



Original article

Nipple sparing mastectomy: Surgical and oncological outcomes from a national multicentric registry with 913 patients (1006 cases) over a six year period



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ABSTRACT

Background: Nipple sparing mastectomy is deemed surgically and oncologically safe based on a long lasting literature data from reviews of single institution series. This study aims at evaluating surgical and oncological outcomes of NSM on a large multi-institutional scale, by means of the Italian National registry. **Methods:** In July 2011 a panel of Italian specialists agreed upon and designed a National database of NSM. Centers with at least 150 cancers per year and following the National follow-up schedule guidelines could participate inserting any NSM case performed, retrospectively and prospectively from that moment on. In March 2015 analysis of data was accomplished. Dataset for this study consists of cases performed in the period between January 1st 2009 and December 31st 2014.

Results: 913 Women were included in the analysis, for a total of 1006 procedures. Prophylactic mastectomies were 124 (12.3%). MRI utilization increased over time. NSM failure rate, with NAC removal for any reason was 11.5%. NAC necrosis rate was 4.8%. Larger skin-flap necrosis rate was 2.3%. Major surgical complications rate was 4.4%. Oncological outcomes were calculated among primitive EBC cases only:

Abbreviations: sd, standard deviation; OR, odds ratio; CI, confidence interval; Ref., reference category; n.c., not computable; IHC, immunohistochemistry; FISH, fluoro in situ hybridization; MRI, magnetic resonance imaging; IORT, intra-operative radiation-therapy; ER, estrogen receptor; PgR, progesterone receptor.

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locoregional recurrences rate was 2.9%, NAC recurrence 0.7%. Systemic recurrence rate was 1.0%. Five deaths (0.7%) were registered.

Conclusions: More than 10% of NSM procedures are prophylactic mastectomies. MRI is gaining more importance over time. Surgical and oncological results show that NSM is effective. This National multicentric analysis enables a comparison of results with no geographical differences and a “safe” state of the art of NSM in Italy.

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Introduction

Breast cancer surgical care had an impressive progress in 20th century [1]. Breast conservative surgery is the most common procedure [2]. Nonetheless mastectomy remains a frequent option, as a choice, as a prophylactic intervention and often as a mandatory indication.

Nipple sparing mastectomy (NSM) is deemed as an extension of breast conservative surgery. The definition of “conservative mastectomy” might appear a contradiction in terms, but becomes appropriate when considering conservation as the maintenance of body image [3].

In 1951 Rice and Strickler realized for a benign disease the first mastectomy with preservation of skin and nipple areola complex (NAC) [4]. In 1962 Freeman introduced the term subcutaneous mastectomy [5]. Nowadays, NSM for breast cancer is used in selected cases, with indications based on tumor's characteristics.

Once patients are carefully selected, NSM is considered appropriate and oncologically safe. There is a long lasting literature data regarding surgical and oncological effectiveness of NSM [6,7]. Despite that, there is a variation in the diagnostic and therapeutic strategy that involves NSM in breast cancer treatment from center to center. Moreover, selection criteria and thus indications are enlarging.

In order to evaluate such variations and reach homogeneous behaviors among specialists, an investigation based on a large set of historical data is necessary. Besides, a multicentric comparison is important to assess oncological and surgical results in accordance with international standards and to confirm the validity and reproducibility of the technique.

The aim of this study is to depict and describe the state of the art of NSM in an entire country, by collecting data from a six-year period using a National registry with contribution of various Italian centers. Primary end-points are the analysis of surgical and oncological outcomes.

Materials and methods

In July 2011 a panel of Italian breast specialists agreed upon and designed an open National database on NSM. The idea was to establish a centralized and homogeneous registry which gathers every single center database. The registry was created as a protected-by-password MySQL client (©2015, Oracle corporation).

Any Italian center with a volume of at least 150 breast cancers per year (according to the EUSOMA guidelines [8]) keen on participating had the possibility to contribute on a voluntary basis registering in a specifically created website (www.nipplesparingmastectomy.it).

Registry is made of 180 items, listed as: baseline patients characteristics, oncological parameters, surgical procedure details, pathological reports, adjuvant therapies, surgical outcomes and oncological outcomes. Follow-up schedule was: clinical examination every 3–6 months for the first 3 years, every 6–12 months for the following 2 years, and once a year ever after; mammogram once

a year; further imagings and examinations only on clinical suspicion (according to Associazione Italiana Oncologia Medica, AIOM, follow-up schedule guidelines, <http://www.aiom.it>).

Each patient submitted to NSM, either prophylactic or therapeutic, could be included in the registry prospectively and retrospectively.

In March 2015 analysis of data for present study was accomplished. Inclusion criterion was: NSM cases referring to the period between January 1st 2009 and December 31st 2014 from centers with at least 15 cases included in the registry in the same period. Included cases from 2009 until 2011 were retrospective, while cases from 2011 to 2014 were prospective. The deadline for data update by every center was March 31st 2015.

Statistical analysis

Standard descriptive statistics were used to summarize data, with respect to demographic and preoperative characteristics. Demographics included patient age, smoking habits, diabetes status, hospital and survival status at last follow-up. Preoperative data were analyzed on all surgical procedures.

Four dichotomous (yes/no) response variables were considered: NAC necrosis, skin-flap necrosis, major surgical complications and loco-regional recurrence. Surgical outcomes were analyzed on all procedures, both prophylactic and therapeutic. On the contrary, oncological adverse outcomes (locoregional recurrences) were investigated among primitive early breast cancer cases only. Except for post-operative NAC necrosis, which was calculated excluding those cases with an intraoperative NAC removal, all other analyses were performed with the intent to treat criterion.

Logistic regression was used to investigate which factors were associated with each response variables. Independent variables of interest for surgical outcomes were: smoke, type of incision, neoadjuvant chemotherapy, preoperative radiation-therapy, type of reconstruction and geographical area. Instead, risk factors included in the locoregional recurrences analysis were: age above 45 years old, tumor's diameter greater than 3 cm, multifocality, pT, pN, ER, PgR, Ki67, HER2, neoadjuvant chemotherapy, adjuvant chemotherapy, hormone therapy, anti-HER2 target therapy, post-operative radiation-therapy and geographical area. Tumor diameter was defined as the biggest focus dimension and measured either by means of MRI, when performed, or mammogram, or eventually by ultrasound for lesion not visible at mammogram and not studied by MRI. The same imaging criterion was adopted to calculate the tumor to nipple distance by every center. In this case the distance was from the nearest focus of tumor and not from the biggest focus. An exact measure was not reported in database and therefore tumor to nipple distance was not used as a variable for statistical analysis.

Multiple logistic regression analyses were performed to account for several confounding variables simultaneously. Multiple logistic regression for surgical outcomes included all variables of interest, while in locoregional recurrences analysis only variables with a *p*-value less than 0.20 were included.

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