

“Unplanned breast-conserving surgery after systemic therapy in locally advanced breast cancer: the results of level II oncoplastic techniques”

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Abstract

BACKGROUND: In patients with breast cancer for whom neoadjuvant chemotherapy (NAC) is planned, it is recommended to mark the primary tumor before treatment (planned surgery). However, surgeons may have to perform breast-conserving surgery on patients whose tumors are not marked (unplanned surgery). This study focused on the results obtained with planned and unplanned level II oncoplastic surgery (OPS) techniques applied to patients after NAC. **METHODS:** Patient groups who underwent planned, unplanned OPS and mastectomy after NAC were compared. Surgical margin status, re-operation and re-excision requirements, ipsilateral breast tumor recurrence (IBTR) and axillary recurrence rates recorded. Long-term local recurrence-free survival (LRFS), disease-free survival and overall survival were evaluated. **RESULTS:** There was no significant difference between the planned and unplanned OPS groups in terms of surgical margin status, re-excision requirement, and mastectomy rates. During an average follow-up period of 43 months, 5.3% and 4% of the patients in the planned OPS group developed IBTR and axillary recurrence, respectively, whereas these rates were 6.6% and 5.3% in the unplanned OPS group. In the mastectomy group, the rates of IBTR and axillary recurrence were found to be 4.1% and 3.8%, respectively. There was no significant difference between the three groups in terms of IBTR (p: 0.06) and axillary recurrence (p: 0.08) rates. **CONCLUSION:** Breast conserving surgery can be applied using level II OPS techniques with the post-NAC radiological examination and marking even if primary tumor marking is not done in the pre-NAC period.

INTRODUCTION:

One of the goals of neoadjuvant therapy is to make the tumor volume-to-breast ratio suitable for breast-conserving surgery (BCS) by reducing the tumor size in patients with large tumors (1). Randomized controlled trials have shown that neoadjuvant therapy increases the rates of BCS and presented suggestions for performing BCS after neoadjuvant chemotherapy (NAC) in patients who are not suitable candidates for BCS at the time of presentation (2,3). The concepts of marking both the primary tumor and the metastatic axillary lymph node in the pre-NAC period, and targeted primary tumor and axillary surgery in the post-NAC period have been developed (4). Concepts regarding surgical margins in patients, who underwent breast surgery after NAC, have become clearer over time, and concerns on this issue have decreased (5,6). There is a consensus that with appropriate surgical intervention, local control can be achieved without mastectomy after NAC (7,8). The main point is to obtain adequate surgical margins with the accurate localization of the tumor.

It is known that BCS was not planned in a group of patients before NAC, therefore tumor marking was not performed, but BCS was thought after NAC (unplanned BCS). It is not possible to perform BCS due to tumor localization problems particularly in patients achieving good clinical response. In some cases, pre-NAC tumor marking cannot be performed due to technical issues. The literature review has shown that there

are studies presenting the results obtained from unplanned BCS after NAC. Conventional BCS techniques were used in these studies. Furthermore, they are relatively old studies, and therefore, neoadjuvant therapy criteria for patients included in these studies are unclear (9,10). Oncoplastic surgery (OPS) is known to ensure larger tissue excision compared to the conventional BCS and provides the opportunity to obtain wider surgical margins (11). It can be advantageous in unplanned BCS. This study focused on the results obtained with planned and unplanned level II OPS techniques applied to patients after NAC.

MATERIALS and METHODS:

This study examined a retrospective series of patients with breast cancer who underwent surgical treatment after NAC between 2012 and 2017. The planned OPS group consisted of patients who were scheduled to undergo OPS before NAC between the specified dates. Tumors of patients in the planned OPS group were marked with metallic clips before neoadjuvant therapy. The unplanned OPS group consisted of patients who underwent OPS after NAC although OPS was not scheduled. Therefore, tumor marking was not performed in these patients. Patients undergoing mastectomy after NAC constituted the mastectomy group. Anthracycline- and taxane-based chemotherapies were applied to patients receiving NAC. Patients with HER2-positive breast cancer received NAC with trastuzumab. For local staging; mammography (MG), breast ultrasonography (USG), axillary USG were performed as standard in the pre-NAC period. Magnetic Resonance Imaging (MRI) was used in the pre and post NAC period in the unplanned OPS group. Post-NAC clinical response was classified as unresponsive, partial, and complete clinical response. Absence of radiological and clinical signs of tumor in the breast and axilla was considered a complete response. A reduction of more than 50% compared to pre-NAC was considered as a partial response whereas a reduction of less than 50% was considered a stable condition.

Patients with minimal edema or skin shrinkage around the tumor were considered to have T4 breast cancer and they had the opportunity to undergo OPS after NAC. Mastectomy was performed in patients who were considered to be at the T4 stage due to diffuse edema, ulceration, peau d'orange appearance, and chest wall invasion. The most common reasons for mastectomy were patient's request, inadequate response to chemotherapy, multicentricity, tumor-to-breast ratio mismatch, complete radiological disappearance of the tumor, and no residual radiological findings. Although OPS was not scheduled initially, it was possible to be performed after NAC in patients with palpable tumors or radiological (MG, MRI, or USG) residual disease (e.g. structural distortion or microcalcification). Patients with radiological residual disease in the unplanned OPS group were operated on after these areas were marked with a wire. Tumors were labeled with titanium clips before the NAC was initiated in the planned OPS group. Fine needle aspiration biopsy (FNAB) was performed for radiologically suspicious axillary lymph nodes. Surgical margins in patients in the unplanned OPS group were determined considering the areas containing microcalcification and structural distortion (residual radiological disease) surrounding the tumor, which were identified through the local staging investigations performed following NAC. If necessary, the areas to be resected were marked with a wire before surgery. Radio-guided occult lesion localization (ROLL) method was used for this purpose in some patients. After resection, specimen radiographs were taken in all patients to determine whether adequate resection was achieved. Routine frozen section examination was not performed for surgical margins; however, when deemed necessary, additional resections were made from the suspicious margins. Sentinel lymph node biopsy (SLNB) was performed in patients without clinical signs of metastasis in axillary lymph nodes before and/or after NAC. The closest surgical margins were used to calculate the average length of the surgical margins. No tumor on ink was considered a negative surgical margin.

Level II OPS techniques were used for the planned and unplanned OPS groups. Techniques were chosen according to tumor localization and tumor-to-breast volume. Racquet and fusiform mammoplasty techniques were used for tumors located in the upper outer quadrant. Radial mammoplasties were preferred for inner quadrant tumors. Vertical mammoplasty techniques were used for tumors located in the upper or lower midline. Furthermore, reduction mammoplasty techniques with superior or inferior flap (wise pattern) were applied to patients who required reduction. Superior flap techniques were used for lower quadrant tumors whereas inferior flap techniques were used for upper quadrant tumors. Batwing and round block techniques

were most commonly used for tumors close to the areola. Patients undergoing OPS received radiotherapy (RT) with 5 Gy + 1 Gy boost dose to the tumor bed. The RT needs of patients who underwent mastectomy were also discussed in the tumor board. Patients were invited for follow-ups at three-month intervals for the first two years and at six-month intervals for the next three years. After five years, the patients were followed at one-year intervals. In addition to physical examinations, annual MG and breast USG examinations were performed as standard. Breast MRI was performed when needed.

Age, body mass index (BMI), menopause status, and tumor characteristics (stage, grade, hormone receptor status, and *CerbB2* status) of the patients were recorded. Surgical margin status, re-operation and re-excision requirements, axillary intervention results, ipsilateral breast tumor recurrence (IBTR), and axillary recurrence rates were also recorded. Long-term local recurrence-free survival (LRFS), disease-free survival (DFS), and overall survival (OS) were evaluated. The IBTR (invasive or in-situ) and regional recurrence were accepted as the events that ended LRFS.

STATISTICAL ANALYSIS: :

Statistical analyses were performed using SPSS version 25 (SPSS Inc; Chicago, IL, USA). Mann-Whitney U test was used for inter-group comparisons. Qualitative data for each group were analyzed using the Student's t-test. Chi-square test was used for quantitative data. Kaplan-Meier analysis was used to determine recurrence rates, LRFS, and OS. A p value of <0.05 was considered statistically significant.

RESULTS:

There were 150 patients in the planned OPS group, 75 patients in the unplanned OPS group, and 340 patients in the mastectomy group. Thirty-eight patients in the unplanned OPS group completed their NAC in external centers, and no preoperative tumor marking was performed in these patients. Although 32 patients did not accept BCS in the pre-treatment period, they requested BCS after NAC. Tumor marking with a titanium clip before neoadjuvant treatment could not be performed in five patients due to technical reasons. When all three groups were evaluated in terms of patient and tumor characteristics, the patients in the mastectomy group were found to be significantly older and the number of those in the postmenopausal period was higher. There was no difference between the groups in terms of pre-NAC stage, grade, and biological characteristics of the tumor. Patient and tumor characteristics of the groups are summarized in Table 1.

In the planned OPS group, complete clinical response was observed in 40 (26%) of the patients whereas 110 (74%) achieved a partial response. These numbers were 29.3% and 70.7% in the planned OPS group, respectively. Twenty-six patients (7.6%) in the mastectomy group were considered to be stable after NAC. Complete clinical response was achieved in 72 patients (21.2%) whereas 242 (71.2%) patients achieved a partial response in the mastectomy group. Mastectomy was performed in 10 patients who were scheduled for OPS before NAC but achieved an inadequate response. Pathologic complete response rate was 9.4% in the whole series.

In the planned OPS group, re-excision was required in 16 (10.6%) patients due to positive or close surgical margins. Eight (5.3%) patients were required re-operation and mastectomy. In the unplanned OPS group, nine (12%) and six (8%) patients underwent re-excision and mastectomy, respectively. The mean distance between the tumor and closest surgical margin was 14 ± 0.6 mm in the planned OPS group and 18 ± 0.4 mm in the unplanned OPS group. There was no significant difference between the groups in terms of surgical margin status, re-excision requirement, and mastectomy rates (Table 2).

Axillary dissection was performed in patients with positive SLNB and patients with clinical suspicious lymph nodes after neoadjuvant therapy. While axillary dissection was performed in 110 (74%) patients in the planned OPS group, 77% of the patients in the unplanned OPS group underwent axillary dissection whereas SLNB alone was performed in 13%. In the mastectomy group, 79% of patients underwent axillary dissection. There was no significant difference between the groups.

During an average follow-up period of 43 months, 5.3% and 4% of the patients in the planned OPS group

developed IBTR and axillary recurrence, respectively, whereas these rates were 6.6% and 5.3% in the unplanned OPS group, respectively. In the mastectomy group, the rates of IBTR and axillary recurrence were found to be 4.1% and 3.8%, respectively. There was no significant difference between the three groups in terms of IBTR (p: 0.06) and axillary recurrence (p: 0.08) rates. The rate of patients developing distant metastasis during the follow-up period was 26%, 29.3%, and 25.2% in the planned, unplanned OPS, and mastectomy groups, respectively (p: 0.2) (Table 2). The mean five-year LRF5 was 90.1% in the planned OPS group whereas it was 91.2% in the unplanned OPS group and 93% in the mastectomy group. There was no significant difference between the groups in terms of LRF5 (p: 0.6) (Figure 1). Five-year OS was found to be 92% in the planned OPS group, 90.3% in the unplanned OPS group, and 89.8% in the mastectomy group. There was no significant difference between the groups in terms of OS (p: 0.9).

DISCUSSION:

The excision volume required to safely perform BCS can be reduced by neoadjuvant therapy (12). Regardless of the administration of neoadjuvant therapy, poor cosmetic outcomes are obtained in cases where large excisions are required to perform BCS (13). Furthermore, surgical margin positivity and re-excision rates are quite high after BCS (14). Oncoplastic surgery allows larger volume excision without impairing cosmetic outcomes and reduces re-excision rates (15). Primary tumor size decreases after neoadjuvant therapy. In such cases, the success of the treatment in terms of local control depends on the accurate tumor localization. It is aimed to excise the accurate area at sufficient volume after NAC by marking the tumor in the pre-NAC period, determining localization by means of seeds containing radioactive material, and applying intraoperative USG. However, pre-NAC marking cannot adequately guide the clinician for tumors showing non-concentric shrinkage patterns. Intraoperative localization techniques may remain inadequate in this regard (16,17). In tumors that shrink into fragments, the residual radiological disease should be evaluated and, if necessary, marked after NAC. At this point, the question of whether unplanned surgery can provide safe oncological results should arise. The answer to this question has been investigated in patients who primarily underwent BCS. In the National Surgical Adjuvant Breast and Bowel Project (NSABP) Protocol B-18 trial, the local recurrence rate was reported to be 15.9% in unplanned surgery and 9.3% in planned surgery. The difference was statistically significant (2). The European Organization for Research and Treatment of Cancer (EORTC) 10920 trial reported higher local recurrence rates with unplanned surgery (3). In a study by Shin et al. (10) involving patients with stage III breast cancer, the results of planned BCS, unplanned BCS, and mastectomy were compared in patients with a tumor size of less than 4 cm after NAC. The authors reported that five-year LRF5 was 90.9% in patients undergoing unplanned surgery, while this rate was 96.3% in patients undergoing mastectomy (10). In the series published by Fitzal et al. (9), BCS was performed in 110 of 221 patients scheduled for mastectomy before NAC. While unplanned surgery was observed to have no disadvantage in terms of local control in patients with a good response to NAC, local recurrence rates were found to be higher in the unplanned surgery arm in patients with an insufficient response. The technique used in all these studies was BCS, but the neoadjuvant therapy criteria were not standard. It should be kept in mind that the number of patients receiving neoadjuvant therapy and the rate of responses to treatment have increased at the present time. Furthermore, advanced imaging techniques may increase the possibility of localization after NAC.

More than 20% of breast volume and a significant amount of breast skin is excised in Level II techniques and simultaneous reconstruction is performed with more complicated and sophisticated glandular flap methods. On the other hand, less than 20% of the total breast volume is excised and the volume excision is limited in Level I techniques. Youssef et al. (18) presented post-NAC OPS results in a series of 70 patients. In this series where tumor marking was not performed before NAC, the rate of IBTR was reported as 4.2% and Level I OPS techniques were applied to 57% of the patients. The mean surgical margin distance was found to be wider in patients for whom Level II techniques were applied (25 mm vs. 10 mm). In the present series, Level II OPS techniques were applied to all of our patients. Although not statistically significant, the mean surgical margin distance was found to be wider in the unplanned surgery group (18 mm vs. 14 mm). Surgeons likely tend to excise more tissue to provide a firm surgical margin in unmarked patients. In a study by Chauhan et al. (19), patients who underwent OPS and BCS after NAC were compared. In the whole series, reduction

in the form of fragmentation was detected at a rate of 44% and the tumor bed was marked with a clip in all patients before NAC. Skin tattooing was performed, if necessary, to promote localization after NAC. While the mean specimen volume and mean surgical margin distance were larger in patients undergoing OPS, the ratio of involved margin and IBTR was lower. In the literature, IBTR rates in patients undergoing planned OPS after NAC were observed to range from 6% to 10% (20,21). A matching case-control study comparing patients who underwent BCS and OPS after NAC was reported from Brazil. Planned surgery was applied to all patients. In this series, the majority of which consisted of patients with T3 tumors, the volume of the excised specimen and mean surgical margin distance were larger in the OPS group. During an average follow-up of 67 months, the rate of IBTR was found to be 10.2%. In this series, Level I OPS techniques were applied to nearly half of the patients in the OPS group. Longer follow-up time and non-standardized surgical techniques may explain the high local recurrence rates in this series (22). Similar results were reported by Mazouni et al. (23) from France. Pre-NAC primary tumor marking was not standard in this series. Post-NAC tumor size and specimen volume were found to be larger in patients undergoing OPS. The re-excision rate was reported to be 2% in patients undergoing OPS whereas it was 9% in patients undergoing BCS. The requirement for mastectomy was 24% vs 18%, respectively, in patients who underwent BCS and OPS (23). In our series, there were no patients who underwent conventional BCS. Although re-excision rates in patients who underwent OPS were found to be higher in our series compared to the said study, the requirement for mastectomy was found to be lower in patients undergoing planned and unplanned OPS. Five-year 5% local recurrence rates, on the other hand, were found to be similar to our series.

In the present series, mastectomy was performed after systemic treatment in the presence of extensive skin involvement, skin edema, chest wall involvement, and diffuse microcalcification. Performing mastectomy in patients with any of these conditions is currently considered as standard treatment. However, we were able to successfully perform OPS after systemic therapy in our patients in the presence of minimal edema and skin shrinkage around the tumor. This feature makes the present study different from others.

Tumor shrinkage after NAC in locally advanced breast cancer may occur in three ways. First, a complete clinical response can be seen in the tumor. In this case, pre-NAC tumor marking makes the planning of surgical treatment easier; however, the previous tumor bed can be still displayed in post-NAC radiological examinations. Surgery can be planned by taking this area as the center. Secondly, tumor sizes can be reduced and a concentric response can be achieved, and no tumor nodules may be seen in the periphery of the tumor. In this case, surgery can be planned by taking residual tumor as a basis in the post-NAC period. The third shrinkage pattern is called the mosaic pattern, where the tumor shrinks by breaking into small pieces. In this case, pre-NAC marking of the tumor is not sufficient to perform the surgery safely. The margins of the nodules located in the periphery of the tumor should be known or marked in the post-NAC period. Secondary surgical intervention is mandatory for patients with involved resection margins, resulting in poor cosmetic outcomes or loss of the breast. It further means increased costs and psychological stress for the patient. The marking of the tumor in both pre- and post-NAC periods is likely to be more meaningful. Figures 2 and 3 present images related to OPS performed with post-NAC wire localization on the patient with a tumor that shrank concentrically with NAC.

This study has shown that BCS can be applied using level II OPS techniques with the post-NAC radiological examination and marking even if primary tumor marking is not done in the pre-NAC period. The rates of re-excision and mastectomy requirement similar to the patients undergoing planned OPS and mastectomy have been obtained in those undergoing post-NAC unplanned OPS. Furthermore, long-term local control rates are similar. The absence of pre-NAC primary tumor marking is not a condition that necessarily requires a mastectomy. Moreover, localized skin involvement and localized edema should not be considered a contraindication for OPS.

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Table and Figure Legends

Table-1. Patient and tumor characteristics of groups

Table-2. Surgical margin, need for re-intervention and recurrence status of groups.

Figure-1. Loco-regional free survival curves of three groups

Figure 2. A. Tumor close to the areola in the upper outer quadrant of the left breast, skin shrinkage, and minimal edema (pre-NAC image). B. Structural distortion and focal asymmetric density in the post-NAC tumor bed. C. Wire-guided marking of this area D. Complete excision of radiological residual area on specimen radiography.

Figure 3. Postoperative image of the patient.

List of abbreviations

Oncoplastic surgery: OPS

Neoadjuvant chemotherapy: NAC

Surgical margin: SM

Locoregional recurrence-free survival: LRFS

Overall survival: OS

Breast-conserving surgery: BCS

Ultrasonography: USG

Magnetic resonance imaging: MRI

Ipsilateral breast tumor recurrence: IBTR

Radio-guided occult lesion localization: ROLL

Sentinel lymph node biopsy: SLNB

Body-mass index: BMI

Breast conserving Surgery: BCS

Mammography: MG

Fine-needle aspiration biopsy: FNAB

Disease-free survival: DFS

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