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Local Recurrence after Breast Reconstruction Surgery in Patients with Early-Onset Breast Cancer

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ABSTRACT

Introduction: In patients with early-onset breast cancer, few studies have reported the medium- to long-term prognosis for immediate breast reconstruction (IBR). Therefore, we evaluated the risk of local recurrence in patients with early-onset breast cancer who underwent mastectomy with IBR.

Methods: Patients diagnosed with early-onset breast cancer (age ≤ 40) were retrospectively analyzed, dividing them into two groups: those who had mastectomy with IBR (reconstruction group) and those who had mastectomy alone (mastectomy group). Additionally, the body mass index (BMI), expression of hormone receptors and human epidermal growth factor receptor-2 (HER2), and breast reconstruction were examined to determine the factors related to local recurrence.

Results: The reconstruction and mastectomy groups included 37 and 61 patients, respectively. The median follow-up period was 68 months, local recurrence was confirmed in 4 cases (12.9% vs. 6.6%) in each group, and distant metastases were confirmed in 4 (12.9%) and 7 (11.5%) cases. No statistically significant difference was observed. Furthermore, a multivariate analysis of the local recurrence risk factors for all mastectomy cases revealed that a BMI of ≥ 27 [hazard ratio (HR) 2.15, 95% confidence interval (CI) 0.39-2.81] and HER2 positivity (HR 1.94, 0.89-48.6) were local recurrence risk factors. However, the implementation of reconstructive surgery was not listed as a risk factor for local recurrence.

Conclusions: IBR did not show a prognostic difference compared with mastectomy alone. We believe IBR is a viable treatment option without increasing local recurrence risk in early-onset breast cancer patients.

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KEYWORDS: early-onset breast cancer, breast reconstruction surgery, local recurrence

Introduction

In Japan, among malignant diseases with an early onset, the incidence of breast cancer increases in women in their 20s and 30s, and it is considered the most common malignant disease affecting women in their 30s (22%).¹⁾

Compared with late-onset breast cancer, early-onset

breast cancer has been reported to demonstrate faster tumor growth, lower survival rates, and higher local recurrence rates.^{2,3)}

In cosmetic-centered breast reconstruction, immediate breast reconstruction (IBR) has a shorter total operation time than delayed reconstruction and reduces the emotional effect of losing one's breast,⁴⁾ making it a useful pro-

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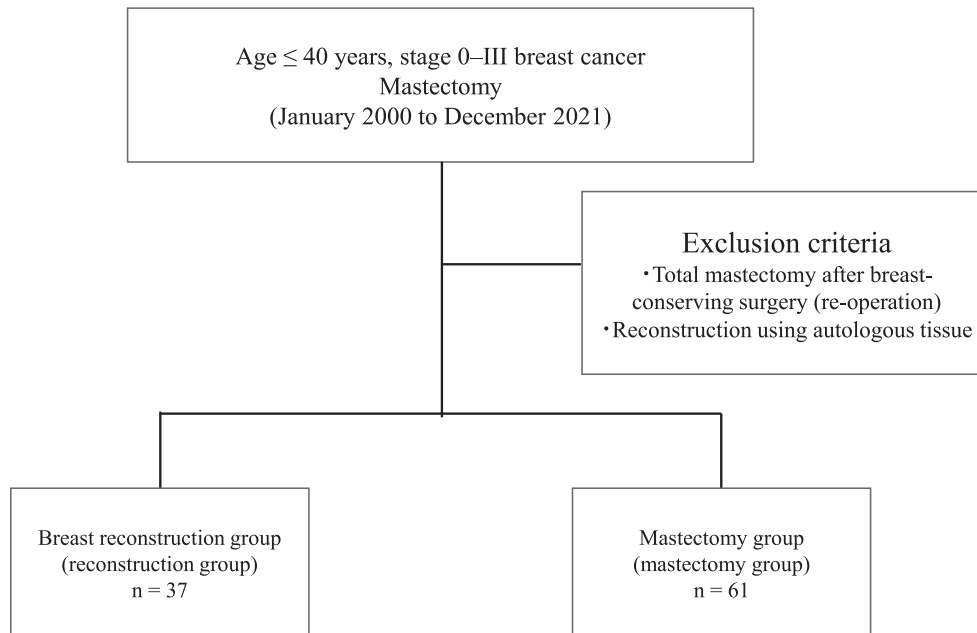


Fig. 1 Flowchart of patient selection.

cedure for patients with breast cancer. IBR, which emphasizes cosmetic appearance, is becoming a popular choice especially among patients with early-onset breast cancer since the introduction of insurance medical treatment for breast reconstruction surgery in Japan in 2013.

However, local recurrence after breast reconstruction remains a problem. In general, the risk factors for local recurrence after total mastectomy include positive margin, tumor diameter, number of lymph node metastases, invasion to the pectoralis major muscle, hormone receptors, age at diagnosis, and vascular invasion.^{5,6)}

In patients with early-onset breast cancer, age is a risk factor for local recurrence. Deciding whether to perform IBR or mastectomy alone is challenging for surgeons or patients. Furthermore, as IBR is a recently established technique, few studies have reported the medium- and long-term prognosis of patients with early-onset breast cancer. Therefore, we investigated the medium- and long-term prognoses after IBR in patients with early-onset breast cancer in comparison with patients who had not undergone breast reconstruction. Considering risk factors for local recurrence after total mastectomy in patients with early-onset breast cancer, we investigated whether breast reconstruction surgery in young patients could be an independent risk factor for local recurrence. In breast reconstruction cases, leaving large amounts of subcutaneous fat leads to an improved cosmetic appearance of the reconstructed breast; however, it is at risk for residual cancer

(positive surgical margins). Thus, in this study, we quantitatively substituted body mass index (BMI) to evaluate subcutaneous fat mass and examine whether it is an independent risk factor for local recurrence.

Methods

Fig. 1 shows the patient selection flowchart. The patients were those diagnosed with stage 0-III breast cancer between January 2000 and December 2021 at Omori Hospital, Toho University Medical Center, and underwent total mastectomy at the age of ≤ 40 years.

Among the patients, those who underwent total mastectomy for local recurrence after breast-conserving surgery and those who underwent autologous tissue reconstruction were excluded. The patients were divided into the group that underwent IBR with the need for skin expansion using a tissue expander (TE) (reconstruction group) and the group that underwent only mastectomy without simultaneous breast reconstruction (mastectomy group).

Surgical method

In our facility, breast reconstruction was performed as a primary two-stage reconstruction method using a TE. Pectoral muscle-preserving mastectomy, including papillary areolar resection, was performed on all target patients, and a TE (Natrell Allergan Japan) was inserted simultaneously in the reconstruction group. A breast surgeon performed the entire procedure. In addition, approximately half a year after the TE had been sufficiently expanded, a

plastic surgeon removed it and replaced it with a silicone implant. Regarding axillary manipulation, axillary dissection was performed in cases with neoadjuvant chemotherapy (NAC). In other cases, a sentinel lymph node biopsy was performed, and axillary dissection was added only in cases with positive metastasis in intraoperative pathological rapid diagnosis. The indications for breast reconstruction surgery were stages 0-III, excluding lesions exposed to the skin.

Pathological analysis

Hormone receptors and human epidermal growth factor receptor-2 (HER2) status were evaluated from needle biopsy specimens in NAC cases and from surgical specimens in other cases. Staging was performed based on the 18th edition of the General Rules for Clinical and Pathological Recording of Breast Cancer.⁷ Regarding surgical margins, “negative margins” occurred if the distance from the tumor was ≥ 5 mm, “near margins” if < 5 mm, and “positive margins” if the margins were exposed to lesions.

Adjuvant therapy and follow-up

Adjuvant drug therapy was performed based on the clinical practice guidelines for breast cancer.⁸⁻¹⁵ Before 2017, axillary lymph node metastases were considered indications for NAC, and from 2018 onwards, tumor diameters > 2 cm (regardless of lymph node metastasis) were considered. Postmastectomy radiotherapy (PMRT) was indicated for cases with metastasis to ≥ 4 axillary lymph nodes. According to the recurrence risk of individual cases, the duration of adjuvant endocrine therapy ranged from 5 to 10 years. A follow-up for recurrence was conducted every 3-6 months during adjuvant drug therapy and annually after the completion of adjuvant therapy. As a follow-up method, ultrasonography and mammography of the unaffected breast were performed for the local area of the breast, and whole-body computed tomography was performed for the evaluation of distant metastasis. Local recurrence was defined as skin and chest wall recurrence in the affected breast, and distant metastasis was defined as recurrence in unresectable lymph nodes and organs. Local recurrence or distant metastasis was determined according to the site of the first recurrence, and distant metastasis included cases in which both were observed simultaneously. The disease-free interval was defined from the date of the initiation of the breast cancer treatment to the first local recurrence or remote metastasis.

Analysis method

Statistical analyses were performed using JMP version

17.0 (SAS Institute, Inc., Cray, NC, USA). The patient background was analyzed using descriptive statistics. Clinicopathological factors were calculated for the two groups using Student's t test or Chi-square test. The overall survival (OS) and recurrence-free survival rates were calculated using the Kaplan-Meier method and tested using the log-rank method. Local and remote recurrences were determined by the cumulative incidence rate. Cox regression was used for multivariate analysis. Statistical significance was defined as $P < 0.05$.

Results

Patient background

Overall, the study included 98 patients with breast cancer. Of these patients, 37 (37.8%) were in the reconstruction group that underwent IBR using TE methods, and 61 (62.2%) were in the mastectomy group that underwent mastectomy alone. Table 1 shows the background of the patients. The mean ages at diagnosis of breast cancer were 36.6 and 36.2 years in the reconstruction and mastectomy groups, respectively, showing no difference. The average BMI values were 22.8 and 22.3, which also showed a similar trend between the two groups. In the reconstruction group, 9 of 37 (24.3%) patients were HER2 positive, and 28 of 37 (75.7%) were ER positive. In the mastectomy group, 19 of 61 (31.1%) patients were HER2 positive, and 38 of 61 (62.3%) were ER positive. No difference in each expression rate was found between the two groups. Although no statistically significant difference in the clinical stage was observed between the two groups, positive lymph node metastasis was frequently observed in the mastectomy group ($P = 0.06$). Several cases were close to the resection margin in the reconstruction group (7 cases, 18.9%) ($P = 0.03$).

Table 2 shows breast cancer treatment. In the reconstruction group, 1 (3.2%) patient received NAC, whereas in the mastectomy group, 21 (34.4%) patients received NAC ($P < 0.01$). In addition, PMRT was performed in 10 (16.4%) cases in the mastectomy group ($P = 0.02$). Adjuvant chemotherapy was performed in 19 (51.4%) and 47 (77.0%) cases.

Local recurrence

The median observation period starting from the date of histological diagnosis of breast cancer in all cases was 68.5 (range, 3-203) months.

In total, eight patients presented with local recurrence at the site of the first recurrence. Notably, 4 (12.9%) pa-

Table 1 Patient background

		Reconstruction group n = 37	Mastectomy group n = 61	P value
Age at diagnosis (years)		36.6 ± 3.5	36.2 ± 3.9	0.31 ^a
BMI		22.8 ± 3.6	22.3 ± 3.6	0.29 ^a
ER positive		28 (75.7%)	38 (62.3%)	0.17 ^b
HER2 positive		9 (24.3%)	19 (31.1%)	0.47 ^b
Stage	0	8 (21.6%)	6 (9.8%)	0.28 ^b
	I	9 (24.3%)	15 (24.6%)	
	II	18 (48.6%)	23 (37.7%)	
	III	2 (5.5%)	17 (27.9%)	
Subtype	DCIS	8 (21.6%)	6 (9.8%)	0.27 ^b
	Luminal	19 (51.4%)	27 (44.3%)	
	Luminal-HER2	9 (24.3%)	11 (18.0%)	
	HER2	0 (0%)	8 (13.1%)	
	TNBC	1 (2.7%)	9 (14.8%)	
T*	<2 cm	12 (32.4%)	19 (31.1%)	0.21 ^b
	≥2 cm	17 (45.9%)	36 (59.0%)	
N	0	29 (78.4%)	36 (59.0%)	0.06 ^b
	1	7 (18.9%)	20 (32.7%)	
	2	0 (0%)	5 (8.2%)	
	3	1 (2.7%)	0 (0%)	
Nuclear grade	1	12 (32.4%)	19 (31.1%)	0.87 ^b
	2	6 (16.2%)	11 (18.1%)	
	3	9 (24.3%)	19 (31.1%)	
	Unknown	10 (27.1%)	12 (19.7%)	
Ly**	Positive	18 (48.6%)	32 (52.5%)	0.73 ^b
	Negative	12 (32.5%)	18 (29.5%)	
	Unknown	7 (18.9%)	11 (18.0%)	
V***	Positive	12 (32.5%)	18 (29.5%)	0.72 ^b
	Negative	18 (48.6%)	32 (52.5%)	
	Unknown	7 (18.9%)	11 (18.0%)	
Resection margin	Close	7 (18.9%)	2 (3.3%)	0.03 ^b
	Positive	0 (0%)	0 (1.6%)	

BMI, body mass index; ER, estrogen receptor; HER2, human epidermal growth factor receptor-2; DCIS, ductal carcinoma *in situ*

*: exclude DCIS Ly **: lymphatic invasion V ***: vascular invasion

^a: Student's t test

^b: Chi-square test

tients in the reconstruction group and 4 (6.6%) in the mastectomy group presented with local chest wall recurrence. The median time from breast cancer surgery to the diagnosis of local recurrence was 47.5 months. The median times in the reconstruction and mastectomy groups were 61.5 and 37 months, respectively. Fig. 2-a shows the cumulative recurrence rate. In the Kaplan-Meier analysis, the 5- and 10-year cumulative local recurrence rates were 7.5% and 27.5% in the reconstruction group and 6.1% and 11.3% in the mastectomy group, respectively. Table 3 shows the post-treatment course of local recurrence cases. For lo-

cally recurrent lesions, systemic treatment was performed after local excision in all cases. No distant metastases were observed in seven cases, except for one death.

Distant metastasis

In this study, 4 (12.9%) cases in the reconstruction group and 7 (11.5%) in the mastectomy group presented with distant metastasis in the first recurrence. The median durations for the diagnosis of distant metastases were 31.5 and 31 months in the reconstruction and mastectomy groups, respectively. Fig. 2-b shows the cumulative incidence rate. The 5- and 10-year rates of remote metastasis were 6.2%

Table 2 Breast cancer treatment

	Reconstruction group n = 37	Mastectomy group n = 61	P value
Axillary operation			NA
Sentinel lymph node biopsy only	29 (78.4%)	36 (59.0%)	
Sentinel lymph node biopsy → dissection	7 (18.9%)	4 (6.6%)	
Axillary dissection	1 (2.7%)	21 (34.4%)	
Drug therapy			
Neo-adjuvant chemotherapy	1 (2.7%)	21 (34.4%)	<0.01 ^a
Adjuvant chemotherapy	19 (51.4%)	47 (77.0%)	<0.01 ^a
Anti-HER2 therapy	11 (27.2%)	19 (31.1%)	0.88 ^a
Endocrine therapy	27 (73.0%)	38 (62.3%)	0.27 ^a
PMRT	1 (2.7%)	10 (16.4%)	0.02 ^a

NA, not available; PMRT, postmastectomy radiotherapy
a: Chi-square test

and 23.0% in the reconstruction group and 11.7% and 21.5% in the mastectomy group, respectively, showing no statistical difference between the two groups.

Survival time

In total, 1 (2.7%) death in the reconstruction group and 5 (8.2%) in the mastectomy group occurred. The 5- and 10-year survival rates were both 96.4% in the reconstruction group, while 95.4% and 85.1% in the mastectomy group, respectively. Fig. 2-c shows the Kaplan-Meier curve. No difference was noted in the OS with or without reconstructive surgery, and the results were comparable (HR 95% CI, $P = 0.65$).

Local recurrence risk factors after mastectomy

Table 4 shows the results of the multivariate analysis of local recurrence risk factors in eight cases of local recurrence among all 98 cases. Among early-onset breast cancers, it has been reported that the prognosis is particularly poor for cases that develop in the 20s.¹⁶⁾ We examined whether there was a difference in prognosis between people in their 20s and after 30 years of age among patients with early-onset breast cancer.

According to Japan movement statistics, women in their 20s and 30s with a BMI of 25 or higher make up about 10% of the same generation.¹⁷⁾ In this study, a BMI of 25 or higher accounted for about 20% of the patients, which is more than the standard rate. Since the rate of BMI 27 or higher was about 10% of the target patients, BMI 27 was examined as a boundary value.

BMI ≥ 27 ($P < 0.01$, HR 2.15, 95% CI 0.39-2.81) and HER2 positivity ($P = 0.02$, HR 1.94, 95% CI 0.89-48.6) were independent risk factors for local recurrence after mastec-

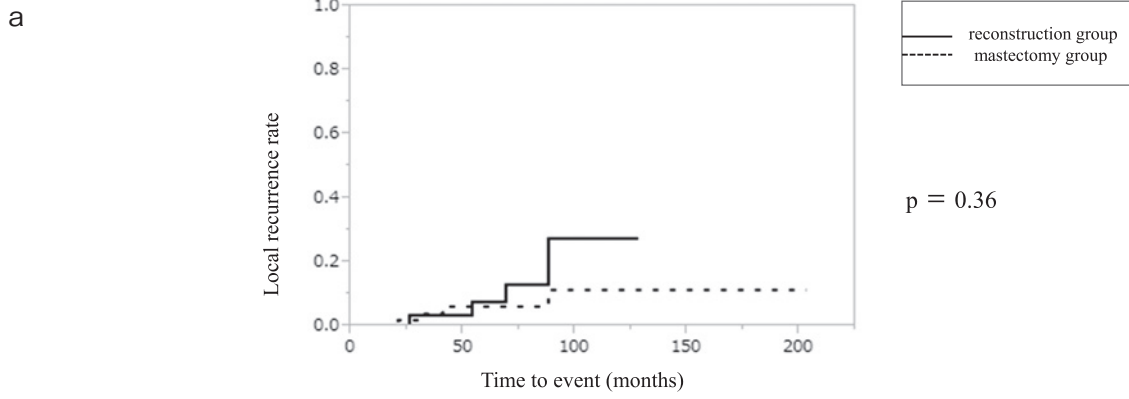
tomy.

Discussion

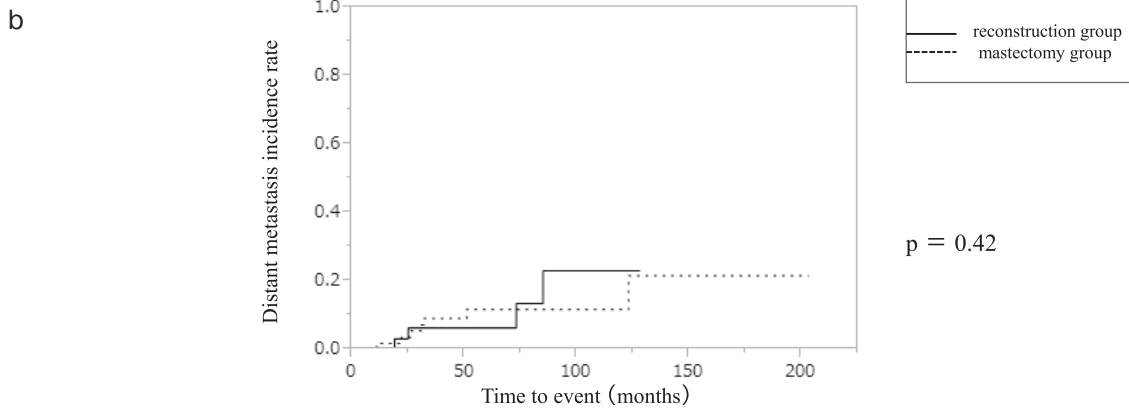
Although several studies have reported examining the risk factors for local recurrences after radical mastectomy, no studies have reported the risk of local recurrence and the safety of IBR limited to breast cancer diagnosed at an early age.

No statistically significant difference in the subtype or clinical stage was found when comparing the mastectomy group and the reconstruction group. However, the finding that the mastectomy group had higher lymph node metastasis-positive cases and NAC cases may suggest that the mastectomy group tended to include several advanced cases. More close-to-resection margin cases were registered in the reconstruction group. This is because breast surgeons are aware of the need to reduce the amount of subcutaneous fat to be excised as much as possible to improve the cosmetic appearance of the reconstructed breasts. Although several close-to-resection margin cases were noted, the absence of difference in the local recurrence rate in the medium- to long-term follow-up compared with the mastectomy group can be thought of as data supporting one-stage breast reconstruction.

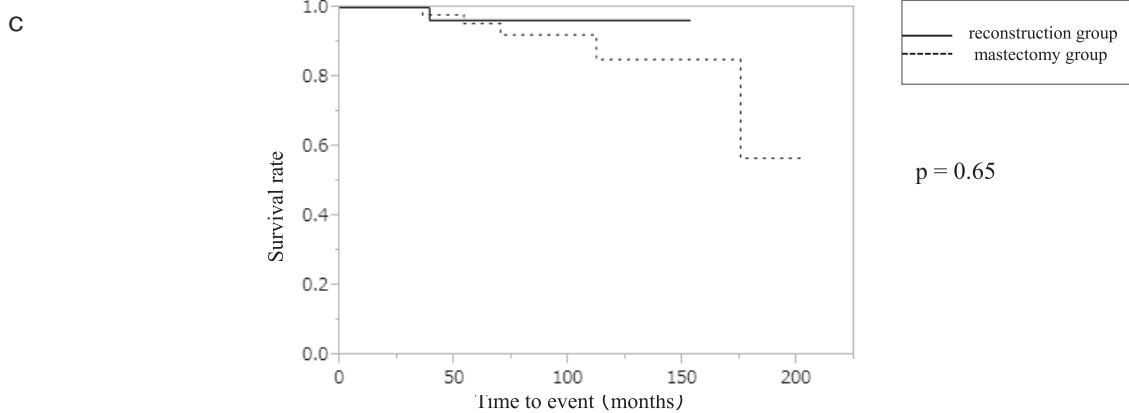
Yamada et al. examined the prognosis of immediate reconstruction using autologous tissue in Japanese patients with early-onset breast cancer aged 23-65 years.¹⁸⁾ The median follow-up period was 73 months, the local recurrence rate was 3.7% for both 5 and 10 years, and the survival rate was 98.6% for 5 years and 96.0% for 10 years. The finding that the local recurrence rate was lower than that



Local recurrence rate	Reconstruction group	Mastectomy group
5-year incidence rate	7.5%	6.1%
10-year incidence rate	27.5%	11.3%



Local recurrence rate	Reconstruction group	Mastectomy group
5-year incidence rate	6.2%	11.7%
10-year incidence rate	23.0%	21.5%



Survival rate	Reconstruction group	Mastectomy group
5-year survival rate	96.4%	95.4%
10-year survival rate	96.4%	85.1%

Fig. 2 Kaplan-Meier survival curve. (a) Cumulative local recurrence rate, (b) cumulative remote metastasis incidence, and (c) overall survival rate

Table 3 Summary of local recurrence cases

No	Group	Age at cancer diagnosis (y)	Stage	Subtype	Resection margin	DFI (month)	Post-recurrence follow-up (month)	Prognosis
1	R	40	IIA	L-H	Negative	26	48	alive/no met
2	R	39	I	L	Close	54	12	alive/no met
3	R	35	IIA	L	Close	88	64	alive/no met
4	R	40	0	DCIS	Close	72	1	alive/no met
5	M	37	IIA	L	Negative	21	49	death
6	M	36	IIIA	L	Negative	88	66	alive/no met
7	M	36	IIIA	L-H	Close	41	66	alive/no met
8	M	36	IIIB	L	Close	33	32	alive/no met

DCIS, ductal carcinoma *in situ*; L, luminal type; L-H, luminal-HER2 type; M, mastectomy group; no met, no distant metastases; R, reconstruction group

Table 4 Local recurrence risk factors after mastectomy

		Univariate analysis		Multivariate analysis	
		<i>p</i>	<i>p</i>	HR	95% CI
Age	<30 years old ≥30 years old	0.31	0.28	0.15	(<0.01, 0.78)
BMI	≥27 <27	0.73	<0.01	2.15	(0.39, 2.81)
ER	Positive Negative	0.20	0.54	1.22	(<0.01, 3.15)
HER2	Positive Negative	0.82	0.02	1.94	(0.89, 48.6)
N	Positive Negative	0.81	0.65	0.05	(<0.01, 0.31)
Breast reconstruction	Performed Not performed	0.45	0.53	0.48	(<0.01, 1.91)
Vascular invasion	(+) (-)	0.75	0.85	0.83	(<0.01, 1.07)
Resection margin	Negative Close	0.03	0.18	0.10	(<0.01, 0.58)

BMI, body mass index; CI, confidence interval; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; HR, hazard ratio

in this study was thought to be caused by the difference in the reconstruction methods (autologous tissue reconstruction and primary/secondary reconstruction using artificial materials). Regarding prognosis, considering that this study only targeted young patients, the results were modest in terms of life prognosis, despite local recurrences. Naguyan et al. examined patients who underwent reconstruction at the age of ≤40 years.¹⁹⁾ The median follow-up period was 10 years, the local recurrence rate was 11.1%, and the survival rate was 82.2% for 5 years and 90.3% for 10 years. Despite the high local recurrence rate in this

study, the survival rate was also sufficient.

Although no statistically significant difference was observed, the incidence of local recurrence tended to be higher than that in the mastectomy group. However, considering the survival rate, the results were by no means inferior to existing reports. All but one patient with local recurrence survived without distant metastasis, suggesting that if appropriate treatment for local recurrence is performed, it may have little effect on the survival rate.

We investigated the independent local recurrence risk factors after mastectomy in patients with early-onset

breast cancer. HER2 positivity was reported as a risk factor for local recurrence in mastectomy;²⁰⁾ however, no study has reported that BMI is a risk factor, and caution is required in surgery in patients with early-onset breast cancer. On the contrary, the use of IBR was not an independent risk factor for local recurrences in patients with early-onset breast cancer.

Limitations of the study

A limitation of this study is that the breast reconstruction method was limited to IBR with the need for skin expansion using TE. In our surgical method, a surgical procedure that leaves various subcutaneous fats was used to expand the skin. However, in IBR without TE, since skin expansion is unnecessary and can be adjusted by filling with autologous tissue, there is little need to retain large amounts of subcutaneous fat; as such, the risk factors for local recurrence after total resection differed depending on the reconstruction method. Despite this background, many patients tend to choose IBR using TE because the surgical wound is smaller, and the operation time is shorter than that of autologous tissue.

In addition, in recent years, breast cancer susceptibility gene (BRCA) mutations have become a problem in early-onset breast cancer. As this study included past cases in which BRCA mutation could not be measured, we have not examined the results according to BRCA mutation.

Conclusion

This study investigated the prognosis of IBR using TE in patients with early-onset breast cancer. Local recurrence tended to be slightly higher than that in mastectomy cases; however, no differences in survival rates were observed. In addition, when the risk factors for local recurrence after mastectomy in patients with early-onset breast cancer were examined, it was suggested that HER2 expression and BMI ≥ 27 may be cited as independent recurrence factors. Early-onset breast cancer tends to have a worse prognosis than common breast cancer, and breast reconstruction can be a treatment option that does not affect the prognosis.

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Authors' contribution: F. Saito and M. Goto contributed to the design of this study. F. Saito wrote the main manuscript's text and con-

tributed the figures. H. Ogata made substantial contributions to the study concept or the data analysis or interpretation. All authors read and approved the final version of the article.

Ethics statement: All methods were carried out in accordance with relevant guidelines and regulations. The need for informed consent from the participants was waived given the retrospective cohort study design, which was approved by the Ethics Committee of Toho University Omori Medical Center (M21050). Omission of obtaining informed consent was approved by the Ethics Committee of Toho University Omori Medical Center. The details of this study were posted on our hospital's website, and potential participants were allowed to opt-out. All experimental protocols were approved by the Ethics Committee of Toho University Omori Medical Center.

Conflicts of interest: None declared.

Consent for publication: Not applicable

Availability of data and materials: The datasets analyzed during the current study are available from the corresponding author on reasonable request.

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