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Everolimus in second line treatment of renal cell carcinoma: Clinical outcomes, tolerability and quality of life in an early cohort of patients

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Background: Renal call carcinoma accounts for 90% of renal cell cancers, with a majority of these being the result of sporadic mutations in the VHL gene, leading to loss of function of VHL. Tumours are dependent on the activation of angiogenesis, leading to the emergence of therapies targeting the vascular endothelial growth factor (VEGF) pathway. Everolimus, an inhibitor of the mammalian target of rapamycin (mTOR), gained approval as an effective second line treatment following the RECORD-1 trial, demonstrating a prolonged PFS and tolerability. Our study in an early cohort of treated patients aimed to establish the effectiveness of Everolimus in clinical practice.

Methods: Patients were identified via applications to the West midlands cancer drugs fund and commenced Everolimus between August 2009 and January 2012. Demographic, outcome and toxicity data were recorded in line with that collected by the RECORD-1 trial and an adapted version of the EORTC QLQ-C30 questionnaire, was sent to patients remaining on follow up.

Results: 47 patients were indentified of which data was available in 44. Performance status (PS) was lower, with 2% Karnofsky score of 100 vs. 28% within the trial as was MSKCC risk: 18% vs. 29% of good and 30% vs. 15% of poor risk patients. Toxicity requiring discontinuation was higher: 23 vs. 10%, while overall quality of life scores were maintained. Progression free survival and overall survival were lower, at 3 months vs. 4.9 months and 8 months vs. 14.8, while objective radiological response was comparable at 57% vs. 63% found in the trial. Median PFS in all patients was 3 months (90 days) vs. 4.9 months in the trial.

Conclusions: PFR and OS is moderately lower than that demonstrated by the RECORD trial, likely to reflect a significantly smaller proportion of patients with favourable prognosis MSKCC. Despite this, a benefit in PFS was seen when compared to placebo, and similar objective response rate to Everolimus treated trial patients. Maintained quality of life was reported, supporting the use of Everolimus in second line treatment.

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