Use of Oncotype DX for guiding adjuvant chemotherapy decisions in early stage invasive breast cancer patients in Alberta

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Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' conclusions
Based on 2 ad hoc retrospective analyses of RCTs in each of LN+ and LN- population, the survival difference between those treated with chemotherapy and those treated with hormones is greater in those with a high risk Oncotype DX score than those with a low risk Oncotype DX score. These studies represent limited, low quality evidence supporting the clinical utility of Oncotype DX to predict benefit from chemotherapy. In addition, this study design has a high risk of bias; 1) the studies are not powered to detect differences among risk subgroups as the subgroup analysis is not part of the original design, 2) ad-hoc analyses are likely to identify 75 spurious relationships due to chance alone, 3) the treatment received and outcome of the women is known and may influence the Oncotype DX risk score classification and finally 4) the generalizability of the population is compromised as the ad-hoc analyses utilized a subset of the original RCT population. Based on 10 observational studies of low to medium quality, Oncotype DX results lead to a change in adjuvant chemotherapy decision in 32% (95% CI : 24%-40%) of cases. There was a high degree of heterogeneity among the studies thus the pooled results must be interpreted with caution. However, all studies reported a change in practice supporting the pooling of results and conclusion that Oncotype DX does result in a clinical change. Oncologists and pathologists in Alberta have mixed opinions which reflect skepticism about the analytic utility of Oncotype DX, especially for patients in the intermediate risk group, as well as a lack of consensus about the communication and usability of the results obtained from IHC4 testing. From a patient perspective, genetic testing may present complex information which may be hard to understand. Therefore, care providers must continue to play an active role in explaining the implications of test results and treatment options. The cost per QALY associated with Oncotype DX compared with Adjuvant! Online for all patients is $3789/QALY. The cost per QALY gained in Alberta varies from other jurisdictions due to the costs of chemotherapy covered within the public healthcare plan. Depending on uptake of Oncotype DX testing among the eligible Alberta patient population, publicly funding Oncotype DX would cost between $367,000 and $3.66 million annually.

Final publication URL

Indexing Status
Subject indexing assigned by CRD

MeSH
Breast Neoplasms; Chemotherapy, Adjuvant; Females

Language Published
English

Country of organisation
Canada

Province or state
Canada
Alberta

English summary
An English language summary is available.

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AccessionNumber
32015000515

Date abstract record published
19/05/2015