

Adverse events of advanced renal cell carcinoma patients treated with targeted therapies in real world setting in Korea.

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Objectives

- This aimed to describe adverse events (AEs) of advanced renal cell carcinoma (RCC) patients treated with targeted therapies in real world setting in Korea.

Methods

- Data for this analysis was derived from an outcomes research on advanced RCC patients, which was a nationwide, multi-centered, and 1 year-prospective observational study conducted from Oct 2016 to Oct 2019 which are representative in treatments for the patients with advanced RCC in Korea. Patients who meet following criteria were eligible;
 - ✓ Advanced RCC patients aged ≥ 19 years,
 - ✓ treated with 1st-line targeted therapy,
 - ✓ newly experiencing one of the AEs (fatigue, hand-foot syndrome, mucosal inflammation, diarrhea, gastro-intestinal symptoms, hypertension, and anorexia),
 - ✓ and taught for self-management of AEs from a medical team
- Patients who were hospitalized, treated with immunotherapy or other systemic chemotherapy were excluded.
- During the 1year observation period, data were collected at baseline, 6month, and 12month.
- During the observational period, patients who died, lost follow-up, changed treatment to immunotherapy, and newly participated in other interventional study were dropped out from the time-point in this study.

Results

- Total 77 patients were enrolled in this study. At baseline, patients are aged mean 62 years old, 72.7% were male, and 40.3% had comorbidities. Of total, 96.1% were clear cell RCC, 64.9%, 20.8%, and 18.2% metastasized to lung, bone, and lymph node, respectively. All were grade ≤ 1 in ECOG PS. Patients have been prevalent with advanced RCC for mean 30 month (899.6 days) and treated with targeted therapy for mean 12 months (343.6 days). Under the targeted therapy, 82.4% patients remained in stable disease(SD), 8.1% showed partial response(PR), and 9.5% achieved complete responses(CR) at baseline (Table 1).
- Excluding the patients who were dropped out from this study and were progressed in disease, 50 patients and 33 patients were followed-up at 6M and 12M. Over the study, SD, PR, CR were 60%, 34%, and 6% at 6M and 66.7%, 27.2%, and 6.1% at 12M, respectively (Table 1)

Table 1. Patients' characteristics

	Baseline (N=77)	6M (N=50)	12M (N=33)
Sex, Male, n(%)	56(72.7)		
Age (years), mean(SD)	62.29(10.3)		
Disease duration (days), mean(SD)	899.6 (1087.5)		
Tx duration (days), mean(SD)	343.60(526.4)		
Histology, n(%)			
Clear	74(96.1)		
Non-clear	3(3.9)		
Comorbidity, n(%)*	31(40.3)		
Operation, n(%)	31(40.3)		
Radiation therapy, n(%)	6(7.8)		
Immunotherapy, n(%)	2(2.6)		
Other chemotherapy, n(%)	1(1.3)		
Response criteria, n(%)			
Stable Disease	61(82.4)	30(60.0)	22(66.7)
Partial Response	6(8.1)	17(34.0)	9(27.3)
Complete Response	7(9.5)	3(6.0)	2(6.1)
ECOG PS, n(%)			
0	58(75.3)	39(78.0)	26(78.8)
1	19(24.7)	11(22.0)	6(18.2)
2~4	0(0.0)	0(0.0)	1(3.0)
Metastasis site, n(%)			
Lung	50(64.9)	31(62.0)	20(60.6)
Bone	16(20.8)	12(24.0)	7(21.2)
Liver	1(1.3)	1(2.0)	1(3.0)
LN	14(18.2)	9(18.0)	6(18.2)
Soft Tissue	0(0.0)	1(2.0)	0(0.0)
Brain	2(2.6)	1(2.0)	0(0.0)
Spine	2(2.6)	2(4.0)	2(6.1)
Pancreas	4(5.2)	3(6.0)	3(9.1)
Others	9(11.7)	6(12.0)	5(15.2)
Interventional schedule change, n(%)		5(10.0)	6(18.2)

Abbr. M, month; n, number; SD, standard deviation; Tx, treatment; ECOG PS, eastern cooperative oncology group performance status; LN, lymph node. * multiple responses.

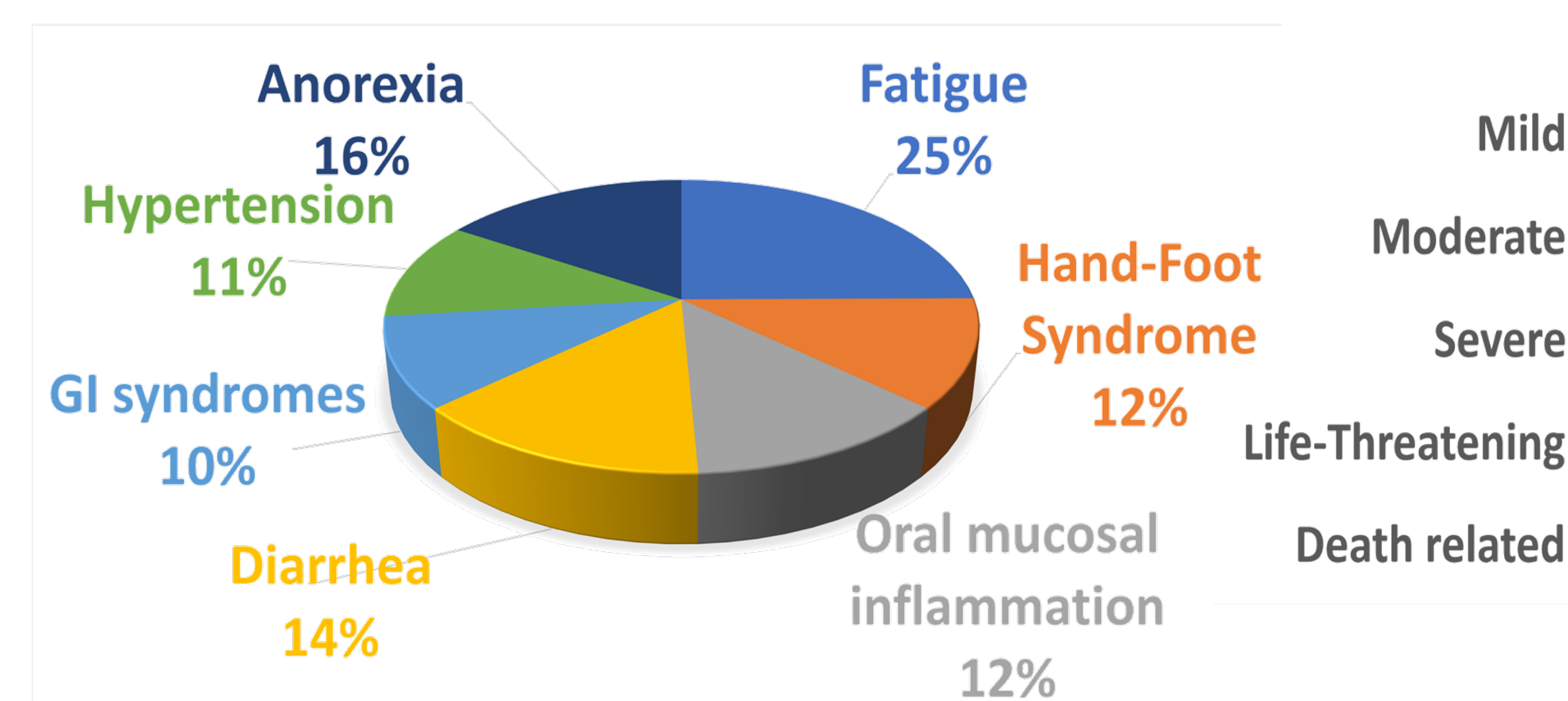


Figure 1. Adverse Events & Grades in total

- Total 210 cases of the 7 AEs in our interest were observed during the study and mean 2.8(standard deviation, SD; ± 1.6) case of AEs were experienced per person. Fatigue (23.8%) was the most frequent AE followed by anorexia (15.7%) and diarrhea (14.3%) (Figure 1).
- Concerning grades, the most AEs (91%) were mild to moderate (Figure 1).
- Other than 7 AEs in our interest, 21 cases of AEs were reported during this study.

Conclusion

- AEs occurring while treating with the targeted therapy in real world practice were observed as manageable in this study. Self-managements of those AEs are required for better health-outcomes.