

Breast Cancer Outcomes Following Immediate Breast Reconstruction with Implants Versus Autologous Flaps: A Propensity Score-Matched Study

Zhen-Yu Wu (✉ wuzyps@gmail.com)

Shanghai East Hospital <https://orcid.org/0000-0003-1731-6370>

Jing Han

Shanghai East Hospital

Hee Jeong Kim

Asan Medical Center

Jong Won Lee

Asan Medical Center

Il Yong Chung

Asan Medical Center

Jisun Kim

Asan Medical Center

Sae byul Lee

Asan Medical Center

Byung-Ho Son

Asan Medical Center

Hyun Ho Han

Asan Medical Center

Jin Sup Eom

Asan Medical Center

Jae Ho Jeong

Asan Medical Center

Gyungyub Gong

Asan Medical Center

Hak Hee Kim

Asan Medical Center

Sei-Hyun Ahn

Asan Medical Center

Beom Seok Ko

Asan Medical Center <https://orcid.org/0000-0001-7831-7874>

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Abstract

Purpose

A large proportion of patients with breast cancer who had mastectomy had undergone breast reconstruction with implants or autologous flaps. However, only a few studies have compared the breast cancer outcomes between the implant-based reconstruction (IBR) and autologous flap reconstruction (AFR). In this study, we retrospectively compared the local recurrence rates, distant metastasis rates, and survival outcomes between immediate IBR and AFR.

Methods

A total of 1530 patients with primary breast cancer who underwent IBR or AFR with nipple-/skin-sparing mastectomy were included. Patients who underwent neoadjuvant systemic therapy were excluded from the study. After propensity score matching by age at diagnosis, T stage, N stage, molecular subtype, mastectomy type, adjuvant radiotherapy status, and follow-up period, 938 patients were 1:1 matched, comprising the well-balanced IBR and AFR groups. Locoregional recurrence-free survival (LRRFS), disease-free survival (DFS), distant metastasis-free survival (DMFS), and breast cancer-specific survival (BCSS) were compared between the matched groups.

Results

After matching, the median follow-up periods were 68 months and 71 months for the IBR and AFR groups, respectively. No significant differences were observed between the IBR and AFR groups regarding the local recurrence (7.2% vs. 5.1%; $P=0.175$), regional recurrence (2.1% vs. 1.5%; $P=0.463$), or distant metastasis (3.2% vs. 3.2%; $P=1.000$) rates. Moreover, no significant difference was observed between the IBR and AFR groups in the LRRFS (hazard ratio, 0.691; 95% CI, 0.433–1.102; $P=0.118$), DFS (hazard ratio, 0.709; 95% CI, 0.468–1.076; $P=0.104$), DMFS (hazard ratio, 1.006; 95% CI, 0.491–2.059; $P=0.987$), or BCSS (hazard ratio, 0.445; 95% CI, 0.111–1.786; $P=0.659$).

Conclusion

In this propensity score-matched analysis of oncologic outcomes in patients with primary breast cancer who underwent immediate breast reconstruction with nipple-/skin-sparing mastectomy, no significant differences were observed between the IBR and AFR groups.

Introduction

With the tremendous improvement in breast cancer survivorship [1, 2], the quality of life (QoL) of patients has become an important aspect that requires consideration in the treatment strategy for breast cancer

[3]. Breast reconstruction provides substantial body image and QoL benefits in patients receiving mastectomy [4, 5]. In the recent decade, immediate breast reconstruction in conjunction with nipple-sparing mastectomy (NSM) or skin-sparing mastectomy (SSM) has gained popularity [6, 7]. Meanwhile, postmastectomy reconstruction options mainly include implant-based reconstruction (IBR) and autologous flap reconstruction (AFR) in the current clinical practice. Previous studies have demonstrated that breast reconstruction using either implants or autologous tissue does not increase the risk of breast cancer recurrence compared to conventional mastectomy without reconstruction [8–12]. However, few studies have compared breast cancer outcomes between the IBR and AFR [13]. Conversely, an increasing number of recent reports on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) have raised concerns about the unexpected impact of implants on carcinogenicity [14–17]. Moreover, patients with breast cancer who had undergone or plan to undergo IBR should know about the relationship between breast implants and cancer recurrence or the differences in recurrence risk between IBR and AFR. A detailed evaluation of the oncologic significance of the different breast reconstruction methods can greatly help in the shared decision-making process between physicians and patients.

Therefore, this matched comparative study aimed to evaluate the difference in the local recurrence rates, distant metastasis rates, or survival outcomes between NSM/SSM with IBR and AFR.

Methods

Study Population

After obtaining the institutional review board's approval, all patients who underwent NSM/SSM and immediate breast reconstruction for breast cancer between January 2010 and December 2016 at the Asan Medical Centre, Seoul, Korea, were reviewed from a prospectively maintained database. Patients who underwent neoadjuvant systemic therapy and are presenting with inflammatory breast cancer or T4 disease, synchronous distant metastasis, or recurrent disease were excluded from the study. A total of 1530 patients with primary breast cancer were included in the analysis, and the study cohort comprised 469 patients who underwent IBR and 1061 patients who underwent AFR with NSM/SSM.

Treatments and Follow-Up

NSM or SSM was performed by breast surgeons, whereas immediate breast reconstruction was performed by plastic surgeons using implants or autologous flaps. Most IBRs were performed using the direct-to-implant method. However, in patients requiring contralateral breast augmentation, the two-stage tissue expander/implant technique was adopted. AFR was performed using a pedicled/free transverse rectus abdominis musculocutaneous flap, free deep inferior epigastric artery perforator flap, extended latissimus dorsi flap, superficial inferior epigastric artery flap, or transverse upper gracilis flap.

Postoperatively, the patients were regularly followed up every three–six months for the first five years and annually thereafter. In patients suspected as having a locoregional recurrence, a fine-needle aspiration, core-needle, or excisional biopsy was performed for pathological confirmation. Lesions with a clear

evidence of distant metastasis in the imaging evaluation were considered as recurrence without pathological examination.

Propensity Score Matching

To reduce the effects of selection bias and potential confounding factors on the comparisons of the oncologic outcomes between the IBR and AFR groups, a propensity score matching was performed to create balanced groups. The following baseline covariates for matching were included: age at diagnosis, T stage, N stage, molecular subtype, mastectomy type, adjuvant radiotherapy status, and follow-up period. The propensity scores were calculated for each of the 1530 patients using a multivariate logistic regression model, and the patients were matched 1:1 into the IBR and AFR groups using caliper restriction to the nearest neighbor without replacement. After the propensity score matching was performed, 469 patients each were included in the IBR and AFR groups.

Statistical Analyses

The endpoints of interest were locoregional recurrence-free survival (LRRFS), disease-free survival (DFS), distant metastasis-free survival (DMFS), and breast cancer-specific survival (BCSS). The locoregional recurrences were classified as biopsy-proven local recurrences in the ipsilateral skin/subcutaneous layer, chest wall, or nipple–areola complex and as regional recurrences (carcinoma metastases) in the ipsilateral axillary, supraclavicular, or internal mammary lymph nodes. Any other site of recurrence was considered as distant metastasis. Patients with initial distant metastasis were excluded from the locoregional recurrence group. In the case of concurrent locoregional recurrence and distant metastasis, each recurrence was counted as an event. The occurrence of contralateral breast cancer was considered as a new primary cancer and not as a recurrence. The follow-up period was calculated from the date of surgery for primary breast cancer. The last follow-up date was defined as the date of death or—if the patient survived through the follow-up period or was lost to follow-up—the date of the patient’s last visit to our clinics for breast cancer surveillance. The LRRFS, DFS, DMFS, and BCSS rates were calculated using the Kaplan–Meier method and compared using the log-rank tests. The hazard ratios and 95% confidence intervals (CIs) were estimated using the Cox proportional hazards model. The chi-squared or Fisher’s exact test was used for intergroup comparisons. All statistical analyses were performed using the International Business Machines Corporation (IBM) Statistical Package for the Social Sciences Statistics for Windows version 24.0 (IBM Corp., Armonk, NY, USA). Two-tailed *P*-values of < 0.05 were considered statistically significant.

Results

Patient, Tumor, and Treatment Characteristics

Table 1 shows the baseline characteristics according to the breast reconstruction methods used of the entire cohort before matching. Significant differences were observed regarding the age at diagnosis, T stage, N stage, molecular subtype, mastectomy type, and radiotherapy status between patients who

underwent IBR and AFR. The patients in the IBR group were more likely to be younger, at the earlier disease stage, and have more favorable molecular subtypes (i.e., hormone receptor [HR]+/human epidermal growth factor receptor-2 [HER2]- or HR+/HER2+) and to undergo NSM than those in the AFR group. Moreover, the patients in the AFR group were more likely to undergo adjuvant radiotherapy than those in the IBR group.

Table 1
Baseline characteristics of the study population before matching

Variables		IBR, n = 469	%	AFR, n = 1061	%	P-value
Age, median (range), years		43 (20–70)		45 (23–71)		
Age, years	< 50	378	80.6	768	72.4	0.001
	≥ 50	91	19.4	293	27.6	
T stage	Tis	85	18.1	122	11.5	0.003
	T1	249	53.1	583	54.9	
	T2	122	26.0	312	29.4	
	T3	13	2.8	44	4.1	
N stage	N0	370	78.9	764	72.0	0.016
	N1	82	17.5	225	21.2	
	N2	13	2.8	48	4.5	
	N3	4	0.9	24	2.3	
Molecular subtype	HR+/HER2-	317	67.6	665	62.7	0.007
	HR+/HER2+	71	15.1	153	14.4	
	HR-/HER2+	57	12.2	203	19.1	
	TN	24	5.1	40	3.8	
Mastectomy type	NSM	332	70.8	525	49.5	< 0.001
	SSM	137	29.2	536	50.5	
Adjuvant RT	Yes	32	6.8	118	11.1	0.009
	No	437	93.2	943	88.9	
AFR, autologous flap reconstruction; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IBR, implant-based reconstruction; NSM, nipple-sparing mastectomy; RT, radiotherapy; SSM, skin-sparing mastectomy; TN, triple-negative						

After the propensity score matching was performed, 938 patients were 1:1 matched, comprising the well-balanced IBR (n = 469) and AFR (n = 469) groups. Table 2 shows the clinicopathologic characteristics of

the matched groups. No significant differences were observed between the matched groups in the selected matching and pathological variables (histotype, histologic grade, nuclear grade, lympho-vascular invasion [LVI] status, or Ki67 index). Table 3 shows the treatment characteristics of the matched groups. No significant differences were observed between the matched groups regarding the axillary surgery, adjuvant hormonal therapy, chemotherapy, and targeted therapy for HER2 + disease.

Table 2
Clinicopathologic characteristics after propensity score matching

Variables		IBR, n = 469	%	AFR, n = 469	%	P-value
Age, median (range), years		43 (20–70)		44 (24–67)		
Age, years	< 50	378	80.6	376	80.2	0.869
	≥ 50	91	19.4	93	19.8	
T stage	Tis	85	18.1	68	14.5	0.472
	T1	249	53.1	267	56.9	
	T2	122	26.0	121	25.8	
	T3	13	2.8	13	2.8	
N stage	N0	370	78.9	371	79.1	0.828
	N1	82	17.5	85	18.1	
	N2	13	2.8	11	2.3	
	N3	4	0.9	2	0.4	
Molecular subtype	HR+/HER2-	317	67.6	318	67.8	0.931
	HR+/HER2+	71	15.1	71	15.1	
	HR-/HER2+	57	12.2	60	12.8	
	TN	24	5.1	20	4.3	
Histotype	In situ cancer	85	18.1	68	14.5	0.234
	IDC	321	68.4	334	71.2	
	ILC	22	4.7	23	4.9	
	Mixed	21	4.5	14	3.0	
	Others	20	4.3	30	6.4	
Ki67 index*	< 20%	244	52.0	240	51.3	0.820

AFR, autologous flap reconstruction; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IBR, implant-based reconstruction; IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; LVI, lympho-vascular invasion; TN, triple-negative

*: Unknown, n = 1

** : Unknown, n = 155

Variables		IBR, n = 469	%	AFR, n = 469	%	P-value
	≥ 20%	225	48.0	228	48.7	
Histologic grade**	1,2	270	70.7	299	74.6	0.223
	3	112	293.0	102	25.4	
Nuclear grade	1,2	336	71.6	355	75.7	0.159
	3	133	28.4	114	24.3	
LVI	Yes	106	22.6	90	19.2	0.199
	No	363	77.4	379	80.8	
AFR, autologous flap reconstruction; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IBR, implant-based reconstruction; IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; LVI, lympho-vascular invasion; TN, triple-negative						
*: Unknown, n = 1						
**: Unknown, n = 155						

Table 3
Treatment characteristics in matched groups

Variables		IBR, n = 469	%	AFR, n = 469	%	P-value
Mastectomy type	NSM	332	70.8	331	70.6	0.943
	SSM	137	29.2	138	29.4	
Axillary surgery	SLNB only	411	87.6	412	87.8	0.921
	ALND	58	12.4	57	12.2	
Reconstruction methods	DTI	430	91.7	NA	NA	NA
	TEI	39	8.3	NA	NA	
	TRAM	NA	NA	282	60.1	
	DIEP	NA	NA	162	34.5	
	eLD	NA	NA	19	4.1	
	SIEA	NA	NA	5	1.1	
	TUG	NA	NA	1	0.2	
Adjuvant RT	Yes	32	6.8	30	6.4	0.793
	No	437	93.2	439	93.6	
Adjuvant HT	Yes	308	65.7	329	70.1	0.142
	No	161	34.3	140	29.9	
Adjuvant CTx	Yes	155	33.0	163	34.8	0.581
	No	314	67.0	306	65.2	
Trastuzumab in HER2+	Yes	52	40.6	51	38.9	0.781
	No	76	59.4	80	61.1	

AFR, autologous flap reconstruction; ALND, axillary lymph node dissection; CTx, chemotherapy; DIEP, deep inferior epigastric artery perforator flap; DTI, direct-to-implant; eLD, extended latissimus dorsi flap; HER2, human epidermal growth factor receptor 2; HT, hormonal therapy; IBR, implant-based reconstruction; NA, not applicable; NSM, nipple-sparing mastectomy; RT, radiotherapy; SIEA, superficial inferior epigastric artery flap; SLNB, sentinel lymph node biopsy; SSM, skin-sparing mastectomy; TEI, tissue expander/implant; TRAM, transverse rectus abdominis musculocutaneous flap; TUG, transverse upper gracilis flap

Recurrence and Survival

After matching, the median follow-up periods were 68 months (range, 9–130) and 71 months (range, 36–132) for the IBR and AFR groups, respectively. Table 4 shows the oncologic outcomes. No significant differences were observed between the IBR and AFR groups regarding the local recurrence (7.2% vs. 5.1%;

$P=0.175$), regional recurrence (2.1% vs. 1.5%; $P=0.463$), distant metastasis (3.2% vs. 3.2%; $P=1.000$), any first recurrence (11.3% vs. 8.1%; $P=0.098$), and breast cancer-associated death (1.3% vs. 0.6%; $P=0.315$) rates. The 5-year cumulative local recurrence rates of the IBR and AFR groups were 6.4% and 4.3%, respectively. The median time to any first recurrence for the IBR and AFR groups were 34 months (range, 3–90) and 37 months (range, 7–94), respectively ($P=0.365$).

Table 4
Oncologic outcomes

Events	IBR, n = 469	%	AFR, n = 469	%	P-value
Local recurrence	34	7.2	24	5.1	0.175
Regional recurrence	10	2.1	7	1.5	0.463
Distant metastasis	15	3.2	15	3.2	1.000
Any first recurrence	53	11.3	38	8.1	0.098
Breast cancer-associated death	6	1.3	3	0.6	0.315

AFR, autologous flap reconstruction; IBR, implant-based reconstruction

Regarding the survival outcomes, no significant difference was observed between the IBR and AFR groups in the LRRFS (hazard ratio, 0.691; 95% CI, 0.433–1.102; log-rank $P=0.118$), DFS (hazard ratio, 0.709; 95% CI, 0.468–1.076; log-rank $P=0.104$), DMFS (hazard ratio, 1.006; 95% CI, 0.491–2.059; log-rank $P=0.987$), or BCSS (hazard ratio, 0.445; 95% CI, 0.111–1.786; log-rank $P=0.659$) (Fig. 1a–d). The 5-year and 10-year LRRFS rates were 91.4% and 88.9% in the IBR group and 93.7% and 91.4% in the AFR group, respectively. The 5-year and 10-year DFS rates were 89.5% and 86.7% in the IBR group and 92.2% and 89.3% in the AFR group, respectively. The 5-year and 10-year DMFS rates were 97% and 96.1% in the IBR group and 97.2% and 95.8% in the AFR group, respectively. The 5-year and 10-year BCSS rates were 99.4% and 97.2% in the IBR group and 99.5% and 97.2% in the AFR group, respectively.

Discussion

A large proportion of patients with breast cancer who had mastectomy had undergone breast reconstruction with implants or autologous tissue [18, 19]. The vast majority of previous outcome studies that compared the IBR and AFR techniques have focused on post-reconstructive complications, patient satisfaction, and/or the QoL of the patient [20–23]. This propensity score-matched study was specifically conducted to evaluate breast cancer outcomes and had found no significant differences regarding the local recurrence, distant metastasis, and survival rates between IBR and AFR in the setting of NSM/SSM.

Breast reconstruction methods using either implants or autologous tissue have their own pros and cons. Multiple previous studies investigating patient-reported outcomes have shown that patients who underwent AFR appear to have higher satisfaction and improved QoL as well as better psychosocial well-being than those who underwent IBR [20–23]. Furthermore, AFRs are less favorable than IBRs as they are

associated with issues with donor site morbidity and a relatively higher incidence of overall complications, but IBRs were observed to have a higher reconstruction failure rate [24].

As an integral part of breast cancer management, the oncologic safety of breast reconstruction should be prioritized. However, to date, no randomized controlled data on the differences in the oncologic safety between mastectomy with breast reconstruction and without breast reconstruction or the oncologic outcomes of different reconstruction methods is available due to ethical concerns. Most existing studies based on retrospective data have documented that both IBR and AFR did not increase the risk of breast cancer recurrence [8–12]. However, conflicting results have indicated that postmastectomy AFR has an increased risk of cancer recurrence compared with mastectomy alone [25].

Few studies have focused on the comparison of the oncologic outcomes between the IBR and AFR groups, especially in the setting of NSM/SSM. Notably, substantial differences in the baseline characteristics and adjuvant treatment strategies between patients undergoing IBR and AFR are often observed, and a comparison of oncologic outcomes between these two approaches requires an appropriate matching of the potential confounding factors. In our prematching cohort, the patients in the IBR group were younger at diagnosis and more likely to undergo NSM compared with those in the AFR group. Moreover, the patients in the AFR group were more likely to present with an unfavorable disease status and receive adjuvant radiotherapy compared with those in the IBR group. To our knowledge, only one previous study has compared the breast cancer outcomes of IBR and AFR through a matched analysis. In a study by Ha et al., they compared the disease-free interval of 247 patients who underwent IBR and 249 patients who underwent AFR by matching the patients' age, tumor stage, and estrogen receptor status [13]. Although they found no significant difference in breast cancer recurrence between the matched groups, the AFR group showed a significantly higher distant metastasis rate associated with histologically aggressive tumors than the IBR group [13]. In that study, however, the number of patients with high Ki67 index included in the AFR group was significantly greater than that in the IBR group after matching, which may have a potential impact on the breast cancer prognosis [13]. In this study, 938 patients were 1:1 well-matched according to age at diagnosis, T stage, N stage, molecular subtype, mastectomy type, and adjuvant radiotherapy status. Moreover, the histopathological features, including tumor histotype, histologic grade, nuclear grade, LVI status, and Ki67 index status, as well as other treatment characteristics, such as axillary surgery, adjuvant hormonal therapy, chemotherapy, and targeted therapy for HER2 + disease, were also similar between the matched groups. However, no significant differences were observed in the recurrence rates and survival outcomes between the matched groups after a long-term follow-up.

Another emerging oncological concern regarding breast reconstruction is the potential effects of breast implants on cancer progression. Recently, cases of BIA-ALCL, which is a unique type of nonHodgkin T-cell lymphoma exclusively associated with textured implants, have been reported worldwide, with a substantial proportion of the cases occurring in patients with breast cancer after IBR [14]. The unexpected carcinogenicity of breast implants has raised additional concerns about any association between the breast implant and breast cancer recurrence. In a recent study by Lee et al., they compared the oncologic

outcomes of patients with breast cancer according to the surface type of implants used for two-stage IBR [26]. Notably, they found that textured implants were statistically significantly associated with decreased DFS compared with smooth implants [26]. The findings of Lee et al. suggest that in addition to the risk of BIA-ALCL, textured implants may also be associated with the increased risk of breast cancer recurrence [26]. Conversely, other previous studies have investigated the recurrence risk following IBR without specifying the implant textures and found no increased risk of recurrence compared with mastectomy alone [8, 9].

This study is limited by its retrospective design from a single institution and the associated selection bias may exist even after matching the key clinical factors. Hidden confounding variables may include, but are not limited to, specific reconstruction methods, surgeon experience and characteristics, and other clinicopathologic factors. However, in the absence of randomized data, our propensity score-matched analysis of a robust series with long-term follow-up provides valuable data on the oncologic comparison of IBR and AFR and may help in the shared decision-making process between physicians and patients regarding breast reconstruction. Furthermore, although the incidence of BIA-ALCL is low, further research on safe alternative reconstruction approaches without BIA-ALCL risk is needed.

Conclusions

In this propensity score-matched analysis of breast cancer outcomes in a large series of patients with primary breast cancer who underwent NSM/SSM with immediate breast reconstruction, no significant differences were observed between the IBR and AFR groups.

Declarations

Compliance with ethical standards

Funding: None.

Conflict of interest: None.

Ethical approval: This study was approved by the institutional review board of Asan Medical Center, Seoul, Korea (No. 20201793). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Because of the retrospective nature of the study, the requirement for informed consent was waived, and the study was conducted with the exemption of consent under IRB deliberation as it used a platform that offers unidentified clinical information for research purposes.

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