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Gastric Cancer

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ORIGINAL ARTICLE



Real-world effectiveness of nivolumab in advanced gastric cancer: the DELIVER trial (JACCRO GC-08)

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Abstract

Background There is no large real-world data regarding efficacy and safety of immunotherapy in gastric cancer (GC). Although some tumors can grow rapidly after immunotherapy, the patient proportions and survival outcomes are unclear in GC.

Methods A multicenter, prospective observational study was performed to evaluate clinical outcomes including survival time, safety, and tumor behavior of nivolumab treatment for patients with advanced GC. Primary endpoint was overall survival (OS), and secondary endpoints included response rate (RR), disease control rate (DCR), progression-free survival (PFS), tumor growth rate (TGR) at first evaluation, and safety.

Results Of 501 enrolled patients, 487 were evaluable (median age 70 years, 71% male, performance status 0/1/2 [42%/44%/14%], 21% HER2-pos, 42% patients with ascites). Median OS was 5.82 months (95% CI 5.29–7.00) with a 1-year survival rate of 30% and median PFS of 1.84 months (95% CI 1.71–1.97). The DCR was 39.4% and the RR was 14.2% (95% CI 10.3–18.8) in 282 patients with measurable lesions. In 219 patients evaluable for TGR, 20.5% were identified as hyperprogressive disease (HPD). OS from the first evaluation of patients with HPD was shorter compared with non-HPD (HR 1.77, 95% CI 1.25–2.51, $P=0.001$), but it was not worse than that of patients with progression and non-HPD (HR 1.05, 95% CI 0.72–1.53, $P=0.8$). A multivariate analysis revealed the presence of peritoneal metastasis was a prognostic factor for OS and PFS.

Conclusions Our real-world data demonstrated the comparable survival time to a previous clinical trial and revealed the frequency and prognosis of patients with HPD in advanced GC treated with nivolumab.

Keywords Gastric cancer · Nivolumab · Hyperprogressive disease · Real-world data

GC-08 参加施設の皆様に感謝申し上げます。
今後とも JACCRO 臨床研究をよろしくお願い致します。