

Contralateral prophylactic mastectomy: a voice for choice

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In response to a growing a body of data showing an increase in the performance of bilateral mastectomies for the treatment of unilateral breast cancer (1-6) there has been a strong rebuttal literature criticizing this approach and implicitly the surgeons who perform contralateral prophylactic mastectomy (CPM) (7,8). It is interesting to observe that two decades after a concerted international effort to endorse breast-conserving surgery (versus mastectomy) as the default treatment for early breast cancer (9,10), the pendulum is now swinging back and mastectomy and CPM rates both are increasing. However, there is a common thread in these two trends: patient choice. Initial skepticism over the oncologic safety of breast-conserving surgery was overcome and ultimately successful because it provided women with a choice in treatment that enhanced well-being. Notably the recent increase in CPM rates has paralleled the burgeoning access to online information and extensive social networking. Current estimates suggest that more than 50% of the global population is online and twothirds of the population of developed countries participate actively in at least one social networking site (11). As a result, more and more patients are coming proactively to their surgeons with a treatment plan in mind.

What are some possible reasons that patients might prefer mastectomy with CPM over breast conservation? There is data to suggest that the following factors contribute:

- (I) Increased uptake in genetic testing for cancer predisposition.
- (II) Increased use of supplemental imaging (such as MRI) and subsequent additional biopsies after a breast cancer diagnosis.
- (III) Concern about a future ipsilateral or contralateral breast cancer and suffering associated with its

attendant treatment.

- (IV) Recognition of the burden (psychological and financial) and limitations of breast cancer screening.
- (V) Concern about the potential undesirable appearance of the radiated breast over time, coupled with technical advances in oncologic breast surgery (nipple-sparing mastectomy) with reconstructive surgery which have led to improvement in the aesthetics of the reconstructed breast. Together these provide women with greater options for enduring symmetry and improved breast appearance.

Or is this driven by questionable advice, inadequate informed discussion or the personal agenda or bias of surgeons? What are the facts?

Analyses from US national databases have shown that the frequency of bilateral mastectomy for unilateral disease has increased by approximately 0.5% per year from 1998 onward, such that mastectomy with CPM now is performed in ~5% to 11% of unilateral early stage cancer patients (1,5). A lower frequency of CPM (~3.1%) but steeper rate of increase has been reported in England (4). At the same time, mainly driven by systemic adjuvant therapy for estrogen receptor-positive breast cancer, the rates of contralateral breast cancer are decreasing over time (12). Despite vociferous debate on the topic at both professional meetings and in the media, it is important to remember that only a small fraction of all women with early stage unilateral breast cancer are choosing bilateral mastectomy (3–11% as described above).

A major focus of discussion around CPM has been the fact that most studies show CPM does not prolong overall survival for average risk women. Women classified as high risk for additional breast cancers, including those with deleterious *BRCA* mutations and those diagnosed at a young age or with early stage ER-negative tumors, do have a modest survival benefit from CPM (13-17). Pursuit of genetic testing and young age at diagnosis have been factors shown repeatedly to associate with the choice for CPM (1,3,18,19). On the other hand, while prospective data is lacking, multiple retrospective studies show that CPM does not improve overall survival for average risk women. This fact has been disseminated widely and effectively (20-22). The increase in CPM rates, in spite of widespread agreement that it does not improve survival, reveals that survival is not the factor driving most women's decisions for CPM.

Overall survival is not the only meaningful oncologic outcome measure. In fact, much of medical oncology therapy (including therapies that are expensive and toxic) has no or minimal effect on overall survival, but rather delays recurrence. Similarly, preventing a second breast event (whether a new ipsilateral or contralateral breast tumor) is also a valid goal of therapy. It is well-established that CPM reduces contralateral breast cancer risk by about 95%, eliminates the need for future breast-specific radiologic screening and its expense, reduces anxiety about breast cancer, and saves the cost and suffering of treating second breast cancers (23-26). Further, not all subsequent breast cancers are diagnosed at an early stage, at least one third are node-positive (13,27). In addition, breast cancer screening is imperfect. At least 15% of cancers are invisible on mammography, and enhanced screening with breast MRI is costly and associated with high false positive, recall and biopsy rates (28,29). Breast density legislation in the United States is spurring growing awareness worldwide of mammographic breast density as a risk factor beyond its masking effect, leading to secondary screening and increases in recall and biopsy rates (30,31). For all these reasons, preventing future breast cancer is a valid potential (albeit low frequency) benefit of CPM.

It is equally critical to recognize that patients and physicians may differ in how they define a beneficial treatment outcome. Psychosocial outcomes and quality of life (QOL) are significant factors that affect a patient's choice of breast cancer treatment. CPM does permanently alter the body, results in impaired or absent erogenous breast sensation, may impair body image and sexuality and, when reconstruction is performed, carries a small risk of reconstruction failure. However, when mastectomy with reconstruction is chosen and performed by skilled multidisciplinary teams using modern techniques, cosmesis is generally excellent and the risk of additional

complications is low (32,33). There has been little prospective assessment of the psychosocial effects of CPM, but several retrospective studies, some with substantial follow-up, suggest most women who undergo CPM are satisfied with their decision (34,35). A recent quality of life (QOL) survey of self-enrolled women using the validated instrument BREAST-Q, found that the women who had a CPM (compared to those who had unilateral mastectomy) reported higher breast satisfaction and psychosocial well-being but no difference in physical or sexual well-being (36). In this study, irrespective of choice for CPM, radiation was associated with lower overall QOL while reconstruction improved QOL domains. In fact, other recent research confirms that QOL issues, rather than survival, are the primary driver in a woman's decision for CPM (37). Detailed interviews of women exploring the key factors influencing the decision for CPM showed that patient definitions of benefits were most often psychological. The investigators found that desire to diminish worry and enhance symmetry were paramount and further suggested the importance of a focus on psychosocial aspects of patient decision-making in the patient-provider CPM discussion. We agree that addressing peace of mind is important in the process of shared decision-making regarding CPM, and emotional benefits are very real to the patient.

When presented with this information, we believe that adult women, who vary in their assessment of the relative importance of the myriad factors involved, are capable of making a choice that best meets their individual needs and reflects their own preferences. As surgeons, our job is to respect these choices unless medically ill-advised. Recently, two widely publicized studies have investigated how well surgeons educate patients regarding CPM.

Katz et al. reported on survey data from women with early breast cancer and surgeons in the Surveillance, Epidemiology and End Results (SEER) Georgia and Los Angeles County registries 2013 to 2015 (7). With a 70% patient response rate, of whom 16% were treated with CPM, and 77% surgeon response rate, the investigators reported that the individual surgeon accounted for 20% of the variation of CPM rates and that surgeons least likely to favor breast conservation had substantially higher CPM rates. However, this study design cannot account for tumor size or location relative to breast size, nor extent of DCIS or ER status. Surgeon surveys were based on hypothetical cases. For the hypothetical average risk woman with a newly diagnosed ER-positive breast cancer, >80% of surgeons

replied that they would recommend against CPM. More variation was reported among surgeons in their response to whether or not they would perform CPM when requested by a patient to do so for a variety of reasons including peace of mind, cosmesis and avoidance of surveillance. Interestingly, a prior study of SEER registry patients in Detroit and Los Angeles County by the senior author found that mastectomy rates were higher when patients reported that they were the primary treatment decision makers (27%), whereas it was lower when patients reported shared decision-making or that the surgeon decided (17% and 5%, respectively) (38). These findings underscore the important role of patient choice driving decisions for mastectomy.

A related study by Jagsi et al. focused on patient surveys from a subset of the same SEER Georgia and Los Angeles County registry patients, of whom 71% completed the survey (8). Overall, 44% reported that they considered CPM and 17% underwent CPM. Among the patients who considered CPM, 24% reported that they believed CPM improved survival. Further, among average-risk patients interested in CPM who perceived no surgeon recommendation against it, 19% had a CPM versus <2% of those who received a surgeon recommendation against CPM. These data suggest that there is a knowledge gap regarding the potential risks and benefits of CPM which the authors suggest is due to surgeons who are unmotivated or unwilling to discuss the risks of CPM, the low likelihood of subsequent contralateral breast cancer, and alternatives such as endocrine therapy that will lower that risk. While we agree that it is incumbent upon surgeons to carefully educate patients regarding CPM, we do not agree that CPM is "excessive treatment" for all average-risk women. Limitations of this study include recall bias inherent in postevent surveys and referral bias. Since the majority of women appear to have been appropriately informed and CPM rates differed across surgeons, how might these differences be explained?

Certainly, surgeons may be influencing a woman's decision, possibly in how they frame CPM and discuss alternatives such as contralateral mastopexy. It is also possible that some surgeons may just refuse to do the procedure. It would be interesting to survey the 21% of women who had a unilateral mastectomy and to ask them how many wanted a CPM but were denied this option by their surgeon. This would seem as reprehensible as coercion or apathy toward CPM. Another likely explanation for varying CPM rates across surgeons is that patients are self-referring to centers with breast surgical oncology and

reconstructive expertise. Surgeons with greater experience and better outcomes with CPM may be more willing to accept a woman's decision to have a CPM, rather than deny her choice. There are other possibilities to explain different CPM rates among surgeons: some surgeons may be recommending CPM, and some surgeons are failing to educate women on the risks of CPM. In addition, it is interesting that contralateral mastopexy for symmetry is not criticized in the same way as is CPM. Like CPM, contralateral mastopexy is a surgical procedure that offers some risk reduction and improved symmetry, but mastopexy also requires long-term imaging surveillance of the remaining breast tissue.

Publicity around these papers reporting that patients may not be optimally nor consistently educated, has driven increased scrutiny of CPM and suggested that surgeons who perform CPM more often than the average are poor quality surgeons. Even worse, patients may be told that CPM is a "bad" choice, creating greater psychosocial distress. We suggest that it is time to remove the negative energy around CPM and instead focus on the real issues of patient autonomy and how to define and deliver thorough and unbiased education regarding this treatment choice.

We agree that providers need to find improved and standardized ways to educate patients about the risks, benefits of, and alternatives to CPM, and to address questions and issues raised by patients that often arise after perusal of the internet, social media or peer discussion. Key elements of this are provision of factually accurate information, while highlighting the concept that personal values may lead individual patients to make different decisions based on the same factual information.

In the 21st century, patient autonomy is a key component of providing medically ethical patient care. Health care providers are charged with educating patients and supporting shared decision-making. Decades ago the medical community worked hard, advocating and enacting legislation to give women the option of breast conservation versus mastectomy, and also insurance coverage for reconstruction and symmetrizing procedures. The choice for CPM is an equally valid treatment choice. Therefore, suggesting that surgeons should "withhold" CPM from medically eligible unilateral breast cancer patients is a denial of patient autonomy and violates ethical principles.

Women differ in the relative importance they place on many things; those relevant to this topic are the importance of reducing the risk of future breast events, risk tolerance versus aversion, burden of screening, retention of an erogenous breast, and perception of breast appearance, body image and sexuality. Treatment options are exactly that—options for treatment—and not a doctor's decision to impose upon an otherwise healthy patient. If we can agree that patient autonomy is a critical component of best practice, we can move ahead constructively to improve patient care.

In order to provide the best possible individualized patient care, we need to shift the focus of this controversy away from whether surgeons are performing too many CPMs, and instead adopt guidelines for patient education and informed consent in the context of patient choice. When patients have optimal education regarding their contralateral breast cancer risk and the risks and benefits of CPM, some will still choose to undergo CPM. Providers need to recognize that the emotional realm is an important part of our human experience and plays a key role in treatment decision-making. Since the majority of women choosing CPM cites fear or anxiety as a primary driver and are later satisfied with their choice, this suggests that emotion is a valid component of the decision-making process that also results in high decision satisfaction and quality of life (34,37).

What is the best way to move back toward patient-centered care in a non-judgmental fashion? We agree that there is a need for more standardized processes and tools for providers in order to best educate patients and provide factual information in an efficient and non-biased way. Once that is accomplished, then we need to respect a patient's right to make a decision about CPM.

There is no gold standard when it comes to personal choice. We believe that it is the surgeon's duty to provide knowledge that permits each patient to make an informed choice, to allay fear and anxiety, and then to work toward shared decision-making that respects patient preferences. We reject the hypothesis that surgeons are pushing women to have bilateral mastectomies. The data above, and our experience treating thousands of patients, support that decisions for CPM are driven by patient choice, which is as it should be. We agree that medical conditions should preclude CPM in some patients. However, for the majority we advocate strongly for the right of adult women to make their own choice of treatment, following informed discussion and time for reflection. We vote for choice.

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