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GYNECOLOGY

Risk of reoperation 10 years after surgical treatment for stress urinary incontinence: a national population-based cohort study

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BACKGROUND: There is a debate about the safety and effectiveness of surgical treatments for stress urinary incontinence. Controversy about the use of synthetic mesh sling insertion has led to an increased uptake of retropubic colposuspension and autologous sling procedures. Comparative evidence on the long-term outcomes from these procedures is needed.

OBJECTIVE: To compare the risk of reoperation at 10 years after operation between women treated for stress urinary incontinence with retropubic colposuspension, mesh sling insertion, and autologous sling procedures.

STUDY DESIGN: The records of admissions to National Health Service hosptials were used to identify women who had first-time stress incontinence surgery between 2006 and 2013 in England. The first incidence of the following outcomes was assessed: further stress incontinence surgery, surgery for a complication (either mesh removal, prolapse repair, or incisional hernia repair), and any reoperation (either further stress incontinence surgery, mesh removal, prolapse repair, or incisional hernia repair). The cumulative incidence of each of these outcomes up to 10 years after surgery was calculated, considering death as a competing event. Multivariable modeling was then used to estimate the reoperation hazard ratios for the different initial surgery types with adjustments for patient characteristics and concurrent prolapse surgery or hysterectomy.

RESULTS: The analysis included 2262 women treated with retropubic colposuspension, 92,524 treated with mesh sling insertion, and 1234 treated with autologous sling. The cumulative incidence of any first reoperation at 10 years was 21.3% (95% confidence interval, 19.5—23.0) after retropubic colposuspension, 10.9% (10.7—11.1) after mesh sling insertion, and 12.0% (10.2—13.9) after autologous sling procedures. The women who had a retropubic colposuspension were significantly more likely to have a reoperation than women who had an autologous sling (adjusted hazard ratio for any reoperation: 1.79 [1.47—2.17]; for further stress incontinence surgery: 1.64 [1.19—2.26]; for surgery for complications: 1.89 [1.49—2.40]), whereas the women who had mesh slings had a similar hazard (for any reoperation: 0.90 [0.76—1.07]; for further stress incontinence surgery: 0.75 [0.57—0.99]; for surgery for complications: 1.11 [0.89—1.36]). A sensitivity analysis excluding the women who had concurrent prolapse surgery or hysterectomy produced similar results.

CONCLUSION: Retropubic colposuspension is associated with higher risk of reoperation at 10 years after surgery than mesh sling insertion or autologous sling procedures, with 1 in 5 women requiring reoperation.

Key words: adverse events, autologous sling, complications, fascial sling, hernia repair, incontinence surgery, mesh removal, pelvic organ prolapse, retropubic coloposuspension, synthetic mesh sling

Introduction

Since its introduction in 1998, synthetic mesh sling insertion has been the treatment of choice for stress urinary incontinence (SUI) in many countries. However, reports of severe adverse events following this treatment has led to a controversy about its use.[1] Some women treated with mesh slings have experienced pain, dyspareunia, persistent incontinence, and mesh exposure.[2,3]

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In England, the volume of patients treated with mesh slings fell from 11,000 in October 2009 to 4000 in 2017/18 in response to reports of adverse outcomes.[4] This has resulted in an increased uptake of alternative surgical procedures for SUI, such as retropubic colposuspension and autologous sling procedures (insertion of slings harvested from the patient's own fascia), which previously were gold standard treatments.[5,6]

A systematic review of the evidence from randomized controlled trials (RCTs) published in 2019 reported comparable effectiveness at the medium term between retropubic colposuspension, mesh sling insertion, and autologous sling procedures, and no evidence of increased adverse events with mesh slings.[7] However, the authors of that review cautioned that sparse data were available on effectiveness and adverse events beyond 1 year. The need for better data on the long-term safety and effectiveness of the surgical procedures used for SUI was also highlighted in a report from the Independent Medicines and Medical Devices Review in the United Kingdom published in 2020.[4]

Several recent studies have used population-based datasets to assess the long-term outcomes following SUI treatment with a mesh sling insertion. A study of 95,000 women in England reported that at 9 years after mesh sling insertion, 3.3% of women had mesh removal and 6.9% either had removal or further SUI surgery.[8] A study of 17,000 women in Scotland compared the postoperative complications, further SUI surgery, and further prolapse surgery between different SUI surgeries.[9] That study reported considerably lower risks of immediate complications and prolapse

AJOG at a Glance

Why was this study conducted?

Reviews have highlighted a need for comparative evidence on the long-term outcomes following the different surgical treatment options for stress urinary incontinence.

Key findings

Retropubic colposuspension is associated with a higher risk of reoperation than mesh sling insertion and autologous sling procedures, with one in 5 women requiring reoperation within 10 years of the initial surgery.

What does this add to what is known?

This study follows up women who had surgery for stress urinary incontinence to 10 years postsurgery, which is longer than any previous large study. We found differences in the reoperation risk between retropubic colposuspension and mesh and autologous sling procedures, which increased between 5 and 10 years of follow-up.

surgery at 5 years with mesh sling insertion than with open retropubic colposuspension, and a comparable risk of further SUI surgery and long-term complications at 5 years. In contrast, a study of 155,000 women in the United States reported that by 9 years of follow-up, the cumulative incidence of further SUI surgery was higher among the women treated with mesh or autologous sling insertion than the women treated with retropubic colposuspension.[10]

This study aimed to estimate the risk of reoperation associated with different types of SUI surgery, including retropubic colposuspension, mesh sling insertion, and autologous sling procedures, up to 10 years after surgery, using administrative hospital data on all the women who had first-time SUI surgery in the English National Health Service (NHS) between 2006 and 2013. We also assessed the risk of specific reoperation types, including further SUI surgery, mesh removal, incisional hernia repair, and prolapse surgery.

Materials and Methods

Data sources

Data on all the admissions to NHS hospitals in England from April 2002 to March 2019 were extracted from Hospital Episodes Statistics (HES), an administrative database of all care episodes in the NHS hospitals in England, with records including patient demographics, dates of admission and discharge, diagnostic and procedure information, and date of death. The NHS hospitals are reimbursed according to the clinical activity recorded in the HES database, so the completeness is expected to be high.[11] The surgical procedures for SUI were identified using the Office for Population Censuses and Surveys Classification of Interventions and Procedures Version 4 (OPCS-4) codes (full OPCS-4 code list in Supplemental Table 1).[12] Urethral bulking agents were excluded, as they are not a surgical procedure and are not expected to provide long-term cure for stress incontinence.

Cohort selection and outcome definition

All women who had a first-time treatment for SUI with retropubic colposuspension (abdominal or laparoscopic), a mesh sling insertion, or an autologous sling procedure between April 1, 2006 and March 31, 2013 were eligible for inclusion. The start of the inclusion period was chosen as mesh-specific OPCS-4 codes only became available in 2006, and the end was chosen to allow at least 6 years of follow-up for each patient. The mesh sling cohort included women who had a retropubic or transobturator midurethral sling (excluding single incision slings) and the autologous sling cohort included women with treatment codes for suprapubic sling and abdominoperineal suspension of the urethra (full OPCS-4 code list in Supplemental Table 1). A concurrent hysterectomy at the time of the initial SUI surgery was defined as the presence of an OPCS-4 code starting with "Q07" (abdominal hysterectomy) or "Q08" (vaginal hysterectomy). A concurrent prolapse repair was defined as the presence of any OPCS-4 code for prolapse repair (full OPCS-4 code list in Supplemental Table 2).

Women were excluded from the cohort if an SUI treatment code (any of the SUI treatments considered in this study, or a record of unspecified SUI surgery ["M53.9"] or urethral bulking agents ["M56.3"]) was included in the record of a hospital admission in the 3 years immediately before surgery. If a patient had a first nonmesh procedure but then went on to have an admission where mesh removal was recorded, it was assumed that the nonmesh procedure was an incorrectly recorded surgery with mesh, and the patient was included in the mesh sling insertion group.

The reoperations considered included mesh removal, further SUI surgery, prolapse surgery, and incisional hernia surgery (full OPCS-4 code list in Supplemental Table 2). Further SUI surgery indicates the recurrence of incontinence symptoms, whereas the other 3 surgeries may be required to treat complications of the initial procedure. Specifically, the risk of hernia is increased with open surgery and following autologous sling procedures owing to a weakness in the support of the anterior abdominal wall resulting from the removal of a piece of the rectus.

For the time-to-event analyses, the primary outcome was defined as the time from first-time SUI surgery to the first occurrence of any of the reoperations. If a patient had 2 of the different reoperations on the same day, the reoperation type was categorized as the first in the following sequence: mesh removal, further SUI surgery, prolapse surgery, hernia repair. This order was chosen to ensure that all the mesh removals were included in the results for the reoperation type. Two secondary

outcomes that were analyzed included the time to the first further stress incontinence surgery and the time to the first surgery for a complication (either mesh removal, prolapse repair, or incisional hernia repair), in each case, with the other event type ignored and death considered the only competing event.

A woman's ethnicity was retrieved from the record of the admission during which the SUI surgery took place. If the ethnicity information was not available in that record but was available in another HES record, the information from that record was used instead. The Index of Multiple Deprivation (IMD), a score covering an area with a typical population of 1500 people, was grouped into quintiles according to the national distribution and used to measure socioeconomic deprivation status.[13] The number of preexisting comorbid conditions at the time of surgery was generated using the algorithm developed by the Royal College of Surgeons of England[14] and was applied to the records of the admission with the SUI surgery and all admissions in the 3 preceding years.

Statistical methods

We estimated the cumulative incidence of any first reoperation (either of further SUI surgery or surgery for a complication) up to 10 years after the SUI surgery, considering death as a competing event. Follow-up for each woman ended at the first reoperation, at the end of the study period (March 31, 2019), after 10 years of follow-up, or death; whichever happened first. The cumulative incidence estimates were also produced for the other 2 outcomes of the first further SUI surgery and the first surgery for a complication.

The estimates of the cumulative incidence of any first reoperation were broken down according to the reoperation type. This was done by estimating the risk of each type of reoperation at each day of follow-up, considering only those patients who were not already censored, dead, or reoperated as being at risk on that day and then summing the estimated risks of each reoperation type at each day to generate the cumulative incidence of each type up to 10 years. The results are interpretable as the percentage of women who had each first reoperation type by 10 years of follow-up, where other potential outcomes were death or the occurrence of another reoperation first.

Fine-Gray competing risks regression models were used to estimate the risk-adjusted subdistribution hazard ratios (HRs), representing the relative differences in the incidence rates of the first reoperations between the 3 types of SUI surgery. The HRs were adjusted for differences between the surgery groups in age, socioeconomic deprivation, number of preexisting comorbidities, ethnicity, year of operation, and concurrent prolapse surgery or hysterectomy (divided into abdominal or vaginal).[15] The HRs estimated by the model can be interpreted as a measure of relative risk; a value of 1 implies no difference, a value >1 indicates an increased incidence compared with the reference, and a value <1 indicates a decreased incidence. Autologous sling was used as the reference category for estimates of HRs between the surgery types. A P value smaller than .05 was considered to indicate a statistically significant result.

One sensitivity analysis was done for the outcome of any reoperation as follows: the HRs were calculated only including the women who did not have a concurrent hysterectomy or prolapse surgery at time of the initial SUI surgery to assess for confounding from the differences in the frequency of these concurrent procedures on reoperation risk.

Results

Descriptive results

The records from a total of 96,020 women were analyzed, including 2262 who had a retropubic colposuspension, 92,524 who had a mesh sling insertion, and 1234 who had treatment with an autologous sling procedure. Most of the women were aged between 40 and 60 years at the time of the initial SUI surgery (Table 1). The groups of women receiving different types of SUI surgery were similar with respect to socioeconomic deprivation status, preexisting comorbidities, and ethnicity. A concurrent hysterectomy was more often carried out in women who had retropubic colposuspension (21.9%) than in women who had a mesh sling insertion (5.7%) or an autologous sling procedure (3.5%). Concurrent prolapse surgery was less frequently carried out in women who had an autologous sling procedure (8.6%) than in women who had a mesh sling insertion (16.9%) or retropubic colposuspension (17.1%).

The average time that women were followed-up to, defined as the time from SUI surgery to death or the end of follow-up, was 9.8 years for women treated with retropubic colposuspension, compared with 8.8 years for women treated with a mesh sling insertion, and 9.6 years for women treated with an autologous sling procedure.

Time-to-event results

There were stark differences in the cumulative incidence of any first reoperation at 10 years between women who had different types of SUI surgery as follows: 21.3% (95% confidence interval [CI], 19.5−23.0) for the women who had retropubic colposuspension, compared with 10.9% (95% CI, 10.7−11.1) for the women who had a mesh sling insertion, and 12.0% (95% CI, 10.2−13.9) for the women who had an autologous sling procedure (Table 2, Figure). Although mesh sling insertion and autologous sling procedures were associated with a similar incidence of any first reoperation, the types were different. Compared with the women who had an autologous sling procedure, the women who had a mesh sling insertion were at risk of having mesh removal (3.0% compared with 0.0%), but they had a lower incidence of further surgery for SUI (2.6% compared with 4.5%), hernia repair (0.7% compared with 1.9%), and prolapse surgery (4.6% compared with 5.5%).

In the analysis of the first surgery for a complication where further incontinence surgery was not considered as a competing event, the 10-year incidence was 15.6% (14.1%−17.2%) for women treated with retropubic colposuspension, compared with 8.8% (8.6%−8.9%)

TABLE 1
Baseline patient characteristics by the type of stress urinary incontinence surgery done (2006–2013)

Baseline characteristics	Retropubic colposuspension n (%) n=2262	Mesh sling insertion n (%) n=92,524	Autologous sling procedure n (%) n=1234
Concurrent prolapse surgery			
Yes	386 (17.1)	15,627 (16.9)	106 (8.6)
No	1876 (82.9)	76,897 (83.1)	1128 (91.4)
Concurrent hysterectomy			
Yes	495 (21.9)	5234 (5.7)	43 (3.5)
No	1767 (78.1)	87,290 (94.3)	1191 (96.5)
Age group (y)			
18–39	288 (12.7)	9687 (10.5)	150 (12.2)
40–49	814 (36.0)	31,390 (33.9)	371 (30.1)
50–59	544 (24.0)	23,777 (25.7)	314 (25.4)
60–69	412 (18.2)	17,181 (18.6)	230 (18.6)
≥70	202 (8.9)	10,484 (11.3)	161 (13.0)
Missing	2 (0.1)	5 (0.0)	8 (0.6)
Deprivation quintile[a]			
1 Most deprived	386 (17.1)	15,264 (16.5)	233 (18.9)
2	406 (17.9)	17,562 (19.0)	276 (22.4)
3	436 (19.3)	19,518 (21.1)	261 (21.2)
4	504 (22.3)	20,066 (21.7)	243 (19.7)
5 Least deprived	512 (22.6)	19,727 (21.3)	215 (17.4)
Missing	18 (0.8)	387 (0.4)	6 (0.5)
Number of comorbid conditions			
0	1743 (77.1)	72,016 (77.8)	921 (74.6)
1	444 (19.6)	17,085 (18.5)	251 (20.3)
2	59 (2.6)	2779 (3.0)	42 (3.4)
3+	16 (0.7)	644 (0.7)	20 (1.6)
Missing	0 (0.0)	0 (0.0)	0 (0.0)
Ethnicity			
White	2078 (91.9)	86,143 (93.1)	1168 (94.7)
Asian or Asian British	54 (2.4)	2086 (2.3)	25 (2.0)
Black or Black British	39 (1.7)	747 (0.8)	9 (0.7)
Other	45 (2.0)	1356 (1.5)	13 (1.1)
Missing	46 (2.0)	2192 (2.4)	19 (1.5)

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for women treated with mesh sling insertion, and 7.8% (6.3%–9.4%) for women who had an autologous sling procedure (Supplemental Table 3). In the equivalent analysis of first further SUI surgery, the 10-year incidence was 7.6% (6.5%–8.8%) for women treated with retropubic colposuspension, compared with 3.5% (3.3%–3.6%) for women who had a mesh sling insertion, and 4.8% (3.7%–6.2%) for women who had autologous sling procedures.

In the fully adjusted model for the hazard of any first reoperation, compared with women who had an autologous sling procedure, women who had a retropubic colposuspension had a considerably higher hazard (adjusted

TABLE 1
Baseline patient characteristics by the type of stress urinary incontinence surgery done (2006–2013) *(continued)*

Baseline characteristics	Retropubic colposuspension n (%) n=2262	Mesh sling insertion n (%) n=92,524	Autologous sling procedure n (%) n=1234
Year of operation			
2006	445 (19.7)	5578 (6.0)	297 (24.1)
2007	396 (17.5)	12,215 (13.2)	214 (17.3)
2008	347 (15.3)	13,560 (14.7)	155 (12.6)
2009	288 (12.7)	13,289 (14.4)	114 (9.2)
2010	246 (10.9)	12,778 (13.8)	101 (8.2)
2011	198 (8.8)	12,349 (13.3)	104 (8.4)
2012	173 (7.6)	11,610 (12.5)	124 (10.0)
2013	169 (7.5)	11,145 (12.0)	125 (10.1)
Missing	0 (0.0)	0 (0.0)	0 (0.0)

[a] Ecological measure of the socioeconomic status, based on the national distribution of the Index of Multiple Deprivation ranking of the patient's local area of residence.
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ratio, 1.79 [1.47–2.17]), whereas women who had mesh slings had a similar hazard (0.90 [0.76–1.07]; Table 3). In the adjusted model for the first surgery for a complication where further incontinence surgery was not treated as a competing event, retropubic colposuspension was associated with higher hazard (1.89 [1.49–2.40]) whereas mesh sling insertion was associated with similar hazard (1.10 [0.90–1.36]). In the equivalent model for the first further stress incontinence surgery, women treated with retropubic colposuspension had a higher hazard (1.78 [1.31–2.42]), and there was weak evidence to show that women treated with a mesh sling had a lower hazard (0.79 [0.60–1.03]).

A sensitivity analysis including only the 76,903 women who did not have a concurrent prolapse repair or hysterectomy at the time of initial SUI surgery returned very similar results (Supplemental Tables 4 and 5). The 10-year cumulative incidence of any reoperation was 19.9% (17.9%–22.2%) for women who had retropubic colposuspension, 9.8% (9.6%–10.1%) for women who had a mesh sling insertion, and 11.1% (9.3%–13.2%) for women who had an autologous sling procedure. In the modeling sensitivity analysis, the adjusted hazard ratio for reoperation for women who had retropubic colposuspension was 1.91 (1.53–2.38) and for women who had a mesh sling insertion it was 0.93 (0.77–1.13).

Comment

Principal findings

Women treated with retropubic colposuspension had nearly double the risk of any reoperation in the first 10 years after SUI surgery, compared with the women treated with a mesh sling insertion or an autologous sling procedure. Concurrent abdominal or vaginal hysterectomy or prolapse surgery alongside the initial SUI surgery were associated with an increased risk of reoperation. Women who had retropubic colposuspension were most likely to have one of these concurrent surgical procedures. However, this did not explain the higher reoperation rates; a sensitivity analysis including only women who did not have concurrent procedures returned similar results.

Mesh sling insertion and autologous sling procedures were associated with a similar overall risk of reoperation. The reoperation types, however, were different. Women who had mesh slings were at risk of having mesh removal but had a lower risk of further SUI surgery, hernia repair, and prolapse surgery.

Results in the context of what is known

Our finding of a 10-year cumulative incidence of further SUI surgery of 21.3% with retropubic colposuspension compared with 10.9% with a mesh sling insertion indicates a greater difference in long-term safety and effectiveness than has previously been reported. For example, a recent systematic review published in 2019 found no evidence of differences between mesh slings and retropubic colposuspension, but it concluded that there was a lack of data on long-term effectiveness and adverse outcomes.[7]

The population-based study in Scotland by Morling et al[9] found that readmissions for further SUI surgery by 5 years were slightly higher for women treated with retropubic colposuspension (6%) than with mesh (4% for retropubic and 5% for transobturator slings). We report a greater difference in the 10-year incidence of further stress incontinence surgery at 7.6% with retropubic colposuspension compared with 3.5% with mesh sling insertion, which is especially relevant for younger women undergoing first-time SUI surgery. In contrast to our study and the one in Scotland and a meta analysis published in 2019,[7] the population-based study in the United

TABLE 2
Cumulative incidence of any first reoperation (95% confidence interval) following stress urinary incontinence surgery by initial surgery type, broken out by reoperation done (2006–2013)

Number of patients at risk	Retropubic colposuspension	Mesh sling insertion	Autologous sling
Total cohort	2262	92,524	1234
At 1 y	2160	89,500	1191
At 5 y	1866	83,460	1089
At 10 y	951	28,483	559
Cumulative incidence of first reoperations (of any type)			
At 1 y	4.2 (3.4–5.1)	3.1 (2.9–3.2)	2.7 (1.9–3.7)
At 5 y	16.0 (14.4–17.4)	7.8 (7.6–7.9)	8.7 (7.2–10.3)
At 10 y	21.3 (19.5–23.0)	10.9 (10.7–11.1)	12.0 (10.2–13.9)
Distribution of first reoperation types at 1 y			
Mesh removal	0	1.3	0.0
Further stress incontinence surgery	1.6	1.0	1.8
Prolapse surgery	2.4	0.8	0.4
Hernia repair	0.2	0.1	0.5
Total	4.2	3.1	2.7
Distribution of first reoperation types at 5 y			
Mesh removal	0	2.4	0.0
Further stress incontinence surgery	5.4	2.1	3.8
Prolapse surgery	8.9	2.9	3.5
Hernia repair	1.6	0.4	1.3
Total	16.0	7.8	8.7
Distribution of first reoperation types at 10 y			
Mesh removal	0.0	3.0	0.0
Further stress incontinence surgery	7.1	2.6	4.5
Prolapse surgery	11.9	4.6	5.5
Hernia repair	2.3	0.7	1.9
Total	21.3	10.9	12.0

Data are presented as percentage.

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States by Jonsson Funk et al[10] reported a higher overall incidence of further stress incontinence surgery at 9 years follow-up with every initial surgery type, and a lower risk at 9 years follow-up with retropubic colposuspension (10.8%) compared with mesh sling insertion (13.0%). As that study evaluated women with specific private medical insurance plans up to age 65 years only in the period from 2000 to 2009, the different findings may be partly attributable to the differences in surgeon experience with mesh sling insertion (which was introduced from 1997) at that time and the patient population analyzed.

Our results are in line with other studies that compared the rates of prolapse surgery following retropubic colposuspension and mesh slings, though ours is the only study to report the cumulative incidence of these procedures over a follow-up period of 10 years. The Scottish population-based study reported that 7% of the women treated with retropubic colposuspension and 2% of the women treated with mesh slings had further prolapse surgery within 5 years, compared with 11.9% and 4.6%, respectively, within 10 years in our analysis.[9] An RCT comparing mesh sling insertion with retropubic colposuspension reported that 7.5% of women in the retropubic colposuspension arm and 1.8% of women in the mesh sling arm were readmitted for prolapse surgery by 5 years.[16] This difference in an RCT setting underlines that the increased prolapse risk associated with retropubic colposuspension can be directly attributed to the initial surgery and not to any residual case-mix

differences. The higher risk is likely to be attributable to the disruption of the vaginal axis leaving the posterior wall of the vagina under pressure or to an intrinsic weakness of the pelvic floor in these women.

Strengths and limitations

A key strength of this study is that it is based on a national population-based cohort of all the women who received SUI surgical treatment in the NHS in England between 2006 and 2013 and who were followed-up until March 31, 2019. Less than 5% of healthcare expenditure in England covers treatment outside the NHS, so the cohort is highly representative of the whole population.[17] The study outcome of reoperation within the NHS is expected to be near 100% complete for the same reason. We analyzed patients up to 10 years after their operation, a longer period than any previous large study, which fills the evidence gap on long-term outcomes.[7,18]

Another strength is that we estimated the cumulative incidence of the first reoperations by the reoperation type. These results illustrate the impact of higher rates of prolapse surgery and further SUI surgery after retropubic colposuspension on the overall risk of reoperation at 10 years. The statistics we report can be readily interpreted by patients and clinicians as the long-term risk of specific first reoperations following SUI surgery.

A limitation of our study is that we had no data on the patient-reported outcomes, which would have given further information about the nature and the severity of adverse outcomes after SUI surgery. Moreover, we had no details of the immediate intra- and postoperative complications or on the need for self-catherization. For 3 of the reoperation types (ie, further SUI surgery for persistent or recurrent incontinence, prolapse operation, or incisional hernia repair), the specific surgical procedure indicates the nature of problems treated. Mesh removal, however, can be done in response to the various adverse events known to be associated with a mesh sling insertion, but the indication for removal is not deducible in this study. In addition, it is likely that reoperations were only carried out if the problem was severe. So the cumulative incidence of reoperations underestimates the frequency of adverse outcomes after SUI surgery across the full spectrum of severity, as many women would choose not to have reoperations and cope with their problems.

Finally, the patients who had different types of SUI surgery may have had different characteristics that are associated with reoperation risk, which were not included in the risk adjustment in our models. However, given the observed risk of reoperation after a retropubic colposuspension is considerably higher than after mesh sling insertion or an autologous sling procedure, it is very unlikely that residual confounding can explain the difference.

Clinical and research implications

The decrease in the use of synthetic mesh sling insertion for continence surgery in many countries has resulted in an increase in nonmesh surgery (ie, retropubic colposuspension and autologous sling procedures).[4] It is important that the patients considering surgery are made aware of the evidence on the risks and benefits from each of these treatments. However, thus far, there have been sparse comparative data on the long-term outcomes. This study provides robust evidence that can be used to counsel women considering surgery.

Women considering surgery should be informed that the 10-year risk of surgery for mesh removal following synthetic sling insertion is approximately 3%, whereas the risk of reoperation for prolapse repair following retropubic colposuspension is over 10%. They should also be informed that the overall reoperation risk following retropubic colposuspension at approximately 20% is twice as high as the risk following surgery with synthetic or autologous slings.

The difference in the reoperation rates between the different SUI surgeries we report does not by itself support a restriction on the use of mesh slings, such as the pause on the routine use of them with the NHS in England

FIGURE
Cumulative incidence of reoperations up to 10 years by initial stress urinary incontinence surgery type, England, 2006 to 2013

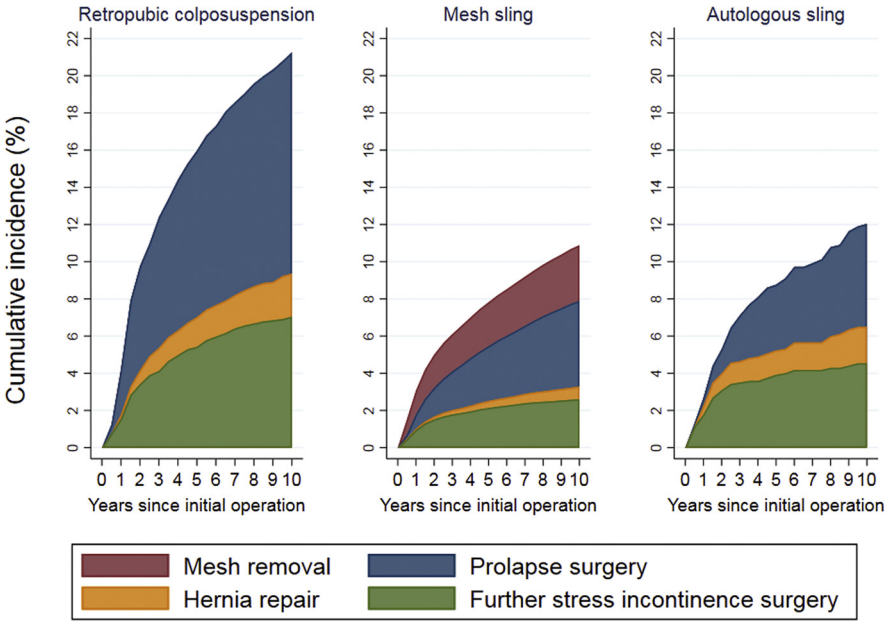

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TABLE 3
Fine-Gray model estimates of the reoperation hazard by the type of initial stress urinary incontinence surgery done for the following 3 outcomes: any first reoperation, first further stress incontinence surgery, and first surgery for a complication (2006–2013)

Characteristic	Subhazard ratio for any first reoperation (95% CI)	Subhazard ratio for first further stress incontinence surgery (95% CI)	Subhazard ratio for first surgery for a complication (95% CI)
Operation type			
Autologous sling	1.00	1.00	1.00
Retropubic colposuspension	1.79 (1.47–2.17)	1.78 (1.31–2.42)	1.89 (1.49–2.40)
Mesh sling insertion	0.90 (0.76–1.07)	0.79 (0.60–1.03)	1.10 (0.90–1.36)
Concurrent prolapse repair			
No	1.00	1.00	1.05 (0.96–1.14)
Yes	1.63 (1.55–1.71)	0.94 (0.85–1.03)	1.05 (0.96–1.14)
Concurrent hysterectomy			
None	1.00	1.00	1.00
Abdominal hysterectomy	1.08 (0.90–1.29)	0.56 (0.38–0.81)	1.37 (1.13–1.65)
Vaginal hysterectomy	1.09 (1.00–1.19)	0.71 (0.59–0.87)	1.18 (1.08–1.30)
Operation year			
2006	1.00	1.00	1.00
2007	1.05 (0.96–1.14)	1.09 (0.94–1.25)	1.05 (0.95–1.15)
2008	0.96 (0.89–1.05)	0.94 (0.81–1.08)	1.01 (0.91–1.11)
2009	0.89 (0.81–0.97)	0.77 (0.66–0.89)	0.94 (0.85–1.03)
2010	0.85 (0.78–0.93)	0.68 (0.58–0.79)	0.90 (0.81–1.00)
2011	0.85 (0.78–0.93)	0.65 (0.56–0.76)	0.94 (0.84–1.04)
2012	0.78 (0.71–0.86)	0.65 (0.55–0.76)	0.83 (0.74–0.92)
2013	0.75 (0.68–0.83)	0.58 (0.49–0.69)	0.84 (0.75–0.94)
Age group (y)			
18–39	1.00	1.00	1.00
40–49	0.95 (0.88–1.01)	0.84 (0.75–0.95)	0.99 (0.92–1.07)
50–59	0.89 (0.83–0.96)	0.72 (0.64–0.81)	0.94 (0.87–1.02)
60–69	0.91 (0.84–0.98)	0.77 (0.68–0.88)	0.92 (0.85–1.00)
≥70	0.77 (0.70–0.84)	0.80 (0.69–0.92)	0.69 (0.62–0.77)
Deprivation quintile,[a] n (%)			
1 Most deprived	1.00	1.00	1.00
2	1.03 (0.96–1.10)	1.03 (0.92–1.15)	1.05 (0.97–1.12)
3	0.96 (0.90–1.02)	0.98 (0.87–1.09)	0.96 (0.89–1.03)
4	0.96 (0.90–1.02)	1.01 (0.91–1.13)	0.97 (0.90–1.04)
5 least deprived	0.94 (0.88–1.00)	0.87 (0.78–0.98)	0.96 (0.90–1.04)
Charlson score			
0	1.00	1.00	1.00
1	1.04 (0.98–1.09)	1.05 (0.96–1.15)	1.04 (0.98–1.10)
2	1.15 (1.02–1.29)	1.15 (0.94–1.40)	1.13 (0.99–1.29)
3+	1.24 (0.98–1.56)	1.68 (1.19–2.36)	1.09 (0.83–1.44)

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TABLE 3
Fine-Gray model estimates of the reoperation hazard by the type of initial stress urinary incontinence surgery done for the following 3 outcomes: any first reoperation, first further stress incontinence surgery, and first surgery for a complication (2006–2013) *(continued)*

Characteristic	Subhazard ratio for any first reoperation (95% CI)	Subhazard ratio for first further stress incontinence surgery (95% CI)	Subhazard ratio for first surgery for a complication (95% CI)
Ethnicity			
White	1.00	1.00	1.00
Asian or Asian British	0.70 (0.60–0.81)	0.82 (0.64–1.05)	0.65 (0.55–0.78)
Black or Black British	0.80 (0.63–1.01)	0.81 (0.54–1.22)	0.81 (0.63–1.06)
Other	0.84 (0.70–1.00)	0.54 (0.37–0.79)	0.90 (0.74–1.09)

CI, confidence interval.

[a] Ecological measure of the socioeconomic status, based on the national distribution of the Index of Multiple Deprivation ranking of the patient's local area of residence.

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that has been in place since 2018. However, there is a need for long-term data from patient-reported outcomes following mesh and nonmesh surgeries to fully understand the relative long-term risks and benefits from these different procedures.

Conclusion

Women considering surgical treatment for SUI should be provided with robust information on its long-term effectiveness and the risk of adverse events. One in 5 women treated with retropubic colposuspension require reoperation within 10 years, whereas mesh sling insertion and autologous sling procedures are associated with considerably lower overall risk. However, the severity of the conditions leading to reoperation may be different between these 3 procedures, and long-term patient-reported outcome data are needed to give a complete picture of the risks and benefits associated with each procedure. ■

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Appendix

SUPPLEMENTAL TABLE 1

Office for Population Censuses and Surveys Classification of Interventions and Procedures Version-4 codes used to identify surgical treatments for stress urinary incontinence

Code	Description	Surgery group
M53.3	Introduction of tension-free vaginal tape	Mesh sling insertion
M53.6	Introduction of transobturator tape	Mesh sling insertion
M52.1	Suprapubic sling operation	Autologous sling
M51.1	Abdominoperineal suspension of urethra	Autologous sling
M52.3	Colposuspension of neck of bladder	Retropubic colposuspension

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SUPPLEMENTAL TABLE 2

Office for Population Censuses and Surveys Classification of Interventions and Procedures Version-4 codes used to identify mesh removal, prolapse surgery, further stress urinary incontinence surgery, and hernia repair

Code	Description	(Re-)operation type
M53.4	Total removal of tension-free vaginal tape	Mesh removal
M53.5	Partial removal of tension-free vaginal tape	Mesh removal
M53.7	Removal of transobturator tape	Mesh removal
M53.8 + Y03.7	Total or partial removal of tension-free vaginal tape	Mesh removal
M57.4	Partial removal of transobturator tape	Mesh removal
P18.1	Complete colpocleisis	Prolapse surgery
P18.2	Partial colpocleisis	Prolapse surgery
P23.2	Anterior colporrhaphy NEC	Prolapse surgery
P23.3	Posterior colporrhaphy NEC	Prolapse surgery
P23.4	Repair of enterocele NEC	Prolapse surgery
P23.5	Paravaginal repair	Prolapse surgery
P23.6	Anterior colporrhaphy with mesh reinforcement	Prolapse surgery
P23.7	Posterior colporrhaphy with mesh reinforcement	Prolapse surgery
P23.8	Other specified repair of prolapse of vagina	Prolapse surgery
P24.2	Sacrocolpopexy	Prolapse surgery
P24.4	Repair of vault of vagina using vaginal approach NEC	Prolapse surgery
P24.6	Repair of vault of vagina with mesh using vaginal approach	Prolapse surgery
P24.7	Sacrospinous fixation of vagina	Prolapse surgery
P24.5	Repair of vault of vagina with mesh using abdominal approach	Prolapse surgery
Q54.4	Suspension of uterus using mesh NEC	Prolapse surgery
Q54.5	Sacrohysteropexy	Prolapse surgery
M53.3	Introduction of tension-free vaginal tape	Further incontinence surgery

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SUPPLEMENTAL TABLE 2

Office for Population Censuses and Surveys Classification of Interventions and Procedures Version-4 codes used to identify mesh removal, prolapse surgery, further stress urinary incontinence surgery, and hernia repair *(continued)*

Code	Description	(Re-)operation type
M53.6	Introduction of transobturator tape	Further incontinence surgery
M52.1	Suprapubic sling operation	Further incontinence surgery
M51.1	Abdominoperineal suspension of urethra	Further incontinence surgery
M52.3	Colposuspension of neck of bladder	Further incontinence surgery
M56.3	Endoscopic injection of inert substance into outlet of female bladder	Further incontinence surgery
T252	Primary repair of incisional hernia using insert of prosthetic material	Hernia repair surgery
T253	Primary repair of incisional hernia using sutures	Hernia repair surgery
T262	Repair of recurrent incisional hernia using insert of prosthetic material	Hernia repair surgery
T263	Repair of recurrent incisional hernia using sutures	Hernia repair surgery
T259	Unspecified primary repair of incisional hernia	Hernia repair surgery

NEC, XXX.

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SUPPLEMENTAL TABLE 3

Cumulative incidences of first surgery for a complication and first further stress incontinence surgery

Characteristic	Retropubic colposuspension	Mesh sling insertion	Autologous sling
Cumulative incidence of first further stress incontinence surgery			
At 1 y	1.6 (1.1–2.1)	1.1 (1.1–1.2)	1.8 (1.2–2.6)
At 5 y	5.8 (4.8–6.8)	2.8 (2.7–2.9)	4.2 (3.2–5.4)
At 10 y	7.6 (6.5–8.8)	3.5 (3.3–3.6)	4.8 (3.7–6.2)
Cumulative incidence of first surgery for a complication			
At 1 y	3.0 (2.4–3.8)	2.2 (2.1–2.3)	0.9 (0.5–1.6)
At 5 y	11.5 (10.3–12.9)	5.9 (5.8–6.1)	4.9 (3.8–6.2)
At 10 y	15.6 (14.1–17.2)	8.8 (8.6–8.9)	7.8 (6.3–9.4)

Data are presented as percentage (interquartile range).

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SUPPLEMENTAL TABLE 4

Cumulative incidence of first reoperations following first stress urinary incontinence surgery which was not accompanied by concurrent prolapse repair or hysterectomy, 2006 to 2013

Characteristic	Retropubic colposuspension	Mesh sling insertion	Autologous sling
Number of patients at risk			
Total cohort	1449	74,361	1093
At 1 y	1389	72,162	1052
At 5 y	1217	67,787	970
At 10 y	627	23,230	508
Cumulative incidence of any first reoperation			
At 1 y	3.9 (2.9–4.9)	2.8 (2.6–2.9)	2.9 (2.1–4.1)
At 5 y	14.4 (12.6–16.2)	6.9 (6.8–7.1)	8.1 (6.5–9.8)
At 10 y	19.9 (17.9–22.2)	9.8 (9.6–10.1)	11.1 (9.3–13.2)
Incidence of different reoperation types at 10 y			
Mesh removal	0.0	3.0	0.0
Further stress incontinence surgery	8.6	2.7	5.0
Prolapse surgery	9.3	3.5	4.5
Hernia repair	2.1	0.7	1.7

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SUPPLEMENTAL TABLE 5

Fine-Gray model results: hazard ratios for differences in first reoperation hazard by initial surgery type, including only first stress urinary incontinence surgeries which were not accompanied by concurrent prolapse repair or hysterectomy, 2006–2013

Characteristic	Subhazard ratio for any first reoperation	95% confidence interval	*P* value
Operation type			<.01
Autologous sling	1.00		
Retropubic colposuspension	1.91	(1.53–2.38)	
Mesh sling insertion	0.93	(0.77–1.13)	
Operation year			<.01
2006	1.00		
2007	1.05	(0.95–1.16)	
2008	0.95	(0.86–1.05)	
2009	0.87	(0.79–0.97)	
2010	0.82	(0.74–0.92)	
2011	0.83	(0.74–0.92)	
2012	0.77	(0.69–0.87)	
2013	0.72	(0.64–0.81)	
Age group (y)			.02
18–39	1.00		
40–49	0.96	(0.88–1.04)	
50–59	0.90	(0.83–0.98)	
60–69	0.93	(0.85–1.01)	
≥70	0.86	(0.77–0.95)	
Deprivation quintile,[a] n (%)			.04
1 Most deprived	1.00		
2	1.03	(0.95–1.11)	
3	0.95	(0.88–1.02)	
4	0.97	(0.89–1.05)	
5 least deprived	0.92	(0.86–1.00)	
Number of comorbid conditions			<.01
0	1.00		
1	1.07	(1.00–1.13)	
2	1.19	(1.04–1.36)	
3+	1.43	(1.12–1.83)	
Ethnicity			<.01
White	1.00		
Asian or Asian British	0.74	(0.62–0.89)	
Black or Black British	0.89	(0.68–1.18)	
Other	0.80	(0.65–1.00)	

[a] Ecological measure of the socioeconomic status, based on the national distribution of the Index of Multiple Deprivation ranking of the patient's local area of residence.

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