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Treatment of Large Ureteral Calculi Using Extra Corporeal Shock Wave Lithotripsy or Laparoscopic Ureterolithotomy: A Prospective Randomized Study

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ABSTRACT

Background: Ureteral calculi larger than ten millimeters are likely to impact and have high endoscopic failure rates, suggesting a good indication for primary ureterolithotomy.

Aim: This study aimed to assess the results of laparoscopic ureterolithotomy and extracorporeal shock wave lithotripsy (ESWL) in management of large Ureteral Calculi as regards the morbidity and stone free rate.

Patients and methods: This prospective randomized research has been performed on 48 cases with large ureteral calculi divided into 2 groups: Group A involved 24 cases that underwent laparoscopic ureterolithotomy and Group B involved the remaining 24 cases that underwent ESWL. The patients were collected from the Outpatient Urology Clinic in Suez Canal University Hospital in Ismailia and from the National Institute of Urology in Cairo from November 2014 till November 2016.

Results: After the procedure, statistically insignificant variance was observed among both studied groups regarding fever (p-value equal 0.074) and hematuria. However, the incidence of residual stone significantly increased with ESWL (33.33% vs. 4.2% in laparoscopy – p = 0.01). No mortality was encountered in our study. In the laparoscopic group, transformation to the open technique has been required in three patients (12.5%), and postoperative leakage ranged between 0 and 1600 ml. 1 case had persistent leakage and required DJ stent.

Conclusion: Laparoscopy is superior to ESWL in single-session clearance of ureteric stones. Nonetheless, it is associated with longer procedure time, longer hospitalization period, and postoperative urine leakage.

Keywords: Ureteral calculi, Laparoscopic ureterolithotomy, ESWL.

INTRODUCTION

The treatment of urolithiasis has changed significantly over recent decades and can now be carried out by various methods with different rates of complete stone elimination and different morbidities incidence [(1)].

Ureteral calculi larger than ten millimeters are likely to be impacted and endoscopic failure rates are high. Therefore, these stones may represent a good indication for primary ureterolithotomy [(2)].

The advantage of a laparoscopic surgery over extracorporeal shock wave lithotripsy or ureteroscopic stone retrieval is the ability to obtain very high stone free rates in only one session [(3)]. Laparoscopic ureterolithotomy was performed through the retroperitoneal method or the transperitoneal approach. But the transperitoneal method has shorter learning curve and less total operative time [(4)]. In comparison to open ureterolithotomy, laparoscopic ureterolithotomy is technically possible and benefits from a lesser mortality rate following surgery and low invasive. It is mostly indicated for large impacted ureteral stones or ESWL or if endoscopic ureterolithotripsy had failed or in the requirement for a concomitant laparoscopic surgery for separate sign [(5)]. Finally, Laparoscopic lumbar ureterolithotomy is a one session efficient safe procedure that ends to a stone free patient with low postoperative pain, good cosmetic incisions and reduced hospital stay, with exposure to possible morbidities and needs high experience [(6)].

The 1ry therapy of choice for renal calculi that are < twenty millimeters and proximal ureteral calculi that are < ten millimeters, which fail to pass spontaneously is extracorporeal shock wave lithotripsy. It's the least invasive method of therapy and has been stated to have great efficacy for calculi throughout the whole urinary tract [(7)]. Extracorporeal shock wave lithotripsy was suggested as the 1st therapy for proximal ureteral calculi that are < ten millimeters in size. However, the optimal therapy for larger proximal ureteral calculi has yet to be determined. Extracorporeal shock wave lithotripsy was stated to have a great success probability in the treatment of ureteral calculi; however, in particular patients, it's significantly lower than that of ureteroscopy [(8)].

The goal of this research was to evaluate the outcomes of laparoscopic ureterolithotomy and ESWL in management of large ureteral calculi as regards the morbidity and stone free rate.

PATIENTS AND METHODS

This prospective randomized research has been performed on 48 patients classified into 2 groups: Group A that involved 24 cases that suffered laparoscopic ureterolithotomy and group B, which involved the remaining 24 patients who underwent ESWL. The

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patients were collected from the Outpatient Urology Clinic in Suez Canal University Hospital in Ismailia and from the National Institute of Urology in Cairo. All techniques have been done in the National Institute of Urology in Cairo over a two-year period, from November 2014 till November 2016.

Inclusion criteria: Patients diagnosed with a single upper ureteric stone (below the UPJ to the superior border of the sacroiliac joint) and the stone size (10 mm to 20 mm in diameter).

Exclusion criteria: Stricture ureter below the stone, urinary tract anomalies, recurrent ureteric stone, active UTI, cardiac and respiratory problems, coagulopathy, pregnancy and previous intraperitoneal surgery.

METHODS

The procedure: Group A: The case was positioned in 45-degree lateral position, under general anesthesia with the operating side up. Closed insufflations of carbon dioxide were done by Veress needle, 14-gauge needle aspiring loaded protective tip. Port design was as follows: Ten-millimeter port has been positioned at the same site of Veress needle, 10-mm 0-degree laparoscope was put in this port. Additional two additional 10- millimeter ports have been positioned below direct endoscopic vision, the first has been inserted under the costal margin at mid clavicular line and the second inserted lateral to rectus abdominis muscle 3 cm above the umbilicus. Mobilization of the colon was done till reaching the ureter. Localization of the stone was done by ureteral pinching using Maryland forceps. Ureterotomy and trapping the stone were performed. A ureteric stent was placed in 17 cases and rest of cases without stent, followed by suturing of the ureterotomy incision in all cases. A tube drain was fixed beside the ureterotomy. Finally, abdominal desufflation was done, followed by closure of the ports by non-absorbable interrupted sutures. Operative period, loss of blood during the operation, requirement for blood transfusion, use of stent and its type, and need for conversion to the open approach were recorded.

Group B: (The type of ESWL generator was electrohydraulic):

System: Dornier Gemini. **Revision:** G. **Date:** 4/2015**.**
Software: 1.5 x. **Number:** k1037556.

In this system, high voltage was applied to two opposing electrodes positioned one mm apart producing an underwater spark discharge. This great voltage spark discharge caused the explosive vaporization of water at the electrode tip generating a spherically expanding SW. All techniques have been conducted under fluoroscopic guidance patients were given intramuscular nalufin. The shock waves per SESSION ranged from 1500 to 3000 with mean (2612.5) at power setting of four (range three to six) and a frequency of 60 to 120 shocks/minutes. The number of ESWL settings were recorded.

Post-procedural care: Patients in both groups have been transmitted to the internal ward after the procedure. Early mobilization was encouraged, and postoperative pain has been evaluated by the visual analogue scale (VAS) with zero for no pain, and ten for the worst pain ever [(9)].

In group A: Close monitoring of the vital signs with frequent abdominal examination was done for all patients. Drain output was also observed and recorded. Plain X-ray of the abdomen and pelvis has been done on the first day postoperatively for the residual radio-opaque stones. Pelviabdominal Ultrasound on the first day postoperatively for the residual radio-lucent stones and for the detection of any collection due to leakage from the ureterotomy.

In group B: A plain film has been recorded following each extracorporeal shock wave lithotripsy session to record fragmentation and prior to the next session to ascertain position and clearance. Clearance has been described as the complete disappearance of the calculus or residual fragments 3 millimeters or less and has been recorded by a plain or CT film 2 weeks following the most recent extracorporeal shock wave lithotripsy session [(10)].

Discharge criteria: Patients in group A were discharged from hospital next day after lap and in group B were discharged in same day of ESWL. All patients were discharged when they were free from complication could tolerate pain with oral medications, and on complete oral intake.

Post-operative medication: Patients in group **A** were discharged with the following treatment: Ciprocin 500 mg tab b.i.d for 1 week, analgesic on demand. Patients in group **B** were discharged with the following treatment: Ciprocin 500 mg tab b.i.d for 1 week, analgesic on demand, Tamsulin 0.4 tab once daily at night.

Follow-up: Follow up visits were scheduled for all patients after discharge. During these visits, clinical, biochemical (urinalysis) and radiological assessment was done (x-ray, US, or CT when needed). In group A patients were followed every week for 1 month and group B patients were followed every two weeks for 3 months. Case has been asked to express his satisfaction with the procedure as good or bad.

Ethical consideration: The research obtained agreement from The Local Ethical and Scientific Committee, Faculty of Medicine, Suez Canal University. All cases felt free to withdraw from the research at any time in accordance with their demands. The study was conducted in accordance with Helsinki Declaration. An informed written consents were signed by all patients following a full explanation of the advantages, benefits, and potential complications of each intervention.

Statistical analysis

Results were statistically analyzed by using statistical package of social sciences (SPSS 27.0, IBM/SPSS Inc., Chicago, IL) Two types of statistical analysis were conducted: Descriptive statistics**:** It included estimates for summarizing the continuous data as mean (X) and standard deviation (SD) or median (Med) and range for skewed data. Frequency with percentage (%) was used for presenting qualitative data. Analytical or inferential statistics: Pearson Chi-square ($\chi 2$) test: It was used to compare between two or more groups regarding one qualitative variable. Fischer's exact test: It was used instead of Chi-Square ($\chi 2$) test when the assumption that at least 80% of the expected frequencies are greater than five was violated (2x2 tables). Monte-Carlo test: It was used instead of Chi-Square ($\chi 2$) test when the assumption that at least 80% of the expected frequencies are greater than five was violated (> 2x2 tables). Independent samples t-test (t test): was used for continuous data to test for significant difference between two normally distributed groups. Assumptions of normality in each group and homogeneity of variances were verified using Shapiro-Wilk test and Levine's test, respectively. Mann-Whitney U-test (Z test): was used for continuous data to test for significant difference between two not normally distributed groups. In all applied tests, the P-values associated with test statistics indicated the significance level at which the null-hypothesis (the hypothesis of no difference) was rejected and it was set at 0.05 so that a P-values ≥ 0.05 are statistically non-significant, P-values < 0.05 are significant, and P-values < 0.01 are highly significant.

RESULTS

The mean age of the involved patients was 42 and 42.38 years in the laparoscopic and ESWL groups respectively. Men represented 75% and 70.8% of the included population in the same two groups respectively, while the remaining patients were women. Both age and gender showed no significant difference among both groups (p-value higher than 0.05) (Table 1).

Table (1): Analysis of demographic data in both studied groups.

		Laparoscopic (Number=24)		ESWL (Number =24)		Test of significance
Age (years)	Mean± Standard deviations	42 ± 10.48		42.38 ± 11.16		t= -0.120 P = 0.905
Sex	Male	18	75%	17	70.8%	χ^2= 0.105 P= 0.754
	Female	6	25%	7	29.2%	

P: probability, Continuous data expressed as mean ± SD, Categorical data expressed as Number (%), T= independent samples t-test, χ^2= Chi-square test.

Statistically insignificant variance was observed among both studied groups regarding associated comorbidities (Table 2).

Table (2): Analysis of associated comorbidities in the two studied groups

	Laparoscopic (N=24)		ESWL (N=24)		Test of significance
DM	4	16.7%	3	12.5%	FET= 0.167 P= 0.683
HTN	2	8.3%	1	4.2%	FET= 0.356 P= 0.551
IHD	0	0%	0	0%	_____

Categorical data expressed as Number (%), FET= Fischer's exact test

Statistically significant variance was observed between both studied groups according to stone size and hydronephrosis (Table 3).

Table (3): Examination of the present history in both studied groups

	Laparoscopic (N=24)		ESWL (N=24)		Test of significance
Pain score	3 (2-4)		2 (2-4)		z= -0.505 P = 0.614
Affected side					
Right	15	62.5%	14	58.3%	χ2= 0.087 P= 0.768
Left	9	37.5%	10	41.7%	
Stone size	14.7 ± 0.34		11.6 ± 0.27		t= 5.353 P < 0001*
Hydronephrosis					
Mild	1	4.2%	13	54.1%	MC= 18.650 P < 0001*
Moderate	19	79.2%	8	33.3%	
Marked	4	16.7%	3	12.5%	

z: Mann-Whitney u-test, χ2= Chi-square test, FET= Fischer's exact test, MC: Monte-Carlo test, *: Statistically significant (p< 0.05).

Statistically significant variance was observed among both examined groups regarding platelets, ALT and AST and no statistically significant difference regarding hemoglobin, pus cells in urine, creatinine and INR (Table 4).

Table (4): Examination of the preoperative laboratory data in both studied groups

	Laparoscopic (N=24)		ESWL (N=24)		Test of significance
Hemoglobin	13.30 ± 1.93		13.34 ± 1.34		t= -0.096 P = 0.954
Platelets	249.96 ± 45.87		329.29 ± 72.33		t= -4.538 P < 0001*
Pus cells in urine	14	58.3%	9	37.5%	X2= 2.087 P= 0.149
Creatinine	1 (0.8-12)		1.05 (0.7-1.7)		z= - 0.260 P = 0.795
ALT	35 (8-60)		23 (7-56)		z= - 2.538 P = 0.011*
AST	33 (12-55)		22 (11-50)		z= - 2.728 P = 0.006*
INR	1.04 ± 0.09		1.02 ± 0.06		t= 1.218 P = 0.299

The procedure time demonstrated a significant rise with laparoscopy than **ESWL**. No patients required intraoperative blood transfusion in our study. There was an increased need for stenting in the laparoscopic group (p = 0.002). The duration of hospitalization showed a significant increase with laparoscopy (p-value less than 0.001) (Table 5).

Table (5): Analysis of the operative data in both studied groups

	Laparoscopic (Number=24)		**ESWL (Number=24)**		**Test of significance**
Procedure time					
30 minutes	0	0%	2	8.3%	MC= 24 P < 0001*
40 minutes	0	0%	2	8.3%	
45 minutes	0	0%	5	20.8%	
50 minutes	0	0%	5	20.8%	
60 minutes	8	33.3%	10	41.6%	
90 minutes	9	37.5%	0	0%	
120 minutes	6	25%	0	0%	
180 minutes	1	4.2%	0	0%	
Stent					
No	7	29.2%	20	83.3%	MC= 15.024 P = 0.002*
DJ	14	58.4%	4	16.7%	
Ureteric	3	12.5%	0	0%	
Hospital stay	3 (1-24)		1		z= - 5.968 P < 0001*

P: probability, Continuous data expressed as median (range), Categorical data expressed as Number (%), z: Mann-Whitney u-test, MC: Monte-Carlo test.

After the procedure, statistically insignificant variance was observed among both studied groups regarding fever (p-value equal 0.074) and hematuria. However, the incidence of residual stone significantly increased with ESWL (33.33% vs. 4.2% in laparoscopy – p = 0.01). The one patient with residual stone was managed by ESWL, while the eight patients in the ESWL group were managed either by ESWL (seven cases) or ureteroscopy (one patient). No mortality was encountered in our study. In the laparoscopic group, transformation into the open technique was required in three cases (12.5%), and postoperative leakage ranged between 0 and 1600 ml. One patient had persistent leakage and required DJ stent (Table 6).

Table (6): Analysis of the postoperative data in both studied groups.

	Laparoscopic (Number=24)		**ESWL (Number=24)**		**Test of significance**
Fever	3	12.5%	0	0%	FET = 3.200 P = 0.074
Residual stone	1	4.2%	8	33.3%	FET= 6.701 P= 0.010*
Management of residual stone					
ESWL	1	100%	7	87.5%	
URS	0	0%	1	12.5%	
Pain score	2 (2-7)		2 (2-7)		z= - 1.034 P = 0.301
Satisfaction					
Good	17	70.8%	16	66.7%	χ2= 0.097 P= 0.755
Bad	7	29.2%	8	33.3%	
Hematuria					
No	8	33.3%	4	16.7%	FET = 1.778 P= 0.182
Microscopic	16	66.7%	20	83.3%	

z: Mann-Whitney u-test.

DISCUSSION

In our study, the mean age of the involved patients was 42 and 42.38 years in the laparoscopy and ESWL groups respectively, with insignificant variance in statistical analysis ($p = 0.905$). Our age distribution is near the age distribution in a previous similar research by **Lopes *et al*.** [11] that stated a mean age of 46 years in patients having ureteric stones.

In our study, most of the included participants were men, as they formed 75% and 70.8% of cases in the laparoscopy and ESWL groups respectively, while the remaining participants were women. This is in accordance with previous study by **Safarinejad** [12] that showed an association between male gender and ureteric stones. The man-to-girl ratio in developing countries ranges from 1.15:1 in Iran.

In the current study, all patients in both study groups had microscopic haematuria during the preoperative evaluation. That could be explained by the direct impact of stone on lining cells of the urinary tract that results in destruction, ultimately allowing blood to leak into urine. The bleeding can be microscopic or gross, depending on the size and impact of the stone [13]. In the current study, stone size had mean values of 14.7 and 11.6 mm in the laparoscopy and ESWL groups, respectively, with a significant increase in the laparoscopy group ($p < 0.001$). Alternatively, **Ozturk *et al*.** [14] reported a comparable stone size between the two groups, as it had mean values of 13.2 and 13.3 mm in the ESWL and laparoscopic groups respectively ($p = 0.24$).

In the current study, pus cells were detected in the urine of 58.3% and 37.5% of patients in the laparoscopy and ESWL groups respectively, with no significant difference between the two groups. Intra operative quinolone vial given, and patients followed post-operative for fever. The literature is less clear regarding pyuria. We found no previous studies regarding the incidence of pyuria in either inpatients or outpatients with renal stones. Studies regarding renal stones and positive urine cultures are few and inconsistent [15].

Our findings revealed a significant prolongation of procedure time in association with the laparoscopic approach ($p < 0.001$). The procedure time showed a significant increase with laparoscopy, which ranged between 60 minutes and 180 minutes with a mean value of 90 minutes, whereas ESWL procedures ranged between 30 minutes to 60 minutes with mean a value of 50.2 minutes. It is reasonable to take more time in the laparoscopic group that is needed for abdominal access, insufflation, dissection, and haemostasis. All these steps are omitted in the ESWL approach. **Lopes *et al*.** [11] agrees with our findings, as the procedure time had a mean value of 44.5 minutes in the ESWL group, while it had a mean value of 215 minutes in the laparoscopic group, with a significant prolongation in association with laparoscopy ($p < 0.001$). No blood loss was encountered in the ESWL group, while it ranged between 50 and 300 ml in the laparoscopic cases, with a significant difference in the statistical analysis ($p < 0.001$). Nonetheless, the majority of laparoscopic cases had less than 50 ml of blood loss. Another study by **Wani and Durrani** [16] agrees with our findings as the average blood loss was 39.83 ml.

In our laparoscopic cases, conversion to the open approach occurred in three cases (12.5%), in two cases the reason for conversion to the open approach was severe fibrosis and failed dissection to identify the ureter and in one case the stone migrated to kidney so open pyelolithotomy was done. **EL-Moula *et al*.** [17] reported a 5.4% conversion rate, while **Wani and Durrani** [16] reported that 0% conversion rate. One could attribute differences in conversion rates to different intraoperative findings, operative theater ergonomics, and surgeon experience. In the current study, stent was inserted (intra operative) in 70.83% of laparoscopic cases, compared to only 16.7% of ESWL cases that was inserted (post-ESWL). There was a significant increase in stenting rates in association with the laparoscopic method. In line with our ESWL results, previous research by **Khanna *et al*.** [18] reported that ureteric stent is still used in about 16.2% of patients undergoing ESWL.

The duration of hospitalization had median values of 3 and 1 days in the laparoscopy and ESWL groups respectively with a significant prolongation in correlation with laparoscopy (p-value less than 0.001). As ESWL is considered less invasive procedure than laparoscopy, it is expected to have shorter hospitalization period in the ESWL group. A research by **Lopes *et al*.** [11] confirmed our findings regarding the increased hospitalization period in association with laparoscopy as it had a mean value of 75.7 hours compared to only 1.9 hours in ESWL cases ($p < 0.001$).

Our findings revealed the occurrence of postoperative fever (more than 38 °C) in three laparoscopic cases (12.5%) that was never detected in the ESWL group. Yet, no significant difference was noted in the statistical analysis ($p = 0.074$). Patients who had fever post-operatively had pus in the urine pre-operative and managed with fluids, antipyretic, anti-biotic based on urine culture. **El-Moula *et al*.** [17] reported an incidence of 4.05% for the same complication whereas **Şahin *et al*.** [19] reported an incidence of 1.4%.

In the present research, we noted insignificant variance among both approaches according to patient satisfaction, which was good in 70.8% and 66.7% of laparoscopic and ESWL cases respectively. A study by **Lopes *et al*.** [11] noted a comparable satisfaction level between laparoscopic and ESWL patients ($p = 0.112$), as 93.3% and 78.6% of patients expressed their satisfaction in the previous two groups respectively.

Our findings revealed the incidence of post-procedural microscopic haematuria in 66.7% and 83.3% of patients in the laparoscopic and ESWL cases respectively with insignificant variance in both groups (p = 0.182). **El-Moula *et al*. [(17)]** reported an incidence of 21.6% for the same complication after laparoscopic ureterolithotomy, while **Al-Marhoon *et al*. [(20)]** reported an incidence of 6.1% for gross haematuria after ESWL in ureteric stone patients.

CONCLUSION

Laparoscopy is superior to ESWL in single-session clearance of ureteric stones. Nonetheless, it is associated with longer procedure time, longer hospitalization period, and postoperative urine leakage. Therefore, the advantages and disadvantages of each approach should be considered according to patient criteria and urologist experience.

DECLARATIONS

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- **Availability of data and material:** Available.
- **Conflicts of interest:** No conflicts of interest.
- **Competing interests:** None.

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