

Comparison of Outcomes in Immediate Implant-Based Breast Reconstruction Versus Mastectomy Alone

Comparer les résultats des reconstructions mammaires immédiates par implant et des mastectomies seules

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Abstract

Objectives: Immediate implant-based techniques are common practice in post-mastectomy breast reconstruction. Previous studies have shown an increased complication rate in the setting of immediate versus delayed, MD reconstruction. We aimed to quantify any additional risk in complications when implant-based immediate breast reconstruction (IBR) is performed versus mastectomy alone. **Materials and Methods:** We retrospectively reviewed all IBR cases and all mastectomies without reconstruction from 2007 to 2011. Patient characteristics, operative details, and complication rates were reviewed and analyzed. **Results:** IBR was performed in 315 consecutive women; mastectomy alone was performed in 401 women. Patients undergoing mastectomy alone were more often older, diabetic, and more frequently underwent neoadjuvant chemotherapy or radiation. Overall complications were higher in the IBR group, most commonly reoperation and delayed wound healing. In a multivariate analysis, IBR, increasing age, body mass index, history of radiation therapy, smoking, and nipple-sparing mastectomy were independently associated with increased risk of complications. However, IBR was only independently associated with increased risk of major complications such as reoperation or readmission for intravenous antibiotics, not minor complications. **Conclusion:** Patients selected for IBR are inherently different than those undergoing mastectomy alone. After adjusting for these differences, the increased risk of complications seen in IBR is moderately increased over the risk of complications in mastectomy alone. The observed increased risk of major complications after IBR is largely due to the aggressive management of complications in the setting of a prosthetic implant. IBR is a safe reconstructive strategy with only a slightly increased risk over mastectomy alone.

Résumé

Objectifs : Les techniques de reconstruction mammaire immédiate par implant sont courantes après une mastectomie. Des études antérieures ont démontré un taux de complication plus élevé après une reconstruction immédiate qu'après une reconstruction tardive. Les auteurs ont cherché à quantifier le risque supplémentaire de complications après une reconstruction mammaire immédiate (RMI) par rapport à une mastectomie effectuée seule. **Matériel et méthodologie :** Les auteurs ont procédé à une analyse rétrospective de toutes les RMI et de toutes les mastectomies sans reconstruction effectuées entre 2007 et 2011. Ils ont étudié et analysé les caractéristiques de patientes, les détails des opérations et le taux de complications. **Résultats :** Selon l'analyse, 315 femmes consécutives ont subi une RMI et 401 femmes, une mastectomie seule. Les patientes qui avaient subi

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une mastectomie seule étaient souvent plus âgées, diabétiques et soumises à une chimiothérapie néoadjuvante ou à une radiothérapie. Les complications globales étaient plus élevées dans le groupe ayant subi une RMI, surtout à cause d'une réopération et d'une guérison plus lente des plaies. D'après une analyse multivariée, la RMI, le vieillissement, l'indice de masse corporelle, des antécédents de radiothérapie, le tabagisme et une mastectomie épargnant le mamelon présentaient une corrélation indépendante avec un risque accru de complications. La RMI présentait seulement une corrélation indépendante avec un risque accru de complications majeures comme une réopération ou une réhospitalisation visant à administrer des antibiotiques par voie intraveineuse, et non de complications mineures. **Conclusion :** Les patientes sélectionnées pour la RMI sont foncièrement différentes de celles qui subissent une mastectomie seule. Après rajustement pour tenir compte de ces différences, le risque de complications observé après une RMI est légèrement plus élevé que celui qui s'associe à une mastectomie seule. Le risque accru de complications majeures observé après une RMI est largement attribuable à la prise en charge énergique des complications après un implant prothétique. La RMI est une stratégie de reconstruction sécuritaire dont le risque est seulement un peu plus élevé que la mastectomie seule.

Keywords

breast implants, mastectomy, breast reconstruction, reconstructive surgical procedures

Introduction

Mastectomy followed by implant-based immediate breast reconstruction (IBR) has become an increasingly common practice in the management of malignant breast disease. Reconstruction may be achieved by several methods including both autologous tissue-based and implant-based approaches. Implant-based reconstruction is most commonly performed as a staged procedure, beginning with the placement of a tissue expander at the time of mastectomy. The expander is then slowly inflated over the following weeks. Adjuvant treatment such as chemotherapy and/or radiation therapy is often completed during the tissue expansion period.^{1,2} Finally, the expander is exchanged for a permanent saline or silicone breast implant. Occasionally, a single-stage implant reconstruction is performed in which the permanent saline or silicone implant is placed at the time of mastectomy.³

The psychosocial and emotional benefits of breast reconstruction have been well-documented in women undergoing mastectomy for breast cancer.⁴⁻⁶ This benefit may be optimized by performing the reconstruction in the immediate post-operative period, as the natural breast skin envelope is preserved, resulting in a superior aesthetic outcome.⁷ There are numerous previous studies validating the safety of skin-sparing mastectomy and immediate reconstruction.^{6,8,9} However, these studies have shown an increased complication rate associated with immediate versus delayed reconstruction.¹⁰⁻¹⁴ Fundamental problems seen in previous studies include small sample size, retrospective design, lack of comparison groups, and failure to account for confounding variables. This latter consideration is of particular import given that women undergoing mastectomy alone versus those undergoing immediate placement of a tissue expander are often quite different in regard to demographics, medical comorbidities, and burden of disease. Fischer et al¹⁵ considered this particular issue in 2014, utilizing American College of Surgeons- National Surgical Quality Improvement Program (ACS-NSQIP) data to review complications in 42 823 patients undergoing mastectomy alone or

immediate TE placement. Although the study is limited by 30-day follow-up, they demonstrated no increased risk of wound, medical, or overall complications after implant-based IBR but did show an increased risk of deep wound infection and unplanned reoperation.

Hence, the purpose of our study was to quantify the risk of post-operative complications associated with IBR compared to mastectomy alone while accounting for key differences between these 2 groups of patients. We were able to include a large number of patients from a single institution, with significantly longer follow-up than previously published. We hypothesized that the risk of complications in immediate breast reconstruction would be modestly increased compared to the risk of complications associated with mastectomy alone, but that this increase could be attenuated by careful patient selection and attention to modifiable risk factors.

Methods

Patient Selection and Data Collection

In order to examine the risk of post-operative complications related to IBR, we conducted a retrospective cohort study. After obtaining institutional review board approval, we enrolled all patients undergoing mastectomy without reconstruction and those undergoing mastectomy with immediate implant-based reconstruction at our tertiary care center between 2007 and 2011. Additional exposures of interest included patient characteristics such as age, height, weight, smoking status, and presence of diabetes. Other exposures measured were related to medical treatment, specifically whether neoadjuvant radiation and/or chemotherapy was given, as well as surgical treatment, including timing and type of reconstruction, type of mastectomy, mastectomy laterality, associated axillary procedure(s), implant type, implant fill volume, use of antibiotic irrigation, and use of acellular dermal matrix.

Post-operative outcomes reviewed included return to the operating room, hematoma, seroma, surgical site infection, and

delayed healing. Hematoma was defined as any hemorrhagic fluid collection, ranging in severity from those managed by observation to those requiring immediate return to OR. Seroma was defined as any non-hemorrhagic fluid collection, both those requiring drainage or aspiration and those managed by observation. The incidence of surgical site infection was measured using Centers for Disease Control and Prevention criteria: (1) purulent drainage; (2) positive aseptically obtained culture; (3) peri-incisional erythema and incision deliberately opened by the surgeon; and (4) physician diagnosis of infection, such as cellulitis for which antibiotics were prescribed. Finally, delayed healing included any indication that the wound was not healing as quickly as expected: eschar, scab, partial skin necrosis, epidermolysis, any change in the skin requiring wound care. In order to examine the types of complications associated with IBR, post-operative outcomes were subclassified as major or minor. Major complication was defined as any complication resulting in return to the operating room, readmission to the hospital, or treatment with intravenous antibiotics. Minor complications included infections requiring only oral antibiotics or delayed healing requiring only local wound care or increased monitoring in the outpatient setting.

Follow-up was defined as the time between mastectomy and the last-documented visit in the electronic medical record that included an examination by a member of the breast or plastic surgery team, including an attending, resident, or Advanced Registered Nurse Practitioner (ARNP). For immediate breast reconstruction, this referred to the last follow-up visit with the implant or tissue expander in place.

Statistical Analysis

Patient characteristics and outcomes were summarized according to whether patients underwent immediate implant-based reconstruction or mastectomy alone and are reported as number and percentage. The χ^2 test was used to test for differences in types of outcomes according to treatment. In order to estimate the adjusted risk difference associated with immediate implant-based reconstruction compared to mastectomy alone, a linear regression model with robust standard errors was fit, with the development of any complication as the dependent variable and the following as independent variables: reconstruction (immediate implant based vs mastectomy alone), age, body mass index (BMI), neoadjuvant radiation therapy, neoadjuvant chemotherapy, smoking, diabetes mellitus, bilateral versus unilateral mastectomy, and axillary procedure (axillary lymph node dissection, sentinel lymph node biopsy, or none). The estimated coefficient for the reconstruction variable was reported as the adjusted risk difference associated with immediate reconstruction. Similarly, the adjusted relative risk of any complication associated with immediate reconstruction was estimated by multivariate Poisson regression with robust variance estimates; the dependent and independent variables were as specified for the linear-regression model. Adjusted relative risks for major and minor complications associated with immediate reconstruction were obtained by fitting similar Poisson regression

Table 1. Characteristics of 716 Patients Undergoing Mastectomy.^a

| Characteristic | Immediate Breast Reconstruction (n = 315) | Mastectomy Alone (n = 401) |
|--------------------------------------|---|----------------------------|
| Characteristic | | |
| Age, years (median, IQR) | 48 (41-55) | 57 (49-66) |
| BMI, kg/m ² (median, IQR) | 26 (22-30) | 27 (23-32) |
| Neoadjuvant radiation | 8 (3) | 39 (10) |
| Neoadjuvant chemotherapy | 55 (17) | 164 (41) |
| Smoking | 35 (11) | 41 (10) |
| Diabetes mellitus | 7 (2) | 46 (11) |
| Mastectomy type | | |
| Unilateral | 186 (59) | 315 (79) |
| Bilateral | 129 (41) | 86 (21) |
| Simple | 25 (8) | 389 (97) |
| Skin-sparing | 280 (89) | 10 (2) |
| Nipple-sparing | 9 (3) | 2 (1) |
| Axillary procedure | | |
| None | 67 (21) | 80 (20) |
| SLNB | 191 (61) | 154 (38) |
| ALND | 57 (18) | 167 (42) |
| Follow-up time | | |
| Median follow-up, months (IQR) | 6.0 (3.8-10.6) | 25.9 (10.4-43.1) |

Abbreviations: ALND, axillary lymph node dissection; BMI, body mass index; IBR, immediate breast reconstruction; IQR, interquartile range; SLNB, sentinel lymph node biopsy.

^aReported as n (%) except where specified.

models, but with major or minor complications (rather than any complication), respectively, as the dependent variable. In order to examine whether any potentially modifiable factors were independently associated with the risk of complication following IBR, a multivariate Poisson regression model with robust variance estimates was fit using data for just those participants who underwent immediate reconstruction. The dependent variable was the development of any complication, and independent variables included those listed above as well as implant type (permanent vs expander), antibiotic soak prior to implantation, and use of acellular dermal matrix. In all multivariate analyses, the Wald test was used to assess statistical significance of factor coefficients. Only 10 of 716 patients had missing data; these were excluded from multivariate analysis. A significance threshold of 0.05 was used for all statistical tests. All analyses were performed using Stata version 13.0 (StataCorp, College Station, Texas).

Results

Clinical data for 716 patients were obtained by chart review. Of these 716, 401 underwent mastectomy alone and 315 underwent immediate reconstruction. These procedures were performed by 5 breast surgeons and 4 plastic surgeons at our institution. Patients undergoing mastectomy alone (n = 401) were noted to be older, more frequently diabetic, and

more likely to have undergone chemotherapy and/or radiation (Table 1). However, the rate of obesity and smoking was similar between the groups. The differences seen in patients undergoing immediate reconstruction ($n = 315$) compared to those undergoing mastectomy likely reflects both physician bias and patient preference. Older and less healthy women are less likely to be considered candidates for immediate reconstruction. In addition, older patients are often less interested in pursuing post-mastectomy reconstruction.¹⁶

Neoadjuvant chemotherapy and radiation were more common among patients undergoing mastectomy alone (Table 1). This difference was almost certainly related to selection bias by surgeons evaluating patients for breast reconstruction. Patients with previous radiation are rarely considered candidates for immediate implant-based reconstruction due to the known increased risk of complications in these patients.^{17,18} In addition, patients with a greater burden of disease, or a more advanced stage tumor, are less likely to be referred to a plastic surgeon for consideration of immediate breast reconstruction.

Surgical approaches used by breast surgeons at our institution include simple, skin-sparing, and nipple-sparing mastectomy. In the mastectomy alone group, simple mastectomy was the most common procedure performed, while in the immediate reconstruction group, skin-sparing mastectomy was the most common technique used (Table 1). Considerations regarding the management and necessity of preservation of the skin envelope for immediate reconstruction explain these differences. In addition, bilateral procedures were more common among women undergoing immediate reconstruction compared to those undergoing mastectomy alone, likely due to the increased number of contralateral prophylactic procedures performed in this group.¹⁹

The surgical technique utilized by breast surgeons was variable. In both the mastectomy alone and immediate reconstruction groups, 60% of mastectomies were performed with the use of tumescence. At our institution, the tumescent solution is a mixture of lactated Ringer's, lidocaine, and epinephrine; the volume injected is determined by the surgeon at the time of the operation. Axillary procedures were performed in the majority of cases in both groups (Table 1). Sentinel lymph node biopsy was the most common axillary procedure among patients undergoing immediate breast reconstruction, with considerably fewer patients requiring a complete axillary lymph node dissection. However, in the mastectomy alone group, nearly half of patients required an axillary lymph node dissection, with many fewer patients having a sentinel lymph node biopsy or no axillary procedure. These differences are likely related to stage of disease at presentation and widely accepted clinical management protocols for the treatment of malignant breast disease.

Among the plastic surgeons, techniques varied as well. In 71% ($n = 224$) of cases, the implant was soaked in antibiotic irrigation prior to placement into the breast pocket. The use of acellular dermal matrix varied among plastic surgeons at our institution, with 58.0% (182 of 314 undergoing IBR) using this product in order to provide adequate coverage of the

implant. The variability in these practices reflects lack of clear consensus in the literature regarding their value in preventing complications.³

Median follow-up time for the immediate reconstruction group was 6.0 months (interquartile range: [IQR]: 3.8-10.6 months). In the mastectomy alone group, follow-up time was considerably longer, with a median of 25.9 months (IQR: 10.4-43.1 months). This difference is largely attributed to the fact that tissue expanders are placed as part of a staged reconstruction with the intention of removing the tissue expander in order to exchange to a permanent implant or autologous reconstruction. Follow-up ended at the time of exchange. For patients undergoing mastectomy alone, follow-up continued until the last documented breast examination by a provider in our institution. This accounts for the markedly shorter follow-up time seen in the immediate breast reconstruction group. Note that planned removal of a tissue expander at the time of permanent implant or autologous reconstruction was not counted as reoperation. Similarly, if a patient undergoing mastectomy alone underwent a subsequent planned autologous or implant-based reconstruction, this was not counted as reoperation. Furthermore, complications related to delayed autologous or implant reconstruction were not included in this study.

Outcomes including return to the operating room, surgical site infection, seroma, hematoma, delayed healing, and implant loss were compared in univariate analyses (Table 2). The overall complication rate was 34.9% ($n = 110$) among patients undergoing immediate reconstruction, compared to 24.7% ($n = 99$) in the mastectomy alone group ($P < .003$), corresponding to a crude risk difference of 10.2% (95% confidence interval [CI]: 3.4%-17.0%) and crude relative risk of 1.41 (95% CI: 1.13-1.78). Return to the operating room for any reason was more common in the IBR group, occurring in 11% ($n = 35$) compared to 2% ($n = 10$) in the mastectomy alone group ($P < .001$). Delayed wound healing was also significantly more common in IBR: 19% ($n = 61$) of immediate breast reconstructions experienced some type of delayed wound healing, compared to only 8% ($n = 32$) of those undergoing mastectomy alone ($P < .001$). The frequency of surgical site infection, hematoma, and seroma was not significantly different between the 2 groups; however, the increased frequency of seroma in the mastectomy alone group was close to reaching statistical significance ($P = .059$). Implant loss occurred in 29 patients undergoing immediate breast reconstruction (9%).

We performed multivariate analysis to estimate the risk attributable to IBR while adjusting for differences between groups in factors known to increase post-operative complications. After controlling for all of the factors listed in Table 3, we found a statistically significant increase in risk of any post-operative complication in patients undergoing IBR. Specifically, the adjusted risk difference was estimated to be 17.2% (95% CI: 9.4%-24.9%; $P < .001$) and the adjusted relative risk was estimated to be 1.82 (95% CI: 1.39-2.37; $P < .001$). In addition, increasing age, BMI, history of radiation therapy, smoking, and nipple-sparing mastectomy were also

Table 2. Outcomes According to Whether Implant-based IBR Was Performed.^{a,b}

| Complication | Immediate Breast Reconstruction (n = 315) | Mastectomy Alone (n = 401) | P ^c |
|------------------------------|--|-------------------------------|-----------------|
| Any | 110 (35) | 99 (25) | .003 |
| Major | 42 (13) | 11 (3) | <.001 |
| Minor | 74 (23) | 90 (22) | .740 |
| Reoperation | 35 (11) | 10 (2) | <.001 |
| Infection | 43 (14) | 39 (10) | .102 |
| Hematoma | 6 (2) | 15 (4) | .148 |
| Seroma | 21 (7) | 43 (11) | .059 |
| Delayed wound healing | 61 (19) | 32 (8) | <.001 |
| Implant loss | 29 (9) | NA | NA |

Abbreviations: IBR, immediate breast reconstruction; NA, not applicable.

^aBold indicates statistical significance at $\alpha = .05$.

^bReported as n (%).

^c χ^2 test.

Table 3. Multivariate Analysis of Factors Associated With Any Complication.^{a,b}

| Factor | Adjusted Risk Ratio ^c | 95% CI | P ^d |
|--|----------------------------------|------------------|-----------------|
| IBR | 1.82 | 1.39-2.37 | <.001 |
| Age | 1.02^e | 1.01-1.03 | <.001 |
| BMI | 1.02^f | 1.00-1.03 | .037 |
| Neoadjuvant radiation therapy | 2.04 | 1.42-2.93 | <.001 |
| Neoadjuvant chemotherapy | 0.79 | 0.59-1.07 | .124 |
| Smoking | 1.57 | 1.18-2.08 | .002 |
| Diabetes mellitus | 1.13 | 0.74-1.74 | .565 |
| Bilateral mastectomy (ref: unilateral) | 1.11 | 0.87-1.42 | .391 |
| Nipple-sparing mastectomy | 2.17 | 1.21-3.88 | .009 |
| Axillary node sampling (ref: none) | - | - | - |
| SLNB | 1.12 | 0.81-1.54 | 0.504 |
| ALND | 1.36 | 0.97-1.91 | 0.078 |

Abbreviations: ALND, axillary lymph node dissection; BMI, body mass index; CI, confidence interval; IBR, immediate breast reconstruction; SLNB, sentinel lymph node biopsy.

^aAnalysis was based on 706 patients, as 10 had missing data for one or more variables.

^bBold indicates statistical significance at $\alpha = .05$.

^cRisk of any complication, adjusted for factors listed in the table.

^dWald test.

^eRisk ratio associated with 1-year increase in age.

^fRisk ratio associated with 1-unit increase in BMI.

independently associated with an increased risk of any complication after mastectomy (Table 3).

In a multivariate model including all factors listed in Table 3 as covariates, IBR was an independent risk factor for major complications, with an adjusted relative risk of 7.10 (95% CI: 3.47-14.51; $P < .001$). However, IBR was not found to be an independent risk factor for minor complications (adjusted relative risk 1.34; 95% CI: 0.97-1.83, $P = .075$). This result was similar to the results of the univariate analysis, demonstrating that the risk of minor complications was similar for those undergoing mastectomy alone or IBR. Therefore, the increased risk of complications attributed to immediate breast

Table 4. Modifiable Factors Among Patients Undergoing Immediate Breast Reconstruction.^a

| Factor | Adjusted Risk Ratio ^b | 95% CI | P ^c |
|--|----------------------------------|-----------|----------------|
| Permanent implant (ref: tissue expander) | 1.54 | 0.92-2.58 | .097 |
| Antibiotic soak | 1.20 | 0.84-1.71 | .323 |
| Acellular dermal matrix | 1.21 | 0.87-1.68 | .257 |

Abbreviations: BMI, body mass index; CI, confidence interval.

^aAnalysis was based on 309 patients, as 6 had missing data for 1 or more variables.

^bRisk of any complication, adjusted for age, BMI, radiation therapy, chemotherapy, smoking, diabetes mellitus, bilateral mastectomy (vs unilateral), nipple-sparing mastectomy (vs simple or skin-sparing mastectomy), axillary-node sampling, and other 2 factors listed in the table.

^cWald test.

reconstruction was primarily related to an increased risk of major complications.

Finally, in order to examine whether any modifiable factors were associated with post-operative complications among those undergoing IBR, we constructed a multivariate model including those factors listed in Table 3 as well as the type of implant placed (permanent vs tissue expander), whether the implant was soaked in antibiotic solution prior to placement, and whether acellular dermal matrix was used. In this subgroup analysis, we did not find any of these 3 factors to be independently associated with the risk of post-operative complication following IBR (Table 4). However, there was a trend toward increased complications in the permanent implant group (adjusted relative risk 1.54; 95% CI: 0.92-2.58, $P = .097$).

Discussion

Several authors have previously reviewed the safety of and complications associated with mastectomy and immediate breast reconstruction.^{1,10,11} Complication rates ranged from 8% to 48% in mastectomy alone, compared to 22% to 31% in IBR. These studies were often limited by small sample size and frequently did not account for differences between groups, specifically the tendency for IBR patients to be younger, with less advanced disease, and less often smokers than the mastectomy-alone groups. We demonstrated a similarly high overall complication rate (25% in the mastectomy alone group and 35% in the IBR group), partially attributable to our very stringent diagnostic criteria for infection and delayed wound healing, capturing patients with even very mild cellulitis or a small area of eschar.

The baseline risk associated with mastectomy and other procedures for malignant breast disease was reviewed by de Blacam et al at Harvard in a retrospective study of the ACS-NSQIP database, reviewing 26 988 patients who had undergone mastectomy and breast conservation therapy.²⁰ Multivariate logistic regression demonstrated that BMI greater than 25 kg/m² and smoking were the only variables associated with increased wound complications after breast

surgery. The increased risk associated with obesity and smoking has been corroborated by several other studies.^{9,13,21} Although this study did not directly compare women undergoing mastectomy alone versus immediate breast reconstruction, it provides relevant information regarding the baseline risks associated with mastectomy.

The recent analysis of the ACS-NSQIP data set examining the outcomes of mastectomy with or without immediate implant reconstruction provides very interesting data regarding the true risk profile of immediate implant-based breast reconstruction.¹⁵ Using propensity matching to account for inherent differences between groups, there was no increased risk of wound, medical, or overall complications after 30-day follow-up. There was, however, an increased risk of deep wound infection and unplanned operation. Several limitations are associated with this analysis, including minimal follow-up time, as well as limited information regarding the details of the complications seen in these patients. Our study differs in that we analyzed a large cohort of patients from a single institution with much longer follow-up, allowing us to more accurately capture the outcome for these patients.

Our study is novel in that we performed a multivariate analysis of multiple complications associated with mastectomy and immediate breast reconstruction in the largest cohort of patients from a single center reviewed to date. We demonstrate that there are considerable differences between the patients selected for either procedure. Women choosing immediate breast reconstruction are more often younger, have fewer medical comorbidities, and less frequently have undergone neoadjuvant chemotherapy or radiation therapy than those selecting mastectomy alone. These variations certainly contribute to the differences in complication rates between these 2 groups. Multivariate analysis controls for these inherent differences between the study groups, allowing for more accurate and clinically applicable analysis of these data.

In our institution, patients selected for IBR had a 10% increased risk of any complication compared to those undergoing mastectomy alone. After adjustment for confounders including age, BMI, radiation therapy, chemotherapy, smoking, diabetes, bilateral versus unilateral mastectomy, type of mastectomy (simple vs skin-sparing mastectomy vs nipple-sparing mastectomy), and axillary procedures (none versus sentinel node biopsy vs axillary lymph node dissection), the absolute increased risk attributable to IBR was estimated to be 17%. That the observed increased risk of complications in those undergoing IBR (10%) was lower than the risk increase attributable to IBR after adjusting for confounders (17%) reflects effective selection of patients for immediate reconstruction based on factors known to be associated with post-operative wound-related complications (see Table 1). That is, surgeon selection of low-risk patients for IBR offsets the increased risk associated with this procedure.

Given that the outcome of “any complication” is of somewhat limited clinical utility due to its composite, heterogeneous nature, we also subdivided outcomes into major and minor complications. After controlling for multiple variables, IBR

was found to be independently associated with an increased risk of major complications including readmission to the hospital or reoperation. Conversely, IBR was not independently associated with minor complications. The risk associated with major complications can be explained by noting that the management of complications in the setting of a prosthetic implant is inherently different than the management of complications in patients undergoing mastectomy alone. For instance, if a patient is noted to have a mild cellulitis with a breast implant in place, she is much more likely to be admitted to the hospital for intravenous antibiotics than a patient with no prosthesis in place. Similarly, if a patient is found to have a clinically significant infection or wound-healing complication in the setting of a breast implant, she is much more likely to undergo a reoperation for implant removal in order to treat the complication adequately. Conversely, most complications in patients undergoing mastectomy alone can be treated on an outpatient basis with oral antibiotics or local wound care; indeed, these rarely require reoperation. Thus, while our findings demonstrate that IBR is certainly associated with an increased risk of “major” complications such as reoperation or admission for intravenous antibiotics, these are complications that are specifically related to the treatment of prosthetic implant complications, where more aggressive therapy is often required to clear infection or facilitate wound healing. When counseling a patient about reconstructive options, we would thus recommend advising the patient that there is indeed an increased risk of complications, in particular reoperation, related to IBR. However, this largely reflects the more aggressive management required in the setting of a prosthetic implant rather than additional danger inherent to the implant itself.

With very careful patient selection, it is possible to reduce the risk associated with mastectomy alone. Overall, patients undergoing mastectomy alone had a 24.7% risk of any complication after surgery. By excluding all patients with a BMI >25, smokers, diabetics, and women with previous radiation, the risk of any complication after mastectomy alone is reduced to 14.3%. This absolute risk reduction of 10% is an important information for the breast surgeon when counseling women prior to mastectomy. On the other hand, after excluding all patients with a BMI >25, smokers, and women with previous radiation, the risk of mastectomy plus immediate breast reconstruction is only reduced from 35.3% to 30.0%. This surprisingly high complication rate, despite optimal patient selection, suggests that there is some additional inherent risk when immediate implant-based breast reconstruction is performed in conjunction with mastectomy. We postulate that this elevated level of risk may be due to inherent issues related to placing an implant below acutely ischemic mastectomy flaps.

In addition, we carefully analyzed each of the breast surgeons and plastic surgeons separately to determine whether there was any correlation with a particular individual’s surgical technique, and we found no such correlation. The only positive correlation identified was a clearly increasing risk of complications with increasing BMI, as previously shown in many other studies.

Although immediate implant-based breast reconstruction is gaining popularity, especially in high-risk patients,^{22,23} the potential advantages of delayed breast reconstruction should still be considered. The previous literature has looked at the rate of complications in immediate versus delayed breast reconstruction,^{14,24} but none have compared the additional risk of delayed reconstruction to mastectomy alone. In order to better understand the high complication rates associated with implant-based breast reconstruction, further study is required to determine the true additional risk of combining delayed implant-based breast reconstruction with mastectomy.

Comparing complication rates between mastectomy and mastectomy with immediate reconstruction is useful for the surgical specialties involved but may be less so for a patient. From a patient's perspective, the comparison would be more useful by putting the risks of mastectomy plus immediate reconstruction against the added risks of mastectomy plus delayed reconstruction. Patients who are considering reconstruction might prefer to know whether there is a worthwhile benefit to combining versus separating those 2 steps. Delayed reconstruction can remove most of the mastectomy risks from the plastic surgical arena, but the patient still has to face those risks and, in fact, runs the risks of surgery and anaesthesia twice.

Delayed reconstruction was not the focus of this study, but other authors have reported complication rates from 33% to 42% after delayed reconstruction.^{13,14} Assuming a patient is considering breast reconstruction, the additive risks of mastectomy and immediate reconstruction would be around 35% in our series. By comparison, with delayed reconstruction, the overall risk of complications might be 25% (for mastectomy alone), plus 33% (for delayed reconstruction), for a total of 58%. The plastic surgeon can avoid the risks of the first step, but that is not true for the patient. What might initially be perceived as a high risk of immediate reconstruction may seem much more reasonable in that light.

In our series, immediate reconstruction was successful in essentially 90% of cases and required an additional intervention in around 10%. Delayed reconstruction, by comparison, requires an additional surgery 100% of the time, to achieve the same goal. So while immediate reconstruction poses its perils, it can be a worthwhile chance to take, especially if the risks are manageable as suggested by this series.

Limitations of this study include its retrospective nature and nonrandomized study design. Randomization would not be possible due to known established risk factors in implant-based breast reconstruction and strong patient preferences regarding reconstructive options. In addition, post-operative radiation was not included as a variable in this study. Given the potential for this factor to contribute to the higher rate of complications in the IBR group, consideration should be given to examining its effect in future studies.

Immediate implant-based breast reconstruction is a common and popular practice in breast reconstruction. However, patients selected for mastectomy alone versus IBR are inherently different. Through multivariate analysis of the largest

cohort reviewed thus far in the literature, we have determined that the risk of complications associated with mastectomy is moderately increased by the addition of IBR. However, the additional "complications" experienced in the immediate-reconstruction group largely reflect the aggressive management of infections and delayed wound healing in the presence of a prosthetic implant rather than harm inflicted by the presence of the implant. Implant-based breast reconstruction can be safely performed provided that patients are educated about the increased rate of reoperation and/or hospital admission specific to implant-related complications. Referral to a plastic surgeon for the discussion of IBR should be offered to all patients planning mastectomy, except in cases that are not safe from an oncologic perspective. We recommend that plastic surgeons continue to use accepted guidelines in selecting patients for IBR, noting the increased risk of complications in patients who are older, smokers, and have undergone previous radiation therapy. We suggest that with appropriate patient selection and education, immediate breast reconstruction is a safe and reliable procedure with only minimal additional risk compared to mastectomy alone.

Authors' Note

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