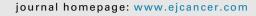


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Original Research

## The influence of gene expression profiling on decisional conflict in decision making for early-stage breast cancer chemotherapy



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### **KEYWORDS**

Decision making; Breast cancer; Gene expression profiling; Decisional conflict; Choice behaviour **Abstract** *Background:* Women with early-stage breast cancer, of whom only 15% will experience a recurrence, are often conflicted or uncertain about taking chemotherapy. Gene expression profiling (GEP) of tumours informs risk prediction, potentially affecting treatment decisions. We examined whether receiving a GEP test score reduces decisional conflict in chemotherapy treatment decision making.

*Methods:* A general population sample of 200 women completed the decisional conflict scale (DCS) at baseline (no GEP test score scenario) and after (scenario with GEP test score added) completing a discrete choice experiment survey for early-stage breast cancer chemotherapy. We scaled the 16-item DCS total scores and subscores from 0 to 100 and calculated means, standard deviations and change in scores, with significance (p < 0.05) based on matched pairs t-tests.

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**Results:** We identified five respondent subgroups based on preferred treatment option; almost 40% did not change their chemotherapy decision after receiving GEP testing information. Total score and all subscores (uncertainty, informed, values clarity, support, and effective decision) decreased significantly in the respondent subgroup who were unsure about taking chemotherapy initially but changed to no chemotherapy (n = 33). In the subgroup of respondents (n = 25) who chose chemotherapy initially but changed to unsure, effective decision subscore increased significantly. In the overall sample, changes in total and all subscores were non-significant.

**Conclusions:** GEP testing adds value for women initially unsure about chemotherapy treatment with a decrease in decisional conflict. However, for women who are confident about their treatment decisions, GEP testing may not add value. Decisions to request GEP testing should be personalised based on patient preferences.

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#### 1. Introduction

Women diagnosed with breast cancer face challenging treatment decisions. Current guidelines suggest that women with human epidermal growth factor receptor 2 (HER2) negative, lymph node negative, and hormone receptor positive disease should be offered adjuvant chemotherapy [1–4]. Yet, it is estimated that only 15% of these cancers may recur, suggesting that many patients will be treated without benefit [1–4]. Consequently, women may experience decisional conflict when making chemotherapy treatment decisions. Decisional conflict is defined as 'a state of uncertainty about the course of action to take' which is 'likely when making choices involving risk or uncertainty of outcomes' [5].

Gene expression profiling (GEP, e.g. OncotypeDX) predicts the likelihood of cancer recurrence and can help identify women who may not benefit from chemotherapy, sparing them from associated toxicity [6-10]. Recently, Epstein *et al.* [11] found GEP to be associated with lower adjuvant chemotherapy use and healthcare spending in women younger than 55 years. Medical oncologists can use GEP, in addition to traditional clinical indicators (e.g. lymph node status and receptor status), to help inform treatment decisions. However, GEP is expensive (Oncotype DX is approximately \$4,000 USD) [12] and oncologists have raised concerns about the need to determine patients' willingness to act on the results, in advance of ordering the test [13]. GEP has received considerable media attention with Canadian breast cancer patients demanding access and reimbursement for GEP.

Although a recent systematic review found no studies to support the clinical utility of GEP (i.e. direct evidence that using GEP to direct treatment decisions improved outcomes in women with breast cancer) [14], previous qualitative research has demonstrated that patients consider GEP results a deciding factor in treatment decisions [15]. Multiple studies have examined how GEP results impact or change treatment decisions in breast cancer patients [16–22]; however, studies are lacking about the impact of GEP on decisional conflict in women from the general population, who are at risk of breast cancer and may ultimately face a decision about GEP. This is important to understand, especially in a publicly funded healthcare system where healthcare decision makers make resource allocation decisions for the population, and are increasingly incorporating public values into reimbursement decisions [23].

Our findings about patient preferences demonstrated that the most important attribute in chemotherapy treatment decisions relative to other attributes – doctor's estimate of the risk of cancer returning, trust in cancer doctor and side-effects of chemotherapy – was GEP test score [24]. As part of this larger research study, we examined whether receiving GEP information and test results changes chemotherapy decisions and decreases decisional conflict in chemotherapy treatment decisions for early-stage breast cancer.

#### 2. Materials and methods

We embedded a scenario and question about preferred chemotherapy treatment option with the traditional version of the decisional conflict scale (DCS) into our discrete choice experiment survey to examine the effect of GEP information and test results on decisional conflict (Fig. 1) [5,25]. The GEP background information that the respondents received included an explanation of GEP scores and how they relate to the benefit from chemotherapy treatment and risk of distant recurrence. A GEP score <18 is considered 'low risk' of cancer returning outside the breast within 10 years and the likely benefit from chemotherapy is low, 18-30 is considered 'intermediate risk' with uncertain benefit, and 31-100 is considered 'high risk' with high benefit [26].

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