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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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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 evaluation, may benefit from short-term endocrine therapy while awaiting surgery. Short-term endocrine therapy has been reported to be well tolerated and results in a modest clinical response. 1,2

Materials and Methods
Treatment: 4 weeks of daily letrozole (2.5 mg) for pre-menopausal women or tamoxifen (20 mg) for pre-menopausal women awaiting surgery. Clinical response was assessed by ultrasound (US) and clinical examination. Endocrine therapy responsiveness and may be used as an indicator of chemosensitive disease. 3-4

Methods
This was an exploratory, hypothesis-generating study. Scatter plots of core biopsy vs excisional specimen results were produced. Pearson correlation coefficients and 95% confidence intervals (CI) were calculated to assess correlation from core biopsies to excisional specimen results. Results are presented as mean difference (95% CI) and p-value from paired t-test.

Strengths
Prospective study of changes in biomarkers in early-stage, ER+ breast cancer treated with endocrine therapy. The clinical significance of the changes in ER, PR and RS observed in this study is not known. There are no data on the prognostic or predictive ability of the RS from tumor excision. In this small, hypothesis-generating study:

Conclusions
In this small, hypothesis-generating study:

• Expression of ER and PR decreases modestly but statistically significant amounts with short-term endocrine therapy. The clinical significance of these observations is unclear.

Conflicts of Interest
None of the authors have financial conflicts of interest related to the manuscript.

References
3  Single Gene Status Menopausal Status
4  Stable disease (SD): other than above
5  Partial Response (PR): disease decreased to ≤50% from baseline ER and PR were decreased by small but statistically significant amounts, as were levels of other markers studied. 8-9
6  Hypothesis tests not pre-specified for changes occurring in the same direction.
7  No hypothesis test for SD/PD changes for ER or PR.
8  P<0.001, t test, paired t-test
9  Not statistically significant. Results are not presented in this manuscript.