Risk Analysis of Early Implant Loss after Immediate Breast Reconstruction: A Review of 14,585 Patients

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BACKGROUND: Early prosthesis loss is an infrequent but serious complication after breast reconstruction. We assessed perioperative risk factors associated with early device loss after immediate breast reconstruction (IBR) using the ACS-NSQIP datasets.

STUDY DESIGN: We reviewed the 2005 to 2011 ACS-NSQIP databases identifying encounters for CPT codes 19357 and 19340. Patients were identified as experiencing a "loss of graft/prosthetic" based on a standard dataset variable. Patients who experienced a device loss were compared with those who did not with respect to perioperative characteristics.

RESULTS: We identified 14,585 patients with an average age of 50.9 ± 10.6 years. A multivariate regression analysis determined that age (>55 years) (odds ratio [OR] 1.66, $p = 0.013$) (risk score = 1), class II obesity (OR 3.17, $p < 0.001$) (risk score = 3), class III obesity (OR 2.41, $p = 0.014$) (risk score = 3), active smoking (OR 2.95, $p < 0.001$) (risk score = 3), bilateral reconstruction (OR 1.67, $p = 0.007$) (risk score = 1), and direct-to-implant (DTI) reconstruction (OR 1.69, $p = 0.024$) (risk score = 1) were associated with early device loss. Odds ratios were used to assign weighted risk scores to each patient, and risk categories were broken into low risk (0 to 1, n = 9,349), intermediate risk (2 to 5, n = 5,001), and high risk (≥6, n = 233) groups. The risk of device loss was significantly higher with increased risk score (0.39% vs 1.48% vs 3.86%, $p < 0.001$).

CONCLUSIONS: Early device loss following IBR is a complex multifactorial process related to identifiable preoperative risk factors. This study demonstrated that age, obesity, smoking, bilateral procedures, and DTI reconstructions are associated with increased risk of implant loss. (J Am Coll Surg 2013;217:983−990. © 2013 by the American College of Surgeons)

Breast reconstruction affords a significant psychosocial and esthetic benefit for patients undergoing mastectomy.[1-4]

CME questions for this article available at http://jacscme.facs.org

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Ethical Approval: Deidentified patient information is freely available to all institutional members who comply with the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) Data Use Agreement. The Data Use Agreement implements the protections afforded by the Health Insurance Portability and Accountability Act of 1996. IRB exemption was approved by our institution.

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.

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Although autologous reconstruction may create a more natural-appearing breast, implant-based breast reconstructions are shorter operations, have faster recoveries, and are without donor site morbidity.[5] Evolving patterns of mastectomy use, along with a rising trend in immediate, bilateral breast reconstruction (IBR), have solidified implant-based breast reconstruction as a standard in the United States.[6-8]

Implant loss is an infrequent but very serious complication after reconstruction and is linked to decreased patient satisfaction and added cost.[1,9] A growing body of literature has emerged assessing risk factors for implant failure,[10-20] but there is a need for better risk assessment data to enhance decision-making, and more generalizable, multi-institutional studies to improve patient counseling regarding modality choice and reconstructive timing. The addition of a clinical risk model and decision-support tool constructed from preoperatively identifiable patient and operative factors would greatly improve care and risk counseling.[20] In this analysis we used the American College of Surgeons National Surgical Quality

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Abbreviations and Acronyms
BMI = body mass index
CPT = Current Procedural Terminology
DTI = direct-to-implant
IBR = immediate breast reconstruction
OR = odds ratio
TE = tissue expander

Improvement Program (ACS-NSQIP) datasets to determine risk factors associated with early (30-day) implant loss.[21] With risk factors derived from our analysis, we created a simple risk assessment tool characterizing 30-day risk of device loss after IBR, which can be used to improve preoperative clinical decision-making.

METHODS

Datasets

The 2005 to 2011 ACS-NSQIP databases were accessed on December 1, 2012 and queried to identify all patients undergoing IBR using implants.[21] Per protocol, 240 Health Insurance Portability and Accountability Act (HIPAA)-compliant variables were collected for each encounter. These 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.

Cohort identification and definitions

We identified patients undergoing breast reconstruction procedures using Current Procedural Terminology (CPT) codes for tissue expander (TE) placement (19357) and implant (19340).[20] Patients with combinations of CPT codes indicating multimodality reconstruction were excluded. Patients under the age of 18 were also excluded.

Patients were considered to have undergone IBR if a mastectomy was performed simultaneously with a reconstructive procedure; patients undergoing a reconstructive procedure without concurrent mastectomy were considered to have undergone delayed reconstruction and were excluded. The CPT codes used to identify mastectomy included partial mastectomy with (19102) and without axillary lymphadenectomy (19101), simple mastectomy (19103), subcutaneous mastectomy (19104), modified radical mastectomy (19107), and radical mastectomy (19105 and 19106).[22] Additionally, the laterality (either unilateral or bilateral) was assessed and noted for each patient.

In addition to predefined ACS-NSQIP variables, which can be accessed at the website (http://site.acsnsqip.org/), we calculated each patient's body mass index (BMI) (kg/m^2). The World Health Organization definition of obesity was used to classify patients with a BMI < 30 kg/m^2 as nonobese and those with BMI ≥ 30 kg/m^2 as obese.[23] Patients were identified as follows: nonobese (BMI < 30 kg/m^2), class I obesity (BMI $= 30$ to 34.9 kg/m^2), class II obesity (BMI $= 34.9$ to 39.9 kg/m^2), and class III obesity (BMI > 40 kg/m^2).

Variables

A variety of patient comorbidities and perioperative risk factors were selected from the NSQIP variables and subjected to univariate analysis. These included baseline health characteristics, past medical and surgical history, preoperative laboratory values, American Society of Anesthesiologists (ASA) physical status, and intraoperative factors such as operative time and intraoperative blood transfusion. The full list and definitions of NSQIP program variables can be found on the ACS-NSQIP website (http://site.acsnsqip.org/). All complications were defined as within 30 days of IBR. Prosthesis loss was defined as a failure of an extracardiac graft or prosthesis that required an unplanned return to the operating room.

Statistical analysis

Categorical variables were analyzed using Pearson chi-square or Fisher's exact tests, while continuous variables were examined with Wilcoxon rank-sum or Mann-Whitney tests. Preoperative and intraoperative variables with a $p \leq 0.10$ on univariate analysis were included in a multivariate logistic regression analysis as independent variables, with implant loss as the dependent variable. All tests were 2-tailed, with statistical significance defined as $p < 0.05$. Analyses were performed using STATA IC 11.0 (StataCorp). Significant risk factors derived from multivariate regression analysis were weighted using odds ratios to create a composite risk score for each patient. Patients were stratified and analyzed based on their total preoperative risk score.

RESULTS

There were 14,585 patients identified from the 2005 to 2011 ACS-NSQIP datasets, with an average age of 50.9 ± 10.6 years and BMI of 26.8 ± 6.3 kg/m^2. The majority of reconstructions were tissue expanders (TE) (85.0%) with direct-to-implant (DTI) reconstructions, totaling 2,190 patients (n = 15.0%). Of the study cohort, 4.6% were diabetic, 13.6% were active smokers, 25.7% were obese (BMI ≥ 30 kg/m^2), and 22.9% had hypertension. A summary of preoperative conditions can be found in Table 1.

The majority of reconstructed wounds were clean (97.8%) and patients were most often American Society

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