Biomarkers in breast cancer

A NOVEL MULTIGENE ASSAY IN CLINICAL PRACTICE - PERFORMANCE AND IMPACT ON CLINICAL DECISIONS

B.V. Sinn1, B.M. Müller1, E. Keil2, A. Lehmann1, C. Richter-Ehrenstein1, J. Prinzler1, M. Schmidt4, M. Dietel1, C. Denkert1

1Department of Pathology, Charité - Universitätsmedizin Berlin, Berlin, GERMANY, 2Breast Center, Parkklinik Weissensee, Berlin, GERMANY, 3Department for Gynecology and Obstetrics, Charité - Universitätsmedizin Berlin, Berlin, GERMANY, 4Department for Gynecology and Obstetrics, Johannes-Gutenberg-Universität Mainz, Mainz, GERMANY

Introduction: In addition to established clinicopathological prognostic factors, genomic multigene assays may assist adjuvant treatment decisions in breast cancer. EndoPredict (EP) is a novel multigene assay to predict the risk of metastasis in patients with estrogen receptor (ER) positive, HER-2 negative breast cancer treated with endocrine therapy alone. It is performed decentralized in pathology laboratories and combines a molecular 8-gene score with clinical data (EPclin score). It provides additional prognostic information compared to standard pathological and clinical factors alone. We investigated the performance of EPclin in clinical practice and performed a retrospective evaluation of its impact of on treatment decision.

Materials and methods: All EPs that were performed during a period of one year at the Department of Pathology of the Charité were evaluated. Clinical and pathological data were extracted from pathology reports. For evaluation of treatment decisions, a questionnaire was sent to the participating gynecologists. It consisted of two questions with two possible answers regarding treatment decision before and after the EP.

Results: 167 tests were successfully performed, 58.8 % in three days or less. 77 patients (46.4 %) were classified as low risk and 89 (53.6 %) as high risk. The estimated median 10-year-risk for metastasis with endocrine therapy alone was 11%. We received questionnaires for 130 patients (77.8 %). Therapy recommendation was changed in 37.7 % of cases after the EP. 16 patients (12.3 %) received additional chemotherapy while 33 (25.4 %) cases were reconsidered to receive endocrine therapy alone. 8 patients (6.1 %) did not agree to the recommendation of the tumor board.

Conclusions: The EndoPredict assay is applicable in daily practice in a molecular pathology laboratory. It markedly changes treatment decisions in ER positive breast cancer.

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