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

A. SANGUINETTI, A. POLISTENA, R. LUCCHINI, M. MONACELLI, S. AVENIA, S. GALASSE, R. CIROCCHI, N. AVENIA

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

Many of the women newly diagnosed with breast cancer do 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 do 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 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-
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 placement 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 incomplete 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-
Correct information to patients undergoing breast-conserving surgery: the medicolegal significance

moval 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 drai-
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 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 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 the breach of duty on the part of 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, to not 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.
Correct information to patients undergoing breast-conserving surgery: the medicolegal significance

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.

References

1. Guadagnoli E, Weeks JC, Shapiro CL, Gurwitz JH, Borbas C, Soumerai SB. Use of breast-conserving surgery for treatment of stage I and stage II breast cancer. J Clin Oncol. 1998;16:101-106.
2. Kotwall CA, Covington DL, Rutledge R, Churchill MP, Meyer AA. Patient, hospital, and surgeon factors associated with breast conservation surgery: A statewide analysis in North Carolina. Ann Surg. 1996;224:419-426.
3. Tarbox BB, Rockwood JK, Abernathy CM. Are modified radical mastectomies done for T1 breast cancers because of surgeon’s advice or patient’s choice? Am J Surg. 1992;164:417-420.
4. Dolan JT, Granchi TS. Low rate of breast conservation surgery in a large urban hospital serving the medically indigent. Am J Surg. 1998;176:520-524.
5. Hulvat MC, Hansen NM, Jeruss JS. Multidisciplinary care for patients with breast cancer. Surg Clin North Am. 2009 Feb;89(1):133-76, ix.
6. Silverstein MJ, Lagios MD, Recht A, et al. Image-detected breast cancer: state of the art diagnosis and treatment. J Am Coll Surg. 2005;201:586-597.
7. Exner R, Krois W, Mittlböck M, Dacic S, Jakesz R, Gnant M, Fitzal F. Objectively measured breast symmetry has no influence on quality of life in breast cancer patients. Eur J Surg Oncol. 2012 Feb;38(2):130-6.
8. Cancer Genome Atlas Network. Comprehensive molecular portraits of human breast tumours. Nature. 2012 Oct 4;490(7418):61-70.
9. Hahn KM, Johnson PH, Gordon N, Kuerer H, Middleton L, Ramirez M, Yang W, Perkins G, Hortobágyi GN, Theriault RL. Treatment of pregnant breast cancer patients and outcomes of children exposed to chemotherapy in utero. Cancer. 2006 Sep 15;107(6):1219-26.
10. Chen AM, Obedian E, Haffty BG. Breast-conserving therapy in the setting of collagen vascular disease. Cancer J. 2001 Nov-Dec;7(6):480-91.
11. Kontos M, Fentiman IS. Systemic lupus erythematosus and breast cancer. Breast J. 2008 Jan-Feb;14(1):81-6.
12. Holmes DR, Schooler W, Smith R. Oncoplastic approaches to breast conservation. Int J Breast Cancer. 2011;2011:303879.
13. Salmon RJ, Remvikos Y, Campana F, Languille O, Magdalena H, Asselain B, Clough KB; Breast Group of the Institut Curie. Neo adjuvant Tamoxifen in post menopausal patients with operable breast cancer. Eur J Surg Oncol. 2003 Dec;29(10):831-4.
14. Itakura K, Lessing J, Sakata T, Heinzerling A, Vriens E, Wisner D, Alvarado M, Eiserman L, Ewing C, Hylton N, Hwang ES. The impact of preoperative magnetic resonance imaging on surgical treatment and outcomes for ductal carcinoma in situ. Clin Breast Cancer. 2011 Mar;11(1):33-8.
15. Riezebos PM, Snoeck MM, Kleine Koerkamp HJ, Strobbe LJ. A field block for breast cancer surgery: technical aspects and a pilot study. Breast J. 2011 Sep-Oct;17(5):550-2.
16. Shah C, Khileian M, Arthur D, Wilkinson JB, Keisch M, Chen P, Vigini FA. Initial clinical experience with multilumen brachytherapy catheters for accelerated partial breast irradiation. Brachytherapy. 2012 Sep-Oct;11(5):369-73.
17. Vaidya JS, Baum M, Tobias JS, Wenz F, Massarut S, Keshtgar M, Hilaris B, Saunders C, Williams NR, Brew-Graves C, Córtica T, Roncadin M, Kraus-Tiefenbacher U, Sütterlin M, Bulsara M, Joseph D. Long-term results of targeted intraoperative radiotherapy (Targit) boost during breast-conserving surgery. Int J Radiat Oncol Biol Phys. 2011 Nov 15;81(4):1091-7.
18. Vaidya JS, Bulsara M, Wenz F. Ischemic heart disease after breast cancer radiotherapy. N Engl J Med. 2013 Jun 27;368(26):2526-7.
19. Hernanz F, Regaño S, Vega A, Gómez Fleitas M. Reduction mammaplasty: an advantageous option for breast conserving surgery in large-breasted patients. Surg Oncol. 2010 Dec;19(4):e95-e102.
20. Munhoz AM, Aldrighi CM, Aldrighi JM. Is necessary the participation of the surgeon plastic in the programming of the surgery conservative of the breast neoplasm? Rev Assoc Med Bras. 2005 Jan-Feb;51(1):5-6.
21. Yi A, Kim HH, Shin HJ, Huh MO, Ahn SD, Seo BK. Radiation-induced complications after breast cancer radiation therapy: a pictorial review of multimodality imaging findings. Korean J Radiol. 2009 Sep-Oct;10(5):496-507.