

## Original article

# Does timing of alloplastic breast reconstruction in older women impact immediate postoperative complications? An analysis of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database



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## ABSTRACT

**Background:** Alloplastic breast reconstruction is safe in well-selected older women. The impact of timing of surgery on complication rates is unknown. This study aimed to determine the immediate (30-day) postoperative complication rates of older women who underwent immediate (IBR) and delayed breast reconstruction (DBR) with alloplastic techniques.

**Methods:** The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database was used to identify women  $\geq 70$  years old with in situ or invasive breast cancer who underwent either IBR or DBR (2005–2016). Outcomes included 30-day postoperative morbidity and mortality.

**Results:** A total of 2,085 older women underwent alloplastic breast reconstruction of which 90% and 10% were IBR and DBR, respectively. Both groups had similar median age, body mass index, and frequency of smoking, diabetes mellitus, and steroid use. Tumors were mainly invasive in the IBR group (83.5%) and in situ in the DBR group (83.3%). IBR had significantly longer operative times (median 154 min vs 98 min,  $p < 0.0001$ ), but equal length of stay (median 3 days vs 3 days,  $p = 0.1$ ). The 30-day overall morbidity (medical or surgical complication) rate was significantly higher in the IBR group (7.5% vs 1.0%,  $p < 0.0004$ ). Women with IBR were significantly more likely to develop infectious complications (6% vs 1%,  $p = 0.002$ ). Cardiac/transfusion, pulmonary, thromboembolic, renal, and neurological morbidity rates were equal between groups. Thirty-day mortality rates were similar across both groups (IBR: 0.05% vs DBR: 0%,  $p = 0.74$ ).

**Conclusions:** While overall thirty-day postoperative complication rates in older women who undergo breast reconstruction were low, there were higher rates of infectious complications in the IBR cohort. The risks and benefits of alloplastic breast reconstruction should be discussed with older women undergoing mastectomy for breast cancer treatment.

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## 1. Background

Breast reconstruction provides psychosocial and quality of life benefits and improves women's body image after breast cancer

surgery [1–5]. Previous studies show some women choose to undergo breast reconstruction to avoid external prosthesis, to wear different types of clothing, to regain femininity, to “feel whole again”, and improve marital and sexual relations [6]. Some data even suggest that breast reconstruction may improve work ability and productivity after breast cancer surgery as improved quality of life, increased self-esteem, and body image positively affect working capacity and performance [7–9].

Older women are less likely to undergo breast reconstruction

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### Abbreviations

ACS	American College of Surgeons
ALND	axillary lymph node dissection
ASA	American Society of Anesthesiology
BMI	body mass index
CHF	congestive heart failure
COPD	chronic obstructive pulmonary disease
CPT	Current Procedural Terminology
DBR	delayed breast reconstruction
IBR	immediate breast reconstruction
ICD-9	International Classification of Diseases Ninth Revision
IQR	interquartile range; min, minutes
LN	lymph node
NSQIP	National Surgical Quality Improvement Program
PCI	percutaneous coronary intervention
PMRT	post-mastectomy radiation therapy
PUF	participant user data file
SLNB	sentinel lymph node biopsy
SURPAS	Surgical Risk Preoperative Assessment System

[10,11]. The rates of breast reconstruction in older women range from 4 to 14%, whereas up to 42% are reported in younger women [12–14]. The low uptake is perhaps attributed to perceptions that older women have higher complication rates, lack interest in their body image, that age or comorbidities preclude reconstructive surgery, and older women have less access to reconstruction centers [6,12,13,15–19]. Regardless, there is a subset of older women who pursue breast reconstruction and may not be at an increased risk of complications. Several studies have confirmed the safety of alloplastic breast reconstruction in select older women with breast cancer [17,20,21].

Breast reconstruction can be performed either at the time of mastectomy or in a delayed fashion. Immediate breast reconstruction (IBR) is more popular due to its superior esthetic outcomes, higher levels of psychosocial well-being, and lower costs relative to delayed breast reconstruction (DBR) [1,5,22–25]. Despite these benefits, DBR is preferred in certain women, including those with significant medical comorbidities who may need medical optimization, patients with planned post-mastectomy radiation therapy (PMRT), or in women who want to postpone the decision regarding breast reconstruction.

The optimal timing for breast reconstruction in older women with respect to complications remains unknown. Previous studies comparing complications rates and other clinical outcomes between IBR and DBR have either excluded older women or lacked subgroup analysis [26–29]. Although the decision of when to carry out breast reconstruction depends on multiple aspects (e.g. patient preference and need for PMRT), determining the effect timing has on early postoperative outcomes is important for women who are candidates for either approach. The growing interest among older women for breast reconstruction emphasizes the need for developing age-specific data. Early postoperative outcomes are important as they relate to health care costs, health care quality, and patient satisfaction [30,31]. Additionally, these data would provide surgeons and patients with information to guide and enhance preoperative risk discussion, assist in reconstructive modality selection, and to improve the understanding of postoperative risks. This study aimed to determine the immediate (30-day) postoperative complication rates of older women ( $\geq 70$  years old) with breast cancer who underwent IBR or DBR.

## 2. Methods

### 2.1. Data source

A retrospective analysis of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) participant user data file (PUF) database was performed. ACS NSQIP is an outcome-based clinical database of select 30-day post-operative medical and surgical complications of patients who undergo surgery at over 716 affiliated hospitals worldwide. Abstractors collect patient demographics, preoperative risk factors, surgical variables, and complications and all-cause mortality. The reliability of the data abstraction is periodically checked by repeat sample abstraction. ACS NSQIP data are freely available to institutional members who comply with the data use agreement. Ethics Review Board has deemed this retrospective review of de-identified data exempt from institutional review.

### 2.2. Participants

Women  $\geq 70$  years old with a pathologic diagnosis of in situ [International Classification of Diseases Ninth Revision (ICD-9) code 233.0] or invasive breast cancer (ICD-9 code 174.0–9) who underwent breast reconstruction between 2005 and 2016 were identified. The age of 70 was used to define the older women cohort following the recommendations proposed by the Breast International Group [32] and because breast cancer guidelines recommend screening women up to the age of 69 [33]. American Medical Association Current Procedural Terminology (CPT) codes were used to identify exclusively alloplastic breast reconstruction procedures (19340, 19342, and 19357). IBR was captured as any event in which an alloplastic breast reconstruction CPT code accompanied a mastectomy (CPT codes 19180, 19240, 19303, 19307) in the same encounter. DBR was captured with alloplastic breast reconstruction CPT codes that were not accompanied by a concurrent mastectomy CPT code or if the primary surgery had the CPT code 19342, which specifically represented delayed insertion of prosthesis. Exclusion criteria were as follows: males, concurrent non-breast surgery, concurrent surgical procedures in the breast (e.g.: revision or removal of implant, nipple reconstruction, and autologous reconstruction), and patients missing data for any of the previous inclusion or exclusion criteria.

### 2.3. Covariates

Extracted data included patient demographics (age and race), comorbidities [smoking, alcohol consumption, diabetes mellitus, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), previous percutaneous coronary intervention (PCI), hypertension, bleeding disorder, and steroid use], type of tumor (in situ or invasive breast cancer), receipt of neoadjuvant chemotherapy 30 days before surgery, surgical variables [type of reconstruction and lymph node (LN) surgery], operative time, and length of stay, as defined in the ACS NSQIP database user guide [34]. Lymph node surgeries (sentinel lymph node biopsy and/or axillary lymph node dissection) were captured with CPT codes 19162, 19302, 19240, 19307, 38740, 38745, 38500, 38525, 38792, and 38900. The American Society of Anesthesiology (ASA) score was used as a surrogate for the severity of systemic comorbidities. ACS NSQIP does not collect information on prophylactic antibiotics or tumor stage. ACS NSQIP also does not provide any geographic, site-specific, or surgeon-specific information to ensure the privacy of both the participating sites and surgeons.

## 2.4. Outcomes

Outcomes included 30-day morbidity (a composite of surgical and medical complications) and 30-day all-cause mortality. Surgical complications included superficial, deep and organ space surgical site infection (SSI); wound disruption; bleeding requiring transfusion and prosthesis failure. Medical complications included urinary tract infection, cardiac arrest, myocardial infarction, mechanical ventilation for >48 h, pneumonia, re-intubation, septic shock, deep venous thrombosis, pulmonary embolism, progressive renal failure, acute renal failure, and stroke. To mitigate the confusion typically encountered interpreting the numerous different ACS NSQIP outcomes, we used clinically meaningful Surgical Risk Preoperative Assessment System (SURPAS) clusters as described by Meguid et al. [35]. This approach was derived using factor analysis and clinical judgment to define clinically interpretable complication clusters in lieu of the main ACS NSQIP postoperative morbidities. Modified SURPAS clusters used in this study included: infectious, cardiac/transfusion, pulmonary, venous thromboembolic, renal, neurologic, and prosthesis failure. Complications were treated as dichotomous variables (0 or  $\geq 1$ ). Information regarding severity and treatment of complications is not recorded by ACS NSQIP.

## 2.5. Statistics

Data management and analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Variables were compared across breast reconstruction types using the  $\chi^2$  test for categorical variables and Mann Whitney *U* test for continuous variables. All tests were 2-sided. A *p*-value of <0.05 was considered statistically significant. Multivariable regressions were not used to compare groups due to the low event rate and risk of sparse data bias [36].

## 3. Results

### 3.1. Study cohort

Fig. 1 illustrates the cohort development process. A total of 2,085 older women underwent alloplastic breast reconstruction of which 89.9% (*n* = 1,876) and 10.1% (*n* = 209) were IBR and DBR, respectively.

### 3.2. Patient, tumor, and surgery characteristics

Table 1 summarizes patient, tumor and surgery characteristics. Both reconstruction groups had similar median age and body mass index (BMI); women in both groups were predominantly Caucasian. The frequency of certain comorbidities, namely smoking, diabetes mellitus, and steroid use was similar across both groups (*p* > 0.05). Compared to women who underwent DBR, those who underwent IBR were more likely to consume alcohol (27.5% versus 10.5%, *p* < 0.0001) and have a history of dyspnea (7.7% versus 2.9%, *p* < 0.01) and a previous PCI (1.8% versus 0%, *p* < 0.0001). Distribution of ASA class differed between groups (*p* = 0.06), as more older women with DBR were in ASA class  $\geq$  III than women with IBR (36.5% vs. 31.6%).

Invasive tumors were more frequently noted in women who had IBR than DBR (83.5% versus 16.8%, *p* < 0.0001). In situ tumors were significantly more common women who underwent DBR (83.3% versus 16.5%, *p* < 0.0001). Data on concomitant LN surgery was only available in the IBR group, of which 53.4% underwent the following procedures: sentinel lymph node biopsy (34.9%) or axillary lymph node surgery (18.4%). Compared to the DBR group, older women

with IBR had longer median operative times (154 minutes vs 98 minutes, *p* < 0.0001), but equal median length of stay (3 days vs 3 days, *p* = 0.1). Only 1.1% of women received neoadjuvant chemotherapy, all of whom belonged to the IBR group.

### 3.3. Immediate (30-day) postoperative complications

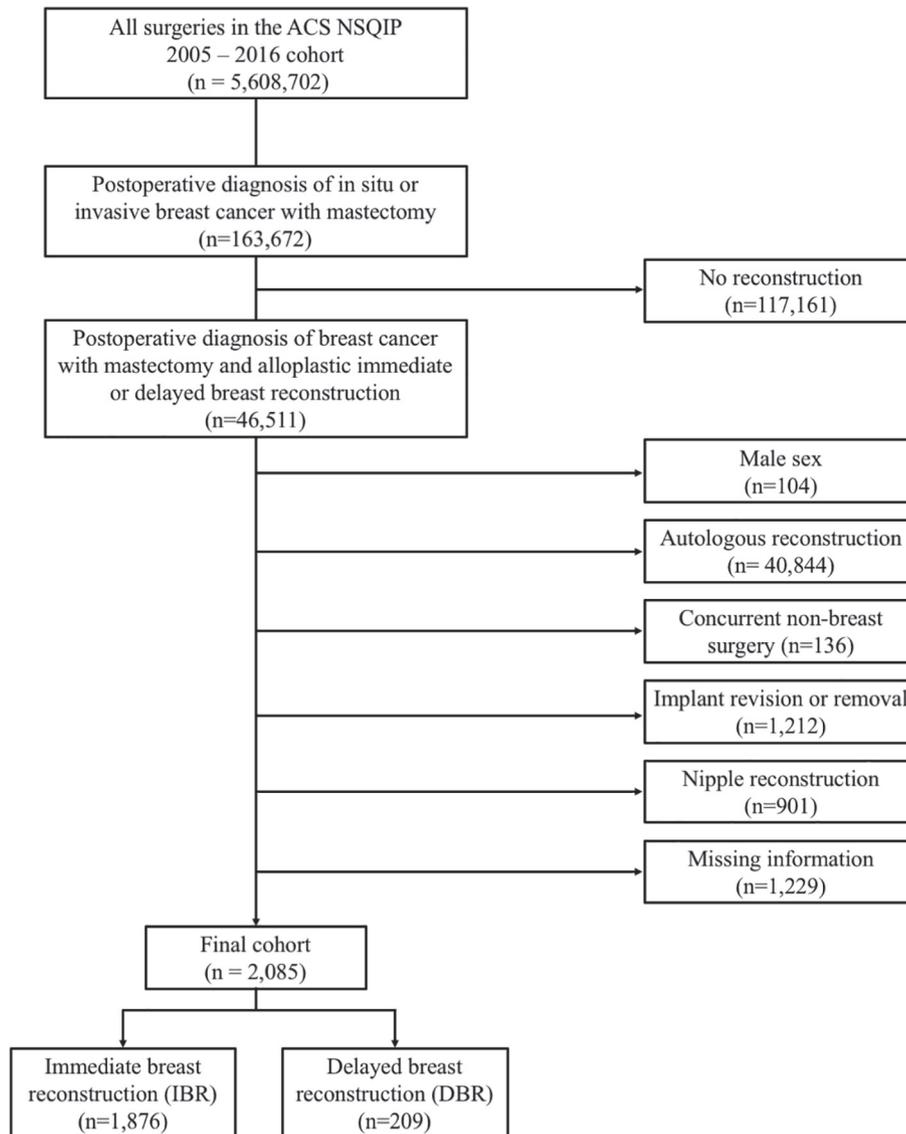
Table 2 summarizes the 30-day postoperative morbidity and mortality of older women who underwent IBR or DBR. The 30-day overall morbidity (medical or surgical complication) rate was significantly higher in the IBR group (7.5% vs 1%, *p* = 0.0004). Compared to the DBR group, older women who underwent IBR were significantly more likely to develop infectious complications (6% vs 1%, *p* = 0.002). Superficial SSI was significantly more frequent after IBR than DBR (2.8% vs 0%, *p* = 0.01). The rates of cardiac/transfusion, pulmonary, venous thromboembolic, renal, and neurological morbidity were similar between groups (*p* > 0.05). Prosthesis failure was only noted in seven patients (0.4%) who underwent IBR while none of those who underwent DBR developed this complication. The all-cause 30-day mortality rate did not differ by timing of reconstruction (IBR 0.05% versus DBR 0%, *p* = 0.74).

## 4. Discussion

This study used a large multi-institutional database to assess the rate of complications among older women with in situ or invasive breast cancer who underwent alloplastic breast reconstruction. The 30-day overall morbidity (medical or surgical complication) rate was significantly higher among women who underwent mastectomy with IBR than those who underwent DBR. Infectious complications were significantly more common in women after mastectomy with IBR than after DBR. Cardiac/transfusion, pulmonary, thromboembolic, renal, and neurological morbidity rates were similar between groups. Mortality within 30 days of surgery was a rare event in both reconstruction groups.

Alloplastic breast reconstruction has previously been shown to be safe in select older women. In this study both the IBR and DBR groups had low rates across all complications. The most common complication in the IBR group was from the infectious cluster, particularly SSI. This phenomenon has been previously described in the literature for women of all ages. Olsen et al. reported that the incidence of SSI and noninfectious wound complications was slightly higher for alloplastic IBR compared with DBR [37]. It has been hypothesized that IBR may have a higher SSI rate because there is substantial dead space and a hypovascular field in which the implant is placed, compared with the surgical field of DBR [38]. There is also a risk the implant can be infected and a higher risk of seroma formation when the breast cancer surgery is performed in the same procedure. The presence of two surgical teams and longer operative time may also increase the risk of SSI. Additionally, over half the women who underwent IBR also had LN surgery, which tends to increase the risk of wound infection, particularly in the case of axillary lymph node dissection [39,40]. Neoadjuvant chemotherapy, another well-known risk factor for infectious after alloplastic breast reconstruction [39], was also only noted in the IBR group, possibly contributing to the difference in infectious outcomes between the two groups. The effect of neoadjuvant chemotherapy on DBR would only be apparent on the primary mastectomy, but data on this cannot be obtained via ACS NSQIP. However, the remainder of the complications were quite low in both reconstruction groups. Hence if the infectious complications in both groups are disregarded, the 30-day postoperative complication rate is approximately 1% regardless of approach.

Previous studies assessing immediate postoperative



**Fig. 1.** Patient selection strategy to identify older women with in situ or invasive breast cancer who underwent alloplastic immediate (IBR) or delayed breast reconstruction (DBR) in the 2005 to 2016 American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) participant use data file (PUF) database.

complications in older women who undergo alloplastic reconstruction have shown similar rates. This is further supported by a systematic review of the literature by Oh et al. [17], which also suggested that the complication rates were not that higher in older women relative to younger women. Even though older women tend to have many more comorbidities than younger women, the absolute difference in complication rates between these two age groups is surprisingly small. This may be because the women who undergo breast reconstruction are very well-selected. These women are likely to have good functional status and favorable tumor biology despite having some comorbidities. Of note, in this study cohort, the median BMI tended to be high and hypertension was present in at least 60%, which could have increased the risk of postoperative complications as these are factors known to increase the risk of complications following alloplastic breast reconstruction [41].

The ideal timing for alloplastic breast reconstruction in older women is a challenging question to answer. Despite being a major part of the breast cancer population, only 0.03%–12% of women over 70 years of age undergo breast reconstruction [17]. This makes

acquiring data difficult and requires the use of large datasets necessary. However, a limitation is that these databases do not always contain all clinically relevant information. Studies comparing IBR and DBR sometimes combine alloplastic and autologous reconstruction in their analyses thereby incorrectly reporting that one type of reconstruction is better than the other [42,43]. The few studies comparing alloplastic IBR and DBR report mixed results. When compared with DBR, Sanati-Mehrziy et al. showed that IBR was associated with significantly lower medical and surgical complications [27]. In contrast, the Michigan Breast Reconstruction Outcome Study reported a higher tendency of two-year postoperative complications in IBR than DBR (52% versus 36%,  $p=0.269$ ) [44]. A retrospective study of 1,170 patients who underwent alloplastic breast reconstruction suggested that timing of reconstruction was not a significant predictor of complications [41]. The paucity of DBR in many of these studies, including ours, limits a comparison with IBR.

The increase in infectious complications with IBR needs to be balanced against its advantages. Women who undergo IBR benefit from a reduced recovery time, a better esthetic outcome, a greater

**Table 1**  
Patient and treatment characteristics of older women who underwent alloplastic immediate (IBR) or delayed breast reconstruction (DBR).

Variable <sup>a</sup>	Immediate breast reconstruction (IBR) (n = 1,876)	Delayed breast reconstruction (DBR) (n = 209)	P-value
<b>Patient characteristics</b>			
Age (years old), median (IQR)	73 (71–77)	73 (71–75)	0.1
BMI (kg/m <sup>2</sup> ) <sup>b</sup> , median (IQR)	27.1 (23.8–30.9)	26.6 (23.4–30.2)	0.26
<b>Race</b>			
White	1,524 (81.2)	160 (76.6)	0.0007
African American	127 (6.8)	20 (9.6)	
American Indian	0 (0)	2 (1.0)	
Asian	35 (1.9)	2 (1.0)	
Hispanic	3 (0.2)	0 (0)	
Native Hawaiian	5 (0.3)	0 (0)	
Unknown	182 (9.7)	25 (12.0)	
<b>Comorbidities</b>			
Smoking	105 (5.6)	13 (6.2)	0.71
Alcohol consumption	516 (27.5)	22 (10.5)	<0.0001
Diabetes mellitus	220 (11.7)	31 (14.8)	0.19
Dyspnea	145 (7.7)	6 (2.9)	0.01
COPD	73 (3.9)	5 (2.4)	0.28
CHF	7 (0.4)	0 (0)	0.38
Previous PCI	34 (1.8)	0 (0)	<0.0001
Hypertension	1,203 (64.1)	126 (60.3)	0.27
Bleeding disorder	26 (1.4)	4 (1.9)	0.54
Steroid use	39 (2.1)	1 (0.5)	0.11
<b>ASA class</b>			
I	39 (2.1)	1 (0.5)	0.06
II	1,244 (66.3)	132 (63.2)	
III	570 (30.4)	76 (36.4)	
IV	23 (1.2)	0 (0)	
<b>Tumor characteristics</b>			
Tumor type			
In situ	310 (16.5)	174 (83.3)	<0.0001
Invasive	1,566 (83.5)	35 (16.8)	
<b>Treatment characteristics</b>			
Year of operation			
2005–2006	141 (7.5)	0 (0)	<0.0001
2007–2010	540 (28.8)	0 (0)	
2011–2013	689 (36.7)	2 (1.0)	
2014–2016	506 (27.0)	207 (99.0)	
<b>Lymph node surgery</b>			
SLNB	656 (34.9)	–	–
ALND	346 (18.4)	–	
None	874 (46.6)	–	
Neoadjuvant chemotherapy	20 (1.1)	0 (0)	<0.0001
Operative time (min), median (IQR)	154 (113–206)	98 (69–134)	<0.0001
Length of stay (d), median (IQR)	3 (2–3)	3 (2–3)	0.1

Abbreviations: ALND, axillary lymph node dissection; ASA, American Society of Anesthesiology; BMI, body mass index; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; d, days; IQR, interquartile range; min, minutes; PCI, percutaneous coronary intervention; SLNB, sentinel lymph node biopsy.

<sup>a</sup> Denotes n, (%) unless otherwise specified.

<sup>b</sup> Calculated using height and weight.

sense of self-esteem and quality of life as the results are immediately apparent, better body posture, and lower surgery and recovery-related costs [25,45–50]. However, the notion that DBR may be more favorable because it has lower infectious complication rates should not be misinterpreted as a recommendation to routinely recommend delaying reconstruction in older women. Furthermore, the DBR complications reported herein should be added to the complication rates from the primary mastectomy as these patients have two separate operations. However, these data are not available as information from the primary mastectomy cannot be retrieved from ACS NSQIP.

The following limitations should be considered when interpreting this study. Due to the very low event rate, particularly in the DBR group, we were unable to adjust for patient comorbidities and perform a multivariable analysis. This was further compounded by the fact that DBR only comprised 10% of our cohort. However, the rate of DBR was within the reported rate in the literature (8–17%) [1,51]. Adjusting would run the risk of sparse data bias and thereby inflated estimates of the relative risk of complications between groups. Another limitation derives from the type of data ACS NSQIP

collects. There is a limited 30-day follow up time on postoperative complications, which means long-term morbidity (e.g.: implant failure, lymphedema, chronic pain, fibrosis, cosmetic result, and neurosensory disturbances) that is highly relevant to breast reconstruction is falsely low. For example, the prosthesis failure rate in the IBR group was well below the reported range in the literature (0.8–2.7%) [52–55], but this may reflect the short follow up time. Additionally, there is a lack of surgery specific complications such as seroma, hematoma, and fat necrosis, which are likely more prevalent after breast reconstruction. The data reported in this study are not generalizable to all older women. There is selection bias in the women who underwent breast reconstruction as these patients may have been more motivated to seek reconstruction. Women with comorbidities may have been dissuaded by themselves or their surgeons to undergo breast reconstruction. ACS NSQIP uses data predominantly from academic institutions located in the Western hemisphere which limits the applicability of these findings across all patient populations and types of health centers. Lastly, as with any large-volume dataset, there may be observer bias, underreporting, and limited accuracy and completeness of

**Table 2**

Immediate (30-day) postoperative morbidity and mortality by modified Surgical Risk Preoperative Assessment System (SURPAS) clusters for older women who underwent alloplastic immediate (IBR) versus delayed breast reconstruction (DBR).

Variable, n (%)	Immediate breast reconstruction (IBR) (n = 1,876)	Delayed breast reconstruction (DBR) (n = 209)	P-value
Infectious cluster	113 (6.0)	2 (1.0)	0.002
Wound disruption	15 (0.8)	0 (0)	0.19
Superficial surgical site infection	53 (2.8)	0 (0)	0.01
Deep surgical site infection	22 (1.2)	0 (0)	0.12
Organ space surgical site infection	16 (0.9)	1 (0.5)	0.57
Sepsis	7 (0.4)	0 (0)	0.38
Urinary tract infection	11 (0.6)	1 (0.5)	0.84
Cardiac/transfusion cluster	12 (0.6)	0 (0)	0.25
Cardiac arrest	0 (0)	0 (0)	–
Myocardial infarction	0 (0)	0 (0)	–
Bleeding requiring transfusion	12 (0.6)	0 (0)	0.25
Pulmonary cluster	6 (0.3)	0 (0)	0.41
On mechanical ventilator > 48h	0 (0)	0 (0)	–
Pneumonia	3 (0.2)	0 (0)	0.56
Re-intubation	1 (0.05)	0 (0)	0.74
Septic shock	2 (0.1)	0 (0)	0.64
Venous thromboembolic cluster	14 (0.8)	0 (0)	0.21
Deep venous thrombosis	9 (0.5)	0 (0)	0.32
Pulmonary embolism	9 (0.5)	0 (0)	0.32
Renal cluster	1 (0.05)	0 (0)	0.74
Progressive renal failure	1 (0.05)	0 (0)	0.74
Acute renal failure	0 (0)	0 (0)	–
Neurological cluster	0 (0)	0 (0)	–
Stroke	0 (0)	0 (0)	–
Implant failure cluster	7 (0.4)	0 (0)	–
Implant failure	7 (0.4)	0 (0)	–
Overall morbidity (medical and/or surgical)	140 (7.5)	2 (1.0)	0.0004
All-cause 30-day mortality	1 (0.05)	0 (0)	0.74

coding and data recording. Regardless of these limitations, this large sample size afforded by the ACS NSQIP database allows for analysis that cannot be performed with smaller single-center studies and stimulates future studies.

## 5. Conclusions

Immediate (30-day) postoperative complication rates in older women who undergo either IBR or DBR are low. Alloplastic breast reconstruction is safe in well-selected older women with breast cancer. These results can be used to counsel patients about the potential 30-day postoperative complication rates after IBR and DBR. The increase in infectious complications with IBR needs to be balanced against the advantages of IBR. Because assessing all the variables that influence the decision-making to undergo IBR or DBR (e.g.; adjuvant treatment, medical comorbidities, patient preference) were not part of this study, one reconstructive approach cannot be recommended over the other. The data presented herein should be used when counselling older women about the realistic immediate postoperative outcomes of IBR and DBR, highlighting its overall safety in well-selected cases. With foreseeable increasing interest in alloplastic breast reconstruction amongst older women, patients and their surgeons will need to collaborate in a shared decision-making process to identify the best timing of alloplastic breast reconstruction while incorporating cancer treatment needs, patient functional status, and patient preference. To plan breast reconstruction in older women, the primary focus should be effective age-appropriate oncological treatment, around which the desired esthetic results must be tailored to prevent complications.

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