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Immediate Effects of the Initial FDA Notification on the Use of Surgical Mesh for Pelvic Organ Prolapse Surgery in Medicare Beneficiaries

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Abstract

Aims—Prompted by increased reports of complications with the use of mesh for pelvic organ prolapse (POP) surgery, the FDA issued an initial public health notification (PHN) in 2008. We proposed to determine if the numbers of POP cases augmented with surgical mesh performed in U.S. Medicare beneficiaries changed relative to this PHN.

Methods—Using administrative healthcare claims for beneficiaries enrolled in the U.S. Medicare program from 2008 to 2009, we identified women who underwent POP surgery with and without surgical mesh by procedural and diagnosis coding. In addition to comparing cases with and without mesh, we also calculated rates (number of cases per 100,000 female beneficiaries) and compared these relative to the timing of the PHN.

Results—We identified 104,185 POP procedures, of which 27,839 (26.7%) included mesh material and 76,346 (73.3%) did not. Between the last three quarters of 2008 and the first three of 2009, the rates of mesh cases increased (40.3–42.1, $P < 0.001$) and those without mesh decreased (115.5–111.4, $P < 0.001$). Inpatient procedures decreased and outpatient procedures increased for both those with and without mesh augmentation. For inpatient procedures, the relative use of biologic graft and synthetic mesh material did not vary over the study period.

Conclusions—A substantial number of Medicare beneficiaries underwent mesh POP procedures in 2008–2009. However, despite the PHN cautioning about potential mesh complications, the numbers of mesh cases continued to rise in the immediate period after the PHN.

Keywords

pelvic organ prolapse; surgical mesh; U.S. Food and Drug Administration; U.S. Medicare program

INTRODUCTION

Pelvic organ prolapse (POP) is a common condition affecting up to 40% of women and correlates with increasing age.¹ Definitive treatment is surgical and one out of every ten U.S. women will undergo surgery in her lifetime.² Prompted by high failure rates, pelvic surgeons began incorporating new augmentation materials to substitute for poor quality pelvic floor tissue to improve outcomes. Buttressed by early reports of improved durability over traditional POP repairs, as well as by perceived ease of use and decreased morbidity, the incorporation of mesh materials in surgical procedures for POP has substantially increased over the last decade.

While use of mesh materials has been associated with improvement in successful outcomes,³ there has been emerging concern for the number of complications specific to synthetic mesh, such as exposure through vaginal epithelium, infection, pain, urinary problems, and recurrence of POP. The incidence of such complications prompted a public health notification (PHN) from the U.S. Food and Drug Administration (FDA) in October 2008.⁴ While one would envision that the FDA notification would alter practice patterns for the use of mesh, the effect of the PHN on surgical procedures for POP is unknown. For this study, we proposed to determine if the utilization of mesh decreased in response to the PHN in a national cohort of U.S. Medicare patients. We performed an analysis of Medicare claims data from patients undergoing POP surgery in 2008–2009 to document any changes in the numbers of procedures incorporating mesh materials relative to timing of the FDA notification.

MATERIALS AND METHODS

After obtaining formal Internal Review Board exemption, we performed a retrospective study using administrative medical claims for female beneficiaries enrolled in the U.S. Medicare program in 2008–2009. Using standard analytic files for inpatient and outpatient services for all enrollees (100% sample), we identified women who underwent POP surgery during this time period if claims were present that contained pertinent current procedural terminology (CPT) codes and international classification of diseases, 9th Revision (ICD-9) diagnosis and procedural codes for POP surgery (see Table I). Any duplicate records for a given procedure were reviewed and excluded. We then abstracted information regarding: patient age; race; state of residence, categorized to region according to U.S. Census definitions; surgery date; concomitant incontinence procedures and/or hysterectomy; medical comorbidity (calculated by Charlson Comorbidity index⁵); procedure setting (inpatient or outpatient); and hospital volume, dichotomized to low (<75th percentile) and high (≥75th percentile).

Based on the presence of specific ICD-9 (70.94, “insertion of biological graft,” and 70.95, “insertion of synthetic graft or prosthesis”) and CPT (57267, “insertion of mesh or other prosthesis for repair of pelvic floor defect”) add-on codes, we categorized POP procedures as to the inclusion of augmentation material (mesh and no mesh). These codes are specific to POP procedures, as opposed to other procedures that may involve mesh or graft (i.e., anti-incontinence procedures). While these codes may be billed multiple times for a given procedure (specifically 57267), we evaluated procedures at the level of a single claim and not based on the number of codes listed. While the term “mesh” may have multiple connotations, sometimes specifically referring to synthetic prosthetic material,⁶ we defined mesh for this study as any augmentation material, including synthetic and biologic materials.

Using summary data on enrolled beneficiaries from the denominator file for each year, we calculated rates of cases per 100,000 women, including 95% confidence intervals and

reported these for the calendar quarters (3-month intervals) immediately before and after the PHN in October 2008 (4th quarter) to measure any immediate effect of the PHN on the number of mesh cases. We used these intervals because information on dates is reported only by quarter in the Limited Data Set Medicare files. We also compared changes in the number of cases in the three calendar quarters after the announcement relative to the preceding three quarters, using Pearson's chi-squared tests. All programming and statistical analyses were performed with SAS version 9 (SAS Institute, Cary, NC) and/or STATA version 11.1 (StataCorp, College Station, TX).

RESULTS

We identified 104,185 procedures performed for POP in 2008–2009, of which 27,839 (26.7%) included mesh and 76,346 (73.3%) did not. Demographic and clinical information on these women is presented in Table II. While fewer cases in 2008 included mesh (45.6% with mesh vs. 48.3% without mesh, $P < 0.001$), in 2009 a greater proportion included mesh (54.4% vs. 51.7%, $P < 0.001$).

The numbers of mesh and non-mesh cases per 100,000 female beneficiaries by calendar quarter are depicted in Figure 1. Mesh procedures increased from 40.3 (95% CI: 39.4–41.0) in the last three quarters of 2008 to 42.1 (41.3–42.9) in the first three quarters of 2009 ($P < 0.001$), while the number of non-mesh cases decreased from 115.5 (114.2–116.7) to 111.4 (110.1–112.6) ($P < 0.001$).

Figure 2 documents the rates of inpatient and outpatient cases by mesh status. For cases including mesh, inpatient procedures insignificantly decreased after the PHN, from 27.9 (26.2–28.5) to 27.4 (26.7–28.0), while outpatient procedures increased significantly from 12.4 (12.0–12.8) to 14.7 (14.3–15.2) ($P < 0.01$). For cases not including mesh, inpatient procedures decreased significantly, from 88.5 (87.3–89.6) to 80.2 (79.1–81.2) ($P < 0.01$), and outpatient procedures increased from 27.0 (26.4–27.6) to 31.1 (30.5–31.9) ($P < 0.01$). Figure 3 shows the rates of inpatient procedures specifically incorporating synthetic or biologic augmentation materials across calendar quarters of the study period. There were no significant differences in the use of either material.

DISCUSSION

In our analyses of U.S. Medicare claims data, mesh use in this population of women who underwent POP surgery was substantial, although still only used in a minority (27%) of POP cases. Furthermore, it appears that the FDA's PHN in October 2008 had little immediate effect on decreasing the numbers of POP procedures performed that incorporated mesh material. In fact, over the period of study, we identified an overall increasing trend in the use of mesh material, as well as a decreasing trend in the cases not using mesh.

Prompted by an increased number of reported complications to the manufacturer and user facility device experience (MAUDE) database, the FDA issued a PHN on the use of surgical mesh in October 2008.⁴ In the notification, the FDA highlighted the increased number of complications and recommended that surgeons obtain specialized training in techniques for mesh placement and that patients should be well informed during the consent process as to the potential risks involved. All procedures with transvaginal mesh, including POP and stress urinary incontinence, were included in the PHN. In a subsequent safety communication in July 2011, the FDA issued an update to the original PHN on surgical mesh for POP,⁷ which again highlighted the increased reporting of complications associated with the use of surgical mesh in procedures for POP specifically. In addition, the update

included summary results from a systematic literature review that suggested no improvement in outcomes in POP surgeries that included mesh over those without mesh.

There are few reported data available to document how many POP procedures are performed annually with mesh material. In the most recent PHN update, the FDA estimated that 300,000 women of all ages underwent POP surgery in 2010, of which 1 in 3 cases (~100,000) included synthetic mesh material and 3 of 4 (~75,000) mesh procedures were performed vaginally.⁷ We identified approximately 104,000 Medicare beneficiaries over a 2-year period that underwent POP surgery, of which 27% included any mesh material. This corresponds to a ratio of approximately 1 in 4 cases of POP surgery that included mesh material, slightly less than the FDA's estimate.

The use of synthetic mesh is not particularly well documented in pelvic surgery, although anecdotally it seems to be increasing. In a survey completed in 2006 by 259 members (30%) of the American Urogynecological Society (AUGS), 150 (58%) indicated that they use synthetic mesh for vaginal reconstructive POP surgery and 221 (93%) use it for abdominal sacrocolpopexy (ASC).⁸ In a survey of U.K. gynecologists, while only 11% would use mesh for a primary repair of anterior POP, 56% would do so for recurrent cases in 2010, which is an increase from 34% in 2005.⁹

Complications associated with surgical mesh are not uncommon. In a systematic literature review commissioned by the U.K. National Institute for Health and Clinical Excellence (NICE), the authors reported a mesh erosion rate of 10.2% for anterior POP repairs incorporating non-absorbable synthetic mesh.¹⁰ In additional reviews specifically of apical POP procedures, investigators report mesh erosion rates of 4.6–10.7%¹¹ and, for ASC specifically, of 3.4%.¹² In a meta-analysis of all transvaginal POP procedures collectively, mesh erosions occurred in 10.3% of cases.¹³ Due to the growing incidence of mesh-specific complications, the International Urogynecological Association (IUGA) and the International Continence Society (ICS) issued a joint statement on terminology and classification of complications related to prostheses and graft materials inserted during female pelvic floor surgery.⁶

Due to limitations in coding, we could only differentiate between different types of surgical mesh products, specifically synthetic versus biologic materials, for the inpatient cases and not for the outpatient cases. At least for the inpatient procedures, the proportions of cases including synthetic or biologic graft were not different in our analyses, suggesting that there was not a noticeable shift from synthetic towards biologic graft materials. Even though the PHN specifically addresses concerns regarding synthetic materials, vaginal erosions of biologic materials are reported in up to 6% of cases.¹⁰ Thus when considering the potential burden of any mesh complication in this group of women, it is reasonable to include these cases in our overall report to quantify the numbers of patients at risk.

In addition, procedure coding based on ICD-9 codes specifically used for the inpatient claims files do not allow for consistent differentiation between vaginal and abdominal surgical approaches to POP repair. The primary concern of the PHN is with mesh placed through a vaginal incision (i.e., transvaginal placement) as opposed to that placed via an abdominal incision (i.e., ASC). Unfortunately, because of this limitation, we were not able to determine if providers changed their approach to mesh placement from a transvaginal to a trans-abdominal (i.e., ASC) placement in response to the PHN. In our data, ASC was not performed as an outpatient procedure; if surgeons transitioned to ASC, we would have expected to see an increase in inpatient procedures, a trend that we did not document, as discussed above. Nevertheless, mesh complications also occur with ASC, including in 6.6% of patients participating in a large randomized clinical trial.¹⁴ Therefore, although we did

not distinguish these procedures, reporting on all patients implanted with surgical mesh or biological graft material regardless of route of placement is important as all these women may be at risk for future complications.

Our study is subject to other limitations as well. Administrative claims-based research does not include patient-specific factors that may determine mesh use, including patient preference, stage of POP, and any previous treatments before Medicare enrollment. We were also unable to abstract provider characteristics, such as surgeon specialty, which is associated with practice patterns regarding POP and SUI surgery¹⁵; physician specialty and training may contribute to attitudes on mesh use as well. Reimbursement for POP procedures may also be driving trends in pelvic mesh use, although our present results do not include cost estimates. Finally, the U.S. Medicare program is limited to people aged 65 or older or qualifying for disability and, as such, data from Medicare claims may not be generalizable to the U.S. population. Nevertheless, Medicare patients constitute a significant portion of women undergoing POP surgery: 27.5% of all inpatient POP patients in 2003, according to data collected in the National Hospital Discharge Survey, were Medicare patients.¹⁶

Despite these limitations, our study presents comprehensive data on the numbers of Medicare beneficiaries who underwent POP with mesh material in 2008–2009. Furthermore, our analyses suggest that the initial FDA safety communication released in October of 2008 did not immediately affect the numbers of POP procedures performed with mesh. Our study period is short, and it may be that any effects of the PHN could be delayed because of lag time for dissemination of the announcement. Changes in patterns of use may not have been captured in this analysis. While the updated FDA PHN in July 2011 most likely had a more dramatic effect on mesh use, the effect of the earlier announcement is less clear. It may be that dissemination of the PHN was limited and did not reach the intended audience. In addition, for many surgeons, the warnings about complications were unexpected, as few had likely encountered any such issues in their own patients and there were few published reports of complications prior to the PHN. Medicare data are not yet available for 2011, so any analyses of the effect of this announcement must wait. Nevertheless, our data highlight the substantial number of older U.S. women who may be at risk for future mesh-related complications after POP surgery.

CONCLUSIONS

The number of Medicare beneficiaries who underwent mesh-augmented POP procedures in 2008–2009 was substantial, although three times as many underwent non-mesh procedures. Despite the FDA's PHN warning about potential complications related to pelvic mesh for POP surgery, mesh-augmented cases continued to rise in the immediate period after the announcement. Analyses of additional time intervals are needed to determine if meaningful changes in mesh use have occurred more recently.

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Fig. 1. Rates of POP cases with and without mesh augmentation per 100,000 Medicare beneficiaries by 3-month periods (calendar quarters) in 2008–2009. The timing of the FDA’s public health notification (PHN) on mesh on October 20, 2008 is indicated by the dotted line. Hash marks represent 95% confidence intervals.

Fig. 2.

Rates of POP cases with and without mesh augmentation per 100,000 Medicare beneficiaries by 3-month periods (calendar quarters) in 2008–2009, stratified by operative setting (inpatient and outpatient). The timing of the FDA's public health notification (PHN) on mesh on October 20, 2008 is indicated by the dotted line.

Fig. 3.

Rates of inpatient POP cases incorporating either biologic graft or synthetic mesh materials per 100,000 Medicare beneficiaries by 3-month periods (calendar quarters) in 2008–2009. The FDA released its public health notification concerning pelvic mesh on October 20, 2008 (4th quarter). Hash marks represent 95% confidence intervals.

TABLE I

ICD-9 and CPT Procedure Codes for Surgical Treatments of Pelvic Organ Prolapse (POP), Hysterectomy, and Urinary Incontinence

CPT	Description	ICD-9	Description
Surgical mesh-specific procedure codes			
57267 ^a	Insertion of mesh or other prosthesis for repair of pelvic floor defect (used in association with CPT codes 45560, 57240, 57250, 57260, 57265, 57285)	70.94 ^a	Insertion of biological graft
		70.95 ^a	Insertion of synthetic graft or prosthesis
POP procedures			
45560 ^b	Rectocele repair	70.50	Repair of cystocele and rectocele, no graft
57240 ^b	Anterior colporrhaphy, repair of cystocele	70.51	Repair of cystocele (anterior colporrhaphy), no graft
57250 ^b	Posterior colporrhaphy, repair of rectocele	70.52	Repair of rectocele, no graft
57260 ^b	Combined anteroposterior colporrhaphy	70.53 ^c	Repair of cystocele and rectocele with graft or prosthesis
57265 ^b	Combined anteroposterior colporrhaphy with enterocele repair	70.54 ^c	Repair of cystocele with graft or prosthesis
57268	Enterocele Repair—vaginal approach	70.55 ^c	Repair of rectocele with graft or prosthesis
57270	Enterocele repair—abdominal approach	70.61	Vaginal construction, no graft
57280	Colpopexy, abdominal approach	70.62	Vaginal reconstruction, no graft
57282	Colpopexy, vaginal, extraperitoneal approach	70.63 ^c	Vaginal construction with graft or prosthesis
57283	Colpopexy, vaginal, intraperitoneal approach	70.64 ^c	Vaginal reconstruction with graft or prosthesis
57284	Paravaginal defect repair, open abdominal approach	70.77	Vaginal suspension and fixation, no graft
57285 ^b	Paravaginal defect repair, vaginal approach	70.78 ^c	Vaginal suspension and fixation with graft or prosthesis
57289	Pereyra procedure, including anterior colporrhaphy	70.92	Other operations on cul-de-sac (repair of vaginal enterocele), no graft
57425, 57426	Laparoscopic sacrocolpopexy	70.93 ^c	Other operations on cul-de-sac with graft or prosthesis
58152	Total abdominal hysterectomy, with colpourethrocystopexy		
58270	Vaginal hysterectomy, with repair of enterocele		
58293	Vaginal hysterectomy, with uro repair, complicated		
58294	Vaginal hysterectomy with enterocele, complicated		
58400, 58410	Uterine suspension		
Hysterectomy			
58150, 58152, 58180	Total or supracervical abdominal hysterectomy	68.3–68.7, 68.9	Total or subtotal vaginal or abdominal hysterectomy
582xx	Abdominal or vaginal hysterectomy		
58541, 58542, 58543, 58544, 58548, 58550, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573	Laparoscopic hysterectomy		

CPT	Description	ICD-9	Description
Incontinence procedures			
57287	Removal or revision of sling for SUI	57.85	Cystourethroplasty and repair of BN
57288	Sling operation for SUI	57.89	Cystopexy NOS
		59.3	Plication of the urethrovesical junction
		59.4	Suprapubic sling operation
		59.5	Retropubic urethral suspension
		59.6	Paraurethral suspension
		59.71	Levator muscle operation (pubococcygeal sling)
		59.72	Injection of implant (urethral bulking agent)
		59.79	Other (Repair of SUI NOS)

^a Add-on codes to be coded after or in conjunction with primary procedures.

^b CPT code 57267 can only be applied to these procedures.

^c ICD-9 codes 70.94, 70.95 can only be applied to these procedures.

TABLE II

Demographic and Clinical Data on Female Medicare Beneficiaries Undergoing POP Surgery 2008–2009, Stratified by Mesh Use

	Mesh (n = 27,839)		No mesh (n = 76,346)		P-value
	Count	% (95% CI)	Count	% (95% CI)	
Age					
<65	3,280	11.8 (11.4, 12.2)	10,913	14.3 (14.1, 14.5)	<0.001
65–69	8,957	32.2 (31.7, 32.7)	23,887	31.3 (31.0, 31.6)	
70–74	7,439	26.7 (26.2, 27.2)	19,198	25.2 (24.9, 25.5)	
75–79	5,041	18.1 (17.6, 18.6)	13,536	17.7 (17.4, 18.0)	
80–84	2,396	8.6 (8.3, 8.9)	6,490	8.5 (8.3, 8.7)	
>84	726	2.6 (2.4, 2.8)	2,322	3.0 (2.9, 3.1)	
Race					
White	26,162	94.0 (93.7, 94.3)	70,426	92.3 (92.1, 92.5)	<0.001
Black	890	3.2 (3.0, 3.4)	2,907	3.8 (3.7, 3.9)	
Hispanic	341	1.2 (1.1, 1.3)	1,370	1.8 (1.7, 1.9)	
Asian	119	0.4 (0.3, 0.5)	596	0.8 (0.7, 0.9)	
Other	205	0.7 (0.6, 0.8)	625	0.8 (0.7, 0.9)	
Region					
Northeast	3,420	12.5 (12.1, 12.9)	10,348	13.9 (13.7, 14.1)	<0.001
South	13,572	49.7 (49.1, 50.3)	33,199	44.4 (44.0, 44.8)	
Midwest	5,337	19.6 (19.1, 20.1)	17,784	23.8 (23.5, 24.1)	
West	4,956	18.2 (17.7, 18.7)	13,381	17.9 (17.6, 18.2)	
Inpatient	18,489	66.4 (65.8, 67.0)	56,465	74.0 (73.7, 74.3)	<0.001
Outpatient	9,350	33.6 (33.0, 34.2)	19,881	26.0 (25.7, 26.3)	
2008	12,700	45.6 (45.0, 46.2)	36,869	48.3 (47.9, 48.7)	<0.001
2009	15,139	54.4 (53.8, 55.0)	39,477	51.7 (51.3, 52.1)	
Hospital volume: low	19,316	69.4 (68.8, 69.9)	59,766	78.3 (78.0, 78.6)	<0.001
Hospital volume: high	8,523	30.6 (30.1, 31.2)	16,580	21.7 (21.4, 22.0)	
Charlson co-morbidity index					
0	21,010	75.5 (75.0, 76.0)	57,454	75.3 (75.0, 75.6)	0.01
1–2	6,687	24.0 (23.5, 24.5)	18,370	24.0 (23.8, 24.4)	
3	142	0.5 (0.4, 0.6)	522	0.7 (0.6, 0.8)	

	Mesh (n = 27,839)		No mesh (n = 76,346)		P-value
	Count	% (95% CI)	Count	% (95% CI)	
Concomitant hysterectomy	3,502	12.6 (12.2, 13.0)	23,341	30.6 (30.3, 30.9)	<0.001
Concomitant sling/SUI surgery	13,903	49.9 (49.3, 50.5)	33,049	43.3 (42.9, 43.7)	<0.001
Repeat surgery	1,470	5.3 (5.0, 5.6)	3,168	4.1 (4.0, 4.2)	<0.001