Comparative Evaluation of Digistain and Oncotype DX in Predicting Metastasis-Free Survival in Early Stage Hormone-Receptor Positive Breast Cancer: A Randomized Study at Charing Cross Hospital

Presenting Author(s) and Co-Author(s):

H. Amrania. Imperial College London, UK
A. Gautam. Imperial College London, UK
M. Sroya. Charing Cross Hospital, London, UK
C. Coombes. Imperial College London, UK
D. Francescatti. Rush Medical College, Chicago, USA
Z. Al-Khalili. Imperial College London, UK
C. Phillips. Imperial College London, UK
A. Magliocco. University of Florida, Orlando, USA
L. Jones. Barts Cancer Institute, London, UK
A. Shabaan. Queen Elizabeth Hospital Birmingham, UK
C. Y. Young. Dept Hospital Pathology Catholic University, Korea St Vincent Hospital, Seoul, South Korea
S. Rane. Tata Memorial Hospital, Mumbai, India

Background: Oncotype DX is an established genomic test for risk stratification in early-stage hormone-receptor positive, HER2-negative breast cancer. Digistain employs mid-infrared spectroscopy to assess tumor aneuploidy, offering a rapid, cost-effective alternative with potential for higher sensitivity. This study aims to compare the predictive accuracy of Digistain against Oncotype DX for metastasis-free survival.

Methods: In this double-blinded study, 233 randomly selected lymph node-negative patients from Charing Cross Hospital, previously scored by Oncotype DX, were reassessed using Digistain. The primary endpoint was metastasis-free survival, with a median follow-up of 6 years.

Results: The comparative analysis revealed a high degree of consistency in risk classification between Oncotype DX and Digistain. After adjusting for missing data, 50% of patients were classified as low-risk by Oncotype DX (defined as <10% risk of recurrence), while Digistain classified 44% of patients within the same risk category. Importantly all patients deemed low-risk by Oncotype DX were consistently categorized as low-risk by Digistain, confirming a robust concordance in risk stratification by both tests. A noteworthy observation involved a single patient classified as low-risk by Oncotype DX but assessed as high-risk by Digistain, who subsequently developed metastatic breast cancer within five years. This case underscores a potentially heightened sensitivity of Digistain in identifying risks of metastasis, suggesting that Digistain may offer critical advantages in precise risk assessment in certain clinical scenarios.

Conclusions: These findings underscore Digistain's potential as a valid alternative to Oncotype DX, with a possible edge in sensitivity for identifying metastasis risk. The congruence in high-risk patient identification and the critical observation of an at-risk patient missed by Oncotype DX highlight Digistain's promise for enhancing clinical decision-making in breast cancer management.