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Pembrolizumab versus cetuximab, concomitant with radiotherapy (RT) in locally advanced head and neck squamous cell carcinoma (LA-HNSCC): Results of the GORTEC 2015-01 "PembroRad" randomized trial

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Background

Based on the hypothesis of a potential synergistic effect of the anti-PD1 pembrolizumab when combined with RT, this new combination was tested in a randomized trial against the well-established standard of care (SOC) cetuximab-RT in LA-HNSCC.

Methods

In this phase II randomized trial, patients with non operated stage III-IVa-b SCC of oral cavity, oropharynx, hypopharynx and larynx and unfit for receiving high dose of cisplatin were enrolled. Patients received once-daily IMRT up to 69,96 Gy concomitant with cetuximab (Cetux-RT arm: 400 mg/m^2 loading dose and 250 mg/m^2 weekly) or pembrolizumab (Pembro-RT arm: 200 mg Q3W during RT). The primary endpoint was 15-month Loco-Regional Control (LRC) rate and secondary endpoints included Progression-free survival (PFS), Overall Survival (OS) and tolerance. To detect a difference between arms of 60% to 80% in 15-month LRC, inclusion of 66 patients per arm was required to achieve a power of at least 0.85 at 2-sided significance level of 0.20.

Results

Between May 2016 and October 2017, 131 patients were randomized and treated by 27 centers: 65 patients in Cetux-RT arm and 66 patients in Pembro-RT arm. The median age was 65 years, 92% were smokers, 60% of oropharynx (46% p16+), 41% of N2c-N3 with 25%, 56% and 19% of stage III, IVa and IVb respectively. Median follow-up was 25 months in both arms. Acute toxicity was lower in Pembro-RT arm than Cetux-RT arm: 74% *vs* 92% patients with at least one grade ≥ 3 acute adverse events (p=0.006), mainly due to dermatitis in radiation field, mucositis and cutaneous rash. LRC at 15 months were 59% in Cetux-RT arm and 60% in Pembro-RT arm, not significantly different: OR=1.05 (95%CI: 0.43-2.59, p=0.91). 2-year PFS rate was 40% in the Cetux-RT arm *vs* 42% in the Pembro-RT arm. There was no significant difference between arms for PFS: HR=0.83 (95%CI 0.53-1.29, p=0.41). 2-year OS rate was 55% in the Cetux-RT arm *vs* 62% in the Pembro-RT arm. OS was not significantly different between arms: HR=0.83 (95%CI: 0.49-1.40, p=0.49).

Conclusions

Compared to the SOC cetuximab-RT, the anti-PD1 pembrolizumab concomitant with RT did not improve carcinologic outcomes but appeared less toxic.

Clinical trial identification

NCT 02707588.

Legal entity responsible for the study

GORTEC.

Funding

GORTEC.

Disclosure

J. Bourhis: Advisory/Consultancy: BMS; Advisory/Consultancy: MSD; Advisory/Consultancy: AstraZeneca; Advisory/Consultancy: Merck. All other authors have declared no conflicts of interest.