EndoPredict®
Breast Cancer Recurrence Test

Clinical Validation of EndoPredict in Pre-Menopausal Women with Estrogen Receptor-Positive (ER+), Human Epidermal Growth Factor Receptor 2-Negative (HER2-) Primary Breast Cancer

ASCO 2021 (Constantinidou A. et al., J Clin Oncol 39, 2021 (suppl 15; abstr 537))

Introduction

EndoPredict is validated to predict distant recurrence-free survival (DRFS) and response to chemotherapy in both pre- and post-menopausal women with ER+, HER2- breast cancer, with the majority of data available in the postmenopausal setting. To further confirm utility in younger patients, this study specifically evaluated the performance of EndoPredict in premenopausal women.

Study Design

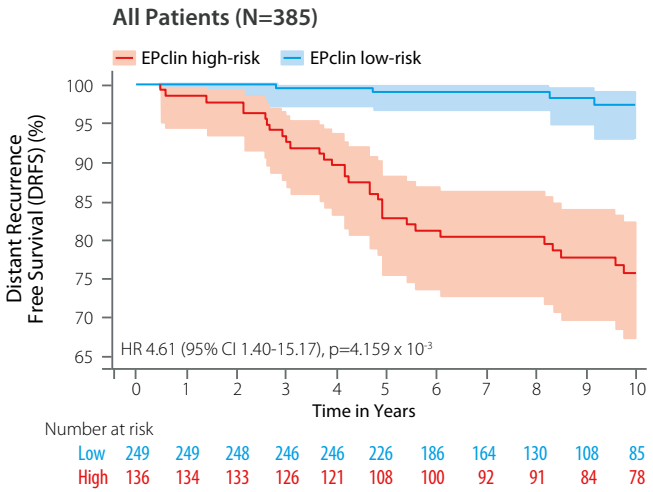
- ER+, HER2- primary breast tumor (pN0-1, <pT3) samples from women who were pre-menopausal at the time of diagnosis and were systemically treated with adjuvant endocrine therapy alone were obtained from the University of Nottingham, UK and the Bank of Cyprus Oncology Centre, Cyprus.
- Primary objective: To evaluate the association between the EPclin risk score (continuous variable) and 10-year distant recurrence (DR).

Methods

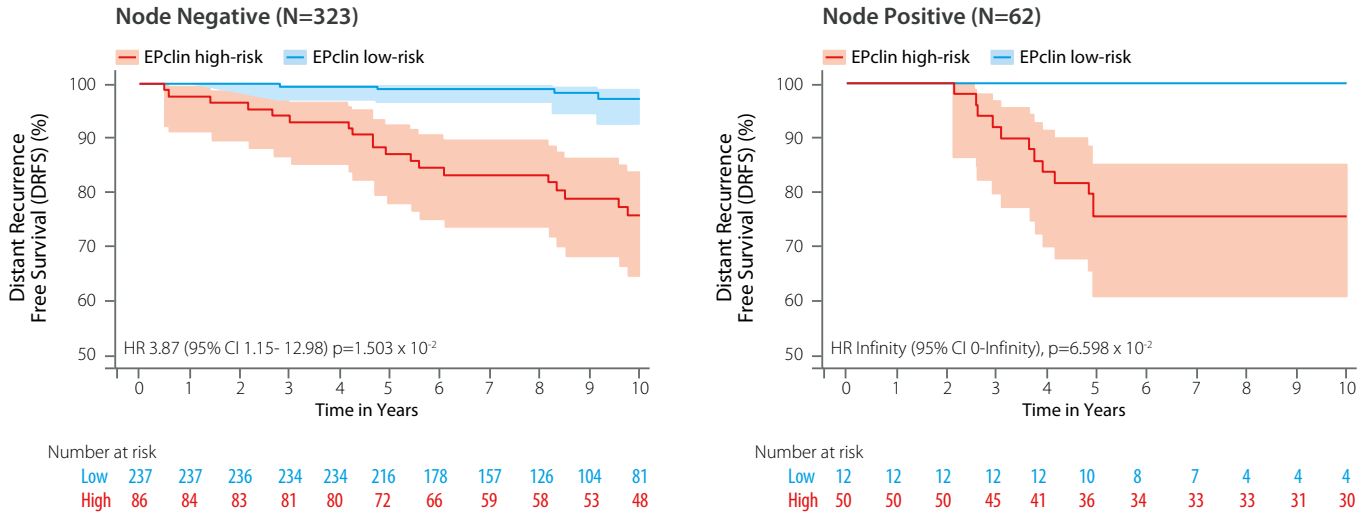
- Samples were tested retrospectively with EndoPredict to produce the 12-gene molecular score (EP) and, in combination with pathologic tumor size and nodal status, the risk score (EPclin).
- Associations of EP and EPclin with 10-year DRFS were evaluated using Cox proportional hazards models stratified by cohort.
- 10-year DRFS was estimated for EP and EPclin high- and low-risk by Kaplan-Meier analysis.

Results

- 385 patients were included in the analysis with a median follow-up of 9.7 years.
- Both EPclin (HR 3.6, p<0.001) and EP (HR 1.3, p<0.001) were strongly associated with increased risk of DR.
- In multivariate cox proportional hazard analysis, EPclin was the only factor significantly associated with the risk of DR within 10 years (HR = 2.91, p<0.001), independent of age, tumor grade, Ki67, ER expression, and PR expression.
- Multivariate cox proportional hazard analysis of EP score and clinical factors demonstrated that EP, tumor size, nodal status, and tumor grade were all significantly associated with distant recurrence.
- 64.7% of all patients were classified as EPclin low risk.
- 10-year DRFS: the EPclin high-risk group had a significantly increased risk of distant recurrence compared to the low-risk group, 76% vs 97% DRFS.
- Similar DRFS results were observed for the EP 12-gene molecular score: high-risk (85%) vs EP low-risk (100%).



- Evaluation of DRFS by nodal status also demonstrated EPclin is strongly associated with the risk of distant recurrence within 10 years regardless of nodal status.



Conclusion

- In this study, with a median follow-up time of 9.7 years, the EP and EPclin scores were highly associated with DRFS in premenopausal women who received adjuvant endocrine therapy alone.
- **Based on these data, pre-menopausal women with EPclin low-risk breast cancer with up to three positive lymph nodes may safely forgo adjuvant chemotherapy in addition to endocrine therapy.**

Bottom Line

- **EndoPredict is validated for both post- and pre-menopausal patients.**
- **These data highlight the importance of testing pre-menopausal women with ER+, HER2- breast cancer with EndoPredict.**
- **EndoPredict identified 65% premenopausal patients with low-risk disease who may safely forgo adjuvant chemotherapy - independent from nodal status.**

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