AB031. S7-2. Consolidating the treatment guidelines of chemotherapy for cholangiocarcinoma between the East and West

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Abstract: Chemotherapy plays an important role in the treatment of cholangiocarcinoma, including for advancedstage disease and as adjuvant therapy after surgery. Recently, the BILCAP study comparing capecitabine with observation after surgery demonstrated a survival benefit of capecitabine. However, according to the NCCN guidelines 2019, the overall survival did not reach statistical significance in the intent-to-treat analysis. In Japan, a phase III study comparing S-1 with observation after surgery (JCOG1202) is under ongoing, and 440 patients have been enrolled. Pooled analysis of the BILCAP and JCOG1202 is proposed in the future. Systemic chemotherapy is the standard of care for patients with advanced-stage cholangiocarcinoma. Gemcitabine plus cisplatin (GC) is



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recognized as the global standard chemotherapy (the ESMO guidelines and NCCN guidelines), based on the results of the ABC-02 study comparing GC with gemcitabine alone. The BT22 study conducted in Japan also demonstrated the survival benefit of GC. GC is also recommended as the standard of care in Japanese guidelines. In 2018, two positive phase III studies have been reported from Japan. The JCOG1113 study comparing gemcitabine plus S-1 (GS) with GC, demonstrated non-inferiority of GS to GC in the overall survival. The KHBO1401 study comparing GC plus S-1 (GCS) with GC demonstrated superiority of GCS over GC in the overall survival. As a result, GS and GCS are recognized as alternative treatments for advanced cholangiocarcinoma in Japan. Recently, microsatellite instability-high (MSI-H) tumors have been shown to benefit from PD-1 blockade, such as pembrolizumab. Pembrolizumab was approved for the treatment of MSI-H tumors, including cholangiocarcinoma, in December 2018, in Japan. FGFR inhibitors and HER-2 inhibitors are currently under investigation for cholangiocarcinomas with FGFR2 gene fusions and HER2 gene amplification, respectively. Treatment strategies using precision medicines such as MSI-H, FGFR2, and HER2 are expected to be established in the near future.

Keywords: Cholangiocarcinoma; chemotherapy; adjuvant therapy; guidelines

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