

Frequency and Risk Factors Associated with Unplanned Return to the Operating Room within the 30-Days Following Free Flap Breast Reconstruction

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ABSTRACT

Background: Unplanned return to the operating room (URO) represents an objective measure of postoperative complications. We aimed to identify the frequency, reasons and risk factors for URO in patients undergoing free flap-based breast reconstruction.

Methods: Using American College of Surgeons National Surgery Quality Improvement Project (ACS-NSQIP) database, we examined the clinical data of patients who underwent free flap breast reconstruction from 2016 to 2020 in the United States. Multivariate regression analysis was used to identify risk factors associated with URO within the 30-day from surgery.

Results: A total of 8,398 patients underwent free flap-based breast reconstruction during the study period. The rate of URO was 11.8%. The majority of URO (54.2%) was occurred within the first two days postoperatively. The four most common reported codes were (17.4%: incision and drainage of hematoma or seroma or fluid collection), (11.3%: revision of reconstructed breast), (7.7%: exploration for postoperative hemorrhage, thrombosis or infection) and (4.4%: incision and drainage, deep abscess or hematoma, soft tissues of neck or thorax). The most common used diagnosis code was (11.0%: post procedure hemorrhage). Multivariate regression analysis showed that operative time longer than > 10 hours [odd's ratio (OR), 1.76], immediate reconstruction (OR,1.34), chronic steroid use (OR,1.87), smoking (OR,1.40), BMI>35 (OR,1.22) and hypertension (OR, 1.19) were independent risk factor for URO.

Conclusion: The rate of URO within the 30-day following free flap-based breast reconstruction is significant (11.8%). The majority of URO was reported within the first two days postoperatively. Hematoma / hemorrhage is the main indications for the return back to the OR.

KEYWORDS

Unplanned return to operating room; Free flap breast reconstruction; Frequency; Risk factors

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INTRODUCTION

While the vast majority of breast reconstruction surgeries are still implant-based, autologous or free flap reconstruction is beginning to emerge as the new gold standard. Benefits include better quality of

life compared to implant-based reconstruction and patient-reported outcomes related to breast satisfaction, physical, psychosocial, and sexual well-being comparable to those without breast cancer^{1,2}. Free flap breast reconstruction can also be a more suitable option for patients ineligible for implants due to insufficient, damaged, or irradiated local tissue³. Despite the benefits and increasing demand, free flap reconstruction is not without risk, notably unplanned return to the operating room (URO).

URO has significant impact to patients, families, and the hospital system. Across all surgical specialties, experiencing an URO is associated with longer hospital stays, increased risk of mortality, and increased overall morbidity compared to no reoperation⁴. In other specialties, patients experiencing URO have been estimated to incur financial burden nearly 5 times more than those without URO⁵.

While data is limited, the rate of URO in microvascular free tissue transfer surgeries, including microsurgical breast reconstruction, has ranged from 9% to 14.5%^{6,7}. Reported risk factors associated with URO also varies widely across studies. Factors thought to increase risk of URO include type of free flaps e.g. Superficial Inferior Epigastric Artery (SIEA) and Superior Gluteal Artery Perforator (SGAP) flaps, elevated BMI, and smoking⁸⁻¹⁰. Additionally, there is currently a paucity within the literature on large-study populations examining risk factors for URO. Knowledge of the risk factors associated with URO might help plastic surgeons minimize the incidence. Therefore, we aimed to 1) to evaluate the rate of URO, 2) to investigate the etiology and 3) to identify independent risk factors of URO in free flap breast reconstruction using the American College of Surgeons- National Surgical Quality Improvement Program (ACS-NSQIP) database in the most recent years in the United States.

MATERIALS AND METHODS

Database

The (ACS-NSQIP) database is a risk adjusted, surgical outcomes-based program designed to measure and improve the quality of surgical care. Trained clinical reviewers prospectively collect the ACS-NSQIP data and validated data from medical records on preoperative risk factors, preoperative laboratory values, intraoperative variables, 30-day

postoperative mortality, and 30-day morbidity on all patients undergoing major surgeries at participant institutions. For example, in 2020, the ACS-NSQIP database contained 902,968 cases submitted from 706 NSQIP-participating sites. The ACS-NSQIP database provides prospective national data with a large sample size making it ideal for identifying important differences in patient risk. In this database, unplanned return to the operating room has been documented in details including the frequency (one, two or more than two), postoperative day returning back to the operating room, diagnosis and procedures were performed during the URO.

Using the NSQIP database, we analyzed discharge data for female breast cancer patients with no age limitation who underwent free flap autologous breast reconstruction surgery from 2016 to 2020. We used Current Procedural Terminology (CPT) codes of 19364 (Breast reconstruction with free flap) and, 19368 (Breast reconstruction with Transverse Rectus Abdominis Myocutaneous [TRAM] flap, single pedicle with microvascular anastomosis) to identify our patient population. The main outcome research unplanned return to the operating room (URO) within the 30 days postoperative period. The URO has been tracked to one, two and more than two return to the operating room.

analyzed perioperative factors included patient characteristics, patient comorbidities, smoking status, steroid use, Body Mass Index (BMI), immediate vs. delayed reconstruction and length of operation. We were unable to evaluate the effect of chemotherapy (in <30 day) and radiation (in last 90 days) as the majority of data were missing.

Statistical Analysis

Multivariate regression analysis was performed to identify independent predictors of URO following free flap breast reconstruction. The adjusted odds ratio (AOR) was calculated in multivariate regression analysis to determine the combined effect of various perioperative factors (age, patient comorbidities, smoking, steroid use, BMI, length of operation and immediate vs. delayed reconstruction) on URO.

All statistical analyses for the ACS-NSQIP were conducted using SPSS version 26 statistical software (IBM Corp., Armonk, NY, USA). Statistical significance was set at P -values <0.05 and odds ratio with the 95% confidence interval does not include the value of one. $AOR > 1$ was considered the risk factor for URO.

RESULTS

A total of 8,398 patients underwent free flap-based breast reconstruction during the study period. Examining patient characteristics, the mean age was 51.0 ± 9.6 years old and 8.6 % of patients were older than 65 years old. The majority of reported race was Caucasian (59.1%), followed by African American (14%) and Unknown/not reported (22.6%). The most common comorbidities were hypertension (23.9%), diabetes mellitus (6.6%) and smoking (5.9%). The majority of the patients were classified in ASA-II (62.3%) and ASA-III (34.5%). 16.3% of patients had a BMI of 35 or higher. The majority of free flap breast reconstruction were delayed reconstruction (delayed: 58% vs. immediate: 42%). The mean operative time was 479 ± 171 (minutes). The mean length of hospital stay was 3.8 ± 3.2 (days) (**Table 1**)

In overall, the rate of URO was 11.8% (988 patients). The majority of these patients had one return to the operating room (777 patient=9.3%); however, 170 patients (2.0%) had two returns and 41 patients (0.5%) had more than 2 returns to the OR within the 30 days after initial operation. URO has been reported from postoperative day (POD)- 0 to 30. The majority of URO (54.2%) was occurred within the first two days postoperatively (POD-0: 16.3%, POD-1: 29.3% and POD-2: 8.6%).

The most common reported CPT procedure codes were 10140 (17.4%: incision and drainage of hematoma or seroma or fluid collection), 19380 (11.3%: revision of reconstructed breast), and 35820 (7.7%: exploration for postoperative hemorrhage, thrombosis or infection). The most common used ICD-10 diagnosis code was L76.32 (11.0%: post procedure hemorrhage (**Table 2**).

Univariate and multivariate regression analyses were conducted to identify risk factors associated with higher URO (**Table 3 and 4**). Multivariate regression analysis showed that operative time longer than > 10 hours (AOR, 1.76, immediate reconstruction (AOR,1.34), chronic steroid use (AOR,1.87), smoking (AOR,1.40), BMI>35 (AOR,1.22) and hypertension (AOR, 1.19) were independent risk factor for URO. Age>65 and diabetes mellitus were not an independent risk factor for URO (**Table 4**).

DISCUSSION

Autologous breast reconstruction is an important part of the continuum of care for breast cancer patients. Despite the reported benefits on patient-reported outcomes like quality-of-life and psychosocial well-being, the risk of unplanned return to operating room remains a significant concern^{1,2}. Therefore, identifying independent risk factors that increase URO rate after free flap breast reconstruction improve perioperative planning and allow for more informed shared decision-making between the patient, family, and surgery team. In this study, we evaluated URO risk factors using data from recent years within the ASC-NSQIP database. 11.8% of patients who underwent autologous breast reconstruction experienced URO within 30 days after surgery. Prior studies using the NSQIP database have found URO after autologous breast reconstruction ranged from 9% to 14.5%.^{6,7}

Our findings expand on prior studies evaluating URO by using a national dataset while specifying timing and etiology of takebacks to the operating room. We found that the majority of URO (54.2%) was within the first two days from surgery, with most incidences occurring at postoperative day 1 (POD1) (29.3%). Similarly, Olaiya et al conducted a retrospective cohort study of 2290 patients in Canada, noting that 86% of their patient population experienced URO within 3 days postoperatively¹¹. In addition, our findings align with the study by Baltodano et al who also used the NSQIP database, determining that URO rate following breast free flap reconstruction was highest during POD1¹². While they had a URO rate of 4.9% at POD1, our study found URO to be 29.3% during that time period. In their study, however, they were not able to determine reason for take-backs.

In our study, the most common diagnosis for URO was hematoma and bleeding. Ali et al similarly found early 1st or 2nd reoperation to be most caused by hematoma/seroma or bleeding¹³. They defined early as reoperation within 2 days from index operation. In free flap breast reconstruction, there are at least two surgical sites involved, so bleeding risk can exist in either area. Flap compromise can result from increased bleeding, which can cause compression on a vascular pedicle or venous outflow

and lead to congestion or thrombosis. Bleeding can be caused by a patient having a bleeding disorder¹⁴. Reconstruction with concomitant mastectomy may increase risk of a bleeding-related complication due to new mastectomy flaps¹³. Overall, it is crucial to obtain an excellent hemostasis in both donor site as well as reconstruction site, while maintaining adequate blood pressure perioperatively. This should decrease the rate of URO due to bleeding/ hematoma which also will contribute the reconstruction success. We found history of hypertension to increase odds of URO by over 2.5; which will reinforce the importance of blood pressure control perioperatively.

One of the strongest risk factors for URO was operative time greater than 10 hours. Patients in our study who had operative time greater than 10 hours had 1.76 times the odds of URO. Previous studies have also evaluated operative time and its influence on URO. Operative time greater than 9 hours to be associated with unplanned reoperation¹³. Haddock et al found every hour of operative time to increase odds of URO by 9% in bilateral DIEP free flap breast reconstruction¹⁵. However, when stratifying their patient population into operative times quartiles, they found that those whose operative times were 9 hours and greater had no significant difference in URO compared to patients whose operative times were in the less than/equal to 5, 5-to-7, and 7-to-9-hour quartiles. Longer operative times (e.g. bilateral reconstruction) might be indicative of the complexity of the procedure (e.g. the complexity of the anatomy and subsequent perforator dissection challenge or anastomoses revisions). Proper planning to minimize the length of anticipated long procedures, especially in bilateral or immediate reconstruction, may help lower the rate of URO.

We found that immediate reconstruction was an independent risk factor for URO (AOR, 1.34; CI:1.17 – 1.53; $P<0.001$). While 58% of our patient population had delayed reconstruction, 42% had immediate reconstruction. In contrast, Olaiya et al did not find reconstruction timing to be associated with URO¹¹. Immediate free flap breast reconstruction, especially when conducted bilaterally, may result in a longer operative time compared to delayed or 2-stage reconstruction^{16,17}. While this may seem like a potential cause for the URO, Issa et al found there was no statistically significant difference in takeback rates between

immediate and delayed deep inferior epigastric perforator flap (DIEP) breast reconstruction¹⁷. There was no significant difference in operative time between a delayed unilateral or bilateral free flap breast reconstruction¹⁶. Solutions that may address this include a team-based model involving co-attending surgeons, as well as preoperative computerized tomography to decrease steps during operation such as perforator identification^{11,18}.

Among patient characteristics and comorbidities, our study found that chronic steroid use, hypertension, smoking, and BMI > 35 to be associated with increased rate of URO. Adequate hypertension control, protocol for smoking cessation initiated 4 weeks before and continued after surgery, as well as weight management in cases of delayed reconstruction might help to reduce the risk of URO. In contrast with our study, Ali et al did not find hypertension, smoking nor obesity to be a risk factor for unplanned reoperation after multivariable analysis¹³. However, they defined it as BMI > 30, a lower BMI threshold than our study which may have included higher-risk patients. However, consistent with our study, Sudduth et al in a study evaluating free flap breast reconstruction outcomes in patients by WHO BMI classes, with Class II and III including those with BMI > 35, they found patients with Class III obesity to have highest incidence of return to OR¹⁸. Patients with elevated BMI may have larger flaps which would involve higher complexity and potential higher surgical complication risk. Obesity has also been found to impair myofibroblast and collagen production, impairing wound healing, which may further increase risk of complication^{19,20}. Proactive surgical planning in patients with elevated BMI includes addressing underlying comorbidities to optimize health preoperatively, while ways to optimize post-surgical recovery can include application of negative pressure dressings or quilting sutures to the incision¹⁸. Income, as a proxy for socioeconomic status, has been linked to hypertension, smoking rate, obesity disparities. It may be a potential avenue to investigate in future studies as a factor, among other socioeconomic variables, that can be addressed to improve post-surgical outcomes.

Interestingly, older age as defined as > 65 years and diabetes were not associated with increased risk of URO. Although, diabetes mellitus was found to be a risk factor for URO in univariate but this was not

consistent with multivariate regression analysis. Similar to our study, Olaiya et al did not find diabetes to be associated with URO¹¹. An explanation they provided was that preoperative health optimization may reduce surgical complication risk from comorbidities. While older age is a non-modifiable risk factor, diabetes can be addressed through better control of blood sugar and proper coordination with the interdisciplinary team to do so.

There are limitations to this study similar to retrospective studies using large databases, therefore some factors that have been reported to increase risk of URO may not had been captured by the database. This includes details such as flap type, anticoagulation, surgeon experience, or hospital volume. Flap type was unfortunately not be able to be assessed in our study given the nature of the data gathered from the national database. Additionally, we were unable to identify the accurate rate of URO for flap compromise (e.g. flap ischemia/ congestion) Mahmoudi et al noted that surgeon experience, with greater number of years, may lead to increased free flap success, even over hospital volume²¹. Also, flap compromise is a surgical complication that cannot necessarily be ascertained from the NSQIP database. Other studies have reported reasons for takebacks due to flap issues most commonly being related to venous compromise. One retrospective study of 605 patients undergoing free flap breast reconstruction reported a rate of 2.8% (17/605) requiring take-back for flap compromise related to circulatory issues. Venous thrombosis was the cause in a majority of these take-backs (12/17, 70.9%), with only one case related to arterial insufficiency (1/17, 5.9%)²². Another study reported a rate of 3.8% (29/758) for DIEP flaps for breast reconstruction requiring take-back due to venous congestion²³. Of the 2,103 breast reconstruction free flaps in their study, Coriddi et al found 47 (2.2%) to experience vascular compromise requiring takeback²⁴. Nearly two-thirds of these flaps (30/47, 63.8%) were related to venous compromise, with a third arterial (16/47, 34.0%). Additionally, patient-reported outcomes were not recorded in the database which can limit correlations of postsurgical outcomes with psychosocial impact or patient satisfaction.

CONCLUSIONS

We found an 11.8% unplanned return to operating

room rate within 30 days after free flap breast reconstruction, with a majority occurring within two days postoperatively. The most common diagnosis indicating URO was hematoma/hemorrhage. Our findings may help with preoperative counseling and surgical planning. Optimizing hemostasis and blood pressure control perioperatively as modifiable risks factors could reduce the possibility of URO. Also, it is crucial to educate patients on the possibility of unplanned return to OR after surgery in consultation which will make the process of takeback less stressful for the patients. However, future prospective studies would be required to confirm these findings.

ETHICAL APPROVAL

This study has been accepted for podium presentation at the American Society for Reconstructive Microsurgery Annual Meeting, January 20-24, 2023 at the JW Marriott Turnberry in Aventura, Florida.

FINDINGS

None of the Authors has any financial disclosures.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interests.

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