Oncotype DX for Early Stage, Lymph Node-Negative Breast Cancer: A Review

Context
Breast cancer is the most common cancer diagnosis in Canadian women older than 20. It is one of the leading causes of cancer deaths in Canadian women, second only to lung cancer. For patients with estrogen receptor-positive (ER+) and lymph node-negative (LN–) early stage breast cancer, the decision about adjuvant chemotherapy after surgery has traditionally been guided by clinical and pathological factors together with clinician and patient preferences. However, certain biological features of breast cancers can indicate whether the cancer is more or less likely to grow rapidly or return in another part of the body. Testing for these features can help guide the decision of whether to undergo adjuvant chemotherapy.

Technology
Oncotype DX (ODX) is a gene expression profiling test designed to measure the 10-year risk of tumour recurrence in early breast cancer following initial diagnosis. The risk of tumour recurrence is reported as a 21-gene signature or recurrence score (RS) on a scale of 0 to 100. The RS is translated into one of three categories of risk: low (RS < 18), intermediate (RS 18 to 30), or high (RS > 30).

Issue
A review of the clinical effectiveness of ODX in LN–, ER+, and human epidermal growth factor receptor 2 (HER2) negative early stage breast cancer patients, together with a review of clinical guidelines will help to guide decisions about the use of ODX in these patients.

Methods
A limited literature search was conducted of key resources, and titles and abstracts of the retrieved publications were reviewed. Full-text publications were evaluated for final article selection according to predetermined selection criteria.

Key Messages
In patients with early stage breast cancer that is LN– (and ER+, and HER2–):

- ODX has an impact on approximately 30% of treatment plans.
- ODX primarily results in lower rates of adjuvant chemotherapy (low risk score), but in some cases the test suggests adjuvant chemotherapy when it was not initially planned (high-risk score).
- The impact of ODX for patients in the intermediate-risk category is uncertain.

ER = estrogen receptor.
HER2 = human epidermal growth factor receptor 2.

Results
The literature search identified 222 citations, of which 32 were deemed potentially relevant. An additional 10 articles were identified from the grey literature. Of these 42 reports, 14 met the criteria for inclusion in this review: 2 health technology assessments, 2 systematic reviews, 4 prospective cohort studies, and 6 clinical practice guidelines.

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