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Individualized Management of 1-2 cm Kidney Stones in the Lower Pole Calyces

Alt Pol Kalikslerinde Olan 1-2 cm'lik Böbrek Taşlarının Kişiye Özel Yönetimi

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Abstract

Objective: We aimed to determine the individualized management of middle-sized kidney stones in the lower pole calyces that can be removed using shock wave lithotripsy (SWL) (Group A), flexible ureteroscopic retrograde intrarenal surgery (RIRS) (Group B) and micro-percutaneous lithotomy (micro-PNL) (Group C).
Materials and Methods: Patients who had 1-2 cm kidney stones in the lower pole calyces whose calyceal necks (length: <10 cm, and width: > 5mm), pelvicalyceal angle (>30^{o}) and relatively shorter stone-skin distance as determined based on tomographic urography results were included in the study. Patients with renal cystine, whewellite stones or stones with a hardness above 1000 Hounsfield units were excluded. The groups were not formed randomly. Contarily, treatment methods were explained to the patients and let them decide the treatment method for themselves. Each group consisted of 34 patients.
Results: After excluding nine patients who were lost to follow-up, the study was completed with 93 patients at the final analysis. Stone-free rate was lower in Group A (47%) than Groups B (80.5%) and C (77%) (p<0.001). The mean number of sessions was 2.1 for Group A, 1.55 for Group B and 1 for Group C (p<0.001). Average procedure costs were $169, $1427, and $947 for Groups A, B, and C, respectively (p<0.001). Median length of hospital stay for Groups A, B, and C was 1, 20, and 48 hours (p<0.001), respectively, and 2, 3.9 and 5.5 working days were lost, respectively (p<0.001).
Conclusion: RIRS and micro-PNL had more stone-free rate, but number of working days were lost with lower medical expenditures in the SWL group. The priority of the patients should be determined, and the choice of treatment should be decided in collaboration with them.
Keywords: lower calyx, middle sized kidney stone, shock wave lithotripsy, retrograde intrarenal surgery, micro-percutaneous nephrolithotomy, cost-efficiency

Öz

Amaç: Alt pol kalikslerinde şok dalga litotripsi (SWL) (Grup A), fleksibl üreteroskopik retrograd intrarenal cerrahi (RIRS) (Grup B) ve mikroperkütan litotomi (micro-PNL) (Grup C) ile çıkarılabilen orta büyüklükteki böbrek taşlarının bireyselleştirilmiş yönetimini belirlemeyi amaçladık.
Gereçler ve Yöntemler: Alt kaliks grubunda 1-2 cm arası taşı olan, çekilen tomografik ürografide kaliks boynu uzun yada dar olmayan (uzunluk: <10 cm ve genişlik: > 5 mm), kaliks-pelvis arasındaki açısı dar olmayan (>30^{o}) ve cilt-taş mesafesi uzak olmayan hastalar çalışmaya alındı. Taşın sertliği 1000 Hounsfield ünitesi üzerinde olan, bilinen sistin yada whewellite taşlı hastalar çalışmadan hariç tutuldu. Gruplar randomize değildi. Aksine, tedavi yöntemleri hastalara anlatılarak kendilerinin karar vermeleri istendi. Her grup 34 hastadan oluşuyordu.
Bulgular: Takipten çıkan dokuz hasta hariç tutulduktan sonra son analizde 93 hasta ile çalışma tamamlandı. Taşsızlık oranı Grup A'da (%47) Grup B'ye (%80,5) ve C'ye (%77) göre daha düşüktü (p<0.001). Ortalama seans sayısı Grup A için 2,1, Grup B için 1,55 ve Grup C için 1 idi (p<0.001). Ortalama prosedür maliyetleri Grup A, B ve C için sırasıyla 169$, 1427$ ve 947$'dı (p<0,001). Medyan hastanede kalış saati Grup A, B ve C için sırasıyla 1, 20 ve 48 saat idi (p<0,001) ve çalışma günü kayıpları sırasıyla 2, 3,9 ve 5,5 gün idi (p<0,001).
Sonuç: RIRS ve mikro-PNL'de taşsızlık oranı daha yüksekti, ancak SWL'de iş günü kaybı ve maliyet daha düşüktü. Hastanın önceliğinin ne olduğu belirlenip, tedavi seçimine birlikte karar verilmelidir.
Anahtar kelimeler: alt kaliks, böbrek orta boy taşları, şok dalga tedavisi, böbrek içi cerrahi, mikro perkütan nefrolitotomi, maliyet-etkinlik

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Introduction

Urinary stone disease affects roughly 15% of the population [1]. Kidney stones are most seen in the lower pole calyces [2]. Retrograde intrarenal surgery (RIRS), percutaneous nephrolithotomy (PNL), and shock wave lithotripsy (SWL) are all minimally invasive methods used to treat kidney stones. Patients with stones in the lower pole calyces are treated differently from those with stones in the upper and middle pole calyces. Because lower pole calyceal stones must ascend the infundibulum of the lower pole, reach the renal pelvis, and then depart the kidney into the ureter, making their removal extremely difficult [3].

Many urologists choose SWL as a low-morbidity outpatient option, and many patients tolerate it. PNL is recommended as the primary choice by the European Association of Urology (EAU) for stones bigger than 2 cm and SWL or RIRS for stones smaller than 1 cm. However, the optimal treatment choice for medium-sized lower pole calyceal stones measuring 1 to 2 cm is still up for debate [4]. Furthermore, it is known that SWL is linked to insufficient fragment clearance from the lower pole [5].

Because it has a high success rate regardless of stone size, PNL is currently the standard treatment of choice for large stones (> 2 cm) and is also preferred by many urologists for the treatment of multiple renal stones or stones in the dependent parts of the kidney, such as the lower pole. However, the substantial risk of morbidity outweighs the advantage of high stone-free rate [6]. Miniaturized PNLs with smaller nephroscopes can reduce surgical morbidity. In the removal of renal stones, its efficiency is comparable to that of normal PNL. Miniaturized nephroscopes have calibers ranging from 4.8 to 22 F, with mini-PNL (14-22 F), ultramini-PNL (13 F), and micro-PNL (4.8 F) being the most used ones [7].

Flexible ureteroscopy, which was originally used to treat lower pole calyceal stones that were resistant to SWL, may be a less intrusive option to percutaneous treatments [8]. RIRS is becoming more popular as a main treatment for these stones, with greater stone-free rates than SWL and lower patient morbidity than PNL.

Medical expenditures for treating stone disease involve direct and indirect costs. All medical expenses (e.g., prescriptions, hospitalization charges, all consumables and non-consumables required during surgery) are considered direct costs, whereas indirect costs include the patient's lost working days [9]. Health-care systems and individuals nowadays desire shorter hospital stays, speedier return to work, maximum cost efficiency, and higher surgical success rates [10,11].

We compared the safety, efficacy, and cost-effectiveness of SWL, RIRS, and micro-PNL in this study to determine an individualized management for 1-2-cm stones in the lower pole calyces.

Materials and Methods

Study Population and Design

This study had a prospective, non-randomized design. Patients who had 1-2 cm kidney stones in the lower pole calyces with calyceal necks (length: <10 cm, and width: > 5mm), pelvicalyceal angle (>30^{o}) and relatively shorter stone-skin distance, and stone hardness lower than 1000 Hounsfield units as determined based on tomographic urography results were included in the study. The groups were not randomized. The treatment methods were explained to the patients and requested them to decide their treatment preferences by themselves. All patients were included in the study by selecting the appropriate treatment modality. When each group had 34 patients, participation in the study was terminated. In all, 102 patients were divided into three groups (34 patients to each): Group A was managed by SWL, Group B by RIRS, and Group C by micro-PNL. The study was carried out between February 2021 and February 2022 in a single center. Presence of a solitary or abnormal (horseshoe or pelvic kidney) kidney, renal insufficiency, pregnancy, urinary tract infection, radiolucent stone, calyceal diverticular stone, pre-existing metabolic stone disease (whewellite stone, cystinuria, renal tubular acidosis, etc.), a double-j or a nephrostomy tube inserted before surgery, and patients younger than 18 or older than 75 years were excluded from the study. Patients who used antithrombotic drugs were not treated, even with RIRS, to prevent bias.

All procedures were performed by the same surgical team. The urologist who performed the operations was experienced in all these procedures. All patients' urine cultures were sterile before operation. The stone surface was calculated using the formula: height x width x 0.25 x π).

Informed, written consent was obtained from all patients. Ethical approval was granted by University of Health Sciences Sancaktepe Training and Research Hospital Ethics Committee (date: 27.01.2021; decision #: 88).

Surgical Procedure

The endoscopic instruments used had a caliber of 4.8 Fr for micro-PNL (PolyDiagnost, Pfaffenhofen, Germany). Flexible cystoscopes or ureteroscopes were not used, and only a laser lithotripsy was employed in micro-PNL (**Figure 1**). Nephrostomy tubes were not inserted in any patient who underwent micro-PNL. A double-J ureteral stent was placed when required in the presence of pelvic perforation, residual stone, and intraureteral stone migration. For RIRS, diagnostic ureteroscopy was performed with a semi-rigid 6/7.5 Fr ureteroscope (Richard Wolf, Knittlingen, Germany). A 7.5 Fr flexible ureteroscope (Flex X2, Karl Storz, Tuttlingen, Germany) was utilized for the primary operation. A holmium: YAG laser was used to fragment the stones down to the size of 272 microns. The stones were dusted rather than removed using a basket or other equipment. For SWL therapy, an Argemet A1000 device (Turkey) was employed at a frequency of 90 shocks per minute**.** The starting voltage for SWL was 14 kV for 500 SWs, then raised in 2 kV increments every 500 shock waves (SWs) until stone fragmentation started, or up to a maximum value of 24 kV. Stone disintegration was confirmed both by the SWL operator and the surgeon in charge by radiographic control.

The cost of procedure per case included the money spent to purchase disposable materials (e.g., guide, urethral catheter, cover set, gloves), special materials (access sheath for RIRS, dilator set for micro-PNL), drugs (e.g., antibiotics, IV fluids for replacement, analgesics), in addition to hospitalization cost per day, and fees charged for stent removal and endoscopy. The daily bed cost (approximately 20 USD) is standard for patients operated on in

Turkey. The daily bed cost in the National Health Care System of Turkey is approximately 10% of the monthly minimum wage and was calculated as a reference guide for other physicians who are working in different health insurance systems. The average costs of the instruments used per procedure were calculated using the data obtained from the relevant records of the previous five years. Instrument costs encompass money spent for purchase and repair of the instrument. The case number of lifetime cycles were 70 for micro-PNL and 35 for flexible ureteroscope. Total costs include the costs of the procedure plus the mean cost of endoscopy per case. The Argemet A1000 SWL device (Turkey) has a 200-case maintenance cycle, and the maintenance fee is $3000.

Figure 1. Micro-PNL surgical equipment

Outcome Assessment

The primary outcome measures were the stone-free rate and cost, while the time to return to daily activities and length of hospital stay were the secondary outcome measures. Since SWL was conducted in an outpatient environment, hospitalization was measured by the number of hours spent in the hospital. Every SWL session lasted at least one hour, including premedication. The time to return to daily activities was determined by patient self-report. Daily life activity was defined as the patient being able to work at full capacity at the same level as preoperatively, without moderate or severe pain and limitation of movement. In addition, the total period elapsed till return to daily life activities increased by the number of working days lost owing to severe lower urinary tract symptoms before starting to work. Operative time was not assessed because SWL was not performed under anesthesia in an operation room and fluoroscopy time was assessed instead. Stone-free status was defined as lack of any residual stone or a clinically insignificant 3 mm- residual stone on non-contrast computed tomographic examination performed three months following the last procedure. Secondary procedures involved a semi-rigid ureteroscopy performed for ureter stones. Clavien-Dindo classification was used to categorize the complications. Clavien-Dindo grade ≥ 2 complications were included in the statistical analysis.

Statistical Analysis

The mean age, body-mass index (BMI), stone surface area, fluoroscopy time, length of hospital stay, time to return to normal daily activities, treatment cost, stone-free rate (SFR), and complication rates were compared between groups. Statistical analysis showed that the patients in each treatment group were normally distributed, with a standard deviation of 10. The expected true difference in the success rate of surgery was 10%. The type I error probability associated with this null hypothesis test was 0.05. To reject the null hypothesis that the surgical success rates of the two groups were the same, we needed to investigate 30 individuals in each group with a probability of 0.8. The estimated rate of patient loss to follow-up was 10%. All participants were stratified by computer-generated pseudorandom numbers according to surgical procedures. The Statistical Package for the Social Sciences (SPSS, Chicago, IL, USA) version 17 for Windows was used for statistical analysis. To compare groups, one-tailed ANOVA and Pearson chi-square tests were performed. A Tukey test was used for post-hoc analysis. Level of statistical significance was defined as a p value of less than 0.05.

Results

After nine patients were excluded due to lack of follow-up information, the final study contained 93 individuals. Mean age, BMI, and stone surface area were comparable between groups (**Table 1**). Patients were monitored for at least three months. Group A had a lower SFR (47%) than Groups B (80.5%) and C (77%) ($p<0.001$) (**Table 2**).

Median hospital stay was shorter in Group A (1 hour) than in Groups B (20 hours) and C (48 hours) ($p<0.001$). Each SWL session lasted one hour, including premedication. Thus, the minimum hospitalization time was one hour in the SWL group. In the SWL group, three patients were hospitalized for seven, and three patients for one day. Subcapsular hematomas developed in two patients hospitalized for seven days were resolved with only bed rest. One patient was hospitalized for three days because of fever, and three patients were interned for one day due to renal colic unresponsive to medication. Hence, the maximum hospital stay was 168 hours (7 days) in Group A. Patients who underwent RIRS and micro-PNL were routinely discharged the next day. However, some of them had longer hospitalization periods due to the presence of pain, fever, gross hematuria, and sepsis. Thus, the maximum hospital stays were 144 hours (6 days) in the micro-PNL and 192 hours (8 days) in the RIRS group. Sepsis occurred in two patients in the RIRS group, and gross hematuria in one patient in the micro-PNL group.

The mean number of sessions was 2.1 in Group A, 1.55 in Group B, and 1 in Group C ($p<0.001$). The mean number of working days lost was lower in Group A (2 days) than in Groups B (3.9 days) and C (5.5 days) ($p<0.001$). In the SWL group, the total working time lost was calculated as four hours (half of a working day), including time spent for coming to the hospital, evaluation, and treatment processes, and return to work or home.

In other words, each SWL session means a loss of half a working day. The mean number of sessions was 2.1 in the SWL group, so the mean number of working days lost should have been about one day, but it increased to two days due to complications developed in patients. In the RIRS group, removal of a double-j stent resulted in loss of a working day as well as the need for a control or emergency visit in an extra session in more than half of the patients, and prolonged hospitalization due to complications, all of which increased the mean number of working days lost approximately four-fold. In the micro-PNL group, the median hospitalization time was two days, along with the half-day spent for the control visit resulted in an exact loss of 2.5 working days. However, we recommended bed rest for at least two days for our patients. Taking into account urinary tract infections, hematuria, and the prolonged hospitalization required for some patients, on an average, 5.5 working days were lost.

The mean cost of procedures was $169, $1427, and $947 for Groups A, B, and C, respectively ($p<0.001$). The cost of all materials used throughout the procedure was also documented (**Table 3**). These were the direct costs, that is, the money that the health system rather than the patients spent. Complication rates were similar between groups (**Table 2**). The most severe complication was sepsis, and none of the patients received blood transfusions or were transferred to the intensive care unit. Sepsis occurred in two patients, one in the SWL group and one in the RIRS group.

Table 1. The detail of the groups

	SWL (Group A)	RIRS (Group B)	Micro-PNL (Group C)	P value
Patient number (n)	30	31	32	
Mean Age (years) ± sd	45±11.2	48.1±13.1	42.8±13.5	0.237
Gender (male/female)	21/9	20/13	19/16	0.430
Mean BMI (kg/m²) ± sd	25.8±3	25.4±2.8	25.1±3	0.582
Side (right/left)	13/15	16/17	20/15	0.655
Mean stone surface area (mm²) ± sd	190.6±77	201±42.5	212±82	0.852

Table 2. Outcomes of the procedures

	SWL (Group A)	RIRS (Group B)	Micro-PNL (Group C)	P value
Patient number (n)	30	31	32	
Mean fluoroscopy time (second) ± sd	46.1±30.3	34.3±22.4	127.8±59	**<0.001**
Stone-free rate (%)	47.7%	80.5%	77%	**<0.001**
Median hospital staying (hours) ± (min-max)	1 (1-168)	20 (16-192)	48 (12-144)	**<0.001**
Mean loss of working day (day) ± sd	2±3.7	3.9±2.5	5.5±3.6	**<0.001**
Mean number of sessions ± sd	2.1±0.9	1.55±0.75	1±0	**<0.001**
Mean cost of procedures ($) ± sd	169±193	1427±501	947±344	**<0.001**
Complication rate	6.7%	12.9%	9.4%	0.438

Table 3. Costs for each spend unit ($) (N.A.: Not applicable)

	SWL	RIRS	Micro PNL
Prophylaxis, premedication or anesthesia	25	65	35
Disposable materials	25	270.5	219.4
Special materials	34	367.3	194.3
Lithotripter (laser fiber, pneumatic or ultrasonic tip)	N.A.	125	125
Post-procedure drugs	40	37	39.3
Total bed cost	20	82.2	114
Double-j extraction cost	N.A.	130	N.A.
Cost of tool per case	15	350	200
Total	169	1427	947

Discussion

In recent years, many technological developments, such as advanced optical system technologies, have been used in the management of upper urinary tract stones. In the majority of published studies comparing different treatment options for urinary stone disease, the most common parameters were SFR and complications of each technique. However, when selecting an option, the cost-effectiveness of the technique to be used should also be considered. In addition, when calculating the cost of the surgical procedure applied, it is necessary to evaluate the indirect cost parameters such as the total number of working days lost as well as the cost of the materials used.

Because of the high recurrence rate and the possibility of reoperation after treatment of 1-2 cm stones in a lower pole calyx, a rational treatment approach that provides maximum SFR which is a key parameter in evaluating the efficacy of a stone management procedure with minimal morbidity is needed, [12]. Although SWL has been the preferred option for lower pole calyceal stones for many years, its low SFRs have prompted clinicians to seek alternatives. Because of the disadvantages of SWL for this group of stones, RIRS and PNL are now the preferred treatment options [13].

Based on the available literature data, the SFR for the first session of SWL is around 46-64% [14,15]. Similar to these data, our SFR was 47.7% which was statistically significantly lower compared to the other groups. The SFR of the first session of RIRS has been reported as approximately 60-65% [13,16]. In this study, it was 80.5%. The SFR for micro-PNL has been reported as 83% [17,18], while in our study it was 77%.

Post-procedural complications are among the main reasons for long hospital stays and delays in patients' return to daily life. Further, the cost of the procedures increases when complications occur [19]. The mean hospital stay for RIRS has been reported as 1-2 days, compared to 1.1-2.4 days for micro-PNL [11,17]. Usually, uncomplicated SWL is an outpatient procedure, but it may still result in the loss of a working day. Similar to literature, the mean hospital stay in our study was shorter in Group A (1 hour) than in Groups B (20 hours) and C (48 hours). Our results showed that the greater the degree of invasiveness, the longer the hospital stay. The daily hospital bed cost was $20, which is approximately 6% of the monthly minimum wage in Turkey. Although it is cheaper than in other countries, other hospital, and medical expenses are comparable because disposable materials and endoscopes are imported. This phenomenon may seem to be an advantage favoring invasive procedures in terms of direct costs. However, there are conflicting data in the literature regarding the length of time it takes a urolithiasis patient to return to daily activities. For example, Demirbas et al. [20] reported length of hospital stay as 11.26 days for ultra-mini PNL, while Xun et al., [21] indicated 5.76 days for standard PNL. In a study from Spain, although the direct costs of URS/RIRS were higher than those of ESWL, no statistically significant difference was found between them in terms of indirect costs [22]. We think that the length of hospital stay differs dependent on local conditions. In our clinic, we encouraged patients to return to daily activities as soon as possible. The mean number of working days lost for SWL (2 ± 3.7 days), RIRS (3.9 ± 2.5 days), and micro-PNL (5.5 ± 3.6 days) were as indicated ($p<0.001$). Although the highest average number of working days lost was detected in Group C, the number of working days lost was in the narrowest range in this group due to lower contingency. We cannot calculate a net amount of financial loss for a working day lost because each patient's daily earnings are different. However, if we accept that the daily earnings are similar for each patient group, we can say that the cost of the procedure increases in line with the degree of invasiveness of the treatment method used. The costs of each procedure may vary by country and by healthcare system [23]. There are few studies on the cost of SWL, but many studies report that the procedure cost was lower for patients with lower stone burden, decreased Hounsfield unit of stone density (<1000), and more favorable renal anatomy [3,24]. Perez et al. reported the direct cost of one session of ESWL as $1690.5 [22]. Regarding the other methods, the mean cost of RIRS in Germany is $951, while in England it is $1398. A miniaturized PCNL in Germany costs $562, while the same procedure in England costs $749 (11). In a Turkish study, the total medical expenditures for RIRS and micro-PNL were reported to be $1250 and $962, respectively [25]. In this study, the mean procedure costs were $169, $1427, and $947 for Groups A, B, and C, respectively. As mentioned before, our RIRS cost was higher than that of the micro-PNL procedure in consideration of the use of a routine access sheath and the insertion, and then removal of a double-j stent.

In summary, our study offered a detailed analysis of the safety, efficacy, and cost-effectiveness of these three procedures used for stone extraction. Like all medical problems, management of urinary stone disease imposes a significant socio-economic burden. Moreover, there are financial and social costs related to the working days lost, and the direct costs of the procedures may actually convey greater importance. On the other hand, failure both to determine the Hounsfield units of the stones and also to perfom stone analysis are potential limitations of the study.

Conclusion

The stone-free rates were relatively higher in RIRS and micro-PNL, but the number of working days lost, and medical expenditures were lower in SWL. SWL can thus be attempted first, and if it is unsuccessful, RIRS or micro-PNL can be performed with comparable efficiency and medical procedure cost. Before making a treatment decision, it is necessary to give patients detailed information about the pros and cons of each of the three procedures and consider their decision. In addition, treatment options should be reviewed with patients in consideration of their socioeconomic status.

Ethics Committee Approval: Ethical approval was granted by University of Health Sciences Sancaktepe Martyr Prof. Dr. Ilhan Varank Training and Research Hospital Ethics Committee (date: 27.01.2021; decision #: 88).
Informed Consent: An informed consent was obtained from all the patients.
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– M.Y.S., A.Y.; Materials – M.Y.S., A.Y.; Data Collection and/or Processing – M.Y.S., A.Y.; Analysis and/or Interpretation – C.Y., G.B.; Literature Search – M.Y.S., A.Y.; Writing Manuscript – C.Y., M.Y.S.; Critical Review – C.Y., G.B.
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