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EPIDEMIOLOGY

The impact of hospital volume on patient safety indicators following post-mastectomy breast reconstruction in the US

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Abstract

Introduction Despite the growing spotlight on value-based care and patient safety, little is known about the influence of patient-, reconstruction-, and facility-level factors on safety events following breast reconstruction. The purpose of this study is to characterize postoperative complications in light of hospital-level risk factors.

Methods Using the National Inpatient Sample, all patients who underwent free flap and prosthetic breast reconstruction from 2012 to 2014 were identified. Predictor variables included patient demographic and clinical characteristics, type and timing of reconstruction, annual hospital reconstructive volume, hospital bed size, hospital setting (rural vs. urban), and length of stay. Patient safety indicators (PSIs) were based on the Agency for Healthcare Research and Quality's designation of preventable hospital complications: venous thromboembolism, bleeding, wound complications, pneumonia, and sepsis. Logistic models were used to analyze outcomes.

Results The sample included 103,301 women, of which 27,695 (26.8%) underwent free flap reconstruction. 3.6% of patients experienced ≥ 1 PSI, most commonly wound PSI (4.9% and 2.5% for free flap and prosthetic reconstruction, respectively). Significant predictors of PSIs included rural setting ($p < 0.01$) and Elixhauser score ≥ 4 ($p < 0.01$) for the free flap group, and delayed reconstruction ($p < 0.01$) for the prosthetic group. Annual reconstructive facility volume was not associated with increased odds of PSIs in either prosthetic or free flap reconstruction ($p > 0.05$).

Conclusion PSIs were associated with rural hospitals and greater comorbidities for patients undergoing reconstruction with free flaps. Annual reconstructive facility volume was not associated with adverse inpatient outcomes with either method of reconstruction.

Keywords Breast reconstruction · Patient safety · Patient safety indicator · Hospital volume · Procedural volume

Introduction

Despite growing interest in patient safety, little is known about the influence of patient-, reconstructive-, and facility-level factors on hospital-acquired conditions following breast reconstruction. Specifically, to date there is no investigation considering the effects of annual hospital reconstructive volume and outcomes. As an increasingly common surgical option for women undergoing mastectomy, nearly 40% of women currently choose to undergo breast reconstruction following mastectomy [1]. Reconstructive operations increase the overall incidence of postoperative complications by 17–30% compared to mastectomy alone [2–4]. Additionally, compared to prosthetic reconstruction, autologous operations are associated with a higher overall complication rate [4]. While many adverse outcomes may occur weeks to months after surgery, the operation itself and the subsequent inpatient stay represent the period with greatest likelihood of adverse events.

Depending on the reconstructive approach, women are admitted for one to seven days following breast reconstruction, thus, exposing patients to well-known risks of hospitalization. The current trend towards implementing enhanced

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recovery after surgery pathways may improve the overall incidence of hospital-acquired conditions, although this has never been investigated. Additionally, facility-level factors and patient variables may be associated with different rates of complications. We aimed to analyze the incidence of inpatient hospital-acquired complications associated with autologous and prosthetic breast reconstruction. We hypothesized that hospital breast reconstructive volume would be associated with a decreased likelihood of patient safety indicators, after adjusting for patient and facility-level variables.

Methods

Data

Data were extracted from the National Inpatient Sample (NIS) from 2012 to 2014. These years were chosen as the most recently available. Years prior to 2012 were not included given methodologic differences in sampling prior to 2012 that preclude making comparisons in hospital volume across this divide. As the largest national all payer database, the NIS represents a 20% sampling of all admissions across 46 states within the United States, excluding federal hospitals [5]. Encounters were identified using International Classification of Disease (ICD) 9th Edition codes. Free flap breast reconstruction was identified with ICD-9 codes 8573 (free transverse rectus abdominis flap), 8574 (deep inferior epigastric artery perforator flap), 8575 (superficial inferior epigastric artery flap), and 8576 (superior gluteal artery perforator flap.). Thigh based flaps such as the profunda artery perforator and transverse upper gracilis were not included given these flaps are not coded in ICD-9. Prosthetic breast reconstruction was identified with ICD-9 code 8595. Immediate versus delayed breast reconstruction was determined based on the presence of an ICD-9 code for mastectomy (8541, 8542, 8543, 8544, 8545, 8546, 8547, 8548) at the time of reconstruction.

Variables

Patient-level variables included age, race, income quartile, radiation history, and Elixhauser comorbidity index. The Elixhauser was chosen as the most sensitive comorbidity index when using administrative data [6]. Reconstruction-level variables included free flap versus prosthetic along with immediate versus delayed reconstruction. Facility-level factors included those predefined in the NIS including urban/rural status, teaching status, and facility bedside. These variables were created by the Healthcare Cost and Utilization Project (HCUP) and are standardized within the database [7]. Annual hospital volume was defined as the annual incidence of reconstructions per unique hospital identifier in the NIS as performed in similar analyses [8].

Outcome

Patient safety indicators were extracted using ICD-9 codes according to established categories as recommended by the Agency for Healthcare Research and Quality (AHRQ) [9]. The PSI variable consisted of post-admission diagnoses with a high-positive predictive value for complications in surgical populations [10]. These diagnoses related to five domains: hospital-acquired pneumonia, sepsis, venous thromboembolic events (VTE), peri-procedural bleeding (hematoma and bleeding combined), and postoperative wound complications (see appendix for ICD-9 codes). Given the NIS is an inpatient database, we were unable to include outcomes related to revision surgery or secondary operations outside the index hospitalization.

Analysis

Microsurgical and prosthetic breast reconstructions were analyzed separately. Each was modeled with stepwise logistic regression. The outcome variable was binary (i.e., positive or negative for a PSI), and all variables above were included as explanatory variables. Sampling weights were applied per Healthcare Cost and Utilization Project (HCUP) recommendations. Model fitness was assessed with c-statistics (i.e., area under the curve). Significance was determined at an alpha level of 0.05. Missing data were infrequent in our analysis; however, for the race variable there were missing data in 5–6% of encounters. The missing indicator method was used in the regressions to account for these cases [11].

Results

The weighted sample consisted of 103,310 women, of which 27,695 (26.8%) underwent free flap and 75,615 (73.2%) underwent prosthetic reconstruction. A total 3.6% of encounters experienced at least one PSI during their inpatient admission (Fig. 1). A significant difference, however, was noted when stratifying patients based on reconstructive modality; 5.9% experienced at least once PSI following free flap reconstruction vs. 2.8% following prosthetic reconstruction ($p < 0.01$). Of those experiencing a PSI, a majority had two distinct events (e.g., wound and sepsis, or VTE and pneumonia). A minority of patients experienced three PSIs (< 0.01%), and no patients experienced four or more. The most common PSI was wound-related (4.9% following free flap vs. 2.5% following prosthetic reconstruction; $p < 0.01$), followed by bleeding (3.9% [free flaps] vs. 1.9% [prosthetic reconstruction]; $p < 0.01$) (Fig. 2). The remaining PSIs were

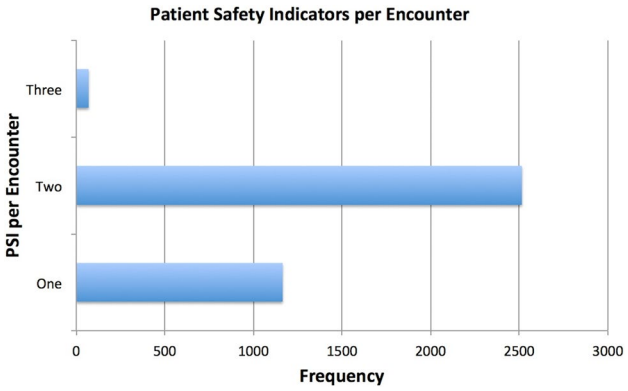

Fig. 1 Distribution of patient safety indicators per encounter

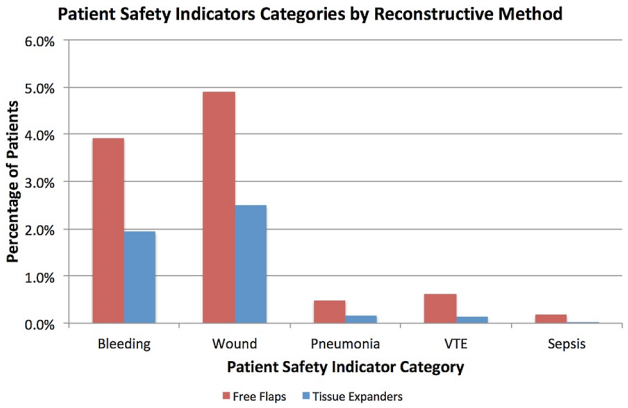

Fig. 2 Patient safety indicator categories by reconstructive method

rare. VTE occurred in 0.6% of free flaps and 0.1% of prosthetic reconstructions; $p < 0.01$). Pneumonia was reported in 0.5% of free flaps and 0.2% of prosthetic reconstructions; $p < 0.01$). Sepsis occurred in 0.2% of free flaps and less than 0.1% of prosthetic reconstructions; $p < 0.01$).

Prosthetic reconstruction model

The mean age at the time of prosthetic reconstruction was 51.1 years [standard deviation (SD) 10.7]. White was the most common race, appearing in 70.7% of encounters followed by black (8.9%) and Hispanic (7.3%). The most frequent income quartile was the wealthiest (i.e., top quartile) representing 39.5% of cases; the poorest quartile was the least frequent at 13.4% of encounters. The mean Elixhauser comorbidity score was 1.01 (SD 1.14). Evaluating surgical variables, 66.9% of patients underwent immediate reconstruction, and 5.8% had a history of radiation therapy. Regarding facility-level variables, the mean annual volume of prosthetic reconstruction was 18.1 cases per year (SD 21.3). The majority (59.6%) of operations occurred in large hospitals compared to 15.9% in small hospitals. Rural hospitals accounted for 1.9% of all prosthetic reconstructions. The mean length of stay following prosthetic reconstruction was 1.9 days (SD 1.3, interquartile range 1–2).

For demographic predictors of PSI events (Table 1), age and Elixhauser comorbidity index were not associated; however, race and income status were significant predictors. Hispanic race had significantly decreased odds of PSIs compared to white race (OR 0.56, 95% CI 0.35–0.90, $p = 0.02$).

Table 1 Multivariable analysis evaluating patient safety indicators (PSIs) in prosthetic breast reconstruction patients

	Odds ratio	95% Confidence interval
Patient-level factors		
Age	1.00	0.99–1.01
Race		
White	Reference	
Black	1.06	0.76–1.48
Hispanic*	0.56	0.35–0.90
Asian	0.99	0.56–1.76
Other	1.24	0.77–2.00
Unknown	0.92	0.59–1.46
Income quartile		
1	Reference	
2	0.73	0.53–1.02
3	0.77	0.56–1.05
4*	0.74	0.55–0.99
Unknown	0.80	0.37–1.73
Elixhauser score		
≤ 1	Reference	
2	1.14	0.87–1.49
3	1.23	0.85–1.77
≥ 4	1.31	0.85–2.02
Reconstruction-level factors		
Immediate reconstruction**	0.64	0.52–0.79
History of radiation therapy	1.14	0.79–1.64
Facility-level factors		
Annual reconstructive volume	1.00	1.00–1.01
Hospital size		
Small	Reference	
Medium	0.90	0.65–1.25
Large	0.97	0.73–1.29
Hospital type		
Urban teaching	Reference	
Rural	1.40	0.75–2.59
Urban non-teaching	1.01	0.79–1.28
Length of stay, mean (SD)**	1.49	1.41–1.57

SD standard deviation, *CI* confidence interval, *PSI* patient safety indicator

*$p < 0.05$

**$p < 0.001$

For income status, compared to the poorest quartile, the wealthiest quartile had significantly reduced odds of PSIs (OR 0.74, 95% CI 0.55–0.99, $p = 0.04$). For reconstructive-level factors, there was a significant association with immediate reconstruction such that the odds of a PSI were lower compared to delayed reconstructions (OR 0.64, 95% CI 0.52–0.79, $p < 0.01$). There was no association with history of radiotherapy. For facility-level factors, annual hospital volume, hospital size, and urban setting were not associated with PSIs. Length of stay was a significant predictor of PSIs with an OR of 1.49 (95% CI 1.41–1.57, $p < 0.01$). The c-statistic for this model was 0.74.

Free flap model

The mean age at the time of free flap reconstruction was 50.9 years (SD 9.4). White was the most common race, seen in 65.4% of encounters followed by black (14.1%) and Hispanic (8.5%). In terms of income quartiles, the wealthiest quartile was the most frequent (38.0%), while the poorest quartile was the least common (15.9%). The mean Elixhauser comorbidity score was 1.1 (SD 1.2). Looking at surgical variables, 38.9% of encounters were immediate reconstructions, and 16.4% of cases had a documented history of radiation therapy. Regarding facility-level factors, the weighted mean annual volume of free flap breast reconstruction was 24.7 cases per year (SD 20.4). The majority of operations occurred in large facilities, as determined by bed size, at 66.0%, followed by medium in 20.1% of encounters. Only 0.4% of operations occurred in the rural setting. Finally, the mean length of stay was 4.6 days (SD 3.6, interquartile range 4–5).

Looking at demographic predictors of PSI events (Table 2), age, race, and income quartile were not associated; however, baseline comorbidities as measured through Elixhauser indices demonstrated a significant relationship. Patients with a score ≥ 4 showed an increased odds of a PSI of 1.95 (95% CI 1.28–2.97, $p < 0.01$). Looking at reconstruction-level factors, immediate versus delayed reconstruction and history of radiation therapy showed no significant relationship with PSIs. For facility-level factors, annual hospital volume did not predict PSI events nor did hospital size. Hospital setting was significantly associated with PSI; rural designation was associated with increased odds of a PSI event compared to urban teaching hospitals (OR 3.77, 95% CI 1.19–11.95, $p = 0.02$). Finally, length of stay was a notable predictor of PSIs with an OR of 1.29 (95% CI 1.23–1.35, $p < 0.01$). The c-statistic for this model was 0.79.

Table 2 Multivariable Analysis evaluating patient safety indicators (PSIs) in free flap breast reconstruction patients

	Odds ratio	95% Confidence interval
Patient-level factors		
Age (mean, SD)	1.01	0.99–1.02
Race, % (n)		
White	Reference	
Black	1.09	0.77–1.54
Hispanic	0.69	0.42–1.14
Asian	1.17	0.62–2.21
Other	0.98	0.52–1.85
Unknown	1.42	0.86–2.35
Income quartile, % (*n*)		
1	Reference	
2	1.64	0.77–2.50
3	1.24	0.83–1.86
4	1.21	0.82–1.78
Unknown	1.50	0.63–3.55
Elixhauser comorbidity, % (*n*)		
≤ 1	Reference	
2	1.29	0.95–1.74
3	1.34	0.89–2.01
≥ 4*	1.95	1.28–2.97
Reconstruction-level factors		
Immediate reconstruction	1.02	0.80–1.31
History of radiation therapy	1.04	0.76–1.42
Facility-level factors		
Annual reconstructive volume	1.00	0.99–1.01
Hospital size		
Small	Reference	
Medium	1.15	0.74–1.79
Large	1.27	0.88–1.85
Hospital type		
Urban teaching	Reference	
Rural*	3.77	1.19–11.95
Urban non-teaching	1.22	0.85–1.74
Length of stay, mean (SD)**	1.29	1.23–1.35

SD standard deviation, *CI* confidence interval, *PSI* patient safety indicator

*$p < 0.05$

**$p < 0.001$

Adjusted probability of PSI by length of stay

LOS was a significant predictor in both models. In order to determine the adjusted LOS, a predict function was performed on both models to generate adjusted LOS. PSIs were plotted as a function of adjusted LOS for both groups. In these functions, every additional day of inpatient admission was associated with an increase in PSIs of 1.5% for free flap patients and 1.6% for prosthetic reconstruction patients (Fig. 3).

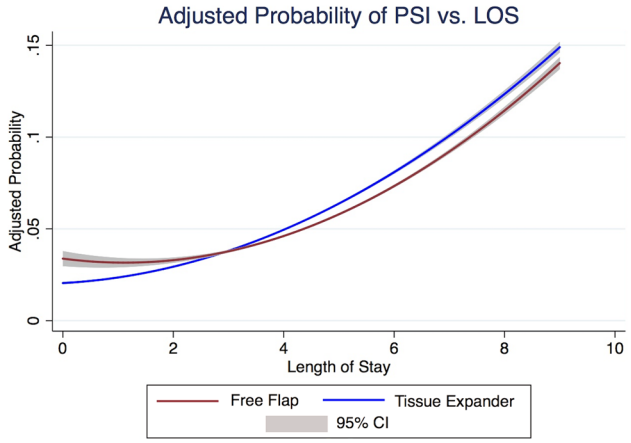

Fig. 3 Adjusted patient safety indicator per postoperative day by reconstructive method

Discussion

This study is the first to quantify the incidence of patient safety indicators (PSI) following breast reconstruction. While prior investigations have evaluated the incidence of immediate complications following breast reconstruction [12–14], this study focused on specific hospital-acquired conditions delineated by the AHRQ [9]. The rates of PSIs were relatively low, only appearing in 3.6% of all breast reconstructions. This low rate of PSIs agrees with the findings reported by Hernandez-Boussard et al. that illustrated the low rate of adverse events associated with breast reconstruction [15]. Also, the pattern of free flaps associating with greater immediate complications (5.9% vs. 2.8%) is also demonstrated in the literature [16, 17]. Similarly, the relative ratio of prosthetic reconstruction outnumbering free flap reconstruction was consistent with known national trends [18].

Uniquely, our investigation evaluated how facility-level factors associated with PSIs. Growing interest in hospital volume and facility expertise has led to multiple investigators to evaluate the relationship between surgeon and hospital volume with outcomes. To date, evidence is mixed, but at least in the orthopedic [19], cardiac [20], and general surgery literature [21, 22], studies have shown improved outcomes with higher volume. This has led to the *volume pledge* movement [23] whereby surgeons and facilities have agreed not to perform specialized operations when not commonly practiced. Our analysis did not demonstrate a significant relationship between hospital reconstructive surgery volume and PSIs; this was true for both free flap and prosthetic reconstructions.

Aside from annual reconstructive volume, we also analyzed hospital size as defined by HCUP (i.e., small, medium, large). Once again, this variable did not show a significant association with the incidence of PSIs. We hypothesize that the procedural aspects of breast reconstruction and relatively healthy patients explain this finding. Breast reconstruction technically does not involve operating on high-risk structures such as abdominal viscera or large caliber vasculature; thus, the margin of error is likely much higher in terms of intraoperative complications translating into PSIs. Additionally, unlike cardiac or bariatric patients who are more comorbid, breast reconstruction patients are relatively healthy in general. In this study, the mean Elixhauser comorbidity index was 1.01. Thus, as healthier patients, breast reconstruction patients are less likely to experience any PSI, regardless of facility familiarity with breast reconstruction [24].

Though reconstructive volume and facility size did not associate with PSIs, facility setting (i.e., rural versus urban) was associated with increased PSIs in free flap reconstruction. Free flap breast reconstruction requires specialized instruments and staff familiar with performing microvascular tissue transfer. Surgeons with limited microsurgical experience may be performing these operations at rural hospitals, and the staff working at these facilities may be inexperienced in caring for these patients. Conversely, this pattern was not observed for prosthetic reconstructions, whereby rural hospital setting was not associated with increased PSIs. These operations are technically much simpler and shorter; thus, unfamiliarity with these cases may not translate into a higher incidence of PSIs. These results suggest that rural hospitals may be safe to perform prosthetic reconstructions. Additionally, rural facilities should establish referral networks with larger urban centers to ensure that women are provided equitable opportunity for all methods of post-mastectomy breast reconstruction, including free flaps.

In terms of modifiable risk factors, patient-level variables are static (e.g., age, comorbidities) and not actionable in terms of risk reduction. However, other variables, such as facility, are fluid and have the potential to lead to improvements in patient care if changed. Length of stay is another modifiable risk of interest in transforming health care delivery. Patients who had longer inpatient stays for both flaps and prosthetic reconstructions had significantly greater rates of PSIs. The direction of causality is uncertain (i.e., patients who have complications will stay longer, and patients who stay longer will experience complications); however, hospitalization is a well-known risk factor associated with contracting hospital-acquired conditions [25, 26]. Every day a patient remains in the hospital, she has increased exposure to hospital-acquired infections, immobility leading to deep venous thrombosis, and medication errors [25, 27, 28]. Our analysis demonstrated that risk of PSI is fairly flat for free flap reconstruction in the first three postoperative days. After postoperative day 4, the rate increases steeply, and by hospital day 7, there is a 10% change of PSI occurring. Contrary to popular

belief, prosthetic reconstruction carries a similar risk of PSI with prolonged hospitalization. Pre-pectoral prosthetic reconstruction has led many to question whether inpatient admission is even necessary [29, 30]; nonetheless, this analysis occurred prior to widespread adoption of pre-pectoral reconstruction, whereby pain control from sub-muscular implant placement was the most common reason for admission [31]. Whereas free flaps have essentially equal risk of PSI in up until postoperative day three, risk of PSI following prosthetic reconstruction increases steadily every postoperative day, and even surpasses free flap risk profiles by hospital day three.

In terms of non-modifiable risk factors, higher income status was associated with a decreased likelihood of PSIs in prosthetic reconstruction. This trend was not observed in free flap reconstruction. One could hypothesize that patients of lower income status may have more comorbidities which predispose for complications; however, the model was adjusted for this potential source of confounding by inclusion of the Elixhauser comorbidity index. Other potential explanations include differences in the way patients of lower socioeconomic status experience the health system. Prior studies evaluating PSIs in minorities and lower socioeconomic patients have demonstrated that, even after adjusting for other patient-level variables, socioeconomic status is independently associated with a higher incidence of PSIs [32]. This could be an area of future investigation using qualitative studies to understand why these patients experience more complications.

Limitations

PSI attribution between surgeon and facility cannot be determined. The NIS does not include any surgeon identifiers, and thus all conclusions are drawn at the facility level. Plausibly, high-volume surgeons perform cases in various locations, which could be better marker of patient safety compared to facilities. Nonetheless, PSIs are used in multiple areas of the literature and are a well-validated means of capturing quality delivery.

The study is also limited by its retrospective nature and use of a national database. The accuracy of data is limited by the NIS methodology including facility-level diagnosis and procedure coding. Missing data vary and were infrequent in our analysis. Race was missing in 5–6% of encounters, which is consistent with methodology reports from the NIS [33]. These data were handled appropriately using the missing indicator method [34]. As an inpatient database limited to the index admission, we also cannot evaluate post-discharge secondary operations or revision surgery, which could be of interest in relating to facility-level variables such as procedural volume.

Conclusion

Patient safety indicators were more common following free flap compared to prosthetic breast reconstruction, albeit these events were relatively uncommon in all encounters. Reconstructive surgery volume and hospital size were not associated with the frequency of PSIs in either free flap or prosthetic reconstruction. Rural hospital setting was associated with increased PSIs for free flap reconstruction, which suggests that these operations may be better performed in urban centers; this trend was not noted for prosthetic reconstructions. Length of stay was a significant predictor for PSIs, and may be the greatest opportunity for modifiable risk reduction in surgical care delivery following breast reconstruction.

Compliance with ethical standards

Conflict of interest Dr. Momeni is a consultant for Allergan, AxoGen, Sientra, and Stryker. No payment or compensation was received for this study. Dr. Sheckter, Dr. Rochlin, and Ms. Kiwanuka, and Dr. Curtin have no conflicts of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent No consent was indicated given de-identified national database (Nationwide Inpatient Sample). Data were accessed by Dr. Sheckter who holds a data use agreement with the Healthcare Cost and Utilization Product.

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