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prosthetic breast reconstruction
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A further step towards
evidence-based and personalized surgery.**



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Therapeutic nipple-sparing mastectomy combined with endoscopic immediate prosthetic breast reconstruction via axillary incision: a further step towards evidence-based and personalized surgery.

INTRODUCTION: *Nipple-sparing mastectomy is an oncologically validated technique for selected breast cancer patients and allows to improve aesthetic results and patients' quality of life. Conventional skin incisions are often a suboptimal solution due to the visibility of the scars. Aim of this work is to show our innovative technique, which allows to perform nipple-sparing mastectomy, lymph-node surgery, and endoscopic immediate prosthetic breast reconstruction using a single cosmetic axillary incision.*

MATERIALS AND METHODS: *Between June 2016 and October 2019, 14 consecutive patients underwent therapeutic nipple-sparing mastectomy with endoscopic immediate reconstruction via axillary incision; inclusion criteria were cup A or B breasts and tumors less than 3 cm in diameter. Data were recorded in order to evaluate reproducibility, feasibility, safety, aesthetic outcomes and patients' quality of life.*

RESULTS: *Mean age was 46 years old (range: 34-54 years); median tumor size was 1.7 cm; average follow-up time was 11 months (range 3-42); median operation time was 340 minutes; mean hospital stay was 4,1 days. Tumor-free margins were obtained in all 14 cases. No local-regional recurrence occurred during follow-up. No major complications were experienced. No systemic complications were observed. All patients were satisfied with their aesthetic results, especially the absence of visible scars.*

CONCLUSIONS: *Therapeutic nipple-sparing mastectomy with endoscopic immediate prosthetic reconstruction via axillary incision is a safe and appropriate procedure in cup A and B breasts, alternative to conventional techniques. It allows to improve aesthetic outcomes and patients' quality of life thanks to a single well-hidden axillary scar.*

KEY WORDS: Axillary Incision, Breast Cancer, Endoscopic Breast Reconstruction, Nipple-Sparing Mastectomy, Oncological and Aesthetic Outcomes, Quality of Life.

Introduction

Today, breast conserving surgery (BCS) followed by radiotherapy has been definitively validated as the gold

standard treatment of patients with early stage breast carcinoma.

Mastectomy remains a valid surgical alternative in selected cases and is usually associated with immediate breast reconstructive procedures. When a BCS cannot guarantee adequate local control and good cosmetic results, total mastectomy should be selected^{1,2}.

Various surgical techniques can be adopted when planning a total mastectomy but in the last years newer procedures called "conservative mastectomies" are emerged¹⁻³.

The most innovative of these procedures is the nipple-sparing mastectomy (NSM) that allows to remove the

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entire glandular tissue preserving skin envelope and nipple-areola complex (NAC). NSM is oncologically safe and permits to achieve high patient satisfaction and better aesthetic results than other conventional mastectomies⁴.

The most commonly used skin incisions are lateral-radial, inframammary crease, periareolar with lateral extension and transareolar with lateral extension⁵⁻⁷. However, these conventional incisions are a suboptimal and imperfect cosmetic solution due to the visibility of the scars, nipple displacement and the risk of vascular damage to NAC. The aim of this work is to show our innovative surgical technique, which allows to perform a safe NSM, lymph-node surgery, and endoscopic immediate prosthetic breast reconstruction (E-IPBR) using a single cosmetic axillary incision.

Materials and Methods

Patients were prospectively selected from June 2016 to October 2019. This procedure was offered to selected patients with cup A or B breasts and tumors less than 3 cm in diameter, multicentric breast cancer, or cases of diffuse intraductal neoplasia. In addition, tumors had to be situated greater than 1 cm from the NAC. Careful staging of disease and accurate selection of candidates to the procedure with clinical assessment, ultrasonography, mammography and magnetic resonance imaging were performed (Fig. 1a). All patients had to have a body mass index (BMI) of less than 30 kg/m², no associated comorbidities and be classified as low risk for anesthesia. The procedure was not performed in patients who were found to have oversized breasts,

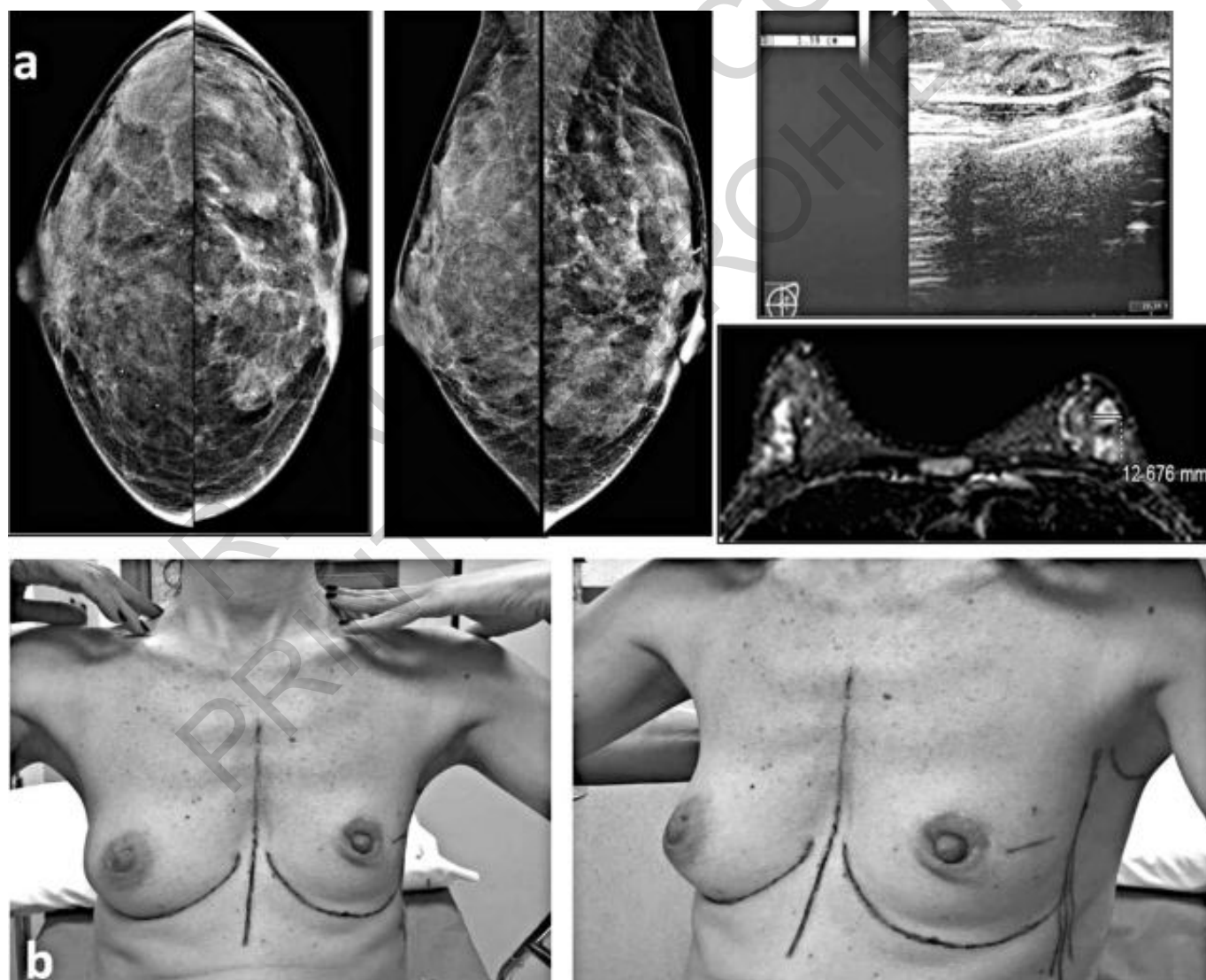


Fig. 1: Preoperative radiological assessment (ultrasonography, mammography and magnetic resonance imaging)(a); preoperative pictures of 45 years-old patient planned for NSM combined with E-IPBR via axillary incision and contralateral symmetrization with implant (b).

ptosis of grade >2, or those who were obese or heavy smokers, and those who had undergone previous radiation therapy. Those characteristics were considered as exclusion criteria due to their associated high risk of complications as skin flap necrosis and/ or infections. A multidisciplinary discussion in a dedicated "Surgery Board" was always performed; an algorithm shared with the plastic surgeons, based on anamnestic, morphological, functional criteria, was used in order to choose the better reconstruction technique; preoperative radiological localization of tumor and/or calcifications by ultrasonography and/or mammography was always performed. Also, intraoperative radiological and pathological evaluation of the specimen for the definition of the lesions and the margins of resection was obtained. The breast tissue was always weighed to determine the subsequent reconstruction volumes. Skin flaps viability was checked in real time using indocyanine green fluorangiography. The type of implant was chosen based on the shape and weight of the breast,

the shape of the chest but also the patient's wishes; a contralateral procedure was performed to achieve symmetry if necessary.

METHODOLOGICAL APPROACH

The protocol for this prospective development study was discussed in "Multidisciplinary Board" with the scientific directorate before patient's recruitment, describing selection principles, operative methods, and outcomes to be measured. Before the operation, all patients signed informed consent according to the established regulations. In order to evaluate reproducibility, feasibility and safety, the following morbidity factors were recorded: operation time (from skin incision to the end of skin suture), length of hospitalization and number of complications; data were collected on patient age, BMI, clinical and histological features of cancer, nodal status, receipt of adjuvant chemotherapy, radiotherapy, and hor-

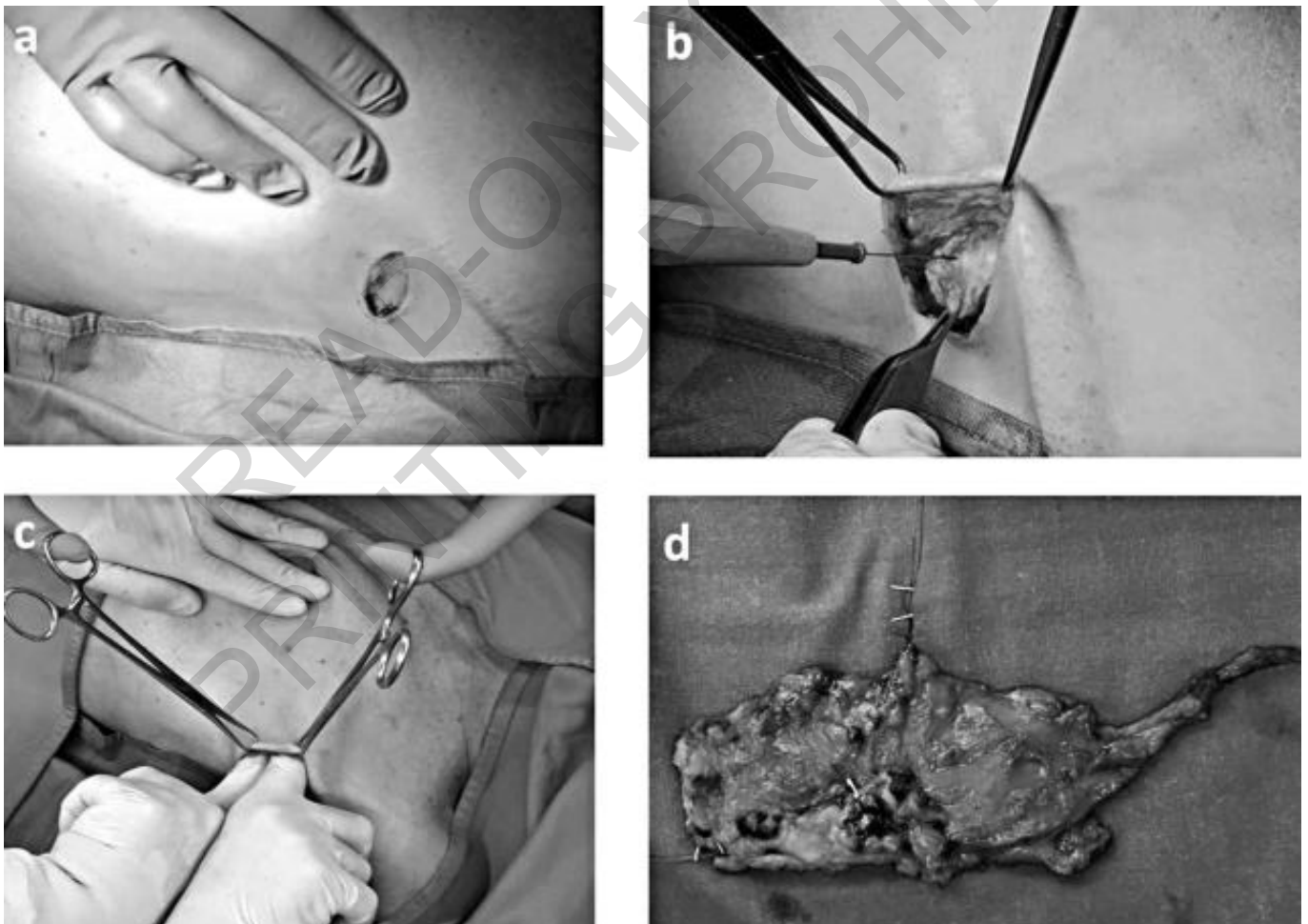


Fig. 2: Intraoperative picture of axillary incision (a); after the incision, skin flap is incrementally elevated from glandular tissue and dissected off the breast by electrocautery(b); the manoeuvre of blunt dissection using the fingertips is used (c); at the end of NSM, the entire gland removed is shown (d).

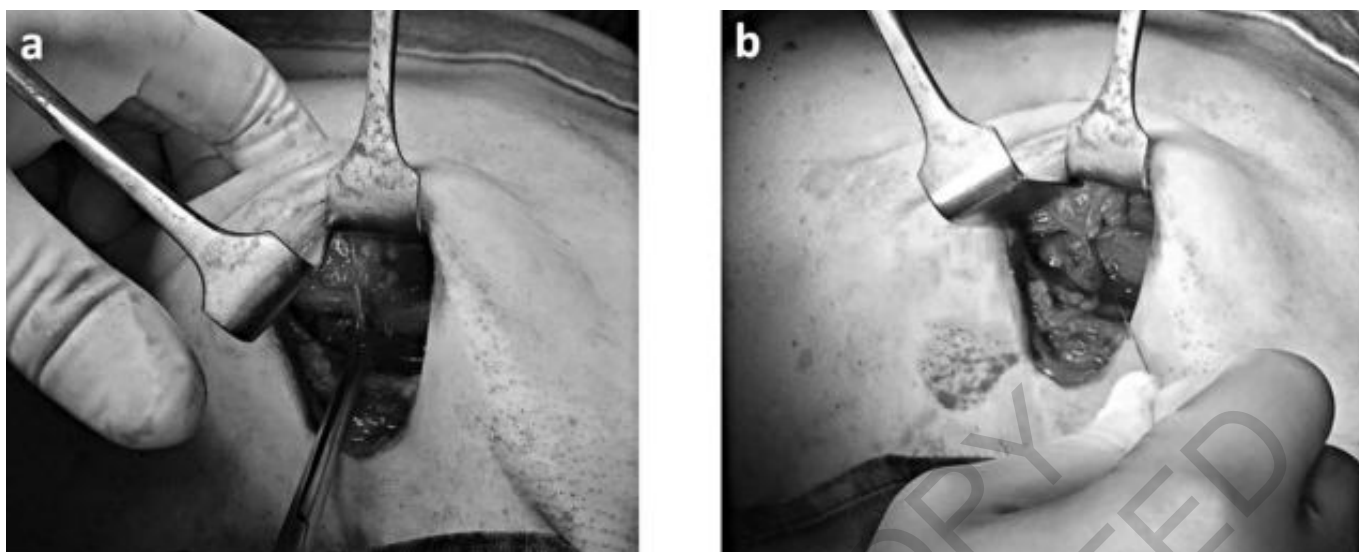


Fig. 3: Retroareolar tissue is identified by upwards spin of nipple (a); then it is marked with surgical thread (b) and excised for frozen section analysis.

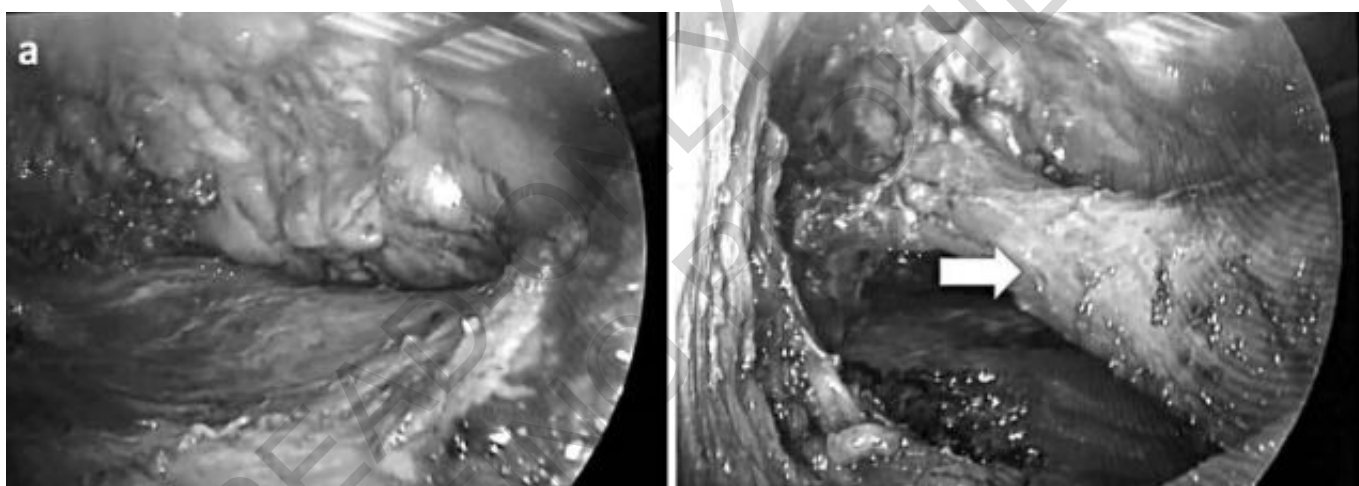


Fig. 4: Systematic circumferential visual endoscopic exploration of surgical cavity post-mastectomy (a) is performed to exclude presence of further macroscopic residues of mammary gland [the yellow arrow indicates the major pectoralis muscle (b)].

monal therapy for future oncological outcome analysis; patients were followed during post-operative period by breast surgeons, plastic surgeons and oncologists. Aesthetic evaluation methods were clinical and photography-based assessments; in order to perform a pre-operative and post-operative comparison, standard anteroposterior and bilateral oblique digital color photographs were taken; evaluation of the cosmetic results was performed by plastic surgeons not involved in the surgery and on the basis of the patients satisfaction. Cosmetic results were classified by the surgeons based on the shape and volume of the reconstructed breast and the symmetry with the contralateral side; they were scored as excellent, good, acceptable, or poor, and the overall result was rated from 4 to 1 (4

= excellent, 3 = good, 2 = acceptable, 1 = poor); the average of each item was used as a final result; the BREAST-Q was used to quantify patient satisfaction and QoL.

SURGICAL TECHNIQUE

An adequate planning of the axillary skin incision together with plastic surgeons was performed (Fig. 1b); in all cases, a 6 cm incision placed in the lowest axillary natural fold along the mid-axillary line allowed to perform a safe nonendoscopic mastectomy, node surgery, and endoscopic submuscular-subfascial direct-to-implant reconstruction (Fig. 2a).

The 6 cm incision located on the lowest axillary fold along the mid-axillary line allows a safe nonendoscopic mastectomy using long blade (19 cm) light retractor (Black & Black Surgical).

After the incision, the skin is carefully dissected off the breast until all anatomic boundaries of the breast are reached and the gland in its entirety is excised. First, mastectomy skin flap is incrementally elevated from glandular tissue and dissected off the breast by electrocautery (Fig. 2b); at this stage, an accurate dissection and a meticulous preparation of the skin flaps and of the NAC is performed without compromising their vitality; the correct surgical plane dissection is in the subdermal fascial plane, which is of variable thickness; the manoeuvre of blunt dissection using the fingertips may be used (Fig. 2c); then, the entire gland is elevated on the prepectoral plane preserving superficial pectoralis fascia; the

gland is subsequently detached by all borders (Fig. 2d), carefully avoiding medial perforators which can provide a significant vascular supply to the skin flaps; retroareolar tissue is identified by upwards spin of nipple (Fig. 3a), marked with surgical thread (Fig. 3b) and excised for frozen section analysis; systematic circumferential palpation and visual endoscopic exploration of prepectoral surgical cavity post-mastectomy is performed to exclude presence of further macroscopic residues of mammary gland (Fig. 4); skin flaps are visualized and trimmed, if necessary, to remove any residual breast tissue and to ensure even flaps. The same axillary incision is conveniently used for lymph nodes surgery.

Finally, E-IPBR is performed by a team of dedicated plastic surgeons (Fig. 5). An operative rigid endoscope with working channel (Richard Wolf, Vernon Hills, IL, USA) (Fig. 5b) is used to dissect the entire submuscular

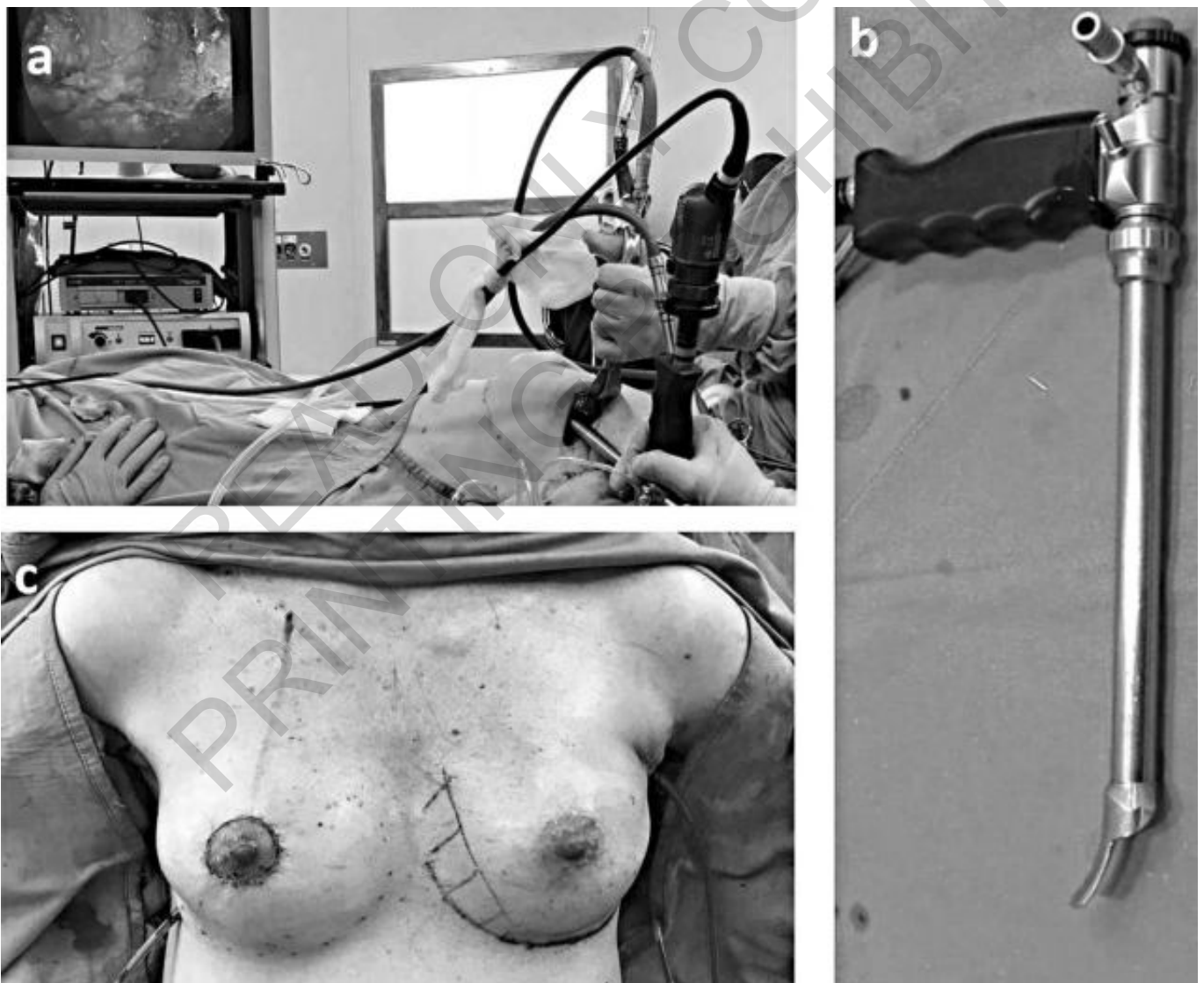


Fig. 5: Intraoperative pictures of E-IPBR after transaxillary NSM (a). An operative rigid endoscope with working channel (b) is used to dissect the entire submuscular subfascial pocket; outcomes at the end of surgery (c).

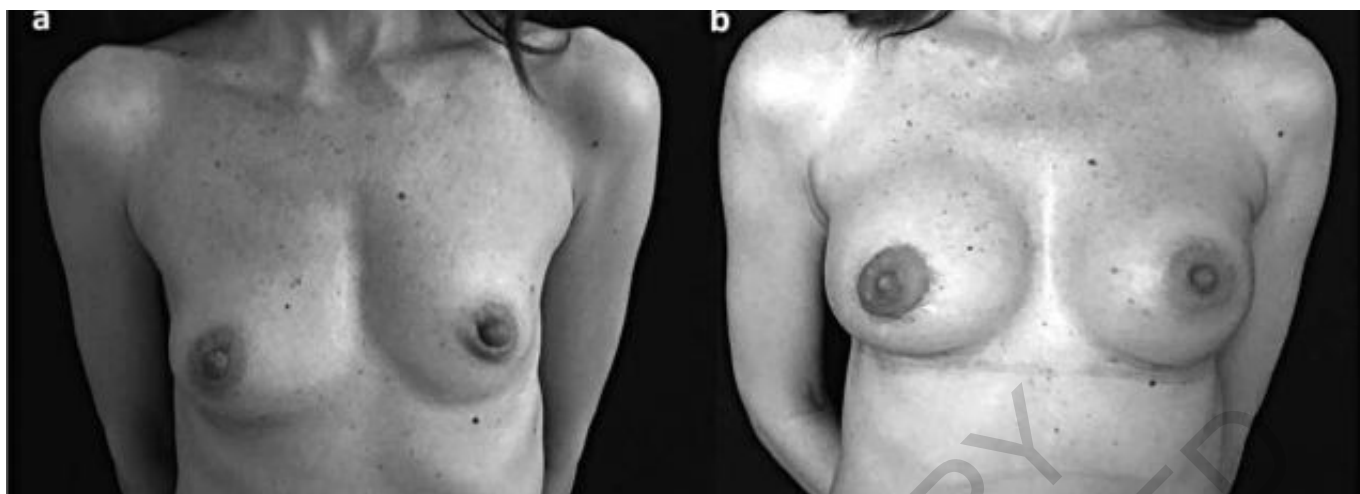


Fig. 6: Preoperative pictures of 45 years-old patient (a). 3-month postoperative picture showed pleasant cosmetic outcomes and a well-hidden mastectomy scar after NSM combined with E-IPBR via axillary incision and contralateral symmetrization with implant (b).

lar-subfascial pocket; then a definitive anatomical textured implant is inserted. The type of prosthesis is chosen based on the shape and weight of the breast, the shape of the chest but also the patient's wishes.

Results

During the study period, a total of 20 procedures were performed in 14 female patients with breast cancer, including six patients with bilateral disease or BRCA1/2 mutation. Mean age of the patients was 46 years old (range: 34-54 years). 11 patients were of normal weight (BMI between 19 and 25 kg/m²) and 3 were of overweight (BMI between 25,1 and 30 kg/m²). 6 patients had cup A breasts and 8 patients cup B. The median tumor size was 1.7 cm ranging from 0 cm (for pathological complete response after neoadjuvant chemotherapy) to 3 cm. 7 patients (50%) had multifocal/multicentric tumor; tumor was unifocal in 7 cases (50%). There were 5 cases (35,7%) of diffuse ductal carcinoma in situ (DCIS) [pTis] and 9 cases (64,3%) of invasive carcinoma. Among the 9 invasive cancers, 4 cases was ypT0 ypN0 cM0 after neoadjuvant chemotherapy; 2 cases were stage I (pT1c[m] pN1[mic] cM0; pT1c[m] pN0 cM0) and 3 were stage IIA (ypT2 ypN0 cM0; pT1c[m] pN1 cM0; ypT1b ypN1 cM0); no stage III or IV patients were enrolled (AJCC TNM Classification–8th Edition). A sentinel node biopsy was performed in all cases of therapeutic mastectomies and was positive in 3 cases, and axillary dissection was performed from the same incision. Tumor-free margins were obtained in all cases. None of the patients had carcinoma or DCIS at the NAC specimen histology necessitating removal of the NAC. Mastectomy weight specimen was on average 139 grams (ranging from 98 to 182 grams).

After NSM, immediate one-stage breast reconstruction with definitive prosthesis was performed in all cases using anatomically shaped textured silicone-filled implants; it was unilateral in 8 cases (57.1%) and bilateral in 6 patients (42.9%). All 8 unilateral breast reconstructions had contralateral aesthetic surgery to achieve symmetry. Among these, 5 patients underwent contralateral breast augmentation, 2 patients underwent periareolar mastopexy, and 1 patient underwent mastopexy with an inverted T pattern. No conversion to conventional NSM-IPBR was performed.

DURATION OF SURGERY

The mean operation time was 340 minutes (range: 240-442 minutes) including therapeutic procedures, E-IPBR and surgery for symmetrization of contralateral breast. Duration of monolateral mastectomy ranged from 2 hours for the first case, when the technical procedure was set up, to 1 hour and 15 minutes for the last patient. After removal of the gland from the surgical cavity, before starting the reconstructive phase, the patient had to be repositioned, which took an additional 30 minutes waiting for plastic surgeons. The E-IPBR time ranged from 2 hours for the first operation to 1 hour and 15 minutes for the last operation. The major surgery was taken for one of the first patients who underwent a bilateral NSM with biopsy of sentinel node and axillary lymphadenectomy and bilateral E-IPBR.

PERIOPERATIVE AND ONCOLOGICAL OUTCOMES

The mean hospital stay was 4,1 days (range 3-5 days); at a median follow-up of 11 months (range 3-42

months); no local regional recurrence occurred during follow-up. A patient with triple negative breast cancer had a brain metastasis 6 months after surgery. No major complications, including hematoma, seroma, skin or NAC full-thickness necrosis or infection were observed for any case. Only 2 patients developed a partial and superficial NAC necrosis resolved conservatively without surgery using dressing changes. No systemic complications were observed. There were no cases of malposition, wrinkling or rippling.

AESTHETIC OUTCOMES AND HEALTH-RELATED QUALITY OF LIFE

The reconstructive and aesthetic outcomes were graded as excellent in 11 cases (78.6%) and good in 3 cases (21.4%). Scar resulted well-hidden in all cases. Patient satisfaction with the breasts (breast shape and symmetry; nipple sensation, position, projection, symmetry, scar appearance and position) was high in 3 patient (21,4%) and very high in 11 patients (78,6%). All patients were very satisfied with the postoperative scar appearance, wound length, and wound position; 13 patients (92,9%) did not reported negative impact on degree of self-esteem, body image perception, femininity, psychosocial and sexual wellbeing. There was only one patient (7m1%) with depression that reported a negative change in social and sexual relationship. All patients who responded would choose the same operation again.

Discussion

NSM is used with increasing frequency in the multidisciplinary treatment of patients with operable breast cancer. This technique allows to remove the entire glandular tissue preserving the skin envelope and the NAC 2-4. Several studies showed that NSM is oncologically safe and allows to achieve high patient satisfaction and better aesthetic results than other conventional mastectomies 3-7. NSM should be considered in breast cancer patients when a conserving approach cannot guarantee adequate local control and good cosmetic results. Common indications to NSM include inability to obtain clear surgical margins with BCS, large tumor size with respect to the breast size, extensive or multicentric disease, as well as cases with contraindications for radiotherapy as well as patient preference 3-5; absolute contraindications to NSM are inflammatory carcinoma, locally advanced tumor infiltrating the skin, clinical and radiological evidence of NAC involvement, pathologic nipple discharge and nipple Paget's disease 2,8. Obesity with high BMI > 30kg/m², large breasts, previous radiotherapy, active smoking, NAC surgery are considered relative contraindications due to the increased risk of NAC necrosis, asymmetries and nipple displacement 3,6-8.

Several studies showed that the aesthetic outcomes and patient' QoL after NSM with reconstruction depend on the type of skin incision and post-operative complications such as skin or NAC full-thickness necrosis 8-15. As regards the choice of skin incision, it is based on breast morphology, cancer topography and often also on surgeon's expertise and his confidence in performing a safe NSM-IPBR with a specific type of incision 15. The most commonly used incisions are lateral-radial, periareolar with lateral extension and transareolar with lateral extension 4-6. However, these conventional incisions are a suboptimal solution due to the visibility of the scars, nipple displacement and risk of skin or NAC necrosis 4,8,9. The inframammary incision is also not an ideal access in small breasts and with minimum-moderate ptosis due to the visibility of the scar in these patients; besides this incision not enable the optimal exposure of the whole parenchyma and may cause a partial disruption of the skin-based blood supply to the NAC 8-11; moreover, it is necessary to make an additional skin incision at the axillary region for the surgical lymph nodes treatment 11.

The ideal technique should create a skin envelope without incisions on the breast surface. As consequence, the recent trends are to move the access further away from the breast envelope by using more aesthetic and performing techniques as such endoscopic NSM or robot-assisted NSM 16-22. However, although these new techniques optimize cosmetic results using an extramammary incision, they have increased technical difficulties and longer operation times 22.

We reported our preliminary experience with a 6-cm incision located on the lowest axillary fold along the mid-axillary line in selected breast cancer patients 18; this single access allows to perform a safe nonendoscopic NSM, sentinel node biopsy/axillary clearance, and an E-IPBR, with the main advantage of only one well-hidden scar. The results of our study confirm the safety, aesthetic efficacy, feasibility and reproducibility of this innovative and standardized technique in the treatment of breast cancer patients with small-medium sized breast (cup A or B) and with minimum-moderate ptosis.

From oncological point of view, our technique with a 6-cm incision located on the lowest axillary fold along the mid-axillary line, allows adequate access to the mammary gland and ensure an appropriate local-regional control, in agreement with recurrence rates available in the Literature for NSM with traditional skin incisions; no local regional recurrence occurred during follow-up. However, in order to optimize oncological outcomes, technical skill and the repetitive performance of standardized tasks are mandatory; careful staging of disease and accurate selection of candidates to NSM with clinical assessment, ultrasonography, mammography and magnetic resonance are necessary; an adequate radiological preoperative study to evaluate the extent of disease, to localize tumor and/or calcifications but also to

define the more appropriate anatomic planes of dissection should be performed; the correct surgical plane dissection is in the subdermal fascial plane; besides, intraoperative radiological and pathological evaluation of the specimen for the definition of the lesions and the margins of resection must be obtained; frozen sections on the retroareolar tissue need to be performed intraoperatively to rule out evidence of tumor cells; systematic circumferential palpation and visual endoscopic exploration of prepectoral surgical cavity post-mastectomy should be performed to exclude presence of further macroscopic residues of mammary gland; the skin flaps should be visualized and trimmed, if necessary, to remove any residual breast tissue.

From aesthetic point of view, our technique allows to obtain better results in patients with cup A or B breasts; it is very pleasant for both surgeons and patient with the main advantage of a “scarless” mastectomy (Fig. 6). The analysis of our study showed that the aesthetic results were graded excellent and good in all cases both by surgeons and patients, especially thanks to the absence of visible scars. As regards QoL, 13 patients (92,9%) did not reported negative impact on degree of self-esteem, body image perception, femininity, psychosocial and sexual well-being thanks to the preservation of the NAC and the presence of a single well-hidden axillary incision. However, in order to optimize aesthetic results, it is necessary to carry out careful planning of the reconstructive stage and use all technical precautions that allow to minimize the risk of surgical complications; the results of our study indicate how the skin incision performed along the middle axillary line preserves NAC vascular integrity reducing the risk of ischemic lesions; in the dissection of the mammary gland, the meticulous preservation of a layer of subcutaneous tissue with a thickness of 2-4 mm below the dermis allows to ensure an adequate vascularisation of skin flaps; besides, intraoperative skin perfusion testing with a fluorescence imaging system may help to evaluate skin flap perfusion in real time and give immediate feedback as to the vascular integrity. In our experience there have been no cases of skin or nipple-areola full-thickness necrosis.

From exquisitely technical point of view, it was a reproducible and feasible surgical procedure alternative to the conventional techniques; although NSM is more demanding for surgeons, the use of a rigid endoscope with an operating channel allows to have an optimal view of the anatomical planes on the monitor with better precision in the use of surgical instruments during the preparation of the submuscular pocket; the mean operation time (340 minutes including therapeutic procedures, E-IPBR and surgery for symmetrization of contralateral breast) was acceptable compared to similar surgery performed with other conventional skin incisions. No conversion to conventional NSM-IPBR was performed; the mean hospital stay was 4,1 days similar to other type of NSM-IPBR; no major complications and systemic complications were observed.

Conclusions

NSM combined with E-IPBR via axillary incision is an innovative, reproducible and feasible surgical procedure, alternative to the conventional techniques. In our study, It is safe and appropriate for breast cancer treatment in cup A and B breast patients and allows to obtain better aesthetic results thanks to a well-hidden scar. Individual knowledge, technical skills and repetitive performance of specific tasks are mandatory to optimize oncological and cosmetic outcomes in evidence-based surgery. Further studies with longer follow-up are needed in order to confirm our promising preliminary clinical experience.

Riassunto

Oggi, la chirurgia conservativa (BCS) associata alla radioterapia adiuvante è stata definitivamente convalidata come il trattamento standard delle pazienti con carcinoma mammario in fase iniziale.

La mastectomia rimane una valida alternativa chirurgica in casi selezionati ed è generalmente associata a procedure ricostruttive immediate. Quando la BCS non può garantire un adeguato controllo locale e buoni risultati estetici, è necessario optare per una mastectomia totale. Varie tecniche chirurgiche possono essere adottate quando si pianifica una mastectomia, ma negli ultimi anni sono emerse nuove procedure chiamate “mastectomie conservative”.

La più innovativa di queste procedure è la mastectomia “nipple-sparing” (NSM) che consente di rimuovere l'intero tessuto ghiandolare preservando l'involucro cutaneo e il complesso capezzolo-areola (NAC). La NSM è oncologicamente sicura e consente di ottenere un elevato grado di soddisfazione da parte delle pazienti con risultati estetici migliori rispetto ad altre mastectomie tradizionali.

Le incisioni cutanee più comunemente utilizzate nella NSM sono quella laterale-radiale, inframammaria, periareolare con estensione laterale e transareolare con estensione laterale. Tuttavia, queste incisioni convenzionali sono una soluzione cosmetica non ottimale e imperfetta a causa della visibilità delle cicatrici, del “deposizionamento” dei capezzoli e del rischio di danni vascolari al NAC.

Lo scopo di questo lavoro è mostrare la nostra innovativa tecnica chirurgica, che consente di eseguire contestualmente una NSM in sicurezza, il trattamento chirurgico dei linfonodi ascellari ed una ricostruzione protesica endoscopica immediata del seno utilizzando un'unica incisione ascellare cosmetica.

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