Variation in availability and use of surgical care for female urinary incontinence: a mixed-methods study

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Scientific summary

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Scientific summary

Background

Urinary incontinence is the involuntary loss of urine and includes subtypes with different underlying aetiologies. Stress urinary incontinence is defined as the loss of urine on physical exertion, sneezing or coughing. Other subtypes of urinary incontinence are associated with urgency to urinate (i.e. urgency urinary incontinence) or symptoms such as increased frequency and nocturia (i.e. overactive bladder). Between 25% and 45% of adult women are affected by urinary incontinence, which has a negative impact on their quality of life. Over the last two decades there has been an aspiration to shift services for women with urinary incontinence from secondary to primary care. At the same time, it is unclear whether or not the current level of provision of surgical services for urinary incontinence is appropriate.

This project started in June 2016, just after discussions began about problems that some women had experienced after insertion of a mid-urethral mesh tape for stress urinary incontinence, including pain, dyspareunia, persistent urinary incontinence and mesh exposure or erosion. During the first 2 years of the project, mid-urethral mesh tape surgery, then the most common surgical treatment for stress urinary incontinence, continued in the English NHS, but the need for a multidisciplinary approach and better information for women considering whether or not to undergo stress urinary incontinence surgery was highlighted. In response to this, an additional objective was added to this project, that is, to explore long-term removal and reoperation rates after mid-urethral mesh tape insertion for stress urinary incontinence. The routine use of mid-urethral mesh tape surgery as a treatment for stress urinary incontinence was then 'paused' by NHS England in July 2018, following recommendations by an independent review [*The Independent Medicines and Medical Devices Safety Review*. 2018. URL: www.immdsreview.org.uk (accessed 19 May 2020)] that had engaged with patients and patient groups about long-term complications. For some patients, mid-urethral mesh tape procedures may remain the only viable treatment option, but the review recommends that they should be used only in selected patients who fully understand the risks and have given informed consent.

Aim and objectives

The aim of the project was to inform and improve the delivery and organisation of surgical services for women with urinary incontinence. The project assessed the availability and use of surgical services for urinary incontinence across England and identified factors that explained the observed variation in use of surgery (including the impact of patients' experiences and expectations, clinicians' judgement, and organisational and contextual factors).

The project analysed existing primary and secondary care administrative data sets and additional data collected from women with urinary incontinence (in interviews) and from clinicians (using an online case vignette survey).

The four objectives of the project were captured in five work packages:

- Objective 1: methods development –
    - to develop a coding framework for urinary incontinence diagnoses and treatments allowing for divergent coding practices among providers (work package 1).

- Objective 2: availability and delivery of services –
  - to assess determinants of geographical variation in the rate of surgery for urinary incontinence (work package 2).
- Objective 3: understanding patients' experiences and expectations –
  - to collect women's own accounts of the impact of urinary incontinence on their lives, and their experiences and expectations of surgical and non-surgical treatments and outcomes, including the many different values that women draw on (work package 3).
- Objective 4: understanding the determinants of referral and surgical treatment –
  - to identify determinants of outpatient referrals and surgery, using a linked primary–secondary care data set (work package 4).
  - to explore the relative importance of specific patient characteristics for clinicians in their decisions about recommending surgery, using case vignettes (work package 5).

Given the changing context of stress urinary incontinence surgery, which eventually led to a 'pause' in mid-urethral mesh tape surgery in the English NHS, additional research was conducted on long-term rates of mesh tape removal and reoperation (work package 6).

Methods

To address work packages 1, 2, 4 and 6, existing primary and secondary care administrative data sets were used. The Hospital Episode Statistics (work packages 1, 2 and 6) database contains records of all inpatient episodes of care in English NHS hospitals (secondary care), with unique patient identifiers allowing the study of longitudinal patterns of care. Diagnostic information is captured using the *International Classification of Diseases*, Tenth Revision, codes and procedures using the Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4, codes. The Clinical Practice Research Datalink (work packages 1 and 4) contains anonymised patient data from > 600 general practices, covering a representative sample of 9% of the UK population (primary care). Diagnostic and treatment information are captured using Read codes. A subset of the Clinical Practice Research Datalink data set has been linked to Hospital Episode Statistics; this linked data set was also used in work package 4.

The consistency, completeness and accuracy of diagnostic and procedure codes relevant for urinary incontinence were assessed in Hospital Episode Statistics and the Clinical Practice Research Datalink. A coding framework was developed allowing for divergent coding practices based on a stepwise 'forward' and 'backward' coding strategy (work package 1).

Multilevel poisson regression models were used to analyse Hospital Episode Statistics data to produce estimates of stress urinary incontinence surgery rates in the 209 Clinical Commissioning Groups and 44 Sustainability and Transformation Partnership areas in England, adjusted for age, socioeconomic deprivation, ethnicity and long-term illness (work package 2).

Semistructured interviews were carried out with women who had urinary incontinence (who were aged > 18 years with no previous urological surgery). The women were purposively sampled from four English urogynaecology outpatient clinics. Transcripts were analysed using a constant comparative method (work package 3).

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Multivariable logistic regression and competing risk survival analysis were used to identify factors associated with referral to secondary care (using Clinical Practice Research Datalink data on their own) and surgical treatment (using Clinical Practice Research Datalink data linked to Hospital Episode Statistics) (work package 4).

An online survey of 18 clinical case vignettes (hypothetical 'paper' patients) was sent to gynaecologists in the UK with a special interest in urogynaecology. The vignettes described patients based on seven clinical characteristics. Gynaecologists indicated how likely they would be to recommend surgery on a five-point Likert scale. Latent class analysis was used to distinguish groups of gynaecologists according to their recommendations (work package 5).

A cohort study using Hospital Episode Statistics data identified all women (aged > 18 years) who had a first-ever mid-urethral mesh tape insertion for stress urinary incontinence between 2006 and 2015. Competing risk survival analysis was used to assess the risk of mid-urethral mesh tape removal (partial/total), reoperation for stress urinary incontinence and any reoperation (i.e. mid-urethral mesh tape removal or reoperation for stress urinary incontinence) (work package 6).

Results

Work package 1

The coding frameworks developed in this work package were used to define cohorts, procedures and outcomes in work packages 2, 4 and 6.

Work package 2

The study of the determinants of geographical variation in the rate of stress urinary incontinence surgery found 27,997 inpatient episodes with a first procedure for stress urinary incontinence between April 2013 and March 2016. The rate of stress urinary incontinence surgery was 40 procedures per 100,000 women per year. There was substantial geographical variation in the surgery rate. Adjusted rates varied from 20 to 106 procedures per 100,000 women per year between Clinical Commissioning Groups and from 24 to 69 procedures per 100,000 women per year between Sustainability and Transformation Partnerships. Annual stress urinary incontinence surgery rates declined from 52 per 100,000 women in 2013 to 36 per 100,000 women in 2015, but geographical variation remained stable. This evidence suggests that women with urinary incontinence in some areas are more likely to be treated surgically than women in other areas.

Work package 3

Interviews with 28 women demonstrated that women's decision-making centred on perceptions of the severity of their urinary incontinence and the seriousness, or risk, of surgery. Women assessed urinary incontinence severity according to their individual circumstances, rather than criteria such as frequency or quantity of leakage, moving the concept of 'severity' beyond commonly used medical definitions to what is important to them. Decision-making around urinary incontinence surgery appeared to be based on multiple criteria, which often changed in priority over time; decisions were rarely made conclusively. Women made sense of evidence in the light of their own experiences and those of others.

Work package 4

The study of the determinants of referral for any type of urinary incontinence identified 104,466 women who were newly diagnosed with urinary incontinence in primary care in the UK between April 2004 and March 2014 (using Clinical Practice Research Datalink data). Almost half (45.8%) of these women were referred to secondary care within 9 years after their visit and 59.5% of those women were referred within 30 days. The 30-day referral rates were lower for women who were older, from a minority ethnic background, underweight (i.e. with a body mass index of < 20 kg/m^2), or severely obese (i.e. with a body mass index of ≥ 40 kg/m^2). The study of the determinants of surgery for urinary incontinence identified 30,312 women who had been referred for urinary incontinence

(using Clinical Practice Research Datalink–mid-urethral mesh tape-linked data). In total, 7.3% of women underwent a urinary incontinence procedure within 1 year of referral, 15.5% within 5 years and 18.1% within 9 years. As with rate of referrals, the surgery rate among women referred was lower for women who were older, from a minority ethnic background, underweight or severely obese.

Work package 5

The analysis of the responses to case vignettes of 245 gynaecologists with a special interest in urogynaecology showed that the type of urinary incontinence (i.e. stress urinary incontinence, stress-predominant or mixed urinary incontinence) was the most important factor in decisions to recommend surgical treatment, followed by previous stress urinary incontinence surgery (i.e. none, bladder neck injection, mid-urethral mesh tape). Five groups of gynaecologists whose practice style differed mainly with respect to their mean recommendation score could be distinguished [mean recommendation scores ranging from 1.25 to 4.04 on a scale with a minimum of 1 ('certainly yes') and a maximum of 5 ('certainly not')].

Work package 6

The cohort study of women with a first mid-urethral mesh tape insertion included 60,194 women with a retropubic insertion and 34,683 with a transobturator insertion. The 9-year removal rate was 3.6% after a retropubic insertion and 2.7% after a transobturator insertion. The 9-year rate of any reoperation, including mesh tape removal, was 4.1% after a retropubic insertion and 5.3% after a transobturator insertion.

Conclusions

First, there was substantial geographical variation in the use of surgery for stress urinary incontinence in the NHS in England, suggesting that women in some areas are more likely to have surgical treatment than women in other areas. The variation is likely to reflect differences in how national guidelines were being interpreted before the 'pause' in mid-urethral mesh tape surgery in the NHS. This geographical variation is mirrored in the finding that there are groups of gynaecologists with different practice styles; mainly their average inclination was to recommend surgery, which seems to correspond to uncertainty about safety and effectiveness of stress urinary incontinence surgery.

Second, the rate of referral from primary to secondary care of women diagnosed with urinary incontinence was high. About one-quarter of women were referred within 30 days of the first primary care record of a urinary incontinence diagnosis. Approximately one in six referred women underwent urinary incontinence surgery within 5 years of referral.

Third, many women with urinary incontinence were referred to secondary care soon after they had discussed their urinary incontinence problems with their general practitioner for the first time, which demonstrates that the involvement of primary care in providing treatment for women with urinary incontinence is limited. As a consequence, for many women, the management of their urinary incontinence is co-ordinated in a secondary care setting.

Fourth, women who had been referred to secondary care and were making decisions about whether or not to have surgery did not assess the severity of their urinary incontinence only by the quantity and frequency of leakage; they considered a broader set of criteria, informed by the impact their urinary incontinence had on their daily lives.

Fifth, within 9 years of a mid-urethral mesh tape insertion, 3.3% of women had undergone a removal procedure, 4.5% had undergone a reoperation for stress urinary incontinence and 6.9% had undergone any reoperation (mesh tape removal and/or reoperation for stress urinary incontinence). Removal rates were lower following transobturator insertions than following retropubic insertions. These findings

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may guide women and surgeons when making decisions about surgical treatment of stress urinary incontinence. However, this study reported only on women who underwent a surgical intervention after mid-urethral mesh tape insertion and did not capture problems that did not lead to surgery.

In summary, the findings suggest that there are potential deficiencies along the whole care pathway for women with urinary incontinence:

- The substantial variation in the use of surgery for urinary incontinence, and in the inclination of gynaecologists to recommend surgical treatment, suggests that there is uncertainty about indications for surgical treatment.
- The high referral rate soon after urinary incontinence is first recorded in primary care indicates that the contribution of primary care in the care of women with urinary incontinence is relatively limited.
- Women's decisions about whether or not to have surgery are based on their personal circumstances and can change over time under the influence of a wide range of factors, whereas clinicians may often focus on more objective measures of severity, such as the quantity and frequency of leakage, which may not reflect women's priorities.

Recommendations for future research

Our research highlights a number of unanswered questions.

First, a national registry of mesh and non-mesh urinary incontinence procedures is being established [National Institute for Health and Care Excellence (NICE). *Collecting Data on Surgery and Surgical Complications*. London: NICE; 2019. URL: www.nice.org.uk/guidance/ng123/chapter/Recommendations#collecting-data-on-surgery-and-surgical-complications (accessed 19 May 2020)]. However, it is important that this registry collects information from women that reflects their concerns, both before and after treatment. This will allow a comparison of all available treatment options using measures that are meaningful to women. These data would also allow future research to explore whether or not patient-reported urinary incontinence severity explains observed variation in referrals and surgery.

Second, research on outcomes of mid-urethral mesh tape surgery has been limited by the procedure codes available; those available for this research (i.e. Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4.7) do not distinguish between partial and total mesh tape removals after transobturator mid-urethral mesh tape insertions. Future research using Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4.8, procedure codes (which have been in use since August 2017) can compare total and partial removal rates between transobturator and retropubic mid-urethral mesh tape insertions.

Third, the observed geographic variation in stress urinary incontinence surgery rates and in gynaecologists' average inclination to recommend surgery, need further exploration. A first step will be to understand for which patients the benefits of surgical treatment outweigh the risks. The national registry described above may be able to provide parameters for modelling quality-adjusted life-years following the available treatment options for women with specific clinical profiles, if the registry collects patient-reported data on urinary incontinence severity and outcomes.

Fourth, our research demonstrates that a relatively large proportion of women were referred to secondary care soon after their urinary incontinence was first recorded. Future research should focus on how better assessment (e.g. history taking, symptom scoring, quality-of-life assessment and physical examination), as well as conservative management (e.g. lifestyle interventions and pelvic floor muscle training) in primary care could reduce the number of women referred to secondary care without negatively affecting outcomes.

Fifth, the National Institute for Health and Care Excellence has recently produced a patient decision aid for women considering stress urinary incontinence surgery [National Institute for Health and Care Excellence (NICE). *Urinary Incontinence and Pelvic Organ Prolapse in Women: Management (NG123)*. London: NICE; 2019. https://doi.org/10.1111/bju.14763]. This patient decision aid provides descriptions of the surgical options, information about short- and long-term outcomes, graphical representations of risk and a chart to help women explore their feelings about the options. However, our interviews with women demonstrated that their decisions are informed not only by quantitative information about possible outcomes but also by their individual circumstances. Future research should explore how decision aids can best support women, acknowledging that decisions are rarely conclusive and that women's priorities can change over time.

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