ARAŞTIRMA MAKALESİ / *RESEARCH ARTICLE*

Survival Comparison and Clinical Characteristics of Sunitinib and Pazopanib in the Treatment of Metastatic Renal Cell Cancer, Single Center Real-Life Data

Metastatik Renal Hücreli Kanser Tedavisinde Sunitinib ve Pazopanibin Sağkalım Karşılaştırılması ve Klinik Özellikleri, Tek Merkez Gerçek Yaşam Verileri

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ABSTRACT

Aim: *Renal cell cancer (RCC) is a tumor with increasing incidence and high morbidity and mortality. Our objective was to compare the progression-free survival (PFS) and overall survival (OS), as well as the clinical and demographic characteristics, of patients diagnosed with metastatic RCC at our center who received treatment with either sunitinib or pazopanib.*

Material and Methods: *The study included 39 patients retrospectively. Clinical and demographic characteristics were extracted from patient records and analyzed using IBM Statistical Package for Social Sciences (SPSS) program version 25. Progression-free survival and OS were analyzed using Kaplan-Meier curves.*

Results: *Among the patients, 30 (76.9%) had clear cell pathology, and 33 (84.6%) had undergone surgery, while 6 (15.4%) were diagnosed through biopsy. First-line treatment with sunitinib was initiated in 28 patients (71.8%), whereas pazopanib was administered to 11 patients (28.2%). The median PFS was 25.8 months, and the median OS was 84.3 months for patients who underwent surgery. In patients diagnosed by biopsy, median PFS was 4.2 months, and median OS was 4.7 months. Progression-free survival (p=0.004) and OS (p<0.001) were longer and statistically significant in operated patients. Patients who received sunitinib as first-line treatment had a median PFS of 25.4 months and a median OS of 50.3 months. In comparison, patients treated with pazopanib in the first-line setting had a median PFS of 24.7 months and a median OS of 56.6 months. There was no statistical difference between sunitinib and pazopanib for both PFS (p=0.767) and OS (p=0.684).*

Conclusion: *PFS and OS were longer in operated RCC patients. There was no difference in PFS and OS between sunitinib and pazopanib in RCC patients first-line treatment.*

Key words: *cancer; operation; overall survival*

ÖZET

Amaç: *Renal hücreli kanser (RHK) insidansı giderek artan, morbidite ve mortalitesi yüksek bir tümördür. Merkezimizde metastatik RHK tanısıyla, sunitinib veya pazopanib tedavisi verilen hastalarımızda progresyonsuz sağkalımı (PFS), genel sağkalımı (OS) ve klinik-demografik özelliklerini araştırmayı amaçladık.*

Materyal ve Metot: *Çalışmaya 39 hasta retrospektif olarak dâhil edildi. Hastaların klinik-demografik özellikleri hasta dosyalarından alındı. IBM Sosyal Bilimlerde İstatistik Paket Programı (SPSS) sürüm 25 kullanılarak analiz edildi. PFS ve OS Kaplan-Meier eğrileri kullanılarak analiz edildi.*

Bulgular: *Clear cell patolojisi olan 30 (%76,9) hastamız vardı. Otuz üç (%84,6) hasta opere olmuştu. Altı (%15,4) hasta biyopsi ile tanı almıştı. Birinci basamak sunitinib tedavisi 28 (%71,8) hastaya, pazopanib tedavisi 11 (%28,2) hastaya başlanmıştı. Cerrahi operasyon geçirenlerde median PFS 25,8 ay, median OS 84,3 ay idi. Biyopsi (bx) ile tanı konulan hastalarda median PFS 4,2 ay, median OS 4,7 ay idi. Opere olan hastalarda PFS (p=0,004) ve OS (p<0,001) daha uzundu ve istatiksel olarak anlamlıydı. Birinci basamakta sunitinib alan hastalarda median PFS 25,4 ay, medyan OS 50,3 aydı. Birinci basamakta pazopanib alan hastalarda median PFS 24,7 ay, medyan OS 56,6 ay idi. Hem PFS (p=0,767) hem OS (p=0,684) için sunitinib ve pazopanib arasında istatiksel fark bulunmadı.*

Sonuç: *Opere olan RHK'lı hastalarda PFS ve OS daha uzundu. Birinci basamakta RHK tedavisinde sunitinib ve pazopanib tercihlerinde PFS ve OS farkı yoktu.*

Anahtar kelimeler: *genel sağkalım; kanser; operasyon*

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Introduction

Renal cell carcinoma (RCC) constitutes approximately 3% of all reported cases of cancer worldwide. It is the eighth most prevalent form of cancer globally, with 30% of patients presenting with metastatic disease at the time of diagnosis[1,2]. The treatment of localized disease is surgical intervention. Approximately 50% of patients demonstrate recurrence within the first five years. The predominant histopathological diagnosis is clear cell, accounting for 80% of cases, followed by papillary, chromophobe, and other rare histopathologies[3,4].

According to Memorial Sloan Kettering Cancer Centre (MSKCC) prognostic factors, RCC is classified into good, intermediate, and poor risk groups. In the good and intermediate risk clear cell RCC (ccRCC) group, sunitinib or pazopanib can be used in first-line treatment[5–7]. Nowadays, according to the International Metastatic RCC Database Consortium (IMDC), combinations with immunotherapy (axitinib plus pembrolizumab, axitinib plus avelumab, lenvatinib plus pembrolizumab, cabozantinib plus nivolumab or ipilimumab plus nivolumab) have gained priority in the patient group with moderate and poor disease[8].

Metastatic RCC demonstrates resistance to cytotoxic therapies. The response to interferon alpha, interleukin 2, and combined cytokine therapies is limited, with numerous side effects observed[9]. The employment of targeted therapies, incorporating VEGF receptor inhibitors such as sunitinib, sorafenib, pazopanib, axitinib, and cabozantinib, has yielded enhanced response rates and augmented survival outcomes[10]. Recent advancements in the field have led to a paradigm shift in treatment approaches, with the integration of immunotherapy and tyrosine kinase inhibitors (TKIs) becoming a prevailing strategy. Sunitinib and pazopanib have analogous mechanisms of action. A comparative analysis of the two drugs reveals that sunitinib primarily causes weakness, fatigue, and hematological problems, while pazopanib is associated with liver toxicity[11,12]. Studies have shown that sunitinib has a better overall survival (OS) contribution, and pazopanib is more selectable in terms of side effects[13].

The objective of this study was to compare the progression-free survival (PFS) and overall survival (OS) data of sunitinib and pazopanib in the initial treatment of patients with metastatic RCC. Additionally, the study sought to investigate the clinical parameters that affect PFS and OS.

Material and Method

The present study retrospectively included 39 patients with metastatic or subsequently metastatic RCC at the time of diagnosis who were admitted to our center between 2010 and 2021. The clinical-demographic characteristics of the patients were obtained from patient files and the hospital information system. Patients with missing data were excluded from the study. The analysis was conducted using IBM Statistical Package for Social Sciences (SPSS) program version 25 software. The primary outcomes of interest were progression-free survival (PFS) and overall survival (OS), which were analyzed using Kaplan-Meier curves. The significance level was set at $p < 0.05$ for all statistical analyses. The study was approved by the clinical research ethics committee (Date: 02/05/2023, Decision No: 2023/299).

Results

Table 1 presents the distribution of patients' clinical findings. As seen in Table 2, the overall median PFS (months) was 25.43 (95% CI: 8.81–42.25). While 2-year PFS was 53.6%, 5-year PFS was 23.5%.

Median PFS times (months) by gender were not statistically significant (p=0.937). While 2-year PFS was 60% in women, 5-year PFS was 21.7%. In men, 2-year PFS was 49.7%, and 5-year PFS was 27.2%.

Median PFS (months) by age groups was not statistically significant (p=0.196). In patients aged ≤65 years, 2-year PFS was 59.8%, and 5-year PFS was 24.6%. In patients aged >65 years, 2-year PFS was 33.3%, and 5-year PFS was 16.7%.

Median PFS times (months) by metastasis site were not statistically significant (p=0.685). The 2-year PFS was 47.4%, and the 5-year PFS was 27.1% in patients with lung metastases. In patients with bone metastases, 2-year PFS was 71.4%, and 5-year PFS was 17.9%. In patients with multiple metastases, 2-year PFS was 45.5%.

Median PFS times (months) by operation groups were statistically significant (p=0.004). The median PFS (months) was 4.26 (95% CI: 2.02–6.50) in the biopsy group and 25.83 (95% CI: 19.50–32.16) in the operated group. The 2-year PFS was 16.7% in the biopsy group. In the operation group, 2-year PFS was 60.3%, and 5-year PFS was 26%.

Median PFS times (months) by stage groups were not statistically significant (p=0.085). In non-metastatic

Table 1. *Distribution of patients' clinical findings (n=39)*

Variables		N	%
Sex	Female	15	38.5
	Male	24	61.5
Age	≤65	30	76.9
	>65	9	23.1
ECOG	0	2	5.1
	1	24	61.5
	2	13	33.3
Smoking	No	24	61.5
	Yes	15	38.5
Comorbidity	No	24	61.5
	HT	8	20.5
	DM	5	12.8
	Other	2	5.1
Operation	Biopsy	6	15.4
	Surgery	33	84.6
Drug	Sunitinib	28	71.8
	Pazopanip	11	28.2
Stage	Not metastatic	9	23.7
	Metastatic	29	76.3
Pathology	Unknown	4	10.3
	Clear	30	76.9
	Chromophobe	2	5.1
	Papillary	3	7.7
LVI	No	14	48.3
	Yes	15	51.7
Grade	I-II	12	40.0
	III-IV	18	60.0
Metastasis area	Lung	19	51.4
	Bone	7	18.9
	Multiple	11	29.7
Progression	No	12	30.8
	Yes	27	69.2
Mortality	Alive	17	43.6
	Ex	22	56.4
		Mean±SD	Median (IQR)
Age		57.54±10.70	55.00 (15.00)
Average follow-up time		44.22±44.08	28.60 (44.07)

Table 2. *PFS comparisons of patients*

PFS (months)	Median (%95 CI)	p
General	25.43 (8.61-42.25)	
Sex		
Female	25.83 (2.25-49.41)	0.937
Male	17.30 (0.00-35.88)	
Age		
≤65	29.30 (20.45-38.14)	0.196
>65	7.40 (0.68-14.12)	
Grade		
I-II	29.30 (0.00-67.74)	0.913
III-IV	25.83 (7.20-44.46)	
LVİ		
No	25.83 (0.00-54.13)	0.914
Yes	24.73 (4.08-45.38)	
Metastasis area		
Lung	11.70 (0.00-32.86)	0.685
Bone	34.46 (2.38-66.54)	
Multiple	17.30 (3.94-30.65)	
Operation		
Biopsy	4.26 (2.02-6.50)	0.004
Surgery	25.83 (19.05-32.16)	
Drug		
Sunitinib	25.43 (0.00-50.98)	0.767
Pazopanib	24.73 (0.38-49.08)	
Stage		
No metastatic	64.43 (-)	0.085
Metastatic	12.00 (0.45-23.54)	

Kaplan Meier curve, Long rank test

patients, 2-year PFS was 77.8%, and 5-year PFS was 77.8%. In metastatic patients, 2-year PFS was 44.8% and 5-year PFS was 17.5%.

As seen in Table 3, the overall median OS (months) was 56.63 (95% CI: 0.00–121.48). 2-year OS was 68.8%, while 5-year OS was 40.7%. Median OS duration (months) by gender was not statistically significant (p=0.864). In women, 2-year OS was 73%, and 5-year OS was 50%. In men, 2-year OS was 65.8%, and 5-year OS was 42.5%.

Median OS durations (months) by age groups were not statistically significant (p=0.281). In patients aged ≤65 years, 2-year OS was 76.1%, while 5-year OS was 43.9%. In those aged >65 years, 2-year OS was 44.4%, while 5-year OS was 29.6%.

Median OS times (months) by metastasis site were not statistically significant (p=0.487). In patients with lung metastases, 2-year OS was 68%, and 5-year OS was 49.5%. In patients with bone metastases, 2-year OS was 71.4%, and 5-year OS was 71.4%. In patients with multiple metastases, 2-year OS was 63.6%, and 5-year OS was 0%.

Table 3. *OS comparisons of patients*

OS (months)	Median (%95 CI)	P
General	56.63 (0.00-121.48)	
Sex		
Female	50.30 (0.00-132.29)	0.864
Male	56.63 (12.37-100.89)	
Age		
≤65	84.36 (1.58-167.17)	0.281
>65	12.56 (0.00-27.95)	
ECOG	84.36(-.-)	0.178
0	56.6(23.54-89.72)	
1	27.1(0.00-54.96)	
2		
Grade		
I-II	56.63 (41.37-71.89)	0.692
III-IV	96.36 (18.48-174.24)	
LVI		
No	96.36 (42.25-150.48)	0.105
Yes	27.10 (0.00-108.73)	
Metastasis area		
Lung	31.03 (0.00-119.19)	0.487
Bone	84.36 (19.83-148.90)	
Multiple	50.30 (12.04-88.55)	
Operation		
Biopsy	4.76 (1.16-8.36)	<0.001
Surgery	84.36 (36.39-132.33)	
Drug		
Sunitinib	50.30 (0.00-125.79)	0.684
Pazopanib	56.63 (0.00-118.64)	
Stage		
No metastatic	- (-)	0.040
Metastatic	30.93 (24.99-36.87)	

Kaplan Meier curve, Long rank test

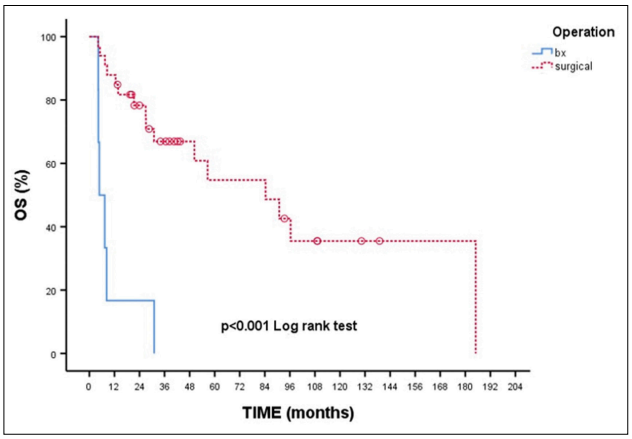

Figure 1. *Overall survival comparison for surgery and biopsy.*

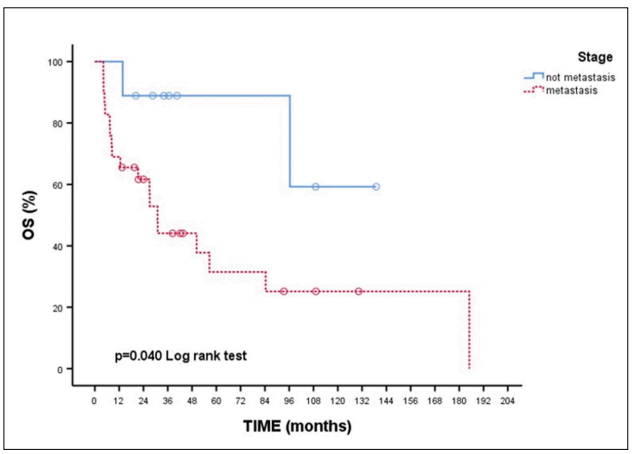

Figure 2. *Comparison of overall survival for patients with initial metastatic disease and those with subsequent metastatic disease.*

Median OS times (months) by operation groups were statistically significant (p<0.001). The median OS (months) was 4.76 (95% CI: 1.16–8.36) in the biopsy group and 84.36 (95% CI: 36.39–132.33) in the surgical group (Fig. 1). The 2-year OS was 16.7% in the biopsy group. In the operation group, 2-year OS was 78.3%, and 5-year OS was 54.7%.

Median OS times (months) by stage groups were statistically significant (p=0.040). Median OS months were not reached in non-metastatic patients (Fig. 2). In metastatic patients, the median OS (months) was 30.93 (95% CI: 24.90–36.87). In non-metastatic patients, 2-year OS was 88.9% and 5-year OS was 88.9%. In metastatic patients, 2-year OS was 61.7%, and 5-year OS was 31.5%.

Univariate analysis showed that operation and stage variables were statistically significant in terms of PFS (p<0.05). These variables, which were found to be significant in univariate analyses, were included in the multivariate Cox regression model, as shown in Table 4. Based on the results of the Multivariate Cox regression model, it was determined that having an operation (OR: 0.30; 95% CI: 0.10–0.87, p=0.026) increased PFS (p=0.009, -2 loglikelihood=142.96).

As a result of univariate analysis, operation and stage variables were found to be statistically significant in terms of mortality risk (p<0.05). As a result of univariate analyses, significant.

These variables were included in the multivariate Cox regression model, as shown in Table 5. The result of the Multivariate Cox regression model showed that

Table 4. *Multivariate Cox regression results for various clinical variables*

PFS	Multivariate	
Variables	HR (95%CI)	p
Operation (Ref:biopsy)	0.30 (0.10-0.87)	0.027
Stage (Ref:No metastatik)	2.33 (0.68-7.98)	0.176

p=0.009, -2 loglikelihood=141.96

Table 5. *Multivariate Cox regression results for various clinical variables*

OS	Multivariate	
Variables	HR (95%CI)	P
Operation (Ref:biopsy)	0.16 (0.05-0.46)	0.001
Stage (Ref:No metastatic)	3.09 (0.68-13.89)	0.141

p<0.001, -2 loglikelihood=108.95

having an operation (OR: 0.16; 95% CI: 0.05–0.46, p=0.001) decreased the risk of death (p<0.001, -2 loglikelihood=108.95).

Discussion

Renal cell cancer is the urinary tract tumor with the highest mortality. There are many different variables affecting prognosis. After interferon therapy, sunitinib and pazopanib, TKI therapies, have contributed to PFS and OS. The treatment of RCC has improved in the last decade with the combination of TKI and immunotherapy[14–17].

In many studies, RCC is seen at a higher rate in males than in females. In the study by Ko et al., the male/female ratio was 2/1[14]. In our study, the male/female ratio was 1.6/1, which was similar to the literature.

In the study by Rini et al., the median age was 60 years; in our study, it was 55 years. The median age in the study by Topal et al. was also 60 years. The younger patient group in our study may be attributable to risk factors such as hypertension[18,19].

The clear cell histopathology rate was 80.5% in the study by Leibovich et al. Similarly, the rate was 87.7% in the study by Patard et al. Likewise, 76.9% of the patients had clear cell histopathology in our study. The preponderance of clear cell histopathology in the extant literature is noteworthy[20,21].

Motzer et al. In the RECORD-1 study, a higher ECOG score was associated with shorter OS. Kim et al. found that a high ECOG score was associated with shorter OS in their study. In our study, no significant relationship was found between ECOG score and OS. This may be due to the small number of patients in our study[22,23].

McKay et al. found that bone and liver metastases were associated with shorter OS. In contrast, the present study found no such association between bone metastasis and OS. While the median OS was found to be numerically higher in patients with bone metastases compared to those with lung and multiple metastases, this difference was not statistically significant[24].

In Wood's study, nephrectomy was associated with prolonged survival. Flanigan et al. and Kassouf et al. recommended nephrectomy for specific metastatic patient groups before systemic immunotherapy and noted that nephrectomy was associated with prolonged survival. In our study, we observed a similar trend, with a longer OS observed in patients who underwent nephrectomy[25–27].

A comparison of sunitinib and pazopanib revealed no significant difference in PFS among patients with metastatic or subsequent metastatic disease. However, OS was found to be superior in patients with subsequent metastatic disease. This observation may be because the disease was not more aggressive in the post-metastatic patient group.

Motzer et al. found no difference in PFS and OS between sunitinib and pazopanib[22]. Consistent with the findings of our study, a lack of statistically significant variance in PFS and OS was observed among patients receiving sunitinib or pazopanib. These findings align with the existing literature on the subject.

The present study has certain limitations. These limitations include the retrospective nature of the study, the limited number of patients, and the absence of prognostic scoring (MSKCC/IMDC).

Conclusion

In the present study, no statistically significant difference in PFS and OS was observed between patients with RCC who received sunitinib as a first-line treatment compared to those who received pazopanib. These findings are consistent with the existing literature on the subject. The present study observed that survival was prolonged in patients who underwent surgery followed by metastasis. The investigation of these data with larger patient groups is expected to contribute to the literature.

Declaration of Interest

The authors declare that they have no conflict of interest.

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