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Interventional treatment of ureteric stones: A prospective randomized controlled trial on comparison of Ho: YAG laser and pneumatic lithotripsy in children.

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Abstract

Urolithiasis in pediatric age group is not similar to that of adults, in regard of aetiology, incidence, and disease course. It is very important to apply minimally invasive surgery for those patients due to the possibility of recurrence in the future. General anesthesia is needed in Extracoprporial Shockwave Lithotripsy (ESWL) in children. So, in cases which require multiple ESWL sessions that mean exposure to more risk of general anesthesia? ESWL is not suitable in cases of large size stones, uric acid stones, cysteine stones and stones masked by bony structure. The study included patients who did not pass detected stones after failure of conservative therapy, stone large to be passed, patients with severe pain or patients with single functioning kidney.

The statistical approach used chi squared test for categorical variables and t test for continuous variables with a p value of less than 0.05 was considered significant. The study succeeded to include 93 child patients with no loss during the follow up period. They were having a total of 111 stones distributed as 59 in Laser group and 52 in pneumatic group. The results of this study showed that age and sex distribution were similar in both groups. The technology has made it possible to access and treat stone within the ureter easier. Holmium laser lithotripsy work primarily through a photo-thermal mechanism that causes stone vaporization and had the ability to fragment all stones regardless of composition. Laser lithotripsy is adding to the health care technologies in Basra city with regards to treatment of ureteric stones. The new experience showed a better safety and efficacy although the older pneumatic approach still have an important role in the management of urolithiasis, considering its low cost and longer durability.

Background: Aim of this study is to compare the possible two modalities namely Ho: YAG and pneumotic lithotripsy in the setting of health care of Basra/Iraq

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Introduction

Urolithiasis in pediatric age group is not similar to that of adults, in regard of aetiology, incidence, and disease course [1]. Underlying abnormalities, like anatomical, metabolic disorders and urinary system infections are claimed to play an important role in the development of pediatric urolithiasis. Therefore, it is very important to apply minimally invasive surgery for those patients due to the possibility of recurrence in the future [2].

General anesthesia is needed in Extracoprporial Shockwave Lithotripsy (ESWL) in children. So, in cases which require multiple ESWL sessions that mean exposure to more risk of general anasthesia. ESWL is not suitable in cases of large size stones, uric acid stones, cysteine stones and stones masked by bony structure [3]. A number of factors must be considered in determining the optimal treatment for patients with renal or ureteral calculi. These factors may be grouped into four broad categories: stone factors, clinical factors, anatomic factors, technical factors [4]. Shock wave lithotripsy still plays an important role for many ureteric calculi, particularly smaller ones, and the addition of percutaneous/antegrade ureteroscopy and laparoscopic ureterolithotomy rounds out the treatment options for large or impacted stones. Selection of treatment based upon factors such as size, location, and others will optimize outcome for patients who have ureteral calculi [5].

The improvements in ureteroscopic technology have enabled retrograde ureteroscopy to become a first-line option for most ureteral stones. Advances have been made in ureteroscopes and the introduction of small caliber semirigid ureteroscopes, as well as lithotripsy techniques such as holmium: yttrium-aluminum-garnet laser lithotripsy and pneumatic lithotripsy have improved the success rates while decreasing the complications [6,7]. The aim of this study is to compare the possible two modalities namely Ho: YAG and pneumotic lithotripsy in the setting of health care of Basra/Iraq.

Materials and Methods

This is a sort of prospective clinical trial implemented for the period July 2017-Mar 2020 in Basra Teaching Hospital. It included 93 patients with ureteric stones on either side. The patients were randomly divided into two groups of 46 and 47 patients respectively. Two treatment options were used for the two groups as follows:

Group 1 (46 patients): Ho: YAG laser lithotripsy (G1)

Group 2 (47 patients): pneumatic lithoclast (G2)

The study included patients who did not pass detected stones after failure of conservative therapy, stone large to be passed, patients with severe pain or patients with single functioning kidney. The exclusions are patients with stones greater than 1.5 cm, renal impairment, congenital abnormality of ureters, urinary tract infections and 11 patients were excluded due to failure of ureteroscope advancement into the ureter. After full history and examination, all patients were fully investigated by general urine exam, KUB, ultrasound, and CT scan. The time of surgery was calculated from the start of lithotripsy till the insertion of DJ catheter. In the preoperative period, all patients had negative urine culture and received IV antibiotics (0.5 gm ceftriaxone) at induction of anesthesia.

The patients were placed in lithotomy position and ureteroscope advance into the bladder then a guide wire was inserted into the ureteral orifice and ureteroscope (6.5 fr) was used in all patients. Stone cone 3 fr (Boston Scientific) was inserted behind the stone to prevent migration. The stones were fragmented by a 0.8 mm lithoclast probe with single fire or Ho: YAG laser with end-firing probe 600 μm, the pulse energy 1.2 J with a pulse rate of 8 Hz. Double J ureteral catheters were inserted in all patients. One week after surgery, all patients were sent for KUB and US to assess the stone free rate. The statistical approach used chi squared test for categorical variables and t test for continuous variables with a p value of less than 0.05 was considered significant.

Results

The study succeeded to include 93 child patients with no loss during the follow up period. They were having a total of 111 stones distributed as 59 in Laser group and 52 in pneumatic group. They were blindly subdivided into two groups of 46 and 47 who were treated by laser lithotripsy and pneumatic lithoclast respectively. The results of this study showed that age and sex distribution were similar in both groups. Age ranged from 7-15 years with an average of 9.8 years and a SD of 3.1 years (Table 1). Similarly, stone size distribution was not statistically different in the two groups (Table 1).

		Group 1 (lithotripsy)	Group 2 (Pneumatic)	Statistical significance
		N=46	N=47	
Age (in years)	Male	9.32 ± 4.12 (n=22)	10.01 ± 3.87 (n=20)	NS
	Female	10.11 ± 3.90 (n=9)	9.86 ± 4.71 (n=12)	
Stone size (mm)		11.23 ± 1.98	10.28 ± 2.30	NS
Stone location	Lower (n)	29 (49.1%)	26 (50.0%)	NS
	Middle(n)	20 (33.9%)	17 (32.7%)	
	Upper (n)	10 (17.0%)	9 (17.3%)	
Total (number of stones)		59	52	

Table 1. Patients and stone characteristics.

The distribution of stone location proved to be not statistically different in the two groups (Table 1). Migration occurred in lithoclast group more frequently where 1 from the middle and 2 from the upper ureteric stones of the lithoclast group migrated contrast to 1 and 1 in the laser group respectively. There was an apparent difference in the rate of fragmentation between the two approaches under study. However, this difference was proved by statistical tests. More obviously, stone disappearance by KUB and ultrasound imaging were more frequent in laser group with a confirmed statistical inference (P value 0.032). Similarly, fragmentation was affected by migration of certain stones (Table 2). Table 2 also shows that success rate is higher with laser lithotripsy with fewer occurrences of complications apart from fever.

		Group 1 (laser lithotripsy)	Group 2 (Pneumatic lithotripsy)	P value
Fragmentation	Lower (n)	29/29 (100%)	24/26 (92%)	NS
	Middle (n)	17/20 (85%)	26/32 (81%)	0.046
	Upper (n)	6/10 (60%)	5/9 (55.5%)	0.025
Residual fragments (need second ureteroscope retrieval)		2/ (5.6%)	5/41 (12.2%)	0.01
Migration		3/59 (5.0%)	4/52 (7.7%)	NS
Stone clearance rate*		51/59 (86.4%)	41/52 (78.8%)	0.032
Perforation		0/59 (0%)	1/52 (3.1%)	NS
Fever (infection)		6/59 (10.1%)	4/52 (7.7%)	NS
Mucosal injury		4/59 (6.7%)	5/52 (9.6)	NS

Table 2. Results of interventions including complications.

*Exclude 4 stones, two of them were due to migration and other 2 because of residual fragments in laser group while in pneumatic lithotripsy we exclude 8 stones, 3 and 5 respectively. The duration of intervention is significantly longer in laser group as concluded by Student's t-test. However, hospital stay is not significantly different (Table 3).

	Group 1 (lithotripsy) N=31	Group 2 (Pneumatic) N=32	Statistical significance
Duration of procedure (mean ± SD) (minutes)	33.7 ± 7.6	25.2 ± 9.3	0.044
Hospital stay (Median in days)	2.4	2.2	NS

Table 3. Duration of procedure and duration of hospital stay.

Discussion

Strength of the study

It is the 1st study done in our locality to compare such modalities as a treatment strategy for uretrolithiasis.

Limitations

So difficult to gain large numbers of pediatrics and adolescents, to engaged in such study.

Important topics in discussion

The technology has made it possible to access and treat stone within the ureter easier. The holmium: YAG laser is a solid state system which can be used to fragment stones of all composition with a fragmentation rate of 90%-100% [8].

Laser lithotripsy has significant advantages over the other lithotripsy techniques the probes for laser lithotripters are more suitable for smaller caliber instruments [9].

The long holmium: YAG pulse duration produces an elongated cavitation bubble that generates only a weak shockwave [10].

This explain the low rate of stone retropulsion with laser lithotripsy (4%) compared with pneumotic lithotripsy (22.5%).

Holmium laser lithotripsy work primarily through a photo-thermal mechanism that causes stone vaporization and had the ability to fragment all stones regardless of composition.

This explains the higher rate of stone clearance with laser lithotripsy (84%) compared with pneumotic lithotripsy (72.5%).
The depth of thermal injury to the urethelium is only 0.5-1 mm and this explains the very low incidence of perforation of the ureter with LL [9]. The only disadvantage of this energy source seems to be the cost of the device and the requirement for eye protection [6]. The Swiss Pneumotic lithoclast was developed in Switzerland in 1989 and clinical results of its use in fragmenting urinary stones were published in the early 1990s [11]. The disadvantage being stone migration up, because of jack hammer mechanism of lithoclast probe [12].

Most of the migrations occurred in proximal ureteric stones. Used lidocain jelly for preventing stone displacement during pneumatic lithotripsy for ureteral calculi. According to Peh et al. Holmium: YAG laser lithotripsy is both effective and safe [13].

In another study conducted by James D et al holmium: YAG laser is even safer in patients with bleeding diathesis [14]. Acomparison of holmium: YAG laser with pneumatic lithotripsy in ureteral calculi fragmentation was done by Jeon et al. in Korea [15]. This study revealed that laser is better than lithoclast in terms of stone free rates as well complication rates. This study also gives similar results. A prospective randomized controlled trial comparing non stented versus stented ureteroscopic lithotripsy by John D et al had given the observation that routine stenting after ureteroscopic intra corporeal lithotripsy with the holmium laser is not required as long as the procedure is uncomplicated [16].

Ureteral calculi that fail with conservative measures require intervention. Endoscopic lithotripsy is going on to be more evolve by progressing on technological advances in all direction and increase the efficacy and safety of ureteral stone treatment.

Improvement and refinements in endoscopic lithotripters are expanded the patient population that need to treatment and included many patients with urinary calculi in this way. [6] However, this is a new experience in Basra city within the setting of Iraqi health system. The relatively short period of working with these new instruments date of installation of device.

This study followed a similar methodological approach of a study implemented in India. However, other studies may follow different tools with a similar approach e.g. Mohammad et al. in Iran [17]. Sample size represented a challenge to this study because of certain limitations peculiar to Iraqi situation. The sample size is essentially lower than other studies like which included 79 patients and which involved 112 patients [6,17]. This study is approximately identical in sample size to another Iraqi study performed in 2012 in Baghdad [18]. Larger scale studies included more than 200 patients [7]. Recently, similar studies were proved to be coherent in the pattern of results they concluded [8].

Finding in current study

In the current study: Age ranged from 7-15 years with an average of 9.8 years and a SD of 3.1 years (Table 1). Similarly, stone size distribution was not statistically different in the two groups, Patient characteristics as results show indicating that sex of patients is essentially not influential factor that there is no significant statistical difference in terms of age, stone size and stone location. This fact is important to exclude any potential effect on the results imposed by the sex of the patients. Likewise, these factors were fixed so that the comparison is exclusive to the mode of intervention. Fixing the basic characteristics of patients was followed by the studies reviewed by the author Maghsoudi et al., Degirmenci et al., Mohammad et al., Shulian et al., Yiu et al. [6,7,17,19,20].

The distribution of stone location proved to be not statistically different in the two groups (Table 1). Migration occurred in lithoclast group more frequently where 1 from the middle and 2 from the upper ureteric stones of the lithoclast group migrated contrast to 1 and 1 in the laser group respectively. There was an apparent difference in the rate of fragmentation between the two approaches under study. However, this difference was proved by statistical tests. More obviously, stone disappearance by KUB and ultrasound imaging were more frequent in laser group with a confirmed statistical inference (P value 0.032). Similarly, fragmentation was affected by migration of certain stones. Table 2 also shows that success rate is higher with laser lithotripsy with fewer occurrences of complications apart from fever. Although fragmentation of stones seems to be similar in both modes of intervention under study, stone free rate is higher in Laser group as compared to pneumatic approach, the duration of intervention is significantly longer in laser group as concluded by Student's t-test. However, hospital stay is not significantly different (Table 2). This conclusion is coherent with a study in Iran, Turkey and in a local study [7,17,18].

Conclusion

Laser lithotripsy is adding to the health care technologies in Basra city with regards to treatment of ureteric stones. The new experience showed a better safety and efficacy although the older pneumatic approach still have an important role in the management of urolithiasis, considering its low cost and longer durability.

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