Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: population based cohort study

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ABSTRACT

OBJECTIVE

To assess the use of mesh in pelvic organ prolapse surgery, and compare short term outcomes between procedures using and not using mesh.

DESIGN

All inclusive, population based cohort study.

SETTING

Statewide surgical care captured in the New York Statewide Planning and Research Cooperative System.

PARTICIPANTS

Women who underwent prolapse repair procedures in New York state from 2008 to 2011.

MAIN OUTCOMES MEASURES

90 day safety events and reinterventions within one year, after propensity score matching. Categorical, time to event, and subgroup analyses (<65 and ≥65 year age groups) were conducted.

RESULTS

Of 27 991 patients in total, 7338 and 20 653 underwent prolapse repair procedures with and without mesh, respectively. Mesh use increased by 44.7%, from 1461 procedures in 2008 to 2114 procedures in 2011. Most patients in the cohort were younger than 65 years (62.3% (n=17 424/27 991)). However, more patients were aged 65 years and older in the mesh group than in the non-mesh group (44.3% (n=3249) *v* 35.4% (n=7318)). Complications after surgery were not common, irrespective of the use or non-use of mesh. After propensity score matching, patients who received the surgery with mesh had a higher chance of having a reintervention within one year (mesh 3.3% *v* no mesh 2.2%, hazard ratio 1.47 (95% confidence interval 1.21 to 1.79)) and were more likely to have urinary retention within 90 days (mesh 7.5% *v* no mesh 5.6%, risk ratio 1.33 (95% confidence interval 1.18 to 1.51)), compared with those who received surgery without mesh. In subgroup analyses based on age, mesh use was associated with an increased risk of reintervention within one year in patients under age 65 years, and increased risk of urinary retention in patients aged 65 years and over.

CONCLUSIONS

Despite multiple warnings released by the US Food and Drug Administration since 2008, use of mesh in pelvic organ prolapse surgery continues to grow. In this statewide comprehensive study, mesh procedures were associated with an increased risk of reinterventions within one year and urinary retention after surgery.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Mesh is thought to reduce rates of recurrence after pelvic organ prolapse surgery and provide better anatomical results

However, multiple alerts have been released by the US Food and Drug Administration, relating to safety events and complications from mesh use

It is unclear how often mesh is used, and whether short term outcomes after use differ from those after non-use

WHAT THIS STUDY ADDS

The use of mesh based repairs in pelvic organ prolapse surgery continues to increase even three to four years after regulatory alerts

In a propensity matched analysis using a large, all inclusive, observational longitudinal cohort of New York state, patients undergoing mesh based surgery were at increased risk of urinary retention after surgery and reintervention at one year follow-up

Patients younger than 65 years old were at higher risk for reintervention and those aged 65 years and older were at higher risk of complications

Introduction

In 1996, the first mesh—a synthetic graft—was approved for the surgical treatment of incontinence by reinforcing weakened tissue.[1] Twelve years later, the US Food and Drug Administration (FDA) released a public health notification that placed the use of mesh for pelvic organ prolapse (POP) under national scrutiny.[2] In 2011, the FDA updated safety communication and added a caution for transvaginal placement of mesh in POP surgery, reporting 1503 events from the Manufacturer and User Facility Device Experience (MAUDE) database from 1 January 2008 to December 2010 associated with mesh repair.[3 4] In addition, the FDA alerted that complications increased fivefold over time.[5] Subsequently, the safety of surgical mesh has been the target of major media coverage[6 7] and has led to several lawsuits.[8]

POP occurs when the uterus or vaginal walls weaken and descend, causing a variety of symptoms including pressure, pain, bleeding, and incontinence. Previous studies have reported a large increase of mesh or graft use in female patients with POP undergoing surgical repair during the past decade.[9 10] Importantly, mesh use has been reported to rise even in the year after the first FDA announcement.[11] Although a year is a relatively short period to ascertain the trend, the possible rise in use of mesh has major implications for an estimated 200 000 inpatient procedures for POP conducted each year in the United States alone.[12] Moreover, POP is a highly prevalent condition, and the national estimates have been difficult to attain owing to a lack of reporting and treatment. There is evidence that an estimated lifetime risk of receiving surgical intervention for POP is around 11% by the age of 80 years in the USA.[13] Owing to an ageing population, the rates of POP interventions are predicted to grow.[14] Importantly, the recent National Health and Nutrition Examination Survey (NHANES) study[15] has reported that most women with POP are younger than 65 years.

Mesh repair for POP is mostly performed transvaginally (>75%), and was thought to reduce rates of prolapse recurrence and provide better anatomical results than procedures not using mesh.[16 17] However, comparative randomized trials and population based studies of prolapse repair surgery with and without mesh reported conflicting results and were limited by small size and patient selection.[18-21] A 2013 Cochrane review did not report increased failure occurrence with mesh repair, but it was limited by overall size (<500 patients) and lacked data for safety and patient morbidity.[22] There were also limitations to the FDA MAUDE database reports, such as missing denominators and no safeguards to prevent multiple reports to the database for the same complication in one patient. These factors may have artificially inflated the number of events with erroneous estimates of mesh safety.

We did major population cohort based analyses using all inclusive data of women undergoing POP surgery in the state of New York. Because most patients with POP are younger than 65 years, the dataset is uniquely positioned to address the use and outcomes of mesh compared with Medicare data, which is limited to populations older than 65 years old. We assessed both the use of mesh and short term outcomes to determine the safety of mesh in POP surgery, compared with procedures not using mesh. The study's secondary objective was to conduct subgroup analyses by age.

Methods

Data source

Our data source was an all inclusive cohort that was created using information from the New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS). Established in 1979, SPARCS is an all age group, all payer database that collects patient and treatment information for every hospital discharge, ambulatory surgery, outpatient service, and emergency department admission in New York state.[23] The data contain patient characteristics, primary and secondary diagnoses and procedures, and length of stay and charges. A unique personal identifier is assigned to every patient and encrypted to allow longitudinal analyses without compromising the confidentiality of the records.

Study population

Patients undergoing surgeries for POP between 2008 and 2011 were identified using ICD-9-CM procedure codes (international classification of diseases, 9th revision, clinical modification) and CPT-4 codes (current procedural terminology coding system, 4th ed; web appendix A). In our study, mesh was defined as any augmenting material, including synthetic and biological materials, and was determined by specific ICD-9 procedure codes and CPT-4 codes.

We further restricted the cohort to patients who received a diagnosis of POP (ICD-9-CM 618.0-618.9; web appendix B). We included records of patients who underwent their first prolapse repair procedure in SPARCS within the 2008-11 study period (2011 was the latest available year). Patients were tracked for previous prolapse repair procedures (since 1995) before their identified surgery date within the study period, and those who had any type of prolapse repair surgery before the index date were excluded from the analyses.

Variable definitions and study endpoint

Patient characteristics included age (<45, 45-54, 55-64, 65-74, ≥75 years), race (white and non-white), insurance status (Medicare, Medicaid, Commercial, and other), and comorbidities. We identified relevant comorbidities by using algorithms validated by Elixhauser and colleagues.[24] Concurrent hysterectomy was identified based on ICD-9-CM procedure codes and CPT-4 codes (web appendix A). Concomitant sling procedures were also identified (ICD-9-CM 59.5, CPT-4 57288). Institution related characteristics included service type (inpatient and outpatient), facility ownership (state owned, non-state owned/non-profit, and freestanding surgical centre), facility academic status, and facility POP procedure volume. Hospital ownership and teaching status was obtained by linking to the American Hospital Association database using facility names. Facility procedure volume was calculated as average annual volume of POP, and categorized as low, medium, and high based on tertiles.

Outcomes included 90 day safety and one year follow-up for reintervention after the initial procedure. Safety events at 90 days included medical complications (acute myocardial infarction, stroke, pulmonary embolism, perioperative shock, deep venous thrombosis, and respiratory complications), bleeding, postoperative urinary tract infections, urinary retention, bladder injury, and other surgical complications. We also examined 90 day readmission into inpatient services and emergency rooms. Reintervention was determined on the basis of repeated prolapse repair procedures and mesh revision procedures (CPT-4 57295, 57296, 57415). Patients who had death recorded in SPARCS during the one year follow-up were censored.

Statistical analyses

We compared baseline characteristics between patients groups. Events and percentages were presented for patient demographics, comorbidities, and institution related characteristics. Propensity score matching was used to adjust for differences in baseline characteristics between mesh and no mesh groups.[25] We did multivariable logistic regression based on patient characteristics (age, race, and insurance status), procedure year, concurrent hysterectomy or sling procedure, comorbidities, service type, facility academic status, ownership, and procedure volume to obtain propensity scores for each individual. We then performed nearest neighbor matching of the two groups at a 1:1 fixed ratio, using a caliper width of 0.2 of the standard deviation of the logit of the propensity score. Balance achieved by matching was assessed by examining differences in baseline variables between patients undergoing prolapse repair with and without mesh placed before and after propensity score matching.

Variables such as age and insurance status were collected for every patient with no missing value. Comorbidities were derived from ICD-9-CM coding and therefore were not subject to missing data issues. We created a missing category for patients with missing

race information. Patients who had missing values for variables regarding hospital characteristics were excluded from propensity score matching.

Safety events and complications within 90 days and reintervention within one year were determined before and after propensity score matching. We assessed differences between groups using χ^2 tests in the entire cohort and stratified Mantel-Haenszel χ^2 tests for paired data in the matched cohort. Risk ratios were calculated accordingly. Time to event analyses were also conducted in both cohorts to compare the risk of undergoing reintervention between groups. We constructed Kaplan-Meier curves to determine freedom from reintervention within one year after procedure. A Cox proportional hazard model was used to assess the differences in risks of reintervention between groups. Accordingly, we used conditional Cox regression for matched cohorts.[26] A proportional hazards assumption was tested to confirm the adequacy of the model.

We did subgroup analyses by stratifying the entire cohort into two age groups (<65 and ≥65 years). Trends of mesh related and non-mesh procedure frequencies were determined in the two age groups. We also performed propensity score matching within each group. Outcomes, including 90 day safety and reintervention within one year following initial procedure, were assessed using the same strategy described for the main analyses. We did a sensitivity analysis within each hospital and matched patients by demographics and comorbidities. All analyses were performed using SAS version 9.3 (SAS Institute).

Patient involvement

There was no patient involvement in this study.

Results

Of 27 991 women undergoing POP repairs between 2008 and 2011 in New York state, 7338 received a surgery with mesh and the remaining 20 653 had surgery without mesh placed. Overall, the number of patients undergoing prolapse repair surgery remained stable during the four year study period (fig 1). Between 2008 and 2011, the number of mesh based procedures increased from 1461 to 2114 procedures.

Patient characteristics

Most patients undergoing prolapse repair surgery were younger than 65 years (62.3% (n=17 424); table 1). More patients were aged 65 years and older in the mesh group than in the non-mesh group (44.3% (n=3249) *v* 35.4% (n=7318)). In addition, 38.5% (n=2827) of patients who received prolapse repair with mesh had a concurrent hysterectomy, while 51.3% (n=10 590) of patients who underwent prolapse repair without mesh received a hysterectomy at the same time. Proportions of patients who had concomitant sling procedures in mesh and no mesh group were 20.0% (n=1464) and 14.4% (n=2974), respectively. Comorbidity profiles were similar, except that prevalence of hypertension was higher in the mesh group than non-mesh group (39.7% (n=2912) *v* 33.9% (n=7004)).

Most procedures were performed in the inpatient setting (73.3% (n=20 516)) and in non-state owned, non-profit facilities (92.0% (n=25 753)). Patients in the mesh group were more likely than those in the non-mesh group to have received surgery in the inpatient setting (76.6% (n=5618) *v* 72.1% (n=14 898)) and in teaching facilities (52.7% (n=3866) *v* 42.6% (n=8749)). After propensity score matching, all baseline characteristics were balanced between the two groups.

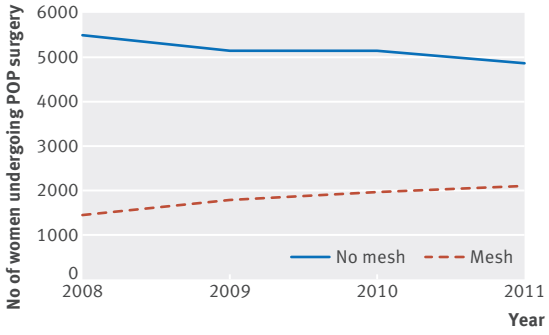

Fig 1 | Trends of prolapse repair surgery with or without mesh placed from 2008 to 2011 in New York state

90 day safety

Patients who received prolapse repair surgery with mesh were more likely to have urinary retention than patients who received the surgery without mesh (7.5% (n=551) *v* 5.4% (n=1106); table 2). Propensity score matching resulted in 7295 patients in each group, but the difference was still significant (mesh 7.5% *v* no mesh 5.6%, risk ratio 1.33 (95% confidence interval 1.18 to 1.51), P<0.001). We also observed no difference in adverse medical events (2.5% (n=185) *v* 2.4% (n=173)), bleeding (1.5% (n=110) *v* 1.3% (n=97)), urinary tract infection (3.4% (n=247) *v* 3.1% (n=229)), bladder injury (0.8% (n=59) *v* 0.6% (n=42)) and other surgical complications (2.3% (n=170) *v* 2.0% (n=147)) following prolapse repair procedures between mesh and no mesh groups, after propensity score matching.

One year follow-up of reintervention

After propensity score matching, mean follow-up time of the cohort was 45.1 weeks, and 3.3% (n=240) of mesh recipients versus 2.2% (n=164) of no mesh recipients had at least one reintervention within one year following the initial procedure (table 2). Mesh recipients had a 66% higher risk of reintervention within one year than patients without mesh (hazard ratio 1.66 (95% confidence interval 1.41 to 1.94); fig 2). After propensity score matching, the difference remained significant (mesh 3.3% *v* no mesh 2.2%, 1.47 (1.21 to 1.79); fig 3). Within one year only, 22.1% (53/240) of patients received mesh again if initial surgery was with mesh (table 2). Similarly, 25.6% (42/164) of patients received mesh when undergoing reintervention for initial surgery that did not include mesh.

Subgroup and sensitivity analysis

From 2008 to 2011, mesh use increased by 43.3% in patients younger than 65 years and by 46.4% in those aged 65 years and older (web appendix C). In the younger group, 23.5% (4089/17 424) had surgery with mesh placed, while 30.8% (3249/10 567) of patients aged 65 years or older received the mesh based procedure. Safety event occurrence differed between the groups (web appendix D). After propensity score matching, mesh use

Table 1 | Demographics and comorbidities of patients undergoing POP surgery with or without mesh, placed between 2008 and 2011 in New York state

	Before propensity score matching			After propensity score matching		
	Mesh (n=7338)	No mesh (n=20 653)	Difference (%)	Mesh (n=7295)	No mesh (n=7295)	Difference (%)
Year						
2008	1461 (19.9)	5498 (26.6)	6.7	1460 (20.0)	1445 (19.8)	0.2
2009	1784 (24.3)	5157 (25.0)	0.7	1779 (24.4)	1742 (23.9)	0.5
2010	1979 (27.0)	5152 (24.9)	2.0	1966 (26.9)	2000 (27.4)	0.5
2011	2114 (28.8)	4846 (23.5)	5.3	2090 (28.6)	2108 (28.9)	0.2
Age (years)						
<45	603 (8.2)	3387 (16.4)	8.2	601 (8.2)	611 (8.4)	0.1
45-54	1428 (19.5)	4971 (24.1)	4.6	1425 (19.5)	1449 (19.9)	0.3
55-64	2058 (28.0)	4977 (24.1)	3.9	2048 (28.1)	2020 (27.7)	0.4
65-74	2096 (28.6)	4656 (22.5)	6.0	2079 (28.5)	2040 (28.0)	0.5
≥75	1153 (15.7)	2662 (12.9)	2.8	1142 (15.7)	1175 (16.1)	0.5
White patients*	6077 (82.8)	15 581 (75.4)	7.4	6037 (82.8)	6017 (82.5)	0.3
Insurance						
Medicare	2884 (39.3)	6756 (32.7)	6.6	2863 (39.2)	2869 (39.3)	0.1
Medicaid	500 (6.8)	2389 (11.6)	4.8	498 (6.8)	464 (6.4)	0.5
Commercial	3780 (51.5)	10 935 (53.0)	1.4	3761 (51.6)	3807 (52.2)	0.6
Other	174 (2.4)	569 (2.8)	0.4	173 (2.4)	155 (2.1)	0.2
Concurrent procedure						
Hysterectomy	2827 (38.5)	10 590 (51.3)	12.8	2823 (38.7)	2749 (37.7)	1.0
Sling	1464 (20.0)	2974 (14.4)	5.6	1446 (19.8)	1423 (19.5)	0.3
Comorbidities						
Coronary artery disease	320 (4.4)	745 (3.6)	0.8	318 (4.4)	303 (4.2)	0.2
Hypertension	2912 (39.7)	7004 (33.9)	5.8	2893 (39.7)	2889 (39.6)	0.1
Congestive heart failure	48 (0.7)	116 (0.6)	0.1	47 (0.6)	38 (0.5)	0.1
Diabetes	811 (11.1)	1952 (9.5)	1.6	802 (11.0)	748 (10.3)	0.7
Chronic pulmonary disease	798 (10.9)	2069 (10.0)	0.9	795 (10.9)	767 (10.5)	0.4
Obesity	317 (4.3)	915 (4.4)	0.1	315 (4.3)	316 (4.3)	0.0
Anemia	231 (3.1)	717 (3.5)	0.3	231 (3.2)	188 (2.6)	0.6
Peripheral vascular disease	64 (0.9)	154 (0.7)	0.1	63 (0.9)	61 (0.8)	0.0
Cerebrovascular disease	17 (0.2)	29 (0.1)	0.1	16 (0.2)	11 (0.2)	0.1
Renal failure	58 (0.8)	126 (0.6)	0.2	57 (0.8)	55 (0.8)	0.0
Depression	481 (6.6)	1332 (6.4)	0.1	481 (6.6)	1332 (6.4)	0.1
Inpatient service	5618 (76.6)	14 898 (72.1)	4.4	5583 (76.5)	5525 (75.7)	0.8
Facility ownership						
State	583 (8.0)	1565 (7.6)	0.4	579 (7.9)	520 (7.1)	0.8
Non-state, non-profit	6745 (92.0)	19 008 (92.3)	0.3	6713 (92.0)	6771 (92.8)	0.8
Freestanding	NR	26 (0.1)	0.1	NR	NR	0.0
Teaching facility	3866 (52.7)	8749 (42.6)	10.1	3847 (52.7)	3957 (54.2)	1.5
Facility volume						
Low	1896 (25.8)	7307 (35.4)	9.5	1888 (25.9)	1803 (24.7)	1.2
Medium	2147 (29.3)	6978 (33.8)	4.5	2137 (29.3)	2222 (30.5)	1.2
High	3295 (44.9)	6368 (30.8)	14.1	3270 (44.8)	3270 (44.8)	0.0

NR=not reportable for events ≤10.
*0.8% patients missing race information.

was associated with a 36% higher risk of developing urinary retention after surgery among the older age group (mesh, 9.2% (292/3187) *v* no mesh, 6.7% (215/3187), P<0.001). However, the difference between the procedure groups was not as obvious in patients younger than 65 years (6.1% (249/4057) *v* 5.3% (214/4057), P=0.09).

Mean follow-up time was 45.3 weeks for patients younger than 65 years and 44.9 weeks for patients aged 65 years and older (web appendices E and F). After propensity score matching, mesh use was associated with a significantly higher risk of undergoing a reintervention in younger patients (hazard ratio 1.76 (95% confidence interval 1.35 to 2.31)). We saw no significant difference in reintervention between the two groups in older patients (1.16 (0.86 to 1.56)). Sensitivity analyses with propensity score matching of the groups performed within each hospital showed consistent results (web appendix G).

Discussion

Principal findings

In this study, we used the entire dataset of New York state and included all women undergoing POP surgeries. We found that since the release of the FDA warning in 2008, mesh use continued to increase in POP repairs from 21% in 2008 to 30% in 2011. We also found that use of mesh was associated with an increased risk of reintervention within one year following the initial

Table 2 | 90 day safety events and one year follow-up of reintervention following POP surgery with or without mesh, placed between 2008 and 2011 in New York state

	Before propensity score matching			After propensity score matching*		
	Mesh (n=7338)	No mesh (n=20 653)	Risk ratio (95% CI)	Mesh (n=7295)	No mesh (n=7295)	Risk ratio (95% CI)
90 day safety						
Medical complications	186 (2.5)	451 (2.2)	1.16 (0.98 to 1.37)	185 (2.5)	173 (2.4)	1.07 (0.87 to 1.31)
Bleeding	110 (1.5)	316 (1.5)	0.98 (0.79 to 1.22)	110 (1.5)	97 (1.3)	1.13 (0.87 to 1.49)
Urinary tract infection	249 (3.4)	662 (3.2)	1.06 (0.92 to 1.22)	247 (3.4)	229 (3.1)	1.08 (0.90 to 1.29)
Urinary retention	551 (7.5)	1106 (5.4)	1.40 (1.27 to 1.55)‡	554 (7.5)	408 (5.6)	1.33 (1.18 to 1.51)‡
Bladder injury	59 (0.8)	93 (0.5)	1.79 (1.29 to 2.47)‡	59 (0.8)	42 (0.6)	1.40 (0.95 to 2.09)
Other surgical complications	172 (2.3)	436 (2.1)	1.10 (0.93 to 1.31)	170 (2.3)	147 (2.0)	1.16 (0.93 to 1.44)
Inpatient readmission	392 (5.3)	1042 (5.0)	1.06 (0.95 to 1.19)	390 (5.3)	365 (5.0)	1.07 (0.93 to 1.23)
Emergency room readmission	633 (8.6)	1997 (9.7)	0.89 (0.82 to 0.97)	631 (8.6)	601 (8.2)	1.05 (0.94 to 1.17)
One year follow-up						
Reintervention†	241 (3.3)	419 (2.0)	1.66 (1.41 to 1.94)‡	240 (3.3)	164 (2.2)	1.47 (1.21 to 1.79)‡
Reintervention with mesh	53 (0.7)	104 (0.5)	—	53 (0.7)	42 (0.6)	—

Data are no (%) of events unless stated otherwise.
*Risk ratios and P values calculated using the stratified Mantel-Haenszel test.
†Effect measure presented is hazard ratio, P value obtained using the Cox proportional hazard model.
‡P<0.05.

procedure, and increased occurrence of urinary retention complications at 90 days postoperatively. However, these findings were found to be age dependent in the subgroup analyses. Reintervention risk was significantly increased only in the younger age group (<65 years), whereas no increased risk was observed among older patients. Urinary retention complications associated with mesh use were only significant among people aged 65 years and older.

Comparison with previous studies

Our results on increased mesh use substantiate previous investigations. Reynolds and colleagues found a significant increase in mesh use among Medicare beneficiaries (mostly patients over 65 years old) immediately after the FDA notice,[11] from 25.6% in 2008 to 27.7% in 2009, but one year was a relatively short period to evaluate the trend. Our results advance these findings and provide new evidence in age groups younger than 65 years old. The majority (72.5%) of patients with POP are aged 65 years[15] and cannot be studied using Medicare data. We found that up to four years after the FDA warning, there has been a consistent trend towards increased mesh use. In addition, we have reliable data related to mesh use, because ICD-9-CM procedure and CPT-4 codes for mesh procedures were released in late 2004 and 2007. We believe that studies done before 2008 may have inaccurately classified mesh patients as no mesh patients.

In terms of comparative outcomes, the FDA reported that the most frequently reported complications include mesh erosion, pain, infection, bleeding, dyspareunia, organ perforation, urinary problems, and recurrent prolapsed.[2] Although we did not study specific complications, we focused on reintervention as a main endpoint of our analyses. Reintervention after surgery is likely to represent a symptomatic recurrent prolapse or mesh expo-

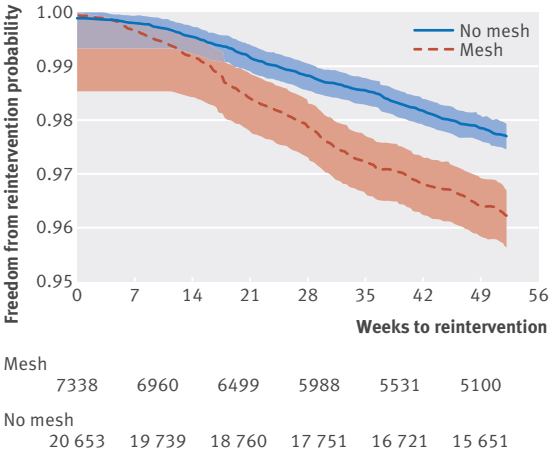

Fig 2 | Time to reintervention within one year following POP surgery with or without mesh placed between 2008 and 2011 in New York state, before propensity score matching. Kaplan-Meier plot shows numbers of patients at risk and 95% Hall-Wellner bands

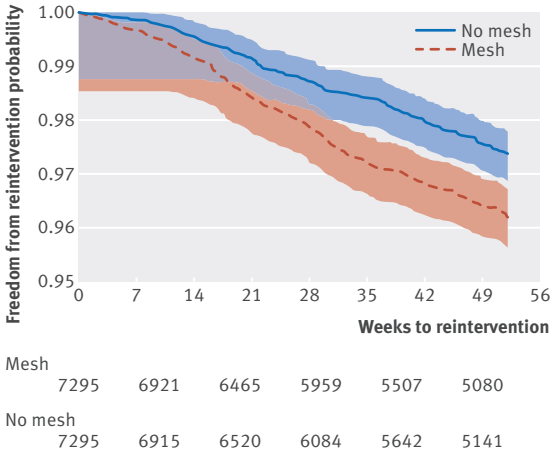

Fig 3 | Time to reintervention within one year following POP surgery with or without mesh placed between 2008 and 2011 in New York state, after propensity score matching. Kaplan-Meier plot shows numbers of patients at risk and 95% Hall-Wellner bands

sure that requires additional treatment.[27] Therefore, we adopted a patient centered approach by focusing on chance or risk of undergoing surgery again. Relying on reintervention as an important patient centered endpoint is being common in surgery. For example, in hip and knee replacement, device failure was captured through reintervention in recent high profile publications rather than reasons for reintervention, such as device component failure, loosening, or bone necrosis.[28 29]

A few studies have been conducted to examine the reoperation rate after mesh use separately among different age groups. Kaufman and colleagues found younger age and sexual activity to be risk factors for mesh exposure after transvaginal mesh repair.[30] Younger patients tend to be more sexually active and are more likely to develop mesh exposure because of tissue friction.[31] These publications might at least partly explain our findings related to higher reoperation rate among younger women who underwent prolapse repair with mesh.

Our results related to urinary retention substantially advance recent findings reported in Medicare beneficiaries who underwent POP surgery between 2007 and 2008.[21] In this study, urinary retention was found to be significantly higher in mesh use than in surgeries with no use of mesh (12% *v* 8%). In another randomized controlled trial with a mean patient age of 65 years, similar results were found; mesh patients had higher risks of bladder-emptying difficulties during hospitalization.[18]

Another study reported that the prevalence of any urinary incontinence directly increases with advancing age.[32] The older population is inherently at a higher risk for such complications, and specific risks should be discussed with patients over 65 years old before undergoing POP surgery. In our study, we found that women aged 65 years and older were more likely to undergo POP surgery with mesh than women younger than 65 years old (31% *v* 23%, between 2008 and 2011). A 2012-13 survey of patient knowledge and perceptions of grafts found a substantially differential effect of age; older groups were less aware of transvaginal graft surgery.[33] It is possible that the older populations are less educated about mesh and less likely to be aware of FDA warnings. Therefore, more mesh education should also be geared towards older patients before POP surgery.

Strength and limitations of study

There were some limitations to New York state data. While transabdominal procedures were reported to account for less than 25% of POP surgery, we were unable to distinguish between vaginal and abdominal mesh completely with current codes. To minimize the proportion of abdominal procedures and reduce the possible bias, we removed patients with CPT-4 codes specific to abdominal procedures. In addition, information regarding the severity of POP cannot be captured through administrative data. However, there has not been standard instruction on the use of mesh regarding the severity of POP.

Mesh has been considered better in recurrent prolapsed,[34] and because we excluded patients with a history of previous prolapse surgery, such bias would be attenuated. We applied statistical methods to minimize the residual confounding and reduce imbalance between groups. Potential unmeasured confounding may also have been caused by limitations of the observational study design, for example, physicians' and patients' preferences. We were not aware of any evidence quantitatively or qualitatively showing the relation between preferences, differential mesh use, and prolapse repair surgery outcomes.

Therefore, with most confounders being captured, we believe our results are likely to be quite robust. Only patients who underwent reinterventions were captured in our patient centered approach. Mesh erosions, new onset stress urinary incontinence, and new onset urge incontinence were not included in these analyses. In addition, inherent with administrative data, miscoding, and undercoding could happen with patient records. Follow-up of patients might also be incomplete using state database. To avoid loss of follow-up due to relocation of patients to another state or country, follow-up was limited to one year, and we excluded the residents of other states.

To the best of our knowledge, this is the first major cohort based study addressing the safety of mesh. In addition, this is the first study comparing mesh outcomes stratified by age groups. The inclusion of entire New York state's data, recent years, and all age groups makes this study unique and also important in defining age dependent mesh safety. The cohort was additionally matched to controls for confounding variables, which further strengthened the comparisons made between mesh and no mesh groups.

Policy implications

This study helps to fill the knowledge gap in many ways. We have identified that mesh use continues to rise, and therefore, more research needs to be conducted to ensure its safety; younger generations are at higher risk for reintervention; older populations are at higher risk for complications with lower rates of mesh awareness, and thus should be educated further on these complications.

The FDA has ordered manufacturers of surgical mesh to conduct post market surveillance studies.[35] However, it will take years before data become available. As the *New York Times* noted, the "device has been on the market for years and been implanted in hundreds of thousands of patients".[7] Our study can help inform regulators, clinicians, and patients in the light of limited clinical trial data, and illustrates the importance of IDEAL principles that highlight the need for technology surveillance after widespread adoption.[36] Large observational national and regional studies are the main tools for evaluation of patient selection, practice, and outcomes of surgery after widespread adoption[36] within the IDEAL framework, and our study is unique from this perspective.

Conclusions

Despite multiple warnings released by the FDA since 2008, use of mesh in pelvic organ prolapse surgery continues to grow. In this statewide comprehensive study comparing prolapse repair with and without mesh, mesh procedures were associated with an increased

risk of urinary retention and reintervention in the following year. Our findings should help regulators, clinicians and patients better understand mesh safety and provide age specific evidence for risks and benefits.

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Contributors: BC, JM, and AS were responsible for the study concept and design. AS acquired the data. JM and AS analyzed and all authors interpreted the data. BC, JM, and AS drafted the manuscript. All authors critically revised the manuscript for important intellectual content. JM and AS were responsible for the statistical analysis. AS supervised the study and is the guarantor.

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Ethical approval: The study was approved by the Weill Cornell Medical College institutional review board (protocol no 1209013064).

Data sharing: technical appendix and statistical code available from the corresponding author at ars2013@med.cornell.edu; dataset available from SPARCS at https://www.health.ny.gov/statistics/sparcs/access/.

The lead authors (study guarantors) affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Web appendix: Supplementary online content