## Title
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# Effectiveness of Mesh Compared With Nonmesh Sling Surgery in Medicare Beneficiaries

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## Abstract

**Objective:** To assess the effectiveness of mesh compared with nonmesh slings placed in different surgical settings, as measured by the frequency of complications within 1 year.

**Methods:** We performed a retrospective cohort study of Medicare beneficiaries undergoing sling surgery from 2006 to 2008 in hospital outpatient departments and hospital-based ambulatory surgery centers. Slings were identified and categorized according to the use of mesh by Healthcare Common Procedure Coding System codes and temporary “C” Healthcare Common Procedure Coding System codes. Patients were followed for 1 year after each procedure to identify complications. Logistic models were fit to assess relationships between sling type, surgical setting and various complications.

**Results:** We identified 6,698 Medicare beneficiaries who underwent mesh sling procedures and 445 Medicare beneficiaries who underwent nonmesh sling procedures. The overall frequency of complications was similar between the two groups, at 69.8% and 72.6% in the mesh and nonmesh groups (p=0.22). Infectious complications were the most common complication at 45.4% and 50.1% of the mesh and nonmesh groups (p=0.06). Patients undergoing mesh procedures were less likely than patients undergoing nonmesh procedures to require management for bladder outlet obstruction (13.9% compared with 19.3%; adjusted odds ratio [OR] 0.66, 95% confidence interval [CI] 0.52–0.85), and were less likely to have a subsequent sling removal and revision or urethrolysis (2.7% compared with 4.7%; adjusted OR 0.56, 95% CI 0.35–0.89).

**Conclusion:** Frequencies of most complications were similar regardless of the use of mesh except for the management of bladder outlet obstruction. These results did not differ based on the surgical setting where the sling procedure was performed.

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## Introduction

Surgical technology has evolved tremendously over the last two decades, resulting in the development of procedures with decreased morbidity and faster recovery. These changes have facilitated the migration of select procedures from the hospital outpatient department to the ambulatory surgery center , where they typically can be performed at a lower cost per episode.[1] Anti-incontinence surgery is a perfect example of this shift. With the development of polypropylene mesh for use in midurethral slings in the mid-1990s,[2] rates of sling procedures have dramatically increased,[3] replacing older, more invasive inpatient procedures, such as the Burch colposuspension.[4]

These changes in incontinence surgery, however, are not without at least two potential pitfalls, both of which are related to quality and effectiveness of care. First, some worry that the use of mesh for female pelvic surgery may result in higher rates of complications, despite the fact that the use of synthetic materials for stress urinary incontinence surgery has been well studied and is likely to be used until a better approach is developed. In 2008, the U.S. Food and Drug Administration (FDA) issued a Public Health Notification warning about the potential for serious mesh-associated complications for both stress urinary incontinence and pelvic organ prolapse surgery,[5] While the FDA later limited the warning to pelvic organ prolapse surgery,[6] uncertainty about the use of mesh for stress urinary incontinence remains.[7,8] Second, it is possible that performing these procedures in an operating environment with less regulatory oversight may negatively affect the quality of care. Only recently have the Centers for Medicare and Medicaid Services mandated quality reporting for ambulatory surgery centers.[9]

For these reasons, we used national Medicare data to better understand relationships between sling type, the outpatient delivery setting and complications after sling surgery. Findings from this study will help to inform all stakeholders about potential quality concerns related to these issues for this common procedure.

## Materials and Methods

We performed a retrospective cohort study of fee-for-service Medicare beneficiaries undergoing outpatient sling surgery from 2006 to 2008 using a database representing a 20% sample of national Medicare claims. This database was provided through an appropriate data use agreement with the Centers for Medicare and Medicaid Services. We identified women aged 66–99 years who underwent a sling procedure during this period, defined as claims with Healthcare Common Procedure Coding Systems codes 57288 (sling operation for stress incontinence [eg, fascia or synthetic]) and 51992 (for the laparoscopic approach). If a woman had more than one sling procedure during this time period, we chose the first one to represent the index procedure. Claims were reviewed during the period of 12 months after the index procedure for the development of complications. We chose this 12-month window, as opposed to a longer time interval, because the vast majority of such events occurred within this timeframe. We chose the years 2006 to 2008 because of Medicare's requirements for the use of explicit codes for sling material type at hospital-based ambulatory surgery centers and outpatient departments.

Ambulatory surgery centers operate exclusively for certain Medicare-approved procedures that do not require hospitalization and that are not expected to exceed 24 hours of admission following the procedure. Additionally, these facilities are not permitted to share space with a hospital.[10] Ambulatory surgery centers can be either freestanding or hospital-based, depending on the ownership of the facility (ie, independent ownership or ownership by a hospital or institution).[11] One benefit of ambulatory surgery centers is that they specialize in

performing certain specialty procedures and often become more efficient than their hospital-based counterparts; however, this may be at the cost of the availability of institutional resources such as the availability of multidisciplinary specialty care and other resources such as intensive care units. For the purposes of this study, we focused on hospital-based ambulatory surgery centers due to their use of codes for sling materials during the time period examined. Hospital-based outpatient surgery departments, on the other hand, are not limited by Medicare in the type of procedures that they can perform and receive different payment rates (usually lower) for the same surgical procedures that are performed in ambulatory surgery centers.[12]

Once the index procedure was identified, we examined all claims for that patient for the year prior to ensure the absence of another sling procedure. Next, we excluded women who did not have full Medicare entitlement, represented by enrollment in Medicare parts A and B, which spanned 1 year before and after the index procedure. This ensured that we would be able to appropriately follow women over the course of the study. Additionally, women who had a procedure for pelvic organ prolapse within 30 days of their index sling procedure were excluded in order to distinguish complications associated with the sling procedure as opposed to those due to prolapse surgery.

Next, we used 'C' Healthcare Common Procedure Coding System codes to determine the type of material used for each sling procedure. As defined by the Centers for Medicare and Medicaid Services, C-codes are used to characterize items that may qualify for "pass through" payment under the Outpatient Prospective Payment System (OPPS). These codes are only valid for hospital based outpatient surgical procedures and services,[13] which is why our study was limited to hospital-based outpatient surgery departments and hospital-based ambulatory surgery centers. While they are not used for billing purposes, failure to report C-codes during this period would invariably result in the denial of the claims.[14] The codes used to classify slings according to the use of mesh were: C1771 (repair device, urinary incontinence, with sling graft), C1781 (mesh; implantable), C1762 (connective tissue, human, includes fascia lata), and C1763 (connective tissue, non-human; includes synthetic).

Complications associated with sling surgery were measured at the patient level and included 1) postoperative urologic complications (ie, urinary complications, hemorrhage or hematoma, accidental puncture or laceration of the bladder during the procedure, and disorder of the bladder), 2) infectious complications (ie, kidney infections, urinary tract infections, and complications or infections due to a urethral catheter), 3) new diagnosis of urgency, 4) new diagnosis of pelvic pain, 5) new diagnosis of bladder outlet obstruction (ie, bladder neck obstruction, incomplete bladder emptying, overflow incontinence, slowing of urinary stream, and retention), 6) management of outlet obstruction (ie, urethrolysis, sling removal and revision, urethral dilation, catheterization, cystostomy, and urethral dilation, urethrotomy), 7) cystoscopy, 8) urodynamics, and 9) repeat incontinence procedures (ie, collagen injections, abdominovaginal vesical neck suspension, Kelly plication, and repeat sling procedures). Specific codes are shown in Box 1. Diagnoses of new pelvic pain or of new urgency were based on a washout period of 1 year (ie, no claims for these diagnoses in the 12-month period preceding the index procedure). Additionally, we assessed a composite measure that indicated the development of any of these adverse events within 1 year of the index procedure.

## Statistical analysis

Our exposures of interest included the type of material used (mesh compared with no mesh) and the delivery setting for the procedure (hospital outpatient department compared with hospital-based ambulatory surgery centers). Logistic regression models were fit separately for each complication, adjusting for patient demographics (ie, age and race). We also

adjusted for comorbidity using established methods that enumerated diagnoses for the year preceding the index procedure.[15] To further minimize confounding, we also adjusted models for contextual factors, derived from the Area Resource File (ARF),[16] that have the potential to mediate sling use, including socioeconomic class (percent of persons living below poverty level, median income level), education (percent of persons with a college education or higher,) percent persons living in a urban environment, and the local capacity for sling surgery (ie, the number of practicing urologists and gynecologists). A similar model was fit to assess relationships between our exposures of interest and the development of any complication. Our final sample contained 6,698 patients who had mesh slings placed and 445 patients who had nonmesh slings placed. This sample provided 80% power to detect an odds ratio of 1.35 at the 5% significance level.

All analyses were performed using SAS v9.2 (Cary, NC). The significance level was set at 0.05 and all testing was two-sided. The institutional review board at the University of Michigan approved this study. The requirement for informed consent was waived.

## Results

Between 2006 and 2008, 12,707 slings surgeries were identified by appropriate *Current Procedural Terminology* (*CPT*) 4 codes. After exclusionary criteria were applied, a total of 7,143 Medicare beneficiaries met our study criteria and underwent an outpatient sling procedure at either a hospital outpatient department or hospital-based ambulatory surgery center. Of these patients, 6,698 (93.8%) and 445 (6.2%) women had procedures using mesh and nonmesh materials, respectively. Demographic and regional characteristics were comparable between the two groups (Table 1). The mean age of women in the mesh and nonmesh groups was 70.1 years and 69.5 years, respectively (p=0.20). Patients treated with mesh tended to live in regions with higher levels of affluence (p=0.04) and education (p<0.01). The use of preoperative urodynamics and cystoscopy did not differ significantly between groups, with urodynamics being performed in 66.6% of the mesh group and 64.0% of the nonmesh group (p=0.28) and cystoscopy being performed in 46.0% of the mesh group and 47.4% of the nonmesh group (p=0.56). Although our study was underpowered to detect a difference in surgical setting, no difference was detected in our sample with regards to setting between the mesh and nonmesh groups, with 96.6% of women with mesh slings and 97.3% of women with nonmesh slings having their procedures in hospital outpatient departments (p=0.40).

The frequencies of complications occurring within 12 months after the index sling procedure are shown in Table 2. Overall, 69.8% of the mesh group and 72.6% of the nonmesh group developed at least one complication (p=0.22). Most complications were minor, as infectious complications were present in 45.4% and 50.1% of the mesh and nonmesh groups, respectively (p=0.06). The development of urologic and infectious complications; new diagnoses of urgency, pelvic pain, and bladder outlet obstruction; and the use of diagnostic testing (ie, cystoscopy and urodynamics) and repeat incontinence procedures were comparable between the mesh and nonmesh groups. However, 19.3% of women with nonmesh slings required postoperative procedures for bladder outlet obstruction compared to only 13.9% of those with mesh slings (p<0.01). More specifically, in a subset analysis of this group, a higher percentage of women required sling removal and revision or urethrolysis procedures in the nonmesh group compared with the mesh group, with 4.7% compared to 2.7% (p=0.03).

After adjusting for differences between patients, women treated with mesh had lower risk of developing an infectious complication (adjusted OR 0.82, 95% CI 0.68-1.00), of requiring a secondary procedure for bladder outlet obstruction (adjusted OR 0.66, 95% CI 0.52-0.85),

and of having a sling removal and revision or urethrolysis (adjusted OR 0.56, 95% CI 0.35-0.89) compared with those treated with nonmesh slings (Table 3). We observed no differences in the likelihood of a complication according to the hospital based delivery setting in our sample, with 72.8% of patients developing a complication in hospital-based ambulatory surgery centers compared to 69.8% in hospital outpatient surgical departments (adjusted OR 1.09, 95% CI 0.81-1.46), although this study was underpowered to detect a small difference

## Discussion

Our study has at least two important findings with respect to the surgical management of patients with urinary incontinence. First, complications occurring within 1 year of hospital-based outpatient sling placement were relatively common regardless of whether mesh was used, although the majority of these were minor. However, contrary to supposition about the potential for deleterious effects of mesh in female incontinence surgery, both cohorts of patients had comparable overall complication rates. In fact, patients undergoing nonmesh procedures had a less favorable complication profile in that they were more likely to require a subsequent intervention for bladder outlet obstruction, including sling removal and revision or urethrolysis procedures. Importantly, this study used population-based data to demonstrate comparable rates of complications between patients treated with and without mesh. Second, consistent with our prior observations with respect to quality,[17] the likelihood of complications did not vary with respect to the surgical setting in our sample, although our study was underpowered to detect a small difference.

Prior work has explored adverse events related to slings using claims data. Rates for infectious complications, postoperative urologic complications, repeat incontinence procedures, postoperative pelvic pain,[18] and sling removal and revision or urethrolysis[19] from these studies were similar to our findings; however, rates for a new diagnoses and treatment for outlet obstruction were slightly lower than in our study.[18] Despite these differences, which may be likely attributable to selection bias (ie, our study only looked at patients undergoing sling surgery in isolation, as opposed to patients undergoing sling surgery in combination with other pelvic floor procedures), our results are consistent with rates of outlet obstruction published in several institutional case series,[20,21] and support the FDA's most recent comment on the safe and effective use of mesh sling for the treatment of stress urinary incontinence.[22]

Our finding of higher rates of obstruction and its subsequent management among nonmesh patients is consistent with the generalizable knowledge in this area. Invariably, most nonmesh slings are pubovaginal, which are placed at the bladder neck and are typically associated with higher rates of obstruction and voiding dysfunction compared with midurethral slings.[23] One meta-analysis showed that midurethral slings had a significantly lower risk of storage lower urinary tract symptoms (OR 0.31; 95% CI 0.10, 0.94) and a lower risk of reoperation (OR 0.31; 95% CI 0.12, 0.82) compared with pubovaginal slings.[24-27] Our findings are also consistent with American Urological Association Guidelines that suggest that synthetic slings have similar efficacy and less morbidity than nonmesh surgical techniques.[28]

An additional strength of this study is that we were able to investigate quality across different hospital-based outpatient delivery settings. Historically, some have argued that the relocation of cases to the more independent, and generally less regulated, environment of ambulatory surgery centers(albeit freestanding as opposed to hospital-based) may result in gaps in quality, due to limited availability of potentially important services and clinical expertise.[29] Our finding of similar complications between the two hospital delivery settings

is consistent with prior work in this area demonstrating similar complication and admission rates between hospitals and freestanding ambulatory surgery centers.[17]

Our findings should be interpreted with a several limitations in mind. First, we used medical claims to ascertain index procedures, whether or not mesh was used and all complications. However, because most of these codes are tightly linked to reimbursement, we do not view this as a major weakness. Second, we recognize that we could have potentially misclassified procedures as representing primary sling procedures based on our exclusion criteria of having a sling in the previous year. In other words, if a woman had a prior sling procedure more than 1 year before the date of their index sling, we would have missed this and included them in our analyses. However, since both mesh and nonmesh slings are viable options for repeat incontinence procedures,[30-32] this misclassification could have occurred in both groups. Third, we recognize that slings placed using mesh materials can be placed using various approaches (ie, transobturator and retropubic), which have been shown to have slightly different outcomes for voiding dysfunction requiring surgery. One randomized controlled trial reported that 2.7% of slings placed using the retropubic approach and 0% of slings placed using the transobturator approach required surgery for voiding dysfunction.[33] However, because our rate of sling removal and revision and urethrolysis procedures did not exceed 2.7%, we feel that a stratified analysis based on the approach of mesh insertion would not affect our results. Fourth, we recognize that our study was unable to address effectiveness as it relates to health-related quality of life and to patient satisfaction, as these measures are not available in medical claims. In their absence, however, other important aspects of effectiveness were able to be evaluated in the form of complications, which are important outcomes for payers and policy makers in determining payment and coverage decisions. Finally, because we studied Medicare beneficiaries undergoing procedures in hospital-based facilities, our findings may not be generalizable to younger patients or those procedures performed in freestanding ambulatory surgery centers.

These limitations notwithstanding, most complications after sling surgery do not vary with respect to whether or not mesh was used nor do they differ according to the delivery setting, although this study was underpowered to detect a small difference with regard to surgical setting. However, complications for bladder outlet obstruction, inclusive of sling removal and revision and urethrolysis, were higher among the nonmesh group compared with the mesh group. These data should further allay concerns about the use of mesh for stress incontinence surgery and those related to the effectiveness of care provided by ambulatory surgery centers.

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## Table 1

Demographic and Regional Characteristics of Women Who Underwent Sling Procedures Using Mesh and Nonmesh Materials.

| | Mesh | Nonmesh | *P* |
|---|---|---|---|
| Number of procedures | 6,698 | 445 | |
| Age in years, mean (SD) | 70.1 (10.6) | 69.5 (10.3) | 0.20 |
| Race, n (%) | | | |
| White | 6279 (93.9) | 424 (95.5) | 0.21 |
| Non-white | 408 (6.1) | 20 (4.5) | |
| Charlson Score, n (%) | | | |
| 0-2 | 6239 (93.2) | 416 (93.5) | 0.85 |
| 3 or more | 459 (6.9) | 29 (6.5) | |
| Percent living below the poverty level, (SD) | 13.7 (5.1) | 14.1 (5.3) | 0.04 |
| Median income level, mean (SD) | $48,726 (12,379) | $46,142 (12,100) | <0.01 |
| Percent with college education or higher, (SD) | 21.9 (9.0) | 20.9 (8.6) | 0.02 |
| Percent in an urban population, (SD) | 69.4 (28.0) | 67.5 (28.5) | 0.16 |
| Number of practicing gynecologists per region, mean (SD) | 82.3 (173.9) | 65.6 (149.8) | 0.01 |
| Number of practicing urologists per region, mean (SD) | 21.4 (43.1) | 18.2 (36.4) | 0.11 |
| Surgical setting | | | |
| Hospital outpatient facility, n (%) | 6467 (96.6) | 433 (97.3) | 0.40 |
| Hospital based ambulatory surgery center, n (%) | 231 (3.5) | 12 (2.7) | |
| Preoperative urodynamics, n (%) | 4462 (66.6) | 285 (64.0) | 0.28 |
| Preoperative cystoscopy, n (%) | 3080 (46.0) | 211 (47.4) | 0.56 |

SD, standard deviation.

**Table 2**

Complications of Mesh and Nonmesh Slings Within 1 Year of Surgery.

| | Mesh | Nonmesh | *P* |
|---|---|---|---|
| Any complication | 69.8 (68.7-70.9) | 72.6 (68.2-76.7) | 0.22 |
| Urologic complications | 16.7 (15.8-17.6) | 18.7 (15.1-22.6) | 0.29 |
| Infectious complications | 45.4 (44.2-46.6) | 50.1 (45.4-54.9) | 0.06 |
| New diagnosis of urgency | 19.6 (18.6-20.5) | 22.7 (18.9-26.9) | 0.11 |
| New diagnosis of pelvic pain | 6.4 (5.8-7.0) | 6.2 (4.1-9.0) | 1.00 |
| New diagnosis of bladder outlet obstruction | 10.6 (9.9-11.4) | 13.3 (10.3-16.8) | 0.10 |
| Management of outlet obstruction* | 13.9 (13.1-14.8) | 19.3 (15.8-23.3) | <0.01 |
| Sling removal and revision or urethrolysis | 2.7 (2.4-3.1) | 4.7 (2.9-7.1) | 0.03 |
| Cystoscopy | 17.7 (16.7-18.6) | 15.1 (11.9-18.7) | 0.18 |
| Urodynamics | 7.5 (6.8-8.1) | 8.8 (6.3-11.8) | 0.31 |
| Repeat incontinence procedures | 6.8 (6.2-7.4) | 6.3 (4.2-9.0) | 0.77 |

Data are % (95% confidence interval) unless otherwise specified.

* Includes sling removal and revision, urethrolysis, catheterization, cystostomy, urethral dilation, urethrotomy

## Table 3

Likelihood of Developing Complications Among Women Treated With Mesh Relative To Those Treated With Nonmesh Slings.

| | Odds Ratio | 95% CI |
|---|---|---|
| Any complication | 0.85 | 0.69-1.06 |
| Urologic complications | 0.87 | 0.68-1.11 |
| Infectious complications | 0.82 | 0.68-1.00 |
| New diagnosis of urgency | 0.82 | 0.65-1.04 |
| New diagnosis of pelvic pain | 1.04 | 0.68-1.58 |
| New diagnosis of bladder outlet obstruction | 0.75 | 0.57-1.00 |
| Management of outlet obstruction * | 0.66 | 0.52-0.85 |
| Sling removal and revision or urethrolysis | 0.56 | 0.35-0.89 |
| Cystoscopy | 1.21 | 0.93-1.58 |
| Urodynamics | 0.83 | 0.59-1.17 |
| Repeat incontinence procedures | 1.09 | 0.73-1.61 |

CI, confidence interval

Models are adjusted for age, race, poverty level, urban population, college education, Charlson score, surgeon specialty, and surgical setting.

* Includes sling removal and revision, urethrolysis, urethral dilation, catheterization, cystostomy, urethrotomy

## Box 1

Procedure and Diagnosis Codes Used.

| Procedure and Diagnosis Groups | Codes |
|---|---|
| Urologic Complications | (ICD-9 codes): 665.7, 996.3, 997.5, 568.81, 608.83, 998.1, 998.10, 998.2, 998.6, 998.4, 998.4x, 998.7x, 593.3, 596.1x-596.9x, 596.2, 596.6, 596.7, 597.0, 596.1, 565.11, 619, 596.76 |
| Infectious complications | (ICD-9 codes): 590.10, 590.80, 590.9, 595, 595.0, 595.3, 595.89, 595.9, 599, 599.0, 599.7, 996.31, 996.64, 996.65, 998.5 |
| Pelvic pain | (ICD-9 codes): 625, 625.8, 625.9, 788.9, 789.9 |
| Urge incontinence | (ICD-9 codes): 788.31, 596.51 |
| Diagnosis of outlet obstruction | (ICD-9 codes): 596.0 , 596.00, 599.6, 788.2, 788.21, 788.29, 788.38, 788.62 |
| Management of outlet obstruction | (CPT4 codes): 57287, 53620 , 53660, 51701, 51010 , 51040, 52270, 52281 , 52285, 53500 |
| Cystoscopy | (CPT4 codes): 52000, 52204, 52281 |
| Urodynamics | (CPT4 codes): 51725, 51726, 51795, (76000) |
| Repeat incontinence procedures | (CPT4 codes): 51715, 51990, 51992, 51845, 57220, 57288 |
| Office removal of mesh | (CPT4 code): 10120 |
| Pelvic organ prolapse repairs | (CPT4 codes): 45560, 57240, 57289, 57250, 57260, 57265, 57267, 57268, 57270, 57280, 57282, 57283, 57284, 58152, 58270, 58280, 59294, 58293, 58400, 58410 |

ICD-9, International Classification of Diseases, Ninth Revision

CPT, *Current Procedural Terminology*