LONG-TERM RATE OF MESH SLING REMOVAL FOLLOWING MID-URETHRAL MESH SLING INSERTION AMONG WOMEN WITH STRESS URINARY INCONTINENCE

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KEY POINTS

Question

What are the long-term mesh removal rates following mid-urethral mesh sling insertion among women with stress urinary incontinence?

Findings

In this retrospective cohort study that included 95,057 women who underwent mid-urethral mesh sling insertion for stress urinary incontinence, the rate of sling removal was 3.3% at 9 years.

Meaning

These findings may inform decision making when choosing treatment for stress urinary incontinence.

52 **ABSTRACT**

53 **Importance**

54 There is concern about outcomes of mid-urethral mesh sling insertion for women with stress urinary
55 incontinence. However, there is little evidence on long-term outcomes.

56 **Objective**

57 To examine long-term mesh removal and reoperation rates in women who had a mid-urethral mesh
58 sling insertion for stress urinary incontinence.

59 **Design and participants**

60 Population based retrospective cohort study including 95,057 women aged 18 or older who had a
61 first-ever mid-urethral mesh sling insertion for SUI in the National Health Service hospitals in
62 England between 1 April 2006 and 31 December 2015. Women were followed up until 1 April 2016.

63 **Exposures**

64 Patient and hospital factors and retropubic or transobturator mesh sling insertions.

65 **Main Outcomes**

66 Primary outcome was the risk of mid-urethral mesh sling removal (partial or total) and secondary
67 outcomes were reoperation for stress urinary incontinence, and any reoperation including mesh
68 removal, calculated with death as competing risk. A multivariable Fine-Gray model was used to
69 calculate subdistribution hazard rations (sdHR) as estimates of relative risk.

70 **Results**

71 The study population consisted of 95,057 women (median age, 51 years, IQR, 44-61 years) with first
72 mid-urethral mesh sling insertion, including 60,194 with retropubic insertion and 34,863 with
73 transobturator insertion. Median follow-up time was 5.5 years (IQR 3.2-7.5 years). Rate of mid-
74 urethral mesh sling removal was 1.4% (95% CI 1.3%-1.4%) at one year, 2.8% (2.7%-2.9%) at five
75 years and 3.3% (3.2%-3.4%) at nine years. Risk of removal declined with age. The 9-year removal
76 risk after transobturator insertion (2.7%; 2.5%-2.9%) was lower risk than after retropubic insertion
77 (3.6%; 3.5%-3.8%; sdHR 0.72, 0.62-0.84). Rate of reoperation for stress urinary incontinence was
78 1.3% (95% CI: 1.3%-1.4%) at one year, 3.5% (95% CI: 3.4%-3.6%) at five years, and 4.5% (95% CI:

4.4%-4.6%) at nine years. Rate of any reoperation including mesh removal was 2.7% (2.6%-2.8%) at one year, 5.5% (5.4%-5.7%) at five years and 6.9% (6.7%-7.1%) at nine years.

Conclusions and Relevance:

Among women undergoing mid-urethral mesh sling insertion, the rate of mesh sling removal at 9 years was estimated as 3.3%. These findings may guide women and their surgeons when making decisions about surgical treatment of stress urinary incontinence.

INTRODUCTION

Stress urinary incontinence (SUI) affects approximately one in three women over the age of 18 at some point in their lives, with substantial effects on quality of life.[1,2] It has recently been estimated that a woman who is currently 18 years old has a 14% chance to undergo surgery for SUI during her lifetime, based on claims data covering a period between 2002 and 2011 in the USA.[3] Synthetic mid-urethral mesh sling insertion (MUS) was developed as a less invasive alternative to major abdominal surgery for SUI and its use is supported by professional bodies.[4-7] In 2010, based on industry estimates, approximately 250,000 MUS operations for SUI were performed in the USA.[8]

There is concern about problems that some women experience following MUS insertion, including pain, dyspareunia, persistent urinary incontinence, and exposure or erosion.[9,10] However, there is little randomized clinical trial evidence on these longer term outcomes.[1]

Recent evidence from routine practice in Scotland (1997-2016) and England (2007-2015) suggests about 10% of women who had MUS inserted were admitted for a complication (combining those related to heamorrahage, infection, pain and mesh removal) within five years, with 5% undergoing further continence surgery.[11,12] Reviews of urogynecologic mesh conducted by the Food and Drug Administration in the USA, the Scottish government and the English National Health Service[13-15] concluded that complications are 'not rare' and that there is insufficient evidence on longer term outcomes.[8,14] The continued use of MUS for SUI was recommended but only with improved communication to patients of the risks and benefits of mesh and non-mesh procedures.

This study aimed to examine the long-term mesh removal and reoperation rates in women who had a MUS insertion for stress urinary incontinence. The study used administrative hospital data to identify all women who had a first MUS insertion for SUI in English National Health Service (NHS) hospitals between 2006 and 2016, and followed them up for up to 10 years.

METHODS

The use of the Hospital Episode Statistics (HES) data for the purpose of national clinical audits and and evaluations of care delivered by the NHS was approved by the Confidentiality Advisory Group of the NHS Health Research Authority (15/CAG/0148).

Study design

This study is a national population-based retrospective cohort study using HES data. HES contains records of all inpatient admissions to NHS hospitals in England[16], with data on patient demographics (age, sex and ethnicity), the admission (date of admission and discharge) and clinical information. Diagnostic information is coded using the International Classification of Diseases, 10th revision (ICD-10).[17] Operative procedures are described using the UK Office for Population Censuses and Surveys classification, 4th revision (OPCS-4).[18] It has been demonstrated that the accuracy of HES data is sufficiently robust to support their use for research and managerial decision-making.[19]

All women aged 18 years or older who underwent a MUS insertion procedure for SUI for the first time between 1 April 2006 and 31 December 2015 were identified. SUI was defined by the ICD-10 code N39.3. Mesh sling insertions were defined by the OPCS-4 codes M53.3 (introduction of tension-free vaginal tape) and M53.6 (introduction of transobturator tape). These codes to identify retropubic and transobturator mesh sling insertions were introduced in April 2006, the start of the study period, and formed the coding standards in HES for the duration of the study. The procedure was considered to be a first-ever mesh sling insertion ('initial' procedure) if there was no record of a mesh sling procedure in the preceding three years. Follow-up was from date of initial procedure to date of a mesh sling removal, reoperation, or to the end of the follow-up period (31 March 2016), whichever was earlier. As a consequence, the minimum follow-up period was three months and the maximum 10 years.

Outcomes

The primary outcome, 'mesh sling removal following the initial insertion', was defined as total or partial removal of retropubic mesh sling insertion (OPCS-4 codes M53.4 and M53.5) or removal of a transobturator insertion (OPCS-4 code M53.7). Further definitions of codes can be found in eTable 1. Due to coding limitations, it was not possible to distinguish partial and total removals following transobturator insertions. The secondary outcomes, 'reoperation for SUI' was defined as a further SUI procedure (OPCS-4 codes in eTable 1), and 'any reoperation' included both mesh removals and reoperation for SUI. The OPCS -4 codes used to identify the outcomes (MUS removal and reoperation for SUI) were used in HES throughout the study period.

Patient factors

Data on patient factors were extracted from HES: age at initial procedure date, Index of Multiple Deprivation (IMD), an area-based measure of economic deprivation based on postcode of residence at the time of the initial procedure[20], grouped into quintiles according to the national distribution, ethnic background (white, Asian/Asian-British, black/black-British, or other based on ethnicity information specified by the patients), number of comorbidities (defined using the RCS Charlson Comorbidity Index[21], grouped as 0 or 1 or more), route of mesh sling insertion (retropubic or transobturator), previous non-mesh SUI procedures in the preceding thre years and concurrent prolapse operations (defined using codes listed in eTable 2) in the same episode of care as the initial MUS insertion for SUI. Ethnicity is considered in this study because previous studies have suggested that there are variations in care for women with SUI from different ethnic and socio-economic backgrounds.[22] In hospital settings, guidelines state that ethnicity should be self-reported by patients wherever possible, with assistance from relatives, interpreters or advocates as required.[23] The groupings of the 2001 Census are used.

Organisational factors

Two organisational factors related the hospital where the initial procedure was carried out were also extracted from HES: the number of MUS insertions performed at the year of initial operation (annual

'volume'; OPCS-4 codes: M53.6 or M53.3); and the hospitals' status as a specialist urogynecology unit according to whether they were accredited by the British Society of Urogynaecology unit at any point in time during the inclusion period.[24]

Statistical analyses

The cumulative incidence function was used to estimate removal and reoperation risk as a function of time from the initial procedure to first mesh sling removal or first reoperation with death as a competing event and patients reaching the end of the follow-up period as censoring event.[25] Because the primary interest of this study was in the absolute risk of mesh sling removal and reoperation to support medical decision, we used a multivariable Fine-Gray model to estimate subdistribution hazard ratios (sdHR) to assess the association between patient and organisational factors and the risk of removal or reoperation and or mesh removal, with robust standard errors to account for within-hospital homogeneity in outcomes.[26] A sdHR of 1 implies no association, a sdHR < 1 a decrease of the risk compared to the reference category, and a sdHR > 1 an increase. We tested whether the assumption of proportional subhazards was met by inspecting the cumulative incidence as a function of time for the categories of each of the patient and organisational factors. We also reran the competing risk regression analysis, including time interactions separately for each of the patient and organisational factors.

Multiple imputation was used to deal with missing values for ethnicity with statistical coefficients obtained from 10 imputed datasets, pooled using Rubin's rules.[27] Estimates are reported with 95% confidence intervals (CI). Wald tests were used to test whether the association of patient and organisational factors with removal or reoperation risks were statistically significant. All reported p values were 2-sided and 0.05 was used as the significance level. All statistical calculations were performed using Stata 14.[28] To assess whether the results were robust to coding changes introduced in 2006, regression analyses were repeated in two separate sensitivity analyses, first, starting the study period one year later, on 1 April 2007 (rather than 2006), and second, including the previous coding standards to identify procedures.

RESULTS

112,152 women were identified as having undergone a first MUS insertion (Figure 1) between 1 April 2006 and 31 December 2015. 17,095 patients were excluded because they were not resident in England, did not have a diagnostic code indicating SUI, or had been treated as private patients (many NHS hospitals have private wards where private patients may use the services of the hospital provider)[29]. Of the included 95,057 women, 60,194 (63.3%) had a retropubic and 34,863 (36.7%) a transobturator insertion and they were all followed up until the end of the follow-up period. Median follow up time was 5.5 years for women who did not have a mesh sling removal and who were alive at the end of follow-up (interquartile range 3.2 and 7.5 years). The median follow-up times for women who had retropubic and transobturator insertion were 5.4 years (IQR 3.1-7.6 years) and 5.6 years (IQR 3.4-7.5 years) respectively. The women's median age was 51 years (IQR 44-61 years), and 19.8% had one or more comorbidities. 18.1% had a concurrent prolapse operation in the same episode as their MUS insertion (Table 1).

Mesh sling removal

Mesh sling was removed in 1.4% (95% CI: 1.3%-1.4%) of the women at one year, in 2.7% (95% CI: 2.6%-2.8%) at five years, and in 3.3% (95% CI: 3.2%-3.4%) at nine years after the initial insertion, accounting for the competing risk of death (Table 1 and Figure 2). The risk of removal was higher (at all time points) in women who had a retropubic insertion than in those who had a transobturator insertion (3.6% compared to 2.7% at nine years after insertion, Table 1, Figure 3). This difference remained after adjusting for other risk factors (sdHR for transobturator insertion: 0.72, 95% CI: 0.62-0.84). The risk of mesh sling removal decreased with age (4.4% for women 18-39 years compared to 2.1% for women over 70 years of age at nine years after insertion, sdHR 0.46, 95% CI: 0.38-0.56) (Table 1). We did not find an indication that the assumption of proportional subhazards was violated, except for the route of mesh sling insertion variable. While a visual inspection of Figure 3 does not suggest violation of the assumption, the competing risk regression with a time varying component for

route of mesh sling insertion show that the difference between cumulative incidence for removals following retropubic and transobturator insertions declines over time.

Reoperation for SUI

Risk of reoperation for SUI was 1.3% (95% CI: 1.3%-1.4%) of the women at one year, in 3.5% (95% CI: 3.4%-3.6%) at five years, and in 4.5% (95% CI: 4.4%-4.6%) at nine years after the initial insertion, accounting for the competing risk of death (Table 2 and Figure 2). The risk of reoperation was higher (at all time points) in women who had transobturator insertion than in those who had a retropubic insertion (5.3% compared to 4.1% at nine years after insertion, Table 2, Figure 3). This difference remained after adjusting for other risk factors (sdHR for transobturator insertion: 1.31, 95% CI: 1.14-1.51). Higher risk of reoperation for SUI was associated with having undergone a non-mesh continence procedure prior to the initial MUS insertion in this study (8.1% for women who had a bulking injection and 4.5% for women who did not, sdHR 1.74, 95% CI: 1.32-2,29; 11.1% for women who had another non-mesh SUI procedures and 4.5% for women did not, sdHR 2.60, 95% CI: 1.85-3.65) (Table 2). We did not find an indication that the assumption of proportional subhazards was violated.

Any reoperation (mesh removal and/or reoperation for SUI)

The risk of any reoperation (mesh removal and/or reoperation for SUI) following the initial MUS insertion was 2.6% at 1 year (95% CI: 2.5%-2.7%), 5.5% at five years (95% CI: 5.4%-5.7%) and 6.9% at nine years (95% CI: 6.7%-7.1%, Table 3). The risk of any reoperation was not statistically significantly different after retropubic or transobturator insertion (Table 3) Asian/Asian-British had a lower risk of reoperation than women from a white ethnic background (5.4% compared to 7.0% at nine years after insertion, sdHR 0.75, 95% CI: 0.59 -0.96). Higher risk of any reoperation was associated with having undergone a non-mesh continence procedure prior to the initial MUS insertion in this study (10.3% for women who had a bulking injection and 6.9% for women who did not, sdHR 1.55, 95% CI: 1.20-1.99; 14.5% for women who had another non-mesh SUI procedures and 6.9% for women did not, sdHR 2.29, 95% CI: 1.66-3.14) (Table 3). We did not find an indication that the

assumption of proportional subhazards was violated, except for the route of mesh sling insertion variable. The competing risk regression with a time varying component for route of mesh sling insertion show that the difference between cumulative incidence for any reoperations following retropubic and transobturator insertions declines over time.

Of the 95,057 women in the cohort, 5,328 (5.6%) had at least one reoperation (for mesh removal and/or reoperation for SUI) (eTable 3). As their first reoperation, 2,276 (2.4%) women had a sling removal operation, 1,957 (2.2%) had a repeat mesh sling insertion, and 1,075 (1.1%) had a non-mesh SUI operation. The risk of sling removal as the first reoperation following the initial MUS insertion was 1.3% at 1 year (95% CI: 1.2%-1.3%), 2.4% at five years (95% CI: 2.3%-2.5%) and 2.9% at nine years (95% CI: 2.8%-3.1%. Amongst the 1,957 women who had a repeat mesh sling insertions, 1592 (81.3%) were without sling removal as compared with 143 (7.3%) with concurrent sling removal. Remaining 244 (125%) of repeat mesh sling insertions were recorded with an additional unspecified revisional procedure code (one of 12 non-specific OPCS-4 codes, eTable 1). The risk of repeat sling insertion as the first reoperation for SUI following the initial MUS insertion was 0.9% at 1 year (95% CI: 0.8%-0.9%), 2.1% at five years (95% CI: 2.0%-2.2%) and 2.7% at nine years (95% CI: 2.5%-2.8%). The risk of a non-mesh SUI operation as the first reoperation for SUI was 0.4% at 1 year (95% CI: 0.4%-0.5%), 1.2% at five years (95% CI: 1.1%-1.2%) and 1.5% at nine years (95% CI: 1.4%-1.6%) (Table 3).

Types of subsequent operations by initial route of insertion are provided in eTable 4. Of the 95,057 women in the cohort, 1832 (1.9%) had only removal operations and 1681 (1.8%) had only insertion operations in the follow-up period. 0.9% of women had multiple types of operations (removals, insertion and non-mesh SUI operations).

By April 2016, 490 women who had initially received a retropubic mesh sling had undergone a total removal operation during the study period. Of these 490 women, 56 (11.4%) had a repeat MUS insertion following the total removal operation. Therefore, only 434 (0.7%) of the 60,194 women who

had an initial retropubic insertion had their mesh sling fully removed without any subsequent insertion (eTable 4). Presented as the cumulative incidence according to time from the initial procedure, the total removal rates of a retropubic mesh sling without a reinsertion were 0.4% (95% CI: 0.3%-0.4%) at one year, 0.7% (95% CI: 0.7%- 0.8%) at five years and 0.9% (95% CI: 0.8%-1.0%) at nine years (Figure 4).

DISCUSSION

Within nine years of an MUS insertion, 3.3% of women had a removal procedure, 4.5% had a reoperation for SUI and 6.9% had any reoperation (mesh removal and/or reoperation for SUI). Removal rates were lower following transobturator insertions than following retropubic insertions, and rates of reoperation for SUI were lower following retropubic insertions than following transobturator insertions. Risks of removal and any reoperation (mesh removal and/or reoperation for SUI) were higher among young women and among women from a white ethnic background. These findings, showing lower removal rates after tranobturator insertions, are in line with earlier studies from Scotland and England.[11,12] However, these studies did not provide cumulative incidence results for removal and reoperation (mesh removal and/or reoperation for SUI) as a function of time after reoperation[11] or include admissions for complication without surgery[12], which complicates a direct comparison.

In routine practice in the English NHS, risks of MUS removal were 2.7% at five years and 3.3% at nine years, however, 99.3% of women who had an initial retropubic MUS insertion between 1 April 2006 and 31 December 2015 still had a full or partial MUS in situ at the end of the study period. This can be understood because most removals were partial removals and many women had another mesh sling inserted (eTable 4 and Figure 5). Due to coding limitations, the proportion of women who had at least a partial MUS in situ after a sling insertion and removal could only be estimated for women who had a retropubic insertion, but it is unlikely that these results would be markedly different for women who had a transobturator insertion.

306 The present results demonstrate that removal and reoperation risks were associated with the insertion
307 route and patient factors. The risk of a removal was about 30% lower if the mesh sling had been
308 inserted via the transobturator route, which may be explained by the removal of transobturator sling
309 being a more complicated procedure. However, the risk of any reoperation, also including partial or
310 total mesh sling removals, was not associated with the route of insertion which, albeit indirectly,
311 indicates that risk of a reoperation for SUI is higher in women who had a transobturator insertion. A
312 Cochrane review also found that the risk of reoperation is higher after a transobturator mesh sling
313 insertion, but this came from four small trials including only 695 women.[1]
314
315 The risk of mesh removal or any reoperation (mesh removal and/or reoperation for SUI) was
316 considerably lower in older patients and in women from non-white ethnic backgrounds, but an
317 association with socio-economic deprivation was not observed. These findings demonstrate that
318 removal and reoperation risks may be associated with women's background. However, it is not
319 possible to disentangle potential explanations for these difference in risks, which range from higher
320 morbidity to differences in severity of the underlying condition that led to surgery as well as to how
321 women perceived possible issues related to having a mesh sling inserted and their choices about
322 seeking further clinical advice and treatment.
323
324 The use of mesh sling as a treatment for female SUI is rapidly decreasing in the UK with a reduction
325 by about 50% between 2008 and 2017.[30] This highlights a change in patient choice and surgical
326 practice which is likely to reflect concerns about longer-term complications, outcomes and risk of
327 further surgery after MUS insertion.
328
329 To our knowledge, this is the largest study of outcomes following MUS insertions for SUI in almost
330 100,000 women. The administrative hospital dataset had near-100% coverage of patients treated in the
331 English NHS, reducing the risk of selection bias. Furthermore, it is likely that at least 90% of all
332 incontinence procedures carried out in England are provided by the NHS, given that the total annual
333 spending on private health care in England is about 5% of the total annual spending on the NHS.[31]

Limitations

This study has several limitations. First, some relevant clinical and patient characteristics (e.g. smoking, severity of incontinence, obesity) and the reasons why removal or reoperations were carried out were not available.

Second, this study only reported on women who underwent a surgical intervention after the mesh sling insertion.[32] The advantage of this approach is that within administrative hospital data the accuracy for procedural coding is greater than for diagnostic coding.[19] In this way, this study avoided overestimation of the complication rate or inconsistency in coding, problems that are recognised when diagnosis codes are being used for this purpose or when outpatient visit are being used as an indicator of further healthcare use.[33] However, this approach did not capture any problems that did not lead to surgical treatment.

Third, new procedure codes for retropubic and transobturator mesh sling insertions were introduced in April 2006, the start of the study period. Prior to this, these procedures were recorded along with other non-classified procedures. Some inaccuracies may have resulted where certain units continued to use the old coding standard in the first year of the study period. However, the findings were robust to sensitivity analyses starting the study period one year later and to including the previous coding standards.

Fourth, three times as many partial removals as total removals were performed following retropubic mesh sling insertions. This study was unable to explore the type of the removal following transobturator insertions because removal type was not captured for these insertions. Therefore, the effect of the more challenging operative procedure to remove transobturator slings cannot be commented on.

Fifth, coding limitations mean that this study cannot provide insight into why MUS slings were removed. The most common diagnostic code recorded in removals episodes is T83 (Complications of genitourinary prosthetic devices, implants and grafts) which is unable to capture the commonly reported problems following MUS insertion such as mesh exposure, pain, voiding dysfunction and other diagnoses. The finding that mesh removal is more common after retropubic MUS insertions may suggest that voiding problems are a leading reason for removals, although patient-reported data is required to provide insight into the reasons for MUS removal.

Conclusions

Among women undergoing mid-urethral mesh sling insertion, the rate of mesh sling removal at 9 years was estimated as 3.3%. These findings may guide women and their surgeons when making decisions about surgical treatment of stress urinary incontinence.

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Contribution to Authorship

The study was conceived and designed by all authors. IGU and JBM performed the statistical analyses. JvdM, DGT, JD, DE-H and LD assisted with the interpretation of results. RSG, IGU, JBM, DE-H and JvdM wrote the manuscript, with input from all other authors. Joint senior authors (DGT and JvdM) and joint first authors (IGU and RSG) have made an equal contribution to this study and manuscript.

Disclosure of Interests

All authors declare no competing interests.

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Access to Data

Ipek Gurol-Urganci had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Details of Ethics Approval

Not required for the analysis of anonymised routinely collected administrative data.

REFERENCES

1. Ford A, Rogerson L, Cody DJ, Aluko P, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. *The Cochrane database of systematic reviews.* 2017(7).
2. Coyne KS, Kvasz M, Ireland AM, Milsom I, Kopp ZS, Chapple CR. Urinary incontinence and its relationship to mental health and health-related quality of life in men and women in Sweden, the United Kingdom, and the United States. *Eur Urol.* 2012;61(1):88-95. doi: 10.1016/j.eururo.2011.1007.1049. Epub 2011 Jul 1026.
3. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. *Obstetrics and gynecology.* 2014;123(6):1201-1206.
4. Aigmueller T, Trutnovsky G, Tamussino K, et al. Ten-year follow-up after the tension-free vaginal tape procedure. *American journal of obstetrics and gynecology.* 2011;205(5):496.e491-495.
5. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *International urogynecology journal and pelvic floor dysfunction.* 1996;7(2):81-85; discussion 85-86.
6. Ward K, Hilton P, The United Kingdom and Ireland Tension-free Vaginal Tape Trial Group. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. *Bmj.* 2002;325:67.
7. AUGS-SUFU. *Position Statement: Mesh Midurethral Slings for Stress Urinary Incontinence.* 2018.
8. U.S. Food & Drug Administration. Considerations about Surgical Mesh for SUI. 2018; https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm.
9. NHS England. Mesh complications. 2017.
10. Maggoire U, Agrò E, Soligo M, Li Marzi V, Digesu A, Serati M. Long-term outcomes of TOT and TVT procedures for the treatment of female stress urinary incontinence: a systematic review and meta-analysis. *International urogynecology journal.* 2017;28(8):1119-1130.
11. Morling J, McAllister D, Agur W, et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997–2016: a population-based cohort study. *The Lancet.* 2017;389(10069):629-640.
12. Keltie K, Elneil S, Monga A, et al. Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women. *Scientific Reports.* 2017;7(1):12015.
13. NHS England. Mesh Oversight Group Report. 2017.
14. Scottish Government. Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women. 2017; http://www.gov.scot/Resource/0051/00515856.pdf. Accessed 16/09/2017.
15. U.S. Food & Drug Administration. FDA public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence 2008.
16. NHS Digital. Hospital Episode Statistics. 2010; http://content.digital.nhs.uk/hes. Accessed 10/08/2017.
17. World Health Organization. International Statistical Classification of Diseases and Related Health Problems 10th Revision. 2010; http://apps.who.int/classifications/icd10/browse/2010/en. Accessed 05/08/2017.
18. NHS Digital. OPCS Classification of Interventions and Procedures. 2006; http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp. Accessed 05/08/2017.
19. Burns E, Rigby E, Mamidanna R, et al. Systematic review of discharge coding accuracy. *Journal of public health (Oxford, England).* 2012;34(1):138-148.

20. Department for Communities and Local Government. The English indices of deprivation 2015; https://www.gov.uk/government/collections/english-indices-of-deprivation.
21. Armitage JN, van der Meulen JH, Royal College of Surgeons Co-morbidity Consensus G. Identifying co-morbidity in surgical patients using administrative data with the Royal College of Surgeons Charlson Score. *The British journal of surgery.* 2010;97(5):772-781.
22. Siddiqui NY, Levin PJ, Phadtare A, Pietrobon R, Ammarell N. Perceptions about female urinary incontinence: a systematic review. *International urogynecology journal.* 2013.
23. Mathur R, Bhaskaran K, Chaturvedi N, et al. Completeness and usability of ethnicity data in UK-based primary care and hospital databases. *Journal of public health (Oxford, England).* 2013.
24. BSUG. Accreditation of Units: Standards for Service Provision in Urogynaecology Units: Certification of Units. 2017; http://bsug.org.uk/pages/information/accreditation-of-units/102.
25. Putter H, Fiocco M, Geskus R. Tutorial in biostatistics: competing risks and multi-state models. *Stat Med.* 2006;26(11):2389-2430.
26. Austin PC. A Tutorial on Multilevel Survival Analysis: Methods, Models and Applications. *Int Stat Rev.* 2017;85(2):185-203.
27. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med.* 2011;30(4):377-399.
28. *Stata Statistical Software* [computer program]. Version Release 14. College Station, TX: StataCorp LP; 2014.
29. NHS Digital. *HES Data Dictionary: Admitted Patient Care.* 2018.
30. NHS Digital. Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh 2018; https://digital.nhs.uk/data-and-information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy.
31. King's Fund. *The UK private health market.* 2014.
32. Mitropoulos D, Artibani W, Graefen M, et al. Reporting and Grading of Complications After Urologic Surgical Procedures: An ad hoc EAU Guidelines Panel Assessment and Recommendations. *European urology.* 2011;61(2):341-349.
33. Keltie K, Cole H, Arber M, et al. Identifying complications of interventional procedures from UK routine healthcare databases: a systematic search for methods using clinical codes. *BMC medical research methodology.* 2014;14(126).
34. Fine J, Gray R. A proportional hazards model for the subdistribution of a competing risk. *Journal of American Statistical Association.* 1999;94:496–509.

495 **Table 1:** Risk of mesh sling removal following initial mesh sling insertion

		Risk of removal[1] (%)				
	Number (%)	**1-year (95% CI)**	**5-year (95% CI)**	**9-year (95% CI)**	**Subdistribution hazard ratio (95% CI)[2]**	**P-value[3]**
All: crude risk (n/N, %)		1275/90215 (1.4)	1508/52715 (2.9)	240/6981 (3.4)		
All: adjusted risk	95057 (100)	1.4 (1.3, 1.4)	2.7 (2.6, 2.8)	3.3 (3.2, 3.4)		
Age at initial surgery (years)						
18-39	10292 (10.8)	2.0 (1.7, 2.2)	3.6 (3.2, 4.0)	4.4 (3.9, 4.9)	Reference	<0.001
40-49	33094 (34.8)	1.5 (1.4, 1.6)	2.9 (2.8, 3.1)	3.7 (3.4, 4.0)	0.83 (0.74, 0.93)	
50-59	24664 (26.0)	1.4 (1.2, 1.5)	2.8 (2.6, 3.1)	3.4 (3.1, 3.6)	0.77 (0.68, 0.87)	
60-69	16877 (17.8)	1.0 (0.8, 1.1)	2.1 (1.9, 2.3)	2.5 (2.2, 2.8)	0.56 (0.48, 0.66)	
70+	10130 (10.7)	0.9 (0.8, 1.1)	1.7 (1.5, 2.0)	2.1 (1.7, 2.5)	0.46 (0.38, 0.56)	
Index of multiple deprivation						
1 Most deprived quintile	16136 (17.0)	1.3 (1.1, 1.5)	2.7 (2.4, 2.9)	3.2 (2.9, 3.5)	Reference	0.12
2	18277 (19.2)	1.5 (1.3, 1.7)	2.9 (2.7, 3.2)	3.5 (3.2, 3.8)	1.12 (0.97, 1.30)	
3	20468 (21.5)	1.3 (1.1, 1.5)	2.5 (2.3, 2.8)	3.0 (2.7, 3.3)	0.96 (0.83, 1.12)	
4	20779 (21.9)	1.3 (1.1, 1.4)	2.6 (2.4, 2.9)	3.2 (2.9, 3.6)	1.01 (0.87, 1.18)	
5 Least deprived quintile	19397 (20.4)	1.5 (1.3, 1.7)	2.8 (2.5, 3)	3.5 (3.2, 3.9)	1.08 (0.92, 1.25)	
Ethnic background[4]						
White	83451 (95.8)	1.4 (1.3, 1.5)	2.7 (2.6, 2.8)	3.3 (3.2, 3.4)	Reference	0.08
Asian/Asian-British	2049 (2.4)	0.9 (0.5, 1.3)	2.1 (1.6, 2.9)	2.9 (2.0, 4.1)	0.73 (0.51, 1.05)	
Black/black-British	576 (0.6)	1.7 (0.9, 3.0)	2.3 (1.3, 3.7)	2.3 (1.3, 3.7)	0.71 (0.42, 1.19)	
Other	1057 (1.2)	0.9 (0.5, 1.6)	1.9 (1.2, 2.9)	2.8 (1.6, 4.5)	0.73 (0.49, 1.09)	
Missing (n=7924, 8.3%)						
Route of mesh sling insertion						
Retropubic	60194 (63.3)	1.6 (1.5, 1.7)	3.0 (2.9, 3.2)	3.6 (3.5, 3.8)	Reference	<0.001
Transobturator	34863 (36.7)	0.9 (0.8, 1.0)	2.2 (2.0, 2.3)	2.7 (2.4, 2.9)	0.72 (0.62, 0.84)	

Table 1 (continued)		Risk of removal[1]				
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)	Subdistribution hazard ratio (95% CI)[2]	P-value[3]
Comorbidities[5]						
None	76252 (80.2)	1.4 (1.3, 1.5)	2.7 (2.6, 2.8)	3.3 (3.2, 3.5)	Reference	0.37
1 or more	18805 (19.8)	1.3 (1.1, 1.5)	2.7 (2.4, 2.9)	3.0 (2.7, 3.3)	1.05 (0.94, 1.17)	
Previous bulking injection						
No	94349 (99.2)	1.4 (1.3, 1.5)	2.7 (2.6, 2.8)	3.3 (3.1, 3.4)	Reference	0.36
Yes	709 (0.8)	0.7 (0.3, 1.6)	3.0 (1.9, 4.6)	3.3 (2.1, 5.0)	1.21 (0.80, 1.83)	
Previous other stress urinary incontinence procedure						
No	94710 (99.6)	1.4 (1.3, 1.4)	2.7 (2.6, 2.8)	3.3 (3.1, 3.4)	Reference	0.13
Yes	347 (0.4)	2.6 (1.3, 4.7)	4.2 (2.4, 6.8)	4.2 (2.4, 6.8)	1.50 (0.89, 2.52)	
Concurrent prolapse repair						
No	77932 (82.0)	1.4 (1.3, 1.4)	2.7 (2.6, 2.8)	3.3 (3.1, 3.4)	Reference	0.09
Repair with mesh	817 (0.9)	1.7 (1.0, 2.8)	3.4 (2.3, 4.9)	3.9 (2.6, 5.6)	1.43 (0.98, 2.08)	
Repair without mesh	16308 (17.2)	1.4 (1.2, 1.6)	2.7 (2.5, 3.0)	3.3 (2.9, 3.6)	1.07 (0.93, 1.22)	
Specialist urogynecology unit						
No	75695 (79.6)	1.3 (1.2, 1.4)	2.6 (2.5, 2.7)	3.1 (3.0, 3.3)	Reference	0.17
Yes	19362 (20.4)	1.7 (1.6, 1.9)	3.2 (2.9, 3.4)	3.8 (3.5, 4.2)	1.17 (0.94, 1.47)	
Annual volume of mesh sling insertions						
< 60	28939 (30.3)	1.3 (1.2, 1.4)	2.5 (2.3, 2.7)	3.0 (2.8, 3.3)	Reference	0.21
60-119	44228 (46.5)	1.4 (1.3, 1.5)	2.7 (2.6, 2.9)	3.4 (3.2, 3.6)	1.07 (0.92, 1.24)	
≥120	21990 (23.1)	1.5 (1.3, 1.6)	2.8 (2.6, 3.0)	3.4 (3.1, 3.7)	1.02 (0.82, 1.28)	

[1]Cumulative incidence function and corresponding 95% confidence interval (95% CI) according to time after initial insertion.
[2] Sub-hazard ratios calculated with competing risks regression model (Fine & Gray[34]) adjusted for all patient and hospital factors in table.
[3]P value obtained from Wald test
[4]Ethnicity percentages calculated for non-missing data
[5]Number of comorbidities derived from Royal College of Surgeons Charlson Comorbidity Index

Table 2: Risk of reoperation for stress urinary incontinence following initial mesh sling insertion

		Risk of reoperation for stress urinary incontinence[1] (%)				
	Number (%)	**1-year (95% CI)**	**5-year (95% CI)**	**9-year (95% CI)**	**Subdistribution hazard ratio (95%CI)[2]**	**P-value[3]**
All: crude risk (n/N, %)		1252/90215 (1.4)	2087/52715 (3.9)	391/6981 (5.6)		
All: adjusted risk	95057 (100)	1.3 (1.3, 1.4)	3.5 (3.4, 3.6)	4.5 (4.3, 4.7)		
Age at initial surgery (years)						
18-39	10292 (10.8)	1.1 (1.0, 1.3)	3.3 (3.1, 3.5)	4.5 (4.2, 4.8)	Reference	0.29
40-49	33094 (34.8)	1.3 (1.1, 1.4)	3.4 (3.2, 3.7)	4.2 (3.9, 4.6)	0.91 (0.80, 1.03)	
50-59	24664 (26.0)	1.6 (1.4, 1.8)	3.7 (3.4, 4.1)	4.6 (4.2, 5.0)	0.92 (0.81, 1.05)	
60-69	16877 (17.8)	1.7 (1.4, 1.9)	3.8 (3.4, 4.2)	4.3 (3.9, 4.8)	1.00 (0.86, 1.16)	
70+	10130 (10.7)	1.1 (1.0, 1.3)	3.3 (3.1, 3.5)	4.5 (4.2, 4.8)	0.99 (0.83, 1.18)	
Index of multiple deprivation						
1 Most deprived quintile	16136 (17.0)	1.3 (1.1, 1.5)	3.5 (3.2, 3.8)	4.2 (3.9, 4.6)	Reference	
2	18277 (19.2)	1.4 (1.2, 1.5)	3.7 (3.4, 4.0)	4.9 (4.5, 5.4)	1.08 (0.96, 1.23)	
3	20468 (21.5)	1.3 (1.2, 1.5)	3.5 (3.2, 3.7)	4.3 (4.0, 4.7)	0.99 (0.87, 1.13)	
4	20779 (21.9)	1.4 (1.2, 1.5)	3.8 (3.5, 4.1)	4.9 (4.5, 5.3)	1.09 (0.94, 1.26)	
5 Least deprived quintile	19397 (20.4)	1.3 (1.1, 1.4)	3.1 (2.8, 3.3)	4.1 (3.8, 4.5)	0.92 (0.78, 1.09)	
Ethnic background[4]						
White	83451 (95.8)	1.4 (1.3, 1.4)	3.5 (3.4, 3.7)	4.6 (4.4, 4.8)	Reference	
Asian/Asian-British	2049 (2.4)	0.8 (0.5, 1.2)	2.5 (1.9, 3.3)	3.1 (2.3, 4.0)	0.74 (0.54, 1.01)	
Black/black-British	576 (0.6)	1.0 (0.4, 2.1)	3.1 (1.8, 4.9)	3.4 (2.0, 5.3)	0.71 (0.46, 1.10)	
Other	1057 (1.2)	0.8 (0.4, 1.5)	2.4 (1.5, 3.5)	2.8 (1.7, 4.2)	0.70 (0.45, 1.07)	
Missing (n=7924, 8.3%)						
Route of mesh sling insertion						
retropubic	60194 (63.3)	1.2 (1.1, 1.3)	3.1 (3.0, 3.3)	4.1 (3.8, 4.3)	Reference	<0.001
transobturator	34863 (36.7)	1.5 (1.4, 1.6)	4.1 (3.9, 4.4)	5.3 (5.0, 5.7)	1.31 (1.14, 1.51)	

Table 2 (continued)		Risk of reoperation for stress urinary incontinence[1] (%)				
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)	Subdistribution hazard ratio (95%CI)[2]	P-value[3]
Comorbidities[5]						
None	76252 (80.2)	1.3 (1.2, 1.4)	3.4 (3.3, 3.6)	4.5 (4.3, 4.7)	Reference	0.35
1 or more	18805 (19.8)	1.5 (1.3, 1.7)	3.8 (3.5, 4.1)	4.4 (4.0, 4.8)	1.04 (0.95, 1.14)	
Previous bulking injection						
No	94349 (99.2)	1.3 (1.2, 1.4)	3.5 (3.3, 3.6)	4.5 (4.3, 4.7)	Reference	<0.001
Yes	709 (0.8)	2.9 (1.8, 4.3)	6.9 (5.1, 9.1)	8.1 (5.9, 10.6)	1.74 (1.32, 2.29)	
Previous other stress urinary incontinence procedure						
No	94710 (99.6)	1.3 (1.2, 1.4)	3.5 (3.3, 3.6)	4.5 (4.3, 4.7)	Reference	<0.001
Yes	347 (0.4)	4.9 (3.0, 7.6)	9.1 (6.3, 12.6)	11.1 (7.8, 15.1)	2.60 (1.85, 3.65)	
Concurrent prolapse repair						
No	77932 (82.0)	1.4 (1.3, 1.4)	3.6 (3.5, 3.7)	4.7 (4.5, 4.9)	Reference	0.001
Repair with mesh	817 (0.9)	2.8 (1.9, 4.2)	4.9 (3.5, 6.6)	6.2 (3.9, 9.3)	1.32 (0.94, 1.84)	
Repair without mesh	16308 (17.2)	1.1 (0.9, 1.3)	3.0 (2.7, 3.3)	3.7 (3.3, 4.1)	0.80 (0.69, 0.93)	
Specialist urogynecology unit						
No	75695 (79.6)	1.3 (1.2, 1.4)	3.5 (3.4, 3.6)	4.5 (4.3, 4.8)	Reference	0.84
Yes	19362 (20.4)	1.4 (1.2, 1.5)	3.5 (3.2, 3.8)	4.4 (4.0, 4.8)	1.02 (0.81, 1.29)	
Annual volume of mesh sling insertions						
< 60	28939 (30.3)	1.2 (1.1, 1.4)	3.4 (3.2, 3.6)	4.4 (4.1, 4.8)	Reference	0.37
60-119	44228 (46.5)	1.4 (1.3, 1.5)	3.6 (3.5, 3.8)	4.7 (4.4, 4.9)	1.09 (0.96, 1.24)	
≥120	21990 (23.1)	1.3 (1.1, 1.4)	3.4 (3.1, 3.6)	4.3 (4.0, 4.7)	1.03 (0.83, 1.28)	

[1]Cumulative incidence function and corresponding 95% confidence interval (95% CI) according to time after initial insertion.
[2] Sub-hazard ratios calculated with competing risks regression model (Fine & Gray[34]) adjusted for all patient and hospital factors in table.
[3]P value obtained from Wald test
[4]Ethnicity percentages calculated for non-missing data
[5]Number of comorbidities derived from Royal College of Surgeons Charlson Comorbidity Index

Table 3: Risk of mesh removal or reoperation for stress urinary incontinence following initial mesh sling insertion

		Risk of any reoperation[1] (%)				
	Number (%)	**1-year (95% CI)**	**5-year (95% CI)**	**9-year (95% CI)**	**Subdistribution hazard ratio (95%CI)[2]**	**P-value[3]**
All: crude risk (n/N, %)		2415//90215 (2.7)	3216/52715 (6.1)	553/6981 (7.9)		
All: adjusted risk		2.6 (2.5, 2.7)	5.5 (5.4, 5.7)	6.9 (6.7, 7.1)		
Age at initial surgery (years)						
18-39	10292 (10.8)	3.1 (2.8, 3.4)	6.3 (5.8, 6.9)	8.3 (7.6, 9.2)	Reference	0.01
40-49	33094 (34.8)	2.5 (2.3, 2.7)	5.4 (5.2, 5.7)	7.1 (6.7, 7.4)	0.86 (0.79, 0.94)	
50-59	24664 (26.0)	2.5 (2.3, 2.7)	5.6 (5.3, 5.9)	6.8 (6.4, 7.2)	0.86 (0.78, 0.95)	
60-69	16877 (17.8)	2.5 (2.3, 2.7)	5.4 (5.1, 5.8)	6.6 (6.1, 7.1)	0.83 (0.74, 0.94)	
70+	10130 (10.7)	2.5 (2.2, 2.9)	5.3 (4.9, 5.8)	6.1 (5.5, 6.7)	0.79 (0.68, 0.91)	
Index of multiple deprivation						
1 Most deprived quintile	16136 (17.0)	2.5 (2.2, 2.7)	5.5 (5.1, 5.9)	6.6 (6.1, 7.1)	Reference	0.13
2	18277 (19.2)	2.7 (2.4, 2.9)	5.8 (5.5, 6.2)	7.3 (6.8, 7.8)	1.08 (0.97, 1.20)	
3	20468 (21.5)	2.5 (2.3, 2.7)	5.4 (5.0, 5.7)	6.5 (6.1, 7.0)	0.98 (0.88, 1.08)	
4	20779 (21.9)	2.6 (2.3, 2.8)	5.7 (5.3, 6.0)	7.2 (6.8, 7.7)	1.05 (0.94, 1.17)	
5 Least deprived quintile	19397 (20.4)	2.6 (2.4, 2.9)	5.3 (5.0, 5.7)	6.9 (6.4, 7.4)	1.00 (0.88, 1.13)	
Ethnic background[4]						
White	83451 (95.8)	2.6 (2.5, 2.7)	5.6 (5.4, 5.8)	7.0 (6.8, 7.2)	Reference	0.01
Asian/Asian-British	2049 (2.4)	1.5 (1.1, 2.1)	4.3 (3.5, 5.3)	5.4 (4.2, 6.8)	0.75 (0.59, 0.96)	
Black/black-British	576 (0.6)	2.7 (1.6, 4.2)	5.0 (3.4, 7.1)	5.0 (3.4, 7.1)	0.73 (0.51, 1.05)	
Other	1057 (1.2)	1.7 (1.1, 2.6)	3.9 (2.8, 5.2)	5.2 (3.6, 7.3)	0.74 (0.54, 1.01)	
Missing (n=7924, 8.3%)						
Route of mesh sling insertion						
retropubic	60194 (63.3)	2.7 (2.6, 2.9)	5.5 (5.3, 5.7)	6.8 (6.5, 7.0)	Reference	0.61
transobturator	34863 (36.7)	2.3 (2.1, 2.4)	5.7 (5.4, 5.9)	7.2 (6.8, 7.5)	1.03 (0.92, 1.16)	

Table 3 (continued)		Risk of reoperation[1] (%)				
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)	Subdistribution hazard ratio (95%CI)[2]	P-value[3]
Comorbidities[5]						
None	76252 (80.2)	2.5 (2.4, 2.6)	5.5 (5.3, 5.7)	7.0 (6.7, 7.2)	Reference	0.22
1 or more	18805 (19.8)	2.7 (2.5, 2.9)	5.8 (5.4, 6.1)	6.6 (6.2, 7.1)	1.05 (0.97, 1.13)	
Previous bulking injection						
No	94349 (99.2)	2.6 (2.5, 2.7)	5.5 (5.4, 5.7)	6.9 (6.7, 7.1)	Reference	0.001
Yes	709 (0.8)	3.6 (2.4, 5.2)	8.9 (6.8, 11.4)	10.3 (7.9, 13.2)	1.55 (1.20, 1.99)	
Previous other stress urinary incontinence procedure						
No	94710 (99.6)	2.6 (2.5, 2.7)	5.5 (5.4, 5.7)	6.9 (6.7, 7.1)	Reference	<0.001
Yes	347 (0.4)	7.0 (4.6, 10.0)	12.5 (9.2, 16.3)	14.5 (10.7, 18.8)	2.29 (1.66, 3.14)	
Concurrent prolapse repair						
No	77932 (82.0)	2.6 (2.5, 2.7)	5.6 (5.4, 5.8)	7.0 (6.8, 7.3)	Reference	0.001
Repair with mesh	817 (0.9)	4.3 (3.1, 5.9)	7.8 (6.0, 9.8)	9.6 (6.9, 12.8)	1.43 (1.09, 1.87)	
Repair without mesh	16308 (17.2)	2.4 (2.2, 2.7)	5.2 (4.8, 5.6)	6.3 (5.8, 6.8)	0.92 (0.83, 1.01)	
Specialist urogynecology unit						
No	75695 (79.6)	2.5 (2.4, 2.6)	5.5 (5.3, 5.6)	6.8 (6.6, 7.1)	Reference	0.37
Yes	19362 (20.4)	3.0 (2.8, 3.2)	5.9 (5.6, 6.3)	7.2 (6.7, 7.7)	1.08 (0.91, 1.29)	
Annual volume of mesh sling insertions						
< 60	28939 (30.3)	2.4 (2.2, 2.6)	5.3 (5.0, 5.6)	6.7 (6.3, 7.1)	Reference	0.4
60-119	44228 (46.5)	2.7 (2.5, 2.8)	5.7 (5.5, 6.0)	7.1 (6.8, 7.4)	1.07 (0.96, 1.20)	
≥120	21990 (23.1)	2.6 (2.4, 2.8)	5.5 (5.2, 5.8)	6.8 (6.4, 7.3)	1.02 (0.86, 1.20)	

[1]Cumulative incidence function and corresponding 95% confidence interval (95% CI) according to time after initial insertion.
[2] Sub-hazard ratios calculated with competing risks regression model (Fine & Gray[34]) adjusted for all patient and hospital factors in table.
[3]P value obtained from Wald test
[4]Ethnicity percentages calculated for non-missing data
[5]Number of comorbidities derived from Royal College of Surgeons Charlson Comorbidity Index

List of Figures & Legends

Figure 1: Study cohort selection process of women aged 18 and above who had a first-ever mesh sling insertion in the English National Health Service

Figure Legend: Study cohort selection process of women aged 18 years and above who had a first-ever mesh insertion in the English National Health Service from2006-2015. ICD-10 indicates International Classification of Diseases, version 10.

Figure 2: Mesh sling removal, reoperation for stress urinary incontinence and any reoperation according to time after initial mesh insertion in 95,057 women

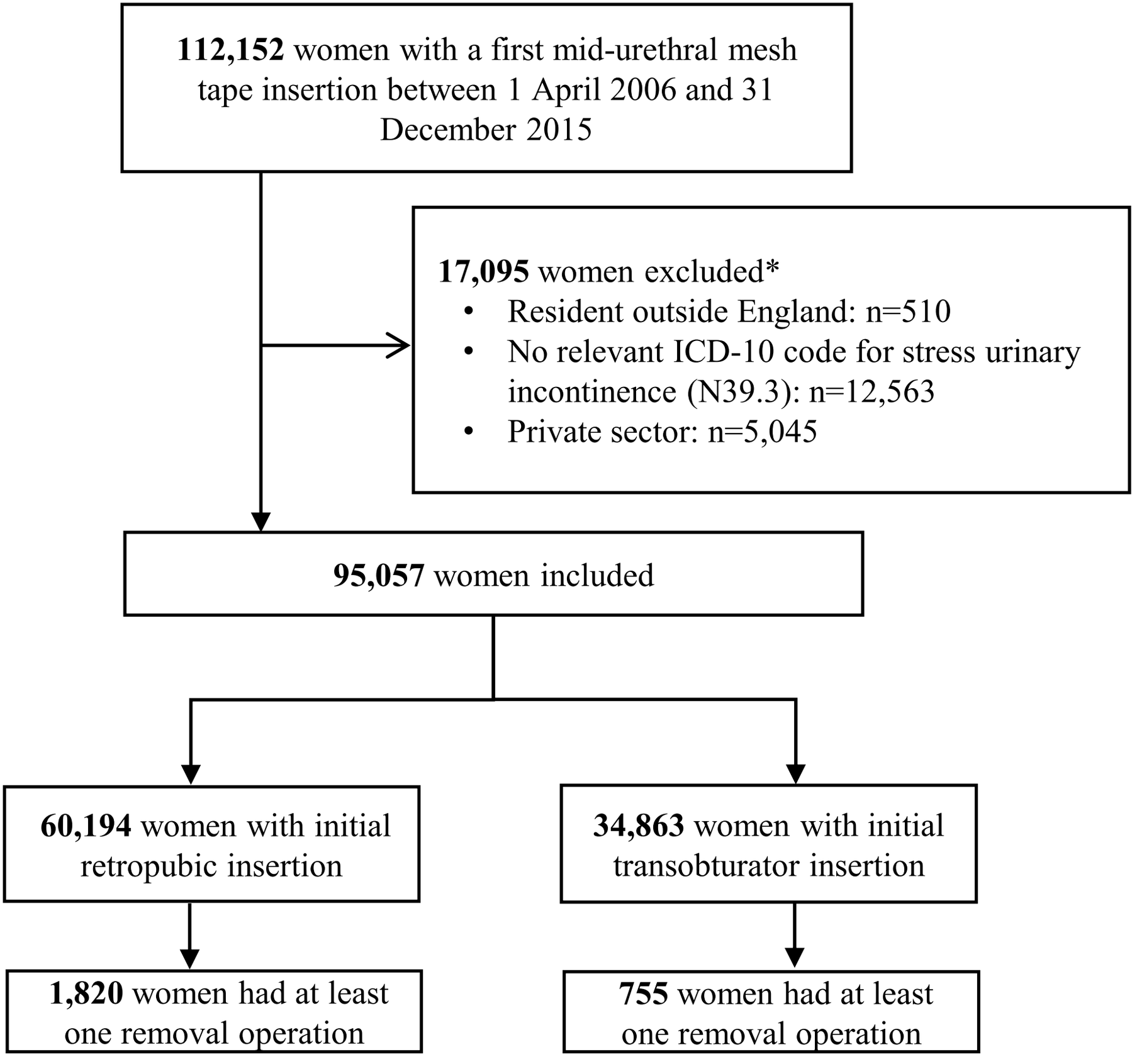
Figure Legend: Cumulative incidence of mid-urethral sling removal, reoperation for stress urinary incontinence and any reoperation (mesh removal and/or reoperation for stress urinary incontinence), with death from any cause as a competing risk. The median time of follow-up was 5.5 years (interquartile range 3.2 and 7.5 years) in women who did not have a mesh sling removal and were alive at the end of follow-up.

Figure 3: Mesh sling removal and reoperation for stress urinary incontinence according to time after initial insertion in 95,057 women by route of insertion

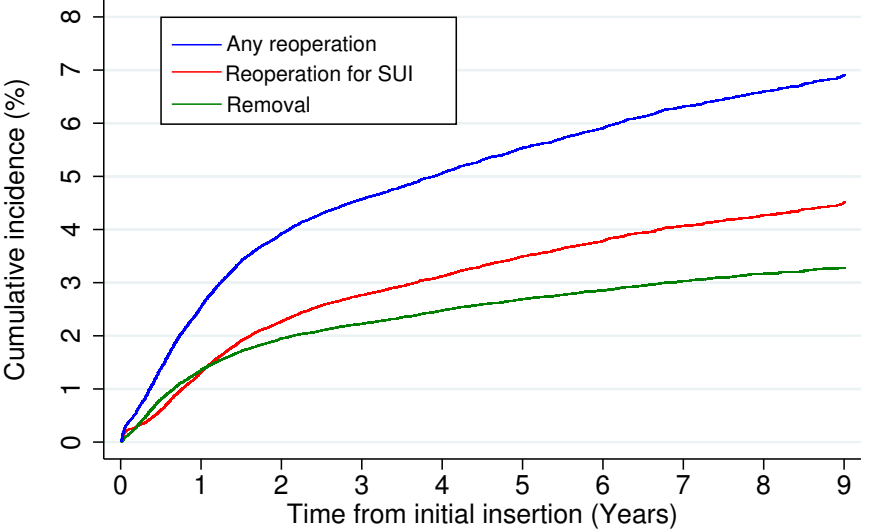
Figure Legend: Cumulative incidence of mid-urethral sling removal and reoperation for stress urinary incontinence by route of initial mesh insertion with death from any cause as a competing risk. The median time of follow-up was 5.4 years (interquartile range 3.1 to 7.6 years) in women who had an retropubic insertion and 5.6 years (interquartile range 3.4 to 7.5 years) in those who had a transobturator insertion.

Figure 4: Total sling removal with no subsequent mid-urethral sling insertion according to time after initial insertion in 60,194 women who had mesh sling inserted via retropubic route

Figure Legend: Cumulative incidence of mid-urethral sling removal surgery without subsequent insertion in 60,194 women who had mid-urethral mesh sling inserted via retropubic route, with death from any cause as a competing risk.

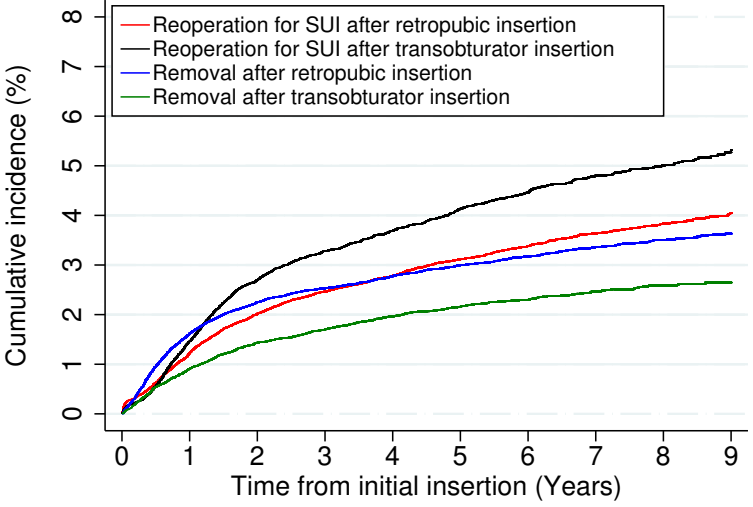


*1,023 episodes failed on multiple criteria



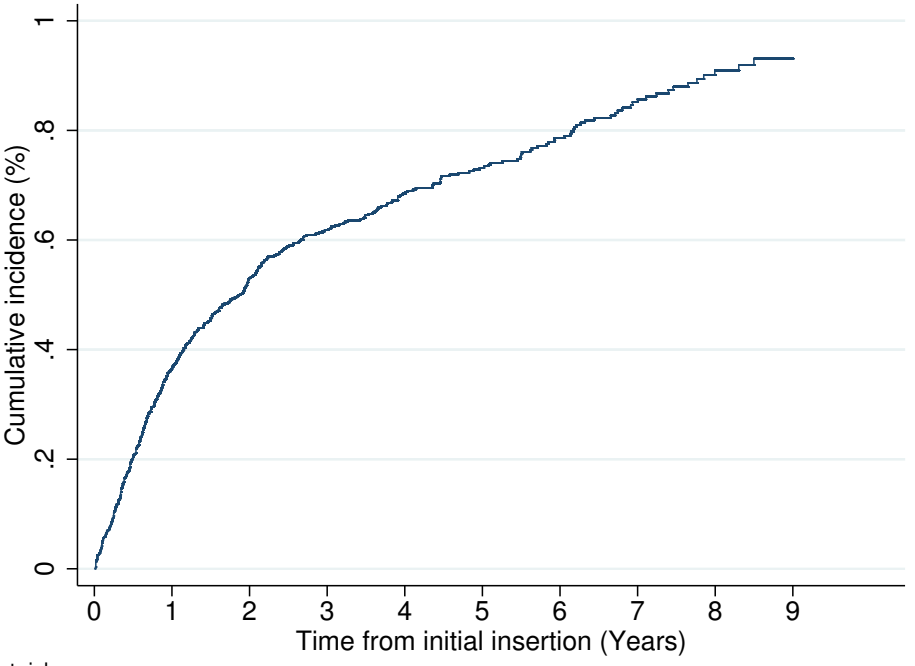
Number at risk

Any reoperation:	95057	87800	79221	69654	59871	49499	38802	27821	16708	6428
Reoperation for SUI:	95057	88963	80661	71050	61170	50628	39730	28535	17148	6590
Removal:	95057	88940	80955	71514	61664	51207	40308	29058	17502	6741



Number at risk

Reoperation after retropubic:	60194	56153	50864	44624	38297	31650	25101	18294	11440	4662
Reoperation after transobturator:	34863	32810	29797	26426	22873	18978	14629	10241	5708	1928
Removal after retropubic:	60194	55920	50732	44620	38330	31751	25230	18466	11546	4710
Removal after transobturator:	34863	33020	30223	26894	23334	19456	15078	10592	5956	2031



Number at risk

Removals:	60194	55920	50732	44620	38330	31751	25230	18466	11546	4710