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Flexible ureteroscopy versus retroperitoneal laparoscopic ureterolithotomy in the management of upper ureteric stones measuring from one to two centimeters: randomized prospective study

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Abstract

This prospective study aims to compare the clinical efficacy and safety of flexible ureteroscopy versus laparoscopic ureterolithotomy in the management of upper ureteric stones measuring from one to two centimeters. his randomized-prospective study was conducted on 64 patients admitted from Urology unit, Ain Shams University in the period from October 2020 till September 2022; only 56 patients were analyzed statistically and 8 patients were excluded due to shortage in post- operative data and follow up. Patients were divided into two groups Group A consists of 31 patients and Group B consists of 25 patients with matched age, gender and body mass index (BMI). In our study, The VAS score at 6 hours post-operative and day 1 post-operative was found to be 5.32 and 2.71 in FURS group and was found to be 7.28 and 3.28 in RPLU group respectively showing significant difference with (p-value <0.001 and 0.016 respectively) between the two groups with more satisfaction in FURS group mostly due to the absence of trocars incisions. The complications were classified according to modified Clavien classification system. No major complications such as septic shock or death were reported in either treatment groups. As regards the recovery to work in postoperative and follow up periods in the present study, there was a significant difference between both groups with (P-value <0.001), as we found that it takes about 4.56 ± 0.82 days in RPLU group and 3.06 ± 1.91 days in FURS group to return daily routine activities. As regards the stone free rate in follow up periods in the present study, there was a significant difference between both groups with (P-value 0,02), as we found that it was 100% and 80,6% in RPLU and FURS group respectively. Our success rate in RPLU group was found to be 100% in comparison to Irfan Nazir Mir et al which was 93.4% (28/30) with two patients (2/30) converted to open ureterolithotomy, either due to technical snag or due to difficulty in localizing the ureter laparoscopically. Both F-URS and TPLU were safe and effective surgical procedures for treatment of large proximal ureteral stones. However, RTLU had a higher stone-free rate with comparable operating time and complication rate as compared to F-URS. Also as regards to postoperative pain, shorter hospital stay and faster return to daily activities, both have almost similar results.

Keywords: Flexible Ureteroscopy; Retroperitoneal Laparoscopic Ureterolithotomy; upper Ureteric Stones.

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1. Introduction

Urolithiasis is a common disorder in normal urological practice, however, it is quite expensiv[1] . 22% of all stones in the urinary system are ureteral, and 66% to 71% of them are found in the distal ureter. The likelihood of accidental passing is normally between 35% and 58% if the thickness of the ureteral calculi is less than 6 mm. There is a 12% possibility that ureteral stones larger than 6 mm and less than 8 mm in diameter would gradually discharge themselves.[2,3] The expense of managing each individual stone episode will continue to raise the societal cost of managing urolithiasis. As a result, the ultimate purpose should be to optimize protocols while avoiding duplicate or costly diagnostic tests or unsuitable therapies[1] . Urolithiasis therapy has evolved dramatically, and several techniques with different rates of total stone clearance, extra operating needs, and consequences are now available. Because of the development of new minimally invasive procedures, the usage of open surgery for the removal of ureteric stones is now obsolete. Though flexible ureteroscopy with laser lithotripsy has more morbidity, it has become the main technique with higher overall removal rates when compared to the shock wave lithotripsy approach.[4] The use of electrohydraulic, pneumatic, and laser lithotriptors for stone fragmentation has risen in importance, leading to fewer indications for

open surgery .[5,6] This prospective study aims to compare the clinical efficacy and safety of flexible ureteroscopy versus laparoscopic ureterolithotomy in the management of upper ureteric stones measuring from one to two centimeters.

2. Patients and Methods

This randomized prospective study based on closed envelope method was done at Ain Shams University Hospitals on 56 patients during a period of 2 years. Adult patients more than 18 years old with upper ureteric stones measuring (10-20mm) were enrolled in the study. While any patient with UTI, coagulopathy, underwent previous open surgery, presence of bladder pathology, unfit for surgery, pregnant women and any patient refused to participate in the study were excluded from the study. Our study was guided by the study published at 2016 by Sahin et al "Flexible ureteroscopy versus laparoscopy for the treatment of patients who initially presented with obstructive pyelonephritis". The main comparison was done on the retreatment proportion. Group sample sizes of 25 and 25 achieve 80% power to reject the null hypothesis of zero effect size when the population effect size is 0.80 and the significance level (alpha) is 0.050 using two-sized z test. This sample size would be enough to compare other quantitative parameters as hospitalization period and VAS score.**[7]** All patients were consented after explaining the detailed study and operation's procedures. Moreover their privacy was maintained and no personal, medical, operative data was disclosed to third party. All patients were subjected to Pre-operative evaluation, radiological evaluation with special emphaises on abdomeno-pelvic ultrasound and C.T. without contrast then with contrast when needed, Peri-operative preparation as a prophylactic antibiotic was given to all patients pre-operative on table. Finally, Post-operative follow up as patients were followed up for 3 months post-operatively for the evaluation of outcome; including early recovery, any postoperative complications.

2.1 Study Procedures

This study included 56 patients with upper ureteric stones measuring (10-20 mm). All patients were subdivided into 2 groups: **Group (A):** includes 31 patients underwent flexible ureteroscopy with holmium laser. **Group (B):** includes 25 patients underwent retroperitoneal laparoscopic ureterolithotomy.

2.1.1 Study Interventions

2.1.1.1 Operative technique

One group of surgeons was responsible for all the procedures. Flexible uretroscopy with laser was done in the following steps: Under anesthesia, patient was positioned in lithotomy position. Diagnostic cystoscopy. Ureteric orifice identification is done, guide wire positioned, gradual ureteric dilatation, access sheath was inserted and flexible ureteroscpy was done with stone fragmentation (dusting mode), then insertion of ureteric catheter/stent and uretheral catheterization. Retroperitoneal Laparoscopic ureterolithotomy will be done in the following steps: Under anesthesia, Patient was positioned in standard flank position for retroperitoneal approaches, access port placement, camera trocar and the other two trocars, identification of ureter and stone site, ureteral incision, stone removal, stent placement, ureteral repair and Drain replacement. Blood loss estimation was done by direct measurements of blood volume loss were performed as follows. The whole suction system was heparinised before surgery (25,000 IU of heparin in saline solution) and a continuous flow of saline solution prevented any clotting of blood loss. The required volumes of heparin and saline solutions were carefully recorded. Intraoperative wash and blood losses were suctioned through surgical drains into a canister at the end of the surgical procedure. The total volume contained in the canister was measured after the end of the surgical procedure by a system capable of determining differences up to ±10 mL. The mean blood loss was determined by subtracting the added fluids (heparin and saline solutions) from the total volume contained in the surgical canister.

2.2 Statistical Analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges. Also qualitative variables were presented as number and percentages. The comparison between groups regarding qualitative data was done by using ***Chi-square test*** and/or ***Fisher exact test*** when the expected count in any cell found less than 5. The comparison between two independent groups with quantitative data and parametric distribution was done by using ***Independent t-test*** while with non parametric distribution was done by using ***Mann-Whitney test***. The confidence interval was set to 95% and the margin of error accepted was set to 5%.

3. Results and Discussion

The present study included a total of 56, medically fit patients, with upper ureteric stone, selected on OPD basis, admitted from Urology unit, Ain Shams University in the period from August 2020 till August 2022. The patients were operated by a single expert team of surgeons. The results were collected and analyzed statistically based on the stone size, mean operative time, hospital stay (in days), success rate, stone free rate and complications. They were divided into two groups; Group A consists of 31 patients who underwent Flexible ureteroscopy (FURS) with holmium-YAG laser lithotripsy and Group B consists of 25 patients who underwent Retroperitoneal Laparoscopic Ureterolithotomy (RPLU). Cavidalk et al in their study of 150 patients divided the patients into two groups 70 patients underwent RPLU and 80 patients underwent FURS. While Sahin et al studied 42 patients, 22 underwent TPLU and 20 underwent FURS. **[7,8]** . Prabhakar and colleagues performed FURS in their series of 30 patients and reported a mean hospitalization time of 1 day. In their series of 100 patients, Hatipoğlu and colleagues reported a mean hospitalization time of 1.3 days. Cavidalk et al in their study of 80 patients found a mean hospitalization time of 1.19 days, while the average hospitalization time in our study was calculated to be 1 day in FURS group **[15-8]** . Demirkesen and colleagues in their series of eight patients, reported a mean hospitalization time of 3.25 days. Bayer and colleagues in their series of 24 patients, reported a mean hospitalization time of 3.4 days. In their series of 101 patients, Gaur and colleagues reported a mean hospitalization time of 3.5 days **[18-16]** .

Table 1: Comparison between **Group A** and **Group B** regarding age, gender and BMI

Demographic data		Group A No. = 31	Group B No. = 25	Test value	P-value	Sig.
Age (yrs)	Mean±SD Range	42.42 ± 12.66 19 – 63	39.88 ± 12.26 20 – 63	0.757•	0.452	NS
Gender	Females Males	6 (19.4%) 25 (80.6%)	3 (12.0%) 22 (88.0%)	0.555*	0.456	NS
BMI (kg/m2)	Mean±SD Range	27.68 ± 2.99 23 – 34	27.28 ± 2.85 23 – 33	0.504•	0.616	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*:Chi-square test; •: Independent t-test

Table 2: Comparison between **Group A** and **Group B** regarding stone parameters

Stone parameters		Group A No. = 31	Group B No. = 25	Test value	P-value	ig.
Stone size	Mean±SD Range	16.94 ± 2.21 12 – 20	15.84 ± 2.43 12 – 20	1.767•	0.083	S
Laterality	Rt Lt	13 (41.9%) 18 (58.1%)	11 (44.0%) 14 (56.0%)	0.024*	0.877	S
Haunsfield Unit	Mean±SD Range	1127.42 ± 140.71 850 – 1400	1140.00 ± 252.07 750 – 1600	-0.236•	0.814	S
Hydronephrosis	M Mo S	14 (45.2%) 10 (32.3%) 7 (22.6%)	10 (40.0%) 8 (32.0%) 7 (28.0%)	0.249*	0.883	S

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*:Chi-square test; •: Independent t-test

Table 3: Comparison between **Group A** and **Group B** regarding duration of procedure and amount of blood loss

		Group A No. = 31	Group B No. = 25	Test value	P-value	ig.
Duration of procedure (min)	Mean±SD Range	48.84±7.96 35 – 62	82.60±24.56 62 – 155	-7.212•	0.000	S
Blood Loss (ml)	Mean±SD Range	23.9 ± 7.35 10 – 40	70.96 ± 6.54 60 – 85	25.019•	0.000	S

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
•: Independent t-test

Table 4: Comparison between **Group A** and **Group B** regarding conversion/ termination

Conversion/Termination	Group A No. = 31	Group B No. = 25	Test value	P-value	Sig.
Negative Positive	29 (93.5%) 2 (6.5%)	25 (100.0%) 0 (0.0%)	1.673	0.196	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test

Table 5: Comparison between **Group A** and **Group B** regarding percentage of patients with stricture.

		Group A	Group B	Test value	P-value	Sig.
Stricture	Negative Positive	29 (93.5%) 2 (6.5%)	25 (100.0%) 0 (0.0%)	1.673	0.196	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test

Table 6: Comparison between **Group A** and **Group B** regarding with postoperative data.

		Group A	Group B	Test value	P-value	ig.
		No. = 31	No. = 25			
Need for Analgesia	No Yes	13 (41.9%) 18 (58.1%)	5 (20.0%) 20 (80.0%)	3.053*	0.081	S
Analgesia	Mean±SD Range	30.00 ± 0.00 30 – 30	38.50 ± 8.75 30 – 60	4.115•	<0.001	S
Free Stone Rate (FSR 100%)	No Yes	6 (19.4%) 25 (80.6%)	0 (0.0%) 25 (100.0%)	5.419*	0.020	
Hospital stay (days)	Mean±SD Range	1.00 ± 0.00 1 – 1	1.16 ± 0.55 1 – 3	1.589≠	0.112	S
Recovery to Work (days)	Mean±SD Range	3.06 ± 1.91 2 – 9	4.56 ± 0.82 3 – 6	4.690≠	<0.001	S

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; •: Independent t-test; ≠: Mann-Whitney test

Table 7: Comparison between **Group A** and **Group B** regarding VAS score at 6 hours post-operative and day (1)post-operative.

		Group A	Group B	Test value	P-value	ig.
		No. = 31	No. = 25			
VAS Score 6 hours post-operative	Mean±SD Range	5.32 ± 1.19 3 – 8	7.28 ± 1.31 4 – 9	4.664≠	<0.001	S
VAS Score Day 1 post-operative	Mean±SD Range	2.71 ± 0.86 1 – 4	3.28 ± 0.74 2 – 5	2.407≠	0.016	

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
≠: Mann-Whitney test

Table 8: Comparison between **Group A** and **Group B** regarding operative and postoperative complications according to modified Clavien classification system.

		Group A	Group B	Test value	P-value	Sig.
		No. = 31	No. = 25			
Grade I						
Mucosal injury	o es	29 (93.5%) 2 (6.5%)	25 (100.0%) 0 (0.0%)	1.673*	0.196	NS
Stent related discomfort	o es	28 (90.3%) 3 (9.7%)	23 (92.0%) 2 (8.0%)	0.048*	0.827	NS
Delayed GI movement	o es	30 (96.8%) 1 (3.2%)	24 (96.0%) 1 (4.0%)	0.024*	0.877	NS
Grade II						
Perforation	o es	29 (93.5%) 2 (6.5%)	25 (100.0%) 0 (0.0%)	1.673*	0.196	NS
Fever	o es	28 (90.3%) 3 (9.7%)	23 (92.0%) 2 (8.0%)	0.048*	0.827	NS

-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test

The present study of 25 patients showed a hospitalization time of 1.16 day in RPLU group. So, as regards hospitalization time in our study there was no statistical significance between both FURS and RPLU groups (p-value 0.112). As regards the mean stone size in our study was 15.84 ± 2.43 in RPLU group and 16.94 ± 2.21 mm in FURS group with no significant difference between both groups (P-value 0.083). Cavidalk et al in their study the mean stone diameter was17 mm in RPLU group and 15.8 mm in FURS group (P-value 0.074). While, Sahin et al reported a stone size of 19.9 and 19.6 mm in TPLU and FURS groups respectively with no significant difference between both groups (P-value 0.698). **[7,8]** . Cavidalk et al in their study reported that the mean operational time was 80 and 45 min in RPLU and FURS group, respectively (P-value 0.01), **[8]** while Sahin S et al reported a mean operation time was 74.1±12.2 and 78.1±6.4 minutes and minutes in TPLU and FURS group, respectively (p=0.192). In our study, the mean operative time was calculated to be 82.60 ± 24.56 and 48.84 ± 7.96 min in and minutes in RPLU group and FURS group with significant difference (p-value 0.00) may be due to familiarity of endoscopic procedure and experienced hands in FURS **[7,8]** . In the present study, the mean blood loss intraoperative was observed to be 23.9 ± 7.35 ml FURS group and 70.96 ± 6.54 ml in RPLU group with significant difference between both groups (P-value 0.00). This difference was due to the nature of each procedure and the need of trocars insertion and intra-abdominal dissection. Sahin et al. reported that 58.8 ml was the blood loss in TPLU group **[7]** . Zahid Mohd Rather et al reported that 70.5 ml was the mean blood loss in 94 patients underwent RPLU. **[19]** but Binbin Jiao et al reported only 12.02± 8.11 ml in the study of 48 patients underwent FURS **[20]** . In our study, The VAS score at 6 hours post-operative and day 1 post-operative was found to be 5.32 and 2.71 in FURS group and was found to be 7.28 and 3.28 in RPLU group respectively showing significant difference with (p-value <0.001 and 0.016 respectively) between the two groups with more satisfaction in FURS group mostly due to the absence of trocars incisions. Sahin et al recorded that the mean VAS score obtained 6 hours after surgery was 6.4±1.3 in TPLU versus 5.1±1.6 in F-URS (p=0.008) and on the first postoperative day mean VAS was 4.3±1.0 in TPLU versus 3.6±1.2 for F-URS (p=0.093)**[7]** . The complications were classified according to modified Clavien classification system. No major complications such as septic shock or death were reported in either treatment groups. Sahin et al reported that the overall complication rate was 22.7% in TPLU, and 35% in F-URS. This difference of complications between the two groups was not statistically significant (p=0.591 **.[7]** In our study, the complication rate was found to be 31.43% in FURS group and 20% in RPLU group with no statistical significance.

In the present study, the intraoperative ureteric mucosal injury was found to be 2 out of 31cases (2/31) (6.5%) in FURS group and 0 out of 25 cases (0/25) (0.0%) in RPLU group. This was similar to Sahin S et al that reported only 1 patient in FURS group to have mucosal injury **[7]** . In our study, The Stent related discomfort in postoperative and follow up periods were found to be 3/31 (9.7%) in FURS group and 2/25 (8.0%) in RPLU group with no significant difference (P-value 0.827). This was also similar to Sahin et al that reported only 2 patients in each group to complain from stent related symptoms**[7]** . Sahin et al. reported 4 cases of ileus in their study which included 1 patient in FURS group and 3/22 in laparoscopic group **.[7]** In the present study, the delayed GIT movement in postoperative and follow up periods was found to be 1/31 (3.2%) in FURS group and 1/25 (4.0%) in RPLU group with no significant difference (P-value 0.877). The intraoperative ureteric Perforation in our study was found to be 2/31 (6.5%) in FURS group and 0/25 (0.0%) in RPLU group with no significant difference (P-value 0.196). This was comparable with Sahin et al. **[7]** findings with only 1 patient reported (out of 20 patients) in FURS group. In our study, the perforation was due to false passage and LASER effect. The postoperative fever was found to occur in 3/31 (9.7%) in FURS group and 2/25 (8.0%) in RPLU group with no significant difference (P-value 0.827). This was similar to Sahin S et al findings in FURS group and reported cases of fever among laparoscopic group. **[7]** The reported cases in our study were suffering from repeated UTI and pyuria. As regards the recovery to work in postoperative and follow up periods in the present study, there was a significant difference between both groups with (P-value <0.001), as we found that it takes about 4.56 ± 0.82 days in RPLU group and 3.06 ± 1.91 days in FURS group to return daily routine activities, which were better findings than in Sahin S et al who found that it took about 13.3±1.7 days in TPLU and 9.0±1.6 days in F-URS with (P-value <0.001) **[7]** . As regards the stone free rate in follow up periods in the present study, there was a significant difference between both groups with (P-value 0,02), as we found that it was 100% and 80,6% in RPLU and FURS group respectively, which were similar to Sahin et al 100% and 80% in TPLU and FURS group respectively with (P-value 0,043). **[7]** while Cavidalk et al showed no significant difference in their study as they reported the stone free rate was 95.7% and 93.75% in RPLU and FURS group, respectively (P-value 0.081). **[8]** these results reflect that the laparoscopy has higher stone free rate and this make sense with the nature of procedure which remove the stone as one piece without fragmentation, unlike FURS which depends on stone fragmentation and converting the single stone to multiple insignificant tiny gravels. Our success rate in RPLU group was found to be 100% in comparison to Irfan Nazir Mir et al which was 93.4% (28/30) with two patients (2/30) converted to open ureterolithotomy, either due to technical snag or due to difficulty in localizing the ureter laparoscopically. Similar observations to those of Irfan Nazir Mir et al were observed by various previous studies. This difference was due to exclusion of patients who underwent previous abdominal surgery from our study **[11,15,19]**.

4. Conclusion

The results of our study showed that both F-URS and RPLU were safe and effective surgical procedures for treatment of large proximal ureteral stones. However, RTLU had a higher stone-free rate with comparable operating time and complication rate as compared to F-URS. Also as regards to postoperative pain, shorter hospital stay and faster return to daily activities, both have almost similar results.

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