Perioperative risk predictors for gender affirming surgery in the NSQIP database

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Introduction: *Gender affirming surgeries (GAS), such as phalloplasty (PLPs) and vaginoplasty (VGPs), are important aspects of medical care for transgender patients. Here, we aim to better characterize patient demographics and surgical outcomes for PLPs and VGPs using the National Surgical Quality Improvement Program (NSQIP). We hypothesized that frailty indices would be predictive of perioperative PLP and VGP risk and outcomes for PLPs and VGPs.*
Materials and methods: *Primary GAS, specifically PLPs and VGPs performed from 2006-2020 were identified in NSQIP. Baseline frailty was based on NSQIP's modified frailty index (mFI) and preoperative morbidity probability (morbprob) variable.*
Results: *Fifty-eight PLPs and 468 VGPs were identified. The overall 30-day complication rate for*

PLP was 26%, with 17% of total patients experiencing minor complications and 16% experiencing major complications. The overall, minor, and major complication rates for VGP were 14%, 7%, and 9% respectively. Readmissions and reoperations occurred in 7% PLP and 5% VGP patients. No deaths occurred in either group within 30 days. The mFI scores were not predictive of 30-day complications or LOS. NSQIP morbprob was predictive of 30-day complications for both PLP (OR 4.0, 95% CI 1.08-19.59, p = 0.038) and VGP (OR 2.39, 95% CI 1.46-3.97, p = 0.0005). NSQIP's morbprob was also predictive of extended LOS for PLP patients (6.3 ± 1.3 days, p = 0.03).
Conclusions: *This study describes patient characteristics and complication rates of PLPs and VGPs. The NSQIP preoperative morbprob is an effective predictor of surgical complications and is better than the mFI.*

Key Words: gender affirming surgery, vaginoplasty, phalloplasty, risk prediction, frailty, surgical outcomes, NSQIP

Introduction

Gender affirming surgery (GAS) is an essential option for transgender and gender non-conforming (TGNC)

individuals undergoing transition as it may provide significant psychological and quality-of-life benefits.[1] Phalloplasty (PLP) and vaginoplasty (VGP) are two common types of genital reconstruction performed for gender affirmation.[2] According to a recent survey conducted by the Williams Institute, over 1.6 million adults identify as TGNC in the United States.[3] With the increasing number of self-identifying TGNC and the improving accessibility of surgical options for transition, it becomes important to study patient experiences with genitourinary GAS. The prevalence of genitourinary GAS is estimated at 4%-13%, with nearly half of transgender women and nearly one-

quarter of transgender men reporting a desire to undergo such procedures.[4]

While PLP and VGP are important operations, they are associated with risks including infection, bleeding, and delayed wound healing. Previous literature has documented surgical site infections (SSIs) following approximately 50% of procedures, with greater rates of infection observed for female-to-male versus male-to-female reconstruction.[5] Similarly, wound dehiscence has been observed in up to 5% of VGPs and 11% of PLPs. Furthermore, major complications, which are less common but grant significant morbidity and mortality, include cardiac events, pulmonary embolism, and sepsis. Studies have demonstrated that the possibility of complications are a significant factor in a patient's choice to undergo these procedures.[6] Given these risks, there has been a recent focus on strategies to minimize complications and improve surgical outcomes. Although numerous studies have characterized postoperative outcomes following genitourinary GAS, conclusions have been variable, and it remains unclear whether patient-specific factors may predict such complications.[7-11] The few studies that have reported on personalized predictors of risk have generally been limited by single surgeon or single institutional data with small sample sizes, thereby restricting their generalizibility.[12-14]

The National Surgical Quality Improvement Program (NSQIP) is a nationwide database of surgical outcomes, which investigators have used to develop several indices which improve patient selection and minimize postoperative complications. These include the modified frailty index (mFI), which considers functional status and four common conditions (diabetes, hypertension, COPD, CHF), and the NSQIP morbprob, which accounts for patient-specific factors and independent predictor variables using a proprietary logistic regression model. While both metrics have been validated within NSQIP for other surgeries, neither has been assessed for gender-affirming genitourinary surgery.

Previous studies have used the NSQIP database to perform descriptive studies outlining demographics and complications for VGP but have been limited in the scope of years of NSQIP data analyzed.[15-19] Fewer studies have attempted to characterize outcomes after PLP using NSQIP. Existing GAS studies have not stratified by specific procedure, for instance analyzing female-to-male GAS (metoidioplasty, phalloplasty) as a whole and have also been relatively limited in their scope of years of data analyzed.[16-19] Moreover, to date,

no studies have aimed to predict perioperative risk using preoperative factors, nor have they used NSQIP-specific frailty indices to evaluate outcomes.

In this study, we aim to describe the baseline characteristics of patients undergoing PLP or VGP and analyze the outcomes and complication rates associated with these procedures using NSQIP data from 2006–2020. We hypothesize that frailty indices, such as mFI and morbprob, predict preoperative risk and complication rates for patients undergoing PLP and VGP.

Materials and methods

All PLP and VGP cases performed between 2006-2020 were identified in NSQIP using current procedural terminology (CPT) codes for PLP (55980) and VGP (55970, 57335, 57291, 57292). These CPT codes were obtained from the official Centers for Medicare and Medicaid Services (CMS) website coding section on GAS services for gender dysphoria.[20] These codes were also specifically selected to be less encompassing than prior NSQIP studies looking at GAS to avoid erroneously including other cases associated with GAS, such as revision urethroplasty, as their perioperative risk is likely different from de novo VGP or PLP performed for TGNC patients.[15-19] To more accurately query primary GAS, we excluded all cases with ICD-10 codes not related to gender dysphoria.

Descriptive statistics were calculated for baseline demographics including age, race, and medical comorbidities including diabetes mellitus, impaired functional status, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), hypertension, smoking status, chronic steroid use, bleeding disorder, and presence of open wound preoperatively. Similarly, operative parameters including operative time and hospital length of stay (LOS) and 30-day surgical outcomes including minor complications, major complications, need for reoperation, hospital readmission, and mortality, were captured. Of note, the 30-day reoperation and readmission rate most likely captured short-term surgical complications and were unlikely to reflect later staged or unexpected secondary surgeries.

Minor complications were defined as urinary tract infections (UTIs), superficial SSIs, pneumonia, and bleeding requiring transfusion within 30 days; major complications were defined as instances of sepsis, deep vein thrombosis (DVT), stroke, reintubation requirement, renal failure, myocardial infarction (MI), pulmonary embolism (PE), septic shock, would

dehiscence, cardiac arrest, deep wound infection, organ space infection, or mortality within 30 days of operation, largely in line with previously published studies describing complications with the NSQIP database.[21] Overall complication rate included any of the aforementioned events.

Frailty indices

NSQIP modified 5-item frailty index

The two frailty indices compared in this study are the modified 5-item NSQIP frailty index (mFI) and the NSQIP morbidity probability (morbprob) variable. Frailty was first calculated using the mFI, a previously validated measure that was abbreviated from the original 11-item NSQIP frailty index.[22] The mFI assigns one point for each of the five comorbidities: non-independent functional status, hypertension requiring medication, COPD, CHF, and diabetes. Patients with a frailty score ≥1 were placed in the frail cohort. This is largely in line with previous studies that have defined a mFI of 0 as a "nonfrail" cohort to compare against.[23] Patients with mFI scores of 1 or more were grouped together in the frail cohort instead of being stratified by score ranges given the limited number of patients and relatively healthy patient cohort.

NSQIP morbidity probability

NSQIP morbprob scores were available in the database. The morbprob is calculated using a spatial autoregressive model from 42 preoperative variables recorded in the NSQIP database.[24] Few studies have studied the morbprob variable; a study on bariatric surgery divided the scores into five unequal groups, and another study on hepatectomies used a 75th percentile cut off (40%) although the median was 36%.[24,25] Due to a small sample size, particularly of PLPs, we studied the morbprob variable as a binary. Patients with a morbprob score ≥ 10%, the midpoint of the patients' frailty scores in this dataset, were placed in the frail cohort.

Statistical analysis

Binary logistic regressions were performed to assess the predictive value of mFI and the NSQIP morbprob score for the overall complication rate. Odds ratios, 95% confidence intervals, and p values were calculated using likelihood ratio tests. Student's t-tests were performed to assess associations between the frailty indices and LOS. All tests were two tailed, and p < 0.05 was considered significant. All statistical analyses were performed using JMP Pro 16.2 (Cary, NC, USA).

Results

Fifty-eight cases of PLP and 468 cases of VGP were identified in the NSQIP database from 2006-2020. Patient demographics, baseline comorbidities, surgical measures, and complications were characterized for both operations, Table 1. Mean patient age was 38.4 and 36.6 for PLP and VGP, respectively. Smoking history was observed in 15% and 10% and hypertension was present in 9% and 7% of cases for PLP and VGP, respectively. All other comorbidities were observed in less than 3% of patients in either cohort. The average operative time for PLP and VGP was 331 minutes and 263 minutes, and the average LOS was 5.1 days and 4.3 days for PLP and VGP respectively.

Overall, 30-day complications occurred in 15 (26%) PLP patients, with 10 (17%) patients experiencing minor complications, including urinary tract infections, superficial wound infections, and perioperative bleeding requiring transfusion, and 9 (16%) experiencing major complications including occurrences of sepsis, DVT, stroke, reintubation, renal failure, myocardial infarction, pulmonary embolism, septic shock, would dehiscence, deep wound infections, and cardiac arrest. The overall, minor, and major complications rates for VGPs were 14%, 7%, and 9%. Common complications included wound opening, UTI, bleeds, and superficial SSIs. Unplanned readmissions and reoperations each occurred in 7% PLP and 5% VGP patients. No deaths occurred within 30 days post-operation in either cohort.

Table 2 and 3 show the results of binary logistic regressions to evaluate the factors associated with overall complications and length of hospital stay. Using the mFI morbidity probability for patients undergoing VGP, 42 (9.0%) were considered frail, and 426 (91.0%) were considered nonfrail. Among patients undergoing PLP, 5 (8.6%) were considered frail, and 52 (91.4%) were nonfrail. In the morbprob score, analysis was performed with 227 (48.5%) of VGP patients had higher preoperative risk, and 34 (58.2%) of PLP patients also had higher preoperative risk. A higher NSQIP preoperative morbidity was predictive of 30-day complications for both PLP (OR 4.0, 95% CI 1.08-19.59, p = 0.038) and VGP (OR 2.39, 95% CI 1.46-3.97, p = 0.0005). For PLP, morbprob ≥ 10% was predictive of extended LOS (6.3 ± 1.3 vs. 2.9 ± 0.8, p = 0.03). Conversely, this metric predicted a marginal, though statistically significant, difference in LOS amongst VGP patients (4.5 ± 0.2 vs. 4.0 ± 0.2, p = 0.03). In contrast, a higher mFI was not predictive of 30-day complications for PLP. Notably, for VGPs, higher mFI scores were numerically associated with higher complication rates (OR 2.02, 95% CI 0.94-4.09,

TABLE 1. **Anticoagulated vs. non-anticoagulated patient demographics**

	Phalloplasty (n = 58)	Vaginoplasty (n = 468)
Mean age (yrs)	38.4 ± 11.8	36.6 ± 12.6
Race		
White	33 (56.9%)	322 (68.8%)
Black	14 (24.1%)	83 (17.7%)
Asian	4 (6.9%)	24 (5.1%)
Native American	1 (1.7%)	4 (0.9%)
Unknown	6 (10.3%)	35 (7.5%)
Comorbitities*		
Diabetes mellitus	0 (0.0%)	13 (2.7%)
Dependent functional status	0 (0.0%)	0 (0.0%)
COPD	0 (0.0%)	2 (0.4%)
CHF	0 (0.0%)	0 (0.0%)
Hypertension	5 (8.6%)	32 (6.8%)
Smoking	9 (15.5%)	47 (10.0%)
Chronic steroid use	0 (0.0%)	7 (1.5%)
Bleeding disorder	0 (0.0%)	2 (0.4%)
Open wounds	0 (0.0%)	1 (0.2%)
Surgical measures		
Mean op time (mins)	330.9 ± 232.8	262.6 ± 112.1
Mean length of hospital stay (days)	5.1 ± 6.4	4.3 ± 3.4
Readmissions	4 (6.9%)	22 (4.7%)
Reoperations	4 (6.9%)	22 (4.7%)
30-day complications		
Overall complications	15 (25.9%)	66 (14.1%)
Minor complications	10 (17.2%)	31 (6.6%)
Major complications	9 (16.4%)	40 (8.6%)
Specific complications		
Superficial SSIs#	6 (10.3%)	10 (2.1%)
Deep SSIs#	1 (1.7%)	4 (0.9%)
Organ space SSIs#	1 (1.7%)	1 (0.2%)
Sepsis	1 (1.7%)	2 (0.4%)
Urinary tract infection	2 (3.5%)	10 (2.1%)
Bleeding req. transfusion	4 (6.9%)	11 (2.4%)
Wound dehiscence	4 (6.9%)	36 (7.7%)

*comorbidities not observed in any phalloplasty or vaginoplasty patients include the following: dyspnea, ascites, renal failure, dialysis, disseminated cancer, recent weight loss, and blood transfusion; #SSI = Surgical Site infection

p = 0.072), though this association was not statistically significant.

Age and race were not predictive of overall complication rate or LOS for PLP or VGP. Interestingly, for VGP, age was associated with operative time only, with the oldest and youngest patient groups tending to have longer mean operative times as compared to patients of intermediate ages.

Discussion

In this study, we evaluated the complications for patients undergoing primary GAS in the NSQIP database from 2006-2020. We also analyzed the predictive value of the modified frailty index and the morbprob for 30-day complications. PLP was far less common than VGP within our dataset. Major and

TABLE 2. **Predictors of overall complications following phalloplasties and vaginoplasties**

| | Phalloplasty | | | Vaginoplasty | | |
	Odds ratio	95% CI	p value	Odds ratio	95% CI	p value
Age (yrs)						
19-39	--			--		
39-59	0.87	0.25-2.96	0.87	1.44	0.85-2.39	0.17
≥ 59	1.38	0.06-16.38	0.81	0.94	0.31-2.36	0.90
Race						
White	--			--		
Black	1.07	0.24-4.16	0.93	1.61	0.88-2.85	0.12
Other	1.59	0.08-2.89	0.54	0.85	0.37-1.74	0.66
NSQIP modified frailty index						
0	--			--		
≥ 0.2	0.70	0.03-5.23	0.75	2.02	0.94-4.09	0.072
NSQIP morbidity probability						
< 10%	--			--		
≥ 10%	4.00	1.08-19.59*	0.038*	2.39	1.46-3.97*	0.0005*

minor postoperative complications occurred more frequently following PLP than VGP. This is consistent with other studies which have demonstrated high complication rates for PLP, likely owing to the complex nature of this procedure.[26] Superficial skin and soft tissue infections were the leading complications following PLP while wound dehiscence was more common in individuals undergoing VGP.

TABLE 3. **Predictors hospital length of stay following phalloplasties and vaginoplasties**

| | Phalloplasty | | | Vaginoplasty | | |
	Mean	Standard error	p value	Mean	Standard error	p value
Age (yrs)						
19-39	2.2	1.2	0.93	4.4	0.2	0.23
39-59	4.8	1.3		3.9	0.2	
≥ 59	4.3	3.8		4.6	0.5	
Race						
White	4.8	1.1	0.93	4.4	0.2	0.11
Black	5.5	1.7		3.7	0.3	
Other	5.5	2.0		4.2	0.4	
NSQIP modified frailty index						
0	5.0	0.9	0.35	4.2	0.2	0.49
≥ 0.2	6.2	0.9		4.5	0.4	
NSQIP morbidity probability						
< 10%	2.9	0.8	0.03*	4.5	0.2	0.03*
≥ 10%	6.3	1.3		4.0	0.2	

We found that over one-quarter of patients undergoing PLP developed a complication within 30 days, similar to rates demonstrated in other studies.[7,27,28] In addition to the 30-day complications investigated in this study, PLP has been previously associated with a number of long term urologic sequelae including urethral strictures, fistulas, and flap necrosis. Remington et al found that 33% of PLP patients developed urethral complications and 10% developed flap complications, with both being more common in transgender as compared to cisgender individuals.[7] VGP patients in our study also had a high complication rate, with 14% experiencing subsequent adverse events, which parallels rates reported by older studies in the literature.[29] As in our study, wound dehiscence, necrosis, and urinary tract infections are the most commonly reported short-term complications, while long-term complications include vaginal stenosis, fistula, and poor wound healing.[12,14,30,31]

There are limited data on the rates and drivers of short-term complications following genitourinary GAS. This study builds upon previous literature while offering insights into risk prediction for these increasingly important procedures. The Modified Frailty Index was not associated with surgical outcomes or complications in this cohort, while the NSQIP morbprob was predictive of overall complications. Individuals with a NSQIP morbprob probability ≥ 10% had significantly increased odds of 30-day postoperative complications.

It is worthwhile to note that the group of patients undergoing genitourinary GAS—individuals who are largely younger and less comorbid than the average United States surgical patient—is likely healthier than the population from which the mFI indicator was derived.[22,32-34] As mFI considers frailty alongside four common comorbid conditions, it may not adequately capture the factors contributing to adverse outcomes among the sample of patients evaluated in our study. In fact, only 9% of PLP patients had any of the conditions considered by the mFI. As such, our results suggest that NSQIP's morbprob, which accounts for more patient-specific factors, may be a useful tool to predict perioperative outcomes and determine potential risk for gender-affirming genitourinary surgery. Given that these procedures are not emergent, improved risk prediction can facilitate shared decision-making to ensure that patient experiences are optimized without worsening any health conditions.

Despite high complication rates, patient satisfaction is high, and demand for genitourinary GAS remains elevated.[14,31,35] It is important to understand the factors associated with short-term complications in order to appropriately select and counsel patients. Our study supports the belief that traditional risk factors may not always clearly be associated with surgical outcomes.[12,14] Similarly, in our study, there was no association between the rate of surgical complications and the traditional, comorbidity-based modified 5-item frailty index. This indicates that new paradigms are necessary to approach risk approximation in this patient cohort, which has many differences when compared to the traditional urology patient.

In contrast to the traditional NSQIP morbprob, the spatial autoregressive model which incorporates 1 year of data, Raymond et al performed a study incorporating 5 years of data, finding that high-risk patients were more likely to underestimate their surgical risk versus low-risk patients. They reported that the review of risk assessments applied clinically with almost 70% of patients engaging in risk reduction measures prior to GAS.[6] Hence, it is apparent that preoperative risk approximation can significantly impact patient behavior in the GAS population. Unfortunately, information on the variables used in NSQIP's spatial autoregressive model are not available. However, it would be valuable for future studies to construct a regression model using these variables to determine which factors are the most predictive of perioperative risk, ultimately, allowing the construction of a procedure-specific calculator for patient counseling.

This study has several limitations. Given the novelty of primary GAS, there are a variety of surgical techniques used, and complication rates are known to vary widely based upon technique. However, these factors are not reported in a standardized fashion, making them difficult to compare across studies or within NSQIP itself.[28,36] PLP in particular is a more involved surgery with increased morbidity and higher complications rates which often requires a multidisciplinary team compared to VGP, which are some of the reasons why PLP is performed less than VGP and represented less in NSQIP. However, given the novelty of and variance within these procedures, our method of identifying and filtering these cases using CPT and ICD-10 codes may have missed procedures coded differently in the NSQIP database. Furthermore, a retrospective study through a large database like incurs some expected limitations. NSQIP does not provide data on urology-specific or long term complications such as urethral stricture, fistula development, or delayed graft failure. These complications are important following genitourinary reconstruction and confer notable functional and

quality-of-life implications. Another database limitation is that some of the complications, such as wound dehiscence and urinary tract infections, could have different levels of severity in and of themselves that could not be ascertained. Although our study offers valuable insight into near-term complications, future studies of these other complications are necessary to comprehensively evaluate patient outcomes and optimize satisfaction.

Conclusions

Understanding patient-specific predictors of short-term complications is necessary as these are key considerations for patients choosing to undergo non-emergent GAS procedures. This NSQIP analysis characterized patient characteristics and experiences surrounding genitourinary GAS performed from 2006-2020 in the United States. Our results suggest that NSQIP mFI does not predict complications, while the NSQIP morbprob, a patient-specific metric including several preoperative factors, appears to be a better predictor of perioperative risk. This finding warrants future research surrounding the development of procedure-specific risk-stratification models to guide preoperative counseling for patients undergoing genitourinary GAS. ☐

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