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COMPARATIVE STUDY BETWEEN THE EFFICACY OF EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY AND URETEROSCOPY WITH PNEUMATIC LITHOTRIPSY FOR TREATMENT OF DISTAL URETERIC CALCULI

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Abstract

The efficacy of extracorporeal shock wave lithotripsy (ESWL) and ureteroscopy (URS) are compared for the treatment of distal ureteral calculi with respect to patient satisfaction and efficacy.

This is a prospective study where a total of 85 patients with solitary radiopaque distal ureteral calculi were treated with ESWL (n = 55) using Siemens lithotripter (Electromagnetic lithotripter) or URS (n = 30). Patient and stone characteristics, treatment parameters, clinical outcomes, and patient satisfaction were assessed for each group.

The two groups were comparable in regard to patient age, sex and stone size. The stone-free status for ESWL and URS at 3 months was 76.3% and 97.5%, respectively (p<0.0001). No ureteral perforation or stricture occurred in the URS group. Patient satisfaction was high for both groups including 90% for URS and 80% for ESWL (p = 0.002).

In conclusion, URS is more effective than ESWL for the treatment of distal ureteral calculi. ESWL was more often performed on an outpatient basis and showed a trend towards less flank pain and dysuria, fewer complications and quicker convalescence. Patient satisfaction was significantly higher for URS according to the questionnaire used in this study.

Introduction

Urinary lithiasis can cause a greater or lesser degree of obstruction of the lower ureter depending on the size of the calculus, urothelial edema and the degree of impaction requiring instrumental treatment sometimes as an urgent procedure. In the past 25 years, the treatment of these calculi has evolved from ureterolithotomy to ureteroscopy (URS)[1], extracorporeal shockwave lithotripsy (ESWL)[2] and endoscopic lithotripsy[3,4]. Advances in the design of the ureteroscope and ongoing development in ESWL have greatly impacted the management of ureteric stones[5]. The indications for ureteroscopic lithotripsy have increased with smaller semi-rigid ureteroscopes and reliable laser technology and the production of more flexible instruments has further expanded the indications for endoscopic intervention. Despite the definite success of endourological stone treatment, ongoing questions about optimum management remain debated among urologists.

ESWL and URS are currently accepted treatment modalities for distal ureteral calculi. Some authors[6,7] favor ESWL while others[8-10] prefer URS. For both treatment modalities stone-free rates of more than 90% have been reported[7,9,10]. The American Urological Association Ureteral Stones Clinical Guidelines Panel has found both to be acceptable treatment options for patients, based on the stone-free results, morbidity, and retreatment rates for each respective therapy. However, costs and patient satisfaction or preference were not addressed[11]. The aim of this study is to compare the efficacy and safety of ESWL and URS for distal ureteral calculi with respect to

patient satisfaction and treatment efficacy.

Materials and methods

A total of 85 patients undergoing therapy for distal ureteral calculi between January 2004 and January 2009 were included in this study. Patients presented with radio-opaque ureteral stones distal to the bony pelvis on excretory urogram or computed tomography (CT) which had not passed spontaneously within 3 weeks. Patients were included in the study only if the intervention, either ESWL or URS, was the primary modality and there was a minimum follow-up period of 3 months. Patients for whom either therapeutic modality was contraindicated because of pregnancy, urinary tract infection, or coagulation disorders were excluded from the study. After defining the indications of treatment, the patients were made aware of both the modalities of treatment and their probable complications. The need for anesthesia, stent, urethral manipulation, possible complications, need for repeated follow up especially after ESWL, and the cost factor involved, were explained to the patient. The patients were then asked to choose the mode of treatment. ESWL was performed using the Siemens lithotripter. All patients were positioned prone and the calculi were localized with fluoroscopic guidance. All patients were given sedatives or analgesics and the level of shockwave energy was progressively increased till satisfactory stone fragmentation within the patient's comfort is obtained. URS was performed with rigid 8F Wolf ureteroscope following dilatation of ureteric orifice if needed. The stones were disintegrated with the Pneumatic lithotripter. Placement of a ureteral stent at the conclusion of the procedure was done for all patients. All patients were administered prophylactic antibiotic. Complete stone clearance was assessed at three months follow up. Patients were followed-up to assess the success rates and complications of the two procedures. The follow up schedule was similar in both groups of patients. Plain x-rays were obtained 2 weeks after discharge and thereafter if residual fragments persisted. Treatment failure was based on the need for further surgical intervention during follow-up or failure to become stone-free within 3 months[7]. At initial follow-up, patients were given a questionnaire, which we use for all patients with urolithiasis in this study based on published data about the factors that influenced patient satisfaction[7,9] (Table-I). Those with total score of 8 or less were considered satisfied with the procedure. Data were analyzed using student t-test.

Results

Thirty patients were treated with URS (male/female:18/12), while 55 (male/female: 32/23) patients were treated by ESWL. Patient's age varied between 18 and 60 years, with maximum number of patients between 30 to 45 years of age. There were no significant differences in the mean age, sex ratio and stone size in both groups (Table-II). For the extracorporeal modality, i.e. ESWL, the mean stone size was 10.4 ± 5.3 mm (range 4 to 27) (Table-II). In this group, 90% received intramuscular analgesia or sedation and 10% without the need for analgesia. All the patients (100%) had treatments as an outpatient procedure but all patients needed frequent follow-up visits. The average number of shock waves was 3000 at 10-20 kV. Stone-free status at 1 month and 3 month were 40% (n=22) and 76.3% (n=42), respectively. There were no major complications. Dysuria and loin pain were observed in 15 patients (27.3 %). In total, 48 patients (87.2%) required more than one session of ESWL for disintegration. Thirteen patients (23.6%) failed to respond to ESWL, six of them were referred to have

URS, four were subjected to open ureterolithotomy and three refused further treatment and disappeared for follow up. (Table- III). Considerable differences with regard to patient satisfaction were noted with a mean score of 5.03±3.08. Of the patients 42 (76.3%) were satisfied and will recommend the procedure to the others while 13 (23.6%) who required retreatment or URS would prefer to have URS for recurrence (Table-III). For the intracorporeal modality, i.e. URS with pneumatic lithotripsy, the mean stone size was 9.2 ± 5.4 mm (range, 4 to 27) (Table-2). In this group, 100% of patients had general anesthesia. All the patients had treatments as an inpatient procedure (100%) mainly for pain control, infection and stent-related symptoms but all patients needed less frequent visits for follow-up than ESWL. After URS, ureteric double J stent was kept in all patients (100%) for 4 weeks. All the stones were fragmented using the Pneumatic lithotripter. In 4 patients (13.3%) the initial attempt of URS failed due to failure to adequately dilate the ureteric orifice. Open surgery was required for two patients (6.6%) who had a hard 25 mm stone. The proximal migration of calculus occurred in 3 patients (10%) who were treated by ESWL. All other 21 patients (70%) were treated successfully with complete disintegration of their stones .Mean hospital stay in URS was two days. Dysuria and loin pain were seen in 13 patients (43.3 %). No long-term complications, such as ureteric stricture, were documented during the follow-up period. Oral pain medication was used in 86% of the URS compared with 74% of ESWL cases (p = 0.019). Follow-up was significantly shorter for the URS group (4.2 ± 3.4 versus 5.8 ± 3.0 weeks, p = 0.0001) (Table-3). Stone-free status at 1 month and 3 months were 93% and 97.5%, respectively. The mean satisfaction score was 4.03 ± 2.08 which is significantly different from the ESWL group (p = 0.043).

Discussion

Ureteric stones have a high probability of spontaneous clearance. Spontaneous passage should be favored if possible[11,12]. According to a meta-analysis by the AUA Guidelines Panel, newly diagnosed stones with a diameter < 5 mm will pass in up to 98%, depending on the degree of obstruction, urothelial odema and degree of impaction[11]. With close controls and in absence of risk factors like impaired renal function, pain, urinary tract infection or fever, these stones can be followed safely until spontaneously cleared. However, most authors recommend not exceeding 4-6 weeks, especially for obstructive ureteric calculi[13,14]. These data show that the success rate is strongly influenced by the timing of therapeutic intervention[9]. The sooner therapy is initiated, the more stones that might have pass spontaneously will be treated and, thus, false results in favor of the chosen procedure will be obtained. In particular small stones have a high spontaneous passage rate and so therapeutic intervention should be delayed to allow clearance[9]. Peschel et al.[9] have reported on the differences that they have encountered in dealing with distal ureteral calculi with both ESWL and URS (rigid or semi-rigid). URS was significantly better in terms of shorter operative time, fluoroscopy time and time to achieve a stone free status. The authors recommend URS as first-line treatment for smaller stones (< 5 mm) that do not pass spontaneously. In our series patient satisfaction was uniformly high in both groups but only significantly higher for URS (90 %, 19 patients) compared to shock wave lithotripsy (80%, 34 patients) (p = 0.002). Also, patient willingness to undergo a repeated procedure of the same type favored URS. No true validated instrument exists for comparing patient symptoms and satisfaction with these different treatment options[15]. The efficacy of the treatment cannot be only judged by the stone free

rate but various other parameters like postoperative symptoms, patient willingness to undergo a repeated procedure or to recommend it and the time of return to normal activity. The satisfaction criteria in this study were more extensive. In our series from the patient viewpoint achieving a stone-free state as soon as possible is the ultimate goal once the therapeutic approach has been chosen by most of the patients. Patient satisfaction generally reflected treatment success. When assessing the efficacy of treatment an important consideration is the time it makes to achieve a stone free status. Peschel et al.[9] also concluded that in this respect there are considerable differences between ESWL and URS. Therefore, most patients in their study were satisfied with URS but would not be satisfied with ESWL. Pearle et al.[7] found no significant difference in postoperative symptoms between the two treatment groups despite the presence of a ureteral stent in virtually all patients who underwent URS but only 16% of the ESWL group. Their sample size may preclude statistical significance but there was a definite trend towards fewer symptoms in regard to bladder irritability with shock wave lithotripsy. The ESWL group used less pain medication for a shorter period compared with the URS group, and patient satisfaction slightly favored ESWL[7]. They recommended ESWL with a HM3 lithotripter as first-line treatment for distal stones. In our series, oral pain medication was used by 74% of the ESWL group compared to 86% of the URS cases, (p=0.019), and the duration of analgesic use was significantly longer in the URS group (p = 0.029). Despite this our patients favored URS because of the longer time to obtain a stone free status with the ESWL in addition to the other parameters in the questionnaire. In this respect our results are in agreement with those of Peschel et al.[9]. From a retrospective review of planned same-day discharge after ureteroscopy in 114 patients, Wills and Burns[16] concluded that ureteroscopy should be considered as an outpatient procedure In our study all patients subjected to URS were treated as inpatient cases because of the need for antibiotic and analgesia requirements. Given the high success rates for both treatment modalities in our study, treatment success must also consider secondary outcome parameters, such as complications rates, patient satisfaction, procedural efficacy and cost. Complication rates are low for the treatment modalities. Complications associated with ESWL are generally mild and related to fragment passage. In this study, although not reaching statistical significance, there is an increase in minor complications occurred with URS compared to ESWL. Consequently, ESWL is a marginally safer modality associated with few if any long-term sequelae. However, the invasiveness of ureteroscopy cannot be neglected. A comprehensive review of acute endoscopic injuries reported in the literature from 1984 to 1992 identified 314 ureteric perforations that occurred in 5117 procedures (6.1%) and complete ureteric avulsion in another 17 procedures, though infrequent, were documented (0.3%)[17]. Harmon et al.[18] observed a decrease in overall complications from 20% to 12% during a 10-year period which were attributed to smaller ureteroscopes and increased surgeon's experience. Schuster et al.[19] suggested a significant reduction in ureteric perforation with a less operative time and postoperative complications with the surgeon's experience. Proximal migration of stones occurred in 3 patients (10%), which is less than what had been reported[20,21]. With the emergence of flexible ureteroscopes, migrated stones could be retrieved with basket. We still use rigid ureteroscopes for all ureteric calculi. In our study, all patients (100%) of the URS group had a double-J ureteric stent inserted. Routine placement of ureteral stent after ureteroscopic stone has been

considered the standard of care in most centers but Denstedt et al.[22] performed a prospective trial of non-stented versus stented ureteroscopic lithotripsy, and concluded that patients without a stent have significantly fewer symptoms in the early post-operative period, while there were no differences in terms of complications and stone free status. In addition it is also important to notice that with ESWL, more follow-up visits to the clinic were required until a stone-free state was achieved and at each visit, the patient was exposed to radiation from plain radiography. On the other hand, an important disadvantage of URS is that the procedure has to be performed under general or spinal anesthesia as compared to ESWL, which uses intramuscular analgesia. This exposes the patient to the risks of anesthesia and makes it unfavorable to patient with significant medical problems but there are some reports on local anesthesia combined with intravenous sedation for URS[23,24]. The need for anesthesia during ESWL depends largely on the energy source. While spark gap lithotripters (HM-3, MFL 5000) are highly effective, they are also more painful for the patient, whereas piezoelectric shock wave lithotripsy is associated to the least pain yet low efficacy. We could not find difficulty in stone localization under sedation with the Siemens lithotripter. We suggest that the choice of treatment modality for ureteric stones will depend on the patient since the expertise for both modalities are equally available. Patient's factors will include acceptance of invasive procedure, physical health and preference for earlier stone-free status. Open surgery was required for two of the patients with hard large stones. Sharma et al[25] reported that open mini-access ureterolithotomy to be a safe and reliable minimally invasive procedure. Success rates for shock wave lithotripsy may differ according to the lithotripter used. It is important to stress that the results with shock wave lithotripsy are truly machine specific and cannot be translated to use with other lithotripters[26]. The Siemens Lithotripter that is used proved in different series to be very effective in the treatment of renal and ureteral calculi[27].

In summary, ESWL offers minimal invasiveness but a higher risk of treatment failure compared to URS which reaches immediate high stone free rates. ESWL is a marginally safer modality associated with few if any long-term sequelae. Treatment decisions have to be drawn individually taking into account patients preference, personal experience and local equipment. The results of this study suggest that ureteroscopy is preferable to ESWL for treatment of distal ureteral calculi since it is significantly more efficient with higher patient satisfaction.

Table I: postoperative questionnaire

	0	1	2	3
Postoperative symptoms				
Dysuria	**No**	**Mild**	**Moderate**	**Severe**
Hematuria	**No**	**Microscop.**	**Macroscopic-no clots**	**With clots**
Loin pain	**No**	**Mild**	**Moderate**	**Severe**
Time to normal activity	**0-1 day**	**2-3 day**	**3-6 days**	**>6 days**
Global satisfaction	**Yes**	**Not sure**	**No**	
Willingness to repeat	**Yes**	**Not sure**	**No**	
Recommend. the proced.	**Yes**	**Not sure**	**No**	

Table II: Baseline comparability of the two treatment groups

	ESWL	Ureteroscopy	p Value (t-test)
N. patients	55	30	1.103
Mean age ± SD (year)	42.3 ±12.0	45.3 ± 14.0	
Male to female ratio	1: 0.3	1: 0.5	0.121
Mean stone size ± SD (mm)	10.4 ± 5.3	9.2 ± 5.4	

Table III: Results of ESWL versus Ureteroscopy

	ESWL	Ureteroscopy	p Value	(URS)
No. of auxiliary procedures	13 (23.6%)	11 (36.6 %)	< 0.0001	URS & open ESWL & open
Dysuria and loin pain	15 (27.3%)	13 (43.3%)	0.128	
Mean follow-up ± SD (wks)	5.8 ± 3.0	4.2 ± 3.4		
Patient satisfaction (score)	5.03 ± 3.08	4.02± 2.08	0.043	
Patient satisfaction (No.)	34 (80%)	19 (90 %)	0.002	
Postoperative analgesia	41 (73.9%)	26 (86.7%)	0.019	
Mean period of analgesia (days)	1.9 ± 1.5	2.4 ± 1.5		

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