OVERVIEW

1. Background

Nipple Sparing Mastectomy (NSM) entails the conservation of the nipple–areola complex (NAC) as well as the skin envelope while performing a complete excision of all the mammary gland; NSM is a recently introduced alternative to modified radical, total and skin sparing mastectomy where the NAC is removed and it is also different from subcutaneous mastectomy.

NSM and immediate breast reconstruction has been practiced more and more often in the last decade in treating invasive breast cancer as well as precancerous conditions such as DCIS and for women with an increased risk of developing breast cancer.

One significant advantage of the NSM technique is the removal of the whole breast tissue as a radical surgical procedure while preserving native breast integrity, the nipple-areola complex as well as the submammary fold, therefore improving the cosmetic outcomes.

As rates of NSM continue to increase, it is important to retrieve confirmatory evidence in support of the oncologic safety of the technique for therapeutic as well as risk reducing indications in high-risk patients. Women, whether affected by breast cancer or exposed to an increased risk, deserve full information on the advantages and drawbacks of NSM, as derived from solid investigations.

2. Relevance

There is a need for this international registry because:

1. New surgical techniques need to be proven feasible, safe and validated before implementation. A well-designed prospective database is required to reduce uncertainty regarding NSM;
2. At present, a randomized clinical trial for nipple sparing techniques vs. conventional mastectomy (followed by reconstruction) is neither feasible nor ethical;
3. NSM is only performed by a limited number of breast units - therefore most patients and physicians are not fully informed about this alternative to a traditional mastectomy and reconstruction;
4. No standardized staging, surgical technique or surveillance protocol for NSM is presently available;
5. There is a need for a network of interested clinicians to optimize NSM techniques in an evidence based way to identify and promote best patterns of care.

Primary objective is:
To determine oncological safety of NSM

3. Methodology

Prospective, observational, multinational web-based Quality registry

4. Study population

Intention to undergo a Nipple Sparing Mastectomy with immediate reconstruction
- Stratified in two distinct groups (two parallel studies):
  • DCIS or invasive breast cancer
• Risk reducing mastectomy

5. Countries

Global access, expert centers

6. Progress

Web-based dataset is being designed and developed at this moment
Testing the demo version
Testing the final version
Launch date: 2016

Website

WORK GROUP

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