



## Position Paper

## Quality control in prophylactic mastectomy for women at high risk of breast cancer

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## 1. Background

It has been evaluated that approximately 7–10% of breast cancers are related to a gene mutation. The rapid development of genetic counselling clinics and a better clinical investigation of hereditary cancers will dramatically increase the number of women at risk requiring prophylaxy, namely a prophylactic mastectomy (PM). Knowing that these women have a 50–90% risk of developing a breast and/or ovary cancer during their lifetime [1], they will require some kind of preventive measures. Although PM remains a very controversial indication [2] it has been proven that PM reduces the risk of breast cancer by more than 90% [3]. Moreover, immediate breast reconstruction can reduce psychological problems due to the mutilation.

Different techniques (more or less conservative) are available to reconstruct the breast and the nipple areola complex. Excellent cosmetic results can be achieved in approximately 60% of cases. Nevertheless, complications are not exceptional [4,5], cutaneous necrosis and capsular contractures are observed in approximately 30% of cases, especially when the glandular tissue has been removed close to the dermis. Primary breast cancers following prophylactic surgery have been reported in literature [6]. It is therefore mandatory to increase the quality of the surgical preventive procedure, avoiding psychological distress and improving cosmetic results.

## 2. Counselling measures

A complete counselling process should be undertaken including detailed information on the PM, related surgical risks and possible unsatisfactory cosmetic results. Women should have enough time to become aware of the entire process they will undergo.

### 2.1. Diagnostic process

The genetic risk of breast cancer is suspected on the basis of family history: for example the presence of at least two or three close relatives with a history of cancer. Different protocols are available to evaluate the risk according to the number of relatives, age and type of cancer. The results of this family questionnaire should be completed with a BRCA test in order to obtain objective proof of the genetic risk.

### 2.2. Counselling process

In cases of positive BRCA tests, the real counselling process begins, because (in cases of *BRCA1* mutation) the woman now knows that she is at a high risk of developing a breast and/or ovarian cancer during her lifetime.

The first discussion will be with the medical genetist in order to evaluate the risk. The different protocols available for cancer prevention should be presented: surveillance with periodic mammograms and ultrasound examinations, chemoprevention, bilateral prophylactic mastectomy and/or oophorectomy with or without hormonal replacement treatment.

When surgical prevention is the choice of the woman, she should be referred to the surgeon in order to get information on the type of operation and the possible immediate reconstruction.

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### 2.3. The mastectomy procedure

Two different techniques are currently performed and the choice should be discussed in detail with the woman. The final decision concerning the technique to adopt will take into account the woman's preference. The first one is a subcutaneous mastectomy (SCM) which preserves the nipple areola complex (NAC). In this case, preservation of the blood supply and avoidance of secondary necrosis of this NAC, makes it necessary to keep a certain amount of glandular tissue behind the nipple and the areola.

Therefore, this operation cannot completely avoid the risk of cancer developing in the ducts localised behind the NAC. The second option is the so-called 'skin-sparing mastectomy' (SSM) with complete removal of the NAC. The first procedure is less mutilating and most women prefer to preserve the areola wherever possible. To make a choice between the two techniques, Magnetic Resonance Imaging (MRI) can be very helpful to pre-operatively evaluate the connections between the glandular tissue and the retro-areolar dermis. Nevertheless, in many Breast Cancer Centres the choice is in favour of SSM with secondary reconstruction of the NAC.

The surgeon performing the reconstruction should explain the different techniques available. The best cosmetic results are usually obtained using the autologous tissue reconstruction by the Transverse Rectus Abdominal Musculocutaneous (TRAM) flap pedicled or free. This technique can sometimes result in abdominal sequelae (scarring, bulge, skin necrosis, muscular defect). As an alternative, Europe has largely adopted the technique of implant reconstruction that avoids the above-mentioned abdominal sequelae, but has cosmetic results that can sometimes be sub-optimal.

Before surgery, women should be offered psychological support and the possibility to meet specialised nurses and eventually other women, who have had the same experience.

Awareness should be checked in subsequent consultations with the surgeon and the other members of the team.

A complete clinical and radiological examination of the breasts using mammography, ultrasound and eventually MRI should be performed before the operation.

### 2.4. Outcome measures

- Two sessions with the medical geneticist and the other members of the counselling team, especially with the surgeons should be performed in at least 70% of cases.
- The selection of women at risk should be done using BRCA mutation tests in at least 70% of cases.
- Preoperative assessment by mammography and ultrasound should be carried out in 100% of cases.

## 3. Surgery

Surgery should be performed in a specialised centre including a breast unit and a plastic/reconstructive surgery unit.

Mastectomy should be performed by a well trained breast surgeon. In most cases, a SSM will be performed (the so-called skin-sparing mastectomy). However, when the radiological examination, such as MRI, shows that the subcutaneous tissue underneath the NAC is essentially made of fat and little glandular tissue, a SCM preserving the NAC can be offered to women who must be made aware of the additional limited risk of developing a tumour.

PM is usually performed by a breast surgeon and the plastic surgeon is called upon to reconstruct the breast. In some centres, a well trained surgeon will perform both procedures when he is competent in both fields. In cases where a two-team approach is available, it is worthwhile asking the plastic surgeon to plan the operation together with the breast surgeon.

In cases of SSM, the skin incision should be circular including the nipple-areolar complex and in cases of SCM, it should only be peri-areolar, preserving the NAC. In any case of SSM, particular attention should be given to the blood vessel network underneath the skin, to guarantee the preservation of a blood supply. When the glandular tissue is adherent to the skin, it may be difficult to completely remove the glandular tissue and preserve the healthy skin.

The preoperative MRI can be useful in such situations, and the dissection with the help of the endoscope can improve the quality of the resection and the final result. Once the specimen has been removed, it is necessary to check carefully under the dermis with the light of the valve or with the endoscope that the breast tissue has been removed everywhere underneath the skin.

The surgical specimen marked with stitches, should always be sent for histological examination and all the fresh tissue should be frozen and kept for further examinations. Axillary lymph-nodes should not be removed (for any reason), and sentinel node biopsy is not indicated, but in cases of accidental removal of some of the first nodes in the axillary tail, they should be histologically examined.

Histological examination should be carried out on serial slices of the specimen and the distance between the slices should not exceed 0.5 cm.

### 3.1. Outcome measures

- SSM is the first surgical choice and SCM, preserving the nipple areola complex, should be adopted only in presence of a very small amount of glandular tissue.

- PM should reduce the risk of developing breast cancer in high-risk women. In this group, after PM the incidence and the mortality rate of breast cancer should not exceed the natural risk of the general population of each country.
- 100% of the PMs should be decided and planned together with the plastic surgeon.
- 100% of the histological examinations should be carried out on serial slices of the specimen and the distance between the slices should not exceed 0.5 cm.

#### 4. Breast reconstruction (BR)

After SSM or SCM the reconstruction could be performed either with prosthetic material or with autologous tissue transfer.

##### 4.1. BR with prosthesis

After mastectomy, the retromuscular plan will be undermined and wide enough to allow a good symmetry once the prosthesis has been introduced. It is preferable to use a saline implant which can be filled up *in situ* in order to make the introduction of the prosthesis easier and to prevent damaging the margins of the scar.

The use of an expander can provide an opportunity to obtain a better symmetry and to better adapt the size of the definitive implant and the size of the cutaneous envelope. However, this technique generally requires a two-step procedure and does not avoid the risk of contracture.

A very frequent complication of BR with implants is the contracture of the periprosthetic capsula. This contraction of the pocket around the implant results in disabling morphology, and hardness of the reconstructed breast.

Modifications in shape and consistency occur in 15–20% of cases and can become evident several months or years after the BR. This complication is much more frequent when the prosthesis is not covered by the muscle and inserted behind the skin. However, the retromuscular position of the implant also has some drawbacks. The retromuscular position of the implant does not allow the natural shape of the breast to be reproduced with its natural ptosis.

The reconstructed breast is usually round in shape and globular, and can be strongly distorted in cases of contraction of the pectoralis muscles. Moreover, in large breasts the SCM and, in some cases, even the SSM leave a large amount of skin which does not fit with the volume of the prosthesis inserted behind the muscle. This discrepancy can be limited by removing a part of the skin envelope. This procedure is safe for SSM, while it increases the risk of nipple areola complex necrosis, reducing the blood vessels network in

cases of SCM. In addition, there is a 2% risk of infections and prosthesis removal, and the final excellent cosmetic results can be achieved in only 50–60% of cases. These findings limit the proposed use of a PM and should be taken seriously, particularly given that cosmetic results will inevitably be viewed differently by women with cancer when satisfactory results are accepted compared with cases of PM where excellent results are expected and should be achieved. This issue should be investigated and extensively discussed.

Autologous tissue transfer: once the glandular resection has been performed, the shape of the breasts can best be reconstructed with a bilateral musculocutaneous deepithelialised flap. The volume required is variable depending on the original volume of the breast. The TRAM flap procedure, free or pedicled normally provides enough subcutaneous fat to reshape both breasts whatever their volume.

The final aesthetic result can be similar to the natural breast. In cases of SCM, the flap should be totally deepithelialised.

When the nipple areola complex has been removed (SSM), a small patch of skin can be saved on the flap in order to be placed on the resulting defect; the colour and the nipple are reconstructed later on, under local anaesthesia.

The main drawback of this technique is the abdominal scar and the risk of abdominal sequelae. This operation should probably be contraindicated in young patients wishing to become pregnant in the future.

##### 4.2. Outcome measures

- The final cosmetic result of the reconstructed breast following PM should be excellent (with complete satisfaction on behalf of the woman), in at least 75% of cases.
- Minor complications as infection, persistent pain, limited skin necrosis, etc, should be expected in less than 10% of cases.
- Asymmetry of the breast with modification in shape (and consistency) and contracture of periprosthetic capsula should occur in less than 20 and 10%, respectively.
- 100% of women undergoing PM should be completely informed by the plastic surgeon of the type of operation they are undergoing and the possible complications should be explained in detail.
- 95% of women undergoing PM should be followed up with an annual physical examination carried out by a breast and plastic surgeon.
- When the correct positioning of the implant is to be assessed, ultrasound examination should be adopted in 100% of cases.
- If a possible rupture of the implant is suspected, MRI should be prescribed in 100% of cases.

## 5. List of attendees

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