

Phase II trial evaluating the use of 21-gene recurrence score (RS) to select preoperative therapy in hormone receptor (HR)-positive breast cancer.

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Background: Hormone receptor (HR)- positive breast cancer patients (pts) typically have lower pathological responses to pre-operative chemotherapy than HR-negative breast cancers. Objective: We evaluated the pathologic and radiologic response rates to pre-operative endocrine therapy or chemotherapy, as directed by RS, in pts with HR-positive resectable breast cancers. **Methods:** Pts with HR-positive breast cancers had RS performed on the initial diagnostic biopsy. Pts were treated pre-operatively as follows based on RS: ≤ 10 , exemestane +/- goserelin for 6 to 12 months (ET); 11 to 25 randomized to ET or docetaxel-cyclophosphamide (TC) for 6 cycles (CT); ≥ 26 , CT. **Results:** From 4/2009 to 12/2012, 66 pts signed consent for RS testing and 46 are evaluable for efficacy analysis. Median age is 57 (40 to 78); one-third of pts are African-American; 41% have clinically node positive disease. RS ranged from 2 to 57. 28 pts received CT: Pathologic complete response (PCR) rate was 10% and 60% of cancers were down-staged based on initial T-stage. Radiologic response is available for 20 pts: complete radiologic response (CRR) 15%, partial RR (PRR) 40%, progressive disease (PD) 5%. In 11 pts with RS 11 to 25: PCR 0%, down-staged 45%, up-staged 18%, radiologic responses: CRR 17%, PRR 50%, PD 17%. In 17 pts with RS ≥ 26 : PCR 18%, down-staged 71%, up-staged 0%, radiologic responses: CRR 14%, PRR 36%, PD 0%. 18 pts received ET for between 6 to 22 months, 5 remain on study and have not had surgery: PCR 0%; down-staged 38%; up-staged 15%; radiologic responses: CRR 13%, PRR 40%, PD 0%. There was no correlation between RS and efficacy of ET. To date, 3 pts have relapsed, all of whom received CT. **Conclusions:** This is the first prospective use of the 21-gene RS to select pre-operative therapy for pts with HR-positive breast cancer. Pre-operative CT results in tumor down-staging in the majority of cancers with RS ≥ 11 , though it appears to be more effective with RS ≥ 26 . ET was moderately effective in down-staging cancers with RS ≤ 25 . Updated results will be presented. Clinical trial information: NCT00941330, NCT00832338.