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Modification of The Round Block Technique in The Management of Early Stages of Breast Cancer: A Randomized Controlled Clinical Trial for The Assessment of Oncological Safety and Cosmetic Outcomes

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ABSTRACT

Background: The round block technique (RBT) is an oncoplastic technique used in the excision of peri-areolar breast lesions especially in small to medium-sized breasts with moderate ptosis. **Objective:** Our study aims to introduce the technique of modified round block technique (MRBT) and to compare RBT and MRBT in peripherally located tumors as regards the oncological safety and cosmetic outcomes.

Patients and methods: From October 2018 to October 2021, a randomized controlled clinical trial was conducted on 40 female patients with early stages of breast cancer. Patients selected had tumors at least 2 cm away from the nipple-areola complex (NAC) and an expected excision volume not exceeding 20% of the breast volume. Patients' demographic data and tumor characteristics were recorded and analyzed. **Results**: The MRBT group has a significantly shorter operative time (P-value 0.016). Positive margin involvement was recorded in 2 cases requiring re-excision in the RBT group. Six patients developed seroma formation which was significantly higher in the MRBT group (P-value 0.048). A significantly lower mean change in areolar diameter was observed in the MRBT group (P-value 0.032). Two cases developed local recurrence, one in each group. No cases of distant metastasis were encountered during the follow-up. MRBT group has a significantly higher cosmetic outcome than RBT (P-value 0.03). **Conclusion:** The MRBT is an oncoplastic technique suitable for the excision of breast tumors in different breast quadrants especially peripherally located tumors in patients with small to medium-sized breasts and when the excision volume is not exceeding 20% of the breast volume.

Keywords: Breast conservation, Oncoplastic, Round block technique.

INTRODUCTION

Breast malignancy is now considered the most prevalent site—specific malignancy in females and the major cause of death related to cancer in women between in the age of 20 to 60 years [(1)].

The principles of breast cancer surgery have evolved over the last few decades with a shift from a modified radical mastectomy (MRM) to wide local excision (WLE) and adjuvant radiotherapy. This shift is primarily because of the advancements in understanding the pathology and biology of breast cancer. The multi-modality in the therapies to combine local and systemic control, comprising breast-conserving surgery and radiotherapy, endocrine treatment, and chemotherapy, has led to a decrease in the postoperative morbidities without affection of the oncological results. Hence, the breast-conserving therapy (BCT), comprising wide local excision and axillary surgery (either sentinel lymph node biopsy (SLNB) or axillary LN clearance, followed by radiotherapy, is now the standard treatment of choice in patients with early stages of breast cancer [(2,3)].

It is worth mentioning that the introduction of neoadjuvant chemotherapy for patients with locally advanced breast cancer can aid in the reduction of the tumor size, rendering inoperable tumors operable. In addition, this expands the role of breast-conserving surgery in the management of such cancers. The concept of oncoplastic breast surgery has been recently introduced. It incorporates plastic surgery techniques in the field of breast surgery allowing larger excisions of tumors and increasing the safety margin without an impact on the aesthetic outcomes; Eventually improving the psychological impact on the patients following mastectomy and aesthetically unacceptable deformities of breast-conserving surgery [(4,5)].

The round block technique (RBT) is an oncoplastic technique used in the excision of peri-areolar breast lesions especially in small to medium-sized breasts with moderate ptosis [(6)].

The aim of our study is to introduce the technique of modified round block technique (MRBT) and to compare RBT and MRBT in peripherally located tumors as regards the oncological safety and cosmetic outcomes.

PATIENTS AND METHODS

From October 2018 to October 2021, a randomized controlled clinical trial was conducted on 40 female patients with early stages of breast cancer (T1, T2 / N0, N1 / M0) in the Breast Unit in the Faculty of Medicine, Ain Shams University.

Patients selected had tumors at least 2 cm away from the nipple-areola complex and an expected excision volume not exceeding 30% of the breast volume. Patients with locally advanced breast cancer or retro areolar breast cancer were excluded from the study. Also, patients with any contraindication to chest radiotherapy were excluded from the study.

The patients were randomized into 2 groups: The first group (*Group A*) comprising 24 cases to perform RBT, and the second group (*Group B*) comprising 16

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cases to perform MRBT. Randomization was done using the "closed envelope method".

All the patients were subjected to full history taking and physical examination including the breast and axillary examination. Mammography and breast ultrasound were performed on all patients. Histopathological and immunohistochemistry were done using core biopsy from suspected lesions confirming the malignant nature of the lesion. The metastatic work-up was done as per our institutional protocols. The patients' demographic data and tumor characteristics were recorded.

All the participating patients were subjected to discussion by our multidisciplinary team (MDT) in the breast unit for decision-making to participate in the study.

Surgical procedure:

The operation is carried out under general anesthesia. Preoperative markings were done with the patient in the supine position. In the cases of RBT, the tumor excision margin is marked first, then the circumferential outer and inner periareolar incisions were marked (**Figure 1**).

The inner one is about 4 cm in diameter along the areolar margin and the outer one is 1 to 2 cm outside the inner one. The area between both lines is de-epithelialized incising the dermis facing the lesion (**Figure 4**).

The flap is raised at the same plane as mastectomy exposing the breast tissue containing the tumor. In the case of MRBT, after the tumor resection margin is marked, a single periareolar incision is marked (**Figure 2**), then dissection down to the subcutaneous tissue in a circumfrential manner along the whole circumference of the NAC separating it from the surrounding skin allowing better exposure of the breast tissue (**Figure 3**).

The vascularity of the NAC is maintained through the underlying glandular tissue through the 4^{th} and 5^{th} intercostal vessels (**Figures 5 and 6**).

Figure (1): Preoperative marking of the RBT.

Figure (2): Preoperative marking of MRBT.

Figure (3): Circumferential Incision for MRBT.

Figure (4): Complete de-epithelialization of the skin between the outer and inner incision lines in RBT.

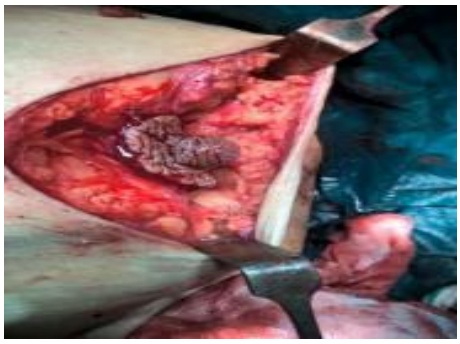

Figure (5): Complete mobilization of the NAC.

Figure (6): Complete mobilization of the NAC and circumferential dissection.

The tumor is excised down to the pectoral fascia in a wedge shape facing radially the NAC. The tumor

margins are marked and the specimen is sent for histopathology and marginal assessment using an intraoperative frozen section (**Figure 7**).

In case of certain margin involvement, re-excision is done till reaching free margins. The tumor bed is marked by clips for the guidance of further radiotherapy. After hemostasis, the breast parenchyma is approximated using dermo-glandular flaps and the defect is closed with 2/0 vicryl absorbable sutures.

A closed suction drain is placed. The skin is narrowed using non-absorbable PDS suture in a purse string manner acting as a cerclage to restore the original areolar size. The skin and areola were closed with continuous subcuticular absorbable sutures or interrupted non-absorbable sutures (**Figures 8, 9 and 10**).

Figure (7): Complete mobilization of the NAC and delivered specimen marked by threads after resection.

Figure (8): Immediate postoperative result of MRBT.

Figure (9): Immediate postoperative result of MRBT.

Figure (10): Immediate postoperative result of RBT.

The axillary surgery was done through a separate axillary incision in the form of a sentinel lymph node biopsy. In the case of positive SLNB, level I and II axillary dissections were done.

The operative data including positive margins and the need for re-excision, the weight of the specimen, the type of axillary surgery, and the operative time were estimated and assessed.

The patients were discharged on the first postoperative day with a drain in place. The drains were removed when discharge was less than 50 cc/24 hours. The postoperative reviewing of the patients was performed in the outpatient clinic after one week and two weeks for assessment of the presence of postoperative complications and to plan the adjuvant therapy and reviewed monthly for 3 months then according to our institutional follow-up schedule. Complications were recorded and assessed (**Figures 11, 12, 13 and 14**).

Figure (11): Postoperative outcome of MRBT after 2 months.

Figure (12): Postoperative outcome of MRBT after 2 weeks.

Figure (13): Postoperative outcome of MRBT after 2 weeks.

Figure (14): postoperative outcome of RBT after 2 months.

The follow-up schedule for all patients was reviewing the patient through our multidisciplinary team every four months for the first 3 years and every 6 months for the next 2 years. Bilateral sono-mammography was requested every year.

The cosmetic outcome was assessed by asking the patient herself to rate the result of surgery as regards breast symmetry, scarring, and degree of satisfaction using the Harvard 4-point scale (excellent, good, fair, or poor). The objective assessment is done by two specialized breast surgeons not participating in the study and also rated on a 4-point scale (excellent, good, fair, or poor). The surgeon's evaluation is based on five criteria (breast symmetry, breast tissue defects, position and deformity in NAC, scarring, and retraction).

Ethical Consideration:

This study was ethically approved by the Ethical Committee of the Faculty of Medicine, Ain Shams University. Written informed consent was obtained from all participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical Analysis

The collected data were introduced and statistically analyzed by utilizing the Statistical Package for Social Sciences (SPSS) version 20 for windows. Qualitative data were defined as numbers and percentages. Chi-Square test and Fisher's exact test were used for comparison between categorical variables as appropriate. Quantitative data were tested for normality by Kolmogorov-Smirnov test. Normal distribution of variables was described as mean and SD, and independent sample t-test was used for comparison between groups. P value ≤0.05 was considered to be statistically significant.

RESULTS

The current study included 40 female patients diagnosed with early stages of breast cancer in different breast quadrants, with the majority in the upper outer quadrant in 18 patients (45%). Most of the patients had small to medium-sized breasts in 32 patients (80%), and 8 patients had large breasts and refused to perform other volume displacement or reduction procedures and preferred to perform the procedure. Ten patients received neoadjuvant chemotherapy for positive axillary lymph nodes and HER-2 enriched. **Table 1** summarizes patients' demographic data and tumor characteristics.

Table (1): Patients' demographic data and tumor characteristics.

Number of patients (n)	**40**
Mean age (SD) (range) years	48 ± 3.2 (41-62)
Mean body mass index (range) kg/m2	30.7 ± 3.2 (26-38)
Breast cup size (n) (%)	
• B	20 (50)
• C	12 (30)
• D	8 (20)
Comorbidities (n) (%)	
• Diabetes mellitus	2 (5)
• Hypertension	4 (10)
• No comorbidities	34 (85)
Tumor side (n) (%)	
• Right	26 (65)
• Left	14 (35)
Tumor location (n) (%)	
• Upper outer	18 (45)
• Upper central	12 (30)
• Upper inner	2 (5)
• Lower outer	8 (20)
Mean tumor size (SD) (range) cm	2.42 ± 0.6 (1.7-4)
Mean distance between tumor and NAC (SD) (range) cm	5.2 ± 1.4 (3 – 8)
Pathological tumor type (n) (%)	
• Invasive ductal carcinoma	34 (85)
• Invasive lobular carcinoma	6 (15)
TNM classification (n) (%)	
• T1	22 (55)
• T2	18 (45)
• N0	30 (75)
• N1	10 (25)
• N2	0 (0)
• M0	40 (100)
• M1	0 (0)
Neoadjuvant chemotherapy (n) (%)	10 (25)

A total of 24 patients performed the standard RBT, and 16 patients performed the MRBT. The mean operative time was significantly lower in the MRBT group than in the RBT group (105.8 versus 120.7 minutes, respectively; P-value 0.01). The presence of positive surgical margin involvement was observed in the intraoperative frozen section in two cases of the RBT group and re-excision was done reaching free surgical margins. No positive margin involvement was observed in the MRBT group; however, this finding was not statistically significant. Concerning the postoperative complications, the only complication was seroma formation observed in 6 patients (in 2 patients in the RBT group and in 4 patients in the MRBT group), all of them were managed conservatively. Only two cases required percutaneous ultrasound-guided aspiration. This finding showed a statistical significance between both groups (P-value 0.048).

The mean change in the NAC diameter was statistically significant between both groups (1.4 versus 0.33 cm in the RBT and the MRBT group, respectively: P-value 0.032). However, no patients required revision surgery for correction of the areolar size.

The least follow-up period for our study was one year (the mean follow-up was 18 months and ranged between 12 and 23 months). Two cases had local recurrence one in RBT and the other in the MRBT group at the follow-up period of 16 and 19 months respectively, both cases were treated with salvage mastectomy. No cases of distant metastasis were observed during the period of follow-up. The operative and postoperative outcomes are summarized in **Table 2**.

Table (2): Operative findings and postoperative sequelae of the studied patients.

Variable	Group A: RBT (n=24)	Group B: MRBT (n=16)	P-value
Mean operative time (SD) (range) min	120.75 ± 30.2 (86 – 160)	105.8 ± 21.6 (71 – 145)	0.016
Intraoperative margins assessment (n) (%)			
• Positive	2(9.09)	0 (0)	0.432
• Negative	22 (91.6)	16 (100)	
Mean weight of specimen (SD) (range) gm	58 ±7.2 (45 -105)	64 ± 12.3 (50 -112)	0.342
Axillary surgery (n) (%)			
Sentinel lymph node biopsy	21(87.5)	14 (87.5)	0.763
Axillary dissection (level I and II)	3(12.5)	2 (12.5)	
Postoperative complications (n) (%)			
Wound infection	0 (0)	0 (0)	(-)
Hematoma	0 (0)	0 (0)	(-)
Seroma	2 (8.3)	4 (25)	0.048
Partial NAC necrosis	0 (0)	0 (0)	(-)
Impairment of nipple sensation	0 (0)	0 (0)	(-)
Mean change in NAC diameter (SD) (range) cm	1.12 ± 0.4 (0.9 – 2.3)	0.25 ± 0.1 (0 – 0.6)	0.032
Fat necrosis	0 (0)	0 (0)	(-)
Local recurrence	1 (4.1)	1 (6.25)	0.815
Distant metastasis	0 (0)	0 (0)	(-)

As regards the cosmetic outcomes, a significant difference was observed between both groups (**P-value 0.03**).
The results of the RBT group as assessed by the patients were excellent in 22 patients, good in 1 patient, fair in 1 patient, and no poor results. The results assessed by the surgeons were excellent in 20 patients, good in one patient, fair in 3 patients, and no poor results.
The results of the MRBT group as assessed by the patients were excellent in 14 patients, good in 2 patients, and no fair or poor results. The results assessed by the surgeons were excellent in 14 patients, good in 2 patients, and no fair or poor results.

The average percentage of excellent results was 87.5%, good in 7.5%, and fair in 5% of cases. Details of the results of the cosmetic outcomes are listed in **Table 3**.

Table (3): Cosmetic outcome evaluation of the studied patients.

Cosmetic outcome (n) (%)	Patients' assessment		Surgeons' assessment		Average (n) (%)		Total (n) (%)	P-value
	RBT	MRBT	RBT	MRBT	RBT	MRBT	Total	0.03
• Excellent	22 (91.6)	14 (87.5)	20 (83.3)	14 (87.5)	21 (87.5)	14 (87.5)	35 (87.5)	**0.06**
• Good	1 (4.1)	2 (12.5)	1 (4.1)	2 (12.5)	1 (4.1)	2 (12.5)	3 (7.5)	**0.04**
• Fair	1 (4.1)	0 (0)	3 (12.5)	0 (0)	2 (8.3)	0 (0)	2 (5)	**0.02**
• Poor	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	(-)

DISCUSSION

Many factors may negatively affect the aesthetic results of breast-conserving surgery. These factors may include larger tumor size to breast ratio, and inner quadrant tumors (for example lower inner quadrant tumors leading to the characteristic bird beak deformity).

Although the utilization of the periareolar incision in oncoplastic RBT as an optimum incision for tumor excision to provide a nearly scarless breast surgery, it may act as a challenge in the management of more peripherally located tumors, especially in small to medium-sized breasts with small diameter of the NAC. In our study, we performed both the RBT and MRBT for peripherally located tumors at least 2 cm away from the NAC. In the study by **Ogawa *et al.*** [9] they performed the RBT for tumors that require resection under the NAC, and performed the MRBT for peripherally located tumors.

In our study, we performed the MRBT, by using a single periareolar incision along the areolar margin, the periareolar skin is preserved and so the problem of the latter widening of the NAC does not occur, in addition, the position of the NAC is maintained. The same incision was advocated in the study by **Zaha *et al.*** [7]. The procedure provides excellent access upon the circumferential dissection of the subcutaneous tissue to all breast quadrants, and access to the tumors situated peripherally away from the NAC. In the study by **Ogawa *et al.*** [9] they described the skin incision by removal of the skin between outer and inner periareolar circles in the same design as that of the RBT.

The blood supply of the NAC is preserved through the 4th and 5th intercostal perforator vessels through the underlying pectoral muscle and breast tissue [10].

The aim of this study is to introduce the MRBT and to compare its complications with that of the RBT as regards operative procedure, oncological safety, complications, and cosmetic results.

In the current study, the mean age was 48 years old; this was in favor of the study by **Kim *et al.*** [8] reporting a mean age of 49.6 years [8]. Other studies reported a higher mean age of 57 and 57.2 years respectively [7,9].

Most of the patients in our cohort had small to medium-sized breasts (80%), which is similar to the study by **Ogawa *et al.*** [9]. In the study by **Zaha *et al.*** [7], only patients with small to medium-sized breasts (A or B breast cup size) were included in their study. It should be noted that 20 % of patients in our study had large breasts and refused to perform other volume displacement or reduction procedures and preferred to perform the procedure to avoid contralateral symmetrization.

In our study, we performed the procedures for patients with breast lesions in different breast quadrants. This is similar to the study by **Ogawa *et al.*** [9], but contradicts with the study by **Zaha *et al.*** [7], in which they performed the MRBT for tumors limited to the upper half of the breast only.

In the current study, the estimated mean tumor diameter was 2.4 (SD 0.6) cm, this agrees with other studies reporting a mean tumor diameter of 2.2 and 1.7, respectively. The recorded mean operative duration in our study was 112.3 (SD 25.3) minutes, this may be in favor of the study by **Ogawa *et al.*** [9] (mean operative time of 96 mins), and with the study by **Zaha *et al.*** [7], reporting a mean operative time of 130 minutes.

The mean operative time was significantly lower in the MRBT group than in the RBT group (105.8 and 120.7 minutes, respectively; P-value 0.016). This may be attributed to the superior exposure access to the lesion in MRBT due to circumferential mobilization which facilitates excision of the mass with a good safety margin.

Concerning complications, 6 patients in our study developed seroma formation comprising 15% of the total number of cases (two patients in the RBT group and 4 patients in the MRBT group). In the study by **Zaha *et al.*** [7], they reported complications in the form of hematoma in three cases (7.5%) and were managed conservatively. In another study by **Ogawa *et al.*** [9], they reported complications in 5 cases (27%). A significantly higher rate of seroma was reported in the MRBT group (p-value of 0.048), this finding can be explained by extensive subcutaneous dissection performed in the MRBT.

In our study, no cases of NAC necrosis were reported in both groups. This outcome is better and contradicts with the study by **Ogawa *et al.*** [9] in which 22% of cases developed partial NAC necrosis, and is in favor of the results by **Zaha *et al.*** [7], reporting no cases with NAC necrosis.

The sensation of the NAC was intact in all cases, similar to that in the study by **Zaha *et al.* [7].** The nerve supply of the NAC is through the lateral and anterior cutaneous branches of the 3rd, 4th, and 5th intercostal nerves [11]. The anterior cutaneous branches run superficially and terminate at the margin of the NAC, while the lateral cutaneous branches have a deep course within the pectoral fascia and supply the NAC from beneath. This may explain why the sensation is preserved in MRBT.

Positive margin involvement was observed in 2 cases (5%) during frozen section assessment in the RBT group and required re-excision. this is comparable with the study by **Zaha *et al.* [7],** reporting involvement of positive margins in five cases (12.5%).

Concerning the cosmetic outcome, we reported excellent and good results in 87.5% and 7.5% of cases respectively. This agrees with the results reported by **Zaha *et al.* [7],** they reported excellent and good results in 65% and 10% of patients respectively, but is highly comparable with the results reported by **Ogawa *et al.* [9]** observing excellent & good results in 16.6% & 44.3% of patients respectively.

On the other hand, fair & poor results were observed in 5% & 0% of patients respectively, this agrees with the results reported by **Zaha *et al.* [7],** they reported fair and poor results in 7.5% and 2.5% of patients respectively, but is highly comparable with the results of **Ogawa *et al.* [9],** (27.8% and 11.1%, respectively). The high percentage of fair and poor cosmetic outcomes in the study by Ogawa *et al.* may be explained by the fact that the excision volume was more than 25% of the breast volume. In our study, we selected cases with an expected excision volume not exceeding 20% of breast volume.

Patients with an excision volume of 30 to 40% may be candidates for other volume displacement procedures. Another important technical point is that we performed a cerclage (purse string skin technique to narrow the skin wound to the original size of the NAC. This step avoided the marked change in the NAC diameter and later onset widening in the NAC and alteration in the NAC position. This probably enhances the cosmetic outcomes. The mean change of the NAC diameter was significant between the RBT and the MRBT group was 1.12 +/- 0.4 and 0.25+/- 0.1 cm respectively (P-value 0.032). This may be attributed to that the periareolar skin is preserved and not excised in case of MRBT. A significant difference in the cosmetic outcomes was apparent on comparison of both groups (P-value 0.3).

In our study, we reported two cases of local recurrence; this disagreed with other studies by **Zaha *et al.* [7]** and **Kim *et al.* [8],** who reported no cases of local recurrence. This may be attributed to the relatively long follow-up period (mean follow-up of 16 months and ranged between 12 to 23 months). On the other hand, we reported no cases of distant metastasis which agreed with other studies.

It is worth mentioning that one of the strengths of our study is the relatively long period of follow-up and the relatively large number of patients. This agrees with the study by **Zaha *et al.* [7],** which included 40 patients, and contradicts the study by **Ogawa *et al.* [9]** which included only 18 patients.

CONCLUSION

The MRBT is an oncoplastic technique suitable for the excision of breast tumors in different breast quadrants especially peripherally located tumors in patients with small to medium-sized breasts and when the excision volume is not exceeding 20% of the breast volume. It is oncologically safe and has fewer complications. When compared with RBT it has a shorter operative time and superior cosmetic outcomes and avoids the later onset widening of the NAC and change in the NAC position.

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Conflict of interests: There is no conflict of interests.

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