

Minimal access nipple-sparing mastectomy – the current European landscape

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Abstract

Minimal access nipple-sparing mastectomy (M-NSM), performed with endoscopic systems or with surgical robot assistance, is a novel alternative to the classic approach to nipple-sparing mastectomies. Leading advancements in M-NSM have primarily come from Asia. We gather experts' opinions from six European countries to establish the current status of M-NSM in Europe. An eight-question survey was designed to explore M-NSM's historical background and current standing in various local settings. We collected data from 6 European countries, including Italy, Spain, France, Switzerland, Belgium, and Poland. The number of centers offering M-NSM procedures in each reported country ranges 1–9. The number of procedures performed annually in four centers exceeds 10. In all reported countries, current national breast cancer recommendations do not include M-NSM, and this procedure is not explicitly covered by any of the national health care providers. All experts have indicated the need for training in M-NSM surgery as a primary way to incorporate these techniques as a standard procedure. Minimal access nipple-sparing mastectomy is still a tool used by a narrow group of specialists in Europe. The main obstacle to broader implementation remains the extra cost of M-NSM, which requires reimbursement from the health care providers. Training courses, data collection, and demonstration of its benefits are the key to promoting M-NSM among breast surgeons and patients.

Key words: minimal access nipple-sparing mastectomy, robot-assisted nipple-sparing mastectomy, endoscopic nipple-sparing mastectomy, endoscopic mastectomy, robotic mastectomy.

Introduction

Nipple-sparing mastectomy (NSM) is a standard procedure for women who need to remove their mammary glands for oncological or prophylactic reasons [1, 2]. Prepectoral breast reconstruction is a current trend in NSM [3]. However, a long skin incision and placing the implant under the skin, unprotected by muscles, increases the risk of wound dehiscence and implant exposure [4].

Minimal access nipple-sparing mastectomy (M-NSM), performed with standard endoscopic systems (endoscopic nipple-sparing mastectomy – E-NSM) or with surgical robot assistance (robotic nipple-sparing mastectomy

– R-NSM), is the rational alternative to the classic approach to NSM with prepectoral implant placement [5]. Shortening the length of the skin incision and moving it away from the implant's direct compression can lead to fewer complications and achieve a 'hidden scar' effect.

The genesis of M-NSM can be traced back to the late 1990s when Japanese surgeons recommended an endoscopic partial mastectomy and then total mastectomy as a viable solution to improve cosmetic outcomes and to decrease the morbidity associated with breast cancer surgery [6–9]. In 2014, Antonio Toesca performed the first robotic NSM (R-NSM) at the European Institute of Oncology in Milan [10]. Since this time, breast surgery

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Submitted: 18.10.2024

Accepted: 23.12.2024

through minimal access/minimal access breast surgery has gained popularity worldwide. However, based on the currently described patients' series, the leading countries in M-NSM surgeries originated from Asia. The popularity of M-NSM among Asian women is likely due to their high esthetic consciousness, the expectation of short scars to reduce the risk of keloid formation, and smaller breasts, which are more relevant/appropriate to these procedures [11–13].

The data on the implementation of M-NSM in Europe is scarce. In the recently presented meta-analysis comparing post-operative outcomes of minimal access versus conventional nipple-sparing mastectomies in breast cancer patients, 8 out of 10 studies came from Asia (Taiwan, Korea, and China; total number of patients in M-NSM cohort = 747), and only two studies emerged in Europe (France and Italy with 87 and 40 patients, respectively) [14]. Thus, we opted to gather experts or pioneers of M-NSM from different European countries and inquire about this surgery's historical background and position in local settings.

The aim of the study was to ascertain/establish M-NSM deployment/use in breast cancer centers across Europe.

Material and methods

A questionnaire with eight questions has been created to record the start and background of the M-NSM in each country and to analyze its current state. Endoscopic breast surgeons who perform minimally invasive breast surgery at European breast cancer centers were contacted by email to respond to a questionnaire. Out of nine invitations, seven were accepted. Two experts from Spain unified their statements and were further analyzed as one. Therefore, we collected data from 6 European countries, including Italy, Spain, France, Switzerland, Belgium, and Poland. Table 1 contains all questions and the expert's answers.

Results

In Europe, minimal access to robot-assisted nipple-sparing mastectomy was initiated in Italy in 2014 and followed by France in 2018. In 2021 and 2022, R-NSM was introduced in Belgium and Spain, respectively. Experts from Switzerland and Poland did not confirm R-NSM surgery in their countries.

Endoscopic NSM has already been reported in 5 European countries listed except for Belgium. It was first introduced in Italy in 2016 and then in France and Spain in 2018. This technique was reported in Switzerland (2021) and Poland (2023).

The number of centers offering M-NSM in each reported country ranges from 1 (Belgium) to 9 in Spain. The number of procedures performed annually in four

centers exceeds 10 (two in Spain, one in Italy, and one in Poland).

At least one M-NSM workshop was held in four countries, including France, Italy, Spain, and Poland. Spain hosts over three M-NSM workshops annually, while Italy is the country that organizes the most workshops, around one per month.

In all reported countries, current national breast cancer recommendations do not include endoscopic or robotic nipple-sparing mastectomy. Minimal access nipple-sparing mastectomy are not explicitly covered by any of the national health care providers.

All experts identified insufficient reimbursement as the main obstacle to the broader implementation of M-NSM. Other factors hindering its adoption include longer operating time, low number of experienced M-NSM surgeons, and the poor appreciation for the 'hidden scar' effect, as reported by some surgeons and patients.

All experts have indicated the need for workshops and sharing experience in M-NSM among breast surgeons as a primary way to incorporate these techniques as a standard procedure. The following solution included conducting clinical studies to validate the procedure's safety, creating an international database, and collaborating with national scientific societies to support M-NSM advancement.

Discussion

Despite scientific reports documenting E-NSM for more than 20 years and R-NSM for 10 years, our survey indicates that its implementation in Europe is still in its early stages. Even in Italy, the pioneer country in robotic approaches, only two cancer centers currently offer this method to their patients. While this approach is available in two centers in Spain, it is still unknown in 3 out of 6 reported countries. We stated that breast surgeons scarcely use robot assistance in daily practice, which contrasts with the estimated number of da Vinci systems in Europe, which is around 1500 [15]. The absence of the widespread use of versatile endoscopy in breast surgery, as E-NSM is performed in unique numbers of/just a few reported countries, makes it even more noticeable.

We reported that even in specialized robotic or endoscopic breast centers, the annual number of M-NSM cases is low, not exceeding 50. A limited number of patients may result from restricted indications for M-NSM. The preferred candidates for M-NSM are women who have breasts that are small or medium in size (cups A, B, and C). In large and ptotic breasts (size D and above), M-NSM is technically challenging and increases the likelihood of ischemia of the nipple-areola complex [16, 17]. At the beginning of 2024, the Intuitive da Vinci Single-Port surgical system received the European CE mark for breast procedures, which may increase the popularity of robotic breast surgery beyond clinical studies [18].

Table 1. The expert responses to the eight-point questionnaire aimed to report the onset and current status of endoscopic nipple-sparing mastectomy and robotic nipple-sparing mastectomy in Europe

Country and name of the author	Belgium	Italy	France	Poland	Spain	Switzerland
When was the first E-NSM/R-NSM performed in your country?	R-NSM in 2021	R-NSM: 2014, Toesca <i>et al.</i> [10], Endoscopic: 2016, Franceschini <i>et al.</i> [28]	R-NSM: 2016, Sarfati <i>et al.</i> [29], E-NSM: 2018, Rathat <i>et al.</i> [30]	E-NSM: 2023, Pluta <i>et al.</i> [31]	E-NSM: 2018 (I. Larraga in Hospital Mutua de Terrassa, Barcelona) R-NSM: 2022 (L. Blay in Hospital Germans Trias i Pujol)	It was performed in 2021 in Lausanne, never reported. Since October 2023 in Sion
What is the number of centers where E-NSM/R-NSM is available?	Not known, presumably at least 1	E-NSM: 3 and R-NSM: 2 <ul style="list-style-type: none"> Candiolo Cancer Institute FPO-IRCCS Turin (E-NSM/R-NSM) Vita-Salute San Raffaele University, Milan (E-NSM) Policlinico Gemelli, Rome (E-NSM) Azienda Ospedaliera Universitaria Verona (R-NSM) 	R-NSM: 2 and E-NSM: 2 <ul style="list-style-type: none"> Gustave Roussy, Paris (R-NSM) CHU Lyon (R-NSM) CHU Montpellier (E-NSM) Clinique du Fief de Grimoire Poitiers (E-NSM) 	E-NSM: 2 established centers: <ul style="list-style-type: none"> Instytut-CZMP, Łódź Alfred Sokolowski Memorial Hospital, Walbrzych E-NSM starting centers: <ul style="list-style-type: none"> Opolskie Centrum Onkologii (Opole) Szpital Kliniczny MSWiA w Olsztynie (Olsztyn) Narodowy Instytut Onkologii oddział w Krakowie (Kraków) 	R-NSM and E-NSM: 9, including: Established centers: <ul style="list-style-type: none"> Hospital de Torrejón (Madrid) (E-NSM) Hospital Germans Trias i Pujol (Barcelona) (E-NSM/R-NSM) Hospital Mutua de Terrassa (Barcelona) (E-NSM) Complejo Hospitalario Universitario de Ourense (Ourense) (R-NSM) Starting centers <ul style="list-style-type: none"> Hospital La Paz (Madrid) Fundación Tejerina (Madrid) Hospital del Mar (Barcelona) Hospital de Vic (Barcelona) Complejo Hospitalario Universitario Insular (Canarias) 	Two: Sion and Lausanne
How many E-NSM/R-NSM are carried out annually in your country or breast center?	Unknown	The estimate number of E-NSM/R-NSM: 50 patients/year	The estimate number of E-NSM: 10 patients/year, and R-NSM: 10 patients/year	The estimate cumulative number of E-NSM: 50 patients/year	The estimate number of E-NSM/R-NSM: 40-50 patients/year. Hospital de Torrejón (Madrid): 10-12 Hospital Germans Trias i Pujol (Barcelona): 6-8 Hospital Mutua de Terrassa (Barcelona): 4-6 Complejo Hospitalario Universitario de Ourense (Ourense): 20-25 The hospitals initialing E-NSM/R-NSM: 2-3 patients/year	The estimate cumulative number of E-NSM/R-NSM: 15 patients/year

Table 1. Cont.

Country and name of the author	Belgium	Italy	France	Poland	Spain	Switzerland
Have E-NSM/R-NSM workshops been carried out in your country?	No	Yes, around one workshop every month	E-NSM 0 R-NSM: yes, June 2024, first one	Yes, 1 in March 2024	Yes, we have held more than 5 workshops since 2018. We are currently organizing 3 annual workshops	No
Does your national breast cancer recommendation include E-NSM/R-NSM?	No	No, E-NSM or R-NSM techniques are not included in national recommendations	No	No	Not yet. This technique is not currently considered in the recommendations	No
Does your health care system promote E-NSM/R-NSM financially?	No	No, the national health system does not cover the exciding/associated costs	No	No	Neither the national nor territorial/regional health system. Financial and management support is provided solely by the hospitals	No
What are your thoughts on the primary obstacle to the widespread use of E-NSM/R-NSM in your country?	Costs, no/few experienced surgeons	For R-NSM the costs are too high, the technique is difficult to be learned from/for the breast surgeon without any experience of robotic surgery	E-NSM: operative time. Poor appreciation of the value of hidden scars. R-NSM: costs and access, operative time. Poor appreciation of the value of hidden scars	Most of the surgeons are not familiar with the techniques. The possible high costs of robotic surgery	Difficulties for implementation in general: • lack of knowledge of the surgical technique • lack of knowledge of the advantages Difficulties: • preference for DIEP whenever possible in the Functional Breast Unit of some Hospital/hospitals. • increase in surgical/operative time • the slight increase in costs • the difficulty of changing the technique that always creates rejection as it implies a new learning and paradigm shift	The principal obstacle is the costs that are higher than open mastectomy: • the cost of GelPort and sealing device, in total probably CHF 700 more than open surgery and an additional cost of operating room occupancy • (in Switzerland 1 h is estimated at CHF 10 000 • additional cost: carbon dioxide volume, instrument sterilization • this increase in costs is supported only by the hospital, as the reimbursement is the same as for open mastectomy

Table 1. Cont.

Country and name of the author	Belgium	Italy	France	Poland	Spain	Switzerland
What should be done to incorporate E-NSM/R-NSM into standard surgical procedures in your country?	More training opportunities so a broader group of surgeons is confident with the technique and therefore can expand and share their knowledge/experience to others, also more studies on oncological safety of endoscopic/robotic procedures	We need more publications on quality of life data and oncological data	National publications and workshops. Acceptance from the national breast cancer societies	Surgical workshops. Cooperation with national medical societies	E-NSM: 2018 (I. Larrañaga in Hospital Mutua de Terrassa, Barcelona) R-NSM: 2022 (L. Blay in Hospital Germans Trias i Pujol)	The increase in total costs for primary E-NSM/R-NSM could be mitigated by the following factors: Disseminating the advantages of the technique among doctors, government, and the community. Arranging specialized workshops. Trials proving that this technique provides less early and late surgical complications, decreases hospital stay, less secondary esthetic interventions, and the same oncological outcomes.

DIEP – deep inferior epigastric artery perforator flap

According to our report, most centers with high-volume M-NSM procedures have offered a workshop in this field. Furthermore, the opportunity for M-NSM training was indicated as one of the crucial ways to spread the techniques. The European Society of Surgical Oncology’s inclusion of R-NSM in their upcoming congress and the robotic webinar on their schedule/program is a positive aspect [19]. Surprisingly, E-NSM is not included in any ESSO session.

There have been no reported countries where M-NSM is included in national breast cancer guidelines. Similarly, the European Society of Medical Oncology still omitted M-NSM in its breast cancer guidelines even though in 2017, at the 15th St. Gallen International Breast Cancer Conference, robot-assisted mastectomy was already recognized as an option for selected patients [20, 21]. The conservative attitude towards M-NSM may be partly due to the relatively short follow-up of patients who have undergone endoscopic or robot-assisted mastectomy. However, in a single institution, a large number of minimal access vs. conventional breast surgery (603 and 1809 early breast cancer patients, respectively) with a median follow-up of 84 months, estimated long-term oncological outcomes have not been significantly different [22]. The increasing number of studies support this observation, proving that M-NSM is technically feasible and safe from surgical and oncological points of view [23–25]. It should prompt European oncological societies to include M-NSM in their recommendations.

As a primary obstacle, most experts indicated the additional cost of M-NSM. The procedure requires the use of dedicated disposable single-ports and endoscopic sealing devices. However, the cost of surgery is mainly associated with the type of systems assisted during mastectomy. In Taiwan, Lai et al. assessed that introducing robotic systems to nipple-sparing mastectomies almost doubles the cost of the classic approach (USD 10 672 vs. USD 6182, respectively) [26]. It is less costly to adopt 3D-endoscopic systems, which increase the cost up to USD 7760 (a difference of less than USD 1600 compared to the 2D E-NSM). The operating cost may differ across Europe, and it is crucial to establish a genuine financial impact of M-NSM in specific countries.

Alongside the higher costs of M-NSM, we demonstrated that the need for specialized training in M-NSM is still a challenge in European countries. However, Europe allows R-NSM with CE mark, unlike the Food and Drug Administrations restriction for robotic breast surgery in the United States [18, 27]. It is an excellent opportunity for broader adoption of M-NSM provided these financial and educational challenges can be overcome.

Experts emphasized the significant ways to strengthen the role of M-NSM in breast surgery by collecting data and conducting international clinical studies. Thus, our study has the potential to foster European cooperation to promote these innovative techniques.

The main limitation of this report is that it might not reflect the situation in all Europe as we directed the question to the subjectively gathered experts. To avoid blurring the information, we opted to receive one opinion from particular countries, except Spain, with two experts' views unified in one. Furthermore, the panelists/researchers have provided estimated information about the number of cancer centers that perform these procedures as well as the estimated number of annual surgeries. Thus, we called this report a landscape that allows us to define the main issue that hindered the implementation of M-NSM in Europe.

Conclusions

Robotic and endoscopic approaches are still tools for a narrow group of specialists. The training courses, data collection, and demonstration of study results are the key to promoting M-NSM among breast surgeons and patients. The main obstacle to wide implementation remains the extra cost of M-NSM, which requires reimbursement from the health care providers. However, if further studies prove the safety profile of M-NSM, the need for patients to get surgery with barely visible scars will prevail over the economic factors.

Disclosures

1. Institutional review board statement: Not applicable.
2. Assistance with the article: None.
3. Financial support and sponsorship: None.
4. Conflicts of interest: None.

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