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Prognostic Significance Of HER2 Expression In Advanced Gallbladder Cancer

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Background : Gallbladder carcinoma (GBC) is an aggressive malignancy with high mortality and poor prognosis and new targeted therapeutic options are needed. The aim of this study is to evaluate the clinicopathological significance of human epidermal growth factor receptor 2 (HER2) overexpression and amplification in advanced GBC and to provide evidence for targeted therapy in the future.

Methods : Tissue microarrays were constructed with 137 advanced GBC cases who underwent surgery and were pathologically confirmed as T3 or T4 between 2010 and 2017. Immunohistochemistry (IHC) and silver-enhanced in situ hybridization (SISH) for HER2 were performed using scoring criteria for gastric cancer. Only cases with an IHC score of 3+ or an IHC score of 2+ and proven gene amplification (HER2/CEN17 ratio ≥ 2.0) were considered HER2 positive.

Results : IHC for HER2 was negative (0 & +1) in 83.0% (122/137), equivocal (+2) in 8.2% (12/137) and positive (+3) in 8.8% (13/137) of cases. HER2 gene amplification by SISH was observed in 40.9% (56/137) of cases, 28.9% (22/76), 50.0% (18/36), 33.3% (4/12), and 92.3% (12/13) of IHC 0, 1+, 2+, and 3+, respectively and HER2 positive was observed in 11.7% (16/137) of cases. The overall survival rates of the patients with HER2 gene amplification and adjuvant chemotherapy were significantly worse than the patients without HER2 gene amplification (29.9 vs. 44.6, $p=0.027$) and adjuvant chemotherapy (17.5 vs. 41.8, $p=0.004$).

Conclusions : Although there was no significant independent prognostic factor in multivariate analysis, HER2 gene amplification showed the possibility as a prognostic factor in advanced GBC. Prospective standardized HER2 testing and randomized control studies are needed to prove clinical efficacy of targeted HER2 inhibition in advanced GBC.

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