



# Twenty-five years of risk-reducing mastectomies and immediate breast reconstruction – lessons learned from a single institution

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**Abstract:** Risk-reducing mastectomy is an established surgical option for patients with inherited high risk for breast cancer. At the Karolinska University Hospital, a structured care plan for this patient group has been developed over a 25-year period. This paper describes the gradual evolution of patient care and surgical technique at a single high-volume university hospital. The results presented are based upon multidisciplinary collaborative efforts, prospective and retrospective studies and the patients' and their partners' own experiences after approximately 700 risk-reducing mastectomies. For women at high risk for breast cancer, a multidisciplinary approach is considered crucial for both pre- and postoperative assessment. The importance of accurate and personalized preoperative counseling and patient participation in decision making is stressed, and different surgical techniques are described.

**Keywords:** Risk reducing mastectomy; breast reconstruction; prevention; BRCA mutation carriers

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## Introduction

“One day my doctor called to inform me that the tests showed that I had inherited a very high risk for breast cancer. I was also told that removing both breasts would almost exclude the risk of getting breast cancer. Later I had a referral to the plastic surgeons, who informed me about the procedure, and I chose to have the operation. I was not mentally prepared, although the breasts had no positive impact on my life except for breast feeding. After 20 years, I still have less sensation in my new breasts and feel uncomfortable in intimate situations. The operation has negatively affected my sexuality. Nevertheless, I do not regret having had the operation, and my anxiety of getting breast cancer is almost gone”. These reflections originate from a series of prospective and retrospective studies from asymptomatic women with an increased risk for breast

cancer treated at the Karolinska University Hospital Sweden from 1994–2018 by our collaborative group.

Before the cloning of the two highly penetrant tumor suppressor genes, *BRCA1* & *BRCA2*, women from families at high risk were identified through a clinical and laboratory collaboration with geneticists and oncogeneticists (with molecular workup). They were offered regular surveillance or risk-reducing surgery of the breasts and ovaries. The Mayo studies that had been published showed a more than 90% risk reduction after bilateral risk-reducing breast mastectomy (BRRM) in asymptomatic high-risk individuals (1). After cloning the genes, these findings were corroborated by the Mayo group and others (2,3). Other studies showed a higher incidence of breast cancer in women who chose surveillance over BRRM (4). Initially, however, this irrevocable surgical procedure was considered controversial, with various rates of uptake (5).

At the Karolinska University Hospital, a multidisciplinary group of specialists and nurses was founded in 1999 with a psychologist attached to the team. A contact nurse served as a liaison between the different specialists and the patient. Regular team conferences were established, and all cases identified either by mutation screening or by risk assessment instruments, initially by using Claus tables and later by BOADICEA, were discussed (6,7). Women opting for surgery were interviewed, and prospective trials started to evaluate complications and health-related quality of life before and after the surgeries. The aim of this paper is to describe the significant experiences and developments over more than 25 years and after approximately 700 procedures. During the last 5 years, approximately 50 women per year have been operated at Karolinska.

### Surveillance program

Initially, both women who were found to be at an inherited increased risk for breast and ovarian cancer and those who had been diagnosed with breast cancer were offered to participate in a surveillance program with regular controls, including (I) clinical breast examination, (II) mammogram and (III) ultrasound at regular intervals. To assess the sensitivity and specificity of the different modalities, 632 women at high risk from the hereditary cancer clinics in Stockholm were followed from 2002–2012. Any women with an estimated high risk, proven mutation carriers, and women with a history of breast or ovarian cancer who were five years disease free and had a normal mammogram one-year pre-study were eligible for inclusion. All screening modalities were blinded, coded and assessed. After 5 screening rounds, the clinical breast exam was deemed insufficient and not relevant as a screening modality. Ultrasound was found to be superior to mammography. When MRI became clinically available, it was added to the surveillance program. The screening program has thereafter been modified. Currently, the recommendations from the hereditary cancer clinic for women at elevated risk for breast cancer state that asymptomatic individuals with a known mutation in the *BRCA1*, *BRCA2*, *PALPB2*, *CHEK2* or *ATM* gene should be offered imaging with mammography and ultrasound at six-month intervals and yearly MRI. Carriers below the age of 30 undergo ultrasound and MRI at the same intervals. Those with an intermediate life time risk of 20–29% according to BOADICEA and with no proven mutation are offered yearly mammography and ultrasound (8).

### Preoperative counselling

From the beginning of the program, it was obvious that emotional support to the women at high risk was needed and that individualized preoperative information regarding surgical options had to be given. Over time, the information has become structured and is addressed in a stepwise fashion, as the women's psychological readiness for understanding the risk and the consequences of the surgical procedure varies. From the start, the multidisciplinary team included a psychologist, with whom all women were offered contact. The psychologist assessed the expectations of the women and their psychosocial situations. Communication regarding risk was done by professional genetic counsellors. All cases were discussed in the multidisciplinary team before risk-reducing surgery was offered, after a unanimous decision. At a first joint appointment with the breast surgeon and plastic surgeon, women were informed about the possibility of BRRM, and meticulous information about risks and benefits with the procedure was given. Patient photographs pre- and postoperatively were shown to serve as a model for what could be expected in their case. A contact nurse was the core manager of the team and was readily available for any woman who needed more information or support. This structured approach with a contact nurse as a navigator for the patient and the team is still our *modus operandi*. All women are seen in the hereditary cancer clinic once after genetic testing and workup for information regarding risk estimation, mutation analysis (if done) and information about self-examination. If any breast symptoms are present, they are referred to a breast unit. Discussion regarding BRRM is undertaken if the estimated life time risk is beyond 24% and the woman has proven mutation carrier status. All women eligible for surgery are discussed at regular multidisciplinary conferences, after which they are offered a first surgical appointment with a plastic surgeon to discuss possible reconstructive options. Very rarely, a woman opts to undergo mastectomy only.

### Technical aspects of BRRM

The team approach for mastectomy and breast reconstruction has prevailed since the start. Breast surgeons and plastic surgeons perform the mastectomy and reconstruction as one team, except in cases where autologous flaps are employed with microsurgical techniques. Extreme care to remove all breast tissue has always been a cornerstone, sometimes with the cost of very



**Figure 1** Before and one year after BRRM using mastectomy incisions, reconstruction with expander implants, nipple re-grafting and tattoo of the areola. BRRM, bilateral risk-reducing mastectomy.

thin skin flaps, 0.5 to 1 cm thickness. Still, no mastectomy can be sure to be one hundred percent complete, an important fact conveyed to every woman undergoing BRRM.

### *Mastectomy*

Conventional mastectomy incisions were used in the beginning, and the nipple areola complex (NAC) was removed. The nipples were re-grafted after securing a specimen from the base. If premalignant or malignant features were found in the nipple base biopsy, the nipple was later removed. We have not at any time used frozen sections (*Figure 1*).

Satisfactory results were obtained in the majority, but graft failure of the nipple sometimes occurred, and the reconstructed and tattooed NAC would then have an unnatural appearance. Gradually, more skin-saving NAC-sparing procedures came into use, and an upper areola incision, sometimes Omega-type or with a lateral extension, became the standard technique for women with small to average-sized breasts. In cases of larger breast volumes or skin excess, Wise pattern incisions were performed (*Figure 2*). Nipple-sparing mastectomy incisions close to the areola may result in scars that retract the NAC from its natural position. They may also impair the blood supply and thus increase the risk of necrosis of the areola or depigmentation (*Figure 3*). At present, most BRRMs are performed through inframammary incisions, which

seem to give the most natural breast appearance with a less obvious scar (*Figure 4*). This technique is technically more challenging, especially for reaching the axillary tail. In a medium-sized breast, a lateral lazy-S incision may allow for a technically easier mastectomy.

### *Reconstruction*

Expander implants have been the foremost commonly used reconstruction mode with a submuscular placement and total muscular coverage by the pectoralis major and serratus muscle. Tattooing of the areolae and removal of the filling ports have been done as outpatient procedures under local anesthesia. Revision surgeries have been frequent due to unanticipated procedures such as capsular contracture, the need for adjustment of implant position and size or implant loss due to infection or flap necrosis. In a national audit including 223 Swedish women who had undergone BRRM from 1995 to 2005 with a mean follow-up of 6.6 years, the implant loss was 10 percent, and 64 percent of the women underwent unanticipated secondary surgeries (9).

At present, submuscular placement of microtextured anatomical implants with muscle cover, but when possible only serratus anterior fascia for lateral cover, as a one-stage procedure has become the standard technique for breast sizes up to an estimated breast volume of approximately 300–350 cc. This often results in high patient satisfaction and is cost-saving. Permanent expandable anatomical implants are used for larger and/or ptotic breasts with



**Figure 2** Patient with a history of reduction mammoplasty and massive weight loss before and after BRRM using Wise pattern incisions, reconstruction with expander implants, nipple re-grafting and tattoo of the areola. BRRM, bilateral risk-reducing breast surgery.



**Figure 3** After upper areola incision, deformation and postoperative depigmentation of the areola.

excess skin and continue to be a greater surgical challenge with a higher risk for complications. Combining the Wise pattern incision with the use of an autologous dermal sling can improve the aesthetic results because the NAC can sometimes be saved and repositioned on a dermal pedicle (*Figure 5*). We rarely use acellular dermal matrices or meshes. The technique has been evaluated by our unit in a recently published randomized trial for breast cancer patients using a porcine ADM, showing more adverse

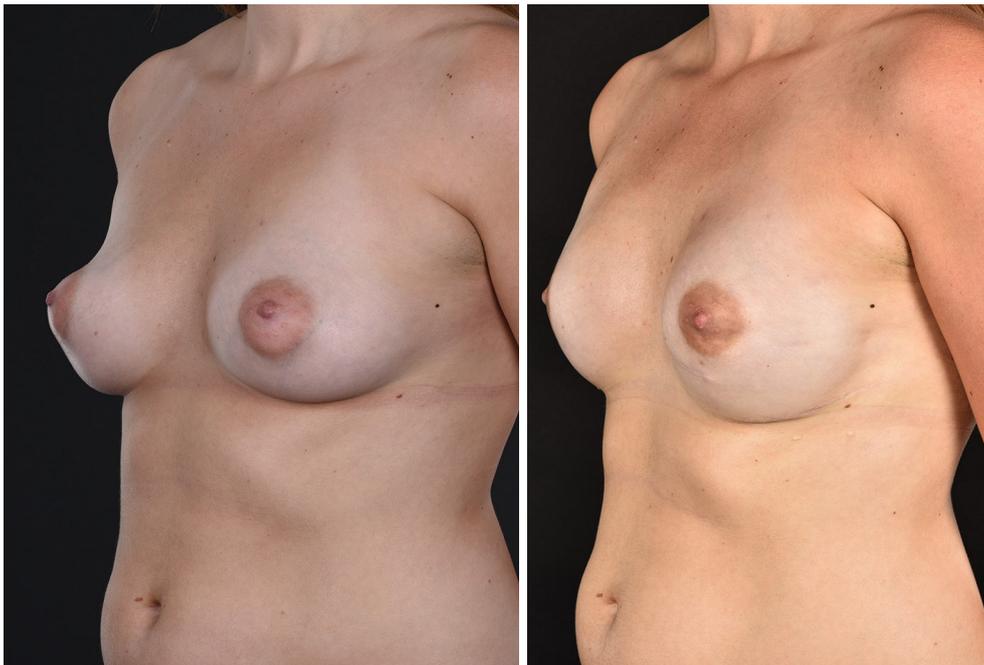
complications associated with the use of ADM (10). We have not used pre-pectoral implant positioning in BRRM patients because the long-term result of this reconstruction is still unclear, and the technique also includes the use of a large piece of ADM. Breast reconstruction using implants in young and middle-aged women is a procedure that will necessitate future surgery because of capsule formation and bodily changes in the individual. This is important to address in the preoperative information given.

#### *Autologous reconstruction*

In selected cases, autologous reconstruction is done, mainly using deep inferior epigastric perforator (DIEP) flaps. This technique is highly preferred for women with previous radiotherapy to the chest wall, as implant reconstruction often gives less satisfactory results due to capsular contracture (*Figure 6A,B*). In 2018, 13 percent of the BRRMs at the Karolinska were autologous, and the demand is increasing. Autologous fat transplantation has been used with good results in women with subcutaneous irregularities after mastectomy and reconstruction but often requires several sessions (11).

#### **Management of postoperative pain**

The placement of an implant behind the pectoralis major muscle causes pain and discomfort with unsatisfactory



**Figure 4** Before and after BRRM with inframammary incisions and permanent implants. BRRM, bilateral risk-reducing breast surgery.



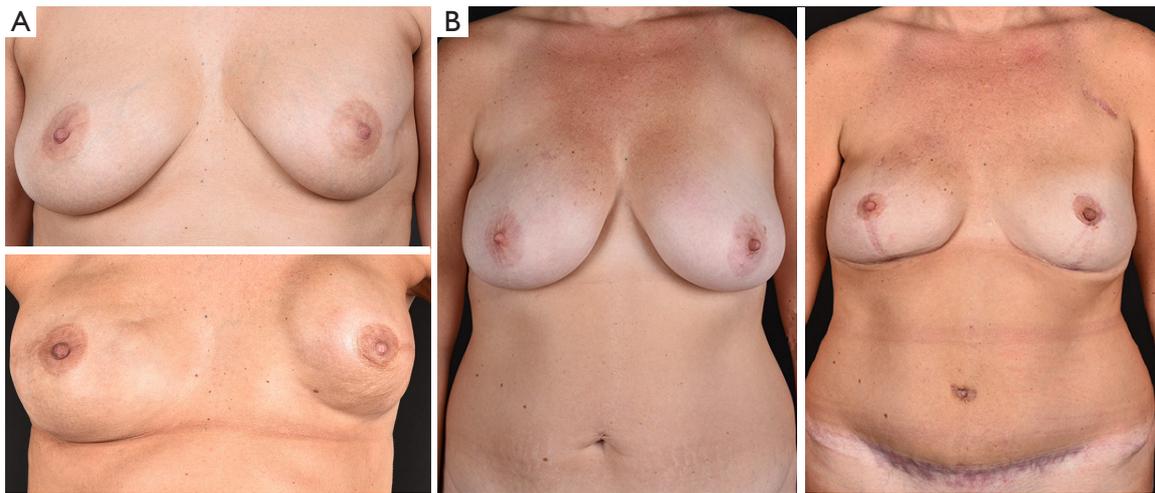
**Figure 5** After BRRM using Wise pattern incisions, the nipple-areola complex saved and repositioned on a dermal pedicle. BRRM, bilateral risk-reducing breast surgery.

outcomes using opioids and paracetamol only. In a series of studies including randomized trials, it was concluded that self-administered opioids were not safe during the postoperative period and in the long term the addition of long-acting local anesthetics was superior and effective in pain control and in reducing opioid consumption (12). The addition of non-steroidal anti-inflammatory drugs (NSAIDs) further improved pain control, but when used continuously with patient-controlled analgesia (PCA pumps), more bleeding occurred (13). For almost 20 years, indwelling catheters with solely ropivacaine became routine and further

reduced the opioid consumption (14). Currently, our pain management regime includes the pectoralis and serratus blocks administered perioperatively by the surgical team, gabapentin for 2–3 days during the peri- and postoperative period, and paracetamol and coxibs. Opioids are used cautiously due to side effects and are rarely needed after the first few days. Hospital stay has been reduced from 5–7 to 2–3 days.

### Safety of procedure and regional differences

The goal of BRRM is that the patient be saved from breast cancer. A national inventory commissioned by the Swedish Oncogenetic Group invited all participating university units to contribute clinical information of high-risk and proven mutation carriers who had undergone BRRM. From 1995–2005, 223 cases were reported from eight Swedish units. All cases had an increased risk of breast cancer proven by mutation screen or by risk assessment analyses. The majority were done in 2/8 units, and patients from Karolinska dominated. One case of disseminated cancer was reported during the follow up, and very few serious complications occurred. Implants were predominantly used. At that time, only one unit performed autologous reconstructions (9).



**Figure 6** Breast reconstruction after radiotherapy. (A) Patient with a history of breast cancer on the left side, treated with breast-conserving mastectomy and radiotherapy. Before and after BRRM and reconstruction with implants, capsular contraction on the irradiated side. (B) Patient with a history of breast cancer on the right side, treated with breast-conserving mastectomy and radiotherapy. Before and after BRRM and reconstruction with bilateral DIEP flaps. BRRM, bilateral risk-reducing breast surgery; DIEP, deep inferior epigastric perforator.

### Quality-of-life studies and patient-reported outcomes after BRRM

The risk of having breast cancer can be effectively reduced by RRM, and a recently published Cochrane analysis confirms this, though prospective studies are warranted (15). The medical community initially raised concerns over this radical approach. The “Angelina Jolie effect” later had a massive impact on mainly consumer-driven requests for genetic testing and increased public knowledge about RRM (16,17). How the surgery affects the individual who has undergone this radical approach and experiences her changed body every day was equally important to evaluate. Several quality-of-life studies with patients’ self-reported outcomes and experiences (PROM and PREM) were performed. Having a clinical and academic psychologist on the team facilitated the prospective and retrospective trials from the start of the structured care process and onwards (18-23). Both quantitative and qualitative studies of these women in the short and long term contributed knowledge to the clinical management and nursing, as it became evident that information was lacking and that women needed time to decide and to mourn the breast loss. Further, it was important to maintain realistic expectations of the procedure. Findings from our studies have been corroborated by others: women are less anxious after BRRM, and their QOL is not affected (24).

When asked specifically about bodily symptoms, women report loss of sensibility in the short and long term, a sense of being uncomfortable in intimate situations, loss of sensitivity in the breast, negatively affecting sexual pleasure after BRRM, and the texture of the breast being hard (20,25-28). These findings are also in line with other studies (29-31). However, we have not encountered patients who strongly regret their decision to undergo BRRM, and in general, patients are satisfied with the procedure.

### Summary

During a 25-year period of managing this challenging asymptomatic but psychologically affected patient group, several important steps have been taken. From the patients, a wealth of knowledge has emerged that has enabled adjustments in nursing. Technical advances in devices and surgical performance skills together with experience have led to a more tailored approach. The hospital stay has almost halved, and most patients resume work after four to six weeks. Revision surgeries over the long term due to capsule formation and patients’ bodily changes are necessary. Risk-reducing mastectomy is a procedure limited to a restricted group of patients at a substantially high risk of getting breast cancer who should be well informed and counselled and managed by a dedicated team that also audits the results (*Table 1*).

**Table 1** Lessons learned

Indications for RRM—strict and according to guidelines for women at high risk for breast cancer. Discussed in multidisciplinary teams
Preoperative assessment and information—assure that patients are well informed and evaluated regarding expectations of the procedure, including their psychosocial situation. RRM is not an emergency procedure
Perioperative management—use a standardized pain regimen, use opioids sparingly
Surgical and reconstructive technique—tailored to the native breast volume and shape. Perform a safe mastectomy to assure maximum glandular excision and avoidance of flap necrosis. Inframammary incisions preferred but technically more challenging. Provide the possibility of both implants and autologous reconstructive techniques. Should be performed by a dedicated surgical-reconstructive team
Postoperatively—audit results

RRM, risk-reducing mastectomy.

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