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THROMBOEMBOLIC COMPLICATIONS OF SLING SURGERY FOR STRESS URINARY INCONTINENCE AMONG FEMALE MEDICARE BENEFICIARIES

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Abstract

Objectives—A dearth of relevant literature exists on thromboembolic complications after female pelvic surgery. Guidelines on DVT prophylaxis are therefore derived from expert opinion. We sought to determine the rate of thromboembolic complications after sling surgery for stress urinary incontinence among female Medicare beneficiaries age 65 and over.

Methods—We analyzed the 1999–2001 Medicare Public Use Files provided by the Centers for Medicare and Medicaid Services on a 5% national random sample of beneficiaries. Women undergoing sling procedures between January 1, 1999 and July 31, 2000 were identified by CPT-4 codes and tracked for 12 months. Diagnoses of postoperative thromboembolism (DVT/PE) were identified with ICD-9 codes. Multivariate analysis determined independent risk factors for developing a thromboembolic event.

Results—A total of 1,356 slings were performed in the 5% sample of female Medicare beneficiaries during the 18-month index period. Concomitant prolapse surgery was performed in 467 (34.4%) cases. At three months after surgery, thromboembolic complications had occurred in 0.9% of women undergoing a sling alone and in 2.2% of women undergoing concomitant prolapse surgery ($p=0.05$). Multivariate analysis revealed that concomitant prolapse surgery was associated with nearly three times the odds of thromboembolic complications (OR 2.86, 95% CI 1.10–7.45).

Conclusions—A low rate of thromboembolism occurred after an isolated sling procedure. However, the increased rate of DVT and PE among women undergoing sling surgery combined with prolapse repair emphasizes the need for appropriate DVT prophylaxis in this group.

Keywords

pulmonary embolism; Medicare; claims data; pelvic prolapse

Introduction

Deep venous thrombosis (DVT) and pulmonary embolism (PE) are leading causes of preventable perioperative morbidity and mortality. Existing data on the true prevalence of thromboembolic disease, including both occult and clinically diagnosed disease, indicate that there are 5 million cases of DVT and nearly 600,000 cases of PE per year¹. Some suggest that, due to the intrinsic inaccuracy of clinical diagnosis, these figures underestimate the true burden of disease². Fatal PE, a direct outcome of DVT, causes approximately 10% of hospital deaths and has been described as one of the leading causes of preventable in-hospital mortality^{3,4}. Failure to diagnose and prevent DVT is associated with significant health care costs and morbidities; inadequate prophylaxis and delayed diagnosis correlate with delayed hospital discharge, subsequent readmission, risk of post-thrombotic syndrome, recurrent thrombosis and chronic venous valvular incompetence^{4,5}.

Female sling and prolapse repair surgeries combine elements of urologic and gynecologic procedures. Without appropriate prophylaxis, DVT and PE rates for patients undergoing major pelvic urologic procedures, such as radical prostatectomy, are as high as 51% and 22%, respectively^{1,6}. These estimates are significantly higher than those reported for intra-abdominal and gynecologic operations, which approach 30% for DVT and 14% for PE among patients not receiving prophylaxis^{1,7}. Due to these high rates of venous thromboembolism, “pay-for-performance” measures being implemented across the United States are emphasizing DVT prophylaxis in surgical patients. In fact, Medicare has included DVT prophylaxis in the Surgical Care Improvement Project, a set of quality measures in surgery that are currently publicly reported and will likely be tied to reimbursement in the future^{8,9}. Despite this emphasis on DVT prophylaxis, little is known regarding the risk of venous thromboembolism after female sling and prolapse repair procedures. In this study, we used Medicare claims data to determine the rate of thromboembolic complications after sling surgery among female Medicare beneficiaries age 65 and over. We sought to determine factors associated with the risk of thromboembolic complications, including both patient and provider variables.

Material and Methods

We analyzed the 1999–2001 Medicare Public Use Files provided by the Centers for Medicare and Medicaid Services on a 5% national random sample of beneficiaries. Randomization was based on the last two digits of subjects’ Health Insurance Claim Number, which is based on the Social Security Number. Women undergoing sling procedures between January 1, 1999 and July 31, 2000 were identified by Physicians Current Procedural Terminology Coding System (4th edition, CPT-4) code 57288 (sling procedure for stress incontinence, fascia or synthetic) and tracked for 12 months after surgery. Subjects were also tracked for six months before surgery to assess for comorbidities, as measured by the Charlson comorbidity index. The Charlson index score represents the sum of weighted International Classification of Diseases (9th revision, ICD-9) diagnosis codes for each comorbid condition¹⁰.

Demographic characteristics, such as patient age and ethnicity, clinical characteristics such as comorbidity^{10,11}, and complications, were obtained from an analytical file created from three Medicare Standard Analytic Files representing hospital inpatient, hospital outpatient, and physician-supplier part B care. Previous studies have applied this methodology using Medicare claims data^{12–14}. Using the inpatient, outpatient, and physician-supplier files, key postoperative outcomes were identified using all available CPT-4 and ICD-9 codes for relevant procedures and diagnoses among female Medicare beneficiaries, as previously

described. The specific ICD-9 diagnosis codes used for thromboembolism, including DVT and PE, occurring within one year after the index sling procedure, are shown in Table 1.

Multivariate analysis was used to control for covariates that may influence outcomes, including patient age, race, and comorbidities, in addition to surgeon variables (volume and specialty). We sought to determine risk factors for developing a thromboembolic event, including patient factors (race, age, and comorbidity), surgeon factors (volume and specialty), and whether concomitant prolapse surgery was performed at the time of the sling. This study was granted human subjects exemption by the University of California Los Angeles Institutional Review Board.

Results

A total of 1,356 slings were performed in a 5% national random sample of female Medicare beneficiaries during the 18-month index period. This extrapolates to more than 18,000 slings per year. As previously reported, 69% of subjects had a Charlson score of zero, indicating low comorbidity¹⁵. Caucasian women underwent 95.0% of the slings performed during the index period. Concomitant prolapse surgery was performed in 467 (34.4%) cases. At three months, overall thromboembolic complication rate was 1.3%. Thromboembolic complications occurred in 0.9% of women undergoing a sling alone and in 2.2% of women undergoing a sling combined with prolapse repair ($p=0.05$, Table 2). By one year after surgery, overall thromboembolic complication rate was 2.4%. Thromboembolic complications occurred in 1.8% of women undergoing a sling only and in 3.6% of women undergoing concomitant prolapse surgery ($p=0.055$). The difference in rate of arterial embolism/thrombosis (ICD-9 codes 444.22 and 444.81) between the two groups (sling vs. sling plus prolapse repair) was statistically significant at both three months and one year after surgery. Although arterial thromboembolism is not usually considered a post-operative complication, we included it in our analysis because treating physicians may use it as a code for venous thromboembolism¹⁶.

Multivariate analysis revealed that concomitant prolapse surgery was associated with nearly three times the odds of thromboembolic complications at three months after surgery (OR 2.86, 95% CI 1.10-7.45), and two times the odds at one year after surgery (OR 2.11, 95% CI 1.03-4.32, Table 3). No patient variables, including age, race, and comorbidity, or surgeon variables, including volume (the number of procedures a surgeon performs) and specialty (urology vs. gynecology), were significantly associated with the rate of thromboembolic complications.

Comment

To our knowledge, this study is the first to specifically evaluate venous thromboembolism rates in women undergoing sling surgery at a national level. We identified two principle findings that may have important practice implications. First, we found that the overall rate of thromboembolic complications after isolated sling surgery was low (less than one percent at three months). The Urinary Incontinence Treatment Network (UITN) performed a multi-center randomized clinical trial comparing outcomes of slings to outcomes of Burch colposuspension procedures¹⁷. There was only one DVT among the 327 patients who underwent a sling. The low rate of venous thromboembolism identified by the UITN study and ours may be influenced by three major factors. First, it is not clear from our database whether or not patients received DVT prophylaxis; however, previous research has shown that half of abdominal surgery patients at high risk for DVT (e.g patients with cancer) did not receive appropriate prophylaxis, so it is unlikely that a large proportion of sling patients received prophylaxis¹⁸. Second, our venous thromboembolism rates are observed in a

clinical, rather than experimental, setting. This means that DVT screening was unlikely routine, but instead based on clinical suspicion. This will lead to a lower detected rate of venous thromboembolism. However, our 1 year follow-up should capture virtually all clinically meaningful events, and previous research has shown that the majority of thromboembolic events occur within 2 months of surgery¹⁹. Third, this study, as with all database studies, is only as good as the coded data; however, Medicare claims data has been previously validated for investigating post-surgical complications²⁰. Also, we could not differentiate between bladder neck slings and minimally invasive mid-urethral slings, though rates of DVT were very low overall, and a difference between sling types may not have been detectable. Despite these issues, it seems that the rate of venous thromboembolism after sling surgery alone for female incontinence is reliably low.

Second, we found that concomitant prolapse repair nearly tripled the rate of thromboembolic complications. Concomitant prolapse repair likely increases thromboembolic risk via all three mechanisms in Virchow's triad¹ (venous stasis, endothelial injury, and hypercoagulability). Prolapse repair entails prolonged operative time in the dorsal lithotomy position and more extensive pelvic dissection resulting in an increased duration of venous stasis and hypercoagulability, as well as increased endothelial injury. Despite this, women in the Medicare sample who underwent a sling with combined prolapse repair had a rate of DVT/PE much lower than that previously described for other gynecologic operations^{1,7}. The low overall rate of thromboembolic complications we identified may be due to the fact that the majority of these cases were likely performed vaginally, rather than abdominally.

The most recent published guidelines for the prevention of venous thromboembolism come from the ACCP Seventh Conference on Antithrombotic and Thrombolytic Therapy⁴. The evidence-based guidelines derived from this conference include a risk stratification system for surgical patients, classifying patients into low, moderate, high and highest risk groups based on patient-specific, medical and surgical associated risk factors. Women over age 65 undergoing pubovaginal sling and prolapse surgery without other risk factors are categorized as *high risk level* patients, thus demanding thromboprophylaxis strategies that correspond to this ACCP risk level. Although older women undergoing an isolated sling procedure fit in the *high risk* category based on age criteria, our findings suggest that prophylaxis in older women without risk factors might not be indicated. We recognize a need for more adequately powered randomized trials in order to determine the optimal regimen in these patients.

Although the rate of DVT/PE after combined sling/prolapse repair was lower than that after other pelvic surgeries, this increase in event frequency (vs. sling alone) leads us to suggest DVT prophylaxis for this group regardless of age. However, given the relatively low overall DVT/PE rate among women undergoing combined sling and prolapse surgery (2.2% at three months), for women without risk factors, it may be sufficient to avoid pharmacologic prophylaxis (e.g. low molecular weight heparin) and simply provide mechanical prophylaxis (graduated compression stockings or intermittent pneumatic compression devices)²¹. Given the potential risk of bleeding after vaginal surgery, most pelvic surgeons would likely prefer to reserve pharmacologic prophylaxis for women in the highest risk category, such as those with cancer or a previous history of venous thromboembolism.

Conclusions

This study used Medicare claims data to determine that the overall rate of clinically significant thromboembolic complications at three months was 0.9% among women undergoing isolated sling surgery for stress incontinence and more than doubled in women undergoing concomitant prolapse surgery. The increased risk of DVT and PE among women

undergoing sling surgery combined with prolapse repair warrants appropriate DVT prophylaxis based on patient-specific risk factors.

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Table 1

ICD-9 diagnosis codes used for thromboembolism occurring within one year after the index sling procedure

ICD-9 Code	Thromboembolic Complications
444.22, 444.81	Arterial embolism, thrombosis
415.1	Pulmonary embolism and infarction
451.2, 451.81, 451.9, 453.8	Embolus, phlebitis not specified
451.11, 451.19	Thrombophlebitis of deep veins of lower extremities
453.8	Venous embolism or thrombosis of other specified veins

Table 2

Comparison of Thromboembolic Complications (Sling Only vs. Sling with Concomitant Prolapse Repair), Cumulative Number (%)

Complication	By 3 months after Surgery			By 1 Year after Surgery		
	Sling Without Prolapse Repair	Sling With Prolapse Repair	P value	Sling Without Prolapse Repair	Sling With Prolapse Repair	P value
Arterial embolism, thrombosis	0 (0.00)	3 (0.67)	0.02*	0 (0.00)	4 (0.89)	.005*
Pulmonary embolism and infarction	2 (0.23)	4 (0.89)	0.09	3 (0.35)	5 (1.11)	0.09
Overall thromboembolic complications	5 (0.58)	3 (0.67)	0.84	12 (1.38)	8 (1.78)	0.58
Embolus, phlebitis not specified	1 (0.12)	2 (0.44)	0.23	5 (0.58)	4 (0.89)	0.51
Venous embolism or thrombosis of other specified veins	2 (0.23)	2 (0.44)	0.50	6 (0.69)	5 (1.11)	0.43
Overall thromboembolic complications	8 (0.92)	10 (2.22)	0.05**	16 (1.84)	16 (3.56)	0.055***

Table 3

Multivariate Regression Analysis for Outcomes

Characteristics	Thromboembolic complications after sling, OR (95%)	
	By 3 months after Surgery	By 1 Year after Surgery
Index sling with prolapse (vs. without)	2.86 (1.10-7.45) *	2.11 (1.03-4.32) *
Sling by urologist (vs. gynecologist)	2.59 (0.57-11.73)	1.58 (0.58-4.26)
Low surgeon volume <=3 slings per 2 year period (vs. >6)	1.47 (0.46-4.73)	1.29 (0.55-3.02)
Mid surgeon volume 4-6 slings per 2 year period (vs. >6)	0.68 (0.15-3.10)	0.56 (0.18-1.75)
Non-white race/ethnicity (vs. white)	1.15 (0.15-8.94)	0.60 (0.08-4.53)
Age 65-69 (>75) years	1.21 (0.40-3.67)	0.93 (0.40-2.150)
Age 70-74 (>75) years	0.92 (0.28-3.07)	0.83 (0.34-2.00)
Charlson Score >=1 (v =0)	1.90 (0.74-4.90)	1.18 (0.56-2.45)

*
p<0.05