COMPARISON OF EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY VERSUS URETEROSCOPIC HOLMIUM: YAG LASER LITHOTRIPSY FOR PROXIMAL URETERAL CALCULI. A RCT AT TERTIARY CARE CENTRE

Muhammad Naeem[1], Asad Shamsher[1], Zahid Ullah Khan[1], Rizwan Ullah[1], Qaiser Iqbal[1], Bakhtawar Gul Wazir[1], Asif Malik[1]

ABSTRACT

Objective: To compare the efficacy of laser ureteroscopic lithotripsy versus extracorporeal shockwave lithotripsy in the treatment of proximal ureteral stones of size between 10mm to 15mm.

Material and Methods:

This study was conducted in the Institute of Kidney Diseases, Hayatabad, Peshawar from May, 2012 to April, 2016. This study is randomized controlled trial. Two hundred and eighty-two patients with 10 – 15 mm proximal ureteric stone, one group were treated with ESWL and second with ureterorenoscopic manipulation by using an 8.0 or 8.5 Fr semi rigid ureteroscope. Intracorporeal lithotripsy was performed by using Ho: YAG laser. The stone free rate was compared between groups by considering size of stone at two weeks after procedure.

Results: Stone clearance among patients undergoing ESWL was effective in 68.8% (n=97) while in the URSL group 80.85% (n=114) were treated successfully.

Conclusion: Both Laser URSL & ESWL are well accepted minimally invasive modalities of treatment for proximal ureteric stones. We conclude that Laser URSL in the treatment of patients with proximal ureteric stones has yielded superior results as compared to the ESWL group in treatment of patients with proximal ureteric stones of size 1-1.5cm.

Key words: ESWL, URSL, Ureteric Stone etc.

INTRODUCTION

Urolithiasis is a common disease with globally increasing incidence and significant socio-economic implications, with a peak incidence around the third to fourth decade of life[1,2]. There are many options for urologists to treat ureteral stones that range from 8 mm to 12 mm including ESWL and ureteroscopic holmium laser lithotripsy[3] while ESWL and ureteroscopy are effective and minimally invasive procedures. The choice of ESWL or ureteroscopy for ureteric stone management is one of the most commonly debated controversies in endourology[4]. Most of the comparative studies between ESWL and ureteroscopy are not conclusive and at times ambiguous[5,6]. While some studies are in favor of ESWL, others concluded that ureteroscopy is the preferable approach[7,8].

Laser technologies are established standard modalities for application on lithotripsy[1]. The introduction of the Ho: YAG laser have broadened the indications for ureteroscopic stone managements (URS) to include larger stone sizes throughout the whole upper urinary tract[2]. Furthermore, recent developments in the design of ureteroscopy and endoscopic instruments have enabled the URS to replace the open surgery treatments for urinary calculi over the last decade as a minimally invasive modality.

The Nephrolithiasis Guidelines of both the European Association of Urology (EAU) and American Urological Association (AUA) have focused on the changes in ureteral stone managements. According to these guidelines, the extracorporeal shock wave lithotripsy (SWL) and URS remain the two primary treatment modalities for the management of symptomatic ureteral calculi[3]. This was based on their meta-analysis. There was no difference in stone-free rates between SWL and URS after all primary procedures in the proximal ureter (82% versus 81%, respectively). This was dependent on the stone size. For small proximal stones (<10 mm), SWL stone free rate was higher than URS (90% versus 80%, respectively), however, for larger stones (>10 mm), URS stone free rate was superior (79% versus 68%, respectively). Interestingly, URS yields better stone-free rates for distal stones independent of the size (94.5%5 versus 74%, respectively)[3].

Department of urology, IKD/HMC Peshawar

Address for correspondence:
Dr. Mohammad Naeem
Department of urology, IKD/HMC Peshawar
Email: mnaeem04@yahoo.com
Phone: +92-333-9119697

METHODOLOGY

The study was conducted after getting approval from hospitals ethical and research committee. Patients with symptoms of ureteric colic registered in OPD were followed by detailed history and thorough examination. The patients meeting the inclusion criteria were included in the study. Patients were allocated to either group A or B by lottery method. The purpose, risks and benefits of the study were explained to all included patients, they were assured that the study is purely conducted for research and data publication and a written informed consent was obtained from all included patients explaining merits and demerits of both treatment options. Preoperative necessary investigations like blood complete, renal function tests, urine R/E and C/S, imaging studies, including x-rays KUB, ultrasonography, intravenous pyelography or CT Urography were done to evaluate for stone size, pelvicaliceal system anatomy and other pathology. Group A was treated with ureteroscopic laser lithotripsy and group B treated with ESWL. The first group was admitted and surgery was done the next day, while the patients in group B was treated as outpatients on day care basis. ESWL was performed using the MODULITH SLX-F2 (STORZ, Switzerland).

All patients were put in prone position and the calculi were localized with fluoroscopy for the radiopaque stones and ultrasound guidance was used for radiolucent stones for focusing. The level of shock wave energy was progressively stepped up taking into consideration patients' comfort and level of pain till fragmentation of stones within the ease of the patient. URS was performed with semi rigid 8 Fr. KarlStorz Ureteroscope. The stones were disintegrated with laser lithotripsy by using Ho: YAG laser. Placement of ureteral stent was left at the discretion of the operating surgeon. All patients were given prophylactic antibiotics. After completion of the procedure, at-hand fluoroscopy was performed to know the stone-free status of the ureter. Stone fragments less than 5mm, non-obstructive were considered insignificant residual fragments. Patients in each of the two groups were followed-up to assess the efficacy of the two procedures. Complete stone clearance was assessed at two weeks follow-up. Fragments more than 5mm with obstructive symptoms or requiring additional treatment modality after two weeks were considered significant residual fragments.The follow-up schedule is same for both groups of patients i.e. 2 weeks interval. Complete examination and investigations were performed at follow-up visits. All the data was recorded in a pre-structured proforma.

RESULTS

The study included a total number of two hundred & eighty-two patients with proximal ureteric stones, which were divided in two equal groups. Patients in one group were treated by Extracorporeal Shock Wave Lithotripsy & another group was dealt with Ho: YAG laser lithotripsy with Ureterorenoscopy.

Age distribution among 282 patients was 43(15%) patients were in age range < 20 years, 42(15%) patients were in age range 21-30 years, 96(34%) patients were in age range 31-40 years, 46(16%) patients were in range 41-50 years, 56(19.85%) patients were in range 51-60 years. Mean age was 35.34 years SD $\pm$11.9. (As shown in Fig.1 & Table 1).

Gender distribution among 282 patients was analyzed as 159(56.38%) patients were male and 123(43.6%) patients were female. (As shown in Table 2).

Stone clearance among patients undergoing ESWL was effective in 68.8% (n=97) and was not successful in 31.2 % (n=44), while in the URSL group 80.85% (n=114) were treated successfully and in 19.1 %(n=27) patients with proximal ureteric stones the stone clearance efficacy was noteffective. This shows that the efficacy in terms of stone clearance was highly significant in both groups (p=0.020) (as shown in Table 3).

When age was stratified among the two groups in comparison, we got the following results. Mean age+ SD were 35.20 years $\pm$ 11.96SD in the ESWL group while the mean ages were 35.47$\pm$11.83SD in the URSL group. The age range was from 18 to 60. Minimum age of patient was 18 years and maximum 55 years among the patients having proximal ureteric stones. The mean age comparison between the two groups was not significant (p=0.901)

The mean Stone size among patients treated with ESWL was 11.58mm $\pm$1.35SD, while on the other hand mean stone size was 11.58mm $\pm$ 1.40SD respectively. The most frequently occurring stone size was in the range of 11 to 12mm. stone size distribution was also insignificant with p-value = 1.00.

Gender wise stratification shows that out of 159 patients (56.4%) among male patients 80(50.3%) were

Table No 1: Age Distribution (N=282)

Age	Frequency	Percentage
≤ 20	43	15%
21-30	42	15%
31-40	96	34%
41-50	46	16%
51-60	56	20%
Total	282	100%

Table No 2: Gender Distribution (N=282)

Age	Frequency	Percentage
Male	159	56.38%
Female	123	43.6%
Total	282	100%

Table No 3: Comparison of Eswl and Ursl Stone Clearence (N=282)

			Group		Total	p-value
			ESWL	URSL		
Stone clearance	No	Count	44	27	71	0.020
		% within Group	31.2%	19.1%	25.1%	
	Yes	Count	97	114	211	
		% within Group	68.8%	80.80%	74.8%	
Total		Count	141	141	282	
		% within Group	100.0%	100.0%	100.0%	

Table No 4: Stratification of Eswl and Ursl in Stone Size Distribution (N=282)

	Group	N	Mean	Std. Deviation	Std. Error Mean	p-value
Stone size	ESWL	141	11.58156	1.35307	.11395	1.0
	URSL	141	11.58156	1.40994	.11874	

Table No 5: Stratification of Eswl and Ursl in Gender Distribution (N=282)

			Group		Total	p-value
			ESWL	URSL		
Gender	Male	Count	80	79	159	0.905
		% within Group	56.7%	56%	56.38%	
	Female	Count	61	62	123	
		% within Group	43.2%	44%	43.6%	
Total		Count	141	141	282	
		% within Group	100.0%	100.0%	100.0%	

treated by ESWL and 79(49.6%) were managed by URSL. while out of a total 123(43.6%) among female patients 61 (49.5%) were included in ESWL group and 62(50.4%) were managed by URSL. Sex distribution among between the two groups was insignificant with a p-value=0.905. (As shown in Table 5).

DISCUSSION

Urolithiasis has afflicted humans throughout the known history of mankind. In 1901 the British archeologist E. Smith found a 5000-year-old bladder stone at the funeral site of El Amah, Egypt[20].

The overall probability of urinary stones formation in an individual varies in different parts of the world. The prevalence of Urolithiasis in the developed world is about 10-15 % and in the developing world like ours, it is the most common disease in our daily urological practice. Pakistan is also situated in the hub of stone belt.

No part of the human urinary tract is immune to stone formation. So Stones can be found in kidneys, ureters, bladder and even the urethra. Stones found in the upper part of ureter are called proximal ureteric stone.Technically proximal ureteric stone is defined "as the stone in ureteral segment between the ureteropelvic junction and the upper border of the sacroiliac joint[1].

The management of stone disease has travelled for centuries from herbal medication to the tremendous development in modern day endourologic and extracorporeal shock wave lithotripsy modalities of treatment. Various research studies have addressed the effectiveness of different sources of energy to disintegrate stones in the ureter.

There are several Intracorporeal lithotripsy (URSL) alternatives, such as electro hydraulic lithotripsy, ultrasonic lithotripsy, pneumatic, and holmium laser lithotripsy. Among these treatment options we use laser lithotripsy, successfully for ureteral stone treatment. According to the literature the success rate of laser lithotripsy appears to be higher than 90%. ESWL can be a modality treatment for most upper urinary tract stones, because of its simplicity, noninvasiveness and minimal morbidity. However, some stones are difficult to fragment by ESWL or the fragments may remain in the urinary tract even after successful fragmentation of the stone.

Variable stone clearance rates have been re-

ported in published literature. In a study conducted by Razaghi et al, for stones between 1-2 cm size, the URSL group showed an efficacy of stone clearance for upper ureteric stone to be 82.1% which approximate our stone clearance results in terms of efficacy which is 84.1%. However, the mean stone size in his study (10mm+5.6SD) is smaller than our study results which is (11.80mm+1.40 SD).[21]

Our study results show comparable results in terms of mean stone size, mean age and efficacy of stone clearance to a national study showing efficacy of 80.85% in terms of stone clearance URSL in the proximal part of ureter.

Cui Y in 160 patients showed stone clearance rates of more than 90% for ESWL and Laser Lithotripsy[10]. In the study by Ghoneimet al., they reported a stone-free rate of SWL in the management of impacted proximal ureteral stone to be 90% and 86.7% in the stented and non-stented group of patients, with an overall stone-free rate of 88.3%[11]. Omar M Aboumarzouk showed that Stone free status for laser was 87.7% in sixty-four patients[12] while Mohammed S. showed that stone clearance was 88% for ureteric stones treated by ESWL[13]. Mohammad F. Ahmed at al showed in 99 patients that stone free rate was 66% for upper ureteric stones at end of 4 weeks for laser lithotripsy($p<0.05$)[14] while Hafez and colleagues showed the stone free rate at 3 months after the last ESWL treatment session as 79.2%[15]. Ryoji Takazawa showed the overall stone free rate after one session of laser lithotripsy was 80.4%[16]. Study by Joshi HN et al showed that stone free rate was 72% in the case of renal and 86.6% in the case of ureteric stones in first session. In three months follow up (three sessions) it was 95.4% and 97.2% respectively for renal and ureteric stones.

In relation to size the stone free rate in <10mm, 10-15mm and > 15mm was 97%, 97% and 90% respectively[17]. Pearle and Lee found that the patients have a higher satisfaction with ESWL versus URS[18]. Results from a meta-analysis of five studies indicated that ureteroscopically treated patients needed more auxiliary procedures than those who underwent ESWL[19]. Another published research study showed inferior success rate of ESWL for proximal ureteric stones as compared to our success of ESWL for proximal ureteric stones.[121]

The strength of my study is that it is the first randomized control trial study in the present set up, on this very important and common topic. This study has generated some local statistics about the management of proximal ureteric stones in our adult study population and the results of this study can now be used as a first-hand evidence to make modifications in our local guidelines for the treatment and follow up of patients with proximal ureteric stones. Moreover, it is a larger sample size study compared to the other nationally and some of the internationally published studies on this topic.

Our study has certain limitations particularly that we couldn't asses the hardness of stone on CT scan measuring the house field (HU) units of stone density, before embarking upon the desired modality of treatment because it may a confounding factor in especially in ESWL group. Moreover, our patients' follow-up in both groups was for a very short period of time.

This study is implicated on urologists, surgical specialists, nephrologists, & general medical practitioners who come across the patients suffering from proximal ureteric stones. There are some unanswered questions regarding the efficacy of stone clearance that why out of 282 patients, some of the patients were able to successfully clear the stone while others couldn't make it in spite of similar stone size in both of the treated groups. So, further research is desired to have an answer to these unanswered queries.

CONCLUSION

Both Laser URSL & ESWL are well accepted minimally invasive modalities of treatment for proximal ureteric stones. We conclude that Laser URSL in the treatment of patients with proximal ureteric stones has yielded superior results as compared to the ESWL group in treatment of patients with proximal ureteric stones of size 1-1.5cm.

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