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Original article

Acceptance and adherence to chemoprevention among women at increased risk of breast cancer

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ABSTRACT

Background: Chemoprevention is an option for women who are at increased risk of breast cancer (five year risk ≥1.7%). It is uncertain, however, how often women accept and complete five years of therapy and whether clinical or demographic factors predict completion.

Methods: Medical records were abstracted for 219 women whose five year risk of breast cancer was ≥1.7% and who were offered chemoprevention while attending a high risk breast clinic at the Moffitt Cancer Center. We examined the likelihood of accepting chemoprevention and completing five years of therapy, and potential clinical and demographic predictors of these outcomes, using multivariable logistic regression and survival analysis models.

Results: There were 118/219 women (54.4%) who accepted a recommendation for chemoprevention and began therapy. The likelihood of accepting chemoprevention was associated with lifetime breast cancer risk and was higher for women with specific high risk conditions (lobular carcinoma in situ and atypical ductal hyperplasia). Women with osteoporosis and those that consumed alcohol were also more likely to accept medication. There were 58/118 (49.2%) women who stopped medication at least temporarily after starting therapy. Based on survival curves, an estimated 60% of women who begin chemoprevention will complete five years of therapy.

Conclusions: A substantial percentage of women at increased risk of breast cancer will decline chemoprevention and among those that accept therapy, approximately 40% will not be able to complete five years of therapy because of side effects.

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Introduction

It is estimated that 235,000 women will be diagnosed with breast cancer in 2014 [1]. Several medications have been shown to reduce the incidence of breast cancer, including the selective estrogen receptor modulators (SERM) tamoxifen [2,3], and raloxifene [3,4], and more recently, aromatase inhibitors including exemestane [5] and anastrozole [6].

The use of medications to reduce breast cancer incidence (chemoprevention) has been recommended for women at increased risk of breast cancer [7,8] and are generally taken over a five year time period. It is estimated that more than 10 million women are eligible for chemoprevention [9]. Despite these recommendations, acceptance of chemoprevention among women has been limited [10].

Previous studies that have examined uptake and adherence to chemoprevention have had important limitations. Many studies have assessed women's likelihood of accepting chemoprevention when posed as a theoretical decision, rather than their actual acceptance in real clinical settings [11,12]. In addition, most studies have not assessed rates of chemoprevention adherence among women who begin therapy [13].

To address these limitations, we examined acceptance and adherence to chemoprevention among women attending a high risk breast clinic within an NCI Comprehensive Cancer Center. We

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hypothesized that acceptance and adherence to chemoprevention would be related to the woman's individual risk of breast cancer, as estimated by the Gail Model, or by SEER population estimates (for women with lobular carcinoma in situ).

Material and methods

The H. Lee Moffitt Cancer Center Breast Surveillance Clinic provides care to women at increased risk of breast cancer because of family history (excluding those with known deleterious mutations in BRCA or other risk conferring genes) or a risk-conferring condition demonstrated by biopsy (e.g. lobular carcinoma in situ, atypical ductal hyperplasia, atypical lobular hyperplasia). The clinic provides comprehensive risk assessment, counseling on risk reduction options, and ongoing screening systematically to all women who attend the clinic. Recommendations for chemoprevention are made on the patient's initial visit to the breast surveillance clinic. For patients that elect to begin chemoprevention, prescriptions are provided by the breast surveillance clinic and are not managed by referring physicians or primary care providers.

For most women, breast cancer risk was estimated using the Gail model, providing 5-year and lifetime risk estimates [14]. The Gail model has been validated in several settings [15] but may underestimate breast cancer risk in women with atypical hyperplasia [16] and women with family history of breast cancer in second degree relatives [17]. For women with LCIS (for whom the Gail model has not been validated), 5-year and lifetime breast cancer risks were estimated using SEER population estimates [18]. Women were generally followed every six months (regardless of whether chemoprevention is being used) with imaging modalities selected based on the woman's level of risk. Most women (94%) were referred to the clinic from other providers within the Moffitt Cancer Center.

In March 2011, the patient scheduling database was used to identify all patients seen in the breast surveillance clinic during the interval 12/1/2006 through 03/14/2011. The scheduling system identified 387 women that had been seen at least one time during that interval. From this group we identified 260 women that had sufficiently elevated risk to consider chemoprevention (5-year Gail Model risk $\geq$1.7%, or lobular carcinoma in situ). There were 41 women excluded (Fig. 1) because of either 1) a contraindication to medication ($n = 18$) or 2) no evidence in the medical record that chemoprevention had been recommended ($n = 23$). The remaining 219 women who were offered chemoprevention constituted the study sample of interest.

The dates of initial appointment for this group ranged from 4/26/04 to 3/9/2011 and the dates of last recorded visit in the medical record ranged from 1/2/2008 to 11/08/2012. Women had on average 5.8 (SD 3.5) visits in the clinic and the average length of follow up for the cohort was 33.3 months (SD 21.2).

Medical records of this patient cohort were abstracted by two trained and experienced research abstractors. Data abstracted included breast cancer risk factors (age, age at menarche, age at first live birth, family history of breast cancer in first degree relatives,

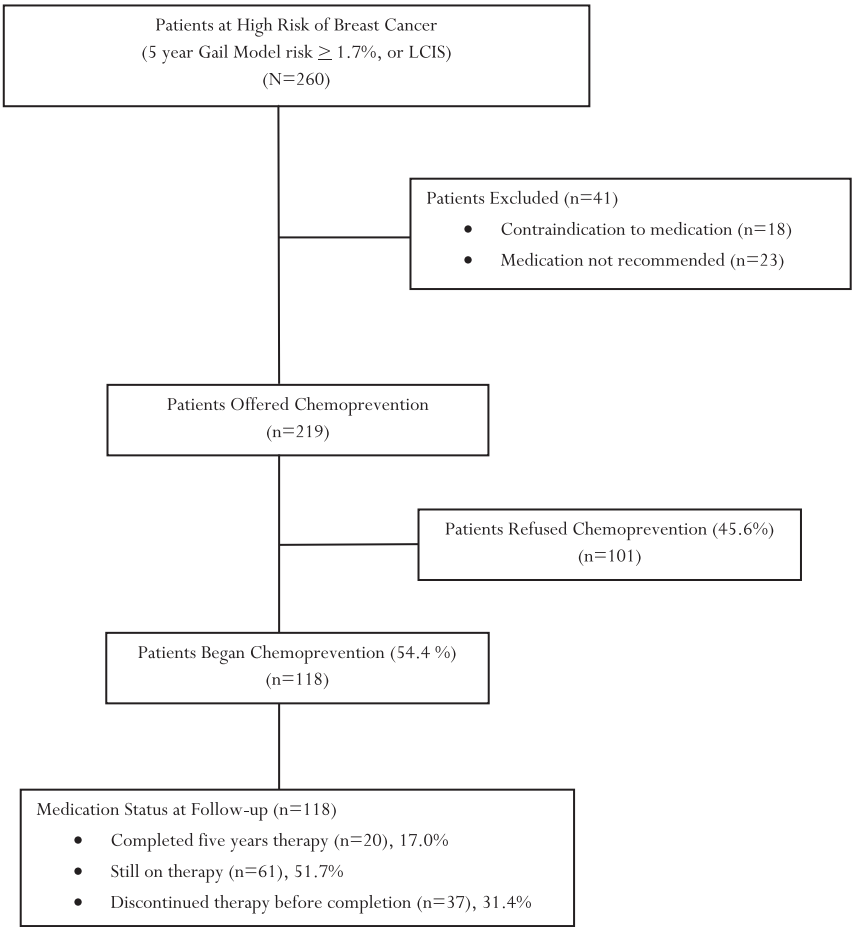

Fig. 1. Summary of high risk breast cohort and use of chemoprevention.

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