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ORIGINAL ARTICLE

Efficacy of oncoplastic breast-conserving surgery combined with intraoperative radiotherapy on early breast cancer

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Summary

Purpose: *To explore the efficacy and safety of oncoplastic breast-conserving surgery (OBCS) combined with intraoperative radiotherapy (IORT) in the treatment of early breast cancer (EBC).*

Methods: *The clinical data of 114 EBC patients treated in our hospital from January 2014 to May 2016 were retrospectively analyzed. The patients were divided into OBCS + IORT group (OBCS group, n=32) and standard BCS (SBCS) + IORT group (SBCS group, n=82) according to different treatment methods. The operation-related indexes, the weight of breast tissues resected, the surgical margin, the postoperative cosmetic effect on affected breasts and quality of life, the incidence of postoperative complications, postoperative tumor recurrence and patient's survival were compared between the two groups.*

Results: *The operation time of patients in OBCS group was significantly longer than in SBCS group, the amount of intraoperative blood loss and postoperative drainage was significantly smaller than in SBCS group, and the postoperative hospital stay was obviously shorter than in SBCS group. The incidence rates of postoperative hematoma and poor incision healing in OBCS group were obviously lower than in SBCS group. The weight of breast tissues resected, and minimum and maximum surgical margin were all evidently larger in OBCS group than in SBCS group. After operation, the excellent/good rate of breast appearance in OBCS group was significantly higher. After operation, the satisfaction with breast appearance, the score of each dimension in the short-form 36-item health survey questionnaire (SF-36) and average score in OBCS group were remarkably superior to those in SBCS group.*

Conclusions: *OBCS combined with IORT is safe and effective in the treatment of EBC, which can not only effectively ensure the surgical margin in BCS and reduce the incidence of surgical complications, but also obtain a better cosmetic effect and satisfaction with breast appearance, and improve the postoperative quality of life of patients.*

Key words: *oncoplastic breast-conserving surgery, radiotherapy, breast cancer, early, efficacy*

Introduction

The morbidity rate of breast cancer (BC) ranks first in gynecologic malignant tumors. Statistics indicate that there were 1.8 million deaths of BC around the world in 2013 and 1.38 million new cases [1]. Breast-conserving surgery (BCS) combined with postoperative adjuvant radiotherapy has become the standard therapeutic regimen for early BC (EBC), whose local and regional control rates and long-term survival rate are similar to those of total mastectomy [2,3]. Intraoperative radiotherapy (IORT) is a type of accelerated partial breast irradiation technique, namely the one-time high-dose irradiation on the tumor or tumor bed during operation. The application of IORT in BCS

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can not only improve the local irradiation dose on the tumor bed, but also better protect the surrounding normal tissues [4,5].

Compared with standard BCS (SBCS), oncoplastic BCS (OBCS) focuses on the postoperative repair of breasts, which can effectively maintain the breast appearance and reduce the risk of incision disunion. However, some authors argue that OBCS is less effective in ensuring the surgical margin than SBCS [6,7]. In the present study, the clinical data of 114 EBC patients treated in our hospital from January 2014 to May 2016 were retrospectively analyzed, and the efficacy and safety were compared between OBCS + IORT and SBCS + IORT in the treatment of EBC, in the hope of providing a basis for developing the better clinical therapeutic strategy for such patients.

Methods

General data

The clinical data of 114 EBC patients treated in our hospital from January 2014 to May 2016 were collected. The patients were 32.3-69.8 years old with an average of 47.7±9.4 years old, and they were divided into OBCS + IORT group (OBCS group, n=32) and SBCS + IORT group (SBCS group, n=82). All patients were pathologically diagnosed with invasive ductal carcinoma or ductal carcinoma *in situ* before operation, the diameter of lesions was measurable, and all operations were performed by the same surgical team. Patients with positive margin needed to undergo a second extended excision to obtain negative margin. None of the patients underwent contralateral breast symmetrical surgery. Inclusion criteria: patients aged ≥18 years old, those with Karnofsky performance scale score ≥70 points, and those pathologically diagnosed with pT1-2/N0-1/M0 BC after operation. Exclusion criteria: patients with a history of radiotherapy in the ipsilateral breast, chest wall, lung or lymph node, or those with inflammatory BC, bilateral BC, BC recurrence or complicated with other malignant tumors. The general clinical data had no statistically significant differences between the two groups (p>0.05), and they were comparable in the baseline (Table 1). All patients enrolled adhered to the *Declaration of Helsinki* and signed the informed consent. This study was approved by the ethics committee of the 80th Group Army Hospital of Chinese PLA.

Operation methods

SBCS: According to the results of preoperative imaging and pathological examinations, the lesion site was determined, and the incision scheme recommended by the National Surgical Adjuvant Breast and Bowel Project was adopted. An arc-shaped incision was made on the surface of the tumor along the Langer's line if the tumor was above the nipple plane, while a radial incision was made if the tumor was on or below the nipple plane. Before treatment of axilla, biopsy was performed for sentinel lymph nodes using the methylene blue tracer, and

Table 1. Baseline demographic and clinical characteristics of the studied patients

Characteristics	*SBCS group (n=82) n (%)*	*OBCS group (n=32) n (%)*	*p value*
Age, years	47.34±9.02	48.56±8.81	0.515
BMI (kg/m^2)	21.83±2.34	21.27±1.59	0.216
Tumor diameter (cm)	2.1±0.7	2.3±0.5	0.143
T staging			0.823
T_1	57 (69.5)	21 (65.6)	
T_2	25 (30.5)	11 (34.4)	
N staging			0.815
N_0	61 (74.4)	23 (71.9)	
N_1	21 (25.6)	9 (28.1)	
Pathological type			0.696
Invasive ductal carcinoma	72 (87.8)	25 (78.1)	
Invasive lobular carcinoma	6 (7.3)	3 (9.4)	
Ductal carcinoma *in situ*	4 (4.9)	3 (9.4)	
Medullary carcinoma	0 (0)	1 (3.1)	
Molecular subtyping			0.746
Luminal A	43 (52.4)	18 (56.3)	
Luminal B	20 (24.4)	9 (28.1)	
HER-2 Over-expression	8 (9.8)	3 (9.4)	
Triple-negative	11 (13.4)	2 (6.3)	

Standard breast-conserving surgery; OBCS: Oncoplastic breast-conserving surgery; BMI: Body Mass Index; HER: Human Epidermal Growth Factor receptor.

then sentinel lymph nodes were resected, followed by rapid frozen section examination. Axillary lymph node dissection was conducted in the case of positive sentinel lymph nodes, otherwise no dissection was conducted. In this study, 10 cases with positive sentinel lymph nodes were treated with ipsilateral axillary lymph node dissection. After IORT, extended excision was performed for normal tissues at 1-2 cm around the mass. After excision of the lesion, the lymph nodes around the breast were dissected without suturing the surgical cavity. If the excision range was large, fibrin and serum could be filled to ensure the integrity of breast appearance [8].

OBCS: The lesion was resected in the same way as SBCS. After lymph node dissection, OBCS was performed, in which the gland was directly sutured, the breast was reshaped and suspended, and the breast tissues were filled via rotation and lifting. At the same time, the out-of-position nipple-areolar complex was moved to the central position. The double-ring, Ω-style, racket-shaped incision or inverted T-shaped mammoplasty, as well as partial latissimus dorsi muscle flap, adjacent flap and inferior pedicle flap transfer repair could be used [9].

IORT: In the operating room, the Mobetron 1000 mobile electron beam IORT system was used for intraoperative irradiation of visible tumors and normal tissues at 2 cm around them before tumor excision, and its accessories were carefully disinfected before operation. Irradiation dose: a single dose of 8 Gy as a complementary dose for patients with positive sentinel lymph nodes, and 15 Gy as the radical dose for patients with negative sentinel lymph nodes. According to the size of tumor, different energy and collimators were selected, so that 90% of the prescribed dose could cover normal tissues at 2 cm around the tumor, with a dose rate of 10 Gy/min.

Observation indexes

The time of operation, the amount of intraoperative blood loss, hospital stay and postoperative complications were observed and recorded in the two groups. The surgical margin was determined as follows: After excision of specimens in both groups, the direction was marked using suture and pathological examination of paraffin sections after staining the cut age.

The postoperative cosmetic effect on breasts was compared between the two groups, and the objective evaluation criteria for breast aesthetics were as follows [10]: Excellent: The nipple on the affected side is naturally erect, the horizontal gap of two nipples is ≤2 cm, the two breasts are symmetrical, the shape and sense of touch of the affected breast have no obvious differences from the unaffected breast, and there is no breast lifting or deformity caused by the scar of the affected breast, with normal skin. Good: The nipple on the affected side is not naturally erect, the horizontal gap of two nipples is 2-3 cm, the two breasts are basically symmetrical, the affected breast has basically normal or slightly poorer shape than the unaffected breast, and its sense of touch is a little bad, with slightly light skin color. Poor: The nipple on the affected side is deviated, the horizontal gap of two nipples is >3 cm, the two breasts are obviously asymmetrical, the affected breast is significantly smaller than the unaffected breast, and its sense of touch is bad, with rough skin and rubber-like changes. Excellent/good rate = (excellent cases + good cases)/total cases × 100%. The satisfaction with cosmetic effect on breasts was surveyed using a questionnaire. The quality of life was evaluated using the short-form 36-item health survey questionnaire (SF-36), including 8 dimensions: physiological function, physiological role, somatic pain, general health, vitality, social function, emotional role and mental health. The higher the score, the higher the quality of life [11].

The patients were followed up at 1, 3, 6 and 12 months after treatment, and every 3-6 months thereafter, until May 2019. The tumor recurrence in patients was recorded. Local recurrence refers to local relapse in the breast and supraclavicular lymphatic drainage region, and it was determined based on clinical physical examination and imaging examination results.

Statistics

SPSS 22.0 software (IBM, Armonk, NY, USA) was used for statistical analyses. Measurement data were expressed as mean±standard deviation, and t-test was performed for intergroup comparison. Enumeration data were expressed as rate (%), and x^2 test was performed for intergroup comparison. The survival curves were plotted using the Kaplan-Meier method and log-rank test was used to detect survival differences between two groups. $P<0.05$ suggested statistically significant difference.

Results

Comparison of operation-related indexes between the two groups

In OBCS group, the time of operation was significantly longer than that in SBCS group [(155.6±26.4) min *vs.* (105.2±21.3) min], and the difference was statistically significant ($p<0.001$). In OBCS group, the amount of intraoperative blood loss and postoperative drainage was significantly smaller than that in SBCS group [(104.3±13.9) mL *vs.* (118.2±10.9) mL, $p<0.001$; (133.8±34.1) mL *vs.* (211.6±39.3) mL, $p<0.001$], and the postoperative hospital stay was obviously shorter than that in SBCS group [(9.1±2.5) d *vs.* (12.9±2.3) d, $p<0.001$]. The incidence rates of postoperative hematoma and poor incision healing in OBCS group were obviously lower than those in SBCS group, showing statistically significant differences ($p=0.022$, $p=0.046$), while the incidence rates of short-term complications (incision infection, subcutaneous hemorrhage, disruption of incision, papillary necrosis and upper extremity edema) and long-term complications (skin shrinkage and fat necrosis) had no statistically significant differences between the two groups ($p>0.05$). In terms of radiotherapy-related adverse reactions, there were 2 cases and 6 cases of mild breast fibrosis in the irradiation field in SBCS group and OBCS group, respectively, which did not

affect the cosmetic effect. Grade I radiation-induced lung injury occurred at 3-6 months after IORT in 6 cases and 15 cases in SBCS group and OBCS group, respectively, while no IORT-related hematologic toxicity was observed (Table 2).

Comparison of weight of tissues resected and surgical margin between the two groups

The weight of tissues resected and minimum and maximum surgical margin were all evidently larger in OBCS group than those in SBCS group, and the differences were statistically significant (p<0.001) (Table 3). A second extended excision was performed in 1 case in OBCS group and 5 cases in SBCS group due to positive margin, displaying no statistically significant difference (p>0.05).

Comparison of postoperative cosmetic effect and satisfaction with breast appearance

After operation, the excellent/good rate of breast appearance in OBCS group [93.8% (30/32)] was evidently higher than that in SBCS group [82.9% (68/82)], and the difference was statistically significant (p<0.05) (Table 4). In the questionnaire survey about the patient's satisfaction with breast appearance, none of the patients in OBCS group thought that a second breast repair or reconstruction was needed, including 16 cases of great satisfaction, 14 cases of satisfaction, 2 cases of general satisfaction and 0 case of no satisfaction. 95.1% (78/82) of the patients in SBCS group thought that a second breast repair or reconstruction was not needed, including 14 cases of great satisfaction, 42 cases of satisfaction, 22 cases of general satisfaction and 4 case of no satisfaction. It can be seen that the satisfaction degree of breast appearance in OBCS group was remarkably superior to that in SBCS group (p=0.001).

Comparison of quality of life between the two groups

After operation, the score of each dimension in SF-36 and the average score in OBCS group were remarkably higher than those in SBCS group, and there were statistically significant differences (p<0.05) (Table 4).

Follow-up results of patient's survival

The mean follow-up time was 29.1±6.3 months and 28.4±5.9 months in the two groups until May 2019. No distant recurrence and metastasis oc-

Table 2. Comparison of parameters related to surgery

Parameters	*SBCS group (n=82)*	*OBCS group (n=32)*	*p value*
Operation time (min)	105.2±21.3	155.6±26.4	0.001
Blood loss (ml)	118.2±10.9	104.3±13.9	0.001
Postoperative drainage volume(ml)	211.6±39.3	133.8±34.1	0.001
In-hospital time (day)	12.9±2.3	9.1±2.5	0.001
Recent complications, n (%)			
Incision infection	2 (2.4)	1 (3.1)	0.837
Hematoma	34 (41.5)	6 (18.8)	0.022
Subcutaneous hemorrhage	10 (12.2)	2 (6.3)	0.353
Disruption of incision	1 (1.2)	0 (0)	0.503
Poor incision healing	12 (14.6)	1 (3.1)	0.046
Nipple necrosis	0 (0)	0 (0)	1.000
Upper limb edema	1 (1.2)	0 (0)	0.530
Long-term complications, n (%)			
Skin shrinkage	13 (15.8)	4 (12.5)	0.652
Fat necrosis	1 (1.2)	0 (0)	0.530

SBCS: Standard breast-conserving surgery; OBCS: Oncoplastic breast-conserving surgery.

Table 3. Comparison of specimen weight and margins of the studied patients in two groups

Parameters	*SBCS group (n=82)*	*OBCS group (n=32)*	*p value*
Mean specimen weight (g)	59.9±9.7	93.4±10.9	0.001
Mean distance to nearest (cm)	9.8±1.5	12.3±2.6	0.001
Mean distance to furthes test (cm)	15.9±2.3	25.0±5.2	0.001

SBCS: Standard breast-conserving surgery; OBCS: Oncoplastic breast-conserving surgery

Table 4. Comparison of postoperative cosmetic effect and SF-36 scale score of patients in the two groups

	SBCS group (n=82)	*OBCS group (n=32)*	*p value*
Cosmetic effect, n (%)			
Excellent	37 (45.1)	23 (71.9)	0.001
Good	31 (37.8)	7 (21.9)	0.001
Poor	14 (17.1)	2 (6.2)	0.001
SP-36			
Physical functioning	73.3±8.2	85.1±10.2	0.001
Role-Physical	74.6±8.3	87.7±10.4	0.001
Bodily pain	74.0±8.6	81.4±8.8	0.001
General health	78.1±8.9	82.5±10.0	0.024
Vitality	77.2±9.1	84.3±9.7	0.001
Social functioning	74.3±8.9	83.3±9.3	0.001
Role-Emotional	75.5±8.8	86.8±9.4	0.001
Mental health	71.1±7.9	79.7±8.6	0.001
Average score	75.6±9.9	84.4±9.6	0.001

SBCS: Standard breast-conserving surgery; OBCS: Oncoplastic breast-conserving surgery

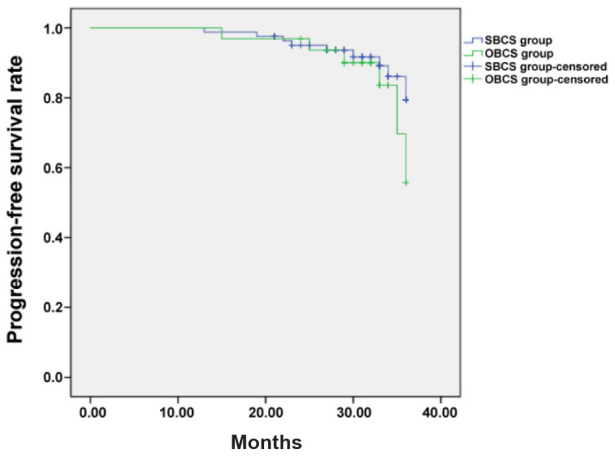

Figure 1. Kaplan-Meier survival curves of patients in SBCS group and OBCS group. The difference between progression-free survival rate of patients between SBCS group and OBCS group had no statistical significance (p=0.309).

curred in all patients at 3 years after operation. There was 1 case of death of cerebral infarction in SBCS group and 1 case of death of traffic accident in OBCS group. The overall survival rate was 98.8% (81/82) and 96.9% (31/32), respectively, and the difference was not statistically significant (p>0.05). The postoperative 3-year local recurrence rate was 11.0% (9/82) and 18.8% (6/32), respectively, and the progression-free survival rate was 89.0% and 81.2%, respectively, in the two groups. During the follow-up period, 9 patients in SBCS group had local recurrence of BC, including six cases in the ipsilateral breast and 3 cases in the ipsilateral axilla. Six patients in OBCS group had local recurrence of BC, including 3 cases in the ipsilateral breast and 3 cases in the ipsilateral axilla. All recurrent patients underwent radical resection, and no recurrence and metastasis occurred as of the end of follow-up. The survival curves in the two groups were plotted using the Kaplan-Meier method. According to the log-rank test, no statistically significant difference was found in progression-free survival rate between the two groups (p=0.309) (Figure 1).

Discussion

SBCS combined with postoperative whole breast radiotherapy is one of the conventional therapies for EBC. Compared with postoperative whole breast radiotherapy, IORT is more accurate in target location, which can better protect normal tissues and increase the local irradiation dose. One-time high-dose irradiation can avoid the accelerated re-proliferation of residual tumor cells in fractional external irradiation, and shorten the treatment time while increasing the local control rate. In addition, IORT also evades the inconvenience caused by postoperative long-course whole breast radiotherapy and reduces the treatment expenses. There is a growing number of clinical studies showing that for some EBC patients, IORT may be able to completely replace postoperative whole breast radiotherapy and become a new treatment option for BC patients [12-14].

Studies have found that OBCS combines plastic surgery and oncology, which avoids breast deformity and dissatisfaction of breast appearance, and improves the postoperative cosmetic effect on breasts through reshaping and non-glandular tissue filling on the premise of ensuring the safe margin and achieving radical cure [15]. In this

study, the postoperative cosmetic effect and satisfaction degree of breast appearance in OBCS group were remarkably superior to those in SBCS group, and the differences were statistically significant ($p<0.05$).

OBCS completely preserves and repairs the breast shape, the psychological impact on patients significantly declines after operation, and the family and social pressure is also significantly reduced, so the postoperative quality of life of patients in OBCS group was obviously better than that in SBCS group, indicating that OBCS is also positive in the overall improvement of patients' quality of life. In addition, De et al. [16] pointed out that OBCS has broader indications than SBCS, and it can conserve breasts and keep aesthetics in EBC patients with large lesions and central tumor location. Moreover, the scars are hidden after commonly-used doublering, Ω-style, racket-shaped incision or inverted T-shaped mammoplasty, further improving the postoperative cosmetic effect.

To obtain a good postoperative cosmetic effect, the surgical residual cavity is not sutured, and serum and fibrin are filled in SBCS, thus raising the pressure in the residual cavity, increasing the incision tension, and affecting the incision healing. The occurrence of various postoperative complications will delay the adjuvant therapy in different degrees. In this study, the incidence rates of postoperative hematoma and poor incision healing in OBCS group were obviously lower than those in SBCS group, because the surgical residual cavity was repaired via rearrangement of non-cancer glands in OBCS, thus benefitting the incision healing, similar to the research results of Losken et al [17].

The scope of safe margin of BCS is still controversial, and its definition depends mainly on the consensus and agreement of medical organizations in every country. In this study, surgical margin >10 mm was more easily available in OBCS than SBCS. It is reported that there is a great difference in the surgical margin in OBCS. In many studies, the positive criterion is the invasion of tumor into the stained margin, and the positive margin rate is 0-26.2%, while 2 mm is the criterion for safe margin, and its positive rate is 8.0-16.6% [18,19]. Giacalone et al [20] took 5 mm as the criterion for safe margin, and the negative margin was more easily available in OBCS, similar to the results in this study. In this study, it was also found that the 3-year tumor recurrence had no statistically significant difference between the two groups, suggesting that OBCS can also meet the requirement of safe margin under the premise of ensuring the excision scope, and avoid the changes in breast shape due to wide surgical margin [21].

There are some limitations in this study, such as the limited sample size, short follow-up time and incomprehensive follow-up content. The objective evaluation of the long-term efficacy of OBCS combined with radiotherapy requires the support of rigorous, highly reliable, large-sample perspective clinical research.

Conclusions

OBCS combined with IORT is safe and effective in the treatment of EBC, which can not only effectively ensure the surgical margin in BCS and reduce the incidence of surgical complications, but also obtain a better cosmetic effect and satisfaction with breast appearance, and improve the postoperative quality of life of patients.

Conflict of interests

The authors declare no conflict of interests.

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