# Successful sunitinib treatment of metastatic renal cell carcinoma in a patient with end stage renal disease on hemodialysis

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Sunitinib is a tyrosine kinase inhibitor with a low toxicity profile and proven activity against metastatic renal cell carcinoma (mRCC). However, there is very limited data on the effect of sunitinib on end stage renal disease owing to mRCC. We report our experience with the use of sunitinib in a patient with mRCC and end stage renal disease undergoing hemodialysis. *Anti-Cancer Drugs* 20:848–849 © 2009 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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## Introduction

Sunitinib is a small molecule oral tyrosine kinase inhibitor that exhibits potent antineoplastic activity and has been used effectively for metastatic renal cell carcinoma (mRCC) and gastrointestinal stromal tumors after the failure of imatinib mesylate treatment [1,2]. However, it is not known whether it is safe to administer sunitinib to patients with renal failure, and whether dose adjustment is necessary. We administered the standard dose of sunitinib to a patient with mRCC and end stage renal disease (ESRD) on maintenance hemodialysis. Side effects were tolerable and there was a complete response.

#### Case report

A 54-year-old male patient with a 13-year history of diabetes mellitus was diagnosed with ESRD due to diabetes mellitus 4 years ago (August 2004), and hemodialysis was begun in January 2007. A computed tomography scan revealed a 5 × 6 cm mass in the left kidney. The patient underwent a radical nephrectomy and was diagnosed with clear cell RCC. In July 2007, multiple lung metastases developed, and sunitinib was administered following a regimen of 50 mg per day for 4 weeks for every 6 weeks. Hemodialysis for 3 h was carried out three times weekly. Grade 1 fatigue and nausea and grade 2 thrombocytopenia and neutropenia were observed. On the follow-up computed tomography scan taken after six cycles (March 2008), a complete clinical response was noted (Fig. 1). The patient remains in complete remission at 20 months with no evidence of significant adverse effects.

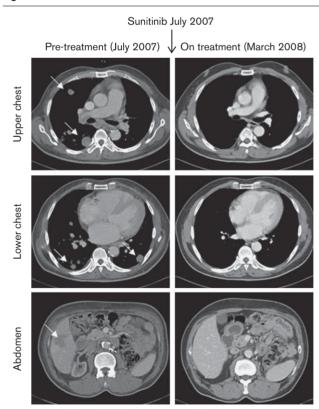
# **Discussion**

RCC is a rare but serious complication in ESRD patients [3,4]. Such patients have an increased incidence of RCC

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when compared with the general population. Sunitinib is now frequently used in patients with metastatic RCC and gastrointestinal stromal tumors refractory to imatinib

Fig. 1



Response to sunitinib in metastatic renal cell carcinoma. The white arrows point to multiple metastatic lesions.

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[1,2]. Clinical trials include only patients with good organ function, and the pharmacokinetics in patients undergoing hemodialysis treatment have not previously been reported. The major metabolites of sunitinib malate are metabolized primarily through the liver [1]. According to Motzer *et al.* [5] the main side effects in patients with normal renal function were fatigue, diarrhea, nausea, vomiting, etc., and among the unusual results of laboratory tests, abnormal hematological reactions such as neutropenia, thrombopenia, leucopenia, etc. were abundant. Two thirds of the cases had elevated creatine levels and 1% was reported to be of grade 3.

In the case reported above, we administered the standard dose of sunitinib to a patient with mRCC and ESRD on maintenance hemodialysis. The treatment proved to be safe and well tolerated. The patient showed no significant adverse effects except grade 1–2 thrombocytopenia, neutropenia, fatigue, and nausea. After six cycles, the multiple metastases in the lung showed a complete response as assessed by computed tomography scan. Our experience is consistent with a recent case study demonstrating that the pharmacokinetics of standard dose sunitinib and its metabolite do not change in patients with ESRD on hemodialysis [6,7]. According to the data

of Motzer *et al.* [5] 31% of mRCC cases gave a partial response to sunitinib, and 48% were stable, but no complete response was observed.

The implication of our study is that standard dose sunitinib can be safely and successfully administered to clear cell mRCC patients with ESRD on hemodialysis, although complete responses are very rare.

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