INTERIM RESULTS OF THE PRO KIDNEY REGISTRY

PATIENT-REPORTED OUTCOMES IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA TREATED WITH SYSTEMIC FIRST-LINE THERAPY

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Conflicts of Interest:

Werner, Thorsten: Honoraria: BMS, Ipsen; Reimbursement for training expenses: BMS, Ipsen; Reimbursement for travel expenses: BMS, Ipsen

Scheffler, Michael: Honoraria: Sanofi, Novartis, Pfizer; Consultant: Janssen-Cilag

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Approval and registration:

The study was approved by the responsible ethics committee and is conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. This study is registered at ClinicalTrials.gov with identifier NCT02537743.

Literature:

1 Krebs in Deutschland für 2013/2014. 11. Ausgabe. Robert Koch-Institut (Hrsg) und die Gesellschaft der epidemiologischen Krebsregister in Deutschland e.V. (Hrsg). Berlin, 2017

2 Leitlinienprogramm Onkologie (Deutsche Krebsgesellschaft, Deutsche Krebshilfe, AWMF): Diagnostik, Therapie und Nachsorge des Nierenzellkarzinoms, Langversion 1.2, 2017, AWMF Registernummer: 043/017OL, http://leitlinienprogramm-onkologie.de/Nierenzellkarzinom.85.0.html

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INTRODUCTION

Each year nearly 15.000 patients are diagnosed with renal cell carcinoma (RCC) in Germany.[1] RCC patients are treated with systemic therapies such as tyrosine kinase inhibitors, mTOR inhibitors, anti-VEGF antibodies, cytokines or immune therapy.[2] These different molecular targeted therapies achieve similar efficacies.[2] Therefore, patient reported outcomes (PROs) on the patients' quality of life are becoming increasingly important for determination of the overall benefit of molecular targeted therapies.

Thus, the primary objective of this study is to collect real life PROs regarding quality of life of RCC patients.

METHODS

This prospective, open-label, multicenter, non-interventional PRO cohort study recruits patients with inoperable or metastatic renal-cell carcinoma (mRCC) in Germany. Data are collected using a tablet-technology based digital device (**Figure 1**). The primary objective is to gather PROs from mRCC patients at begin and during systemic first-line treatment in a real world setting using the questionnaires Functional Assessment of Cancer Therapy Kidney Symptom Index 19 (NCCN-FACT FKSI-19: 19 items) and Functional Assessment of Chronic Illness Therapy - Fatigue subscale (FACIT-F: 13 items). Furthermore, patients are asked about the influence of treatment and illness on daily life and about treatment side effects (8 items). PROs are assessed at baseline and then monthly for a maximum of two years. Descriptive statistics are used to analyze the data.

Table 1: Baseline patient characteristics

No. of patients included	**83**
No. of evaluable patients with questionnaires	total 74 (100%)
Age in years	
Median (min - max)	67 (46 - 83)
Gender	
Female	19 (26%)
Male	55 (74%)
Karnofsky performance score	
≥ 70	67 (91%)
< 70	4 (5%)
Missing	3 (4%)
Histology	
Clear-cell	55 (74%)
Non-clear-cell	4 (5%)
Unknown	10 (14%)
Missing	5 (7%)
Common locations of metastasis	
Lung	37 (50%)
Bone	22 (30%)
Lymph nodes	18 (24%)
Adrenal	13 (18%)
First-line therapies	
Pazopanib	41 (55%)
Sunitinib	16 (22%)
Temsirolimus	5 (7%)
Interferon α plus everolimus or bevacizumab	4 (5%)
Nivolumab	2 (3%)
Other	3 (4%)
Missing	3 (4%)
Motzer Score (categorized)	
0: Favorable risk	13 (18%)
1-2: Intermediate risk	36 (49%)
3-5: Poor risk	7 (9%)
Missing	18 (24%)

RESULTS

In this interim analysis data from 83 mRCC patients consecutively enrolled from 32 sites between August 2015 and July 2018 are presented. In this time 426 questionnaires were filled in total.

The median age of the patients was 67 years (range 46-83 years), 74% of patients were male and 74% of patients had a clear-cell RCC (**Table 1**). Pazopanib (55%) and sunitinib (22%) were the most frequently used antineoplastic drugs for palliative first-line therapy (**Table 1**). 22 patients (30%) died during the study period.

After six months of treatment, the mean FKSI-19 total score remained unchanged compared to baseline (**Figure 2A**). Likewise, no differences were observed for the subscales physical, emotional and function/well-being (**Figure 2A**) or for patients treated with pazopanib or sunitinib (**Figure 2B**). Overall, treatment associated side effects slightly worsened within the first six months, however with a tendency of improvement during the subsequent treatment period (**Figure 2C**). Treatment was especially associated with worsening of diarrhea (**Figure 2D**). In contrast, fatigue and activities of daily living were unaffected by treatment (**Figure 3**).

Limitations

Inoperable or metastatic RCC is a rather rare disease[1]. Accordingly, only 83 patients have been recruited in PRO Kidney so far. The observation period is not yet completed for all of these patients, so that only few questionnaires have been regained at the later time points to date. Furthermore, it is expected that the questionnaire return rate will decrease in the course of time and with progression of disease.

CONCLUSION

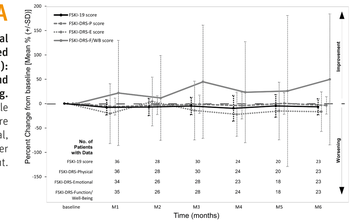
This interim analysis of the PRO Kidney cohort study revealed that pazopanib is the most frequently used first-line treatment option for mRCC patients. The present PRO data indicate that patients' quality of life remains unchanged after start of systemic palliative first-line treatment and this seems to be independent of the used antineoplastic drug. Although patients are bothered by specific treatment side effects such as diarrhea, the patients continue to perform their activities of daily living.

Figure 1

Figure 2

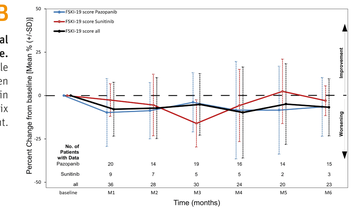
A

Figure 2A: FKSI-19 total score and disease related symptom subscales (DRS): physical, emotional, and function/well-being.
There are no remarkable changes in FKSI-19 total score and DRS physical, emotional, and function/well-being after six month of treatment.



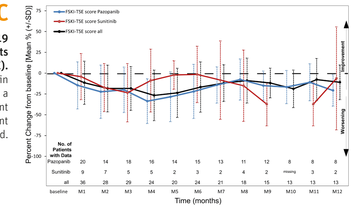
B

Figure 2B: FKSI-19 total score.
There are no remarkable differences between pazopanib and sunitinib in FKSI-19 total score after six month of treatment.



C

Figure 2C: FKSI-19 treatment side effects subscale (TSE).
TSE slightly worsened within the first six months, with a tendency of improvement during subsequent treatment period.



D

Figure 2D: FKSI-19 Item C5 "I have diarrhea".
Treatment was associated with worsening of diarrhea independent of the kind of treatment.

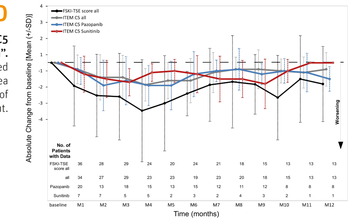


Figure 3

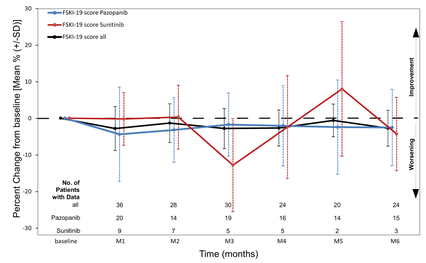


Figure 3: FACIT-F total score.
Fatigue and activities of daily life were unaffected by treatment.