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Comparison of active surveillance *vs.* partial nephrectomy results in small renal masses

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Abstract

Aim: Incidentally diagnosed renal cancers have increased with the increase in imaging modalities. Incidentally diagnosed masses are smaller in size and there are conflicts in the management of these 3,259 masses. Active surveillance (AS) and surgery are the treatment options. In our study, we aimed to compare the data of patients who underwent these two methods.

Methods: The data of 34 patients who underwent AS and 89 patients who underwent surgery were retrospectively analyzed. AS patients were defined as Group 1 and surgical patients as Group 2. Treatment options were determined according to tumor characteristics, patient age, comorbidities, and surgical risks. The Eastern Cooperative Oncology Group (ECOG) performance score and the Charlson Comorbidity Index (CCI) were used to assess comorbidity in each patient. AS patients were offered surgical treatment when their tumors reached > 4 cm in maximal diameter or had rapid tumor growth rates.

Results: The mean patient age was 74.06 ± 6.78 in Group 1 and 58.82 ± 7.60 in Group 2 ($P < 0.001$). The ECOG performance score was > 1 in all patients in Group 1, while the rate of ECOG > 1 was 59.6% in Group 2 ($P < 0.001$). CCI was 8.09 ± 0.75 in Group 1 and 3.94 ± 1.14 in Group 2 ($P < 0.001$). Mortality rates developed in 10 (29.4%) patients in Group 1 and 3 (3.4%) patients in Group 2. Regarding 5- and 10-year cancer-specific survival (CSS), the 5-year survival rate was 81.1% in Group 1 and 97.7% in Group 2, and the 10-year CSS was 63.2% in Group 1 and

89.5% in Group 2, which was statistically higher in Group 2 (*P*: 0.0022).

Conclusion: Although AS has worse outcomes than surgery in terms of CSS, it is a recommended option for patients with older age and poor performance scores.

Keywords: Small renal masses, renal cell carcinoma, active surveillance, partial nephrectomy, radical nephrectomy

INTRODUCTION

The widespread use of non-invasive abdominal imaging [ultrasonography, computed tomography (CT), magnetic resonance imaging (MRI)] has led to a significant increase in the number of incidentally diagnosed small renal masses (SRMs)[1]. Incidentally diagnosed masses are generally smaller in size and the treatment of these masses varies according to tumor size, tumor location, patient status, and metastatic status[2]. The decision-making process in the management of SRM, especially those smaller than 4 cm, directly affects the cancer-specific survival (CSS) rates and quality of life of patients[3]. Therefore, early diagnosis and optimal management of SRM are of great importance for both individual patients and healthcare systems[3]. The standard treatment for SRM is partial nephrectomy (PN), but the active surveillance (AS) strategy is one of the strategies used in patients who cannot undergo surgery due to accompanying comorbidities[4]. It has been suggested that AS may reduce the need for invasive procedures for patients with certain criteria[5]. On the other hand, PN is a surgical procedure performed to obtain a more radical outcome for SRM, which may have a positive effect on the survival rates of patients[6].

There is no common consensus on how to approach especially the elderly patient group in SRMs. The scope of the study is limited to SRMs and includes a detailed examination of data on the specific criteria to be followed during the clinical course of these masses, the patient selection process and treatment outcomes. However, the analyzed data aim to evaluate the efficacy of both modalities, with important implications for clinical practice.

METHODS

This study was approved by our institutional ethical review committee (Decision No: 2024/09-17 Date: 10.10.2024). It was conducted in accordance with the Declaration of Helsinki on human subjects. Patients who were diagnosed with < 4 cm renal mass and underwent AS or surgery between 2010-2019 in our hospital were analyzed retrospectively. Patients with any syndrome and/or familial inherited renal cell carcinoma (RCC), and patients with metastatic disease at presentation were not included in the cohort. Treatment options were based on tumor characteristics, patient age, comorbidities, and surgical risks. In this study, there were no predefined selection criteria for treatment options. Only patients with solid or cystic T1a SRMs treated with radical nephrectomy (RN), PN, or AS were included in the study. Renal tumors were staged according to the 2009 TNM classification. R.E.N.A.L nephrometry score was calculated in all patients to be operated and PN-RN surgical decision was performed accordingly[7].

After inclusion and exclusion criteria, data from 34 patients who underwent AS and 89 patients who underwent surgery were retrospectively analyzed.

Patient follow-up was performed every 3-6 months during the first year and annually thereafter by physical examination, blood sampling, and radiologic imaging; chest and abdominal contrast-enhanced CT and/or MRI were used for radiologic imaging. Tumor size was defined as the largest diameter of the tumor measured in the axial or coronal planes during the post-nephrographic contrast imaging phase.

All patients who underwent AS underwent biopsy to obtain a preliminary pathological examination because of the possibility of future treatment. In patients who underwent surgery, the pathologic diagnosis was based on the pathologic examination of the specimen.

American Society of Anesthesiologists (ASA) scores, Eastern Cooperative Oncology Group (ECOG) performance score, and Charlson Comorbidity Index (CCI) were used to evaluate comorbidity in each patient. AS patients were recommended to undergo surgical treatment when their tumors reached > 4 cm in maximal diameter or when they had rapid tumor growth rates. The end of follow-up was defined by either patient death or surgical treatment.

Statistical analysis

Statistical data analyses were performed using IBM SPSS Statistics for Windows version 25 (IBM Corp., Armonk, NY, USA). Data were presented as the mean ± standard deviation and the median, inter-quartile ranges (IQR). The distribution of continuous variables was assessed by Shapiro-Wilk's test. Mann-Whitney *U* tests were used to compare the continuous variables based on the distribution. The Chi-square test (Fisher Exact, Continuity Correction, Pearson Chi-Square) was used to compare the categorical variables. Kaplan-Meier analysis was used to evaluate overall survival (OS). Kaplan Meier model was obtained using R software (R Foundation for Statistical Computing, Vienna, Austria) survival, survminer, and dplyr packages. A significance level of $P < 0.05$ was considered statistically significant.

RESULTS

In our study, 34 patients who underwent AS were defined as Group 1 and 89 patients who underwent surgery were defined as Group 2. When the demographic data of both groups were compared, the mean patient age was 74.06 ± 6.78 in Group 1 and 58.82 ± 7.60 in Group 2 ($P < 0.001$). Body mass index (BMI) was higher in Group 1 (32.91 ± 5.08 *vs.* 29.99 ± 5.07). Regarding the comorbidities of the patients, hypertension, coronary artery disease (CAD), and chronic obstructive pulmonary disease (COPD) were found to be higher in Group 1 ($P < 0.001$), while no difference was found in terms of diabetes mellitus (DM) and asthma. The ECOG performance score used in the evaluation of comorbidity was > 1 in all patients in Group 1, while the rate of ECOG > 1 was 59.6% in Group 2 ($P < 0.001$). CCI was 8.09 ± 0.75 in Group 1 and 3.94 ± 1.14 in Group 2 ($P < 0.001$). The comparison results of the demographic data of the patients are shown in Table 1.

Hemoglobin, glomerular filtration rate (GFR), platelet count, and platelet-to-lymphocyte ratio (PLR) were statistically lower in Group 1, while preoperative and postoperative first-week creatinine levels were lower in Group 2. There was no difference between the groups in terms of neutrophil count, postoperative first-week GFR value, and neutrophil-to-lymphocyte ratio (NLR). In the comparison of radiological results, tumor size was 3.08 ± 0.48 in Group 1 and 3.2 ± 0.58 in Group 2 and no difference was found. There was no difference found between the groups in terms of tumor localization and laterality of the tumor. There was no difference between the groups regarding tumor subtype and Fuhrmann grade in pathological examination. Of the patients who underwent surgery, 86 (96.6%) underwent PN and 3 (3.4%) underwent RN. The surgical margin positivity rate was 6.7%. PN was performed in 3 (8.8%) of 34 patients who underwent AS due to the high rate of increase in tumor size during follow-up. Metastatic progression was detected in 1 (2.9%) of the patients who underwent AS and 1 (1.1%) of the patients who underwent surgery.

The follow-up period was 84.1 ± 35.8 months in Group 1 and 90.7 ± 39.2 months in Group 2 and no statistical difference was observed between the groups. During the follow-up period, mortality rates developed in 10 (29.4%) patients in Group 1 and 3 (3.4%) patients in Group 2. The mortality rate was

Table 1. Comparison of demographic data of active survival and surgery group

Variables	Total (*n* = 123) Mean ± SD	AS (*n* = 34) Mean ± SD	Surgery (*n* = 89) Mean ± SD	*P* value
Age (year)	63.03 ± 10.04	74.06 ± 6.78	58.82 ± 7.60	**< 0.001**[+]
Gender *n*, (%)				0.386[*]
Male	71 (57.7)	17 (50.0)	54 (60.7)	
Female	52 (42.3)	17 (50.0)	35 (39.3)	
BMI (kg/m^2)	27.80 ± 5.22	28.91 ± 5.08	26.99 ± 5.07	**0.008**[+]
DM *n*, (%)				0.352[*]
No	68 (55.3)	16 (47.1)	52 (58.4)	
Yes	55 (44.7)	18 (52.9)	37 (41.6)	
Hypertension *n*, (%)				**< 0.001**[*]
No	63 (51.2)	5 (14.7)	58 (65.2)	
Yes	60 (48.8)	29 (85.3)	31 (34.8)	
CAD *n*, (%)				**< 0.001**[*]
No	102 (82.9)	15 (44.1)	87 (97.8)	
Yes	21 (17.1)	19 (55.9)	2 (2.2)	
COPD *n*, (%)				**< 0.001**[++]
No	107 (87.0)	24 (70.6)	83 (93.3)	
Yes	16 (13.0)	10 (29.4)	6 (6.7)	
Asthma *n*, (%)				0.354[**]
No	108 (87.8)	28 (82.4)	80 (89.9)	
Yes	15 (12.2)	6 (17.6)	9 (10.1)	
ASA *n*, (%)				**< 0.001**[++]
I	13 (10.6)	0 (0.0)	13 (14.6)	
II	31 (25.2)	0 (0.0)	31 (34.8)	
III	61 (49.6)	16 (47.1)	45 (50.6)	
IV	18 (14.6)	18 (52.9)	0 (0.0)	
ECOG *n*, (%)				**< 0.001**[*]
0	36 (29.3)	0 (0.0)	36 (40.4)	
> 1	87 (70.7)	34 (100.0)	53 (59.6)	
CCI	5.09 ± 2.13	8.09 ± 0.75	3.94 ± 1.14	**< 0.001**[+]

[+]Mann Whitney *U* test, [*]continuity correction test, [++]Pearson chi-square test, [**]Fisher exact test. AS: Active surveillance; BMI: body mass index; DM: diabetes mellitus; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; ASA: American Society of Anesthesiologists; ECOG: Eastern Cooperative Oncology Group; CCI: Charlson Comorbidity Index.

statistically higher in Group 1 patients ($P < 0.001$). Comparisons of laboratory, radiologic, pathologic, and follow-up results are shown in Table 2.

CSS was 93.5 months in Group 1 and 114.6 months in Group 2. CSS was statistically higher in patients who underwent surgery (*P*: 0.007). CSS results between the groups are shown in Table 3. Regarding 5- and 10-year CSS, the 5-year survival rate was 81.1% in Group 1 and 97.7% in Group 2, and the 10-year CSS was 63.2% in Group 1 and 89.5% in Group 2, which was statistically higher in Group 2 (*P*: 0.0022). In the follow-up of active follow-up patients, a total of 7 patients were found to have mortality due to other causes. Of these patients, 3 had CAD, 2 had Cerebrovascular accident, 1 had COPD, and 1 had DM-related mortality. In the group of patients who underwent surgery, 1 patient had mortality due to other causes, and this was CAD. Results regarding 5-10-year CSS are shown in Table 4 and the Kaplan-Meier curve [Figure 1].

DISCUSSION

Clinical management of renal masses is of critical importance in terms of following the course of the disease and making treatment decisions[8]. Renal masses are benign or potentially malignant[9]. The main goal in the management of these masses is to increase patient survival, maintain quality of life, and minimize the risk of complications[9]. The standard treatment for SRM is PN, but in some cases, treatment options such as AS, radiofrequency ablation (RFA), and cryotherapy are also available[10]. Carbonara *et al.* reported a success

Table 2. Comparison of laboratory, radiological, pathological and follow-up data of both groups

Variables	Total (*n* = 123) Mean ± SD Median (IQR)	AS (*n* = 34) Mean ± SD Median (IQR)	Surgery (*n* = 89) Mean ± SD Median (IQR)	*P* value
Hemoglobin (g/dL)	12.15 ± 1.73	11.18 ± 1.36	12.53 ± 1.71	**< 0.001**[+]
Creatinine (mg/dL)	1.30 ± 0.26	1.47 ± 0.22	1.24 ± 0.25	**< 0.001**[+]
GFR (mL)	87.47 ± 20.45	77.76 ± 17.12	91.18 ± 20.48	**0.002**[+]
Creatinine (week 1) (mg/dL)	1.31 ± 0.41	1.4 ± 0.52	1.1 ± 0.31	**< 0.001**[+]
GRF (week 1) (mL)	77.53 ± 22.20	76.05 ± 21.33	79.73 ± 23.76	0.241[+]
Neutrophil (×10^3 cells/mm^3)	4,743.09 ± 1,541.45	4,808.82 ± 1,684.04	4,717.98 ± 1,492.75	0.941[+]
Lymphocytes (×10^3 cells/mm^3)	3,485.36 ± 1,267.87	3,705.88 ± 1,483.64	3,324.72 ± 1,143.98	0.089
Platelet (×10^3 cells/mm^3)	284,374 ± 200,042	230,441 ± 91,961	304,977 ± 225,285	**0.014**[+]
NLR	1.75 ± 1.02	1.67 ± 1.15	1.78 ± 0.97	0.185[+]
PLR	98.60 ± 67.29	73.61 ± 38.81	108.15 ± 73.34	**0.010**[+]
Tumor size (cm)	3.1 ± 0.50	3.08 ± 0.48	3.2 ± 0.58	0.248[+]
Tumor location *n*, (%) Upper Middle Lower	 25 (20.3) 47 (38.2) 51 (41.5)	 8 (23.5) 14 (41.2) 12 (35.3)	 17 (19.1) 33 (37.1) 39 (43.8)	0.678[++]
Tumor side *n*, (%) Right Left	 66 (53.7) 57 (46.3)	 19 (55.9) 15 (44.1)	 47 (52.8) 42 (47.2)	0.918[*]
Subtype *n*, (%) Clear cell Papillary Chromophobe Other	 92 (74.8) 10 (8.1) 15 (12.2) 6 (4.9)	 28 (82.4) 2 (5.9) 2 (5.9) 2 (5.9)	 64 (71.9) 8 (9.0) 13 (14.6) 4 (4.6)	0.556[++]
Fuhrman *n*, (%) I II III IV	 42 (34.1) 40 (32.5) 30 (24.4) 11 (8.9)	 13 (38.2) 10 (29.4) 7 (20.6) 4 (11.8)	 29 (32.6) 30 (33.7) 23 (25.8) 7 (7.9)	0.785[++]
Tumors increase size (cm/year)	0.32 ± 0.15	0.32 ± 0.15	-	-
From AS to surgery *n*, (%)	3 (8.8)	3 (8.8)	-	-
Metastatic progression *n*, (%)	2 (1,6)	1 (2.9)	1 (1.1)	-
Surgery type *n*, (%) PN RN	 87 (96.7) 3 (3.3)	 1 (100) -	 86 (96.6) 3 (3.4)	-
Surgical margin *n*, (%) Negative Positive	 84 (93.3) 6 (6.7)	 1 (100) -	 83 (93.2) 6 (6.8)	-
Mean follow-up (months)	126.4 ± 36.9	134.1 ± 35.8	119.7 ± 39.2	0.118
Mortality *n*, (%) No Yes	 110 (89.4) 13 (10.6)	 24 (70.6) 10 (29.4)	 86 (96.6) 3 (3.4)	**< 0.001**[**]

[+]Mann Whitney *U* test, [*]continuity correction test, [++]Pearson chi-square test, [**]fisher exact test. AS: Active surveillance; SD: standard deviation; IQR: inter-quartile ranges; GFR: glomerular filtration rate; NLR: neutrophil-to-lymphocyte ratio; PLR: platelet-to-lymphocyte ratio; PN: partial nephrectomy; RN: radical nephrectomy.

Table 3. Cancer-specific survival of SRM patients undergoing SRM AS and surgery

Groups	Cancer-specific survival time (months) (95%CI)	HR (95%CI)	*P* value
AS	93.57 (79.57-107.57)	Reference	-
Surgery	114.63 (108.24-121.015)	0.163 (0.044-0.609)	**0.007**

SRM: Small renal mass; AS: active surveillance; HR: hazard ratio; CI: confidence interval.

Table 4. 5- and 10-year cancer-specific survival rates, standard errors and 95%CI

Groups	Cancer-specific survival rate (SE)	95%CI
5 years survival		
AS	0.811 (0.0694)	0.686-0.959
Surgery	0.977 (0.0163)	0.945-1.000
10 years survival		
AS	0.632 (0.0975)	0.467-0.855
Surgery	0.895 (0.0793)	0.753-1.000

CI: Confidence interval; SE: standard error; AS: active surveillance.

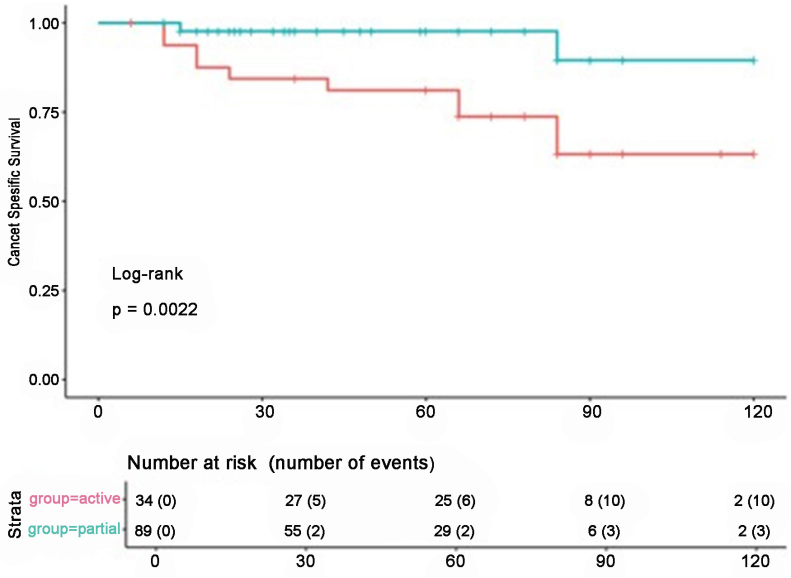

Figure 1. Kaplan Meier survival curve (Log-rank *Chi-Square* 9.381; *P* = 0.0022).

rate of over 93% with RFA and cryotherapy[11]. In addition, since the complication risk of both methods is very low, they are especially suitable for patients who are not surgical candidates.

AS aims to prevent patients from surgical risks, anesthesia effects, and postoperative complications[12]. However, overlooking the growth potential of the masses during the follow-up process may have negative consequences on the patient's health status. In particular, the need for surgical intervention when a certain growth rate is reached or symptoms develop is one of the risks of this method[12]. On the other hand, PN allows surgical removal of the masses and is generally accepted as an effective method for controlling tumors. However, this approach may increase the risk of complications and prolong the patient's recovery[13]. Therefore, it is necessary to evaluate which treatment option to apply to the patient on a case-by-case basis and discussions about these are ongoing[14].

American and European guidelines state that AS is an optimal strategy for localized SRM in patients with reduced life expectancy due to age or comorbidities, but the criteria for inclusion in AS are not clear[15,16]. The most common criteria are age, comorbidities, clinical stage (pT1a, < 3 cm tumors), incidental diagnosis, unifocal and sporadic tumor character (no familial forms, not hereditary)[15,16]. In this regard, Jacobs *et al.* investigated the role of factors such as tumor size, CCI, ECOG performance score, and GFR in patients with

SRM. The ideal criteria were tumor diameter ≤ 4 cm, BMI ≥ 2, ECOG ≥ 2, and GFR < 60 mL/min. In conclusion, they emphasized that the combination they defined as tumor diameter < 3 cm, ECOG ≥ 2, and the presence of endophytic tumor was the most ideal method for AS and surgery should be performed in patients who did not meet these criteria[17]. In another study, Audenet *et al.* claimed that patients with SRM were less suitable for surgery if CCI > 4[18]. In our study, it was observed that the age of the patient was higher and comorbidities were more common in patients with AS. Among comorbidities, hypertension, COD, and COPD were more common in patients with AS. ASA score, CCI, and ECOG score, which indicate the performance status of the patient, were higher in patients who preferred AS. Our results support that AS strategy can be applied especially in patients of advanced age and with higher comorbidities.

There is a growing number of studies focusing on the role of inflammatory markers in the clinical practice of RCC[19-21]. However, existing articles emphasize the role of specific parameters derived from peripheral blood counts (e.g., NLR, PLR), but direct comparisons between different markers are absent[19,21]. One study proposed PLR as the most reliable marker for CSS prediction in non-metastatic clear cell RCC patients[22]. Zapała *et al.* reported that high NLR was an independent factor for CSS, while high NLR and PLR were effective on CSS. There are conflicting reports regarding the superiority of different inflammatory markers and none of them has been clearly proven to have the highest prognostic value[19-23]. In our study, it was observed that the hemogram value was lower in AS patients. Since comorbidities were higher in AS patients, we think that this condition developed secondary to chronic disease anemia. Platelet values were within normal limits in both groups and statistically lower in patients with AS. In terms of the rates of hematologic parameters studied to predict prognosis, the PLR rate was statistically lower in the AS group in our study.

In patients for whom AS is recommended, the annual rate of increase in tumor size is a determining factor for definitive treatment[24]. SRM has been reported to have a lower rate of increase. In this regard, Chawla *et al.* found a growth rate of 0.28 cm/year in a meta-analysis of 234 SRM with a median follow-up period of approximately 3 years[25]. Volpe *et al.* found annual growth rates of 0.1 cm/year and Rosales *et al.* found 0.34 cm/year in SRM[26,27]. In the Cleveland Clinic experience, up to 43% of SRM showed no growth[28]. Pierorazio *et al.* included 223 patients with renal masses in T1a stage in AS protocol and performed surgery in masses with an annual growth rate > 0.5 cm and exceeding 4 cm. Surgery was performed in 9.4% of the patients during follow-up. They found that 28% of the patients who underwent surgery had benign pathologies[29]. In our study, the annual tumor increase of the patients who underwent AS was 0.32 cm, which was consistent with the literature. In the AS group, we performed surgery on 3 patients who showed faster growth and whose tumor size exceeded 4 cm. All pathologies of these 3 patients were clear cell carcinoma.

In terms of metastasis, it has been reported that SRM shows 1%-2% metastatic disease progression in selected patients in long-term follow-up[30]. Kunkle *et al.* performed a meta-analysis of oncologic outcomes for more than 6,000 SRMs and concluded that there was no significant difference in the incidence of metastatic progression regardless of whether the lesions were excised, ablated, or observed[31]. In our study, one patient in each group was found to have metastasis during follow-up. Therefore, although it is not possible to predict the malignant potential of SRMs from their initial size or subsequent growth rate, it can be concluded that SRMs are more likely to be lower grade, lower stage and less likely to be metastatic.

In various studies, 5-year OS and CSS rates for SRM with AS and surgery vary[32-36]. In T1a SRMs with AS, Patel *et al.* found a 5-year OS rate of 83% in the follow-up of 71 patients[33]. Pierorazio, on the other hand, found a CSS rate of 75% in their AS series of 223 patients[29]. For patients who underwent PN, Lai *et al.*

reported 89.6%, Tanagho *et al.* 91.7%, Thampson *et al.* 95%, and Guan *et al.* 100% survival[32-37]. In our study, both 5- and 10-year CSS were reported. While 5-year CSS was 81.1% and 10-year CSS was 63.2% in AS patients, 5- and 10-year CSS in patients who underwent surgery were 97.7% and 89.5%, respectively. We can say that surgery is associated with higher survival in SRM.

Our study has some limitations. The limitations are the small number of patients, retrospective design, and single center. Patients in the AS group were older, which may have affected the outcome of the survival analyses.

In conclusion, AS in SRM is mostly applied to elderly patients with comorbidities and poor performance, whereas surgical treatment is applied to patients with better performance. Patients who undergo surgery have a higher survival compared to AS patients. In this patient group, a decision should be made by considering the current conditions of the patient.

DECLARATIONS

Authors' contributions

Conception: Arikan Y, Beyan S, Keskin MZ
Design: Arikan Y, Kuscuoglu C, Ilbey YO
Supervision: Arikan Y, Keskin MZ
Data collection: Beyan S, Arikan Y, Kuscuoglu C
Analysis: Emir B, Arikan Y
Literature review: Arikan Y, Beyan S, Emir B
Writing: Arikan Y, Beyan S
Critical review: Keskin MZ, Ilbey YO

Availability of data and materials

The data of the study are available from the corresponding author upon reasonable request.

Financial support and sponsorship

None.

Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

All procedures performed in studies involving human participants were by the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by The University of Health Sciences, Izmir Tepecik Training and Research Hospital Ethical Committee, Izmir, Turkey (Decision No: 2024/09-17 Date: 10.10.2024). Written informed consent was obtained from patients who participated in this study.

Consent for publication

Not applicable.

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