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Racial and Socioeconomic Disparities in Short Term Urethral Sling Surgical Outcomes

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Abstract

Objective: To evaluate the association of racial and socioeconomic factors with the risk of adverse events in the first 30 days following urethral sling placement.

Methods: We accessed non-public data from the Office of Statewide Health Planning and Development in California from 2005-2011. All female patients who underwent an ambulatory urethral sling procedure in the entire state of California over the study period were identified (CPT 57288). Our main outcome was any unplanned hospital visits within 30 days of the patient's surgery in the form of an inpatient admission, revision surgery, or emergency department visit.

Results: 28,635 women were identified who underwent outpatient urethral sling placement. Within 30 days, 1,628 women (5.7%) had at least one unplanned hospital visit. In the adjusted multivariate model, Black race and Medicaid insurance status were both independently associated with an increased odds of having an unplanned hospital visit (OR=1.80, $p<0.01$ and OR 1.53, $p<0.01$, respectively). This significance persisted even when controlling for patient comorbidities, demographics and facility characteristics.

Conclusions: We find that, similar to what has been reported in other fields, disparities in outcomes exist between socioeconomic and racial groups in the field of Urogynecology.

Introduction:

Female stress urinary incontinence (SUI) is a common problem for which an estimated 200,000 procedures are performed annually, the majority of which are urethral slings (1,2). Although slings are effective and safe, certain complications such as urethral obstruction leading to urinary retention, vaginal mesh exposure, urinary tract erosion or pain may necessitate surgical sling revision. Given the high prevalence of urethral sling placement, there has been great interest in characterizing the complications of this procedure. A long-term all-cause sling revision rate of 3-4% has been well documented in large population based studies (3,4). The short-term adverse event rate has also been recently characterized in large studies at 3.5-5.7% (5,6).

Despite a growing body of literature detailing the complication rate from sling placement, there are few studies exploring the potential impact of racial and socioeconomic factors. In contrast, other surgical fields such as general surgery (7,8), cardiac surgery (9), and oncology (9-15) have published extensively on the impact of socioeconomic and racial factors on outcomes, with many of these studies reporting disparities in outcomes based on these factors.

Given the remarkable prevalence of urethral sling procedures, identifying the effects of racial and socioeconomic status on outcomes is paramount. In addition, while not directed at urethral slings, the 2011 FDA warning concerning the use of synthetic vaginal mesh for pelvic organ prolapse repair has inadvertently lead to the increased scrutiny of synthetic urethral slings. This makes the study of urethral sling outcomes, and the factors associated with its

failure, all the more crucial. We seek in this study to explore the impact of socioeconomic and racial factors on the short-term (30-day) adverse event rate following urethral sling placement.

Methods:

With approval from the California Protection of Human Subjects Committee, we accessed non-public data from the Office of Statewide Health Planning and Development (OSHPD) from the state of California for the years 2005-2011. These datasets include information from every single non-federal inpatient hospitalization and surgery (Patient Discharge Dataset, PDD), ambulatory surgery (Ambulatory Surgery Dataset, ASD) and emergency department visit (Emergency Department Dataset, EDD) from the entire state of California. Each encounter contains 25 diagnosis codes and 20 procedure codes and provides demographic information such as patient age, payer type, race/ethnicity, home zip code and facility of service. In addition to coding for diagnoses associated with that encounters surgery or reason for admission, the diagnosis codes also encompass the patient's past medical history.

We identified all female patients who underwent an ambulatory urethral sling procedure (Current Procedural Terminology [CPT] 57288). We limited our cohort to outpatient surgeries because there is no reliable coding for inpatient urethral sling procedures in the datasets (the PDD utilizes ICD-9 procedure codes). Any patient who had concurrent surgical procedures, with the exception of cystoscopy (CPT 52000), were also excluded to avoid contamination. This

method of exclusion provided a further benefit as the autologous fascial sling procedure is accompanied by a separate procedure code for the graft harvest, and we did not wish to include this sling type. Our primary outcome was any hospital encounter within 30 days of the index surgery, in the form of an ambulatory surgery (urethral sling revision-CPT 52827 or urethrolysis-CPT 52500); b) inpatient admission; or c) emergency department visit. We defined these unplanned visits as adverse events or complications.

We explored the association between incidence and type of 30-day unplanned hospital visit and patient race, payer type, comorbidities, home zip code, median income and hospital surgical volume. We defined our racial/ethnic groups as White (White, non-Hispanic women), Hispanic (White, Hispanic women), Black, Asian or other/unknown. Payer data was categorized as Medicare, Medi-Cal/Medicaid, Private or Other. Each center was also assigned to a quartile based on it's surgical volume compared to all facilities (Q1 lowest surgical volume, Q2, Q3, or Q4). Q1 was defined as less than 88, Q2 as 88-159, Q3 as 160-293, and Q4 as at least 294 slings placed during the study period. To control for baseline individual risk, we identified all individuals with a history of diabetes mellitus type 2, hypertension, smoking status, and vascular disease as comorbidities. Finally, as we did not have each individual patient's income, we used their home zip codes and median income as a metric. This data was obtained from the Franchise Tax Board Open Data Portal (16) and each income was assigned a quartile (Q1<$23101, Q2 as $23101-$43827, Q3 as $43827-$64102 and Q4> $64102).

As emergency department adverse events were the most prevalent of the unplanned visits, we performed a subset analysis evaluating the reason for emergency department visit based on the primary diagnosis associated with the encounter. A total of 309 unique International Classification of Diseases 9th Revision (ICD-9) diagnoses were identified and reviewed. We combined codes relating to similar conditions and created a variable categorizing the ER diagnoses as “likely”, “possibly” or “not likely” related to the index sling surgery. For example, 78820 "Retention of urine NOS", 7802 "Syncope and collapse" and 9913 "frostbite NEC/NOS" were defined as likely, possibly and not likely related to the patient's surgery, respectively. Generally speaking, urologic diagnoses or wound problems were defined as likely related to the surgery. Diagnoses such as a pulmonary process, dehydration or constipation were coded as possibly related. Statistical Analysis

Univariate analysis was performed with the chi-square test for categorical variables, and the Student T-test for continuous variables. Medians were compared with the Kruskal-Wallis test. Multivariate mixed effects logistic regression models were constructed to explore the independent fixed effects of patient age, race/ethnicity, hospital surgical volume, payer type, comorbidities and income on the probability of a complication occurring. The random effect was the facility of surgery, which controlled for any baseline disparity in surgical risk at the facility level, not accounted for by our fixed effects. A p-value less than 0.05 indicated statistical significance. All statistical assumptions were tested for validity. Statistical analysis was performed with R 3.3.2 software.

Results:

After exclusions, a cohort of 28,635 women were identified who underwent ambulatory urethral sling placement. The mean age of the final study cohort was 54.7 years (±12.7). The cohort was predominantly White (63.7%), with Black women making up the smallest racial group (1.7%). The most common payer type was Private insurance (68.4%), followed by Medicare (14.5%), Medicaid (4.5%) and all others (1.4%) (Table 1). Patients were older in the Medicare group (mean 70.1 years) as opposed to the Private (52.4 years) and Medicaid groups (46.8 years). Hispanic women were youngest overall (mean 50.6 years) ($p<0.01$) (Table 1). Although there was a clear pattern when it came to payer type and comorbidity (Medicare patients had the highest rate of each comorbidity), the association between race and comorbidity was more variable. Although Black women had the highest rate of hypertension, their rates of diabetes were similar to that of the Hispanic and Asian groups at approximately 8%, Whites had a lower rate at 4.6%.

Whites overall had the highest rate of vascular disease and both White and Black women had comparatively higher rates of smoking as compared to the other groups (Table 1).

Of the 28,635 primary sling placements, 1,628 patients had at least one unplanned hospital visit (5.7%) within 30 days. Of these, 1,257 (77.2%) were in the form of an emergency department visit, 295 (18.1%) were inpatient admissions and 77 (4.7%) were sling revisions (Figure 1). Univariate analysis

revealed differences in unplanned hospital visit rates based on race/ethnicity (Figure 1) and payer status (Figure 2). Black women had a higher overall 30-day event rate (10.5%, $p<0.01$) and higher surgical revision rates than all other groups (0.6%, $p<0.05$) (Figure 1). Hispanic women had a slightly higher rate of an adverse event, primarily in the form of emergency department visits (6.5% versus 5.7% overall rate). There was a significantly higher 30-day event rate in those with Medicaid insurance (12.9% versus 5.7% overall rate, $p<0.01$) (Figure 2). There was no significant univariate association between volume of the facility and a 30-day adverse event.

There was also an association between race and payer type. Specifically, both Black women (11.4%) and Hispanic women (8.7%) had a higher rate of Medicaid insurance status, compared to Whites (3.1%) and Asians (2.8%) ($p<0.01$). Although we did not find any clear association between surgical volume and patient demographics, we did observe an association between insurance payer type and hospital surgical volume as Medicaid status was associated with low volume centers. The Medicaid patients had their surgeries at the lowest volume centers 48.5% of the time, versus 21.0% and 34.4% for those with Private or Medicare insurance, respectively ($p<0.01$). In other words, those with private insurance had their procedure at a top volume facility 31.0% of the time, compared to 12.8% for women with Medi-Cal/Medicaid.

Overall, 46.1% and 30.4% of the Emergency Department diagnoses were “likely” and “possibly” related to the patient's procedure, respectively. While this did not vary by race, it did vary by payer type. In those who were Privately

insured, 49.1% of emergency department diagnoses were “likely” related to their sling surgery, as opposed to a 39.9% or 37.9% rate for Medicare and Medicaid patients respectively (p<0.01). The most common overall diagnosis associated with presentation to the emergency department was pain (19.4%), followed by urinary retention (18.6%). Regarding race and emergency department diagnosis, the only significant association was a higher rate of catheter related problems in Black (2.7%), Hispanic (2.7%) and Asian women (5.1%) as compared to White women (0.8%) (p=0.01). When considering payer type, constipation made up 0.9% of the diagnoses for the Privately insured versus 2.4%, 2.0% and 8.0% for those with Medicare, Medicaid or other insurance, respectively (p=0.01). Of note, approximately 1.5% of the Emergency Department visits were for problems with a catheter already in place. While this rate did not vary by payer type, it did for race/ethnicity with white patients having the lowest rate of catheter problems (0.8%) versus 2.7%, 2.7% and 5.1% for Hispanic, Black and Asian women, respectively (p=0.01).

Multivariate modeling, controlling for all comorbidities, demographics and baseline facility risk, revealed that Medicaid payer status, Black race and presence of diabetes mellitus were all independently associated with increased odds of having an early adverse event (Table 2). With the Medicare patients as reference, the Medicaid patients had increased odds of having an adverse event (OR 1.53, p<0.01), while the Privately insured women had lower odds (OR 0.62, p<0.01). With White women as the reference group, only Black women had increased odds of having an adverse event (OR 1.80, p<0.01). However, when

Asian women were the reference group, both Black (odds 2.26, p<0.01) and Hispanic (odds 1.36, p=0.03) women had significantly higher odds of a complication. There was no association between hospital surgical volume and adverse event rate.

Discussion:

In this large population based study of 28,635 women undergoing a urethral sling procedure, there was a significant discrepancy in outcomes based on racial and socioeconomic factors. We found that Black race and Medicaid insurance status were both independently associated with increased risk of an early adverse event. These results are particularly troublesome when considering the adverse event rates for Black women (11.0%) and those with Medicaid insurance (12.9%) were both double that of the entire cohort (5.7%). Furthermore, these effects are observed even when controlling for comorbidities and other demographic factors.

One study, most similar to our own, explored the association between race and outcomes in patients undergoing surgery for stress urinary incontinence. They analyzed exclusively Medicare patients and found that non-white women undergoing sling surgery were twice as likely to have non-urological complications, pelvic organ prolapse and urinary obstruction over the one year post-operative period (17). We not only identified an identical trend in our Medicare patients, but also found that this trend was persistent across all ages and payer types.

Unfortunately, this association between race, payer status and poor outcomes has been observed in other medical fields in several studies. Le et al. noted that Black women not only present with colon cancer at a higher stage, but also have a higher risk of death, even when presenting with identically staged disease as compared to other races (14). A study by Barocas et al. explored the impact of race on outcomes for bladder cancer managed surgically and, similar to our study, found that Black patients not only had higher rates of adverse outcomes, but were also more likely to receive care at low volume centers (13). Another study reported that patients receiving care at a "high Medicaid hospital" suffered from poorer colon cancer outcomes (15). Unlike our study, however, they found that controlling for hospital volume eliminated the effect of insurance status. This difference is likely due to their analysis of Medicare rates at the facility level, as opposed to the more granular patient level, as performed in our analysis. Also, similar to our findings, other studies have also reported a trend towards increased adverse event rates in Hispanic patients and contrasting the superior outcomes in Asian patients (14,18)

Our study is limited, like most administrative datasets, by a lack of granularity. Although we did control for common comorbidities, demographics and baseline risk associated with each hospital, we did not have specific patient income (we estimated this based on patients home zip code), patient education status or individual physician data. However, the latter's limitation is greatly tempered by our inclusion of the random effect of facility in our modeling, effectively controlling for baseline facility risk. Our results are also dependent on

practitioners coding for diagnoses correctly, (e.g. a patient with dysuria may have been coded incorrectly as having a urinary tract infection), however we believe we accounted for this by grouping diagnosis by condition. Finally, we are unable to identify adverse events that were not in the form of a hospital admission, surgical intervention or inpatient admission, such as those that were treated in a physician's office.

Despite these limitations, our study has many strengths. Most importantly it fills a gap in the understanding of the socioeconomic and racial impact on the short term adverse event rate following urethral sling placement. We expand on current literature to include all patient ages and payer types as well as facility types. Furthermore, our study is a large population based analysis, and unlike other studies, our follow-up captures every single emergency department visit, inpatient admission or operation performed at any hospital in the entire state of California, regardless of where the index operation was. While our analysis did not include subsequent care outside of California, we feel this impact is likely low secondary to the short 30-day study period.

Conclusion:

Although the overall 30-day adverse event rate following urethral sling placement is low, it is significantly impacted by patient race and payer status. Black race and Medicaid insurance status were both independently associated with increased adverse event rates and this association persisted even when controlling for baseline comorbidities and demographics. Our findings can be utilized to develop strategies to improve outcomes. Possible strategies worthy of

consideration includes increasing access to care and support services (such as encouraging the patient to call the clinic prior to presenting to the Emergency room and providing social work contacts), providing informational materials in laymen's terms and reviewing this information with the patient, and working to understand a patient's specific barriers to care to better address them (such as providing Taxi-Vouchers if transportation is a problem, or providing information in the patients native language). Research efforts implementing these strategies are underway, and their outcomes deserve follow up and application to the field. (19).

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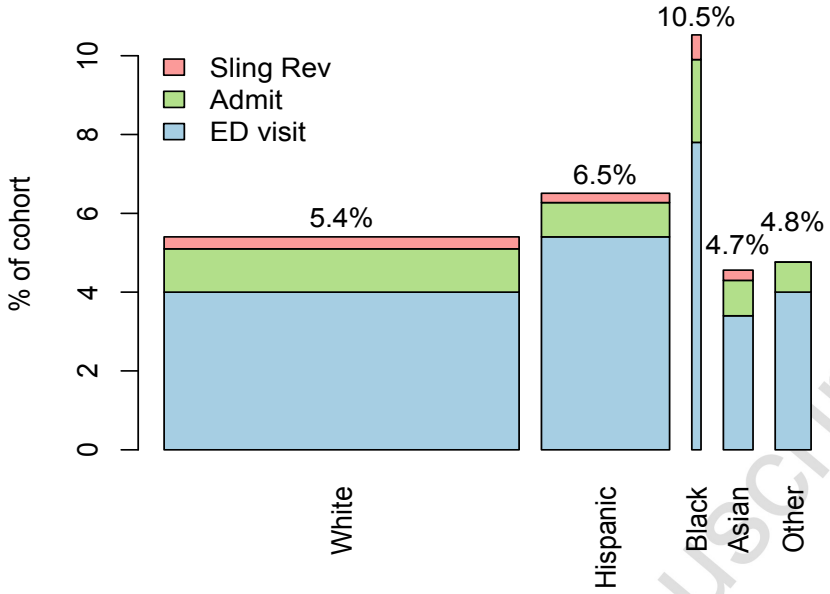
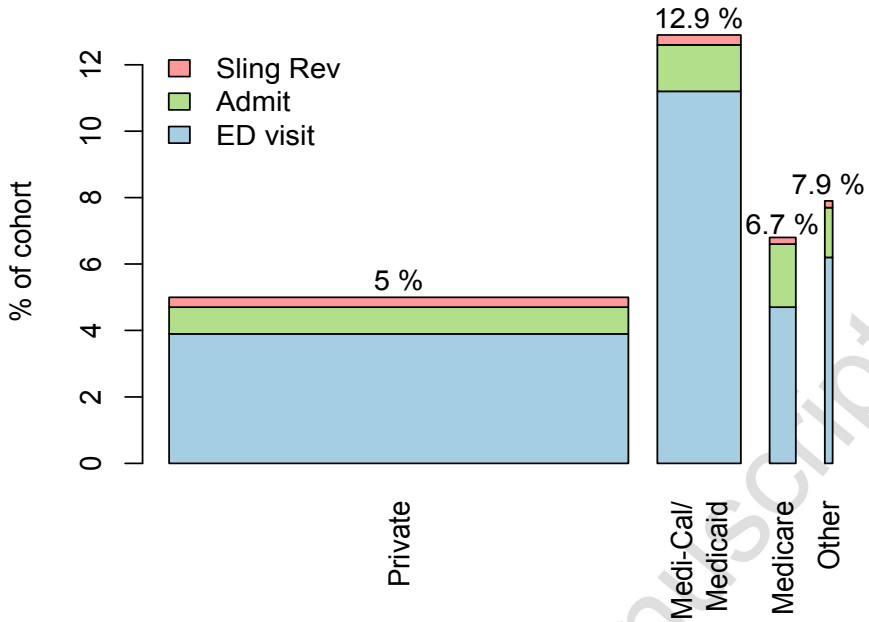
Figure 1: Overall 30-day unplanned hospital visits stratified by race, scaled to cohort size



Race	Total events within 30 days[1]	Emergency department visit[1]	Inpatient admission[1]	Sling revision[1]
Total cohort n=28,635	1,628 (5.7%)	1,257 (4.5%)	294 (1.0%)	77 (0.28%)
White n=18,230 (63.7%)	989 (5.4%)	737 (4.0%)	198 (1.1%)	54 (0.3%)
Hispanic n=6,577 (23.0%)	430 (6.5%)	357 (5.4%)	57 (0.9%)	16 (0.2%)
Black n=474 (1.7%)	50 (10.5%)	37 (7.8%)	10 (2.1%)	3 (0.6%)
Asian n=1,518 (5.3%)	71 (4.7%)	52 (3.4%)	15 (0.9%)	4 (0.3%)
Other n=1,836 (6.3%)	88 (4.8%)	74 (4.0%)	14 (0.8%)	0 (0.0%)
	p<0.01	**p=0.02**		

[1] **Number of patients (% of total cohort)**

Figure 2: Overall 30-day unplanned hospital visits stratified by insurance type, scaled by cohort size



Payer Type	Total events within 30 days [1]	Emergency department visit [1]	Inpatient admission[1]	Sling revision[1]
Total cohort n=28,635	1,628 (5.7%)	1,257 (4.5%)	294 (1.0%)	77 (0.28%)
Private n=22,798 (68.4%)	1148 (5.0%)	893 (3.9%)	193 (0.8%)	62 (0.3%)
Medicare n=4147 (14.5%)	281 (6.7%)	194 (4.7%)	77 (1.9%)	10 (0.2%)
Medicaid n=1300 (4.5%)	168 (12.9%)	146 (11.2%)	18 (1.4%)	4 (0.3%)
Other n=390 (1.4%)	31 (7.9%)	24 (6.2%)	6 (1.5%)	1 (0.2%)
	p<0.01	**p=0.02**		

[1] **Number of patients (% of total cohort)**

Table 1: Demographic characteristics of women undergoing sling placement in California

	n (%)	Age[1] (SD)	Smoker* (%)	HTN*,[2] (%)	DM*,[3] (%)	CAD/PVD*,[4] (%)	Income[5]
Total	28,365	54.7 (12.7)	2,679 (9.4%)	6,246 (21.8%)	1,655 (5.8%)	521 (1.8%)	$43,830
Payer							
Private	22,798 (68.4%)	52.4 (11.1)	2,144 (9.4%)	4,460 (19.7%)	1,100 (4.8%)	291 (1.3%)	$45,149
Medicare	4,147 (14.5%)	70.1 (9.4)	314 (7.6%)	1,462 (35.3%)	415 (10.0%)	202 (4.9%)	$42,424
Medicaid	1,300 (4.5%)	46.8 (10.3)	194 (14.9%)	256 (19.7%)	124 (9.5%)	19 (1.5%)	$36,307
Other	390 (1.4%)	54.0 (11.5)	27 (6.9%)	68 (17.4%)	16 (4.1%)	9 (2.3%)	$39,468
p-value		0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Race							
White	18,230 (63.7%)	56.3 (12.8)	2,071 (11.4%)	4,043 (22.2%)	842 (4.6%)	399 (2.2%)	$47,345
Hispanic	6,577 (23.0%)	50.6 (11.4)	395 (6.0%)	1,413 (21.5%)	579 (8.8%)	68 (1.0%)	$37,522
Black	474 (1.7%)	53.5 (11.8)	67 (14.1%)	160 (33.8%)	41 (8.6%)	8 (1.7%)	$39,135
Asian/PI	1,518 (5.3%)	55.6 (12.9)	54 (3.6%)	415 (27.3%)	122 (8.0%)	29 (1.9%)	$42,388
Other	1,836 (6.3%)	53.6 (11.6)	92 (5.0%)	215 (11.7%)	71 (3.9%)	17 (0.9%)	$43,511
p-value		0.02	<0.01	<0.01	<0.01	<0.01	<0.01

1-In years. Mean (Standard Deviation), 2-Hypertension, 3-Diabetes Mellitus type II, 4-History of coronary artery disease or peripheral vascular disease, 5- Median yearly income (of patient's home zipcode). *-Percentage is the proportion of payer type or race with that comorbidity.

Table 2: Multivariate model

Parameter	Multivariate OR (95% CI)	p-value
Payer		
Medicare	Reference	
Medicaid	1.53 (1.20-1.95)	p<0.01
Private	0.62 (0.52-0.73)	p<0.01
Other	1.12 (0.74-1.71)	p=0.60
Race		
White	Reference	
Black	1.80 (1.34-2.50)	p<0.01
Hispanic	1.10 (0.97-1.30)	p=0.15
Asian	0.80 (0.62-1.10)	p=0.13
Other	0.91 (0.71-1.18)	p=0.53
Comorbidity		
Hypertension	1.10 (0.98-1.30)	p=0.08
Diabetes Mellitus	1.30 (1.08-1.60)	p<0.01
CAD/PVD	1.20 (0.88-1.80)	p=0.08
Smoking	1.10 (0.97-1.40)	p=0.12
Facility Volume Quartile	1.00 (0.96-1.10)	p=0.60
Income Quartile[1]	1.00 (0.97-1.10)	p=0.60
Age (years)	0.99 (0.99-0.99)	p<0.01

1-Quantile based on patient's home zipcode median income (in relation to all zipcodes in our sample)