

RESULTS FROM A PROSPECTIVE CLINICAL STUDY ON THE IMPACT OF ONCOTYPE DX ON ADJUVANT TREATMENT DECISION MAKING IN A COHORT OF 142 UK PATIENTS.

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Goals: International guidelines support the use of the Oncotype DX derived Recurrence Score (RS) to provide additional prognostic and predictive information in early breast cancer but experience in the UK is limited. In our prospective study we evaluate this test for the NHS and its impact on costs (subject of a separate abstract) and treatment recommendations by UK oncologists.

Methods: 150 tests were made available to consecutive patients with ER+, pN0 or pN1mic early breast cancer who had no contraindication to adjuvant chemotherapy (CT) and who would accept chemotherapy if recommended. CT recommendations of oncologists based on Adjuvant! Online figures were recorded at an initial consultation and again after a second consultation once the RS was available.

Results: Analysis is based on 142 patients. (150 tests performed, 3 failed to give a result, 3 repeated tests giving a result on the second block, one bilateral and one test stopped because the patient withdrew from the study). Initial treatment recommendations changed in 38 (26.8%) cases. Of the patients initially recommended CT + HT (total 57 patients), 26 (45.6%) patients were spared chemotherapy after review of the RS. Of the 85 patients initially recommended HT only (total 85 patients), 12 (14.1%) were changed to HT+CT. Further analysis shows that Grade and PR by IHC are correlated to RS. (Spearman rank correlation for grade is 0.05, 95%, CI 0.36 to 0.61 and for PR by IHC is -0.49, 95%, CI -0.60 to -0.35). If testing had been confined to patients initially recommended chemotherapy and patients with Grade 2/3 tumours plus a PR by IHC of 6 or less (84 patients) then 35 of the 38 (92.1%) changes in CT recommendations would have been included and the cost the test avoided in 58 (40.8%) of the patients.

Conclusion: The results of our study suggest that Oncotype DX is applicable and feasible to perform in UK patients with a reduction in the use of adjuvant chemotherapy consistent with findings of other reported studies. RS added prognostic information beyond information provided by Adjuvant!

Decision	Patient Number	% of Patients	% change
HT only Unchanged	73	51.41%	
HT only Changed to HT + CT	12	8.45%	14.11%
CT + HT Unchanged	31	21.83	
CT + HT Changed to HT alone	26	18.31%	45.61%