

Scientific Article

Comparing Accuracy of Thermoplastic Mask versus Commercial Bra for the Immobilization of Pendulous Breast During Radiation Therapy Treatment: A Retrospective Cohort Study



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Abstract

Purpose: This study aimed to compare thermoplastic mask with bra in terms of setup reproducibility and immobilization of pendulous breasts during radiation therapy (RT).

Methods and materials: Forty-two female patients with breast cancer treated with either intensity modulated RT or 3-dimensional conformal RT were retrospectively reviewed. Of these, 21 benefited from thermoplastic mask immobilization and 21 used a bra. Setup accuracy was evaluated using consecutive cone beam computed tomography/electronic portal imaging device sessions over the first 3 days before treatment (systematic setting), followed by weekly cone beam computed tomography/electronic portal imaging device (random settings), and compared with the reference image to calculate the corresponding translational shift (setup error) in the 3 planes. Average absolute shift values in both systematic and random settings were compared between the 2 groups. Accuracy was analyzed by comparing the percentage of pooled settings within ± 0.05 and ± 0.1 cm of the reference image.

Results: Compared with a bra, use of the mask was associated with a smaller longitudinal shift in systematic settings (difference in mean: 0.27 cm; $P = .027$; Mann-Whitney U test) and a lesser lateral shift in random setting (difference in mean: 0.19 cm; $P = .005$; Mann-Whitney U test). In the pooled systematic settings, the mask performed relatively better than the bra in the lateral and longitudinal planes, with no statistical significance. In pooled random settings, mask showed greater accuracy than bra in the lateral plane with 86.0% versus 58.9% accuracy at ± 0.5 cm ($P < .001$) and 48.8% versus 21.7% accuracy at ± 0.1 cm ($P < .001$), respectively. There was no significant difference in the incidence of radiodermatitis between the 2 groups. However, a hypofractionation regimen was associated with a lower incidence of radiodermatitis, and the severity of skin reactions was positively correlated with treatment dose (unstandardized regression coefficient: $B = .001$; correlation coefficient: $r = .571$; $P < .001$).

Conclusions: Masks provide superior reproducibility compared with commercially available bras.

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Introduction

Breast cancer continues to be the leading type of cancer in Saudi Arabia in term of frequency, accounting for 17% of overall adult malignancies, with a rapidly increasing incidence during recent decades. Breast cancer represents nearly one-third of newly diagnosed cancers in Saudi women, with the highest age-adjusted distribution being 38.2% among patients aged 30 to 59 years.¹⁻⁶ The global mortality-to-incidence ratio has been decreasing in recent years due to advancements in cancer management. Nevertheless, due to the increasing incidence, the burden of breast cancer remains high, with an estimated 10 deaths per 100,000 individuals in the Arab world and >35 deaths per 100,000 in Western Europe and Afghanistan, which are the highest rates globally.^{7,8}

The standard treatment for most women with breast cancer is local excision by surgery, followed by radiation therapy (RT), enabling excellent local control rates (up to 95%) and comparable mortality rates to mastectomy.⁹⁻¹² Accurate delivery of RT using advanced techniques, such as intensity modulated RT (IMRT), necessitates effective immobilization, particularly for pendulous breasts, which poses a challenge in the treatment of breast cancer in RT.¹³ Conventionally, thermoplastic masks were developed to stabilize pendulous breasts, thereby providing more reproducible settings over the course of RT. Several authors have published data on the accuracy and reproducibility of patient settings using thermoplastic masks or compared setup errors across different breast-immobilizing techniques.¹³⁻¹⁶ The aim of such studies is to determine the best immobilization technique, which consistently enables using a minimal margin to avoid performing daily setup corrections. However, these studies showed conflicting results, and no consensus recommendation has been reached.

The other concern regarding accuracy of radiation delivery is to reduce the risk of acute radiodermatitis, a frequent adverse effect of adjuvant breast RT that may be of variable severity. A multicenter randomized trial reported that 30% of patients developed radiodermatitis after postoperative IMRT for breast cancer, and this incidence increased to nearly 50% with standard RT using wedges. IMRT uses small beams of varying intensities, thereby providing a more homogeneous dose compared with standard 3-dimensional conformal RT (CRT).¹⁷

This study was conducted to compare reproducibility and skin reaction between 2 immobilization techniques (thermoplastic mask and commercial bra) used for post-operative RT. The study was based on the hypothesis that masks enable more reproducible settings than bras, but may cause more skin side effects.

Methods and materials

Design and setting

This was a retrospective chart review including women with histologically confirmed breast cancer who were treated with adjuvant RT after local excision between January 2013 and December 2019. Participants were recruited and followed at the radiation oncology unit. The study received ethical approval from the hospital's institutional review board.

Population and sampling

The population included patients with pendulous breasts who underwent conservative surgery for histologically confirmed breast cancer with adjuvant RT, using either 3-dimensional CRT or IMRT, while using a thermoplastic breast mask or bra for breast immobilization. Male patients, women with nonpendulous breasts, and those who underwent radical mastectomy were excluded. Additionally, patients who had bolus were not included.

Forty-one eligible patients were reviewed: 21 patients who were immobilized with a standard thermoplastic breast mask, 20 patients who used a bra, and 1 patient who was added prospectively to the bra group to complete equivalent size. Thus, the total number of patients included was 42.

Patient setup and positioning

All patients were positioned supine on the breast board that is fixed to the treatment couch with an indexer, with both arms up and an indexed cushion under the knees. To verify patient setup accuracy, cone beam computed tomography (CBCT)/electronic portal images were taken for the first 3 fractions, then weekly, before each treatment session. In some cases, where setup reproducibility was inconsistent due to obesity, daily CBCT/electronic portal images were necessary. The CBCT/electronic portal images were compared with the reference image by the radiation therapist to calculate the translational shift (setup error), in millimeters, in the 3 planes (lateral [X], longitudinal [Y], and vertical [Z]) per the coordinate system used in ICRU report 62.¹⁸ Online shifts using automatic table displacement values were performed before RT.

Determination of interfraction errors

Interfraction errors were defined from the pretreatment CBCT/electronic portal images taken after patient setup

and before treatment. Systematic errors were the translational setup errors of the CBCT/electronic portal images taken during the first 3 fractions of treatment, and random errors were defined by the translational errors in the CBCT/electronic portal images taken weekly.

Radiation therapy dose and energy

Two dose regimens were used for RT. Thirteen patients received the standard protocol of 200 cGy per fraction, once daily, 5 days per week, over 25 fractions, for a total dose of 5000 cGy. The 29 other patients received a hypofractionated protocol of either 4240 cGy in 16 fractions or 4005 cGy in 15 fractions (see Table 1 for the exact number of patients with a hypofractionated protocol in each arm). Patients were treated with or without a boost of 1000 cGy in 5 fractions.

Skin reactions

Patients were assessed weekly in the review clinic by the radiation oncologist, and the occurrence of any acute skin reaction was documented. Late skin reactions were not documented.

Heart and lung dosimetry

The dosimetry analyses were carried out by calculating heart V_{30} and ipsilateral lung V_{20} , corresponding to the

percentage of heart volume receiving 30 Gy and the percentage of ipsilateral lung volume receiving 20 Gy, respectively. Furthermore, the mean dose received by the heart (heart D_{mean}) and ipsilateral lung (lung D_{mean}) were computed and analyzed.

Statistical methods

The data were collected and coded in a Microsoft Excel sheet and transferred for statistical analysis to the Statistical Package for Social Sciences, version 21.0 for Windows (SPSS Inc, Chicago, IL). Categorical variables are presented as frequency and percentage, and continuous variables are presented as mean \pm standard deviation (SD). A comparison of participants' demographic and clinical characteristics between the mask and bra groups was carried out using an independent t test for discrete variables and the χ^2 test. Average absolute shift values were computed for both systematic and random settings for each plane and were compared between the 2 groups (mask vs bra) using both parametric (independent t test) and nonparametric (Mann-Whitney U test) tests. The same tests were used to compare heart V_{30} , heart D_{mean} , lung V_{20} , and lung D_{mean} .

Percentage accuracy was calculated at 2 levels (± 0.5 cm and ± 0.1 cm) as the proportion of sessions with a setup error within the given range, by plane, in systematic and random settings separately, and was compared between mask and bra using the χ^2 test. Linear regression

Table 1 Patient characteristics

Characteristic	Total (n = 42)	Bra (n = 21)	Mask (n = 21)	P-value
Age (y) mean \pm SD	56.67 \pm 9.64	58.38 (9.86)	56.95 (9.60)	.637
Breast side				
Right	16 (40.5)	8 (38.1)	8 (42.9)	
Left	26 (59.5)	13 (61.9)	13 (57.1)	.751*
Histology				
DCIS	3 (7.1)	3 (14.3)	0 (0.0)	
IDC	37 (88.1)	18 (85.7)	19 (90.5)	
IMC	2 (4.8)	0 (0.0)	2 (9.5)	.081
Elapsed time (d), mean \pm SD	29.36 \pm 9.77	32.57 \pm 10.19	26.14 \pm 8.37	.031 [†]
Dose by session (cGy), mean \pm SD	245.26 \pm 30.68	234.57 \pm 33.78	255.95 \pm 23.41	.022 [†]
Total dose (cGy), mean \pm SD	4442.19 \pm 386.46	4558.00 \pm 440.09	4326.38 \pm 290.39	.051
No. of fractions	18.64 \pm 4.32	20.10 \pm 4.81	17.19 \pm 3.28	.028 [†]
Fractionation regimen				
Standard (2 Gy)	13 (31.0)	10 (47.6)	3 (14.3)	
Hypofractionation (2.65-2.67 Gy)	29 (69.0)	11 (52.4)	18 (85.7)	.043 ^{†,‡}
Boost				
Yes	7 (16.7)	6 (28.6)	1 (4.8)	
No	35 (83.3)	15 (71.4)	20 (95.2)	.093 [‡]

Abbreviations: DCIS = ductal carcinoma in situ; IDC = invasive ductal carcinoma; IMC = invasive mammary carcinoma; SD = standard deviation.

* χ^2 test.

[†] Statistically significant difference ($p < .05$).

[‡] Fisher's exact test.

was used to analyze the correlation between total treatment and maximal skin reaction level (range, 0-4); results are presented as unstandardized regression coefficient (B) and correlation coefficient (r). A *P* value of < .05 was considered to reject the null hypothesis.

Results

Participant characteristics

A total of 42 patients were included in the study (21 patients each in the bra and mask groups). Mean age \pm standard deviation was 56.67 (\pm 9.64) years without significant differences between the 2 groups (*P* = .637). Lesions were localized in the left breast in 26 patients (59.5%), and invasive ductal carcinoma was the most frequent histologic type (*n* = 37; 88.1%). The duration of treatment ranged between 18 and 52 days (mean \pm standard deviation: 29.36 \pm 9.77 days) and was approximately 6 days shorter in the mask group (*P* = .031), resulting in a lower number of fractions by patient (*P* = .028) with reference to the bra group. Consequently, although the mean radiation dose by session was approximately 20 cGy higher in the mask group compared with the bra group (*P* = .022), patients in the mask group received a total radiation dose that is 230 cGy lower than those in the bra group, a difference that was nearly significant (*P* = .051; Table 1).

Comparing immobilization reliability of mask versus bra: Accuracy analysis

Comparing mean absolute shifts

Compared with bra use, the use of a mask was associated with a lesser longitudinal shift in systematic settings (difference in mean: 0.27 cm; *P* = .027; Mann-Whitney *U* test) and lesser lateral shift in random settings (difference in mean: 0.19 cm; *P* = .005; Mann-Whitney *U* test). Mask performance was similar to bra performance in the vertical plane in both systematic and random settings (*P* > .05; Table 2).

Comparing percentage accuracy (pooled analysis)

By pooling all systematic settings, the mask was slightly superior to bra in terms of accuracy in the lateral and longitudinal planes but less accurate in the vertical plane; however, none of these comparisons reached the statistical significance level. By pooling random settings, mask performed better than bra in terms of accuracy in the lateral plane with 86.0% versus 58.9% accuracy within \pm 0.5 cm (*P* < .001) and 48.8% versus 21.7% accuracy within \pm 0.1 cm (*P* < .001), respectively. Otherwise, the 2 immobilization methods performed similarly in the longitudinal and vertical planes (*P* > .05; Table 3).

Comparing safety of mask versus bra: Radiodermatitis

Table 4 presents the incidence and severity of radiodermatitis in the bra versus mask groups. The incidence of radiodermatitis was lower in the mask group (33.3% vs 61.9%); however, the comparison was not statistically significant (*P* = .064). Regarding severity, no statistically significant difference was observed between the 2 immobilization methods using both the χ^2 test (*P* = .366) and median test (median grade: 2 [bra] vs 1 [mask]; *P* = .122).

Association of radiodermatitis with treatment parameters

The severity of radiodermatitis was positively correlated with the total treatment dose, modeling an increase to the next severity grade for every 800 cGy increment in total dose (unstandardized regression coefficient: B = .001; correlation coefficient: *r* = .571; *P* < .001; Fig 1). Furthermore, regardless of bra or mask use, radiodermatitis was more frequent among patients who received a standard fractionation regimen (12 of 13 patients; 92.3%) versus those who received 2.65 to 2.67 Gy (8 of 29 patients; 27.6%; *P* < .001). By stratifying the fractionation regimen by group, the incidence of radiodermatitis was higher in patients receiving a standard regimen in both the bra (90% vs 36.4%; *P* = .024) and mask (100% vs 22.2%; *P* = .026) groups versus those receiving a hypofractionated regimen, respectively. On

Table 2 Mean absolute shifts (in cm) between bra and mask

Setting	Plane	Bra		Mask		<i>P</i> -value	
		Mean	SD	Mean	SD	Independent <i>t</i> test	Mann-Whitney <i>U</i> test
Systematic setting (average of first 3 days)	Lateral	0.45	0.23	0.36	0.25	.226	.217
	Longitudinal	0.70	0.69	0.43	0.36	.123	.027*
	Vertical	0.31	0.23	0.33	0.21	.832	.649
Random setting (average)	Lateral	0.44	0.20	0.25	0.23	.005*	.005*
	Longitudinal	0.37	0.19	0.30	0.25	.343	.212
	Vertical	0.25	0.73	0.14	0.09	.478	.158

Abbreviation: SD = standard deviation.

* Statistically significant difference (*p* < .05).

Table 3 Percentage accuracy of pooled systematic and pooled random settings in bra versus mask

Plane	Accuracy level (shift)	Percentage accuracy, %		P-value
		Bra	Mask	
Systematic settings		(n = 50)	(n = 45)	
Lateral	±0.5 cm	68.0	75.6	.415
	±0.1 cm	20.0	26.7	.442
Longitudinal	±0.5 cm	62.0	71.1	.348
	±0.1 cm	20.0	28.9	.313
Vertical	±0.5 cm	82.0	73.3	.309
	±0.1 cm	54.0	35.6	.071
Random settings		(n = 175)	(n = 86)	
Lateral	±0.5 cm	58.9	86.0	<.001*
	±0.1 cm	21.7	48.8	<.001*
Longitudinal	±0.5 cm	68.0	69.8	.887
	±0.1 cm	28.0	39.5	.060
Vertical	±0.5 cm	94.3	93.0	.689
	±0.1 cm	69.7	60.5	.136

Percentage accuracy calculated as the percentage of pooled settings within the given accuracy level. Test used was χ^2 test. Significance level: $P < .05$.

* $P < .05$.

the other hand, no significant association of radiodermatitis was found with radiation energy used ($P = .942$) or the use of boost ($P = .229$; results not presented in tables).

Dosimetry analysis

Data for heart V_{30} and D_{mean} were available for 25 of 26 patients who were treated for left breast cancer, of whom 13 were from the bra group and 11 from the mask group. Data for ipsilateral lung V_{20} and D_{mean} were

Table 4 Incidence and severity level of radiodermatitis in bra versus mask groups

Grade	Bra		Mask		P-value
	n	%	n	%	
Incidence					
Absent or mild (grade 0-1)	8	38.1	14	66.7	
Presence	13	61.9	7	33.3	.064
Severity level					
Grade 0	3	14.3	5	23.8	
Grade 1	5	23.8	9	42.9	
Grade 2	10	45.6	5	23.8	
Grade 3	2	9.5	2	9.5	
Grade 4	1	4.8	0	0.0	.366
Median	2		1		.0122*

* Median test (χ^2 was used otherwise).

available for 40 patients, of whom 21 were from the bra group and 19 from the mask group. Unavailable data were lost during the upgrade of the Eclipse planning system. A comparison showed no statistically significant difference in any of the parameters between the 2 groups; however, the mask was associated with lower variance in all these parameters (Table 5).

Discussion

Accuracy and limitations of thermoplastic mask

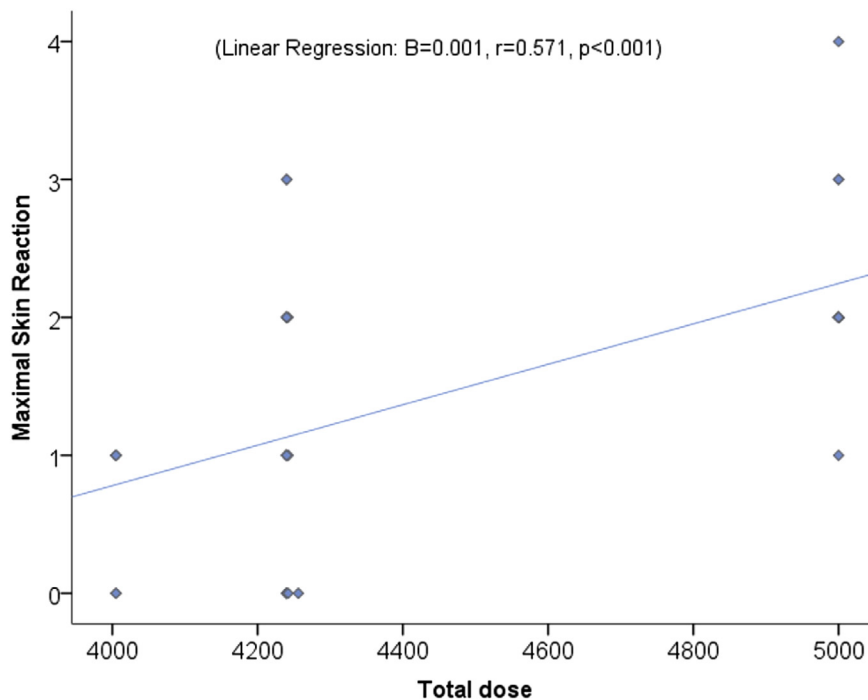
Several techniques and devices have been used to achieve satisfactory breast immobilization during RT and are adopted as the technique of choice depending on center preference. Among these devices are breast boards, breast cups, wireless bra, micropore tape, vacuum bags, plastic L-shaped supports, breast rings, and stockings.^{19,20}

The present study demonstrated that the use of a thermoplastic mask in a supine-positioned pendulous breast reduced the average longitudinal setup error by 0.27 cm in systematic settings and the average lateral setup error by 0.19 cm in random settings compared with the use of a simple bra. These observations were supported by pooled analysis showing better performance of the mask in the lateral and longitudinal planes. Of note, although not all these comparisons were statistically significant, some were clinically significant because shifts <0.5 cm did not require repositioning of the patient.

On the other hand, pooled analysis showed a tendency of lower performance in the vertical plane by the mask compared with the bra. Although the latter observation did not reach statistical significance, this may be explained by the supine position causing the breast to flop down after setting the rigid mask, whereas the bra provides better fit to the breast shape due to its elasticity. Such an issue is challenging and a limitation of the mask. This calls for a novel approach, which was resolved by cutting the mask around the top circumference so the breast is open anteriorly and supported posteriorly, providing better immobilization of the breast in the vertical plane.

Accuracy of thermoplastic mask in the literature

Several authors have assessed the accuracy of a thermoplastic mask and other breast immobilization techniques, but no studies have specifically compared the 2 aforementioned techniques. A Chinese study by Xiugen et al analyzed setup errors by CBCT in a similar population of 25 patients who were immobilized using a neck-and-breast thermoplastic mask and an IMRT session. The authors reported average systematic (1.20-1.40 mm) and random (1.40-3.00 mm) errors, which is lower than the error values in our study. Furthermore, the authors did not



B: unstandardized regression coefficient (slope), r = correlation coefficient.

Figure 1 Linear correlation between total dose and maximal skin reaction.

evidence any correlation between setup errors and patient anthropometrics, including height, weight, and body mass index. The authors concluded that the mask is effective in improving the accuracy of RT in patients with breast cancer.¹³

Comparable with our findings, Strydhorst et al reported relatively large random errors of 4.0, 12.0, and 4.5 mm in the lateral, longitudinal, and vertical planes, respectively, with high standard deviations. The authors opined that such errors and variance can be explained by respiratory motion and concluded that a mask is effective, stressing the necessity of carrying out daily image guidance to achieve such performance.¹⁴ However, the effectiveness of the mask might be questionable with regard to the observations from comparative studies. A study by Agostinelli et al compared the use of thermoplastic mask immobilization (8 patients) versus free breast (8 patients) in setup reproducibility with Accuray Hi-Art HT. The authors reported a minor impact of mask use in the lateral and longitudinal planes, along with a reduced error variance in the vertical plane without impact on the Van Herk's margins. The authors concluded that daily setup corrections are needed even when a mask is used.¹⁵

Interestingly, Biston et al compared thermoplastic mask with 3 other breast immobilization devices among 24 women with breast cancer (6 women in each group). The results showed that mask performance ranked second

after the BlueBag system with Arm-Shuttle (Elekta, Sweden), with no statistically significant difference between the 2 techniques in a pairwise comparison.²¹

Impact of bra use and other immobilization techniques

Several authors explored the use of a bra and its impact on setup reproducibility or the incidence of post-RT skin reactions. For example, Keller et al compared the use of a commercially available bra/bustier among large-breasted women during simulation and treatment session with no bra regarding acute skin reactions. The findings showed a higher incidence of grade 2 to 3 radiodermatitis with bra use, which was associated with a more than 5-fold risk. On the other hand, the use of a bra in left-sided tumors enabled a significant reduction in the heart and lung in the radiation fields, which constitutes an advantage.²² In contrast, the percentage of heart and lung volumes and mean doses were comparable in the 2 groups in the present study; however, the mask was associated with reduced variance, notably in mean doses received by the heart and lungs. Further analysis showed that this difference in variance is most likely explained by the mask group having mostly 1 fractionation regimen (hypofractionation), whereas the bra group was divided

Table 5 Summary of dose-volume histogram–based analysis for the planning target volume

Parameters	Bra	Masks	P-value 1	P-value 2
Heart V ₃₀ , %	6.00 ± 3.66	5.67 ± 2.30	.790	.810
Heart D _{mean} , cGy	493.98 ± 269.09	440.18 ± 120.20	.531	.574
Ipsilateral lung V ₂₀ , %	20.55 ± 6.76	21.40 ± 6.46	.686	.688
Ipsilateral lung D _{mean} , cGy	1092.88 ± 338.33	1075.16 ± 281.43	.859	.830

Values are mean ± standard deviation. Tests used were independent *t* test (*P*-value 1) and Mann-Whitney *U* test (*P*-value 2).

between the 2 regimens. This bias is due to a shift in the preferred dose prescription protocol at our institution from standard to hypofractionation, which coincided with the use of the thermoplastic mask, although some physicians still use the standard fractionation.

Kawamura et al evaluated setup reproducibility and accuracy using a customized commercially available bra for prone position immobilization and found that the use of a bra was effective in achieving tumor volumetric overlap as opposed to no bra.²³ Other techniques included a study by Xiang et al that compared single-pole with double-pole position in terms of patient comfort, radiation dosimetry, and setup reproducibility. The authors reported decreased average treatment dose and better patient-reported comfort in the single-pole position, with no difference in setup errors.²⁴ In the present study, we did not assess patient comfort; however, patient positioning as described is consistent with the literature recommendation regarding setup reproducibility.^{20,21}

Thermoplastic mask and skin reactions

Contrary to other data showing that the use of a mask increased the surface dose and subsequently increased skin reactions,²⁵ in this study, patients with a mask experienced nearly 2 times less grade 2 to 4 skin reactions. However, stratified analysis demonstrated that this is related to the difference in fractionation regimen and eventually to the total dose prescription. Indeed, all but 3 patients in the mask group received the hypofractionated protocol, whereas 10 of 21 patients in the bra group received the standard dose protocol. Patients treated with hypofractionated protocols are well known to have generally less acute skin side effects.²⁶

Another factor that might contribute to increasing skin reactions in patients using a bra could be that all skin folds may not have been removed when positioning the breast within the bra, notably in the inframammary or axillary regions. The latter is where severe radiodermatitis is observed, which was similarly reported by Keller et al.²² Additionally, Keller et al found that the use of IMRT rather than 3-dimensional CRT reduced the risk of dermatitis associated with bra use.²² In the present study, most patients received IMRT, except for 3 patients in the bra group.

Limitations

In this study, patient comfort was not assessed, although it can be assumed that the bra offers better comfort. Other limitations of this study are that patients received different dose regimes in the 2 groups, which reduces the clinical significance of the difference in skin reactions. The retrospective nature of the study is a limitation in this regard. Furthermore, due to the short follow-up, only acute skin reactions were reported. Finally, the sample size was small due to the limited number of patients with pendulous breasts treated at our institute. These limitations may undermine the generalizability of the findings, notably when comparing the risk of acute skin reactions.

Conclusions

This retrospective study showed superior performance of thermoplastic mask in pendulous breast immobilization during 3-dimensional CRT or IMRT session compared with the use of a commercial bra. The performance of the mask was more significant in lateral and longitudinal immobilizations of pendulous breast tissue, whereas the bra enabled better immobilization in the vertical plane. Unexpectedly, the incidence and median severity grades of radiodermatitis in the mask group were nearly 2 times lower than in the bra group; however, these results are probably due to more frequent use of hypofractionation. Secondly, this study demonstrated a positive correlation of the incidence and severity of radiodermatitis with the total treatment dose received.

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