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Association of the Digistain Prognostic Score with outcomes in patients with HR-positive HER2-negative breast cancer

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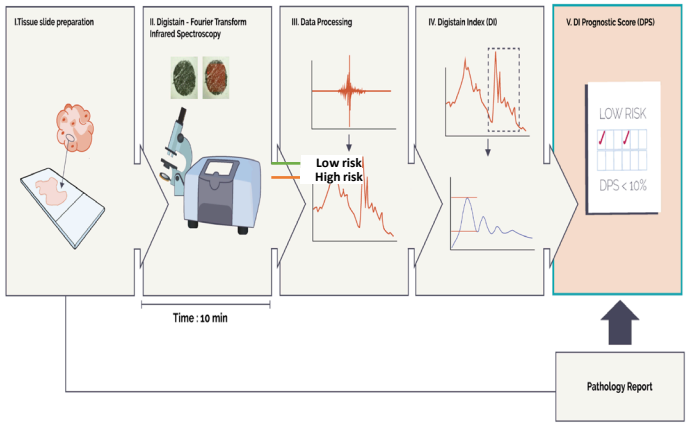
Introduction

- An unmet need exists for a high-performing, cost-effective accessible prognostic test to guide decision making in early breast cancer
- A novel tool has been developed that uses mid-infrared spectroscopy of formalin-fixed tumour biopsy samples to determine the 'Digistain Index' (DI), which reflects the level of aneuploidy within the tumour[1,2]
- DI has been shown to univariately correlate with tumour grade[3]
- Here we describe the validation of Digistain Prognostic Score (DPS), developed by incorporating DI with clinicopathological features



Methods

- Infrared spectrometry was performed on existing tissue microarrays to determine the DI and DPS of 801 patients with HR-positive HER2-negative primary breast cancer with ≤3 positive lymph nodes (LN) who had received systemic endocrine therapy only
- Receiver operator characteristics curves were constructed and area under the ROC curve (AUC) calculated to assess the ability of DPS to predict RFS, recurrence and OS in the total population and in 3 subgroups:
  - LN negative: 68.4%
  - Premenopausal (based on age <50 years): 30.5%
  - Postmenopausal (age >60 years): 37.0%
- Median follow up was 12.7 years

Results

- DI was significantly associated with OS

Cox proportional hazard model for estimating the contribution of variables to predict OS (N=801)

Variable	Hazard ratio (95% CI)
Grade	1.81 (1.46–2.30)***
Size	1.37 (1.19–1.57)***
Age	1.04 (1.03–1.06)***
LN stage	1.78 (1.34–2.36)***
DI	4.49 (1.08–18.67)*

*p<0.05; ***p<0.001

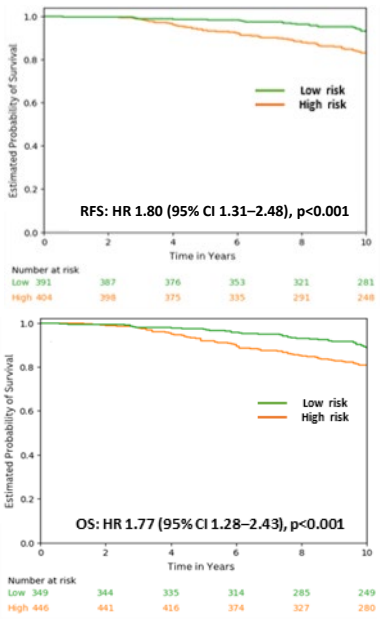
- When DI was incorporated with other clinicopathological variables, DPS showed high accuracy and predictive performance in the total population and the different subgroups (data not shown)

Accuracy for prediction of risk scoring for outcomes in the total population

	AUC		NPV	
	5 years	10 years	5 years	10 years
RFS	0.81	0.75	0.99	0.94
Recurrence	0.81	0.75	0.99	0.94
OS	0.77	0.69	0.97	0.90

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

Event distribution over time based on DPS classification for low and high risk in the total population



Hazard ratio (95% CI) for outcomes according to DPS-based risk multivariate model high-low classification in the total population and subgroups

	Total population	LN negative	Age <50 years	Age >60 years
RFS	1.80 (1.31–2.48)***	1.63 (1.08–2.48)*	1.91 (1.11–3.28)*	1.99 (1.18–3.34)***
Recurrence	1.83 (1.32–2.52)***	1.61 (1.06–2.47)*	2.06 (1.18–3.60)*	2.22 (1.31–3.74)**
OS	1.77 (1.28–2.43)***	1.38 (0.92–2.07)	2.16 (1.09–4.28)*	1.66 (1.08–2.57)*

*p<0.05; **p<0.01; ***p<0.001

Conclusions

- Digistain Prognostic Score showed high accuracy and predictive performance, and stratified patients with early breast cancer into low or high risk
- Considering its low cost, rapidity and accessibility, Digistain has potential as an alternative or addition to existing prognostic tools across real-life clinical practice, including under-resourced settings

References

1. Amrania H, et al. Opt Express 2012;20:7290–9.
2. Amrania H, et al. Faraday Discuss 2016;187:539–53.
3. Amrania H, et al. Converg Sci Phys Oncol 2018;4:025001.

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