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Bilateral Prophylactic Mastectomy Rarely More Cost-Effective Than Screening Mammography for High Risk Women

Highlights Need for More Sensitive and Economical Screening Techniques

Abstract: Cost-Effectiveness of Bilateral Prophylactic Mastectomy in Patients at High Risk for Breast Cancer Without a Known BRCA Mutation

April 30, 2015, Orlando--Annual screening mammography is significantly more cost-effective than bilateral prophylactic mastectomy (BPM) (surgical removal of healthy breasts) in managing the care of most women at high risk for breast cancer. Women with a known BRCA gene mutation, which carries an exceptionally high risk, are a notable exception.

These were the findings of a study presented this week at the American Society of Breast Surgeons (ASBrS) Annual Meeting by lead researcher Dr. Brandy Edwards of the University of Virginia. The study found that a woman's projected lifetime breast cancer risk must reach approximately 50% for BPM to deliver cost benefits for the number of lives saved. The typical woman's risk of breast cancer is 12% averaged over the course of her lifetime. Factors such as a family breast cancer history, certain benign breast conditions and hormone use place a woman at elevated risk.

"Cost-effectiveness analysis is an increasingly important tool to aid in clinical decision-making, particularly in today's age of healthcare reform," said Dr. Edwards. "Previous studies have made the economic case for prophylactic procedures in women with BRCA mutations or in contralateral mastectomies for patients with cancer in the other breast. This is the first study to demonstrate that a woman without breast cancer or known genetic mutation must have substantial risk to cost-justify prophylactic surgery."

The study relied on a Markov model, a validated statistical methodology utilized in numerous scientific studies to simulate effects that change over time. Model parameters included costs, sensitivity and

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specificity of screening modalities, and mortality rates. The study assumed a 90 percent breast cancer risk reduction with BPM. It focused on patients beginning at age 30 and assumed that full lifetime risk would be met at age 80. Sensitivity analyses were conducted to analyze how changes in the model parameters affected the results.

“Based on information in published literature, we also adjusted the model to account for expected patient preferences for BPM compared to screening,” noted Dr. Edwards. “These numbers also demonstrate that BPM should primarily be considered in women with very high risk. When accounting for these patient preferences, an approximate 50% lifetime risk still emerged as the point where BPM would be considered a cost-effective alternative to screening. However, while cost-effectiveness studies are a valuable tool to compare interventions, the results should not be the sole criterion for deciding whether or not a certain treatment should be used or covered by health insurance. At the end of the day, this is a highly personal decision that must be made on a patient-by-patient basis.”

The study also found that annual screening with a combination of mammography and MRI based on Medicare reimbursement rates was never more cost-effective than BPM at any risk level and that the additional survival benefit associated with combined screening is very small when compared to mammography screening alone.

“Today, technology brings significant breakthroughs in the diagnosis and treatment of disease at a rapid pace,” concluded Dr. Edwards. “But, physicians have to examine costs and benefits because healthcare is not an infinite resource. Clearly there is a need for additional affordable screening technologies for women at high risk for breast cancer. While prophylactic mastectomy is appropriate for some women, it can carry steep costs, both economically and in quality-of-life, because prophylactic surgery isn’t without risk.”

Abstract, Official Proceedings**Presenter:** Brandy Edwards**Institution:** University of Virginia**Title:** Cost-Effectiveness of Bilateral Prophylactic Mastectomy in Patients at High Risk for Breast Cancer Without a Known BRCA Mutation

Objective: Previous comparative effectiveness studies have demonstrated the cost-effectiveness of contralateral prophylactic mastectomy in younger breast cancer patients, as well as that of bilateral prophylactic mastectomy (BPM) with bilateral salpingo-oophorectomy in women with BRCA mutations, but high-risk patients without BRCA mutations or personal history of breast cancer are not addressed. We sought to identify the particular risk level beyond which BPM becomes more cost-effective than annual breast cancer screening.

Methods: Using TreeAge Pro 2014 software, we developed a Markov model with 25,000 Monte Carlo simulations and conducted sensitivity analyses to simulate the costs and effects of BPM vs screening. Model parameters, including costs, cancer incidence, and mortality rates, as well as patient preference ratings, were derived from published literature or national databases. BPM was assumed to be associated with a 90% risk reduction of breast cancer based on published findings. Analyses were conducted with and without quality adjustment by patient preference. Base-case analyses focused on patients starting at 30 years of age and assumed that a patient's lifetime risk of breast cancer would be met at age 80. The lifetime risk of breast cancer and cost of MRI screening was varied to assess their impact on results.

Results: Both unadjusted and patient preference-weighted analyses demonstrate that BPM becomes more cost-effective than screening with annual mammography alone at a lifetime breast cancer risk of 50% when mean costs of BPM vs screening were estimated to be \$21,042.50 and \$20,980.44, respectively. At the cost of MRI based on Medicare reimbursement rates, breast cancer screening using combined mammography and MRI was never more cost-effective than BPM at any level of lifetime risk. Varying the cost of MRI demonstrated that at a lifetime risk of 20%, the threshold at which annual MRI screening is recommended by the American Cancer Society, the cost of an MRI would have to be less than \$177.74 to be more cost-effective than BPM.

Conclusion: In women who are at increased risk for breast cancer without a known BRCA mutation or personal history of breast cancer, BPM becomes more cost-effective than annual mammographic screening at an estimated lifetime risk of 50% and therefore should be reserved for women at markedly elevated risk. Additional screening modalities for use in high-risk women with a lower cost than MRI are needed. The results are sensitive to varying costs of screening modalities and patient preferences.

Abstract, Updated as of 4/15/15**Presenter:** Brandy Edwards**Institution:** University of Virginia**Title:** Cost-Effectiveness of Bilateral Prophylactic Mastectomy in Patients at High Risk for Breast Cancer Without a Known BRCA Mutation**Background:** Previous studies have examined the cost-effectiveness of contralateral prophylactic mastectomy in younger breast cancer (BC) patients as well as that of bilateral prophylactic mastectomy (BPM) with bilateral salpingo-oophorectomy in women with BRCA mutations. We sought to identify the level of lifetime risk at which BPM becomes a cost-effective alternative to screening.**Methods:** We developed a Markov model to simulate the total accrued costs and effects of BPM vs screening at varying levels of estimated lifetime risks. Model parameters were derived from published literature and from national databases. BPM was estimated to yield a 90% risk reduction of BC. Analyses were conducted with alternative estimates for patient preference. The baseline case was 30 years of age and assumed that a patient's lifetime risk of BC would be met by age 80. Sensitivity analyses were conducted to account for variation in key model estimates.**Results:** BPM with breast reconstruction was a cost-effective alternative at lifetime risks of 43% and 26% for willingness-to-pay (WTP) thresholds of \$50,000 and \$100,000 per LY, respectively. When preference ratings were implemented into the Markov model, BPM with reconstruction was cost-effective at estimated lifetime risks of 57% and 51% for WTP thresholds of \$50,000 and \$100,000 per QALY, respectively. Combined screening with mammography and MRI was never cost effective at these thresholds when compared to mammography screening or BPM in either model.**Conclusion:** BPM should primarily be considered in women at substantially high risk. Additional, less expensive screening modalities for use in high risk women are needed.