Is Mastectomy Overused? A Call for an Expanded Research Agenda

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Surgery is the cornerstone of definitive treatment for most women with breast cancer. By the mid-1980s, several randomized trials had demonstrated that lumpectomy with radiation therapy confers the same survival benefit as modified radical mastectomy for women without metastatic disease (Fisher, Bauer, Margolese, et al. 1985; National Institutes of Health 1990). Since that time, clinicians, researchers, patients, and women's health advocates have voiced numerous concerns regarding women's experiences with breast cancer surgery. A primary concern in both clinical medicine and public discourse is that, given that there are two surgical alternatives, mastectomy is overused.

There have been several "framings" or definitions of problems regarding breast cancer surgical treatment over the past 2 decades. Early discussions of problems or controversies in breast cancer treatment focused on the issue of patient informed consent (Montini 1997; Nayfield, Bongiovanni, Alciati, et al. 1994). Media attention given to women who had awakened from a diagnostic biopsy to find that their breast had been removed fueled public outcry. Concerns about breast cancer surgeons' disregard for informed consent requirements were coupled with perceptions that there was an unusual slowness to the acceptance and dissemination of lumpectomy with radiation therapy as an appropriate surgical alternative to mastectomy (Montini 1997).

More recent research and discussion regarding breast cancer surgical treatment have centered around the fact that mastectomy remains the most common surgical approach in many geographic regions and patient subgroups. Patient advocacy groups, along with some clinicians and policymakers, have argued that too many women receive mastectomies. Breast conserving surgery (BCS) with radiation is perceived as a superior surgical choice for most women because it is less invasive, preserves the breast, and may thus serve to reduce body image concerns, sexual functioning problems, and/or other psychosocial sequela postsurgery. There is some empirical evidence suggesting

that postsurgical psychological adjustment may be less difficult for women receiving BCS (Levy, Herberman, Lee, et al. 1989; Margolis, Goodman, Rubin, et al. 1989; Schain, Findlay, D'Angelo, et al. 1985). In a meta-analysis, Moyer (1997) found small advantages for BCS in regard to postsurgical psychological, marital, and sexual adjustment.

Not all studies, however, support the premise that postsurgical quality of life is better for women receiving BCS compared with mastectomy (Ganz, Schag, Lee, et al. 1992; Irwig and Bennetts 1997). The surgical approaches may be equivalent in terms of adjustment to or satisfaction with the surgery. Even so, some argue that equivalence should not be construed as justification for a higher use of mastectomy (Page and Jensen 1996; Starreveld 1997). If the treatments are truly equal, then policies and practices should emphasize the use of BCS. Indeed, the National Cancer Institute Consensus Development Conference on the treatment of early stage breast cancer declared that although the treatments are equivalent in most respects, BCS is preferable because it preserves the breast (National Institutes of Health 1990).

Based on this literature, researchers have largely focused on the relative use of the two procedures as measures of progress and quality of care. The results of this research suggest that the use of BCS increased slowly and minimally in many areas while stagnating in others (Farrow, Hunt, and Samet 1992; Lazovich et al. 1991; Samet, Hunt, and Farrow 1994). In addition, mastectomy remains the most common surgical treatment for breast cancer patients in many regions. Lazovich, Solomon, Thomas, et al. (1999) reported that for stage I breast cancer during 1995, the rate of BCS ranged from 41% to 71% across Surveillance, Epidemiology, and End Results (SEER) tumor registries. For stage II patients, mastectomy was the most common surgical approach in all SEER regions. These findings, coupled with the fact that breast cancer surgical treatment also varies by provider/hospital characteristics and patient sociodemographics (such as age, race, and socioeconomic

This work was funded by a grant from the National Cancer Institute (CA75140) and the Veterans Administration Center for Practice Management and Outcomes Research, Ann Arbor, MI. Dr. Katz was also supported by a Robert Wood Johnson Generalist Faculty Scholar Award.

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characteristics), are viewed as evidence that problems still exist in terms of the overuse of mastectomy (Michalski and Nattinger 1997; Morris et al. 2000; National Cancer Policy Board 1999; Nattinger, Gottlieb, Hoffman, et al. 1996; Nattinger, Gottlieb, Veum, et al. 1992).

Research has also demonstrated that BCS with radiation therapy affords the same survival rate as mastectomy for women with ductal carcinoma in situ, some of whom are perceived as optimal candidates for breast conservation (Boyages, Delaney, and Taylor 1999; Fisher, Dignam, Tan-Chiu, et al. 1999; Silverstein 1998). However, modified radical mastectomy remains the most common surgical treatment for women with in situ breast cancer in several population-based tumor registry areas, a fact that is viewed as additional evidence that BCS is underutilized (Ernster, Barclay, Kerlikowske, et al. 1996; Morrow 1996; Talamonti 1996; Winchester et al. 1995).

Concerns about overtreatment with mastectomy and lack of patient informed consent, voiced primarily by women's health advocacy groups and some clinicians/researchers, motivated the passage of legislative mandates regarding breast cancer treatment in 20 states between 1979 and 1999 (Montini 1997; Nayfield, Bongiovanni, Alciati, et al. 1994). Almost all of these laws require that information regarding surgical treatment alternatives be provided to breast cancer patients in an informative and unbiased fashion. Nattinger, Hoffman, Shapiro, et al. (1996), using SEER trend data to estimate the impact of these legislative mandates, observed an increase in the rate of BCS that was slightly above expected in three of four SEER sites after a law was passed. However, within a year, BCS rates in all sites reverted to the expected levels. These results—using BCS rates as the litmus test—suggest that breast cancer treatment disclosure laws have had only a small, transient effect on breast cancer surgery in practice.

BREAST CANCER QUALITY OF CARE RESEARCH: WIDENING THE LENS TO CONSIDER PROCESS

Although most health services researchers would agree that assessments of medical care quality should focus on more than just outcomes or utilization patterns, a tacit assumption in many discussions of trends and patterns in breast cancer surgery is that BCS rates are a valid indicator of clinical progress, policy impact, and quality of care. It is not just researchers who are using rates of BCS as an important indicator. Some clinical institutions are promoting their own rates of BCS as a measure of the quality and progressiveness of care provided to

breast cancer patients (e.g., see Cleveland Clinic Web site at www.ccf.org/quality/08-27/08-27j.htm).

It might be the case that mastectomy is overused in the United States. However, we argue that focusing on the single end point of the relative rate of mastectomy versus BCS does not address the most salient issues regarding breast cancer surgical treatment. Importantly, there is no reason to assume that BCS would be the predominant surgical choice if all women were fully informed of the surgical options in a nonbiased fashion. One can argue, with a wealth of data in hand, that the surgical treatments are equivalent in terms of survival. However, there are some significant differences between the two approaches that are likely to be perceived and weighed differently by individual women.

One obvious difference between the two procedures is that there are more contraindications for lumpectomy with radiation therapy than there are for mastectomy (e.g., multifocal disease), although the larger number of contraindications for BCS does not explain the higher use of mastectomy (Morrow, Bucci, and Rademake 1998). Another difference between the two procedures is cost: BCS with a full course of radiation therapy costs more than mastectomy, although when the cost of breast reconstruction is added to the cost of mastectomy, this treatment path becomes significantly more expensive (Desch, Penberthy, and Hillner 1999; Norum, Olsen, and Wist 1997).

More importantly, a key difference between the two surgical approaches is the rate of disease recurrence in the primary breast. Although recurrence is possible after both mastectomy and BCS, many studies have found that the local recurrence rate after BCS is higher than that for mastectomy, even among those who receive a full course of radiation therapy (Cox, Pendas, Ku, et al. 1998; Dalberg, Mattsson, Rutqvist, et al. 1997; Fowble 1999; Margolese 1999). Even for women with ductal carcinoma in situ, the risk of local recurrence after lumpectomy is estimated to be higher than that for mastectomy, with many recurrences involving invasive disease (Boyages, Delaney, and Taylor 1999; Fisher, Dignam, Tan-Chiu, et al. 1999; Silverstein 1998). Fear of recurrence is an important and salient issue for many women in deciding between surgical treatment alternatives, especially those women who are risk averse regarding their health.

In addition, the decision to receive BCS most often involves the decision to receive a several-week course of radiation therapy as well. There are many reasons (in addition to cost) that some women do not want to undergo radiation, including cognitive, emotional, and logistical factors. Fears regarding exposure to radiation and concerns about the travel distance and other

logistical burdens associated with radiation therapy are important predictors of surgical treatment choice, especially in rural areas (Stafford, Szczys, Becker, et al. 1998). As such, higher rates of mastectomy in some geographic areas or patient subpopulations may in part reflect challenges regarding access to and completion of radiation therapy rather than serving as a marker for less progressive physicians and/or lower quality of care.

Another reason that focusing on the relative rates of mastectomy versus BCS is limited is because it neglects the importance of both *process* and *outcome* measures salient to quality of care. The type of surgery received is but one of several components in a decision-making process involving both patients and their providers (most notably surgeons). Focusing on the relative rate of mastectomy versus BCS emphasizes one easily observable end result, yet it fails to consider other salient and interrelated processes and outcomes. This includes women's attitudes and preferences regarding different treatment options, women's satisfaction with the surgery decision-making process, women's satisfaction with the surgery received, and postsurgical health-related quality of life.

Several studies have shown that patient preferences partly explain variations in surgical treatment patterns. In a recent multicenter study of breast cancer treatment among older women, Mandelblatt, Hadley, Kerner et al. (2000) collected information from older breast cancer patients and surgeons as well as from patient charts. With information on patient preference, these researchers found a positive association between a desire to have no further treatment beyond surgery (i.e., no radiation) and mastectomy and a positive association between concerns about body image and BCS. However, it is also important to consider patient satisfaction with the decision-making process and with the surgery received to identify and fully understand any problems associated with breast cancer surgical choice.

A recent literature review of the information needs and preferences of women with breast cancer found that patients and their family members are often dissatisfied with the information they receive (Rees and Bath 2000). In addition, several studies have found that breast cancer patients who did not perceive that they had a surgery choice had a higher number of psychosocial adjustment issues postsurgery, regardless of surgery type (Bilodeau and Degner 1996; Degner, Krisjanson, Bowman, et al. 1997; Gafni, Charles, and Whelan 1998). Kiebert, de Haes, and van de Velde (1991) reviewed the literature and found that whether or not breast cancer patients took part in the treatment decision-making process was significantly associated with postsurgical quality of life issues, mostly those regarding body image. Several other studies have found

that breast cancer patients who were given a choice between surgical treatments had less depression and anxiety than those who were not given a choice, even among those who deferred the decision to their surgeon or another provider (Fallowfield, Hall, Maguire, et al. 1990; Kaplan, Greenfield, and Ware 1989; Street and Voigt 1997). Thus, a growing body of research suggests that *having a choice* between surgical treatments, rather than the specific surgery type itself, is a critical factor in postsurgical satisfaction and adjustment for women with breast cancer.

There is indeed evidence that many physicians do not believe that BCS is as effective as mastectomy and that many breast cancer patients are not given a choice among surgical treatments (Ganz 1992; Tarbox, Rockwood, and Abernathy 1992). However, we challenge the blanket assumption that most women, even if fully informed about surgical options, would embrace BCS as the optimal choice, as there are several reasons that individual women might actually prefer a mastectomy. Variations in the rate of BCS are primarily interpreted as evidence of problems in the structure and process of surgical care (National Cancer Policy Board 1999). However, geographic and subgroup variations also may reflect in part differences in women's preferences and choices regarding surgical treatment. Thus, researchers need to move away from a primary focus on rates of mastectomy versus BCS, widening the research lens to view the degree to which women are being fully informed about surgical treatment options, whether and how they contribute to the decision-making process, and how these process measures are associated with patient satisfaction and quality of life.

INVOLVING PATIENTS IN TREATMENT DECISIONS

Although the importance of patient involvement in breast cancer treatment decisions has become more widely recognized, researching women's preferences regarding participation and control in medical decision making is far from easy. Prior studies on patient participation in complex medical decisions have found substantial variation regarding their preferred degree of control or involvement in clinical decisions. In a small study of breast cancer patients, Pierce (1993, 1996) categorized women into different types of decision makers and found that 40 percent were "deferrers," that is, women who wanted a decision made quickly, did not want additional information, and preferred to follow their physicians' recommendation. Similarly, Degner, Krisjanson, Bowman, et al. (1997) found that approximately one half of breast cancer

patients wanted someone else to make the surgery decision for them or preferred to play a passive role in the process. Many patients prefer strong guidance and assistance when making complicated medical decisions, especially in the midst of a medical crisis (Schneider 1995). In general, older patients and those with lower levels of education are more likely to prefer a passive role in medical decision making.

Such findings, however, should not be overinterpreted or taken as evidence that the notion of patient participation in medical decisions is a privileged concept that does not apply to a significant proportion of patients. As Guadagnoli and Ward (1998) concluded, "Patient participation in decision making is justified on humane grounds alone and that physicians should endeavor to engage patients in decision making, albeit at varying degrees, when more than one effective treatment option exists," as is the case regarding breast cancer surgery for many women. Charles, Gafni, and Whelan (1997) argue that a "shared decision-making model" is preferable to an "informed model," where the patient makes the decision and the physician's role is one of information transfer and to a "paternalistic model" where the patient is left outside of the decision-making process, even if this is the patient's preference.

What do we know about breast cancer patients' experiences with the surgical treatment decision-making process? The results that are available at this time are limited because most studies in this area are based on small samples of convenience from large academic medical institutions. The available information, however, does suggest that we have some reasons to be concerned. Guadagnoli and Ward (1998) found that up to one quarter of breast cancer patients receiving mastectomy did not receive any information on BCS. Other researchers have concluded that many breast cancer patients who want "collaborative roles" in treatment decision making have difficulty achieving this (Bilodeau and Degner 1996; Pierce 1996). In one study, only 42 percent of women with breast cancer believed they had achieved their preferred level of control in the decision-making process (Street, Voigt, Geyer, et al. 1995).

In addition, the results of our own population-based study of 183 women diagnosed in 1998 with nonmetastatic breast cancer raise several concerns regarding the surgical treatment decision-making process (Katz, Lantz, and Zemencuk 2001). This study combined data from the SEER tumor registry for the Detroit metropolitan area, a short telephone interview, and a mailed survey (with a 71 percent response rate, completed by 90 percent of participants within 6 months of diagnosis). Overall, 54 percent of women in the sample received mastectomy, with no differences in surgery type between women with

invasive and noninvasive disease. We also found that fully one third (33 percent) of the women did not perceive that they were given a choice between surgery types. This included some women (14 percent of the total sample) who perceived that they were told they had to have BCS (i.e., mastectomy was not an option) even though they had no reported contraindications for mastectomy. Knowledge regarding the similarities and differences between the two procedures was very low in this sample, even among women who perceived making a surgical treatment choice. In addition, consistent with prior studies, women who perceived less participation in the treatment decision-making process were significantly less satisfied (i.e., only 63 percent of those who did not perceive a surgery choice reported being involved in the decision to the degree that they wanted versus 91 percent of those who perceived making a choice, $p < 0.05$).

The fact that the rates of BCS versus mastectomy were about the same in this population-based sample (even among women with ductal carcinoma in situ) is alone insufficient evidence to support claims of overtreatment. However, when information on patient knowledge and preferences/satisfaction regarding the decision-making process is factored in, the results of this study suggest that there are indeed some areas of concern in the surgical treatment of these breast cancer patients. The high rate at which women did not perceive surgical choice conflicts with state law regarding treatment alternative disclosure and suggests a process in which patient preferences and values are not fully considered. These results underscore the important point that breast cancer patients' experiences and satisfaction with the process by which a treatment decision is made are of critical import.

CONCLUSIONS

Breast cancer surgery is a complex issue from both a clinical and a health services research perspective. However, when public and scholarly discourse includes overt claims or even subtle suggestions that variation in mastectomy rates reflects overtreatment and poor quality of care, the result is the reduction of this complex issue to the sound bite that "mastectomy is bad, and lumpectomy is good." We need to avoid blanket labeling of mastectomy as a less progressive treatment for breast cancer, even among women with early stage disease. Mastectomy is a viable surgical outcome that affords a reduced risk of recurrence in the primary breast and—for most patients—means that they do not have to undergo radiation therapy. For some patients, this reduced

risk is of greater importance than preserving their body image by avoiding mastectomy. In addition, for some women, breast reconstruction can reduce some of the negative psychosocial sequela of losing a breast. Rates, trends, and patterns in the mastectomy rate in a population or its subgroups do not in and of themselves provide evidence of misinformation or malfeasance on the part of clinicians. In fact, for women with no contraindications to either procedure, we should be just as concerned about women who are only offered BCS by their surgeons as we have been about those who are only offered mastectomy.

Others have called for an expanded approach to looking at quality of care issues among breast cancer patients (Mandelblatt, Ganz, and Kahn 1999; Mandelblatt, Hadley, Kerner, et al. 2000; National Cancer Policy Board 1999). In 1992, Ganz wrote that “[a]lthough breast-conserving surgery has been recommended for the majority of women with breast cancer in an early stage, the ideal rate of breast-conserving surgery is unknown.” As Ganz further suggested, we need to find out if underuse of BCS is driven more by surgeons’ attitudes and behaviors than by patient preferences and choice. This search necessarily brings us beyond studies of variation or patterns in surgical treatment rates. However, what researchers should focus on instead has remained less clear.

We propose the following research agenda to advance knowledge regarding breast cancer surgical treatment decisions. First, we need to continue research and surveillance regarding trends, patterns, and subgroup variation in breast cancer surgery outcomes, comparing the rates of mastectomy and BCS. This type of work, which primarily uses data from population-based tumor registries, is critical to our understanding of clinical practice in this important area of women’s health, and needs to continue.

Second, however, we also need more population-based research on surgery decision making and on the extent and nature of problems with the surgical choice process. Much work has already been done in these areas, but the bulk of it was conducted using small convenience samples of middle-class women. Continued attention to the factors associated with surgical treatment type is needed. Simultaneously, however, an expanded focus is needed in regard to patient and provider perceptions of the decision-making process and the degree to which the surgical treatment decision-making process matches the preferences and decision style of the patient. Designing studies that assess the perspectives and experiences of both patients and their providers is essential. Although much of this work will necessarily be retrospective, there is a role for direct observation (for instance, through audio or video recording) of treatment encounters that can shed valuable light on how patients and

providers recall and appraise these events. Admittedly, this type of research is limited by logistical and ethical considerations in requesting research participation from patients and their providers at a time of crisis.

Third, in addition to an enhanced focus on the process, we should also expand the outcomes under investigation beyond surgery type. Mandelblatt, Ganz, and Kahn (1999) recommended several potential outcome measures regarding quality of breast cancer care, including documentation of choice for treatment and documentation of patient participation in the treatment decisions. In addition, we recommend looking at patient satisfaction with the treatment choice and postsurgical quality of life as important outcomes that are potentially related to surgery type, but also may be related to the degree to which the decision-making process matched patient preferences and abilities. Prior empirical work in these areas provides researchers with a good foundation from which to develop and test instruments (Aaronson, Ahmedzai, and Bergman 1993; Degner, Krisjanson, Bowman, et al. 1997; Fallowfield, Hall, Maguire, et al. 1990; Holmes-Rovner, Kroll, Schmitt, et al. 1996; Pierce 1996; Sprangers, Groenvold, and Arraras 1996; Street and Voigt 1997). A necessary focus of this type of research is how the quality of care varies across subpopulations defined by age, race, ethnicity, and socioeconomic status in order to explicate and understand social disparities in experiences and outcomes (Fiscella et al. 2000).

Finally, more interventions regarding decision support for breast cancer patients need to be designed and evaluated, such as those that Sepucha et al. (2000) and Whelan, Levine, Gafni, et al. (1999) described. Counseling or decision support interventions need to be tailored to individual patients' decision-making styles and their needs regarding additional knowledge, assistance, and support (Gafni, Charles, and Whelan 1998). No one particular approach or model for patient participation or shared decision making should be advocated. Rather, what is important is flexibility in the structure of the decision-making process so that individual differences and preferences are respected.

Is mastectomy overused in the United States? We believe that the answer to this important question is quite likely affirmative; that is, that the rate of mastectomy is high, not relative to the rate of BCS, but to the true preferences and desires of women with breast cancer. Focusing on the relative rate of mastectomy versus BCS gives us very little insight into the complex underlying issues and problems. Rather than limiting our research focus to the actual surgical procedures received, much more attention should be given to the process by which decisions about surgery are made

and how this process is linked to more salient patient outcomes, such as quality of life and patient satisfaction. Although such research has substantial scientific challenges, it is critical to the advancement of clinical practice, public policy formation, and consumer advocacy work related to breast cancer treatment.

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