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.