Head & neck squamous

Randomised Phase II Trial of Nivolumab with Stereotactic Body Radiotherapy versus Nivolumab alone in Metastatic Head and Neck Squamous Cell Carcinoma

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PURPOSE

The objective response rate (ORR) for single-agent anti-programmed death receptor 1 (anti-PD-1) therapy is modest in patients with metastatic or recurrent head and neck squamous cell carcinoma (HNSCC). We aimed to test whether radiotherapy may act synergistically with anti-PD-1 therapy to improve response through the abscopal effect.

PATIENTS AND METHODS

We conducted a single-centre, randomised, phase II trial of nivolumab (anti-PD-1 therapy) versus nivolumab plus stereotactic body radiotherapy (SBRT) in patients with metastatic HNSCC. Patients had at least two metastatic lesions: one that could be safely irradiated and one measurable by RECIST version 1.1. Patients were randomly assigned (1:1), stratified by human papillomavirus status, to nivolumab (3 mg/kg intravenously every two weeks) or nivolumab (same dose) plus SBRT (9 Gy × 3) to one lesion. The primary end point was ORR in non-irradiated lesions, which was assessed by RECIST in patients with at least one available set of on-treatment images; safety was assessed in a per-protocol population.

RESULTS

Between 11 March, 2016, and 22 June, 2018, 62 patients were randomly assigned to nivolumab (n = 30) or nivolumab plus SBRT (n = 32). There was no statistically significant ORR difference between arms (34.5% [95% CI, 19.9% to 52.7%] vs. 29.0% [95% CI, 16.1% to 46.6%]; P = 0.86). There was no significant difference in overall survival (P = 0.75), progression-free survival (P = 0.79), or response duration (P = 0.26). Grade 3-5 toxicities were similar (13.3% vs. 9.7%; P = 0.70).

CONCLUSION

We found no improvement in response and no evidence of an abscopal effect with the addition of SBRT to nivolumab in unselected patients with metastatic HNSCC.