Clinical Validation

In Women With Estrogen Receptor-Positive (ER+), Human Epidermal Growth Factor Receptor 2- Negative (HER2-) Primary Breast Cancer

digistain™

Introduction

Independent validation study for a novel, rapid, and cost-effective alternative to transcriptomic risk profiling for the prediction of disease-free survival to identify low risk patients who may forgo adjuvant chemotherapy in women with ER+, HER2- breast cancer.

- 801 patients with HR+, HER2-, ≤3 positive lymph node breast cancer
- No adjuvant chemotherapy: Systemic endocrine therapy where appropriate
- Median follow up 12.7 years

When DI was incorporated with other clinicopathological variables DPS showed high accuracy and predictive performance in the total population and the different subgroups.

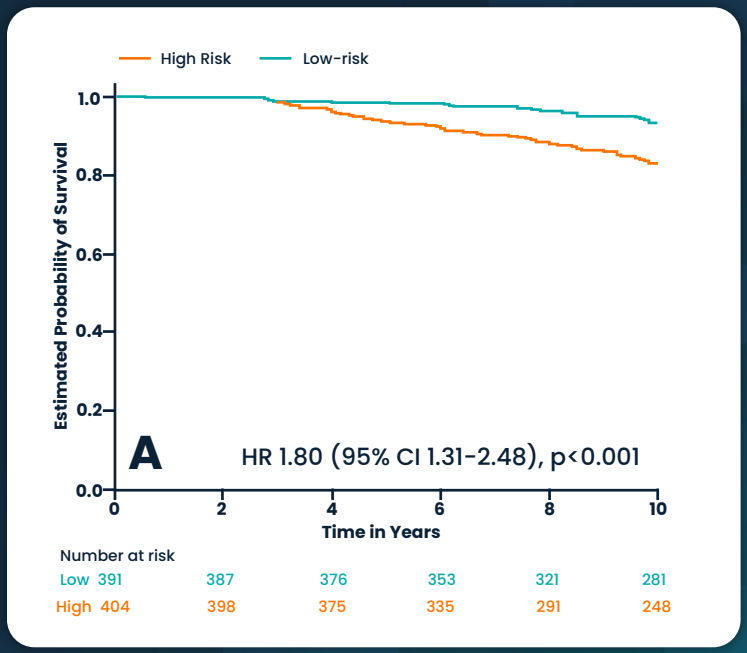
Table 1 – Accuracy for prediction of risk scoring for outcomes in the total population

	AUC	NPV
	10 years	10 years
DPS	0.75	0.94
Recurrence	0.75	0.94
Overall Survival	0.69	0.90

DPS stratified patients as low or high risk in the total population and subgroups including premenopausal women

Graph demonstrates Digistain ability to characterise previously unidentified low risk patients suitable for the safe avoidance of adjuvant chemotherapy.

- High accuracy and predictive performance in HR -positive HER2-negative primary operable breast cancer and ≤3 positive lymph nodes.
- Classifies patients as low or high risk with similar accuracy and predictive performance as that reported for other risk stratification tools.
- Demonstrates clinical utility for low-cost, rapid and widely accessible prognostic testing.
- DPS was highly associated with RFS in ER+, HER2- early-stage primary tumor breast cancer patients who received adjuvant endocrine therapy alone.
- Women with DPS low risk breast cancer with up to 3 lymph nodes may safely forgo adjuvant chemotherapy in favour of endocrine therapy.



References

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