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Trends and Reinterventions in the Surgical Management of Stress Urinary Incontinence among Female Medicare Beneficiaries

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Abstract

Introduction: We compare the use of bulking agents and slings for the treatment of stress urinary incontinence among female Medicare beneficiaries.

Methods: We analyzed data from a 5% national random sample of Medicare claims from 2000 to 2011. Female beneficiaries who underwent a sling or bulking agent procedure were identified based on CPT-4 and ICD-9 procedure codes. Statistical analysis for categorical data determined differences in the distribution of patient demographics and comorbidities. The 90-day adverse events and reinterventions were compared between treatment groups. Time to event analysis was used to determine freedom from reintervention after therapy.

Results: We identified 21,134 and 3,475 patients treated with sling and bulking procedures, respectively. There was a 29.7% increase in the number of sling procedures and a 59.5% decrease in bulking procedures from 2001 to 2011. Patients treated with bulking agents had higher rates of diabetes, cardiovascular disease, heart failure and renal failure (p < 0.01). The 90-day adverse events after both procedures were rare, with the exception of urinary retention, which was increased in women treated with a sling but frequent in both groups (sling 11.3%, bulking agent 8.4%; p < 0.01). A smaller proportion of patients who underwent sling surgery had reinterventions (repeat sling 7.4%, bulking agent 38.2%; p < 0.01). Overall 53.2% of the patients treated with a sling and 76.3% treated with bulking agents who underwent subsequent procedures were treated with the same procedure at the first intervention.

Conclusions: Sling and bulking procedures are safe in terms of short-term performance, although the rates of retention were high in both groups. Patients treated with reinterventions tend to repeat the same therapy instead of converting to another procedure.

Key Words: urinary incontinence, stress; Medicare; aged; suburethral slings; treatment outcome

Abbreviations and Acronyms

FDA = Food and Drug Administration

SUI = stress urinary incontinence

written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

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Stress urinary incontinence, the involuntary leakage of urine with cough, laugh, sneeze or exertion, has a negative impact on a woman's quality of life.^{1,2} Prevalence reports vary greatly, indicating that up to 35% of women suffer from this condition.³ First line SUI treatment focuses on conservative measures, including pelvic floor exercises with or without physical therapy.⁴ Since 1992 sling procedures have gained popularity and have been used frequently, while the use of bulking agents has been gradually decreasing, possibly due to poor cure rates.⁵ Despite this change in specific surgical techniques, the overall number of SUI surgical treatments has been consistent since 2002.^{6,7}

In the last 2 decades the Medicare beneficiary database has been used to assess SUI trends in geographic location, surgical technique and short-term sling outcomes.⁸ We expand on this research by directly comparing the current use and need for reintervention of bulking agents and slings. Analyzing outcomes of the surgical management of SUI among female Medicare beneficiaries will elucidate comparative evidence that will help women and their physicians make better decisions about their choice of therapy.

Methods

We identified female patients who underwent sling surgery or bulking agent injection between 2001 and 2011 from a random sample of 5% of national Medicare beneficiaries age 65 or older. CPT-4 and ICD-9 codes were used to identify sling and bulking procedures (see supplementary Appendix, <u>http://urologypracticejournal.com/</u>). We grouped patients by their first female incontinence procedure in 2001 to 2011. De-identified patients were tracked for 1 year before surgery to assess comorbidities and were followed from the procedure date until in-hospital death or the end of the study period (end of 2011).

Patient characteristics including age, race, procedure year and comorbidities were examined. Relevant comorbidities were identified using algorithms validated by Elixhauser et al.⁹ Safety was evaluated in the first 90 days by capturing surgical complications (bleeding, pelvic pain, urinary retention, mechanical complications) and nonsurgical complications (acute myocardial infarction, stroke, pulmonary complications, pulmonary embolism/deep venous thrombosis) as well as mortality. Reintervention was also defined by CPT-4 and ICD-9 procedure codes as sling, bulking and other SUI procedure (see supplementary Appendix, <u>http://</u> <u>urologypracticejournal.com/</u>). A diagnosis of urinary retention or catheterization procedure served as an intermediate indicator of urinary retention, meaning that the degree of retention could not be quantified in this data set. Patient demographics, comorbidities, posttreatment complications and reinterventions were documented as events and percentages. A chi-square test for categorical variables was performed to determine differences in the distribution of patient demographics and comorbidities, and to compare 90-day safety and reintervention up to the end of the study period between the sling and bulking groups. Temporal trends in procedure volumes for sling and bulking procedures were evaluated graphically. Time to event analysis was used to investigate time to first reintervention after the original procedure, censoring patients at inhospital death or study conclusion. A log rank test was used to assess the difference in freedom from reintervention between the sling and bulking groups. All analyses were performed using SAS® v9.3.

Results

We identified 21,134 and 3,475 patients treated with sling and bulking procedures, respectively, between 2000 and 2011. The annual number of sling procedures increased from 1,349 to 1,750 while the annual number of bulking agent procedures decreased from 459 to 186 (fig. 1).

Patient demographics and comorbidities are shown in table 1. The majority of patients who underwent sling surgery were younger than those who received bulking therapy (65 to 74 years old, sling 64.1%, bulking agent 39.9%; p <0.01). Sling surgeries were less common with increasing age (75 to 84 years old—sling 31.9%, bulking agent 44.6%; 85+ years old—sling 3.9%, bulking agent 15.5%; p <0.01). Diabetes was more prevalent among patients in the bulking therapy group than in the sling cohort (sling 20.7%, bulking agent 25.1%; p <0.01), as was congestive heart failure (sling 7.1%, bulking agent 14.1%; p <0.01), cardiovascular disease (sling 11.6%, bulking agent 17.8%; p <0.01) and renal failure (sling 3.1%, bulking agent 5.0%; p <0.01).



Figure 1. Sling and bulking procedure volume from 2000 to 2011 among Medicare beneficiaries.

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