JAMA | Original Investigation

Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women With Stress Urinary Incontinence

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

OBJECTIVE To examine long-term mesh removal and reoperation rates in women who had a midurethral mesh sling insertion for stress urinary incontinence.

DESIGN, SETTING, AND PARTICIPANTS This population-based retrospective cohort study included 95 057 women aged 18 years or older who had a first-ever midurethral mesh sling insertion for stress urinary incontinence in the National Health Service hospitals in England between April 1, 2006, and December 31, 2015. Women were followed up until April 1, 2016.

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

MAIN OUTCOMES AND MEASURES The primary outcome was the risk of midurethral mesh sling removal (partial or total) and secondary outcomes were reoperation for stress urinary incontinence and any reoperation including mesh removal, calculated with death as competing risk. A multivariable Fine-Gray model was used to calculate subdistribution hazard ratios as estimates of relative risk.

RESULTS The study population consisted of 95 057 women (median age, 51 years; interquartile range, 44-61 years) with first midurethral mesh sling insertion, including 60 194 with retropubic insertion and 34 863 with transobturator insertion. The median follow-up time was 5.5 years (interquartile range, 3.2-7.5 years). The rate of midurethral mesh sling removal was 1.4% (95% CI, 1.3%-1.4%) at 1 year, 2.7% (95% CI, 2.6%-2.8%) at 5 years, and 3.3% (95% CI, 3.2%-3.4%) at 9 years. Risk of removal declined with age. The 9-year removal risk after transobturator insertion (2.7% [95% CI, 2.4%-2.9%]) was lower than the risk after retropubic insertion (3.6% [95% CI, 3.5%-3.8%]; subdistribution hazard ratio, 0.72 [95% CI, 0.62-0.84]). The rate of reoperation for stress urinary incontinence was 1.3% (95% CI, 1.3%-1.4%) at 1 year, 3.5% (95% CI, 3.4%-3.6%) at 5 years, and 4.5% (95% CI, 4.3%-4.7%) at 9 years. The rate of any reoperation, including mesh removal, was 2.6% (95% CI, 2.5%-2.7%) at 1 year, 5.5% (95% CI, 5.4%-5.7%) at 5 years, and 6.9% (95% CI, 6.7%-7.1%) at 9 years.

CONCLUSIONS AND RELEVANCE Among women undergoing midurethral 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.

Supplemental content

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Stress urinary incontinence (SUI) affects approximately 1 in 3 women older than age 18 years 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 United States.[3] Synthetic midurethral mesh sling (MUS) insertion 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 United States.[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 underwent MUS insertion were admitted for a complication (combining those related to hemorrhage, infection, pain, and mesh removal) within 5 years, with 5% undergoing further continence surgery.[11,12] Reviews of urogynecologic mesh conducted by the US Food and Drug Administration, the Scottish government, and the English National Health Service (NHS)[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 nonmesh procedures.

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

Key Points

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

Findings In this retrospective cohort study that included 95 057 women who underwent midurethral 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.

Methods

The use of Hospital Episode Statistics (HES) data for the purpose of national clinical audits 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. The HES database contains records of all inpatient admissions to NHS hospitals in England,[16] with data on patient demographics (age, sex, and race/ethnicity), admission (date of admission and discharge), and clinical information. Diagnostic information is coded using the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision*.[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 an MUS insertion procedure for SUI for the first time between April 1, 2006, and December 31, 2015, were identified. SUI was defined by the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* 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 3 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 (March 31, 2016), whichever was earlier. As a consequence, the minimum follow-up period was 3 months and the maximum was 10 years.

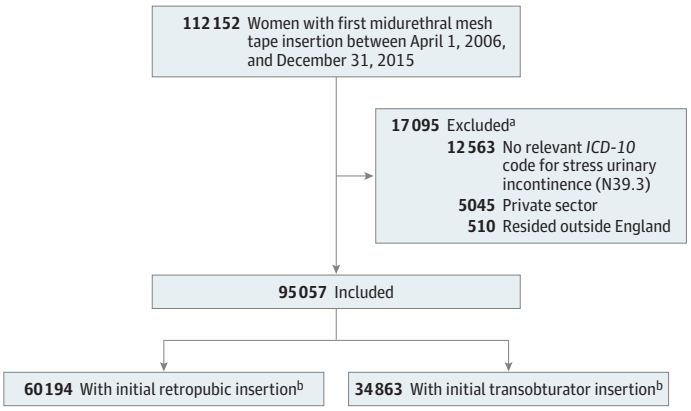
Outcomes

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 in the Supplement. Due to coding limitations, it was not possible to distinguish partial and total removals following transobturator insertions. For the secondary outcomes, "reoperation for SUI" was defined as a subsequent SUI procedure (*OPCS-4* codes in eTable 1 in the Supplement), 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 the HES database throughout the study period.

Patient Factors

Data on patient factors were extracted from the HES database: age at initial procedure date; Index of Multiple Deprivation, 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; racial/ethnic background (white, Asian/Asian British, black/black British, or other based on race/ethnicity

Figure 1. Study Cohort Selection Process of Women Aged 18 Years and Older Who Had a First-Ever Mesh Sling Insertion in the English National Health Service



ICD-10 indicates *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision*.

[a] A total of 1023 episodes failed on multiple criteria.

[b] A total of 1820 patients in the retropubic group and 755 in the transobturator group had at least 1 removal operation.

information specified by the patients); number of comorbidities (defined using the Royal College of Surgeons' Charlson Comorbidity Index,[21] grouped as 0 or ≥1); route of mesh sling insertion (retropubic or transobturator); previous nonmesh SUI procedures in the preceding 3 years and concurrent prolapse operations (defined using codes listed in eTable 2 in the Supplement) in the same episode of care as the initial MUS insertion for SUI. Race/ethnicity is considered in this study because previous studies have suggested that there are variations in care for women with SUI from different racial/ethnic and socioeconomic backgrounds.[22] In hospital settings, guidelines state that race/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.

Organizational Factors

Two organizational factors related to the hospital where the initial procedure was carried out were also extracted from the HES database: 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 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 a 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 (sdHRs) to assess the association between patient and organizational 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] An sdHR of 1 implies no association; an sdHR less than 1, a decrease of the risk compared with the reference category; and an sdHR greater than 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 organizational factors. We also reran the competing risk regression analysis, including time interactions separately for each of the patient and organizational factors.

Multiple imputation was used to deal with missing values for race/ethnicity with statistical coefficients obtained from 10 imputed data sets, pooled using Rubin's rules.[27] Estimates are reported with 95% CIs. Wald tests were used to test whether the association of patient and organizational factors with removal or reoperation risks were statistically significant. All reported *P* values were 2-sided and .05 was used as the significance level. All statistical calculations were performed using Stata version 14 (StataCorp).[28] To assess whether the results were robust to coding changes introduced in 2006, regression analyses were repeated in 2 separate sensitivity analyses: first, starting the study period 1 year later, on April 1, 2007 (rather than 2006), and second, including the previous coding standards to identify procedures.

Results

A total of 112 152 women were identified as having undergone a first MUS insertion between April 1, 2006, and December 31, 2015 (**Figure 1**). A total of 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%) had a transobturator insertion and they were all followed up until the end of the follow-up period. The median follow-up time was 5.5 years for women who were alive at the end of follow-up (interquartile range, 3.2-7.5 years). The median follow-up times for women who had retropubic and transobturator insertion were 5.4 years

(interquartile range, 3.1-7.6 years) and 5.6 years (interquartile range, 3.4-7.5 years), respectively. The women's median age was 51 years (interquartile range, 44-61 years), and 19.8% had 1 or more comorbidities. A total of 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 1 year, in 2.7% (95% CI, 2.6%-2.8%) at 5 years, and in 3.3% (95% CI, 3.2%-3.4%) at 9 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 with 2.7% at 9 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 aged 18-39 years compared with 2.1% for women ≥70 years of age at 9 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 showed that the difference between cumulative incidence for removals following retropubic and transobturator insertions declined over time.

Reoperation for SUI

Risk of reoperation for SUI was 1.3% (95% CI, 1.3%-1.4%) of the women at 1 year, 3.5% (95% CI, 3.4%-3.6%) at 5 years, and 4.5% (95% CI, 4.3%-4.7%) at 9 years after the initial insertion, accounting for the competing risk of death (**Table 2** and Figure 2). The risk of reoperation for SUI was higher (at all time points) in women who had transobturator insertion than in those who had a retropubic insertion (5.3% compared with 4.1% at 9 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 nonmesh 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 nonmesh SUI procedure and 4.5% for women who 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% (95% CI, 2.5%-2.7%) at 1 year, 5.5% (95% CI, 5.4%-5.7%) at 5 years, and 6.9% (95% CI, 6.7%-7.1%) at 9 years (**Table 3**). The risk of any reoperation was not statistically significantly different after retropubic or transobturator insertion (Table 3). Asian/Asian British women had a lower risk of reoperation than women from a white racial/ethnic background (5.4% compared with 7.0% at 9 years after insertion; sdHR, 0.75 [95% CI, 0.59-0.96]). Higher risk of any reoperation was associated with having undergone a nonmesh 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] and 14.5% for women who had another nonmesh 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 showed that the difference between cumulative incidence for any reoperations following retropubic and transobturator insertions declined over time.

Of the 95 057 women in the cohort, 5328 (5.6%) had at least 1 reoperation (for mesh removal and/or reoperation for SUI) (eTable 3 in the Supplement). As their first reoperation, 2276 women (2.4%) had a sling removal operation, 1957 (2.2%) had a repeat mesh sling insertion, and 1075 (1.1%) had a nonmesh SUI operation. The risk of sling removal as the first reoperation following the initial MUS insertion was 1.3% (95% CI, 1.2%-1.3%) at 1 year, 2.4% (95% CI, 2.3%-2.5%) at 5 years, and 2.9% (95% CI, 2.8%-3.1%) at 9 years. Among the 1957 women who had a repeat mesh sling insertion, 1592 (81.3%) were without sling removal as compared with 143 (7.3%) with concurrent sling removal. The remaining 242 (0.3%) of repeat mesh sling insertions were recorded with an additional unspecified revisional procedure code (from 12 nonspecific *OPCS-4* codes; eTable 1 in the Supplement). The risk of repeat sling insertion as the first reoperation for SUI following the initial MUS insertion was 0.9% (95% CI, 0.8%-0.9%) at 1 year, 2.1% (95% CI, 2.0%-2.2%) at 5 years, and 2.7% (95% CI, 2.5%-2.8%) at 9 years. The risk of a nonmesh SUI operation as the first reoperation for SUI was 0.4% (95% CI, 0.4%-0.5%) at 1 year, 1.2% (95% CI, 1.1%-1.2%) at 5 years, and 1.5% (95% CI, 1.4%-1.6%) at 9 years (Table 3).

Types of subsequent operations by initial route of insertion are provided in eTable 4 in the Supplement. 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. A total of 0.9% of women had multiple types of operations (removals, insertions, and nonmesh 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 in the Supplement). 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 1 year, 0.7% (95% CI, 0.7%-0.8%) at 5 years, and 0.9% (95% CI, 0.8%-1.0%) at 9 years (**Figure 4**).

Table 1. Risk of Mesh Sling Removal Following Initial Mesh Sling Insertion

Characteristic	Patients, No. (%)	Risk of Removal, % (95% CI)[a]			Subdistribution Hazard Ratio (95% CI)[b]	*P* Value[c]
		1 y	5 y	9 y		
Crude risk, no./No. (%)		1275/90 215 (1.4)	1508/52 715 (2.9)	240/6981 (3.4)		
Cumulative incidence	95 057 (100)	1.4 (1.3-1.4)	2.7 (2.6-2.8)	3.3 (3.2-3.4)		
Age at initial surgery, y						
18-39	10 292 (10.8)	2.0 (1.7-2.2)	3.6 (3.2-4.0)	4.4 (3.9-4.9)	1 [Reference]	<.001
40-49	33 094 (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	24 664 (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	16 877 (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	10 130 (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	16 136 (17.0)	1.3 (1.1-1.5)	2.7 (2.4-2.9)	3.2 (2.9-3.5)	1 [Reference]	.10
2	18 277 (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	20 468 (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	20 779 (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	19 397 (20.4)	1.5 (1.3-1.7)	2.8 (2.5-3.0)	3.5 (3.2-3.9)	1.08 (0.92-1.25)	
Racial/ethnic background[d]						
White	83 451 (95.8)	1.4 (1.3-1.5)	2.7 (2.6-2.8)	3.3 (3.2-3.4)	1 [Reference]	.07
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	7924 (8.3)					
Route of mesh sling insertion						
Retropubic	60 194 (63.3)	1.6 (1.5-1.7)	3.0 (2.9-3.2)	3.6 (3.5-3.8)	1 [Reference]	<.001
Transobturator	34 863 (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)	
Comorbidities[e]						
None	76 252 (80.2)	1.4 (1.3-1.5)	2.7 (2.6-2.8)	3.3 (3.2-3.5)	1 [Reference]	.37
≥1	18 805 (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	94 349 (99.2)	1.4 (1.3-1.5)	2.7 (2.6-2.8)	3.3 (3.1-3.4)	1 [Reference]	.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	94 710 (99.6)	1.4 (1.3-1.4)	2.7 (2.6-2.8)	3.3 (3.1-3.4)	1 [Reference]	.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	77 932 (82.0)	1.4 (1.3-1.4)	2.7 (2.6-2.8)	3.3 (3.1-3.4)	1 [Reference]	.14
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	16 308 (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	75 695 (79.6)	1.3 (1.2-1.4)	2.6 (2.5-2.7)	3.1 (3.0-3.3)	1 [Reference]	.17
Yes	19 362 (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	28 939 (30.3)	1.3 (1.2-1.4)	2.5 (2.3-2.7)	3.0 (2.8-3.3)	1 [Reference]	.67
60-119	44 228 (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	21 990 (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)	

[a] Cumulative incidence function and corresponding 95% CIs according to time after initial insertion.

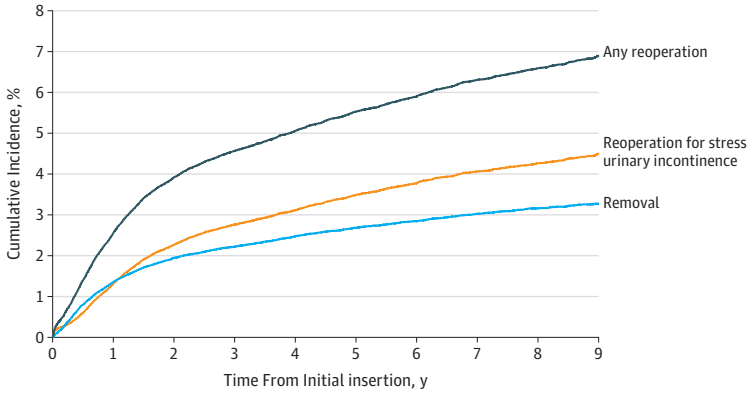
[b] Subhazard ratios calculated with competing risks regression model (Fine and Gray[30]) adjusted for all patient and hospital factors in the table.

[c] *P* value obtained from Wald test.

[d] Race/ethnicity percentages calculated for nonmissing data.

[e] Number of comorbidities derived from the Royal College of Surgeons' Charlson Comorbidity Index.

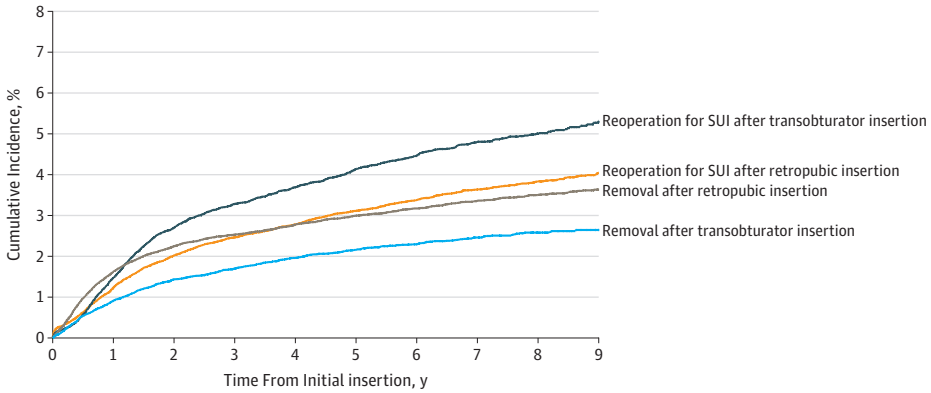
Figure 2. Mesh Sling Removal, Reoperation for Stress Urinary Incontinence, and Any Reoperation According to Time After Initial Mesh Insertion in 95 057 Women



No. at risk										
Any reoperation	95057	87800	79221	69654	59871	49499	38802	27821	16708	6428
Reoperation for stress urinary incontinence	95057	88963	80661	71050	61170	50628	39730	28535	17148	6590
Removal	95057	88940	80955	71514	61664	51207	40308	29058	17502	6741

Any reoperation included mesh removal and/or reoperation for stress urinary incontinence. Death from any cause was included as a competing risk. The median time of follow-up was 5.5 years (interquartile range, 3.2-7.5 years) in women who were alive at the end of follow-up. The cumulative incidence of "Reoperation for stress urinary incontinence" and "Removal" do not sum to the cumulative incidence of "Any reoperation" because some patients had the first 2 concurrently or at different times.

Figure 3. Mesh Sling Removal and Reoperation for Stress Urinary Incontinence (SUI) According to Time After Initial Insertion in 95 057 Women by Route of Insertion



No. at risk										
Reoperation for SUI										
After retropubic insertion	60194	56153	50864	44624	38297	31650	25101	18294	11440	4662
After transobturator insertion	34863	32810	29797	26426	22873	18978	14629	10241	5708	1928
Removal										
After retropubic insertion	60194	55920	50732	44620	38330	31751	25230	18466	11546	4710
After transobturator insertion	34863	33020	30223	26894	23334	19456	15078	10592	5956	2031

Death from any cause was included as a competing risk. The median time of follow-up was 5.4 years (interquartile range, 3.1-7.6 years) in women who had a retropubic insertion and 5.6 years (interquartile range, 3.4-7.5 years) in those who had a transobturator insertion.

Discussion

Within 9 years of 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 racial/ethnic background. These findings, showing lower removal rates after transobturator 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.

Table 2. Risk of Reoperation for Stress Urinary Incontinence Following Initial Mesh Sling Insertion

	Patients, No. (%)	Risk of Reoperation for Stress Urinary Incontinence, % (95% CI)[a]			Subdistribution Hazard Ratio (95% CI)[b]	*P* Value[c]
		1 y	5 y	9 y		
Crude risk, no./No. (%)		1252/90 215 (1.4)	2087/52 715 (3.9)	391/6981 (5.6)		
Cumulative incidence	95 057 (100)	1.3 (1.3-1.4)	3.5 (3.4-3.6)	4.5 (4.3-4.7)		
Age at initial surgery, y						
18-39	10 292 (10.8)	1.1 (1.0-1.3)	3.3 (3.1-3.5)	4.5 (4.2-4.8)	1 [Reference]	.29
40-49	33 094 (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	24 664 (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	16 877 (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	10 130 (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	16 136 (17.0)	1.3 (1.1-1.5)	3.5 (3.2-3.8)	4.2 (3.9-4.6)	1 [Reference]	.03
2	18 277 (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	20 468 (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	20 779 (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	19 397 (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)	
Racial/ethnic background[d]						
White	83 451 (95.8)	1.4 (1.3-1.4)	3.5 (3.4-3.7)	4.6 (4.4-4.8)	1 [Reference]	.05
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	7924 (8.3)					
Route of mesh sling insertion						
Retropubic	60 194 (63.3)	1.2 (1.1-1.3)	3.1 (3.0-3.3)	4.1 (3.8-4.3)	1 [Reference]	<.001
Transobturator	34 863 (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)	
Comorbidities[e]						
None	76 252 (80.2)	1.3 (1.2-1.4)	3.4 (3.3-3.6)	4.5 (4.3-4.7)	1 [Reference]	.35
≥1	18 805 (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	94 349 (99.2)	1.3 (1.2-1.4)	3.5 (3.3-3.6)	4.5 (4.3-4.7)	1 [Reference]	<.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	94 710 (99.6)	1.3 (1.2-1.4)	3.5 (3.3-3.6)	4.5 (4.3-4.7)	1 [Reference]	<.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	77 932 (82.0)	1.4 (1.3-1.4)	3.6 (3.5-3.7)	4.7 (4.5-4.9)	1 [Reference]	.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	16 308 (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	75 695 (79.6)	1.3 (1.2-1.4)	3.5 (3.4-3.6)	4.5 (4.3-4.8)	1 [Reference]	.84
Yes	19 362 (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	28 939 (30.3)	1.2 (1.1-1.4)	3.4 (3.2-3.6)	4.4 (4.1-4.8)	1 [Reference]	.37
60-119	44 228 (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	21 990 (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)	

[a] Cumulative incidence function and corresponding 95% CIs according to time after initial insertion.

[b] Subhazard ratios calculated with competing risks regression model (Fine and Gray[30]) adjusted for all patient and hospital factors in the table.

[c] *P* value obtained from Wald test.

[d] Race/ethnicity percentages calculated for nonmissing data.

[e] Number of comorbidities derived from the Royal College of Surgeons' Charlson Comorbidity Index.

Table 3. Risk of Mesh Removal or Reoperation for Stress Urinary Incontinence Following Initial Mesh Sling Insertion

	Patients, No. (%)	Risk of Any Reoperation, % (95% CI)[a]			Subdistribution Hazard Ratio (95% CI)[b]	*P* Value[c]
		1 y	5 y	9 y		
Crude risk, no./No. (%)		2415/90 215 (2.7)	3216/52 715 (6.1)	553/6981 (7.9)		
Cumulative incidence		2.6 (2.5-2.7)	5.5 (5.4-5.7)	6.9 (6.7-7.1)		
Age at initial surgery, y						
18-39	10 292 (10.8)	3.1 (2.8-3.4)	6.3 (5.8-6.9)	8.3 (7.6-9.2)	1 [Reference]	.01
40-49	33 094 (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	24 664 (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	16 877 (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	10 130 (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	16 136 (17.0)	2.5 (2.2-2.7)	5.5 (5.1-5.9)	6.6 (6.1-7.1)	1 [Reference]	.13
2	18 277 (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	20 468 (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	20 779 (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	19 397 (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)	
Racial/ethnic background[d]						
White	83 451 (95.8)	2.6 (2.5-2.7)	5.6 (5.4-5.8)	7.0 (6.8-7.2)	1 [Reference]	.02
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	7924 (8.3)					
Route of mesh sling insertion						
Retropubic	60 194 (63.3)	2.7 (2.6-2.9)	5.5 (5.3-5.7)	6.8 (6.5-7.0)	1 [Reference]	.61
Transobturator	34 863 (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)	
Comorbidities[e]						
None	76 252 (80.2)	2.5 (2.4-2.6)	5.5 (5.3-5.7)	7.0 (6.7-7.2)	1 [Reference]	.22
≥1	18 805 (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	94 349 (99.2)	2.6 (2.5-2.7)	5.5 (5.4-5.7)	6.9 (6.7-7.1)	1 [Reference]	.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	94 710 (99.6)	2.6 (2.5-2.7)	5.5 (5.4-5.7)	6.9 (6.7-7.1)	1 [Reference]	<.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	77 932 (82.0)	2.6 (2.5-2.7)	5.6 (5.4-5.8)	7.0 (6.8-7.3)	1 [Reference]	.002
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	16 308 (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	75 695 (79.6)	2.5 (2.4-2.6)	5.5 (5.3-5.6)	6.8 (6.6-7.1)	1 [Reference]	.37
Yes	19 362 (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	28 939 (30.3)	2.4 (2.2-2.6)	5.3 (5.0-5.6)	6.7 (6.3-7.1)	1 [Reference]	.40
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	21 990 (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)	

[a] Cumulative incidence function and corresponding 95% CIs according to time after initial insertion.

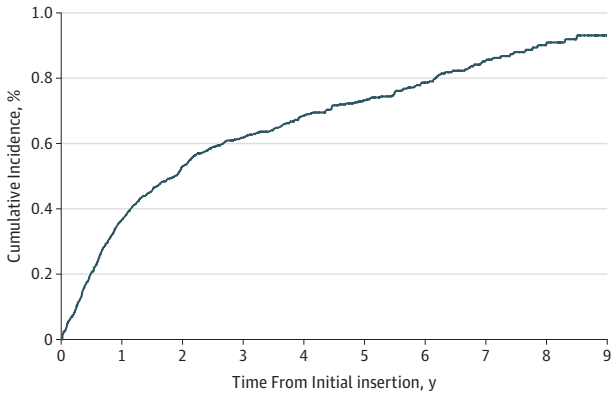
[b] Subhazard ratios calculated with competing risks regression model (Fine and Gray[30]) adjusted for all patient and hospital factors in the table.

[c] *P* value obtained from Wald test.

[d] Race/ethnicity percentages calculated for nonmissing data.

[e] Number of comorbidities derived from the Royal College of Surgeons' Charlson Comorbidity Index.

Figure 4. Total Sling Removal With No Subsequent Midurethral Sling Insertion According to Time After Initial Insertion in 60 194 Women Who Had Mesh Sling Inserted via Retropubic Route



No. at risk										
Removals	60194	55920	50732	44620	38330	31751	25230	18466	11546	4710

Death from any cause was included as a competing risk.

In routine practice in the English NHS, risks of MUS removal were 2.7% at 5 years and 3.3% at 9 years; however, 99.3% of women who had an initial retropubic MUS insertion between April 1, 2006, and December 31, 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 in the Supplement; Figure 4). 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.

The present results demonstrate that removal and reoperation risks were associated with the insertion route and patient factors. The risk of a removal was about 30% lower if the mesh sling had been inserted via the transobturator route, which may be explained by the removal of transobturator sling being a more complicated procedure. However, the risk of any reoperation, also including partial or total mesh sling removals, was not associated with the route of insertion, which, albeit indirectly, indicates that risk of a reoperation for SUI is higher in women who had a transobturator insertion. A Cochrane review also found that the risk of reoperation is higher after a transobturator mesh sling insertion, but this came from 4 small trials including only 695 women.[1]

The risk of mesh removal or any reoperation (mesh removal and/or reoperation for SUI) was considerably lower in older patients and in women from nonwhite racial/ethnic backgrounds, but an association with socioeconomic deprivation was not observed. These findings demonstrate that removal and reoperation risks may be associated with women's background. However, it is not possible to disentangle potential explanations for these differences in risks, which range from higher morbidity to differences in severity of the underlying condition that led to surgery as well as to how women perceived possible issues related to having a mesh sling inserted and their choices about seeking further clinical advice and treatment.

The use of mesh sling as a treatment for female SUI is rapidly decreasing in the United Kingdom, with a reduction by about 50% between 2008 and 2017.[31] This highlights a change in patient choice and surgical practice, which is likely to reflect concerns about longer-term complications, outcomes, and risk of further surgery after MUS insertion.

To our knowledge, this is the largest study of outcomes following MUS insertions for SUI in almost 100 000 women. The administrative hospital data set had near-100% coverage of patients treated in the English NHS, reducing the risk of selection bias. Furthermore, it is likely that at least 90% of all incontinence procedures carried out in England are provided by the NHS, given that the total annual spending on private health care in England is about 5% of the total annual spending on the NHS.[32]

Limitations

This study has several limitations. First, some relevant clinical and patient characteristics (eg, 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.[33] 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 recognized when diagnosis codes are being used for this purpose or when outpatient visits are being used as an indicator of further health care use.[34] 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 nonclassified 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 sensi-

tivity analyses starting the study period 1 year later and to including the previous coding standards.

Fourth, 3 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 removal 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 are required to provide insight into the reasons for MUS removal.

Conclusions

Among women undergoing midurethral 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.

ARTICLE INFORMATION

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REFERENCES

1. Ford AA, Rogerson L, Cody JD, Aluko P, Ogah JA. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev*. 2017;7(7):CD006375.

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.2011.07.049

3. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. *Obstet Gynecol*. 2014;123(6):1201-1206. doi:10.1097/AOG.0000000000000286

4. Aigmueller T, Trutnovsky G, Tamussino K, et al. Ten-year follow-up after the tension-free vaginal tape procedure. *Am J Obstet Gynecol*. 2011;205(5):496.e1-496.e5. doi:10.1016/j.ajog.2011.07.010

5. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 1996;7(2):81-85. doi:10.1007/BF01902378

6. Ward K, Hilton P; 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(7355):67. doi:10.1136/bmj.325.7355.67

7. Advancing Female Pelvic Medicine and Reconstructive Surgery; Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction. *Position Statement: Mesh Midurethral Slings for Stress Urinary Incontinence*. Silver Spring, MD: Advancing Female Pelvic Medicine and Reconstructive Surgery; 2018.

8. US Food & Drug Administration. Considerations about surgical mesh for SUI. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm. Accessed September 19, 2018.

9. NHS England. *Mesh Complications*. Leeds, England: NHS England; 2017.

10. Leone Roberti Maggiore U, Finazzi 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. *Int Urogynecol J*. 2017;28(8):1119-1130. doi:10.1007/s00192-017-3275-x

11. Morling JR, McAllister DA, 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. *Lancet*. 2017;389(10069):629-640. doi:10.1016/S0140-6736(16)32572-7

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. *Sci Rep*. 2017;7(1):12015. doi:10.1038/s41598-017-11821-w

13. NHS England. *Mesh Oversight Group Report*. Leeds, England: NHS England; 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. http://www.gov.scot/Resource/0051/00515856.pdf. Accessed September 16, 2017.

15. US 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*. Silver Spring, MD: US Food & Drug Administration; 2008.

16. NHS Digital. Hospital episode statistics (HES). http://content.digital.nhs.uk/hes. Accessed August 10, 2017.

17. World Health Organization. *International Statistical Classification of Diseases, Tenth Revision (ICD-10)*. Geneva, Switzerland: World Health Organization; 1992.

18. NHS. OPCS classification of interventions and procedures. http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp. Accessed August 5, 2017.

19. Burns EM, Rigby E, Mamidanna R, et al. Systematic review of discharge coding accuracy. *J Public Health (Oxf)*. 2012;34(1):138-148. doi:10.1093/pubmed/fdr054

20. UK Department for Communities and Local Government. The English indices of deprivation. https://www.gov.uk/government/collections/english-indices-of-deprivation. Updated September 30, 2015. Accessed September 19, 2018.

21. Armitage JN, van der Meulen JH; Royal College of Surgeons Co-morbidity Consensus Group. Identifying co-morbidity in surgical patients using administrative data with the Royal College of Surgeons Charlson Score. *Br J Surg*. 2010;97(5):772-781. doi:10.1002/bjs.6930

22. Siddiqui NY, Levin PJ, Phadtare A, Pietrobon R, Ammarell N. Perceptions about female urinary incontinence: a systematic review. *Int Urogynecol J Pelvic Floor Dysfunct*. 2014;25(7):863-871. doi:10.1007/s00192-013-2276-7

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)*. 2014;36(4):684-692.

24. British Society of Urogynaecology. Accreditation of units: standards for service provision in urogynaecology units: certification of units. http://bsug.org.uk/pages/information/accreditation-of-units/102. Accessed September 19, 2018.

25. Putter H, Fiocco M, Geskus RB. Tutorial in biostatistics: competing risks and multi-state models. *Stat Med*. 2007;26(11):2389-2430. doi:10.1002/sim.2712

26. Austin PC. A tutorial on multilevel survival analysis: methods, models and applications. *Int Stat Rev*. 2017;85(2):185-203. doi:10.1111/insr.12214

27. White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. *Stat Med*. 2011;30(4):377-399. doi:10.1002/sim.4067

28. Stata Statistical Software [computer program]. Version Release 14. College Station, TX: StataCorp LP; 2014.

29. NHS Digital. *HES Data Dictionary: Admitted Patient Care*. Leeds, England: NHS England; 2018.

30. Fine J, Gray R. A proportional hazards model for the subdistribution of a competing risk. *J Am Stat Assoc*. 1999;94:496-509. doi:10.1080/01621459.1999.10474144

31. NHS Digital. Retrospective review of surgery for urogynaecological prolapse and stress urinary incontinence using tape or mesh: hospital episode statistics (HES), experimental statistics, April 2008-March 2017. 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. Accessed September 19, 2018.

32. Commission on the Future of Health and Social Care in England. *The UK Private Health Market*. London, England: The King's Fund; 2014.

33. Mitropoulos D, Artibani W, Graefen M, Remzi M, Rouprêt M, Truss M; European Association of Urology Guidelines Panel. Reporting and grading of complications after urologic surgical procedures: an ad hoc EAU guidelines panel assessment and recommendations. *Eur Urol*. 2012;61(2):341-349. doi:10.1016/j.eururo.2011.10.033

34. 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 Med Res Methodol*. 2014;14(126):126. doi:10.1186/1471-2288-14-126