

Correct information to patients undergoing breast-conserving surgery: the medicolegal significance

A. SANGUINETTI, A. POLISTENA, R. LUCCHINI, M. MONACELLI,
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SUMMARY: Correct information to patients undergoing breast-conserving surgery: the medicolegal significance.

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Many of the women newly diagnosed with breast cancer not have access to all the information they need to make the surgical and treatment choices that are most appropriate for them. Research clearly shows

that lumpectomy and other breast-conserving surgeries are just as safe as mastectomy for most women with early stage disease, and yet approximately half will undergo the more disfiguring procedures, but many healthy women who have strong family histories of breast cancer consider prophylactic mastectomies, and their decisions are also based on very limited information, because there are few studies showing the effectiveness of that procedure. This paper delineates how to avoid limited information and biased recommendations is important for a conscious and informed choice by the patients.

KEY WORDS: Breast cancer - Informed consent - Surgical treatment.

Introduction

Breast cancer is the most common malignancy in women in Italy; more than women who are newly diagnosed breast cancer not have access to all the information they need to make the surgical and treatment choices that are most appropriate for them. Unlike previous generations, most of these women who will have several choices to make, including the type of surgery, whether to have radiation, the type of adjuvant therapy (chemotherapy or hormonal therapy), and the type of reconstruction, if any. However, many of these women will not have access to all the information they need to make the choices that are most appropriate for them. There is considerable research evidence that where a woman lives, her income level and health insurance, the type of medical facility, when her doctor was trained, and the doctor's enthusiasm for breast-conserving surgery may have more impact on her surgical treatment than her specific diagnosis. For

example, research has clearly shown that most women who are diagnosed with noninvasive or early-stage breast cancer can be very safely and effectively treated with breast-conserving surgery, and this also applies for older women. And yet, so few women have this surgery that it raises questions about whether they are objectively informed about the advantages and disadvantages of their surgical options (1-4). In addition, the lack of research on some prevention and treatment options makes it impossible for many women to obtain the information they need to make fully informed choices. The purpose of this paper is to delineate how these and other choices made by many breast cancer patients may be based on limited information and sometimes biased recommendations, rather than the objective information needed for informed consent. Informed consent relies on a patient receiving accurate information and freely making a decision based on that information. To that order therefore the doctor must not only diligently perform medical care, but also provide the patient with adequate and complete information so that they can express informed consent. It need to have the information that the consent be properly documented in order to be able to prove compliance with the obligation of information and be produced in the possible lawsuits brought by the patient. The doctor, therefore, must provide the patient with the most appropriate information required for diagnosis, pro-

University of Perugia, Medical School, Endocrine Surgery Unit,
"S. Maria" University Hospital, Terni, Italy

Corresponding author: Alessandro Sanguinetti,
e-mail: sanguinettiale@gmail.com

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gnosis, the prospects and the possible diagnostic and therapeutic alternatives and the foreseeable consequences of the choices; when informing the doctor must take into account the ability to understand, in order to promote their maximum adherence to diagnostic and therapeutic proposals. Any further request for information from the patient must be satisfied.

Breast-conserving surgery

The doctor should therefore inform the patient about his condition: diagnosis and prognosis, proposed treatment, postoperative course expected and possible recovery problems, potential benefits and possible problems (complications) of the proposed treatment, alternatives to the proposed treatment, chances of success of the proposed treatment, organizational deficits of the hospital, including in relation to possible complications, possible outcomes of non-treatment; and lastly the consequences (evolution, complications) of the disease in the event of rejection of the proposed treatment. Appropriate selection of candidates for breast conserving therapy requires a multidisciplinary approach to breast cancer care, including close collaboration between the breast surgeon, radiologist, and radiation oncologist, and when appropriate, the medical oncologist, genetic counselor, and plastic surgeon (surgeon that performs breast reconstruction and breast reshaping procedures) (5). Working together, they will ensure that a complete preoperative assessment has been performed, that the patient is fully informed of her treatment options, and that breast conserving therapy, if performed, is completed with the highest chances of success.

The primary objectives of breast conserving therapy are both cancer control and cosmetic:

- removing of the breast cancer;
- achieving “clear” or “negative” surgical margins, meaning that the removed cancer is surrounded by a rim of normal tissue that does not contain cancer cells;
- achieving a breast cosmetic result that is acceptable to the patient;
- reducing the risk of local recurrence within the breast by the addition of breast radiotherapy.

Establishing a precise diagnosis of malignancy using a needle biopsy is an essential diagnostic step in the preoperative evaluation of any breast abnormality. A preoperative tissue diagnosis enables a fully-informed discussion of the patient’s surgical options, decreases the risk of a positive surgical margin, reduces the total volume of tissue that would be removed from multiple incomplete attempts to remove the cancer, and enables coordination of lymph node surgery among other benefits (6). Needle biopsy should also be followed by pla-

cement of a X-ray visible biopsy site marker (commonly called clip) to facilitate precise localization and complete removal of an abnormality that might become less apparent on the mammograms due to inflammation, bruising caused by the needle biopsy procedure, or from near-complete removal of the abnormality. The cosmetic outcome is influenced by the surgeon’s skill as well as a variety of patient-specific and tumor-specific factors. Skilled breast surgeons have special techniques that are capable of overcoming many of these challenges to achieve a result that is acceptable to the patient. For example, breast conserving surgery may be combined with a breast lift and/or breast reduction procedures to both breasts to improve breast appearance and symmetry. However, these requirements are largely a function of breast size and tumor location. Small breast volume or unfavorable tumor location can produce unacceptable cosmetic results for even a small cancer, while larger breast volume may easily accommodate excision of a large malignancy (7, 8). Use of preoperative chemotherapy or preoperative endocrine therapy may shrink a tumor to a smaller size to make breast conserving therapy possible or more easily achievable. Breast conserving therapy is generally prohibited during the first and second trimesters of pregnancy since radiotherapy would have a harmful effect on the fetus. Nevertheless, selective use of preoperative chemotherapy during the second or third trimesters may preserve the option of breast conserving therapy in a motivated patient if radiotherapy is administered following childbirth (9). In addition, the presence of two or more cancer sites in different quadrants of the breast prevents breast conserving therapy due to concerns that extensive cancer might be present. Widespread suspicious microcalcifications calcium deposits are another barrier to breast conserving therapy due to the difficulty of reliably excluding residual or recurrent disease. For the same reason, a persistently positive or “unclear” margin following unsuccessful breast conserving surgery prevents successful breast conserving therapy. Occasional barriers to breast conserving therapy have traditionally included a history of collagen-vascular disease due to the higher risk of wound complications (10, 11). Multifocality is often considered a barrier to breast conserving therapy, but many patients with limited areas of multifocal disease are able to undergo successful breast conserving therapy if the volume of disease is small compared to the overall breast volume. They may also benefit from oncoplastic breast conserving techniques that combine wide local excision with breast remodeling or reshaping procedures (12, 13). For a good informed consent, it is very important to explain to patients how useful the preoperative localization of the lesion. Needle biopsy should also be followed by placement of a X-ray visible biopsy site marker (commonly clip) to facilitate precise localization and complete re-

removal of an abnormality that might become less apparent on the mammograms due to inflammation, bruising caused by the needle biopsy procedure, or from near-complete removal of the abnormality. Another topic should not be absolutely neglected is related to the importance of surgical margins, and how judging the enough adequate margin. About that, the current consensus view is that a clear margin is achieved when no cancer cells are present at the edge of the removed tumor (*specimen*). On the other hand, an “involved” or “positive” margin is defined as the presence of one or more tumor cells at the edge of the specimen, which raises concerns that tumor cells might have been left within the breast. Positive margins are commonly reported to occur in 20-30% of women undergoing breast conserving surgery, requiring a repeat operation for removal of residual cancer. However, due to thorough pre-operative planning, expert surgical technique, and intraoperative specimen evaluation, rate of positive margins is less than 10%. It is important to understand that even clear margins, do not completely ensure that no tumor cells remain behind in the breast. That’s why breast radiotherapy is needed to control remnant cancer cells that may remain in the breast. Another key element to be addressed in the therapeutic treatment of communication is the possibility and usefulness of pre-operative chemotherapy; multiple studies have demonstrated the ability of preoperative chemotherapy therapy to reduce the size of a cancer that would otherwise be difficult to remove with breast conserving surgery. Consequently, preoperative chemotherapy (neoadjuvant chemotherapy) should be considered in the management of relatively large breast malignancies when breast conserving therapy is desired. Pre-treatment placement of a biopsy site clip within the tumor will aid removal of cancers that might become difficult to feel or see following preoperative chemotherapy. Some tumors may shrink in a symmetrical and concentric manner that greatly facilitates removal using breast conserving surgery (14). About the actual surgical treatment itself, patients should be informed about the 1) type of anesthesia used, 2) possible intraoperative treatment (IORT), and 3) esthetic surgical results.

1) Breast conserving surgery is most commonly performed under general anesthesia supplemented with injection of local anesthesia into the breast. However, under certain circumstances, the procedure may be performed using local anesthesia following administration of a sedative. In either case, injection of sufficient short and long-acting local anesthetics in the skin and in the breast tissue surrounding the surgical site provide prolonged analgesia that will improve patient’s comfort during the initial post-operative recovery period (15).

2) Accelerated partial breast irradiation (APBI) is based on the concept that most breast tumor recurrences

develop within the original tumor bed (16, 17). Focused specifically on the site of the original cancer, APBI provide radiation therapy over smaller volume of the breast and over a shorter period of time (usually less than 1 week). As a result, APBI has increased the acceptability and convenience of breast conserving therapy that traditionally takes up to 6-7 weeks to complete. A number of techniques have been developed to administer APBI, including intracavitary, interstitial, 3-D Conformal, and intraoperative approaches. Each is currently the subject of ongoing research comparing the effectiveness and safety of APBI to standard 6-7-week post-operative whole breast external beam radiotherapy. Five-year follow-up of a randomized controlled trial showed equivalent effectiveness and safety between intraoperative radiotherapy and standard 6-7 week post-operative whole breast external beam radiotherapy (18). APBI requires device-specific adjustment of the breast conserving surgical technique to prepare the breast for radiotherapy treatment delivery. Intraoperative radiotherapy typically requires temporary placement of sutures in the interior of the breast to hold the cavity edges against the radiotherapy device that is inserted into the same open wound. Intraoperative radiotherapy is entirely completed during surgery over 20-30 minutes while the patient is asleep. No radiotherapy device remains in the breast after breast surgery, and no further radiotherapy is usually required after surgery.

3) Breasts are naturally unequal in most women. However, breast asymmetry may become much more pronounced after from breast conserving surgery and potentially have a negative impact on overall breast appearance. Strategies to improve breast symmetry include lifting and/or reducing the opposite breast to improve breast symmetry (19). Lift or reduction of the opposite breast can be performed at the time of the original breast conserving surgery or at a later operation, but should anticipate that the cancer-affected breast will usually experience further shrinkage after treatment with whole breast radiotherapy. A less commonly utilized alternative to lifting or reducing the opposite breast surgery is partial breast reconstruction of the affected breast using tissue from the nearby chest or back (20). Finally, patients should be informed about the potential complications and side effects of this type of surgery well as their implications in percent. A thorough discussion of the benefits, risk, and alternative of breast conserving surgery should include a review of the potential side effects and complications of breast conserving surgery. Accumulation of watery fluid collections called seromas are the most common side effects after breast conserving surgery. Seromas typically cause no symptoms and disappear as the wound heals. However, some seromas may cause discomfort or pain if they get quite large, and can be treated by aspiration or drain-

nage with a syringe and needle. Wound infections may occur in up to 5% of patients undergoing breast conserving surgery and is usually managed by oral antibiotics. Mild bruising is common after breast conserving surgery and goes away after a week or two. Marked bruising might indicate the presence of a hematoma, a buildup of blood in the surgical cavity. Hematomas occur in less than 5% of patients and usually require treatment in surgery to remove the accumulated blood and to ensure that bleeding has stopped. Patients should also be informed about the potential need for re-operation if clear surgical margins cannot be achieved at the time of breast conserving surgery. This might require repeat breast conserving surgery to remove additional tissue or mastectomy if breast conserving surgery cannot be successfully achieved. Short-term and long-term breast pain is usually mild and usually gets better as the wound heals. However, occurs shooting pains may occur in the breast up to 1 year or more after surgery. This is usually caused by healing nerves. Loss of skin or nipple sensation is also a possible side effects of surgery when tiny nerves to the skin are cut during tumor removal. Thickened scars are more common in women with darker skin pigmentation or a history of excessive scarring, but thickened scars may develop in anyone. Your previous pattern of healing is the best predictor of what you should expect after breast conserving surgery. Various over-the-counter scar preparations may be used to reduce scar formation. Low doses of radiation to the skin may also reduce scarring in women with a history of keloid formation. Moderate fatigue is a common complaint after whole breast radiotherapy but does not appear to be a prominent feature of accelerated partial breast irradiation. Breast radiotherapy may also cause breast swelling, skin darkening, skin peeling, and breast tissue fibrosis or hardening (21). All of these symptoms improve over time.

Discussion

Informed consent for breast-conserving surgery and reconstructive surgery is limited partly because physicians themselves lack the information they need to appropriately inform their patients. In all these situations, informed consent should focus on what is not known about long-term risks in addition to what is known about failure rates and local complications. Physicians should provide as much objective information as possible, including long-term follow-up data from their own patients. Signed consent forms provide liability protection and meet research requirements by giving detailed descriptions of the risks, known and unknown. In contrast, health professionals' oral explanations of risks and benefits may be inconsistent with their own written ma-

terials. To improve informed consent for breast cancer patients, we need more information about the process of decision making. It is certainly likely that some women who are accurately and persuasively told that lumpectomies are as safe as mastectomies will choose mastectomies, and that some women who have mastectomies will choose reconstruction even if told that there are serious short-term risks and that the long-term risks are unknown. However, it is likely that better information will change the current pattern of high rates of unnecessary mastectomies followed by reconstruction. Acquisition of informed consent, for Italian case-law, is necessitated by the fact that medical treatment (properly performed) causes more damage to the patient's physical integrity (removal of an organ, amputation of a limb, the post-operative period), then integrates it objectively, the crime of personal injury. Psychologically, the doctor represents and wants this injury (the removal of an organ, amputation of a limb, the postoperative course) then act with malice. Furthermore, the purpose of the incrimination for the crime of intentional personal injury, is irrelevant that the aim of treatment is to treat a disease and not the causation of harm to the patient. The patient's consent (operating as 'due of justification') makes it permissible to the medical act. So, either without the consent or the same is not valid, the doctor responsible for the crime of intentional personal injury (unless acted out of necessity or implementation of a Compulsory Health Treatment). If, then, the injury comes the patient's death - as in this case - doctor is liable for involuntary manslaughter. About the nature of this obligation must be stated that, passed the case law according to which the failure to fulfill its nature would result in pre-contractual liability (Cass. n. 10014/94), it should more properly be framed in contractual obligations. In fact, the professional medical activity qualifies as a complex service that includes a diagnostic phase and therapeutic, and it is after the first doctor-patient contact that places the information requirement, aimed at obtaining the associate membership of the patient to therapy and to proposed treatments. Thus, the breach of duty on the part of the medical information gives rise to a breach of contract, namely a breach of accessory obligation (Cass Information. 7027/2001). In any case, not to incur any liability in negligence, the doctor must exercise due diligence in the patient information process. Compliance with the guidelines issued by the hospital tends to be sufficient to exclude the responsibility of the physician profiles, unless they are wrong to the extent that they can (and have to) be perceived through the basic knowledge that any doctor must possess. However, if your doctor is aware that in the case in the application of the guidelines simply should not endeavor to ensure effective patient education.

Ethical approval

For this type of study formal consent is not required.

Conflict of interest

The Authors declare that they have no conflict of interest.

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