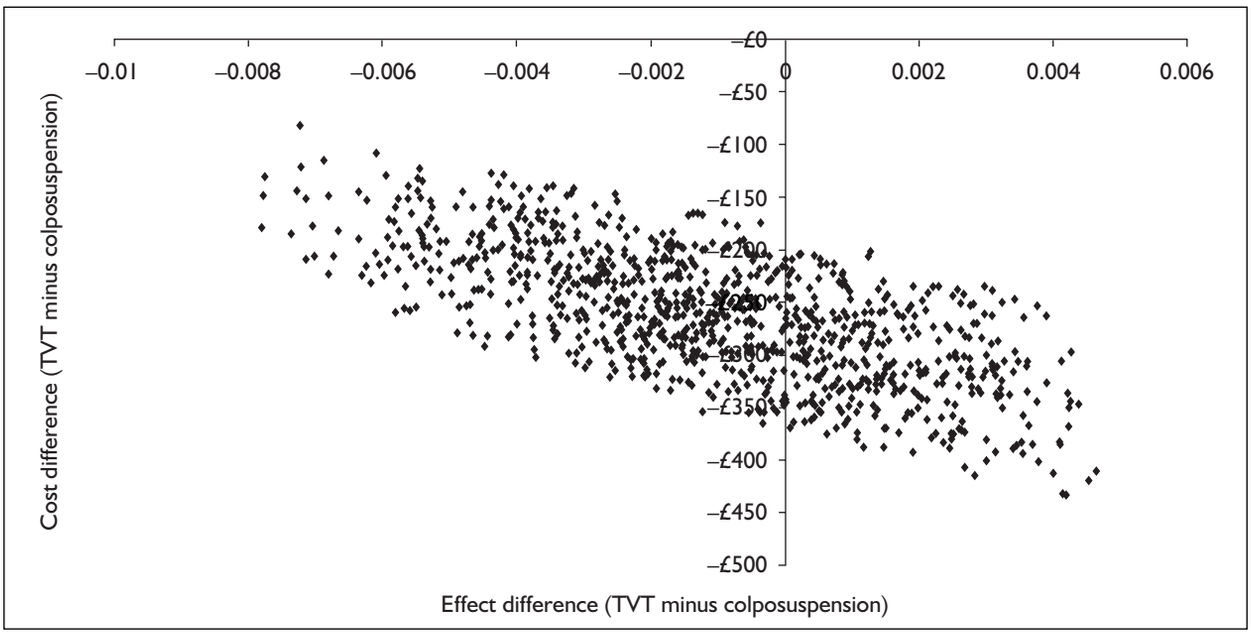

FIGURE 4 *Cost-effectiveness plane for Model 1 based on the Monte Carlo simulations at 5 years for TVT versus open colposuspension*

TABLE 31 *Monte Carlo 2-year simulation results for TVT versus open colposuspension*[a]

Model	TVT costs more and has greater effect than colposuspension (%)	Colposuspension dominates (TVT costs more and has less effect) (%)	TVT costs less but has less effect than colposuspension (%)	TVT dominates (TVT costs less and has greater effect) (%)	TVT costs less than colposuspension (regardless of effect) (%)
Model 1 baseline	0	0	64.8	35.2	100
Model 2 adjusted	0	0	75.8	24.2	100

[a] Information relating to alternative models based on Commercial in Confidence effectiveness data has been removed from this table.

TABLE 32 *Monte Carlo 5-year simulation results for TVT versus open colposuspension*[a]

Model	TVT costs more and has greater effect than colposuspension (%)	Colposuspension dominates (TVT costs more and has less effect) (%)	TVT costs less but has less effect than colposuspension (%)	TVT dominates (TVT costs less and has greater effect) (%)	TVT costs less than colposuspension (regardless of effect) (%)
Model 1 baseline	0	0	54.6	45.4	100
Model 2 adjusted	0	0	57.5	42.5	100

[a] Information relating to alternative models based on Commercial in Confidence effectiveness data has been removed from this table.

in the portion of the cost-effectiveness plane that represents a lower cost but also a lower effect for TVT versus open colposuspension. The curves show the probability that TVT would be considered cost-effective for different threshold values of society's willingness to pay for an additional QALY. The curves in *Figure 5* show that if the decision-maker is unwilling to pay anything extra for an additional QALY, then TVT should be preferred owing to its lower cost. For example, if the decision-maker was willing to pay up to £30,000 there is roughly a 92% chance that TVT is cost-effective relative to open colposuspension based on Model 1. This rate is slightly higher than the probability estimated in the Commercial in Confidence submission, although once again the

TABLE 33 *95% CIs for cost and QALYs and difference in cost and QALYs for Models 1 and 2 for TVT versus open colposuspension*[a,b]

Scenario	Costs (£)		QALYs		Difference in costs (£)	Difference in QALYs
	TVT	Open colposuspension	TVT	Open colposuspension		
Model 1, 2 years	1387–1438	1536–1816	1.582–1.583	1.578 –1.589	–381 to –148	–0.006 to 0.003
Model 1, 5 years	1494–1559	1654–1936	3.869–3.876	3.859–3.885	–382 to –157	–0.008 to 0.010
Model 2, 2 years	1348–1388	1460–1752	1.584–1.586	1.581–1.594	–369 to –115	–0.008 to 0.003
Model 2, 5 years	1434–1491	1567–1859	3.878–3.885	3.868–3.896	–373 to –134	–0.010 to 0.009

[a] 95% CIs are based on the 2.5% and 97.5% Monte Carlo iteration.
[b] Information relating to alternative models based on **[Commercial in Confidence effectiveness data has been removed from this table]**.

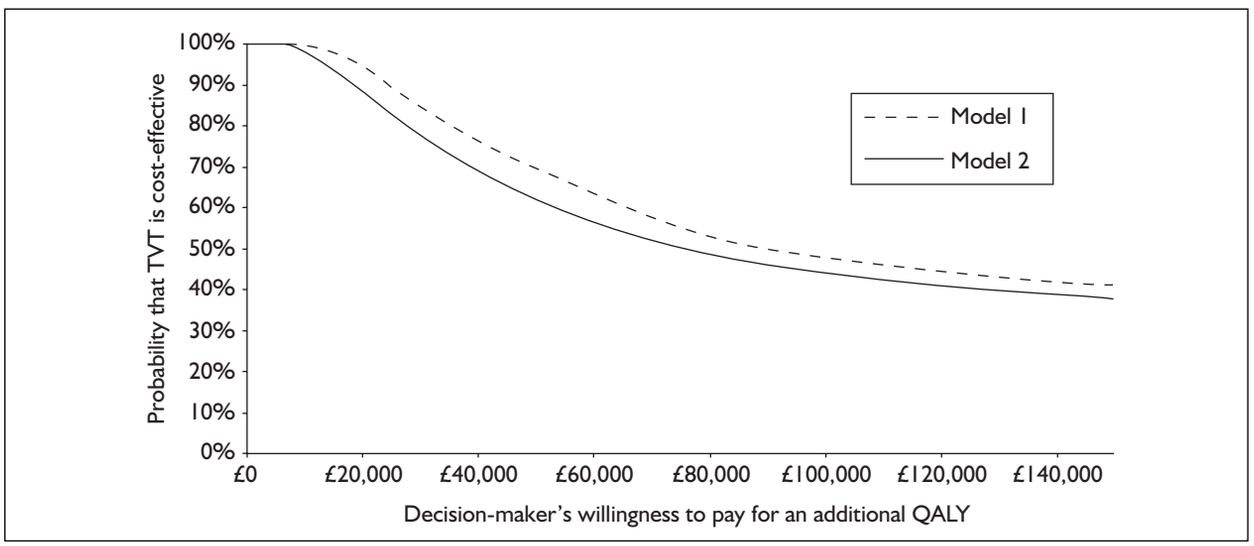

FIGURE 5 *Cost-effectiveness acceptability curves for TVT versus open colposuspension for Models 1 and 2 for 2 years follow-up (curves for models based on* ***[Confidence in Confidence data are not presented]***

results are more favourable for TVT because of the assumed lower effectiveness of retreatment colposuspension.

Sensitivity analyses

Sensitivity analyses were conducted according to various assumptions or parameters in the model and reported for Model 1 for the deterministic model and Models 1 and 2 for the stochastic model.

Deterministic model

As noted earlier, a critical factor that results in the ultimate dominance of TVT over open colposuspension in the deterministic models was the assumption that retreatment open colposuspension would be less effective than primary colposuspension. Re-running Model 1 under the assumption that retreatment open colposuspension was as effective as primary open colposuspension results in a situation in which TVT is never dominant over the 10-year follow-up period in the deterministic estimations (last column of *Table 30*).

Another sensitivity analysis pertained to the assumption that 75% of women whose initial treatment failed would choose retreatment (which was assumed to be open colposuspension in this model). When sensitivity analysis was run based on the assumption that more women would opt for retreatment TVT was dominant from the fourth year and when the likelihood of retreatment was reduced, TVT dominated from the seventh year. The baseline results are between the low and high

estimates as the retreatment rate was increased and reduced by a similar proportion. There were very small changes in the differences in costs and QALYs.

Stochastic model

Table 34 shows the results of the various sensitivity analyses run on the stochastic models in terms of cost, QALYs and differences in costs and QALYs. The first of these [(a) in *Table 34*] relates to the costs for TVT and open colposuspension based on evidence from the systematic review presented in Chapter 3. As this analysis shows, there is relatively little difference in the results.

A second sensitivity analysis [(b) in *Table 34*] related to the use of higher cure rates for TVT. Even when the cure rate for TVT was up to 90%, the probability that TVT was cost-effective was nearly 100% for all the models considered provided that the decision-maker was unwilling to pay anything more for an additional QALY (*Figure 6*). However, the probability of TVT being considered cost-effective reduced to less than 50% if the decision-maker would be willing to pay approximately £50,000 for an additional QALY. The results illustrated in *Figure 6* could be attributed to the fact that when a high cure rate for TVT was used, the cure rate for open colposuspension was bounded at 1 (i.e. open colposuspension did not fail) because the same relative risks were used.

A third sensitivity analysis [(c) in *Table 34*] considered the impact in the stochastic models of a secondary open colposuspension having the same effectiveness as a primary procedure (*Figure* 7). As would be expected, the likelihood that TVT would be considered cost-effective declines as the cost per QALY increases. Other things remaining equal, increasing the length of follow-up from 2 to 5 years led to a further decline in the cost-effectiveness of TVT.

The final sensitivity analysis was based on changing the likelihood that a woman would seek retreatment if primary treatment failed [(d) and (e) in *Table 34*]. Initially it was assumed that 75% of women would seek retreatment. In this analysis, both the 2- and 5-year models indicated that high retreatment rates led to higher probabilities that TVT was cost-effective, as indicated by *Figure 8* [a similar figure for (e) is not shown but would indicate that TVT was less likely to be cost-effective]. This result could be attributed to the fact that the retreatment option in the model was open colposuspension that had lower effectiveness when undertaken as a secondary procedure.

Results for TVT versus laparoscopic colposuspension

As described in the section Costs (p. 39), an attempt was made to estimate the costs of laparoscopic colposuspension by adjusting the costs derived for open colposuspension. Specifically, the length of stay was reduced and the operation time increased. This led to an estimated cost of laparoscopic surgery of £1317, which is very similar to that of open colposuspension. As discussed in Chapter 3, laparoscopic colposuspension is likely to have the same or lower effectiveness than open colposuspension. Economic modelling of TVT versus laparoscopic colposuspension would therefore give similar results to the open colposuspension, or favour TVT more.

Results for TVT versus traditional slings

There was a lack of studies that directly compared traditional slings with TVT, which created difficulty in estimating the cost-effectiveness. To aid this, data relating to the comparison of traditional slings with the most commonly used procedure, open colposuspension, as reported in the section Assessment of effectiveness (p. 17), were used. Three identified non-randomised comparative studies indicated that there were similar rates of cure between traditional slings and TVT.[61,63,65] A Cochrane review found no evidence of a difference between traditional slings and open colposuspension.[150] Therefore, based on the assumption that the effectiveness of traditional slings was the same as open colposuspension and the cost was slightly lower than open colposuspension, the results would be similar to those of TVT versus open colposuspension [as discussed in the section 'Results for TVT versus open colposuspension' (p. 42)]. The estimates of cost and QALYs are presented in *Table 35*. The cost-effectiveness acceptability curves for Models 1 and 2 at 2 years indicate that TVT is likely to be considered cost-effective even when the incremental cost per QALY is as high as £30,000 (*Figure 9*).

Results for TVT versus injectable agents

The estimated cost of injectable treatment based on the available data was £1305 even when the cost of any theatre time was excluded. This compares with the procedure cost of TVT of

TABLE 34 *95% CIs for cost and QALYs and difference in cost and QALYs for Models 1 and 2 for different sensitivity analyses for TVT versus open colposuspension*[a]

Scenario[b]	Costs (£)		QALYs		Difference in costs (£)	Difference in QALYs
	TVT	Open colposuspension	TVT	Open colposuspension		
Revised costs (a)						
Model 1, 2 years	1424–1476	1596–1880	1.582–1.583	1.578–1.589	–404 to 169	–0.006 to 0.004
Model 1, 5 years	1536–1601	1717–2005	3.869–3.876	3.859–3.885	–406 to 178	–0.009 to 0.011
Model 2, 2 years	1373–1424	1516–1812	1.584–1.586	1.581–1.594	–394 to 135	–0.008 to 0.003
Model 2, 5 years	1473–1812	1626–1924	3.878–3.885	3.868–3.896	–393 to 154	–0.011 to 0.009
High cure rates (b)						
Model 1, 2 years	1154–1172	1307–1542	1.597–1.598	1.595–1.602	–379 to 148	–0.006 to 0.004
Model 1, 5 years	1283–1319	1447–1697	3.902–3.904	3.895–3.891	–377 to 165	–0.007 to 0.007
Model 2, 2 years	1144–1161	1295–1522	1.598–1.598	1.596–1.603	–362 to 150	–0.004 to 0.002
Model 2, 5 years	1249–1281	1414–1645	3.905–3.907	3.899–3.914	–369 to 163	–0.007 to 0.006
Secondary colpo same effect (c)						
Model 1, 2 years	1424–1476	1585–1865	1.582–1.584	1.580–1.591	–390 to 160	–0.007 to 0.002
Model 1, 5 years	1536–1601	1702–1989	3.870–3.877	3.865–3.891	–390 to 163	–0.014 to 0.005
Model 2, 2 years	1343–1388	1452–1740	1.585–1.587	1.583–1.596	–355 to 109	–0.009 to 0.002
Model 2, 5 years	1434–1491	1555–1844	3.879–3.886	3.875–3.900	–352 to 122	–0.014 to 0.004
High retreatment rates (d)						
Model 1, 2 years	1444–1507	1583–1893	1.582–1.584	1.579–1.590	–384 to 133	–0.005 to 0.003
Model 1, 5 years	1574–1653	1722–2040	3.874–3.882	3.863–3.889	–397 to 144	–0.007 to 0.011
Model 2, 2 years	1392–1448	1494–1820	1.585–1.587	1.582–1.595	–379 to 148	–0.006 to 0.004
Model 2, 5 years	1501–1570	1622–1943	3.882–3.890	3.872–3.898	–381 to 156	–0.009 to 0.010
Low retreatment rates (e)						
Model 1, 2 years	1330–1373	1492–1743	1.581–1.582	1.577–1.589	–362 to 132	–0.008 to 0.010
Model 1, 5 years	1416–1471	1587–1842	3.865–3.871	3.855–3.882	–374 to 169	–0.010 to 0.010
Model 2, 2 years	1294–1331	1427–1969	1.584–1.585	1.580–1.594	–368 to 115	–0.008 to 0.003
Model 2, 5 years	1369–1415	1518–1778	3.873–3.880	3.864–3.893	–367 to 133	–0.010 to 0.009

[a] 95% CIs are based on the 2.5% and 97.5% Monte Carlo iteration.

[b] (a) Value derived by using revised cost for TVT and colposuspension; (b) values derived by using a cure rate of 90%; (c) a secondary colposuspension procedure has the same effectiveness as a primary procedure; (d) values derived by using retreatment rates of 85% and 40%; (e) values derived by using retreatment rates of 65% and 20%.

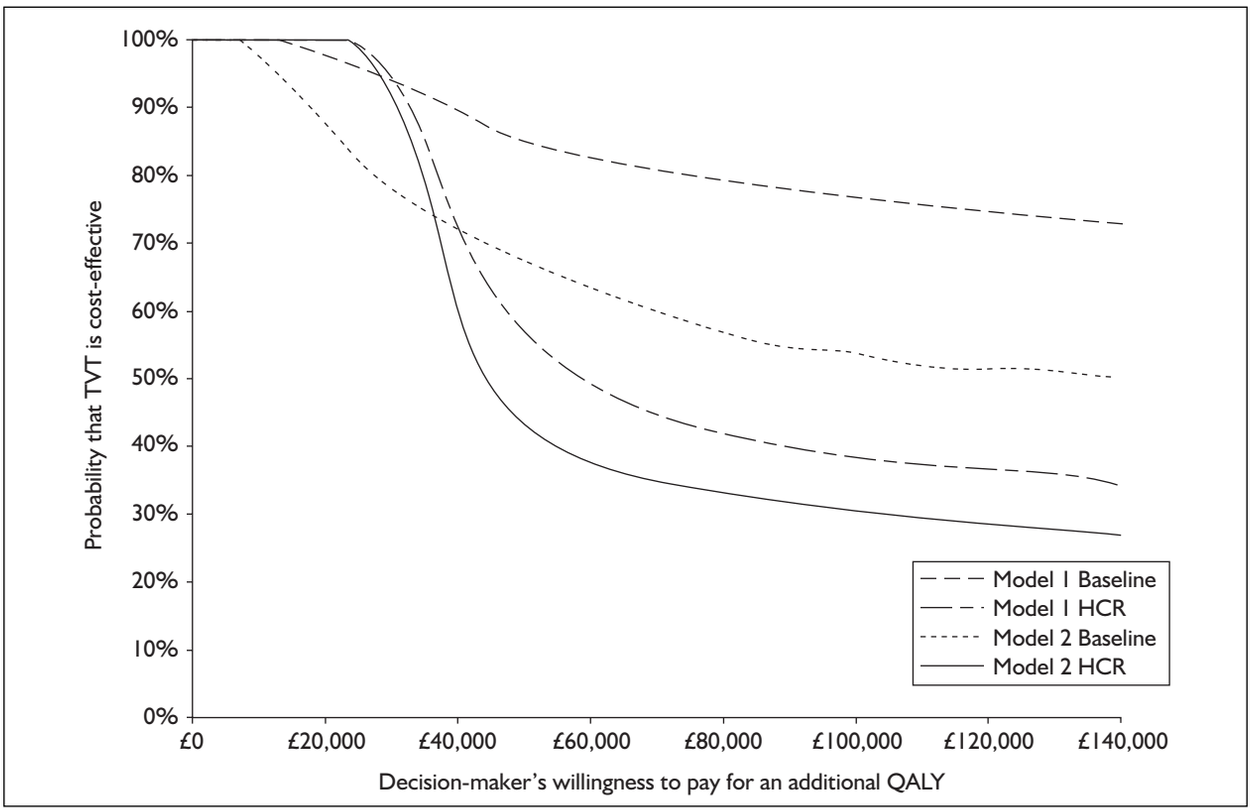

FIGURE 6 *Cost-effectiveness acceptability curves for TVT versus open colposuspension for Models 1 and 2 for the comparison of baseline results with high cure rates (HCRs)*

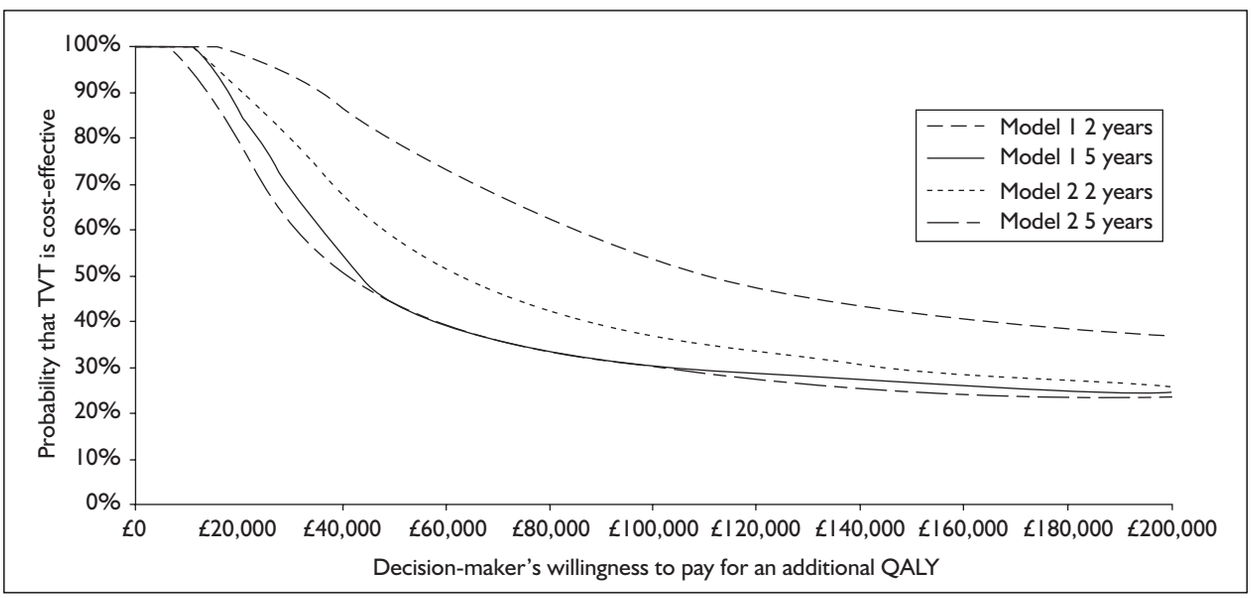

FIGURE 7 *Cost-effectiveness acceptability curves for TVT versus open colposuspension for Models 1 and 2 at 2 and 5 years follow-up when the effectiveness of a secondary open colposuspension is the same as that of a primary open colposuspension*

£1014. As indicated in Chapter 3, there were no studies that directly compared TVT with injectable agents, although there is one known ongoing trial (Appendix 7). However, based on the studies considered in the section Assessment of effectiveness (p. 17), the effectiveness of injectable agents is likely to be considerably lower than that of TVT. TVT will, therefore, be dominant (i.e. be less costly and more effective) compared with injectable agents. Even if it were to be assumed that they had similar effectiveness, TVT would still be dominant owing to the higher cost of injectable agents.

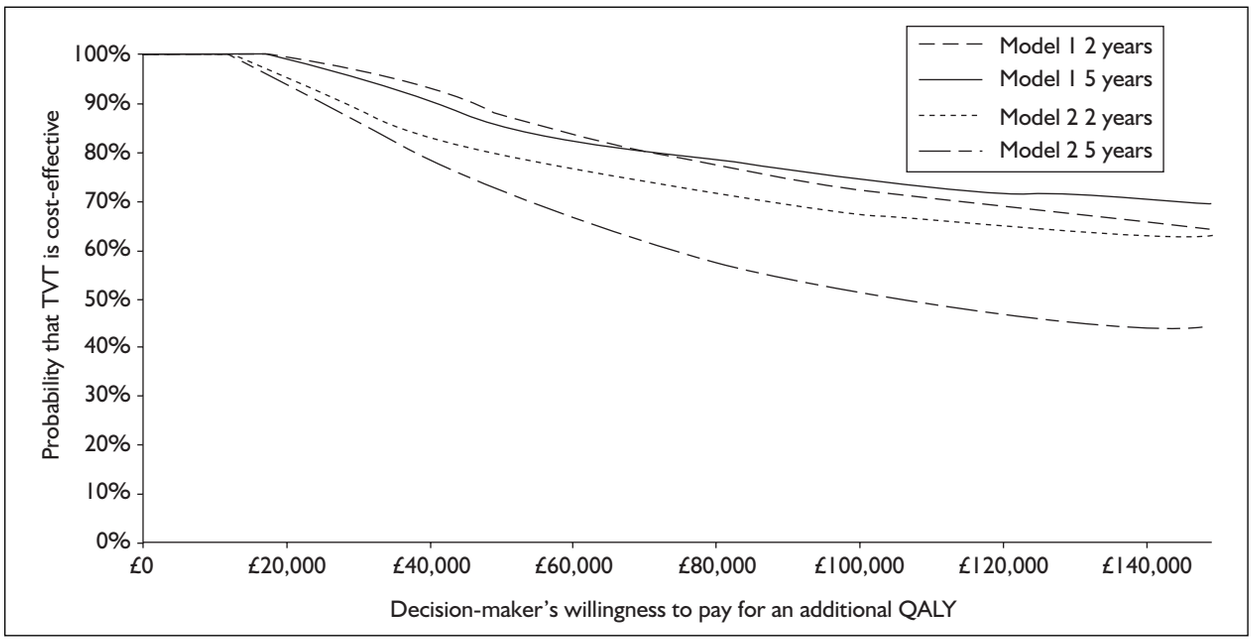

FIGURE 8 *Cost-effectiveness acceptability curves for TVT versus open colposuspension for Models 1 and 2 for 2 and 5 years follow-up for a high chance of retreatment following failure of a primary procedure*

TABLE 35 *95% CIs for cost and QALYs and difference in cost and QALYs for the comparison of TVT with traditional slings*[a]

Scenario	Costs (£)		QALYs		Difference in costs (£)	Difference in QALYs
	TVT	Traditional slings	TVT	Traditional slings		
Model 1, 2 years	1384–1435	1514–1788	1.582–1.583	1.580–1.591	–356 to 128	–0.007 to 0.002
Model 1, 5 years	1490–1555	1626–1908	3.870–3.877	3.864–3.890	–355 to 132	–0.014 to 0.005

[a] 95% CIs are based on the 2.5 and 97.5 Monte Carlo iteration.

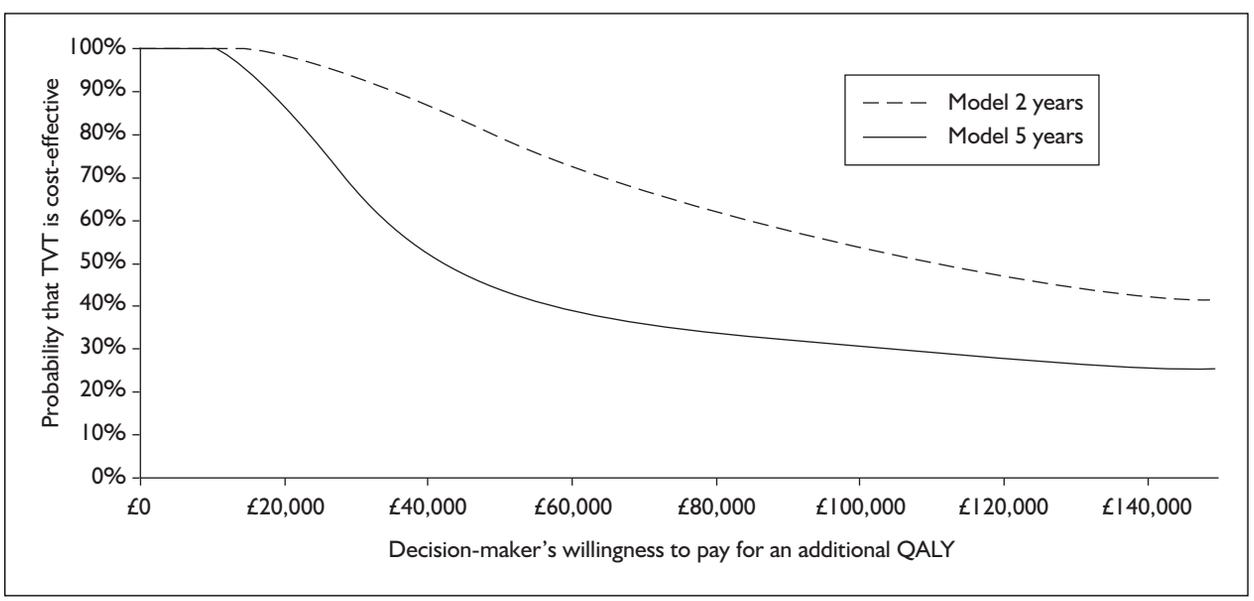

FIGURE 9 *Cost-effectiveness acceptability curves for TVT versus traditional slings at 2 and 5 years (analysis analogous to the results of Model 1 in Figure 5)*

Summary

The Commercial in Confidence industry submission economic evaluation that was available for this review appeared to be well performed, but only reported results for a 6-month follow-up period. The modelling provided in this section contributed to the evidence available for assessing TVT versus alternative treatments by estimating, albeit under various assumptions, the cost-effectiveness of TVT over a longer follow-up period. Furthermore, as discussed in Chapter 3, the data on which this evaluation was performed might be biased, as women who withdrew from the open colposuspension group before surgery tended to have less severe incontinence. For this reason, an adjusted analysis was presented (Models 2 and 4) which assumed that those who withdrew from the largest trial before surgery were cured.

The first year deterministic results were very consistent with the results from the industry submission. Taken as a whole, the additional economic modelling indicates that TVT relative to open colposuspension might be cost-effective and could be the dominant option. The latter conclusion is reliant upon assumptions about what happened to those women who withdrew from the largest trial presurgery and also two assumptions related to the structure of the model. First, based on published evidence, retreatment open colposuspension was assumed not to be as effective as primary open colposuspension. Second, it was assumed that TVT surgery is not going to have a worsening failure rate or serious complication at some future point in time (not yet detected by the RCTs or case series) that would either significantly reduce TVT's effectiveness or even preclude its use. Also, the models assume that if TVT ultimately fails for some proportion of women, the women can proceed to treatment with open colposuspension, the benefit of which would be the same as if this had been the primary procedure rather than retreatment. This beneficial scenario could, of course, be compromised if TVT is ultimately found to fail in a way that prevents subsequent open colposuspension. Failures of this nature have not yet been documented and clinical opinion sought for this report indicated that TVT failure should not generally preclude subsequent treatment with open colposuspension.

The limited data available on direct comparisons between TVT and the other comparators required assumptions to be made (on the basis of the data reported in Chapter 3) about how TVT compared with them. Existing information was centred on comparisons with open colposuspension and the consideration of these data and the limited data on direct comparisons with TVT formed the basis of the comparisons modelled. Although this enabled some estimation of the relative cost-effectiveness, the results are not as robust as they could have been had they been based on good-quality direct comparative data.

The assumption that traditional slings and open colposuspension had similar effectiveness led to similar results for the comparison of TVT with open colposuspension, although in this case the cost and QALY differentials were less than those observed when TVT was compared with open colposuspension. Higher estimated costs and lower cure rates led to the injectable agents being dominated by TVT. Laparoscopic colposuspension was also likely to be dominated by TVT.

As alluded to above, the lack of long-term data also necessitated extrapolation of relatively short-term data to 5 years. These results would only apply in a situation where relative differences in effectiveness of TVT, compared with the comparators, do not change over time. It is not known at this stage whether or not this assumption is valid. Furthermore, lack of good-quality data comparing TVT with the comparators may cause bias. The effect of this on the results is uncertain.

As indicated in the economic systematic review, reported in Chapter 4, there was a lack of good-quality cost data available for the comparators. In most of the analyses presented above the costs used were essentially the same as those used in the industry submission. When the data on operation time and length of stay, reviewed in Chapter 3, were used, however, the estimated incremental cost per QALY was not greatly different.

Notwithstanding the undoubted shortcomings of underlying research, the findings of the analyses reported in this section are similar to those of the industry submission, although they relate to a longer follow-up and, as a result, at a higher incremental cost per QALY there is less likelihood of TVT being considered cost-effective. It is worth noting that in the adjusted analyses TVT is also less likely to be considered cost-effective.

Chapter 6

Implications for other parties

Quality of life for family and carers

Containment of incontinence using pads or protective clothing can put a significant burden not only on the person with incontinence but also on their family and any carers. Each of the different surgical treatments (TVT, open colposuspension, laparoscopic colposuspension, traditional slings and injectable agents) offers the prospect of an improved QoL for the family, carers and patients. As the analysis presented in Chapter 5 illustrates, differences between procedures in QoL cannot be ruled out, although their magnitude would be relatively small compared with the improvement in QoL consequent on successful treatment.

Financial impact for patients and others

The use of containment products can have significant financial implications for sufferers and their carers. Successful surgical treatment would ameliorate this.

Changes in the patient population

The adoption of TVT may increase the number of women considered eligible for surgical treatment for SUI. First, as TVT can be performed under regional or local anaesthesia, it may allow those who might otherwise be considered too frail or unfit for surgery to receive treatment. Second, as TVT is not as invasive as colposuspension or traditional sling procedures, it may attract women to seek treatment who would otherwise not consider their symptoms to be sufficiently severe to warrant surgery.

In both cases, the QoL of the women, their families and any carers would be expected to increase, although the magnitude of any gains is difficult to ascertain. Similarly, the financial impact of increasing the use of surgical interventions is difficult to ascertain. It would initially result in time away from usual activities during a convalescence period, but it might subsequently allow significantly more women to work. It should reduce the need for privately bought containment products and reduce the costs associated with the laundry of soiled linen and clothing.

Chapter 7

Factors relevant to the NHS

As described in Chapter 3, serious complications can occur during TVT and, as for other minimal access techniques, the risk of these is likely to be related to operator experience and skill. Although the nature of the procedure would appear to preclude its use outside specialist centres, appropriate training and supervision would be needed for additional surgeons if its use were to be extended.

An increase in the proportion of women considered eligible for surgery, rather than merely changing the balance between existing treatments, would increase pressure on hospital services. Although TVT takes less time to perform (a surgeon could perform three TVTs in the same time as it takes to perform two open colposuspensions), there could still be an increase in the cost to the NHS because of the increased use of TVT.

The size and nature of any change in cost to the NHS depend on two factors: the extent of substitution of TVT for other more invasive procedures and the extent to which TVT is offered to women who were previously considered ineligible for surgery. Using the cost data presented in Chapter 5 and the data on NHS activity presented in the section Current service provision (p. 5), the annual cost to the NHS of varying scenarios can be modelled, although the published activity may be a conservative estimate of the true number of procedures per year. In *Table 36*, the mean cost differences (and 95% CIs based on 2.5 and 97.5 bootstrap percentiles) are shown for a series of scenarios which differ in terms of the proportion of people receiving TVT and the size of the population treated. Also shown is an estimate of the additional QALYs gained (and 95% CIs based on 2.5 and 97.5 bootstrap percentiles) over 2 years by treating those not previously eligible for surgical treatment. QALY estimates were based on the same data used in the decision models presented in Chapter 5 and in this context assume that additional women treated will experience the same benefit as those currently treated and that the treatment displaced is containment management and not conservative

TABLE 36 *Incremental cost and QALYs compared with the current pattern of management following changes in the proportion of women receiving TVT and increases in the population of women eligible for surgery*[a]

Scenario	Difference in cost from baseline (£)	Difference in QALYs from baseline
A 44% of women receive TVT, population same as baseline	–2446 (–3104 to –1776)	~0
B 64% of women receive TVT, population same as baseline	–£7337 (–9113 to –5327)	~0
C Population of women treated increases by 10%	8184	0.5101 (0.4279–0.5374)
D Population of women treated increases by 30%	24,553	1.5304 (1.838–1.613)
E 44% of women receive TVT, population of women treated increases by 10%	5739 (5080 to 6409)	0.5101 (0.4279–0.5373)
F 44% of women receive TVT, population of women treated increases by 30%	22,108 (21,449 to 22,778)	0.5101 (0.4279–0.5373)
G 64% of women receive TVT, population of women treated increases by 10%	848 (–1129 to 2857)	1.5304 (1.838–1.613)
H 64% of women receive TVT, population of women treated increases by 30%	17,216 (15,240 to 19,226)	1.5304 (1.838–1.613)

[a] Description of baseline: 34% of women receive TVT out of 81 treated per 500,000 of the population.

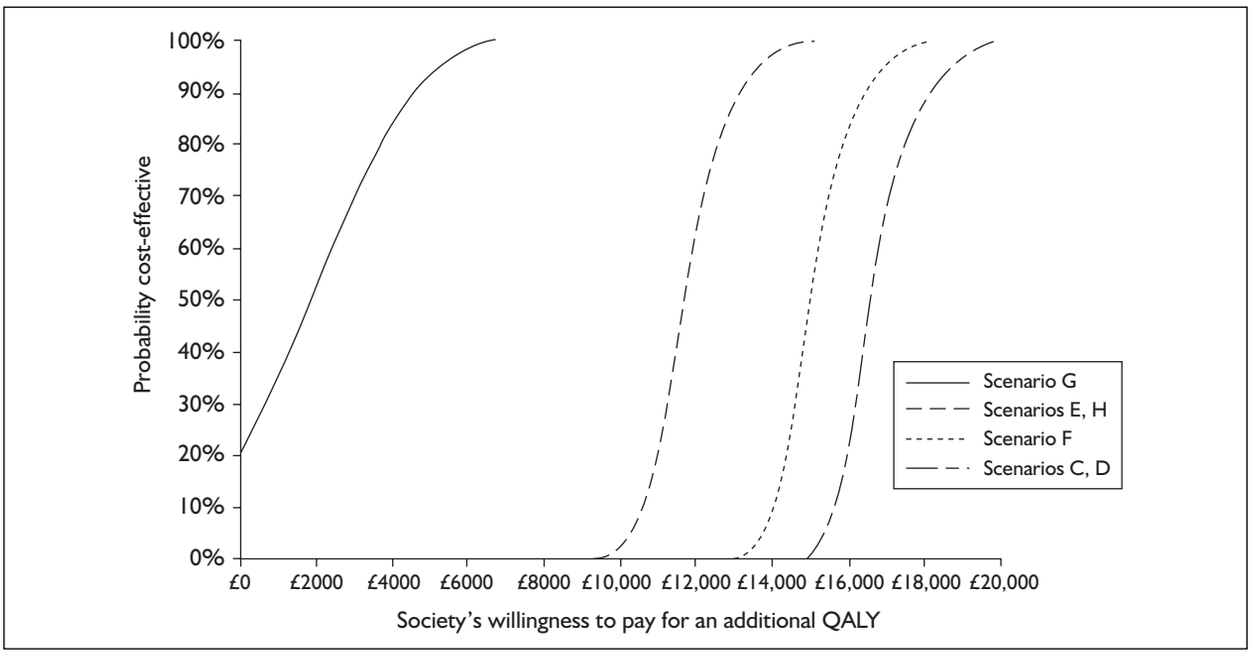

FIGURE 10 *Cost-effectiveness acceptability curves for society's willingness to pay for an additional QALY when the proportion of women receiving TVT increases and the population of eligible women increases*

management. These figures are all based on a typical population of 500,000 people, from whom 81 incontinent women are currently treated surgically.

Increasing the proportion of women receiving a TVT from the current 34% to 44% (scenario A) and 64% (scenario B) results in a reduction in cost to the NHS. The results from Chapter 5 indicate that these savings would, in broad terms, be achieved at a similar level of effectiveness. Increasing the population treated in scenario C by 10% (from 81 to 89 procedures per year) and in scenario D by 30% (to 105 procedures per year) increases the net cost to the NHS by between £8200 and £24,600. Only in the situation where the number of additional women receiving surgery is small will the reduction in cost following substitution of colposuspension for TVT result in a decrease in net cost (scenario G). Nevertheless, increased substitution of TVT for other surgical procedures reduces the magnitude of any increase in NHS cost (scenarios E, F, G and H). Furthermore, although NHS costs may increase, treating more women should provide additional QALYs. *Figure 10* illustrates the likelihood that society might find the additional QALYs gained from the increased uptake of TVT worth the extra cost. The scenarios that are least likely to be cost-effective are C and D, where the number of women treated increases (all the extra women treated receive TVT) but there is no other substitution of TVT for open colposuspension. The scenario most likely to be considered cost-effective is G, where the use of TVT increases up to the rates previously observed for colposuspension and the number of additional women treated is relatively modest.

Chapter 8
Discussion

Taken at face value, this review of the effectiveness and cost-effectiveness of TVT suggests that TVT's effectiveness is near that of the current standard operation, open colposuspension, that its short-term risks are no greater and that under most assumptions it is likely to be considered cost-effective. These conclusions should, however, be treated with caution for a number of reasons.

The most compelling reason for caution is the very limited information currently available about the long-term performance of TVT. The follow-up in RCTs is only up to 2 years and there are very limited data beyond 4 years even from case series. At present, it is not known whether the high 'cure' rates will be sustained. There are examples of the performance of other incontinence procedures deteriorating over time. Also of concern is the current lack of reassurance that TVT will have no unanticipated long-term complication related to the use of tape, such as erosion into the vagina or urinary tract. Late removal of tape can be difficult and traumatic because of the associated tissue reaction. While there is currently no evidence that there will be, any complication that required the need to remove the tape on a wide scale would have significant implications for both women and the health service.

Because of the paucity of long-term data, this review has concentrated on the first 2 years after surgery (basing all the assumptions about later performance used in the economic modelling on this). Even for the initial 2 years, however, the evidence base is incomplete. It is striking that while large numbers of case series have been reported and TVT performed in at least 230,000 women, data are available for only around 470 women participating in five RCTs of TVT (at least two of which were funded by industry). Although case series provide strong evidence of efficacy (that TVT can improve or cure incontinence), RCTs are needed to assess TVT's relative effectiveness and cost-effectiveness in comparison with current standard practice. The RCTs have yet to be fully reported, which further limited their usefulness. Where data were available, they provided estimates of effectiveness that were too imprecise to rule out clinically important differences. The Ward/Hilton trial was based on the premise that an absolute difference in cure rates of 10% was clinically significant. This review shows that the CIs around the most plausible estimates of effect do not rule out this size of difference.

Interpretation of the Ward/Hilton study, the largest and most important of the trials, is further complicated by differential withdrawal of participants, particularly between randomisation and surgery. As discussed in the section The Ward/Hilton trial (p. 25), this is likely to have introduced bias favouring TVT. Depending on the assumptions made about the outcomes of those who withdrew, the various estimates suggest that TVT could be as good as, worse than or better than open colposuspension in terms of cure. The most plausible adjustment suggests that TVT may perform less well than colposuspension, although the difference is not statistically significant (assuming all presurgery withdrawals as successes: RR 0.87; 95% CI 0.76 to 1.01).

Comparison of TVT with the other procedures was even more limited. There was greater reliance on non-randomised comparative studies, case-series data and indirect comparisons using data from systematic reviews of open colposuspension, laparoscopic colposuspension, traditional sling procedures and injectable agents. The estimates of the effectiveness of TVT in respect of these other comparators are therefore relatively precarious, particularly for injectable agents.

Very few data are available, none of which are comparative, on any of the prespecified sub-groups of women, that is, those with mixed incontinence, women receiving TVT as a secondary intervention and women with co-existing prolapse. The data were too limited to judge whether TVT is more or less effective for women with these characteristics.

A further limitation was that data describing the measures of outcome prespecified in the protocol were often not available for eligible studies. This applied in particular to QoL measurements and to cost data. Cost data came from a single study (sponsored by industry), although it appeared to be competently performed. Unfortunately, although

this provided descriptions of resource use and unit costs, it was based on a small number of women and so may have limited generalisability. It was reassuring that the data in this study relating to two principal cost drivers, length of hospital stay and operation time, were consistent with information reported from NHS health episode statistics and other literature. Estimates of the cost of the other procedures had to be derived from the cost data available for TVT and open colposuspension and from data taken from the studies included in Chapter 3. Because of this, estimates of costs for laparoscopic colposuspension and injectable agents may be conservative. If this were the case, however, these procedures would be less rather than more likely to be considered cost-effective compared with TVT.

The search strategy adopted was broad and intended to identify all relevant studies of TVT regardless of their design. Nevertheless, it is possible, despite extensive searching, that some relevant studies were not identified. Members of the editorial base of the Cochrane Incontinence Review Group contributed to this review. This group has done extensive searching for RCTs related to incontinence for its own purposes, so it is unlikely that major RCTs have been missed even if they had been reported in a non-English-language journal.

Subjective rather than objective cure rates were chosen as one of the principal outcomes of this review and later used in the estimation of cost-effectiveness. The reason was that women's perceptions of cure were considered to be more important than quantified leakage. It is possible that women in an RCT allocated their preferred option (presumably most often the less invasive TVT judged on the differential withdrawal rates from the Ward/Hilton trial) might have a tendency to report positive effects, independent of any treatment effect. The evidence reported in *Table 12* suggests, however, that the pattern of results is similar irrespective of whether subjective or objective cure rates are used.

Owing to the paucity of data, there was little opportunity to combine data in a formal meta-analysis. Synthesis of data was also hindered by the lack of consistent reporting of outcomes, which was referred to above. What was apparent from the studies identified was that authors used varying definitions of cure and this applied to both objective and subjective measures. In the Ward/Hilton trial, a relatively strict definition of objective cure was used (less than 1 g change in weight on the pad test), and this is one possible explanation of why their rates of cure were much lower than reported in the majority of other studies.

The other main concern about the case series is the likelihood of significant bias introduced by selective reporting, in terms of both the types of women studied and the choice of cases actually to report. Case series based on full population registries should be less prone to such biases, but this applied to only two of the case series identified in this review. It is notable that many of the case series included in this review involved one of the originators of the procedure.

TVT is only one of a number of recently developed variants of less invasive sling procedures for urinary incontinence. No comparative data from RCTs were identified that compared other variants with either TVT or the other comparators. The consideration of the place of other variants in the management of SUI has therefore not been addressed directly in this review.

The most frequent intraoperative complication reported for TVT is bladder perforation. This should not carry any serious consequences if recognised at the time of the procedure. However, if cystoscopy is not performed, or if the surgeon has limited experience of using this technique (as may apply to some gynaecologists), a missed perforation could expose the woman to a further, more invasive procedure to correct the complication. It is possible that intraoperative complications of TVT, such as bladder perforation, are associated with a 'learning curve' and, as discussed in Chapter 7, this has training implications.

Chapter 9
Conclusions

Implications for the NHS

- The long-term performance of TVT in terms of both continence and unanticipated adverse effects is not known reliably at the moment. The conclusions of this review, particularly in respect of cost-effectiveness, could well change in the light of new evidence.
- Despite relatively few robust comparative data, it appears that in the short to medium term TVT's effectiveness approaches that of alternative procedures currently available, and is of lower cost.
- As TVT is a less invasive procedure, it is likely that some women who would currently be managed non-surgically will be considered eligible for TVT. This group of women has not been formally considered in this review. However, evidence from the review suggests that, although these women would probably experience an increase in QoL, such an extension in use would increase the costs to the NHS.
- Increased adoption of TVT will require additional surgeons proficient in the technique. It is likely that some of the higher rates of complications, e.g. bladder perforation, reported for TVT are associated with a 'learning curve'. Appropriate training will therefore be needed for surgeons new to the operation, in respect of both the technical aspects of the procedure and the choice of women suitable for the operation.

Implications for patients and carers

- TVT, along with open colposuspension and traditional sling procedures, appears to be an effective method of treating urinary incontinence. Unlike these other procedures, the long-term performance of TVT is not yet known.
- TVT has the advantage that it is less invasive than open colposuspension and traditional sling procedures.
- Women previously considered ineligible for surgery (such as the frail elderly) may be suitable for TVT as it is less invasive.
- The other less invasive surgical intervention is injectable agents and this appears to be less effective and more costly than TVT.

Implications for research

- Unbiased assessments of long-term performance (≥5 years) are required from follow-up of controlled trials and/or population-based registries.
- Ideally, there should be more data from methodologically sound RCTs to provide a more secure basis for assessing effectiveness and cost-effectiveness. Current trials (which are generally small) should be fully reported and include long-term follow-up. Further trials should be mounted where uncertainty persists, preferably independent of support from the manufacturers, and use standard outcome measures.
- Ongoing surveillance of TVT would be enhanced by access to a regularly updated systematic summary of evidence from controlled trials, such as through the Cochrane Collaboration.
- Research is needed on possible long-term complications of TVT; this would provide either reassurance of safety or earlier warning of unanticipated adverse effects.
- If the indications for TVT are likely to be broadened to include women who are currently managed conservatively, this should be formally evaluated, ideally in an RCT, before widespread adoption.
- As new evidence about the effectiveness, safety and costs of TVT emerges, this should be incorporated in updated cost-effectiveness analyses.
- Evidence of efficacy (that TVT can be used successfully to treat incontinence) from case series led to the rapid, widespread adoption of TVT before its relative effectiveness (its place within NHS care) and long-term safety were known. Although current evidence suggests that TVT probably is effective and safe, this approach exposed thousands of women to an incompletely evaluated procedure in a poorly controlled way. Future research to evaluate new procedures of this type could avoid this by earlier and wider use of pragmatic RCTs and rigorously organised population-based registries.

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Contributions of authors

June Cody, Cathyrn Glazener, Kirsty McCormack and Laura Wyness completed the review of the effectiveness. Sheila Wallace developed and ran search strategies and obtained papers. Mary Kilonzo conducted the economic evaluation. Sally Stearns conducted the review of economic evaluations and provided supervision, advice and critical comment. Luke Vale and Adrian Grant supervised the conduct and completion of the project.

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Appendix 1A

Use of NHS resources by operations for female urinary incontinence and prolapse in England

Data for suburethral needle suspensions (for urinary incontinence) and anterior vaginal repair (colporrhaphy, usually for prolapse) given for comparison. Primary operation codes used except where indicated in italics that primary and secondary codes are given.

Name of operation	OPCS4 code	No. of finished episodes	Waiting time		Length of stay		Age			Day case	Bed days
			Mean	Median	Mean	Median	Mean	15–59	75+		
2000–01											
TVT	M53.8	2706	190	141	2.9	2	55	66%	7%	5%	7364
Colposuspension	M52.3	3719	209	159	7.1	6	53	73%	3%	0%	25,923
Slings	M52.1	262	176	118	7.2	7	56	59%	8%	2%	1804
Injectables	M56.3	1384	202	160	2.0	2	60	46%	18%	39%	1655
Needle suspension	M51.2	146	251	188	4.4	4	57	62%	13%	7%	595
Anterior repair[a]	P23.2	7767	169	123	5.3	5	61	42%	14%	0%	40,837
1999–2000											
TVT	M53.8	715	132	93	3.0	2	56	65%	9%	3%	1943
Colposuspension	M52.3	4769	212	166	7.1	6	53	74%	2%	0%	33,397
Slings	M52.1	399	230	166	7.0	6	56	63%	7%	6%	2548
Injectables	M56.3	1510	173	128	2.1	2	59	48%	15%	41%	1731
Needle suspension	M51.2	244	223	174	5.5	5	57	61%	10%	0%	1259
Anterior repair[a]	P23.2	8041	175	125	5.5	5	61	44%	13%	0%	43,307
1998–99											
TVT	M53.8	214	169	132	2.9	2	54	66%	7%	0%	614
Colposuspension	M52.3	5663	213	173	7.3	7	53	73%	3%	0%	40,888
Slings	M52.1	441	190	143	7.0	7	55	67%	4%	0%	3000
Injectables	M56.3	1446	157	110	2.1	2	59	47%	17%	38%	1877
Needle suspension	M51.2	453	229	166	6.1	5	58	58%	13%	0%	2685
Anterior repair[a]	P23.2	8095	178	137	5.7	5	61	45%	13%	0%	45,494

[a] Anterior repair/colporrhaphy assumed to be primarily for prolapse.
Source: http://www.doh.gov.uk/hes/

Appendix 1B

Use of NHS resources by operations for female urinary incontinence and prolapse in Wales

Data for suburethral needle suspensions (for urinary incontinence) and anterior vaginal repair (colporrhaphy, usually for prolapse) given for comparison.

Name of operation	OPCS4 code	No. of finished episodes	Age				Day case	Bed days
			Mean	15–59	60–74	75+		
2000–1								
TVT	M53.8	108	54	75%	22%	3%	3%	393
Colposuspension (1°)	M52.3	164	51	81%	17%	2%	1%	1321
(any)		211	51	82%	16%	1%	0%	1671
Abdominal colpo	*without Y50.8*	200	51	82%	17%	2%	1%	1589
Laparoscopic colposuspension	*with Y50.8*	11	50	100%	0%	0%	0%	82
Slings	M52.1	59	52	80%	17%	3%	0%	378
Injectables	M56.3	106	57	60%	32%	8%	40%	121
Needle suspension	M51.2	4	64	25%	25%	50%	0%	19
Anterior repair[a]	P23.2	603	61	44%	43%	13%	0%	3490
1999–2000								
TVT	M53.8	30	57	60%	33%	7%	0%	135
Colposuspension (1°)	M52.3	192	52	77%	21%	2%	0%	1454
(any)		242	52	79%	19%	2%	0%	1876
Abdominal colpo	*without Y50.8*	223	52	78%	20%	3%	0%	1754
Laparoscopic colposuspension	*with Y50.8*	19	51	89%	11%	0%	0%	122
Slings	M52.1	60	51	77%	23%	0%	0%	396
Injectables	M56.3	93	57	57%	35%	8%	28%	162
Needle suspension	M51.2	13	55	69%	15%	15%	0%	78
Anterior repair[a]	P23.2	588	60	45%	42%	13%	0%	3342
1998–99								
TVT	M53.8	13	60	54%	38%	8%	0%	69
Colposuspension	M52.3	202	53	73%	26%	1%	0%	1626
(any)		272	52	77%	20%	3%	0%	2140
Abdominal colpo	*without Y50.8*	258	52	78%	20%	2%	0%	2036
Laparoscopic colposuspension	*with Y50.8*	14	54	71%	21%	7%	0%	104
Slings	M52.1	100	53	69%	29%	2%	0%	761
Injectables	M56.3	116	57	55%	37%	8%	18%	205
Needle suspension	M51.2	23	54	74%	26%	0%	0%	148
Anterior repair[a]	P23.2	666	60	44%	42%	14%	0%	3998

[a] Anterior repair/colporrhaphy assumed to be primarily for prolapse.
Source: http://www.doh.gov.uk/hes/

Appendix 2

Search strategies

Details of search strategies used for locating articles related to TVT and systematic reviews related to the comparator interventions [see Chapter 3 of the report for details of the dates of searches and the years covered by the search (p. 11)]

Cochrane Incontinence Review Group (editorial base – Aberdeen, Scotland, UK)

For all interventions the resources of The Cochrane Incontinence Review Group were utilised. The Group maintains a register of randomised controlled trials related to incontinence and also has limited holdings of reviews on incontinence. All relevant reports of studies and any reviews in file that might be relevant were retrieved.

Search strategies for locating articles relevant to TVT

PubMED via Reference Manager. Initial simple pilot search performed using the terms: TVT or slingplasty. Date of search: 5 December 2001.

MEDLINE, PREMEDLINE, EMBASE, CINAHL, HealthSTAR, The Cochrane Controlled Trials Register (CCTR), The Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effectiveness (DARE), ACP Journal Club, AMED, SPORTDiscus. The following search strategy was run on the databases in OVID (on Digital Island). The online deduplication facility was used on the first five databases listed (maximum permissible) – the subsequent databases were substituted in turn for HealthSTAR.

1. ((urethropex$ or urethrocystopex$) and (tension or tape$)).tw.
2. (tension adj3 vagina$).tw.
3. tvt.tw.
4. slingplast$.tw.
5. sling-plast$.tw.
6. (transvagina$ adj2 tape$).tw.
7. (vagina$ adj2 tape$).tw.
8. (tension adj3 tape$).tw.
9. (trans-vagina$ adj2 tape$).tw.
10. or/1-9
11. remove duplicates from 10

Key: $ = wildcard; tw = textword, i.e. titles and abstracts; adjn = within n words either side.

Database of Abstracts of Reviews of Effectiveness (DARE), HTA database, NHS EED

Simultaneously these three databases were searched using the following terms (the search is saved on the NHS CRD online database as 'tvtsearch'):

transvagina*(s)tape* OR tension(s)urethropex* OR tension(s)vagina*/All fields OR vagina*(s)tape* OR tension(s)tape* OR trans-vagina*(s)tape*/All fields OR sling-plast* OR slingplast* OR tvt/All fields

Key: * = wildcard; (s) words in the same sentence.

BIOSIS (on EDINA) – the following search terms were used (aspects of the BIOSIS interface on EDINA have changed since this search was run):

al: ((transvagina n tape*) OR (vagina* n tape*) OR (tension* n tape*) OR (tension* n vagina*) OR (tension* n urethropex*) OR tvt OR slingplast* OR (sling w plast*))*

Key: * = wildcard; n = words next to each other any order; w = in same order – used instead of hyphen; al = titles, abstract and subjects.

ISI Science Citation Index (Web of Science on MIMAS)

Topic=tvt OR slingplast* OR sling-plast* OR (transvagina* SAME tap*) OR (vagina* SAME tape*) OR (tension SAME tape*) OR (trans-vagina* SAME tape*); DocType=All document types; Language=All languages;

Key: topic = searches in titles, abstracts and keywords; * = wildcard, SAME = same sentence any order.

ISI – Scientific & Technical (via web interface, Web of Science, WOS, on MIMAS)

Topic=tvt OR slingplast* OR sling-plast* OR (transvagina* SAME tape*) OR (vagina* SAME tape*) OR (tension SAME tape*) OR (trans-vaginal SAME tape*) OR (tension SAME vagina*) OR (tension SAME urethropex*); DocType=All document types; Language=All languages; Databases= STP; Timespan=All Years;

Key: topic = searches in titles, abstracts and keywords; * = wildcard, SAME = same sentence any order.

ZETOC (web interface, on MIMAS)
Search terms:

TVT
"Vaginal tape"

International Continence Society (ICS) Conference Abstracts (web interface)

Abstracts for 2001: this is a searchable database – search terms used: TVT; tension.

Abstracts for 2000: this is not a searchable database and only abstracts submitted electronically are available on the web. The 'find' button on the Internet explorer was used to search, in the titles, for the terms: TVT, tension.

UK National Research Register (on CD-ROM, network version)

Search terms used:

TVT
Slingplast*
Tension and tape* (not TVT)

Current Controlled Trials including the metaRegister of controlled trials (web interface)

Search terms used:

TVT
Tape OR tapes
Slingplasty OR slingplasties
Sling OR slings
Incontinence

ClinicalTrials.gov

Search terms used, all terms searched in All fields [ALL-FIELDS]:

TVT
Tension AND (tape OR tapes)
Urethropexy OR urethropexies
Sling OR slings
Incontinence OR incontinent OR continent OR incontinent
Tension-free
Vaginal tape

CRISP (web interface version 2.0)

All fiscal years were searched.

Terms used:

TVT
Tension free (phrase)
Vaginal tape (phrase)
Sling%
Urethropex%

Key: % = wildcard.

Internet search A limited Internet search using the search engine Google was performed. Only the first 40 hits were scanned of 1090 using search terms: TVT incontinence. No links were followed (although if any had indicated an unknown study they would have been explored) and non-English-language sites were only briefly scanned if the character set used was recognised by the computing software. Date of search: 5 December 01.

Search strategies for locating systematic reviews of the comparative interventions

Colposuspension (open or laparoscopic)

MEDLINE, EMBASE and DARE

The following search terms were used. For DARE only lines 28 to 38 inclusive were used. For MEDLINE and EMBASE the online deduplication feature was used.

1. review, academic.pt.
2. review tutorial.pt.
3. review literature.pt.
4. review multicase.pt.
5. review of reported cases.pt.

6. review.pt.
7. bibliography.pt.
8. [(meta-analysis or review literature).sh.]
9. meta-analy$.tw.
10. metaanal$.tw.
11. (systematic$ adj4 (review or overview$)).tw.
12. meta-analysis.pt.
13. [case report.sh.]
14. historical article.pt.
15. meta-analysis.ti.
16. or/1-15
17. review.pt.
18. [(meta-analysis or review literature).sh.]
19. meta-analy$.tw.
20. metaanal$.tw.
21. (systematic$ adj4 (review or overview$)).tw.
22. [case report.sh.]
23. meta-analysis.ti.
24. [meta analysis/]
25. [review/]
26. [literature/]
27. or/17-26
28. colposuspension$.tw.
29. vesicosuspension$.tw.
30. colposuspension$.tw.
31. Burch.tw.
32. urethropex$.tw.
33. (urethrocystopex$ or cystourethropex$).tw.
34. mmk.tw.
35. marshall-marchetti$.tw.
36. urethrovesical suspension$.tw.
37. (paravaginal adj2 (defect$ or repair$)).tw.
38. (obturator$ adj2 (shelf or shelves or shelfs) adj2 (repair$ or procedure$)).tw.
39. or/28-38
40. Burch.tw.
41. urethropex$.tw.
42. (urethrocystopex$ or cystourethropex$).tw.
43. mmk.tw.
44. marshall-marchetti$.tw.
45. urethrovesical suspension$.tw.
46. (paravaginal adj2 (defect$ or repair$)).tw.
47. (obturator$ adj2 (shelf or shelves or shelfs) adj2 (repair$ or procedure$)).tw.
48. [colposuspension/]
49. or/40-48
50. 49 and 27
51. 16 and 39
52. 50 or 51
53. remove duplicates from 52

Injectables

MEDLINE, EMBASE and DARE

The following search terms were used. For DARE only lines 17 to 26 inclusive were used. For MEDLINE and EMBASE the online deduplication feature was used.

1. review, academic.pt.
2. review tutorial.pt.
3. review literature.pt.
4. review multicase.pt.
5. review of reported cases.pt.
6. review.pt.
7. bibliography.pt.
8. (meta-analysis or review literature).sh.
9. meta-analy$.tw.
10. metaanal$.tw.
11. (systematic$ adj4 (review or overview$)).tw.
12. meta-analysis.pt.
13. case report.sh.
14. historical article.pt.
15. meta-analysis.ti.
16. or/1-15
17. ((urethra$ or periurethra$ or transurethra$) adj3 (agent$ or bulk$ or injection$ or injectable$)).tw.
18. injection therapy.tw.
19. injectable$.tw.
20. (injectable$ adj2 agent$).tw.
21. (bulk$ adj3 agent$).tw.
22. (incontinen$ or continen$).tw.
23. exp Urinary Incontinence/
24. 22 or 23
25. 24 and (18 or 19 or 21)
26. 25 or 17 or 20
27. 16 and 26
28. review.pt.
29. (meta-analysis or review literature).sh.
30. meta-analy$.tw.
31. metaanal$.tw.
32. (systematic$ adj4 (review or overview$)).tw.
33. case report.sh.
34. meta-analysis.ti.
35. meta analysis/
36. review/
37. literature/
38. or/28-37
39. ((urethra$ or periurethra$ or transurethra$) adj3 (agent$ or bulk$ or injection$ or injectable$)).tw.
40. injection therapy.tw.
41. injectable$.tw.
42. (injectable$ adj2 agent$).tw.
43. (bulk$ adj3 agent$).tw.
44. (incontinen$ or continen$).tw.
45. exp Incontinence/
46. 44 or 45
47. 46 and (40 or 41 or 43)
48. 47 or 39 or 42
49. 38 and 48
50. 27 or 49

51. remove duplicates from 50

Slings

MEDLINE, EMBASE and DARE

The following search terms were used. For DARE only lines 17 to 26 inclusive were used. For MEDLINE and EMBASE the online deduplication feature was used.

1. review, academic.pt.
2. review tutorial.pt.
3. review literature.pt.
4. review multicase.pt.
5. review of reported cases.pt.
6. review.pt.
7. bibliography.pt.
8. [(meta-analysis or review literature).sh.]
9. meta-analy$.tw.
10. metaanal$.tw.
11. (systematic$ adj4 (review or overview$)).tw.
12. meta-analysis.pt.
13. [case report.sh.]
14. historical article.pt.
15. meta-analysis.ti.
16. or/1-15
17. (incontinen$ or continen$).tw.
18. [exp Urinary Incontinence/]
19. 17 or 18
20. review.pt.
21. [(meta-analysis or review literature).sh.]
22. meta-analy$.tw.
23. metaanal$.tw.
24. (systematic$ adj4 (review or overview$)).tw.
25. [case report.sh.]
26. meta-analysis.ti.
27. [meta analysis/]
28. [review/]
29. [literature/]
30. or/20-29
31. (incontinen$ or continen$).tw.
32. [exp Incontinence/]
33. 31 or 32
34. (sling or slings).tw.
35. bologna.tw.
36. ingelman-sundberg.tw.
37. (34 or 35 or 36) and 19
38. 37 and 16
39. (34 or 35 or 36) and 33
40. 30 and 39
41. 38 or 40
42. remove duplicates from 41

Appendix 3

Details of electronic bibliographic databases searched

Cochrane Incontinence Review Group (editorial base – Aberdeen, Scotland, UK)
The Cochrane Incontinence Review Group maintains a register of randomised controlled trials related to incontinence and also has limited holdings of reviews on incontinence.

MEDLINE (National Library of Medicine, Bethesda, MD, USA; electronic version of Index Medicus) (on OVID on Digital Island, web interface, initial simple search performed on PubMED via Reference Manager)

PREMEDLINE (National Library of Medicine, Washington DC, USA) (on OVID on Digital Island, web interface)

EMBASE (Elsevier Science Publishers BV, Amsterdam, The Netherlands; electronic version of Excerpta Medica) (on OVID on Digital Island, web interface)

CINAHL (Cumulative Index of Nursing and Allied Health Literature: CINAHL Information Systems, Glendale, CA, USA) (on OVID on Digital Island, web interface)

HealthSTAR (National Library of Medicine, Bethesda, MD, USA and the American Hospital Association) (on OVID on Digital Island, web interface)

The Cochrane Library (Update Software, Oxford) (on OVID on Digital Island, web interface)
Contains a number of databases, including The Cochrane Controlled Trials Register (CCTR), the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effectiveness (DARE, NHS Centre for Reviews and Dissemination, York, UK)

HTA database (NHS Centre for Reviews and Dissemination, York, UK produced in collaboration with the secretariat of INAHTA, the International Network of Agencies for Health Technology Assessment, SBU, Stockholm, Sweden)

NHS EED (NHS Economic Evaluation Database) (NHS Centre for Reviews and Dissemination, York, UK and the Department of Health, London, UK)

BIOSIS (Biological Abstracts Inc., USA, electronic version of Biological Abstracts) (web interface, on EDINA

Science Citation Index (Institute for Scientific Information, Philadelphia, PA, USA) (via web interface, Web of Science, WOS, on MIMAS)

ISI – Scientific & Technical Proceedings (Institute for Scientific Information, Philadelphia, PA, USA)(via web interface, Web of Science, WOS, on MIMAS)

ZETOC (The British Library's Electronic Table of Contents to Current Journals and Conference Proceedings, British Library, London, UK) (web interface, on MIMAS)

International Continence Society (ICS) Conference Abstracts (web interface) (International Continence Society, Bristol, UK)

UK National Research Register (NHS Executive, Department of Health, Leeds, UK) (Update Software, Oxford, UK)

Current Controlled Trials including the metaRegister of controlled trials (Current Controlled Trials Ltd, part of the Current Science Group, London, UK and published by BioMed Central)

ClinicalTrials.gov (National Library of Medicine and National Institutes of Health, Bethesda, MD, USA)

CRISP (Computer Retrieval of Information on Scientific Projects) (National Institutes of Health, US Department of Health and Human Services, Bethesda, MD, USA) (web interface)

ACP Journal Club Collection (ACP Journal Club produced by American College of Physicians, Philadelphia, PA, USA and Evidence Based Medicine produced by the BMJ Group, London, UK)(on OVID, web interface)

AMED (Allied and Complementary Medicine) (Health Care Information Service, British Library, London) (on OVID web interface)

SPORTDiscus (Sport Information Resource Centre, Gloucester, Ontario, Canada) (on OVID, web interface)

Appendix 4

Data extraction form for technology assessment review (TAR): tension free vaginal tape for stress incontinence

Reviewer ID: _____ **Date of data extraction** _____

Study Details						
Study ID:			**TVT ID:**			
Published ☐	**Unpublished** ☐		**Economic data provided:**	**Yes** ☐	**No** ☐	
Other papers this study may link with: (Study I.D/TVT ID)			**Cost data provided:**	**Yes** ☐	**No** ☐	

Study Design				
				Duration of follow up
RCT	☐	**Comparative observational study**	☐	
Systematic review (of RCTs)	☐	**Population-based registries**	☐	
Systematic review (of non-randomised or mixed designs)	☐	**Other observational study**	☐	
Description of study design:				

Details of comparisons		
(List all included in study)		**Description of included interventions**
1. TVT	☐	
Open Colpo	☐	
Open Sling	☐	
Injectables	☐	
Lap Colpo	☐	
Other	☐	

Participant details	
Number of participants randomised or included in study:	
Criteria for Inclusion:	**Criteria for Exclusion:**

Participant details (continued)				
Were participants (Some or All)	**Yes**	**No**	**Unclear**	**Not applicable**
(a) Undergoing a secondary intervention (after failed previous incontinence surgery)?	☐	☐	☐	☐
(b) With co-existing prolapse?	☐	☐	☐	☐
(c) With mixed incontinence? (i.e. stress incontinence with urge incontinence &/or detrusor instability)	☐	☐	☐	☐
Other comments on participants:				
Setting and timing				
Location/Setting of study/ No. of surgeons involved:				
Recruitment period:				
Source of participants:				

Patient characteristics				
Number of women	**2. A**	**B**	**C**	**3. Whole Group**
Age (years)				
Parity				
Duration of incontinence				
Undergoing secondary intervention (*n*)				
Co-existing prolapse (*n*)				
Mixed incontinence (*n*)				
Post-menopausal (*n*/%)				
On oestrogen (*n*/%)				

Subjective measures	**2. A**	**B**	**C**	**3. Whole Group**
Number not cured <12 months 12–24 months >24 months **Subjective failed/ unchanged rate** <12 months 12–24 months >24 months **Pad changes** (No. over 24 hours) **Incontinent episodes** (No. over 24 hours) **New urge symptoms or urge incontinence** (No. of women) Objective measures 4. **Number not cured** (using –ve cystometrogram and/or pad test) <12 months 12–24 months >24 months **Pad test** (mean volume) or weight of urine loss **Surgical outcomes** **No. treatments required to achieve max. benefit** (Injectables only) **Duration of operation** (min) **Blood loss** (ml) **General anaesthetic** (number of women) **Time in hospital** (days) (0 if day case)				

Outcomes continued	2. A	B	C	3. Whole Group
Post-operative pain (<2 weeks)				
Persistent pain (>2 months/after discharge from hospital)				
Voiding dysfunction/ difficulty after 3 months (with/without urodynamic confirmation)				
New detrusor instability (urodynamic diagnosis)				
New or recurrent prolapse				
General peri-operative complications (**specify**, e.g. haemorrhage, DVT, urinary tract and visceral injuries, wound infection, urinary retention delaying discharge, bacteriuria, bladder perforation, UTI)				
Complications specific to type of intervention (**specify,** e.g. tape erosion, surgery to remove tape, particle migration)				
Readmission rates for complications				
Later (repeat) incontinence surgery				
Later prolapse surgery				
Time to return to normal activities (days)				

Outcomes continued	**5. A**	**6. B**	**7. C**	**8. Whole Group**
Rate of self-catheterisation (No. of women)				
Dyspareunia (pain during intercourse)				
Mortality/death				
Health status measures				
Condition-specific health measures (related to incontinence)				
Generic health status measures (e.g. SF-36)				
Psychological measures (e.g. hospital anxiety and depression scale)				
Other relevant outcomes:				

Comments

Appendix 5

Quality assessment checklist

TVT ID: _____

Study identifier:
(surname of first author + year of publication)

_____

Assessor initials: _____

Date form completed: _____

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

Yes	1
No	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
If the main outcomes are first mentioned in the Results section, the question should be answered no.

Yes	1
No	0

3. *Are the characteristics of the patients included in the study clearly described?*
In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case–control studies, a case-definition and the source for controls should be given.

Yes	1
No	0

4. *Are the interventions of interest clearly described?*
Treatments and placebo (where relevant) that are to be compared should be clearly described.

Yes	1
No	0

5. *Is the distribution of principal confounders in each group of subjects to be compared clearly described?*
A list of principal confounders is provided.

Yes	1
Partially	1
No	0

6. *Are the main findings of the study clearly described?*
Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below.)

Yes	1
No	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

Yes	1
No	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided.)

Yes	1
No	0

9. *Have the characteristics of patients lost to follow-up been described?*
   This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

Yes	1
No	0

10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

Yes	1
No	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
    The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

Yes	1
No	0
Unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*
    The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

Yes	1
No	0
Unable to determine	0

13. *Were the staff, places and facilities where the patients were treated representative of the treatment the majority of patients received?*
    For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

Yes	1
No	0
Unable to determine	0

Internal validity – bias

14. *Was an attempt made to blind study subjects to the intervention they have received?*
    For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

Yes	1
No	0
Unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

Yes	1
No	0
Unable to determine	0

16. *If any of the results of the study were based on 'data dredging', was this made clear?*
    Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

Yes	1
No	0
Unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?*
    Where follow-up was the same for all study patients the answer should be yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

Yes	1
No	0
Unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*
    The statistical tests used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

Yes	1
No	0
Unable to determine	0

19. *Was compliance with the intervention/s reliable?*
    Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*
    For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrate the outcome measures are accurate, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

Internal validity – confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited from the same population?*
    For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

Yes	1
No	0
Unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited over the same period of time?*
    For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

Yes	1
No	0
Unable to determine	0

23. *Were study subjects randomised to intervention groups?*
    Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example, alternate allocation would score no because it is predictable.

Yes	1
No	0
Unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

Yes	1
No	0
Unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*
This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

Yes	1
No	0
Unable to determine	0

26. *Were losses of patients to follow-up taken into account?*
If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to determine main findings, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

Power

27. *Was a power calculation provided?*

Yes	
No	

Checklist summary

Sub-scale (possible)		**Score**
Reporting	(10)	
External validity	(3)	
Internal validity – bias	(7)	
Internal validity – confounding	(6)	
Total score	(26)	

Date form last revised: 18 March 2002

Appendix 6

Quality assessment checklist for systematic reviews

Assessor initials: **Date form completed:**

Study identifier:
(surname of first author, year of publication)

TVT ID:

1. **Were the search methods used to find evidence (primary studies) on the primary question(s) stated?**

NO	
PARTIALLY	
YES	

Comments:

2. **Was the search for evidence reasonably comprehensive?**

NO	
PARTIALLY	
YES	

Following done:	
Language restrictions	Yes/No
Hand searching	Yes/No
Reference lists	Yes/No
Authors contacted	Yes/No

Comments:

3. **Were the criteria used for deciding which studies to include in the review reported?**

NO	
PARTIALLY	
YES	

Author specifies:	
Type of study	Yes/No
Participants	Yes/No
Intervention(s)	Yes/No
Outcome(s)	Yes/No

Comments:

4. **Was bias in the selection of articles avoided?**

NO	
PARTIALLY	
YES	

Author specifies:	
Explicit selection criteria used	Yes/No
Independent screening of full text by at least two reviewers	Yes/No

Comments:

5. Were the criteria used for assessing the validity of the studies that were reviewed reported?

NO	
PARTIALLY	
YES	

Author specifies:	
Criteria used to assess methodological quality	Yes/No

Comments:

6. Was the validity of all of the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analysing the studies that are cited)?

NO	
PARTIALLY	
YES	

Author specifies:	
Assessments of included studies using explicit criteria reported	Yes/No

Comments:

7. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?

NO	
PARTIALLY	
YES	

Author specifies:		
Meta-analysis	Outcome of interest	Yes/No
	Model used	Yes/No
	Test for heterogeneity	Yes/No
Qualitative	Why meta-analysis inappropriate	Yes/No
	How then made sense of data	Yes/No
Both	Sensitivity analysis	Yes/No

Comments:

8. Were the findings of the relevant studies combined appropriately relative to the primary question the review addresses?

NO	
PARTIALLY	
YES	

Interventions homogeneous	Yes/No
Outcome measures homogeneous	Yes/No
Participants homogeneous	Yes/No
How unit analysis errors were handled	Yes/No
Settings comparable	Yes/No

Comments:

9. Were the conclusions made by the author(s) supported by the data and/or the analysis reported in the review?

NO	
PARTIALLY	
YES	

Conclusions consistent with results	Yes/No
Conclusions do not go beyond the data	Yes/No
No evidence not interpreted as no effect	Yes/No
Strength of recommendations for practice consistent with level of evidence (uncertainty)	Yes/No
Recommendations for research consistent with identified shortcomings	Yes/No

Comments:

10. Overall, how would you rate the methodological quality of this review?

Extensive bias		Major bias		Minor bias		Minimal bias
1	2	3	4	5	6	7

Comments:

Appendix 7

Ongoing studies involving TVT

Name of study	Study design	Interventions	Start date	End date	Any other information known
Persson, Sweden	RCT	TVT vs laparoscopic colposuspension	Unknown	End 2001	Approx. 70 patients randomised. Length of follow-up: unknown. Paper accepted for publication in *Acta Obstet Gynecol Scand*[164] Funder: unknown
Valpas, Finland	RCT	TVT vs laparoscopic colposuspension	Unknown	Ongoing	Approx. 128 patients randomised. So far two conference abstracts published but no useable cure rates. A 6-week and 1-year follow-up so far[165,166]
German/Czech multicentre study	RCT	TVT vs Burch	Unknown	Unknown	Total numbers of patients unknown. Length of follow-up: at least 6 months. Only publication (so far in English) is a conference abstract by Halaska *et al.* (2001)[44] included in table of RCTs Funder: unknown
Malcolm Lucas in Swansea	RCT (as stated in NRR)	TVT vs sling vs Pelvicol	1 October 2000	1 October 2002	Part of multicentre study Funder: not given in NRR
Hilton, Newcastle upon Tyne	RCT (sealed envelope)	TVT vs fascial sling	1 June 1998	Ongoing	For recurrent stress incontinence Funder: Ethicon Planned recruitment is 146; 20 recruited so far
ARB Smith, Manchester	RCT (as stated in NRR)	TVT vs fascial sling	20 May 1999	20 May 2000	For recurrent stress incontinence Planned as multicentre study ? centres. Glasgow did not begin Funder: not given in NRR
Cardozo, King's	RCT (sealed envelope)	TVT vs injectables	Approx. September 2001	Ongoing	Participants: those with stress urinary incontinence not suitable for conventional bladder neck surgery – so far most have had previous incontinence surgery Injectable agent: Macroplastique Funder: unknown 27 participants recruited so far (at 27 June 2002). Planned recruitment of 56 participants

continued

Name of study	Study design	Interventions	Start date	End date	Any other information known
Courtney Watson, Arrowe Park in Wirral	RCT (as stated in NRR)	TVT vs injectables	1 May 1999	1 January 2002	For recurrent stress incontinence, participants with low UCP only Early stopping – less than 15 participants randomised Injectable: Macroplastique Funder: 'Own account'(as stated in NRR)
Landon, Leeds	Comparative	TVT vs injectables	1 January 2000	1 January 2002	Anatomy – 3D ultrasound – pelvic floor changes after intervention Funder: not given in NRR
Norris, Nottingham	?	Anaesthesia for TVT	10 June 2001	28 February 2002	Anaesthesia: propofol and remifentanil Planned recruitment: ?20 patients ?total or each arm Funder: not given in NRR
Planned but not yet funded					
Hilton, Newcastle upon Tyne	RCT – electronic internet based service	TVT + prolapse repair vs prolapse repair	Not yet funded		Stress incontinence associated with genitourinary prolapse Planned to recruit 450 in 2+ centres

Appendix 8

List of included studies

A total of 117 reports of 80 studies, two population-based registries and 12 systematic reviews.

Abrams P, Martin K, Bulmer P, Donovan J, Hilton P. Responsiveness of the Bristol female lower urinary tract symptoms questionnaire (BFLUTS-Q) to surgical intervention in a randomised controlled trial. Proceedings of the 30th Annual Meeting of the International Continence Society, 28–31 August 2000, Tampere, Finland. 2000; A173.

Adile B, Lo Bue A, Gugliotta G, Cucinella G, Caputo A. TVT for surgical treatment of female urinary incontinence: short and long term follow-up [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000; **11**(Suppl 1):S112.

Adile B, Liguori P, Pisapia G, Alvino G, Bova C. TVT for surgical treatment of female stress urinary incontinece – an Italian multicentric study. Two years follow-up [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2001; **12**(Suppl 3):286.

Arunkalaivanan AS, Barrington JW. Comparison of porcine pubo vaginal sling (Pelvicol) vs tension free vaginal tape (TVT) in the surgical management of stress incontinence [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;**12**(Suppl 3):31.

Atherton MJ, Stanton SL. How does the TVT produce continence? A comparison of bladder neck elevation and mobility after TVT and colposuspension [Abstract]. *Neurourol Urodyn* 1999;**18**:370–1.

Atherton MJ, Stanton SL. TVT and colposuspension: comparisons and contrasts of possible mechanisms [Abstract]. *Neurourol Urodyn* 2000;**19**:396–8.

Azam U, Frazer MI, Kozman EL, Ward K, Hilton P, Rane A. The tension-free vaginal tape procedure in women with previous failed stress incontinence surgery. *J Urol* 2001;**166**:554–6.

Bae JH, Kim HJ, Lee JG. Repair of lateral cystocele using TVT guide needle combined with TVT for stress urinary incontinence [Abstract]. Proceedings of the 31st Annual Meeting of the International Continence Society, 18–21 September 2001; Seoul, Korea. 2001; Abstract No. 322.

Barrington JW, Edwards G, Swart M. The use of TVT as a day case procedure [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000;**11**(Suppl 1):S90.

Bettin St, Fischer W, Tunn R. TVT-Plasty (according to Ulmsten) in urinary incontinence [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000; **11**(Suppl 1):S125.

Bezerra CA, Bruschini H. Suburethral sling operations for urinary incontinence in women (Cochrane Review). The Cochrane Library. Oxford: Update Software; 2002.

Bidmead J, Cardozo L. Sling techniques in the treatment of genuine stress incontinence. *Br J Obstet Gynaecol* 2000;**107**:147–56.

Black N, Downs S. The effectiveness of surgery for stress incontinence in women: a systematic review. Proceedings of the 26th Annual Meeting of the International Continence Society, 27–30 August 1996, Athens, Greece, 1996; 222.

Black NA, Downs SH. The effectiveness of surgery for stress incontinence in women: a systematic review. *Br J Urol* 1996;**78**:497–510.

Bunyavejechevin S, Santingamkun MHSA, Wisawasukmon W, Bunyarattavej P, Limpaphayom K. Tension-free vaginal tape for the trreatment for stress urinary incontinence in women with pelvic organ prolapse: the preliminary study [Abstract]. Proceedings of the 31st Annual Meeting of the International Continence Society, 18–21 September 2001; Seoul, Korea. 2001; Abstract No. 255.

Cabezon A, Valenzuela A, Leyton R, Silva M, Valero G. Tension-free-vaginal tape (TVT) for the treatment of stress urinary incontinence: a Chilean multicenter experience [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000;**11**(Suppl 1):S114.

Chaliha C, Stanton SL. Complications of surgery for genuine stress incontinence. *Br J Obstet Gynaecol* 1999;**106**:1238–45.

Chung MK, Bradley AB, Chung RP. TVT for treatment of urinary incontinence in obese women [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000; **12**(Suppl 1):S47.

Chung MK, Bradley A, Chung R. TVT for treatment of urinary incontinence in obese women [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2001; **12**(Suppl 1):44.

Cucinella G, Adile B, Gugliotta G, Lo Bue A, Grifo S, Caputo A. A prospective randomized study comparing laparoscopic Burch versus TVT. Two years follow-up [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;**12**(Suppl 3):S107.

Dainer M, Hall CD, Choe J, Bhatia NN. The Burch procedure: a comprehensive review. *Obstet Gynecol Surv* 1999;**54**:49–60.

Downs S, Black N. Systematic review of the literature on the effectiveness of surgery for stress incontinence in

women. Kelk T, editor. London: Department of Public Health & Policy Publications, London School of Hygiene & Tropical Medicine; 1996. Report No. 21.

Duckett J. The use of periurethral injectables in the treatment of genuine stress incontinence. *Br J Obstet Gynaecol* 1998;**105**:390–6.

Dungl A, Geiss IM, Riss PA. Voiding problems and quality of life after TVT [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000;**11**(Suppl 1):S83.

Ferrari A, Vigano R, Quellari P, Frigerio L. Tension free vaginal tape (TVT) following previous surgery and X-ray therapy [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000;**11**(Suppl 1):S107.

Fischer M. Tension free vaginal tape (TVT) in the elderly [Abstract]. Proceedings of the 31st Annual Meeting of the International Continence Society, 18–21 September 2001; Seoul, Korea. 2001; Abstract No. 337.

Foote AJ. To push or pull? Transvaginal tape versus prolene sling [Abstract]. Proceedings of the 31st Annual Meeting of the International Continence Society, 18–21 September 2001; Seoul, Korea. 2001; Abstract No. 267.

Foote AJ. Which is the best minimally invasive procedure? TVT versus laparoscopic colposuspension [Abstract]. Proceedings of the 31st Annual Meeting of the International Continence Society, 18–21 September 2001; Seoul, Korea. 2001; Abstract No. 268.

Fynes M, Murray C, Carey M, Rosamilia A, Dwyer P. Prognostic factors for continence outcome following tension free vaginal tape – an observational study [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000; **11**(Suppl 1):S33.

Gandini LM, Vigano R, Frigerio L, Filippis S, Ferrari A. Perineal ultrasound evaluation after TVT (tension free vaginal tape) operation [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000;**11**(Suppl 1):S99.

Glavind K, Larsen EH. Results and complications of tension-free vaginal tape (TVT) for surgical treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;**12**:370–2.

Granata P, Napolitano V, Bifulco G, Di Spiezio SA, Scherillo A, Granata M, *et al*. TVT (tension free vaginal tape) associated with cystopexy and correction of rectocele in patients with stress urinary incontinence (SUI). *Urogynaecologia Int J* 2000; **14**:111–15.

Haab F, Sananes S, Amarenco G, Ciofu C, Uzan S, Gattegno B, *et al*. Results of the tension-free vaginal tape procedure for the treatment of type II stress urinary incontinence at a minimum followup of 1 year. *J Urol* 2001;**165**:159–62.

Halaska M, Kolbl H, Petri E, Danes L, Voigt R, Otcenasek M, *et al*. Preliminary results of a prospective randomized study comparing Burch colposuspension and tension-free vaginal tape – urodynamic and sexuological aspects. *Neurourol Urodyn* 2001;**20**:421–2.

Han HC. The use of tension-free vaginal tape in treating women with stress urinary incontinence [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000;**11**(Suppl 1):S29.

Han WHC. Burch colposuspension or tension-free vaginal tape for female stress urinary incontinence? *Int Urogynecol J Pelvic Floor Dysfunct* 2001; **12**(Suppl 3):S23.

Hung MJ. Tension free vaginal tape versus traditional polypropylene pubovaginal sling for the treatment of stress urinary incontinence [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;**12**(Suppl 3):253.

Hyoung JK, Lee JG. Short-term results of tension-free vaginal tape (TVT) procedure for women with stress urinary incontinence [Abstract]. Proceedings of the 31st Annual Meeting of the International Continence Society, 18–21 September 2001; Seoul, Korea. 2001; Abstract No. 242.

Jacquetin B, Fatton B, Fernandez-Busserolles M. Comparative results of isolated TVT versus prolapse ure associated TVT: 171 cases with one to three years follow-up [Abstract]. Proceedings of the International Continence Society (ICS), 30th Annual Meeting, 28–31 August 2000, Tampere, Finland. 2000; Abstract No. 436.

Jarvis GJ. Surgery for genuine stress incontinence. *Br J Obstet Gynaecol* 1994;**101**:371–4.

Jomaa M. TVT – tension free vaginal tape for surgical treatment of recurrent female stress urinary incontinence in local anesthesia: a prospective open study at 3 years follow up [Abstract]. *Int Urogynecol J Pelvic Floor Dysfunct* 2000;**11**(Suppl 1):S33.

Jomaa M. Combined tension-free vaginal tape and prolapse repair under local anaesthesia in patients with symptoms of both urinary incontinence and prolapse. *Gynecol Obstet Invest* 2001;**51**:184–6.

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Appendix 9

Summary of the quality assessment of included studies

Assessment item	Number of studies			
	Yes	No	Partially	Unable to determine
Reporting:				
Is the hypothesis/aim/objective of the study clearly defined?	79	1	–	–
Are the main outcomes to be measured clearly described in the Introduction or Methods section?	67	13	–	–
Are the characteristics of the patients included in the study clearly described?	62	18	–	–
Are the interventions of interest clearly described?	45	35	–	–
Is the distribution of principal confounders in each group of subjects to be compared clearly described?	21	21	38	
Are the main findings of the study clearly described?	58	22	–	–
Does the study provide estimates of the random variability in the data for the main outcomes?	34	46	–	–
Have all important adverse events that may be a consequence of the intervention been reported?	50	30	–	–
Have the characteristics of patients lost to follow-up been described?	41	39	–	–
Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	24	56	–	–
External validity:				
Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	24	–	–	56
Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	3	–	–	77
Were the staff, places and facilities where the patients were treated representative of the treatment the majority of patients received?	1	3	–	76
Was an attempt made to blind study subjects to the intervention they have received?	–	75	–	5
Was an attempt made to blind those measuring the main outcomes of the intervention?	–	7	–	73
If any of the results of the study were based on 'data dredging', was this made clear?	74	3	–	3
In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case–control studies, is the time period between the intervention and outcome the same for cases and controls?	40	34	–	6
Were the statistical tests used to assess the main outcomes appropriate?	76	–	–	4
Was compliance with the intervention/s reliable?	79	–	–	1
Were the main outcome measures used accurate (valid and reliable)?	74	–	–	6
Internal validity – confounding (selection bias):				
Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited from the same population?	38	7	–	35

continued

Assessment item	Number of studies			
	Yes	No	Partially	Unable to determine
Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited over the same period of time?	46	–	–	34
Were study subjects randomised to intervention groups?	2	71	–	7
Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	1	72	–	7
Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	22	43	–	15
Were losses of patients to follow-up taken into account?	43	17	–	20
Power: Was a power calculation provided?	2	78	–	–

Appendix 10

Summary of the quality assessment of the comparative studies

Assessment item	Number of studies			
	Yes	No	Partially	Unable to determine
Reporting:				
Is the hypothesis/aim/objective of the study clearly defined?	9	–	NA	–
Are the main outcomes to be measured clearly described in the Introduction or Methods section?	8	1	NA	–
Are the characteristics of the patients included in the study clearly described?	5	4	NA	–
Are the interventions of interest clearly described?	2	7	NA	–
Is the distribution of principal confounders in each group of subjects to be compared clearly described?	–	5	4	NA
Are the main findings of the study clearly described?	3	6	NA	–
Does the study provide estimates of the random variability in the data for the main outcomes?	3	6	NA	–
Have all important adverse events that may be a consequence of the intervention been reported?	–	9	NA	–
Have the characteristics of patients lost to follow-up been described?	1	8	NA	–
Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	5	4	NA	–
External validity:				
Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	1	–	NA	8
Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	–	–	NA	9
Were the staff, places and facilities where the patients were treated representative of the treatment the majority of patients received?	–	–	NA	9
Was an attempt made to blind study subjects to the intervention they had received?	–	7	NA	2
Was an attempt made to blind those measuring the main outcomes of the intervention?	–	–	NA	9
If any of the results of the study were based on 'data dredging', was this made clear?	7	1	NA	1
In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case–control studies, is the time period between the intervention and outcome the same for cases and controls?	5	3	NA	1
Were the statistical tests used to assess the main outcomes appropriate?	8	–	NA	1
Was compliance with the intervention/s reliable?	9	–	NA	–
Were the main outcome measures used accurate (valid and reliable)?	8	–	NA	1
Internal validity – confounding (selection bias):				
Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited from the same population?	4	1	NA	4

continued

Assessment item	Number of studies			
	Yes	**No**	**Partially**	**Unable to determine**
Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited over the same period of time?	4	–	NA	5
Were study subjects randomised to intervention groups?	–	5	NA	4
Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	–	5	NA	4
Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	1	3	NA	5
Were losses of patients to follow-up taken into account?	1	6	NA	2
Power:				
Was a power calculation provided?	–	9	NA	–

Appendix 11

Summary of the quality assessment of case series >2 years

Assessment item	Number of studies			
	Yes	No	Partially	Unable to determine
Reporting:				
Is the hypothesis/aim/objective of the study clearly defined?	16	1	NA	–
Are the main outcomes to be measured clearly described in the Introduction or Methods section?	15	2	NA	–
Are the characteristics of the patients included in the study clearly described?	12	5	NA	–
Are the interventions of interest clearly described?	15	2	NA	–
Is the distribution of principal confounders in each group of subjects to be compared clearly described?	6	2	9	NA
Are the main findings of the study clearly described?	14	3	NA	–
Does the study provide estimates of the random variability in the data for the main outcomes?	10	7	NA	–
Have all important adverse events that may be a consequence of the intervention been reported?	14	3	NA	–
Have the characteristics of patients lost to follow-up been described?	10	7	NA	–
Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	4	13	NA	–
External validity:				
Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	9	–	NA	8
Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	–	–	NA	17
Were the staff, places and facilities where the patients were treated representative of the treatment the majority of patients received?	–	–	NA	17
Was an attempt made to blind study subjects to the intervention they had received?	–	17	NA	–
Was an attempt made to blind those measuring the main outcomes of the intervention?	–	4	NA	13
If any of the results of the study were based on 'data dredging', was this made clear?	16	–	NA	1
In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case–control studies, is the time period between the intervention and outcome the same for cases and controls?	10	6	NA	1
Were the statistical tests used to assess the main outcomes appropriate?	16	–	NA	1
Was compliance with the intervention/s reliable?	17	–	NA	–
Were the main outcome measures used accurate (valid and reliable)?	17	–	NA	–
Internal validity – confounding (selection bias):				
Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited from the same population?	8	2	NA	7

continued

Assessment item	Number of studies			
	Yes	No	Partially	Unable to determine
Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited over the same period of time?	9	–	NA	8
Were study subjects randomised to intervention groups?	–	17	NA	–
Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	–	17	NA	–
Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	5	8	NA	4
Were losses of patients to follow-up taken into account?	11	2	NA	4
Power:				
Was a power calculation provided?	–	17	NA	–

Appendix 12

Summary of the quality assessment of case series <2 years

Assessment item	Number of studies			
	Yes	No	Partially	Unable to determine
Reporting:				
Is the hypothesis/aim/objective of the study clearly defined?	49	–	NA	–
Are the main outcomes to be measured clearly described in the Introduction or Methods section?	40	9	NA	–
Are the characteristics of the patients included in the study clearly described?	41	8	NA	–
Are the interventions of interest clearly described?	24	25	NA	–
Is the distribution of principal confounders in each group of subjects to be compared clearly described?	12	13	24	NA
Are the main findings of the study clearly described?	38	11	NA	–
Does the study provide estimates of the random variability in the data for the main outcomes?	18	31	NA	–
Have all important adverse events that may be a consequence of the intervention been reported?	34	15	NA	–
Have the characteristics of patients lost to follow-up been described?	27	22	NA	–
Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	14	35	NA	–
External validity:				
Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	13	–	NA	36
Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	3	–	NA	46
Were the staff, places and facilities where the patients were treated representative of the treatment the majority of patients received?	–	3	NA	46
Was an attempt made to blind study subjects to the intervention they had received?	–	49	NA	–
Was an attempt made to blind those measuring the main outcomes of the intervention?	–	1	NA	48
If any of the results of the study were based on 'data dredging', was this made clear?	46	2	NA	1
In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case–control studies, is the time period between the intervention and outcome the same for cases and controls?	21	24	NA	4
Were the statistical tests used to assess the main outcomes appropriate?	47	–	NA	2
Was compliance with the intervention/s reliable?	49	–	NA	–
Were the main outcome measures used accurate (valid and reliable)?	45	–	NA	4
Internal validity – confounding (selection bias):				
Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited from the same population?	23	4	NA	22

continued

Assessment item	Number of studies			
	Yes	**No**	**Partially**	**Unable to determine**
Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited over the same period of time?	31	–	NA	18
Were study subjects randomised to intervention groups?	–	48	NA	1
Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	–	49	NA	–
Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	5	8	NA	4
Were losses of patients to follow-up taken into account?	29	9	NA	11
Power:				
Was a power calculation provided?	1	48	NA	–

Appendix 13

Summary of the quality assessment of systematic reviews

Assessment item	Number of studies		
	Yes	**No**	**Partially**
1. Were the search methods used to find evidence (primary studies) on the primary question(s) stated?	11	–	1
2. Was the search for evidence reasonably comprehensive?	8	1	3
3. Were the criteria used for deciding which studies to include in the review reported?	6	4	2
4. Was bias in the selection of articles avoided?	5	6	1
5. Were the criteria used for assessing the validity of the studies that were reviewed reported?	4	8	–
6. Was the validity of all of the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analysing the studies that are cited)?	4	7	1
7. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?	6	2	4
8. Were the findings of the relevant studies combined appropriately relative to the primary question the review addresses?	8	2	2
9. Were the conclusions made by the author(s) supported by the data and/or the analysis reported in the review?	11	1	–

	1	**2**	**3**	**4**	**5**	**6**	**7**
10. Overall, how would you rate the methodological quality of this review?	–	–	5	1	1	1	4

Appendix 14

Summary of the quality assessment of systematic reviews for each set of comparators

Colposuspension vs comparators

Assessment item	Number of studies		
	Yes	No	Partially
1. Were the search methods used to find evidence (primary studies) on the primary question(s) stated?	5	–	1
2. Was the search for evidence reasonably comprehensive?	4	1	1
3. Were the criteria used for deciding which studies to include in the review reported?	3	2	1
4. Was bias in the selection of articles avoided?	2	3	1
5. Were the criteria used for assessing the validity of the studies that were reviewed reported?	2	4	–
6. Was the validity of all of the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analysing the studies that are cited)?	2	4	–
7. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?	3	2	1
8. Were the findings of the relevant studies combined appropriately relative to the primary question the review addresses?	4	–	2
9. Were the conclusions made by the author(s) supported by the data and/or the analysis reported in the review?	6	–	–

	1	2	3	4	5	6	7
10. Overall, how would you rate the methodological quality of this review?	–	–	3	–	1	–	2

Traditional slings vs comparators

Assessment item	Number of studies						
	Yes		No		Partially		
1. Were the search methods used to find evidence (primary studies) on the primary question(s) stated?	5		–		–		
2. Was the search for evidence reasonably comprehensive?	4		1		–		
3. Were the criteria used for deciding which studies to include in the review reported?	3		2		–		
4. Was bias in the selection of articles avoided?	2		2		1		
5. Were the criteria used for assessing the validity of the studies that were reviewed reported?	2		3		–		
6. Was the validity of all of the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analysing the studies that are cited)?	2		3		–		
7. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?	3		1		1		
8. Were the findings of the relevant studies combined appropriately relative to the primary question the review addresses?	3		1		1		
9. Were the conclusions made by the author(s) supported by the data and/or the analysis reported in the review?	4		1		–		
	1	**2**	**3**	**4**	**5**	**6**	**7**
10. Overall, how would you rate the methodological quality of this review?	–	–	2	–	1	–	2

Laparoscopic colposuspension vs comparators

Assessment item	Number of studies		
	Yes	No	Partially
1. Were the search methods used to find evidence (primary studies) on the primary question(s) stated?	2	–	–
2. Was the search for evidence reasonably comprehensive?	2	–	–
3. Were the criteria used for deciding which studies to include in the review reported?	2	–	–
4. Was bias in the selection of articles avoided?	2	–	–
5. Were the criteria used for assessing the validity of the studies that were reviewed reported?	1	1	–
6. Was the validity of all of the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analysing the studies that are cited)?	1	–	1
7. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?	2	–	–
8. Were the findings of the relevant studies combined appropriately relative to the primary question the review addresses?	2	–	–
9. Were the conclusions made by the author(s) supported by the data and/or the analysis reported in the review?	2	–	–

	1	2	3	4	5	6	7
10. Overall, how would you rate the methodological quality of this review?	–	–	–	–	–	1	1

Injectables vs comparators

Assessment item	Number of studies		
	Yes	No	Partially
1. Were the search methods used to find evidence (primary studies) on the primary question(s) stated?	3	–	–
2. Was the search for evidence reasonably comprehensive?	–	1	2
3. Were the criteria used for deciding which studies to include in the review reported?	–	2	1
4. Was bias in the selection of articles avoided?	–	3	–
5. Were the criteria used for assessing the validity of the studies that were reviewed reported?	–	3	–
6. Was the validity of all of the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analysing the studies that are cited)?	–	3	–
7. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?	1	–	2
8. Were the findings of the relevant studies combined appropriately relative to the primary question the review addresses?	1	1	1
9. Were the conclusions made by the author(s) supported by the data and/or the analysis reported in the review?	3	–	–

	1	2	3	4	5	6	7
10. Overall, how would you rate the methodological quality of this review?	–	–	2	1	–	–	–

Appendix 15

Summary of included studies (RCTs)

Study	Study setting	Intervention	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Cucinella, 2001[43]	Urogynae-cology Dept (Italy)	*N* = 113 TVT (57) vs Laparoscopic Burch (56)	**Inclusion:** USI **Exclusion:** Previous surgery for USI, additional surgery to repair coexisting pelvic floor defects	(6–24 months)	TVT 53 (37–72) Lap Burch 51 (38–65)	**Parity:** TVT 2.3 (1–4), Lap Burch 2.5 (1–5) **Body weight** (kg): TVT 70 (46–84), Lap Burch: 73 (48–88) **Post-menopausal:** (on oestrogen) TVT 19 (33%), Lap Burch 38 (68%) **Secondary intervention:** No **Co-existing prolapse:** No **Mixed incontinence:** No	**At 3 months** TVT 57/57 (100%), Lap Burch 56/56 (100%) **At 6–24 months** TVT 53/57 (93%), 3 (5%) signific-antly improved Lap Burch 45/56 (80%), 1 (1.75%) significantly improved	NR	**New urge symptoms/ incon:** TVT 0/57, Lap Burch 0/56 **Duration of operation:** TVT <30 min, Lap Burch 60–90 min **General anaesthetic:** TVT 0, Lap Burch 56/56 (100%) **Spinal anaesthetic:** TVT 57/57 (100%), Lap Burch 0/57 **LOS:** TVT 1 day, Lap Burch 2 days **Bladder perforation:** TVT 3/57 (5%), Lap Burch 0/56 **Haematoma retzius:** TVT 0/57, Lap Burch 2/56 (3.6%)	**Voiding dysfunction at 3 months:** TVT 0/57, Lap Burch 0/56	NR	Abstract Learning curve 15 days training for TVT 6 months training for Lap Burch

continued

Study	Study setting	Intervention	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N*	Objective cure rate *n*/*N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Halaska, 2001[44]	Multicentre, University Hospitals, Women's Departments, (Czech Republic and Germany)	*N* = 26 TVT (15) vs Burch (11)	**Inclusion:** NR **Exclusion:** NR	6 months	TVT 58.33 (5.19) Burch 53.36 (6.07)	**Parity:** TVT 2.13 (0.46) **Burch** 1.82 (0.27) **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	NR	NR		VAS no difference between groups at 6 months	NR	Abstract Main outcome was sexual function Unclear if SD or SE reported
Han, 2001[45]	Urogynae-cology Unit (Singapore)	*N* = 50 TVT (25) vs Burch (25)	**Inclusion:** SUI, failed physio-therapy previously **Exclusion:** NR	6 months	NR	**Parity:** NR **Duration of stress incontinence:** TVT 49 months, Burch 70.4 months **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** No	NR	NR	**Duration of operation:** TVT 23 min, Burch 48 min **Blood loss:** TVT 130ml, Burch 354 ml **LOS** (mean days) TVT 1.4, Burch 3.4 **Post-operative pain:** TVT 23/25 (92%), Burch 23/25 (92%) **Bladder perforation:** TVT 1, Burch 0 **Blood transfusion:** TVT 0, Burch 1	Catheter required > 3 days TVT 2/25 (8%), Burch 4/25 (16%)		Abstract

continued

Study	Study setting	Intervention	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Liapis, 2000[46], 2002[47]	Obstetrics & Gynaecology Dept, Urogy-naecology Unit (Greece)	*N* = 71 TVT (36) vs Burch (35)	**Inclusion:** USI **Exclusion:** >1st degree prolapse, previous incon surgery, detrusor instability, urethral closure pressure <30 cmH_2O	TVT 22 months Burch 24 months	TVT 46.5 (32–62) Burch 48.4 (35–64)	**Parity:** TVT 1.9 (0.8), Burch 2.1 (1.1) **BMI:** TVT 26.6 (2.1) Burch 27.2 (2.2) **Secondary intervention:** No **Co-existing prolapse:** No **Mixed incontinence:** No	TVT 30/36 (83.3%) Burch 30/35 (85.7%)		**Duration of operation:** TVT 20 min, Burch 58 min **Spinal anaesthetic:** TVT 36/36 (100%), Burch 35/35 (100%) **LOS:** TVT 2.1 (SD 1.1), Burch 5.7 (SD 2.2) **Bladder perforation:** TVT 4/36 (11%), Burch 0 **Haematoma:** TVT 0, Burch 2/36 (5.5%) **UTI:** TVT 5/36 (13.9%), Burch 2/35 (5.7%)	**New detrusor instability:** at 6 months TVT 6/36 (16.6%), Burch 5/35 (14%) **Time to return to normal activities:** TVT 10 days, Burch 21 days		Abstract Unclear how patients were allocated to groups

continued

Study	Study setting	Intervention	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Ward, 2001[42,48–55]	Multicentre 14 centre, Gynaecology, Urogynae-cology, Urology Units in both university teaching and district general hospitals (UK and Republic of Ireland)	*N* = 344 TVT (175) vs Burch (169) 5 withdrew before surgery from TVT group, 23 from colpo-suspension group	**Inclusion:** USI, completed family **Exclusion:** Detrusor instability, vaginal prolapse requiring treatment, previous surgery for prolapse or incon, major degree of voiding dysfunction, neurological disease and allergy to anaesthetic	Ongoing 5 year trial. Results available for first 2 years	TVT 49 median (42, 56 IQR) Burch 50 (44, 58 IQR)	**Parity:** (median, IQR) TVT 2 (2, 3) Burch 2 (2, 3) **BMI:** (median, IQR) TVT 27 (24, 30) **Previous hysterectomy:** TVT 53/170 (31%), Burch 48/146 (33%) **Menopausal:** TVT 71/170 (42%), Burch 61/146 (42%) **On oestrogen:** 59/170 (35%), Burch 57/146 (39%) **Secondary intervention:** No **Co-existing prolapse:** No **Mixed incontinence:** No	**At 6 months:** TVT 103/159 (64.8%) Burch 90/127 (70.9%) **At 1 year:** CIC **At 2 years:** CIC	**At 6 months:** (based on cystometry and pad test) TVT 115/156 (73.7%), Burch 86/131 (66%), (pad test alone) TVT 128/156 (92.1%), Burch 109/131 (83.2%) **At 1 year:** CIC **At 2 years:** CIC Attenders' analysis: **6 months** TVT 82% Burch 83% **At 12 months** CIC **At 2 years** CIC	**Duration of operation:** TVT (median IQR) 40 min (30, 48), Burch 50 min (35, 60) **General anaesthetic:** TVT 3/170 (1.8%), Spinal 3/170 (1.8%), Burch 145/146 (99.3%) One spinal anaesthetic **Blood loss: (median IQR)** TVT 50 ml (30,100), Burch 128 ml (74,200) **LOS: (mean days)** TVT 2.2 (1.9), Burch 6.5 (1.78) **Post-operative pain:** TVT 35/170 (21%), 133/146 (91%) **Bladder perforation:** TVT 15/170 (9%), Burch 3/146 (2%) **DVT:** TVT 0, Burch 3/146 (2%) **Tape erosion:** at 6 months TVT 1/170 (0.6%) Burch n/a **Incisional hernia:** TVT 0, Burch 3/146 (2%)	**New urge symptoms/ incon:** At 6 months (report does not differentiate between groups) **Voiding dysfunction:** 6 months TVT 5/159 (3.1%), Burch 19/127 (15%) without urodynamics TVT 11/170 (9%), Burch 8/146 (7%) with urodynamics **New detrusor instability:** 6 months TVT 13/156 (8.3%), Burch 14/131 (10.7%) **Readmission rates:** at 24 months CIC **Time to return to normal activities:** (median IQR) TVT 3 (2,4), Burch 6 (4,8) **Rate of self-catheteris-ation: At 6 months** TVT 5/170 (3%), Burch 19/146 (13%) **At 24 months** CIC **Dyspareunia:** CIC	**B-FLUTS** only at 6 months no significant difference **SF-36** At 6 months TVT scored better on QoL for the domains of role limitation, social functioning, vitality and mental health **Patient satisfaction:** TVT 145/170 (85%), Burch 119/146 (82%) At 24 months CIC	Abstract 6 months data, abstract 24 months data. Personal communication for 6 months (submitted paper to *BMJ*) and 24 months data. Attenders analysis assumes non-attenders had same outcome as attenders

[CIC]Data supplied on a commercial in confidence basis has been removed from this table.

Appendix 16

Summary of non-randomised comparative studies

Study	Study setting	Intervention	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Arunkalaivanan, 2001[56]	Obst. & Gynae. Dept (UK)	*N* = 161 TVT (94) vs Sling (67) 177 followed up (62/94 TVT, 55/67 Sling)	**Inclusion:** NR **Exclusion:** NR	16.39 months (min. 6 months)	55	**Parity:** Comparable **Secondary intervention:** NR **Co-existing prolapse:** NR **Mixed incontinence:** NR	**Cured:** TVT 54/62 (87%), Sling 46/55 (83%) **Improved:** TVT 4/62 (6.5%), Sling 5/55 (9.4%)	NR	**Duration of operation:** TVT 33.8 min, Sling 33.0 min			Abstract Ongoing trial Cure rates based on diary, pad test
Atherton, 1999,[57] 2000[59]	Urogynae-cology Unit, St George's Hospital, London (UK)	*N* = 16 TVT (9) vs Burch Colpo (7)	**Inclusion:** USI **Exclusion:** Prior prolapse procedure, significant prolapse, MUI, voiding difficulty	3–4 weeks	50 (10.2 SD)	**Weight (kg):** 74.7 (22.2 SD) **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** 0/16	**Cured:** TVT 8/9 (89%), Colpo 7/7 (100%) **Improved:** TVT 1/9 (11%), Colpo 0/0	NR	**New urge symptoms/ incon:** TVT 1/9 (11%), Colpo 3/7 (42.8%)			Abstract Cure rates based on symptoms
Atherton, 2000[58]	Urogynae-cology Unit, St George's Hospital, London (UK)	*N* = 36 TVT (20) vs Colposuspens-ion (16)	**Inclusion:** No previous surgery for incontinence, USI **Exclusion:** Prolapse, detrusor instability	6 months	51 (10.7 SD) whole group	**Parity (median, range):** 2 (0–11) **Weight (kg):** 73 (19.1) **Secondary intervention:** No **Co-existing prolapse:** No **Mixed incontinence:** No	NR	**Cured:** TVT 15/20 (74%), Colpo 14/16 (88%) **Improved:** TVT 5/20 (25%), Colpo 2/16 (12%)	**New urge symptoms/ incon:** TVT 3/20 (10.5%), Colpo 2/16 (12.5%)			Abstract Cure rates based on urodynamics

continued

Study	Study setting	Intervention	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Foote, 2001[61]	(Australia)	*N* = 127 TVT (46) vs Lap colpo (81) 102 followed up-TVT (34), Lap colpo (68)	**Inclusion:** USI **Exclusion:** NR	6 months	TVT 57.6, Lap colpo 50.5	**Weight (kg):** TVT 75.8, Lap colpo 69.6 **Secondary intervention:** TVT 6/46 (13%), Lap colpo 0/68 **Co-existing prolapse:** No **Mixed incontinence:** No	TVT 28/34 (82.4%), Lap colpo 64/68 (94.1%)	NR	**Duration of operation:** TVT 31.2 min, Lap colpo 66.8 min **Blood loss (ml):** TVT 69, Lap colpo 95.3 **LOS:** TVT 3.3 days, Lap colpo 3.5 days **Intra-operative complications:** TVT 10/46 (21.7%), Lap colpo 5/81 (6.2%)	**Time to return to normal activities:** TVT 22 days, Lap colpo 22 days.		Abstract Women in TVT group possibly same as in Foote (2001)[60] Younger women allocated to lap colpo, older to TVT Cure rates based on diary
Foote, 2001[60]	Private hospital for TVT, Public hospital for Prolene Sling (Australia)	*N* = 86 TVT (46) vs Prolene Sling (PS) (40) 72 followed up (34 TVT, 38 PS)	**Inclusion:** USI **Exclusion:** NR	6 months	TVT 57.3, PS 60.8	**Parity:** TVT 2.7, PS 3.2 **Weight (kg):** TVT 76.9, PS 76.1 **Secondary intervention:** NR **Co-existing prolapse:** NR **Mixed incontinence:** NR	**Cured and Improved:** TVT 28/34 (82%), PS 32/38 (84%)	NR	**Duration of operation:** TVT 31.2 min, PS 47.8 min **Blood loss (ml):** TVT 69, PS 102 **LOS:** TVT 3.3 days, PS 5.6 **Bladder perforation:** TVT 10/46 (21.7%), PS 4/40 (10%) **Intra-operative complications:** TVT 10/46 (21.7%), 4/40 (10%) **Post-operative complications:** TVT 12/34 (33%), PS 19/38 (50%)	**Cutting sling:** TVT 1/46 (2.2%), PS 2/40 (5%) **Time to return to normal activities:** TVT 22.4 days, PS 19.6 days		Abstract Women in TVT group possibly same as in Foote (2001)[61] Women in private hospital had TVT, women in public hospital had PS Cure rates based on diary

continued

Study	Study setting	Intervention	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Hung, 2001[62]	Obstetrics & Gynaecology Dept (Taiwan)	*N* = 89 TVT (24) vs Sling (65) 89 followed up TVT 23/24, Sling 57/65	**Inclusion:** USI, MUI, with/without additional gynaecological operations **Exclusion:** NR	Unclear (early surgical outcome and QoL)	TVT 63.3, Sling 55.0	**Secondary intervention:** TVT 6/23 (26.1%), Sling 4/57 (7%) **Co-existing prolapse:** NR **Mixed incontinence:** TVT 20/23 (87%), Sling 33/57 (57.9%)	Unclear	Unclear	**Tape/Sling revision rate:** TVT 3/23 (13%), Sling 3/57 (5.3%)		**Urogenital Distress Inventory:** Improved: TVT 79.8%, Sling 77.8%	Abstract One surgeon carried out all procedures Cure rates based on Incontinence Impact Questionnaire, Urogenital Distress Inventory Short Form
Liang, 2001[63]	Obstetrics & Gynaecology Dept (Taiwan)	*N* = 91 TVT (30) vs Needles (35) vs Lap Colpo (26)	**Inclusion:** Anatomic stress urinary incon **Exclusion:** NR	22 months (12–43 months)	NR	**Secondary intervention:** NR **Co-existing prolapse:** NR **Mixed incontinence:** NR	**TVT:** 26/30 (86.7%), **Needle:** 30/35 (84.6%), **Lap colpo:** 20/26 (77.1%) Unclear whether these relate to subjective or objective cure rates		**Duration of operation:** TVT 30.6 (6.2 SD), **Needle** 102.2 (49.5 SD), **Lap colpo** 113.4 (24.5 SD)			Abstract One urogynaecologist performed all operations Lap colpo was chosen for patients with gynaecological diseases Cure rates based on urodynamics, pad test, diary
Lukanovic, 1999[64]	Obstetrics & Gynaecology Dept (Slovenia)	*N* = 75 TVT (60) vs Lap Burch (15)	**Inclusion:** Proved stress urinary incon **Exclusion:** Severe prolapse	All at 4 months				**Cured:** TVT: 58/60 (97%) Lap colpo 14/15 (91%)				Abstract Cure rates based on pad test, urodynamics,
Yalcin, 2001[65]	University Hospital (Turkey)	*N* = 79 TVT (51) vs Burch colpo (28)	**Inclusion:** USI **Exclusion:** NR	Max. TVT 30 months, Colpo 44 months	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	**Cured:** TVT 46/51 (90%), Colpo 15/28 (53.5%) **Improved:** TVT 5/51 (10%), Colpo 10/28 (35.7%)	NR				Abstract No description of how cure was measured

Appendix 17

Summary of included studies (case series >2 years follow-up)

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Bettin, 2000[66]	Obst. & Gynae. Dept (Germany)	206	**Inclusion:** NR **Exclusion:** NR	77/206 1 year 22/206 2 years	55	**Secondary intervention:** 27/206 (13%) **Co-existing prolapse:** 89/206 (43%) **Mixed incontinence:** 71/206 (34.4%)	NR	**Cured:** At 1 year 66/77 (85.7) At 2 years 19/22 86.4) **Improved:** Unclear	**Local anaesthetic:** 130/206 (63%) **Bladder perforation:** 11/206 (5.3%) **Haematoma:** 2/206 (1%) **Obturator nerve irritation:** 2/206 (1%) **Pelvic vein thrombosis:** 1/206 (0.5%)		**VAS:** 90% scored 0–2 (Good)	Abstract Cure rates based on VAS, urodynamics
Jomaa, 2000[69]	Obst. & Gynae. Dept (Sweden)	25	**Inclusion:** Recurrent SUI **Exclusion:** NR	3 years	55.8 (40–75)	**Secondary intervention:** Yes **Co-existing prolapse:** Unclear **Mixed incontinence:** 7/25	**Cured:** 21/25 (84) **Improved:** 4/25 (16)	**Cured:** 21/25 (84) **Improved:** 4/25 (16)	**Blood loss (ml):** 50 (10–250) **Bladder perforation:** 3/25 (12%)			Abstract Cure rates based on diary, stress test, QoL with VAS, pad test

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Jomaa, 2001[71]	Obst. & Gynae. Dept (Sweden)	62	**Inclusion:** USI **Exclusion:** NR	60 months (48–78 months)	52.7 (30–64)	**Parity:** 2 (1–7) **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** 6/62 (9.7%)	**Cured:** 59/62 (95.2) **Improved:** 2/62 (3.2)	**Cured:** 59/62 (95.2) **Improved:** 2/62 (3.2)	**Local anaesthetic:** 62/62 **LOS:** All same day or morning after **Bladder perforation:** 0/62 **Defective healing:** 0/62 **Retropubic bleeding:** 1/62 (1.6%) **Tape rejection:** 0/62	**New urge symptoms/ incon:** 2/62 (3.2%) **Reoperation:** 1/62 (1.6%) for laparotomy		Abstract Cure rates based on QoL, VAS, stress test, diary, pad test
Jomaa, 2001[70]	Obst. & Gynae. Dept (Sweden)	32	**Inclusion:** USI, signs of prolapse **Exclusion:** NR	Up to 24 months	54 (31–74)	**Parity:** 2 (0–5) **Duration of incontinence:** 13 (2–29) **Faecal incontinence:** 1/32 (3.1%) **Previous hysterectomy:** 3/32 (9%) **Secondary intervention:** 2/32 (6.3%) **Co-existing prolapse:** 32/32 **Mixed incontinence:** NR	**Cured:** 30/32 (94) **Improved:** 1/32 (3.1)	**Cured:** 30/32 (94) **Improved:** 1/32 (3.1)	**Blood loss:** 75 ml (25–300) **General anaesthetic:** 0/32 **LOS:** (mean days) 2 (1–5) **Bladder perforation:** 1/32 (3%) **Defective healing:** 0/32 **Tape rejection:** 0/32 **Urinary retention:** 0/32	**New/ recurrent prolapse:** 0/32		Cure rates based on diary, stress test, urodynamics, QoL

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Kinn, 2001[72]	Urology Dept (Sweden)	75 (a) primary incontinence surgery (44) (b) previous surgery (31)	**Inclusion:** SUI, failed PFMT, urge incontinence **Exclusion:** Neurological conditions	24 months	59.8 (11.9 SD) (39–83)	**Parity:** 6 nulliparous **BMI** (c)<24 (n = 10), (d) 24–28 (n = 43), (e) >28 (n = 22) **Previous hysterectomy**: 18/75 (24%) **Uterine prolapse surgery:** 3/75 (4%) **Previous radiation therapy:** 2/75 (2.7%) **Detrusor instability:** 4/75 (5.3%) **Secondary intervention:** 16/75 (21.3%) **Co-existing prolapse:** Unclear **Mixed incontinence:** 23/75 (31%)	**Cured:** 60/75 (80) **Improved:** 7/75 (9)	**(a)** 31/44 (70.5) **(b)** 17/31 (54.8) **(c)** 7/10 (70) **(d)** 30/43 (69.8) **(e)** 9/22 (41)	**Duration of operation:** 39 min **General anaesthetic:** 0/75 **Spinal anaesthetic:** 2/75 (2.7%) **LOS:** all mean 24 hours **Local anaesthetic:** 73/75 (97.3%) **Bladder perforation:** 3/75 (4%) **Permanently increased urge:** 2/75 (2.7%) **Tape erosion:** 2/75 (2.7%) **Transient urge:** 4/75 (5.3%) **Urinary retention (temporary):** 9/75 (12%) **UTI:** 2/75 (2.7%)	**Time to return to normal activities:** 12 days (8 SD) **Reoperation:** 1/75 (1.3%) (tape caused obstruction and had to be cut)	**BFLUTS:** significant difference in frequency, leakage and pad use	Cure rates based on VAS (0–100), diary, pad test, urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Liapis, 2001[73]	Obst. & Gynae. Dept (Greece)	68 (A: 50 TVT only B: 18 TVT with anterior colporrhaphy)	**Inclusion:** USI **Exclusion:** Detrusor instability, previous operation of genital tract, prolapse	2 years	A: 53.8 (8.5 SD) B: 54.2 (8.1 SD)	**Parity:** A: 2.1 (0.9 SD); B: 2.1 (1.3 SD) **BMI:** A: 28.4 (2.5 SD); B: 27.2 (3.3 SD) **Secondary intervention:** Unclear **Co-existing prolapse:** 68/68 **Mixed incontinence:** No	**Cured:** A: 45/50 (90), B: 16/18 (88.8) **Improved:** A 2/50 (4), B 1/50 (2)	**Cured:** A: 45/50 (90), B: 16/18 (88.8) **Improved:** A 2/50 (4), B 1/50 (2)	**Duration of operation:** 28 min (11 SD) **General anaesthetic:** 0/68 **Spinal anaesthetic:** 68/68 **LOS:** (mean days) 2 (1–3) **Bladder perforation:** 4/68 (5.9%) **Bleeding:** 0/68 **Haematoma:** 0/68 **Tape rejection:** 0/68 **UTI:** 2/68 (2.9%)	**New urge symptoms/ incon:** 6/68 (8.8%) **New detrusor instability:** 3/68 (5%) **New or recurrent prolapse:** 0/68		Cure rates based on pad test
Migliari, 1999[74]	(Italy, Sweden)	50	**Inclusion:** USI **Exclusion:** NR	36 months	57 (11 SD)	**Parity:** 2 (0–4) **Secondary intervention:** NR **Co-existing prolapse:** NR **Mixed incontinence:** NR	**Cured:** 44/50 (87) **Improved:** 5/50 (11)	NR	**Local anaesthetic:** 49/50 (98%) **Defective healing:** 0/50 **Tape rejection:** 0/50			Abstract

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Nilsson, 2001[76]	Multicentre 3 centres, (Sweden, Finland)	90 consecutive patients	**Inclusion:** USI, grade I cystocele not requiring surgical intervention **Exclusion:** Previous incontinence surgery, detrusor instability, intrinsic urethral sphincter deficiency	Median 56 months (48–70 months)	Median 57 (40–91)	**Parity:** median 2 (0–4) **Duration of incontinence:** median 13 (2–25) years **Post-menopausal:** 53/90 (58.8%) **Oestrogen:** NR **Secondary intervention:** 0/90 **Co-existing prolapse:** Unclear **Mixed incontinence:** 25/90 (28%) **Urge symptoms:** 26/90 (29.4%)	**Cured:** 72/85 (84.7) **Improved:** 9/85 (10.6) Mixed incontinence **Cured of urge:** 14/25 (56)	**Cured:** 72/85 (84.7) **Improved:** 9/85 (10.6) Mixed incontinence **Cured of urge:** 14/25 (56)33	**Duration of operation:** Median 30 min (15–55) **General anaesthetic:** 0/90 **LOS:** (median days) 2 (1–5) **Bladder perforation:** 1/90 (1.1%) **Defective healing:** 0/90 **Infection of operating site:** 1/90 (1.1%) **Intraoperative bleeding >200 ml:** 3/90 (3.3%) **Recurrent UTI:** 1/90 (1.1%) **Retropubic haematoma:** 3/90 (3.3%) **Tape rejection:** 0/90 **UTI (within 2 months):** 7/90 (7.8%) **Pad test median (range):** pre-op 40.5 (11–315), post-op 0 (0–35)	**Voiding dysfunction after 3 months:** 0/90 **New/ recurrent prolapse:** 2/90 (2.2%) **New urge/incon:** 5/85 (5.9%)	**VAS:** Median (range) pre-op 75 (35–100), post-op 0 (0–90)	Surgeons were experienced urogynae-cologists in TVT procedure 5/90 could not be fully evaluated The LOS varied at the different centres, reflecting different policies of post-op care Cure rates based on diary, stress test, pad test, QoL

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Nilsson, 2001[75]		85 14 (<50 years), 38 (50–59 years), 15 (60–69 years), 18 (>70 years)	**Inclusion:** USI **Exclusion:** NR	Median 56 months (48–70 months)	Median 57 (40–91)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** 0/85	At 4 years **Cured:** 85.7 (<50 years), 89.5 (50–59 years), 80 (60–69 years), 77.8 (>70 years) **Improved:** 14.3% (<50 years), 7.9 (50–59 years), 2.6 (60–69 years), 11.1 (>70 years)	NR	**General anaesthetic:** 0/85 **Local anaesthetic:** 85/85			Abstract 26/85 (30.6%) were followed up for 5 years (Nilsson, 2001[76])
Ohkawa, 2001[77]	Multicentre Urology Dept (Japan)	203	**Inclusion:** SUI, intrinsic sphincter deficiency, type III incontinence **Exclusion:** NR	24 months	57 (31–82)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	173/203 (85)	132/203 (65)				Abstract A cumulative continence score was used Cure rates based on questionnaire, stress test and/or pad test
Olsson, 1999[78]	Obst. & Gynae. Dept (Sweden)	51	**Inclusion:** Stress incontinence for average of 5 years **Exclusion:** NR	36 months	52.9 (34–80)	**Parity:** 2 (0–5) **Duration of incontinence:** 5 years **Post-menopausal:** 28/51 (55%) **Oestrogen:** 28/51 (55%) **Secondary intervention:** 3/51 (6%) **Co-existing prolapse:** 10/51 (20%) **Mixed incontinence:** 10/51 (20%)	**Cured:** 46/51 (90) **Improved:** 3/51 (5.9)	**Cured:** 46/51 (90)	**Duration of operation:** 45 min (20–60) **Spinal anaesthetic:** 7/51 (14%) **LOS:** (mean days) 2 **Bladder perforation:** 1/51 (2%) **Defective healing:** 1/51 (2%) **UTI:** 1/51 (2%) **Haemorrhage:** 0/51 **Tape rejection:** 0/51	**Voiding dysfunction:** 0/51 **Recurrent UTI:** 1/51 (2%) **Long-term urinary retention:** 0/51 **Readmission rates:** after 14 days 1/51 **Time to return to normal activities:** 21 days (7–30)		Cure rates based on pad test, stress test, VAS

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Rezapour, 2001[81]	Obst. & Gynae. Dept (Sweden)	34	**Inclusion:** Recurrent stress urinary incontinence **Exclusion:** Intrinsic sphincter deficiency, prolapse	48 months (36–60)	58.9 (10 SD)	**Parity:** 2 (0–4) **Secondary intervention:** 34/34 **Co-existing prolapse:** 0/34 **Mixed incontinence:** NR	**Cured:** 28/34 (82.4) **Improved:** 3/34 (8.8)	**Cured:** 28/34 (82.4) **Improved:** 3/34 (8.8)	**LOS:** (mean days) 4 (1–6) **Bladder perforation:** 1/34 (2.9%) **Significant intra/post-op complications:** 0/34 **Local anaesthetic:** 34/34	**New urge/ symptoms:** 1/34 (2.9%)	**QoL:** pre-op 89% (17 SD) post-op 8.5% (15 SD) negative impact of urinary incontinence on daily life	Cure rates based on diary, pad test, urodynamics, QoL
Rezapour, 2001[80]	Obst. & Gynae. Dept (Sweden)	80	**Inclusion:** Mixed incontinence **Exclusion:** Predominant urge symptoms, significant detrusor instability, small bladder volumes (≤200 ml)	48 months (36–60)	59.2 (11 SD)	**Parity:** 2 (0–4) **Duration of incontinence:** 8.1 years **Post-menopausal:** 49/80 (61.3%) **On oestrogen:** 49/80 (61/3%) **Secondary intervention:** Unclear **Co-existing prolapse:** 0/80 **Mixed incontinence:** 80/80	NR	**Cured:** 68/80 (85) **Improved:** 3/80 (4)	**General anaesthetic:** 0/80 **Local anaesthetic:** 80/80 **LOS:** Intention to discharge same day or day after surgery **Bladder perforation:** 1/80 (1.3%) **Defective healing**: 0/80 **Excessive bleeding:** 1/80 (1.3%) required blood transfusion **Small haematoma:** 6/80 (7.5%) **Tape rejection:** 0/80	**Readmission rate:** 1/80 (1.3%) (surgical intervention for haematoma)	**QoL:** pre-op 67%, post-op 14% negative impact of urinary incontinence on daily life	Surgeons were experienced urogynae-cologists familiar with TVT procedure 1/80 with excessive bleeding was on anticoagulant medication Cure rates based on stress test, pad test, QoL, urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Rezapour, 2001[79]	Obst. & Gynae. Dept (Sweden)	49	**Inclusion:** SUI, Intrinsic sphincter deficiency **Exclusion:** NR	48 months (36–60)	66.1 (11 SD)	**Parity:** 2 (0–5) **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** 0/49	**Cured:** 36/49 (73.5) **Improved:** 6/49 (12.2)	**Cured:** 36/49 (73.5) **Improved:** 6/49 (12.2)	**Duration of operation:** 35 min (12 SD) **General anaesthetic:** 0/49 **Local anaesthetic:** 49/49 **Bladder perforation:** 1/49 (2%) **Small haematoma:** 5/49 (10.2%)			Surgeons were experienced urogynae-cologists familiar with TVT procedure Cure rates based on stress test, urodynamics, diary, pad test, QoL
Tunn, 1999[82,83]	Obst. & Gynae. Dept (Germany)	134	**Inclusion:** Clinical and urodynamic clarification of urinary incontinence & sonographic assessment of bladder neck **Exclusion:** NR	94/134 (6months) 51/134 (12 months) 15/134 (24 months)	54 (11 SD)	**Secondary intervention:** NR **Co-existing prolapse:** 43/134 (32.1%) **Mixed incontinence:** 61/134 45.5% **Masked UI:** 12/134 (9%)	NR	Overall **Cured:** 13/15 (86.6) **Improved:** 2/15 (13.4)	**Local anaesthetic:** 91/134 (68%) **Bladder perforation:** 8/134 (5.9%) **Dysuria:** 7/134 (5.2%) **Retrosymphy-seal haematoma:** 1/134 (0.7%) **Obturator nerve irritations:** 2/134 (1.5%) **Pelvic vein thrombosis:** 1/134 (0.7%)	**Dyspareunia:** 0/134		Abstract Cure rates based on urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Ulmsten, 1996[25]	Obst. & Gynae. Dept (Sweden)	75	**Inclusion:** USI, typical history of stress incontinence **Exclusion:** Previous surgery	24 months	52 (36–81)	**Parity:** 0.5 (0–3) **Secondary intervention:** 0/75 **Co-existing prolapse:** NR **Mixed incontinence:** 0/75	**Cured:** 63/75 (84) **Improved:** 6/75 (8)	**Cured:** 63/75 (84) **Improved:** 6/75 (8)	**Duration of operation:** 22 min (16-42) **General anaesthetic:** 0/75 **Local anaesthetic:** 75/75 **LOS:** All had overnight stay **Bladder perforation:** 0/75 **Defective healing:** 0/75 **Tape rejection:** 0/75 **UTI:** 5/75 (6.7%)	**New urge symptoms/ incon:** 0/75 **Time to return to normal activities:** 10 days (7–21) **Voiding dysfunction >3 months:** 0/75		These are the first reports of the new TVT procedure (modified IVS procedure) All surgeons involved were experienced in vaginal surgery Objective cure based on stress test, urodynamics, pad test, patient reporting
Ulmsten, 1999[84]	Urogynae-cology Dept (Sweden)	50	**Inclusion:** NR **Exclusion:** Urge incontinence, prolapse, previous incontinence surgery	36 months	57 (SD 11)	**Multiparous:** 42/50 (84%) **Nulliparous:** 8/50 (16%) **Duration of incontinence:** >3 years 50/50 (100%) **Secondary intervention:** No **Co-existing prolapse:** No **Mixed incontinence:** No		**6 months:** 40/50 (80) **12 months:** 43/50 (86) **24–36 months:** 43/50 (86)	**Duration of operation:** 29 min (SD 10, range 16–47) **General anaesthetic:** 0/50 **LOS:** all <24 hours **Haemarro-hage >300 ml:** 0/50 **Defective healing:** 0/50 **Tape rejection:** 0/50 **Urinary retention >100 ml:** 0/50	**Voiding dysfunction >3 months:** 0/50 **Recurrent UTI:** 0/50		Prospective consecutive patients Ten patients were also included in Ulmsten (1998)[41]

Appendix 18

Summary of included studies (case series <2 years follow-up)

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Adile, 2000[85]	Urogynae. Dept (Italy)	31	**Inclusion:** NR **Exclusion:** NR	6 months and 12 months	51 (33–87)	**On oestrogen:** 31/31 **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	At 6–18 months 27/31 (87)	NR	**Duration of operation:** 23 min **General anaesthetic:** 0/31 **Bladder perforation:** 2/31 (6.5%) **Other complications:** 0/31	**New urge symptoms/ incon:** 0/31		Abstract
Adile, 2001[86]	Multicentre Urogynae. Dept. (Italy)	237	**Inclusion:** SUI mean grade II, urethra hypermobile **Exclusion:** NR	(12–24 months)	49.2 (33–87)	**Parity:** 3.1 (1–3) **Caesarian section:** 9/34 (26.5%) **Abdominal hysterectomy:** 21/34 (61.7%) **Vaginal hysterectomy:** 4/34 (11.7%) **Secondary intervention:** 34/237 (14.3%) **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	**Cured:** 214/237 (90.3%) **Improved:** 12/237 (5.1)	Unclear	**Duration of operation:** 28 min **Spinal anaesthetic:** 237/237 **Bladder perforation:** 12/237 (5.1%) **Intra-op complications:** 0/237 **Post-op complications:** 0/237			Abstract

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Azam, 2001[87]	Urogynae. Dept (2 centres in UK, 1 centre in Australia)	67	**Inclusion:** Previous surgery for USI, >1 year history of stress incontinence **Exclusion:** NR	12 months	49 (38–78)	**Secondary intervention:** 166/600 (28%) **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	NR	54/67 (80.6)	**Duration of operation:** 49 min **General anaesthetic:** 2/67 (3%) **Spinal anaesthetic:** 42/67 (62.7%) **Local anaesthetic:** 23/67 (34.3%) **LOS:** 34/67 (51%) ⩽1 day **Required non-opiate analgesia:** 55/67 (82%) **Required intramuscular opiates:** 12/67 (17.9%) **Bladder perforation:** 13/67 (19.4%) **Blood transfusion:** 0/67 **Excessive bleeding:** 0/67 **Retropubic haematoma:** 0/67 **Suspected UTI:** 7/67 (10.4%) **UTI:** 5/67 (7.5%) **Wound infection:** 0/67	**New detrusor overactivity:** 5/67 (7.5%) at 3 months		Cured rates based on urodynamics and pad test. Surgery performed by 3 surgeons in UK and 1 surgeon in Australia. All bladder perforations occurred in the 1st 20 patients (13/20 65%). The bladder perforations may represent a learning curve for surgeons using TVT in patients with previous incontinence surgery. 2 of the authors have financial interest or other relationship with Johnson & Johnson

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Bae, 2001[88]	Urology Dept (Korea)	16	**Inclusion:** SUI, moderate degree cystocele (grade II-III) **Exclusion:** NR	6 months	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	15/16 (93.8)	NR	**Duration of operation:** 53 min (42–72) **General anaesthetic:** 3/16 (18.8%) **Local anaesthetic:** 13/16 (81.2%) **LOS:** 1.8 (1–3) **Bladder perforation:** 0/16 **Haematoma:** 0/16			Abstract
Barrington, 2000[89]	Gynaecology & Anaesthetics Dept (UK)	36	**Inclusion:** NR **Exclusion:** NR	At 7 days	54 (32–73)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	**Cured:** 32/36 (89%) **Improved:** 3/36 (8)	NR	**Duration of operation:** 29 min (16–47)			Abstract Very short follow-up
Bunya-vejchevin, 2001[90]	Obst. & Gynae. Dept (Thailand)	9	**Inclusion:** USI, prolapse **Exclusion:** NR	At 1 month	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** 9/9 (100%) **Mixed incontinence:** Unclear	**Cured:** 3/3 at 12 months (100)	NR	**Duration of operation:** 33.3 min (8.29 SD) **LOS:** 3.33 (2.74 SD) **Bladder perforation:** 0/9 **Defective healing:** 0/9 **Severe blood loss:** 0/9 **Urinary retention:** 1/9 (11%)			Abstract Unclear how Cured was measured

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Cabezon, 2000[91]	Multicentre University Hospital (Chile)	65	**Inclusion:** USI **Exclusion:** NR	12 months	52 (39–71)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	65/65 (100)	65/65 (100)	**Duration of operation:** 25 min (17–37) **LOS:** 1.3 days (1–5) **Bladder perforation:** 2/65 (3.1%) **Urinary retention:** 6/65 (9.2%)			Abstract Cured rates based on stress test, QoL (UDI/IIQ)
Chung, 2000[92,93]	Obst. & Gynae. Dept Private community hospital (USA)	91 TVT alone or combined with other surgery	**Inclusion:** USI **Exclusion:** NR	NR	(34–79)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** 0/91	91/91 (100) are cured or improved	91/91 (100) are cured or improved	**Duration of operation:** 18–40 min **Bladder, bowel, vascular injury:** 0/91 **Superficial suprapubic eccymoses:** occurred occasionally			Abstract Ongoing study Unclear how Cured was measured
Dungl, 2000[94]	Obst. & Gynae. Dept (Austria)	20 (10 TVT only, 10 TVT in combination with other procedure)	**Inclusion:** NR **Exclusion:** NR	(3–20 months)	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** 6/10 (60%) **Mixed incontinence:** Unclear	**Improved:** TVT only 10/10 (100%), **TVT in combination** 6/10 (60)	NR		**Readmission rate:** TVT in combination: 1/20 (5%) (to cut tape)	**Very satisfied:** 7/10 (70%) TVT only, 4/10 (40%) TVT in combination **Satisfied:** 3/10 (30%), TVT only, 2/10 (20%) TVT in combination	Abstract Unclear how Cured was measured

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Ferrari, 2000[95]	Gynaecology Dept (Italy)	36	**Inclusion:** Previous gynaecological surgery or radiotherapy, severe stress incontinence **Exclusion:** NR	15.2 months (4.4–42.2 months)	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	**Cured:** 32/36 (88.8) **Improved:** 3/36 (8.5)	Unclear	**Local anaesthetic:** 16/36 (46%) **Spinal anaesthetic:** 20/36 (54%) **LOS:** 2 days (1–12) **Bowel perforation:** 1/36 (2.8%) **Urinary retention:** 1/36 (2.8%)	**Readmission rate:** 1 (to cut tape after 10 days) (2.8%)		Abstract Unclear how Cured was measured
Fischer, 2001[96]	Urology Dept	45	**Inclusion:** SUI, USI, urge incontinence, born before 1926 **Exclusion:** NR	14 months	80 (75–85)	**USI:** 15/45 (33.3%) **Secondary intervention:** 6/45 (13.3%) **Co-existing prolapse:** 21/45 (47%) **Mixed incontinence:** 30/45 (66.7%)	32/45 (72)	NR	**Duration of operation:** 38 min **General anaesthetic:** 1/45 (2.2%) **Local anaesthetic:** 39/45 (86%) **Spinal anaesthetic:** 5/45 (12%) **Bladder perforation:** 2/45 (4.4%) **Heavy bleeding:** 0/45 **Relevant haematoma:** 0/45	**Persistent pain >2 months after discharge from hospital:** 2/45 (4.4%) **New urge symptoms:** 3/45 (6.6%)		Abstract Elderly population

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Fynes, 2000[97]	(Australia)	103	**Inclusion:** USI, MUI **Exclusion:** NR	6 months	60 (29–89)	**Detrusor overactivity:** 18/103 (17.5%) **Voiding difficulty:** 5/103 (4.9%) **Bladder hyper-sensitivity:** 3/103 (2.9%) **Secondary intervention:** 53/103 (51.5%) **Co-existing prolapse:** 0/103 **Mixed incontinence:** 26/103 (25.2%)	77/103 (75)	NR	**General anaesthetic:** 0/103 **Local anaesthetic:** 92/103 (89%) **Spinal anaesthetic:** 11/103 (11%) **Persistent pain >2 months after discharge:** 16/103 (15.5%) **Bladder perforation:** 16/103 (15.5%) **Division of tape:** 4/103 (3.9%) **Haematoma:** 7/103 (6.8%) **Tape erosion:** (1/103 (1%) at 5 months **UTI:** 15/103	(14.6%)	**New urge symptoms/ incon:** 11/78 (14.1%) **Voiding difficulty/ dysfunction at 3 months:** 28/99 (28%) **Readmission rate:** 1/103 (10%)	**Satisfaction score >80%:** at 6 weeks 78/103 (76%) at 6 months 64/103 (66%)
Gandini, 2000[98]	Obst. & Gynae. Dept (Italy)	10	**Inclusion:** USI **Exclusion:** NR	5.7 months (3–6)	NR	**Secondary intervention:** Yes **Co-existing prolapse:** Unclear **Mixed incontinence:** No	**Cured:** 8/10 (80) **Improved:** 1/10 (10)	NR				Abstract Unclear how Cured was measured

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Glavind, 2001[99]	Obst. & Gynae. Dept (Denmark)	31	**Inclusion:** SUI, failed previous conservative treatment **Exclusion:** NR	3 months *n* =31, 12 months *n* =15	56 (33–73)	**Duration of incon:** 11 years (2–40) **Secondary intervention:** 5/31 (16%) **Co-existing prolapse:** No **Mixed incontinence:** 10/31 (32%)	At 3 months 27/31 (87) At 12 months 12/15 (80)	NR	**Local anaesthetic:** 29/31 **Spinal anaesthetic:** 1/31 **LOS:** 1 day 28/31 (90.3%), 3 days 3/31 (9.7%) **Bladder perforation:** 3/31 (9.7%) **Urethro-vaginal fistula:** 1/31 (3.2%) **Urinary retention:** 0/31 **Wound infection:** 0/31	**New urge symptoms/ incon:** 2/31 (6.5%) **Readmission rate:** 1/31 (3.2%) **Dyspareunia:** 0/31		High dropout at 1 year
Granata, 2000[100]	Urogynae. Dept (Italy)	35	**Inclusion:** USI, prolapse, stable bladder **Exclusion:** Previous pelvic surgery TVT + sometimes other operations	6 months *n* = 30 12 months *n* = 5	56 (31–78)	**Secondary intervention:** No **Co-existing prolapse:** 26/35 (74%) **Mixed incontinence:** No **Post-menopausal:** 30/35 (85.7%)	33/35 (94.3)	NR	**Duration of operation:** 60 min (40–80) **Blood loss:** 60 ml **Spinal anaesthetic:** 35/35 **Bladder perforation:** 0/35	**New urge symptoms/ incon:** 0/35		

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Haab, 2001[101]	Urology and Gynaecology Dept (France) Recruitment period April 98–April 99	62	**Inclusion:** Type II SUI (urethral hypermobility) **Exclusion:** Urge incontinence, detrusor overactivity, sphincter deficiency, prolapse	16.8 months (12–24 months) median 16.2 months	62.8 (28–86) 7 SD	**On oesteogen:** 62/62 for 3 months prior to surgery **Secondary intervention:** 16/62 (25.8%) (7 colpo, 9 BNS) **Co-existing prolapse:** 0/62 **Mixed incontinence:** 0/62	**Cured:** 54/62 (87.1) **Improved:** 6/62 (9.7)	**Cured:** 54/62 (87.1) **Improved:** 6/62 (9.7)	**Duration of operation:** 23 min (16–42) (11 SD) **Local anaesthetic:** 20/62 **Spinal anaesthetic:** 42/62 (67.7%) **General anaesthetic:** 0/62 Pain 0/62 **LOS** (median days) 1.5 (1–4) **Bladder perforation:** 6/62 (9.6%) **Infection:** 0/62 **Tape rejection:** 0/62	**New urge symptoms/ incon:** 4/62 (6.5%) **Persistent pain >2 months after discharge from hospital:** 0/62 **Readmission rate:** 1/62 (1.6%) at 13 months (sling release) **Dyspareunia:** 0/62 **Symptomatic dysuria:** 5/62 (8%)	**VAS:** 9.3 (1.1 SD) in 'Cure' group, 7.7 (2.5 SD) in 'Improved' group	A history of surgery for stress incontinence seems to be a risk factor for bladder perforation 31% previous incontinence surgery, 2.1% no previous surgery Cured rates based on VAS, pad test, stress test, urodynamics
Han, 2000[102]	Urogynae. Dept (Singapore)	100	**Inclusion:** SUI **Exclusion:** NR	6 months	57.2	**Parity:** 3.8 **Secondary intervention:** 8/100 **Co-existing prolapse:** Unclear **Mixed incontinence:** 8/100	95/100 (95)	95/100 (95)	**Duration of operation:** 29 min (20–45) **Blood loss <200 ml:** 100/100 **LOS:** 1.7 days TVT only, 2.8 days TVT + hysterectomy **Bladder perforation:** 1/100 **Paralytic ileus:** 2/100 **Wound pain:** 1/100 **Wound infection:** 1/100	**Voiding difficulty:** 1/100		Abstract Cured rates based on urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Virtanen, 2000[135]	Gynaecology Dept (Finland)	34	**Inclusion:** SUI, MUI **Exclusion:** NR	11 weeks (7–16)	61	**Parity:** 2 **BMI:** 28 **Secondary intervention:** 6/34 (17.6%) **Co-existing prolapse:** Unclear **Mixed incontinence:** 7/34 (20.6%)	34/34 (100)	NR	**Local anaesthetic:** 34/34 **Bladder, urethral or ureteral perforation:** 0/34 **Haematoma:** 0/34 **Infection:** 0/34			Abstract
Hyoung, 2001[103]	University Hospital (Korea)	73	**Inclusion:** USI **Exclusion:** NR	6.5 months (3–13) (0.26 SD)	53.3 (25–79) (1.2 SD)	**Secondary intervention:** Unclear **Co-existing prolapse:** Yes 34/73 (47%) **Mixed incontinence:** Unclear	At 3 months **Cured:** 54/73 (73.9) **Improved:** 15/73 (20.5)	At 3 months **Cured:** 54/73 (73.9) **Improved:** 15/73 (20.5)	**Duration of operation:** 33.5 min (12–70) (1.4 SD) **Local anaesthetic:** 65/73 **General anaesthetic:** 8/73 (11%) **LOS:** 3.2 days (2–7) (0.08 SD) **Bladder perforation:** 0/73 **Blood loss requiring transfusion:** 0/73 **Delayed healing:** 0/73 **Tape rejection:** 0/73			Abstract Cured rates based on questionnaire and pad test
Klutke, 2000[105]	Division of Urology, Obst. & Gynae. Dept (USA)	20	**Inclusion:** USI **Exclusion:** Prolapse	3 weeks	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** 0/20 **Mixed incontinence:** Unclear	17/20 (85)	17/20 (85)	NR			Cured rates based on urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Klutke, 2001[104]	Multicentre, 4 centres (USA)	55	**Inclusion:** USI **Exclusion:** NR	6 months and 12 months	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	At 12 months 37/49 (75.5)	At 6 months 42/48 (87.5)	**Bladder perforation:** 10/55 (18.2%) **Haematoma:** 1/55 (1.8%)			Abstract
Kulseng-Hanssen, 1999[106]	Obst. & Gynae. Dept (Norway)	71 39 USI 32 MUI	**Inclusion:** USI, MUI, previous incontinence surgery **Exclusion:** NR	6 months (5–24 months)	58 (36–87)	**Secondary intervention:** 18/71 (25.4%) **Co-existing prolapse:** Up to 8 women **Mixed incontinence:** 32/71 (45%)	NR	63/71 (88.7)	**LOS:** median 2 (1–10) **Local anaesthetic:** 71/71 **Bladder perforation:** 1/71 (1.4%) **Haematoma:** 1/71 (1.4%) **UTI:** 11/71 (15.5%)	**New urge symptoms/ incon:** USI patients 10/39 (25.6%), MUI patients 18/32 (56.3%)		Abstract All operations performed by 2 surgeons Cured rates based on stress test
Kwok, 2001[107]	Obst. & Gynae. Dept (Hong Kong)	9	**Inclusion:** USI **Exclusion:** NR	Median 10 months	Median 51 (39–64)	**Duration of incontinence:** Median 5 years (1–15) **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	NR	NR	**Duration of operation:** Median 40 min (35–65) **Blood loss (ml):** Median 100 (30–300) **Spinal anaesthetic:** 9/9 **LOS:** (median days) 3 (2–4) **Urinary retention:** 4/9 (4.4%) **UTI:** 2/9 (22.2%)	**Readmission rate:** 2/9 (22.2%) cystoscopy and urethral dilatation		Abstract One urogynae-cologist performed all operations

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Lebret, 2001[108]	Urology Dept (France)	100 (a) First 50 operations (learning curve) (b) Second 50 operations (experienced period) Combined for results	**Inclusion:** USI, failed PFMT **Exclusion:** Urge incontinence	At least 12 months	60.2 (38–87)	**Secondary intervention:** 21/100 **Co-existing prolapse:** 15/100 **Mixed incontinence:** 0/100	NR	77/100 (77) Sub group analysis (a) without prolapse 68/85 (80) (b) with prolapse 9/15 (60)	**General anaesthetic:** (a) 8/50 (16%), (b) 10/50 (20%) **Local anaesthetic:** (a) 28/50, (b) 7/50 **Spinal anaesthetic:** (a) 14/50, (b) 33/50 **Bladder perforation:** (a) 11/50 (22%) (b) 4/50 (8%) **Dysuria:** (a) 7/50 (14%) (b) 3/50 (6%) **Late bladder erosion:** (a) 1/50 (2%) (b) 1/50 (2%) (at 7 months and 11 months) **Retention:** (a) 10/50 (20%) (b) 3/50 (6%) **Retropubic haematoma:** 2/100 **Tape migration:** 2/100 **Tape rejection:** 0/100	**Readmission rate:** 4/100 for tape section, 2/100 for surgical ablation **New urge symptoms/ incon:** 5/100 Pelvic pain (<3 months): (a) 4/50 (8%), (b) 2/50 (4%)		6 surgeons performed operations There is a definite learning curve for surgeons in order to avoid bladder perforation and post-op retention Cured rates based on stress test and pad test

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Lima, 2001[109]	(Brazil)	25 (21 FU) (4 excluded as not met protocol) Some had TVT + other procedures	**Inclusion:** NR **Exclusion:** NR	13.1 months	58.3 (35–76)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	**Cured:** 18/21 (85.7) **Improved:** 2/21 (9.5) (based on diary analysis) 13/21 (62) (based on simplified score by Groutz)	16/21 (76.2) (based on pad test)	NR			Abstract One surgeon performed all procedures Cured rates based on diary, pad test, QoL (based on simplified score by Groutz, 2000)[167]
Lo, 2001[111,112]	Obst. & Gynae. Dept (Taiwan)	82	**Inclusion:** USI **Exclusion:** Pelvic relaxation syndrome, detrusor overactivity, urge incontinence, prolapse > stage I	12 months	57 (30–65)	**Parity:** 3 (1–6) **Secondary intervention:** 6/82 (7.3%) **Co-existing prolapse:** 0/82 **Mixed incontinence:** 0/82	NR	76/82 (92.7)	**Duration of operation:** 25 min (18–35) **Local anaesthetic:** 82/82 (100%) **Blood loss (ml):** 75 (20–100) **LOS (days):** 2 (1–4) **Major intra/post-op complications:** 0/82 **Defect healing of wound:** 0/82 **Tape rejection:** 0/82 **Pad test (g):** pre-op 45 (7–100), post-op 3 (0–13)	**Later (repeat) incon surgery:** 1/82 (1.2%) **Voiding dysfunction:** 0/82 **New detrusor overactivity:** 0/82		

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Lo, 2002[110]	Obst. & Gynae. Dept Urogynae. & Anesthesiology Division (Taiwan)	45	**Inclusion:** USI, failed conservative treatment with PFMT, ⩾65 years **Exclusion:** Detrusor overactivity, urge incontinence	19.7 months (12–34) median 18 months	69.1 (65–85)	**Parity:** median 5 (2–9) **Post-menopausal:** 45/45 **On oestrogen:** 45/45 **Secondary intervention:** 15/45 (33.3%) **Co-existing prolapse:** 16/45 (35.6%) **Mixed incontinence:** 0/45	41/45 (91)	NR	**Duration of operation:** 21 min (18–35) **Blood loss (ml):** 72 (30–250) **General anaesthetic:** 453/45 **LOS:** (median days) 1 (0–3) **Pad test (g):** pre-op 28.9 (9–109), post-op 1.5 (0–15) **Bladder perforation:** 2/45 (4.4%) **Defective healing of wound:** 0/45 **Tape rejection:** 0/45 **UTI:** 5/45 (11%)	**New urge symptoms/ incon:** 2/45 (4.4%) **Persistent pain:** 2/45 (4.4%) **Voiding dysfunction:** 0/45 **New detrusor overactivity:** 2/45 (4.4%)		Operations performed by one surgeon Elderly patients only

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Meschia, 1999,[113] 2000,[114] 2001[115]	Multicentre (6 centres) Urogynae. Dept (Italy)	404	**Inclusion:** USI, MUI **Exclusion:** NR	Median 21 months (12–35)	57 (31–83)	**Parity:** 2 (0-12) **Nulliparous:** 18/404 (4.5%) **BMI:** 26 (17–36) **Post-menopausal:** 275/404 (68%) **Secondary intervention:** 78/404 (19%) **Co-existing prolapse:** 86/404 (21%) **Mixed incontinence:** 118/404 (29%)	**Cured:** 372/404 (92.1) **Improved:** 17/404 (6.6)	365/404 (90.3)	**Duration of operation:** 41 min (15–165) **Blood loss (ml):** 51 (10–1200) **General anaesthetic:** 24/404 (6%) **Spinal anaesthetic:** 202/404 (50%) **Local anaesthetic:** 178/404 (44%) **LOS:** 2.9 (1–18) **Bladder perforation:** 24/404 (6%) **Defective healing:** 2/404 (0.5%) **Obturator nerve injury:** 1/404 (0.2%) **Retropubic bleeding:** 2/404 (0/5%) **Retropubic haematoma:** 6/404 (1.5%)	**Readmission rate:** 2/404 (0.5%) (tape cut)	**VAS:** 0.7 (0–10)	Surgeons were of varied experience 12/404 (3%) had occult incontinence Cured rates based on questionnaire, VAS, stress test, urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Moran, 2000[116]	Obst. & Gynae. Dept, Urogynae. Unit (UK)	40	**Inclusion:** SUI, failed PFMT, stable bladder, negative MSU specimen **Exclusion:** Previous incontinence surgery, previous prolapse surgery, voiding dysfunction	12.3 months (6–24)	51.1 (33–86)	**Parity:** 2 (2–4) median (range) **BMI:** 25.1 (19–35) **Secondary intervention:** 0/40 **Co-existing prolapse:** Unclear **Mixed incontinence:** 0/40	**Cured:** 32/40 (80) **Improved:** 7/40 (18)	38/40 (95)	**Duration of operation:** 42 min (25–65) **Blood loss <300 ml:** 40/40 **General anaesthetic:** 0/40 **Local anaesthetic:** 40/40 **LOS:** (mean days) 2.2 (2–4) **Bladder perforation:** 2/40 (5%) **Inner thigh pain:** 1/40 (2.5%) **Left groin pain:** 1/40 (2.5%) **Mesh infection or rejection:** 0/40 **UTI:** 1/40 (2.5%) **Time to return to normal activities:** 15.4 days (7–42)			Cured rates based on urodynamics, pad test)

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Mukherjee, 2001[117]	Obst. & Gynae. Dept (UK)	242	**Inclusion:** USI **Exclusion:** NR	6 months	56 (34–79) (10.5 SD)	**BMI:** 34.8 (30–56) (4.9 SD) 58 BMI <25, 98 BMI 25–29, 87 BMI ⩾30 **Secondary intervention:** Unclear **Co-existing prolapse:** Yes (number NR) **Mixed incontinence:** Yes (number NR)	**Cured:** 220/243 (96) BMI <25: 49/58 (84.5) BMI 25–29: 93/98 (94.9) BMI >30: 78/87 (89.6)	NR	**Spinal anaesthetic:** 242/242 **Retropubic haematoma:** 2/242 (0.8%) **Wound infection:** 0/242	**Readmission rate:** 2/242 (0.8%)	**King's QoL:** Highly significant improvement ($p < 0.001$)	No significant difference in complications between obese and other groups
Mutone, 2000[118]	(USA)	14	**Inclusion:** USI **Exclusion:** NR	6 weeks		**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** No	14/14 (100)	13/14 (90)				Abstract Ongoing study
Mutone, 2001[119]	Division of Female Pelvic Medicine & Reconstructive Surgery, Division of Biostatistics (USA)	49 underwent TVT 43 met inclusion criteria 35 agreed to participate in study	**Inclusion:** USI **Exclusion:** no pre-op urodynamic testing, patient's inability to follow up	6 weeks	61.2 (10.9 SD)	**Parity:** Median 3 (1–6) **White:** 33 (94.3%) **Post-menopausal:** 30/35 (85.7%) **Secondary intervention:** 12/35 (34.3%) **Co-existing prolapse**: 6/35 (17%) **Mixed incontinence**: 5/35 (14.3%)	32/35 (91.4)	29/35 (82.9)	**General anaesthetic:** 7/35 (20%) **IV & local anaesthetic:** 25/35 **Spinal anaesthetic:** 3/35 **Bladder perforation:** 1/35 (2.9%) **Urinary retention:** 1/35 (2.9%) **Other complications:** 0/35	**Readmission rate:** 1/35 (2.9%) **New detrusor overactivity:** 0/35 **Voiding dysfunction:** 1/35 (3%)		Study was supported by Gynecare, Division of Ethicon

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Natale, 2000[121]	Urogynae. Unit (Italy)	59	**Inclusion:** USI **Exclusion:** NR	13.1 months (3–20)	54.4 (34–78)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	NR	55/59 (93.2)				Abstract Cured rates based on urodynamics
Natale, 2000[120]	Urogynae. Unit (Italy)	120	**Inclusion:** USI **Exclusion:** Prolapse	19.8 months (3–36 months)	55.8 (33–79)	**Parity:** 0–9 **Post-menopausal:** 91/120 (75.8%) **Secondary intervention:** Unclear **Co-existing prolapse:** 0/120 **Mixed incontinence:** 25/120 (20.8%)	115/120 (95.8)	NR	**Bladder perforation:** 19/120 (15.8%) **Haematoma:** 1/120 (0.8%) **Bleeding:** 1/120 (0.8%)	**Voiding dysfunction after 3 months:** 1/120 (0.8%)		Abstract Unclear how Cured was measured

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Niemczyk, 2001[122,123]	Division of Urology, Division of Urogynae., Obst. & Gynae. Dept (USA)	100	**Inclusion:** SUI, failed PFMT, oestrogen replacement or urinary sphincter tone-enhancing medication **Exclusion:** Active UTI, neurological conditions	2 months	61.8 (33–90)	**Parity:** 2.3 **Gravity:** 2.9 **Duration of incon:** all ⩾12 months **Detrusor overactivity:** 16/100 (16%) **Secondary intervention:** 31/100 (31%) **Co-existing prolapse:** Unclear **Mixed incontinence:** 52/100 (52%)	3 weeks 82/93 (88.2), at 2 months 46/54 (85.2)	NR	**Pad changes (no. per 24 h):** 3.7 (pre-op), 0.5 (3 weeks), 0.4 (2 months) **Duration of operation:** 35.5 min (19–99) **Local anaesthetic:** 97/100 (97%) **Spinal anaesthetic:** 3/100 (3%) **LOS:** 0.11 days **Bladder perforation:** 23/100 (23%) **Fungal vaginitis:** 1/100 (1%) **Injury to small intestine, ureter or rectum:** 0/100 **Retropubic haematoma:** 1/100 (1%) **Retained plastic sheath:** 1/100 (1%) **Tape erosion:** 0/100 **Tape infection:** 0/100 **Urinary retention:** 5/100 (5%) **UTI:** 8/100 (8%)	**New urge symptoms/ incon:** 3/93 (3.2%) 3 weeks, 5/54 (9.3%) 2 months **Readmission rates:** 1/100 (1%)	**Perceived pain during surgery:** 19/100 (19%) **Experienced minimal or no discomfort during surgery:** 67/100 (67%)	Surgeons practised on 3 fresh cadavers

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Nilsson, 1998[124]	Obst. & Gynae. Dept (Finland)	31	**Inclusion:** USI **Exclusion:** NR	8 months (2–12)	53 (35–79)	**Parity:** 1.6 (0–4) **BMI:** 25 (20–31) **Duration of incontinence:** 7.5 years (1–25) **Previous hysterectomy:** 12/31 (38.7%) **Previous Caesarean section:** 4/31 (12.9%) **Secondary intervention:** 6/31 (19.4%) **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	NR	31/31 (100)	**Duration of operation:** 22 min (15–30) **Blood loss (ml):** 22 (<25), 8 (25–50), 1 (200) **Local anaesthetic:** 31/31 **LOS:** 23 day case, 8 overnight stay **Pad test (g):** pre-op 61 (11–200), post-op 3 (0–7) **Intraoperative complication:** 0/31 **Bladder injury:** 0/31 **Haematoma:** 1/31 (3.2%) **Post-op infections:** 0/31 **Tape rejection:** 0/31 **UTI:** 1/31 (3.2%)	**Time to return to normal activities:** 15 days (10–19)	**VAS for severity of incontinence:** pre-op 65 (35–98), post-op 2 (0–8)	Cured rates based on pad test

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Nilsson, 2001[125]	Obst. & Gynae. Dept, Uro-dynamic Unit, University Hospital (Sweden)	161	**Inclusion:** USI, recurrent stress incontinence, MUCP <20 cmH_2O, mixed incontinence, mild grade I and II cystocele without residual urine, failed PFMT. **Exclusion:** Women requiring concomitant surgery, prolapse	16 months (7 SD) (6–24 months)	Median 56 (29–81)	**Parity:** median 2 (0–9) **Duration of incon:** median 10 years (1–50) **BMI:** Median 25 (19–35) **Post-menopausal:** 104 (64.6%) **Previous hysterectomy:** 66/161 (37.9%) **Secondary intervention:** 45/161 (27.9%) **Co-existing prolapse:** 0/161 **Mixed incontinence:** 59/161 (36.6%)	**Cured:** 140/161 (87) **Improved:** 11/161 (7)	**Cured:** 140/161 (87) **Improved:** 11/161 (7)	**Duration of operation:** median 22 min (10–40) **Blood loss:** Median 15.9 ml (52.7 SD) **LOS:** Day case 129/161 (80%); overnight or maximum or 4 days 10% **Local anaesthetic:** 161/161 (100%) **Minor complication:** 32/161 (19.9%) **Major complication:** 0/161 **Bladder perforation:** 6/161 (3.7%) **Blood loss >200 ml:** 3/161 (1.9%) **Defective healing:** 0/161 **Retropubic haematoma:** 2/161 (1.2%) **Tape rejection:** 0/161 **Urinary retention:** 7/161 (4.3%) **UTI:** 10/161 (6.2%) **Wound infection:** 3/161 (1.9%) **Pad test (g):** Median (range) pre-op 59 (10–365), at 24 months 0 (0–33)	**New urge symptoms/ incon:** 5/161 (3.1%) **Post-op pain <2 weeks:** 1/161 (0.6%) **Readmission rate:** 1/161 (0.6%) (wound infection)	**VAS on severity of symptoms:** pre-op 75 (25–100), at 24 months 2 (0–83)	2 surgeons performed all operations Cured rates based on VAS, urodynamics, stress test, pad test

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
O'Sullivan, 2000[126]	2 centres (UK and Ireland)	63 recruited 43 followed up	**Inclusion:** Recurrent SUI **Exclusion:** NR	8.9 months	NR	**Secondary intervention:** Yes 43/43 (100%) **Co-existing prolapse:** Unclear **Mixed incontinence:** Yes 23/43 (53%)	**Overall** 34/43 (80) (a) 16/22 (73) (b) 19/21 (89)	NR	**Local anaesthetic:** (a) 22/43 **General anaesthetic:** (b) 21/43 **Bladder perforation:** (a) 6/22 (27.3%), (b) 1/21 (4.8%) **Bleeding problems:** (a) 2/22 (9%), (b) 1/21 (4.8%) **UTI:** (a) 1/22 (4.4%), (b) 2/21 (9.5%)	**Readmission rate:** 1/43 (2.3%) **New urge incon:** 3/43 (7%)		Abstract General anaesthetic appears better than local
Papavassiliou, 2000[127]	Urology Dept (Greece)	36	**Inclusion:** USI **Exclusion:** NR	3–18 months	NR	**Secondary intervention:** Unclear **Co-existing prolapse:** 5/36 (13.9%) **Mixed incontinence:** Unclear	**Cured:** 27/36 (75.5) **Improved:** 8/36 (22)	27/36 (75.5)	**Duration of operation:** 40–45 min **LOS:** 1–4 days **Local anaesthetic:** 56/56 (100%) **Bladder perforation:** 4/36 (11.1%) **Delayed healing:** 0/36 **Erosion of urethra:** 0/36 **Infection:** 0/36 **Tape rejection:** 0/36			Abstract

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Parekh, 2000[128]	(USA)	83	**Inclusion:** USI, MUI **Exclusion:** NR	3.3 months	56	**Parity:** 2 **Weight (kg):** 79 **Detrusor overactivity:** 60/83 (73%) **Concomitant surgery:** 14/83 (17%) **Secondary intervention:** 20/83 (24%) **Co-existing prolapse:** Unclear **Mixed incontinence:** 60/83 (72%)	72/83 (87)	68/83 (82)	**Blood loss (ml):** 104 **General anaesthetic:** 4/83 (5%) **Spinal anaesthetic:** 12/83 (15%) **Local anaesthetic:** 67/83 (80%) **Bladder perforation:** 4/83 (4.8%)	**New detrusor overactivity:** 5/23 (22%)		Cured rates based on urodynamics
Riva, 1998[129]	Obst. & Gynae. Dept (Italy)	34	**Inclusion:** SUI, prolapse **Exclusion:** NR	8 months (1–16)	56.9 (37–80)	**BMI:** 25.8 (18.3–32.1) **Secondary intervention:** Unclear **Co-existing prolapse:** Yes **Mixed incontinence:** 3/34 (9%)	NR	32/34 (94)	**Local anaesthetic:** 34/34 **LOS:** 1.7 days **Bladder injury:** 3/34 (8.8%) **Tape rejection:** 0/34 **Laparotomy:** 1/34 (3%)	**New detrusor overactivity:** 1/34 (2.9%)		Abstract Cured rates based on urodynamics
Rufford, 2001[130]	Urogynae. Dept	23	**Inclusion:** TVT as a secondary procedure **Exclusion:** NR	6 months	NR	**Secondary intervention:** 23/23 **Co-existing prolapse:** 3/23 (13%) **Mixed incontinence:** 13/23 (56%)	22/23 (95.7)	17/21 (80.9)	**Tape broke during insertion:** 1/23 (4.3%)	**New detrusor overactivity:** 2/21 (9.5%) **Later (repeat) incon surgery:** 1/23 (colpo)		Abstract Cured rates based on urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Sander, 2002[131]	Multicentre Obst. & Gynae. Dept (Denmark)	45	**Inclusion:** USI, MUI **Exclusion:** NR TVT + other procedures 5/45	At 12 months	54.8 (33–73)	**Secondary intervention**: 2/45 (4.4%) **Co-existing prolapse:** Unclear **Mixed incontinence:** 16/45 (35.6%)	**Cured:** 39/45 (87) **Improved:** 6/45 (13)	29/33 (87.9)	**Bladder perforation:** 1/45 (2.2%) **Urinary retention:** 4/45 (8.9%) **Spinal anaesthetic:** 4/45 (9%) **Local anaesthetic:** 41/45 (91%)	**Pad test (g/24 h):** pre-op 88, post-op 3 **Incon episodes/24 h:** pre-op 5.3, post-op 0.4 **Readmission rate:** 3/45 (6.7%) **Self-catheterisation:** 2/45 (4.4%) **New urge symptoms/incon:** 1/45 (2.2%) **New detrusor overactivity:** 1/45 (2.2%) **Voiding difficulty >3 months:** 2/45 (4.4%) **Readmission for repeat surgery for incontinence** 1/45 (2%) (injectables)		Cured rates based on pad test and diary

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N* (%)	Objective cure rate *n/N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Schiotz, 2000[132]	Obst. & Gynae. Dept (Norway)	42	**Inclusion:** Severe SUI, used protection daily **Exclusion:** NR	16 months (6–27)	50 (36–77)	**Weight:** 69 kg (49–136) **Secondary intervention:** 14/42 (33.3%) **Co-existing prolapse:** 7/42 (16.7%) **Mixed incontinence:** 5/42 (11.9%)	35/41 (85.4)	33/41 (80.5)	**Duration of operation:** 34 min (21–57) **Local anaesthetic:** 38/41 (92.7%) **Spinal anaesthetic:** 1/41 (2.4%) **General anaesthetic:** 2/41 (4.9%) **LOS:** 37/41 (90.2%) ≤1 day, 4/41 (9.8%) >1 day **Bladder perforation:** 2/42 (4.8%) **Deep infection:** 0/41 **Defective healing:** 1/41 (2.4%) **Significant bleeding (intra/post-op):** 0/41 **Skin infection:** 1/41 (2.4%) **Tape rejection:** 0/41 **UTI:** 0/41	**New urge symptoms/ incon:** 0/41 **Voiding dysfunction:** 0/41 **Readmission rate:** 1/41 (2.4%) for revised incision		One participant excluded from analysis as procedure converted to Stamey needle suspension (41 analysed) Cured rates based on stress test, questionnaire, pad test
Sebastio, 2000[133]	Urology Dept (Italy)	22	**Inclusion:** USI **Exclusion:** Prolapse >1st degree	At 4 months	56.3 (30–69)	**Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** 0/22	NR	21/22 (95.5)		**New urge symptoms/ incon:** 0/22		Cured rates based on pad test, urodynamics

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Soulie, 2001[134]	Multicentre (5 centres) Urology depts of 4 private hospitals, 1 university hospital (France)	52 (TVT only 44, TVT with prolapse repair 8)	**Inclusion:** Urinary stress incontinence requiring surgical treatment **Exclusion:** Psychiatric patients, neurogenic and hypercontract-ile bladders	15.2 months (6–36 months)	64 (37–91)	**Duration of incon:** All >6 months **Secondary intervention:** 29/52 (56%) **Co-existing prolapse:** 8/52 (15%) **Mixed incontinence:** 12/52 (23%)	43/52 (83)	NR	**Duration of operation:** 30 min (20–60) **Local anaesthetic:** 6/52 (11.5%) **Spinal anaesthetic:** 43/52 (82.7%) **General anaesthetic:** 3/52 (5.8%) **LOS:** (mean days) 2.5 (1–7) TVT only, 4.3 (2–17) TVT with prolapse repair **Bladder perforation:** 6/52 (11.5%) **Sling infection:** 0/52 **Tape rejection:** 0/52 **Transient dysuria:** 4/52 (7.7%) **Transient urinary retention:** 9/52 (17.3%) **Urethral or vaginal erosion:** 0/52			Surgeons were experienced in USI using vaginal approach, some had short specific training in TVT

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Ulmsten, 1998[41]	Multicentre (6 centres) (Sweden and Finland)	131	**Inclusion:** USI **Exclusion:** Previous surgery for stress incontinence, symptoms/ signs of prolapse	At or over 12 months	53 (35–88)	**Parity:** 2 (0–5) **Duration of incon:** 3 years (mean) **Secondary intervention:** No **Co-existing prolapse:** No **Mixed incontinence:** No	**Cured:** 119/131 (91) **Improved:** 9/131 (7)	**Cured:** 119/131 (91) **Improved:** 9/131 (7)	**Duration of operation:** 28 min (19–41) **Local anaesthetic:** 131/131 (100%) **LOS:** 118/131 (90%) day cases, 6/131 (4.6%) 1 overnight stay 7/131 (5.4%) >2 overnight stay **Bladder perforation:** 1/131 (0.8%) **Defect healing:** 0/131 **Tape rejection:** 0/131 **Haematoma:** 2/131 (1.5%) **Wound infection:** 1/131 (0.8%) **Time to return to normal activities:** 14 days (10–21)			Prospective surgeons 'taught' on 2–3 patients Cured rates based on QoL, VAS, pad test, stress test

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N* (%)	Objective cure rate *n*/*N* (%)	Perioperative outcomes	Other outcomes	Health status measures	Notes
Wang, 1998[136,137]	Multicentre (Taiwan)	72	**Inclusion:** USI, MUI, demonstrable stress incontinence **Exclusion:** Previous incontinence surgery, prolapse	12 months (median) (3–18 months)	42.7 (22–74)	**Parity:** 4.1 (0–7) **Secondary intervention:** No **Co-existing prolapse:** No **Mixed incontinence:** 11/72 (15%)	61/70 (87)	58/70 (83)	**Duration of operation:** 29 min (20–51) **Blood loss (ml):** 75 (20–280) **Blood loss >200 ml:** 11/70 (16%) **Spinal anaesthetic:** 72/72 (100%) **LOS:** 3 days (2–8) **Bladder perforation:** 3/70 (4.3%) **Defect healing:** 0/70 **Tape rejection:** 0/70 **UTI:** 4/70 (5.7%)			70 completed follow-up Cured rates based on pad test
Yalcin, 2000[138]	Obst. & Gynae. Dept (Turkey)	29	**Inclusion:** USI **Exclusion:** NR TVT + other procedures 13/29 (45%)	9/29 (>12 months) 10/29 (>6 months) 10/29 (6 months)	NR	**TVT only:** 16/29 (55.2%) **TVT with additional procedure:** 13/29 (44.8%) **Secondary intervention:** Unclear **Co-existing prolapse:** Unclear **Mixed incontinence:** Unclear	NR	NR	**Bladder perforation:** 2/29 (6.9%) **Intraoperative significant haemorrhage:** 1/29 (3.4%) **Nerve injury:** 1/29 (3.4%) **UTI:** 2/29 (6.9%)			Abstract No significant difference found between 2 groups

Appendix 19

Summary of included studies (population-based registries)

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Kuuva, 2002[139,140]	Population-based registry 38 hospitals (4 university hospitals, 13 central hospitals, 21 local hospitals) (Finland)	1455	**Inclusion:** NR **Exclusion:** Hospital not using standard TVT equipment, hospital used as TVT training centre	2 weeks to 2 months	NR	**Secondary intervention:** NR **Co-existing prolapse:** NR **Mixed incontinence:** NR	NR	NR	**Total complications:** 367/1455 (25.2%) **Bladder perforation:** 56/1455 (3.8%) **Blood loss >200 ml:** 27/1455 (1.9%) **Defective healing:** 10/1455 (0.7%) **Injury of epigastric vessel:** 1/1455 (0.1%) **Injury of obturator nerve:** (1/1455 (0.1%) **Retropubic haematoma:** 27/1455 (1.9%) **Vaginal haematoma:** 1/1455 (0.1%) **Haematoma outside retropubic area:** 7/1455 (0.5%) **Tape rejection:** 0/1455 **Urethral lesion:** 1/1455 (0.1%) **Urge symptoms:** 11/1455 (0.8%) **UTI:** 59/1455 (4.1%) **Venous thrombosis:** 1/1455 (0.1%) **Vesicovaginal fistula:** 1/1455 (0.1%) **Wound infection:** 12/1455 (0.8%)			Figures suggest a learning period of approx. 15 operations is required for good results Cystoscopy should be performed after each passing of the needle

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n*/*N*	Objective cure rate *n*/*N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Tamussino, 2001[141,142] Up to 1 May 2000	Population-based registry for all TVT operations (Austria) Information from 29 gynaecology units	806 (443 TVT only, 363 TVT combined with other procedures)	**Inclusion:** NR **Exclusion:** NR	NR	NR	NR	NR	NR	**Duration of operation:** 30 min (10–120) TVT only, 85 min (20–390) TVT in combination **LOS (days):** 6 (0–37): TVT only 4 (0–37), TVT in combination 7 (2–13) **General anaesthetic:** 57/443 (13%) TVT only, 132/363 (36%) TVT in combination **Local anaesthetic:** 204/806 (27%): TVT only 189/443 (46%), TVT in combination 15/363 (4%) **Spinal anaesthetic:** 404/806 (50%): TVT only 189/443 (43%), TVT in combination 215/363 (60%) **LOS:** 4 (0–37) TVT only, 7 (2–13) TVT in combination **Bladder perforation:** 35/806 (4.3%): TVT only 20/443 (45%), TVT in combination 15/363 (4%) **Bleeding:** 19/806 (2%): TVT only 11/443 (2.5%), TVT in combination 8/363 (2%)	**Mortality:** 0/806 **Reoperation rate:** 20/806 (2.5%): TVT only 10/443 (2.3%): TVT in combination 10/363 (2%)		

continued

Study	Study setting	No. of participants	Inclusion/ exclusion criteria	Mean duration of follow-up (range)	Mean age (range)	Characteristics of participants	Subjective cure rate *n/N*	Objective cure rate *n/N*	Perioperative outcomes	Other outcomes	Health status measures	Notes
Tamussino, 2001[143,144] Information from 55 gynaecology units Up to 1 May 2001	Population-based registry for all TVT operations (Austria)	2795 [1640 (59%) TVT only, 1155 (41%) TVT combined with other procedures]	**Inclusion:** NR **Exclusion:** NR Additional procedures: vaginal hysterectomy and anterior repair 460; simple hysterectomy 121; other 574.	NR	Median 60 years (28–93)	**Secondary intervention:** 773/2795 (28%) **Co-existing prolapse:** NR **Mixed incontinence:** NR	NR	NR	TVT alone **General anaesthetic:** 193/1640 (12%) **Local anaesthetic:** 727/1640 (44%) **Spinal anaesthetic:** 711/1640 (43%) **Bladder perforation:** 52/1640 (3%) **Increased bleeding:** 33/1640 (2%) **LOS:** 3 days Overall **Operating time:** 30 min (10–120) **General anaesthetic:** 684/2795 (24%) **Local anaesthetic:** 782/2795 (28%) **Spinal anaesthetic:** 1314/2795 (47%) **Bladder perforation:** Overall 75/2795 (3%); primary intervention 41/2022 (2%); secondary intervention 34/773 (4%) **Increased bleeding:** 65/2795 (2%); primary intervention 50/2022; secondary intervention 15/773 (2%) **UTI:** 17% **LOS:** 7 days	**Reoperation rate:** 68/2795 (2%) **Reasons:** Relating to tape (39 to loosen, remove or cut tape or to place suprapubic catheter); haematoma 19; bowel injury 1		

Appendix 20

Summary of included studies (systematic reviews)

Systematic reviews of colposuspension

Study	Search strategy	No. of studies/ women included	Cure rates		Operative outcomes	Later complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Black, 1996[35,145,146]	MEDLINE 1966 to 1995; EMBASE 1980 to June 1995; Science Citation Index 1980 to June 1995; British Library of Information Index 1995; experts consulted; hand searched reference lists **Included:** Randomised and non-randomised evidence **Excluded:** review articles, case series, case studies, articles on men	No. of studies: 76	95% CI 91% to 98% Primary procedures more effective than repeat procedures Benefit maintained for at least 5 years		Comparative rates with: – anterior repair (no difference); – needle suspension (no difference); – slings (fewer bladder perforations)	Comparative rates with: – anterior repair (no difference); – needle suspension (no difference); – slings significantly more episodes for residual urine, urinary retention and uterine prolapse and bladder perforation			Predetermined validated check-list for measuring study quality was used[35]

continued

Study	Search strategy	No. of studies women included	Cure rates		Operative outcomes	Later complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Chahila, 1999[147]	MEDLINE 1966 to 1997; hand searching of reference lists **Included:** Randomised and non-randomised evidence; English language only **Excluded:** Review articles, case series, case studies, articles on men	**No. of studies:** 9 **No. of women:** 816			**High blood loss:** 0.6 to 7.3% (2 studies) **Urinary tract and visceral injury:** 1.1 to 6% (3 studies) **Wound infection:** 0.5% (1 study)	***De novo* detrusor over-activity:** 14.7% to 18.4% (2 studies) **Voiding difficulty:** 16 to 25% (2 studies) **Prolapse:** 8 to 25.7% (5 studies) **Pain:** 12 to 27% (2 studies) **Dyspareunia:** 0.1 to 4% (2 studies)		**Worse general health:** 7% (1 study) **Worse mental health:** 25%	

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Operative outcomes	Later complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Dainer, 1999[148]	MEDLINE; hand searching of reference lists **Included:** Randomised and non-randomised evidence; English language only; Burch colposuspension only	**No. of studies:** Up to 17 **No. of women:** Up to 1419	*Primary procedures:* <1 year: 85.9% (17 studies) 1–2 years: 85.2% (5 studies) 2–5 years: 82.7% (11 studies) 5–12 years: 89.8% (7 studies) 10–20 years: 69% (1 study) *Secondary procedures:* <1 year: 60.6% (17 studies) 1–2 years: 62% (5 studies) 2–5 years: 66% (11 studies) 5–12 years: 82.4% (7 studies)		Not separately reported	Overall complication rate: Up to 41.2% (voiding dysfunction, detrusor over-activity, cystotomy, ureteral injury, septic sequelae, wound or urinary tract infections, haemorrhage) More serious complications include venous thrombo-embolism and vesicovaginal fistulae and enterocele *De novo* detrusor over-activity: 5 to 27%			

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Operative outcomes	Later complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Jarvis, 1994[149]	Hand search of 16 scientific journals 1970–1994 **Included:** Randomised and non-randomised evidence	**No. of women:** 1726	**All women:** 89.6% (1726 women)	**All women:** 84.3% (2300 women) **Primary operation** 89.8% (95% CI 87.6 to 92.1) **Secondary operation** 82.5% (95% CI 76.3 to 88.7)		**Pain:** Up to 12% in one study **Prolapse (new or recurrent):** 13.6% (range 2.5–26.7%) **Voiding disorder:** 12.5% (3–32%) **New detrusor over-activity:** 9.6% (4–18%)			Definition of cure strictly defined as total continence (much improved not accepted) Review limited to women with urodynamic stress incontinence only
Lapitan, 2003[150]	Incontinence Review Group Trials Register, based on MEDLINE, CINAHL, The Cochrane Controlled Trials Register and hand searching of journals and conference proceedings, up to March 2002; hand searching of reference lists; experts consulted **Included:** Randomised or quasi-randomised controlled trials only; open abdominal retropubic suspensions	**No. of trials:** 282 **No. of women:** 2403	**<1 year:** 81.8% (17 trials, 876 women) **1–5 years:** 80.4% (15 trials, 728 women) **>5 years:** 58.1% (3 trials, 93 women)	**<1 year:** 87.9% (15 trials, 767 women) **1–5 years:** 81.5% (13 trials, 616 women) **>5 years:** 67.2% (4 trials, 125 women)	**Perioperative complications:** 15% (12 trials, 347 women) **Complications inherent to procedure:** 3.1% (6 trials, 353 women)	**New urge incontinence:** 5.7% (10 trials, 387 women) **New detrusor overactivity:** 7.2% (16 trials, 712 women) **Voiding difficulty:** 5.3% (14 trials, 656 women) **Prolapse:** 13.1% (7 trials, 375 women) **Repeat incontinence surgery:** 3.3% (4 trials, 272 women)			

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Operative outcomes	Later complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Leach, 1997[151]	MEDLINE searched 1966–1994 Hand searching of reference lists **Included:** Peer-reviewed publications in English, 12 month minimum follow-up, randomised and non-randomised evidence **Excluded:** Abstract only, concomitant prolapse surgery, original data absent	**No. of studies:** 282 **No. of women:** Up to 6044	**<24 months:** 84% median (95% CI 77 to 89) (943 patients) **24–47 months:** 84% (80 to 88%) (1870 patients) **>48 months:** 84% (79 to 88) (2196 patients)		**Blood transfusions:** 5% (3–8%) **Significant intra-operative complications:** 2% (1–3%) **Not significant intra-operative complications:** 3% (1–4%) **Significant peri-operative complications:** 4% (3–5%) **Not significant peri-operative complications:** 14% (14–15%)	**Complications requiring surgery:** 2% (1–3%) **New detrusor over-activity:** 11% (8–16%) **Retention over 4 weeks:** 5% (3–7%) **Permanent retention:** <5% **Death:** similar to other elective vaginal/ abdominal surgery, 5/10,000	**LOS:** 0–5 days **Resumption of normal activities:** Typically 6 weeks		

Systematic reviews of laparosopic colposuspension

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Lose, 1998[152]	Searches of MEDLINE January 1991–January 1997; proceedings of ICS 1991–1996; hand searching of reference lists **Included:** Randomised and non-randomised evidence included; English language only; laporoscopic colposuspension only	**No. of studies:** 15	**Randomised study:** Colposuspension significantly better (1 trial) **Non-randomised studies:** 68.6–100% (95% CI 47 to 100) (4 retrospective studies)		No data reported		Faster return to normal activities (3 studies) Conversion to open operation in 6–26% (3 studies) Operative times significantly longer than open LOS shorter (4 studies)		
Moehrer, 2002[153]	Incontinence Review Group Trials Register, based on MEDLINE, CINAHL, The Cochrane Controlled Trials Register and hand searching of journals and conference proceedings, up to April 2001; hand searched reference lists; experts consulted **Included:** Randomised or quasi-randomised controlled trials only; open abdominal retropubic suspensions	**No. of trials:** 8 **No. of women:** 233	93.7% (3 trials, 175 women)	76.4% (5 trials, 229 women)	**Perioperative complications:** 6.9% (5 trials, 233 women) **Bladder perforation:** 4.8% (4 trials, 187 women)	**Voiding dysfunction:** 5.2% (3 trials, 172 women) **New detrusor overactivity:** 5.4% (4 trials, 205 women) **Repeat incontinence surgery:** 10% (1 trial, 30 women)			

continued

Systematic reviews of suburethral sling procedures

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Bezerra, 2001[30]	Incontinence Review Group Trials Register, based on MEDLINE, CINAHL, The Cochrane Controlled Trials Register and hand searching of journals and conference proceedings, up to March 2001; hand searched reference lists; experts consulted **Included:** Randomised or quasi-randomised controlled trials only; open abdominal retropubic suspensions	**No. of trials:** 7 **No. of women:** 298	**<1 year:** 81% (7 trials, 226 women) **>1 year:** 82% (4 trials, 94 women)	**<1 year:** 87% (3 trials, 45 women) **>1 year:** 86% (1 trials, 36 women)		**Complications:** 33.8% (5 trials, 228 women) **Voiding dysfunction:** 19.6% (2 trials, 46 women) **Urgency/urge incontinence:** 37.5% (4 trials, 200 women) **Detrusor over-activity:** 14.4% (6 trials, 111 women) **Prolapse:** 2.8% (1 trial, 36 women)			
Black 1996[35,145,146]	As reported for colposuspension	As reported for colposuspension	79% (95% CI 72 to 85)			Significantly more complications after slings than after colpo-suspension or anterior repair (residual urine, urinary retention, perforation of bladder and uterine prolapse)			Predetermined validated checklist for measuring study quality was used[35]

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Bidmead, 2000[154]	Searches of MEDLINE 1966–April 1999; hand searched reference lists and other relevant journals **Included:** Randomised and non-randomised evidence included; primary and secondary procedures	**No. of studies:** 31	73–93% **Primary procedure:** 90% (several studies) **Women with prolapse:** 89% cured, and 92% of prolapse (1 study)	61–100%	**Wound haematoma:** 3% **UTI:** 5%	Similar to those of other vaginal or suprapubic operations Pain and dyspareunia also reported **Voiding difficulties:** 2.2–16% (23 studies) **Long-term self-catheterisation:** 1.5–7.8% **New detrusor overactivity:** 7% (95% CI 3 to 11) (range 3–30%) (15 studies) **Sling erosion:** 1–23% (14 studies)			
Jarvis, 1994[149]	As reported for colposuspension	As reported for colposuspension	**All women:** 82.4% (1712 women)	**All women** 85.3% (720 women) **Primary operation** 93.9% (95% CI 89.2 to 98.6) **Secondary operation** 86.1% (95% CI 82.4 to 89.8)		**Postoperative wound infection:** 12% (range 4.7–48%) **Fistula following surgery:** 1% **Voiding disorder:** 10.4% (2–20%) **New detrusor overactivity:** 16.6% (4–29%)			Definition of cure strictly defined as total continence (much improved not accepted) Review limited to women with urodynamic stress incontinence only

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Leach, 1997[151]	As reported for colposuspension	As reported for colposuspension	**<24 months:** 82% median (95% CI 73 to 89) (135 women) **24–47 months:** 82% (73 to 89%) (344 women) **>48 months:** 83% (75 to 88%) (473 women)		**Blood transfusions:** 5% (3–8%) **Significant intra-operative complications:** 3% (1–6%) **Not significant intra-operative complications:** 8% (5–12%) **Significant peri-operative complications:** 7% (5–10%) **Not significant peri-operative complications:** 12% (8–17%)	**Complications requiring surgery:** 3% (2–5%) **New detrusor overactivity:** 7% (3–11%) **Retention over 4 weeks:** :85% (6–11%) **Permanent retention:** <5% **Death:** Similar to other elective vaginal/abdominal surgery, 5/10,000 **Wound infection:** 0.01%		**LOS:** 0–5 days **Resumption of normal activities:** Typically 6 weeks	

Systematic reviews of injectables

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Other outcomes	Health status measures	Notes
			Subjective	Objective					
Duckett, 1998[155]	MEDLINE search. Secondary hand search of references produced by the initial MEDLINE search **Included:** Stress urinary incontinence; injectables included autologous fat, Teflon, collagen, silicone	**No. of studies:** 64	**Autologous fat >12 months:** 33% **Teflon:** range 7–70% **Collagen:** average 40–60% (range 7–83%) **Silicone:** <1 year 60–70%; >1 year 31–60%		**UTI:** 20%	Risk of complications generally low or short-lasting **Risk of migration (highest first):** Teflon; silicone **Teflon:** Risk of particle migration **Collagen:** Risk of hypersensitivity in 3% of women **Detrusor over-activity:** Mostly rare **Dysuria:** Very common **Voiding dysfunction:** None	**Ease of injection (easiest first):** Fat/collagen; Teflon; silicone **Biodegrad-ability (best first):** Fat; collagen; Teflon; silicone **Need for pre-op allergy test:** Collagen **Cost (highest first):** Silicone; collagen; Teflon; fat		Many studies had small sample sizes, short follow-up or disparate populations Learning curve effect (cure rate improved with experience)
Jarvis, 1994[149]	As reported for colposuspension	As reported for colposuspension	**All women:** 56.4% (319 women)	**All women:** 60.2% (133 women) **Primary operation:** 45.5% (95% CI 28.5 to 62.5) **Secondary operation:** 57.8% (95% CI 43.2 to 72.4)					Definition of cure strictly defined as total continence (much improved not accepted) Review limited to women with urodynamic stress incontinence only

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Other outcomes	Health status measures	Notes
			Subjective	Objective					
Su, 1999[156]	MEDLINE search 1973–1998 **Included:** urinary incontinence; injection; female. Injectables included autologous fat, Teflon, collagen, silicone **Excluded:** Not English language	**No. of studies:** 20 **No. of women:** 982	**Overall improvement rate:** 66.5% (range 18–95) **Teflon:** all studies: 62.5% (11 studies, 467 women) >1 year 34% (18–54) (4 studies, 112 women) **Collagen:** 78% (6 studies, 445 women) >1 year 79% (48–95) (4 studies, 370 women) **Fat:** 60% (3 studies, 70 women) >1 year 63% (57–65) (2 studies, 38 women)			**Teflon:** UTI; urethral fiborsis; paraurethral abscess, urethral diverticulum; granuloma with urethral wall prolapse; migration of particles **Collagen:** *De novo* urinary urgency; expense; need for repeat injections **Fat:** Likelihood of reabsorption (30–60%); infection **Silicone:** Risk of particle migration			Cure and improvement rates reported together

Appendix 21

Directly comparative data from systematic reviews

Systematic reviews of open colposuspension vs traditional slings

Study	Search strategy	No. of studies/ women included	Cure rates		Operative complications	Later complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Black, 1996[35,145,146]	MEDLINE 1966–1995; EMBASE 1980–June 1995; Science Citation Index 1980–June 1995; British Library of Information Index 1995; experts consulted; hand searched reference lists **Included:** Randomised and non-randomised evidence included **Excluded:** Review articles, case series, case studies, articles on men	**No. of studies:** 4 prospective (2 RCTs), 12 retrospective	Cure assessed in various ways but largely on 'surgeons' subjective views' In prospective studies – no difference in cure rate. One study out of 12 retrospective studies reports a difference in cure (lower cure with sling)		Higher risk following sling in the one study that looked at perforation of bladder	Higher risk following sling in the one study that looked at complications	NR	Not reported by any included studies	Authors' conclusion: No evidence of difference in cure between slings and colposuspension but fewer than 150 patients in prospective studies

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Operative complications	Later complications	Operative care	Health status measures	Notes
			Subjective	Objective					
Lapitan, 2003[150]	Incontinence Review Group Trials Register, based on MEDLINE, CINAHL, The Cochrane Controlled Trials Register and hand searching of journals and conference proceedings, up to March 2002; hand searched reference lists; experts consulted **Included:** Randomised or quasi-randomised controlled trials only; open abdominal retropubic suspensions	**Max. no. of trials:** 282 **Max. no. of women:** 2403	**<1 year:** (2 trials; *N* = 70) RR 0.94 (95% CI 0.84 to 1.06) **1–5 years:** (1 trial, *N* = 72) RR 1.67 (95% CI 0.43 to 6.46 **>5 years:** No trials	**<1 year:** (3 trials; *N* = 98) RR 0.80 (95% CI 0.66, 0.96 **1–5 years:** (1 trial, *N* = 72) RR 0.94 (95% CI 0.80, 1.11 **>5 years:** No trials	**Perioperative complications:** (4 trials, *N* = 187) RR 1.15 (95% CI 0.42 to 3.18)	**New urge incontinence:** (1 trial, *N* = 72) RR 0.40 (95% CI 0.08 to 1.93) **New detrusor overactivity:** (1 trial, *N* = 9) RR 2.0 (95% CI 1.0 to 4.0) **Voiding difficulty:** (2 trials, *N* = 103) RR 0.17 (95% CI 0.03 to 0.94) **Prolapse:** (2 trial, *N* = 106) RR 5 (95% CI 0.9 to 27.7) **Repeat incontinence surgery:** No trials	Shorter operation time and LOS for colposuspension Operation time (1 trial, *N* = 29) WMD –6.02 min (95% CI –12.56 to 0.52) LOS (3 trials, N = 137) WMD –2.03 (95% CI –2.59 to –1.47)		Same data reported in the Cochrane review comparing slings to other procedures[30] RR less than 1 favours colposuspension

continued

Systematic reviews of open colposuspension vs laparosopic colposuspension

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Other outcomes	Health status measures	Notes
			Subjective	Objective					
Lose, 1998[152]	Searches of MEDLINE January 1991–January 1997; proceedings of ICS 1991 to 1996; hand searched reference lists **Included:** Randomised and non-randomised evidence included; English language only; laporoscopic colposuspension only	**No. of studies:** 1 RCT, 4 non-randomised comparative studies	<1 year: RCT colposuspension signficantly better (1 trial, $N = 60$) ($p = 0.03$) [open 97% (95% CI 83 100); lap 73%] **Non-randomised studies:** No difference identified in individual studies. Pooled rates not reported		Comparative data not reported	Comparative data not reported	Pooled data not reported Laparoscopic converted to open operation in 6 to 26% (3 studies) Operative times significantly longer than open operations (2 non-RCTs) LOS shorter in laparoscopic (4 non-RCTs)	Faster return to normal activities (3 studies)	

continued

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Other outcomes	Health status measures	Notes
			Subjective	Objective					
Moehrer, 2002[153]	Incontinence Review Group Trials Register, based on MEDLINE, CINAHL, The Cochrane Controlled Trials Register and hand searching of journals and conference proceedings, up to April 2001; hand searched reference lists; experts consulted **Included:** Randomised or quasi-randomised controlled trials only; open abdominal retropubic	suspensions	**No. of trials:** 8 **No. of women:** 233	<1.5 year: (3 trials, *N* = 365) RR 1.00 (95% CI 0.95 to 1.06)	<1.5year: (5 trials, *N* = 477) RR 0.89 (95% CI 0.82, 0.98) significant difference favouring open colposuspension	**Perioperative complications:** (5 trials, 487 women) RR 1.16 (95% CI 0.59 to 2.29) **Bladder perforation:** (4 trials, 395 women) RR 3.02 (95% CI 0.90 to 10.11)	New detrusor overactivity (4 trials, *N* = 425) 0.92 (95% CI 0.43 to 1.98)	**Voiding dysfunction:** (3 trials, 352 women) RR 0.96 (95% CI 0.41 to 2.24) **Repeat incontinence surgery:** (1 trial, 60 women) RR 7.00 (95% CI 0.38 to 129.93)	

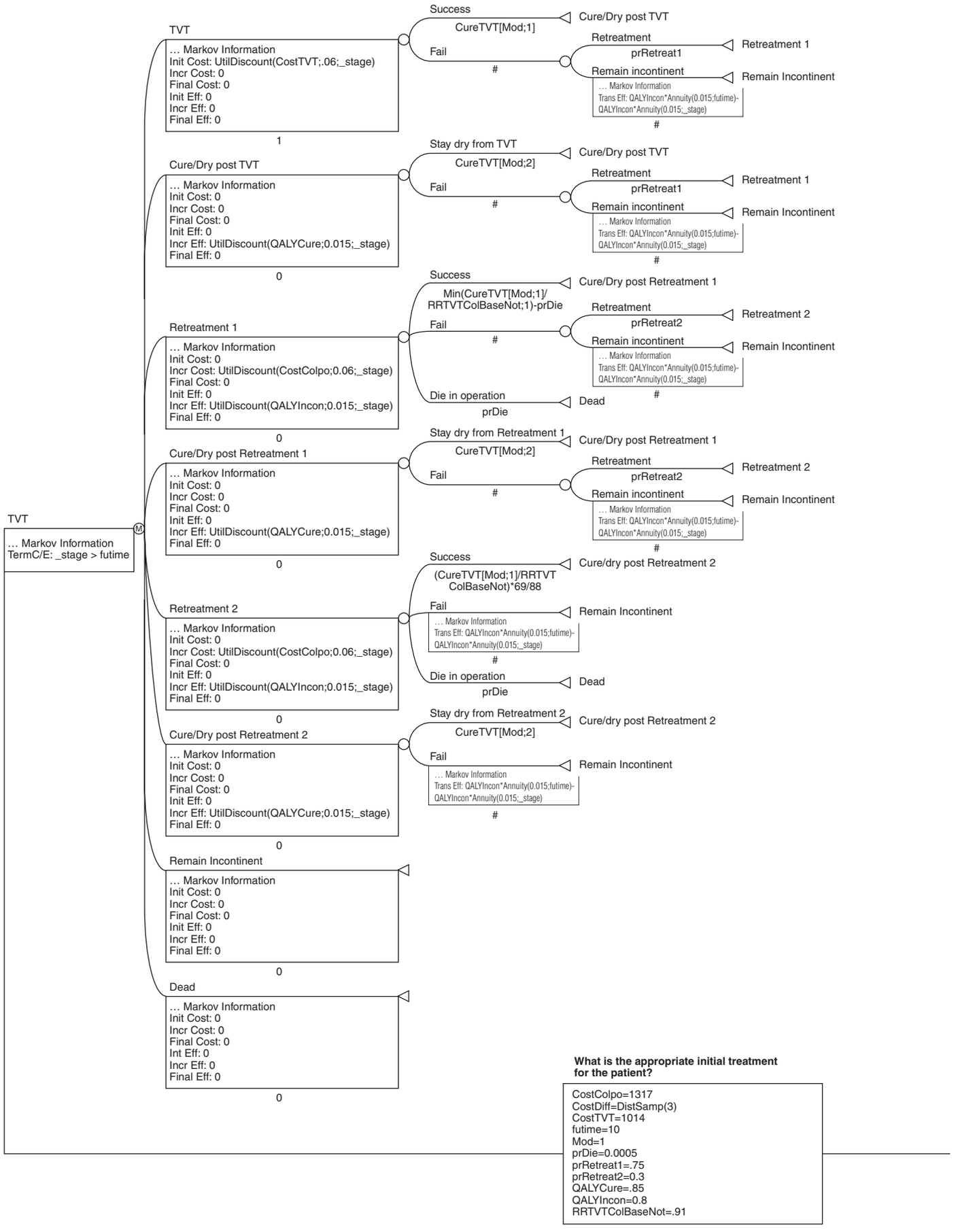
continued

Systematic reviews of colposuspension vs injectables

Study	Search strategy	No. of studies/ women included	Cure rates		Perioperative outcomes	Complications	Other outcomes	Health status measures	Notes
			Subjective	Objective					
Lapitan, 2003[150]	Incontinence Review Group Trials Register, based on MEDLINE, CINAHL, The Cochrane Controlled Trials Register and hand searching of journals and conference proceedings, up to March 2002; hand searched reference lists; experts consulted **Included:** Randomised or quasi-randomised controlled trials only; open abdominal retropubic suspensions	**Max. no. of trials:** 282 1 trial comparison with injectables (67 collagen, 67 surgery, 2 refused collagen and 13 refused) **Max. no. of women:** 2403	Higher cure rates at 1 year with colposuspension RR 1.36 (95% CI 1.02 to 1.8)	Not reported	Not reported	36 events for collagen, 84 for surgery ($p = 0.003$)	Not reported	No difference in 7 of the 8 domains of SF-36 No statistical difference in disease specific IIQ	1 trial reported as an abstract only

Appendix 22

Structure of the economic model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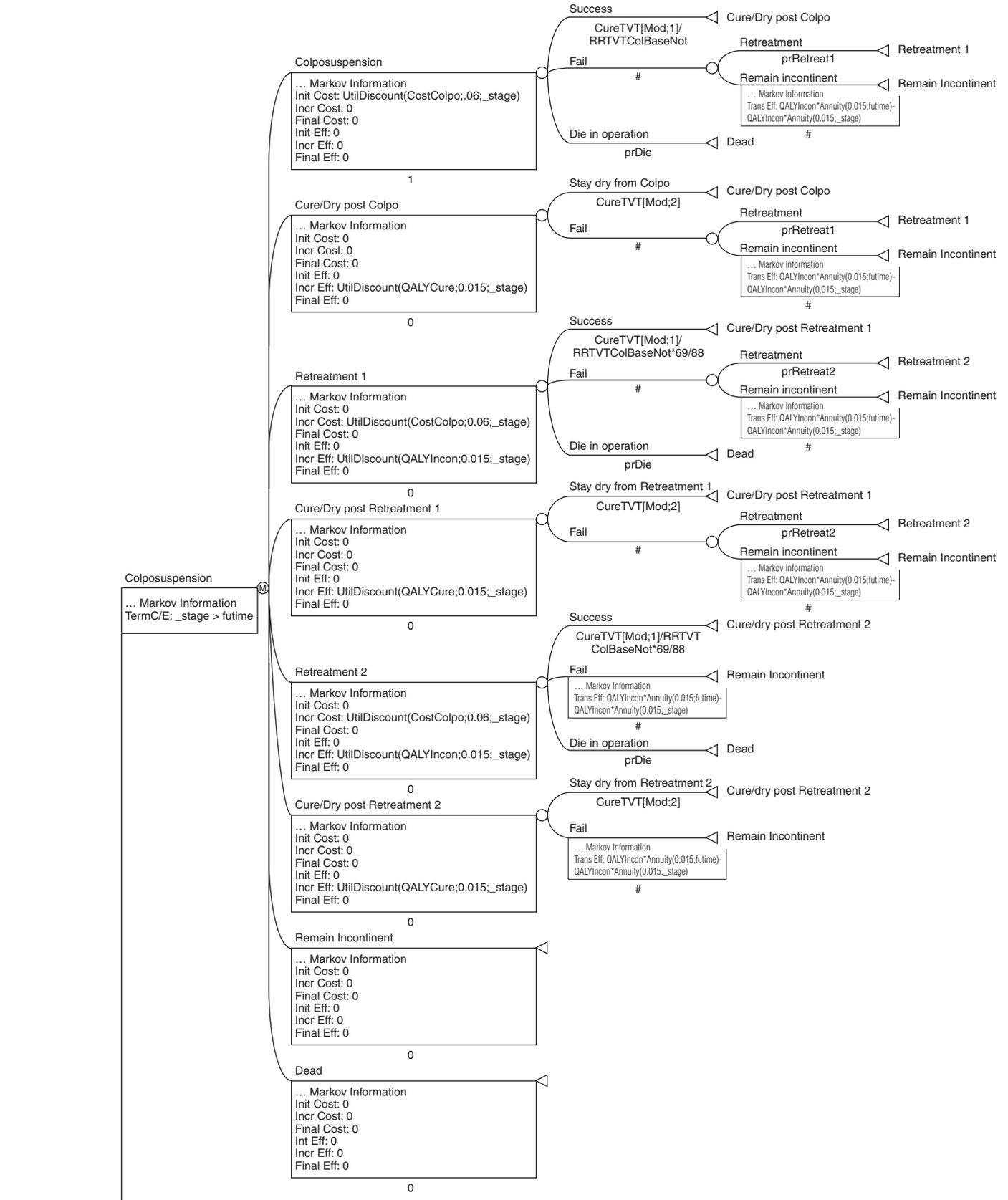
… Markov Information
TermC/E: _stage > futime
M
TVT
… Markov Information
Init Cost: UtilDiscount(CostTVT;.06;_stage)
Incr Cost: 0
Final Cost: 0
Init Eff: 0
Incr Eff: 0
Final Eff: 0
1
Success
CureTVT[Mod;1]
Cure/Dry post TVT
Fail
#
Retreatment
prRetreat1
Retreatment 1
Remain incontinent
Remain Incontinent
… Markov Information
Trans Eff: QALYIncon*Annuity(0.015;futime)-
QALYIncon*Annuity(0.015;_stage)
#
Cure/Dry post TVT
… Markov Information
Init Cost: 0
Incr Cost: 0
Final Cost: 0
Init Eff: 0
Incr Eff: UtilDiscount(QALYCure;0.015;_stage)
Final Eff: 0
0
Stay dry from TVT
CureTVT[Mod;2]
Cure/Dry post TVT
Fail
#
Retreatment
prRetreat1
Retreatment 1
Remain incontinent
Remain Incontinent
… Markov Information
Trans Eff: QALYIncon*Annuity(0.015;futime)-
QALYIncon*Annuity(0.015;_stage)
#
Retreatment 1
… Markov Information
Init Cost: 0
Incr Cost: UtilDiscount(CostColpo;0.06;_stage)
Final Cost: 0
Init Eff: 0
Incr Eff: UtilDiscount(QALYIncon;0.015;_stage)
Final Eff: 0
0
Success
Min(CureTVT[Mod;1]/
RRTVTColBaseNot;1)-prDie
Cure/Dry post Retreatment 1
Fail
#
Retreatment
prRetreat2
Retreatment 2
Remain incontinent
Remain Incontinent
… Markov Information
Trans Eff: QALYIncon*Annuity(0.015;futime)-
QALYIncon*Annuity(0.015;_stage)
#
Die in operation
prDie
Dead
Cure/Dry post Retreatment 1
… Markov Information
Init Cost: 0
Incr Cost: 0
Final Cost: 0
Init Eff: 0
Incr Eff: UtilDiscount(QALYCure;0.015;_stage)
Final Eff: 0
0
Stay dry from Retreatment 1
CureTVT[Mod;2]
Cure/Dry post Retreatment 1
Fail
#
Retreatment
prRetreat2
Retreatment 2
Remain incontinent
Remain Incontinent
… Markov Information
Trans Eff: QALYIncon*Annuity(0.015;futime)-
QALYIncon*Annuity(0.015;_stage)
#
Retreatment 2
… Markov Information
Init Cost: 0
Incr Cost: UtilDiscount(CostColpo;0.06;_stage)
Final Cost: 0
Init Eff: 0
Incr Eff: UtilDiscount(QALYIncon;0.015;_stage)
Final Eff: 0
0
Success
(CureTVT[Mod;1]/RRTVT
ColBaseNot)*69/88
Cure/dry post Retreatment 2
Fail
… Markov Information
Trans Eff: QALYIncon*Annuity(0.015;futime)-
QALYIncon*Annuity(0.015;_stage)
#
Remain Incontinent
Die in operation
prDie
Dead
Cure/Dry post Retreatment 2
… Markov Information
Init Cost: 0
Incr Cost: 0
Final Cost: 0
Init Eff: 0
Incr Eff: UtilDiscount(QALYCure;0.015;_stage)
Final Eff: 0
0
Stay dry from Retreatment 2
CureTVT[Mod;2]
Cure/dry post Retreatment 2
Fail
… Markov Information
Trans Eff: QALYIncon*Annuity(0.015;futime)-
QALYIncon*Annuity(0.015;_stage)
#
Remain Incontinent
Remain Incontinent
… Markov Information
Init Cost: 0
Incr Cost: 0
Final Cost: 0
Init Eff: 0
Incr Eff: 0
Final Eff: 0
0
Dead
… Markov Information
Init Cost: 0
Incr Cost: 0
Final Cost: 0
Int Eff: 0
Incr Eff: 0
Final Eff: 0
0
What is the appropriate initial treatment
for the patient?
CostColpo=1317
CostDiff=DistSamp(3)
CostTVT=1014
futime=10
Mod=1
prDie=0.0005
prRetreat1=.75
prRetreat2=0.3
QALYCure=.85
QALYIncon=0.8
RRTVTColBaseNot=.91



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We look forward to hearing from you.

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