



Potential First-line therapy
for metastatic non-clear cell
RCC patients



First-line Sunitinib is recommended in metastatic renal cell carcinoma (mRCC), but it is frequently associated with relevant toxicities and subsequent dose reductions. Alternative schedules, such as 2-week-on treatment and 1-week-off (2/1 schedule) ensures safety and tolerability.¹

According to the report from 2015 American Society of Clinical Oncology Annual Meeting Sunitinib was superior overall compared with Everolimus at delaying disease progression.¹

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Sunitinib 50 mg Capsule

First-Line Treatment in Metastatic RCC

Sunitinib administered with a 2/1 schedule is more Effective and Safer for mRCC

The standard Sunitinib schedule of 4 weeks on and 2 weeks off (4/2 schedule) is associated with troublesome toxicities, researchers sought to assess the efficacy and safety of a 2/1 Sunitinib dosing schedule compared with the standard 4/2 schedule.

In the multicenter, open-label, phase 2 trial, researchers enrolled 74 treatment-naïve patients with clear-cell type mRCC and randomly assigned them to receive Sunitinib in a 4/2 or 2/1 schedule.

Results

	4/2 schedule	2/1 schedule
6-month Failure-Free Survival rate	44%	63%
Objective Response Rates	36%	47%
The median time to progression	10.1 months	12.1 months
Safety	Neutropenia, fatigue, rash, stomatitis, hand-foot syndrome are more frequently observed	Mild Rash, stomatitis, and hand-foot syndrome less frequently observed

Provides better tolerability to the patients

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First-Line Treatment in Metastatic RCC

ASPEN study (a randomized phase 2 international trial of Sunitinib vs Everolimus) in Patients With Metastatic Non-Clear Cell Renal Cell Carcinoma

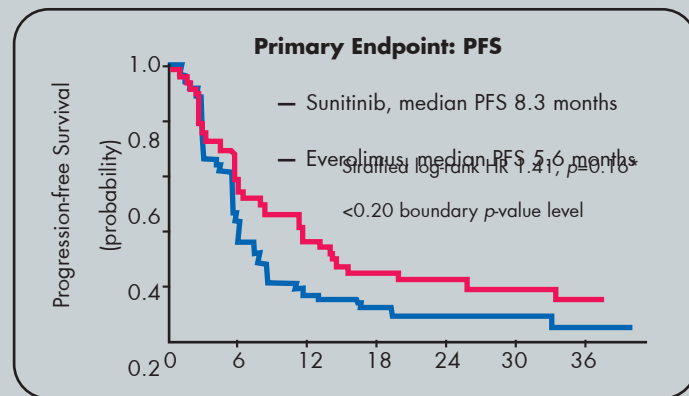
Methods

108 patients were enrolled between September 2010 and October 2013 across 17 sites and three countries. The median age was 63 and 75% of the patients were male.

Among the 108 patients, 66% had metastatic papillary disease, 15% had chromophobe, and 19% were unclassified histology. None of the patients had prior systemic therapy and were randomly assigned to receive either Everolimus (57 patients) or Sunitinib (51 patients) until their tumors progressed.

Results

Sunitinib was more effective for papillary-type kidney cancers and for better prognosis patients.



Conclusion

Papillary and unclassified RCC seemed to benefit more from Sunitinib, while chromophobe trended slightly towards better outcomes with Everolimus.

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First-Line Treatment in Metastatic RCC

Benefits of Sunitinib 2/1 treatment schedule over the traditional schedule 4/2

- ▶ Provide better tolerability and quality of life
- ▶ Significant reduction in grade ≥ 3 toxicities
- ▶ Longer progression free survival and median overall survival



Advanced or Metastatic Renal Cell Carcinoma (RCC)

Advanced Gastrointestinal Stromal Tumor (GIST)