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Özgün araştırma / Original research

Standart Perkütan Nefrolitotomi ve Tüpsüz Perkütan Nefrolitotomi Sonuçlarının Karşılaştırılması: Tüpsüz Gerçekten Üstün mü? Prospektif Randomize Çift Kör Çalışma

A Comparison of Standard Percutaneous Nephrolithotomy and Tubeless Percutaneous Nephrolithotomy: Does Tubeless Realy Superior? A Prospective Randomized Double-Blind Study

Huseyin Kocakgol[1], Senol Adanur[2], Ali H. Yilmaz[3], Fatih Ozkaya[2], İbrahim Karabulut[4], Ozkan Polat[2]

[1] Department of Urology, Kanuni Training and Research Hospital, Trabzon, Turkey
[2] Department of Urology, Faculty of Medicine, Ataturk University, Erzurum, Turkey
[3] Department of Urology, Bilecik State Hospital, Bilecik, Turkey

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Yazışma / Correspondence
Dr. Hüseyin Koçakgöl
ORCID: 0000-0002-7683-3282
Kanuni Training and Research Hospital
Department of Urology
Trabzon, Turkey
Tel: +90 506 284 6185
Fax: +90 462 341 5641
E-mail: hsynkocakgl@gmail.com

Özet

Amaç: Standart PNL ve tüpsüz PNL yapılan hasta gruplarının güvenlik, etkinlik ve hasta konforu açısından karşılaştırılmalarını amaçladık.

Gereç ve Yöntemler: PNL endikasyonu alan 78 hasta çalışmaya alındı. Standart PNL yapılan 38 hasta Grup I ve tüpsüz PNL prosedürü uygulanan 40 hasta Grup II olarak randomize edildi. Çalışma prospektif randomize çift kör çalışma olarak dizayn edildi. Operasyon sonunda aktif kanaması olan ve multipl akses kullanılan hastalar çalışma dışı bırakıldı. Ameliyat sonrası ağrı ve komplikasyonların değerlendirilmesinde sırasıyla VAS (visual analogue scale) ve modifiye Clavien sınıflaması kullanıldı.

Bulgular: Yaş, cinsiyet, taş boyutu, taşların böbrekteki lokalizasyonları, taraf gibi verilerde iki hasta grubu arasında istatistiksel fark yoktu (P>0,05). Yine perioperatif verilerde; operasyon süresi, skopi süresi, taşsızlık oranları, peroperatif kreatin ve hemoglobin değişimi, kan transfüzyonu, VAS 2-VAS 3 ağrı skorları, analjezik gereksinimi, ateş ve ek cerrahi gerektiren komplikasyonlarda iki grup arasında istatistiksel fark bulunmadı (P>0,05). VAS 1 skoru ve hastanede kalış süreleri açısından her iki grup karşılaştırıldığında, her iki parametre tüpsüz PNL grubunda istatistiksel olarak anlamlı düşük bulundu (P=0,003).

Sonuç: Tüpsüz PNL operasyonu, erken postoperatif dönemde daha az ağrı ve kısa hastanede kalış süresi gibi avantajları ve stan-

Abstract

Objective: We aimed to compare patient groups who underwent either a standard percutaneous nephrolithotomy (PNL) or tubeless PNL for safety, effectiveness and patient comfort.

Material and Methods: 78 patients were included in the study. Patients who underwent the standard PNL (n=38) or tubeless PNL (n=40) were randomized into Groups 1 and 2, respectively. This study was designed as a prospective, randomized, double-blind investigation. Patients who had active bleeding at the end of the operation and those with multiple access tracts were excluded from the study. To evaluate postoperative pain and complications, a visual analogue scale (VAS) and a modified Clavien classification were used, respectively.

Results: A statistically significant difference was not found between the two patient groups for demographic data (age and gender), or for size, laterality, and intrarenal location of the stone(s) (p>0.05). Perioperative data, including operative and fluoroscopy times and stonefree rates, perioperative changes in creatinine and haemoglobin values, blood transfusion, VAS 2 to 3 pain scores, analgesic requirements, fever and complications requiring additional surgical treatment were not statistically different between groups (p>0.05). A VAS 1 pain score and hospital stays were significantly decreased in the tubeless PNL group (p=0.003).

dart PNL operasyonuna göre anlamlı olmayacak derecede düşük komplikasyon oranları ile deneyimli cerrahlar tarafından etkin ve güvenle uygulanabilecek endoürolojik bir yöntemdir.

Anahtar Kelimeler: Böbrek taşları, Perkütan nefrolitotomi, Standart PNL, Tüpsüz PNL, Ağrı, Hastanede kalış süresi

Conclusions: Tubeless PNL surgery is an effective and safe endourological procedure that can be performed by experienced surgeons. Its advantages over standard PNL include less pain during the early postoperative period, shorter hospital stays but the rates of complications are not significantly lower.

Keywords: Renal Stones Percutaneous Nephrolithotomy, Standard PNL, Tubeless PNL, pain, hospitalization time.

INTRODUCTION

The current gold standard treatment used in the treatment of both kidney stones larger than 2 cm and extracorporeal shock wave lithotripsy (ESWL)-resistant stones is percutaneous nephrolithotomy (PNL). As defined in the European Association of Urology 2017 guideline, PNL is applied in three ways: a standard PNL, where a nephrostomy catheter is inserted in the insertion tract after the operation; a tubeless PNL, where only the ureteral stent is applied without the nephrostomy tube; and a totally tubeless PNL, where neither the nephrostomy tube nor ureteral stent is applied. In studies in selected patients, the tubeless PNL has been superior to the standard PNL in terms of hospital stay, postoperative pain and patient comfort. (1-3) Unlike previous studies, we designed this study as a prospective double-blind and randomized study, which aimed to more objectively compare patients treated with either standard PNL or tubeless PNL.

MATERIAL AND METHODS

A total of 78 patients over 18 years of age who were examined and had indications for a PNL operation in the University Hospital Urology Clinic between July 2013 and November 2014 were evaluated in this randomized prospective double-blind study. This study was approved by the Ethics Committee. The patients were divided into two groups, the standard PNL or tubeless PNL group. Patients treated with the standard PNL were in Group I, while patients treated with the tubeless PNL were in Group II. The PNL was administered after antibiotic therapy in patients having bacterial reproduction in the urine culture in the preoperative phase. Antibiotic prophylaxis and antithrombotic prophylaxis were applied before and after the operations in all patients. All operations were carried out by one experienced urologist (S.A.).

As part of the inclusion criteria, patients who did not have any congenital renal anomalies and who had not undergone any open kidney surgery or PNL operation were accepted into the study. Patients were excluded from this study if they had a significant haemorrhage at the end of the operation or if they required multiple access during the operation and a second session of PNL was planned in the near future due to residual stones.

Patient assignments to a group were by selection of a sealed envelope by a third person, and both the surgeon and patient were blind to this information. The surgeon was informed about the result of the draw at the end of the procedure. Then, according to this result, the operation was concluded as a standard PNL or tubeless PNL.

The size of the stones, the largest diameter of the stones and the diameter perpendicular to it were measured in the Picture Archiving Communication Systems (PACS) and were calculated in mm^2. For multiple stones, the total stone size was obtained by measuring all the stones one by one.

A clinically insignificant fragment presence (≤ 4 mm) or a total stone-free result was accepted as a success. ESWL or retrograde intrarenal surgery (RIRS) was planned as a secondary treatment for clinically significant stones larger than 4 mm.

TECHNIQUE

Under general anaesthesia, a 5F or 7F (French) open-ended ureteral catheter was placed into the ureter in the lithotomy position. The pelvicalyceal system anatomy was presented by administering an opaque substance (diluted about 1/2) into the ureteral catheter in the presence of C-arm fluoroscopy in the prone position. In the presence of fluoroscopy, the appropriate calyx was entered in a monopolar plane with an 18-G (gauge) needle. Infracostal access was performed for

Table 1. The Demographic Data of Patients and Stone Characteristics

	Standard PNL	Tubeless PNL	P Value
Age (year)	44,7±14,7(18-77)	48,7±17(18-87)	0,277
Gender n (%)			
Male	26(%68,4)	24 (%60)	0,438
Female	12 (%31,6)	16 (%40)	
Side n (%)			
Right	23 (%60,5)	18 (%45)	0,170
Left	15 (%39,5)	22 (%55)	
Size (mm^2)	786,2 ±586	716,6±401,5	0,881
Stone Type n (%)			
Single	10 (%26,3)	9 (% 22,5)	
Multipl	14 (%36,8)	19 (%47,5)	0,318
Staghorn	14 (%36,8)	12 (%30)	

all patients. Supracostal access was not required. After entering the collecting system, a 0.035-inch hydrophilic guide wire was sent into the system. The tract was dilated with Amplatz dilators over the guide wire. Considering the width of the calyx and the sizes of the stones, a 24F or 26F sheath access was placed in the system in all operations.

After the 19F nephroscope entered the kidney, the stones were fragmented with a pneumatic lithotripter or an ultrasonic lithotripter and taken out with the appropriate forceps. Before ending the surgery, a rigid nephroscope or flexible cystoscope, and finally fluoroscopy, were used to check all calyces and the renal pelvis for residual stones.

At the end of the operation, the result was determined by a sealed envelope method and reported to the surgeon. The operation was then terminated according the draw and a standard PNL or tubeless PNL was performed. In patients with a standard PNL, a 14F Malecot or Nelaton catheter was placed as a nephrostomy tube. In the tubeless PNL group, a 4.8F or 6F double-J (DJ) stent was placed antegradely. Nephrostomy catheters in patients who had a standard PNL were removed after the postoperative haematuria became transparent without an antegrade nephrostogram examination. DJ stents in patients with a tubeless PNL were removed under short-term anaesthesia at postoperative week two or three.

A visual analogue scale (VAS) was used by asking patients to rate their pain between 0 to 10. To be more objective, these scores were given in face-to-face interviews with a third person other than the surgeon or the researcher who conducted the study. A score of 0 was the absence of pain, while a score of 10 was the most severe pain. Pain scores were recorded separately as: VAS 1: postoperative 6^{th}hour; VAS 2: postoperative 12^{th} hour; and VAS 3: postoperative 24^{th}hour.

Statistical analyses were carried out using the SPSS program (version 17) with Pearson chi square tests, Fisher's exact tests and Mann-Whitney U tests. Furthermore, in SPSS, a power analysis was performed in terms of the adequacy of the number of the patients. In the statistical analyses, $p<0.05$ was considered statistically significant.

RESULTS

The demographic characteristics of patients in Groups I and II, the characteristics of the stones and the statistical results between the two groups are listed in Table 1.

When the success rates in these groups were examined, 26 (68.4%) of 38 patients in Group I and 32 (80%) of 40 patients in Group II were stone free. There was no significant difference between groups in terms of success rates ($p> 0.05$). In total, a stone-free result was achieved in 12 (46%) of 26 patients with complete staghorn stones and in 46 (88%) of 52 patients without staghorn stones.

In both groups, 20 (25.6%) patients with clinically significant residual stones were treated with ESWL, and 12 patients were treated with RIRS. Since one of the remaining two patients became pregnant during the follow-up period, and there was no stone detected using RIRS in the other patient. The results between perioperative data and Groups I and II are listed in Table 2.

When complications required additional surgery under general anaesthesia (Clavien degree 3B), results were compared, a ureterorenoscopy (URS) was performed in two patients who had ureteral stones on the same side in Group I in the postoperative follow-up. In Group II, a haemorrhage occurred in one patient during the postoperative follow-up and a DJ stent was re-inserted due to the elution of the previous DJ stent. There was no significant difference between the two groups ($p> 0.05$) when they were compared in terms

Table 2. The Perioperative Data of Patient Groups

*	Group I (n: 38)	Group II (n: 40)	P Value
Operation Length (minute)	132,7±53,1	131,6± 35,2	0,909
Fluoroscopy Length (minute)	3,6 ±1,5	3,3 ±1,2	0,331
Hgb Loss (gr/dl)	2,4±1,02	1,99±0,98	0,056
Creatinine Change (mg/dl)	0,076±0,19	0,050±0,18	0,107
Blood Transfusion (unit)	0,21±0,7	0,1±0,4	0,010
VAS 1 (6^{th}hour)	6,2 ±1,8	4,8±1,8	0,003
VAS 2 (12^{th}hour)	3,79±2,08	3,90±1,8	0,891
VAS 3 (24^{th}hour)	3,58±1,9	3,18±2,7	0,475
Analgesic Dose**	1,21±1,16	1,02±1,12	0,444
Hospital Stay (day)	3,82±1,4	2,95±1,2	0,003
Success Rate n (%)	26(%68,4)	32(%80)	0,242

**Parameters are given with avarage and standard deviation values*

*** 1 dose analgesic: 1 ampoule 3ml-75 mg diklofenac sodium*

of postoperative complications requiring additional surgery under general anaesthesia. No complications were observed in our study that matched Grades 3A, 4A/4B or 5 criteria. The modified Clavien classifications of the complications are listed in Table 3.

CONCLUSIONS

In the literature, PNL operations resulting in the placement of a nephrostomy tube at the end of the PNL procedure to aid in drainage and haemostasis of the pelvicalyceal system are called standard PNL. (4-6, 11) However, PNL operations without a nephrostomy tube, which were first proposed by Wickham et al. (7) in 1984, are called tubeless PNL operations. The majority of tubeless PNL series are administered to patients with a usual intra operative course or low complication potential. (8, 9)

Although the indications for a PNL operation are defined in detail in the international guidelines, there is no worldwide consensus for nephrostomy tube indications. Zilbermann et al. (10), in a meta-analysis, recommended the use of a nephrostomy tube placement in cases of more than two accesses, intraoperative active bleeding, intraoperative prominent collecting system perforation, complicated cases, intrathoracic injuries and in patients having a PNL application planned for a second time. However, there are different approaches in the literature. In a retrospective study by Isac et al. (12) in 2014 comparing standard PNL and tubeless PNL with wider indications, no exclusion criteria were set except for bilateral PNL procedures. In their study, one of the two surgeons completed the whole case using the standard PNL, while the other used the tubeless PNL. As the result of the study, it was suggested that the tubeless PNL was safe for all cases, regardless of active bleeding or collecting system perforations. Furthermore, a nephrostomy tube placement was only recommended in patients who were going to have PNL for a second time due to a residual stone. However, in this study, the use of lower access numbers in the tubeless PNL group appears to be a remarkable point in the methodology of the study. According to the European Association of Urology Guideline 2017, tubeless and total tubeless PNL procedures are safe alternatives for uncomplicated PNL operations. Furthermore, it has been suggested to place nephrostomy tubes in patients with residual stones, intraoperative severe bleeding, patients with a solitary kidney, haemorrhagic diathesis, ureteral obstruction, collecting system perforations, a percutaneous chemolysis plan or a PNL planned for the second time.

The literature findings suggest that from a small number of prospective randomized studies, careful preoperative patient selection, limited inclusion criteria and tubeless PNL are applied in uncomplicated operations (15-18). Tefekli et al. (17) selected patients

Table 3. Complication Data According Modified Clavien Classification

Complication n (%)	Group I	Group II	Clavien Grade
Pain Requiring Analgesic	22 (%57)	22 (%55)	Grade I
Fever	4 (%10,5)	1 (%2,5)	Grade I
Blood Transfusion	4 (%10,5)	2 (%5)	Grade II
Persistent Hematuria	0 (% 0)	1 (%2,5)	Grade 3B
Ureteral Obstruction	2 (%5,2)	2 (%5)	Grade 3B

with a simple isolated lower pole or pelvic stone without hydronephrosis in their prospective study in 2006. Patients with previous ESWL or renal surgical history, abnormal congenital urinary system, high creatinine level and single renal disease were excluded from the study. In addition, patients with intraoperative operation times of more than two hours, intraoperative complications, those requiring additional access, and being scheduled for a second PNL due to residual stones, were not included in the study. Importantly, the preoperative and intraoperative inclusion criteria are considerably limited in these studies.

Among the current prospective randomized studies, the study performed by Shoma et al. (19) is different from the other studies. In their study, patients were randomized to tubeless PNL or standard PNL groups using a preoperative sealed envelope drawing method, similar to our study. However, unlike our study, patients with complete staghorn stones and those with collecting tubule perforations were not included in the study. In addition, the randomization of patients was provided through a sealed envelope drawing method within the knowledge of the surgeon before the operation. In our study, only patients with a history of an open operation and congenital renal anomalies of the kidney were excluded from the study, thus, with the aim of comparing homogeneous patient groups in preoperative patient selection.

In our study, patients with significant bleeding at the end of the operation, those who were subjected to multiple access, and those who were to be administered a PNL for a second session due to postoperative residual stones were excluded from the study. Thus, the aim was a postoperative comparison of tubeless PNL and standard PNL results in homogeneous patient groups. In addition, the results of the sealed envelope draw were hidden from the surgeon until the end of the operation in order to carry out the study with a more objective approach. Thus, unlike Shoma et al., PNL operations were intended to be performed in the standard course rather than being focused on the result. To our knowledge, the fact that our study was both a double-blind and a prospective randomized study, it is the first study of this nature. We believe this study will provide valuable contributions to the literature in terms of the reliability of the PNL.

Even though the tubeless PNL was first introduced about 30 years ago, in 1986, Winfield et al. (20) reported major complications in two patients due to the early removal of the nephrostomy tube. This led to a decreased use of the tubeless PNL procedure for many years and resulted in the standardization of the nephrostomy tube in PNL operation. (10) However, in recent years, shorter hospital stay, less postoperative pain and analgesic requirements, insignificant difference in postoperative complications and positive contributions to patient comfort have brought the tubeless PNL forward and led to an increased interest in this surgical procedure. (10-14) Zilbermann et al. (10) assessed standard PNL and tubeless PNL complications in their meta-analysis and reported no significant difference in complication rates between the two groups. In the Singh et al. (15) study in 2008 on whether the morbidity rate of tubeless PNL is lower, 60 selected patients were operated on by a single urologist. Patients with a stone size less than 3 cm, operations less than 2 hours, uncomplicated cases and single access patients were included in the study. In that study, 30 patients per group were evaluated in the standard PNL group and tubeless PNL group. There were no major complications in the tubeless PNL group, while there was bleeding in one patient in the standard PNL group. There was no significant difference between the two groups in terms of major and minor complications ($p>0.05$).

In our study, no patients developed urinoma or prolonged urine leakage from the tract. When the complication rates in the patient groups were compared, no significant difference was found between the two groups ($p>0.05$).

This study, which we planned and carried out as a prospective randomized study with broad inclusion criteria, revealed its superiority over previous studies in the sense that it was performed as a double-blind study, as opposed to previous studies. The limitations of our study include the fact that there were no patients with supracostal access, we used access sheaths of two

different diameters.

The tubeless PNL results in a shorter postoperative hospital stay and less pain in the early postoperative period. Furthermore, it is an effective and safe method that can be applied by experienced endourologists with no significant difference in complications.

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Compliance with ethical standards:

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