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RESEARCH PAPER

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Short-term urinary catheter usage in endoscopic skull base surgery and impact on urinary tract infection and reconstructive outcomes

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Abstract

Objectives: Hospital-acquired catheter-associated urinary tract infections (UTIs) have been regarded as preventable adverse events, yet their risk in endoscopic skull base surgery (ESBS) has not been well described despite common use. We determine the incidence of UTI following ESBS and identify contributing clinical factors.

Methods: Retrospective review was conducted for a cohort of 229 consecutive adult patients who underwent endoscopic endonasal surgery for treatment of any skull base pathology between July 2018 and June 2022 at a tertiary academic skull base surgery program. Postoperative UTI comprised the primary outcome. Independent variables included patient demographics, use and length of urinary catheterization, and pre-existing genitourinary conditions.

Results: Nosocomial UTIs were identified in 1.3% (3/229) of patients, occurring on postoperative days 2, 9, and 14, respectively; all were catheter-associated. Overall, 86.0% (197/229) of patients received urinary catheters (mean duration 2.2 ± 1.8 days). Compared to those without, patients with UTI were older (70.0 ± 15.4 vs. 52.2 ± 16.8 years, $p = 0.034$), had lengthier stays (94.7 ± 126.8 vs. 5.9 ± 8.4 days, $p < 0.001$), and had prolonged catheterizations (9.3 ± 5.5 vs. 2.1 ± 1.5 days, $p < 0.001$). Preoperative genitourinary conditions were also associated with UTI development, namely, chronic urinary retention/obstruction (66.7% vs. 4.0%, $p = 0.006$), urinary incontinence (66.7% vs. 6.2%, $p = 0.013$), prostate disease (100.0% vs. 17.8%, $p = 0.035$), and renal dysfunction (100.0% vs. 9.7%, $p = 0.001$). Among intraoperative cerebrospinal fluid leak patients, postoperative CSF leak incidence was not associated with catheter use versus nonuse (3.3% vs. 12.5%, $p = 0.276$).

Conclusion: Although UTIs are uncommon in ESBS patients, advanced age, length of stay, duration of indwelling urinary catheterization, and comorbid genitourinary conditions may elevate risk.

KEYWORDS
catheter-related infections, endoscopic endonasal approach, iatrogenic disease, postoperative complications, skull base neoplasms, skull base surgery, urinary catheterization, urinary tract infections

Key points

- In a single-center cohort of endoscopic skull base surgery patients, nosocomial postoperative urinary tract infections (UTI) were uncommon (1.3%).
- Advanced age, length of stay, duration of indwelling urinary catheterization, and comorbid genitourinary conditions elevated UTI risk.
- Among patients experiencing intraoperative cerebrospinal fluid (CSF) leak, postoperative CSF leak incidence was not associated with urinary catheter use versus nonuse.

INTRODUCTION

Urinary tract infections (UTIs) constitute 40% of all nosocomial infections, and complicate an estimated 1%–2% of operations in the United States.[1–3] UTIs are associated with greater postoperative morbidity, increased length of hospitalization, and higher risk of readmission.[1,4,5] Considered preventable adverse events, hospital-acquired UTIs have become a major focus of healthcare quality improvement projects under the Joint Commission and Centers for Medicare and Medicaid Services (CMS).[6,7]

Prevention of postoperative UTIs must begin with an investigation of risk so that interventions can be optimized for the population of interest. Previous research has identified a number of risk factors in different surgical populations, including advanced age, female sex, diabetes mellitus, congestive heart failure, and pre-existing renal failure.[8–12] The relationship between UTIs and indwelling urinary catheters is particularly well documented, with the duration of catheterization widely reported as the strongest predictor of UTI development in hospitalized patients.[13–15]

In the context of endoscopic skull base surgery (ESBS) and management of cerebrospinal fluid (CSF) leaks, indwelling urinary catheters have traditionally been routinely employed to prevent postoperative bladder dysfunction. Elevated intrabdominal pressure, a potential consequence of urinary retention and associated straining, has been demonstrated to correlate with the risk of increased intracranial pressure through both mechanical and Cushing reflex components.[16–18] They may also promote compliance with bedrest precautions by reducing patient mobility and facilitating accurate fluid balance assessment after pituitary surgery, where transient endocrinopathy is not uncommon.[19–21] Thus, urinary catheterization has become ingrained in the traditional canon of conservative CSF leak management, along with bedrest, lumbar drainage, and stool softeners.[19] Although national data is lacking for UTI incidence following skull base surgery, catheter-associated (CAUTI) or not, recent analyses of the National Surgical Quality Improvement Project report that UTIs complicate approximately 1.5% of transsphenoidal pituitary resections.[13,19,22]

ESBS practice patterns vary widely according to the expertise of individual surgeons and evidence-based clinical guidelines remain limited.[19,23] Few studies have investigated the ways in which patient characteristics and perioperative factors influence surgical complications, and none have described risk factors for postoperative UTI.[19] Therefore, this study was designed with two main objectives: (1) to determine the incidence of UTI following ESBS at a tertiary academic medical center and (2) to identify UTI risk factors within this patient population to guide future clinical practice.

MATERIALS AND METHODS

Retrospective chart review

Following approval by the University of California, Irvine Institutional Review Board, retrospective chart review was conducted at a single-center, tertiary academic medical center. Consecutive adult (≥18 years) patients who underwent a primarily endoscopic endonasal approach for any skull base pathology between July 2018 and August 2022 were screened and patients without an active UTI diagnosis upon presentation were included. Pediatric patients were excluded. The joint skull base surgery team consisted of one rhinologist (E. C. K.) and four neurosurgeons with a shared consensus regarding the technical and postoperative principles of skull base surgery. Indwelling urinary catheterization was routinely performed at our institution as a conventional measure for bladder dysfunction prevention in the context of intraoperative anesthetics, for monitoring fluid status in the setting of possible diabetes insipidus following sellar/parasellar surgery, and rehabilitation of function given postoperative analgesics and immobility as part of anticipated bedrest for postoperative precautions. Standard postoperative infection prophylaxis, largely directed toward the surgical site (e.g., sinonasal tract), consists predominantly of an oral amoxicillin-clavulanate regimen, which is substituted by oral trimethoprim-sulfamethoxazole or clindamycin in the presence of penicillin allergy.

Nursing and inpatient progress notes were identified in an electronic medical record (Epic Systems) and reviewed for occurrence of UTI in the immediate postoperative period, which represented the primary study outcome. Secondary outcomes of interest included postoperative day of UTI diagnosis, predominant organism cultured, and subsequent culture-directed antibiotic received. Independent demographic and clinicopathological variables extracted included age, race and ethnicity, sex, body mass index, length of stay in-hospital, placement and duration of an indwelling urinary catheter, and postoperative prophylactic oral antibiotic received. Known preoperative diagnoses of genitourinary comorbidities were also examined as independent study variables, and encompassed documented chronic urinary retention or obstruction, urinary incontinence, prostate disease, previous UTIs, renal dysfunction, and diabetes mellitus with chronic complication.

Statistical analysis

All statistical analyses were performed using R (version 4.0.5; The R Foundation for Statistical Computing) in RStudio (version 1.4.1106) and $p < 0.05$ were considered statistically significant. Independent samples *t* tests and Fisher's exact tests were applied to comparisons of continuous and categorical independent variables, respectively, by urinary catheterization use versus nonuse and by postoperative UTI status. Univariate Firth's bias-reduced logistic regression was also performed using the profile penalized log-likelihood method to generate predicted coefficients and 95% confidence intervals (CI) of the primary outcome incorporating the input of independent demographic and clinicopathological variables of interest.[24,25] Variables found to be significantly associated with the primary study outcome on univariate analysis qualified for inclusion as covariates in a multivariable regression model. Secondary outcomes describing the nature and treatment of UTI incidences were qualitatively summarized.

RESULTS

A total of 237 consecutive patients were screened. Three patients with active UTI on presentation and five pediatric patients were subsequently excluded to produce a final cohort of 229 patients. The mean age overall was 52.4 ± 16.8 years (range: 18–89) and female patients comprised 48.9% (112/229) of the study population. 86.0% (197/229) of all patients received postoperative urinary catheterizations for the mean length of 2.2 ± 1.8 days (range: 1–15). Pathology represented the only significant factor driving urinary catheter placement, with pituitary adenomas making up the majority of catheterized patients (62.4%, 123/197) but not their noncatheterized counterparts (21.9%, 7/32) ($p < 0.001$). Complete demographic and clinicopathological characteristics are summarized by urinary catheterization status in Table 1.

During the immediate postoperative course, UTIs were diagnosed in 1.3% (3/229) of patients included for analysis and occurred on postoperative days 2, 9, and 14, respectively. All were catheter-associated. Cultured microorganisms include *Escherichia coli*, *Candida*, and *Enterococci* species and were treated successfully with ceftriaxone, fluconazole, and metronidazole, respectively, with no long-term sequelae. Compared to those without, patients with postoperative UTI had lengthier stays (94.7 ± 126.8 vs. 5.9 ± 8.4 days, $p < 0.001$) and prolonged catheterizations (9.3 ± 5.5 vs. 2.1 ± 1.5 days, $p < 0.001$). Notably, no significant difference in urinary catheter utilization was found between UTI versus no UTI cohorts (100.0% vs. 85.8%, $p > 0.999$). A preoperative history of genitourinary conditions was also associated with UTI development, namely, chronic urinary retention/obstruction (66.7% vs. 4.0%, $p = 0.006$), urinary incontinence (66.7% vs. 6.2%, $p = 0.013$), prostate disease (100.0% vs. 17.8%, $p = 0.035$), and renal dysfunction (100.0% vs. 9.7%, $p = 0.001$) (Table 2). Among patients with intraoperative CSF leaks ($n = 130$), postoperative CSF leak incidence was not associated with indwelling catheter use versus nonuse (3.3% vs. 12.5%, $p = 0.276$).

On univariate penalized-likelihood logistic regression, postoperative management variables associated with UTI included length of stay in days (coefficient (B) [95% CI] = 0.026 [0.012, 0.107]) and duration of urinary catheterization in days (0.537 [0.266, 0.929]) (Table 3). Preoperative history significant for chronic urinary retention or obstruction (3.642 [1.534, 6.107]), urinary incontinence (3.196 [1.116, 5.636]), prostate disease (3.121 [0.567, 8.062]), previous UTI (2.620 [0.161, 4.739]), and renal dysfunction (4.153 [1.775, 9.066]) were similarly associated with UTI incidence on univariate analysis. Overall, routine postoperative urinary catheterization was not significantly associated with UTI (0.157 [−2.210, 5.067]). On multivariable analysis, no included covariate independently predicted postoperative UTI.

DISCUSSION

According to a recent evidence-based review by Abiri et al.,[19] no dedicated studies on postoperative urinary catheter use exist in the current ESBS literature despite their pervasive use. In this single-center tertiary care academic center cohort of 229 patients who underwent ESBS, routine urinary catheterization was demonstrated to be relatively safe, with CAUTI identified in a paucity (1.3%) of patients. Compared with patients who did not develop CAUTI, these patients were associated with advanced age, prolonged hospital admission, and longer duration of catheterization. Patients with CAUTI were also more likely to have pre-existing genitourinary conditions such as documented chronic urinary retention or obstruction, incontinence, or renal dysfunction. However, none of these factors were independently predictive of postoperative UTI, likely due to low incidence overall. Notably, the use of indwelling catheters did not affect the incidence of postoperative CSF leak. Thus, the current study suggests that, though low in the present cohort, the risk of CAUTI should be more carefully considered given the practice of such routine urinary catheterization for the ESBS population, particularly when extended catheterization and other relevant risk factors are present.

TABLE 1 Demographic and clinicopathologic characteristics of the study cohort by postoperative urinary catheterization.

Characteristics	Urinary catheter (*n* = 197)	No urinary catheter (*n* = 32)	*p* Value
Age (years, mean ± SD)	51.9 ± 16.6	55.7 ± 18.0	0.238
≥65 [*n* (%)]	47 (23.9)	11 (34.4)	0.387
50–64 [*n* (%)]	67 (34.0)	8 (25.0)	
<50 [*n* (%)]	83 (42.1)	13 (40.6)	
Race [*n* (%)]			
Non-Hispanic White	76 (38.6)	11 (34.4)	0.848
Hispanic	76 (38.6)	12 (37.5)	
Black/African American	7 (3.6)	1 (3.1)	
Asian	33 (16.8)	8 (25.0)	
AIAN	1 (0.5)	0 (0)	
Other	4 (2.0)	0 (0)	
Sex [*n* (%)]			
Female	98 (49.7)	14 (43.8)	0.529
Male	99 (50.3)	18 (56.3)	
BMI (kg/m^2, mean ± SD)	30.0 ± 8.1	28.3 ± 7.0	0.268
Pathology [*n* (%)]			
Pituitary adenoma	123 (62.4)	7 (21.9)	<0.001*
Rathke cleft cyst	18 (9.1)	1 (3.1)	
Meningioma	10 (5.1)	0 (0)	
Craniopharyngioma	13 (6.6)	0 (0)	
Chordoma	2 (1.0)	0 (0)	
Sinonasal malignancy	4 (2.0)	6 (18.8)	
Primary CSF leak	19 (9.6)	4 (12.5)	
Other	8 (4.1)	14 (43.8)	
Length of stay (days, mean ± SD)	7.6 ± 19.0	3.8 ± 3.9	0.257

Abbreviations: AIAN, American Indian and Alaska Native; BMI, body mass index; CSF, cerebrospinal fluid leak; SD, standard deviation.
*$p < 0.05$.

A traditional rationale for routine catheter use in these patients is the prevention of straining associated with urinary retention, which may trigger shifts in intracranial pressure and disruption of skull base defect healing through both mechanical processes as well as the Cushing reflex causing vasopressin release.[16–18] Another notable benefit is the facilitation of timely monitoring and response for fluid status changes as a result of transient endocrinopathy during the postoperative period particularly following resection of pituitary masses.[19–21] Finally, indwelling urinary catheters contribute to the prevention of postoperative bladder dysfunction and facilitation of adherence to bedrest recommendations.[19] However, given that urinary catheterization did not appear to affect key skull base reconstruction outcomes in the present cohort, this study may provide evidence for increased stewardship and greater efforts toward selective use and reduced duration of catheterization in the setting of ESBS postoperative management as the first dedicated investigation on this topic.

Postoperative UTI and CAUTI are largely preventable causes of significant morbidity, prolonged hospital stay, increased healthcare costs, and heightened risk of mortality in hospitalized patients.[26,27] Several other studies have described postoperative rates of UTI and CAUTI in neurosurgery and otolaryngology patients, but none have analyzed these outcomes in patients undergoing ESBS.[4,14,19,28–30] Our reported postoperative CAUTI incidence of 1.3% was comparable with rates described in prior literature. A recent retrospective single-center case-control study in a neurointensive care unit reported CAUTI incidence at 1.5%.[28] Similarly, in two distinct studies of head and neck free flap surgery cohorts, postoperative UTI rates were 2.0%–2.1% with CAUTI incidence at 0.56%–0.98%.[4,30] Our findings also largely aligned with published literature on risk factors

TABLE 2 Demographics, treatment, and preoperative conditions comparisons of endoscopic skull base surgery patients by postoperative UTI status.

Items	UTI ($n = 3$)	No UTI ($n = 226$)	p Value
Age (years, mean ± SD)	70.0 ± 15.4	52.2 ± 16.8	0.068
≥65 [n (%)]	2 (66.7)	56 (24.8)	0.190
50–64 [n (%)]	1 (33.3)	74 (32.7)	
<50 [n (%)]	0 (0)	96 (42.5)	
Race [n (%)]			
Non-Hispanic White	2 (66.7)	85 (37.6)	0.791
Hispanic	0 (0)	88 (38.9)	
Black/African American	0 (0)	8 (3.5)	
Asian	1 (33.3)	40 (17.7)	
AIAN	0 (0)	1 (0.4)	
Other	0 (0)	4 (1.8)	
Sex [n (%)]			
Female	1 (33.3)	111 (49.1)	>0.999
Male	2 (66.7)	115 (50.9)	
BMI (kg/m^2, mean ± SD)	32.9 ± 4.3	29.7 ± 8.0	0.494
Length of stay (days, mean ± SD)	94.7 ± 126.8	5.9 ± 8.4	<0.001*
Indwelling urinary catheter			
Yes [n (%)]	3 (100.0)	194 (85.8)	>0.999
No [n (%)]	0 (0)	32 (14.2)	
Duration (days, mean ± SD)	9.3 ± 5.5	2.1 ± 1.5	<0.001*
Postoperative prophylactic antibiotic			
Oral amoxicillin-clavulanate	3 (100.0)	188 (83.2)	>0.999
Other oral antibiotic	0 (0)	38 (16.8)	
Urinary retention/obstruction			
Yes	2 (66.7)	9 (4.0)	0.006*
No	1 (33.3)	217 (96.0)	
Urinary incontinence			
Yes	2 (66.7)	14 (6.2)	0.013*
No	1 (33.3)	212 (93.8)	
Prostate disease			
Yes	2 (100.0)	21 (17.8)	0.035*
No	0 (0)	97 (82.2)	
Past UTI			
Yes	1 (33.3)	9 (4.0)	0.126
No	2 (66.7)	217 (96.0)	
Renal dysfunction			
Yes	3 (100.0)	22 (9.7)	0.001*
No	0 (0)	204 (90.3)	

(Continues)

TABLE 2 (Continued)

Items	UTI ($n = 3$)	No UTI ($n = 226$)	p Value
DM2 w/chronic complication			
Yes	1 (33.3)	14 (6.2)	0.185
No	2 (66.7)	212 (93.8)	

Abbreviations: AIAN, American Indian and Alaska Native; BMI, body mass index; DM2, diabetes mellitus type 2; SD, standard deviation; UTI, urinary tract infection.

*$p < 0.05$.

TABLE 3 Predictors of postoperative urinary tract infection status: univariate and multivariable penalized-likelihood Logistic regression analysis.

Covariate	Univariate		Multivariable	
	B (95% CI)	p Value	B (95% CI)	p Value
Age	0.071 (−0.005, 0.177)	0.072		
<65 years	Reference			
≥65 years	1.185 (−0.167, 3.254)	0.088		
Race				
Other	Reference			
Non-Hispanic White	1.015 (−1.019, 3.418)	0.320		
Sex				
Male	Reference			
Female	−0.476 (−2.878, 1.557)	0.643		
BMI	0.051 (−0.064, 0.108)	0.243		
Length of stay (days)	0.026 (0.012, 0.107)	0.001*	0.000 (−0.026, 0.080)	0.984
Urinary catheterization				
No	Reference			
Yes	0.157 (−2.210, 5.067)	0.917		
Urinary catheter duration (days)	0.537 (0.266, 0.929)	<0.001*	0.133 (−0.229, 0.832)	0.479
Postoperative prophylactic antibiotic				
Other oral antibiotic	Reference			
Oral amoxicillin-clavulanate	0.357 (−2.005, 5.266)	0.806		
Urinary retention/obstruction				
No	Reference		Reference	
Yes	3.642 (1.534, 6.107)	0.001*	1.631 (−7.076, 9.947)	0.536
Urinary incontinence				
No	Reference		Reference	
Yes	3.196 (1.116, 5.636)	0.004*	1.738 (−6.215, 7.396)	0.487
Prostate disease				
No	Reference		Reference	
Yes	3.121 (0.567, 8.062)	0.016*	0.173 (−5.925, 5.849)	0.948

TABLE 3 (Continued)

Covariate	Univariate B (95% CI)	*p* Value	Multivariable B (95% CI)	*p* Value
Past UTI				
No	Reference		Reference	
Yes	2.620 (0.161, 4.739)	0.039*	2.736 (−16.109, 9.842)	0.391
Renal dysfunction				
No	Reference		Reference	
Yes	4.153 (1.775, 9.066)	<0.001*	0.958 (−6.823, 5.823)	0.600
DM2 w/chronic complication				
No	Reference			
Yes	2.174 (−0.263, 4.259)	0.075		

Abbreviations: BMI, body mass index; DM2, diabetes mellitus type 2; UTI, urinary tract infection.
*$p < 0.05$.

for postoperative UTI and CAUTI. Duration of catheter placement, female sex, diabetes mellitus, catheter insertion outside of the OR, stool incontinence, and genitourinary anatomical or functional abnormalities have all been associated with increased risk of CAUTI in a variety of surgical and nonsurgical patient populations.[14,28,31]

Reported CAUTI incidence has been demonstrated to vary depending on data collection methodology. In this study, we identified CAUTI via retrospective chart review of nursing and inpatient progress notes. Conversely, identification of CAUTI via International Classification of Diseases, Ninth Revision, Clinical Modification billing codes may be prone to underreporting as some catheter use may be documented in nursing and progress notes yet escape discharge coding.[4,32,33] Indeed, a single-center study found that manual physician review of records identified a greater number of CAUTIs when compared to billing code retrieval from the same patient records.[32]

Evolving policy and reimbursement structuring from the CMS such as those implemented through the Hospital-Acquired Condition Reduction Program may also have had a relevant effect on historically reported incidence of CAUTI. Financial disincentives have had the intention of motivating modification of hospital best practices and reduction of preventable CAUTI incidence. However, a report published by Medicare & Medicaid Research Review found that 3 years after the implementation of CMS nonpayment policies, there was not a statistically significant decrease in reported hospital-associated CAUTI.[34]

Such financial penalization could instead have had the unintended effect of incentivizing undercoding of CAUTI, reductions in the frequency of UTI testing, and increases in the prescription of prophylactic antibiotics.[4] Since the designation of present-on-admission (POA) was introduced as a billing option associated with nosocomial UTIs, its use has dramatically increased.[33,35] A 2018 analysis of over 65 million Medicare fee-for-service hospitalizations found that just 0.06% of these were associated with a coded CAUTI; of these, 91% were marked as POA.[35] As a result of reductions in coding for CAUTI alongside simultaneously increasing reporting of POA-designated UTIs, hospital reimbursements have not significantly been impacted via the HAC program.[35] Thus, it remains to be seen whether such restructuring of reimbursement and disincentive mechanisms leads to an ameliorating effect on the incidence of preventable UTIs widely.

This study has several important limitations. The detection of UTIs relied on urinalysis and urine cultures, which were not routinely sent in this cohort but rather only in the setting of concerning symptoms or as indicated in a systemic inflammatory response syndrome workup. The retrospective nature of the study may have further introduced information bias due to reliance on accurate and thorough charting in the electronic medical record and potentially incomplete documentation represented in the resulting data set. Risk of selection bias favoring underreporting of adverse events was similarly relevant as an inherent limitation of studies without prospective data collection. Additionally, as a study originating from a single tertiary academic center, generalizability to other center types or populations may be limited. Finally, the low overall incidence of postoperative UTI in our study cohort may conceal potentially significant associations due to an underpowered sample. Nonetheless, to our knowledge, this study represents the first dedicated study of UTI incidence and contributing factors following ESBS. We report a low risk of UTI complication due to urinary catheter use in our ESBS patient population and suggest that with greater attention to relevant CAUTI risk factors and appropriately selective use, postoperative urinary catheterization in ESBS patients may continue to constitute a safe routine practice.

CONCLUSION

Indwelling urinary catheters are routinely employed following ESBS to prevent postoperative bladder dysfunction, promote compliance with bedrest precautions, and facilitate accurate fluid balance

assessment. Thorough understanding of urinary catheterization association with postoperative UTI incidence in the ESBS patient population is critical to mitigating risk of a preventable nosocomial complication. We report no significant correlation between urinary catheter use and incidence of postoperative UTI, though advanced age, length of stay, duration of indwelling urinary catheterization, and comorbid genitourinary conditions may contribute to elevated risk. Furthermore, the use of indwelling catheters did not appear to affect skull base reconstruction outcomes. Greater understanding of postoperative UTI risk factors and innovation of best practices for UTI prevention will ensure that postoperative urinary catheterization continues to constitute a safe routine practice in ESBS patients.

AUTHOR CONTRIBUTION

Jonathan C. Pang: Conceptualization; methodology; formal analysis; data curation; writing—original draft; writing—review and editing; visualization. **Lauren Michelle**: Writing—original draft; writing—review and editing. **Kelsey M. Roman**: Writing—original draft; writing—review and editing. **Arash Abiri**: Methodology; supervision; **Theodore V. Nguyen**: Writing—review and editing. **Benjamin F. Bitner**: Writing—review and editing. **Frank P. K. Hsu**: Supervision. **Edward C. Kuan**: Conceptualization; methodology; writing—review and editing; supervision.

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The authors have nothing to report.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Please contact the corresponding author with requests of deidentified patient data, which may be made available to researchers, policy makers, and clinicians whose proposed use of the data has been approved by all the authors.

ETHICS STATEMENT

This retrospective cohort study was conducted under approval of the Institutional Review Board at the University of California, Irvine.

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