


Current trends and outcomes of breast reconstruction following nipple-sparing mastectomy: results from a national multicentric registry with 1006 cases over a 6-year period

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Abstract

Background Reconstruction options following nipple-sparing mastectomy (NSM) are diverse and not yet investigated with level IA evidence. The analysis of surgical and oncological outcomes of NSM from the Italian National Registry shows its safety and wide acceptance both for prophylactic and therapeutic cases. A further in-depth analysis of the reconstructive approaches with their trend over time and their failures is the aim of this study.

Methods Data extraction from the National Database was performed restricting cases to the 2009–2014 period. Different reconstruction procedures were analyzed in terms of their distribution over time and with respect to specific indications. A 1-year minimum follow-up was conducted to assess reconstructive unsuccessful events. Univariate and multivariate analyses were performed to investigate the causes of both prosthetic and autologous failures.

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Results 913 patients, for a total of 1006 procedures, are included in the analysis. A prosthetic only reconstruction is accomplished in 92.2 % of cases, while pure autologous tissues are employed in 4.2 % and a hybrid (prosthetic plus autologous) in 3.6 %. Direct-to-implant (DTI) reaches 48.7 % of all reconstructions in the year 2014. Prophylactic NSMs have a DTI reconstruction in 35.6 % of cases and an autologous tissue flap in 12.9 % of cases. Failures are 2.7 % overall: 0 % in pure autologous flaps and 9.1 % in hybrid cases. Significant risk factors for failures are diabetes and the previous radiation therapy on the operated breast.

Conclusions Reconstruction following NSM is mostly prosthetic in Italy, with DTI gaining large acceptance over time. Failures are low and occurring in diabetic and irradiated patients at the multivariate analysis.

Keywords Nipple-sparing mastectomy · Breast reconstruction · Tissue expander · Direct-to-implant · Autologous breast reconstruction

Introduction

Nipple-sparing mastectomy (NSM) can be, nowadays, considered as an extension of breast conservative surgery (BCS). The definition of “conservative mastectomy” reflects this concept [1], since NSM implies maintenance of

the entire exterior envelope and entails a reconstruction, as for volume and shape, of the native breast. This translates in obvious psychological and cosmetic advantages for all operated women [2].

A procedure equal to NSM was first described by Rice and Strickler in 1951 for a benign disease [3]. The so-called “subcutaneous mastectomy” was then introduced in 1962 by Freeman, once again for benign lesions [4]. Starting from the 1990s, NSM has been used for breast cancer in selected cases, with indications based on the tumor’s characteristics.

Despite the lack of randomized clinical trials comparing NSM to other types of mastectomy, its acceptance is widespread and there is a long lasting literature data, regarding surgical and oncological effectiveness of NSM [5–8]. A similar absence of Level IA evidence involves the best surgical procedure for the reconstruction in the case of NSM. An immediate reconstructive approach is necessary whenever the conservative mastectomy step has been completed. Such reconstruction, by the way, can be achieved in so many ways and with so many surgical differences.

An analysis of surgical and oncological outcomes from the Italian National NSM registry has recently been published [5], showing safety and effectiveness of NSM on a national scale, albeit in an observational cohort, non-randomized study. This study is a further in-depth investigation on the second step of NSM: breast reconstruction. The

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aims are the depiction of current trends and the analysis of choices in specific situations. Moreover, failures of the different procedures are evaluated, based on a large set of multicentric historical data.

Materials and methods

The description of the Italian National Database on NSM (www.nipplesparingmastectomy.it) has previously been published along with its details [5]. Briefly, the project started in 2011, when every Italian center, fitting the EUSOMA criteria for a surgical breast unit [9], could enter any case of NSM, either prophylactic or therapeutic, performed from the year 2000. The registry contained 180 items for every single case, including a specific section on the type of reconstruction adopted. In March 2015, the project ended and a first data extraction was performed for the previous study [5]. The analysis was restricted to a 6-year period, from January 1st 2009 until December 31st 2014 and to centers with at least 15 cases entered in the registry in the same period. Included cases from 2009 until 2011 were retrospective, while cases from 2011 to 2014 were prospective. As for the purposes of this study, a further investigation was pursued using parameters, such as the adopted types of reconstruction (prosthetic, with or without soft-tissue replacement devices, autologous or hybrid), their distribution over time, and their correlation to other important baseline, and oncological variables. Autologous breast reconstruction by means of an abdominal flap was not divided up in transverse rectus abdominis myocutaneous (TRAM) flap, either free or pedicled, deep inferior epigastric perforator (DIEP) flap, and superficial inferior epigastric artery (SIEA) flap, since this distinction was not considered in the database design in 2011. Moreover, the outcome of reconstruction was also evaluated, considering reconstructive failure rate as the main indicator of it. In the case of prosthetic reconstruction, a failure was defined as the prosthesis removal due to complications within 1 year from NSM, in accordance with the Centers for Disease Control and Prevention (CDC) guidelines for prosthetic breast surgery [10]. While in the case of autologous flap reconstruction, failure was defined as flap necrosis, either partial or total, or as a change of reconstruction strategy, both requiring a second surgical revision, again within 1 year. In the outcome evaluation, only patients with an updated reconstructive follow-up until 1 year from NSM were included, with or without the completion of second stages for tissue expander (TE) reconstructions. Last update of the 2014 cases was completed in December 2015. All the analyses were conducted as per an intent-to-treat criterion, even including those cases of nipple-areola complex (NAC) removal, for different

reasons and at different timings, as described, in detail, in the previous study [5].

Statistical analysis

Standard descriptive statistics were used to summarize data. Indications and surgical failures of different reconstructive procedures following NSM were the main objectives of the analysis. Pearson's Chi-square test and Fisher exact test, where appropriate, were used to assess differences in clinical and biological characteristics between different types of reconstruction subgroups.

Univariate and multivariate analyses of reconstructive failures were performed, excluding cases without a complete 1-year follow-up. The following risk factors were considered for failures: age, smoke, diabetes, type of reconstruction, oncological stage, neoadjuvant chemotherapy, and pre-operative RT. Multiple logistic regression analyses were performed to account for several confounding variables simultaneously and included all variables of interest. A two-tailed *p* value less than 0.05 was considered significant. All analyses were performed using the STATA version 13 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

Results

Fifteen Italian Centers fit the inclusion criteria in the selected 6-year time span (2009–2014). From data extraction, 913 patients are included in the analysis, with 93, 10.2 %, bilateral NSM interventions, accounting for a total of 1006 cases. Patients' baseline characteristics and distribution among different geographical areas are reported elsewhere [5].

Reconstructions performed with prosthetic devices only, either by TE or by a direct-to-implant (DTI) reconstruction, are 92.2 % of all cases (Table 1). Soft-tissue replacement devices, either acellular dermal matrixes (ADM), or synthetic meshes, are used in 15.8 % of TE cases, while their use increases up to 68.5 % in DTI reconstructions. In the case of a hybrid procedure, prosthetic plus autologous tissue (3.6 % of cases), latissimus dorsi (LD) flap is almost always adopted except for one case of abdominal flap used in combination with an implant. No other types of flap rather than abdominal and LD are reported. The distribution of procedures with respect to the objective of NSM, therapeutic versus prophylactic, shows some differences (Table 2). In particular, DTI is significantly less adopted in therapeutic NSMs rather than prophylactic, 26.5 versus 35.6 %, respectively. Among therapeutic procedures, twenty-six cases (3.4 %) were performed for recurrence in a breast with a history of the previous RT. There is not a

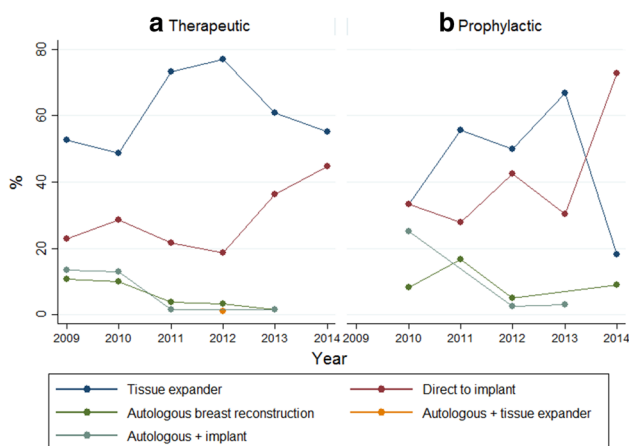
Table 1 Distribution of the different types of reconstruction among the 1006 cases of NSM

Type of reconstruction	N	%
Prosthetic	928	92.2
Tissue expander, TE (two-stage) (TE + soft-tissue replacement devices 31/650, 15.8 %)	650	64.6
Direct-to-implant, DTI (one-stage) (DTI + soft-tissue replacement devices 107/278, 68.5 %)	278	27.6
Autologous breast reconstruction	42	4.2
Abdominal flaps	36	3.6
Latissimus dorsi flap	6	0.6
Hybrid (prosthetic plus autologous)	36	3.6
Autologous + tissue expander	3	0.3
Autologous + implant	33	3.3

Table 2 Distribution of the types of reconstruction in the groups of therapeutic and prophylactic NSMs

	Therapeutic	Prophylactic
Tissue expander	586 (66.4 %)	64 (51.6 %)
Direct-to-implant	234 (26.5 %)	44 (35.6 %)
Autologous breast reconstruction	34 (3.9 %)	8 (6.45 %)
Autologous + tissue expander	3 (0.3 %)	0 (0.0 %)
Autologous + implant	25 (2.8 %)	8 (6.45 %)

p = 0.01

**Fig. 1** a, b Time trend of different types of reconstruction in therapeutic (a) and prophylactic (b) NSM

preferred surgical procedure in this case, with no significant results. Nonetheless, among prosthetic reconstructions, DTI is only 15.4 % and autologous reconstructions overall are 11.5 %.

Time trend of every single type of procedure, both for therapeutic and prophylactic NSM, is reported in Fig. 1a and b, respectively.

As for reconstructive failure rate evaluation, data with a reconstructive 1-year updated follow-up are available for 965 cases out of 1006.

Failures are 2.7 % overall, ranging from 0 % of pure autologous breast reconstruction to 9.1 % of autologous

Table 3 Reconstruction failures within 1 year from NSM

Tissue expander	17/620	(2.7 %)
Direct-to-implant	6/267	(2.3 %)
Autologous breast reconstruction	0/42	(0.0 %)
Autologous + tissue expander	0/3	(0.0 %)
Autologous + implant	3/33	(9.1 %)

Statistical analyses were performed excluding cases without a complete 1-year follow-up

plus implant (3 cases out of 33). The results are shown in Table 3. The univariate analyses of the association between reconstructive failure and type of reconstruction, baseline characteristics, and several oncological parameters show a significant *p* value for smoke, diabetes, and pre-operative RT. At the multivariate analysis, the association is confirmed significant for diabetes and pre-operative RT, smoke does not reach statistical significance, but the OR of a failure is 2.7 for smoking patients versus non-smoking (Table 4).

Discussion

While much attention has been given to evaluate surgical and oncological safety of NSM, few studies investigate and compare the different approaches to immediate reconstruction in the NSM setting.

Table 4 Univariate and multivariate analyses of reconstructive failures with the different types of reconstruction, baseline characteristics, and oncological parameters

Reconstructive failure analysis	Failure N = 26	No failure N = 939	OR (95 % CI) p value	Adjusted OR (95 % CI) p value
Age >45 years	17/26 (65.4 %)	535/939 (57.0 %)	1.42 (0.63, 3.23) 0.395	0.84 (0.31, 2.29) 0.739
Smoke	7/25 (28.0 %)	84/742 (11.3 %)	3.05 (1.24, 7.51) 0.016	2.71 (0.86, 8.55) 0.089
Diabetes	2/26 (7.7 %)	5/779 (0.6 %)	12.9 (2.4, 69.9) 0.003	20.07 (3.17, 127.2) 0.001
Type of reconstruction				
Tissue expander	17/26 (65.4 %)	603/939 (64.2 %)	Ref.	Ref.
Direct-to-implant	6/26 (23.1 %)	261/939 (27.8 %)	0.81 (0.32, 2.10) 0.671	1.10 (0.36, 3.41) 0.858
Autologous breast reconstruction	0/26 (0.0 %)	42/939 (4.5 %)	n.c.	n.c.
Autologous + tissue expander	0/26 (0.0 %)	3/939 (0.3 %)	n.c.	n.c.
Autologous + implant	3/26 (11.5 %)	30/939 (3.2 %)	3.55 (0.99, 12.77) 0.053	3.23 (0.77, 13.61) 0.110
Oncological stage				
Prophylactic	3/26 (12.0 %)	109/865 (12.6 %)	Ref.	Ref.
Stage 0	3/26 (12.0 %)	161/865 (18.6 %)	0.68 (0.13, 3.42) 0.637	0.90 (0.14, 6.02) 0.916
Stage I	10/26 (40 %)	250/865 (28.9 %)	1.45 (0.39, 5.38) 0.576	1.34 (0.25, 7.14) 0.732
Stage II	8/26 (32 %)	303/865 (35.0 %)	0.96 (0.25, 3.68) 0.952	1.02 (0.18, 5.65) 0.984
Stage III	1/26 (4 %)	42/865 (4.9 %)	0.87 (0.09, 8.55) 0.901	0.82 (0.06, 10.39) 0.878
Neoadjuvant chemotherapy	3/26 (11.5 %)	82/939 (8.7 %)	1.36 (0.40, 4.64) 0.620	2.34 (0.62, 8.85) 0.211
Pre-operative radiation	3/21 (14.3 %)	22/782 (2.8 %)	5.76 (1.58, 20.99) 0.008	8.27 (2.00, 34.24) 0.004

Statistical analyses were performed excluding cases without a complete 1-year follow-up

Significant values are shown in bold

OR odds ratio, CI confidence interval, Ref. Reference category, n.c. not computable

To date, there are no randomized trials, to our knowledge, comparing different reconstructive options in NSM [8]. As for the depiction of reconstructive options distribution on a large scale with multicentric data, the largest report is from the American Society of Plastic Surgeons [11], regarding breast reconstruction after mastectomy overall, not only in the case of NSM. The results for the year 2014 show that out of 102,215 breast reconstructions, TE/two-stage reconstruction is adopted in 73.0 % of cases, DTI in 8.2 %, and autologous flaps are used in 18.8 % of cases. Among flaps, DIEP is the most frequently adopted with 7.6 %. Hybrid cases are not specified in this report. In terms of trends variation over time, a national report from USA shows that over a 10-year period (1998–2008) implant use increases for all the mastectomy procedures but particularly for bilateral and contralateral prophylactic mastectomies, whose rate rose to 12 and 15 %, respectively [12]. A similar significant difference in trend of implant reconstructions versus autologous is confirmed by another American paper over the period 1998–2007 [13]. On the contrary, another national report from the UK, still regarding trends in breast reconstruction for any type of mastectomy not only NSM, displays a decrease in implant-only reconstruction (from 95.42 % in 1996 to 84.92 % in 2012), counterbalanced by an increase in abdominal autologous flaps reconstruction (0.44 % in 1996 and 2.76 % in 2012). LD or implant-assisted LD is still the

main autologous flap in UK for the year 2012, but showing a steady decline [14]. Few studies analyze breast reconstructions trends for NSM only. In a recent paper from USA, on a single-institution retrospective series of 482 cases, the overall 5-year (2007–2012) report shows that DTI reconstructions are 59.3 %, TE 38.4 % and autologous flaps 2.3 %. Timewise, though, DTI increases from 28.57 to 67.7 %, TE decreases from 71.43 to 29.5 %, and autologous reconstruction rises from 0 to 2.8 % [15].

In a recent review of the literature of studies regarding reconstruction after NSM from 1970 to 2013, the overall number of TE/two-stage reconstructions is 45.5 %, DTI is 40.7 %, and autologous flaps is 13.8 % [8].

Reconstruction failures after NSM are reported to be 1 % in a 353 cases series of implant-based reconstructions from MSKCC [16]. An implant loss rate of 1.9 % is presented in the aforementioned Colwell's paper of 500 cases [15].

The results of this study, from the Italian National Registry, display that reconstruction following NSM is achieved by prostheses only in 92.2 % of cases, by means of pure autologous tissues in 4.2 % and by a hybrid technique in the remainder. These numbers are quite similar to single-institution Colwell's study [15], even though autologous flaps are increasing in that paper. Comparison with the other national trends is difficult, since these are data limited to NSM, while all other national reports are referring to post-mastectomy reconstructions overall.

Interpretation of data is also very difficult to do, because several variables might interfere. Time and costs of procedures, complications, surgical expertise, and cultural factors might be all involved. A theoretical explanation with economic reasons and symmetry ease in bilateral interventions is advocated by Albornoz for the American implants rate increase [17].

Among prosthetic reconstructions, DTI is gaining wide acceptance in Italy. This preference towards DTI is significantly expressed in prophylactic NSMs, which are often bilateral or contralateral risk-reducing procedures in a double-mastectomy setting. Reasons for this increase can also be found in the introduction in the recent years of soft-tissue replacement devices, such as ADMs and synthetic meshes, which are mostly adopted in the DTI cases to have a larger pocket and an effective support for the one-step reconstructions with definitive implants.

Autologous flaps reconstruction, either pure or hybrid, is performed with a higher percentage (11.5 %) in therapeutic recurrence cases when RT has previously been adopted. The 0 % failure rate of pure autologous tissues reconstructions might sound in contradiction with its decrease over time. Nonetheless, prosthetic reconstruction displays a very low failure rate as well, 2.7 and 2.3 % for TE and DTI, respectively.

Reasons for reconstruction failures are significantly represented by diabetes and history of pre-operative RT. Smoke, albeit not statistically significant at the multivariate analysis, increases more than two times the chances of failure. Therefore, patients with these risk factors should be particularly cautious and well informed in the decision-making process of a breast reconstruction. Autologous flaps should be considered in these circumstances, even referring patients to centers with higher volumes and expertise in this field.

This study represents a unique national survey on breast reconstruction limited to the NSM cases with multicentric and well-distributed data on a large sample over a moderately long period of time. Limits are represented by the retrospective nature of a portion of cases, from the year 2009 until 2011, and by the intrinsic biases of a voluntary non-controlled report. Moreover, reconstructive issues are limited to an analysis of distribution and indications of different surgical procedures and their 1-year failure rate, not including any long-term functional, psychological, and cosmetic outcomes, both objective and subjective. These aspects should be further assessed to really appreciate the best reconstructive approach.

Conclusions

In conclusion, reconstruction during an NSM procedure is mainly prosthetic in Italy. DTI is becoming as common as a two-stage reconstruction and is preferably chosen in the

prophylactic procedures. Failures are higher in prosthetic cases, but are quite rare, and occur mostly in the prosthetic reconstructions of diabetic and previously irradiated patients.

Compliance with ethical standards

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Conflict of interest All Authors disclaim any conflict of interest.

Ethical standards The study was conducted in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. No institutional ethical approval was required.

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