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Comparative Study between Flexible Ureteroscopy and Semirigid Ureteroscopy in Management of Upper Ureteric Stones using Laser Lithotripsy

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ABSTRACT

Background: There are various options in the management of proximal ureteral stones, which includes medical expulsive therapy, extracorporeal shock wave lithotripsy (ESWL), ureteroscopy (URS; retrograde), percutaneous nephrolithotomy (PCNL), laparoscopy (LAP), and open surgery.

Objective: The aim of this study was to evaluate the efficacy and safety of both semirigid and flexible ureteroscopy in management of upper ureteric stones using laser lithotripsy.

Patients and Methods: To achieve this goal, this prospective study was done at the urology department, Ain Shams University Hospitals on 60 patients with upper ureteric stones less than 2 cm in size. They were divided into groups of 30 patients in each group. Patients in group A were treated by semirigid ureteroscopy. While patients in group B were treated by flexible ureteroscopy using laser lithotripsy in both procedures.

Results: Stone free rate was 90.0% in group A while it was 93.3% in group B. Mean operative time was 55.07 ± 13.24 min in Group A while it was 64.63 ± 17.33 min in Group B. Success rate was 76.7% in group A, while it was 90.0% in group B. 20% of patients in group A had intra or postoperative complications in the form of: 6.7% of cases had failure to access to the stone, in 3.3% of cases there was upward migration of stone toward kidneys, 3.3% of cases had ureteral submucosal injury, 3.3% of patients had postoperative fever and 3.3% of patients developed haematuria.

Conclusion: Flexible ureteroscopy is a favorable option for patients having proximal ureteral stones with higher stone free rate and success rate. On the other hand, semirigid ureteroscopy is an acceptable alternative for treatment of proximal ureteral stones. Flexible ureteroscopy costs is much higher compared to semirigid ureteroscopy

Keywords: Flexible Ureteroscopy; Semirigid Ureteroscopy; Upper Ureteric Stones.

INTRODUCTION

Urinary calculi is the third most common affliction of the urinary tract, exceeded only by urinary tract infections and the pathological conditions of the prostate. The prevalence of urinary tract stone disease is estimated to be 2-3% [(1)].

Patients with urolithiasis constitute an important part of everyday urological practice. The optimal clinical management of this disease requires knowledge of the diagnostic procedures, the rational treatment of acute stone colic, stone expulsive treatment and the modern principles of stone removal [(2)].

The primary goal of complete stone clearance for the management of proximal ureteral stones is to preserve renal function, prevent further stone growth, cure infection, and relieve obstruction [(3)].

There are various options in the management of proximal ureteral stones, which includes medical expulsive therapy, extracorporeal shock wave lithotripsy (ESWL), ureteroscopy (URS; retrograde), percutaneous nephrolithotomy (PCNL), laparoscopy (LAP), and open surgery [(4)].

Before the year 1980, open ureterolithotomy was being performed widely, nowadays in the management of ureteral stones ESWL (Extracorporeal Shock Wave Lithotripsy) and endoscopic interventions are preferred [(5)]. Open ureterolithotomy is no longer considered as a valid option in a well equipped endourological center [(6)].

Nowadays, extracorporeal shock wave lithotripsy (ESWL) and ureteroscopy (URS) are the most commonly performed treatment options in the management of proximal ureteral stones. Although the European Association of Urology (EAU) urolithiasis guidelines showed that both URS and ESWL should be considered as a first-line therapy for proximal ureteral stones, the optimal treatment of these stones still remains debatable [(4)].

In proximal ureteral stones smaller than 1cm, ESWL constitutes the first treatment alternative. However, difficulties encountered during visualisation of the stone, presence of impacted and/or calcium oxalate monohydrate and cystine stones, actual health state of the patient lower the success rates of ESWL and lead to preference of URS in such cases [(7)].

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Ureteroscopes can be classified by their performance characteristics into rigid, semirigid and flexible types [8].

In recent years, the advent of smaller-caliber semirigid ureteroscopes (4.5 and 6 Fr) and advances in efficient intracorporeal lithotriptors such as electrohydraulic, ultrasonic, pneumatic and holmium laser have resulted in high success and low morbidity rates. Pneumatic lithotripsy (PL) was first introduced in the early 1990s [9].

Introduction of holmium laser into the market and worldwide accepted use of this laser during ureteroscopy (URS) makes the stone clearance rates better even for the stones up to 20mm [10].

With the advancements in the designs of ureteroscopes, stone disintegration systems and endourologic techniques, most of the kidney stones and large proximal ureteral stones can be managed by flexible ureteroscopy (F-URS) nowadays [11].

Narrow working channel of the flexible URS that force the manipulation of auxiliary instruments and higher procedural costs can be mentioned among the main restrictions of the flexible URSs. However, in cases where safe use of rigid and semi-rigid ureteroscopes is impossible or in the situation of stone migration into intrarenal collecting system, flexible URSs remain the optimal option [12].

AIM OF THE WORK

To compare the clinical outcome of semirigid ureteroscopy and flexible ureteroscopy in management of upper ureteric stones using laser lithotripsy regarding to stone clearance rate, success rate, time factor, complications cost benefits.

SUBJECTS AND METHODS

Our study was a prospective randomized double armed clinical trial done over 60 patients complaining of upper ureteric stones less than 2 cm in diameter. Patients underwent either flexible ureteroscopy or semi-rigid ureteroscopy randomly by closed envelope method according to 1: 1 ratio. The procedures were done at Ain shams university Hospitals. The patients were divided into two groups.

The study was approved by the Ethics Board of Ain Shams University and an informed written consent was taken from each participant in the study.

Group A: Included patients who underwent semi rigid ureteroscopy using laser lithotripsy (30 patients).

Group B: Included patients who underwent flexible ureteroscopy using laser lithotripsy (30 patients).

Inclusion criteria:

All adult patients aged between 20-60 years old with upper ureteric stone less than 2cm in diameter were included regardless sex, previous stone management.

Exclusion criteria:

- Patient with an upper ureteric stone 2 cm or more in diameter.
- Bleeding tendency.
- Uncontrolled UTI.
- Pregnancy.
- Skeletal malformations making positioning & targeting impossible.
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Preoperative evaluation:

- Detailed history & physical examination
- Routine preoperative investigations:
  - CBC, bleeding profile, kidney functions, liver functions, blood suger.
  - CXR, ECG.
- Urine analysis, urine culture & sensitivity.
- Radiological evaluation:
  - Plain KUB.
  - Pelvi-abdominal ultrasound.
  - Intra venous urography (IVU).
  - Non contrast multislice CT abdomen & pelvis (NCMSCT) in patients with radiolucent stones.
  - Renogram when needed.
- Preoperative medical assessment.
-

Treatment procedures:

Grop A: Semirigid URS using laser lithotripsy procedure:

- All patients were given prophylactic antibiotic at the induction of anesthesia.
- Patients were placed in the dorsal lithotomy position and were prepared and draped in asterile fashion before the start of the procedure.
- Urethrocystoscopy was performed to evaluate the urethra, bladder, and identification of ureteric orifices.
- Access to the ureter was achieved initially with straight floppy tipped guide wire that was introduced through the working channel of the 22Fr. Cystoscope under fluoroscopic monitoring.
- Ureteric orifice dilatation.
- Advancement of semirigid ureteroscope (R. Wolf-Germany 6/7.5Fr.) over/along guidewire
- Visual identification of stone endoscpically under fluid irrigation.
- Stone destruction using 20 W holmium: YAG laser (Karl Storz-Germany), A 200- 365 μm laser fibre with an energy output of 0.8-1.5 J at 8–15 Hz but the

joule and hertz of energy could be changed during the operation according to the stone hardness and efficacy of lithotripsy.
- Open ended ureteral catheter 7Fr. was passed over guide wire and a retrograde pyelogram was performed.
- Insertion of double j or ureteric catheter when needed.
- Insertion of uretheral catheter.

Group B: Flexible URS using laser lithotripsy procedure:
- All patients were given prophylactic antibiotic at the induction of anesthesia.
- Patients were placed in the dorsal lithotomy position and were prepared and draped in asterile fashion before the start of the procedure.
- Urethrocystoscopy was performed to evaluate the urethra, bladder, and identification of ureteric orifices
- Access to the ureter was achieved initially with straight floppy tipped guide wire that was introduced through the working channel of the 22Fr. Cystoscop under fluoroscopic monitoring.
- Gradual ureteric dilatation up to 14 Fr.
- Introduction of ureteral access sheath 12 Fr.
- Advancement of flexible ureteroscope (Fiber optic Karl Storz _ Germany 7.5Fr.) over/along guidewire
- Visual identification of stone endoscpically under fluid irrigation.
- Stone destruction using 20 W holmium: YAG laser (Karl Storz-Germany), A 200- 365 µm laser fibre with an energy output of 0.8-1.5 J at 8–15 Hz but the joule and hertz of energy could be changed during the operation according to the stone hardness and efficacy of lithotripsy.
- Open ended ureteral catheter 7Fr. was passed over guide wire and a retrograde pyelogram was performed.
- Insertion of double j or ureteric catheter when needed.
- Insertion of uretheral catheter.

Post- operative care:

Immediately after finishing the procedure all patients were evaluated for general condition and any suspected abdominal complications.

Patients follow up:

For all patients any complications, costs, operative time and outcome were recorded. Patients were followed up one day post operative by KUB for radio-opaque stones and Non contrast multislice CT abdomen andpelvis (NCMSCT) for radiolucent stones.

Pelvi-abdominal US, Intra venous urography (IVU), if needed till clearance of stones.

Statistical analysis

Data were collected and analyzed. All statistical calculations were done using computer programs SPSS (Statistical Package for the Social Science; (**SPSS** Inc., Chicago, IL, USA) version 20 for Microsoft Windows. The comparison between two groups with qualitative data was done by using ***Chi-square test***. The comparison between two groups regarding quantitative data with parametric distribution was done by using ***Independent t-test.*** The confidence interval was set to 95% and the margin of error accepted was set to 5%.

RESULTS

Table (1): Demographic data.

		No. = 60
Sex	Female	12 (20.0%)
	Male	48 (80.0%)
Age	Mean±SD	39.38 ± 8.99
	Range	22 – 55
Size	Mean±SD	10.62 ± 2.67
	Range	7 – 19
Laterality	Right	33 (55.0%)
	Left	27 (45.0%)

Table (2): Comparison between group A and group B regarding demographic data.

		Group A semi rigid	**Group B flexible**	**Test value**	**P-value**	**Sig.**
		No. = 30	**No. = 30**			
Sex	Female	6 (20.0%)	6 (20.0%)	0.000*	1.000	NS
	Male	24 (80.0%)	24 (80.0%)			
Age	Mean±SD	39.90 ± 8.47	38.87 ± 9.59	0.442•	0.660	NS
	Range	24 – 55	22 – 55			
Size	Mean±SD	10.14 ± 2.95	11.09 ± 2.31	-1.389•	0.170	NS
	Range	7 – 19	8 – 17			
Laterality	Right	17 (56.7%)	16 (53.3%)	0.067*	0.795	NS
	Left	13 (43.3%)	14 (46.7%)			

> 0.05 NS: Non significant; < 0.05 S: Significant; < 0.01 HS: Highly significant

*:Chi-square test; •: Independent t-test

Table (3): Comparison between group A and group B regarding operative time, stent application, clearance rate, success rate, complications.

		Group A semi rigid	Group B flexible	Test value	P-value	Sig.
		No. = 30	No. = 30			
Operative time (min)	Mean±SD Range	55.07 ± 13.24 37 – 88	64.63 ± 17.33 39 – 95	2.401*	0.019	S
Ureteral stent	Ureteric cathter JJ	5 (16.7%) 25 (83.3%)	6 (20.0%) 24 (80.0%)	0.111*	0.739	NS
Clearance rate	Free Residual	27 (90.0%) 3 (10.0%)	28 (93.3%) 2 (6.7%)	0.218*	0.640	NS
Success rate	Success Failure	23 (76.7%) 7 (23.3%)	27 (90.0%) 3 (10.0%)	1.920	0.166	NS
Complication	Negative Failure to access Migration of stone Fever "UTI" Submucosal passage Haematuria	24 (80.0%) 2 (6.7%) 1 (3.3%) 1 (3.3%) 1 (3.3%) 1 (3.3%)	27 (90.0%) 0 (0.0%) 0 (0.0%) 1 (3.3%) 1 (3.3%) 1 (3.3%)	3.176*	0.673	NS
Complication category	Negative Positive	24 (80.0%) 6 (20.0%)	27 (90.0%) 3 (10.0%)	1.176*	0.278	NS

> 0.05 NS: Non significant; < 0.05 S: Significant; < 0.01 HS: Highly significant
*:Chi-square test; •: Independent t-test

Table (4): Comparison between group A and group B regarding cost effectiveness:

		Group A	Group B	Test value	P-value	Sig.
Cost effectiveness	Mean ± SD	26018.33 ± 683.86	47161.67 ± 1520.93	-69.445	0.000	HS
	Range	25000 – 27000	45000 – 50000			

> 0.05 NS: Non significant; < 0.05 S: Significant; < 0.01 HS: Highly significant
*:Chi-square test; •: Independent t-test

DISCUSSION

Proximal ureteral stones can be managed by various techniques including extracorporeal shock wave lithotripsy (ESWL), ureterorenoscopy (URS) with semirigid or flexible instruments, laparoscopic approache antegrade ureterolithotripsy and open surgery. The decisions about the choice of therapy depends on the stone factors like localization, size, density and radiolucency, anatomical factors, obstruction, technical capacity of the department, patient's preference and surgeon's skills [13].

Recent developments in the market about miniaturization of semirigid and F-URS and holmium: YAG laser in URS applications attracted the attentions' of the urologists and markedly improved the success rates of treating proximal ureteral and renal stones [14].

With the miniaturization and advancements in the designs of ureterorenoscopes, stone disintegration systems and endourologic techniques, most of the ureteral stones can be managed by URS nowadays. Usage of holmium: YAG laser during URS makes the stone clearance better in a single session even for the proximal ureteral stones > 10mm [15].

- ***Stone free rate***

Galal et al. [16] reported that stone free status which was achieved at the end of the procedure was 68% in group 1 using semirigid ureteroscopy and 91% in group 2 using flexible ureteroscopy.

Abdullateef et al. [17] reported that stone free rate of flexible ureteroscopy was 88% (59/67) which was higher than semirigid ureteroscopy that was79% (52/66).

Alkan et al. [18] reported that stone free after treatment with semirigid ureteroscopy was 76.5% while after treatment with flexible ureteroscopy it was 87.5%.

Yencilek et al. [19] reported that stone free rate at the end of the procedure was 75.9 %(41/54) in group using semirigid ureteroscopy and 96.4%(27/28) in group using flexible ureteroscopy.

Karadag et al. [20] reported that Initial stone free status which was achieved after disintegration of the stones < 4 mm or complete extraction of the fragments decided by the surgeon at the end of the procedure was 63.4% (40/63) in group 1 using semirigid ureteroscopy and 86.8% (53/61) in group 2 using flexible ureteroscopy. This rate increased to 71.4% (45/63) in group 1 and 90.1% (55/61) in group 2 at 1st month radiologic controls. Third month radiologic investigations revelaed a stone free rate of 77.7% (49/63) in group 1 and 93.4% (57/61) in group 2. All these results showed us the superiority of F-URS in terms of achieving a stone free status.

In our study the stone-free rate was 90.0% (27/30) in semirigid ureteroscopy group while it was 93.3% (28/30) in flexible ureteroscopy group after single session.

- ***Operative time:***

Galal et al. [16] reported that the mean operative time in rigid ureteroscopy group was 40.9 ± 16.4 min. while it was 48.4±13.8 min in flexible ureteroscopy group.

Alkan et al. [18] ***indicated*** that the mean operative time in semirigid ureteroscopy group was 34.1 ± 1.5 min. while it was 49.4 ± 2.3 min in flexible ureteroscopy group

Karadag et al. [20] found that the mean operative time in semirigid ureteroscopy group was 64.71 ± 16.11 min. while it was 84.06 ± 16.7 min in flexible ureteroscopy group.

In our study the operative time ranged from 37 – 88 min with mean value of 55.07 ± 13.24 min in semirigid ureteroscopy group and ranged from 39 – 95 min with mean value of 64.63 ± 17.33 min in flexible ureteroscopy group.

- ***Success rate:***

Galal et al. [16] displayed that Procedures were successfully completed in 49/72 (68%) patients in rigid URS group and 57/63 (90.5%) patients in flexible URS group.

Failure in rigid URS group (n=23) was due to inability to advance the ureteroscope to the level of stone due to stone impaction with associated ureteral edema (n=7), stone migration (n=9) 3 of them were completed using F-URS while JJ inserted in other 6 patients for further ESWL. In 2 patients, the procedure was aborted due to mild ureteral perforation and JJ stent was inserted. Five patients were considered unsuccessful in early follow-up due to large residual stone fragments.

In patients of flexible URS group (n=6) with unsuccessful access to the stone, due to inability to pass the access sheath due to narrow ureteral lumen even after trial of dilation. In all cases JJ stent was left for 15 days.

Karadag et al. [20] *showed* that the success rate of reaching to the stone, making a successful access and reach to the stone in 48/63 (76%) of the cases in semirigid URS group and 57/61 (93%) of the patients in flexible URS group. This value showed the superiority of F-URS in reaching to the proximal ureteral stones.

In patients of semirigid URS group with unsuccessful access to the stones (n = 9) (5 tortuosity, 2 narrow caliber of the ureter and 2 serious stenosis) and stone migration into the kidneys (n = 6), JJ catheters were inserted and operations were terminated. They were referred to another center for ESWL or F-URS applications. In patients of flexible URS group with unsuccessful access to the stone (n = 4). The reason of unsuccessful access in these patients was narrow caliber of the ureters.

Alkan et al. [18] ***demonstrated*** that rigid ureteroscope could have not been advanced up to the proximal ureter in5 patients (5/68; 7%). Internal stents were left in place in these cases, and the procedures were completed with flexible ureteroscope after 15 days. Ureteral stones were pushed back to the renal collecting system during the procedure in 8 patients (8/68; 12%). (5stones during ureteroscopy, 3 stones during lithotripsy), and lithotripsy was completed using flexible ureteroscope. Residual stone fragments larger than 2mm, most of which were located in the lower calyces on postoperative imaging studies, were detected in3 patients (3/68; 9%)

Since neither flexible ureteroscope nor access sheath could have been advanced up to the proximal ureter in4 patients (4/64; 6%) due to ureteral pathology such as a narrow ureteric lumen and ureteral strictures, the procedures were postponed for 15 days. The residual fragments greater than 2 mm remained in4 patients(4/64; 6%).

Yencilek et al. [19] *revealed* that 13 failures (24.1%) in the semirigid group, the most frequent cause was stone migration into the kidney (n=9, 16.7%), followed by blurred vision due to evident hematuria (n=2, 3.7%), inability to reach the stone because of prominent angulation of the proximal ureter (n=1, 1.9%), and ureteral avulsion (n=1, 1.9%). JJ stents were placed in 10 cases and stone removal was applied by flexible URS in two cases. Two ureteral strictures distal to the stone in the semirigid group were managed by balloon dilatation before the operation. Of these,

the URS procedure was successfully finished in one and a 12-month follow-up showed no recurrence of stricture. In the other case, ureteral avulsion caused conversion to open surgery, and the case was classified as a failure.

In the flexible group, although the stones migrated into the pelvis renalis/calix in three cases (10.7%) they were removed from the kidney with a Nitinol basket during the operation and the cases were classified as success. On the other hand, bleeding originating from mucosal injury was the reason for failure in one case (3.6%). After insertion of JJ stents, this stone was treated with subsequent ESWL.

In our study we could make a successful access and reach to the stone in 23/30 (76.7%) of the cases in semirigid URS group and 27/30 (90%) of the patients in flexible URS group. This value showed the superiority of F-URS in reaching to the proximal ureteral stones. In semirigid URS group Failure to access to the stone in 2 cases (6.7%), one case was recorded in male patient extremely tall with tight ureter and another case with kinked and tortuous ureter. Upward migration of stone toward kidney was observed in 1case (3.3%). So, the procedure completed by using flexible ureteroscopy with the advantages of deflexion and rotation. Ureteral submucosal passage (perforation) was happened in 1case (3.3%) that was managed by double J application. Three patients (10%) were considered unsuccessful in early follow-up due to large residual stone fragments ≥ 4 mm.

In flexible URS group ureteral submucosal passage (perforation) occured in 1case (3.3%) that was managed by double J application. Two patients (6.7%) were considered unsuccessful in early follow-up due to large residual stone fragments ≥ 4 mm.

- ***Complications***:

Galal et al. [16] reported that complications which noted in rigid URS group were in the form of:

- Ureteral perforation was observed in 2 patients (2.8%)).
- Unsuccessful access to the stone in 7 (9.7%) patients.
- Stone migration in 9 (12.5%) patients.
- Postoperative hematuria was observed in 15 (21%) patients .
- Renal colic and fever occurred in 4 (5.5%) patients.

While in flexible URS group they were in the form of:

- Unsuccessful access to the stone in 6 (9.5%) patients.
- Postoperative hematuria was observed in 11 (17%) patients
- Renal colic and fever occurred in 3 (4.7%).

Alkan et al. [18] ***indicated*** that complications which noted in semirigid URS group were in the form of:

- Major intraoperative complications (ureteral avulsion and ureteral perforation) in 2 (3%; 2/68) patients.
- Minor ureteral trauma were seen in 6 (9%; 6/68) patients.
- Intraoperative minor hemorrhage was seen in 1 (1%; 1/68) patients.
- Posoperative urinary tract infections were observed in 2 (3%; 2/68) Patients.
- Postoperative renal colic were seen in 4 (6%; 4/68) Patients.

While in flexible URS group they were in the form of:

- Minor ureteral trauma were seen in 3 (5% 3/64) patients.
- Intraoperative minor hemorrhage was seen in 4 (6%; 4/64) patients.
- Posoperative urinary tract infections were observed in 1 (2%; 1/64) patients.
- Postoperative renal colic were seen in 5 (8%; 5/64) patients.

Karadag et al. [20] reported that complications which noted in semirigid URS group were in the form of:

- Postoperative fever was observed in 7 (11.1%) patients.
- Bleeding was noted in 13 (20.6%) patients.
- Ureteral injury occured in 4 (7.9%) patients.

While in F-URS group they were in the form of:

- Ureteral perforation below the ureteropelvic junction occured in 1 (1.6%) patient.
- Postoperative fever was observed in 8 (13.1%) patients.
- Bleeding was noted in 5 (9.8%) patients
- Ureteral injury occured in 2 (3.2%) patients from

In our study: In group A (Semirigid URS) there was 24 cases (80%) free of complications and 6cases (20%) complicated in the form of:

- Failure to access to the stone in 2 cases (6.7%)
- Upward migration of stone toward kidney in 1case (3.3%).
- Ureteral submucosal passage (minor trauma) in 1case (3.3%).
- Fever in 1 case (3.3%).
- Hematuria in 1case (3.3%).

While in group B (Flexible-URS) there was 27 cases (90.0%) free of complications and 3 cases (10.0%) complicated in the form of:

- Ureteral submucosal passage (minor trauma) in 1case (3.3%).
- Fever in 1case (3.3%).
- Hematuria in 1case (3.3%).

- ***Cost effectiveness:***

To the best of our knowledge, there has been no published article comparing the outcomes of flexible URS (F-URS) against semirigid URS for treatment of proximal ureteral stones regarding cost effectiveness.

In our study flexible ureteroscopy costs were much higher compared to semirigid ureteroscopy which must be taken in consideration while choosing the plan of treatment of ureteral stones especially in a developing country like Egypt where health insurance is not covering all populations.

CONCLUSION

Flexible ureteroscopy is a favorable option for patients having proximal ureteral stones with higher stone free rate and success rate; on the other hand semirigid ureteroscopy is an acceptable alternative for treatment of proximal ureteral stones. Flexible ureteroscopy costs were much higher in comparison with semirigid ureteroscopy.

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