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The Effect of Timing on Breast Reconstruction Outcomes in Diabetic Women

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Background: This study examines the effect of timing (immediate vs delayed) on postoperative morbidity in diabetic women undergoing breast reconstruction after mastectomy.

Methods: We reviewed the National Surgical Quality Improvement Program (NSQIP) databases from 2005 to 2012 for all diabetic women undergoing breast reconstruction. Multivariable logistic regression was used to estimate the risk of 30-day overall complications in the immediate versus delayed cohorts. Additionally, we retrospectively reviewed outcomes for all Johns Hopkins Hospital diabetic patients undergoing breast reconstruction from 2005 to 2014.

Results: In the NSQIP, 1,408 diabetic women underwent breast reconstruction: 958 (68%) immediate and 450 (32%) delayed. In the immediate group, 10.75% of patients developed a 30-day overall complication, compared with 7.78% of patients in the delayed group. On multivariable analysis, the odds of developing 30-day overall complications were significantly higher (adjusted odds ratio = 1.68; $P = 0.033$) for the immediate compared with the delayed cohort. In the Johns Hopkins Hospital cohort, 114 reconstructions were performed in 52 diabetic women: 59 (51.8%) immediate and 55 (47.2%) delayed. On long-term follow-up (median = 16.5 months), 41.0% of immediate reconstructions developed a surgical complication compared with 27.8% of delayed reconstructions. Deep infections ($P = 0.026$), seroma formation ($P = 0.003$), reconstruction failure ($P = 0.001$), and reoperation rates ($P = 0.001$) were significantly increased in the immediate cohort.

Conclusions: Among diabetics seeking breast reconstruction, delaying the reconstructive surgery from the mastectomy is associated with decreased postoperative morbidity. It also appears that the 30-day postoperative time point available in the NSQIP does not fully reflect the magnitude of the long-term complications these diabetic patients will develop. *(Plast Reconstr Surg Glob Open 2016;4:e1090; doi: 10.1097/GOX.0000000000001090; Published online 25 October 2016.)*

Immediate breast reconstruction rates have risen dramatically in the United States during the past decade.[1] Despite studies demonstrating higher complication rates, immediate reconstruction has been demonstrated to be safe and cost-effective when compared with delayed reconstruction.[2–4] Patients with diabetes mellitus are increasing in prevalence and pose a significant challenge for surgery.[5] Diabetes mellitus can increase the risk of infection and delay wound healing, adding to postoperative morbidity.[6–8] Among breast reconstruction patients, diabetics experience a higher incidence of overall complications compared with nondiabetics, particularly with autologous reconstruction.[9,10] However, the literature lacks studies examining how the timing of breast recon-

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struction affects postoperative outcomes in the diabetic population.

Early postoperative outcomes are becoming increasingly relevant because of their association with health care costs, health care quality, Medicare reimbursements, and patient satisfaction.[11,12] The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database is a large, prospective national data set encompassing data from over 200 hospitals. The limitations of the NSQIP have been documented, including follow-up limited to 30 days and lack of pertinent outcomes for breast reconstruction (ie, fat necrosis, hematoma, capsular contracture).[9] However, to our knowledge, no one has scrutinized the NSQIP database by analyzing it alongside a single institution's experience of specific breast reconstruction cohorts.

This study aimed to determine the effect of timing on outcomes in diabetic patients undergoing breast reconstruction using a large multi-institutional database, the NSQIP, to identify the optimal timing for least postoperative morbidity. A second objective was to validate the NSQIP database for breast reconstruction outcomes using a comparison with results from The Johns Hopkins Hospital (JHH) experience.

METHODS

In the first part of this study, we performed a retrospective analysis of patients in the NSQIP database. Deidentified patient data files from January 1, 2005, to December 31, 2012, were reviewed on all female diabetics undergoing breast reconstruction. Diabetic patients undergoing breast reconstruction with and without mastectomy were identified using the following Current Procedural Terminology (CPT) codes: 19340, 19342, and 19357 for prosthetic breast reconstructions; 19361, 19364, 19367, 19368, and 19369 for autologous breast reconstructions; and 19160, 19162, 19180, 19182, 19200, 19240, 19260, 19301, 19302, 19303, 19304, 19305, 19306, and 19307 for mastectomies. Immediate reconstruction included all events in which a reconstruction CPT code accompanied a mastectomy CPT code in the same encounter. Delayed reconstruction included all events in which a reconstruction CPT code was found without a concurrent mastectomy CPT code.

The NSQIP-defined demographic and preoperative variables were compared between the immediate and delayed reconstruction groups. They included demographic information (race, age, admission year, and body mass index class), preoperative risk factors (operation time, smoking status, inpatient status, alcohol intake, wound infection, corticosteroid use, and operation within the previous 30 days), and comorbidities (cardiovascular, respiratory, hepatobiliary, renal, neurologic, and hemato-oncologic). Outcomes were categorized as overall complications, surgical complications, medical complications, reconstruction failure, and reoperation. Surgical complications were defined as superficial infection, deep infection, organ space infection, wound dehiscence, and flap/prosthesis failure. Medical complications included pneumonia, unplanned reintubation, pulmonary embolism, ventilator dependence for greater than 48 hours, renal insufficiency, acute renal failure, urinary tract infection, stroke, coma, cardiac arrest, and myocardial infarction. Overall complications were defined as a sum of all surgical and medical complications.

Stata version 13.1 (StataCorp LP, College Station, Tex.) was used to analyze differences in the immediate and delayed cohorts. Significance was defined as $P < 0.05$. As a preliminary analysis, associations between variables and outcomes were examined using crosstabulation and unadjusted univariate analysis to inspect for missing data and data errors and to identify potential confounders and effect modifiers. Chi-square test and Fisher's exact test were used, as appropriate, to compare categorical outcomes. t Test and Wilcoxon rank-sum test were used to compare continuous outcomes. A multivariable logistic regression model was fitted to estimate the association between timing of breast reconstruction and 30-day overall complications. Variables were selected using clinical relevance and change-in-estimate methods and included in a stepwise forward manner.[13] Likelihood ratio tests were used to examine effect modification and departures from linearity.

In the second part of this study, we performed a retrospective analysis of all diabetic patients at JHH undergoing immediate and delayed breast reconstruction. Institutional Review Board approval was sought and received. Electronic medical records for all patients that had undergone breast reconstruction at our institution from January 1, 2005, to July 31, 2014, were handsearched to identify those with a diagnosis of diabetes and taking oral medication or insulin. Patients were included in the immediate reconstruction cohort if they received any sort of reconstructive modality (prosthetic or autologous) in the same operation as their mastectomy and in the delayed reconstruction cohort if they received any sort of reconstructive modality (prosthetic or autologous) on a separate operation from their mastectomy. Patients undergoing a 2-staged reconstruction (ie, those who received a tissue expander on the day of their mastectomy and a final prosthetic or autologous reconstruction at a later date) were included in both immediate and delayed groups. This was done to ensure that our data were comparable to those available in the NSQIP.

Demographic and preoperative variables collected from JHH patient medical records mirrored data available in the NSQIP. Outcomes were similarly categorized as overall complications, surgical complications, medical complications, reconstruction failure, and reoperation. However, surgical complications included all those specified in the NSQIP in addition to seroma, fat necrosis, hematoma, mastectomy skin necrosis, and abdominal hernia. Differences in demographics, preoperative risk factors, and outcomes between immediate and delayed reconstructions were compared.

Finally, overall morbidity, surgical morbidity, medical morbidity, reconstruction failure, and reoperation rates were compared between the NSQIP and JHH diabetic cohorts.

RESULTS

NSQIP Patient Demographics and Outcomes

A total of 1,408 patients met the inclusion criteria, of which 958 (68%) received immediate reconstructions and 450 (32%) received delayed reconstructions (Fig. 1). Within the immediate reconstruction cohort, 802 (84%) received prosthetic reconstructions and 156 (16%) received autologous reconstructions. Within the delayed reconstruction cohort, 332 (74%) received prosthetic reconstructions and 118 (26%) received autologous reconstructions. Demographic information for the NSQIP database population is presented in Table 1. The demographic information and preoperative risk factors of the patients in the immediate and delayed reconstruction cohorts are compared in Table 2. Significant differences existed among the immediate and delayed reconstruction groups in median operation time (138.5 ± 161 min vs. 205 ± 116 min; $P < 0.001$) and inpatient status (78.91% vs. 44.22%; $P < 0.001$).

The unadjusted postoperative outcomes for the immediate and delayed reconstruction cohorts are presented in Table 3. Reconstruction failure rates (1.57% vs. 0.22%; $P = 0.027$) were significantly higher in the immediate reconstruction group, whereas the rate of acute renal failure (0% vs. 0.44%; $P = 0.039$) was significantly higher in the delayed group. Rates of overall morbidity (10.75% vs. 7.78%; $P = 0.080$) and surgical morbidity (10.02% vs. 6.89%; $P = 0.056$) were higher in the immediate group, although these only trended toward statistical significance.

We fitted a multivariable logistic regression model to adjust for age, smoking status, preoperative anemia, inpatient status, type of reconstruction, and operation year. We tested this model for departures from linearity using likelihood ratio tests, showing no statistical evidence for such departures. Likewise, we tested for effect modification from variables identified with Mantel-Haenszel analysis as potential effect modifiers, finding no evidence for effect modification from type of reconstruction ($P = 0.76$), smoking status ($P = 0.26$), or preoperative anemia ($P = 0.32$).

Unadjusted and adjusted odds ratios (ORs) from this model are presented in Table 4. Notably, diabetic women undergoing immediate reconstructions had significantly higher odds of 30-day overall complications, as compared with the delayed reconstruction group [adjusted OR = 1.68; 95% confidence interval (CI) = 1.04–2.72, $P = 0.033$]. Additionally, autologous reconstructions were associated with significantly higher 30-day overall complications than prosthetic reconstructions (adjusted OR = 2.50; 95% CI = 1.63–3.85; $P < 0.001$).

Immediate reconstruction among diabetics was also associated with significantly higher 30-day surgical complications compared with delayed reconstructions (adjusted OR = 1.75, 95% CI = 1.05–2.9, $P = 0.029$). In contrast, no statistically significant association was found for medical complications between the 2 groups (adjusted OR = 0.93, 95% CI = 0.25–3.42, $P = 0.914$).

The odds of reconstruction failure within immediate reconstruction were significantly higher compared with delayed reconstruction within diabetics (unadjusted OR = 7.14; 95% CI = 0.94–54.47; $P = 0.027$). After adjustment for confounders, immediate reconstruction had higher odds of reconstruction failure than delayed, but without statistical significance (adjusted OR = 5.61; 95% CI = 0.67–47.25; $P = 0.112$). There was

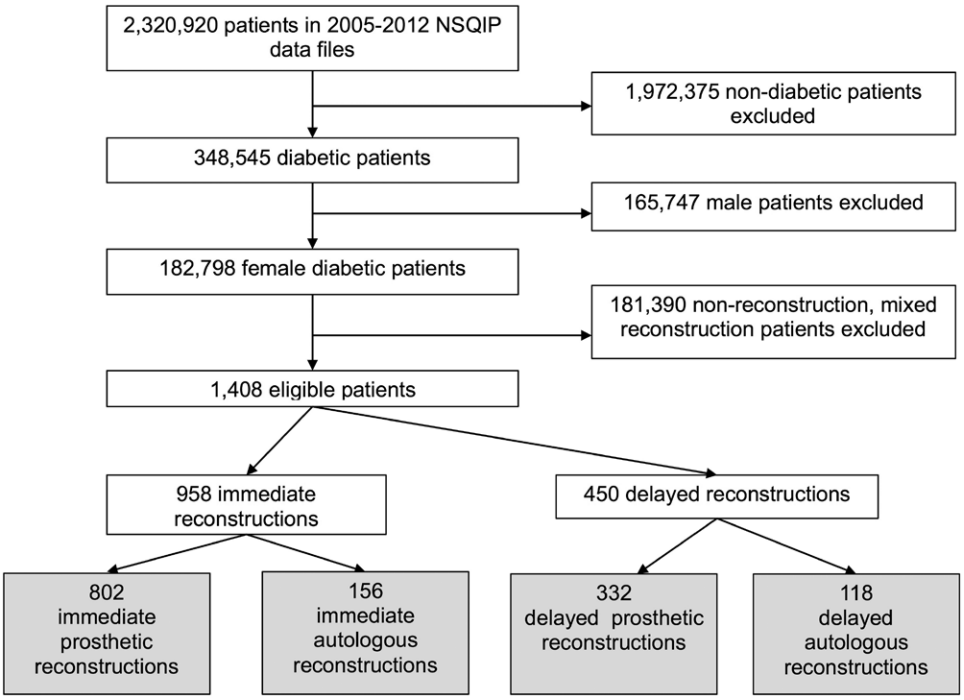

Fig. 1. Patient selection strategy identifying patients with diabetes undergoing breast reconstruction in the 2005 to 2012 NSQIP Patient User File.

Table 1. Characteristics of Women with Diabetes in the NSQIP Database (n = 1408) and JHH (n = 52) Undergoing Breast Reconstruction

	No. (%)	
	NSQIP	JHH
Overall population	1,408	52
Race		
Asian or Pacific Islander	38 (2.7)	1 (1.9)
White	814 (57.8)	27 (51.9)
African-American	199 (14.1)	21 (40.4)
Latino	119 (8.5)	—
Other	10 (0.7)	3 (5.8)
Mean age ± SD, y	58.3±9.4	53.9±9.3
Admission year		
2012–2014*	379 (26.9)	24 (46.2)
2009–2011	731 (51.9)	19 (36.5)
2005–2008	298 (21.2)	9 (17.3)
Mean BMI ± SD, kg/m^2	32.6±7.0	31.9±5.7
Normal	177 (12.6)	3 (5.8)
Overweight	373 (26.5)	12 (23.1)
Obese	847 (60.2)	25 (48.0)
Unknown	—	12 (23.1)
Timing of reconstruction, patients		
Immediate	958 (68.0)	39 (52.0)
Delayed†	450 (32.0)	36 (48.0)
Total no. of reconstructions		
Immediate reconstructions	958 (68.0)	59 (51.8)
Delayed reconstructions	450 (32.0)	55 (48.2)
Reconstructive modality		
Prosthesis	1134 (80.5)	89 (78.1)
Autologous	274 (19.5)	25 (21.9)

*The category of admission year from 2012 to 2014 only encompasses the NSQIP patients from 2012.
†Of the 36 patients undergoing delayed reconstruction in the JHH cohort, 23 patients received a prior first-stage reconstruction with tissue expander at the time of mastectomy.
BMI, body mass index.

Table 2. Preoperative Risk Factors of Women with Diabetes in the NSQIP Undergoing Breast Reconstruction (n = 1408)

	Immediate (n = 958)	Delayed (n = 450)	*P*
Age, mean ± SD, y	58.4 (9.6)	58.2 (9.1)	0.775
Race			
Asian or Pacific Islander	28	10	0.421
White	543	271	
African-American	125	74	
Latino	85	34	
Other	6	4	
BMI, mean ± SD	32.6±7.2	32.6±6.6	0.665
Operation time, median ± IQR, min	205±116	138.5±161	<0.001*
Smoking	95	50	0.492
Inpatient status	756 (78.91%)	199 (44.22%)	<0.001
Alcohol intake in previous 2 wk	2	2	0.202
Open wound, with or without infection	9	9	0.099
Corticosteroid use for chronic condition	19	4	0.131
Operation within previous 30 d	27	3	0.077
Composite cardiovascular morbidity†	112	42	0.186
Composite respiratory morbidity‡	19	10	0.768
Composite hepatobiliary morbidity§	0	0	—
Composite renal morbidity¶	6	1	0.315
Composite neurologic morbidity‖	26	5	0.056
Composite hematooncologic morbidity**	43	20	0.97

*Wilcoxon rank-sum test.
†Composite cardiovascular morbidity includes dyspnea, congestive heart failure, angina, previous myocardial infarction, previous percutaneous coronary intervention, previous cardiac surgery, history of peripheral vascular disease, and gangrene.
‡Composite respiratory morbidity includes pneumonia, chronic obstructive pulmonary disease, and ventilator dependence in the previous 48 hours.
§Composite hepatobiliary morbidity includes ascites in the previous 30 days and esophageal varices in the previous 6 months.
¶Composite renal morbidity includes acute renal failure and dialysis.
‖Composite neurologic morbidity includes an impaired sensorium in the previous 48 hours, hemiplegia, paraplegia, quadriplegia, coma lasting >24 hours, history of transient ischemic attack, stroke, and tumor involving the central nervous system.
**Composite hemato-oncologic morbidity includes bleeding disorder, weight loss >10% in the previous 6 months, disseminated cancer, chemotherapy in the past 30 days, and radiotherapy in the past 90 days.
BMI, body mass index; IQR, interquartile range.

no significant difference in reconstruction failures between reconstruction modalities. We also did not find any statistically significant differences between timing and reconstructive modality in regards to reoperation rates.

JHH Patient Demographics and Outcomes

A total of 52 documented diabetic women underwent 114 breast reconstructions at JHH between January 1, 2005 and July 31, 2014. Thirty-nine patients underwent 19 unilateral and 20 bilateral immediate reconstructions (59 total immediate reconstructions) and 36 patients underwent 17 unilateral and 19 bilateral delayed reconstructions (55 total delayed reconstructions). The majority of patients underwent 2-staged reconstruction using tissue expanders in the first stage followed by either implants or autologous reconstruction (n = 23). General demographic information of diabetic women undergoing breast reconstruction at JHH is presented in Table 1. The demographic information and preoperative risk factors of the patients in the immediate and delayed reconstruction cohorts were not significantly different (Table 5).

The unadjusted postoperative outcomes for the immediate and delayed reconstruction cohorts are presented in Table 6. At 30-day follow-up, reoperation rates were significantly higher in the immediate cohort (12.8% vs. 0%; $P = 0.028$); however, the rates of overall and surgical morbidity did not significantly differ between the 2 groups. The rates of reoperation at the 60-day postoperative time point remained significantly different between the 2 cohorts (15.4% vs. 0%; $P = 0.014$). On long-term follow-up (median = 16.5 months, range = 0.5–150 months), the rates of reconstruction failure (25.6% vs. 0%; $P = 0.001$) and reoperation (30.8% vs. 2.8%; $P = 0.001$) differed significantly between the 2 cohorts. At long-term follow-up, all reconstruction failures and reoperations occurred within the prosthetic group. The overall, surgical, and medical morbidity was not statistically significant between the 2 groups at the 60-day postoperative time point and on long-term follow-up.

Comparison of NSQIP and JHH Outcomes

A comparison of the 30-day postoperative outcomes using data from the immediate reconstruction cohorts in the NSQIP and JHH differed significantly. Compared

Table 3. Unadjusted Postoperative Outcomes by Timing for Women with Diabetes in the NSQIP Undergoing Breast Reconstruction (n = 1408)

	Immediate (%; n = 958)	Delayed (%; n = 450)	*P*
Overall morbidity	103 (10.8)	35 (7.8)	0.080
Surgical morbidity	96 (10.0)	31 (6.9)	0.056
Superficial infection	30 (3.1)	12 (2.7)	0.633
Deep infection	30 (3.1)	8 (1.8)	0.144
Organ space infection	14 (1.5)	8 (1.8)	0.655
Wound dehiscence	19 (2.0)	6 (1.3)	0.389
Flap/prosthesis failure	15 (1.6)	1 (0.2)	0.027
Medical morbidity	8 (0.8)	5 (1.1)	0.614
Pneumonia	1 (0.1)	1 (0.2)	0.584
Unplanned reintubation	1 (0.1)	1 (0.2)	0.584
Pulmonary embolism	2 (0.2)	0 (0.0)	0.332
Ventilator (>48 h)	1 (0.1)	1 (0.2)	0.584
Renal insufficiency	2 (0.2)	0 (0.0)	0.332
Acute renal failure	0 (0.0)	2 (0.4)	0.039
Urinary tract infection	2 (0.2)	3 (0.7)	0.178
Stroke/cerebrovascular accident	1 (0.1)	0 (0.0)	0.493
Myocardial infarction	0 (0.0)	1 (0.2)	0.144
Deep vein thrombosis	1 (0.1)	0 (0.0)	0.493
Sepsis	10 (1.0)	2 (0.4)	0.254
Septic shock	2 (0.2)	2 (0.4)	0.438
Reconstruction failure	15 (1.6)	1 (0.2)	0.027
Reoperation	35 (3.7)	25 (5.6)	0.094

with the NSQIP, JHH data using only the outcome variables available in the NSQIP demonstrated a significantly higher percentage of medical morbidities ($P = 0.008$), reconstruction failures ($P = 0.005$), and reoperations ($P = 0.005$). Comparing the NSQIP with JHH 30-day morbidity and JHH long-term morbidity data yielded statistically significant ($P < 0.05$) differences in overall morbidity, surgical morbidity, medical morbidity, reconstruction failure, and reoperation rates. In the delayed cohort, a comparison of 30-day postoperative outcomes in the NSQIP and JHH data using only the outcome variables available in the NSQIP did not yield any significant differences in morbidity. This trend continued when the NSQIP data were compared with JHH 30-day morbidity; however, when 30-day postoperative outcomes in the NSQIP were compared with JHH long-term follow-up data, overall morbidity ($P < 0.001$) and surgical morbidity ($P < 0.001$) were significantly higher in the JHH patient population.

DISCUSSION

Our analysis of diabetic females in the NSQIP undergoing breast reconstruction demonstrates that those who undergo an immediate reconstruction have significantly higher odds of developing 30-day overall and surgical complications compared with those undergoing delayed reconstruction. Autologous reconstructions were associated with higher overall, surgical, and medical complications compared with prosthetic reconstructions. However, the odds of reconstruction failure and reoperation at 30 days postoperatively did not differ based on breast reconstruction timing or modality within the NSQIP data set. Analysis of JHH data compared with the NSQIP data showed significant discrepancies between the 2 data sources.

Previous studies have established that diabetic patients are at a higher risk of developing complications after surgery,[14,15] and perioperative hyperglycemia may be the determining factor.[16,17] High blood glucose levels negatively affect the mobilization and phagocytotic ability of neutrophils and monocytes, predisposing to infection.[18,19] Diabetics may also have aberrant molecular and cellular signaling pathways, affecting keratinocyte and fibroblast migration, extracellular matrix remodeling, and angiogenesis, and thus causing wound-healing deficiencies.[20–22] In addition, hyperglycemia increases inflammatory cytokines and reactive oxygen intermediates, resulting in endothelial cell

Table 4. Unadjusted and Adjusted OR for the Association between Immediate Breast Reconstruction and Autologous Reconstruction and Study Outcomes

				Simple Regression Analysis			Multivariable Regression Analysis		
Outcome	Group	n	Complications (%)	Unadjusted OR	95% CI	*P*	Adjusted OR	95% CI	*P*
	Delayed (baseline)	450	35 (7.78)						
	Immediate	958	103 (10.75)	1.43	0.96–2.13	0.081	1.68	1.04–2.72	0.033
	Prosthetic (baseline)	1134	90 (7.94)	2.46	1.69–3.6	<0.001	2.5	1.63–3.85	<0.001
30-d overall complications	Autologous	274	48 (17.52)						
30-d surgical complications	Delayed (baseline)	450	31 (6.89)	1.51	0.99–2.29	0.057	1.75	1.06–2.9	0.029
	Immediate	958	96 (10.02)						
	Prosthetic (baseline)	1134	85 (7.5)	2.23	1.5–3.32	<0.001	2.24	1.43–3.51	<0.001
	Autologous	274	42 (15.33)						
30-d medical complications	Delayed (baseline)	450	5 (1.11)	0.75	0.24–2.3	0.615	0.93	0.25–3.42	0.914
	Immediate	958	8 (0.84)						
	Prosthetic (baseline)	1134	6 (0.53)	4.93	1.64–14.79	0.004	5.88	1.63–21.1	0.007
	Autologous	274	7 (2.55)						
Reoperation	Delayed (baseline)	446	25 (3.66)	0.64	0.38–1.08	0.094	1.2	0.65–2.23	0.565
	Immediate	956	35 (5.61)						
	Prosthetic (baseline)	1130	45 (3.98)	1.41	0.77–2.57	0.262	1.2	0.59–2.44	0.615
	Autologous	272	15 (5.51)						
Reconstruction failure	Delayed (baseline)	450	1 (0.22)	7.14	0.94–54.47	0.027	5.61	0.67–47.25	0.112
	Immediate	958	15 (1.57)						
	Prosthetic (baseline)	1134	4 (1.46)	1.39	0.44–4.33	0.574	1.73	0.51–5.82	0.378
	Autologous	274	12 (1.06)						

OR, odds ratio.

dysfunction and a prothrombotic environment.[23–25] Given these known hematological and vascular abnormalities, optimizing the surgical course of diabetic patients is especially important.

Recent analysis of diabetes with respect to postoperative complications after breast reconstruction has yielded mixed results. In a single-center study of 893 patients undergoing autologous reconstruction, Miller et al found no significant difference in flap and donor-site complications between diabetics and nondiabetics.[26] Fischer et al analyzed the NSQIP database from 2005 to 2010 and showed increased postoperative surgical complications within diabetics, but found no statistical significance when adjusted for other confounding variables.[2] They also found immediate reconstruction to be independently associated with increased postoperative surgical complications. Qin et al studied the NSQIP database from 2005 to 2012 and found that both insulin-dependent and non-insulin-dependent diabetics were associated with significantly higher surgical and overall complications after autologous reconstruction than nondiabetics.[9] However, the study only examined immediate reconstructions. Our analysis corroborated previous findings of autologous-based reconstructions with increased overall and surgical morbidity in the early postoperative period and also elucidated that immediate reconstruction is associated with increased risk of early overall and surgical morbidity among diabetics.

Autologous and prosthetic reconstructions predispose patients to distinct postoperative complications. However, our multivariable model established immediate timing as an independent risk factor for overall and surgical morbidity among diabetics even after controlling for reconstruction modality. An explanation for this association is likely multifactorial, and may include contamination of the surgical field during mastectomy, poor skin flap viability, and increased inflammation due to the mastectomy. These problems are likely to be exacerbated in diabetic patients who are more susceptible to infection.[3] Our NSQIP analysis identified superficial and deep surgical site infection as the predominant early surgical complications among the diabetic cohort. Additionally, postoperative radiation after immediate reconstruction has previously been shown to increase early surgical site complications,[27] which may compound the already compromised wound-healing abilities in diabetic patients.

Table 5. Preoperative Risk Factors of Women with Diabetes Undergoing Breast Reconstruction at Johns Hopkins Hospital (n = 52)

	Immediate (n = 39)	Delayed (n = 36*)	*P*
Age, mean ± SD, y	55.0±9.2	53.3±9.9	0.453
Race			
Asian or Pacific Islander	1	0	1.00
White	22	20	1.00
African American	13	14	0.639
Other	3	2	1.00
BMI, mean ± SD	31.8±5.4	30.5±6.2	0.374
Operation time, mean ± SD, min	256.5±104.8	346.4±235.4	0.082
Smoking	5	2	0.265
Hypertension	21	15	
Corticosteroid use for chronic condition	2	1	1.00
Congestive heart failure	0	2	0.227
Previous percutaneous coronary intervention	2	1	1.00
Bleeding disorder	2	0	0.494
Weight loss >10% in previous 6 mo	3	3	1.00
Chemotherapy in previous 30 d	2	1	1.00
Radiotherapy in pervious 30 d	6	5	1.00

*Of the 36 patients who underwent a delayed reconstruction, 23 patients received a prior first-stage reconstruction with tissue expander at the time of mastectomy

BMI, body mass index.

Table 6. Unadjusted Postoperative Comparison of 30-day, 60-day, and Long-term Complications in Immediate (n = 39, 59 Reconstructions) and Delayed (n = 36, 55 Reconstructions) Breast Reconstructions

	30-D Morbidity			60-D Morbidity			Long-term Morbidity		
	Immediate	Delayed	*P*	Immediate	Delayed	*P*	Immediate	Delayed	*P*
Overall morbidity, n (%)*	11 (28.2)	5 (13.9)	0.131	14 (35.9)	7 (19.4)	0.113	16 (41.0)	10 (27.8)	0.228
Surgical morbidity, n (%)*	10 (25.6)	5 (13.9)	0.204	13 (33.3)	7 (19.4)	0.174	15 (38.5)	10 (27.8)	0.327
Superficial infection, n	0	2	0.231	1	3	0.276	3	3	0.930
Deep infection, n	2	0	0.496	2	0	0.496	6	0	0.026
Flap/prosthetic failure, n	3	0	0.090	3	0	0.090	13	0	<0.001
Wound dehiscence, n	0	2	0.231	0	3	0.069	0	3	0.069
Seroma, n	3	0	0.090	5	0	0.027	9	0	0.003
Fat necrosis, n	2	1	0.600	3	2	0.706	4	3	0.768
Hematoma, n	2	0	0.496	2	0	0.496	3	0	0.090
Mastectomy skin necrosis, n	5	1	0.112	5	1	0.112	5	1	0.112
Capsular contracture, n	0	0	—	0	0	—	0	2	0.231
Medical morbidity, n (%)*	2 (4.9)	0 (0.0)	0.494	2 (4.9)	0 (0.0)	0.494	2 (4.9)	0 (0.0)	0.494
Myocardial infarction, n	1	0	1.00	1	0	1.00	1	0	1.00
Urinary tract infection, n	1	0	1.00	1	0	1.00	1	0	1.00
Donor site morbidity, n (%)*	0 (0.0)	1 (2.8)	0.480	0 (0.0)	1 (2.8)	0.480	1 (2.6)	1 (2.8)	1.00
Abdominal hernia, n	0	0	—	0	0	—	1	0	1.00
Umbilical site necrosis, n	0	1	0.480	0	1	0.480	0	1	0.480
Reconstruction failure, n (%)*	3 (7.7)	0 (0.0)	0.089	3 (7.7)	0 (0.0)	0.089	10 (25.6)	0 (0.0)	0.001
Reoperation, n (%)*	5 (12.8)	0 (0.0)	0.026	6 (15.4)	0 (0.0)	0.014	12 (30.8)	1 (2.8)	0.001

*Calculated as a percentage of patients.

Although the NSQIP permitted high-powered statistical analysis, the database has several limitations that prompted our evaluation of the JHH cohort. The chief limitations include the limited follow-up period of 30 days, no delineation of unilateral versus bilateral reconstructions, and omission of pertinent complications after breast reconstruction procedures. In addition, inconsistent reporting of prior radiation exposure prevented us from adjusting for it in our multivariable model. Although these limitations have been cited previously, there has been no evaluation of their importance by comparing the NSQIP data with the institutional data.

When comparing results from JHH data with the NSQIP on *immediate* reconstructions, we found significantly higher 30-day medical morbidity, reconstruction failure, and reoperation rates than those captured in the NSQIP even after restricting these data to the variables available in the NSQIP. Furthermore, these differences were amplified when taking into account additional variables in the JHH chart review and when comparing with 60-day and long-term follow-up complication rates. This was likely due to our inclusion of additional surgical complications (ie, seroma, fat necrosis, hematoma, mastectomy skin necrosis, and capsular contracture) unavailable in the NSQIP. In contrast, our analysis on delayed reconstruction data from the 2 data sources found that differences only became significant when comparing long-term follow-up rates from JHH data with 30-day NSQIP rates. This second analysis was underpowered as compared with the one on immediate reconstructions, potentially explaining the fewer differences detected.

The findings from our JHH patients at 60-day and long-term follow-up indicate that a substantial number of diabetic patients undergoing breast reconstruction develop postoperative complications outside of the 30-day window captured by the NSQIP. A significant number of patients continue to develop complications even after the 60-day follow-up, particularly in implant-based reconstructions. Most of the complications that occurred after the 60-day time point were associated with infection and reconstruction failure. Notably, the number of deep infections in the immediate group tripled from the 60-day time point to long-term follow-up, flap/prosthetic failures quadrupled, and seromas nearly doubled. Reconstruction failure rates at long-term follow-up tripled when compared with the 60-day time point and reoperation rates doubled. It is noted that the low number of patients in the JHH diabetic cohort poses a limitation to draw powerful statistic conclusions.

Another notable limitation of using the NSQIP database for breast reconstruction studies is the inability to differentiate 2-staged reconstructions (ie, delayed immediate) from purely immediate or delayed reconstructions. As the popularity of a 2-stage reconstructive procedure increases, particularly in patients receiving postmastectomy radiotherapy, it is becoming increasingly clear that the complication profiles of these procedures may be different from patients receiving an immediate reconstruction with permanent implants or flaps, or a truly delayed reconstruction without any involvement from a plastic surgeon at the time of mastectomy. Therefore, staged procedures must be evaluated as a separate cohort. The JHH portion of this study classified staged reconstruction patients in the immediate and delayed cohorts, which could limit our interpretation of outcomes due to potential within-patient variations that were not taken into account in the analysis due to a small sample size. However, even though the institutional practice of JHH favors the two-staged procedure, a separate group was not delineated for staged procedures in an effort to mirror the NSQIP database.

CONCLUSIONS

Using a large, multicenter database, immediate breast reconstruction was found to be associated with higher risk of early postoperative complications in diabetic women. Additionally, autologous breast reconstruction is independently associated with higher risk of complications in this population, which is in agreement with previous studies. Our evidence suggests that performing delayed breast reconstruction decreases postoperative complications in diabetic patients; however, this must be balanced with the known improvements in quality of life for immediate reconstruction. Future studies may further delineate staged from true immediate and delayed reconstruction patients.

Although composed of robust multi-institutional data, NSQIP-based analyses should be interpreted with caution with regards to breast reconstruction outcomes. Our study showed that the NSQIP data might not entirely reflect the complication profile of diabetic patients undergoing breast reconstruction as evidenced by our institutional data. These differences warrant further exploration for other patient groups and surgical outcomes, particularly for those procedures whose complications are not recorded by the NSQIP.

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The Johns Hopkins Medicine Institutional Review Board approved this retrospective study of Johns Hopkins Hospital breast reconstruction patients. This study conforms to the Declaration of Helsinki ethical principles for medical research.

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