Increasing Use of Contralateral Prophylactic Mastectomy: A Counterintuitive Trend

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A recent study has provided evidence that the use of contralateral prophylactic mastectomy (CPM) is increasing.[1] Over the 5-year period from 1998 to 2003, the CPM rate doubled. Prior studies have shown that the surgical procedures chosen by patients are most commonly influenced by physician and surgeon recommendation. This has been observed in the choice of CPM as well.[2] The data strongly suggest that CPM is being recommended more frequently. A strong case can be made that that is exactly the opposite of what should be occurring at present.

Women are increasingly being treated for primary breast cancer with breast conservation. This change was accelerated by the National Institutes of Health Consensus Development Conference Statement in 1990, advising breast conservation. Randomized trial data demonstrated equivalent survival with breast preservation, making the ablation of the breast unnecessary. It is from the shrinking pool of women who are advised to have mastectomy rather than breast conservation that discussions regarding CPM arise. These discussions reveal a perceived risk of contralateral cancer that usually exceeds reality. Yet because the number of women having mastectomy is diminishing, one might expect the CPM rate to diminish as well. That the number is growing suggests that physicians and surgeons are often misinformed and, in turn, misinforming.

Ethics and Risks
The ethics of removing a normal organ are complex. The indication is based on risk. Such risk can be more accurately assigned today than previously. Just as good cancer management demands accurate diagnosis and staging, recommendations regarding surgical prophylaxis require accurate risk prediction. The risk must be clearly discussed as well. It is possible to conflate the risk of contralateral breast cancer with a patient's unstated concerns: the risk of death from breast cancer, the risk of later mastectomy, or the risk of chemotherapy at a future date. The risks to be avoided by CPM must be contrasted with the risks posed by CPM. This additional surgical procedure increases the risk of complications and the cost of the procedure. It is always accompanied by loss of the sensual sensation of the nipple-areolar complex. In CPM, removing the only remaining nipple removes all breast sensual sensation.

Patients who have agreed to CPM typically report satisfaction with the choice they have made. Those who are specifically questioned about what should be mentioned during the informed consent process report slower arousal, and some report difficulty in achieving full arousal. CPM removes the only "normal breast," which otherwise would become the focus of foreplay after unilateral mastectomy. Some regret the ultimate results of the breast reconstruction, and others experience a diminished sense of sexuality.

How much risk justifies the removal of a normal organ? Is it properly done to alleviate patient anxiety? Should it be done on patient request? Prophylactic organ removal is generally performed because of a specific risk of mortality or morbidity and the appropriate degree of anxiety that accompanies that risk. Matters of bioethics aside, one could not expect the removal of a healthy breast on request to be covered by standard insurance policies. When patient anxiety is the indication for surgery, the issue becomes whether the anxiety is specifically related to significant risk or is more generic and multifaceted.

The focus of the consulting physician or surgeon is, first, the actual mortality risk posed by the contralateral breast and, second, the risk of an additional neoplasm that would require further treatment. For a woman facing mastectomy, the underlying assumption is usually that another mastectomy would be required if contralateral breast cancer were to develop. In patients under surveillance after breast cancer, the need for a contralateral mastectomy is uncommon. Should a breast cancer arise, it can usually be treated with breast-conservation therapy, preserving nipple
and areolar sensation and breast appearance.

**Patient and Physician Misperceptions**

The patient's perceived risk often derives from first principles: Both breasts have the same parents, "ate the same diet," and lived in the same environment, so if cancer develops in one breast, the other breast must be very likely to develop a cancer, too. It is hoped that whatever the woman's medical condition, the consulting physician will provide a more sophisticated discussion of risk, differentiating the minimal risk of mortality from the actual risk of a new primary. Many physicians have been taught that 1% of patients per year will develop a contralateral breast cancer. That number reflects surveillance bias in follow-up of treated patients, as has been well described. Population-based data suggest that the incidence among all breast cancer patients taken together is roughly 0.5% per year. But population numbers must be tailored to the risk of the specific individual, not lumped together. Various modifiers allow more precision, and the first such modifier is age. Women who develop breast cancer in their 30s or 40s have an increased risk of contralateral breast cancer in the 15% to 20% lifetime range as a natural history baseline. Most breast cancer occurs in women in their 50s, who have less than a 10% lifetime risk, or women in their 60s, with less than a 5% lifetime risk of contralateral breast cancer in population-based reports from Scandinavia.

Family history, especially of bilateral breast cancer and early breast cancer, also relates to increased risk.[3] These factors, taken together with youth, are indicators of hereditary breast cancer families. Undertaking CPM on the basis of presumed hereditary risk is inappropriate today, when genetic testing of the individual and possibly other family members allows definition of BRCA1 or BRCA2 mutations or the absence of such mutation in an individual from an afflicted family. The role of CPM in BRCA1/2 mutation carriers is discussed below. Family history and youth as factors related to increased risk of contralateral breast cancer from the era prior to genetic testing for BRCA1/2 are now invalid for better-defined subpopulations. Invasive lobular carcinoma has been found to be associated with increasing frequency of CPM.[1]

This arises from the long-held belief that contralateral breast cancer is increased in women with this disease. Invasive lobular carcinoma, however, is not an indicator of increased risk of contralateral breast cancer. In the era prior to routine breast imaging, mirror-image biopsies of the contralateral breast were advocated in some centers. It was more common to find "cancer" in these biopsies when invasive lobular cancer was at issue. As contralateral mastectomy was performed for lobular carcinoma in situ as well as for contralateral invasive breast cancer, incidence of the procedure increased. Very large studies of invasive lobular carcinoma in the modern era, with good imaging to eliminate simultaneous contralateral disease (less obvious than contralateral infiltrating ductal carcinoma), have found that there is no difference in the frequency of contralateral breast cancer between patients with invasive lobular carcinoma and those with infiltrating ductal disease.[4-8]

Nonetheless, that misunderstanding lingers and influences recommendations. All such baseline risks of contralateral breast cancer are reduced today by adjuvant systemic therapy for the primary. Oophorectomy and tamoxifen lower contralateral breast risk by approximately half. Aromatase inhibitors lower risk by nearly 75%. For patients treated with only cytotoxic chemotherapy, there is also a reduction of contralateral breast cancer by half.[9]

**Other Susceptible Populations**

Women in whom atypical ductal hyperplasia or lobular carcinoma in situ are found in either the ipsilateral breast or in prior biopsies in the contralateral breast are also more likely to be given a recommendation for CPM. Treatment of this population with tamoxifen has shown a 50% to 75% reduction in the subsequent incidence of breast cancer, effectively lowering the risk associated with the atypical diagnosis to approach or equal that of the general population. Another population that is sometimes advised to consider prophylactic mastectomy comprises women whose primary tumors were mammographically occult. The availability of magnetic resonance imaging (MRI) to screen women with mammographically occult primaries has dramatically reduced this concern. The use of surveillance with MRI for women with prior breast cancer diagnoses further reduces concerns that mastectomy may be required, given the earlier detection of new contralateral disease. No convincing data, even from series prior to contemporary breast imaging with digital and MRI images, suggest that a contralateral primary affects survival. The concern about symmetry is cited by some patients, and may result in a decision to have bilateral mastectomy with no reconstruction. Clearly, symmetry is improved in that circumstance, but at what cost? The increasing use of skin-sparing mastectomy with immediate reconstruction has greatly diminished the need for procedures on the uninvolved breast to create symmetry with breast reconstruction. It is now possible to create symmetrical breasts routinely, without any reduction of
the contralateral breast. Women who take the opportunity of skin-sparing mastectomy and reconstruction to reform their breast to a preferred shape may elect to have their contralateral breast shaped in mirror fashion. This, again, is not a clear indication for mastectomy with its drawbacks.

**BRCA Mutations**

Women with BRCA1/2 mutations, or those with a family history strongly suggesting such mutations but who have refused genetic testing, clearly present a population at increased risk for contralateral breast cancer. The lifetime risk for contralateral breast cancer after a primary in a woman with a BRCA1/2 mutation is between 40% and 60%. For those women who undergo premenopausal oophorectomy, that risk is halved. For those whose primary was receptor-positive, tamoxifen also reduces risk. Such women clearly have a residual risk that makes CPM an entirely reasonable option. The procedure greatly reduces the risk of contralateral breast cancer and anxiety concerning that risk, while completely eliminating neither.

Some women faced with a new diagnosis of breast cancer and the finding of a BRCA mutation elect breast-conserving treatment and hold prophylactic surgery for a later date. Others elect mastectomy and hold CPM for a later date, and others proceed with bilateral mastectomy. The risks are in a range that makes any of these reasonable alternatives. The one downside of proceeding to bilateral prophylactic mastectomy is that the next 5 years may produce an intervention that would lower risk even more dramatically than aromatase inhibitors have. The mortality risk associated with the delay of a few years is extremely small in the era of MRI surveillance.

The acid test of the logic involved in CPM would arise in a theoretical discussion with a woman who had chosen breast-conserving therapy for a tumor likely to be controllable by those techniques. She could have preserved nipple sensation on the involved breast, while lowering the risk of contralateral disease by the prophylactic mastectomy. Such a discussion clearly enters the realm of the absurd. No one able to have breast-conserving treatment considers CPM.

**Sufficient Cause**

Where then do we stand with the ethics of prophylactic removal of normal organs? This clearly should not be done on request. This is true of gallbladders, appendices, right colons, and various other body parts. The role of the physician and surgeon is to control access to such procedures. Not only is consent required, but also institutional validation of the social contract by granting privileges to certain people for the performance of specific procedures.

The task of tissue committees in hospitals is to make certain that normal tissue and organs are not removed without sufficient cause. When such procedures are undertaken by the patient's choice, they are considered too elective to require insurance coverage, on the premise that insurance is a pooled fund for dealing with medical problems, not personally elective procedures. Patients who have anxiety regarding the shape of a portion of their body that is distorted or injured are generally covered by insurance. Those with anxiety based on preference for a different shape are not covered. Physicians and surgeons must determine to what degree the anxiety supporting prophylactic surgery is valid and when it arises as a symptom of generalized anxiety states. The other consideration is to what degree we as physicians and surgeons may be contributing to the removal of normal organs by misinformation regarding risk.

**Conclusions**

Women facing mastectomy who consider CPM and decide, with conflicted emotions, not to proceed, are almost always profoundly grateful several months later to have been dissuaded from CPM. At a time when we can define the risk of contralateral breast cancer for an individual more specifically than ever before, having demonstrated that certain histologic types such as lobular invasive cancer are not at increased risk, when we can monitor that organ more successfully than ever before for the early development of small primary cancers, and when we can reduce the incidence of contralateral cancer in a majority of patients by systemic therapies, it is distressing to see an increasing incidence of CPM.

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For the PRO Perspective, see Dr. Tuttle's commentary here:
Counseling Breast Cancer Patients on Contralateral Prophylactic Mastectomy: The Physician's Role

**References:**

References


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