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Rare Adverse Effects of Sunitinib in Metastatic Renal Cell Carcinoma- A Case Report

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Abstract

Aim and Background: *Sunitinib, a tyrosine kinase inhibitor, is commonly used for advanced renal cell carcinoma (RCC) but is associated with significant adverse effects. This report aims to highlight a rare case of accelerated hypertension, acute pulmonary edema, and cutaneous vasculitis leading to gangrene caused by Sunitinib.*

Case Description: *A 69-year-old male with metastatic RCC presented with acute breathlessness, severe hypertension, and a gangrenous ulcer on the right great toe after six months of Sunitinib therapy. His medical history included chronic kidney disease, diabetes mellitus, and systemic hypertension. Investigations revealed anemia, thrombocytopenia, renal impairment, and cutaneous vasculitis. As all thesigns and symptoms could also be attributed to use of Sunitinib, it was discontinued, and the patient was treated with non-invasive ventilation, hemodialysis, and supportive care, resulting in clinical stabilization.*

Conclusion: *This case demonstrates a rare but significant complication of Sunitinib therapy. The timely cessation of the drug and appropriate supportive care were crucial in improving the patient's condition.*

Clinical Significance: *Clinicians must remain vigilant for severe adverse effects in patients on Sunitinib, particularly those with pre-existing comorbidities. Regular monitoring and patient education are essential for the early detection and management of complications, ensuring better treatment outcomes.*

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Introduction

Sunitinib malate is an oral multitargeted receptor tyrosine kinase inhibitor used primarily for metastatic renal cell carcinoma (mRCC) and gastrointestinal stromal tumours [1]. While effective, its use is associated with various adverse effects, including hypertension, fatigue, and dermatological manifestations.

It is important for clinicians and intensivists to be aware of the possible side effects, so as to correctly manage the dosing of drugs like Sunitinib. This report details a case of a 69-year-old male patient who experienced multiple complications related to Sunitinib therapy.

Case Presentation

A 69-year-old gentleman with a known diagnosis of left renal cell carcinoma with bone and lung metastasis presented to our department with acute onset breathlessness and accelerated hypertension over one day. His medical history included type II diabetes mellitus, systemic hypertension, hypothyroidism, and chronic kidney disease (CKD) managed medically. In addition to his antihypertensives and oral hypoglycemic agents, he was initiated on Tab. Sunitinib 25mg daily for two weeks followed by one week off , for the past 6 months .

On admission, he exhibited severe pallor, tachycardia (heart rate-119/min), and significantly elevated blood pressure (190/120 mmHg). Respiratory rate was 28 breaths per minute with orthopnoea and oxygen saturation was 94% on non-invasive BiPAP. A gangrenous ulcer was observed on the great toe of his right foot (Fig 1) accompanied by lividoid lesions on the tips of digits of both feet (Fig 2). The dorsalis pedis and posterior tibial pulses were palpable bilaterally and confirmed with arterial Doppler.

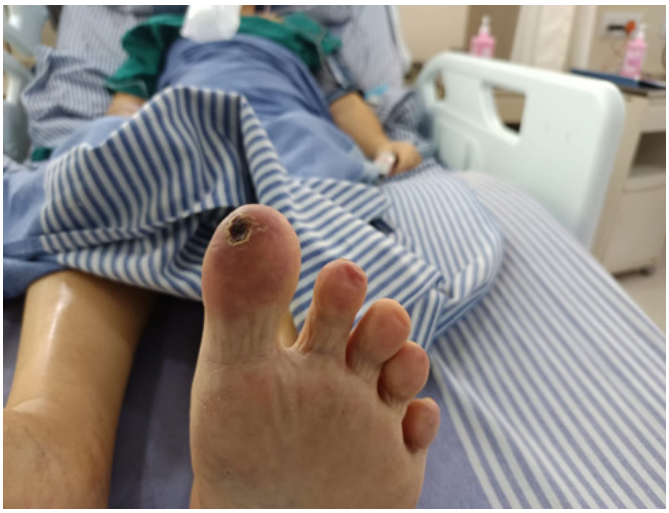

Figure 1: Gangrenous Ulcer on (R) Great Toe

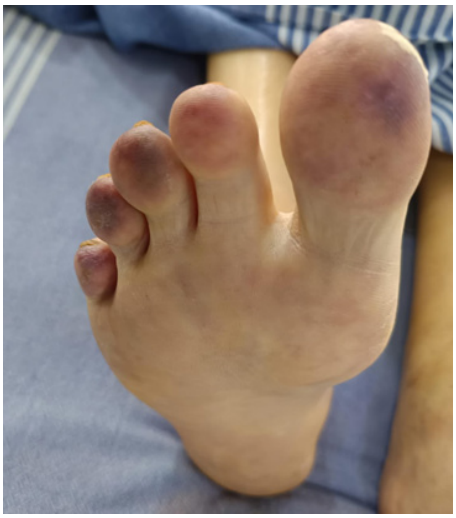

Figure 2: Lividoid Lesions on (L) foot

The patient reported pain in the great toe with bluish discoloration for two weeks without any preceding trauma. There was no history of fever, hematuria, joint pain, or abdominal discomfort. He was unaware about possible complications of Sunitinib and had missed a follow up with his doctor. The investigations on admission (Table 1) showed thrombocytopenia, anaemia and high creatinine values.

Table 1: Investigations

Test	Value on D1	aCTCAE Grade[2]	Value on D8
Haemoglobin (g/dl)	5.8	III	8.6
TLC (cells/mm3)	10,530		6820
Platelet count (cells/ mm3)	68000	III	85,000
Creatinine (mg/dl)	4.8	III- IV	2.6
Urea (mg/dl)	67		50

[a]CTCAE – Common Terminology Criteria for Adverse events.

Peripheral Smear – RBCs were predominantly normocytic normochromic with few microcytes. Platelet count was decreased and WBCs showed neutrophil predominance. No evidence of schistocytes or dysplasia.

Though NT proBNP was raised(24000pg/ml), ECG and ECHO did not show any signs of myocardial ischemia. An abdominal ultrasound revealed a well-defined hypo echoic lesion arising from the mid-pole of the left kidney with no signs of obstruction.

The patient was diagnosed as acute pulmonary oedema with accelerated hypertension, AKI on CKD, bicytopenia and cutaneous vasculitis of toes leading to gangrenous ulcer on the right great toe. As all the finding could be attributed to adverse effects of Sunitinib, it was withheld. Patient was initiated on Non invasive BIPAP ventilation and haemodialysis in the ICU. One unit of packed red blood cell was transfused and he was started on antibiotics. Platelet count increased spontaneously after 4 days. With supportive treatment his condition improved. The cutaneous lesion was managed conservatively and there was no progression of gangrene. He was discharged home after two weeks in the hospital with clear instructions for follow -up.

The patient comes for twice weekly haemodialysis. The wound on the toe shows signs of healing. After discussion with the Oncologist, Sunitinib will be restarted once the wound is healed and after arterial Doppler evaluation of both lower limbs.

Discussion

Renal cell carcinoma accounts for more than 85% of kidney cancers and the estimated 5year survival in patients with metastatic renal cell carcinoma is less than 30% [2]. Sunitinib is a tyrosine kinase inhibitor, that produces an increased response rate, progression free survival and overall survival in renal cell carcinoma [1]. Sunitinib's side effects can include hypertension and various dermatological reactions such as cutaneous vasculitis. The hand and foot skin reaction was the most frequent cutaneous toxicity. Alopecia, stomatitis, skin colouring (face or hair), sublingual splinter haemorrhage, facial oedema, facial erythema, palmar and plantar erythrodyesthesia are among the other cutaneous toxicities. Other cutaneous toxicities have little effect on the course of treatment, but HFSR and severe stomatitis necessitate adjustments to the therapy to alleviate symptoms. Renal side effects include hypertension, proteinuria, renal insufficiency and thrombotic microangiopathy. Usually the renal adverse effects are mild to moderate and partially reversible after cessation of Sunitinib. This drug is also known to cause myelosupression with neutropenia and thrombocytopenia which is reversed on stopping the drug [3,4]. The mechanism behind these adverse effects may involve endothelial dysfunction and vascular damage due to its action on multiple receptor tyrosine kinases involved in angiogenesis and inflammation.

In this case, the patient's acute presentation following Sunitinib use, raises concerns about its safety profile in patients with pre-existing conditions such as CKD and diabetes mellitus. The acute worsening of renal functions could be multifactorial. Renal cell carcinoma can cause immune mediated thrombocytopenia but the improvement in platelet count after stopping Sunitinib points to the drug as the cause. The development

of gangrene on the skin, which is classified as grade II- III in Common terminology Criteria for Adverse Effects (CTCAE) is particularly alarming and underscores the importance of recognizing early signs of vascular compromise in patients receiving targeted therapies. Previous studies have shown that around 20% patients discontinue therapy with Sunitinib due to adverse effects [5]. The intermittent dosing of Sunitinib is planned to mitigate the potential bone marrow and other toxicities.

Management strategies should include immediate cessation of Sunitinib upon suspicion of severe adverse effects along with supportive care. Patient education about the warning signs of complications can lead to early detection of adverse effects and better reversibility [6].

Conclusion

This case illustrates a rare but significant complication associated with Sunitinib therapy in a patient with advanced renal cell carcinoma. Clinicians must remain vigilant for potential adverse effects in patients undergoing treatment with targeted therapies like Sunitinib. Good patient education, regular monitoring and prompt intervention can mitigate severe adverse events associated with these medications.

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Conflict of Interest: All authors declare that there is no conflict of interest to disclose and no funding was received for this work.

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