A Non-randomized, Observational Trial of Short-term Pre-operative Endocrine Therapy in ER Positive Breast Cancer to Investigate Changes in Genomic Expression Using the Oncotype DX® Recurrence Score®

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Breast Cancer to Investigate Changes in Genomic Expression Using the Oncotype DX® Recurrence Score®

• Single gene cut-point values (reference normalized expression, log2 scale):

Materials and Methods

Objective

• The 21-gene Recurrence Score (RS) assay has been shown to be a predictor of both short-term neoadjuvant endocrine therapy has been reported to be well tolerated and chemotherapeutic and pathologic response.

• Pre-operative systemic treatment is commonly employed for women with locally advanced breast cancer whose resections may be delayed for 30 to 60 days while they undergo pre-operative endocrine therapy while awaiting surgery.

• Short-term neoadjuvant endocrine therapy has been reported to be well tolerated and results in a medicated clinical response.

• Only 3 pre-menopausal patients; too few to examine potential differences by menopausal status.

• Decreases in ER have been observed following short term aromatase inhibitor treatment, as was RS (r = 0.89), following short term neoadjuvant endocrine therapy.

• Clinical response was assessed by ultrasound (US) and clinical examination.

• Pre-operative endocrine therapy may benefit from receiving pre-operative endocrine therapy while awaiting surgery.

• The 21-gene Recurrence Score (RS) assay has been shown to be a predictor of both chemotherapeutic and pathologic response.

• Hypothesis tests not pre-specified

• Summary and Discussion

• Expression of ER and PR, and HER2 from core biopsies and excisional specimens were correlated (Pearson correlation coefficients, r = 0.87, 0.72 and 0.77, respectively).

• Prospective study of changes in biomarkers in early-stage, ER+ breast cancer treated with chemotherapy.

Results

• 21 patients consented to this study and initiated short-term neoadjuvant therapy:

• 8 patients did not have evaluable core and excisional specimens

• 1 patient had no residual cancer in the excisional specimen

• Prospective study of changes in biomarkers in early-stage, ER+ breast cancer treated with chemotherapy.


• No significant change in overall statistical significance in ER relative to ER+ status.

• The clinical significance of these observed changes are unclear.

• HER2-negative breast cancer has been demonstrated in multiple clinical studies; none of these patients had received neoadjuvant therapy.

• There are no data on the prognostic or predictive ability of the RS in tumor samples obtained after neoadjuvant therapy.

• The clinical significance of the changes in RS and PR is therefore unclear.

Conclusions

• In this small, hypothesis-generating study:

• Expression of ER and PR increased small but statistically significant amounts with neoadjuvant therapy and a small but statistically significant increase in RS was noted.

• The clinical significance of these observed changes are unclear.

• Decreases in ER have been observed following short term aromatase inhibitor treatment in several studies. 3, 4 but not others. 6

Background

Pre-operative systemic treatment is commonly employed for women with locally advanced breast cancer. Women with early-stage, hormone receptor-positive breast cancer whose resections may be delayed for 30 to 60 days while they undergo pre-operative endocrine therapy may benefit from receiving pre-operative endocrine therapy while awaiting surgery.

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• Pre-operative systemic treatment is commonly employed for women with locally advanced breast cancer whose resections may be delayed for 30 to 60 days while they undergo pre-operative endocrine therapy while awaiting surgery.

• Short-term neoadjuvant endocrine therapy has been reported to be well tolerated and results in a medi-

• Only 3 pre-menopausal patients; too few to examine potential differences by menopausal status.

• Potential selection bias.

• Hypothesis tests not pre-specified.

• Expression of ER and PR, and HER2 from core biopsies and excisional specimens were correlated (Pearson correlation coefficients, r = 0.87, 0.72 and 0.77, respectively).

• Prospective study of changes in biomarkers in early-stage, ER+ breast cancer treated with chemotherapy.


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