A PROSPECTIVE STUDY OF RE-EVALUATION OF THE HER2 STATUS IN METASTATIC OR RECURRENT LESIONS IN GASTRIC CANCERS WITH HER2-NEGATIVE PRIMARY TUMORS: GASTHER-1

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Aim: To investigate the HER2 positivity rate in corresponding metastatic or relapse lesions in gastric cancers (GCs) with HER2-negative primary tumors.

Methods: Patients (pts) with unresectable, metastatic or recurrent gastric/gastroesophageal junction (GEJ) adenocarcinoma and who will receive 1st-line chemotherapy, were eligible if HER2 was negative in primary gastric tumor. HER2 positivity was defined as IHC 3+ or IHC 2+/FISH+ by the GC scoring system. HER2 status was evaluated in metastatic or recurrent lesions.

Results: From May 2011 to Feb 2014, 175 eligible pts were enrolled. Baseline characteristics were as follows: initially metastatic/locally advanced/recurrent disease = 60(34.3%)/1(0.6%)/114(65.1%); primary tumor location, GEJ ∼ fundus/body/antrum/diffuse stomach = 15(8.6%)/92(52.6%)/56(32.0%)/12(6.9%); Lauren classification, intestinal/diffuse/mixed = 57(32.6%)/101(57.7%)/17(9.7%); primary tumor specimens for HER2 assessment, biopsy/gastrectomy = 52(29.7%)/123(70.3%); and HER2 IHC score in primary tumor, 0/1/2 = 144(82.3%)/18(10.3%)/13(7.4%). The median time interval of HER2 assessment between primary and relapse sites was 28.8 months (range 3.7-158.2). HER2 in metastasis or recurrence was evaluated in peritoneum (21.1%), liver (16.6%), ovary (16.6%), lymph node (12.6%), locoregional site (13.7%), and others (19.4%). Adjuvant chemotherapy had been given in 91 pts (52.0%) between HER2 assessment at primary and relapse sites. Since HER2 re-evaluation in metastasis or relapse identified 10 pts with HER2-positive tumor, the conversion rate for HER2 positivity was 5.7% (95% CI 2.3-9.1%). HER2 assessment in liver metastasis was significantly associated with the converted HER2 positivity (liver vs others = 5/29 [17.2%] vs 5/146 [3.4%; p = 0.012] while other baseline characteristics, disease status, a type of specimen, time interval between primary and metastatic/recurrent lesions, and prior exposure to chemotherapy did not show significant associations.

Conclusions: Re-evaluation for the HER2 status should be considered in metastatic or recurrent lesions even if the primary tumor is HER2-negative in GC.

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