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Optimizing HER2 assessment in breast cancer - Application of automated image analysis

Human epidermal growth factor receptor 2 (HER2) is a receptor for circulating growth factor, stimulating uncontrolled cell proliferation. Trastuzumab reacts with HER2 and arrests the cells in the G1 phase. Immune system-directed cell killing is probably also involved in the anti-cancer effect. In breast cancer, overexpression of HER2 occurs in 15%, and analysis of HER2 expression is therefore pivotal for treatment decision. A cohort of 462 patients, stained with Roche's ready-to-use HER2 test was used. The HER2-CONNECT algorithm evaluates the IHC staining reaction of HER2, based on cell membrane connectivity. The connectivity translates into the classic diagnostic score for HER2 expression (0, 1+, 2+ or 3+) in agreement with the ASCO/CAP guidelines. The automated reading was compared to manual reading, and for the borderline (2+) to manual reading of the HER2 gene expression on fluorescence in situ hybridization (FISH). Manual reading demonstrated a sensitivity of 85.0% and a specificity of 86.0% with 14.1% inconclusive samples. Using HER2-CONNECT, sensitivity increased to 97.6% and specificity to 95.5%. Less than 4.5% of the cases were deemed in conclusive. Total agreement when comparing HER2-CONNECT with manual IHC supplemented by FISH in borderline cases was 92.8%. Using the HER2-CONNECT digital image analysis algorithm based on IHC detection of HER2 protein expression on tumour cell membranes, less than 4.5% of the cases were inconclusive whether overexpressed or not. Compared to manual reading, the need for supplementary FISH testing is reduced by 67.7%. In the routine diagnostic setting, this would have significant impact on cost reduction and turn-around-time.

Biography

Martin Kristensson has been with Visiopharm since 2011 where he currently works as the VP, Technical Sales for Europe. He received his MSc in Biomedical Engineering from the Technical University of Denmark in 2011, specializing in Signal and Model based Diagnostics, combined with Image Diagnostics and Radiation Physics. In 2014, he became a certified Project Manager at Copenhagen Business Academy. He has provided numerous research algorithms to researchers.

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