Background Tumor programmed death-receptor/ligand-1 (PD-L1/ PD-L1) expression negatively correlates with cancer prognosis and overall survival, and has been shown to predict clinical responses to immunotherapy for head and neck cancers. 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 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 (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.

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.

Acknowledgements This study was funded by MSD. Cerner Enviza received funding for the conduct of the study and development of the abstract.

REFERENCES

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 (IRB number: 201901757B0C501).