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Supine versus prone percutaneous nephrolithotomy: A comparison of efficacy and safety in obese patients

Supin ve pron perkütan nefrolitotomi: obez hastalarda etkinlik ve güvenlik karşılaştırması

Taner Kargı¹ , Mithat Ekşi¹ , Ubeyd Sungur¹ , Osman Özdemir¹ , Serdar Karadağ¹ , İsmail Evren¹ ,
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ÖZET

Amaç: Obez hastalarda supin ve pron perkütan nefrolitotomiyi (PNL) etkinlik ve güvenlik açısından karşılaştırmak.

Gereç ve Yöntemler: Ocak 2011 ile Eylül 2020 tarihleri arasında Dünya Sağlık Örgütü (WHO) vücut kitle indeksi (VKİ) ≥ 30 kg/m² sınıflamasına göre 2 cm'den büyük böbrek taşı olan, supin veya pron pozisyonda PNL uygulanan hastalar retrospektif olarak çalışmaya dahil edildi. Demografik özellikler, intraoperatif, postoperatif veriler ile birlikte Modifiye Clavien Derecelendirme Sistemi'ne göre komplikasyonlar listelendi. Hastalar taşsızlık durumu belgelenecek 3 ay boyunca takip edildi.

Bulgular: Toplam 156 obez hastanın 74'üne (%47,4) supin PNL (grup 1) ve 82'sine (%52,6) pron PNL (grup 2) uygulandı. Hemoglobin düşüşü pelvikalsiyel akses sayısı, kan transfüzyonu, hastanede kalış süresi, komplikasyon oranları, taşsızlık durumu açısından gruplar arasında istatistiksel olarak anlamlı fark yoktu ($p > 0.05$). Pelvikalsiyel akses yeri (üst, orta, alt kaliksler) iki grup arasında anlamlı olarak farklıydı (grup 1'de sırasıyla %18,9, %32,4, %42,6, grup 2'de %3,2, %19,3, %77,5) ($p < 0,001$). Ortalama ameliyat süreleri gruplar arasında istatistiksel olarak farklı saptandı (sırasıyla grup 1'de $97,2 \pm 18,1$ dakika, grup 2'de $119,5 \pm 18,9$ dakika) ($p < 0,001$).

Sonuç: PNL, hem supin hem de pron pozisyonda uygulanabilen obez hastalarda böbrek taşlarının tedavisinde güvenli ve etkili bir yöntemdir. Hasta karakteristiği göz önünde bulundurularak, supin pozisyonda üst kaliksten erişim de tercih edilebilir. Ek olarak, supin pozisyonun pron pozisyona göre en büyük avantajı daha kısa ameliyat süresine sahip olmasıdır.

Anahtar Kelimeler: perkütan nefrolitotomi, obez, supin, pron

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This study was approved by the Ethics Committee of University of Health Sciences, Dr.Sadi Konuk Training and Research Hospital Ethical Committee (Approval Number: 2021/282). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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ABSTRACT

Objective: To compare prone and supine percutaneous nephrolithotomy (PNL) in obese patients with respect to efficacy and safety.

Material and Methods: Individuals with kidney stones larger than 2 cm undergoing either prone or supine position PNL were included in the study based on the World Health Organization (WHO) classification of body mass index (BMI) ≥ 30 kg/m² between January 2011 and September 2020 retrospectively. Demographic characteristics, intraoperative, postoperative data, and complications according to Modified Clavien Grading System were listed. Patients were followed for 3 months, documenting their stone-free status.

Results: Out of the total 156 obese patients, 74 (47.4%) underwent supine PNL (group 1), and 82 (52.6%) were prone to PNL (group 2). There was no statistically significant difference between the groups concerning hemoglobin drop, the number of pelviccalyceal access, blood transfusion, length of hospital stay, complications rates, and stone-free status ($p > 0.05$). The location of pelviccalyceal access (upper, middle, lower calyces) was significantly different (18.9%, 32.4%, 42.6% in group 1, 3.2%, 19.3%, 77.5% in group 2, respectively) ($p < 0.001$). Mean operative times were statistically different between the groups (97.2 ± 18.1 minutes in group 1, 119.5 ± 18.9 minutes in group 2, respectively) ($p < 0.001$).

Conclusion: In the prone or supine position, PNL is a safe and effective method for managing kidney stones in obese patients. Access through the upper calyx may be favored in the supine position considering to patient's characteristics. Additionally, the supine position has the greatest advantage over the prone position due to shorter operative times.

Keywords: *percutaneous nephrolithotomy, obese, supine, prone*

INTRODUCTION

The worldwide prevalence of obesity has been rising rapidly. The Global Burden of Disease Study revealed that 603.7 million adults worldwide were affected by obesity in 2015 (1). Obesity is commonly associated with conditions increasing comorbidity, especially cardiovascular disease and Type-2 diabetes mellitus (2). Numerous studies have reported that the risk of kidney stone formation is higher in obese individuals (3-5). Both the accompanying health conditions and the various technical issues due to greater skin-to-stone distance (such as difficult visualization of the stone and the need for longer surgical instruments) lead to challenges in the management of kidney stones for patients with obesity.

The standard first-line treatment of renal calculi larger than 2 cm is percutaneous nephrolithotomy (PNL) (6). Also, many studies have emphasized that PNL effectively manages obese patients with kidney stones (7,8). As a result of the associated comorbidities in obese individuals, it is suggested that PNL, apart from the standard prone position, may be performed more reliably in the supine position due to the cardiopulmonary advantages it provides (9). Examining the current literature regarding PNL for obese patients, most studies have been designed to contrast the results of obese and non-obese patients in the same position (supine or prone) (10-13). In this study, for only adults with obesity, we compare prone and supine PNL, which are frequently applied at our clinic, in terms of efficacy and safety. Thus, we aim to present a new perspective on the current literature.

MATERIAL AND METHODS

Following the local ethics committee approval (2021-282/17.05.2021) and receiving written consent from the patients, a retrospective review was conducted. Those who presented with stones larger than 20 mm and/or did not have any success with other treatment methods undergoing PNL in their management were involved in this study. The records of 156 individuals in total with a body mass index (BMI) of 30–39,9 kg/m² (obese) and BMI ≥ 40 kg/m² (morbidly obese) are according to the World Health Organization classification between January 2011-September 2020. Patients with a BMI < 30 kg/m², under 18, urinary system anomaly, severe bleeding diathesis, uncontrolled diabetes, and hypertension were excluded from the study. These individuals were operated on in the supine (74 patients) and prone position (82 patients) by surgeons experienced in both surgical techniques at our clinic upon explaining the procedures to the pa-

tient in detail, along with forming a collaborative decision. Diagnosis of patients was made by ultrasonography and a contrast-enhanced imaging modality (CT urography/IVP). The supine PNL group was classified as Group 1, and the prone PNL group as Group 2. Demographic characteristics of the subjects (age, gender, BMI, hydronephrosis grade), preoperative, perioperative, and postoperative data, and complications were compared between groups. The longest axis of the stone was defined as the stone's size. In the case of more than one stone, the sum of all stone diameters was accepted as the stone size. Those with stones in the pelvis and one calyx were described as semi-staghorn, and those with stones in the pelvis and more than one calyx were considered staghorn calculus. Complete blood count (CBC), biochemical tests, coagulation tests, urinalysis, and urine culture, were performed on all patients preoperatively. All individuals were given prophylactic antibiotics. Appropriate antibiotic therapy was administered to patients with positive urine cultures. The surgeries were carried out when the preoperative urine cultures were sterile. For each participant conducting a CBC test after surgery, postoperative hemoglobin (Hb) values were measured and subtracted from preoperative values, and a drop in Hb levels was obtained. The Modified Clavien Grading System was used to analyze complications. Clavien grade I and II complications were regarded as minor, and Clavien grade III, IV, and V ones as major complications.

In Supine PNL, patients were placed in the Galdakao-modified Valdivia position (14). Also, to facilitate the puncture, the abdominal adipose tissue was often pulled to the contralateral side with an adhesive tape, and retrograde insertion of a 5 French (F) ureteral catheter was performed at this position. For prone PNL, a 5F ureteral catheter was placed in a retrograde fashion in the lithotomy position. Afterward, repositioning the patient, the prone position was achieved. In both techniques, access to the pelvicalyceal system was accomplished with fluoroscopy and/or ultrasonography following retrograde pyelography with a ureteral catheter and calyx dilatation. After forming a tract with the sequential plastic dilator, 30F Amplatz was inserted, and access was established via a 28F rigid nephroscope (Karl Storz). A pneumatic lithotripter fragmented the stone (ELMED, vibrolith), and the fragments were extracted with stone forceps and irrigation. Additional calyceal access was created as required. Following the procedure, a 14F nephrostomy catheter was placed in the renal pelvis. Double J (DJ) stent was inserted depending on the surgeon's preference. In all of the patients included in this study, the nephrostomy catheter was removed on the 3rd postoperatively, and the DJ catheter was taken out in the third week.

Kidney, ureter, and bladder (KUB) X-ray graphy or non-contrast CT were applied to the patients postoperatively on the first and third days to assess stone-free status. The success criterion was complete stone clearance or clinically insignificant residual fragments (<4 mm). This study was carried out following the principles of the Declaration of Helsinki.

Statistical Analysis

Categorical data were given in terms of numbers and percentages. Mean and standard deviation values were calculated for numerical data. Kolmogorov-Smirnov test was used to analyze the normal distribution of numerical data. The student's t-test was utilized to compare normally distributed numerical data. In order to contrast the mean of non-normal distributions, the Mann-Whitney U test was used. The frequencies of categorical variables were compared with Pearson Chi Square and Fisher's exact test. P-value below 0.05 was considered statistically significant. Statistical analysis was performed using Statistical Package of Social Sciences version 21 (IBM SPSS Statistics; IBM Corp., Armonk, NY).

RESULTS

The mean age of the patients were 50.5 ± 10.9 years for group 1 and 48.5 ± 11 years for group 2. The mean BMI was 36.4 ± 4.2 kg/m² for group 1 and 37.1 ± 3.1 kg/m² for group 2.

There was no significant difference between the two groups regarding mean age, gender, BMI, laterality, and the American Society of Anesthesiologists (ASA) score. There was no meaningful difference between the groups' preoperative hemoglobin, creatinine, and GFR levels. Also, neither group observed no significant variance concerning hydronephrosis grades (Table 1).

Table 1. Demographic characteristics, preoperative, intraoperative and postoperative data

Parameters (mean ± SD ; %)	Total (n=156)	Group 1 "Supine" n= 74 (47.4)	Group 2 "Prone" n= 82 (52.6)	p-Value
Age (years)	49.4 ± 11	50.5 ± 10.9	48.5 ± 11	0.255
Gender (n ; %)				0.212
Male	95 (60.9)	48 (64.9)	47 (57.3)	
Female	61 (39.1)	26 (35.1)	35 (42.7)	
BMI (kg/m²)	36.8 ± 3.6	36.4 ± 4.2	37.1 ± 3.1	0.248
Laterality (n ; %)				0.332
Right	70 (44.9)	34 (45.9)	36 (43.9)	
Left	86 (55.1)	40 (54.1)	46 (56.1)	
Previous ESWL History (n ; %)	15 (9.6)	6 (8.1)	9 (11)	0.597
Kidney Stone Surgery History (n ; %)				0.590
PNL	12 (7.7)	5 (6.8)	7 (8.5)	
Open Pyelolithotomy	6 (3.8)	4 (5.4)	2 (2.4)	
Pre-op Hb	13.7 ± 1.9	13.9 ± 1.6	13.5 ± 2.2	0.122
Post-op Hb	12.6 ± 1.8	12.9 ± 1.5	12.3 ± 2	0.062
Hb Drop	1.1 ± 0.7	1 ± 0.7	1.1 ± 0.7	0.595
Hydronephrosis (n ; %)				0.626
0	9 (5.8)	4 (5.4)	5 (6.1)	
1	29 (18.6)	12 (16.2)	17 (20.7)	
2	63 (40.4)	32 (43.2)	31 (37.8)	
3	53 (34)	26 (35.1)	27 (32.9)	
4	2 (1.3)	0 (0)	2 (2.4)	
Number of Access Tracts	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.3	0.968
Access Location (n ; %)				<0.001
Upper Calyx	19 (10.6)	16 (18.9)	3 (3.2)	
Middle Calyx	46 (25.7)	28 (32.4)	18 (19.3)	
Lower Calyx	114 (63.7)	42 (48.6)	72 (77.5)	
Operation Time (min)	108.9 ± 21.6	97.2 ± 18.1	119.5 ± 18.9	<0.001
Convalescence (day)	7.3 ± 1.2	7.3 ± 1.3	7.3 ± 1.1	0.813
LOS (day)	2.5 ± 1.1	2.5 ± 1.1	2.5 ± 1	0.703
Complications (n ; %)				0.900 [†]
Absent	131 (84)	63 (85.1)	68 (82.9)	
Minor (Clavien Grade 1-2)	21 (13.5)	9 (12.2)	12 (14.7)	
Major (Clavien Grade 3-4-5)	4 (2.6)	2 (2.7)	2 (2.4)	
Blood Transfusion (n ; %)	5 (3.2)	2 (2.7)	3 (3.7)	0.549
SFS On Post-op Day 1 (n ; %)				0.536
Present	89 (57.1)	42 (56.8)	47 (57.3)	
Absent	67 (42.9)	32 (43.2)	35 (42.7)	
Requirement of Additional Treatment (n ; %)	40 (25.6)	23 (31.1)	17 (20.7)	0.147
Type of Additional Treatment (n ; %)				0.283
Absent	116 (74.4)	51 (68.9)	65 (79.3)	
ESWL	27 (17.3)	17 (23)	10 (12.2)	
F-URS	8 (5.1)	3 (4.1)	5 (6.1)	
Second-Look PNL	5 (3.2)	3 (4.1)	2 (2.4)	0.669
SFS On Post-op Month 3 (n ; %)	135 (86.5)	65 (87.8)	70 (85.4)	0.815

SD, Standard Deviation; ESWL, Extracorporeal Shock Wave Lithotripsy; PNL, Percutaneous Nephrolithotomy; Hb, Hemoglobin; F-URS, Flexible Ureteroscopy; LOS, Length of Hospital Stay; SFS, Stone free status; Pre-op, Preoperative; Post-op, Postoperative ! Fisher Exact Test

Table 2. Stone Characteristics

Parameters (mean ± SD ; %)	Total (n=156)	Group 1 "Supine" n= 74 (47.4)	Group 2 "Prone" n= 82 (52.6)	p-Value
Stone Size (mm)	31.3 ± 10.2	31.8 ± 9.9	30.8 ± 10.5	0.544*
HU value of stones	844.5 ± 314.6	854.1 ± 282.8	835.8 ± 342.3	0.718*
Number and Characteristics Of Stones (n ; %)				0.981 [†]
Single	66 (42.3)	32 (43.2)	34 (41.5)	
Semi-staghorn	24 (15.4)	11 (14.9)	13 (15.9)	
Staghorn	27 (17.3)	12 (16.2)	15 (18.3)	
Multiple	39 (25)	19 (25.7)	20 (24.4)	

HU, Hounsfield Unit. *Independent t Test! Chi Square Test

Table 3: Complications according to the Modified Clavien Grading System

(n ; %)	Supine Position (Group 1)	Prone Position (Group 2)
Grade I		
Renal colic	5(6.8)	3(3.7)
Fever	2(2.7)	6(7.3)
Grade II		
Blood Transfusion	2(2.7)	3(3.7)
Grade IIIa		
Urinary Leakage	2(2.7)	1(1.2)
Grade IV		
Cardiac System (MI)	-	1(1.2)
Grade V		
	-	-
Minor complications	9(12.2)	12(14.7)
Major complications	2(2.7)	2(2.4)
Total complications	11(14.9)	14(17.1)

MI, Myocardial infarction

There was no considerable difference between the groups regarding mean stone size, number, and characteristics of stones and Hounsfield unit (HU). Whilst the mean stone size was 31.8 ± 9.9 mm in the supine group; it was 30.8 ± 10.5 mm in the prone group (Table 2). There was no significant difference in the mean number of access tracts in both groups (Table 1). Access through upper calyx in supine PNL was demonstrated to be considered significant, whilst lower calyx was favored in prone PNL ($p < 0.001$) (Table 1). Mean operative times were significantly different between the groups; it was shown to be 97.2 ± 18.1 min in group 1 and 119.5 ± 18.9 min in group 2 ($p < 0.001$). Complications were observed in 11 (14.9%) patients of group 1 and 14 (17.1%) patients of group 2. Most of the complications in both groups were minor. 2 (2.7%) individuals were identified in group 1 with hemorrhage requiring blood transfusion and 3 (3.7%) in group 2. No significant variance was noted regarding the mean postoperative Hb drop between the two groups (Table 1). The rates of major complications were 2.7% for group 1 and 2.4% for group 2, respectively. DJ stent was inserted due to urinary leakage from the tract after removal of the nephrostomy catheter for 2 patients in group 1 and 1 in group 2 (Clavien Stage IIIa). In the prone position, 1 patient was admitted into the intensive care unit (ICU) for observations due to the development of myocardial infarction (MI) during the operation. Following ICU monitoring, the patient was discharged upon stabilization of the clinical condition (Clavien Stage IV). No mortality was detected in either group (Table 3). The length of hospital stay (LOS) and convalescence for both groups were identical. The success rates evaluating the stone-free status

on postoperative day 1 were 56.8% for the supine group and 57.3% for the prone group. The rates of requiring additional treatments were similar between the two groups. Whilst second-look PNL was performed for 3 (4.1%) patients in group 1, it was done for 2 (2.4%) individuals in group 2. Also, there was no considerable difference between the groups in relation to the second-look PNL application rates. Concerning the evaluation of stone-free status on postoperative month 3, success was achieved in 65 (87.8%) patients overall for the supine group and 70 (85.4%) patients for the prone group. No significant difference was identified between the groups' first and second stone-free status assessments (Table 1).

DISCUSSION

Treatment options from non-invasive to invasive include extracorporeal shock wave lithotripsy (ESWL), flexible ureteroscopy (F-URS), and PNL. According to stone size and BMI, treatment preferences may vary. Despite being the most non-invasive procedure, ESWL's inadequacy in treating large kidney stones (>2 cm) and the drop in success rates as the skin-to-stone distance increases have caused it to be a less preferable option concerning the treatment of nephrolithiasis in obese patients (15,16). Besides, F-URS is a treatment option applicable to the management of obese patients as it is a retrograde procedure and is not affected by the skin-to-stone distance. However, it is established that the efficacy of F-URS reduces as the stone size increases, and following the procedure, many additional interventions are required (17,18). This situation repeatedly exposes obese patients to the risk of anesthesia, given the accompanying comorbid conditions.

The European Association of Urology 2021 guidelines recommend PNL as the first treatment choice for renal calculi larger than 2 cm (6). Many studies evaluated the relationship between BMI and PNL and emphasized that PNL is an effective and safe procedure for obese individuals with kidney stones (11,19,20). In Alyami et al.'s study, patients who underwent PNL were divided into 4 groups ideal body weight (BMI <25 kg/m²), overweight (BMI 25–29 kg/m²), obese (BMI 30–39 kg/m²) and morbidly obese (BMI ≥40 kg/m²). It was reported that the stone-free rates of all 4 groups were similar, with the rates being 90%, 87%, 90%, and 80%, respectively. As for the study of Shohab et al., individuals treated with PNL were separated into 3 groups normal weight (BMI <24 kg/m²), overweight (BMI 24.1–30 kg/m²), obese (BMI >30 kg/m²) and in another study, only 2 groups were formed as obese and non-obese. In both studies, stone-free rates of participants with obesity were similar to other groups (19,20).

Patients need not be repositioned in supine PNL shortens operative time (9). Considering that changing positions becomes more challenging, particularly for obese patients, supine PNL may have a great advantage in terms of operative time. In a study conducted by Desoky et al. examining the impact of BMI on flank-free modified supine PNL, participants were divided into 4 groups of normal weight (18.5 ≤ BMI <25 kg/m²), overweight (25 ≤ BMI <30 kg/m²), obese (30 ≤ BMI <40 kg/m²) and morbidly obese (BMI ≥40 kg/m²). It was revealed that along with similar stone-free rates, there was no significant difference in the mean operative times (87.2, 87.4, 87.9, and 88.7 minutes, respectively) in each of the 4 groups (12). Moreover, another study evaluated the effect of obesity on supine PNL results by allocating patients into 2 groups of non-obese and obese and similarly stated that there was no remarkable difference in terms of success rates and mean operation times of both groups (13).

Studies demonstrate that concerning treating nephrolithiasis in obese patients, both prone PNL and supine PNL are safe techniques with high effectiveness and emphasize that the complication rates for individuals with obesity are similar to those of the general population (10,13). In a study done by Şimşek et al., patients who underwent PNL in the prone position were divided into 4 groups according to BMI: normal body weight (BMI <25 kg/m²), overweight (BMI 25–29.9 kg/m²), obese (BMI 30–39 kg/m²) and morbidly obese (BMI >40 kg/m²). It was reported that there was no significant difference related to the complication rates between all groups (10). Additionally, in the study conducted by Ferreira et al., it was indicated for obese and non-obese patients who had PNL performed that no considerable difference was identified in terms of overall complication rates (13.8% and 13.6%, respectively, as Clavien grade ≥1) and major complication rates (8.4% and 5%, respectively as Clavien grade ≥3) (13).

On review of the current literature concerning PNL in patients with obesity, most of the studies were designed to compare the results of obese and non-obese participants in the same position (supine or prone) (10-13). For a more objective evaluation of nephrolithiasis in obese patients, some authors highlighted the need to contrast the advantages and disadvantages of these two positions within the same study (8). In our study, for only obese patients, we compared prone PNL and supine PNL, frequently performed at our clinic, in terms of efficacy and safety. It was observed in this study that along with similar additional treatment requirements for both groups, stone-free rates in postoperative month 3 were respectively 87.8% and 85.4% in supine and prone groups. Although the success rate was slightly greater in the supine group, no significant difference was detected. Upper calyx access was significantly higher for the supine group than for the prone group ($p < 0.001$). We believe the reasons for favoring the supine position in obese patients include that in the prone position, possibly the higher intra-abdominal pressure compared to the supine position and the resulting push of kidneys more towards the head create challenges for upper calyceal puncture and that especially in the supine position, benefitting from the increased mobility of kidney, there are some advantages associated with both respiratory manipulations of anesthesia and desired manual positioning of the kidney by the surgeon.

Moreover, after the literature, operation times were noted to be significantly shorter for supine PNL. Although both groups' minor and major complication rates were identical, it is remarkable that 1 patient in the prone group developed MI (clavien stage 4) intraoperatively. Also, the hospital stay and convalescence duration were similar in both groups.

The main limitation of our study is its retrospective nature and being a single-center study. Prospective randomized studies should confirm our findings. Another limitation is that surgeries performed by more than one surgeon may affect the results by disrupting the homogeneity. However, the strength of our study is that, not in a single position for patients undergoing PNL according to BMI, it compares prone and supine PNL in terms of efficacy and safety for only obese individuals. As a result, we consider that our study will offer a new perspective to the current literature.

CONCLUSION

PNL is a safe and effective method in treating nephrolithiasis for obese patients, whether performed in the prone or supine position. Upper calyx access may also be favored in a supine position according to the patient's needs. The supine position provides significantly shorter operative times.

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Evaluation intelligibility of urology consent forms

Üroloji onam formlarının anlaşılabilirliğinin değerlendirilmesi

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ÖZET

Amaç: Bu çalışmada üroloji kliniğinde invaziv işlemler için kullanılan onam formlarının hastalar tarafından anlaşılabilirliğini araştırdık. Kliniğimizde kullanılan onam formlarını hangi yaş ve eğitim gruplarının kavrayabileceği değerlendirildi.

Gereç ve Yöntemler: Bu araştırmada Ateşman ve Bezirci-Yılmaz tarafından Türkçe için önerilen iki anlaşılabilirlik formülü kullanılmıştır. Çalışmada 69 ayrı onam formu değerlendirildi.

Bulgular: Onam formları Ateşman anlaşılabilirlik indeksi kullanılarak değerlendirildikten sonra çalışmada ortalama 62,02 puan elde edilmiştir. Bu değer, 9 ve 10. sınıf eğitim düzeyine sahip bir kişinin metni anlayabileceğini gösterir. Bezirci-Yılmaz indeksi aynı formlar incelendiğinde ortalama 11,13 puan vermiştir. Bu değer, onam formlarının 10 ve 11. sınıf eğitim düzeyine sahip olanlar tarafından anlaşılabilirliğini göstermektedir.

Sonuç: Çalışmamızda hastalara operasyon öncesi verilen bilgilendirilmiş onam formlarının hastalar tarafından anlaşılmasında yetersiz kaldığı tespit edilmiştir. Literatürde daha önce yapılan çalışmalarda da benzer bulgular elde edilmiştir. Bilgilendirilmiş onam formları oluşturulurken her ülkenin kendi sağlık okuryazarlığı ve eğitim düzeyi dikkate alınmalıdır.

Anahtar Kelimeler: üroloji onam formları, anlaşılabilirlik, üroloji

ABSTRACT

Objective: In this study, we investigated the understanding of the consent forms used for invasive procedures in the urology clinic by the patients. It was evaluated which age and education groups could comprehend the consent forms used in our clinic.

Material and Methods: In this investigation, we employed two intelligibility formulas proposed by Ateşman and Bezirci-Yılmaz for Turkish. In the study, 69 separate consent forms were evaluated.

Results: An average of 62.02 points was obtained in the study after evaluating the consent forms using the Ateşman intelligibility index. This value indicates that a person with a 9 and 10th education level will be able to comprehend the text. The Bezirci-Yılmaz index yielded an average of 11.13 points when the same forms were analyzed. This value indicates that consent forms can be understood by those with a 10 and 11th grade education grade.

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This study was approved by the Antalya Training and Research Hospital Clinical Researches Ethic Committee (Approval Number: 17-14. Date: 04/11/2021). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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Conclusion: In our study, it was found that the informed consent forms given to the patients before the operation were insufficient to be understood by the patients. Similar findings were obtained in previous studies in the literature. Each country's own health literacy and education level should be taken into account when creating informed consent forms.

Keywords: urology consent forms, intelligibility, urology

INTRODUCTION

The term "intelligibility" refers to the reader's ability to comprehend a text. Today, mathematically developed scales can be used to determine a text's intelligibility. This has been accomplished using a variety of approaches (1). Gunning-Fog looked at the length of words, the number of words in a phrase, and the number of sentences in a text to see which age group it could be understood by in 1952 (2). In addition to indicating the age at which intelligibility occurs, the Flesch-Kincaid value also showed the level of intelligibility based on the reader's educational grade (3).

While evaluating consent forms, criteria such as the number of sentences, the number of words in the sentences, the number of syllables in the words, and the use of technical terms were used. In this method, more than 40 criteria for intelligibility were identified (4). The Turkish Urology Association created consent forms for clinical usage in urology and published them on their website. The goal of this study is to see how well the consent forms published by the Turkish Urology Association are understood by people of various ages and educational levels.

MATERIAL AND METHODS

In our country (Turkey), many different consent forms are used in different clinics. Consent forms include general consents and customized consents specific to the invasive procedure to be performed. The 69 consent forms recommended and widely preferred in clinical use by the Turkish Urology Association were analyzed in this study.

Each form was saved in the Notepad software from Microsoft (Microsoft Corporation, Redmond, WA). The clarity of the texts was evaluated according to the criteria prepared by Ateşman and Bezirci-Yılmaz for Turkish consent forms. The software prepared by Bezirci-Yılmaz was used for the evaluation.

Ateşman readability formula:

It is a formula based on word and sentence length and was developed by adapting the Flesch reading ease formula to Turkish. According to this formula, it is understood that a text is easy to read as its readability score approaches 100 and difficult to read as it approaches 0.

Readability score = $198,825 - 40.175 \times \text{word length (total syllables / total words)} - 2,610 \times \text{sentence length (total words / total sentences)}$.

Bezirci-Yılmaz readability formula:

It is a formula developed in 2010 based on the statistical characteristics of Turkish, using the number of words in the sentences in the texts, word length and different formulas. The readability level calculated by multiplying the syllable numbers of the words with their unique numbers is formulated as follows:

OKS: Average word count

H3: Average number of 3-syllable words

H4: Average number of 4-syllable words

H5: Average number of 5-syllable words

H6: Average number of words with 6 or more syllables

According to this formula, as the number of words in the sentences in the texts increases, the readability level of the texts decreases. Likewise, the increase in word length complicates the readability of words and sentences. The result obtained from this formula is a text. It reports which class level it addresses in the education system of our country.

RESULTS

Consent forms in our study were analyzed according to the Ateşman intelligibility index and an average score of 62.02 was obtained. It was seen that this result corresponded to the comprehension by the ninth and tenth grade students. In the evaluation made according to the Bezirci-Yılmaz criteria, the agreement of the texts was 11.13. This result showed that the evaluated consent forms were understandable at the tenth and eleventh grade levels. When the consents were evaluated according to Ateşman criteria, it was revealed that ten consents were intelligible at the eleventh and twelfth grade levels. While two consents were at the seventh and eighth grade levels, one consent was intelligible at the thirteenth grade level. The other forms were considered to be understandable by students in high school (grades 9, and 10). At the primary school level, no form was considered to be understandable. When evaluated according to the Bezirci-Yılmaz criteria, it was revealed that 8 consents were at primary school, 36 consents were at high school (grades 9, 10, 11, 12), 24 consents were at undergraduate level (grades 13, 14, 15), and one consent was intelligible at graduate level (Table 1 and table 2). The results were analyzed with statistical analysis and data evaluation program, and the average of the readability index was determined. Statistical Package of Social Sciences 22 (SPSS Chicago, IL, USA) program was used for analysis. Continuous variables were expressed as mean±standard deviation and median (25th percentile–75th percentile), while categorical variables were expressed as numbers and percentages. Numerical data made between more than 2 independent groups in the study One-way analysis of variance was used for comparisons.

Table 1. The relationship between the Ateşman comprehensibility index and the comprehensibility level and results

Index	Comprehensibility Level	Results
90 – 100	Can be easily understood by students in 4th grade and below	
80 – 89	Can be easily understood by students in 5th and 6th grade	
70 – 79	Can be easily understood by students in 7th and 8th grade	2
60 – 69	Can be easily understood by students in 9th and 10th grade	56
50 – 59	Can be easily understood by students in 11th and 12th grade	10
40 – 49	Can be easily understood by students in 13th or 15th grade (undergraduates)	1
30 – 39	Can be easily understood by university graduates	
≤ 29	Can be easily understood by university postgraduates	

Table 2. The relationship between the Bezirci-Yılmaz comprehensibility index and the comprehensibility level and results

Index	Education Level	Results
1–8	Primary school	8
9-12	High school	36
12-16	Undergraduate	24
16+	Postgraduate	1

DISCUSSION

Fresch developed the first substantial version of intelligibility in 1948 (5). To calculate the ease of reading according to the Fresch form, the ratio of syllables to words and words to sentences was used. Mclaughlin devised the Simple Gobbledygook (SMOG) measurement in 1969. The SMOG value is determined by counting words containing three or more letters. Syllables and sections are evaluated by using at least ten phrases taken from the first, middle and last parts of the text. The level of intelligibility related to the value is determined after applying the mathematical formulas (6).

The Automatic Readable Index (ARI) formula was developed by Simit and Senter in 1967 to standardize the clarity of documents used in the US military. The length of words in documents and the number of letters in all words are calculated. As a result, the text's intended audience is determined (7).

The Ateşman formula was created in Turkey in 1997. While the length of Turkish sentences was between nine and ten words, the length of the words was found to be 2.6 syllables. When these data are combined with Ateşman's mathematical method, it is possible to establish the educational level the text is appropriate for (8).

In 2010, Bezirci-Yılmaz proposed a new intelligibility formula for Turkish. This formula uses the total amount of words, sentences, syllables, letters, and words containing more than four syllables. According to the average number of syllables in the words in the text, a word distribution graph is made. The information gathered determines the text's intelligibility based on the reader's educational level (9).

In the study of Ebem et al. published in 2019, ninety different intravenous and intramuscular consents were evaluated according to Ateşman and Bezirci-Yılmaz formulas. The intelligibility of the intramuscular and intravenous consent forms used in this study was found to be quite low. According to Ebem et al., Ateşman's intelligibility score of 56 points corresponded to students in the eleventh and twelfth grades. The result was in agreement with the present study. Again in the study, it was found that 9.43 points correspond to the 10th and 11th grades according to the Bezirci-Yılmaz intelligibility criteria. Although this result is compatible with the present study, the level of intelligibility is lower than the Bezirci-Yılmaz index (10).

In a study conducted at a Dermatology Center in Tehran, the clarity of the forms used was investigated using the Flesch-Kincaid and Gunning-Fog indices. It was seen that the examined forms were understandable at the level of 11th grade students. The researchers regarded this as an exceedingly poor level of comprehension of the consent documents.

The American Medical Association and the National Institutes of Health conducted a research with seven different formulas, including Flesch Kincaid. According to the research, consent forms for invasive treatments were written at a level of intelligibility equivalent to a fifteenth-grade education level on average. The average education level of adults living in the United States is eighth grade. Understanding the forms used for interventional procedures is extremely difficult due to the low level of education. The American National Institutes of Health recommended that consent forms for invasive procedures be written at an appropriate level for sixth-year students.

Shuba et al. examined 113 different consent forms used for oncology patients receiving radiotherapy at 89 different clinics. It was found that the 100 forms examined were understandable at the tenth to fourteenth grade education level. The number of intelligible consent forms at the eighth and sixth grade levels was found to be four each. In the study of Shuba et al., it was revealed that patient consent forms should be written in a better understandable way (11).

It is legally and ethically obligatory for patients to understand what will be done to them before an invasive procedure and to sign an informed consent form. The individual providing consent must be properly informed and capable of consenting to the intervention. To properly inform the patient, complete information regarding why the intervention is essential, how it will be performed, the patient's advantages, potential problems, and other treatment options should be provided.

Sönmez et al. evaluated the readability of consent forms for open, endoscopic, and laparoscopic surgery in a previous urology study and found no statistically significant difference between the three groups. In their study, Sönmez et al. used criteria such as sentence length, number of words and number of syllables in words in consent forms. Patients' anxiety levels are likely to be high prior to surgery, which may influence the text's readability. In addition, the size and quality of the font used in the text are also factors that affect readability. It can be said that new informed consent forms should be prepared according to the demographic characteristics of the patient such as age, education level, gender, and whether or not she has visual impairment. In Turkey, which has an average education level of 6.51 years, consent forms should be written legibly and according to a lower education level. For a visually impaired patient, it will be much more difficult to read a consent form before an invasive procedure. These patients should be provided consent documents that are more clear and understandable. In this area, more research is required (12).

CONCLUSION

As a result, it was revealed that the comprehensibility of the consent forms used in the urology clinic of the training and research hospital, which is a tertiary hospital, was quite low. Considering that the incidence of diseases such as benign prostatic hyperplasia, prostate cancer, kidney cancer and bladder cancer, which occupy a large place in the urology clinic, increases with age, the patient group requiring interventional procedures will be above the average age of the Turkish population. The education level of elderly patients in Turkey is likely to be lower than the national average. As a result, any informed consent form used in the urology clinic should be understandable by at least primary school graduates. It was observed that the agreement of the consent forms examined in our study was low in line with the findings of similar studies. Consent forms should be prepared by considering the education level of each country. In this way, the legal liability limits of healthcare workers can be better established.

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Evaluation of the effectiveness of vesical imaging-reporting and data system (VI-RADS) scoring in predicting muscle invasion of bladder cancer

Mesane kanserinin kas invazyonunu öngörmede vezikal görüntüleme-raporlama ve veri sistemi (VI-RADS) skorlamasının etkinliğinin değerlendirilmesi

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ÖZET

Amaç: Biz bu çalışmada mesane kanserinin kas invazyonunu preoperatif tahmin etmede "Vesical Imaging Reporting and Data System" (VI-RADS) skorumu sisteminin doğruluğunu araştırmayı amaçladık.

Gereç ve Yöntemler: Ağustos 2020 ile Mart 2022 arasında preoperatif mp-MRG çekilen mesane kanserli hastalar çalışmaya dahil edildi. Mesane tümörleri deneyimli bir üroradyolog tarafından VI-RADS skorumu sistemi ile değerlendirildi. VI-RADS skoru, kas invazyonunu belirlemek için postoperatif patoloji ile karşılaştırıldı. VI-RADS ≥ 3 ve VI-RADS ≥ 4 kesme noktası için duyarlılık, özgüllük, pozitif öngörü değeri (PÖD), negatif öngörü değeri (NÖD) ve doğruluk hesaplandı.

Bulgular: Toplam 102 hastanın dördünde benign patoloji (Üç hastada sistitis sistika, bir hastada nefrojenik adenom) saptandı. Çalışmaya kalan 98 hasta dahil edildi. 38 hastada kasa invaziv ve 60 hastada ise kasa invaziv olmayan mesane kanseri saptandı. Kas invazyonunu belirlemede VI-RADS skorunun eşik değeri 3 olarak alındığında duyarlılık, özgüllük, PÖD, NÖD ve doğruluğu sırasıyla %92, %85, %94, %80 ve %88 olarak hesaplandı. Bununla beraber VI-RADS skorunun eşik değeri 4 olarak alındığında duyarlılık, özgüllük, PÖD, NÖD değeri ve doğruluğu sırasıyla %82, %95, %89, %91 ve %90 saptandı.

Sonuç: Sonuç olarak mesane mp-MRG, VI-RADS kriterleri eşliğinde VI-RADS eşik değeri 3 veya 4'ün kas invaziv mesane kanserinin saptanmasında başarılı bir yöntem olup tanılabilir performansı artırabilir.

Anahtar Kelimeler: mesane kanseri, ürogenital kanserler, MRG, VI-RADS

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This study was approved by the Ethics Committee of Çam and Sakura City Hospital (Approval Number: KA EK/2022.01.08).


All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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ABSTRACT

Objective: In this study, we aimed to investigate the accuracy of the “Vesical Imaging Reporting and Data System” (VI-RADS) scoring system in predicting preoperative muscle invasion of bladder cancer.

Material and Methods: Patients with bladder cancer who underwent pre-operative mp-MRI between August 2020 and March 2022 were included in the study. Bladder tumors were evaluated by an experienced urologist using the VI-RADS scoring system. The VI-RADS score was compared with postoperative pathology to determine muscle invasion. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated for the VI-RADS ≥ 3 and VI-RADS ≥ 4 cut-off points.

Results: Benign pathology (cystitis cystica in three patients, nephrogenic adenoma in one patient) was found in four of 102 patients. The remaining 98 patients were included in the study. Muscle-invasive bladder cancer was detected in 38 patients and non-muscle-invasive bladder cancer in 60 patients. When the threshold value of the VI-RADS score was taken as 3 in determining muscle invasion, sensitivity, specificity, PPV, NPV value and accuracy were calculated as 92%, 85%, 94%, 80% and 88%, respectively. However, when the threshold value of the VI-RADS score was taken as 4, sensitivity, specificity, PPV, NPV value and accuracy were found to be 82%, 95%, 89%, 91% and 90%, respectively.

Conclusion: In conclusion, bladder mp-MRI is a successful method in the detection of muscle-invasive bladder cancer with a VI-RADS threshold value of 3 or 4, accompanied by VI-RADS criteria, and may increase the diagnostic performance.

Keywords: bladder cancer, MRI, urogenital cancers, VI-RADS

AMAÇ

Mesane kanseri üriner sistemin sık görülen bir malignitesi olup erkeklerde kadınlara göre yaklaşık dört kat daha sık görülmektedir. Mesane kanseri için mesleki ve çevresel faktörler (metal işleme, boya, kauçuk, aromatik bileşikler, suda arsenik ve nitrat gibi), diyet ilgili faktörler (kahve, sigara), enfeksiyon (şistozomiyaz ve alt üriner sistem bakterileri), ilaçlar (pioglitazon), hastanın yaşı, cinsiyeti, ırkı ve sosyoekonomik durumu gibi çeşitli çok sayıda risk faktörü vardır (1-4).

Mesane kanseri ürotelyal karsinom, skuamöz epitelyal karsinom ve adenokarsinom gibi çeşitli tiplere ayrılabilir ve bunların %90'dan fazlası ürotelyal karsinomdur. Ürotelyal karsinomlar histolojik dereceye göre düşük ve yüksek dereceli; kas invazyonuna göre kasa invaziv veya kasa invaziv olmayan olarak sınıflandırılır. Kasa invaziv olmayan mesane kanserleri (KİOMK) genellikle düşük dereceli olup daha iyi prognoza sahiptirler. KİOMK'un yaklaşık üçte biri tanı anında yüksek dereceli olup bu hastaların ise yaklaşık %20-25'i takiplerinde kasa invaziv kansere progrese olmaktadır. Kasa invaziv mesane kanserleri ise kötü prognoza sahip olup agresif tümörlerdir. Bu nedenle mesane kanserinin tedavisi ve tedavi başarısı hastalığın evresine bağlıdır (5-7).

Transabdominal ultrasonografi (USG) mesane kanserlerinin saptanmasında önemli yer tutar. Ancak kılavuzların çoğu, lokal invazyonun değerlendirilmesi, uzak metastazın araştırılması ve üst üriner sistem tutulumunun değerlendirilmesi için USG'nin etkinliğini yetersiz bulup kesitsel görüntüleme önermektedir (8). Manyetik rezonans görüntüleme (MRG); yumuşak doku rezolüsyonunun yüksek olması ile mesane kanserinin evrelemede (primer tümör için lamina propria ve detrusor invazyonunun, perivezikal yağ, komşu organ veya pelvik yan duvar invazyonunun ve bölgesel lenf nodu metastazının değerlendirilmesinde) en sık tercih edilen kesitsel görüntüleme yöntemidir. T2 ağırlıklı (T2A), difüzyon ağırlıklı (DAG) ve dinamik kontrastlı inceleme (DKİ) görüntülemelerini birleştiren multiparametrik MRG (mp-MRG) mesane kanserinin tanısında ve lokal evrelemede konvansiyonel MRG'nin başarısını artıran bir yöntem olarak dikkat çekmektedir (9). 2018 yılında mesane kanserinde mp-MRG' in klinik kullanımı ve raporlanmasını standardize etmek amacıyla “Vesical Imaging Reporting and Data System” (VI-RADS) kriterleri yayınlanmıştır. VI-RADS kriterleri mesane kanseri lokal evrelemesine odaklanmış olup özellikle kas invazyonu varlığını gösterebilmeyi amaçlamıştır (8).

Biz bu çalışmada mesane kanserinin kas invazyonunu preoperatif tahmin etmede VI-RADS skora sisteminin doğruluğunu araştırmayı amaçladık.

GEREÇ VE YÖNTEMLER

Ağustos 2020 ile Mart 2022 arasında retrospektif olarak sistoskopik muayene ile tanı alan primer mesane kanserleri çalışmaya dahil edildi. Daha önce mesane kanseri tanısı olan ve/veya intravezikal tedavi alan hastalar, son üç gün içerisinde sistoskopik muayene olan veya daimi sondalı hastalar çalışmaya dahil edilmedi. Mp-MRG çekimi esnasında mesane dolumu yeterli olmayan hastalar çalışmadan çıkarıldı.

Çalışmaya dahil edilen tüm hastalarda optimal mesane dolumu sağlamak için görüntüleme 1-2 saat önce hastaya idrarını yapması talimatı verilerek veya hastanın tolerans düzeyine bağlı olarak muayeneden 30 dakika önce hastaya 500-1000 ml su içmeye başlaması sağlandı (10,11). Mesanede hava artefaktına neden olabileceğinden sistoskopi işleminden minimum 2-3 gün sonra mp-MRG çekildi. MRG protokol optimizasyonu yapılarak, yüksek uzaysal çözünürlük nedeniyle tüm hastalarda 3,0 Tesla MRG tercih edildi. Mp-MRG incelemesinde; sagittal T1 ağırlıklı (T1A), sagittal, koronal ve aksiyal T2 ağırlıklı (T2A), yüksek b değerli DAG-b değerleri (0,800,1000,1500), ADC haritalama yapıldı. DKİ'de 0.1 mmol/kg gadolinyum bazlı kontrast madde 1,5–2,0 ml/s hızla otomatik enjektör ile verilerek, prekontrast ve kontrast sonrası 20 saniye aralıklarla ardışık aynı seride altı kez görüntü ve perfüzyon alındı.

Deneyimli bir üroradyolog tarafından mp-MRG incelenerek mesane kanseri şüphesi olan lezyonlar VI-RADS skorlama sistemi ile değerlendirildi. Tüm lezyonlar 5 kategoriden oluşan VI-RADS skorlarına göre sınıflandırıldı (8).

VI-RADS 1: Kas invazyonu olası değil (<1 cm'nin altındaki tümörler)

VI-RADS 2: Kas invazyonu olası değil (≥ 1 cm'nin altındaki tümörler) (Şekil 1)

VI-RADS 3: Kas invazyonu varlığı şüpheli

VI-RADS 4: Olası kas invazyonu varlığı

VI-RADS 5: Olası kas ve perivezikal invazyonu varlığı (Şekil 2)

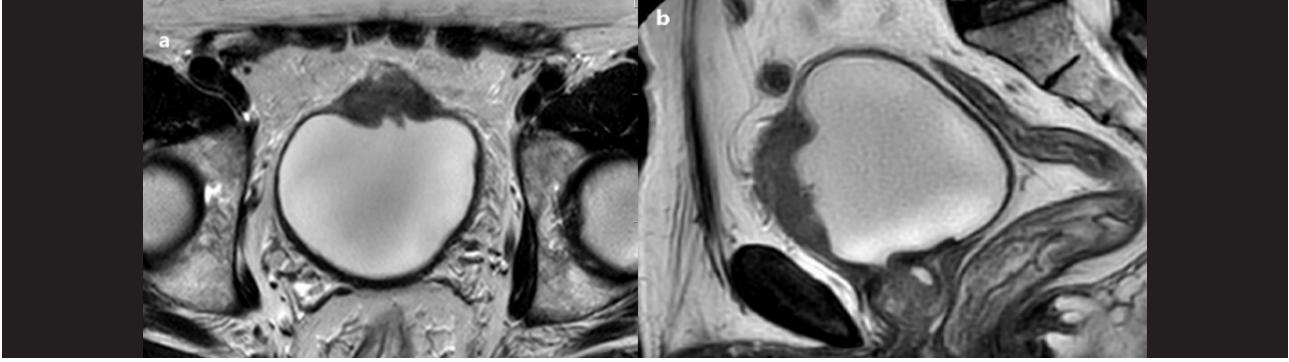
Birden fazla sayıda tümörü olan hastalarda, VI-RADS skoru en yüksek olan tümör, indeks lezyon olarak kabul edildi. Tüm hastaların VI-RADS skoru deneyimli üroradyolog tarafından preoperatif olarak hesaplandı. VI-RADS skoru ile transüretal rezeksiyon-mesane (TUR-M) yada radikal sistektomi patoloji sonuçları kas invazyonu açısından karşılaştırıldı. Hastaya TUR-M sonrası radikal sistektomi yapıldı ise referans olarak sistektomi patolojisi kullanıldı. Kas invazyonu belirlemede farklı eşik değerleri için VI-RADS skorlarının sırasıyla duyarlık, özgüllük, pozitif öngörü değeri (PÖD), negatif öngörü değeri (NÖD) ve doğruluğu hesaplandı.

Çalışmamız için Başakşehir Çam ve Sakura Şehir Hastanesi Klinik Araştırmalar Etik Kurulu'ndan 2022.01.08 protokol numarası ile etik kurul onayı alınmıştır.

Verilerin istatistiksel analizi SPSS v26.0 (IBM Corp., Armonk, NY, USA) programı kullanılarak yapıldı. Nitel ölçümler (cinsiyet, patolojik tanı yöntemi, T evresi, histolojik grade) sayı ve yüzde olarak, nicel ölçümler (yaş, MRG ile TUR-M arasında geçen süre) ise ortalama ve standart sapma olarak özetlendi. Hastaların VI-RADS skorları ile patoloji sonuçları kas invazyonu açısından ki-kare testi kullanılarak karşılaştırıldı. Farklı eşik değerleri için VI-RADS skorlarının sırasıyla duyarlılık, özgüllük, PÖD, NÖD ve doğruluğu hesaplandı.



Şekil 1. Mesane kubbesinde aksiyal T2A (a), koronal T2A (b) ve aksiyal DWI (c) sekansında kalınlaşmış iç katmana sahip stalklı seçilen VI-RADS 2 lezyon. Hastanın patoloji sonucu yüksek dereceli noninvaziv üroepitelyal karsinom olarak raporlanmıştır.



Şekil 2. Mesane anterior duvarında aksiyal T2A (a) ve sagittal T2A (b) serilerde muskularis propriaya ekstrevezikal yağlı planlara uzanan VI-RADS 5 lezyon. Hastanın patoloji sonucu yüksek dereceli invaziv üroepitelyal karsinom olarak raporlanmıştır.

BULGULAR

Toplam 102 hastanın patolojik değerlendirilmesinde dört hastada benign patoloji (üç sistitis sistika, bir nefrojenik adenom) saptandı. Çalışmaya kalan 98 hasta dahil edildi. Hastaların 83 (%84)'ü erkek, 15 (%16)'ı kadın idi. Hastaların ortalama yaşı $63,9 \pm 11,65$ idi. MRG ile TUR-M/radikal sistektomi arasında geçen ortalama süre 12,3 gün idi. Hastaların patolojik tanısı 68 hastada (%69) TUR-M; 30 hastada ise (%31) sistektomi ile yapıldı (Tablo 1).

Hastaların patolojik T evresi incelendiğinde 21 (%21) hastada Ta, 39 (%40) hastada T1 ve 38 (%39) hastada ise T2 ve üzeri mesane kanseri saptandı. Histolojik dereceleri ise 17 (%17) hastada düşük dereceli, 81 (%83) hastada ise yüksek dereceli mesane kanseri saptandı. Hastaların mp-MRG incelendiğinde 31 hastanın VI-RADS skoru 1, 23 hastanın skoru VI-RADS 2, 10 hastanın skoru VI-RADS 3, 16 hastanın skoru VI-RADS 4 ve 18 hastanın skoru VI-RADS 5 olarak değerlendirildi (Tablo 2).

Kas invazyonu olan hastalarda median VI-RADS skoru 4 iken kas invazyonu olmayan hastalarda median VI-RADS skoru 1 olarak hesaplandı. Kas invazyonunu saptamada eşik değeri olarak VI-RADS skoru 3 olarak alındığında duyarlılık, özgüllük, PÖD, NÖD değeri ve doğruluğu sırasıyla %92, %85, %94, %80 ve %88 olarak hesaplandı. Eşik değeri VI-RADS skoru 4 olarak alındığında duyarlılık, özgüllük, PÖD, NÖD'leri ve doğruluğu sırasıyla %82, %95, %89, %91 ve %90 hesaplandı (Tablo 3).

Tablo 1. Demografik veriler

	Hasta sayısı(%)
Cinsiyet	
Erkek	83 (84)
Kadın	15 (16)
Yaş (yıl)*	$63,9 \pm 11,65$
MRI ile TUR*M arasında geçen süre (gün)*	$12,3 \pm 6,3$
Patolojik TanıYöntemi	
TUR-M	68 (69)
Radikal Sistektomi	30 (31)
T evresi	
Ta	21 (21)
T1	39 (40)
T2 ve üstü	38 (39)
Histolojik Grade	
Düşük	17 (17)
Yüksek	81 (83)

*:(ort±std)

Tablo 2. VI-RADS skorları

VI-RADS Skoru	Kas İnvazyonu Yok	Kas İnvazyonu Var	p
VI-RADS 1	31	0	0,001
VI-RADS 2	20	3	0,004
VI-RADS 3	6	4	1,000
VI-RADS 4	3	13	0,001
VI-RADS 5	0	18	0,001

Tablo 3. Kas invazyonunu göstermekte eşik VI-RADS skoru ile doğruluğun değerlendirilmesi

VI-RADS Skoru	Duyarlılık(%)	Özgüllük(%)	Negatif Öngörü Değer(%)	Pozitif Öngörü Değer(%)	Doğruluk
≥1	100	0	100	39	39
≥2	100	52	100	57	70
≥3	92	85	94	80	88
≥4	82	95	89	91	90
≥5	48	100	75	100	80

TARTIŞMA

Son yıllarda kullanılan VI-RADS skorum sisteminin ana amaçları; mesane kanserinin MRG protokollerini standardize etmek, ürolog ve radyologlar arasındaki iletişimi geliştirmek için yapılandırılmış bir raporlama sistemi sunmak ve mesane kanserinde kas invazyonu için risk skorumu sağlamaktır (12). Woo ve arkadaşlarını tarafından altı çalışma ve 1770 hastadan oluşan ilk meta analizde VI-RADS'ın kas invazyonunun öngörmede duyarlılığı %83, özgüllüğü ise %90 olarak bulunmuştur. Bu çalışmalar arasında standardizasyonun olmadığı; manyetik alan gücünün (3 T ve 1.5 T), T2 ağırlıklı görüntü kesit kalınlığının (3 mm ve 4 mm) ve VI-RADS skoru eşik değerinin (≥3 ve ≥4) farklılıklarından kaynaklanan heterojenite mevcut olduğu görülmektedir (13). Biz çalışmamızda bu heterojeniteyi azaltmak amacıyla tüm hastalarda 3 Tesla MRG ve 3 mm kesit kalınlığı kullandık.

Jazayeri ve arkadaşlarının 2021'de yayınladığı 22 çalışma ve 5414 MRG raporundan oluşan başka bir metaanalizde kas invazyonunu tahmin etmek için optimal VI-RADS eşik değeri 3 olarak belirlendiğinde %89 duyarlılık ve %84 özgüllük sağladığı gösterildi. Bu çalışmada VI-RADS 3 skorunun eşik değer olarak seçilmesinin çalışmalar arası heterojeniteyi azalttığı gösterilmiştir (14). Del Giudice ve arkadaşlarının 2022'de yayınladığı 20 çalışma ve 2477 hasta verilerinin incelendiği metaanalizde eşik değeri VI-RADS 3 iken duyarlılık %87, özgüllük %86; eşik değeri VI-RADS 4 iken duyarlılık %78, özgüllük %94 olduğu gösterilmiştir (15). Bizim çalışmamızda da literatüre benzer şekilde eşik değer VI-RADS 3 iken duyarlılık %92, özgüllük %85; eşik değer VI-RADS 4 iken duyarlılık %82, özgüllük %95 olduğu saptanmıştır.

Kas invazyonunu göstermede eşik değer olarak hangi skorun kabul edileceği farklı klinik senaryolara göre değişebilir. Örneğin, VI-RADS 3 skoru; yüksek dereceli, tekrarlayan, çoklu ve veya daha büyük lezyonlarda seçilebilirken; VI-RADS 4 skoru daha agresif lezyonlar için eşik değer olarak tanımlanabilir (12). Bizim çalışmamızda VI-RADS 3 skoru ile VI-RADS 4 skoru eşik değer olarak karşılaştırıldığında; VI-RADS 3 skorunda duyarlılık ve NÖD daha yüksek iken, VI-RADS 4 skorunda özgüllük, PÖD ve doğruluk oranları daha yüksek bulunmuştur.

Eşik değerinden bağımsız olarak VI-RADS skoru performansının duyarlılığı %90-95 ve özgüllüğü %88-93 olup yüksektir (15). Yakın zamanda Del Giudice ve arkadaşları, VI-RADS 5 skorunun duyarlılığını %90,2; özgüllüğünü %98,1 bulup, ekstrevezikal tutulumlu lokal ileri mesane kanserini tanımlamada tanısallık performansını oldukça başarılı bulmuşlardır (16). Yüksek duyarlılık ve özgüllük değerleri sayesinde VI-RADS skorum sistemi ile tanı için yapılan TUR-M'nin kas dokusunu örnekleyememesi ya da TUR-M uygulanamayacak

hastaların T evrelemesi tanımlanabilir. Bizim çalışmamızda da VI-RADS 5 skoru olan 18 hastanın 5 tanesinde TUR-M esnasında kas dokusu mevcut değildi. Fakat radikal sistektomi sonrası nihai patolojide 18 hastanın tümünde kas invazyonu saptanmıştır.

Çalışmamızın limitasyonlarına bakıldığında çalışmaya sadece primer mesane kitlelerinin dahil edilmesi, hasta sayısının düşük olması ve görüntülerin tek bir üroradyolog tarafından tek merkezde değerlendirilmesi limitasyonlarımız olarak sayılabilir. Bununla birlikte tek bir üroradyolog tarafından değerlendirilmesi çalışmanın homojenitesini artırmaktadır.

SONUÇ

Mesane kanserinde kas invazyonunun saptanması en önemli prognostik faktörlerdendir. Günümüzde özellikle MRG'deki teknolojik yenilikler, mesane kanserinin radyolojik olarak lokal evrelendirmesini kolaylaştırmaktadır. Sonuç olarak mesane mp-MRG, VI-RADS kriterleri eşliğinde VI-RADS eşik değeri 3 veya 4'ün kas invaziv mesane kanserinin saptanmasında başarılı bir yöntem olup kas invazyonunun tanısal performansını artırmaktadır.

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Factors predicting biochemical recurrence following robot-assisted radical prostatectomy: single-center experience

Robot yardımcı radikal prostatektomi sonrasında biyokimyasal rekürrensi predikte eden faktörler: tek merkez deneyimi

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ÖZET

Amaç: Bu çalışmada uzun takip süresine sahip hastalarda Biyokimyasal Rekürrens (BCR) gelişimini predikte eden faktörleri araştırmayı hedefledik.

Gereç ve Yöntemler: Robot Yardımlı Radikal Prostatektomi (RARP) uygulanan 758 hastanın verileri geriye dönük olarak tarandı. Postoperatif dönemde prostat spesifik antijen (PSA) değerlerinin 0,2 ng/mL ve üzeri saptanması BCR olarak kabul edildi. BCR gelişmeyen grup Grup 1, BCR gelişen grup Grup 2 olarak sınıflandırıldı.

Bulgular: Ortalama yaş iki grup arasında benzerdi. BCR gelişen grupta PSA değerleri anlamlı oranda yüksek izlendi ($p<0,001$). BCR gelişen grupta biyopsi gleason skoru (GS), risk sınıflaması ve spesmene ait GS oranları anlamlı olarak yüksek izlendi (sırasıyla $p=0,02$, $p<0,001$, $<0,001$). BCR gelişen grupta pozitif cerrahi sınır (PSM), ekstra prostatik yayılım (EPE), seminal vezikül invazyonu (SVI) ve lenf nodu pozitifliği (LNI) oranları anlamlı olarak yüksek izlendi. Çok değişkenli analizlerde; PSA, risk sınıflaması, spesmene ait GS, PSM, SVI ve T evreleri anlamlı parametreler olarak izlendi.

Sonuç: BCR gelişimini predikte eden değerler PSA, risk sınıflaması, spesmene ait GS, PSM, SVI ve T evresidir. Bu konuda ortak kabul gören modellerin yaygınlaşması ile hasta yönetimi ve hasta beklentilerinin optimizasyonunun sağlanabileceği kanaatindeyiz.

Anahtar Kelimeler: robot yardımcı radikal prostatektomi, biyokimyasal rekürrens, prostat kanseri, PSA

ABSTRACT

Objective: In this study, we aimed to investigate factors predicting the development of biochemical recurrence (BCR) in our clinical experience with patients over a long follow-up.

Material and Methods: The data of 758 patients who underwent robot-assisted radical prostatectomy (RARP) were retrospectively reviewed. In the postoperative period, the prostate-specific antigen (PSA) value is measured as 0.2 ng/mL and above, regarded as biochemical recurrence (BCR). The non-BCR group was regarded as Group 1, and the BCR group as Group 2.

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This study was approved by the Ethics Committee of Health Science University, Ümraniye Training and Research Hospital (Approval Number: 233, Date: 23/06/2022). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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
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Results: The mean age was similar between the two groups. The PSA values were significantly higher in the group that developed BCR ($p<0.001$). The biopsy Gleason score (GS), risk classification, and specimen GS were significantly higher in this group ($p=0.02$, $p<0.001$, and $p<0.001$, respectively). The BCR group also had statistically significantly higher positive surgical margin (PSM), extraprostatic extension (EPE), seminal vesicle invasion (SVI), and lymph node invasion rates. According to the multivariate analyses, PSA, risk classification, specimen GS, PSM, SVI, and T stage were significant parameters in the prediction of BCR.

Conclusion: The parameters that predict the development were determined as the PSA value, risk classification, specimen GS, PSM, SVI, and T stage. The widespread adoption of commonly accepted methods will help achieve better patient management and optimize patient expectations.

Keywords: robot-assisted radical prostatectomy, biochemical recurrence, prostate cancer, PSA

INTRODUCTION

Prostate cancer (PCa) is the most common non-cutaneous cancer. It is the most common cause of cancer-related death in male patients (1). Biochemical recurrence (BCR) is relevant to metastasis and mortality and is observed at rates reaching 27% after radical prostatectomy (RP) (2–4). Although surgery is a good option, 4–25% of these cases progress to metastatic disease within 15 years (5). Therefore, identifying patients at high risk due to PCa and their early treatment may lead to better oncological outcomes. In addition, identifying cases at low risk of BCR will prevent unnecessary additional treatments (6, 7).

Many studies have been conducted, and models such as CAPRA score and Kattan nomograms have been established based on data obtained from large series to predict BCR (3, 8–11). The search for more predictive models has increasingly continued with the multiparametric magnetic resonance imaging (mp-MRI) technique and better identification of lesions, coupled with developments in nuclear medicine (9, 10). In this study, we aimed to investigate factors predicting the development of BCR in our clinical experience with patients over a long follow-up period.

MATERIAL AND METHODS

Patient Selection

After receiving approval from the local ethics committee (2022/233), the data of 758 patients who underwent robot-assisted RP (RARP) for PCa at Umraniye Training and Research Hospital between January 2016 and December 2020 were reviewed. Patients who performed preoperative radiotherapy or hormone therapy for PCa, and those with detected or suspected metastases during staging were not included in the study. Further excluded from the study were patients with a follow-up of less than 1 year, those with unavailable postoperative follow-up data, and those referred to adjuvant radiotherapy.

Preoperatively, a whole-body bone scan and cross-sectional abdominopelvic computed tomography were performed to evaluate the presence of metastasis among the patients determined to be moderate and high risk according to the risk classification. All the operations were undertaken using the da Vinci XI surgical systems® (Intuitive Surgical Inc., Sunnyvale, California, USA) and the Frankfurt technique described by Wolfram et al (12). Pneumoperitoneum was created with a Veress needle. A total of 5 ports were placed, one for the camera port, one for the assistant port, and three for the robot arms. All surgeries were performed transperitoneally. The operative stages were defined as; patient positioning, trocar placement, and robot docking. After these steps, dissection of the seminal vesicles and entering the extraperitoneal space were performed. Incision of the bladder neck was performed after ligating the dorsal venous complex. Finally, prostatic pedicles, neurovascular bundle preservation, and anastomosis were performed. Bilateral nerve-sparing surgery was performed in cases with preoperative potency and no suspicion of extraprostatic extension (EPE). According to the Partin nomogram, pelvic lymph node dissection was performed in cases with a risk of nodal metastasis greater than 5%.

The follow-up was performed in the first postoperative month, followed by every three months for two years and every six months after that. Whether they developed BCR, two groups were divided.

Data Collection

All the specimens were evaluated clinically and pathologically as stated as to the 2009 TNM classification of the "American Joint Committee on Cancer, seventh edition" (13). The patients were divided into classes low, moderate, and high-risk (14). A positive surgical margin (PSM) was defined as the presence of a tumor in the inked margins. The prostate specific antigen (PSA) value measured as 0.2 ng/mL and above in two consecutive measurements in the postoperative period was accepted as BCR. Any increase in the Gleason score (GS) from the biopsy result to the RP specimen result was considered a GS upgrade. In addition, the patients with a GS of 3+4 in biopsy and 4+3 in the RP specimen were accepted to have a GS upgrade.

Statistical Analysis

Numbers and percentages were used to show the categorical data. The mean and standard deviation values were used to show numerical data. The normality tests of numerical data were performed by using the Shapiro-Wilk test. Numerical data normally distributed were compared with the Student's t-test, and the Mann-Whitney U test was used to compare non-normally distributed numerical data. The categorical data were compared with the Pearson chi-square test. A p-value was regarded as significant at the <0.05 level. The univariate and multivariate binary logistic regression analyses were used to analyze factors predicting BCR development. Statistical analyses were done with the Statistical Package for the Social Sciences version 21 (IBM SPSS Statistics; IBM Corp., Armonk, NY).

RESULTS

Patient Characteristics

A total of 758 patients were included. Table 1 presents the demographic, preoperative, and postoperative data of the 98 (12.9%) patients that developed BCR and 660 (87%) patients that did not develop BCR. The mean age, body mass index, and American Society of Anesthesiologists score were similar. In the BCR group, the PSA values were significantly higher ($p < 0.001$). This group had significantly higher biopsy GS, risk classification, and specimen GS values. The PSM, EPE, the rate of the invasion of seminal vesicle (SVI), and lymph node (LNI) rates were different between groups. The mean follow-up duration of all the patients and the time to BCR in those that developed recurrence were calculated as 33.2 ± 14.3 months and 11.3 ± 10 months, respectively.

Univariate and Multivariate Analyses

In the univariate analysis, PSA, biopsy GS, risk classification, specimen GS, PSM, EPE, SVI, LNI, and T stage were determined to be significant parameters. In multivariate analysis, PSA, risk classification, specimen GS, PSM, SVI, and T stage were significant parameters predicting BCR (Table 2).

Table 1: Demographic and clinical data

	Total (n)	Non-BCR, n (%)	BCR, n (%)	p
Number of patients (mean \pm SD)	758	660 (87)	98 (12.9)	
Age (years)	63.3 \pm 6	63.1 \pm 4	64 \pm 7.3	0.233
BMI (kg/m ²)	27.4 \pm 2.3	27.3 \pm 3.4	27.6 \pm 3.7	0.633
PSA (ng/dL)	8.4 \pm 7	8.1 \pm 5.1	12.3 \pm 4.2	<0.001
PV (cc)	52 \pm 18.3	51.3 \pm 7.8	54 \pm 3.2	0.323
Biopsy GS				0.02
3+3	469 (61.8)	446 (67.5)	23 (23.4)	
3+4	159 (20.9)	139 (21)	20 (20.4)	
4+3	75 (9.8)	53 (8)	22 (22.4)	
4+4	48 (6.3)	20 (3)	28 (28.5)	
4+5	7 (0.9)	2 (0.3)	5 (5.1)	

Risk					<0.001
Low		576 (75.9)	535 (81)	41 (41.8)	
Moderate		110 (14.5)	82 (12.4)	28 (28.5)	
High		72 (9.4)	43 (6.5)	29 (29.5)	
Blood loss (cc)		170 ± 120	169.2 ± 110.3	173.4 ± 130 ± 2	0.745
Upgrade, n (%)		303 (39.9)	255 (38.6)	48 (48.9)	0.037
Specimen results, n (%)					<0.001
GS					
	3+3	298 (38.6)	289 (43.7)	9 (9.1)	
	3+4	323 (42.6)	300 (45.4)	23 (23.4)	
	4+3	93 (12.2)	60 (9)	33 (33.6)	
	4+4	22 (2.9)	7 (1)	15 (15.3)	
	4+5	22 (2.9)	4 (0.6)	18 (18.3)	
PNI		668 (88.1)	587 (87.5)	90 (91.8)	0.121
PSM		121 (15.9)	63 (9.5)	58 (59.1)	<0.001
EPE		233 (30.7)	172 (26)	61 (62.2)	<0.001
SVI		82 (10.8)	37 (5.6)	45 (45.9)	<0.001
T stage					<0.01
	2	454 (59.8)	412 (62.4)	42 (42.8)	
	3	289 (38.1)	255 (38.6)	34 (34.6)	
	4	15 (1.9)	3 (0.4)	12 (12.2)	
LNI		22 (2.9)	27 (3.5)	16 (16.3)	0.02
Follow-up duration (month)		33.2 ± 14.3	33 ± 17.2	35.2 ± 11.5	n/a
Time to BCR (month)		11.3 ± 10	11.4 ± 9.2	11 ± 10.3	n/a

SD: Standard deviation, BCR: Biochemical recurrence, BMI: Body mass index, PV: Prostate volume, GS: Gleason score, PNI: Perineural invasion, PSM: Positive surgical margin, EPE: Extraprostatic extension, SVI: Seminal vesicle invasion, LNI: Lymph node invasion

Table 2: Results of the univariate and multivariate analyses

	Univariate			Multivariate		
	HR	95% CI	P	HR	95% CI	P
PSA	1.233	1.103-1.444	0.03	1.502	1.470-1.602	0.037
Biopsy GS	2.112	1.077-4.322	0.04			
Risk	7.553	4.143-11.162	<0.001	4.278	2.165-6.244	0.025
Specimen results						
GS	2.774	1.278-4.322	0.01	1.322	1.032-3.228	0.041
PSM	9.997	7.163-13.554	<0.001	14.554	8.563-18.224	<0.001
EPE	6.554	5.322-8.133	0.012			
SVI	9.199	7.888-11.203	0.02	4.322	2.655-6.433	0.047
LNI	3.444	2.056-7.544	0.039			
T stage	3.555	2.465-6.233	0.01	4.588	3.988-6.122	0.048

HR: Hazards ratio, CI: Confidence interval, GS: Gleason score, PSM: Positive surgical margin, EPE: Extraprostatic extension, SVI: Seminal vesicle invasion, LNI: Lymph node invasion

DISCUSSION

The cancer control indicators following RP include pathologically organ-confined disease with negative margins, BCR, local invasion, metastases, and overall and cancer-specific survival (5). BCR is often the earliest marker of tumor recurrence after RP (15). The development of BCR after RP may be relevant to higher rates of metastasis and mortality (16). The rate of the BCR was 27% in a study with a 10-year follow-up after RP (17). Therefore, it is important to establish preoperative predictive models and risk classification systems for BCR.

After RP, the interval between BCR and metastasis development has been reported as 8 years, from metastatic disease to mortality as 5 years (15). BCR is one of the most important markers of mortality. For this reason, it is important to manage alternatives such as close follow-up and early intervention (18). In the last few decades, more recent models, e.g., the CAPRA score, have been developed to replace older methods, such as the Kattan nomograms and Han tables (8, 16, 19, 20). Researchers have also attempted to strengthen such models by integrating the findings from the developing mpMRI technology and molecular evaluations (10, 21–23).

Wald et al. revealed a correlation between early BCR, preoperative serum PSA levels, and specimen GS, PSM, EPE, SVI, and LNI (24). Another study on BCR showed that GS detected in the specimen and the pathological stage was closely related to BCR (25). Similarly, Tağcı et al. reported a relationship between LNI and early BCR (26) another study by Ekşi et al., risk classification, mpMRI findings, PSM, SVI, and T stage were noted as significant parameters predicting BCR (11). In our study, the multivariate analysis revealed PSA, risk classification, specimen GS, PSM, SVI, and T stage to be the predictive parameters of BCR. In addition to the nomograms established for this purpose, more advanced algorithms can be created by integrating artificial intelligence and machine learning methods into hospital information systems (5, 11). We consider that as the external validation of such created models is undertaken and current knowledge increases, there will be more common and widely accepted models that can predict BCR.

The large scope of our patient selection criteria and the relatively adequate follow-up period in terms of BCR development are the main advantages. The retrospective nature is the main limitation of our study.

CONCLUSION

The parameters that predicted the development of BCR in the postoperative period in the patients who underwent RARP for PCa were determined as PSA, risk classification, specimen GS, PSM, SVI, and T stage. The widespread use of commonly accepted methods will help achieve better patient management and optimize patient expectations.

Conflict of Interest: The authors declare to have no conflicts of interest.

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Ethical Approval: The study was approved by the Ethic Committee of Health Science University, Ümraniye Training and Research Hospital (Approval Number: 233, Date: 23/06/2022). The study protocol conformed to the ethical guidelines of the Helsinki Declaration.

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Comparison of conventional and castroviejo needle holders in terms of vascular anastomosis time in renal transplant

Böbrek naklinde vasküler anastomoz zamanı açısından konvansiyonel portegü ile castroviejo portegünün karşılaştırılması

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ÖZET

Amaç: Renal vasküler yapıların anastomoz süresinin uzamaması, sıcak ve soğuk iskeminin potansiyel zararlı etkisini en aza indirmek adına önemlidir. Çalışmamızın amacı, renal transplantasyon esnasında vasküler anastomozda kullanılan portegü tasarımının, anastomoz süresine olan etkisini belirlemektir.

Gereç ve Yöntemler: Eylül 2011 ve Şubat 2020 tarihleri arasında kliniğimizde yapılan böbrek nakli vakaları retrospektif olarak incelendi. Anastomozlarda kullanılan iki tip portegüye göre hastalar gruplara ayrıldı. Grup 1'de konvansiyonel tipte, Hegar tipi makas tutucusuna sahip Ryder Diadust, düz, 180mm (7") portegü kullanılmıştır. Grup 2'de, kalem portegü tipinde, Castroviejo Durogrip TC Micro Needle Holder, düz, 215mm (8 ½") kullanılmıştır. Her iki grup arasında demografik özellikler, vasküler karakteristikler ve vasküler anastomoz süreleri karşılaştırılmıştır.

Bulgular: Toplam 75 hasta çalışmaya dahil edildi. Grup 1'de toplam 39 (52%), Grup 2'de 36 (48%) hasta mevcuttu. Tüm hasta grubunda ortalama arter sayısı $1,2 \pm 0,4$, ortalama arter çapı $5,3 \pm 1,2$ mm bulunmuş olup, her iki grup arasında bu değerler arası istatistiksel anlamlı fark yoktu ($p=0,196$ ve $0,304$, sırasıyla). Ortalama arteryal anastomoz süresi Grup 1'de $15 \pm 5,1$, Grup 2'de $10 \pm 3,9$ dakikadır. Ortalama venöz anastomoz süreleri ise Grup 1'de $18,4 \pm 6,1$ ve Grup 2'de $14,7 \pm 4$ dakikadır. Yapılan istatistiksel analizde Grup 2'de arteryal ve ven anastomoz sürelerinin anlamlı olarak Grup 1'den daha kısa olduğu bulunmuştur ($p= 0,038$ ve $p= 0,020$, sırasıyla).

Sonuç: Çalışmamızda, renal transplant esnasında yapılan anastomozda kalem tipi Castroviejo portegü kullanılan grupta renal arteryal ve venöz anastomoz sürelerinin anlamlı olarak daha kısa olduğu bulunmuştur.

Anahtar Kelimeler: böbrek nakli, vasküler anastomoz, portegü

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This study was approved by the Ethics Committee of University of Health Sciences, Dr.Sadi Konuk Training and Research Hospital Ethical Committee (Approval Number: 2022-12-17, Date: 20/06/2022). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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ABSTRACT

Objective: It is important that the anastomosis time of renal vascular structures is not prolonged to minimize the potentially harmful effect of warm and cold ischemic times. This study aimed to determine the effect of the needle holder design used in vascular anastomosis during renal transplantation on the duration of anastomosis.

Material and Methods: Patients that underwent renal transplantation at our clinic between September 2011 and February 2020, were divided into groups according to the two types of needle holders used in anastomoses. In Group 1, a conventional, Hegar-type, straight, 180-mm (7") Ryder Diadust needle holder was used. In Group 2, a pen-type, straight, 215-mm (8 ½") Castroviejo Durogrip TC micro needle holder was used. Demographic characteristics, vascular characteristics, and vascular anastomosis times were compared between the two groups.

Results: A total of 75 patients were included in the study. There were 39 (52%) patients in Group 1 and 36 (48%) patients in Group 2. The mean number of arteries was 1.2 ± 0.4 , and the mean arterial diameter was 5.3 ± 1.2 mm in the whole cohort, with no statistically significant difference between the two groups ($p=0.196$ and 0.304 , respectively). The mean arterial anastomosis time was 15 ± 5.1 minutes in Group 1 and 10 ± 3.9 minutes in Group 2. The mean venous anastomosis times were 18.4 ± 6.1 in Group 1 and 14.7 ± 4 minutes in Group 2. In the statistical analysis, the arterial and vein anastomosis times were found to be significantly shorter in Group 2 than in Group 1 ($p=0.038$ and $p=0.020$, respectively).

Conclusion: In our study, it was observed that the renal arterial and venous anastomosis times were significantly shorter in the group in which the pen-type Castroviejo needle holder was used in anastomoses performed during renal transplantation.

Keywords: renal transplant, vascular anastomosis, needle holder

INTRODUCTION

During renal transplantation, the warm ischemia period in which the kidney is removed from ice but reperfusion is not yet achieved is called anastomosis time. Previous studies have shown that a prolonged anastomosis time has a negative effect on delayed graft function (DGF) (1-3).

Ensuring the successful anastomosis of blood vessels is critical in many modern surgical procedures. It is usual to perform vessel anastomosis not only for organ transplants but also for other procedures, such as post-traumatic vessel repairs and free tissue transfers under a microscope (4). It is important that the anastomosis time of renal vascular structures is not prolonged to minimize the potentially harmful effect of warm and cold ischemic times. The success of anastomosis depends on the meticulous application of the technique with appropriate tools (1). The needle holder should be suitable for the suture size and depth (5). Choosing the right surgical instrument has the potential to be an influencing factor in surgical success.

With the evolution of modern surgical techniques, the importance of the design of surgical instruments has increased (6). The physical differences of surgeons require the design of instruments in a wide range of power and size, which is further necessitated by the increased risk of musculoskeletal diseases due to occupational reasons (7). The choice of size for the needle holder depends on the purpose and size of the suture, and the surgeon's preference. Although there are only limited studies on the effect of the needle holder design on the surgical technique, the Frimand needle holder has been shown to reduce suturing time and surgical stress in the experimental setting (8).

This study aimed to determine the effect of the needle holder design used in vascular anastomosis during renal transplantation on the duration of anastomosis.

MATERIAL AND METHODS

Patients that underwent renal transplantation at our clinic between September 2011 and February 2020 were retrospectively evaluated and included in the study. The study included cases in which venous anastomosis to the external iliac vein and arterial anastomosis to the external iliac artery had been performed. Patients that did not undergo primary renal transplantation and those with autosomal dominant

polycystic kidney disease, concomitant native nephrectomy, or vascular pathologies that would seriously affect the anastomosis were excluded from the study. In addition, patients who underwent end-to-end vascular anastomosis were excluded from the study. In addition to the demographic characteristics of the patients, the number of graft vessels, and the duration of arterial and venous anastomoses were recorded. The mean diameter of an artery was calculated by summing the diameters of all arteries and dividing the result by the total number of arteries. The mean anastomosis time of an artery was calculated by summing the anastomosis times of all arteries and dividing the result by the total number of arteries. The mean arterial anastomosis time per mm arterial diameter was determined by dividing the mean anastomosis time by the mean arterial diameter. The venous anastomosis time and the mean venous anastomosis time per mm vessel diameter were calculated in a similar manner. The arterial anastomosis time was defined as the time taken to perform the anastomosis of the renal artery to the external iliac artery, and the venous anastomosis time as the time taken to perform the anastomosis of the renal vein to the external iliac vein.

Two types of needle holders were used in anastomoses, and the patients were divided into two groups accordingly. In Group 1, a conventional, Hegar-type, straight, 180-mm (7") Ryder Diadust needle holder was used. In Group 2, a pen-type, straight, 215-mm (8 ½") Castroviejo Durogrip TC micro needle holder was used. Demographic characteristics, vascular characteristics, and vascular anastomosis times were compared between the two groups.

Surgical Technique:

Our transplant team consisted of four people, two working on donor nephrectomy and two on the recipient transplant procedure. Living donor nephrectomies were performed laparoscopically via the transperitoneal route. All the kidneys evaluated in the study, including those of cadaveric origins were left kidneys. All the graft kidneys were placed retroperitoneally in the right iliac fossa. The kidney transplant procedure was performed by two surgeons (A.F.G., S.K.) and both were experienced in the use of both needle holders. The preference for the use of needle holders was determined according to the personal preferences of the surgeons on a case-by-case basis.

Incision Site and Length

Epilation was performed with a shaver on the morning of the surgery. After the patient was placed on the operating table, povidone iodine was used with a sponge for the first wash, and regular povidone iodine was used twice for the final preparation. The incision started from the point where the angle formed by the transverse line drawn from the navel and the umbilical-spina iliaca anterior superior line intersected the lateral side of the rectus muscle, as previously described in the literature (9).

The epigastric arteries in all patients and the round ligament in women were usually dissected to allow exposure, but the spermatic cord was protected by retracting it medially by releasing the border of the inguinal canal. Penetration into the peritoneal cavity was avoided, and any opening in the peritoneum was repaired before continuing with the incision. Strict bleeding control was applied before the kidney was placed. After entering the retroperitoneal space and revealing the anatomy of the iliac vessels and confirming their suitability for transplantation, the vessels were prepared by ligating all lymphatics.

Anastomosis

After preparing the implantation site, the graft was placed in its temporary position for the better evaluation of the anastomotic site. The external iliac artery and external iliac vein were used as the first choice in vascular anastomoses. To prevent twisting or rotation, vessel clamps were used after confirming the exact length and position of the anastomotic site. The Bulldog clamp was preferred for the internal iliac artery and vein, and the Satinsky clamp for the side clamping of the external iliac and common iliac arteries. Heparinized isotonic solution was used for vascular irrigation. For end-to-side anastomosis, the lower corner of the graft artery was spatulated. Arterial anastomosis was started by placing sutures at two corners, as described by Carrel and Gutrie in 1905 (10). Posterior arterial anastomosis was performed firstly. Since the needle is considered to be weaker than the host artery, the needle was passed from inside to

outside in the renal artery and from outside to inside in the host artery to prevent intimal separation. Then, the posterior layer was sutured, and anterior layer anastomosis was started from both corners. The entire anastomosis procedure was performed circumferentially with a single proximal corner suture. 6-0 Prolene sutures were used for venous and arterial anastomoses. Ureteral anastomosis was performed with the extravesical modified Lich-Gregoir technique.

Categorical data were presented as numbers and percentages. Data on continuous variables were presented as mean and standard deviation. Normally distributed data were compared between the two groups using the dependent-samples t-test, and non-normally distributed data using the Mann-Whitney U test. Frequencies of categorical variables were compared using the Pearson chi-square test. A p value of <0.05 was considered statistically significant. Statistical analyses were performed using the Statistical Package for the Social Sciences version 21 (IBM SPSS Statistics; IBM Corp., Armonk, USA).

RESULTS

After applying the inclusion and exclusion criteria, a total of 75 patients were included in the study. The patients' demographic data, arterial characteristics, and anastomosis times are given in Table 1. The mean age of the patients was 38.7 ± 13.3 years. Fifty (66.7%) patients were male and 25 (33.3%) were female. There were 39 (52%) patients in Group 1 and 36 (48%) in Group 2. There was no significant difference between the two groups in terms of age and gender ($p = 0.103$ and $p = 0.148$, respectively). The mean number of arteries was 1.2 ± 0.4 , and the mean arterial diameter was 5.3 ± 1.2 mm in the whole cohort, with no significant difference between the two groups ($p = 0.196$ and 0.304 , respectively). The mean arterial anastomosis time was 15 ± 5.1 minutes in Group 1 and 10 ± 3.9 minutes in Group 2. The mean venous anastomosis times were 18.4 ± 6.1 minutes in Group 1 and 14.7 ± 4 minutes in Group 2. In the statistical analysis, the arterial and venous anastomosis times were found to be significantly shorter in Group 2 than in Group 1 ($p = 0.038$ and $p = 0.020$, respectively).

Table 1. The patients' demographic data, arterial characteristics, and anastomosis times

Parameters (mean \pm SD)	Total n = 75	Conventional needle holder n = 39 (52%)	Castroviejo needle holder n = 36 (48%)	p
Age (years)	38.7 ± 13.3	41.7 ± 13.8	35.5 ± 12.2	0.103*
Gender (n ; %)				0.148"
Male	50 (66.7)	28 (71.8)	22 (61.1)	
Female	25 (33.3)	11 (28.2)	14 (38.9)	
Number of arteries	1.2 ± 0.4	1.1 ± 0.3	1.2 ± 0.5	0.196*
Arterial diameter (mm)	5.3 ± 1.2	5.1 ± 0.8	5.5 ± 1.6	0.304*
Arterial anastomosis + (min)	11 ± 4.2	15 ± 5.1	10 ± 3.9	0.038 [§]
Venous anastomosis + (min)	16.6 ± 5.5	18.4 ± 6.1	14.7 ± 4	0.020 [*]

*Independent-samples t-test "Chi square & Mann-Whitney U test + presented as median (interquartile range)

DISCUSSION

In renal transplant, the duration of cold ischemia is one of the most important risk factors for DGF, inferior graft survival and function (11). However, until recently, only little was known concerning the effects of warm ischemia time on both short-term and long-term renal allograft function (12). It is suggested that warm ischemia time plays a key role in DGF after renal transplantation with both cadaveric and living donor procedures (2,3). Warm ischemia time refers to two different periods in the transplantation process: the first is related to organ harvesting and the second is related to the time of vascular anastomosis in the recipient. The temperature of the graft can rise rapidly to the metabolic threshold of 15 °C within 20 minutes of removing the kidney from ice. The heating of the graft increases cellular metabolism and leads to potentially

harmful changes in the transplanted kidney (13). DGF is important since it may lead to longer hospital stay and need for dialysis, resulting in impaired renal allograft function and shorter survival (12). In the literature, the most important evidence is related to the detrimental effect of warm ischemia time on renal function in partial nephrectomy (14). In a study examining the partial nephrectomy of solitary kidneys, it was found that each minute of warm ischemia was associated with a 6% increase in the risk of acute kidney injury and a 4% increase in the risk of new-onset end-stage renal disease (15). In the current study, we examined the arterial and venous anastomosis times separately rather than directly evaluating the warm ischemia time or anastomosis time. We determined that both arterial and venous anastomosis times were significantly shorter in the group where the pen-type Castroviejo needle holder was used compared to the conventional needle holder group.

Conventional needle holders are based on scissor configuration, and although this is sufficient in standard operations, it may be insufficient in cases requiring deep and narrowly located vascular and plastic suturing. A conventional needle holder can only be comfortably rotated up to 180° in the hand, and squeezing and unwinding the needle cause the momentary loss of control. This creates a serious handicap in cases like vascular anastomosis (16).

The Webster needle holder, which has a similar design to the Ryder Diadust needle holder we utilized in our study, uses the wrist that supinates between the supinator and external muscles and the radius and ulna, much like holding a fork. On the contrary, a pen needle holder (e.g., Castroviejo needle holder) requires finger twisting between the thumb and index finger and the inner and outer muscles of the middle finger, just like holding a pen or sticks, and it consists an important role mainly in microsurgery (17). It is designed for smooth and fine stitching, as there is less forearm muscle movement due to easy finger bending. The Castroviejo needle holder was patented in 1953 by Ramón Castroviejo, an ophthalmologist to be used for the above-mentioned purposes. The needle holder was originally designed to meet the need for fine instruments in ophthalmological procedures (18). The Hegar type consists of a forceps handle similar to the ends of a conventional needle holder, but the movement of the handle is reversed by the "X" configuration (16). In the locked position, it relieves tension on the fingers during needle manipulation. In the unlocked position, the needle holder is still able to hold objects under certain pressures. In addition, the Castroviejo needle holder can be easily rotated through wrist and finger manipulations (18). Compression tension is sufficient to hold the needle during normal suturing and will only loosen when subjected to unusual pressure that can bend or break the needle (16). The narrow handle occupies less space and allows for the stitched area to be seen more easily, and another advantage of this instrument is that it can be easily used with either hand.

To the best of our knowledge, there are very few studies in the literature comparing needle holder types in terms of anastomosis time and ergonomics. Ohata et al. compared pen-type and Hegar-type needle holders electromyographically in terms of forearm mobility during skin suturing (17). In that study, the microsurgeons were reported to perform less forearm movements with the pen needle holder, but the authors noted that this group was more experienced with this type of needle holder. Less experienced microsurgeons were accustomed to the webster type needle holders and had to do more forearm movement with the pen needle holder. They attributed this to 'motor skill learning'; i.e., the ability to use the tool almost automatically, without engaging attention or working memory, since they practiced it for a long time (19,20). This shows the importance of instrumentation habits of the surgeon as well as the design of the instrument. However, the surgeons in our study were proficient in both types of needle holders, which partially eliminates the experience variable in the comparison of anastomosis times.

Averay et al. investigated whether the type of needle holder had an effect on anastomotic construction time in an equine cadaver model. In end-to-end jejunojejunal anastomosis, they compared three needle holders (16.5 cm Frimand, 16 cm Mayo-Hegar, and 20.5 cm Mayo-Hegar) and stated that there was no significant difference in anastomosis times (21). The Frimand needle holder showed greater consistency in construction and suture times. In another article, it was reported that the design of the grip part of the

needle holder improved suturing performance, increased comfort, and reduced difficulties by providing a more appropriate wrist posture (5). There are also authors suggesting that more simulation and skill laboratory practice may be beneficial for surgeons to gain sufficient expertise prior to clinical practice in order to reduce anastomosis time and increase efficacy (11).

Our study has certain limitations, with two most important are its retrospective nature and limited number of patients. However, since the operations evaluated in our study were performed by two surgeons at a single center, the homogeneity of the cases made the comparison more significant despite the poor generalizability of the findings. In addition, since the choice of a needle holder will affect the anastomosis time depending on the operator's preference and experience, our results do not necessarily reveal the superiority of one instrument over the other. Lastly, the design of our study does not reflect the early and late effects of the difference in instrumentation on graft outcomes.

CONCLUSION

In our study, it was observed that the renal arterial and venous anastomosis times were significantly shorter in the group using a pencil type Castroviejo needle holder for anastomosis during kidney transplantation, compared to the group using a conventional needle holder. Shorter anastomosis times have the potential to reduce the duration of warm ischemia, and thus positively affect graft function. Further studies are needed in this regard.

Conflict of Interest: The authors declare to have no conflicts of interest.

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Ethical Approval: The study was approved by the Ethics Committee of University of Health Sciences, Dr.Sadi Konuk Training and Research Hospital (Decision No: 2022-12-17, Date: 20.06.2022). The study protocol conformed to the ethical guidelines of the Helsinki Declaration.

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Aim&Scope

Amaç ve Kapsam

Amaç

Endoüroloji Bülteni, Endoüroloji Derneği' nin bilimsel, hakemli, açık erişimli yayınıdır. Derginin mali giderleri Endoüroloji Derneği tarafından karşılanmaktadır. Topluluğumuz kar amacı gütmemekte; üroloji alanında akademik eğitim standartları yükseltmeyi, teknik bilimsel ve sosyal etkinlikler ile ulusal ve uluslararası kurumlar arası etkileşimi arttırmayı hedeflemektedir. Dergi yılda 3 sayı olarak, Ocak, Mayıs ve Eylül aylarında yayınlanır.

Derginin yayın dili Türkçe ve İngilizcedir. Tüm yazıların başlık ve özetleri hem İngilizce hem Türkçe olarak yayınlanır.

Endoüroloji Bülteni' nin amacı bilimsel kaliteli araştırma makaleleri, derlemeler, editöre mektuplar, vaka raporları ve cerrahi teknik raporlarına ek olarak, üroloji ile ilişkili cerrahi öyküsü, etik, cerrahi eğitim, adli tıp alanlarında çeşitli makaleler yayınlayarak literatüre katkıda bulunmaktır.

Bültenin hedef okuyucusu öncelikle üroloji – alt branş uzman ve tıpta uzmanlık öğrencileri (yan dal öğrencileri) olmakla birlikte, sağlık bilimlerinin diğer branşlarındaki ve genel tıp uzmanlarından üroloji ile ilgilenen hekimlerdir. Ayrıca ürolojinin ilişkili olduğu tıp dışı bilimlerden uzman ve öğrenciler de Endoüroloji Bülteni' nin doğal paydaşlarıdır.

Kapsam

Endoüroloji Bülteni'nde, yüksek bilimsel kalitede araştırma makaleleri, nadir karşılaşılan olgu sunumları, karşıtlık makaleleri, editöre mektup, konusunda uzman kişilerce hazırlanmış güncel literatür hakkındaki derlemeler, cerrahi teknikleri içeren video yazılar ve Endoüroloji alanında dünyaca bilinirliği olan kişiler tarafından hazırlanan güncel ve gelecekteki pratiğe yönelik yorumlar yayınlanır.

Endoüroloji Bülteni, üroloji ve ürolojiyi ilgilendiren konularda orijinal makaleleri, olgu sunumlarını ve derlemeleri yayın için kabul eden hakemli bir dergidir.

Endoüroloji Bülteni, Endoüroloji Derneği'nin yayın organıdır. Dergi yılda 3 sayı olarak, Ocak, Mayıs ve Eylül aylarında yayınlanır.

Endoüroloji Bülteni; bağımsız, tarafsız ve çift-kör değerlendirme ilkelerine sahip uluslararası, bilimsel, açık erişim, çevrimiçi bir dergidir.

Endoüroloji Bülteni' nin dili Türkçe ve İngilizcedir.

Derginin editöryal ve yayın süreçleri, Uluslararası Tıp Dergisi Editörleri Komitesi (ICMJE), Dünya Tıp Editörleri Birliği (WAME), Yayın Etiği Komitesi (COPE) ve Avrupa Bilim Editörleri Birliği (EASE) kurallarına uygun olarak şekillenmektedir. Dergi, İnsan gönüllüleri üzerinde yapılan tıbbi araştırmalarda Etik İlkeler konusunda Dünya Tıp Birliği (WMA) Helsinki Bildirgesi' ne uygun olarak yayın yapmaktadır. Bilimsel Yayıncılıkta Şeffaflık ve En İyi Uygulama İlkelerine uygundur (doaj.org/bestpractice).

Dergide yayınlanan yazılarda yer alan ifadeler veya görüşler Endoüroloji Derneği, editörler, yayın kurulu ve / veya yayıncının görüşlerini değil, yazarın görüşlerini yansıtır. Editörler, editörler kurulu ve yayıncı, bu tür materyaller için herhangi bir sorumluluk kabul etmemektedir.

Dergiye yazı göndermek, bunların işlenmesi ve yayınlanması ücretsizdir. Değerlendirme ve yayın sürecinde yazarlardan herhangi bir ücret talep edilmez.

Yayınlanan tüm içeriğe <https://endourolojibulteni.com/category/arsiv/> adresinden ücretsiz olarak erişilebilir.

Dergiye gönderilecek tüm yazılar, www.dergipark.gov.tr/tr/pub/endouroloji adresinde bulunan çevrimiçi başvuru sistemi aracılığıyla sunulmalıdır. Dergi kuralları, teknik bilgiler ve gerekli formlar da aynı sayfada bulunabilir.

Endoüroloji Derneği, dergide yayınlanan tüm içeriğin ulusal ve uluslararası telif hakkına sahiptir.

Dergi dijital ortamda online yayınlanmaktadır.

Bülten ile ilgili tüm işlemler ve yayın ücretsizdir. Değerlendirme ve yayın sürecinde yazarlardan herhangi bir ücret talep edilmez.

Aim

Endourology Bulletin is a scientific, referred, open access publication of the Endourology Society. Society is a non-profit organization, and it aims to increase the standards in the field of urology, including the education of academicians, professionals, and the public. The society also aims to create or make contributions to the development of technical, scientific, and social facilities. For this purpose, it also cooperates with any related institutions, organizations, foundations, and societies from the national and international areas.

The Endourology Society covers the journal's financial expenses. The journal is published three times a year- in January, May, and September, respectively, and the journal's language is Turkish and English.

The purpose of the Endourology Bulletin is to contribute to the literature by publishing urological manuscripts such as scientific articles, reviews, letters to the editor, case reports, reports of surgical techniques, surgical history, ethics, surgical education, and articles of forensic medicine.

The target group of the journal consists of academicians working in the field of urology, urologists, residents of urology, and all other fields of expertise and practitioners interested in urology.

Urology specialists, medical specialty fellows, and other specialists interested in the field of urology are the journal's target audience.

Scope

All published content is available for free at www.dergipark.gov.tr/en/pub/endouroloji.

All manuscripts submitted to the journal should be submitted through the online application system available at www.dergipark.gov.tr/en/pub/endouroloji.

Instructions for authors, including technical information and required forms, can be found at the journal's website www.dergipark.gov.tr/en/pub/endouroloji.

Editorial and publication processes of the journal are shaped following the guidelines of the international organizations such as the [International Council of Medical Journal Editors \(ICMJE\)](#), the [World Association of Medical Editors \(WAME\)](#), the [Council of Science Editors \(CSE\)](#), the [Committee on Publication Ethics \(COPE\)](#), the [European Association of Science Editors \(EASE\)](#).

The journal conforms with Principles of Transparency and Best Practice in Scholarly Publishing (doaj.org/bestpractice).

The statements and/or opinions indicated in the articles published at the journal reflect the author's views, not the opinions of the editors, editorial board and/or the Endourology Society; Editors and publishers do not accept any responsibility for such materials.

No fee is required for submitting articles, evaluating, processing, or publishing the authors.

The Endourology Society has national and international copyright to all content published in the journal.

The journal is published online.

Author Guidelines

Yazarlara Bilgi

Yazarlar, Endüroloji Bülteni'ne bir makale gönderirken makalelerinin telif hakkını dergiye vermeyi kabul etmiş sayılır. Eğer yazarın çalışmasının basılması reddedilirse, yazının telif hakkı yazarlara geri verilir.

Dergi, yazarların yayın haklarını kısıtlama olmaksızın saklamasını sağlar.

Yazarların kimlik bilgileri ve e-posta adresleri hiçbir şekilde başka amaçlar için kullanılmamaktadır.

Gönderilen yazıların daha önce yayınlanmamış olması veya başka bir dergide değerlendirme aşamasında olmaması gerekmektedir.

Gönderilen yazılar herhangi bir kongrede takdim edilmiş ise bu durum gönderilen makalede dipnot olarak bildirilmelidir.

Derginin Yayın Kurulu, tüm itirazları Yayın Etik Komitesi (COPE <https://publicationethics.org/resources/flowcharts/handling-post-publication-critiques>) kuralları çerçevesinde ele alır. Bu gibi durumlarda, yazarlar temyiz ve şikayetleri ile ilgili olarak yayın kuruluyla doğrudan iletişime geçmelidir. Gerekli olduğunda, dahili olarak çözülemeyen sorunları çözmek için bir ombudsman atanabilir. Editör, tüm temyiz ve şikayetler için karar verme sürecindeki nihai otoritedir.

Derginin editöryal ve yayın süreçleri, International Council of Medical Journal Editors (ICMJE <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/>) yönergelerine göre şekillendirilmektedir.

Endüroloji Bülteni yayıncılıkta şeffaflık ve en iyi uygulama ilkelerine uygundur (DOAJ <https://doaj.org/apply/transparency/>).

Bir yazının yayın için kabul edilmesinde en önemli kriterler özgünlük, yüksek bilimsel kalite ve alıntı potansiyelinin varlığıdır.

Dergide yayınlanmak üzere gönderilen yazılar, daha önce başka bir yerde yayınlanmamış ve yayınlanmak üzere gönderilmemiş olmalıdır. Bir kongrede tebliğ edilmiş ve özeti yayınlanmış çalışmalar organizasyonun adı, yeri ve tarihi belirtilmek şartı ile kabul edilebilir.

Deneysel, klinik, ilaç çalışmalarının ve bazı vaka raporlarının araştırma protokollerinin Etik Kurul tarafından uluslararası sözleşmelere uygun olarak onaylanması (Dünya Tıp Birliği Helsinki Deklarasyonu "İnsan Denekleri ile İlgili Tıbbi Araştırmalar İçin Etik İlkeler" <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>) gereklidir. Gerekli görülmesi halinde yazarlardan etik kurul raporu veya bu rapora eşdeğer olan resmi bir yazı istenebilir.

- Üzerinde deneysel çalışma yapılan gönüllü kişilere ve hastalara uygulanan prosedürler ve sonuçları anlatıldıktan sonra onaylarının alındığını ifade eden bir açıklama yazının içinde bulunmalıdır.
- Hayvanlar üzerinde yapılan araştırmalarda acı ve rahatsızlık verilmemesi için yapılan uygulamalar ve alınan tedbirler açık olarak belirtilmelidir.
- Hasta onamı, etik kurulun adı, etik kurul toplantı tarihi ve onay numarası ile ilgili bilgiler makalenin "Gereç ve Yöntem" bölümünde de belirtilmelidir.
- Hastaların gizliliğini korumak, yazarların sorumluluğundadır. Hasta kimliğini ortaya çıkarabilecek fotoğraflar için, hasta ve/veya yasal temsilcileri tarafından imzalanan onayların alınması ve yazılı onay alındığının metin içerisinde belirtilmesi gereklidir.

Dergimize gönderilen tüm yazılar intihal tespit etme programı (iThenticate) ile değerlendirilmektedir. Benzerlik oranının %20 ve altı olması önerilmektedir.

Derginin Yayın Kurulu, tüm itirazları Yayın Etik Komitesi (COPE) kuralları çerçevesinde ele alır. Bu gibi durumlarda, yazarlar temyiz ve şikayetleri ile ilgili olarak yayın kuruluyla doğrudan iletişime geçmelidir. Gerekli olduğunda, dahili olarak çözülemeyen sorunları çözmek için bir ombudsman (bağımsız denetçi) atanabilir. Baş Editör, tüm temyiz ve şikayetler için karar verme sürecindeki nihai otoritedir.

Yazarlar, Endüroloji Bülteni'ne bir makale gönderirken makalelerinin telif hakkını dergiye vermeyi kabul etmiş sayılır. Eğer yazarın çalışmasının basılması reddedilirse, yazının telif hakkı yazarlara geri verilir.

Endüroloji Bülteni'ne gönderilen her makale, adı geçen yazarların tümünün imzaladığı yazar katkı ve yayın hakları devir formu ile birlikte gönderilmelidir. (<https://dergipark.org.tr/tr/journal/3154/file-manager/17373/download>)

Şekiller, tablolar veya hem basılı hem de elektronik formatlardaki diğer materyaller de dahil olmak üzere başka kaynaklardan alınan içeriği kullanan yazarların telif hakkı sahibinden izin almaları gerekir. Bu husustaki hukuki, mali ve cezai sorumluluk yazarlara aittir. Endüroloji Bülteni'nde yayınlanan yazılarda belirtilen ifadeler veya görüşler yazarlara aittir. Editörler, editörler kurulu ve yayıncı, bu yazılar için herhangi bir sorumluluk kabul etmemektedir. Yayınlanan içerikle ilgili nihai sorumluluk yazarlara aittir.

Author Guidelines

Authors' credentials and e-mail addresses are not used for other purposes.

The submitted articles should be previously unpublished and should not be under consideration by any other journal.

If whole or a part of the submitted articles are presented in any congress, this should be noted in the submitted article.

The journal's Editorial Board handles all appeal and complaint cases within the scope of Committee on Publication Ethics (COPE) guidelines. In such cases, authors should contact the editorial office directly regarding their appeals and complaints. When needed, an ombudsperson may be assigned to resolve cases that cannot be resolved internally. The Editor in Chief is the final authority in the decision-making process for all appeals and complaints.

The editorial and publication processes of the journal are shaped following the guidelines of the International Council of Medical Journal Editors (ICMJE).

The journal conforms to the Principles of Transparency and Best Practice in Scholarly Publishing (DOAJ).

Originality, high scientific quality, and citation potential are the most important criteria for a manuscript to be accepted for publication. Manuscripts submitted for evaluation should not have been previously presented or already published in an electronic or printed medium. Manuscripts presented in a meeting should be submitted with detailed information on the organization, including the name, date, and location of the organization.

An approval of research protocols by the Ethics Committee following international agreements (World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects") is required for experimental, clinical, and drug studies and some case reports. If required, ethics committee reports or an equivalent official document will be requested from the authors.

- For manuscripts concerning experimental research on humans, a statement should be included that shows that written informed consent of patients and volunteers was obtained following a detailed explanation of the procedures they may undergo.
- For studies carried out on animals, the measures taken to prevent pain and suffering of the animals should be stated clearly.
- Information on patient consent, the name of the ethics committee, and the ethics committee approval number should also be stated in the Materials and Methods section of the manuscript.
- It is the authors' responsibility to protect the patients' anonymity carefully. For photographs that may reveal the identity of the patients, releases signed by the patient or their legal representative should be enclosed.

All submissions are screened by a similarity detection software (iThenticate), and the limitation without similarity is 20%.

When submitting a manuscript to Endourology Bulletin, authors accept to assign the copyright of their manuscript to the journal. If rejected for publication, the manuscript's copyright will be assigned back to the authors. Endourology Bulletin requires each submission to be accompanied by an Author Contribution&Copyright Transfer Form (available for download <https://dergipark.org.tr/>). Authors must obtain permission from the copyright holder when using previously published content, including figures, tables, or any other material in both print and electronic formats. In this regard, legal, financial, and criminal liabilities belong to the author (s).

Statements or opinions expressed in the manuscripts published in Endourology Bulletin reflect the author's views (s) and not the opinions of the editors, the editorial board, or the publisher; the editors, the editorial board, and the publisher disclaim any responsibility or liability for such materials. The final responsibility regarding the published content rests with the authors.

PREPARATION OF MANUSCRIPT

YAZININ GÖNDERİMİ

Makaleler yalnızca online olarak <https://dergipark.org.tr/pub/endouroloji> adresinden gönderilebilir. Başka bir yolla gönderilen yazılar değerlendirilmeye alınmayacaktır.

Dergiye gönderilen yazılar, öncelikle yazının dergi kurallarına uygun olarak hazırlanmasını ve sunulmasını sağlayacakları teknik değerlendirme sürecinden geçer. Derginin kurallarına uymayan yazılar, teknik düzeltme talepleri ile gönderen yazara iade edilir. Editör, ana metni değiştirmeden düzeltme yapabilir. Editör, yukarıda belirtilen şartlara uymayan makaleleri reddetme hakkını saklı tutar.

Yazarların aşağıdaki belgeleri göndermeleri gerekir:

- Yazar katkı ve Yayın Hakkı Devir Formu
- Bilgilendirilmiş Onam Formu
- ICMJE Çıkar Çatışması Formu
- Başlık Sayfası (Makale Başlığı, kısa başlık, yazarın adı, unvanı ve kurumu, sorumlu yazarın iletişim bilgileri, araştırmayı destekleyen kuruluş varsa kuruluşun adı)
- Ana belge (Tüm makalelerde, ana metinden önce de Özet bölümü yer almalıdır)
- Şekiller (JPEG formatı)
- Tablolar (en fazla 6 tablo)

Ana Belgenin Yayına Hazırlığı

Yazılar bilgisayar ile çift aralıklı olarak 12 punto büyüklüğünde ve Times New Roman karakteri ile yazılmalıdır. Her sayfanın bütün kenarlarında en az 2.5 cm boşluk bırakılmalıdır. Ana metin, yazarların adları ve kurulları hakkında hiçbir bilgi içermemelidir. Yayın çeşitleri;

Araştırma Türü	Özet	Kelime Sayısı	Referans Sayısı	Tablo ve Figürler
Özgün Araştırma	250	4000	30	10
Derleme	250	5000	100	10
Olgu Sunumu	300	2000	20	10

Özgün makaleler yapılandırılmış bir Özet (abstract) (Giriş, Gereç ve yöntemler, Bulgular, Sonuçlar, Referanslar, Tartışma, gerekli ise Onam, Figürler; resim, grafik çizim, video, Tablolar) içermelidir.

Olgu sunumları için yapılandırılmış Özet gerekmez. Özet bölümü 300 sözcük ile sınırlandırılmalıdır. Özet de kaynaklar, tablolar ve atıflar kullanılamaz. Özün bittiği satırın altında sayısı 3-5 arasında olmak üzere anahtar kelimeler verilmelidir.

Türkiye dışındaki ülkelerden yazı gönderen yazarlar için Başlık, Özet, Anahtar Kelimeler ve yazıyla ilgili diğer bazı temel bölümlerin Türkçe olarak gönderilmesi zorunlu değildir. Bu bölümlerin çevirileri, yazarlar tarafından gönderilen özgün İngilizce metinler dikkate alınarak dergi editörlüğü tarafından yapılacaktır.

Makalede kullanılan tüm kısaltmalar, ilk kullanımda tanımlanmalıdır. Kısaltma, tanımı ardından parantez içinde verilmelidir.

Ana metinde bir ilaç, ürün, donanım veya yazılım programından bahsedildiğinde, ürünün adı, ürünün üreticisi, üretim şehri ve üreten şirketin ülkesi de dahil olmak üzere ürün bilgileri (ABD'de ise devlet dahil) parantez içinde verilmelidir.

Anahtar kelime seçimi için lütfen Index Medicus'un (MeSH) tıbbi konu başlıklarına bakınız: <https://meshb.nlm.nih.gov/MeSHonDemand>.

Tüm kaynaklara, tablolara ve şekillere ana metinde atıfta bulunulmalı ve kaynaklar, ana metinde geçen sıraya göre numaralandırılmalıdır. Kullanılan semboller, sembollerin standart kullanımlarına uygun olmalıdır.

Özgün Araştırma makaleleri klinik veya temel araştırma sonuçlarını içermeli, eleştirel okuyucular için kabul edilebilir olacak kadar iyi belgelenmelidir. En fazla 4000 kelime olmalı ve sırasıyla aşağıdaki başlıkları içermelidir;

- Başlık (hem Türkçe hem İngilizce)
- Özet (hem Türkçe hem İngilizce)
- Anahtar Kelimeler (hem Türkçe hem İngilizce)
- Giriş
- Gereç ve yöntemler
- Bulgular

- Tartışma
- Sonuçlar
- Şekillerin ve tabloların başlıkları (gerekirse)
- Kaynaklar

Olgu sunumları en fazla 2000 kelime olmalı ve sırasıyla aşağıdaki başlıkları içermelidir;

- Başlık (hem Türkçe hem İngilizce)
- Özet (hem Türkçe hem İngilizce)
- Anahtar Kelimeler (hem Türkçe hem İngilizce)
- Giriş
- Olgu sunumu
- Tartışma ve Sonuç
- Şekillerin ve tabloların başlıkları (gerekirse)
- Kaynaklar

Derlemeler yapılandırılmış olmalı, en fazla 5000 kelimedenden oluşmalı ve sırasıyla aşağıdaki başlıkları içermelidir;

- Başlık (hem Türkçe hem İngilizce)
- Özet (hem Türkçe hem İngilizce)
- Anahtar Kelimeler (hem Türkçe hem İngilizce)
- Ana metin
- Sonuç
- Şekillerin ve tabloların başlıkları (gerekirse)
- Kaynaklar

Sistemik derlemeler için yazarla PRISMA yönergelerine uymalıdır; <http://www.prisma-statement.org/documents/PRISMA%202009%20checklist.pdf>

Editöre Mektuplar en fazla 1000 kelime olmalı ve aşağıdaki alt başlıkları içermelidir;

- Başlık
- Anahtar kelimeler
- Ana metin
- Şekillerin ve tabloların başlıkları (gerekirse)
- Kaynaklar

Şekillerin ve tabloların yayına hazırlığı

- Şekiller, grafikler ve fotoğraflar, makale yükleme sistemi aracılığıyla ayrı dosyalar (JPEG formatında) halinde sunulmalıdır.
- Dosyalar bir Word belgesine veya ana belgeye gömülmemelidir.
- Şeklin alt birimleri olduğunda; alt birimler tek bir görüntü oluşturmak için birleştirilmemelidir. Her alt birim, başvuru sistemi aracılığıyla ayrı ayrı sunulmalıdır.
- Şekil alt birimlerini belirtmek için görüntüler Arabik rakamlarla (1,2,3...) numaralandırılmalıdır.
- Gönderilen her bir şeklin en düşük çözünürlüğü 300 DPI olmalıdır.
- Şekillerin başlıkları ana belgenin sonunda listelenmelidir.
- Bilgi veya resimler hastaların tanımlanmasına izin vermemelidir. Kullanılan herhangi bir fotoğraf için hastadan ve/veya yasal temsilcisinden yazılı bilgilendirilmiş onam alınmalıdır.

Tablolar ana belgeye gömülmeli veya ayrı dosyalar halinde sunulmalıdır. Tablo sayısı altı adet ile sınırlandırılmalıdır. Tüm tablolar, ana metinde kullanıldığı sırayla art arda numaralandırılmalıdır. Tablo başlıkları ve açıklamaları ana belgenin sonunda listelenmelidir.

Kaynaklar

Kaynaklar yazıda kullanılan kaynaklar cümlelerin sonunda parantez içinde belirtilmelidir. Kaynaklar makalenin sonunda yer almalı ve makalede geçiş sırasına göre sıralanmalıdır. Kaynaklar yazarların soyadlarını ve adlarının baş harflerini, makalenin başlığını, derginin adını, basım yılını, sayısını, başlangıç ve bitiş sayfalarını belirtmelidir. Altı ve daha fazla yazarı olan makalelerde ilk 3 yazardan sonrası için 'et al.' veya 've ark.' ifadesi kullanılmalıdır. Kısaltmalar Index Medicus' a uygun olmalıdır.

Kaynakların sonuna alıntı yapılan makalelerin doi linki eklenmelidir.

Örnekler

Makaleler için:

1. Tasci A, Tugcu V, Ozbay B, Mutlu B, Cicekler O. Stone formation in prostatic urethra after potassium-titanyl-phosphate laser ablation of the prostate for benign prostatic hyperplasia. J Endourol 2009;23:1879-81. <https://doi.org/10.1089/end.2008.0596>

Kitap için:

1.Günalp İ: Modern Üroloji. Ankara: Yargıçoğlu matbaası, 1975. Kitap bölümleri için: Anderson JL, Muhlestein JB. Extra corporeal ureteric stenting during laparoscopic pyeloplasty. Philadelphia: W.B. Saunders; 2003. p. 288-307

Web sitesi için;

Gaudin S. How moon landing changed technology history [Internet]. Computerworld UK. 2009 [cited 15 June 2014]. Available from: <http://www.computerworlduk.com/in-depth/it-business/2387/how-moon-landing-changed-technology-history/>

Bildiriler için;

Proceedings of the Symposium on Robotics, Mechatronics and Animatronics in the Creative and Entertainment Industries and Arts. SSAISB 2005 Convention. University of Hertfordshire, Hatfield, UK; 2005.

Tez için;

Ercan S. Venöz yetmezlikli hastalarda kalf kası egzersizlerinin venöz fonksiyona ve kas gücüne etkisi. Süleyman Demirel Üniversitesi Tıp Fakültesi Spor Hekimliği Anabilim Dalı Uzmanlık Tezi. Isparta: Süleyman Demirel Üniversitesi. 2016.

Geri Çekme veya Reddetme

Yazıyı Geri Çekme: Gönderilen yazının değerlendirme sürecinde gecikme olması vb. gibi gerekçelerle yazıyı geri çekmek ve başka bir yerde yayınlamak isteyen yazarlar yazılı bir başvuru ile yazılarını dergiden geri çekebilirler.

Yazı Reddi: Yayımlanması kabul edilmeyen yazılar, gerekçesi ile geri gönderilir.

Kabul sonrası

Makalenin kabul edilmesi durumunda, kabul mektubu iki hafta içinde sorumlu yazara gönderilir. Makalenin baskıdan önceki son hali yazarın son kontrolüne sunulur. Dergi sahibi ve yayın kurulu, kabul edilen makalenin derginin hangi sayısında basılacağına karar vermeye yetkilidir.

Yazarlar, makalelerini kişisel veya kurumsal web sitelerinde, uygun alıntı ve kütüphane kurallarına bağlı kalarak yayınlatabilirler.

PREPARATION OF MANUSCRIPT

Manuscripts can only be submitted through the journal's online manuscript submission and evaluation system, available at <https://dergipark.org.tr/> Manuscripts submitted via any other medium will not be evaluated.

Manuscripts submitted to the journal will first go through a technical evaluation process where the editorial office staff will ensure that the manuscript has been prepared and submitted following the journal's guidelines. Submissions that do not conform to the journal's guidelines will be returned to the submitting author with technical correction requests. The editor reserves the right to reject manuscripts that do not comply with the aforementioned requirements. Corrections may be done without changing the main text.

Authors are required to submit the following:

- Author Contribution&Copyright Transfer Form,
- Informed Consent Form
- ICMJE Disclosure of Interest Form
- Title Page (including Title of Manuscript, Running title, author (s) 's name, title, and institution, corresponding author's contact information, Name of the organization supporting the research)
- Main document (All articles should have an abstract before the main text).
- Figures (Jpeg format)
- Tables (max 6 tables)

Preparation of the Main Document

The articles should be written double-spaced in 12 pt, Times New Roman character and at least 2.5 cm from all edges of each page. The main text should not contain any information about the authors' names and affiliations.

Publication Types;

Type of Article	Abstract	Text (Word)	References	Table&Figures
Original Article	250	4000	30	10
Review Article	250	5000	100	10
Case Reports	300	2000	20	10

Original articles should have a structured abstract. (Aim, Material and Methods, Results, Conclusion). For case reports, the structured abstract is not used. Limit the abstract to 300 words. References, tables, and citations should not be used in an abstract. Authors must include relevant keywords (3-5) on the line following the end of the abstract. The Turkish title, abstracts, and Turkish keywords are not required for the international authors. The editorial office will provide these.

All acronyms and abbreviations used in the manuscript should be defined first, both in the abstract and in the main text. The abbreviation should be provided in parentheses following the definition.

When a drug, product, hardware, or software program is mentioned within the main text, product information, including the name of the product, the producer of the product, and city and the country of the company (including the state if in the USA), should be provided in parentheses.

All references, tables, and figures should be referred to within the main text, and they should be numbered consecutively in the order they are referred to within the main text. The symbols used must be nomenclature used standards.

Original Research Articles should be maximum of 4000 words and include subheadings below;

- Title (both in Turkish and English)
- Abstract (both in Turkish and English)
- Keywords (both in Turkish and English)
- Introduction
- Material and Methods
- Results
- Discussion
- Conclusions
- Figures and Tables Legend (if necessary)
- References

Case Reports should be maximum of 2000 words and include subheadings below;

- Title (both in Turkish and English)
- Abstract (both in Turkish and English)
- Keywords (both in Turkish and English)
- Introduction
- Case Presentation
- Discussion and Conclusion
- Figures and Tables Legend (if necessary)
- References

Literature Reviews should be maximum of 5000 words and include subheadings below;

- Title (both in Turkish and English)
- Abstract (both in Turkish and English)
- Keywords (both in Turkish and English)
- Main text
- Conclusion
- Figures and Tables Legend (if necessary)
- References

Letters to the editor should be maximum of 1000 words and should include subheadings below;

- Title
- Keywords
- Main text

- Figures and Tables Legend (if necessary)
- References

Preparation of the Figures and Tables

The submission system should submit figures, graphics, and photographs as separate files (in JPEG format).

- The files should not be embedded in a Word document or the main document.
- When there are figure subunits, the subunits should not be merged to form a single image. Each subunit should be submitted separately through the submission system.
 - Arabic numbers should number images to indicate figure subunits.
 - The minimum resolution of each submitted figure should be 300 DPI.
 - Figure legends should be listed at the end of the main document.
 - Information or illustrations must not permit the identification of patients, and written informed consent for publication must be sought for any photograph.

Tables should be embedded in the main document or submitted as separate files, but if tables are submitted separately, please note where it is suitable in the main text. Tables are limited to six tables. All tables should be numbered consecutively in the order they are used to within the main text. Tables legends should be listed at the end of the main document.

References

The references used in the article must be written in parenthesis at the end of the sentences. References should be numbered in the order they appear in the text and placed at the end of the article. References must contain surnames and initials of all authors, article title, name of the journal, the year, and the first and last page numbers. Articles with 6 or more authors 'et al.' are mixed with the first three authors. Abbreviations should be according to index Medicus.

Authors must add the DOI (Digital object identifier) at the end of each reference.

For Examples;

Article in journal: 1. Tasci A, Tugcu V, Ozbay B, Mutlu B, Cicekler O. Stone formation in prostatic urethra after potassium-titanyl-phosphate laser ablation of the prostate for benign prostatic hyperplasia. *J Endourol* 2009;23:1879-81. <https://doi.org/10.1089/end.2008.0596>

For Books: 1.Güenalp İ: Modern Üroloji. Ankara: Yargıçoğlu matbaası, 1975. Chapters in books: Anderson JL, Muhlestein JB. Extra corporeal ureteric stenting during laparoscopic pyeloplasty. Philadelphia: W.B. Saunders; 2003. p. 288-307

For website; Gaudin S. How moon landing changed technology history [Internet]. *Computerworld UK*. 2009 [cited 15 June 2014]. Available from: <http://www.computerworlduk.com/in-depth/it-business/2387/how-moon-landing-changed-technology-history/>

For conference proceeding; Proceedings of the Symposium on Robotics, Mechatronics and Animatronics in the Creative and Entertainment Industries and Arts. SSAISB 2005 Convention. University of Hertfordshire, Hatfield, UK; 2005.

For Thesis; Ercan S. Venöz yetmezlikli hastalarda kalf kası egzersizlerinin venöz fonksiyona ve kas gücüne etkisi. Suleyman Demirel University Faculty of Medicine Sports Medicine Department Thesis. Isparta: Suleyman Demirel University. 2016.

Retraction or Reject; Manuscript Retraction: For other reasons, authors may withdraw their manuscript from the journal with a written declaration.

Manuscript Reject

The manuscripts which are not accepted to be published are rejected with explanations.

AFTER ACCEPTANCE

If the manuscript is accepted, the acceptance letter is sent within two weeks, the last version of the manuscript is sent to the author for the last corresponding. The journal owner and the editorial board are authorized to decide which volume of the accepted article will be printed.

Authors may publish their articles on their personal or corporate websites by linking them to the appropriate cite and library rules.

Peer Review Process

Yayın Değerlendirme Süreci

Çift-Kör Değerlendirme Süreci

1. Makale Başvurusu

İlgili yazar, makalesini Dergipark çevrimiçi sistemi aracılığıyla dergiye gönderir.

2. Editöryal Değerlendirme

Editörlük, ilgili makalenin derginin yazım kurallarına göre düzenlenip düzenlenmediğini kontrol eder. Bilimsel içeriği bu aşamada değerlendirmez.

3. Editör tarafından değerlendirme

Editör, makalenin orijinal olup olmadığını denetler. Değilse, makale ret edilerek süreç tamamlanır.

4. Hakem Daveti

Editör, makalenin bilimsel içeriğinin değerlendirilmesi için konu ile ilgili hakemlere davet gönderir. Genellikle 2 hakeme davet gönderilir. İlgili yazıyı hakemlerden birisi ret diğeri kabul ettiği takdirde, bölüm editörü uygun görürse üçüncü bir hakemin incelemesi için davetiye gönderebilir.

5. Davete Yanıt

Seçilen hakemler, daveti gönderilen yazıyı kendi uzmanlıklarına, çıkar çatışmalarına ve kullanılabilirlik durumlarına karşı gizli olarak değerlendirir. Daha sonra kabul veya reddetmektedirler.

6. İnceleme Süreci

Hakem, makaleyi çeşitli açılardan değerlendirdikten sonra (15 gün içerisinde) eleştiri ve önerilerini içeren hakem değerlendirme formunu editöre gönderir. Major veya minör revizyonlar sonrasında hakem yazıyı tekrar değerlendirmek istemiş ise öneri ve eleştiriler yazarlara iletilerek düzeltilmiş yazıyı tekrar sisteme yüklemeleri istenir. Bu süreç hakemin kabul veya ret cevabı verene kadar devam eder.

7. Derginin Değerlendirme Süreci

Bölüm Editörü, genel bir karar vermeden önce geri gönderilen tüm değerlendirmeleri dikkate alır. Hakem değerlendirme sonuçları çok farklıysa, editör bir karar almadan önce fazladan bir fikir edinmek için ek bir inceleme isteyebilir.

8. Kararın İletilmesi

Bölüm Editörü, yazı hakkındaki son kararına hakem isimleri gizlenerek hakem raporlarını da ekler ve yazara çevrimiçi sistem ve e-mail aracılığı ile gönderir.

9. Sonraki Adımlar

Makale kabul edilirse, dil editörüne gönderilir. Bu aşamalardan sonraki adımlar;

- Son kopya gönderisi
- Mizanpaj
- Düzeltilmeler
- Yayınlanacak gönderilerin erken baskı olarak web sayfasına yerleştirilmesi
- Sayı oluşturulması
- İçindekiler sayfası düzenlenmesi
- Web sitesinde sayı olarak yayınlanması ve baskı

*Kurum içi değerlendirme sürecinde; çift kör değerlendirme sürecindeki adımlar izlenmektedir.

The Double-Blind Peer Review Process

1. Submission of Paper

The corresponding author submits the paper via Dergipark online system to the journal.new

2. Editorial Office Assessment

Editorial Office checks the paper's composition and arrangement against the journal's Author Guidelines to make sure it includes the required sections and stylizations. The quality of the paper is not assessed at this point.

3. Appraisal by the Editor

Editor checks that the paper is appropriate for the journal and is sufficiently original and interesting. If not, the paper may be rejected without being reviewed any further.

4. Invitation to Reviewers

Editor sends invitations to individuals he or she believes would be appropriate reviewers. As responses are received, further invitations are issued, if necessary, until the required number of acceptances is obtained – commonly this is 2.

5. Response to Invitations

Potential reviewers consider the invitation as anonymous against their own expertise, conflicts of interest and availability. They then accept or decline. If possible, when declining, they might also suggest alternative reviewers.

6. Review is Conducted

The reviewer sets time aside to read the paper several times. The first read is used to form an initial impression of the work. If major problems are found at this stage, the reviewer may feel comfortable rejecting the paper without further work. Otherwise they will read the paper several more times, taking notes so as to build a detailed point-by-point review. The review is then submitted to the journal, with a recommendation to accept or reject it – or else with a request for revision (usually flagged as either major or minor) before it is reconsidered.

7. Journal Evaluates the Reviews

The Section Editor considers all the returned reviews before making an overall decision. If the reviews differ widely, the editor may invite an additional reviewer so as to get an extra opinion before making a decision.

8. The Decision is Communicated

The Section Editor sends a decision email to the author including any relevant reviewer comments as anonymous.

9. Next Steps

If accepted, the paper is sent to language Editor. If the article is rejected or sent back for either major or minor revision, the Section Editor should include constructive comments from the reviewers to help the author improve the article. At this point, reviewers should also be sent an email or letter letting them know the outcome of their review. If the paper was sent back for revision, the reviewers should expect to receive a new version, unless they have opted out of further participation. However, where only minor changes were requested this follow-up review might be done by the Section Editor. After these;

- Copyedit submission
- Layout
- Corrections
- Publishing the submissions on the web page as early print
- Creating issues
- Organize Table of Contents
- Publishing the issue on the web page and printing hardcopy

**We are applying the same steps on The Double-Blind Peer Review Process when we got the in-house submission.*



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<http://endouroloji.org.tr>