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Research Article



Pazopanib Treatment in Soft Tissue Sarcoma (Single Center Experience)

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Abstract

Objectives: Soft tissue sarcomas are a heterogeneous group of tumors accounting for less than 1% of adult malignancies. In this study, we examined patients who received pazopanib for soft tissue sarcoma.

Factors affecting mortality and overall survival in soft tissue sarcoma patients using pazopanib were investigated.

Methods: This study is a retrospective single-center study.

Results: Fifty-three patients (median age: 42 years) were included. The median duration of follow-up in our cohort was 34 months. Before pazopanib, 37 patients (69.8%) received first-line, 12 patients (22.6%) received second-line and 4 patients (7.5%) received third-line chemotherapy. The median duration of pazopanib therapy was 7 months (range, 1–82). Median progression-free survival (PFS) and median overall survival was 7 months (range, 1–83) and 12 months (range, 1–83), respectively. Patients who received radiotherapy for curative or palliative purposes had significantly longer PFS (p=0.040). Eight patients required dose reduction due to adverse effects. Grade 4 adverse effects occurred in only 2 patients. After pazopanib, 36 patients (67.9%) did not receive any treatment.

On Cox regression analysis, not receiving any treatment after pazopanib was associated with 3.052-fold higher mortality. A 1-unit increase in PFS was associated with 1.15-fold lower risk of mortality.

Conclusion: In this study, pazopanib was found to be an effective and safe drug for advanced soft tissue sarcoma. Patients who received palliative radiotherapy for curative or palliative purposes had significantly longer PFS. Receiving treatment after pazopanib and longer PFS was associated with reduced mortality.

Keywords: Soft tissue sarcomas, pazopanib, targeted therapy, oncology

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Soft tissue sarcomas are a heterogeneous group of diseases that account for less than 1% of all malignancies in adults,^[1] but with more than 100 subtypes.^[2] In 50%–60% of cases, the disease involves the extremities.^[3] The incidence of soft tissue sarcoma is approximately 3 in 100000. ^[4] Approximately half of the patients are over the age of 65 years.^[5] While the basic treatment of the disease is surgery, pre-operative and post-operative radiotherapy and che-

motherapy are frequently used treatment options. In advanced stages of the disease, multikinase inhibitors, such as pazopanib, have also been introduced into routine practice. The reported mean survival of patients with metastatic disease is approximately 12–18 months. [6] In this study, we evaluated patients who received pazopanib therapy for soft tissue sarcoma at the Istanbul University Oncology Institute between January 2010 and August 2021.

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Methods

Study Design and Patient Characteristics

This was a retrospective study of patients with soft tissue sarcoma who received pazopanib therapy at the Istanbul University Oncology Institute Medical Oncology Outpatients Unit. Metastatic soft tissue sarcoma patients older than 18 years of age who used pazopanib for at least 1 day were included in the study. Patients younger than 18 years of age were not included in the study. Medical charts of patients who were treated between January 2010 and August 2021 were reviewed and the patients who were eligible for the study were included.

Assessment of Clinical Parameters

The following variables were assessed: age at the time of diagnosis, sex, histological subtype, tumor site, whether operated, whether radiotherapy was performed, time elapsed from diagnosis to initiation of pazopanib treatment, number of treatment lines before pazopanib, whether there were adverse effects necessitating pazopanib dose reduction, final status of patients, factors affecting overall survival and mortality. Clinical condition of the patients was evaluated according to the Eastern Cooperative Oncology Group (ECOG) classification. Adverse effects were evaluated according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.

Statistical Analysis

R-Studio 1.4.1103 software was used for statistical analysis. Categorical variables are expressed as frequency (percentage), while continuous variables are expressed as median (range). Median survival and follow-up times were calculated by Kaplan-Meier method. Differences in median survival between different subgroups were assessed using log rank test. Factors affecting mortality were evaluated by Cox regression analysis and the results reported as odds ratios. P values < 0.05 were considered indicative of statistical significance for all statistical analyses.

Follow-up period was calculated from the date of admission to our hospital until the last visit to our hospital. Time to pazopanib treatment was calculated as the period from the date of the first diagnosis of the disease until the date of initiation of pazopanib treatment. Duration of pazopanib treatment was calculated from the date of initiation of pazopanib treatment until the withdrawal of pazopanib treatment for any reason. Progression-free survival was calculated from the date of initiation of pazopanib treatment until withdrawal of pazopanib treatment due to disease progression or death. Overall survival was calculated from the date of initiation of pazopanib treatment until death.

Ethics Approval

The study has been approved by the Istanbul University Oncology Institute Academic Board. Ethical approval was provided by the Istanbul Medical Faculty Ethics Committee. Researchers have read the latest version of the World Medical Association Declaration of Helsinki and the newly published Good Clinical Practices Guide/Good Laboratory Practices Guide of the Turkish Ministry of Health, and have conducted the study accordingly.

Results

Fifty-three patients (28 female and 25 male; median age: 42 years [range 18-71]) were included in the study. The median duration of follow-up was 34 months. Performance score was ECOG (Eastern Cooperative Oncology Group) 0 in 12 patients (22.6%), ECOG 1 in 21 patients (39.6%), ECOG 2 in 13 patients (24.5%), and ECOG 3 in 7 patients (15.1%). The demographic, clinicopathological characteristics and treatment details are summarized in Table 1. The most common sites of soft tissue sarcoma in our cohort were: lower extremity, 21 patients (39.6%); intra-abdominal, 12 patients (22.6%); upper extremity, 8 patients (13.2%), and head and neck, 7 patients (13.2%). The most common histologic subtypes were: fusiform cell sarcoma (subtype not identified), 23 patients (43.3%); leiomyosarcoma, 7 patients (13.2%); synovial sarcoma, 6 patients (11.3%), and liposarcoma, 4 patients (7.5%). 44 patients (87%) were operated for curative or palliative purposes, while 9 patients (13%) were not operated. Radiotherapy was applied to 38 patients (71.6%) for curative or palliative purposes. Before pazopanib, 37 patients (69.8%) received first-line of chemotherapy, 12 patients (22.6%) received second-line, and 4 patients (7.5%) received third-line chemotherapy. Median time elapsed between diagnosis of soft tissue sarcoma and initiation of pazopanib treatment was 19 months (range, 4-130). Median duration of pazopanib therapy was 7 months (range, 1-82). All patients were started on 800 mg pazopanib daily. In 8 patients, the dose was reduced to 400 mg due to adverse effects that required dose reduction. The mean daily dose of pazopanib was 739.6 mg while the median daily dose was 800 mg (range, 400–800 mg). In 45 patients, there was no adverse effect requiring dose reduction. Dose reduction was required due to mucositis in 2 patients (grade 3), hand-foot syndrome in 1 patient (grade 3), toxic hepatitis in 1 patient (grade 4), fatigue in 2 patients (grade 3), neutropenia in 1 patient (grade 4), and cough in 1 patient (grade 3). After pazopanib, 36 patients (67.9%) did not receive any other treatment, while 15 patients (28.3%) received first-line chemotherapy and 2 patients (3.7%) received second-line chemotherapy (Table 1).

Table 1. Table showing patient subgroups	
Number of patients	53
Median age	42 (18-71)
Sex	
Female	28 (52.8%)
Male	25 (47.2%)
ECOG Performance Score	
ECOG 0	12 (22.6%)
ECOG 1	21 (39.6%)
ECOG 2	13 (24.5%)
ECOG 3	7 (13.2%)
Location	
Lower extremity	21 (39.6%)
Intraabdominal	12 (22.6%)
Upper extremity	8 (15.1%)
Head and Neck	7 (13.2%)
Back	2 (3.2%)
Vertebra	1 (1.8%)
Thoracal wall	1 (1.8%)
Intracranial	1 (1.8%)
Histological subtypes	
Fusiform Cell Sarcoma (No subtyping)	23 (43.3%)
Leiyomyosarcoma	7 (13.2%)
Synovial Sarcoma	6 (11.3%)
Liposarcoma	4 (7.5%)
Angiyosarcoma	3 (5.6%)
Malignant Peripheral Nerve Sheath Tumor	3 (5.6%)
Epitheloid Sarcoma	2 (3.7%)
Alveolar Soft Part Sarcoma	2 (3.7%)
Pleomorphic Rhabdomyosarcoma	1 (1.8%)
Sarcoma with Hemangiopericytamatous Differentiation	1 (1.8%)
Clear cell sarcoma	1 (1.8%)
History of Surgery	
Operated	44 (87)
Non-Operated	9 (13%)
History of Radiotherapy	
Radiotherapy	38 (71.6%)
No radiotherapy	15 (28.4%)
Treatments Prior to Pazopanib	
1 line	37 (69.8%)
2 line	12 (22.6%)
3 line	4 (7.5%)
Adverse Effects Requiring Dose Reduction	
Patients with adverse effects not requiring dose reduction	45 (84.9%)
Patients whose drug dose was reduced due to grade 3 side effects	6 (11.3%)
Patients whose drug dose was reduced due to grade 4 side effects	2 (3.7%)
Treatment after Pazopanib	
Patients without any treatment	36 (67.9%)
First line treatment	15 (28.3%)
Second lines treatment	2 (3.7%)

The median PFS (Progression Free Survival) in our cohort was 7 months (range, 1-83), while the median OS(Overall Survival) was 12 months (range, 1–83) (Fig. 1). The median PFS was comparable in female and male patients (7 months [range, 1–83] and 7.5 months [2–55], respectively; p=0.775). The median OS was also comparable in female and male patients (12 months [range, 1-83] and 12 months [range, 3-55], respectively; p=0.542). There was no significant difference in the median PFS according to the location of soft tissue sarcoma (lower extremities: 9 months; intra-abdominal: 12 months; sarcoma originating from other parts of the body: 9 months [p=0.661]) (Fig. 2). Similarly, there was no significant difference in median OS according to the tumor location (lower extremities: 10 months; upper extremity, 13 months; intra-abdominal location, 12 months; and sarcoma originating from other parts of the body, 12 months [p=0.803]). The median PFS of operated patients was (10 months) was longer than that of non-operated patients (7 months); however, the difference was not statistically significant (p=0.961). The median OS of operated patients and non-operated patients was 12 months and 10 months, respectively (p=0.886). The median PFS of patients who did not receive palliative radiotherapy (12 months) was signifi-

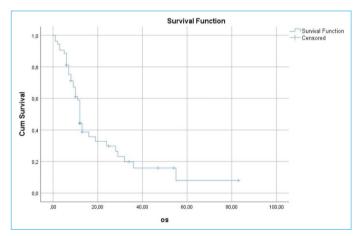


Figure 1. Kaplan-Meier graphic showing Overall Survival of all patients.

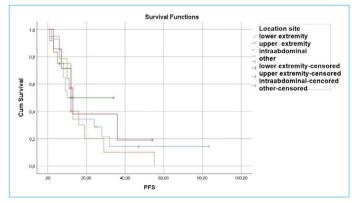


Figure 2. Kaplan-Meier graphic showing PFS by location site.

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cantly longer than that of patients who received palliative radiotherapy (7 months; p=0.040) (Fig. 3). The median OS of patients who did not receive palliative radiotherapy (12 months) was also longer than that of patients who received palliative radiotherapy (9 months); however, the difference was not statistically significant (p=0.218) (Fig. 4). The median PFS was not significantly different between patients who received first-line chemotherapy before pazopanib (10 months) and those who received second- or third-line chemotherapy before pazopanib (9 months; p=0.423) (Fig. 5). Similarly, the median OS was 12 months each in patients who received first-line chemotherapy before pazopanib and those who received second- or third-line chemotherapy before pazopanib (p=0.423). The median PFS of patients who required pazopanib dose reduction due to adverse effects (10 months) was shorter than that of patients who did not require pazopanib dose reduction (12 months); however, the difference was not statistically significant (p=0.178). Similarly, the median OS was comparable in patients who required pazopanib dose reduction due to adverse effects

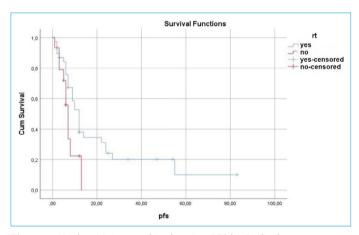


Figure 3. Kaplan-Meier graphic showing PFS by Radiotherapy status.

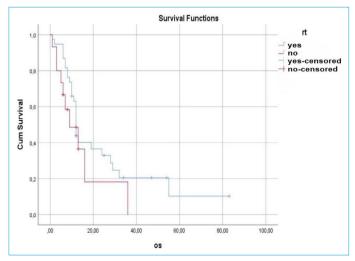


Figure 4. Kaplan-Meier graphic showing OS by radiotherapy status.

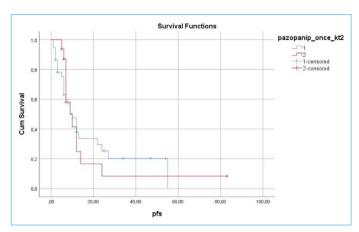


Figure 5. Kaplan-Meier graphic showing PFS by treatment before Pazopanib.

and those who did not require pazopanib dose reduction (11 months and 12 months, respectively; p=0.681). The median PFS and median OS of patients who received post-pazopanib treatment was longer than that of patients who did not receive post-pazopanib treatment, but the difference was not statistically significant (median PFS: 16 months and 12 months, respectively [p=0.480]; median OS: 16 months and 12 months, respectively [p=0.756]). As of most recent follow-up, 38 patients (71.6%) had died and 15 patients (28.4%) were still alive. The 1-year survival rate was 30.7%, 2-year survival rate was 19.2%, 3-year survival rate was 7.7%, and 5-year survival rate was 1.9% (Tables 2, 3). Sex, operation status, post-pazopanib treatment, and PFS were considered as variables that potentially affected mortality. On Cox regression analysis, post-pazopanib treatment status and PFS were found to significantly affect mortality (p=0.010 and <0.001, respectively). Not receiving post-pazopanib treatment was associated with 3.052-fold higher risk of mortality. Moreover, a 1-unit increase in PFS was found to reduce the risk of mortality (1/0.872 = 1.15) by 1.15 times. Other variables (sex, being operated) showed no significant effect on mortality (p=0.404 and 0.401, respectively) (Table 4).

Discussion

In this study, patients with soft tissue sarcoma who received radiotherapy for curative or palliative reasons had significantly higher PFS than patients who did not receive radiotherapy (p=0.040). The covariates affecting mortality were examined and it was found that receiving post-pazopanib treatment and longer PFS decreased mortality.

Pazopanib is a multikinase inhibitor that primarily inhibits vascular endothelial growth factor (VEGF)-1, VEGF-2, VEGF-3, platelet-derived growth factor receptor A (PDGFR- α), and C-KIT tyrosine kinases. The US FDA approved the pazopanib for treatment of soft tissue sarcomas in 2009. [7]

Table 2. Table showing progression-free survival by patient subgroups.

	Median OS (months)	%95 CI Lower	%95 CI Upper	р
All patients	7 (1-83)			
Median progression-free survival by location site				
Lower Extremity	9	3.079	2.965	
Upper Extremitty	9	1.309	6.434	
Intraabdominal	12	4.277	3.617	
Other	9	2.880	3.354	0.661
Median progression free survival by operation status				
Operated	10	7.515	12.485	
Non-operated	7	5.539	8.461	0.961
Median progression free survival by radiotherapy status				
Radiotherapy	12	9.637	14.363	
No radiotherapy	7	5.709	8.291	0.040
Median progression-free survival by treatments prior to pazopanib				
Fisrt line chemotherapy before pazopanib	10	6.412	13.588	
Second-third line chemotherapy before pazopanib	9	4.165	13.835	0.423
Median progression-free survival by presence of adverse effects requiring	dose reduction			

Table 3. Table showing overall survival by patient subgroups

	Median OS (months)	%95 CI Lower	%95 CI Upper	р
All patients	12 (1-83)			
Median survival by location site				
Lower Extremity	10	5.619	14.383	
Upper Extremitty	13	10.949	15.051	
Intraabdominal	12	10.341	13.659	
Other	12	11.058	12.942	0.803
Median survival by operation status				
Operated	12	10.461	13.359	
Non-operated	10	7.078	12.922	0.886
Median survival by radiotherapy status				
Radiotherapy	12	11.168	12.832	
No radiotherapy	9	1.402	16.598	0.218
Median survival by treatments prior to pazopanib				

Soft tissue sarcomas most frequently occur in the agegroup of 40–50 years. The median age of patients in our cohort was 42 years. [8] Soft tissue sarcomas are slightly more common in males than females. [9] The percentage of female patients in our study was slightly higher than that of male patients.

Approximately 50%–60% of soft tissue sarcomas occur in the extremities. In our cohort, 54.7% of patients had extremity sarcomas. The most commonly reported histological subtypes of soft tissue sarcomas are malignant fibrous histiocytoma, liposarcoma, leiomyosarcoma, and fibrosarcoma. However, in our cohort, the most common histo-

logical subtypes were fusiform cell sarcoma (subtype not identified), leiomyosarcoma, synovial sarcoma, and liposarcoma. The demographic characteristics of patients in our cohort and the distribution of the location of tumors were consistent with published literature, but histological subtypes were different from those reported in literature.

Surgery is the main treatment method for local or locally advanced stage of the disease.^[10] Studies have shown that metastasectomy^[11] and radiotherapy in the metastatic stage are associated with a good prognosis.^[12] In our study, previous surgery showed no significant effect on PFS, but radiotherapy significantly improved the PFS.

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Table 4. Table showing the factors affecting mortality

							%95 CI for Exp(B)
	В	SE	Wald	df	Sig	Exp(B)	Lower-Upper
Post-Pazopanib treatment	1.116	0.432	6.685	1	0.010	3.052	1.310–7.111
PFS	-0.137	0.030	20.359	1	< 0.001	0.872	0.822-0.926
First line chemotherapy before pazopanib	12	10.224	13.776				
Second-third lines chemotherapy before pazopanib	12	7.369	16.631	0.423	3		
Median survival by presence of adverse effects requiring dose reduction							
Patients with adverse effects requiring dose reduction	11	8.971	13.029				
Patients with adverse effects not requiring dose reduction	12	10.198	13.802	0.681			
Median survival by post-Pazopanib treatment status							
Post-Pazopanib treatment	12	9.704	14.296				
No post-Pazopanib treatment	16	9.493	22.507	0.756	5		
Patients with adverse effects requiring dose reduction	10	-	-				
Patients with adverse effects not requiring dose reduction	12	9.038	14.962	0.178	3		

In the multi-center Phase-3 study of pazopanib (PAL-ETTE),^[13] 369 patients were randomized in a ratio of 2:1 and the median PFS and median OS were 4.6 months and 12.5 months, respectively. The median age of patients in the pazopanib arm in this study was 55 years, with 56% receiving second- or higher-line chemotherapy prior to pazopanib. The most common causes of dose reduction were hypertension, fatigue, diarrhea, anorexia, nausea and vomiting, hand-foot syndrome, and elevated liver enzymes. Only 1 patient experienced grade 4 side effects.

In a study conducted by Karaağaç et al. in a real-world setting (n=79),[14] the median PFS was 3.97 months, and the median OS was 11.4 months. In their study, the median age of patients was 49.6 years, and 38% of the patients received second- or higher-line chemotherapy prior to pazopanib. Grade 4 adverse effects were observed in only 5 patients (5.1%). In another real-world analysis by Koca et al. (n=103) [15], the median PFS was 4.3 months, and the median OS was 10.1 months. The median age of patients was 50 years, and 49% of patients received second- or higher-line chemotherapy prior to pazopanib. Grade 3–4 side effects were observed in 29% patients, and dose reduction was performed in 32% patients. In the real-life analysis of Chung Ryul Oh et al. (n=347),[16] the median PFS was 5.3 months and the median OS was 12 months. The median age of patients was 51 years, and 44.1% patients had received second- or higherline chemotherapy prior to pazopanib. Grade 3 adverse effects were observed in 2.3% patients. No cardiac or hepatic adverse effects were observed.

The PFS in our cohort was longer than that in the abovementioned studies, while the OS was comparable. The longer PFS in our study may be attributable to the fact that we could not use pazopanib as a second-line treatment in 67.9% of our patients and our patient population was younger. When the adverse effect profile was examined, in our study, grade 3 adverse effects were observed in 11.3% patients and grade 4 adverse effects were observed in 3.7% patients. Although the incidence of adverse effects in our cohort was different from that in previous studies, the rarity of grade 4 adverse effects and lack of mortality due to drug toxicity suggests the safety of the drug.

Limitations of the Study

Some limitations of our study should be acknowledged. This was a retrospective single-center study with a small sample size, which may have introduced an element of bias. Moreover, histological subtype analysis was not available for a large number of patients.

Conclusion

Pazopanib is an effective and safe drug for metastatic soft tissue sarcoma. Patients who received radiotherapy for curative or palliative reasons had a significantly longer PFS than patients who did not receive radiotherapy. However, no significant difference in OS or PFS was observed between the other subgroups. Earlier use of pazopanib may result in longer PFS. Receiving treatment after pazopanib and longer PFS were associated with lower mortality.

Disclosures

Ethics Committee Approval: Ethics committee approval of the study was obtained from the ethics committee of Istanbul University Istanbul Faculty of Medicine.

Data Aviability Statement: The data of the study is available on my computer and can be shared if requested.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

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Authorship Contributions: Concept – M.P., M.B., M.E.; Design – M.P., M.B., M.E.; Supervision – M.P., M.B., M.E.; Materials – M.P., M.B., M.E.; Data collection &/or processing – M.P.; Analysis and/or interpretation – M.P.; Literature search – M.P.; Writing – M.P.; Critical review – M.P.

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