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The Role of the Surgeon on Outcomes of Vaginal Prolapse Surgery With Mesh

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Abstract

Introduction—Adverse outcomes after surgery for pelvic organ prolapse (POP) with mesh are often attributed to the mesh material with little attention paid to the influence of surgeon factors. We used a national data set to determine whether surgeon case volume and specialty influenced vaginal prolapse surgery outcomes with mesh.

Materials and Methods—Public Use File data on a 5% random national sample of female Medicare beneficiaries were obtained from the Centers for Medicare and Medicaid Services. Women with a diagnosis of POP who underwent surgery with mesh between 2007 and 2008 were identified by relevant *International Classification of Diseases, 9th Revision, Clinical Modification* and *Current Procedural Terminology, 4th Edition* procedure codes. Outcomes were compared by surgeon case volume and specialty.

Results—From 2007 to 2008, 1657 surgeries for POP were performed with mesh. Low-, intermediate-, and high-volume surgeons performed 881 (53%), 408 (25%), and 368 (22%) of the cases with mesh, respectively. The cumulative reoperation rates for low-, intermediate-, and high-volume providers were 6%, 2%, and 3%, respectively. The difference in reoperation rates between low and intermediate and low- and high-volume surgeons was statistically significant ($P=0.007$ and 0.003 , respectively). There was no significant difference in reoperation rates between gynecologists and urologists when vaginal mesh was implanted for POP surgery.

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Conclusions—Low-volume surgeons performed most of the vaginal prolapse repairs with mesh and had significantly higher reoperation rates. Surgeon experience must be a consideration when reporting mesh-related complications of POP surgery.

Keywords

surgeon; volume; vaginal prolapse; mesh; outcomes

The overall prevalence of pelvic floor disorders among communitydwelling women has been estimated at 25%, whereas the prevalence of pelvic organ prolapse (POP) is between 3% and 6%.^{1,2} Contemporary reports indicate a 10-year recurrence rate of up to 25% after surgery for POP, with the anterior compartment being the most frequent site of recurrence.³ Addressing the apical compartment is of utmost importance in POP reconstructive surgery, and we previously reported that performing a concomitant apical suspension procedure at the time of anterior colporrhaphy reduces reoperation rates.⁴ Despite this observation, simultaneous apical procedures are often not performed at the time of cystocele repair, possibly due to the technical difficulties associated with these procedures.

Pelvic organ prolapse mesh “kits” were introduced as an alternative to traditional apical suspension procedures and are utilized by both gynecologists and urologists. Compared with an abdominal sacrocolpopexy these kits provide a minimally invasive and arguably less technically challenging procedure for the treatment of apical prolapse while also decreasing the recurrence rate associated with vaginal native tissue anterior repair.⁵ After increased use of vaginally placed mesh for POP, the number of mesh-related complications increased, ultimately resulting in the issuance of safety communications regarding the use of mesh for vaginal POP surgery by the Food and Drug Administration (FDA) in 2008 and 2011.^{6,7}

The wide variability of the incidence of mesh-related complications reported by different authors suggests that surgical technique plays an important role.^{8–12} Surgeon volume has been shown to correlate with improved outcomes in many surgical specialties including gynecology, urology, general surgery, and orthopedics.^{13–19} In addition to surgeon volume, surgeon specialty may also influence outcomes. We previously reported that both high-volume surgeons and gynecologists, as opposed to urologists, were more likely to address concomitant prolapse at the time of stress incontinence surgery, thereby reducing the number of subsequent operations for concomitant pelvic floor disorders.^{20,21}

As several manufacturers of vaginal mesh products are currently performing FDA-mandated postmarket safety studies, we thought it timely to report on the association of both surgeon volume and specialty on outcomes of vaginal POP reconstruction with mesh before the first FDA safety communication.

Materials and Methods

The Institutional Review Board of the University of California, Los Angeles, determined this study to be exempt. Medicare Public Use File data, composed of national deidentified administrative and claims data on a random 5% sample of the US Medicare population, were obtained from the Centers for Medicare and Medicaid Services. An analytical cohort was

identified that included female Medicare beneficiaries 65 years and older. Within this cohort, a subset of women who underwent vaginal prolapse surgery during a 2-year period, 2007-2008, were identified by relevant *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)* and *Current Procedural Terminology, 4th Edition (CPT-4)* codes previously described.⁴ Furthermore, the insertion of vaginal mesh in this subset of women was identified by the presence of *CPT* code 57267 (insertion of mesh or other prosthesis for repair of pelvic floor defect, vaginal approach). The year 2007 was specifically chosen as during this period *CPT* code 57267 was well established, and thus allowed accurate capture of procedures involving insertion of mesh. This period also preceded the first FDA safety communication so that it reflected practice patterns with mesh before the much publicized litigation. Additional *ICD-9-CM* and *CPT-4* codes were subsequently used to identify which of these subjects had a reoperation (Appendix 1).

Surgeons who performed the above procedures were classified as either low-, intermediate-, or high-volume providers based on the number of transvaginal POP surgeries with mesh performed during the study period. Absolute numbers were not indicated as surgeon volume was based on a random 5% sample. We chose not to multiply surgeon volume by a factor of 20 simply to achieve a 100% sample estimate, as this would likely be a gross overestimation of surgeon volume.

The frequency distribution of surgeon volume was largely skewed such that 53% of surgeons performed only 1 procedure annually, 25% performed 2 procedures annually, and the remaining 22% performed 3 or more POP repairs with mesh per year (Fig. 1). Therefore, high and low surgeon volume was empirically determined by the natural top 25th and lowest 75th percentiles, respectively. Based on this, low-volume surgeons were defined as those performing 1 case annually, intermediate-volume surgeons performed 2 cases annually, and high-volume surgeons were defined as those performing 3 or more cases annually.

Cumulative reoperation rates were analyzed both by surgeon volume and specialty (gynecologist or urologist). The reoperation rates were determined by previously described specific *CPT* codes reported after the initial surgery in 2007–2008.⁴ Fisher exact test was used to detect statistically significant differences between patient groups.

Results

From 2007 to 2008, 1657 transvaginal surgeries for POP (5% sample) were performed with mesh based on *CPT* 57267. Of these, low-volume surgeons (1 case annually) performed 881 (53%) of the procedures, intermediate-volume surgeons (2 cases annually) performed 408 (25%) of the procedures, and high-volume providers (3 or more cases annually) performed 368 (22%) of the procedures (Fig. 1). Of the 368 procedures performed by high-volume surgeons, 171 (46%) of the procedures were done by surgeons performing 3 cases annually, and the remaining 197 (54%) of the procedures were done by surgeons performing 4 to 8 cases annually. Interestingly, only 16 (4%) of these 368 procedures were done by surgeons performing at least 8 vaginal mesh surgeries annually.

The cumulative reoperation rate 1 year after vaginal POP repair with mesh was significantly higher for low-volume surgeons when compared with intermediate-volume surgeons (6% vs 2%, $P = 0.007$) and high-volume surgeons (6% vs 3%, $P = 0.003$). The cumulative reoperation rates did not significantly differ between intermediate- and high-volume surgeons (2% vs 3%, $P = 0.5$).

Of the 1657 vaginal prolapse repairs with mesh, gynecologists and urologists performed 1209 (73%) and 438 (26%) procedures, respectively (Fig. 2). A small percentage of POP repairs with mesh was performed by general surgeons ($n = 10$, 0.6%). The cumulative reoperation rates for gynecologists and urologists were equivalent at 4%. Although overall reoperation rates were low for both specialties, the most commonly reported CPT codes when a reoperation occurred were mesh removal (CPT 57295 revision/ removal of prosthetic vaginal graft, vaginal approach; CPT 57296 revision/removal of prosthetic vaginal graft, abdominal approach; CPT 57287 removal or revision of sling) or insertion of mesh (CPT 57267) in combination with another prolapse procedure.

Discussion

The first FDA public health notification issued in 2008, regarding the use of mesh for vaginal surgery, was produced in response to reports of over 1000 complications associated with vaginal surgery with mesh.⁶ The most common complications reported were mesh extrusion, infection, pain, and urinary problems.⁶ After an additional 2874 reports of complications were received by the FDA, a second communication in 2011 advised the public about possible complications related to use of mesh for POP surgery and provided a set of questions for patients to ask their doctor before agreeing to surgery.⁷

Subsequently, much publicized litigation has attributed mesh-related complications to the properties of synthetic mesh products; however, we propose that surgeon characteristics should be considered as a factor in mesh-related complications as well. The use of mesh for abdominal sacrocolpopexy dates back to 1962. Although this procedure is associated with mesh exposure, other mesh-related complications have not been reported to nearly the same degree as vaginally placed mesh.^{22,23} Similarly, the use of mesh for mid-urethral slings has resulted in positive outcomes overall. In fact, use of mesh for slings was not included in the 2011 FDA safety communication, and mesh mid-urethral slings are considered the worldwide standard of care for the treatment of stress urinary incontinence.^{7,24}

Not surprisingly, we observed lower reoperation rates among high-volume surgeons and propose that increased surgeon experience has an influential role in outcomes of vaginal surgery with mesh. Multiple studies have shown that surgeon experience, using volume as a proxy, is an indicator of both patient outcomes and cost.^{13–21} In our study, most vaginal prolapse repairs with mesh were performed by low- and intermediate-volume surgeons. As expected, low-volume surgeons had the highest reoperation rates. Also reinforcing the relationship of volume and outcomes, as opposed to specialty, was our finding that reoperation rates were not different between gynecologists and urologists.

The findings of our study suggest that surgeon inexperience may have contributed to a significant proportion of mesh-related complications, prompting the first FDA safety communication in 2008. Given that 78% of vaginal prolapse surgeries with mesh in our study were performed by low- and intermediate-volume surgeons, it is possible that the number of negative mesh-related outcomes subsequent to the study period may have been reduced if more of the cases had been performed by high-volume surgeons. We anticipate that mesh-related complications will decrease over time as ongoing litigation may limit the performance of these types of procedures to only surgeons who have demonstrated proficiency with the use of vaginal mesh. Furthermore, we expect that the threat of mesh litigation has caused a large proportion of low-volume surgeons to discontinue performing vaginal POP procedures with mesh. The result of this will likely be a natural restriction of vaginal mesh use to high-volume surgeons and possibly improved outcomes.

The strength of our study lies in the fact that the Centers for Medicare and Medicaid Services Public Use File data enables the analysis of a large sample of patients within a broad geographic distribution; however, we recognize that there are inherent limitations to claims-based analyses. Specifically, diagnoses are identified by *ICD-9-CM* codes that lack clinical detail, and therefore, we do not know the severity of complications that were reported. Furthermore, the influence of patient-related comorbidities could not be determined within our cohort. In addition, the cohort analyzed in this study represents only a 5% random sample of Medicare beneficiaries. We also acknowledge that performing more than 3 cases a year of any procedure does not constitute “high volume,” but the observation that over 50% of the surgeons implanting mesh only performed these procedures once a year reinforces the notion that surgeon inexperience likely contributed to the reported mesh complications.

Although this population may be reflective of the heterogeneous sample of Medicare beneficiaries, the cohort does not accurately represent the patient population of most surgeons. A Medicare sample does not take into account patients less than 65 years of age. Most surgeons have a case mix that includes patients aged 65 years and more and younger patients who are not represented by Medicare. Last, a 5% sample does not allow us to calculate the exact overall volume for a specific surgeon. We chose not to multiply surgeon volume by a factor of 20 to achieve a 100% sample estimate, as this would likely be a gross overestimation of surgeon volume.

Conclusions

Low-volume surgeons performed most vaginal prolapse repairs with mesh before the first FDA safety communication and had significantly higher reoperation rates. Surgeon experience must be a consideration when reporting mesh-related complications of POP surgery.

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Appendix 1: International Classification of Diseases, 9th Revision, Clinical Modification and Current Procedural Terminology, 4th Edition Codes Used to Identify Postoperative Complications

ICD-9-CM	CPT
54.11 Exploratory laparotomy	49000 Exploratory laparotomy
55.02 Percutaneous nephrostomy tube placement	50392 Percutaneous nephrostomy tube placement
56.74 Ureteroneocystostomy	50780 Ureteroneocystostomy
57.1/57.81/57.94 Cystotomy/cystorrhaphy, suture of bladder wound/urethral/catheterization (simple)	51701 Ureteral/bladder catheterization (simple)
58.5 Removal or revision of sling/urethrolysis	51800 Revision of bladder/urethra
70.71 Colporrhaphy, suture of injury of vagina	51860 Cystorrhaphy, suture of bladder wound
99.0 Blood transfusion	52281 Cystourethroscopy with dilation of stricture
553.21 Incisional hernia	52332 Insertion of ureteral stent
569.83 Perforation of rectum	53660/53661/53665 Dilation of female urethral stricture
590.80 Pyelonephritis unspecified	57200 Colporrhaphy, suture of injury of vagina
593.3 Stricture or kinking of ureter (postoperative)	57210 Colpoperineorrhaphy, suture of injury of vagina/perineum
595/595.0/595.9 Cystitis, acute cystitis, cystitis unspecified	57295 Revision/removal of prosthetic vaginal graft
596.6 Rupture of bladder, nontraumatic	57296 Revision/removal of prosthetic vaginal graft
599.0 Urinary tract infection, site not specified	57287 Removal or revision of sling
599.6 Urinary obstruction	58520 Hysterorrhaphy, repair of ruptured uterus
625.6 Dyspareunia	
788.2 Retention of urine	
902.50–902.59 Injury to iliac blood vessels	
902.81–902.89 Injury to other specified blood vessels of abdomen and pelvic	
902.9 Injury of blood vessels of abdomen/pelvis	
996.3/996.30/996.39 Mechanical complication of genitourinary device, implant, and graft/unspecified/other	
996.6 Infection and inflammatory reaction because of internal prosthetic device implant and graft	
996.76 Other complication of internal (biologic/synthetic) prosthetic device, implant, and graft	
998.2 Accidental puncture or laceration during a procedure	
998.3 Disruption of operative wound	

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Figure 1.
Number of transvaginal POP repairs with mesh by surgeon annual volume based on 5% random sample.

Figure 2.
Number of transvaginal POP repairs with mesh by specialty based on 5% random sample.