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Development and validation of multi-modal artificial intelligence (AI) tests at ABCSG

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Translational research studies, with the aim of developing, testing, and validating new biomarkers, tumour signatures or assays, are becoming increasingly important in modern oncology. These studies are the basis for new diagnostic

tools and thus for targeted and personalised therapies, which are often used in clinical trials and everyday clinical practice. The Austrian Breast and Colorectal Cancer Study Group (ABCSG) is conducting several translational research projects and collaborations, as the extensive collection of bio-specimens and data from previous ABCSG trials is a valuable resource for such projects.

Currently, the choice of treatment for breast cancer patients is mainly based on clinicopathological factors such as tumour size, nodal status, hormone receptor status, and HER2 status. In addition, the assessment of recurrence risk through genomic testing plays a crucial role and is considered by many physicians as an additional tool in their treatment decision-making. Genomic assays, such as OncotypeDX®, MammaPrint®, Prosigna®, EndoPredict®, or OncoMark®, assess the risk of distant recurrence based on gene expression data in hormone receptor-positive (ER+), HER2-negative breast cancer patients. All of these tests are relatively expensive, require the processing of physical tumour samples, and consume tissue that could be used for advanced molecular profiling in the future. Some tests can be performed in local pathology laboratories, which means extra work for pathology departments and requires technical expertise, trained staff, and expensive instruments.

For other tests, tissue has to be sent to central laboratories, and patients have to wait several days for a test result. In addition to genomic testing, histopathological features are routinely evaluated by pathologists to stratify the patient's risk. These features include histological grade, tumour-infiltrating lymphocytes, and Ki67 expression. These or other primarily morphological features could complement genomic scores with independent prognostic information and lead to new, improved prognostic models.

Together with our cooperation partners, we develop and validate tests for stratification of patients with breast cancer based on digital pathology and clinical characteristics, using novel artificial intelligence (AI) methods. Advances in the field of self-supervised learning have enabled the development of more effective methods for learning meaningful features from imaging data. Specifically, we will use models trained with self-supervised learning to extract features from digitised haematoxylin and eosin (H&E)-stained slides. These features are not based on pre-determined characteristics, and their extraction does not require manual processing by pathologists. Instead, these AI models autonomously determine the most prominent features by learning from millions of images. We expect that AI-powered features extracted from digital pathology images can be used to predict important patient characteristics and their long-term outcomes.

The tests will be developed and validated using data from thousands of patients with breast cancer across many patient cohorts including patients from previous ABCSG trials. These AI tests should accurately predict time to distant recurrence at least as reliably as currently used genomic assays in ER+ HER2- patients, but without any laboratory work and in real-time. In addition, they could also perhaps be applied across all major breast cancer subtypes, including triple-negative breast cancer patients (TNBC) for whom no diagnostic tools are currently recommended by clinical guidelines. The ultimate goal is that our AI tests can improve accuracy, expand applicability to a wider range of patients, and improve access to treatment selection tools.