

UTILIZATION OF ONCOTYPE DX TO GUIDE TREATMENT FOR EARLY STAGE BREAST CANCER

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Introduction

- Therapy for women with early stage breast cancer typically includes, surgery and radiation therapy.
- If patients have hormone-receptor positive breast cancer, they are offered adjuvant endocrine therapy with estrogen blocking drugs.
- Patients considered at high risk of recurrence are also offered adjuvant chemotherapy (ACT).

Introduction

- The decision to consider an early stage breast cancer patient high risk and thus appropriate for treatment with ACT has historically been made using clinical and pathologic features along with patient and provider preferences.
- However, using these guidelines has resulted in the vast majority of patients receiving ACT even though only a small proportion of them can be expected to recur within five years without ACT.
- Thus many patients undergo the toxicity of ACT without the benefit.

Introduction

- The Oncotype Dx (ODX) assay can identify early stage patients with a high risk for recurrence based on a calculated recurrence score based on the expression of 21 genes.
- The ODX assay can identify patients who are most likely to benefit from adjuvant chemotherapy – and those who will not benefit and, thus, can be spared the morbidity associated with chemotherapy.
- The ODX assay was the only genetic assay broadly available during the study period, but little is known about its use.

Study objective

- The purpose of this project was to describe the utilization of ODX among a population based cohort of California breast cancer patients, identify predictors of use of ODX, and determine how utilization of the ODX assay influenced treatment of patients with early stage breast cancer.

Methods

- The study population for this project was identified through the CCR and included all patients resident in California and diagnosed with early stage breast cancer between January 2008 and December 2010
- Eligibility was defined as Stage I or II, node negative, estrogen or progesterone receptor positive, and HER2 negative.

Methods

- MediCal (California Medicaid) data from the California Dept. of Health Care Services, and ODX utilization data from Genomic Health, were linked to patient data at the California Cancer Registry.

Results – Utilization of ODX

- A total of 23,789 patients were defined as eligible for the ODX test.
- Overall 26.7% of eligible patients were tested with ODX
- Women aged 65 or older were much less likely than women under age 50 to be tested (15.1% versus 41.4%).

Results – predictors of ODX use

- Black women were slightly less likely, and Asian women slightly more likely than non-Hispanic white women to receive ODX.
- Patients covered by Medi-Cal were less likely to receive the ODX assay than non-Medi-Cal members (17.7% vs 27.5%).
- Patients residing in low SES census tracts had the lowest receipt of the test, with the proportion receiving the test increasing with SES category.

Results – predictors of ACT receipt

RS Score	N	Received ACT N (%)
<18 (low benefit)	3416 (53.9%)	247 (7.2%)
18-31 (Unclear benefit)	2389 (37.7%)	774 (32.4%)
>31 (High benefit)	534 (8.4%)	336 (62.9%)

Result – predictors of ACT receipt

- In multivariable analysis, only age was a significant predictor of receipt of chemotherapy for patients with a score indicating high risk of recurrence.
- Women over age 65 with a high score were 1/3 as likely to receive chemotherapy.

Conclusions

- Only a small proportion of breast cancer patients eligible for the ODX assay were tested between 2008-2010 in California
- Older women and poor women were less likely to be tested
- Reasons for lack of testing are unknown, but are likely related to patients and physicians making decisions to treat (or not) without using the assay
- Cost is unlikely to be a factor as the test is covered by MediCal, Medicare and most insurance

Conclusions (cont.)

- What is perhaps more surprising is that among patients who did receive the test, and whose results indicated a high benefit of chemotherapy, only 63% received treatment.
- However, it is likely that CCR data on chemotherapy are incomplete, and this is a major limitation of the study.

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