

Palliative Immunotherapy in Head and Neck Squamous Cell Carcinoma

Real-World, Single-Centre Data

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44

PATIENTS TREATED

29

1ST-LINE PEMBROLIZUMAB

15

2ND-LINE NIVOLUMAB

2020–2025

STUDY PERIOD

Introduction

- Pembrolizumab (1st-line) and nivolumab (2nd-line) are approved monotherapies for recurrent/metastatic HNSCC, per KEYNOTE-048 and CheckMate-141.
- This study reports real-world outcome and toxicity data from a single UK centre.

Methods

- Retrospective single-centre analysis, 2020–2025.
- Cohorts: 1st-line pembrolizumab or 2nd-line nivolumab in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC).
- Outcomes: overall survival (OS), progression-free survival (PFS), PD-L1 CPS subgroups, and immune-related adverse events (irAEs).

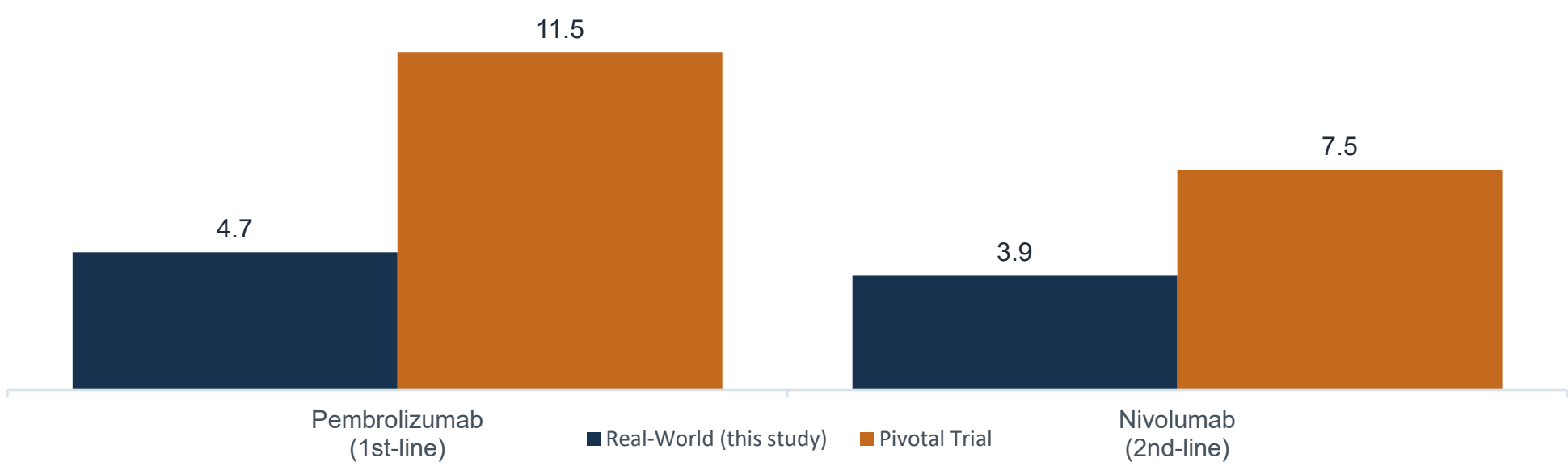
Conclusion

- Higher PD-L1 CPS was associated with numerically improved outcomes with pembrolizumab; the nivolumab cohort was too small and had insufficient CPS data to assess this relationship.
- Patients developing irAEs had longer OS, reaching statistical significance in the nivolumab cohort (p=0.02); this exploratory finding should be interpreted cautiously given the small sample size.
- Both therapies were well tolerated in real-world use.
- Real-world OS was notably lower than pivotal trial data (right) — potentially reflecting differences in patient selection and disease characteristics between routine practice and clinical-trial populations.

Baseline Patient Characteristics

Characteristic	Category	Pembro (n=29)	Nivo (n=15)	Characteristic	Category	Pembro (n=29)	Nivo (n=15)
Age (years)	Median	61	63	Alcohol status	Never	5 (17.2%)	2 (13.3%)
	Range	48–86	37–75		Former heavy drinker	2 (6.9%)	0 (0.0%)
Sex	Male	20 (69.0%)	14 (93.3%)		Former light drinker	0 (0.0%)	0 (0.0%)
	Female	9 (31.0%)	1 (6.7%)		Current heavy drinker	3 (10.3%)	2 (13.3%)
Smoking status	Never smoker	7 (24.1%)	3 (20.0%)	ECOG PS	Current light drinker	4 (13.8%)	3 (20.0%)
	Ex-smoker	10 (34.5%)	4 (26.7%)		Not documented	15 (51.7%)	8 (53.3%)
	Current smoker	6 (20.7%)	2 (13.3%)		0	12 (41.4%)	11 (73.3%)
	Not recorded	6 (20.7%)	6 (40.0%)		1	17 (58.6%)	4 (26.7%)

Real-World vs. Pivotal Trial: Median OS (months)



Real-world median OS was 59% lower with 1st-line pembrolizumab and 48% lower with 2nd-line nivolumab than in their respective pivotal trials.

First-Line Pembrolizumab · n = 29

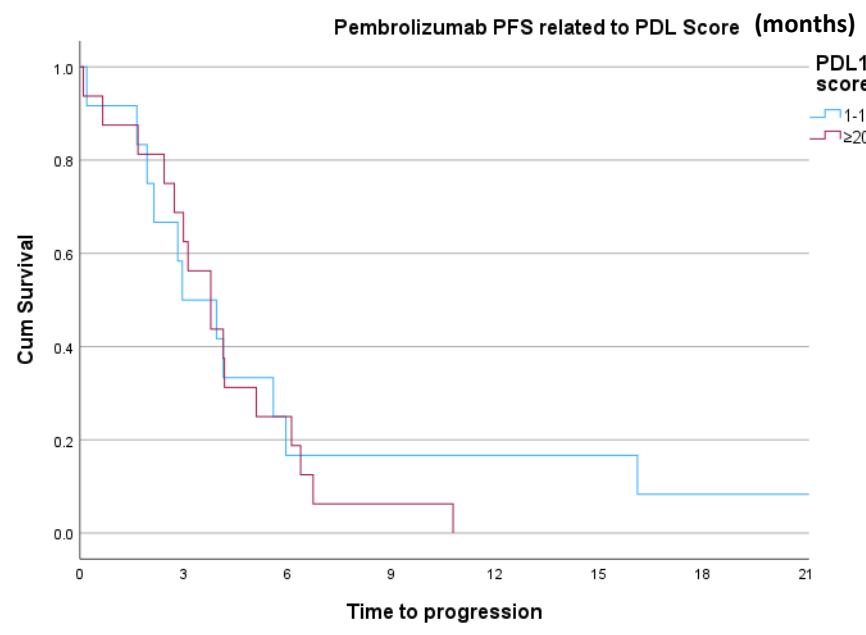
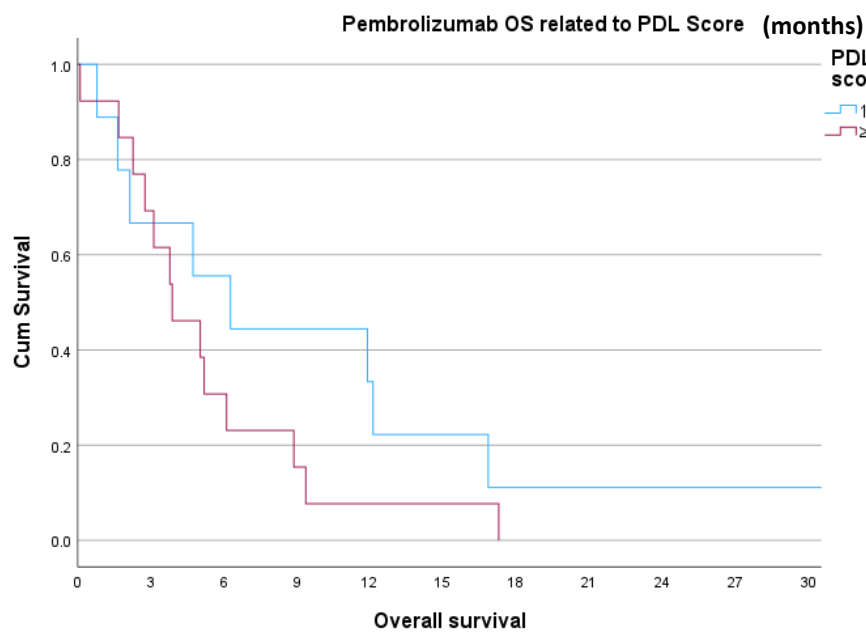
4.7 mo

MEDIAN OS
95% CI 3.1–6.3

3.7 mo

MEDIAN PFS
95% CI 2.5–5.0

- PFS: 2.9 mo (CPS 1–19) vs 3.7 mo (CPS ≥20), p=0.24.
- irAEs in 34% (10/29): 24% grade 1–2, 10% grade 3 (incl. 2 pts with grade 3 diabetic ketoacidosis).
- OS 6.1 mo with irAEs vs 2.7 mo without (p=0.45).
- 6 pts received 2nd-line platinum/5-FU chemotherapy; 2 had good symptomatic response to palliative radiotherapy.



Second-Line Nivolumab · n = 15

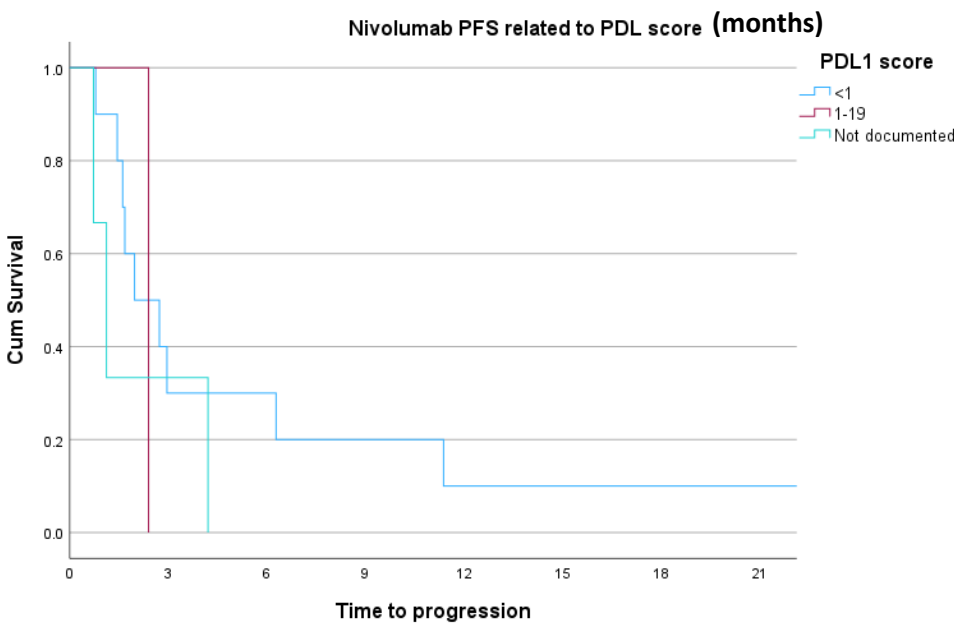
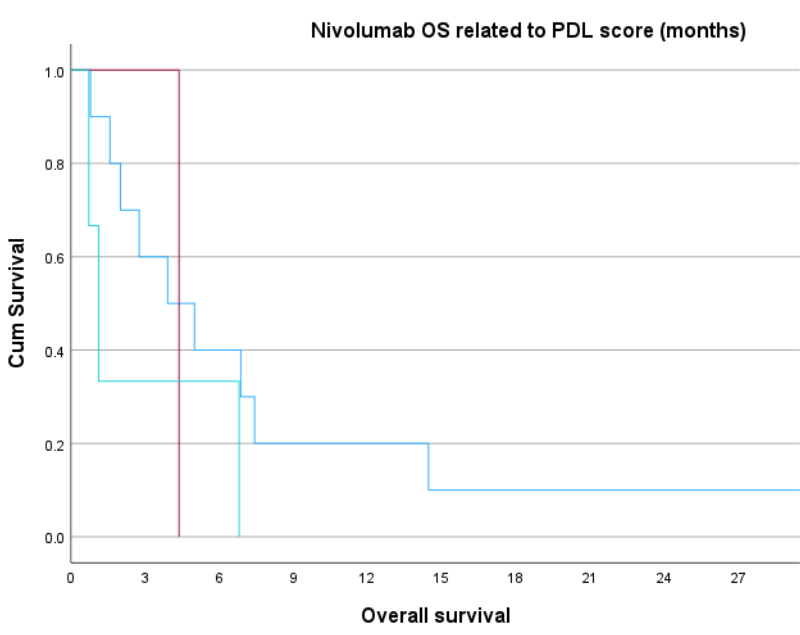
3.9 mo

MEDIAN OS
95% CI 0.6–6.9

1.9 mo

MEDIAN PFS
95% CI 0.6–3.2

- OS 3.9 mo (CPS <1) vs 4.4 mo (CPS 1–19).
- irAEs in 27% (4/15): 20% grade 1–2, 7% grade 3.
- OS 7.4 mo with irAEs vs 2.7 mo without (p=0.02).
- 1 pt continues therapy with stable disease; 1 stopped for toxicity; 2 subsequently received palliative radiotherapy.



Best Response by PD-L1 CPS (n = 29)

PD-L1 CPS	No of Pts	CR	PR	SD	PD
< 1	1	0	1	0	0
1 – 19	11	0	3	1	7 (2)*
≥ 20	17	1	2	4	10 (4)*

* Number of patients who died before having a scan due to progressive disease.

Immune-Related Adverse Events by Grade

Type	No. Events	G1	G2	G3	G4
Endocrine – Diabetes	2	0	0	2	0
Endocrine – Adrenal	1	0	0	1	0
Endocrine – Thyroid	5	0	5	0	0
Gastrointestinal	5	1	2	2	0
Mucositis	1	0	0	1	0
Skin	2	0	2	0	0

Counts reflect the number of irAE events by organ system; some patients experienced more than one irAE type or grade.

Best Response by PD-L1 CPS (n = 15)

PD-L1 CPS	No of Pts	CR	PR	SD	PD
< 1	8	0	1	3	4(3)*
1 – 19	1	0	0	0	1
≥ 20	0	0	0	0	0
Unknown	6	0	0	0	6 (2)*

* Number of patients who died before having a scan due to progressive disease.

Immune-Related Adverse Events by Grade

Type	No. Events	G1	G2	G3	G4
Endocrine – Adrenal	1	0	1	0	0
Endocrine – Thyroid	1	0	1	0	0
Gastrointestinal	1	0	1	0	0
Skin	1	0	1	0	0
Hepatitis	1	0	0	1	0

Counts reflect the number of irAE events by organ system; some patients experienced more than one irAE type or grade.

References

- Burtneß B, Harrington K, Greil R, et al. Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic HNSCC (KEYNOTE-048). Lancet. 2019;394:1915–1928.
- Ferris RL, Blumenschein G Jr, Fayette J, et al. Nivolumab for recurrent squamous-cell carcinoma of the head and neck (CheckMate-141). N Engl J Med. 2016;375(19):1856–1867.