

Discussion: immediate post-mastectomy breast reconstruction followed by radiotherapy: risk factors for complications

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Dr. Cowen and co-authors should be commended for their efforts to describe patterns and correlates of complications after mastectomy with immediate tissue expander/implant reconstruction and adjuvant post-mastectomy radiotherapy. It is important for clinicians to understand the outcomes and predictors of successful breast reconstruction among patients receiving radiotherapy. Post-mastectomy radiation therapy is now considered to be an integral component of cancer treatment for many patients. Radiation therapy is associated with a two-thirds reduction in the relative risk of loco-regional failure and a survival benefit in appropriately selected patients [1]. However, radiation is not without its risks. Several retrospective studies have suggested that radiation increases the risk of post-operative complications in patients with expander/implant reconstructions [2]. Therefore, understanding the risk factors for post-operative complications in the setting of reconstruction and radiation will help to improve the informed consent process and assist clinicians and patients alike with treatment decision-making.

The investigators have performed a thoughtful multi-center cohort study with a prospective design. The

reliability and validity of the study results are dependent on the quality of the measures along with statistical efforts to control for potential biases. Randomized control trials are the gold standard for producing high level evidence. However, it is not always feasible to perform randomized clinical trials, when evaluating surgical treatments that are highly dependent on patient preferences such as breast reconstruction. In these situations, multi-center cohort studies can provide high level evidence. However, the cohort study cannot ensure an equal distribution of known and unknown factors that may impact the treatment outcome. The authors were correct in using regression analyses to control for possible known confounding factors that may not be evenly distributed in the study sample. However, the authors would have produced a more statistically robust study, if they had controlled for certain other patient and clinical factors that are known to be associated with surgical complications with post-mastectomy breast reconstruction.

For example, the authors found an interesting association between the surgeon and incidence of capsular contracture in the multivariate analysis. The reasons are unclear, but were suggested to be related to surgical control of hemostasis. It would be helpful to include in the regression model factors known to be associated with the incidence of capsular contracture, such as postoperative infection and hematoma [3, 4]. There could be an interaction between the surgeon and one of these complications that would provide better insight into this association. The type of implant was also not controlled for in the analyses. The incidence of capsular contracture can vary by the type of implant material (silicone vs. saline) and the type of implant shell (textured vs. smooth) [5, 6]. In addition, while the investigators are to be commended for requiring some degree of homogeneity of radiation doses and

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techniques, the treating radiation oncologists were allowed some discretion regarding target definition, which should be controlled for in the regression model. For example, although coverage of the regional nodal basins appears common among French radiation oncologists, some radiation oncologists only treat the regional nodal basins in patients with greater burden of disease [7]. These variations in radiation delivery could mediate the relationship observed between tumor size, nodal status, and outcome.

The authors presented a prediction model of reconstruction failure that can be very useful to clinicians with the informed treatment decision-making process. The model included three variables that were significant in the bivariate comparisons: presence of smoking, T3 or larger tumors and positive lymph nodes. The association of these independent variables with reconstruction failure makes clinical sense. However, the prediction model may be more accurate if it had included other independent variables that are known to be associated with surgical complications, such as body-mass index, comorbidities like diabetes and the type of implant used for reconstruction [8, 9]. We hypothesize that including these other variables may make the associations found even stronger.

We commend the authors for evaluating patient-reported satisfaction with the surgical outcome. Patient-reported measures of health outcomes are gaining recognition in both local and national health policy arenas. The National Institutes of Health in 2004 formed the patient-reported outcomes measurement information system that was aimed at establishing accurate and efficient measurement of patient-reported symptoms and other health outcomes [10]. Ultimately, the measures should be reliable (prove the same result repeatedly in the same population under the same testing conditions), valid (measure what they are supposed to measure), responsive (able to detect significant changes over time), and feasible to apply [11]. Unfortunately, at the time of this study, the Breast-Q was not available, which is the only validated patient satisfaction measure specific to breast outcomes in the post-mastectomy population [12].

Patient satisfaction with breast reconstruction has several domains related to symmetry, softness, projection, and size. In addition, most satisfaction and quality of life measures use a five-point Likert response scale to improve the sensitivity of the results [13, 14]. The authors note that they have performed detailed assessment of patient quality of life that they will report separately, and we look forward to that report. The preliminary satisfaction results presented in this study have questionable validity and reliability, as they are limited to responses to one general satisfaction question with a dichotomous response (yes or no). Furthermore, the authors did not control for the type of implant, the presence of nipple reconstruction, the use of a

symmetry procedure or the time from completion of reconstruction to survey administration, which are all potential confounders of patient satisfaction [14, 15]. We hope that they will consider controlling for these factors when they present the more complete results of their patient-assessed outcomes.

In summary, the authors have performed an important clinical study describing risk factors and complications associated with immediate post-mastectomy reconstruction and radiation. Although this study has some limitations regarding its measures and analyses, the authors describe important clinical risk factors associated with radiation and reconstruction that are relevant to the informed treatment decision-making process. Evidence from prospective, multi-center cohort studies is particularly important as increasing numbers of patients face decisions regarding post-mastectomy radiation therapy and reconstruction.

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