Risk Analysis and Stratification of Surgical Morbidity after Immediate Breast Reconstruction

John P Fischer, MD, Ari M Wes, BA, Charles T Tuggle, MD, Joseph M Serletti, MD, FACS, Liza C Wu, MD, FACS

BACKGROUND: Surgical complications after breast reconstruction can be associated with significant morbidity, dissatisfaction, and cost. We used the ACS-NSQIP datasets from 2005 to 2011 to derive predictors of morbidity and to stratify risk after immediate breast reconstruction (IBR).

STUDY DESIGN: Surgical complications after implant and autologous reconstruction were assessed using the ACS-NSQIP 2005 to 2011 datasets. Patient demographics, clinical characteristics, and operative factors were associated with the likelihood of experiencing a surgical complication. A "model cohort" of 12,129 patients was randomly selected from the study cohort to derive predictors. Weighted odds ratios derived from logistic regression analysis were used to create a composite risk score and to stratify patients. The remaining one-third of the cohort (n = 6,065) were used as the "validation cohort" to assess the accuracy value of the risk model.

RESULTS: On adjusted analysis, autologous reconstruction (odds ratio [OR] 1.41, $p < 0.001$), American Society of Anesthesiologists physical status ≥ 3 (OR 1.25, $p = 0.004$), class I obesity (OR 1.38, $p < 0.001$), class II obesity (OR 1.91, $p < 0.001$), class III obesity (OR 1.70, $p < 0.001$), and active smoking (OR 1.46, $p < 0.001$) were associated with complications. Risk factors were weighted and patients were stratified into low (0 to 2, n = 9,133, risk = 7.14%), intermediate (3 to 4, n = 1,935, risk = 10.90%), high (5 to 7, n = 1,024, risk = 16.70%), and very high (8 to 9, n = 37, risk = 27.02%) risk categories based on their total risk score ($p < 0.001$). Internal validation of the "model cohort" using the "validation cohort" was performed demonstrating accurate prediction of risk across groups: low (7.1% vs 7.1%, respectively, $p = 0.9$), intermediate (10.9% vs 12.0%, respectively, $p = 0.38$), high (16.7% vs 16.8%, respectively, $p = 0.95$), and very high (27.0% vs 30.0%, respectively, $p = 1.0$).

CONCLUSIONS: Surgical complications after IBR are related to preoperatively identifiable factors that can be used to accurately risk stratify patients, which may assist with counseling, selection, and perioperative decision-making. (J Am Coll Surg 2013;217:780–787. © 2013 by the American College of Surgeons)

Breast reconstruction affords a significant psychosocial and aesthetic benefit for patients.[1-4] Complications, however, can adversely affect recovery,[4] satisfaction,[5] and cost utilization.[6] Both autologous and implant-based reconstruction have well established advantages and disadvantages, namely, autologous reconstruction affords a naturally appearing breast while implant-based reconstruction allows for shorter recovery and avoidance of donor site morbidity.[7-12] With the continued rise of immediate breast reconstruction (IBR), generalizable outcomes data assessing risk is needed.[13]

As our understanding of outcomes develops and population-level, multicenter data become increasingly available, reconstructive surgeons will be better equipped to counsel and inform patients regarding the risks and benefits of surgery, to preoperatively risk stratify their patients, to improve patient safety, and to navigate the timing and modality of reconstruction. Creation of a simple, accurate clinical risk assessment tool derived

Disclosure Information: Nothing to disclose.

Disclaimer: The ACS-NSQIP and the hospitals participating in the ACS-NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors of this study.

Received May 13, 2013; Accepted July 1, 2013.

From the Division of Plastic Surgery, Hospital of the University of Pennsylvania, Philadelphia, PA (Fischer, Wes, Serletti, Wu) and the Section of Plastic Surgery, Yale School of Medicine, New Haven, CT (Tuggle).
Correspondence address: John P Fischer, MD, Division of Plastic Surgery, University of Pennsylvania, 3400 Spruce St, Philadelphia, PA 19104. email: John.Fischer2@uphs.upenn.edu

ISSN 1072-7515/13/$36.00
http://dx.doi.org/10.1016/j.jamcollsurg.2013.07.004

Abbreviations and Acronyms

ASA = American Society of Anesthesiologists
BMI = body mass index
IBR = immediate breast reconstruction
IBRRAS = immediate breast reconstruction risk assessment scale
OR = odds ratio

from prospective data would be instrumental in addressing these aims. In this analysis, we examined the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database to determine risk factors associated with early (30-day) surgical morbidity after immediate breast reconstruction (IBR).[14] We used risk factors derived from our analysis to create a simple risk tool, the IBR risk assessment scale (IBRRAS).

METHODS

Database and analytic cohort

The 2005 to 2011 ACS-NSQIP databases were accessed on December 1, 2012 and queried to identify all female patients undergoing IBR.[14] Per NSQIP protocol, 240 Health Insurance Portability and Accountability Act (HIPAA)-compliant variables were collected for each encounter. Deidentified patient information is freely available to all institutional members who comply with the ACS-NSQIP Data Use Agreement. The Data Use Agreement implements the protections afforded by the Health Insurance Portability and Accountability Act of 1996. Institutional Review Board / Human Investigation Committee exemption was approved by our institutions.

Variables included patient demographic information, preoperative comorbidities and risk factors, perioperative laboratory results, information related to intraoperative proceedings and complications, as well as postoperative morbidity and mortality data for the subsequent 30-day period. Audits conducted through 2010 showed a 1.8% disagreement rate for program variables.

Women undergoing IBR procedures were identified using 2010 Current Procedural Terminology (CPT) codes for concurrent mastectomy and reconstruction: mastectomy included partial mastectomy with (19102) and without (19101) axillary lymphadenectomy, simple mastectomy (19103), subcutaneous mastectomy (19104), modified radical mastectomy (19107), and radical mastectomy (19105, 19106); implant-based reconstructions included immediate implant (19340) and tissue expander placement (19357); autologous reconstructions included the latissimus dorsi (LD) flap (19361), pedicled transverse rectus abdominus myocutaneous (pTRAM) (including microsurgical supercharging) (19367, 19368, 19369), and free transverse rectus abdominus myocutaneous (fTRAM) (19364).

Outcome

Our primary outcome was surgical complications, which included prosthetic or flap loss, unplanned return to the operating room, deep wound infection, superficial surgical site infections, and wound dehiscence. Surgical complications were treated as a dichotomous variable (none vs 1 or more). Information regarding severity was not available. All complications were identified within 30 days of the reconstructive procedure.

Independent variables

Variables indicating patient demographics, comorbidities, and perioperative risk factors were selected for analysis. These included baseline health characteristics, past medical and surgical history, preoperative laboratory values, and American Society of Anesthesiologists (ASA) physical status. The full list and definitions of NSQIP program variables can be found on the ACS-NSQIP website (http://site.acsnsqip.org/). The World Health Organization definition of obesity was used to classify patients with a body mass index (BMI) <30 kg/m^2 as nonobese and those with BMI >30 kg/m^2 as obese.[15] Patients were defined as follows: nonobese (BMI <30 kg/m^2), class I obese (BMI $=$ 30 to 34.9 kg/m^2), class II obese (BMI $=$ 34.9 to 39.9 kg/m^2), and class III obese (BMI $\geq$ 40 kg/m^2). Comorbidities were examined individually, by system, and in aggregate. System-based definitions were as follows: cardiovascular included a history of hypertension, angina, congestive heart failure, myocardial infarction, percutaneous coronary intervention, cardiac surgery, rest pain, or peripheral vascular disease; pulmonary included recent dyspnea, COPD, recent pneumonia, or a recent need for ventilator-assisted respiration; neurologic included paralysis, recent coma, recent delirium, cerebrovascular accident, or transient ischemic attack; and renal included preoperative renal insufficiency and dialysis. In aggregate, overall comorbidity burden was defined as no comorbidity, 1 comorbidity, and 2 or more comorbidities.

Implant-based and autologous reconstructions were defined as described above. We considered all latissimus dorsi flap reconstructions to be autologous reconstructions, whether or not tissue expanders or implants were used to augment autologous tissue. For the purposes of this study, we considered the autologous component to be a more significant aspect of the reconstruction. Bilateral reconstruction and bilateral mastectomy were defined when 2 concurrent CPT codes for the procedure were