UROGYNECOLOGY

Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors

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OBJECTIVE: The objective of the study was to estimate the long-term risk of sling revision/removal after an initial sling and to assess indications (mesh erosion and urinary retention) and predictors of sling revision/removal.

STUDY DESIGN: Using a population-based cohort of commercially insured individuals, we identified women 18 years old or older who underwent a sling (Current Procedural Terminology code 57288) between 2001 and 2010 and any subsequent sling revision/removal (Current Procedural Terminology code 57287). We estimated the cumulative risk of revision/removal annually and evaluated predictors of sling revision/removal using Kaplan-Meier survival curves and Cox proportional hazards models, respectively.

RESULTS: We identified 188,454 eligible women who underwent an index sling. The 9 year cumulative risk of sling revision/removal was 3.7% (95% confidence interval [CI], 3.5–3.9). At 1 year, this risk was already 2.2% and then increased to 3.2% at 4 years before plateauing. With regard to the indication for the sling revision/removal, a greater proportion was due to mesh erosion compared with urinary retention, with a 9 year risk of 2.5% (95% CI, 2.3–2.6) for mesh erosion vs 1.3% (95% CI, 1.2–1.4) for urinary retention. Age had an effect on the revision/removal rates for both mesh erosion and urinary retention, with the higher risks among those aged 18-29 years. The risk of revision/removal for mesh erosion and urinary retention was also elevated among women who had a concomitant anterior or apical prolapse procedure.

CONCLUSION: In this population-based analysis, the 9 year risk of sling revision/removal was relatively low at 3.7%, with 60% of revisions/removals caused by mesh erosion.

Key words: mesh erosion, sling, sling removal, sling revision, urinary retention

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Slings represent the most common surgery for stress urinary incontinence (SUI) and are now considered the gold standard procedure.[1,2] Historically, the term slings referred to bladder neck slings,[3] which remain an effective surgery for SUI.[4] However, midurethral slings now dominate the surgical management of stress incontinence. The uptake of the midurethral synthetic mesh sling has increased dramatically since the introduction of the tension-free vaginal tape in the United States in 1998.[5] Over the last decade, the retropubic midurethral sling has been modified, and the category of midurethral slings now includes transobturator slings as well as minislings.

★ EDITORS' CHOICE ★

The adoption of the midurethral sling was supported by level I evidence, which demonstrated similar 5 year effectiveness of retropubic midurethral slings and Burch colposuspensions,[6] the prior gold standard SUI procedure. Furthermore, randomized trials have reported equivalence between retropubic and transobturator slings at 1 year.[7,8] Although high-quality data from randomized trials exist regarding long-term effectiveness of midurethral slings, the long-term, population-based data are limited regarding the need for repeat surgery to manage complications such as mesh erosion or urinary retention. The best available data on complications suggest that the risk of sling revision/removal for either mesh erosion or retention is fairly low, ranging from ap-

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proximately 1-3%[8,9] and 0.6-1.2%,[8,9] respectively.

To date, the largest observational cohort reported on fewer than 4000 sling procedures followed up for a maximum of 21 months.[9] Thus, long-term follow-up of patients treated in real-world clinical settings are needed to further characterize the rates of repeat surgery to manage complications such as mesh erosion or urinary retention.

The recent Food and Drug Administration (FDA) notification regarding vaginal mesh for prolapse[10] has simultaneously increased the attention directed at midurethral slings because these procedures involve synthetic mesh placed vaginally. Although the FDA notification specifically addresses vaginal mesh prolapse procedures, an update on Jan. 4, 2012, stated that "the FDA continues to evaluate the effects of using surgical mesh for the treatment of urine leakage during moments of physical activity (stress urinary incontinence) and will provide updates on this web page at a later date." Thus, the FDA verdict regarding mesh slings for SUI is pending.

For relatively new procedures, it is critical to conduct long-term outcome assessments. For the midurethral sling, an important outcome to assess is the risk of a sling revision or removal to manage complications such as a mesh erosion or urinary retention.

Given the FDA emphasis on evaluating medical devices involving vaginal mesh and the limited, long-term, population-based data regarding slings, the objective of this study was to estimate the long-term risk of sling revision/removal after an initial sling in a large, population-based cohort. Our secondary objective was to assess the indication for sling revision/removal (mesh erosion and urinary retention) as well as predictors of revision/removal.

Materials and Methods

Data source

We utilized the Thomson Reuters MarketScan Commercial Claims and Encounters and Medicare Supplemental Coordination of Benefits database from 2001 to 2010 (copyright 2011, Thomson Healthcare Inc, Montvale, NJ).[11] This database contains deidentified, individual-level health care utilization and enrollment data for inpatient, outpatient, and pharmacy visits from approximately 100 employer-based plans in the United States. These deidentified data represent the medical experience of privately insured employees, retirees, covered spouses, and dependents. This database has been rigorously evaluated and is valid and reliable.[12] Individuals can be followed up longitudinally using encrypted unique identification numbers, and enrollment data allowed us to determine which individuals have insurance coverage at any point in time. This database provided information on 44.8 million women aged 18 years and older between the years 2001 and 2010. 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 sling

The population of interest included all women aged 18 years and older from 2001 to 2010. The first, or index, sling was identified for each woman, based on current procedural terminology (CPT) code 57288. We included women with at least 90 days of continuous enrollment prior to the procedure. Those with a diagnosis of a urethral diverticulum (*International Classification of Diseases*, 9th revision, clinical modification [ICD-9-CM] code 619.0) or any urinary-genital tract fistula (codes 599.1 and 599.2) in the 90 days prior to the index surgery were excluded. If an additional SUI procedure (ie, a different type of SUI surgery such as a Burch colposuspension) was coded on the same date as the sling, these individuals were excluded. The location for the procedure was also assessed, whether inpatient or outpatient. If both an inpatient and outpatient procedure claim occurred on the same service date, we preferentially included the inpatient procedure.

Sling revision/removal

After the index sling, the first subsequent sling revision/removal was identified using CPT code 57287. If another SUI surgery was performed after the index sling (ie, another sling, Burch colposuspension, bulking agent, etc), the outcomes of these individuals were censored at that surgery date because we were unable to determine whether any subsequent revision/removal was secondary to the index sling or the repeat SUI procedure. Otherwise, individuals were censored at the earliest disenrollment or on Dec. 31, 2010.

In addition to identifying sling revision/removals, we assessed the indication for this procedure based on ICD-9-CM codes for mesh erosion (996.30, 996.39, 996.59, 996.60, 996.65, 996.69, 996.70, 996.76, 996.79, 939.0, 939.2, and 939.9) and urinary retention (596.0, 598.1, 598.2, 598.8, 598.9, 599.6, 599.69, 788.2, 788.21, 788.29, 788.61, 788.62, and 788.65). We did not utilize 629.3 (complication of implanted vaginal mesh and other prosthetic materials), 629.31 (erosion of implanted vaginal mesh), or 629.32 (exposure of implanted vaginal mesh) because these ICD-9 codes were not released until 2011,[13] and thus were not applicable during our study period.

It is important to note that the diagnoses of mesh erosion and/or urinary retention were not mutually exclusive; thus, both mesh erosion and urinary retention could be associated with a single sling revision/removal procedure. For the indication-specific outcome definitions, individuals were censored if they had a revision/removal for another indication.

Statistical analysis

Descriptive statistics were used to characterize the population of women who underwent an index sling procedure. Kaplan-Meier survival curves were used to estimate the cumulative incidence (with 95% confidence intervals [CIs]) of sling revision/removal at 3 months, 6 months, and annually through 9 years of follow-up. We also estimated the cumulative incidence of sling revision/removal for mesh erosion and urinary retention separately. To explore the potential for differences in the risk of these outcomes because of the year when the index sling was placed, we also compared the cumulative risk at 1 year after the index sling,

TABLE 1
Characteristics of women who underwent an index sling

Characteristic	n = 188,454	%
Age at index sling, y		
Median (IQR)	53 (45–61)	—
Mean (SD)	53.7 (11.9)	—
18-29	1314	0.7
30-39	18,429	9.8
40-49	55,248	29.3
50-59	57,208	30.4
60-69	35,150	18.6
70-79	16,183	8.6
≥80	4942	2.6
Year when index surgery performed		
2001	2322	1.2
2002	5026	2.7
2003	8835	4.7
2004	13,350	7.1
2005	17,445	9.3
2006	20,437	10.8
2007	23.066	12.2
2008	30,155	16.0
2009	33,654	17.9
2010	34,164	18.1
Time intervals of follow-up, y		
0 to <2	122,213	64.9
2 to <4	41,022	21.8
4 to <6	16,827	8.9
6 to <8	6528	3.5
≥8	1864	1.0
Outpatient index slings	126,443	67.1
Region		
Northeast	13,724	7.3
Midwest	52,035	27.6
South	92,145	48.9
West	29,624	15.7
Unknown	924	0.5
Concomitant surgery		
Hysterectomy	47,065	25.0
Anterior prolapse procedures	62,469	33.2
Apical prolapse procedures	22,743	12.1
Posterior prolapse procedures	13,198	7.0

IQR, interquartile range.

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stratified by calendar year in which the index sling was performed.

We used Cox proportional hazards models to estimate the adjusted hazard ratio (adjHR) of the following: (1) sling revision/removal separately by decade of age (18-29, 30-39, 40-49, 50-59, 60-69 years) at the time of the index surgery compared with those 70 years of age and older; (2) inpatient vs outpatient procedures; (3) concomitant hysterectomy; and (4) concomitant prolapse procedures.

To further examine the possibility of different effects of these risk factors on revision/removal for mesh erosion and urinary retention, we also estimated the adjHRs separately for each of these outcomes. We estimated 95% confidence intervals on all effect estimates. Statistical analyses were performed using SAS, version 9.2 (SAS Institute, Cary, NC).

RESULTS

Of the 44.8 million women aged 18 years or older from 2001 to 2010, there were 188,454 index sling procedures. The median age of women undergoing surgery was 53 years (interquartile range, 45–61), and approximately 60% of these procedures were performed in women aged 40-59 years of age (Table 1). Table 1 also depicts the year in which the index sling was performed and illustrates that a higher proportion of surgeries were done in the latter years reflecting an increase in the database's enrolled population. Because the majority of procedures were performed in the latter portion of the decade, there are relatively more procedures with shorter time intervals of follow-up (Table 1). Nonetheless, we have 4 or more years of follow-up on 25,219 individuals and more than 8 years on 1864 individuals. A majority of the procedures (67%) was performed on an outpatient basis, and the South had the largest proportion of sling procedures (49%). Concomitant hysterectomy and concurrent prolapse procedures were also common (Table 1).

The cumulative incidence of sling revision/removal for any indication was 3.7% (95% CI, 3.5–3.9) at 9 years of follow-up (Table 2). At 1 year of follow-up, this risk was 2.2% and then increased to

TABLE 2
Cumulative risk of sling revision/removal by indication reported by follow-up time after the index sling

Follow-up after index sling, y	Cumulative risk of revision/removal for urinary retention	Cumulative risk of revision/removal for mesh erosion	Cumulative risk of sling revision/removal for any indication
0.25	0.6 (0.5, 0.6)	0.5 (0.5, 0.5)	1.0 (1.0, 1.1)
0.5	0.8 (0.7, 0.8)	0.9 (0.8, 0.9)	1.6 (1.5, 1.6)
1	0.9 (0.9, 1.0)	1.3 (1.2, 1.3)	2.2 (2.1, 2.2)
2	1.1 (1.0, 1.1)	1.6 (1.6, 1.7)	2.6 (2.5, 2.7)
3	1.2 (1.1, 1.2)	1.9 (1.8, 2.0)	3.0 (2.9, 3.1)
4	1.2 (1.1, 1.3)	2.1 (2.0, 2.2)	3.2 (3.1, 3.4)
5	1.2 (1.2, 1.3)	2.2 (2.1, 2.3)	3.4 (3.3, 3.5)
6	1.3 (1.2, 1.4)	2.3 (2.2, 2.4)	3.6 (3.5, 3.7)
7	1.3 (1.2, 1.4)	2.5 (2.3, 2.6)	3.7 (3.5, 3.9)
8	1.3 (1.2, 1.4)	2.5 (2.3, 2.6)	3.7 (3.5, 3.9)
9	1.3 (1.2, 1.4)	2.5 (2.3, 2.6)	3.7 (3.5, 3.9)

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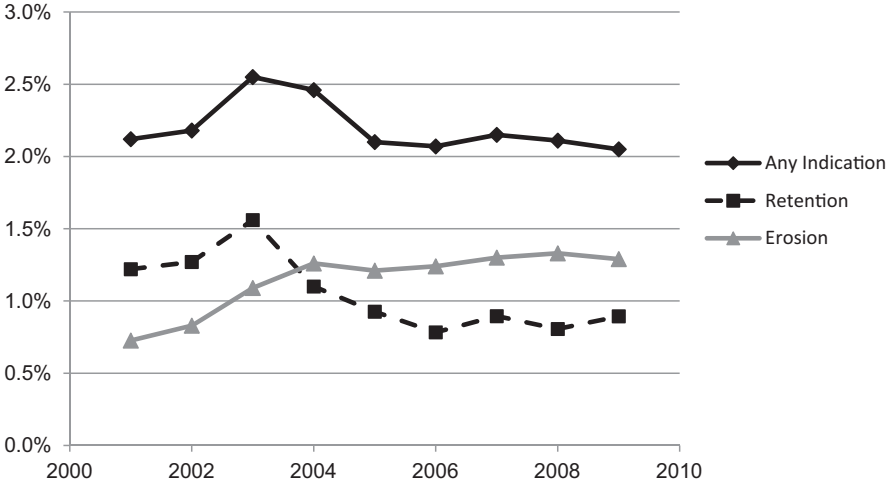
3.2% at 4 years before plateauing. Thus, a majority of sling revision/removals occurred within the first few years after the index surgery. With regard to the indication for the sling revision/removal, a greater proportion was due to mesh erosion compared with urinary retention, with a 9 year risk of 2.5% (95% CI, 2.3–2.6) for mesh erosion vs 1.3% (95% CI, 1.2–1.4) for urinary retention. Focusing on mesh erosion, the risk of revision/removal increased from 1.3% at 1 year to 2.1% at 4 years before leveling off. For urinary retention, the risk was 0.9% at 1 year and then remained fairly stable afterward.

To further evaluate possible changes over time in the risk of revision/removal for mesh erosion and urinary retention, we estimated the 1 year risk for sling revision/removal by indication for each calendar year (Figure). This analysis was prompted because the type of midurethral slings performed (ie, retropubic midurethral slings vs transobturator slings vs minislings) may have changed during the study period. Although the 1 year cumulative risk of sling revision/removal for any indication remained fairly stable over the study period, there was an increase in the 1 year risk of revision/removal for mesh erosion and a decrease in the risk of surgery for retention over the study period (Figure).

We also evaluated predictors of sling revision/removal based on indication using Cox proportional hazards models. For revision/removal because of mesh erosion, all women aged 18-69 years were at higher risk compared with those aged 70 years and older, with the highest risk among those 18-39 years (Table 3). The risk of revision/removal for mesh erosion was also elevated among women who had a concomitant anterior (hazard ratio [HR], 1.18; 95% CI, 1.08–1.29) or apical (HR, 1.24; 95% CI, 1.10–1.41) prolapse procedure but not among those who had a posterior prolapse procedure (HR, 1.06; 95% CI, 0.91–1.24). Women who had a concurrent hysterectomy had a lower risk of revision/removal for mesh erosion (HR, 0.81; 95% CI, 0.73–0.90).

For sling revision/removal because of urinary retention, women aged 18-29 years (HR, 1.91; 95% CI, 1.22–2.99) had a significantly higher risk than women aged 70 years and older. Inpatient procedures were also associated with a higher risk of sling revision/removal for retention compared with outpatient procedures (HR, 1.18; 95% CI, 1.06–1.32). Women who had a concomitant anterior (HR, 1.22; 95% CI, 1.09–1.36) or apical (HR, 1.43; 95% CI, 1.25–1.64) prolapse procedure were also at higher risk of subsequent revision/removal for retention compared with those who did not. Concomitant posterior prolapse procedures and hysterectomy were not associated with any change in the risk of revision/removal for urinary retention.

FIGURE
Cumulative 1 year risk of sling revision for any indication, retention, or mesh erosion, stratified by year of index sling



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COMMENT

In this large, population-based cohort of 188,454 adult women who underwent an index sling, the risk of sling revision/re-

moval was relatively low at 3.7% at 9 years of follow-up. The majority of revisions/removals occurred within 4 years after the index surgery. Mesh erosion, rather than urinary retention, was the indication for a majority of these procedures. We also found that risk factors differed for the 2 primary indications for revision/removal with a stronger effect of age on mesh erosion.

Our findings regarding the risk of sling revision/removal are consistent with the existing literature. In the landmark trial of tension-free vaginal tape (TVT) vs Burch colposuspension, Ward and Hilton[6] reported that 1 of 170 TVTs (0.6%) had obstructed voiding requiring sling revision, and 5 of 170 (2.9%) had erosion/extrusion. Other randomized trials of retropubic vs transobturator slings revealed a 2.7% rate of voiding dysfunction requiring surgery,[7] and the rates of erosions and/or exposures ranged from 1.8 to 3.5%, although not all of these required surgery.[7,8]

Prior to our study, the largest population-based study evaluated 3747 slings over a 21 month time period and found that the rate of sling loosening or transection was 1.2% for retropubic procedures, 1.9% for transobturator slings, and 1.3% for single-incision surgeries.[9] The risk of surgery for vaginal mesh exposure was 0.9% and 1.0% for retropubic and transobturator procedures, respectively.[9] Although several systematic reviews and meta-analyses have been performed with regard to midurethral slings,[14-18] the cumulative number of subjects in these studies remains significantly lower than our study population. We extend the literature in that we evaluated more than 188,000 index slings with annual rates for sling revision/removal based on indication through 9 years of follow-up. Our results suggest that the relatively low rate of sling revision/removal in the short term does not increase dramatically over the first 9 years after surgery.

Our study revealed interesting and surprising findings with regard to the predictors for sling revision/removal. Our results showed a strong effect of age on the risk of sling revision/removal for mesh erosion, with the highest risk among younger women. This finding was surprising, given that urogenital atrophy occurs in older populations, leading to poorer tissue quality with a presumably higher risk for mesh erosion. It is possible that younger women were more sexually active, and sexual activity could be a risk factor for mesh erosion. Alternatively, younger women who are more sexually active may have been more likely to detect mesh erosion and to opt for surgical management. Unfortunately, because slings of all types were coded using CPT code 57288, we were unable to determine which type of sling was associated with a greater risk of mesh erosion.

With regard to sling revision/removal for urinary retention, we found that the youngest age group (women 18-29 years old) was at highest risk for repeat surgery, although the strong gradient of risk by age was not present. These results were also surprising in that older age groups are more likely to suffer from impaired detrusor contractility,[19] which could lead to a higher risk of urinary retention after slings. Perhaps younger women were less tolerant of irritative voiding symptoms or de novo urge incontinence and therefore had a lower threshold to undergo surgical management in attempts to remedy these symptoms. Other variables associated with sling revision/removal for urinary retention and mesh erosion included concurrent anterior or apical prolapse procedures. It is possible that the changes in pelvic support and anatomy associated with anterior and apical prolapse exacerbated urinary retention and compromised healing because of the additional vaginal incisions.

We also found that there were differences in the 1 year risk of sling revision/removal based on the year in which the index sling was performed. The risk of surgery for urinary retention decreased from 2001 to 2010. We hypothesize that as surgeons became more familiar with how to perform slings, their technique improved. Also, the more recent introduction of the transobturator and mini-slings may be associated with a lower risk of surgery for retention because these slings are less compressive around

TABLE 3
Cox regression analyses for time to sling revision/removal

Variable	Retention AdjHR (95% CI)	Mesh erosion AdjHR (95% CI)	Any indication AdjHR (95% CI)
Age, y			
18-29	1.91 (1.22–2.99)	2.52 (1.58–4.00)	2.02 (1.46–2.80)
30-39	1.19 (0.98–1.45)	2.64 (2.19–3.18)	1.69 (1.48–1.93)
40-49	0.87 (0.74–1.02)	2.08 (1.76–2.45)	1.28 (1.14–1.43)
50-59	0.91 (0.78–1.07)	1.89 (1.60–2.22)	1.22 (1.10–1.37)
60-69	0.91 (0.77–1.08)	1.52 (1.28–1.82)	1.10 (0.98–1.24)
≥70 (referent)	—	—	—
Procedure location			
Inpatient	1.18 (1.06–1.32)	1.04 (0.95–1.15)	1.08 (1.00–1.16)
Outpatient (referent)	—	—	—
Concomitant surgery[a]			
Hysterectomy	0.98 (0.87–1.10)	0.81 (0.73–0.90)	0.84 (0.77–0.91)
Anterior prolapse surgery	1.22 (1.09–1.36)	1.18 (1.08–1.29)	1.18 (1.10–1.27)
Apical prolapse surgery	1.43 (1.25–1.64)	1.24 (1.10–1.41)	1.27 (1.16–1.40)
Posterior prolapse surgery	1.02 (0.85–1.23)	1.06 (0.91–1.24)	1.06 (0.94–1.20)

AdjHR, adjusted hazard ratio; *CI*, confidence interval.

[a] Reference group includes those patients who did not have the specified procedure.

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the urethra.[20] On the other hand, the risk of sling revision/removal for mesh erosion increased over the study period. It is possible that transobturator slings and certain minislings leave more mesh traversing the vaginal space, which could increase the risk for mesh erosion. In addition, the FDA 2008 notification may have led to a higher risk of sling revision/removal for this indication because it heightened awareness of mesh erosion as a possible sling complication among both patients and providers.[21]

This study provides comprehensive data on more than 188,000 index sling procedures with long-term follow-up over 9 years in a nationally representative, population-based cohort. One unique aspect of these health care claims data was that we can accurately account for individual contributions to follow-up time with complete capture of subsequent clinical care as long as an individual continued to have insurance coverage. For example, even if a subject with a sling complication did not follow up at the same institution in which the initial sling was performed, follow-up data regarding sling revision/removal was available. Another benefit of this database was that we were able to follow up patients beyond the age of 65 years when they transitioned into Medicare by virtue of the Medicare supplemental data.

This study was limited by the fact that the database included only privately insured individuals, and thus, the results may not be generalizable to uninsured or underinsured individuals. Furthermore, detailed sociodemographic and clinical data such as race, physical examination findings, such as body mass index, and severity of urinary incontinence were not available.

We were also limited by the specificity of CPT codes in the database. Currently there is one encompassing CPT code for all sling procedures, code 57288, which includes traditional bladder neck, retropubic midurethral slings, transobturator slings, and minislings. The proposed FDA rule that would require unique device identifiers (UDIs) will make it possible to distinguish specific types of slings, but it will be many years before long-term outcome data will be available for surgeries in which the UDI has been recorded.[22]

Lastly, we acknowledge that our data do not represent the overall risk of mesh erosion after a sling because some erosions may have been managed conservatively in the office and some erosions managed surgically may have been coded by a different CPT (ie, 57295 revise vaginal graft via vaginal approach) and not CPT 57287, which indicates a sling revision/removal.

In conclusion, after an index sling procedure, the risk of sling revision/removal for either mesh erosion or urinary retention is less than 4% over 9 years of follow-up. The majority of these sling revisions/removals were due to mesh erosion rather than urinary retention. Age, slings performed with concomitant prolapse surgery, and the calendar year of the index sling were associated with the risk of sling revision/removal. Although the FDA evaluation for slings is still pending,[10] these long-term results in a large, population-based cohort are reassuring. However, future studies should aim to study specific sling types in a large cohort of women with long-term follow-up. ■

REFERENCES

1. Oliphant SS, Wang L, Bunker CH, Lowder JL. Trends in stress urinary incontinence inpatient procedures in the United States, 1979-2004. Am J Obstet Gynecol 2009;200:521.e1-6.

2. Jonsson Funk M, Levin PJ, Wu JM. Trends in the surgical management of stress urinary incontinence. Obstet Gynecol 2012;119:845-51.

3. Bezerra CA, Bruschini H, Cody DJ. Traditional suburethral sling operations for urinary incontinence in women. Cochrane Database Syst Rev 2005:CD001754.

4. Albo ME, Richter HE, Brubaker L, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. N Engl J Med 2007;356:2143-55.

5. Food and Drug Administration. 510(K) number K974098. Jan. 28, 1998.

6. Ward KL, Hilton P. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 2008;115:226-33.

7. Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med 2010;362:2066-76.

8. Barber MD, Kleeman S, Karram MM, et al. Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 2008;111:611-21.

9. Nguyen JN, Jakus-Waldman SM, Walter AJ, White T, Menefee SA. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. Obstet Gynecol 2012;119:539-46.

10. Food and Drug Administration Safety Communication: update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Issued on July 13, 2011. Available at: http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm. Accessed June 12, 2012.

11. Thomson Reuters MarketScan Commercial Claims and Encounters Database, 2000-2009. Source: Red Book and MarketScan are registered trademarks of Thomson Reuters (Healthcare) Inc. Available at: http://thomsonreuters.com/products_services/healthcare/healthcare_products/pharmaceuticals/mktscan_res_db/). Accessed June 12, 2012.

12. Hansen LG, Chang S. Health research data for the real world: the Thomson Reuters MarketScan Databases. White paper; 2011.

13. Centers for Disease Control and Prevention. Classification of diseases, conversion table of new ICD-9-CM codes, October 2011. Available at: http://www.cdc.gov/nchs/data/icd9/CNVTB12.pdf. Accessed June 26, 2012.

14. Novara G, Artibani W, Barber MD, et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol 2010;58:218-38.

15. Novara G, Galfano A, Boscolo-Berto R, et al. Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. Eur Urol 2008;53:288-308.

16. Sung VW, Schleinitz MD, Rardin CR, Ward RM, Myers DL. Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis. Am J Obstet Gynecol 2007;197:3-11.

17. Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev 2009:CD006375.

18. Abdel-Fattah M, Ford JA, Lim CP, Madhuvrata P. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: a meta-analysis of effectiveness and complications. Eur Urol 2011;60:468-80.

19. Taylor JA 3rd, Kuchel GA. Detrusor underactivity: clinical features and pathogenesis of an underdiagnosed geriatric condition. J Am Geriatr Soc 2006;54:1920-32.

20. Latthe PM, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 2007;114:522-31.

21. Food and Drug Administration public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse. Issued Oct. 20, 2008. Available at: http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm). Accessed June 12, 2012.

22. Food and Drug Administration. Unique device identification (UDI) proposed rule. Available at: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm310872.htm. Accessed July 27, 2012.