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Health-related Quality of Life Analysis from KEYNOTE-426: Pembrolizumab plus Axitinib Versus Sunitinib for Advanced Renal Cell Carcinoma

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Abstract

Background: In the phase 3 KEYNOTE-426 ([NCT02853331](#)) trial, pembrolizumab + axitinib demonstrated improvement in overall survival, progression-free survival, and objective response rate over sunitinib monotherapy for advanced renal cell carcinoma (RCC).

Objective: To evaluate health-related quality of life (HRQoL) in KEYNOTE-426.

Design, setting, and participants: A total of 861 patients were randomly assigned to receive pembrolizumab + axitinib (n = 432) or sunitinib (n = 429). HRQoL data were available for 429 patients treated with pembrolizumab + axitinib and 423 patients treated with sunitinib.

Outcome measurements and statistical analysis: HRQoL end points were measured using the European Organisation for the Research and Treatment of Cancer Core (EORTC) Quality of Life Questionnaire (QLQ-C30), EQ-5D visual analog rating scale (VAS), and Functional Assessment of Cancer Therapy Kidney Cancer Symptom Index-Disease-Related Symptoms (FKSI-DRS) questionnaires.

Results and limitations: Better or not different overall improvement rates from baseline between pembrolizumab + axitinib and sunitinib were observed for the FKSI-DRS (-0.79%

improvement vs sunitinib; 95% confidence interval [CI] -7.2 to 5.6), QLQ-C30 (7.5% improvement vs sunitinib; 95% CI 1.0-14), and EQ-5D VAS (9.9% improvement vs sunitinib; 95% CI 3.2-17). For time to confirmed deterioration (TTcD) and time to first deterioration (TTfD), no differences were observed between arms for the QLQ-C30 (TTcD hazard ratio [HR] 1.0; 95% CI 0.82-1.3; TTfD HR 0.82; 95% CI 0.69-0.97) and EQ-5D VAS (TTcD HR 1.1; 95% CI 0.87-1.3; TTfD HR 0.98; 95% CI 0.83-1.2). TTfD was not different between treatment arms (HR 1.1; 95% CI 0.95-1.3) for the FKSI-DRS, but TTcD favored sunitinib (HR 1.4; 95% CI 1.1-1.7). Patients were assessed during the off-treatment period for sunitinib, which may have underestimated the negative impact of sunitinib on HRQoL.

Conclusions: Overall, patient-reported outcome scales showed that results between the pembrolizumab + axitinib and sunitinib arms were not different, with the exception of TTcD by the FKSI-DRS.

Patient summary: Compared with sunitinib, pembrolizumab + axitinib delays disease progression and extends survival, while HRQoL outcomes were not different between groups.

Keywords: Advanced renal cell carcinoma; Axitinib; Health-related quality of life; Pembrolizumab; Sunitinib.

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