

890 **NIVOLUMAB PLUS IPILIMUMAB IN ANTI-PD(L)-1 NAÏVE AND EXPERIENCED HCC PATIENTS — SINGLE INSTITUTE EXPERIENCE IN TAIWAN**

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**Background** Immune checkpoint inhibitors (ICIs) are standard therapy for advanced hepatocellular carcinoma (HCC). However, the efficacy of combining nivolumab and ipilimumab in Anti-PD(L)-1 Naïve and Experienced HCC patients remains unclear.

**Methods** We retrospectively reviewed 23 patients with advanced HCC treated with nivolumab and ipilimumab. Objective response rate (ORR), progression-free survival (PFS), overall survival (OS), and treatment-related adverse events (TRAEs) were evaluated.

**Results** A total of 23 patients were included in this study, with a mean age of 55.8 years. The majority of patients were male (73.9%), and 56.5% had HBV, while 2% had HCV. Child-Pugh class A was assigned to 87% of patients, with 13% classified as CPS class B. Imaging findings revealed that 26.1% of patients had portal vein thrombosis (PVT), and 78.3% had metastasis. Among those who received prior targeted therapy, sorafenib, lenvatinib, and regorafenib were administered in 34.8%, 60.9%, and 30.4% of cases, respectively. Regarding previous immunotherapy, 43.7% (10/23) of patients had prior anti-PD(L)-1 treatment, with nivolumab, pembrolizumab, atezolizumab + bevacizumab, and durvalumab administered in 47.8%, 8.7%, 26.1%, and 30.4% of cases, respectively.

The overall responses were as follows: partial response (PR): 17.4%, stable disease (SD): 60.9%, progressive disease (PD): 17.4%, non-assessable (NA): 4.3%. The overall response rate (ORR) was 17.4%, and the disease control rate (DCR) was 78.3%.

Comparison between anti-PD(L)-1 naïve patients and anti-PD(L)-1 experienced patients: ORR (23.1% vs. 10%;  $p=0.41$ ), DCR (92.3% vs. 60%;  $p=0.06$ ). No significant difference in ORR between anti-PD(L)-1 responders and non-responders (0% vs. 12.5%,  $p=0.6$ ).

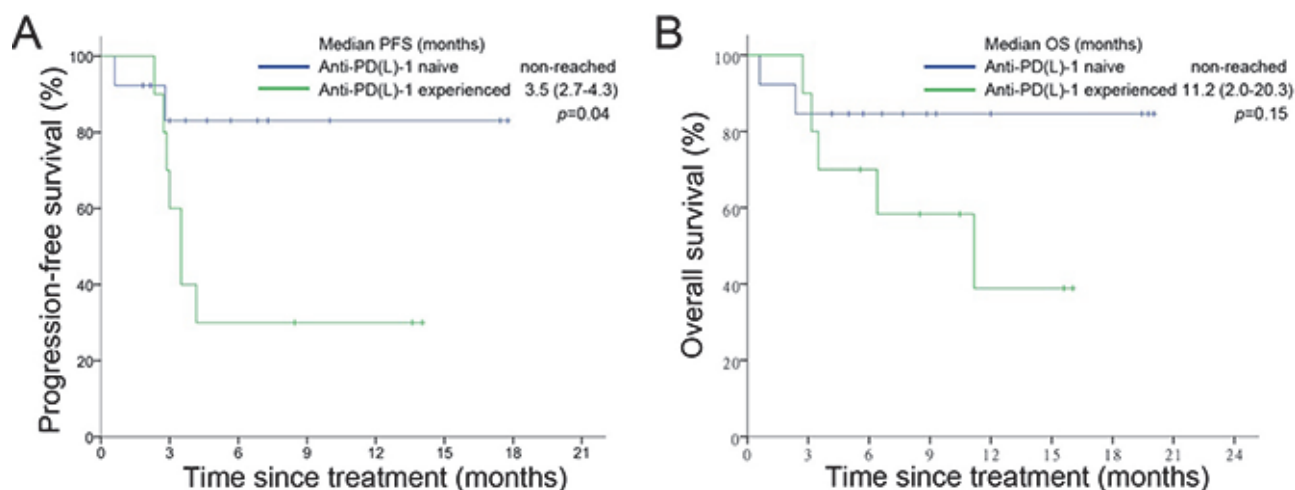
The median follow-up time was 7.7 months. Median OS and PFS were not reached, with survival durations ranging from 0.6 to 20.0 months for OS and 0.6 to 17.8 months for PFS. Patients achieving disease control with nivolumab

combined with ipilimumab had prolonged PFS (non-reached versus 2.7 months,  $p=0.44$ ) and OS (non-reached versus 3.2 months,  $p<0.05$ ) compared to those with progressive disease. Patients who were treatment-naïve to anti-PD(L)-1 therapy had longer PFS (non-reached versus 3.5 months,  $p=0.04$ ) and numerically longer OS (non-reached versus 11.2 months,  $p=0.15$ ) (figure 1).

Adverse events were predominantly Grade 1/2 (43.5%), indicating manageable reactions. Grade 3/4 events occurred in 8.6% (2/23) of patients, including one case of skin rash and one case of hepatitis.

**Conclusions** Nivolumab combined with ipilimumab demonstrated greater effectiveness in anti-PD(L)-1 naïve patients. However, there was no significant difference in efficacy between patients with prior anti-PD(L)-1 response or non-response.

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Abstract 890 Figure 1