# Rates and Risk Factors for Future Stress Urinary Incontinence Surgery after Pelvic Organ Prolapse Repair in a Large Population-based Cohort in California

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**OBJECTIVES** To determine the rate and risk factors for future stress urinary incontinence (SUI) surgery in a large population-based cohort of previously continent women following pelvic organ prolapse (POP) repair without concomitant SUI treatment.

**METHODS** Data from the Office of Statewide Health Planning and Development were used to identify all women who underwent anterior, apical, or combined anteroapical POP repair without concomitant SUI procedures in the state of California between 2005 and 2011 with at least 1-year follow-up. Patient and surgical characteristics were explored for associations with subsequent SUI procedures.

**RESULTS** Of 41,689 women undergoing anterior or apical POP surgery, 1,504 (3.6%) underwent subsequent SUI surgery with a mean follow-up time of 4.1 years. Age (odds ratio [OR] 1.01), obesity (OR 1.98), use of mesh at the time of POP repair (OR 2.04), diabetes mellitus (OR 1.19), white race, and combined anteroapical repair (OR 1.30) were associated with increased odds of future SUI surgery.

**CONCLUSION** The rate of subsequent surgery for de novo SUI following POP repair on a population level is low. Patient and surgical characteristics may alter a woman's individual risk and should be considered in surgical planning. UROLOGY 123: 81–86, 2019. © 2018 Elsevier Inc.


De novo stress urinary incontinence (SUI) in previously continent women is a potential unintended consequence of pelvic organ prolapse (POP) repair. Anatomically, SUI after POP repair is thought to occur as a result of correction of urethral kinking due to prolapse. The Colpopexy and Urinary Reduction Efforts (CARE) trial and later the Outcomes Following Vaginal Prolapse Repair and Midurethral Sling (OPUS) trial reported high rates of de novo SUI after POP repair (43%-57%).[1,2] In order to prevent de novo SUI, some have advocated for prophylactic SUI treatment at the time of POP repair. Given that over 200,000 women undergo POP surgery annually in the United States,[3] the number of women who may potentially undergo a prophylactic SUI treatment at the time of POP surgery is significant.

Approximately half of preoperatively stress continent women will develop de novo SUI after POP surgery, meaning a significant proportion will remain continent.[1,2] Unfortunately, determining who may benefit most from a prophylactic SUI procedure is challenging, as the existing preoperative testing methods used to predict de novo SUI are unreliable.[4] Additionally, SUI treatments are not without risks of their own, including urinary retention, de novo urgency, and in some cases sling erosion/exposure. It is also worth noting that despite the large number of women who developed de novo SUI in the CARE and OPUS trials, only a small percentage choose to undergo future SUI surgery (~5% to 8%).[1,2]

The rate of subsequent SUI surgery after POP repair on a population level is unknown. In order to better understand postoperative de novo SUI, we examine the rates of subsequent SUI surgery following POP repair in a large and diverse population-based cohort in California. Further, we attempt to identify patient-specific risk factors for

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potentially undergoing subsequent SUI surgery, in whom prophylactic SUI surgery should be considered.

## MATERIALS AND METHODS

With approval from the California Protection of Human Subjects committee, we assessed nonpublic data from the California Office of Statewide Health Planning and Development from 2005 to 2011. In the Office of Statewide Health Planning and Development datasets, each individual has a unique identifier that allows longitudinal follow-up between encounters. We examined the Patient Discharge and Ambulatory Surgery datasets, which code for unique inpatient and ambulatory surgery visits, respectively. Together, the Patient Discharge and Ambulatory Surgery datasets cover every single nonfederal surgical encounter within the state of California. Each encounter includes up to 20 surgical procedure codes (the Ambulatory Surgery dataset utilizes Current Procedure Terminology (CPT), while the Patient Discharge dataset utilizes International Classification of Diseases, Ninth Edition (ICD-9) procedure codes) and up to 25 associated diagnosis codes (ICD-9). Additional information regarding patient demographics, race/ethnicity, age, patient comorbidities, and medical insurance status is also included.

All women who underwent anterior, apical, or anteroapical POP repair during the study period were identified. We defined the index case as the first POP repair for an individual during the study period. Women were excluded if they had a history of SUI surgery or a concomitant SUI procedure at the time of their index POP repair. Subjects were also excluded if their index POP repair involved a sling revision/excision (CPT 52827), urethrolysis (CPT 53500 for outpatient setting), or release of urethral stricture (ICD-9 code 58.5 for inpatient procedure).

The compartment or compartments of repair were noted for all POP surgeries (anterior, apical, or posterior). Those who had a posterior repair alone were excluded; however, women undergoing concomitant posterior repair at the time of anterior and/or apical repair were included. We identified all women who had vaginal mesh placed by CPT 57267 for outpatient procedures and any ICD-9 POP repair procedure code that included mention of a graft or prosthesis for the inpatient group. We then identified any member of this cohort who subsequently underwent a SUI surgical procedure (Supplementary appendix Table 1).

### *Statistical Analysis*

Women who had subsequent SUI surgery during the study period made up the cohort for the risk factor analysis. Multivariate analysis was performed using logistic regression models. Our dependent variable was subsequent surgery for SUI and our independent variables included the patient's demographics (age, race/ethnicity, and payer status), medical comorbidities, and the characteristics of the index POP repair (compartment(s) of repair and use of mesh). Statistical analysis was performed with R 3.5.0 software. A two-sided $P$ value of .05 indicated statistical significance.

## RESULTS

A total of 41,689 women underwent anterior and/or apical prolapse repair without a concomitant or identified prior SUI procedure during the study period. The mean age was 59.0 years. Almost half of the study cohort (46.6%) underwent anterior repair alone, while the other half underwent apical repair alone (28.0%) or combined anteroapical repair (25.4%) at the time of index surgery. The cohort was ethnically diverse, with white, Hispanic, Asian, and black race/ethnicities comprising 64.2%, 14.6%, 6.0%, and 2.8%, respectively (Table 1). The overall follow-up time of the group was 4.1 (±1.7) years.

During the study period, a total of 1504 women (3.6%) had a subsequent SUI procedure at a mean time of 1.4 years after their original POP repair. The majority of subsequent SUI repairs occurred in the outpatient setting and were midurethral slings (97%). Those with a subsequent SUI procedure were slightly older (61.3 vs 58.9 years), were more likely to be white (72.3% vs 63.9%), were less likely to have a private payer (55.9% vs 58.6%), and had higher rates of medical comorbidities compared to those who did not undergo subsequent SUI procedure ($P < .05$ for all, Table 2). At the time of index POP repair, women who had a subsequent SUI procedure were more likely to have undergone a combined anterior and apical repair (34.8% vs 25.1%), and less likely to have undergone anterior repair alone (39.8% vs 46.8%) or apical repair alone (25.4% vs 28.1%) compared to those who did not have a subsequent SUI procedure ($P < .05$ for all). Additionally, those undergoing a subsequent SUI surgery were noted to have higher rates of mesh use during POP repair (24.5% vs 12.3%, $P < .01$), were more likely to be diagnosed with diabetes mellitus (11.9% vs 9.8%, $P < .01$), and were more likely to carry a diagnosis of obesity (4.2% vs 2.2%, $P < .01$).

On multivariate modeling, we found that increasing age (odds ratio [OR] 1.01), combined anterior and apical repair (compared to anterior repair alone) (OR 1.30), use of mesh for POP repair (OR 2.04), diabetes mellitus (OR 1.19), and obesity (OR 1.98) were significant positive predictors of undergoing a subsequent SUI surgery ($P < .05$ for all) (Table 3). Black, Asian, and women of other ethnic groups were less likely to undergo a

**Table 1.** Patients' characteristics

| | Total (n = 41,689) | % |
|---|---|---|
| Age (Mean, Years) | 59.0 | – |
| Race | | |
| White | 26,763 | 64.2 |
| Black | 1171 | 2.8 |
| Hispanic | 6106 | 14.6 |
| Asian | 2485 | 6.0 |
| Other | 5164 | 12.4 |
| Comorbidity | | |
| DM | 4105 | 9.8 |
| Obesity | 940 | 2.3 |
| Payer | | |
| Private | 24,401 | 58.5 |
| Medicare | 13,844 | 33.2 |
| Medicaid | 2766 | 6.6 |
| Other | 678 | 1.6 |
| Compartment of repair | | |
| Anterior only | 19,409 | 46.6 |
| Apical only | 11,686 | 28.0 |
| Combination apical and anterior | 10,594 | 25.4 |
| Concomitant posterior repair | 24,591 | 59.0 |
| Use of mesh at index repair | 530 | 12.7 |
| Mean follow-up time (years) | 4.1 | – |

**Table 2.** Comparison of patients who underwent subsequent SUI procedure

| | No Subsequent SUI Procedure (n = 40,185) | Subsequent SUI Procedure (n = 1,504) | *P* Value |
|---|---|---|---|
| Age (Mean, Years) | 58.9 | 61.3 | < .01 |
| Race | | | |
| White | 25,675 (63.9%) | 1088 (72.3%) | < .01 |
| Black | 1149 (2.9%) | 22 (1.5%) | < .01 |
| Hispanic | 5900 (14.7%) | 206 (13.7%) | .31 |
| Asian | 2432 (6.0%) | 53 (3.5%) | < .01 |
| Other | 5029 (12.5%) | 135 (9.0%) | < .01 |
| Comorbidity | | | |
| DM | 3926 (9.8%) | 179 (11.9%) | < .01 |
| Obesity | 877 (2.2%) | 63 (4.2%) | < .01 |
| Payer | | | |
| Private | 23,561 (58.6%) | 840 (55.9%) | .03 |
| Medicare | 13,280 (33.1%) | 564 (37.5%) | < .01 |
| Medicaid | 2690 (6.7%) | 76 (5.0%) | < .01 |
| Other | 654 (1.6%) | 24 (1.6%) | .92 |
| Compartment of repair | | | |
| Anterior only | 18,811 (46.8%) | 598 (39.8%) | < .01 |
| Apical only | 11,303 (28.1%) | 383 (25.4%) | .03 |
| Combination apical and anterior | 10,071 (25.1%) | 523 (34.8%) | < .01 |
| Concomitant posterior repair | 23,690 (59.0%) | 901 (59.9%) | .48 |
| Use of mesh at index repair | 4941 (12.3%) | 368 (24.5%) | < .01 |

subsequent SUI procedure when compared to White or Hispanic race/ethnicity (Table 3, Fig. 1).

## COMMENT

In the current study, we observe a low rate (3.6%) of subsequent SUI surgery in over 40,000 women undergoing anterior and/or apical POP repair without concomitant or prior SUI surgery. We further identify several risk factors (concurrent mesh use in the POP repair, combined anterior and apical POP repair, obesity, diabetes, increasing age and a woman's race/ethnicity) that affect future rates of SUI surgery.

To date, the role of concomitant prophylactic SUI procedures at the time of POP repair remains a topic of debate. In the CARE trial, a high rate (57.4%) of de novo SUI was observed in women who did not undergo concomitant SUI surgery during POP repair and was often cited in support of prophylactic SUI surgery.[1] However, de novo SUI after POP repair is a quality of life issue that can vary in severity and individual bother. This was observed in the CARE trial where at 24 months follow-up, less than half of women who met criteria for de novo SUI actually reported bothersome SUI symptoms (57.9% vs 25.2%, respectively).[5] Further, the rate of subsequent SUI treatment in the control group was even lower (7.9%). Similar findings were reported in the OPUS trial where almost half of the sham group was diagnosed with de novo SUI, but only 4.7% went on to have subsequent midurethral sling surgery.[2] Rates of subsequent SUI surgery in small single center retrospective reviews vary from 2.8% to 34%, possibly reflective of institutional practices.[6,7] By including all cases performed in the state of California during our study period, we avoid this potential issue. Our finding of a low rate of subsequent SUI surgery (3.6%) in a large, ethnically diverse population-based cohort across multiple health care settings is similar to large multicenter trials.[1,2] This large discrepancy in the number of women diagnosed with de novo SUI and the number of women ultimately treated is concerning, and further raises questions as to whether a prophylactic SUI procedure should be performed with all prolapse repairs, when half will not develop SUI symptoms.

**Table 3.** Multivariate predictors of subsequent anti-incontinence procedures after POP repair

| Variable | Odds Ratio | 95% CI | *P* Value |
|---|---|---|---|
| Patient Age | 1.01 | 1.00-1.02 | < .01 |
| Race | | | |
| White | Reference | Reference | Reference |
| Hispanic | 0.89 | 0.76-1.04 | .13 |
| Black | 0.48 | 0.30-0.72 | < .01 |
| Asian | 0.67 | 0.56-0.81 | < .01 |
| Other | 0.55 | 0.41-0.71 | < .01 |
| Comorbidities | | | |
| Obesity | 1.98 | 1.51-2.57 | < .01 |
| Diabetes mellitus | 1.19 | 1.01-1.41 | .03 |
| Payer | | | |
| Medicare | Reference | Reference | Reference |
| Private | 1.11 | 0.96-1.29 | .15 |
| Medicaid | 1.04 | 0.79-1.36 | .76 |
| Other | 1.18 | 0.75-1.78 | .45 |
| Compartment of repair | | | |
| Anterior only | Reference | Reference | Reference |
| Apical only | 0.95 | 0.82-1.09 | .44 |
| Combination apical and anterior | 1.30 | 1.14-1.48 | < .01 |
| Concomitant posterior repair | 0.95 | 0.85-1.07 | .40 |
| Use of mesh at index repair | 2.04 | 1.79-2.32 | < .01 |

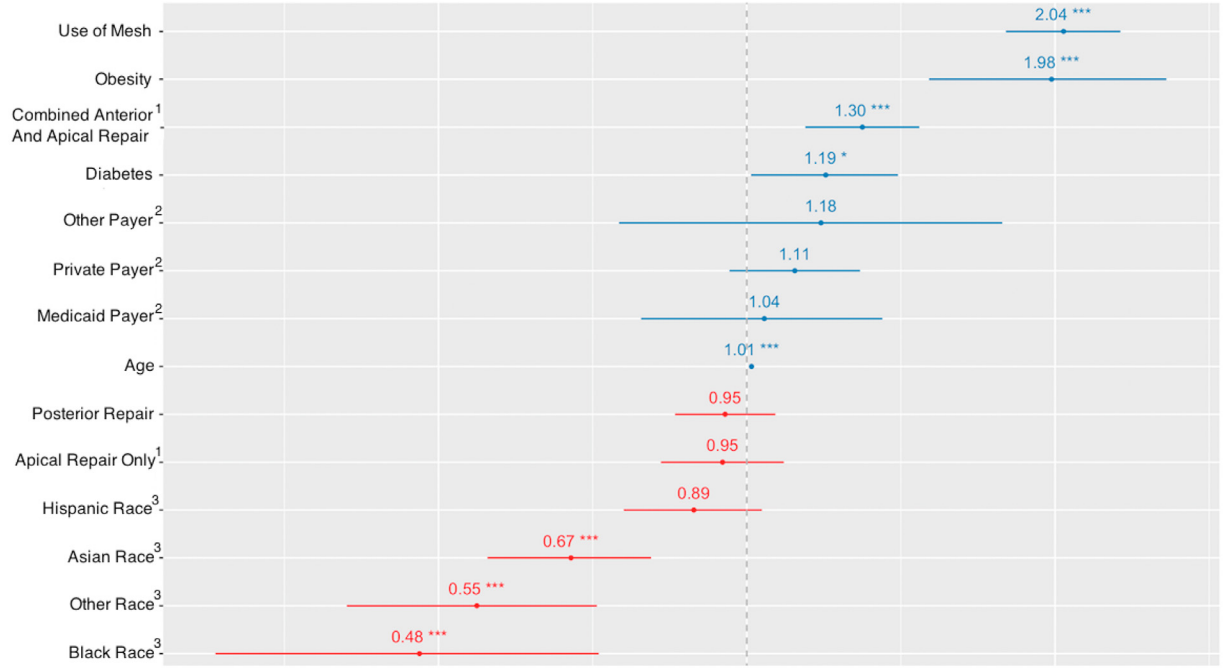


**Figure 1.** Predictors of Subsequent Anti-Incontinence Procedures after POP Repair. *$P$ value less than .05. ***$P$ value less than .01. 1— Reference for anterior and/or apical repair is anterior repair only. 2 — Reference for payer is Medicaid. 3 — Reference for race is Caucasian. Above is the multivariate adjusted odds of factors predicting a future anti-incontinence procedure after index POP repair. The blue intervals to the right of 1 represent factors positively associated with undergoing an anti-incontinence procedure, while the red intervals to the left represent negative associations. The width of the bar indicates the 95% confidence interval of the association. (Color version available online).

As a means to improve upon prophylactic SUI treatment strategies, we sought to characterize variables associated with future SUI surgery. Our attempt to identify risk factors for de novo SUI is not unique. The Pelvic Floor Disorders Network used a subset of 457 patients from the OPUS trial to create a risk calculator to predict the probability of de novo SUI following anterior and/or apical repair and counsel prospective surgical patients on their risk of de novo SUI.[8] They identified younger age at surgery, higher parity, higher body mass index, a positive preoperative stress test, preoperative urge incontinence, diabetes, and the presence of SUI with preoperative prolapse reduction as risk factors for SUI in previously continent women. While valuable, this model was based on a nonethnically diverse population (white population — 85%), a highly select population from academic centers with fellowship-trained surgeons, and a moderate sample size (n = 457). Further, they did not specifically aim to predict rates of bothersome SUI warranting future SUI surgery. By comparison, our cohort is large (n = 41,689), racially/ethnically diverse, and includes women treated at public, private, and academic medical centers with long-term follow-up (mean follow-up time of 4.1 years) and, therefore, may be more generalizable.

Although other studies have evaluated risk factors for developing SUI following POP repair, the role of race/ethnicity in subsequent sling surgery has not been studied.[9-13] We find that race/ethnicity is a significant predictor, with white and Hispanic women having higher odds of undergoing a subsequent SUI surgery, whereas black, Asian, and other ethnicities have a significantly lower likelihood of subsequent SUI surgery. The underlying cause of this difference is not entirely clear. The potential causes of lower SUI surgery rates in minorities may include socioeconomic factors such as access to care or may also include a genetic component. Interestingly, payer type was not predictive of subsequent SUI procedure in our study, which may further support the role of genetics.[14-16] Other barriers to care that may also affect a woman's decision to pursue subsequent SUI surgery can include reluctance to undergo further surgery, inconvenience, language/cultural differences, lack of healthcare knowledge, and poor rapport with the provider, though we are unable to evaluate these secondary to our study design.[17]

We identified obesity, diabetes mellitus, and use of mesh at time of POP repair as risk factors for de novo SUI. Obesity may be associated with SUI due to increased force generated against the anterior vaginal wall resulting in increased frequency and volume of SUI.[12] Diabetes may contribute as a result of microvascular injury, resulting in weakened connective tissue support, neural damage resulting in a weakened urethral sphincter, decreased bladder contractility, and higher volumes of urine production related to glycosuria.[18] The mechanism by which mesh placement at the time of POP repair increases the risk of postoperative SUI is not well understood. One suggested mechanism relates to anterior wall mesh shrinkage

during wound healing, which may result in excessive tensioning of the urethrovesical junction.[10] Further, mesh placement may require aggressive paravesical dissection, resulting in tissue damage and denervation, with resultant intrinsic sphincter deficiency.[10,13] Anterior repairs have also been identified as a risk factor for SUI, independent of mesh use. This is believed to be due to the unkinking of the urethra during repair, thereby unmasking intrinsic sphincter deficiency.[11] Along these lines, we found that combined anteroapical repair is associated with a higher risk of subsequent SUI procedure than anterior or apical alone. While our study lacks specific POP staging data, we suspect that women undergoing combined anteroapical POP repair likely have a more significant degree of prolapse than those undergoing anterior or apical repair alone.[19]

Finally, we found that increasing age is associated with subsequent SUI procedure, though this association is weak (OR 1.01, 95% CI 1.00-1.02). The role of age on de novo SUI risk is mixed in the literature. Some studies suggest younger women are at increased risk of de novo SUI, others suggest older women are at a higher risk, and still others show that age is unrelated.[10,11,13]

To our knowledge, this is the first study to evaluate rates of subsequent sling procedures after POP repair on a population level. They confirm the low rates observed in clinical trials.[1,2] In addition, multiple risk factors were identified in this large, diverse population, which can be used to counsel patients who are considering concomitant sling surgery. However, we acknowledge that, though these risk factors are significant, even the strongest predictor (use of mesh with odds of 2.04) will only increase an individual's risk of subsequent SUI procedure from 3.6% to 7.2%. Therefore, even when risk factors are accounted for, the rates of subsequent SUI procedure remains low, and therefore, a staged procedure, if needed, may be the optimal approach.

Inherent to most large administrative data sets, we are limited in our ability to evaluate granular data, such as physical exam findings, cough stress test results, and preoperative urinary incontinence questionnaires. Further, our use of future surgery for SUI omits women with bothersome SUI who chose to forego SUI surgery or opt for nonsurgical treatments such as injection of periurethral bulking agents in the office setting, the rates of which are not captured by this database. However, we believe subsequent SUI surgery is a strong end point and may provide a clearer picture of true patient bother from SUI than simply the presence of de novo SUI for several reasons. First, only patients with a sufficient degree of bother are likely to choose to undergo a subsequent surgery, and those with mild to moderate SUI may be well managed with nonsurgical treatments. Also, while women are generally able to accurately self-report urinary incontinence, they are less likely to differentiate between SUI, urgency incontinence and stress induced urgency incontinence.[20,21]

The strengths of our study include a large, population-based cohort of over 40,000 women, which to our knowledge is the largest study of subsequent SUI surgery rates and associated risk factors following POP surgery in the literature. The follow-up time of 4.1 years is substantially longer than other published studies. Our study cohort is ethnically diverse and includes the entire state of California rather than a specific region. Thus, we believe our results are more applicable to US populations than small select cohorts in the clinical trials. Additionally, by using a statewide database rather than an institutional cohort, we are more likely to have captured all subsequent surgeries as compared to single institution studies. Although patients may change facilities for subsequent surgeries, our group has previously shown that they are likely to remain within the state of California[22] and we would expect a low likelihood of loss of follow-up.

## CONCLUSION

While the rates of de novo SUI are high in the published literature, the rates of future SUI surgery are low, demonstrated by only a small percentage of women undergoing subsequent SUI surgery after POP repair. Prophylactic SUI surgery at the time of POP repair can be considered in individual cases after consideration of a woman's risk factors specific to her risk of undergoing future SUI surgery.

## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.urology.2018.09.008.

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