PLASTIC RECONSTRUCTIVE & REGENERATIVE SURGERY

2022;1:92-97
DOI: 10.57604/PRRS-030

FEASIBILITY AND SAFETY OF AWAKE ONCOPLASTIC SURGERY FOR BREAST CANCER

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Summary

Background. In the last two decades oncoplastic breast surgery has emerged as a new technique requiring longer time and more complex breast dissection and remodelling. Advantages of awake surgery have been demonstrated in literature, but oncoplastic surgery, due to its complexity, is usually performed under general anaesthesia. The aim of this study is to evaluate feasibility and safety of awake oncoplastic surgery.

Materials and methods. Retrospective observational study on patients who underwent awake oncoplastic surgery from January 2019 to December 2020. Collected data included tumour staging, Estrogen receptor (ER), Progesterone receptor (PR) and Ki67 index, age, BMI, ASA, type of oncoplastic surgery, surgical time, complications, aesthetic outcome evaluated at 6 months by the two breast senior surgeons rated on a five-point scale, patient's satisfaction valuated at 6 months by Breast-Q® questionnaire.

Results. 14 patients were included in the study. Patients' satisfaction was great in term tolerability of awake regimen and satisfaction with the result, as shown using Breast-Q test. Also, surgeon satisfaction was acceptable. No anaesthesiologic compliance were reported in the case series.

Conclusions. Oncoplastic awake surgery is feasible and safe also for level II oncoplasty in well selected patients performing local anaesthesia.

Key words: breast cancer, awake oncoplastic breast surgery, local anaesthesia

Received: August 9, 2022
Accepted: January 31, 2023

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How to cite this article: Vanni G, Pellicciaro M, Materazzo M, et al. Feasibility and safety of awake oncoplastic surgery for breast cancer. PRRS 2022;1:92-97. https://doi.org/10.57604/PRRS-030

INTRODUCTION

Since Halsted's radical mastectomy was described, fortunately much has changed with breast surgery over the years [1]. In 1969 Umberto Veronesi theorized that for the treatment of localized breast cancer it was no longer necessary to remove the entire gland, an intuition that he could confirm

in 1981 when his results were published [2]. Afterwards for decades breast cancer lesions were treated by two surgical options: large tumours underwent mastectomy and small lesions were treated with lumpectomy associated with radiotherapy [3]. As reported in many analyses, when more than 20% of the breast volume is removed there is an increased risk of deformity after standard breast conservative surgery [4]. In this setting, simple reshaping methods are not appropriate and more complex techniques are required [4]. Hence, in the last two decades oncoplastic surgery emerged with the objective to allow oncologically safe breast preservation limiting postoperative deformities [5,6]. This technique combines plastic surgery strategies with a surgical oncology mindset taking into consideration oncological safety, anatomic features, patient's wishes and expectation and preserving breast form [7]. Often, especially for badly localized or large breast lesions, oncoplastic surgical techniques involve a dissection and reshaping of the residual gland (oncoplastic level I) or complex specific oncoplastic techniques (level II) which consist in more than 20 % of gland volume removal and that increase surgical times [4-7]. In this setting, both the surgeon and the anaesthetist prefer to perform the surgery under general anaesthesia. We report, to our knowledge, the first series of cases of oncoplastic surgery level II of the breast in a waking state with the aim of detecting its feasibility and safety also in these patients.

MATERIALS AND METHODS

All patients subjected to awake oncoplastic surgery between January 2019 to December 2020 performed at the Breast Unit of Policlinico Tor Vergata, Rome, Italy were evaluated in this retrospective observational study. Indications to oncoplastic surgery and technique adopted followed the current guidelines and were reported in the study [8]. According to our policy all patients had been evalueted previously by a multidisciplinary team in order to established the optimal treatment and patient selection was based on performance status and evaluation of the ratio between the planned excision volume and the breast volume.

Oncoplastic surgery was distinguished in level I in case of large dissection and reshaping of the residual gland and Level II comprised complex specific oncoplastic techniques as reported in the study [9].

Awake oncoplastic surgery included all the procedures with administration of local anaesthetics or regional anaesthesia (peripheral nerve block, erector spinae block, central neuraxial blocks) without mechanical ventilation. These patients were eligible to receive a mild sedation with Richmond agitation-sedation scale 3-4 without supraglottic or subglottic devices used for ventilation and with spontaneous breathing. According to our policy, and expertise on awake breast surgery it was proposed in selected patients and inclusion criteria are reported in Table I.

Age, BMI, and ASA score were detected from clinical notes and reported in the study.

Surgical time was defined as operating room occupancy and it was considered from the entrance to the exit from the operating room.

Tumour diameter, expressed in centimeters, Estrogen receptor (ER), Progesterone receptor (PR) and Ki67 index, expressed as percentages of positive cells in specimens studied through immunohistochemistry were collected from pathological examination. Overexpression of Her2 gene (HER2+) was identified by IHC or by FISH, as indicated by the recommendations of the 2018 ASCO/CAP, and reported as a dichotomous variable being expressed or not expressed. In addition, tumour staging was collected from phytological reports and reported according to TNM, NCCN guidelines.

The cosmetic outcome was evaluated at 6 months follow-up systematically by the two breast senior surgeons of our Unit and the result was rated on a five-point scale: excellent 5; good 4; fair 3; poor 2; bad 1. This score evaluates the surgeon's satisfaction by analyzing its aesthetic component related to breast oncoplastic surgery.

Each patient underwent through Breast-Q® questionnaire and breast score was reported as Q-score median and range [10]. This score assesses the patient's overall well-being by analysing her psychosocial component as a woman and her satisfaction regarding breast oncoplastic surgery, using specific scales, into scores from 0 to 100 [10].

All data were collected into the database (EXCEL software, Microsoft, Washington, DC, USA). For continuous variables, we calculated and used mean and standard

Table I. Awake surgery inclusion and exclusion criteria.

Inclusion criteria
Informed consent
Axillary lymph nodes clinically or radiologically negative
Absence of muscle invasion by tumor
Absence of anxiety disorder
Absence of history of panic attacks
Exclusion criteria
Bilateral surgery
Patients with the potential for difficult respiratory assistance
Patients with high risk of vomiting and inhalation

Awake surgery criteria; awake surgery was proposed to patients that fulfil all these criteria.

deviation. Categorical data were reported in numbers and relative percentages.

RESULTS

From January 2019 to December 2019 15 patients underwent awake oncoplastic surgery at the Breast Unit of Policlinico Tor Vergata, Rome. One patient (6.7%) was excluded from the study due to anaesthesia regimen conversion from awake to general anaesthesia for patients' anxiety, pain and agitation. Mean age was 71.3-13.5 years and mean BMI 25 ± 5.2. At preoperative examination one patient (6.7%) was scheduled ASA score 4, two patients (13.3%) ASA score 3, seven patients (46.6%) were scheduled ASA score 2 and five patients (33.3%) were designated as ASA score 1.

Out of 15 patients, 9 (60%) patients did not require skin excision or mammoplasty and less than 20% of breast volume was excised and considered oncoplastic Level I. Differently 5 patients (33.3%) required Oncoplastic Level II technique. Out of 5 patients included in the study subjected to Level II oncoplastic: 3 (60%) had tumour size according to the indications, 1 (20%) for tumour localization and 1 (20%) for involved margins after lumpectomy. Only one of these patients (20%) needed a contralateral surgery for breast symmetry, however performed in awake surgery without general anaesthesia due to the high comorbidities and increased anaesthetic risks. Patients subjected to oncoplastic Level II: 2 (40%) patients underwent round block mammoplasty technique, 1 (20%) batwing technique, 1 (20%) V mammoplasty and 1 (20%) J mammoplasty.

Satisfaction of patients were evaluated with the Breast-Q® test and median value and relative ranges are resumed in Table III. Out of 15 patients subjected to oncoplastic surgery 3 (20%) patients fulfilled surgeons' satisfaction and received excellent scores; 5 (33.3%) received good, 4 (26.6%) fair and only 2 (13.3%) outcomes were evaluated poorly. Out of 5 patients subjected to oncoplastic level II surgery cosmetic outcomes were: 2 (40%) excellent, 2 (40%) good and 1 (20%) poor. Cosmetic outcome and relative percentages are resumed in Table III.

Out of 15 patients only 1 (13.3%) patient experienced surgical complications (Clavien Dindo III[a]) due to seroma firstly treated conservative but at the end requiring fine needle aspiration to achieve resolution. Tumors' diameter, TNM staging, predictive and prognostic for breast cancer are resumed in Table IV.

Out of 15 patients 10 (66.6%) were discharged in the first postoperative day, one (6.6%) patient experienced seroma in the third postoperative day. Differently 4 (26.6%) patients were performed in outpatient surgical regimen. Surgical time was 77.5 ± 7.4 minutes.

Table II. Indications for level II oncoplastic techniques and type of surgery

Level II oncoplastic	
Indications	Number of patients (percentage) n = 5
Tumour size	3 (60%)
Involved margins after lumpectomy	1 (20%)
Localization of tumour	1 (20%)
Technique	Number of patients (percentage) n = 5
J mammoplasty	1 (20%)
V mammoplasty	1 (20%)
Round block	2 (40%)
Batwing technique	1 (20%)

Values in parentheses are percentages.

Table III. Cosmetic score: Breast-Q test and cosmetic score

Breast-Q® test	
Topic	Score
Psycho-social well being	79 (74-85)
Sexual well being	66 (74-60)
Preoperative satisfaction	71 (70-73)
Postoperative satisfaction	76 (73-79)
Physical well being	63 (61-67)
Cosmetic Score	
Bad	0
Poor	2 (13.3%)
Fair	4 (26.6%)
Good	5 (33.3%)
Excellent	3 (20%)

Breast-Q® test median score and range; Cosmetic Score number of patients and percentage

DISCUSSION

After the revolution performed by Veronesi et al., for a long period breast cancer lesions were treated by two surgical options: mastectomy for large tumor and lumpectomy associated with radiotherapy for smaller lesions [2,3]. As reported in many studies, when lesion involves more than 20% of the gland volume the risk of breast deformity increases after standard breast conservative surgery [4]. In this setting, simple reshaping methods are not appropriate and more complex techniques are required [4]. Hence, in the last two decades oncoplastic surgery emerged with the objective to limit deformities and to allow oncologically safe breast preservation [5,6]. This strategy combines plastic techniques considering oncological safety [7]. Moreover, oncoplastic

Table IV. Tumour diameter, TNM and predictive and prognostic factors for breast cancer.

TNM	
T	
T in situ	2 (13.3%)
T1	8 (53.3%)
T2	4(26.6%)
T3	1 (6.6%)
N	
N0	14 (93.4%)
N1	1 (6.6%)
M	
M0	15 (100%)
Estrogen receptor %	76.2-34.8
Progesterone receptor %	59.43-38.2
Ki67 index%	18.2-14.1
HER2 (positive)	8 (53.3%)
Diameter cm	1.3-0.56

Values in parentheses are percentages or are reported in mean and standard deviation.

surgery takes into consideration anatomic features of the patient's wishes and expectation and preserves breast form [7]. These techniques involving extensive dissection and remodeling could cause discomfort to patients and to the surgeon if performed under local anaesthesia [7]. Additionally, oncoplastic surgery, especially when using more complex techniques, can take longer and this may affect the patient's agitation [5].

Despite these assumptions, the awake oncoplastic surgery was well tolerated by the patients in our case series. According to this result, Breast-Q® score reported in the study was higher and expressed both patients' satisfaction with the aesthetic result and tolerability of such procedure in the awake regimen.

Also, surgeon satisfaction was great as shown by the cosmetic score, and in no patient, surgeons requested to convert from local to general anaesthesia for technical difficulty.

Benefits and advantages of awake breast surgery in terms of operative room occupancy and length of hospital stay as reported in a previous study are confirmed in this report [11]). These results are comparable with the study conducted immediately following the declaration of COVID-19 pandemic, of awake breast surgery in terms of operative room occupancy and length of hospital stay [11].

Awake oncoplastic breast surgery could reduce anaesthesiologic time, as often local anaesthetics administration or regional anaesthesia (peripheral nerve block, erector spinae block, central neuraxial blocks) are also performed for postoperative pain management after general anaesthesia and could increase time of operatory room occupancy [12,13]. Nerve block techniques, performed with the use of ultrasound, improve postoperative pain control and reduce opioid administration and relative side effects as vomiting and immunological impairment [14,15]. More over a recent study, demonstrated the correlation between opioid receptor and breast cancer cells migration and thus metastatization or recurrence [16,17].

All these strategies were managed to minimize delays for cancer patients due to COVID-19 by prioritizing selected cases, while non-urgent surgical procedures were postponed and waiting lists for benign diseases grew longer [18-20]. As reported in other studies, we strongly believe that measures and strategies adopted during the COVID-19 pandemic could be applied in order to enhance efficiency and resolve the long surgical waiting lists problem also for non-oncological disease [11]. The reduction of operative room occupancy and the reduction of hospital beds play a fundamental role during the pandemic. In addition to the advantages in terms of health resources, awake surgery has shown to bring economic benefits [21-23].

Moreover, as reported in many studies, awake surgery plays a fundamental role regarding the impairment of the immune system [24,25]. General anaesthesia is strongly correlated with surgical stress and impairment of the immune system (reducing cytotoxic activity [26-29]. This reduction can increase the probability of tumour progression as reported in literature [30,33].

Minimally invasive approach and local anaesthesia seem to better preserve immune functions; and should be preferred also for oncoplastic surgery with advantages in oncological and infectiology terms despite the lack of high-level evidence [33-35].

Conversion from local to general anaesthesia can be required due to anxiety and agitation although awake oncoplastic surgery was well tolerated by the patients with satisfaction at the end of the procedure.

Despite the small sample of patients who underwent oncoplastic awake surgery, but based on previous experience of awake breast cancer, we suggest that oncoplastic awake surgery is feasible and safe also for level II oncoplastic technique [11,25]. Awake oncoplastic surgery to be performed needed a good analgesia using advanced techniques such as peripheral nerve block, erector spinae block or central neuraxial blocks. This analgesia is crucial for the surgeon to achieve good aesthetic results. Further randomized studies on larger samples, evaluating both the cosmetic-oncological component and patient tolerability are needed to confirm our results.

Conflict of interest statement

The authors declare no conflict of interest.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author contributions

GV, MP: A
MP: W
MM: S
MM, GI, JC: D
RF, IP, FS, EG, LA: DT
GI, JC: O (english editing)
OCB: O (supervision)
All the authors review and approval of final version to be published.

Abbreviations

A: conceived and designed the analysis
D: collected the data
DT: contributed data or analysis tool
S: performed the analysis
W: wrote the paper
O: other contribution (specify contribution in more detail)

Ethical consideration

The retrospective study was approved by the local Ethical Committee (protocol n. 122/20).
Informed consent is not necessary and feasible due to retrospective nature of the study.
The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.

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