Non-response Bias in Patient Reported Outcomes Research for Breast Reconstruction: Lessons from a Multi-institutional Prospective Cohort Study

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PURPOSE: Survey-based research has emerged as a primary method of evaluating the impact and outcomes of breast reconstruction in an era of patient centered care. Despite increased utilization of patient reported outcomes measures, such as the BREAST-Q surveys, there are few studies assessing non-response among study participants. Differential non-response to surveys threatens the generalizability and validity of studies evaluating patient reported outcomes. The objectives of this study were to identify independent variables associated with non-response to surveys following breast reconstruction to aid in the design and improvement of future patient-reported outcomes research.

METHODS: The Mastectomy Reconstruction Outcomes Consortium is a multi-institutional prospective cohort study involving 11 leading medical centers from the United States and Canada. Data were collected through a combination of self-reported patient surveys and medical record review. Patient reported outcomes including satisfaction with breast and with care (BREAST-Q), depression (PHQ-9), and anxiety (GAD-7) were collected preoperatively and at several intervals postoperatively. Non-response rates to BREAST-Q, PHQ-9, and GAD surveys were measured at one week, three months, one year, and two years postoperatively were 14.5%, 21.8%, 27.8%, and 34.4% respectively. At one year following reconstruction, the rate of non-response ranged from 8.0% to 41.4% among participating centers. Patient race and ethnicity, annual household income, and education were all associated with non-response to the post-operative surveys. Patients undergoing implant-based breast reconstruction were approximately half as likely to respond to BREAST-Q surveys at one year when compared with women who underwent autologous reconstruction. Neither satisfaction with care nor incidence of clinical complications was predictive of non-response to the surveys.

RESULTS: Among 3,083 women included in the analytic cohort, 2,060 (66.8%) underwent autologous, and 166 (5.4%) underwent mixed breast reconstruction. Non-response rates to BREAST-Q surveys at one week, three months, one year, and two years postoperatively were 14.5%, 21.8%, 27.8%, and 34.4% respectively. At one year following reconstruction, the rate of non-response ranged from 8.0% to 41.4% among participating centers. Patient race and ethnicity, annual household income, and education were all associated with non-response to the post-operative surveys. Patients undergoing implant-based breast reconstruction were approximately half as likely to respond to BREAST-Q surveys at one year when compared with women who underwent autologous reconstruction. Neither satisfaction with care nor incidence of clinical complications was predictive of non-response to the surveys.

CONCLUSION: Although patient reported outcomes are increasingly utilized to assess and compare the impact of breast reconstruction procedures, there are few studies evaluating differential non-response rates to survey instruments among study participants. In a multi-institutional, prospective cohort study, racial and ethnic minorities, and women from lower income and education groups were less likely to respond to follow-up surveys. Additionally, women who underwent implant-based breast reconstruction were approximately half as likely to respond to BREAST-Q surveys at one year when compared with women who underwent autologous reconstruction. Researchers studying patient-reported outcomes in breast reconstruction should assess and adjust for non-response bias. Future studies are needed to design and implement effective approaches to improving response rates for patients at high risk of loss to follow-up.

The Total Acute Phase Response Predicts Complications in Children with Musculoskeletal Infection

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PURPOSE: Pediatric musculoskeletal infection leads to intense activation of the acute phase response (APR) that
persists until the infection is cleared by antibiotic therapy and/or surgical management. While the acute phase response is essential for tissue healing and regeneration, over-activation of the acute phase response is maladaptive and may lead to systemic complications including thrombosis, organ failure, and disseminated intravascular coagulation. In the setting of severe infections, continuous activation of the APR has the potential to become dysregulated. The magnitude of the acute phase reaction can be quantified by both the peak concentration of CRP as well as the total duration of CRP elevation through calculating the area under the curve. We hypothesize that the area under the CRP curve is increased in musculoskeletal infection due to continual tissue injury and we believe that this cumulative response over time correlates with the incidence of complications.

METHODS: Pediatric patients with musculoskeletal infection that presented to the emergency room at a single, tertiary care pediatric hospital were identified between 2008 and 2013. CRP values and complications during hospitalization were obtained from the electronic medical record. Complications were defined as deviations from the standard hospital course for musculoskeletal infection, such as deep venous thrombosis, septic emboli, pulmonary edema, pleural effusion, pericardial effusion, delirium, shock and multi-organ failure. Statistical analysis was performed using MATLAB (Natlick, MA) and GraphPad Prism6 (La Jolla, CA).

RESULTS: A total of 119 pediatric patients with musculoskeletal infection were included in the study. Seventeen complications occurred (14%) including 4 cases of septic emboli, 3 cases of pleural effusions, 3 cases of DVT, 2 cases of septic emboli plus DVT, 1 case of delirium, 1 case of toxic shock syndrome, 1 case of pulmonary edema, and 1 case of multi-organ failure. The median area under the CRP curve in cases of musculoskeletal infection with complications was 3303.8 mg day/L, compared to 539.2 mg day/L in cases of musculoskeletal infection without complications (p value < .0001).

CONCLUSION: A dysregulated acute phase response in the setting of musculoskeletal infection has the potential to cause life-threatening complications. The area under the curve is a novel measure of both the intensity and duration of the acute phase response that correlates with the incidence of complications in pediatric patients with musculoskeletal infection. Clinicians should closely monitor for complications in pediatric patients with severe, prolonged musculoskeletal infections.

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Potential Risk Factors for Worsening Abdominal Well-Being after Abdominal Flap Breast Reconstruction: There’s No Such Thing As a Free Tummy Tuck

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PURPOSE: Patient-reported lower satisfaction with the abdomen preoperatively is a strong predictor of undergoing a DIEP flap. This may suggest that patients have specific expectations regarding their postoperative donor site outcomes. Whether these expectations are actually met has not been well documented. Therefore, we evaluated physical well-being of the abdomen before and after flap-based breast reconstruction to determine potential predictors for decreased postoperative abdominal well-being.

METHODS: We retrospectively analyzed a prospectively-maintained institutional breast reconstruction registry, selecting patients who underwent abdominally-based autologous flap breast reconstruction from 2010 to 2015. Our primary outcome was the Physical Well-being of the Abdomen (PWA) domain from the Breast-Q, measured preoperatively and at 6- and 12-month follow-up visits after final reconstruction. We classified patients into 2 groups: those who experienced a clinically-important worsening of PWA (wPWA group) from baseline to 12-month follow-up (defined as a decrease of > 7 points) and those who did not (control group). We used Chi-squared test, t-test, and Wilcoxon rank-sum test to examine potential predictors of worsened PWA. We then fitted a multivariable logistic regression model including variables with p<0.2 in a univariate analysis to estimate which variables may be potential risk factors for worsened PWA.

RESULTS: We identified 142 women who met inclusion and exclusion criteria. Of these, 74 (52%) experienced a clinically-important worsening of PWA, whereas 68