

"Real Life" treatment of patients with advanced or metastatic Renal Cell Carcinoma in German oncology and urology outpatient centers (RCC-Registry)

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1. Background

Until 2006, advanced or metastatic renal cell carcinoma (mRCC) patients were treated with immunomodulators such as interleukins and interferons. Multiple new targeted therapeutics, mainly signal transduction inhibitors, have been developed resulting in fundamental changes of therapeutic standards for patients with mRCC¹. In 2007, recruitment into the registry started in order to survey the treatment of mRCC patients, the course of disease and treatment as well as the therapeutic decision-making processes.

The registry provides an overview of the current treatment of mRCC patients in German outpatient cancer centers. It highlights how new results from clinical studies concerning treatment of mRCC patients are transferred into current medical practice.

2. Methods

1000 mRCC patients will be recruited. Data will be collected for three years from the time of inclusion. Over 100 oncology and urology outpatient centers in Germany are participating.

Inclusion Criteria:

1. Patients with metastatic or locally advanced RCC requiring antineoplastic therapy
2. Start of 1st palliative therapy within 1 year before enrolment
3. Age at least 18 years
4. Informed written consent.

	Sunitinib	Temsirolimus	Bevacizumab + Interferon alpha	Sorafenib	Interferon alpha	Total
Patients (n [%])	380 [61.1%]	81 [13.0%]	70 [11.3%]	53 [8.5%]	14 [2.3%]	622
Gender						
Female (%)	31.3	35.8	31.4	32.1	28.6	31.8
Male (%)	68.7	64.2	68.6	67.9	71.4	68.2
Age (years)^a	67.1	66.7	67.1	67.2	60.6	67.0
± StD	±10.6	±12.3	±9.4	±9.8	±12.3	±10.6
Body Mass Index^b	26.4	26.1	27.6	27.4	25.9	26.6
± StD	±4.2	±5.4	±4.8	±4.8	±4.3	±4.5
MSKCC risk factors^{a,c}	0.8	1.5	1.0	1.0	0.8	0.9
± StD	±0.8	±1.2	±1.0	±0.9	±0.4	±1.0
[0] Favorable (%)	44.3	25.0	37.5	37.0	23.1	39.4
[1-2] Intermediate (%)	51.1	55.6	50.0	56.5	76.9	52.7
[3-5] Poor (%)	4.6	19.4	12.5	6.5	-	7.8
Charlson - Comorbidity Score^d	0.9	0.8	1.0	1.5	0.9	1.0
± StD	±1.3	±1.4	±1.5	±2.3	±1.3	±1.5
Nephrectomy (%)	78.9	69.1	80.0	83.0	50.0	77.0

Table 1. Patients Characteristics of mRCC treatments

Data are mean scores (± StD). Number of patients indicate how many patients were treated with the substances in the first line. All treatments that were received by more than 2% of the patients are shown.

^a At the start of first line therapy. ^b Height and weight are recorded only once. ^c For those patients whose respective parameters have been documented.

^d Charlson - Comorbidity Score indicates, to what extent patients are afflicted because of comorbidities at diagnosis.

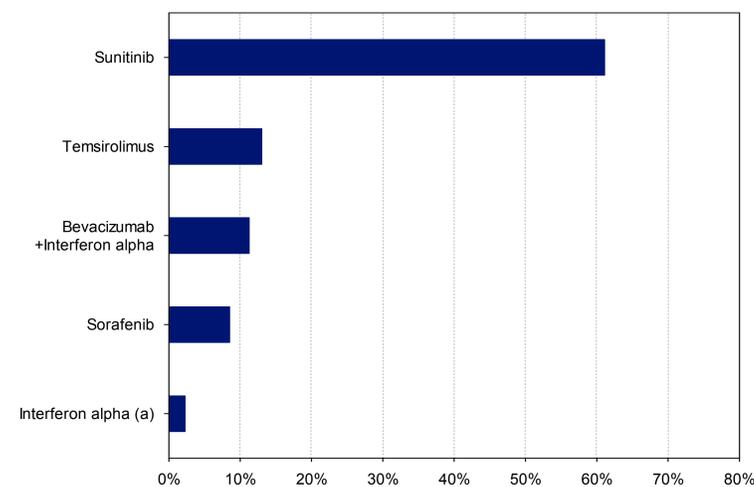


Figure 1. Frequency of compounds applied in the first line therapy
Time period: 1. Jan. 2007 - 15. Nov. 2010 (n=622).
All treatments that were received by more than 2% of the patients are shown.

^a Taken together Interferon alpha monotherapy, Interferon alpha with and without 5-FU and/or Folic acid, Interferon alpha + Vinblastine.

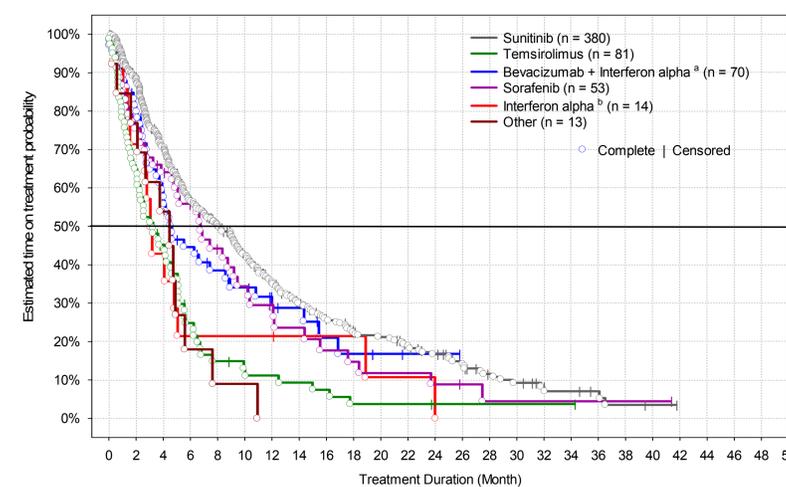


Figure 2. Kaplan-Meier Curves for the duration of first line treatment
Data shown for completed and ongoing therapies. All treatments that were received by more than 2% of the patients are shown.
The duration of ongoing therapies was censored as the date of last documentation.

^a Taken together Interferon alpha monotherapy, Interferon alpha with and without 5-FU and/or Folic acid, Interferon alpha + Vinblastine.
The black line marks the median.

3. Results

By November 2010, 622 patients were enrolled. At the start of systemic therapy mean age was 66 years for male and 69 years for female patients, respectively. Patients had a Charlson-Comorbidity Score of 1.0. The score is higher than in patients with other solid tumors for example colorectal² (0.6) or breast cancer³ (0.5). The majority of patients were classified as intermediate risk by MSKCC criteria (Table 1). 61% of the patients received Sunitinib as 1st-line treatment, 13% received Temsirolimus, 11% were treated with Bevacizumab/Interferon alpha and about 9% received Sorafenib (Figure 1).

Median duration of 1st-line treatment determined using Kaplan-Meier analysis is: Sunitinib: 8.0 months (n=380), Temsirolimus: 3.2 months (n=81), Bevacizumab/Interferon alpha: 4.5 months (n=70) and Sorafenib: 6.7 months (n=53). The duration of ongoing therapies was censored as the date of last documentation; thus the final duration might exceed the given values (Figure 2). After 1st-line treatment with Sunitinib most of the patients received either Sorafenib (29%, n=83) or Temsirolimus (16%, n=46) in the second line.

4. Conclusions

As 1st-line treatment most patients received Sunitinib which was also given longest. On average, patients displayed a Charlson-Comorbidity Score of 1.0. The classification of patients by MSKCC criteria was similar to that found in clinical trials.