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

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CONDENSATION

The 10-year reoperation risk following treatment of stress incontinence with retropubic colposuspension is approximately 20%; twice as high compared to mesh sling or autologous sling procedures.

SHORT TITLE

Reoperation risk following stress urinary incontinence surgery.

AJOG AT A GLANCE

Why was this study conducted?

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

What are the key findings?

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

What does this study add to what is already known?

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

ABSTRACT

Background There is 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 increased uptake of retropubic colposuspension and autologous sling procedures. Comparative evidence on long-term outcomes from these procedures is needed.

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

Study Design Records of admissions to National Health Service hospitals 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 modelling was then used to estimate reoperation hazard ratios (HRs) for different initial surgery types with adjustment for patient characteristics and concurrent prolapse surgery or hysterectomy.

Results The analysis included 2 262 women treated with retropubic colposuspension, 92 524 treated with mesh sling insertion, and 1 234 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. Compared to women who had an autologous sling, women who had retropubic colposuspension were significantly more likely to have a reoperation (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)), while women who had mesh slings had 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 women who had concurrent prolapse surgery or hysterectomy produced similar results.

Conclusion Retropubic colposuspension is associated with higher rates of reoperation by 10 years after surgery than mesh sling insertion or autologous sling procedures, with one in five women requiring reoperation.

KEYWORDS

Retropubic coloposuspension; synthetic mesh sling; autologous sling; fascial sling; pelvic organ prolapse; incontinence surgery; hernia repair; mesh removal; adverse events; complications

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 controversy about its use.[1] Some women treated with mesh slings have experienced pain, dyspareunia, persistent incontinence, and mesh exposure.[2, 3] In England, the volume of patients treated with mesh slings fell from 11 000 in 2009/10 to 4 000 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 were previously gold standard treatments.[5, 6]

A systematic review of the evidence from 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 was available on effectiveness and adverse events beyond one year. The need for better data on long-term safety and effectiveness of 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 long-term outcomes following SUI treatment with a mesh sling insertion. One study of 95 000 women in England reported that at nine years after mesh sling insertion, 3.3% of women had mesh removal and 6.9% had either removal or further SUI surgery.[8] A study of 17 000 women in Scotland compared 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 surgery at five years with mesh sling insertion compared to open retropubic colposuspension, and a comparable risk of further SUI surgery and long-term complications at five years. In contrast, a study of 155 000 women in the United States reported that by 9 years follow up, the cumulative incidence of further SUI surgery was higher amongst women treated with mesh or autologous sling insertion compared to women treated with retropubic colposuspension.[10]

The aim of our study was to estimate the risk of reoperations 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 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 admissions to NHS hospitals in England from April 2002 to March 2019 were extracted from the Hospital Episode Statistics (HES), an administrative database of all care episodes in NHS hospitals in England, with records including patient demographics, dates of admission and discharge, diagnostic and procedure information, and date of death. NHS Hospitals are reimbursed according to clinical activity recorded in the HES database, so the completeness is expected to be high.[11] 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 Appendix 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 1st April 2006 and 31st March 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 six years of follow up for each patient. The mesh sling cohort included women who had a retropubic or transobturator mid-urethral 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 Appendix 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 Appendix 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 code (“M56.3”)) was included in the record of a hospital admission in the three years immediately before surgery. If a patient had a first non-mesh procedure but then went on to have an admission where mesh removal was recorded, it was assumed that the non-mesh

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 Appendix Table 2). Further SUI surgery indicates recurrence of incontinence symptoms, whilst the other three surgeries may be required to treat complications of the initial procedure. Risk of hernia specifically is increased with open surgery, and also following autologous sling procedures, due to weakness in the support of the anterior abdominal wall resulting from removal of a piece of the rectus.

For the time-to-event analyses, the primary outcome was defined as time from first-time SUI surgery to the first occurrence of any of the reoperations. If a patient had two of the different reoperations on the same day, the reoperation type was categorised as the first in the following sequence: mesh removal, further SUI surgery, prolapse surgery, hernia repair. This order was chosen to ensure that all mesh removals were included in the results for reoperation type. Two secondary outcomes analysed included time to first further stress incontinence surgery and time to 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, information from that record was used instead. The Index of Multiple Deprivation (IMD), a score covering an area with a typical population of 1 500 people, was grouped into quintiles according to the national distribution and used to

measure socioeconomic deprivation status.[13] The number of pre-existing comorbid conditions at the time of surgery was generated using the algorithm developed by the Royal College of Surgeons of England,[14] applied to records of the admission with the SUI surgery and all admissions in the three 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 SUI surgery, considering death as a competing event. Follow up for each woman ended at first reoperation, at the end of the study period (31st March 2019), after 10 years of follow up, or death; whichever happened first. Cumulative incidence estimates were also produced for the other two outcomes of first further SUI surgery and 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 not already censored, dead, or reoperated as being at risk on that day, 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 follow up, where other potential outcomes were death or occurrence of another reoperation first.

Fine-Gray competing risks regression models were used to estimate the risk-adjusted subdistribution hazard ratio (HRs) representing the relative differences in the incidence rates of first reoperations between the three types of SUI surgery. The HRs were adjusted

for differences between the surgery groups in age, socioeconomic deprivation, number of pre-existing 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 to the reference and a value less than 1 a decreased incidence. Autologous sling was used as the reference category for estimates of HRs between surgery types. A p-value smaller than 0.05 was considered to indicate a statistically significant result.

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

RESULTS

Descriptive results

Records from 96 020 women were analysed, including 2 262 who had retropubic colposuspension, 92 524 who had a mesh sling insertion, and 1 234 who had treatment with an autologous sling procedure. The majority of women were aged between 40 and 60 years at the time of initial SUI surgery (Table 1). The groups of women receiving different types of SUI surgery were similar with respect to socioeconomic deprivation status, pre-existing comorbidities, and ethnicity. A concurrent hysterectomy was more often carried out in

229 women who had retropubic colposuspension (21.9%) than in women who had a mesh sling
230 insertion (5.7%), or autologous sling procedure (3.5%). Concurrent prolapse surgery was less
231 frequently carried out in women who had an autologous sling procedure (8.6%) than in
232 women who had a mesh sling insertion (16.9%) or retropubic colposuspension (17.1%).

233 The average time that women were followed up, defined as the time from SUI surgery to
234 death or end of follow-up, was 9.8 years for women treated with retropubic
235 colposuspension, compared to 8.8 years for women treated with a mesh sling insertion and
236 9.6 years for women treated with an autologous sling procedure.

237

238 **Time to event results**

239 There were stark differences in the cumulative incidence of any first reoperation at 10 years
240 between women who had different types of SUI surgery: 21.3% (95% confidence interval:
241 19.5% - 23.0%) for the women who had retropubic colposuspension, compared to 10.9%
242 (95% confidence interval: 10.7% - 11.1%) for women who had a mesh sling insertion, and
243 12.0% (95% confidence interval: 10.2% - 13.9%) for the women who had an autologous sling
244 procedure (Table 2, Figure 1). While mesh sling insertion and autologous sling procedures
245 were associated with similar incidence of any first reoperation, the types were different.
246 Compared to women who had an autologous sling procedure, the women who had a mesh
247 sling insertion were at risk of having mesh removal (3.0% compared to 0.0%), but they had a
248 lower incidence of further surgery for SUI (2.6% compared to 4.5%), hernia repair (0.7%
249 compared to 1.9%), and prolapse surgery (4.6% compared to 5.5%).

250 In the analysis of first surgery for a complication, where further incontinence surgery was
251 not considered as a competing event, the 10-year incidence was 15.6% (14.1% - 17.2%) for

252 women treated with retropubic colposuspension, compared to 8.8% (8.6% - 8.9%) for
253 women treated with mesh sling insertion and 7.8% (6.3% - 9.4%) for women who had an
254 autologous sling procedure (Appendix Table 3). In the equivalent analysis of first further SUI
255 surgery, the 10-year incidence was 7.6% (6.5% - 8.8%) for women treated with retropubic
256 colposuspension, compared to 3.5% (3.3% - 3.6%) for women who had a mesh sling
257 insertion and 4.8% (3.7% - 6.2%) for women who had autologous sling procedures.

258 In the fully adjusted model for hazard of any first reoperation, compared to women who
259 had an autologous sling procedure, women who had retropubic colposuspension had
260 considerably higher hazard (adjusted ratio: 1.79 (1.47 - 2.17)), while women who had mesh
261 slings had similar hazard (0.90 (0.76-1.07)). In the adjusted model for first surgery for a
262 complication, where further incontinence surgery was not treated as a competing event,
263 retropubic colposuspension was associated with higher hazard (1.89 (1.49 – 2.40)) whilst
264 mesh sling insertion was associated with similar hazard (1.10 (0.90 – 1.36)). In the
265 equivalent model for first further stress incontinence surgery, women treated with
266 retropubic colposuspension had higher hazard (1.78 (1.31 – 2.42)), and there was weak
267 evidence women treated with a mesh sling had lower hazard (0.79 (0.60 – 1.03)).

268 A sensitivity analysis, including only the 76 903 women who did not have a concurrent
269 prolapse repair or hysterectomy at time of initial SUI surgery, returned very similar results
270 (Appendix Table 4, Appendix Table 5). The 10-year cumulative incidence of any reoperation
271 was 19.9% (17.9% - 22.2%) for women who had retropubic colposuspension, 9.8% (9.6% -
272 10.1%) for women who had a mesh sling insertion, and 11.1% (9.3% - 13.2%) in women who
273 had an autologous sing procedure. In the modelling 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 rate of any reoperation in the first 10 years after SUI surgery, compared to 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 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 similar overall risk of reoperation. The reoperation types were different, however. Women who had mesh slings were at risk of having mesh removal, but had 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 to 10.9% with a mesh sling insertion indicates a

296 greater difference in long-term safety and effectiveness than has previously been reported.
297 For example, a recent systematic review published in 2019 found no evidence of differences
298 between mesh slings and retropubic colposuspension, but it concluded that there was a lack
299 of data on long-term effectiveness and adverse outcomes.[7]

300 The population-based study in Scotland by Morling *et al* found that readmissions for further
301 SUI surgery by five years were slightly higher for women treated with retropubic
302 colposuspension (6%) compared to mesh (4% for retropubic and 5% for transobturator
303 slings).[9] We report a greater difference in the 10-year incidence of further stress
304 incontinence surgery, at 7.6% with retropubic colposuspension compared to 3.5% with
305 mesh sling insertion, which is especially relevant for younger women undergoing first-time
306 SUI surgery. In contrast to our study and the one in Scotland, and a meta analysis published
307 in 2019,[7] the population-based study in the United States by Jonsson Funk *et al* reported
308 higher overall incidence of further stress incontinence surgery at 9 years follow up with
309 every initial surgery type, and a lower risk 9 years follow up with retropubic
310 colposuspension (10.8%) compared to mesh sling insertion (13.0%).[10] As that study
311 evaluated women with specific private medical insurance plans up to age 65 only in the
312 period 2000-2009, the different findings may be partly attributable to differences in surgeon
313 experience with mesh sling insertion (which was introduced from 1997) at that time, and
314 the patient population analysed.

315 Our results are in line with other studies which compared rates of prolapse surgery
316 following retropubic colposuspension and mesh slings, though ours is the only study to
317 report the cumulative incidence of these procedures over a follow-up period of 10 years.
318 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 five years, compared to 11.9% and 4.6% within 10 years in our analysis.[9] A randomised controlled trial 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 five 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 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 women who received SUI surgical treatment in the NHS in England between 2006 and 2013, followed up until 31st March 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, reoperation within the NHS, is expected to be near 100% complete for the same reason. We analysed 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 first reoperations by 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 by 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.

One limitation of our study is that we had no data on patient-reported outcomes which would have given further information about the nature and the severity of adverse outcomes after SUI surgery. We also had no details of immediate intra- and post-operative complications, or on need for self-catherization. For three of the reoperation types (i.e. further SUI surgery for persistent/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 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 if the problem was severe, and 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 non-mesh surgery (i.e. retropubic colposuspension and autologous sling procedures).[4] It is important that patients considering surgery are made aware of the evidence on the risks and benefits from each of these treatments.

However, thus far there has been sparse comparative data on long-term outcomes. This study provides robust evidence which 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% while risk of reoperation for prolapse repair following retropubic colposuspension is over 10%; and also 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 reoperation rates between different SUI surgeries we report does not by itself support a restriction on the use of mesh slings, such as the pause on routine use of them with the NHS in England which has been in place since 2018. However, there is a need for long-term data from patient reported outcomes following mesh and non-mesh surgeries to fully understand the relative long-term risks and benefits from these different procedures.

Conclusion

Women considering surgical treatment for stress urinary incontinence should be provided with robust information on its long-term effectiveness and the risk of adverse events. One in five women treated with retropubic colposuspension require reoperation within ten years, whilst 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 three 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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435

436

437 *Table 1. Baseline patient characteristics by type of stress urinary incontinence surgery done,*
438 *2006-2013.*

	Retropubic colposuspension number (%)	Mesh sling insertion number (%)	Autologous sling procedure number (%)
	2 262	9 2524	1 234
Concurrent prolapse surgery			
Yes	386 (17.1%)	15 627 (16.9%)	106 (8.6%)
No	1 876 (82.9%)	76 897 (83.1%)	1 128 (91.4%)
Concurrent hysterectomy			
Yes	495 (21.9%)	5 234 (5.7%)	43 (3.5%)
No	1 767 (78.1%)	87 290 (94.3%)	1 191 (96.5%)
Age group (years)			
18-39	288 (12.7%)	9 687 (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*			
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	1 743 (77.1%)	72 016 (77.8%)	921 (74.6%)
1	444 (19.6%)	17 085 (18.5%)	251 (20.3%)
2	59 (2.6%)	2 779 (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	2 078 (91.9%)	86 143 (93.1%)	1 168 (94.7%)
Asian / Asian British	54 (2.4%)	2 086 (2.3%)	25 (2.0%)
Black / Black British	39 (1.7%)	747 (0.8%)	9 (0.7%)
Other	45 (2.0%)	1 356 (1.5%)	13 (1.1%)
Missing	46 (2.0%)	2 192 (2.4%)	19 (1.5%)
Year of operation			
2006	445 (19.7%)	5 578 (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%)

* 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.

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.

	Retropubic colposuspension	Mesh sling insertion	Autologous sling
Number of patients at risk			
Total cohort	2,262	92,524	1,234
At 1 year	2,160	89,500	1,191
At 5 years	1,866	83,460	1,089
At 10 years	951	28,483	559
Cumulative incidence of first reoperations (of any type)			
At 1 year	4.2% (3.4%, 5.1%)	3.1% (2.9%, 3.2%)	2.7% (1.9%, 3.7%)
At 5 years	16.0% (14.4%, 17.4%)	7.8% (7.6%, 7.9%)	8.7% (7.2%, 10.3%)
At 10 years	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 year			
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 years			
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 years			
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%***

450 *Table 3. Fine-Gray model estimates of reoperation hazard by type of initial stress urinary*
451 *incontinence surgery done, for three outcomes: any first reoperation, first further stress*
452 *incontinence surgery and first surgery for a complication, 2006-2013.*

	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 (years)			
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*, 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)
Ethnicity			
White	1.00	1.00	1.00
Asian / Asian British	0.70 (0.60, 0.81)	0.82 (0.64, 1.05)	0.65 (0.55, 0.78)
Black / 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)

* 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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454 **List of Figures & Legends**
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456

457 **Figure 1.** Cumulative incidence of reoperations up to 10 years by initial stress urinary
458 incontinence surgery type, England, 2006-2013.

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