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Titel des Beitrags:
Decision impact and feasibility of different ASCO-recommended biomarkers in early breast cancer: Prospective comparison of molecular marker EndoPredict and protein marker uPA/PAI-1.

Abstract:
Adjuvant therapy decisions in early breast cancer are based on accurate risk assessment. Urokinase plasminogen activator (uPA) and plaminogen activator inhibitor-1 (PAI-1) have been the first biomarkers in hormone receptor (HR) positive breast cancer to reach highest level of evidence. The EndoPredict test (EPclin) combines gene expression information with nodal status and tumor size. The aim of this prospective study was to compare uPA/PAI-1 and EPclin as prognostic biomarkers with regard to feasibility, risk stratification and impact on adjuvant therapy recommendation.395 patients with HR positive, HER2 negative, intermediate risk breast cancer were enrolled. Relations and concordance of histologic grading as well as EPclin and uPA/PAI-1 values were assessed by Spearman's rank correlation coefficient and Cohen's Kappa. To compare decision impact of EPclin and uPA/PAI-1 three independent case discussions were held: One with known uPA/PAI-1 and EPclin results, one blinded to EPclin alone and another one blinded to both EPclin and uPA/PAI-1. EPclin could be determined in all 395 (100%), uPA/PAI-1 in 190 (48%) of the tumor samples. EPclin allocated 250 patients (63%) to the low-risk group and 145
patients (37%) to the high-risk group, whereas uPA/PAI-1 allocated 88 patients (46%) to the low-risk
group and 102 patients (54%) to the high-risk group. In 59% of cases, both tests showed concordant
results. EPclin resulted more frequently in a change of therapy recommendation than the uPA/PAI-1
test (46% vs 24%). Recommendation of adjuvant chemotherapy (CTX) was abandoned twice as often
by EPclin (45%) compared to uPA/PAI-1 (22%). In this first prospective comparison of EPclin and
uPA/PAI-1 we found, that EPclin is superior to uPA/PAI-1 with respect to feasibility and decision
impact. This leads to substantial avoidance of adjuvant CTX in endocrine-sensitive, HER2-negative
breast cancer. Data collection for patients’ clinical outcome is ongoing.