Ann Surg Oncol (2016) 23:3133–3137
DOI 10.1245/s10434-016-5369-y

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

Breast Conservation Therapy Versus Mastectomy: Shared Decision-Making Strategies and Overcoming Decisional Conflicts in Your Patients

Julie A. Margenthaler, MD, FACS[1] and David W. Ollila, MD, FACS[2]

[1]Department of Surgery, Washington University School of Medicine, St. Louis, MO; [2]Department of Surgery, University of North Carolina, Chapel Hill, NC

ABSTRACT Although breast-conserving therapy is considered the preferred treatment for the majority of women with early-stage breast cancer, mastectomy rates in this group remain high. The patient, physician, and systems factors contributing to a decision for mastectomy are complicated. Understanding the individual patient's values and goals when making this decision is paramount to providing a shared decision-making process that will yield the desired outcome. The cornerstones of this discussion include education of the patient, access to decision-aid tools, and time to make an informed decision. However, it is also paramount for the physician to understand that a significant majority of women with an informed and complete understanding of their surgical choices will still prefer mastectomy. The rates of breast conservation versus mastectomy should not be considered a quality measure alone. Rather, the extent by which patients are informed, involved in decision-making, and undergoing treatments that reflect their goals is the true test of quality. Here we explore some of the factors that impact the patient preference for breast conservation versus mastectomy and how shared decision-making can be maximized for patient satisfaction.

Breast-conserving therapy (BCT), which includes wide local excision of the tumor followed by irradiation, has become the standard treatment option for women with early-stage invasive breast cancer. Long-term survival following BCT has been shown to be equivalent to that of mastectomy, while also providing an acceptable cosmetic outcome and low morbidity.[1]These results have been corroborated in 5 major prospective, randomized controlled trials in Europe and North America, including the National Cancer Institute (NIH) trial, the European Organization for Research and Treatment of Cancer (EORTC) 10801 trial, the Danish trial, the French trial, and the Italian trial.[2–6]

The decision confronting early-stage breast cancer patients about the disparate surgical treatment options, with statistically equivalent overall survival rates, is actually very complex. In addition, it comes at a time that is emotionally charged when communication between the health care team and the patient can be difficult. Because most patients with early-stage breast cancer are clinically eligible for either surgical option, the decision about type of surgery is considered "preference-sensitive" because the best choice is dependent on the patient preference.[7] Unfortunately, this also tends to create more "decisional conflict" whereby the patient experiences discomfort and doubt as a result of uncertainties in making a preference-sensitive choice.[8]

For the undecided patient, some will choose BCT if educated about their choices and given proper time for decision-making. Conversely, some women once presented the data and given time to make an informed decision prefer mastectomy. How is this possible? Collins et al. prospectively studied patients eligible for BCT and provided a standardized decision support before the surgical consultation.[9] They identified 3 treatment outcomes that discriminated between those choosing BCT versus mastectomy, including "remove breast for peace of mind," "avoid radiation," and "keep breast."[9] Understanding each of these values for the individual patient sitting in front of you provides a framework for shared decision-making.

First Received: 9 May 2016;
Published Online: 27 July 2016

J. A. Margenthaler, MD, FACS
e-mail: margenthalerj@wudosis.wustl.edu

WOMEN WHO PREFER MASTECTOMY

There are multiple reasons why women may choose mastectomy over BCT, but the predominant theme is that of "peace of mind."[10] Broderson and Siersma studied the short-term and long-term psychosocial impact of patients who were recalled for a false-positive screening mammogram. [11] Three years after the false-positive recall, women had consistently greater negative psychosocial consequences compared with women who had a normal mammogram without recall. This effect is surely magnified in the patient who has undergone previous BCT. Women may be less confident that screening and surveillance will be effective for them, especially if the cancer was not detected by routine screening tools. For a newly diagnosed breast cancer patient contemplating BCT, the psychological impact of future intensive surveillance, possible recalls from mammography, and potential future breast biopsies cannot be underestimated. Thus, peace of mind and elimination of screening, recall, and biopsy anxiety make mastectomy an attractive option.

Another important aspect is the motivation for avoidance of radiation therapy. Although the overwhelming majority of women who undergo BCT will never have an ipsilateral breast tumor recurrence (IBTR), the treatment repercussions can be numerous and are not trivial. Hill-Kayser et al. published patient-reported data on the late effects of adjuvant radiation therapy in a population of 354 lumpectomy patients.[12] Nearly 30 % reported fair or poor cosmesis, 48 % reported changes in texture and color of the irradiated skin, 35 % reported chronic pain, numbness, or tingling, and 30 % reported loss of flexibility in the irradiated area. The impact and fear of radiation-induced malignancies is also not trivial. Although they are rare complications in the era of modern radiation therapy, the morbidity and mortality outcomes of radiation-induced malignancies are devastating.[13]

Another significant factor in the rise of mastectomy for women with early-stage breast cancer is related to the increased availability of reconstructive procedures. The improvements in techniques, including advances such as nipple-sparing approaches, make mastectomy a more attractive option for many women. Wang et al. published their outcomes on 633 women undergoing 981 nipple-sparing mastectomies over an 8-year period.[14] Postoperative complications decreased over time with <5 % of patients experiencing major flap or nipple-areolar loss in the more mature period of the study. Over a 5-year period of time, there were only 3 % of patients who suffered a locoregional recurrence, and none of these was in the preserved nipple-areolar complex.[14] However, these procedures are not without their own inherent complications. One of the main arguments in favor of BCT is the lower surgical complications associated with it when compared with mastectomy or bilateral mastectomy.[15,16] In a study of more than 20,000 women in the American College of Surgeons' National Surgical Quality Improvement Program database, bilateral mastectomy was associated with longer hospital stays (adjusted odds ratio [aOR], 1.98–2.09; $p < .001$) and a higher transfusion rate (aOR, 2.52–3.06, $p < .001$) than unilateral mastectomy. Surgical site infections, prosthesis failure, and medical complications occurred at similar rates in the unilateral and bilateral mastectomy groups.[15] Delays to surgical and adjuvant treatment are significantly longer for patients undergoing bilateral mastectomy irrespective of reconstruction.[16] Thus, it is important to counsel patients on their individual risk factors and the realistic expectations of cosmetic outcome in their specific situation.

WOMEN WHO PREFER BREAST-CONSERVING THERAPY

Women who want to make an informed, shared decision because they highly value to "keep (the) breast" must understand the data and steps necessary to have successful BCT.[17] For BCT to be successful, 2 conditions must be met: It must be possible to (1) achieve negative surgical margins while maintaining cosmesis of the breast and (2) safely deliver radiation therapy. Failure to achieve tumor-free surgical margins is associated with higher rates of local recurrence.[17,18] Some women have opted for mastectomy simply because they only want 1 trip to the operating room. However, the definition of a "negative" margin has been a source of controversy, and many women have multiple trips to the operating room in an attempt to deliver "negative" margins. In 2014, to help clarify the margin width issue, The Society of Surgical Oncology and American Society for Radiation Oncology jointly published a meta-analysis of margin width and ipsilateral breast tumor recurrence (IBTR).[17,18] The authors demonstrated that tumor on ink had a 2-fold increase in IBTR compared with no tumors on ink. Furthermore, wider margin widths did not alter IBTR rates. This meta-analysis reinforced that no tumor on ink should be the goal for breast preservation candidates. The anticipated impact of the 2014 SSO-ASTRO consensus guidelines is a decrease in re-excision rates, fewer trips to the operating room, and therefore improved cosmesis.[17,18] Thus, more women can be successfully managed with BCT, if they so desire.

The second condition for BCT to be successful is adjuvant radiation therapy must be completed. Failure to complete adjuvant radiation therapy is also associated with higher rates of local recurrence. This has been demonstrated in prospective, randomized controlled trials as well as the Early Breast Cancer Trialists Group meta-analysis.[1–6,19–25]

Thus, women who embark on BCT must have access to and be committed to adjuvant radiation therapy. Otherwise, they are making an inferior oncologic choice.

The tumor size to native breast size ratio is a factor that impacts the ability to achieve successful BCT with an acceptable cosmetic result. The 2015 American Society of Breast Surgeons Consensus conference to reduce reoperation and improve cosmetic outcomes provided 10 tools.[26] Two tools, specimen imaging/surgeon review and an oncoplastic lumpectomy, both level 2A recommendations, could lead to more successful partial mastectomies in women who may have a borderline tumor/native breast ratio. Specimen imaging and surgeon review allow the operating breast surgeon to make intraoperative decisions and not just depend on a radiologist. Oncoplastic techniques allow larger amounts of breast tissue to be removed during the oncologic procedure while still preserving a high-quality cosmetic outcome.

Early-stage breast cancer patients must be presented the data, especially the SSO-ASTRO Consensus Statement on Margins and the ASBS Consensus Conference to reduce reoperation and improve cosmetic outcomes. Once presented this data, in an unbiased manner, informed patients can then make a decision that fits their desire to "keep (the) breast."[9].

SHARED DECISION-MAKING

The cornerstones of a shared decision-making process are education of the patient and communication. Lee et al. utilized a decision quality instrument to survey stage I–II breast cancer survivors and measure patient knowledge, concordance between goals and treatment, and involvement in decisions.[27] Of 444 patients, only 56 % knew that survival is equivalent between BCT and mastectomy. The majority (89 %) of patients had concordance with their goals, but patients who preferred mastectomy had lower concordance than those who preferred BCT (81 vs. 93 %, $p = .001$). Further, only 49 % of patients reported that their physician asked their preference for treatment. It is clear that patients who are provided a decision aid or tool have higher knowledge scores about their treatment options, have less decisional conflict, and are more satisfied with decision-making.[28]

The breast surgeon must also be aware of their own personal views and biases to make certain that they are providing the patient thorough knowledge about all of the options. One potential source of decisional conflict for the patient is the underlying bias of breast surgeons who tend to prefer BCT to mastectomy. In 1 population-based study of 1844 women, 41 % reported that they made the surgical treatment decision, 37 % reported that it was a shared decision with their surgeon, and 22 % reported that the surgeon made the surgical treatment decision.[29] Only 5 % of patients whose surgeon made the treatment decision underwent mastectomy, compared with 17 % when a shared decision was made, and 27 % when the patient made the treatment decision.[29] These findings are important because they contradict the notion that surgeons are overtreating women with early-stage breast cancer despite guidelines that favor BCT.[30] One argument for the regional variation in surgical treatment patterns is lack of involvement of patients in the decision-making process.[31] On the other hand, the Katz et al. data highlight the possibility that regional variation in treatment may be a result in variation in patient preference for mastectomy rather than lack of education and involvement of the patient in the decision process.[29] In fact, their data suggest that increasing patient involvement increases the mastectomy rates rather than decreasing them.

Given the complexity of the decision facing our patients, how can we determine whether treatment choices are being made that reflect their goals and values? Should we simply set a threshold level for BCT versus mastectomy rates as a quality measure and standard to which we must all adhere? To answer these questions it is important to define the quality measure and its intended purpose. Quality can be measured as an outcome or a process. Although outcome measures are preferred because they directly measure improvement in care, they are often limited by low event rates and the need for risk adjustment. The rate of BCT versus mastectomy would be better categorized as a process measure. Three criteria are used to evaluate a potential process measure. To become a process measure there must be: strong evidence that the care process improved outcomes, documentation that the evidence-based care process was provided, and implementation that has little or no chance of inducing unintended adverse consequences.[32] It would be relatively simple to capture whether the evidence-based care process was provided by simply measuring the individual surgeon rates of BCT versus mastectomy. However, the crude BCT versus mastectomy rates do not take into account individual surgeon and patient factors. Furthermore, the potential for unintended consequences is significant and, frankly, frightening.

In evaluating the use of BCT versus mastectomy rates as a quality measure, one can imagine several scenarios of how such a measure would be used. The most concerning of these is that it could become a public reporting tool aimed to help patients and payors make healthcare choices. However, an unintended consequence of this type of public reporting could lead surgeons to decline to treat certain patients who may tip their BCT/mastectomy balance adversely. At this time, we cannot support the use of BCT versus mastectomy rates as a quality measure because of the lack of a clear association with improved outcome for

individual patients. However, the use of internal measurements of these rates can help inform a physician and institution about their own practice patterns and biases.

For the individual patient faced with a new early-stage breast cancer diagnosis, the decision between BCT and mastectomy is difficult. We must educate patients about the equivalent survival outcomes between BCT and mastectomy and the side effects and complications of the surgical and adjuvant therapies recommended. The patient needs to be involved in the decision-making process and given the time to reflect on those choices so that the treatment selected reflects her personal values and goals. However, at the end of the day, we need to support and respect her decision. Measured maternalism/paternalism can aid the interaction, but ultimately it has little place in the breast surgeon's office. Instead, the ultimate goal is to deliver an unbiased view of the relevant data so that the patient can be empowered to reach a high-quality, shared decision.

REFERENCES

1. Fisher B, Anderson S, Bryant J, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Engl J Med.* 2002;347:1233–41.
2. Jacobson J, Danforth D, Cowan K, et al. Ten-year results of the National Cancer Institute's randomized trial of breast conservation versus mastectomy for stage I and II breast cancer. *N Engl J Med.* 1995;332:907–11.
3. Van Dongen JA, Voogd AC, Fentiman IS, et al. Long-term results of a randomized trial comparing breast-conserving therapy with mastectomy: European Organization for Research and Treatment of Cancer 10801 trial. *J Natl Cancer Inst.* 2000;92:1143–50.
4. Blichert-Toft M, Rose C, Anderson JA, Overgaard M, Axelsson CK, Andersen KW, Mouridsen HT. Danish randomized trial comparing breast conservation therapy with mastectomy: six years of life table analysis. *J Natl Cancer Inst Monogr.* 1992;11:19–26.
5. Arriagada R, Le MG, Rochard F, Contesso G. Conservative treatment versus mastectomy in early breast cancer: patterns of failure with fifteen years of follow-up. *J Clin Oncol.* 1996;14:1558–64.
6. Veronesi U, Cascinelli N, Mariani L, et al. Twenty-year follow-up of a randomized study comparing breast-conserving surgery with radical mastectomy for early breast cancer. N Engl J Med. 2002;347:1227–32.
7. Sepucha K, Folwer F, Mulley A. Policy support for patient-centered care: The need for measurable improvements in decision quality. *Health Aff (Millwood).* 2004;Suppl Web Exclusives: VAR54–62.
8. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Mak.* 1995;15:25–30.
9. Collins ED, Moore CP, Clay KF, et al. Can women with early-stage breast cancer make an informed decision for mastectomy? *J Clin Oncol.* 2008;27:519–25.
10. Molenaar S, Oort F, Sprangers M, Rutgers E, Luiten E, Mulder J, de Haes H. Predictors of patients' choices for breast-conserving therapy or mastectomy: a prospective study. *Br J Cancer.* 2004;90:2123–130.
11. Brodersen J, Siersma VD. Long-term psychosocial consequences of false-positive screening mammography. *Ann Fam Med.* 2013;11:106–15.
12. Hill-Kayser CE, Vachani C, Hampshire MK, Di Lullo GA, Metz JM. Cosmetic outcomes and complications reported by patients having undergone breast-conserving treatment. *Int J Radiation Oncol Biol Phys.* 2012;83:839–44.
13. Brennan MF, Antonescu CR, Maraco N, Singer S. Lessons learned from the study of 10,000 patients with soft tissue sarcoma. *Ann Surg.* 2014;260:416–21.
14. Wang F, Peled AW, Garwood E, et al. Total skin-sparing mastectomy and immediate breast reconstruction: an evolution of technique and assessment of outcomes. *Ann Surg Oncol.* 2014;21:3223–30.
15. Silva AK, Lapin B, Yao KA, Song DH, Sisco M. The effect of contralateral prophylactic mastectomy on perioperative complications in women undergoing immediate breast reconstruction: A NSQIP analysis. *Ann Surg Oncol.* 2015;22:3474–80.
16. Sharpe SM, Liederbach E, Czechura T, Pesce C, Winchester DJ, Yao K. Impact of bilateral versus unilateral mastectomy on short term outcomes and adjuvant therapy, 2003–2010: A report from the National Cancer Data Base. *Ann Surg Oncol.* 2014;21:2920–7.
17. Moran MS, Schnitt SJ, Giuliano AE, et al. Society of Surgical Oncology-American Society for Radiation Oncology consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer. *Int J Radiat Oncol Biol Phys.* 2014;88:553–64.
18. Moran MS, Schnitt SJ, Giuliano AE, et al. Society of Surgical Oncology-American Society for Radiation Oncology consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer. *J Clin Oncol.* 2014;32:1507–15.
19. Clark RM, Whelan T, Levine M, et al. Randomized clinical trial of breast irradiation following lumpectomy and axillary dissection for node-negative breast cancer: an update. Ontario Clinical Oncology Group. *J Natl Cancer Inst.* 1996;88:1659–64.
20. Renton SC, Gazet JC, Ford HT, Corbishley C, Sutcliffe R. The importance of the resection margin in conservative surgery for breast cancer. *Eur J Surg Oncol.* 1996;22:17–22.
21. Liljegren G, Holmberg L, Bergh J, Lindgren A, Tabar L, Nordgren H, Adami HO. 10-year results after sector resection with or without postoperative radiotherapy for stage I breast cancer: a randomized trial. *J Clin Oncol.* 1999;17:2326–33.
22. Forrest AP, Stewart HJ, Everington D, et al. Randomised controlled trial of conservation therapy for breast cancer: 6-year analysis of the Scottish trial. Scottish Cancer Trials Breast Group. *Lancet.* 1996;348:708–13.
23. Clarke M, Collins R, Darby S, et al. Effects of radiotherapy and of differences in the extent of surgery for early breast cancer on local recurrence and 15-year survival: an overview of the randomised trials. *Lancet.* 2005;366:2087–106.
24. Holli K, Saaristo R, Isola J, Joensuu H, Hakama M. Lumpectomy with or without postoperative radiotherapy for breast cancer with favourable prognostic features: results of a randomized study. *Br J Cancer.* 2001;84:164–9.
25. Malmstrom P, Holmberg L, Anderson H, et al. Breast conservation surgery, with and without radiotherapy, in women with lymph node-negative breast cancer: a randomised clinical trial in a population with access to public mammography screening. *Eur J Cancer.* 2003;39:1690–7.
26. Landercasper J, Attai D, Atisha D, et al. Toolbox to reduce lumpectomy reoperations and improve cosmetic outcome in breast cancer patients: The American Society of Breast Surgeons Consensus Conference. *Ann Surg Oncol.* 2015;22:3174–83.

27. Lee CN, Chang Y, Adimorah N, et al. Decision making about surgery for early-stage breast cancer. *J Am Coll Surg.* 2012;214:1–11.
28. Whelan T, Levine M, Willan A, et al. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery. *JAMA.* 2004;292:435–41.
29. Katz SJ, Lantz PM, Janz NK, et al. Patient involvement in surgery treatment decisions for breast cancer. *J Clin Oncol.* 2005;23:5526–33.
30. Morrow M, Strom EA, Bassett LW, et al. Standard for breast conservation therapy in the management of invasive breast carcinoma. *CA Cancer J Clin.* 2002;52:277–300.
31. Wennberg JE. Unwarranted variations in health care delivery: Implications for academic medical centers. *BMJ.* 2002;325:961–4.
32. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM. Accountability measures—using measurement to promote quality improvement. *N Engl J Med.* 2010;363:683–8.