Harnessing Technology: A Comparative Study of AI versus Manual Scoring in HER2 Ultra-Low Breast Cancer. P2-04-30

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Abstract

Background: The advent of targeted therapies using the HER2 receptor as a delivery mechanism in breast cancer, introduced a need for re-evaluation HER2 scoring in previously classified negative cases (2+ ISH -ve; and 1+), as patients with these tumours may benefit from these innovative treatments. At The Christie Hospital. Manchester, U.K., our specialised unit (BTRU) has been exclusively reporting ER, PR, and HER2 status in breast cancers for the past 25 years with a dedicated staff, adhering to consistent technical guidelines and stringent UKAS accreditation standards, with an annual assessment of approximately 1,600 cases. This study aimed to evaluate the performance of an AI solution in the identification of HER2 ultra-low compared to a cohort of reported HER1+ and 0 cases that were manually scored by the BTRU.

Methods: We retrieved a cohort of 288 cases reported as HER1+ or 0 during 2023 (IHC assay: VENTANA Pathway anti-HER2/neu (4B5) rabbit monoclonal primary antibody). The original slides were digitised, scanned at x40, and submitted anonymised to Visiopharm for analysis. No re-scoring of the cases was conducted. The AI system not only provided HER2 scoring but also detailed the total number of tumour cells evaluated, the completeness of membrane staining (complete/incomplete/negative), and staining intensity (weak/moderate/strong).

Results: A total concordance of 85.7% (247 cases) was observed between the AI and previously reported results. The AI upgraded the manual scores in 6 cases from 1+ to 2+ and in 24 cases from 0 to 1+. Conversely, 11 cases originally scored as 1+ were re-evaluated by AI and scored as 0. No significant differences in tumour cell content were noted between concordant and discordant cases.

Conclusions: Overall, there was strong agreement between the two methodologies; however, the AI solution outperformed manual scoring in 24 cases (8.3%), which would otherwise be deemed unsuitable for treatment. Notably, the membrane staining in the 11 cases re-scored by AI as 0, was just bellow the 10% threshold currently established by UK and ASCO/CAP guidelines, underscoring the challenges in achieving precision in borderline cases through manual scoring. Given the unique nature of our unit, it is anticipated that a greater number of discordant cases may be identified in different clinical settings. These findings suggest that incorporating AI tools into pathology practice could enhance patient selection for new therapies, as well as optimising cut-offs for identifying potential responders in future clinical trials.

Introduction

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At The Christie Hospital, Manchester, UK, our specialised Breast Tissue Receptor Unit (BTRU) has been exclusively reporting ER, PR, and HER2 status in breast cancers for the past 25 years with a dedicated staff, adhering to consistent technical guidelines and stringent UKAS accreditation standards, with an annual assessment of approximately 1,600 cases.

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Methods and Materials

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Table 1. Number of matched and mismatched cases comparing between BTRU HER2 scores vs AI generated scores. And Percentage values.

Matched		**Percent**
Total	247	85.7%
Mismatched		
Upgraded from 0 to 1+	24	8.3%
Upgraded from 1+ to 2+	6	2.1%
Downgraded from 1+ to 0	11	3.8%
Total	41	14.2

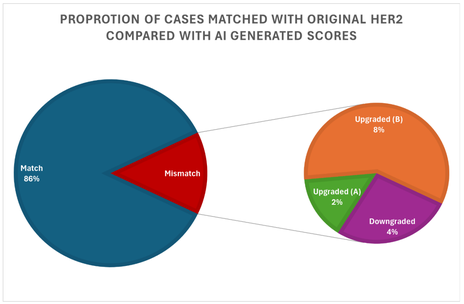

Chart 1. Proportion of cases from BTRU matched to AI generated scores. 85.7% of cases (n=247) matched with original HER2 scores. **Upgraded (A)**: 2% of cases (n=6) was upgraded by AI from HER 1+ to 2+. **Upgraded (B)**: 8% of cases (n=24) cases was upgraded by AI from HER 0 to 1+. **Downgraded:** 4% (n=11) cases were downgraded by AI from HER 1+ to 0.

Conclusions

Overall, there was strong agreement between the two methodologies; however, the AI solution outperformed manual scoring in 24 cases (8.3%), which would otherwise be deemed unsuitable for treatment.
Notably, the membrane staining in the 11 cases re-scored by AI as 0, was just below the 10% threshold currently established by UK and ASCO/CAP guidelines, underscoring the challenges in achieving precision in borderline cases through manual scoring.
Given the unique nature of our unit, it is anticipated that a greater number of discordant cases may be identified in different clinical settings. These findings suggest that incorporating AI tools into pathology practice could enhance patient selection for new therapies, as well as optimising cut-offs for identifying potential responders in future clinical trials.

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