

■ ENGLISH SUMMARY

Gene profiling assays for planning breast cancer treatment

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Background

Gene expression profiling of breast cancer tissue is aimed to help treatment planning for early-stage breast cancer. Gene profiling is stated to define a more precise prognosis than traditional clinicopathological risk markers (age, tumor size, histological grade, hormone receptor expression and lymph node status) or web-based risk calculators based on these markers. Testing should identify the group of patients who do not benefit from adjuvant chemotherapy, thus giving the advantage of avoiding the potential harmful effects and costs of medication.

Aim and methods

This study was planned to assess the effectiveness and cost-effectiveness of three commercial gene expression assays for breast cancer: MammaPrint, OncoType DX and EndoPredict. The study is based on a systematic literature review including 28 studies on prognostic accuracy and 21 on economic evaluations.

Effectiveness

Prognostic and predictive accuracy has been evaluated only in retrospective studies based on variable and partly overlapping patient cohorts. The results of these three tests are proved to have a statistical connection with breast cancer outcomes and some studies show improved risk stratification over standard predictors. However, comparable results with other breast cancer outcome calculators are rare and evidence of clinical utility is lacking. The gene profiling assays do not replace other diagnostic tests, so their usage would increase the costs of the diagnostic pathway.

Conclusions

The available research evidence does not support routine clinical application of these tests. Two ongoing randomized trials are assessing the clinical value of MammaPrint and OncoType DX. Their results will be available in the near future.