ORIGINAL ARTICLE

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Prosnostic Significance of Prognostic Nutrition Index in Metastatic Renal Cell Carcinoma Patients Treated with Tyrosine Kinase Inhibitors

Tirozin Kinaz İnhibitörleri ile Tedavi Edilen Metastatik Renal Hücreli Karsinom Hastalarında Prognostik Nütrisyonel İndeksin Prognostik Önemi

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ABSTRACT

Aim: The purpose of this study was to investigate the prognostic role of pretreatment Prognostic Nutritional Index (PNI) in metastatic renal cell carcinoma (mRCC) patients given pazopanib or sunitinib as first-line targeted therapy.

Materials and Methods: We retrospectively analyzed the treatment modalities, demographic, clinical, and pathological features of 77 patients with mRCC, and calculated prognostic nutritional index. Based on the median value, patients were grouped as those having low and high PNI values. The Kaplan-Meier method was used for survival analysis, and Cox-regression analysis was used for univariate and multivariate analyses.

Results: The overall median progression-free survival (PFS) and overall survival (OS) time for all patients were 15 months [95% confidence interval (CI): 10.9-19.1 months] and 27 months (95% CI: 15.9-38.1 months), respectively. Patients with low PNI had significantly shorter median PFS (11 vs 20 months, p=0.001) and OS (17 vs 40 months, p=0.001) than those with high PNI. In multivariate analysis, PNI was shown as an independent predictor on both OS and PFS. Moreover, Eastern Cooperative Oncology Group-Performance Status was shown as an independent predictor for OS and International Metastatic Renal-Cell Carcinoma Database Consortium-score for PFS.

Conclusion: Low PNI could be a significant prognostic marker for survival in mRCC patients who have received tyrosine kinase inhibitors as first-line target therapy.

Keywords: Metastatic, renal cell carcinoma, prognosis, PNI

ÖZ

Amaç: Bu çalışmada; birinci basamak hedefli tedavi olarak pazopanib veya sunitinib alan metastatik renal hücreli kanser (mRCC) hastalarında tedavi öncesi Prognostik Nütrisyonel İndeksi'nin (PNİ) prognostik rolünü değerlendirmeyi amaçladık.

Gereç ve Yöntem: mRCC'li 77 hastanın tedavi modaliteleri, demografik, klinik ve patolojik özellikleri geriye dönük olarak incelendi ve PNİ hesaplandı. Ortanca değere göre hastalar düşük ve yüksek prognostik nütrisyonel indeks gruplarına ayrıldılar. Sağkalım analizi için Kaplan-Meier yöntemi, tek değişkenli ve çok değişkenli analiz için Cox-regresyon analizi kullanıldı.

Bulgular: Tüm hastalar için genel medyan progresyonsuz sağkalım (PFS) ve genel sağkalım (OS) süresi sırasıyla 15 ay [%95 güven aralığı (GA): 10,9-19,1 ay] ve 27 ay (%95 GA: 15,9-38,1 ay) olarak saptandı. Düşük PNİ'si olan hastalarda, yüksek PNİ'si olan hastalara göre anlamlı olarak daha kısa medyan PFS (11'e karşı 20 ay, p=0,001) ve OS (17'ye karşı 40 ay, p=0,001) saptandı. Çok değişkenli analizde PNİ, hem OS hem de PFS üzerinde bağımsız bir öngörücü olarak gösterildi, ayrıca Eastern Cooperative Oncology Group-Performance Status OS için bağımsız bir öngörücü iken, International Metastatic RCC Database Consortium skoru ise PFS için bağımsız bir öngörücü belirteç olarak gösterildi.

Sonuç: Düşük PNİ, birinci basamak tedavi olarak tirozin kinaz inhibitörleri alan mRCC hastalarında sağkalım için önemli bir öngörücü belirteç olabilir.

Anahtar Kelimeler: Metastatik, renal hücreli karsinom, prognoz, PNİ

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INTRODUCTION

Renal cell carcinoma (RCC) is the 6th most common cancer in men and the 8th most common cancer in women, accounting for 2% to 3% of all adult cancers[1,2]. Most patients are at the stage of localized disease at the time of diagnosis and are cured with surgery, but approximately 30% of patients present local or distant recurrence after nephrectomy[3].

Despite therapeutic alternatives such as targeted therapies and immunotherapy, overall survival (OS) rates in metastatic RCC patients remain poor[4]. There are a number of prognostic indicators that influence a patient's therapy response and survival. Previous studies have revealed the usefulness of prognostic markers such as pathological stage, tumor grade, tumor subtype, sarcomatoid characteristic, tumor necrosis, and microvascular invasion[5,6].

Onodera et al.[7] designed the Prognostic Nutritional Index (PNI), which is a simple index based on albumin and lymphocyte count. It has been shown that lower PNI values are associated with shorter survival. This relationship between survival and PNI has also been investigated in cancers such as breast, colorectal and lung cancers[8-10].

There are limited number of studies evaluating the relationship between PNI and survival in RCC patients[11-14]. In our study, we evaluated the prognostic effect of pre-treatment PNI value on survival in metastatic renal cell carcinoma (mRCC) patients receiving tyrosine kinase inhibitor (TKI).

MATERIALS AND METHODS

Patients

We examined patients diagnosed with mRCC, who were treated with targeted treatment (pazopanib or sunitinib) between August 2013 and September 2021. A total of 90 individuals with mRCC were retrospectively studied, including 74 patients having sufficient data.

This study involved mRCC patients receiving pazopanib or sunitinib as first-line therapy with Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0.1 and 2. serum albumin levels and lymphocyte counts were recorded within one week before the treatment. Patients who did not comply with the above criteria or who had unstable or severe cardiac disease, uncontrolled brain metastases, concurrent malignancies and incomplete data files were excluded from the study.

Data Collection

The treatment methods, epidemiological, pathological, and clinical aspects of patients, and laboratory data of these patients were all searched retrospectively from the hospital database. The variables that were recorded were baseline hemoglobin, neutrophil, platelet (PLT) counts, calcium, albumin, ECOG PS, time to systemic treatment, and date of death or last follow-up. PNI was calculated using the albumin value and total lymphocyte count [The formula of PNI: 0.005X total lymphocyte count (mm^3)+10X serum albumin value (g/dL)]. Different cut-off values for PNI were employed in the study examining the prognostic efficacy of PNI in mRCC, while median values were used in certain studies. It fluctuates from 41 and 51[10,13,14]. We also used median values in our study. The patients were grouped according to the median value, as low PNI (PNI <48.25) and high PNI (PNI ≥48.25).

Statistical Analysis

Percentages were used to represent categorical variables. The mean and standard deviation of continuous variables were calculated (median and range). The chi-square test or Fisher's exact test were used to assess categorical variables.

OS and progression-free survival (PFS) were estimated using the Kaplan-Meier method and difference in survival was calculated using the log-rank test. The prognostic significance of clinical characteristics such as age, gender, history of cytokine and surgical treatment, pathology, number of metastatic locations, PFS, and OS was estimated using the Cox's proportional hazard model with a two-sided 95 percent confidence interval (CI). A p-value of 0.05 was considered as statistically significant. IBM Statistical Package for the Social Sciences Statistics version 23.0 was used to evaluate the clinical data.

RESULTS

Clinicopathological characteristics of patients are shown in Table 1. The median patient age was 64 (minimum: 37-maximum: 91) years. Of the 77 patients, 57 (76%) were male and 20 (23%) were female. The median PNI value was 48.25 (18-52). In the high PNI group, the rate of patients with a favorable International Metastatic RCC Database Consortium (IMDC) score (30.8%) was higher, while in the low PNI group, the rate of patients with a poor IMDC score (39.5%) was significantly higher (p=0.019). In the low PNI group, the central nervous system metastasis was seen at the rate of 17.6% while it was found to be 2.6% in the high PNI group. This difference was found to be statistically significant (p=0.028).

Survival Analysis

The median of OS and PFS for all patients was 27 months (95% CI 15.9-38.1 months) and 15 months (95% CI 10.9-19.1 months), respectively (Figure 1). The median OS was 17 months (95% CI, 7.8-20.2 months) in the low PNI group, and the median OS was 40 months (95% CI, 25.9-54.1 months) in the high PNI group (log-rank p=0.001) (Figure 2).

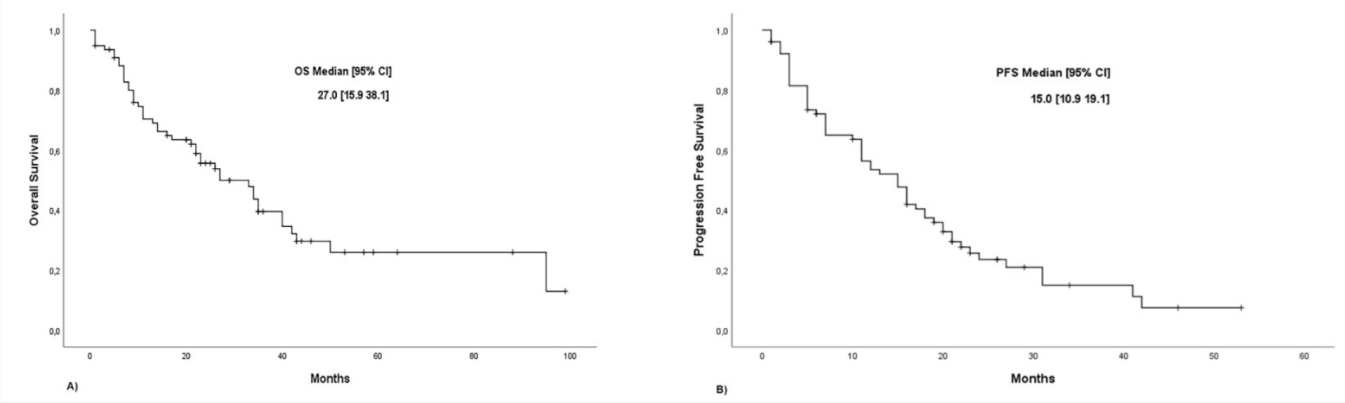

Figure 1. Kaplan-Meier curves showing (A) overall survival and (B) progression-free survival in all the patients

While the median PFS was 11 months (95% CI, 7.7-14.3 months) in those with low PNI, the median PFS was 20 months (95% CI, 16.6-23.4 months) in those with high PNI (log-rank p=0.001). Those with low PNI had significantly shorter OS and PFS compared to the high PNI group (Figure 2).

The median OS was 95 months (95% CI, 7.1-182.9 months), 33 months (95% CI, 21.2-44.8 months), and 14 months (95% CI, 21.2-44.8 months) in those with favorable, intermediate, and poor IMDC scores, respectively (log-rank, p=0.104). Similar results were observed in PFS. Although there was a numerical difference between the groups, the difference was not significant due to the small number of patients (Figure 3).

Table 2 shows a Cox regression analysis of factors that may be predictive for PFS. PNI and IMDC risk status had a significant effect on PFS in univariate Cox regression analysis. In a multivariate Stepwise Cox regression analysis, those with poor PNI had statistically significantly shorter PFS [hazard raito (HR): 2.12, 95% CI 1.17-3.83, p=0.013]. Patients with IMDC poor-risk had a significantly shorter PFS than patients with favorable risk (HR: 2.12 95% CI: 1.17-3.83, p=0.013).

Table 3 shows a Cox regression analysis of factors that may be predictive for OS. In univariate Cox regression analysis, a significant effect of ECOG, PNI, and IMDC status on OS was observed. In multivariate Stepwise Cox regression analysis, shorter OS was observed in those with low PNI (HR: 2.68, 95% CI: 1.45-4.9, p=0.002), and longer OS was observed in those with ECOG-PS 0 and 1 compared to those with ECOG-PS 2 (HR: 0.22 95% CI: 0.08-0.6, p=0.002).

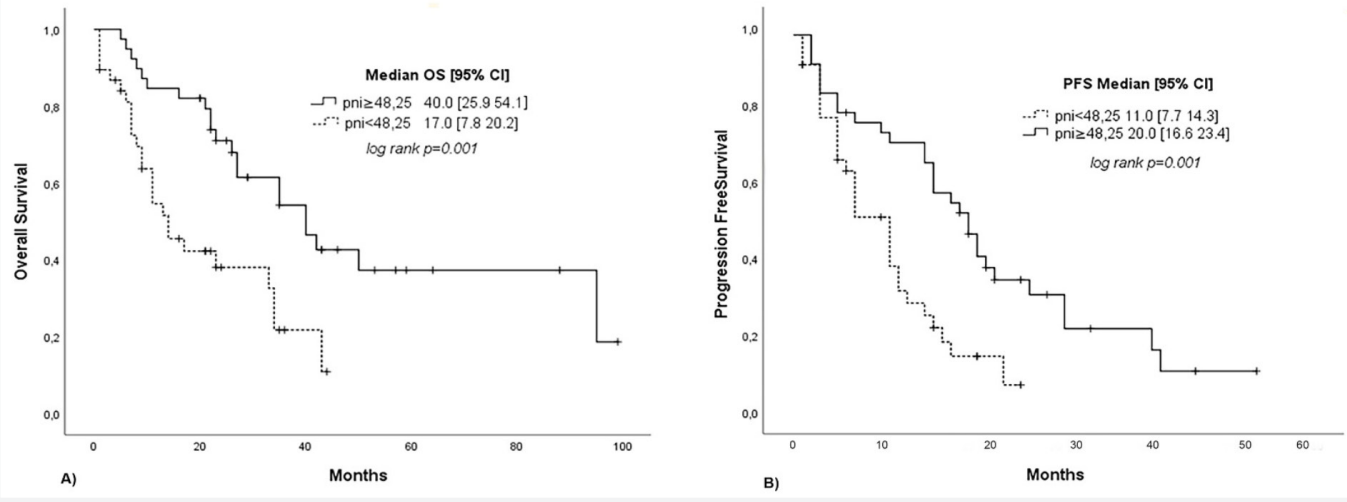

Figure 2. Kaplan-Meier curves showing (A) overall survival and (B) progression-free survival rate stratified by PNI status

PNI: Prognostic Nutritional Index

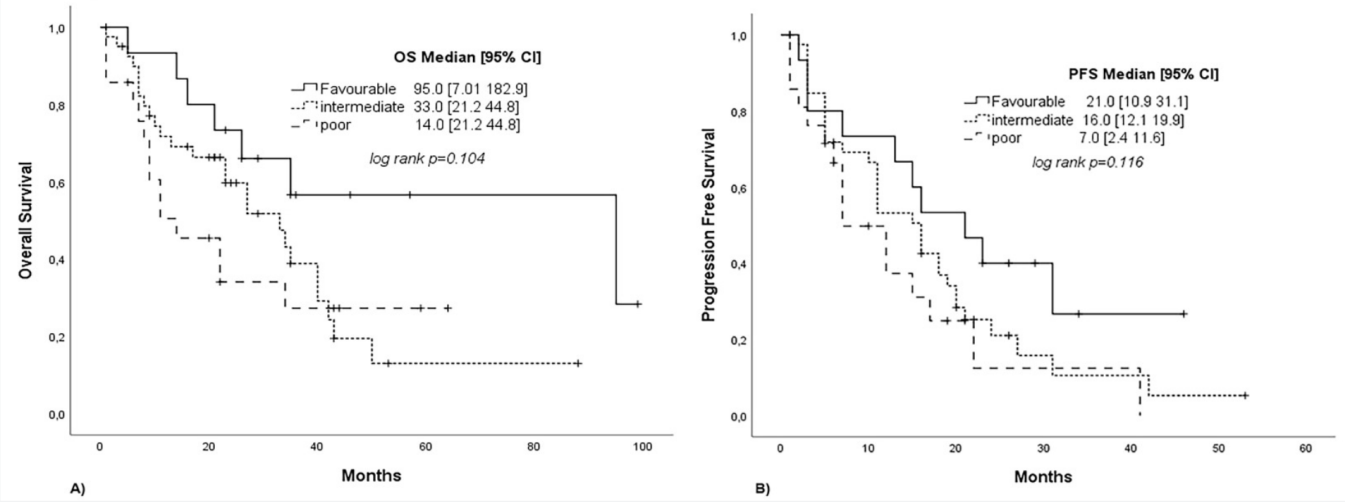

Figure 3. Kaplan-Meier curves showing (A) overall survival and (B) progression-free survival rate stratified by IMDC score

IMDC: International Metastatic RCC Database Consortium

DISCUSSION

In our study, in mRCC patients given sunitinib or pazopanib treatment, significantly shorter OS and PFS were observed in patients with low pretreatment PNI. In addition, while low PNI was a marker for both OS and PFS in multivariate analyses, ECOG-PS was also a marker for OS and IMDC score for PFS.

The nutritional status and immune system are affected by the development and progression of the tumor[15,16]. When tumor progression occurs, a systemic inflammation develops and the nutritional status worsens[17]. Lymphocytes have an important role in cell-mediated immunity, which is one of the important defense mechanisms against cancer in the body[17]. Low lymphocyte count is a parameter that indicates suppression of the immune system, and also creates a favorable microenvironment for tumor development and progression[18]. PNI is considered as a marker reflecting inflammatory and nutritional status since it is a parameter calculated by lymphocyte count and albumin levels[17].

PNI was initially used as a marker to predict postoperative complications in patients undergoing gastrointestinal system surgery[7]. In a study involving operated gastric cancer patients, significantly longer OS and disease-free survival durations were observed in those with high PNI[19]. In a study on colon cancers, it was seen that patients with high PNI had fewer postoperative complications and longer survival[8].

The prognostic effect of PNI in other cancer types has also been evaluated. In the study involving operated lung cancers, patients with low PNI had more postoperative complications and the survival time was found to be significantly shorter in these patients[10]. In patients with castration-resistant prostate cancer, who received abiraterone acetate, the pre-treatment PNI was low, which is seen as a negative prognostic factor for overal survival[20].

Studies evaluating the prognostic effect of PNI in RCC are limited. In the study by Jeon et al.[11], PNI was found to be an independent predictive factor for OS in RCC patients who underwent nephrectomy. In the study of Kang et al.[12], in RCC patients who underwent nephrectomy, dynamic changes in preoperative and postoperative PNI were found to be an independent predictive factor for OS. Kim et al.[21] showed PNI as an independent risk factor for recurrence-free survival and cancer-specific survival in nonmetastatic RCC patients who underwent nephrectomy. In another study, PNI in RCC patients who underwent nephrectomy is a better predictive factor for survival compared to inflammatory indices such as Neutrophil to lymphocyte rati and platelet to lymphocyte ratio[22].

TKI is an important treatment option currently used for mRCC. There are limited studies evaluating the effect of PNI on survival in mRCC patients receiving TKI. In a multicenter retrospective study conducted by Yasar et al.[23], the relationship between the survival and median PNI was evaluated in mRCC patients receiving targeted therapy, and a shorter survival time was observed with low PNI. Similarly, in the study of Kwon et al.[13], mRCC patients who received targeted therapy showed a shorter survival time than those with low PNI. In another single-center retrospective study, shorter OS and PFS were observed in those with low PNI in mRCC who received first-line TKI[14]. In our study, similar to these studies, significantly shorter OS and PFS were observed in those with low PNI.

Table 1. Patient characteristics stratified by the presence of low PNI (<48.25)				
	PNI <48.25 (n=38)	PNI ≥48.25 (n=39)	Total n (%)	p
Sex				
Female	9 (23.7)	11 (28.2)	20 (26)	0.651
Male	29 (76.3)	28 (71.8)	57 (74)	
Histology				
Non-clear cell	8 (21.1)	8 (20.5)	16 (20.8)	0.953
Clear cell	30 (78.9)	31 (79.5)	61 (79.2)	
Age (years)				
<65	19 (50)	26 (66.7)	45 (58.4)	0.138
≥65	19 (50)	13 (33.3)	32 (41.6)	
ECOG-PS				
0-1	34 (89.5)	37 (94.9)	71 (92.2)	0.377
≥2	4 (10.5)	2 (5.1)	6 (7.8)	
IMDC				
Poor	15 (39.5)	6 (15.4)	21 (27.3)	**0.019**
Intermediate	19 (50)	21 (53.8)	40 (51.9)	
Favourable	4 (10.5)	12 (30.8)	16 (20.8)	
CNS metastasis				
Yes	1 (2.6)	7 (17.9)	8 (10.4)	**0.028**
No	37 (97.4)	32 (82.1)	69 (89.6)	
Lung metastasis				
Yes	29 (76.3)	29 (74.4)	58 (75.3)	0.842
No	9 (23.7)	10 (25.6)	19 (24.7)	
Liver metastasis				
Yes	13 (34.2)	7 (17.9)	20 (26)	0.104
No	25 (65.8)	32 (82.1)	57 (74)	
Treatment type		0 (0)	0 (0)	
Pazopanib	15 (39.4)	15 (38.5)	30 (39)	0.827
Sunitinib	23 (60.5)	24 (61.5)	47 (61)	
RECIST				
CR	1 (2.6)	0 (0)	1 (1.3)	0.153
PR	16 (42.1)	26 (66.7)	42 (54.5)	
SD	7 (18.4)	4 (10.3)	11 (14.3)	
PD	14 (36.8)	9 (23.1)	23 (29.9)	
Survival				
Ex	25 (65.8)	21 (53.8)	46 (59.7)	0.285
Alive	13 (34.2)	18 (46.2)	31 (40.3)	

PNI: Prognostic Nutritional Index, ECOG-PS: Eastern Cooperative Oncology Group-Performance score, IMDC: International metastatic RCC data base consortium, CR: Complete response, PR: Parcial pesponse, SD: Stabil disease, PD: Progressive disease, CNS: Central nervous system

The IMDC risk score has an important prognostic feature for survival in mRCC. In our study, there was a numerical difference among IMDC favorable, intermediate, and poor risk groups in both OS and PFS, but due to the small number of our patients, no significant differences were detected in the Kaplan-Mayer graphic (Figure 3). However, in the multivariate analysis, we showed the IMDC risk score as a marker for PFS (Table 3).

Study Limitations

There are some limitations of our study. First of all, it is a single-center retrospective study and secondly, the number of patients is small.

CONCLUSION

In patients with mRCC treated with sunitinib or pazopanib as first-line targeted therapy, we have shown that low pretreatment PNI is related to poor PFS and OS and it improves the accuracy of a known prognostic model. Future prospective trials should try to validate the comprehensive nutritional-immune components that are now being added to the newly developed predictive model for mRCC patients.

Ethics

Ethics Committee Approval: Approval was obtained from the Bakırköy Dr. Sadi Konuk Training and Research Hospital Clinical

Table 2. Univariate and multivariate analyses for prognostic factors on progression-free survival

	Univariable		Multivariable	
Variable	**Hazard ratio (95% CI)**	**p**	**Hazard ratio (95% CI)**	**p**
Age (≥65 years)	1.14 (0.68 1.93)	0.616		
Man vs women	1.18 (0.63 1.99)	0.707		
Histology (non-clear vs. clear)	0.77 (0.39 1.54)	0.461		
ECOG (0-1 vs. 2)	0.50 (0.20 1.25)	0.138		
PNI (<48.25 vs. ≥48.25)	2.37 (1.35 4.16)	**0.003**	2.12 (1.17 3.83)	**0.013**
IMDC		**0.041**		**0.050**
Favourable	1		1	
Intermediate	1.65 (0.81 3.38)	0.171	1.32 (0.71 3.88)	0.244
Poor	2.25 (1.01 5.04)	**0.048**	2.12 (1.17 3.83)	**0.013**
Treatment type		0.117		
Pazopanib	1			
Sunitinib	1.67 (0.84 2.98)	0.080		
CNS metastasis	0.47 (0.18 1.21)	0.115		
Lung metastasis	1.57 (0.84 2.93)	0.155		
Liver metastasis	1.52 (0.85 2.73)	0.160		

PNI: Prognostic Nutritional Index, ECOG: Eastern Cooperative Oncology Group, IMDC: International metastatic RCC data base consortium, CNS: Central nervous system, CI: Confidence interval

Table 3. Univariate and multivariate analyses for prognostic factors on overall survival

	Univariable		Multivariable	
Variable	**Hazard ratio (95% CI)**	**p**	**Hazard ratio (95% CI)**	**p**
Age (≥65 years)	1.18 (0.66 2.12)	0.574		
Man vs women	1.02 (0.53 1.94)	0.956		
Histology (non-clear vs. clear)	1.38 (0.70 2.74)	0.349		
ECOG (0-1 vs. 2)	0.18 (0.07 0.45)	**0.001**	0.22 (0.08 0.60)	**0.002**
PNI (<48.25 vs. ≥48.25)	2.68 (1.45 4.97)	**0.002**	2.42 (1.27 4.58)	**0.007**
IMDC		0.041		0.488
Favourable	1		1	
Intermediate	2.12 (0.87 5.18)	0.099	1.70 (0.68 4.23)	0.257
Poor	2.71 (1.04 7.07)	**0.042**	1.34 (0.45 3.94)	0.600
Treatment type		0.117		
Pazopanib	1			
Sunitinib	1.68 (0.94 2.98)	0.080		
CNS metastasis	0.47 (0.18 1.21)	0.115		
Lung metastasis	1.57 (0.84 2.93)	0.155		
Liver metastasis	1.52 (0.85 2.73)	0.160		

PNI: Prognostic Nutritional Index, ECOG: Eastern Cooperative Oncology Group, IMDC: International metastatic RCC data base consortium, CNS: Central nervous system, CI: Confidence interval

Research Ethics Committee (decision number: 2021-17-03, date: 06.09.2021).

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: S.Y.T, Concept: S.Y.T., M.Y., Design: S.Y.T, M.Y., D.T., Data Collection or Processing: S.Y.T, Analysis or Interpretation: S.Y.T, M.Y., D.T., Literature Search: S.Y.T, İ.G., Writing: S.Y.T, M.Y.

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