The impact of chemotherapeutic regimens on the cost-utility analysis of Oncotype DX® assay

Background

An emerging issue in regards to adjuvant treatment decisions for women with estrogen receptor positive (ER+), HER2 negative (HER2-) early breast cancer (EBC) is how to personalise the adjuvant treatment; whether patients need chemotherapy (CT) with sequential endocrine therapy (ET) or can they be spared from unnecessary CT and treated with 4t HT alone.

- Current decision models are based on pathological and clinical parameters: tumor size, nodal status, hormone receptor status, HER2 status, histological grade, proliferation activity (e.g. MIB1), personal factors, and patient preferences.

- The Oncotype DX breast cancer multigene expression assay (4t HT) has demonstrated that it predicts the likelihood of chemotherapy benefit for early stage breast cancer patients (through a variety of different chemotherapies). (11, 16-23) An emerging issue in regards to adjuvant treatment decisions for women with ER+, HER2- EBC is how to personalise the adjuvant treatment; whether patients need chemotherapy (CT) with sequential endocrine therapy (ET) or can they be spared from unnecessary CT and treated with 4t HT alone.

- The Oncotype DX assay is currently the only multi-gene assay included in the published ACGME and NCCN guidelines for assessing progesterone and predict chemotherapy benefit. (6-7) The hypothesized cost of Oncotype DX® in the actual clinical practice (the actual scenario) is 13894 €/QALY. The decrease in chemotherapy use if Recurrence Score is high risk +9.0% Decrease in chemotherapy use -27.9%

- The model used an expected change in chemotherapy use per the intervention of the Oncotype DX® assay of +2.9% for node-negative patients and -16.9% for node-positive patients. The model predicted an incremental cost-effectiveness ratio (ICER) of 13894 €/QALY is our best estimate for the Oncotype DX® assay in the actual clinical practice (the actual scenario). The cost of chemotherapy was extracted from the official cost database in Hungary (27). Costs, per patient tested (€):

<table>
<thead>
<tr>
<th>CT Regimens</th>
<th>Average age (year) 60,8</th>
<th>Cost of Oncotype DX® type</th>
<th>Recurrence</th>
<th>Deaths</th>
<th>Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAC/ FEC</td>
<td>60,9</td>
<td>2248.25 €</td>
<td>0.147</td>
<td>2 (9)</td>
<td>2 (9)</td>
</tr>
<tr>
<td>TE/ TEC</td>
<td>61 (19,9)</td>
<td>1344.8 €</td>
<td>0.147</td>
<td>3 (11)</td>
<td>4 (13)</td>
</tr>
<tr>
<td>III</td>
<td>65 (20,7)</td>
<td>1310.7 €</td>
<td>0.136</td>
<td>2 (9)</td>
<td>3 (11)</td>
</tr>
</tbody>
</table>

- Results:

  

<table>
<thead>
<tr>
<th>CT Regimens</th>
<th>Average age (year) 60,8</th>
<th>Cost of Oncotype DX® type</th>
<th>Recurrence</th>
<th>Deaths</th>
<th>Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAC/ FEC</td>
<td>60,9</td>
<td>2248.25 €</td>
<td>0.147</td>
<td>2 (9)</td>
<td>2 (9)</td>
</tr>
<tr>
<td>TE/ TEC</td>
<td>61 (19,9)</td>
<td>1344.8 €</td>
<td>0.147</td>
<td>3 (11)</td>
<td>4 (13)</td>
</tr>
<tr>
<td>III</td>
<td>65 (20,7)</td>
<td>1310.7 €</td>
<td>0.136</td>
<td>2 (9)</td>
<td>3 (11)</td>
</tr>
</tbody>
</table>

- Conclusion:

  The ICER associated with using Oncotype DX® in current clinical practice (the actual scenario) is 13894 €/QALY. This value is consistent with any oncology-related health technology and below the "willingness-to-pay" threshold (1200-2000 €/QALY). Oncotype DX® is a cost-effective technology in the Hungarian setting.

Study Objectives:

1. To estimate the cost-effectiveness of using Oncotype DX® for recommended patients in a single-center Hungarian hospital.
2. To estimate the impact of using the Oncotype DX® Recurrence Score (RS) results, for the majority of these recommendations are from (19-21,27) the actual scenario.

Method:

- We included only those patients who had been treated with a non-redundant adjuvant therapy.
- Patients were divided into two subgroups by nodal status: node-negative and 1-3 positive nodes.
- The costs of the different chemotherapies were extracted from the official cost database in Hungary (27).

Note: In Hungary, there are only two quality-approved oncology-related health services: CT and ET. Thus, the oncological decision was limited to these two main treatment modalities.

Results:

- The cost of used Oncotype DX® type was 13894 €/QALY.

Conclusions:

The ICER associated with using Oncotype DX® in current clinical practice (the actual scenario) is 13894 €/QALY. This value is consistent with any oncology-related health technology and below the "willingness-to-pay" threshold (1200-2000 €/QALY). Oncotype DX® is a cost-effective technology in the Hungarian setting.

References:

18 ... /positive, hormone receptor-positive early-stage breast cancer based on Japanese validation study (JBCRG-TR03).
17 ... in lymph node-negative, estrogen receptor-positive, early-stage breast cancer. Am J Manag Care. 2005;11:313-324