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# AI DRIVEN APPLICATION IN DIGITAL PATHOLOGY FOR BREAST CANCER RISK PREDICTION. A SWISS RETROSPECTIVE COHORT STUDY

Abstract Category: Clinical Solid Tumor Oncology

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## INTRODUCTION

The integration of artificial intelligence (AI) in digital pathology holds great promise for improving breast cancer (BC) recurrence risk prediction and treatment decisions. Integrating clinical data with predictive morphological features from standard H&E slides of core needle biopsy or surgical specimens, the Ataraxis AI model demonstrated superior accuracy in a cohort of 377 BC pts from NYU Langone, achieving a C-index of 0.79 compared to genomic test's Oncotype DX's 0.63. This project evaluates the Ataraxis model's predictive performance against Oncotype DX and real-world data (RWD) in a cohort of HR+/HER2- BC pts from Basel University Hospital and Cancer Center Baselland (2010-2021).

## METHODS

A retrospective cohort of 326 HR+/HER2- BC pts, who were previously tested with Oncotype was analyzed, with 269 having pathology slides available. The slides were digitized and processed using Ataraxis' AI-based algorithm. Pathology-based features, extracted by Kestrel, were corroborated with clinical characteristics (T & N stage, age, ER, PR and HER2 status, ductal or lobular histology (Figure 1) to produce a continuous score between 0 and 1 that is predictive of patient risk of cancer recurrence. The concordance (C) index analysis was used to assess how the AI risk ranking of patients aligns with the actual order in which they experienced events and the Oncotype score. A univariate and multivariate Cox proportional model was used to assess impact of AI model and other multiple variables on the outcome. The hazard ratio is estimated from the continuous score for every 0.2 unit increase in our score.

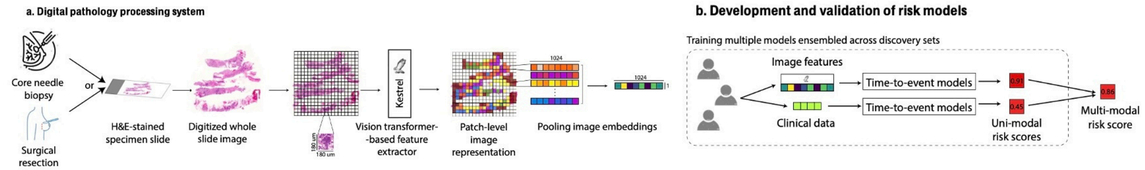


**Fig. 1** The multi-modal AI test for BC involves a. processing of high-resolution digital images of BC specimens using Kestrel, a foundation model trained using self-supervised learning on a pan-cancer dataset of 400 million pathology image patches. b. Extracted pathology and clinical features are used to train supervised time-to-event models predicting breast cancer recurrence or death.

## RESULTS

Of 317 pts, 269 were evaluated. The median tumor size was 20 mm, with 39.43% presenting with node-positive disease. Most patients has stage II disease (57.41%). Oncotype test classified 22% of patients into low, 62% into intermediate, and 17% into high recurrence risk groups. At a median follow up of 62 mo., there were 10% cases of relapse of which 40% distal relapse.

With regards to the disease free interval (DFI) the AI model achieved a C-index of 0.70 [0.60-0.80] and a HR of 3.98 [1.92-8.25, p<0.01] in the Basel cohort (N=269) when compared to RWD, while Oncotype DX achieved a C-index of 0.55 [0.42-0.67] and a HR of 1.76 [0.84-3.64, p=0.13], respectively - see Fig.2. In a pooled analysis, on 858 pts from Basel and two other international cancer centers, tested with Oncotype DX AI, the model re-classified 666/858 (77.6%) pts into different risk categories (Fig. 3). All intermediate Oncotype risk pts (61.3%) were reclassified as low- or high-risk by our AI test. 425/526 (80.4%) intermediate Oncotype-risk pts were reclassified as low-risk and 103/526 (19.6%) as high-risk pts. 103 high Oncotype risk pts (12%) were defined as low-risk by the AI test. Within the intermediate Oncotype risk group, the continuous AI test score was associated with recurrence (HR: 3.45 [1.85-6.42, p<0.01]) - Fig. 4.

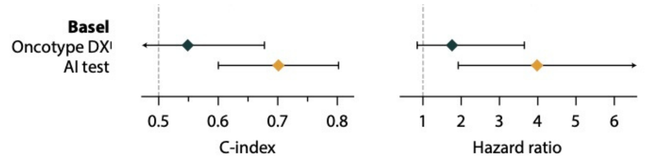


**Fig. 2** The AI model showed more accuracy than Oncotype DX genomic assay in predicting cancer recurrence in HR+ patients

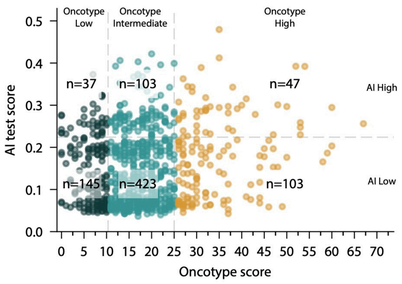


**Fig. 3** Reclassification of the Oncotype low/intermediate/ high recurrence score into high and low risk score by the AI model in a pooled anylasis on 858 pts (Basel Cohort incl)

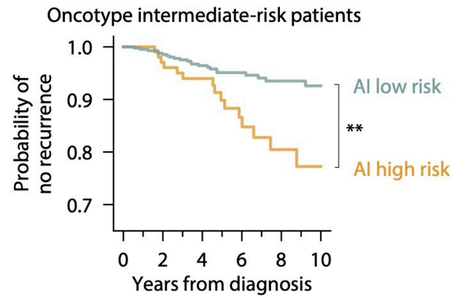


**Fig. 4 T**he Oncotype intermediate RS pts were reclassified into low or high risk by the AI model

## CONCLUSION

The Ataraxis AI model shows improved accuracy in predicting BC recurrence risk compared to Oncotype DX, especially for HR+/HER2- pts. In our Basel cohort, the AI model achieved a C-index of 0.70 versus 0.55 for Oncotype DX, with significant reclassification within the intermediate-risk group. This study is part of a larger project that includes over 3,500 patients across five international centers, covering various breast cancer subtypes.

A prospective clinical trial is scheduled to start in 2025. For details please get in touch with Dr. Diana Chiru (PI).

**Preprint available**

**For additional details or information about the planned prospective clinical trial please get in touch with Dr. Diana Chiru chiru_diana@yahoo.com**