ENDOUROLOGY

Original Article

Comparison of ureteroscopic pneumatic lithotripsy and extracorporeal shock wave lithotripsy for the management of proximal ureteral stones: A single center experience

Proksimal üreter taşlarının tedavisinde üreteroskopik pnömatik ve bedendışı şok dalgalarıyla taş kırmanın karşılaştırması: Tek merkez deneyimi

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Cite this article as: Iqbal N, Malik Y, Nadeem U, Khalid M, Pirzada A, Majeed M, et al. Comparison of ureteroscopic pneumatic lithotripsy and extracorporeal shock wave lithotripsy for the management of proximal ureteral stones: A single center experience. Turk J Urol 2018; 44(3): 221-7.

ABSTRACT

Objective: To evaluate and compare the effectiveness of ureteroscopic (URS) pneumatic lithotripsy versus extracorporeal shock wave lithotripsy (ESWL) in the management of the proximal ureteral stones in terms of stone- free rates, complications and costs involved.

Material and methods: We included 200 patients in Group 1 who underwent ESWL and 200 patients in Group 2 who underwent URS intervention. We used Modulith SL X lithotripter 3rd generation Storz medical for ESWL group while Swiss pneumatic lithoclast was used to break the stone in the URS group. Stone-free status was defined as stone fragment of less than 4 mm on follow- up kidney ureter and bladder X-ray after 3 months of procedure. SPSS version 16 was used for statistical analysis.

Results: The mean age in ESWL and URS groups were 39.21±13.36, and 43.13±13.65 years respectively. Mean stone size was 10.47±3.7 mm (ESWL) and 13.6±6.6 mm (URS). Stone- free rate after single procedure was (125/200 patients) 62.5% for ESWL and (168/200 patients) 84% for URS group (p=0.001). Complications included post procedure sepsis in 3 (1.5%) patient of ESWL, while 7 (3.5%) patients of URS groups. Steinstrasse was seen in 4 (2%) patients of ESWL group. No mortality was seen in both groups. Mean costs for ESWL were US $320±50 while US $1100±150 for URS group (p=0.001).

Conclusion: The stone-free rates after single procedure were significantly higher for the URS group while the complication rates were comparable in both groups. Treatment costs were significantly lower for the ESWL group.

Keywords: Complications; proximal ureter stone; stone-free rate; ESWL; URS.

ÖZ

Amaç: Taşsızlık oranları, komplikasyonlar ve maliyetler açısından üreteroskopik pnömatik ve bedendışı şok dalgalarıyla taş kırmanın etkililiğinin değerlendirilmesi ve karşılaştırılması.

Gereç ve yöntemler: Bedendışı şok dalgalarıyla taş kırma (ESWL) (Grup 1) ve üreteroskopik girişim grubunun (URS) (Grup 2) her birine 200 hasta dahil edilmiştir. Taş kırmak için Grup 1'de Modulith SL X 3. kuşak Storz litotriptörünü, URS grubunda (Grup2) Swiss pnömatik litoklastı kullanılmıştır. Taşsızlık oranı izlem sırasında, işlemden 3 ay sonra çekilen direkt üriner grafide 4 mm'den küçük taş parçacığının kalması olarak tanımlandı. İstatistiksel analiz için SPSS'nin 16. sürümü kullanıldı.

Bulgular: Yaş ortalaması ESWL ve URS gruplarında sırasıyla 39,21±13,36 ve 43,13±13,65 yıl idi. Ortalama taş çapları ESWL ve URS gruplarında sırasıyla 10,47±3,7 mm ve 13,6±6,6 mm idi. Tek bir işlemden sonra taşsızlık oranları ESWL ve URS gruplarında sırasıyla (125/200) %62,5 ve (168/200) %84 idi (p=0,001). Komplikasyonlardan işlem sonrası sepsis ESWL ve URS gruplarında sırasıyla 3 (%1,5) ve 7 (%3,5) hastada görülmüştür. Taş yolu ESWL grubunda 4 (%2) hastada görülmüştür. Her iki grupta ölüm görülmemiştir. ESWL ve URS gruplarında ortalama maliyetler sırasıyla 320±50 ve 1100±150 ABD dolarıydı (p=0,001).

Sonuç: Tek bir işlemden sonra taşsızlık oranları URS grubunda anlamlı derecede daha yüksek, komplikasyon oranları ise her iki grupta benzer oranlardaydı. Tedavi maliyetleri ESWL grubunda anlamlı derecede daha düşük idi.

Anahtar sözcükler: Komplikasyonlar; proksimal üreter taşı; taşsızlık oranı; ESWL; URS.

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Submitted:
12.12.2017

Accepted:
23.02.2018

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Available online at
www.turkishjournalofurology.com

Turk J Urol 2018; 44(3): 221–7
DOI:10.5152/tud.2018.41848

Introduction

Urolithiasis is one of the leading causes of morbidity of the urinary tract system in the world. Within the last few decades the treatment of urinary tract stones has been revolutionized due to introduction of minimally invasive techniques.[1,2] Few decades back ureteral stones were managed by open ureterolithotomy. Then with time there was refinement of semi-rigid ureteroscopes, shock wave lithotripsy (SWL) machines, laparoscopic procedures and flexible ureterorenoscopies (URS) resulting in enormous change in the management of ureteral stones. Each of these modalities have high efficacy when used for the appropriate indication both in adults and children.[3,4] Preferences of patients and surgeons play a pivotal role in the decision of choosing one or the other procedure.[3,4] For treating proximal ureteral stones, SWL is a minimally invasive procedure and can be performed as an outdoor patient procedure, however it has disadvantages as well, such as a high retreatment rate, long treatment time, and poor patient compliance in some cases.[4,5] Within the last few years, ureterorenoscopic treatment of ureteral stone has gained widespread popularity among the surgeons. URS has been strongly advised for patients having distal ureteral calculi which yields high stone-free rates of more than 95%.[6] There are surgeons who are very cautious in using semi-rigid URS for proximal ureteral stones especially in male patients because of longer working distance compared to female patients.[7]

Compared with distal ureteral stones, URS performed for stones in the proximal ureter have been associated with lower success rates which are ascribed to a more difficult access as well as the proximal migration of stone fragments in URS. In some studies it was found that compared with the SWL group treatment cost was higher in the URS group due to hospitalization and inpatient costs.[8] The best modality for the treatment of ureteral stones is still debatable.[8] Patients who stay far from hospital more probably choose URS over SWL to avoid frequent visits because of its high success rate for single treatment.[9] Patient's economic status also effects satisfaction level of the patients regarding choice of URS or SWL for treating their ureteral stones especially in a society like Pakistan where people with middle, and low-income levels have difficulty in coping with the costs incurred in private setups.[10] In literature there is a controversy regarding the financial burden on patients.[8,10]

In this study we also focused on patients' financial constraints and their outcomes in terms of stone-free rates. In past no paper has excluded the obese patients or those having stone density more than 1000 HU or patients having skin to stone distance more than 10 cm from their investigations, when comparing the URS and SWL modalities for the management of proximal ureter stones. We have excluded these confounding factors as well. So this study is the first of its kind performed recently in that we have excluded these above-mentioned confounding factors while comparing the two modalities for the treatment of proximal ureteral stones.

Material and methods

A total of 400 patients were included in both groups. We took the approval of the ethical committee of Shifa International Hospital before conducting this retrospective study. As per departmental policy patients were given choice to undergo either URS or SWL after counselling them about the merits and demerits of both types of modalities. Patients' consent regarding the treatment modality was obtained from them. These patients were having proximal ureteral stones and underwent either SWL or URS from January 2015 to June 2017 at Shifa International Hospital Islamabad Pakistan. Patients were initially diagnosed after taking full history and physical examination, radiological investigations including X-ray KUB, urinary ultrasound (USG) and computed tomography (CT). The size of the stone was indicated as the largest diameter of the stone. We included patients who also had undergone CT scan which gave us information about the stone density and skin to stone distance of the proximal ureteral stones in the study.

Inclusion criteria were as follows: proximal radiopaque and single ureteral stone with a size less than 2 cm; age ≥18 years, body mass index (BMI) <30 kg/m^2, ureter stone density <1000 Hounsfield's units (HU) and skin to stone distance <10 cm. Exclusion criteria were as follows: pregnancy, previous history of ureteral stone procedure, urinary tract infection, BMI >30 kg/m^2, skin to stone distance >10 cm, stone density >1000 HU, multiple ureteral stones, distal and midureter stones, congenital genitourinary anomaly, stone size more than 2 cm, distal ureteral obstruction/stricture, urinary tract infection and coagulation disorder.

URS technique

In URS group, procedure was done under general anesthesia. Initially rigid cystoscopy, connected to video monitor screen was performed (Karl Storz Germany). We used 9Fr/11Fr semirigid ureteroscope (Karl Storz Germany) after introduction of guidewire (0.035 inch, Boston scientific TM Guide, USA) into the ureter under fluoroscopic control (Siemens model no.07721710, Germany). Swiss pneumatic lithoclast was used to break the stone (0.8 mm or 1 mm probe). Dormia basket (Boston scientific 2.8 fr, 3.5 fr and 5 fr) was used to remove the fragmented stones. In some cases if URS could not be introduced up to the stone in the ureter then simply a 6 fr DJ (double J) stent was passed and second URS procedure was planned after 2 weeks. All of the patients in the group were given intravenous antibiotics (3rd generation cephalosporins) for prophylaxis one hour preoperatively and then continued for the next 24 hours after which they were switched to use oral antibiotics for 5 days. If required after

completing URS, a 6 Fr Double J stent was inserted into the ureter. DJ stent was removed after 2 weeks. Foley catheter was removed on the first postoperative day. Procedure was declared successful in case of complete disintegration (residual fragments less than 4 mm on per operative inspection) and clearance of the stone, and a failure if stone could not be broken completely or if it migrated into the kidney. Postprocedural follow-up visits were performed after two weeks and 3 months to see if there was any dilatation of ureter or any fragment larger than 4 mm was still left in the ureter post URS procedure, using plain X-ray KUB and urinary ultrasound (kidneys, ureter, and bladder). The patients were followed up to one year with ultrasonographic monitorization for the development of hydronephrosis suggesting ureteral stricture.

SWL technique

Patients had been counseled about the possible outcomes of the SWL procedure in terms of the stone-free rates and the complications. All patients underwent SWL by standard technique, using a Storz Modulith SLX-MX electromagnetic lithotripter machine (3rd generation). Position of The patient was laid supine on the operating table in most of the cases. Stone was being targeted with the help of fluoroscopy (Modulith SLX-MX) and ultrasound (Aloka SSD-1000). Approximately 90 shock waves were delivered in one minute. The first 500 shocks were delivered at energy level of 2 and next 2000 to 3000 shocks at energy level 3 and 4. The patients were given Intravenous nalbuphin 10 mg if they felt any pain during the procedure. Double J stent was placed in patients especially if size of the stone was greater than 1.5 cm. Procedure was done by a senior expert doctor having vast experience in using ESWL machine. Second SWL session was done if there had been gross residual stones seen on X-Ray KUB and urinary ultrasound even after 2 to 4 weeks after the first SWL session. We defined the stone-free rate to be achieved as no evidence of stone fragments or clinically insignificant residual stone (CIRFs) less than 4 mm in size on a plain X-ray KUB or urinary ultrasound 3 months after the last session of SWL. All procedures in SWL group were day care cases.

Table 1. Patients' demographic characteristics

	Group 1 (SWL), n=200	Group 2 (URS), n=200	p
Mean age, years	39.21±13.36	43.13±13.65	0.83
Mean stone size (mm)	10.47±3.7	13.6±6.6	0.67
Male, n	161	137	0.12
Female, n	39	63	0.11
Right side, n	93	98	0.69
Left side, n	107	102	068
BMI (kg/m^2)	25.3±5.88	24.2±6.19	0.89
Skin to stone distance (cm)	9.2±1.3	9.4±1.1	0.90
Hounsfield unit of stone	789±229	802±192	0.96
Hypertension, n	67	73	0.60
Diabetes mellitus, n	49	52	0.81

SWL: extracorporeal shock wave lithotripsy; URS: ureterrenoscopy

Statistical analysis

Data regarding stone size, stone-free rates, postoperative complications after URS, post procedural complications after SWL and the total costs incurred on patients were noted from the charts review. Data were analyzed using the Statistical Package for Social Sciences, version 16 (SPSS Inc.; Chicago, IL, USA). Frequency and percentage values were calculated for categorical variables such as gender and stone-free status. Mean values and standard deviation, were used for quantitative variables such as age of the patients and stone size. Chi-square test was used for categorical variables like stone free rates and complications between the two groups. Independent sample t-test was used to compare difference between groups for continuous variables. P value of less than 0.05 was considered as statistically significant.

Results

There were 200 patients in each of the SWL and URS groups, respectively. There were no significant differences regarding age, gender, BMI and the comorbidities of patients in both groups (Table 1). The total mean stone size was 10.47±3.7 mm for SWL and 13.6±6.6 mm for ureteroscopy group (p=0.67). While total mean operative time was 60 minutes per session and 80.26±31.01 minutes per procedure for the respective groups. Stone-free rate after single procedure was (125/200 patients) 62.5% for SWL and (168/200 patients) 84% for URS group (p=0.001). Stone-free rates reached to 86% and 98% after second and third sessions of SWL while 94% stone-free rate was achieved for URS group after second procedure (Table 2). Mean treatment costs for SWL, and URS groups were US $ 320±50, and US $ 1100±150 , respectively (p=0.001).

Complications included postprocedural sepsis detected in 3 (1.5%) patients in the SWL group 7 (3.5%) patients in the URS group. Retropulsion of stone fragments into kidney was seen in 15 (7.5%) patients of URS group. Steinstrasse was seen in 4 (2%) patients of SWL group. No mortality was seen in both groups. There were two cases of ureteral perforation in the URS groups which were managed with the insertion of double J stent. One of these case was later on managed with end-to-end ureteral anastomosis. Fever was seen in 3 patients (1.5%) of SWL, and 11 patients (5.5%) of the URS group. Gross hematuria lasting more than one day was seen in 12 patients (6%) in the SWL, and in 19 patients (9.5%) of URS group. Mucosal abrasion was seen in 21 (10.5%) patients in the URS group. Within one year follow

Turk J Urol 2018; 44(3): 221-7
DOI:10.5152/tud.2018.41848

Table 2. Procedural outcomes

	Group 1 (SWL), n=200	Group 2 (URS), n=200	p
Stone-free rate after first session^	62.5% (125/200)	84% (168/200)	0.001
Stone-free rate after second session	86% (172/200)	94% (188/200)	0.01
Stone-free rate after 3rd session	98% (196/200)	….	0.07
Procedural time minutes	60	80.2±31	0.53
Number of sessions (procedures)	1.4±1.1	1.1±0.2	0.78
Hospital stay (days)	Day case	1.4±0.3 days	0.004
Stone retropulsion into kidney (URS)*	…	15 (7.5%)	…
Costs in US dollars approximately#	320 ±50	1100±150	0.001

^Session means procedure number in SWL and semi-rigid URS. *Stone retropulsion occur in intracorporeal pneumatic ureteroscopic lithotripsy. #Costs in Pakistani rupees converted into approximate US dollar
SWL: extracorporeal shock wave lithotripsy; URS: ureterorenoscopy; US: United States of America Dollars

Table 3. Clavien grading system to evaluate complications in both modalities

Clavien grade	URS, n(%)	SWL, n(%)	p
0=No complications	161 (80.5%)	151 (75.5%)	0.27
1=Deviation from normal post procedural course without need for intervention	18 (9%)	29 (14.5%)	0.11
2=mild complications needing intervention	2 (1%)	3 (1.5%)	1.00
3a=postprocedural complications needing intervention without use of general anesthesia	13 (6.5%)	13 (6.5%)	0.83
3b=Complications needing intervention under general anesthesia	5 (2.5%)	3 (1.5%)	0.72
4a=life-threatening complication needing intensive care management (single organ dysfunction)	2 (1%)	1 (0.5%)	1.00
4b= life-threatening complication needing intensive care management (multiple organ dysfunction)	1 (0.5%)	0%	
5=death	0%	0%	1.00

SWL: extracorporeal shock wave lithotripsy; URS: ureterorenoscopy

up of the URS group only single case of ureteral stricture was seen (0.5%). Post- URS SWL was performed in 12 (6%) cases for the clearance of migrated stone fragments (Table 3).

Discussion

The treatment of urinary lithiasis has undergone a lot of improvements during the last few decades. Some of the modern day techniques include minimally invasive modalities such as endoscopic surgery and totally noninvasive options such as SWL. These new options have almost vanished the need for open surgery nowadays.[11,12]

There are some important factors such as stone location, size, composition, surgeon's inclination and patient's choices that play a vital role in the decision regarding the use of open, laparoscopic, SWL or URS for treating ureteral stones. In modern day practice, SWL and URS are considered as the first-line treatment modalities for the treating ureteral stones.[12]

Shock wave lithotripsy is a noninvasive procedure that can be performed as an outpatient procedure, however it has its own disadvantages as long treatment time, high retreatment rate and poor compliance by the patient.[9,12] AUA recommendations indicated that SWL be used as the first-line of management option for a small stone (<1 cm) but indications had not been so clear for using it for proximal ureteral stones of more than 1 cm.[13,14] The advancement in technology has led to introduction of small caliber semi-rigid ureteroscope. A combination of URS and intracorporeal lithotripsy has proven to be a viable alternative to SWL.[13]

In a study done in Pakistan it was concluded that SWL was the preferred choice of treatment for proximal ureteral stones, but ureterorenoscopic manipulation with intracorporeal lithotripsy was also safe for a quicker relief of symptoms in patients with proximal ureteral stones.[15] Laparoscopic approaches are reasonable alternatives in cases, where SWL and URS have failed. However they did not mention the economic burden of these procedures on the patients.

The success rate (stone free rate) of URS has been around 80% in the proximal ureter. It is seen in literature that URS has a higher stone-free rate for stones smaller than or equal to 10 mm in the distal ureter and stones bigger larger than 10 mm in the proximal ureter.[16] It is pertinent here that besides the influence of stone size and position, the efficiency of the URS procedure depends on the experience and skill of the operating urologist as well.[17]

Besides thinking about all the factors while deciding a specific treatment modality, priority should be always given to patient's

preference. Some patients might have concerns regarding the anesthesia requirement and the invasive nature of URS. But there may be other set of patients who might prefer to have their stone removed and the pain alleviated at the earliest possible time, thus avoiding multiple treatment sessions that might be required in case of SWL as treatment modality.[18,19]

It was mentioned in a study that compared with SWL, ureteroscopic removal of ureteral stones achieved a greater stone-free status, but with a higher complication rate and longer hospital stay.[19] Lee et al.[20] reported lack of any significant differences regarding patients' satisfaction for either intervention (URS or SWL). In a study conducted in Egypt, it was reported that the mean costs for SWL and URS were EGP 5700 (EGP=Egyptian Pound) and EGP 6500 respectively.[21] Lee et al.[20] reported costs of USD 1637 for ESWL and USD 2154 for URS. In another study it was reported that SWL was more costly (USD 1255 for hospital costs, and USD 1792 charged to the patient) compared with URS.[22] However, different SWL devices were used in these studies and no recommendations can be made. In one cost-effective study, the cost of SWL was almost GBP (GBP=Great Britain Pound) 1500 and GBP 2200 for URS in patients with ureteral stones, however URS of stones larger than 10 mm diameter in the lower ureter cost GBP 500 less than SWL.[23] In our study the mean costs for SWL and URS groups were US$ 320±50, and US$ 1100±150, respectively (p=0.001).

Stone size is a significant factor affecting the stone-free state following any intervention for the treatment of ureteral stones.[24] One another factor in the context of SWL for ureteral stones treatment is the skin to stone distance, which has also a role in determining stone-free rates.[24] Recent studies have reported that CT scan Houndsfield units is a better predictor of stone composition and potential fragmentation during SWL treatment.[25,26] This area needs to be further explored in future studies. Massoud et al.[26] stated that in patients who have stones of 500 to1000 HU, factors such as body mass index of more than 30 kg/m^2 and a lower calyceal location make them less suitable for SWL. So the studies done previously have not accounted for these confounding factors while comparing the URS and SWL modality for the proximal ureter stones.

Alameddine et al.[27] reported the complications of URS including perforation in 5/103 (4.8%) patients which were treated with double-J stents except one patient who required nephrostomy tube placement and a laparotomy for intraperitoneal drainage of collection.[27] Two patients (1.94%) developed sepsis. Their initial stone-free rate for proximal URS Group was 89%. Their mean stone size was 10 mm±5.5 mm which was smaller as compared to our study. In another study stone- free rate after URS was 86.7%.[28] In a study by Al-Marhoon et al.[29], in SWL of ureteral stones ,the majority of the complications were minor with the most common being the loin pain in 21% of the patients. In a study by Salem et al.[21] complications in the URS group included 4 cases (4%) having mild extravasation which were managed by DJ stenting. While we had 6 (3%) cases with mild extravasation. Aboutaleb et al.[19] reported complications including steinstrasse in 34.8% (SWL group) and 3.7% (URS group) of the patients, and ureter perforation in 0% (SWL) and 7.4% (URS) of the patients. While we had ureteral perforation in 2 cases (1%).

There is marked heterogeneity of evidence in different papers. The burden of stones on the patient, the HU of stones, skin to stone distance, BMI, the urologist's experience and the availability of resources and appropriate technologies remain the principal criteria to inform the patients about the treatment choice for the management of proximal ureteral stones. This study was the first of its kind which took into account the different factors that may affect stone free rates in SWL while comparing the modalities of URS and SWL for proximal ureteral stones. Our results need to be investigated more in larger groups and multicenter prospective studies.

It was a retrospective single center-study which was one of the limitations of this study. It did not take into account the the level of patient satisfaction with the procedures used. However, our sample size was similar to, or relatively better than the very few studies available in the literature. Multicenter prospective study has not been done yet and needs to be done to elaborate the differences between the two aforementioned modalities in the light of CT scan parameters discussed above.

In conclusion, the stone free rates for proximal ureteral stones after single procedure were significantly higher for the URS group while the complication rates were comparable in both groups. However the hospital stay and treatment costs were significantly lower in the the SWL group.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Shifa International Hospital.

Informed Consent: Written informed consent was obtained from patient who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – N.I., Y.M., S.A., U.N.; Design – M.K., A.P., M.M., H.A.M.; Supervision – N.I., S.A., U.N.; Materials –N.I., S.A. Data Collection and/or Processing – M.K., A.P., M.M., H.A.M.; Analysis and/or Interpretation – N.I., Y.M., S.A., U.N.; Literature Search – N.I., S.A., U.N.; Writing Manuscript – N.I., S.A., Y.M.; Critical Review – S.A., N.I.; Other – N.I., S.A.

Turk J Urol 2018; 44(3): 221–7
DOI:10.5152/tud.2018.41848

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors have declared that they did not receive any financial support for this study.

Etik Komite Onayı: Bu çalışma için etik komite onayı Shifa Uluslararası Hastanesi'nden alınmıştır.

Hasta Onamı: Bu çalışmaya katılan hastalardan yazılı hasta onamı alınmıştır.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir – N.I., Y.M., S.A., U.N.; Tasarım – M.K., A.P., M.M., H.A.M.; Denetleme – N.I., S.A., U.N.; Malzemeler –N.I., S.A. Veri Toplanması ve/veya İşlemesi – M.K., A.P., M.M., H.A.M.; Analiz ve/veya Yorum – N.I., Y.M., S.A., U.N.; Literatür Taraması – N.I., S.A., U.N.; Yazıyı Yazan – N.I., S.A., Y.M.; Eleştirel İnceleme – S.A., N.I.; Diğer – N.I., S.A.

Çıkar Çatışması: Yazarlar çıkar çatışması bildirmemişlerdir.

Finansal Destek: Yazarlar bu çalışma için finansal destek almadıklarını beyan etmişlerdir.

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