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Author Manuscript

Int Urogynecol J. Author manuscript; available in PMC 2014 January 16.

Published in final edited form as:

Int Urogynecol J. 2013 August ; 24(8): 1279–1285. doi:10.1007/s00192-013-2043-9.

Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse

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Abstract

Introduction and hypothesis—To estimate the risk of repeat surgery for recurrent prolapse or mesh removal after vaginal mesh versus native tissue repair for anterior vaginal wall prolapse.

Methods—We utilized longitudinal, adjudicated, healthcare claims from 2005 to 2010 to identify women 18 years who underwent an anterior colporrhaphy (CPT 57420) with or without concurrent vaginal mesh (CPT 57267). The primary outcome was repeat surgery for anterior or apical prolapse or for mesh removal/revision; these outcomes were also analyzed separately. We utilized Kaplan–Meier curves to estimate the cumulative risk of each outcome after vaginal mesh versus native tissue repair. Cox proportional hazards models were used to estimate the hazard ratio (HR) for vaginal mesh versus native tissue repair, adjusted for age, concurrent hysterectomy, and concurrent or recent sling.

Results—We identified 27,809 anterior prolapse surgeries with 49,658 person-years of follow-up. Of those, 6,871 (24.7%) included vaginal mesh. The 5-year cumulative risk of *any* repeat surgery was significantly higher for vaginal mesh versus native tissue (15.2 % vs 9.8 %, $p<0.0001$) with a 5-year risk of mesh revision/removal of 5.9%. The 5-year risk of surgery for recurrent prolapse was similar between vaginal mesh and native tissue groups (10.4 % vs 9.3 %, $p=0.70$). The results of the adjusted Cox model were similar (HR 0.93, 95%CI: 0.83, 1.05).

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Presented as an oral presentation at the 33rd Annual Meeting of the American Urogynecologic Society, Chicago, IL, USA, 3–6 October 2012.

Conflicts of interest None.

Conclusions—The use of mesh for anterior prolapse was associated with an increased risk of any repeat surgery, which was driven by surgery for mesh removal. Native tissue and vaginal mesh surgery had similar 5-year risks for surgery for recurrent prolapse.

Keywords

Anterior colporrhaphy; Pelvic organ prolapse; Surgery; Recurrent prolapse; Vaginal mesh

Introduction

The recent US Food and Drug Administration (FDA) safety communication on serious complications from transvaginal mesh [1] heightened awareness of graft augmentation in pelvic organ prolapse procedures among healthcare providers, patients, and the general public [2]. The FDA highlighted complications due to surgical mesh devices such as mesh exposure/extrusion, vaginal scarring/shrinkage, pain, dyspareunia, infection, and organ perforation, as well as the repeat surgeries associated with these complications [3]. A rationale for synthetic mesh augmentation was to address the risk of recurrent prolapse after surgical repair, which has been reported to be as high as 29 % [4]. However, the literature suggests that long-term outcomes with vaginal mesh augmentation may not be better than those with native tissue, especially for surgeries in the apical and posterior compartment of the vagina [3].

Prolapse in the anterior compartment is particularly challenging as the short-term recurrence after anterior colporrhaphy is relatively high [5–8]. Randomized trials of native tissue repair versus mesh augmentation have shown that anatomical cure is higher for mesh procedures [5, 6, 9], and the FDA supports this claim in their systematic review [3]. However, the FDA also noted that “this anatomic benefit may not result in superior symptomatic outcomes or lower rates of repeat surgery for recurrent prolapse” compared with traditional native tissue repair without mesh [1, 3]. Furthermore, the use of synthetic mesh may be associated with mesh complications, which may require additional interventions and surgical repair. A major limitation of the existing literature is that the cohorts studied were relatively small and the length of follow-up was relatively short. In addition, limited data exist regarding the rate of repeat surgery for recurrent prolapse or mesh complications.

Healthcare claims data of commercially insured patients may provide particularly useful information to address this timely and controversial issue, since a large cohort of women can be evaluated with longer-term follow-up. Furthermore, limitations due to loss to follow-up in trials may be mitigated as these data are based on insurance claims. Thus, the objective of this study was to utilize a large, population-based database to estimate the rate of repeat surgery after vaginal mesh versus native tissue repair for anterior vaginal wall prolapse. We also sought to estimate the rates of repeat surgeries due to recurrent prolapse versus mesh complications and to assess predictors of repeat surgery.

Materials and methods

Data source

For this analysis, we utilized 6 years of data (2005–2010) from the *MarketScan*® *Commercial Claims and Encounters (CC&E)* database and *Medicare Supplemental and Coordination of Benefits* database (copyright © 2011 Thomson Healthcare Incorporated Inc. All rights reserved) [10]. The available data included adjudicated, paid healthcare claims for approximately 28.3 million individuals in 2005, increasing to 48.8 million in 2010. Contributing individuals included those with commercial, employment-based insurance, such as employees, their spouses, dependants, as well as retirees. Of note, in 2010, 55.3 % of

the US population, or 170.7 million individuals, had employment-based insurance [11]. These de-identified, individual-level inpatient and out-patient claims were aggregated from approximately 100 payers in the United States. Claims and enrollment data were validated by Thomson Reuters to ensure completeness, accuracy, and reliability. Although the data were anonymized, unique individuals can be followed over time using encrypted identification numbers, and detailed enrollment data ensured that only those individuals who could generate a claim were considered as part of the population at risk at any given time. This study was determined to be exempt from further review by the Institutional Review Board at the University of North Carolina at Chapel Hill.

Inclusion criteria and index surgery

The population at risk included all women aged 18 years and older from 2005 to 2010. Among these women, our goal was to compare women who underwent a native tissue anterior colporrhaphy with those who had an anterior colporrhaphy with mesh augmentation, or vaginal mesh. We identified anterior colporrhaphies based on current procedural terminology (CPT) code 57240 (Table 1). If CPT 57267 (insertion of mesh or other prosthesis for repair of a pelvic floor defect, each site [anterior, posterior compartment], vaginal approach) was present, we counted these surgeries as a vaginal mesh procedures. If CPT 57267 was not present, these surgeries were counted as a native tissue repairs.

In order to assess baseline covariates, including recent urogynecological procedures, we excluded women who did not have at least 6 months of continuous enrollment prior to the first, or index, procedure. We also excluded women who had mesh placed during the baseline period, in order to limit misclassification of our primary exposure, vaginal mesh, and to enable us to attribute future surgery for mesh complications to the index procedure and not prior surgeries. Based on this same rationale, we also excluded women with a prior abdominal or laparoscopic sacrocolpopexy. Similarly, if a procedure to remove or revise mesh (CPT codes 57415, 57426, 57295, and 57296) was performed prior to the index surgery, those women were also excluded (Table 1).

Because the code for mesh insertion, CPT 57267, is not linked to a specific procedure and we wanted to specifically estimate the impact of mesh augmentation for anterior colporrhaphy, we excluded women with other concomitant prolapse procedures, including posterior colporrhaphy (Table 1). For example, if CPT 57267 is listed along with CPT 57260 for an anterior and posterior colporrhaphy, it is impossible to determine if the mesh was placed in the anterior or posterior compartment. Thus, the only way to ensure that mesh was placed in the anterior compartment was to exclude women who underwent other prolapse procedures. Although we excluded concurrent prolapse procedures based on CPT codes (Table 1), we did not exclude concurrent hysterectomy or concurrent sling. Because a sling may also have an impact on the risk of recurrent prolapse, we included both a concurrent sling and any recent sling in the prior 6 months in our definition of a sling procedure.

Repeat surgery

After the initial anterior colporrhaphy, either with native tissue or vaginal mesh, we identified *any* repeat surgery for either recurrent anterior or apical prolapse, or a mesh complication. We defined repeat surgery for recurrent prolapse based on subsequent procedures for anterior prolapse (CPT codes 57240, 57260, 57265, 57284, 57285, 57423) or for apical prolapse (CPT codes 57280, 57282, 57283, 57425). Our rationale for including both anterior and apical procedures was that surgeons may opt for either an anterior and/or apical procedure to manage short-term recurrent anterior vaginal wall prolapse. We defined

surgery for mesh complications based on the following CPT codes: 57415 removal of vaginal foreign body, 57426 revision/removal of vaginal prosthetic graft laparoscopy, 57295 revise vaginal graft via vaginal approach, and 57296 revise vaginal graft via abdominal approach. It is important to note that repeat surgeries for recurrent prolapse and for mesh complications were not mutually exclusive. In addition, if a surgery for a mesh complication occurred prior to a surgery for recurrent prolapse, we opted to censor individuals at the time of the mesh surgery for the analysis of recurrent prolapse. Similarly, in the analysis for mesh complications, we censored individuals who underwent surgery for recurrent prolapse if it occurred prior to the mesh complication.

For surgery for mesh complications, we evaluated this outcome in both the native tissue and the vaginal mesh cohorts, even though mesh complications should not occur in those undergoing a native tissue repair. It is possible that a mesh complication could occur in the “native tissue” cohort if the patient had mesh placed before the baseline period (more than 6 months prior to the index procedure) or if a midurethral sling resulted in a sling revision/removal due to a mesh complication that was not coded using the typical CPT code for sling revision/removal.

Statistical analysis

Using Kaplan–Meier survival curves, we estimated the cumulative risk of repeat surgery for recurrent prolapse or mesh complications overall, and for each outcome separately at yearly intervals. We also estimated the cumulative risk at 2-year follow-up for specific subgroups based on age, calendar year of the index procedure, concomitant or recent sling, and concomitant hysterectomy.

In order to adjust for differences in age, concomitant hysterectomy, or concomitant/recent sling between patients receiving native tissue and those receiving vaginal mesh, we estimated adjusted hazard ratios (HR) using Cox proportional hazards model. We included age as a six-level categorical variable (18–34, 35–44, 45–54, 55–64, 65–74, 75+). Wald Chi-squared statistics were used to test the significance of independent predictors with a two-sided alpha = 0.05. Analyses were performed using SAS, v9.2 (SAS Institute, Cary, NC, USA).

Results

We identified 27,809 anterior prolapse surgeries with 49,658 person-years of follow-up among women aged 18 years. Of these, 20,938 (75.3 %) were native tissue repairs while 6,871 (24.7 %) included vaginal mesh. Women who underwent native tissue repair were younger (median 55 years, interquartile range (IQR) 47, 63) compared with the vaginal mesh surgery (median 59 years, IQR 52, 67, $p < 0.0001$); Table 2). The median duration of follow-up was similar in those receiving native tissue (1.3 years [IQR 0.5, 2.7]) and vaginal mesh (1.4 years [IQR 0.5, 2.7], $p = 0.44$). When evaluating the calendar year in which the index surgery was performed, there were differences between groups with an increase in the proportion of procedures involving vaginal mesh from 2005 to 2010 ($p < 0.0001$). Fewer native tissue repairs had a concomitant or recent sling (62.4 % vs 70.6 %, $p < 0.0001$, but a higher proportion underwent a concurrent hysterectomy (38.3 % vs 18.4 %, $p < 0.0001$; Table 2).

When we estimated the risk of *any* repeat surgery after the index surgery for anterior prolapse, the 5-year cumulative risk was significantly higher for vaginal mesh (15.2 % vs 9.8 %, $p < 0.0001$). However, the 5-year cumulative risk of recurrent prolapse surgery was similar in the two groups (native tissue: 9.3 % [95% CI 8.6, 10.0]; vaginal mesh: 10.4 % [95% CI 8.8, 12.1] $p = 0.70$; Table 3). The difference in the risk of *any* repeat surgery was due

to the significantly higher 5-year risk of mesh complication in the vaginal mesh group (5.9 % [95%CI 5.0, 6.9] compared with native tissue (0.7 % [95%CI 0.5, 0.9], $p<0.0001$).

In order to further evaluate the impact of age, year of index surgery, and concurrent hysterectomy or sling, we estimated the 2-year cumulative risks of repeat surgery for recurrent prolapse and mesh complications in these subgroups of patients. These 2-year estimates are shown in Table 4 as absolute risks with 95%CI. Age at index surgery or year of the index surgery did not yield a definitive trend for surgery for recurrent prolapse at 2 years post-operatively for either the native tissue or the vaginal mesh cohorts. However, concurrent hysterectomy decreased the risk of surgery for recurrent prolapse in the native tissue group (4.4 % [95 % CI 3.9, 4.9] versus 7.8 % [95%CI 7.3, 8.4]) and recent/concurrent sling decreased surgery for recurrent prolapse in both groups (Table 4).

Surgery for a mesh complication was primarily pertinent to the vaginal mesh cohort. There was no consistent trend for mesh surgery based on age, concurrent hysterectomy or recent/concurrent sling. However, the 2-year risk of mesh surgery increased from 2.6 % (95 % CI 0.9, 4.3) in 2005 to 4.8 % (95%CI 3.6, 6.0) in 2008.

We evaluated the risk of any repeat surgery as well as surgery for recurrent prolapse and a mesh complication using Cox proportional hazards models adjusted for age, concurrent hysterectomy, and concurrent or recent sling. Vaginal mesh was associated with an increase in the risk of *any* repeat surgery compared with native tissue (HR 1.33, 95%CI 1.20, 1.46). The risk of surgery for recurrent prolapse was similar in those with vaginal mesh versus native tissue (HR 0.93, 95%CI 0.83, 1.05). Thus, the difference in the rate of repeat surgeries was driven by mesh complications (HR 8.21, 95%CI 6.31, 10.67).

Discussion

In this population-based cohort of 27,809 vaginal procedures for anterior vaginal wall prolapse, the 5-year cumulative risk of repeat surgery was higher for vaginal mesh procedures (15.2 %) than for native tissue surgeries (9.8 %), which was due to subsequent surgeries for mesh removal and not for recurrent prolapse. These estimates are useful in counseling patients regarding the need for reoperation after prolapse surgery.

The 2011 FDA update regarding transvaginal mesh reported that mesh augmentation may provide anatomical benefit in the anterior compartment, but with no improvement in the quality of life [1]. This claim was supported by the initial reports of several randomized trials that found that prolapse procedures utilizing mesh had a lower risk of recurrent prolapse [5, 6, 9, 12, 13]. Systematic reviews and meta-analyses also supported this conclusion [7, 8, 14, 15]. However, limitations of these existing trials included a non-blinded evaluator [3] and a relatively short follow-up of 12 months [5, 9, 13, 16–18]. Furthermore, there was some evidence that any improvement in anatomical outcomes from the use of mesh was of little benefit to the patient, since the few studies that assessed patient-centered outcomes, such as quality of life, failed to show a difference between native tissue and mesh augmentation procedures [12, 14, 17].

While the risk of anatomical recurrence may be lower with mesh augmentation in the anterior compartment, a critical question is whether mesh decreases the need for reoperation for recurrent prolapse. Nieminen et al. reported that 18 % (17 out of 96) in the native tissue and 11 % (11 out of 104) in the mesh group were referred for reoperation for either recurrent prolapse or urinary incontinence by 3 years, a difference that was not statistically significant [6]. In our study, we found that the risk of repeat surgery for prolapse was comparable at 9.3 % for native tissue versus 10.4 % for vaginal mesh by 5 years. Adjusting for differences in

age and other concurrent pelvic organ procedures (hysterectomy and sling) did not meaningfully alter the observed association.

In our analysis, the driving factor for a higher risk of reoperation after mesh augmentation was the need for surgery for a mesh complication. Randomized trials have reported a risk of mesh exposure/extrusion that ranges from 5 % to 19 % [6, 9, 12, 17, 18]. However, some of these mesh exposures/extrusions were managed conservatively, and the proportion of subjects undergoing reoperation in an operating room for mesh complications was approximately 3.2 % to 7.6 % [5, 6, 12, 13]. In an analysis of over 800 prolapse procedures using implanted grafts or mesh, Nguyen et al. reported that the reoperation risk for vaginal mesh exposure was 3.4 % during a 21-month period [19]. These data were comparable to estimates in this report of 3.0 % risk of mesh exposure surgery at 1 year, increasing to 5.9 % at 5 years.

We analyzed predictors of future surgery and found that concurrent hysterectomy and recent/concurrent sling decreased the risk of surgery for recurrent anterior and/or apical prolapse. One explanation is that if uterine prolapse was present, a hysterectomy decreased persistent or recurrent prolapse in the apical compartment. A prior or concurrent sling may also decrease future anterior prolapse given the supportive nature of a sling in the distal anterior compartment. Regarding predictors for surgery for mesh complications, we found that the risk of reoperation was lower for surgeries performed in 2005 and that this risk increased each subsequent year. It is possible that more recently available mesh materials and/or kits may be associated with a higher risk of mesh complications. Another possibility is that less experienced providers began to perform these procedures and had higher complication rates.

The strengths of this study were based in the inherent characteristics of a large, population-based database, which allowed us to evaluate over 20,000 native tissue and 6,800 vaginal mesh procedures for anterior vaginal wall prolapse. These healthcare claims data allowed us to follow patients over time, even if they did not return to their primary surgeon or the hospital of their index surgery for their reoperation. This was an important issue because patients with a complication may seek care from another surgeon at a different institution. Insurance claims data enabled us to capture any reoperations, as long as a patient remained insured. By utilizing data from 2005 to 2010, we were able to provide 5-year cumulative risks, which is significantly longer than the follow-up periods of existing studies.

This study was limited by constraints inherent in the database. This database represents those with health insurance, and thus, the results may not be generalizable to an uninsured population. In addition, data regarding race, physical examination findings, such as body mass index and severity of prolapse, medical history and surgical data were not available, and we were unable to evaluate the impact of these variables on our outcomes. Because we did not have all of the baseline characteristics of the study population, it was possible that a higher proportion of women who underwent vaginal mesh repair had recurrent or more severe prolapse compared with women in the native tissue group. However, given the fact that ~75,000 vaginal mesh procedures were performed in 2010 [3], it was unlikely that mesh was only utilized in women with recurrent prolapse.

As with any secondary data analysis, misclassification may have existed. For example, a small number of women in the native tissue group had mesh complications. We suspect that these women had mesh placed prior to the baseline period and/or had a different type of procedure that involved mesh, such as a sling. Another limitation was that we cannot determine the specific mesh or mesh kit/procedure that was performed, and therefore cannot comment on whether different mesh procedures carry different risks of complications.

Because of limitations imposed by the CPT coding system, which was central to our database, we were forced to exclude certain women from our analysis, in order to limit misclassification of our treatment groups to the greatest extent possible, and to define a more homogeneous cohort, overall, in which the effect of mesh could be evaluated. We have no reason to believe, however, that these a priori exclusions affected either study group preferentially.

Despite these limitations, our study provided insight into the longer-term risk of surgical intervention for recurrent prolapse and mesh complications after native tissue versus vaginal mesh for anterior vaginal wall prolapse. These estimates are valuable in counseling patients regarding what they can anticipate for reoperation rates for recurrent pro-lapse and/or mesh complications. Our results clearly indicated that patients seeking to minimize the risk of future surgery should carefully consider mesh augmentation of the anterior compartment, since the overall risk of future surgery was actually higher in the women receiving mesh. Furthermore, the rate of surgery for recurrent prolapse was no different with or without mesh. Lastly, our findings emphasize the importance of prospective, comprehensive, and long-term assessments of the safety and effectiveness of transvaginal mesh for pelvic organ prolapse.

Acknowledgments

Funding This project was supported by grant number K02HS017950 from the Agency for Healthcare Research and Quality (AHRQ; to M.J.F) and grant number K23HD068404 from the Eunice Kennedy Shriver National Institute of Child Health & Human Development (to J.M.W). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

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Table 1

List of current procedural terminology (CPT) utilized for inclusion and exclusion criteria

Included CPT codes		Excluded CPT codes	
		Prior mesh placed or revised/removed	Concomitant prolapse surgeries
57240	Anterior colporrhaphy	57267	57200
		Insertion of mesh in the vagina	Colporrhaphy, suture of injury of vagina
57267	Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (list separately in addition to code for primary procedure)	57280	57210
		Colpopexy, abdominal approach	Colpoperineorrhaphy
		57425	57250
		Laparoscopy, surgical, colpopexy	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy
		57415	57260
		Removal of impacted vaginal foreign body	Combined anteroposterior colporrhaphy
		57426	57265
		Revision/removal of vaginal prosthetic graft laparoscopic	Combined anteroposterior colporrhaphy; with enterocele repair
		57295	57268
		Revise vaginal graft via vaginal approach	Repair of enterocele, vaginal approach
		57296	57270
		Revise vaginal graft via abdominal approach	Repair of enterocele, abdominal approach
			57280
			Colpopexy, abdominal approach
			57282
			Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, ilioococcygeus)
			57283
			Colpopexy, vaginal; intra-peritoneal approach (uterosacral)
			57284
			Paravaginal defect repair; open approach
			57285
			Paravaginal defect repair; vaginal approach
			57423
			Laparoscopic paravaginal defect repair
			57425
			Laparoscopy, surgical, colpopexy

Table 2

Characteristics of women aged 18 undergoing vaginal mesh versus native tissue repair for anterior vaginal wall prolapse from 2005 to 2010

	Native tissue (n=20,938)	Vaginal mesh (n=6,871)	p value
Age			
Median (years)	55 (IQR 47, 63)	59 (IQR 52, 67)	<0.0001
Range (years)	19–93	22–95	
Age			
18–34	668 (3.2)	84 (1.2)	
35–44	3,262 (15.6)	593 (8.6)	
45–54	6,027 (28.8)	1,591 (23.2)	
55–64	6,594 (31.5)	2,503 (36.4)	
65–74	2,784 (13.3)	1,262 (18.4)	
75+	1,603 (7.7)	838 (12.2)	
Follow-up time			
Median (years)	1.3 (IQR 0.5, 2.7)	1.4 (IQR 0.5, 2.7)	0.44
Calendar year			
2005	3,214 (15.4)	563 (8.2)	<0.0001
2006	2,968 (14.2)	923 (13.4)	
2007	3,145 (15.0)	1,175 (17.1)	
2008	3,652 (17.4)	1,497 (21.8)	
2009	4,197 (20.0)	1,424 (20.7)	
2010	3,762 (18.0)	1,289 (18.8)	
Concomitant surgeries			
Recent/concurrent sling	13,061 (62.4)	4,849 (70.6)	<0.0001
Concurrent hysterectomy	8,018 (38.3)	1,263 (18.4)	<0.0001

Table 3

Cumulative incidence with 95 % confidence intervals (CI) of repeat surgery for either recurrent prolapse or mesh complications for native tissue vs vaginal mesh repair for anterior vaginal wall prolapse

Years of follow-up	Number at risk		Surgery for recurrent prolapse			Surgery for mesh complications		
	Native tissue (n=20,938)	Mesh (n=6,871)	Native tissue (%)	95 % CI	Mesh (%)	Native tissue (%)	95 % CI	Mesh (%)
1	11,805	3,935	5.1	4.8, 5.4	5.0	0.4	0.3, 0.5	3.0
2	7,180	2,358	6.5	6.1, 6.9	6.8	0.5	0.4, 0.6	4.3
3	4,235	1,261	7.5	7.1, 8.0	8.1	0.6	0.4, 0.7	4.9
4	2,291	571	8.5	7.9, 9.0	9.4	0.6	0.5, 0.8	5.9
5	903	152	9.3	8.6, 10.0	10.4	0.7	0.5, 0.9	5.9

Table 4

Cumulative risk of repeat surgery for recurrent prolapse or mesh complications at 2 years for specific subgroups based on Kaplan–Meier estimates

	Surgery for recurrent prolapse			Surgery for mesh complications				
	Native tissue		Vaginal mesh	Native tissue ^b		Vaginal mesh		
	2-year risk	95%CI	2-year risk	95%CI	2-year risk	95%CI		
Age group								
18–34	7.0	4.5, 9.5	7.0	0.9, 13.0	0.3	0, 0.8	4.5	0, 11.0
35–44	5.0	4.2, 5.9	6.2	3.9, 8.5	0.4	0.1, 0.7	5.6	3.2, 8.0
45–54	5.5	4.9, 6.2	5.9	4.5, 7.3	0.6	0.4, 0.9	4.7	3.3, 6.0
55–64	6.9	6.2, 7.6	6.9	5.7, 8.0	0.5	0.3, 0.7	4.6	3.6, 5.7
65–74	8.9	7.6, 10.1	8.0	6.1, 9.8	0.5	0.2, 0.9	2.8	1.6, 3.9
75+	6.7	5.3, 8.1	6.7	4.6, 8.7	0.4	0, 0.8	3.9	2.3, 5.5
Year of index surgery ^a								
2005	6.9	5.9, 7.8	5.5	3.4, 7.6	0.3	0, 0.5	2.6	0.9, 4.3
2006	5.1	4.3, 6.0	4.5	3.1, 6.0	0.5	0.2, 0.8	3.3	2.0, 4.6
2007	6.4	5.5, 7.4	5.9	4.5, 7.4	0.7	0.3, 1.0	4.3	3.0, 5.6
2008	6.3	5.5, 7.2	7.5	6.0, 8.9	0.5	0.2, 0.8	4.8	3.6, 6.0
Recent/concurrent sling								
No	7.4	6.8, 8.1	8.7	7.3, 10.2	0.4	0.2, 0.6	4.7	3.5, 5.9
Yes	5.9	5.5, 6.4	6.0	5.2, 6.8	0.6	0.4, 0.7	4.1	3.4, 4.8
Concurrent hysterectomy								
No	7.8	7.3, 8.4	6.9	6.1, 7.7	0.6	0.4, 0.8	4.3	3.6, 5.0
Yes	4.4	3.9, 4.9	6.3	4.7, 7.9	0.4	0.2, 0.5	4.1	2.7, 5.6

^a2-year cumulative risk based on Kaplan–Meier curves can only be reported for procedures performed in the years 2005–2008

^bRisk of mesh complications in the group with native tissue repair at the time of the index surgery may be non-zero if a fraction of these patients had mesh placed for prolapse more than 6 months prior to the index procedure, or if the mesh complication occurred subsequent to use of mesh for another gynecological indication (such as a sling)