

Clinical Outcome and Running Cost of Holmium Laser Lithotripsy for Ureteroscopic Treatment of Upper Ureteral Calculi

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Abstract: Objective: To evaluate the efficacy, safety and running cost of upper ureteric stones treatment with holmium laser lithotripsy using semirigid ureteroscope. **Patients and Method:** 100 patients with upper ureteral calculi, who underwent ureteroscopic holmium laser lithotripsy using semirigid ureteroscope, were analyzed prospectively. Ninety patients completed the study and ten patients lost to follow up. Patients were evaluated about the gender, age, stone size, ureteral stenting, stone migration, residual stone, operative time, complication, previous ESWL application, hospitalization period and running cost. **Results:** The mean age of our patients was 42.49±13.10 (range: 17-71) years. Procedural failure was observed in 21(23.3%) of 90 patients. Double J stents were fixed in 56 (62%) of the patients. The total success rate was 76.67% and the average cost of laser lithotripsy including disposable elements was 520.12± 135\$. Three patients (3.33%) developed late post operative ureteral stricture. **Conclusion:** Ho: YAG laser lithotripsy using semirigid ureteroscope was effective in managing upper ureteral stones. It has satisfactory stone free rate, although major intraoperative complications may occur.

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Keywords: Ureteroscopy, Holmium: YAG Laser, Lithotripsy.

1. Introduction

According to EUA guidelines 2016 both ESWL and URS are treatment options for proximal ureteric stones < 10 mm and URS is the first choice for proximal ureteric stones > 10 mm then ESWL (Türk et al., 2016). Stone fragmentation through a rigid ureteroscope can be achieved with in situ lithotripsy. There are four types of stone fragmentation include: Ultrasonic, electrohydraulic, pneumatic and laser lithotripsy (Knudsen et al., 2004). The Ho: YAG laser is the most powerful intracorporeal lithotripsy and is considered the gold standard lithotripsy to be used in semirigid and flexible URS due to its ability to fragment all stone types (Leijte et al., 2008; Pierre & Preminger, 2007). The aim of this study was to evaluate the efficacy, safety and running cost of upper ureteral stones treatment with holmium laser lithotripsy.

2. Patients and methods

Between June 2014 and September 2016, a prospective study was done on 100 patients with upper ureteral calculi who were treated by semi rigid ureteroscopy using Auriga QI holmium laser lithotripsy (Star Med Tec Starnberg, Germany) at the department of Urology, Al-Azhar University hospitals, Cairo, Egypt after approval of study protocol by local ethical committee. Patients with single upper ureteral stone from ≤15 mm were included in this study. We excluded patients with

multiple stones, pregnant patients, patients with technical difficulty to pass ureteroscope and patients with renal or hepatic failure. Written informed consents were taken from all patients. All patients were assessed by a full clinical history, CBC, serum creatinine, coagulation profile, urine analysis, and imaging studies in the form of intravenous urography (IVU) and or computed tomography (CT) urography, and ultrasonography. Stone size was measured by using the longest axis of the stone viewed on plain film or sagittal section of CT scan.

All patients were treated under spinal or general anesthesia in lithotomy position with C-arm fluoroscopy guidance. Ureteroscopy was carried out by a 9.5 FR semirigid ureteroscope (Storz). After identification of the ureteric orifice, Retrograde study was done after passing open tip ureteric catheter to localize the stone, show the course of the ureter and sometimes to dislodge the stone to a higher wider place for easy application of the guide wire, Ureteral dilatation was done using balloon dilator or serial Teflon dilators up to 12F- 14F under fluoroscopy guidance and then the semirigid ureteroscope was introduced into the ureteric orifice, and continuous irrigation was used to maintain clear vision. Stone disintegration was performed using a pulsed 30 Watt holmium YAG laser (Auriga QI) via a 365µm laser fiber. The setting of the laser machine were adjusted to produce Pulse energy 800 –1200mJ/pulse with a frequency of 6-12 Hz. the laser fiber was placed 2mm

beyond the tip of ureteroscope & 1mm from urothelium & proceeded until Stone is fragmented to a particle size of 0.2 to 0.3 cm or powdered. Stone fragments were dealt according to their site and size. After finishing the procedure retrograde study was done to check extravasation. Endoscopic inspection was done at the end of the procedure to rule out any residual calculi or trauma. At the end of the procedure, ureteric catheter was placed for 24 hours up to 48 hours or double J stent was placed if intense mucosal edema secondary to an impacted calculus, mucosal laceration, perforation or stone migration to do ESWL or bilateral ureteric stones or single kidney.

Patients were followed up by KUB at day 1, 2 weeks and 3 months postoperatively. Ultrasound was done on day 1 postoperatively, and at 3 months follow up visit. At 3 months visit CTUT was done for patients who had radiolucent stones to document stone free status. At one year visit, patients had imaging studies to detect stone recurrence and diagnosis of late complications.

Stone free status was considered if no residual fragments were detected by imaging studies after three months of follow up. Patients who were found to have residual stones were scheduled for another procedure based on stone size and site.

A statistical analysis of the data was performed using software SPSS version 18. Data were expressed as both number and percentage for categorized data. Quantitative data was presented by mean and standard deviation, while qualitative data was present by frequency distribution. Student t- test was used to compare quantitative data between two groups. P values were estimated and considered statistically significant if less than 0.05.

3. Results

Ninety patients completed the study and 10 patients lost to follow up. Fifty-eight (64.4%) patients were males and thirty two (35.6%) were females; the average age was 42.49+13.10 years (range: 17-71 years). The mean stone size was 10.9+2.74 mm (range 6-15 mm). Fifty-two (57.7%) patients presented with

right sided stones and 38 (42.3%) patients with left sided stones. Eighty-three patients (92.2 %) had radio-opaque stones and the other seven patients (7.8%) had radiolucent stones. A history of ESWL was identified in 13 (14.4%) patients, and 67 patients (74.4%) had previous urological surgical history. Hydronephrosis of grades 1 (n=26; 28.9%), 2 (n=58; 64.4%) and 3 (n=6; 6.7%) was detected. The mean duration of lithotripsy for stone fragmentations into small and removable size was 15.38+5.07 minutes, the stone migration rate was 15.56% which occurred during URS or during laser fragmentation. Thirteen cases (14.4%) had intra operative complications in the form of major perforation and percutaneous nephrostomy was fixed in one case (1.1%), small perforation with minimal extravasation in 11 (12.2%) and gross hematuria in 1 (1.1%) case. Ureteral catheterization was performed in 56 (62.2%) of patients. The mean operative time was 49.78+13.61 minutes.

Success (stone free) rate was achieved in 69 (76.67%). Failures were observed in 21 (23.33%) patients. Failure was due to complete stone migration during URS 14 (15.56%) or residual fragment 7 (7.78%) post laser lithotripsy. Five patients (5.5%) had 2nd session URS to be stone free and sixteen cases (17.8 %) had ESWL session after ureteroscopy.

The average hospitalization period of the patients was 1.4+1.05 days (1-6). The average cost of laser lithotripsy including disposable elements (Guide wire, DJ, dye, ureteric catheter, Dormia basket, balloon dilator, Teflon dilator, laser machine (HOL-YAG), laser fiber and urethral catheter) was 520.12\$. Eight cases (8.9%) had early postoperative complications in the form of fever in 6 cases (6.7%), hematuria in 2 cases (2.2%), 3 cases of 12 (3.3%) who had intraoperative perforation, had late post-operative complications in the form of stricture at follow up of 12 months.

Operative time, stone free rate and complications rate were assessed in the term of stone size, as well as previous history of ESWL as illustrated in the following tables.

Table (1): Data analyses of history of ESWL.

Data	History of previous ESWL N=13	No History of previous ESWL N =77	P value
Mean operative time (minutes)	51.92±7.51	49.42±14.39	0.542
Stone free rate	11(75.3%)	58(84.6%)	0.464
Intraoperative complication	1(7.7%)	12(15.6%)	0.454
Early postoperative complication	0(0%)	8(10.4%)	0.223
Late post operative complication	1(7.7%)	2(2.6%)	0.344

Table 1 illustrates the data analyses of history of ESWL and its impact on the mean operative time ($p=0.542$), stone free rate ($p=0.464$) and complication rate whether intraoperative ($p=0.464$), early post operative ($p=0.223$) or late post operative ($p=0.344$) and none of these factors was statistically significant.

Table 2,3 illustrates the data analyses of stone size, and its impact on the mean operative time (**0.000**) which was statistically significant, stone free rate ($p=0.113$) and complication rate whether intraoperative ($p=0.769$), early post operative ($p=0.272$) or late post operative ($p=0.681$) which were not statistically significant.

Table (2): Data analyses of stone size and mean operative time.

Stone size	6-10	11-15	P value
Operative time (min)	44.27±10.62	56.07±14.03	0.000

Table (3): Data analyses of relation between mean stone size and Success rate, Intraoperative earlyoperative or late post operative complication

Stone size	Success rate (stone free)		T test	P value
	No	Yes		
	11.81±2.562	10.72±2.765	1.600	0.113
Stone size	Intraoperative complication		0.295	0.769
	No	Yes		
	11.01±2.770	10.77±2.682		
Stone size	early postoperative complication		1.105	0.272
	No	Yes		
	10.88±2.741	12±2.726		
Stone size	Late postoperative complication		0.412	0.681
	No	Yes		
	11.00±2.762	10.33±2.517		

4. Discussion

Although ureteroscopic treatment of upper ureteric stones had more complication rates and a longer hospital stay in comparison to ESWL, ureteroscopy was found to have more SFRs, less re-treatment rates and less need for secondary and auxiliary procedures (Türk et al., 2016).

Over the last decade, lasers have been increasingly used for intracorporeal lithotripsy (Breda et al., 2009). In our study the mean duration of lithotripsy for stone fragmentations into small and removable size was 15.38±5.07 minutes which coincides with Mahmoud and Bajalan who reported fragmentation time (14.7 ± 2.6) minutes at a mean stone size 12.34 ± 2.6 mm (Mahmoud and Bajalan, 2016). In our study, a double J stent was used in 56 patients (62.2%) which is reasonable according to study reported by Aydemir et al which revealed DJ Fixation in 54.1 % (Aydemir et al., 2016).

Ureteral stenting after uncomplicated ureteric procedures is not a routine at our institution, However these high DJ fixation rates might be due to the fact that we had high incidence of intense mucosal edema due to impacted stones (18 cases), mucosal laceration (5cases), intra operative perforation (12cases), migration of stones to the upper urinary system (14cases), single kidney (2cases) or bilateral ureteric

stones (5cases). We do not advocate routine stenting because of the intolerable urinary symptoms caused by the stent and placing a stent required more operative time, cost and reoperation for stent removal. Holmium: YAG laser lithotripsy had more advantages from the aspect of operation time. These findings could be best explained by the fact that holmium: YAG lithotripsy vaporizes and de bulks the stone until one or only a few fragments remain which may be grasped by forceps easily (El-feel et al., 2014).

In our study the mean operative time and stone size is 49.78±13.61 and 10.98±2.744 respectively. These findings approach results reported by Mahmoud and Bajalan which revealed mean operative time and stone size 40 ± 26 and 12.34 ± 2.6 respectively (Mahmoud and Bajalan, 2016). Similarly Turkan et al revealed mean operative time and stone size 45 ± 9 and 12.3 ± 3.7 respectively (Turkan et al., 2016). The main factor that affected operative time was stone size ($p=0.000$).

History of ESWL had no statistical impact on the mean operative time ($p=0.542$) Similarly, El-feel et al. found the same results when they conducted a study to assess the difference in operative time according to stone size ($p=0.03$) and history of ESWL ($p=0.6$) (El-feel et al., 2014). The average hospitalization period of the patients was 1.40±1.047

which is comparable to study reported by **Aydemir et al (2016)** who reported hospitalization period 1.09 ± 0.37 days (**Aydemir et al., 2016**).

In our study stone free rate was considered if no residual fragments were detected by imaging study after three months of follow up. In our study the stone free rate is 76.67% which is comparable to the study reported by **Yüksel et al** who reported a success rate of 81.1% for Mean stone diameter 13.08 ± 6.73 mm (**Yüksel et al., 2015**). Similarly **Alkan et al** revealed stone free rate of 76.5%. SFRs and mean stone size were 76.5%, and 9.1 ± 0.4 mm respectively (**Alkan et al., 2015**). **Juan et al** and **Moufid et al** reported a stone free rate of URS Laser to be 58%, 63% respectively and this relatively lower rate might be due to a larger stone size in their study >1.5 cm (**Juan et al., 2012; Moufid et al., 2013**). Our study showed that stone size or grade of hydronephrosis did not affect stone free rate, with p value (0.113) and (0.265) respectively. Similarly, **Yüksel et al (2015)** found the same results when they conducted a study to assess the stone free rate according to degree of hydronephrosis and size of stone p value (0.667) and (0.102) respectively (**Yüksel et al., 2015**). Failures are attributable mostly to stone migration. In our study twenty one (23.33%) cases failure due to complete stone migration during URS 14 (15.56%) or significant residual fragment 7 (7.77%) post laser lithotripsy, five of which (5.5%) needed 2nd URS session to be stone free and sixteen cases (17.8 %) had ESWL session after ureteroscopy. We did not use any occlusion devices to prevent upward migration because such devices were not available in our department. We did not have a flexible ureteroscope, so we used SWL for migrated stones left in renal collecting system.

The stone migration rate in our study was 15.56% which is comparable to the study reported by **Turkan et al** which revealed high stone migration rate (27.7 %). In contrast to **Maghsoudi et al** who revealed stone migration rate 2.4% (**Turkan et al., 2016; Maghsoudi et al., 2008**). In **Turkan et al** study no anti-migration device used to prevent the migration of the stones.

In our study thirteen patients (14.4) had stones that were resistant to ESWL prior to ureteroscopic management; eleventh cases (84.6%) of those who had ESWL before ureteroscopic laser lithotripsy were stone free while 58 cases (75.3%) of those who didn't have ESWL before URS were stone free. Stone free rate didn't differ between both groups with or without previous history of ESWL ($p=0.464$). No statistical difference was found between both groups in the complication rate ($p=0.879$) or operative time ($p=0.542$). Similarly, **El-feel et al.** found the same results when they conducted a study to assess

operative time, stone free rate, complications in relation to history of ESWL ($p=0.657$), ($p=0.228$) and ($p=0.341$) respectively (**El-feel et al., 2014**). The overall complication rate after URS is 9-25% (**Geavlete et al., 2006; Perez Castro et al., 2014**). Although ureteral perforation is one of the most common and serious complications of ureteroscope, but with the use of laser lithotripsy, the risk of perforation becomes less because the depth of thermal effect is 0.5-1 mm (**Manohar et al., 2008; Matlaga et al., 2012**). Clear vision is essential at all times to avoid perforation. Perforation can be caused by the ureteroscope, guide wire, or laser. The rate of perforation in proximal ureteral stone is in the range of 3-9%; however, this rate is steadily decreasing with the improvement in technology and technique (**Matlaga et al., 2012; Preminger et al., 2007**). In our study 13 cases (14.4%) had intraoperative complications in the form of major perforation and nephrostomy fixation in one case (1.1%), small perforation with minimal extravasation in 11 (12.2%) and gross hematuria in 1(1.1%) case. The perforation rate in the current study was 13.3% which is high according to literature. **Khalil M, Schuster et al** and **Perez Castero et al** reported perforation rates of (6.7%), (6.3%) and (1.2%) respectively in patients who had ureteral stones treated with semirigid or flexible ureteroscopy at a single institute (**Khalil M, 2013; Schuster et al., 2001; Perez Castero et al., 2014**). The explanation for the high perforation rate in our study is that we are learning center with urologists of multiple stages of experience, most of these complications occurred due to unskillful practices. We also used a large diameter URS 9.5 fr. The 11 cases with minor perforation were managed with DJ fixation, the other case of major perforation had failed to fix DJ and PCN was fixed and one week later trial of DJ fixation was done which succeeded, this patient at one year follow up did not develop stricture. Three cases of the other 11 cases developed ureteral strictures. Bleeding associated with ureteroscopy was minor and self limited and resulted from trauma to the ureteral orifice during ureteroscope passage or mucosal injury or abrasion during stone fragmentation or manipulation. The hematuria rate in our study is 1.1% which is coinciding with **Perez Castro et al** which revealed intra operative hematuria in 0.8% of cases (**Perez Castro et al., 2014**). Although rare, one of the most serious complications of ureteroscopy is complete ureteral avulsion; but we did not have any case of ureteral avulsion.

Eight cases (8.9%) had early postoperative complications in the form of fever in 6 cases (6.7%), hematuria in 2 cases (2.2%). This results agreed with **Khalil** who reported early postoperative complications in 6.6 % of cases in the form of postoperative

hematuria for 2 days in one (2.2%) case, and postoperative fever in two (4.4%) cases (**Khalil, 2013**).

In our study, 3 cases of 12 (3.3%) who had intraoperative perforation, had ureteral stricture at 12 months. In those three patients endoscopic dilatation with laser endoureterotomy and DJ fixation was done which was subsequently removed without recurrence of the stricture in two cases. A single case needed open surgery (uretero-ureterostomy). Those patients had history of perforation and impacted stones. **Cui et al** had no cases of ureteral stricture in their study which may be due to short term follow up (3-6 months) and he had no case of ureteral perforation (**Cui et al., 2014**). **Perez Castro et al** revealed ureteric stricture in 9 cases (4%) because he had lower perforation rate in 29 cases (1.1%) (**Perez Castro et al., 2014**).

The main disadvantage of laser lithotripsy seems to be the cost of the device and fibers. It can be decreased by using a fiber several times, after re-sterilization. All costs are presented in United States of American Dollar (\$). The data of the global expenditure of disposable elements and laser machine was extracted from the hospital's economic information department. The laser generator and fibers were used for multiple procedures and their mean cost was based on the total number of procedures carried out before it needed replacement. In our study the average cost of laser lithotripsy including disposable elements was 520.12 ± 135 \$. Cost analysis showed that the initial capital cost of laser equipment was 64285\$. The cost of maintenance (repair of laser machine) is 2000\$. The cost of laser fiber is 771.4\$. The laser fiber can be used on an average in 40 procedures after re-sterilization. **Cui et al. (2014)** revealed that the total cost of semirigid laser URS per case was 1180 ± 6258 \$. This cost is higher than our calculated cost because individual cost of surgeons' fees, semirigid URS use, theatre charges and hospital stay was not calculated in our study (**Cui et al., 2014**).

There are some limitations of the current study including small sample size, single institution work the absence of control group and the lack of randomization. Larger randomized series may be necessary to confirm the long-term efficacy of this procedure.

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