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Digital Image Analysis Of Her2 Immunostained Gastric And Gastroesophageal Junction Adenocarcinomas

S.L. Nielsen*, S. Nielsen, M. Vyberg
Aalborg University Hospital, Institute of Pathology, Aalborg, Denmark

Introduction/ Background

Manual assessment of HER2 protein expression in gastric and gastroesophageal junction (GGEJ) adenocarcinomas is prone to inter-observer variability and hampered by tumor heterogeneity and different scoring criteria. Cases are frequently referred to FISH.

Aims

This study aimed to evaluate the accuracy of digital image analysis (DIA) for the assessment of HER2 protein expression.

Methods

110 GGEJ adenocarcinomas were included in TMAs with 3 tissue cores per case. Two immunoassays, PATHWAY® and HercepTest™, and FISH were performed. The HER2 CONNECT™ DIA software as designed for breast carcinoma was applied. Connectivity, calculated by the software, was converted to standard IHC scores applying predetermined cut-off values for breast carcinoma as well as novel cut-off values.

Results

Applying HER2 CONNECT™ with established connectivity cut-off values designed for breast carcinoma resulted in 72.7% sensitivity and 100% specificity for the identification of HER2 positive cases. By application of new cut-off values, the sensitivity was increased to 100%, while the specificity remained 100%. With the new cut-off values, a 36-50% reduction of IHC equivocal cases requiring additional FISH analysis was observed.

Conclusion: HER2 CONNECT™ with adjusted cut-off values seems to be an effective tool for the assessment of HER2 protein expression in GGEJ adenocarcinomas, allowing for a decreased need for FISH analyses.