

## PREVALENCE OF PD-L1 EXPRESSION AMONG PATIENTS WITH RECURRENT AND METASTATIC HEAD AND NECK SQUAMOUS CELL CARCINOMA IN TAIWAN

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**Background** Tumor programmed death-receptor/ligand-1 (PD-1/PD-L1) expression negatively correlates with cancer prognosis and overall survival,<sup>1-6</sup> and has been shown to predict clinical responses to immunotherapy for head and neck cancers.<sup>7</sup> In Taiwan, head and neck cancers continue to show a high prevalence associated with betel quid chewing, a practice endemic to the island. This study aims to evaluate the prevalence of PD-L1 expression in recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) patients in Taiwan.

**Methods** For this multi-centered prospective study, we recruited R/M HNSCC patients who are aged 20 years or older, have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, are ineligible for re-irradiation or curative surgery, and had a biopsy obtained before treatment. PD-L1 expression measured by combined positive score (CPS) and tumor proportion score (TPS) was determined by the PD-L1 IHC 22C3 pharmDx™ kit. The primary endpoint was to estimate the prevalence of PD-L1 expression, characterized by CPS ≥ 1. Exploratory analyses were conducted to evaluate PD-L1 positivity by CPS ≥ 20 and TPS ≥ 50%, and to explore the association of prior first- or second-line systemic treatment and PD-L1 expression.

**Results** Between December 2019 and February 2021, 280 patients from 4 centers were enrolled, including 264 (94.3%) males with median age of 58.0 years. Notably, 211 (75.4%) had a history of betel nut chewing. The primary sites were oral cavity in 192 cases (68.5%), followed by oropharynx 43 (15.4%), hypopharynx 26 (9.3%), and larynx 20 (7.1%). Among patients with oropharyngeal cancer, 13 (30.2%) were p16 positive. Prior to enrollment, 171 (61.1%) patients had received first-line systemic treatment and 68 (24.3%) second-line. The prevalence of PD-L1 (CPS ≥ 1) was 94.3% (264/280) in the total cohort, 93.8% (198/211) in the betel nut exposed subgroup, and 96.6% (56/58) in the non-betel nut exposed subgroup. Furthermore, 46.1% (129/280) of all patients were CPS ≥ 20, and 17.1% (48/280) were TPS ≥ 50%. A total of 159 (93.0%) and 64 (94.1%) patients were CPS ≥ 1 among those that received first-line and second-line systemic treatment, respectively.

**Conclusions** PD-L1 expression was observed in a vast majority (94.3%) of R/M HNSCC patients. There is no difference in PD-L1 prevalence between those with betel nut exposure history and betel nut non-exposed patients. PD-L1 prevalence also does not differ in those that had received prior first-line or second-line therapy, compared to the overall study population.

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**Ethics Approval** The study received ethics approval from National Taiwan University Hospital (IRB number: 201909007RSA), China Medical University Hospital (IRB number: CMUH108-REC2-150), National Cheng Kung University Hospital (IRB number: B-ER-108-252), and Chang Gung Memorial Hospital Kaohsiung Branch (IRB number: 201901757B0C501).

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