Prospective Evaluation of "PreciseBreast" AI Tool in Early-Stage Invasive Breast Cancer Risk Stratification

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BACKGROUND

- Hormone receptor-positive breast cancer is the most common breast cancer subtype among women in the United States.
- Multigene assays (e.g., Oncotype DX® [ODX]) estimate recurrence risk and chemotherapy benefit to guide treatment decisions.
- Limitations of current assays: high cost and long processing times.
- PreciseBreast® (PDxBR) is a novel AI-powered risk score developed by PreciseDx that leverages digital pathology and machine learning, provides a rapid, phenotype-based recurrence risk.

AIM

Evaluate PDxBR as a reliable tool for guiding treatment decisions based on recurrence risk.

METHODS

Study design: Prospective correlational study within a community health system.

Participants: Female patients with newly diagnosed, early-stage, hormone receptor-positive invasive ductal carcinoma eligible for ODX testing.

PDxBR analysis: Pathology slides evaluated using the AI-powered PDxBR assay, incorporating morphologic features such as nuclear pleomorphism, mitotic activity, tubule formation, and tumor-infiltrating lymphocytes.

Risk classifications: ODX: Low (0–25), High (>26). RSClin: Low (≤3%), Intermediate (3–5%), High (>5%)

Statistical analysis: PDxBR and ODX scores were compared using McNemar's test, and PDxBR and RSClin scores were compared using a symmetry test. Turnaround time was compared using a paired t-test.

- Results were for research purposes only and did not influence patient management.



RESULTS

Figure 1. Turnaround Time

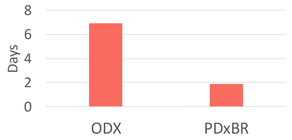


Figure 2. Cost

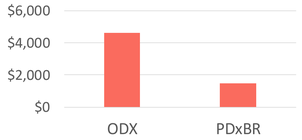


Table 2. Concordance Between PDxBR and ODX

	PDxBR High Risk	PDxBR Low Risk	p-value
ODX High Risk	2 (25.0%)	6 (75.0%)	0.289
ODX Low Risk	2 (4.8%)	40 (95.2%)	

Table 3. Concordance Between PDxBR and RSClin

RSClin Risk	PDxBR High Risk (n, %)	PDxBR Low Risk (n, %)	p-value
High Risk	6 (31.6%)	13 (68.4%)	< 0.0001
Intermediate Risk	2 (7.7%)	24 (92.3%)	
Low Risk	0 (0%)	5 (100%)	

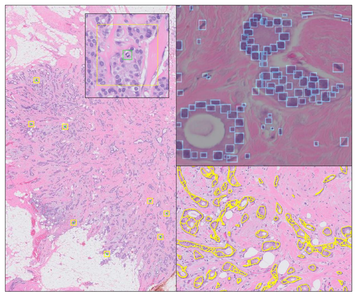


Figure 3. Low-power view of IDC in a 64 y.o. woman with a low-risk PDxBR score (23). Left: mitotic figures highlighted. Right upper: nuclear pleomorphism quantified. Right lower: tubule-forming architecture.

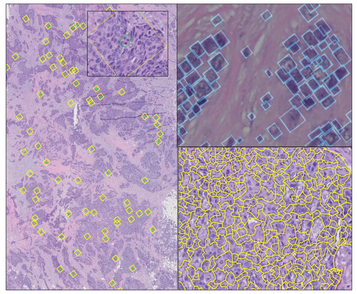


Figure 4. Low-power view of IDC in a 71 y.o. woman with a high-risk PreciseBreast score (73). Left: mitotic figures highlighted. Right upper: nuclear pleomorphism quantified. Right lower: sheet-like glandular architecture.

Table 1. Patient Demographics and Clinical Characteristics

	n = 50
Age at diagnosis (mean/sd)	61.1 (11.1)
Age < 50 (n%)	11 (22.0%)
Stage (n%)	
IA	36 (72.0%)
IB	1 (2.0%)
IIA	9 (18.0%)
IIB	3 (6.0%)
IIIA	1 (2.0%)
Cancer Type (n%)	
Invasive Ductal	47 (94%)
Mixed	3 (6%)
Lymph Node Positive (n%)	9 (18.0%)

DISCUSSION

- PDxBR offers faster turnaround and lower cost than Oncotype DX (ODX).
- PDxBR shows strong concordance with RSClin, with some discordance compared to ODX.
- Larger studies are needed to confirm concordance, non-inferiority, and clinical impact, and to explore reasons for discordant cases.
- Integrating gene expression, clinical factors, and tumour morphology may enhance recurrence-risk prediction.
- AI-based digital pathology tools like PDxBR may provide cost-effective alternatives or complements to multigene assays, especially in resource-limited settings.

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