

KIDNEY CANCER

Sunitinib for patients with a poor prognosis

Patients with renal cell carcinoma (RCC) and poor prognostic features have shown promising responses to treatment with sunitinib—established in previous studies as a standard of care for treatment of RCC—in an expanded-access clinical trial. “The toxicity profile of sunitinib was very similar in our patient population to that seen in the patients who were part of the pivotal trials,” says lead researcher Martin Gore, of the Royal Marsden Hospital, London, UK.

Sunitinib, a potent oral inhibitor of vascular endothelial growth factor, has been approved for the treatment of advanced RCC, and pivotal clinical trials have indicated notable efficacy in patients with metastatic disease. Patients with poor prognostic features, such as those presenting with brain metastases (up to 20% of patients with metastatic RCC), poor performance status, advanced age or non-clear-cell histology, are often excluded from clinical trials.

Thus, there is a paucity of data on the efficacy of targeted therapies in this patient subgroup.

“...[the] overall tumor response rate [was] similar to [that] of a pivotal multicenter phase III trial”

Gore and colleagues launched a multinational, expanded-access clinical trial, providing sunitinib to 4,564 patients with metastatic RCC (321 with brain metastases, 582 with an ECOG performance status of ≥ 2 , 588 with non-clear-cell RCC, and 1,418 aged ≥ 65 years) at the investigators' discretion. Patients self-administered once-daily oral sunitinib 50 mg on a repeated schedule of 4 weeks on treatment and 2 weeks off. “The primary objective of the trial was to gather toxicity data on this wider group of patients,” Gore explains.

The investigators observed an overall tumor response rate of 17%, a median progression-free survival of 10.9 months and a median overall survival of 18.4 months. These findings were similar to those of a pivotal multicenter phase III trial assessing the efficacy of sunitinib treatment for advanced RCC. Furthermore, the safety profile of sunitinib in patients with RCC and poor prognostic features mirrored that reported in previous clinical trials that excluded such patients.

“This work has encouraged groups to examine the role of the novel targeted agents in poorer prognosis patients such as those with cerebral metastases, poor performance status and the elderly,” Gore concludes.

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Original article Gore, M. E. *et al.* Safety and efficacy of sunitinib for metastatic renal-cell carcinoma: an expanded-access trial. *Lancet Oncol.* 10, 757–763 (2009).