

**The impact of the 21-gene assay in the Czech Republic on adjuvant chemotherapy (CT) recommendations and costs in estrogen receptor positive (ER+) early stage breast cancer (ESBC) patients with grade 2 tumors and risk factors.**

Author(s): Katarina Petrakova, Lubos B. Petruzelka, Milos Holanek, Tomas Svoboda, Marketa Palacova, Iveta Kolarova, Zuzana Bielcikova, Zuzana Zbozinkova

Background: Conventional clinical risk factors are imprecise for determining recurrence risk. Multigene classifiers may provide useful information to resolve treatment decisions in the presence of these risk factors. We assessed the impact of the 21-gene assay on frequency and cost of CT usage in ESBC patients with risk factors in Czech medical centers. Methods: Eligible patients had ER+, HER2-, N0, grade 2 tumors and one secondary risk factor (high Ki67, micrometastatic disease, low/negative progesterone receptor expression). Following surgery, a treatment recommendation was formulated, then the 21-gene assay was ordered. Following receipt of the assay results, the treatment recommendation was reevaluated. Changes in treatment decision and influence of the assay result on treatment decision were recorded. Results: The study recruited 200 consecutive patients at 13 centers, with Recurrence Score data available for 196 (109 (55.6%) low, 75 (38.3%) intermediate, and 12 (6.1%) high Recurrence Score results). Overall, 63.7% of treatment recommendations changed after receipt of the assay result (62.2% switched from CHT to HT and 1.5% switched from HT to CHT). Most physicians agreed (59.5%) or strongly agreed (33.5%) that the 21-gene assay influenced their decision. Budget impact analysis in this patient population at the current 23% rate of testing, showed that utilization of the 21-gene assay results in a total budget impact of \$183,019 in 2016 increasing to \$279,806 in 2020. Conclusions: In this population of ESBC patients with grade 2 tumors the 21-gene assay reduced CT use by more than 60%, with >90% of physicians indicating that it influenced their treatment decision. The total budget impact of usage of the 21-gene assay in the Czech Republic is expected to be almost \$282,851 per year in 2020, with part of the assay reimbursement cost compensated for by reduced CT usage. Further health economic studies are warranted to evaluate cost effectiveness.

	After 21-Gene Assay		
	HT	CHT	Total
<b>Before 21-Gene Assay</b>			
<b>HT</b>	42 (21.4%)	3 (1.5%)	45
<b>CHT</b>	122 (62.2%)	29 (14.8%)	151
<b>Total</b>	164	32	196