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Trends in management of pelvic organ prolapse among female Medicare beneficiaries

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Abstract

OBJECTIVE—In the last decade, many new surgical treatments have been developed to achieve less-invasive approaches to prolapse management. However, limited data exist on how the patterns of care for women with pelvic organ prolapse (POP) may have changed over the last decade, and whether mesh implantation techniques have influenced the type of specific compartment repair performed. We used a national data set to analyze the temporal trends in patterns of care for women with POP.

STUDY DESIGN—Data were obtained from Public Use Files from the Centers for Medicare and Medicaid Services for a 5% random sample of national beneficiaries with an *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis of POP from 1999 through 2009. *Current Procedural Terminology, 4th Edition* and *International Classification of Diseases, Ninth Revision, Clinical Modification* procedure codes were used to evaluate nonsurgical and surgical management trends for this cohort. Types of surgery were categorized by prolapse compartment and combinations of repairs. After 2005, when applicable codes became available, mesh or graft repairs were also analyzed.

RESULTS—Over the study time period, the number of women with a diagnosis of POP in any 1 year in our 5% sample of Medicare beneficiaries remained relatively stable (range, 21,245–23,268 per year). Rates of pessary insertion were also consistent at 11–13% over the study period. Of the women with a prolapse diagnosis, 14–15% underwent surgical repair, and there was little change over time in surgical management patterns based on compartment. Most commonly, multiple compartments were repaired simultaneously. There was a rapid increase in mesh use such that in 2009, 41% of all women who underwent surgery (5.8% of the total cohort) had mesh or graft inserted in their repair. Hysterectomy rates for prolapse decreased over time. Rates of vault

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suspension at the time of hysterectomy for prolapse were low; however, they showed a relative increase over time (22% in 1999 to 26% in 2009).

CONCLUSION—Patterns and rates of prolapse repairs remained relatively unchanged from 1999 through 2009, with an exception of a rapid rise in mesh use. These data suggest that the majority of mesh techniques were used for augmentation purposes only, but did not result in an increase in apical repairs performed in the United States. There remains a disappointingly low rate of vault suspension repairs concomitantly at time of hysterectomy for POP.

Keywords

epidemiology; mesh; pelvic organ prolapse; trends

Data from the National Health and Nutrition Examination Survey have estimated that, by the year 2050, more than one-third of the female population age >20 years (an anticipated 29.3 million women) will experience at least 1 pelvic floor disorder (Wu et al,¹ 2009). Of these, 9.2 million women are projected to have pelvic organ prolapse (POP). This increased prevalence of pelvic floor disorders is related to the aging of the US population (Nygaard et al,² 2008), with the number of those age >65 years expecting to more than double to 88.5 million by 2050 (US Census Bureau News).³

However, despite the increasing prevalence of POP, few studies have analyzed management patterns. A prior study by Fialkow et al⁴ assessed rates of surgery performed on a cohort of 251 women enrolled in a health maintenance organization in Seattle who underwent primary surgical management for urinary incontinence or POP. They determined that by age 80 years, the cumulative incidence of primary surgery for urinary incontinence and POP was 11.8% (Fialkow et al,⁴ 2008). Management of patients undergoing hysterectomy also demonstrates an increased risk for the future development of POP (Marana et al⁵). In fact, hysterectomy for POP is a strong predictor of repeat pelvic floor surgery, although this may be due in part to failure to perform concomitant vaginal vault suspension at the time of hysterectomy (Marana et al⁵).

Recently, many new surgical treatments have been developed to achieve efficacious, yet less-invasive approaches to prolapse surgery. However, limited data exist on how the patterns of care for women with POP may have changed over this last decade, and whether mesh implantation has influenced the type of specific compartment repair performed. Studies have demonstrated a significant rise in mesh use in POP surgery since the Food and Drug Administration (FDA) first approved its use in 2004 (Reynolds et al,⁶ Rogo-Gupta et al,⁷ and Funk et al⁸). Despite the increased use of mesh, there are scant data as to whether mesh use has shifted overall rates of surgical management or led to an increase in apical suspensions or rectocele repairs at the time of cystocele repair.

The purpose of this study was to identify temporal trends in the patterns of care for women with POP using Medicare data. We hypothesized that there would be an increase in the number of apical procedures over time, as data are emerging to suggest better outcomes. In addition, we expected that knowledge and awareness of pelvic floor dysfunction among

patients and providers would lead to an increase in the number of women undergoing both surgical and nonsurgical (pessary) management of POP.

Materials and Methods

This study was determined to be exempt by the University of California, Los Angeles, Institutional Review Board. Public Use File data from 1999 through 2009 were obtained from the Centers for Medicare and Medicaid Services for a 5% random national sample of beneficiaries. The 5% cohort available for research was identified and tracked longitudinally based on the last 2 digits of the Medicare beneficiary's health insurance claim number. Patients with POP were identified by one of several *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes for prolapse during this time course. *Current Procedural Terminology, 4th Edition (CPT-4)* and *ICD-9-CM* procedure codes were used to evaluate the surgical procedures performed during the same time period. The codes (listed in the Appendix) were classified and segregated by nonsurgical (pessary) and surgical management. Surgical procedures were classified by compartment (anterior, posterior, and apical). Annual rates were determined by dividing the *CPT-4* and *ICD-9-CM* code rates by the total number of women given a POP diagnosis that year. Combinations of codes for simultaneous compartment repairs were also assessed to capture rates of single and multiple concomitant procedures. The *CPT-4* code for mesh/graft was developed in 2005 (code 57267, "insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach"), therefore the analysis of rates of mesh use apply from 2005 through 2009. Among those patients with a code for hysterectomy, a sub-analysis was performed comparing rates of isolated hysterectomy for prolapse to those with a concomitant vault suspension.

Results

The analytical cohort was comprised of women age 65 years, who received a diagnosis of POP from 1999 through 2009. This cohort served as the denominator for the analysis (Table 1). Each year an average of 22,427 women (range, 21,245–23,268) were given a POP diagnosis. Of these women, 26% received some kind of treatment for their condition each year during the study period (Figure 1). Depending on the year, an average of 12% of women (range, 11–13%) were treated with a pessary. In addition, each year 14–15% of the women underwent surgical repair. These percentages remained relatively stable over the course of 11 years.

Of those who underwent surgery, most often multiple compartments were repaired simultaneously. The most frequent combination performed was anterior, posterior, and apical repairs (14–15%), followed by a combined anterior and posterior repair (12–13%), an anterior and apical repair (11–12%), and a posterior with apical repair (10–12%), respectively. The least commonly performed repairs were colpocleisis (1%) and isolated anterior (4–6%) and posterior (3–4%) repairs.

We separately analyzed rates of hysterectomy with and without concomitant apical repairs (Table 2). Over time there was a decrease in overall rates of abdominal and vaginal

hysterectomies performed for prolapse. Isolated hysterectomy rates (without a concomitant apical repair) decreased from 39–28% of women who had surgery for prolapse. Specifically, vaginal hysterectomies <250 g decreased from 15.1–11.3% among those who had surgery, and rates of “vaginal hysterectomy for prolapse” (*ICD-9-CM* code 68.5) and “other vaginal hysterectomy” (*ICD-9-CM* code 68.59) decreased from 30.8% and 28.2% in 1999 to 19.7% and 16.9% by 2009, respectively (data not shown). The rate of concomitant vault suspension remained low throughout the time periods analyzed, although there was an increase from 22% in 1999 to 26% in 2009.

Rates of mesh use increased over time such that by 2009, 40.9% of patients who underwent prolapse surgery had a code for mesh/graft insertion. Specifically, of 3197 who underwent surgery that year, 1306 had a repair with mesh or graft material (Figures 1 and 2). This is a large increase from 571 of 3317 women (17.2%) in 2005, the first year the mesh/graft code was implemented. The subsequent 3 years showed a successive increase in mesh/graft use, from 28% in 2006 to 31.7% in 2007 and 41.3% in 2008 (Figure 3).

Comment

As the incidence of POP increases, it is important to understand current management practices to identify areas that require growth and substantiation. Our study sought to evaluate the temporal trends in management patterns, mesh use, and concomitant vault suspension at time of hysterectomy in women with POP.

Several key findings are observed in our study. First, approximately 25% of female Medicare beneficiaries with a diagnosis of POP underwent treatment, either with a pessary or surgery, for their condition. Surgical management was slightly more common than management with a pessary, yet surgery rates did not change significantly over time. Additionally, surgical repair of multiple compartments simultaneously was more common than repair of isolated compartment repairs or colpocleisis. These patterns remained relatively stable over the decade. Shah et al⁹ in 2008 analyzed data from the National Health Discharge Survey and National Census from 2003. Colporrhaphy rates varied from 11.4–28.4%, with the highest rates being done among women aged 60–79 years. They reported a colpocleisis rate of 0.1–10.9%, the higher rate being in women aged 80 years. We found a lower rate of surgical repairs than reported by Shah et al⁹ (colporrhaphy rate of 15% and a colpocleisis rate of 0.5–0.7%). The differences between studies may be due to the older age of the Medicare population in our study. Differences between these studies may also exist based on data collection from surveys vs billing codes.

Although trends in surgical prolapse management remained relatively stable over the decade, there was a rapid increase in the adoption of mesh for prolapse repairs. After the implementation of the mesh/graft code in 2005, each year noted a successive increase in mesh use such that by 2009, nearly 41% of repairs involved mesh or graft. This occurred despite the notification issued by the FDA regarding the use of mesh in 2008.¹⁰ The use of mesh and graft use did taper from 2008 through 2009, from 41.3% of surgeries to 40.9%. Such a plateau could have been related to the first mesh notification. However, Reynolds et al,⁶ using a 100% sample of Medicare claims, specifically analyzed the effect of the 2008

mesh warning on mesh use in 2009, and found that the number of mesh cases continued to rise in the immediate period after the FDA warning. Claims-based studies by Funk et al⁸ in 2013 and Rogo-Gupta et al⁷ in 2012 also demonstrated persistently high rates of mesh use well into 2010. Unlike the 2008 warning, the second warning by the FDA¹¹ in July 2011 received a great deal of media attention, likely resulting in a more drastic reduction of mesh use. We await more recent years of Medicare claims data to measure the effect of the 2011 warning on patterns of care.

Despite a sharp rise in use of the mesh and grafts, we found very little change in the number of prolapse surgical procedures overall or the proportion of procedures performed for specific compartments (eg, anterior, apical). Additionally, the increase in mesh/graft use was not associated with an increase in surgery for prolapse overall. Since failure to address apical prolapse is highly correlated with prolapse recurrence and reoperation (Eilber et al,¹² 2013), a potential benefit of mesh kits would be that they provide a means to combine a cystocele repair with an extraperitoneal apical suspension procedure. Although one could assume therefore that a rise in mesh use would be associated with an increased rate of apical suspension procedures, and possible decrease recurrence rates, this was not the case. Our findings suggest that mesh and grafts were used for augmentation purposes only in the majority of cases, but did not necessarily change what type of compartment repair was performed by surgeons.

Over the index period there was a relative increase in rates of vault suspension performed at the time of hysterectomy (from 22–26%). It should be noted that the increase is likely due to an overall decrease in the number of hysterectomies performed (1600 in 1999 to 1194 in 2009) rather than an increase in the rate of concomitant vault suspensions overall. Regardless, there remained a significantly higher rate of isolated hysterectomies compared to combined procedures. This is despite data supporting the need to perform a vault suspension to optimize a successful outcome. A subanalysis of the Medicare data used for this study also evaluated reoperation rates in women undergoing POP surgery, and found a significantly lower rate of reoperation in women who had a concomitant apical repair at time of anterior repair (11% reoperation rate, compared to 20% reoperation rate in isolated anterior repairs) (Eilber et al,¹² 2013). A retrospective population-based cohort study analyzing data over a 38-year time period demonstrated a higher rate of pelvic floor repairs among women who previously had a vaginal or abdominal hysterectomy alone for prolapse (Bandon et al,¹³ 2007). Following a vaginal hysterectomy alone for prolapse, the need for another prolapse repair by 10, 20, and 30 years increased successively from 7.4% to 9.5% to 12.2%, respectively. In a case-controlled study of women who underwent isolated hysterectomy over a 20-year time frame, there was a 1.3 per 1000 women-year incidence of later POP surgery after hysterectomy (Dallenbach et al,¹⁴ 2007). Among hysterectomies performed for prolapse, there was a 4.7 times higher rate of prolapse surgery following the hysterectomy. The risk increased to 8 times if the prolapse was grade 2. Hence, the fact that so few vault repairs are performed at the time of hysterectomy for prolapse suggests a problem in the quality of care provided to women with prolapse.

Conservative management with pessary ranged from 11.3–13.4%. Contrary to our hypothesis, there did not appear to be an increase in pessary use over time. It is possible that

these percentages, which are essentially similar to rates of surgery, are an overestimation. This may be due to pessary coding in patients who had been managed chronically with pessaries (prevalent pessary use), and does not identify patients who choose to undergo a pessary fitting as an initial treatment for their prolapse (incident pessary use). A study utilizing the same database looked specifically in women that were managed with pessaries, and we found that by 1 year after fitting, 12% of women underwent prolapse surgery; with 24% by 9 years (Alperin et al,¹⁵ 2013).

Medicare claims provide data from a large, heterogeneous cohort of patients across a wide US geographic distribution. However, there are limitations to this claims-based analysis. The Medicare data in the cohort we analyzed are limited to those age ≥ 65 years. The mean age of surgery for prolapse in other studies is 56.1 years (Fialkow et al,⁴ 2008), hence ours is an older patient cohort. Additionally, codes are designed for billing purposes primarily and therefore do not provide clinical details regarding patient characteristics, such as symptom severity or reasons for surgery. Some codes do not exist for certain procedures, for example McCall culdoplasty, which may affect the coding of these procedures and slightly skew the data. In addition, we used both *CPT-4* and *ICD-9-CM* procedure codes to capture mesh insertion. However, these codes also include nonmesh graft implantation. This inclusion may have resulted in an overestimation of the use of prosthetic mesh use in this cohort, albeit small. Another limitation to our study is that there may be incorrect coding by physicians as new techniques or products have been incorporated into the practice of prolapse repair, thereby overestimating or underestimating rates of mesh/graft use or repairs of different compartments. Despite these limitations, our work provides insights into trends in clinical management patterns for POP over the course of the last decade.

Conclusion

Patterns and rates of prolapse repairs among women age >65 years remained relatively unchanged from 1999 through 2009, with an exception of a rapid rise in mesh use. This suggests that the majority of mesh techniques were used for augmentation purposes only, but did not result in an increase in apical repairs performed in the United States. Despite evidence supporting the performance of a vault suspension at the time of hysterectomy, this practice continues to be underutilized.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Appendix

International Classification of Diseases, Ninth Revision, Clinical Modification and *Current Procedural Terminology, 4th Edition* procedure codes for prolapse surgery

	ICD-9-CM procedure codes	CPT-4 procedure codes
A Nonsurgical		57160 Pessary 57150 Vaginal irrigation after pessary 57415 Removal of impacted pessary
B Colpocleisis	70.8: Le Fort	57120 Le Fort
C Anterior	Cystocele	

		ICD-9-CM procedure codes	CPT-4 procedure codes
		70.51: Repair of cystocele 70.54: Repair of cystocele with graft or prosthesis	57240 Anterior colporrhaphy ± repair of urethrocele 57289 Pexy ± cystocele
	Paravaginal repair		
	Abdominal		57284 Paravaginal defect with cystocele (abdominal) 57423 Paravaginal defect ± cystocele (laparoscopic)
	Vaginal		57285 Paravaginal defect with cystocele (vaginal)
D	Anterior and apical	C+I	
E	Anterior and posterior	70.50: Repair of cystocele and rectocele 70.53: Repair of cystocele and rectocele with graft or prosthesis	57260 Anterior/posterior colporrhaphy C+G
F	Anterior and posterior and apical		57265 Anterior/posterior colporrhaphy with enterocele C+G+I E+I D+G C+H
G	Posterior	70.52: Repair of rectocele 70.55: Repair of rectocele with graft or prosthesis	45560 Rectocele 56810 Perineoplasty, repair of perineum, nonobstetric 57250 Posterior colporrhaphy ± perineorrhaphy
H	Posterior and apical		G+I
I	Apical	Enterocoele	
	Abdominal		57270 Enterocoele (abdominal)
	Vaginal		57268 Enterocoele (vaginal)
	Unspecified	70.92: Repair of vaginal enterocele 70.93: Repair of vaginal enterocele with graft or prosthesis	
	Uterine or vaginal suspension/colpopexy		
	Abdominal		57280 Colpopexy abdominal approach 57425 Laparoscopy, colpopexy (±ICD-9 procedure code 17.4—robot assisted)
	Vaginal		57282 Colpopexy, vaginal, extraperitoneal (sacrospinous, ilioococcygeus) 57283 Colpopexy, vaginal, intraperitoneal (uterosacral, levator myorrhaphy)
	Unspecified	69.22: Uterine suspension (placation of uterine ligament, hysteropexy, Manchester) 70.77: Vaginal suspension and fixation 70.78: Vaginal suspension and fixation with graft or prosthesis	58400 Uterine suspension 58410 Uterine suspension with presacral sympathectomy
	Hysterectomy		
	Abdominal	68.31: Laparoscopic supracervical hysterectomy	58150 Total abdominal hysterectomy

		ICD-9-CM procedure codes	CPT-4 procedure codes
		68.39: Other unspecified subtotal abdominal hysterectomy	58152 Total abdominal hysterectomy with colpoutherocystopexy (Marshall-Marchetti-Krantz, Burch) 58180 Supracervical abdominal hysterectomy 58541/58570 Laparoscopic hysterectomy <250 g 58543/58571 Laparoscopic hysterectomy >250 g
	Vaginal	68.5: Vaginal hysterectomy for prolapse 68.51: Laparoscopic vaginal hysterectomy 68.59: Other unspecified vaginal hysterectomy	58260 Vaginal hysterectomy <250 g 58267 Vaginal hysterectomy with colpoutherocystopexy (Marshall-Marchetti-Krantz, Pereyra) 58270 Vaginal hysterectomy with enterocele 58280 Vaginal hysterectomy and partial vaginectomy with enterocele 58290 Vaginal hysterectomy >250 g 58292 Vaginal hysterectomy <250 g with enterocele 58293 Vaginal hysterectomy >250 g with colpoutherocystopexy (Marshall-Marchetti-Krantz, Pereyra) 58294 Vaginal hysterectomy >250 g with enterocele
	Unspecified	68.3: Subtotal hysterectomy	
J	Unspecified	70.62: Vaginal reconstruction 70.64: Vaginal reconstruction with graft or prosthesis	56800 Plastic repair of introitus
K	Mesh		57267 Mesh

CPT-4, Current Procedural Terminology, 4th Edition; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.

Treatment Patterns for Pelvic Organ Prolapse

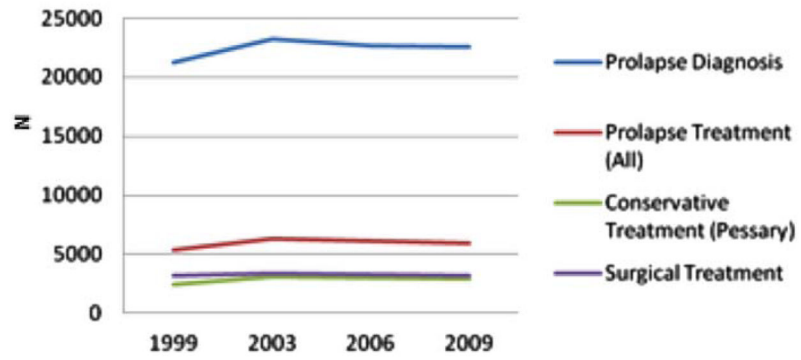


FIGURE 1. Prolapse diagnosis and rates of different management patterns among female Medicare beneficiaries

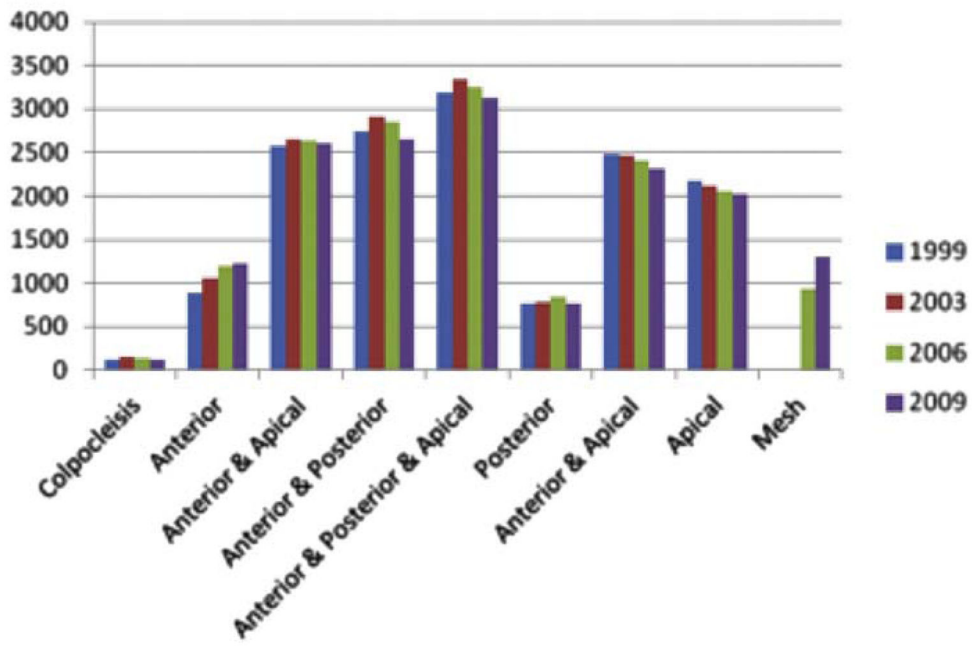


FIGURE 2. Rates of different types and combinations of prolapse repairs among female Medicare beneficiaries

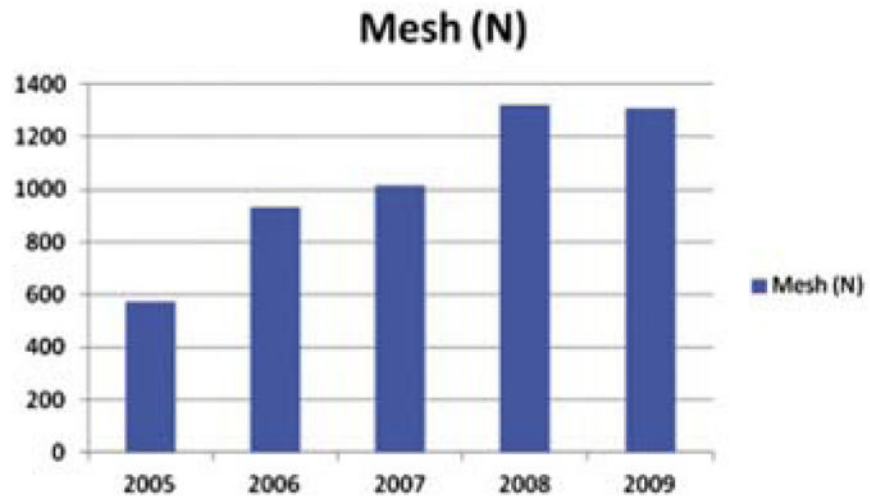


FIGURE 3.
Rates of mesh/graft use from 2005 through 2009

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TABLE 1

Numbers (n) and rates (%) of prolapse repairs among female Medicare beneficiaries

Variable, n (%)	1999	2003	2006	2009
Prolapse diagnosis	21,245	23,268	22,688	22,553
Any prolapse treatment	5417 (25.5)	6280 (27)	6089 (26.8)	5905 (26.2)
Pessary	2403 (11.3)	3118 (13.4)	2985 (13.2)	2953 (13.1)
Any surgical treatment for prolapse	3244 (15.3)	3423 (14.7)	3333 (14.7)	3197 (14.2)
Colpocleisis	115 (0.5)	156 (0.7)	140 (0.6)	120 (0.5)
Anterior	895 (4.2)	1063 (4.6)	1197 (5.3)	1230 (5.5)
Anterior and apical	2577 (12.1)	2646 (11.4)	2630 (11.6)	2601 (11.5)
Anterior and posterior	2747 (12.9)	2910 (12.5)	2851 (12.6)	2654 (11.8)
Anterior and posterior and apical	3196 (15)	3346 (14.4)	3256 (14.4)	3127 (13.9)
Posterior	764 (3.6)	774 (3.3)	835 (3.7)	759 (3.4)
Posterior and apical	2486 (11.7)	2475 (10.6)	2403 (10.6)	2309 (10.2)
Apical ^a	2172 (10.2)	2114 (9.1)	2054 (9.1)	2018 (8.9)
Mesh	0	0	933 (4.1)	1306 (5.8)

^aSee Table 2 for isolated hysterectomy rates.

TABLE 2

Rates of hysterectomy and apical repairs (isolated and concomitant)

Variable, n/%	1999	2003	2006	2009
Isolated hysterectomy	1253 38.6%	1176 34.3%	1038 31.1%	885 27.7%
Combined hysterectomy and vault suspension	347 10.7%	313 9.1%	350 10.5%	309 9.7%
Total no. of hysterectomies	1600	1489	1388	1194
Hysterectomies for prolapse performed with concomitant vault suspension	22%	21%	25%	26%