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COMPARISON OF LAPAROSCOPIC URETEROLITHOTOMY VERSUS MINI-INCISION OPEN URETEROLITHOTOMY: A RANDOMISED STUDY

Urology

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ABSTRACT

Aim: Prospective randomized study on transperitoneal laparoscopic ureterolithotomy (LU/TPLU) versus open mini- incision ureterolithotomy (MIU) for treatment of large impacted proximal ureteric stones and assessment of overall results. **Materials and Methods:** The study was conducted from November 2012 to October 2014 with 40 patients randomly divided into two groups. The two groups were compared for operative time, intraoperative and postoperative complications, blood loss, VAS score comparison, time for drain removal, length of hospital stay, time taken for return to work, and success. Both males and females patients aged above 20 years with upper and middle ureteric calculus of size > 1 cm were randomized into two groups Statistical analysis used: Student t-test, Leven1s test for homogeneity of variance, Chi-square and Fisher Exact test were used with statistical software SAS 9.2 and SPSS 16.0 **Results:** When the two groups were compared, there was no statistically significant difference with regard to the mean age (36.25- 36.10 years), stone size (19.55-20.95 mm) the body mass index (22.66-24.09 kg/m²) and stone clearance (100%). The mean operative time and blood loss in our study was 29.90±5.07 mins./ 46.75±10.17ml in MIU compared to 115.25±20.99 mins./ 81.00±25.27 ml in LU, which was statistically significant. The mean drain removal was (2.15 - 3.15 days) which was statistically significant. The mean hospital stay was (4.05 - 4.95 days) and return to work (8 - 8.96 days) in the present study. **Conclusion:** The present study has documented superior results with MIU in normal BMI patients over Laparoscopic Ureterolithotomy in terms of minimal morbidity, operative time, blood loss, drain removal, and hospital stay. However, lesser pain and cosmetic appearance are in favour of LU.

KEYWORDS

Laparoscopic ureterolithotomy, impacted ureteral calculus, open mini-incision ureterolithotomy, , large ureteric calculus.

INTRODUCTION

Urinary stone disease is a significant health problem that concerns millions of patients worldwide, affecting 2-3% of the human population with a high recurrence rate of up to 50%. They occur most commonly in men aged between 30 years and 60 years.[1,2].Currently, extracorporeal shock wave lithotripsy (ESWL) and ureteroscopic stone removal (URS) are the preferred modalities for the treatment of ureteric stones with antegrade approaches such as percutaneous nephrolithotomy (PNL) may be employed selectively in large impacted upper ureteric stones.[3,4] Regardless of the status of ESWL, URS, or PNL, there are circumstances that decide the best mode of treatment like the stone parameters, characteristics of the patient, or the surgeon's skill.[5]

Surgical management of urolithiasis, particularly cystolithiasis, has been known for over two millennia. Hippocrates (460 BC) also mentions the procedure done by others. The Roman physician Celsius (25 BC–25 AD) provided the earliest accurate description of a lithotomy procedure for bladder stones. Notably, his description remained broadly accurate for the techniques used over the next 1500 years.[7]

Large ureteric calculi pose significant challenge for modern endourological techniques, often requiring several endoscopic procedures or Shock Wave Lithotripsy (SWL) sessions. [8,9,10] SWL is found to be suitable for managing ureteric stones of < 1cm [11,12,13] because as the stone size increases, the chance of clearance decreases and the need for multiple sessions increases. A perusal of literature reported that the stone free rate decreased from 84% to 42% when the stone is > 1cm.[13,14] Majority of the patients are thin built in this region and have relatively bigger stones. Thus, keeping the merits and demerits of both these techniques, the aim of this study, is to compare the two approaches viz MIU and LU for the proximal ureter calculus in non-obese patients. In addition, so far, no randomized prospective study has been reported comparing Mini Incision Ureterolithotomy (MIU) and Transperitoneal Laparoscopic Ureterolithotomy (LU).

MATERIALS AND METHODS

Both male and female patients aged over 20 years with upper and middle ureteric calculus of size > 1 cm were randomized into two groups – group I- MIU and group II- LU. Patients were randomized into a 1:1 ratio. Exclusion criteria were renal insufficiency, uncontrolled coagulopathy, uncontrolled hypertension or other significant co-morbidity, pregnant patients, and obese patients' BMI>30. Apart from the clinical history and examination, complete hemogram, renal function tests, liver function test, urine culture and sensitivity, renal and bladder ultrasound, coagulation profiles, X-ray KUB and IVU were performed in all cases. Approval from ethical commiittee was obtained from RIMS, Imphal.

Operative Steps:

Surgery was conducted with the patient under general/spinal anaesthesia; the patient's position on the table and the surgical approach was determined by the location of the stone on preoperative plain films. For MIU, a 4-5 cm skin incision was used with a muscle-splitting approach to the ureter. In the standard flank approach, the peritoneum was mobilized anteriorly and the psoas muscle identified using long blade retractors and fibre optic/head light. The ureter was identified on the muscle and opened longitudinally directly onto the stone and the stone was removed. The stone was identified by palpating the ureter between thumb and index finger. The ureter is clamped with two Babcock tissue forceps proximal and distal to the stone to prevent migration. Stay sutures were taken on either side of the proposed ureterotomy incision with 3-0 chromic catgut. It is then opened longitudinally directly onto the stone with a 1-cm incision (depending on stone size) and the stone is removed. The patency of the ureter is checked by inserting a feeding tube no. 6 through the ureterotomy wound proximally and distally. The ureterotomy was then sutured with 3-0 catgut and an 20 Fr. abdominal drain tube was placed as a drain in the retroperitoneal space; the ureter was stented with Double J stent 6/26. No. 1 polydioxanone suture (PDS) was used to close the muscle layers and a 2/0 absorbable subcuticular suture/ Skin stapler was used for skin closure.

For Laproscopic Ureterolithotomy (LU) the patients were placed in the lateral decubitus (kidney position) with a bridge at the flank. The ports were placed a) at the lateral edge of the rectus, level with the umbilicus or supraumblical port; b) in the anterior axillary line below the costal margin and c) in the anterior axillary line in the iliac fossa. The carbon dioxide pneumoperitoneum was then created with pressure maintained at 12 mmHg. The colon is reflected medially along the white line of Toldt and the ureter is exposed. The ureter with the stone identified was stabilized by Lap Babcock forceps proximally and ureter incised over the stone with hook diathermy/ scissors. The stone grasping forceps

was used to hold the stone which was removed through 12-mm port site. Ureter was stented with double J stent 6/26. Ureterotomy was then closed with absorbable 3-0 vicryl. The reflected colon was replaced and 22 F soft silastic abdominal tube drain was placed near to suture line. Ports are closed in standard way. A post operative X-ray KUB was taken to confirm stone clearance and Double J stent position. Double J stent was removed cystoscopically under LA after 2-6 weeks in both groups.

RESULTS

Both groups were comparable with respect to number of patients, age, sex, and stone characteristics. There was no statistically significant difference with regard to the mean age (36.25- 36.10 years), stone size (19.55-20.95 mm), site, and the body mass index (22.66-24.09 kg/m²). Primary surgery was indicated in both the Groups (MIU-55% and LU-60%), mainly because the patient wanted best stone clearance in a single sitting when all the treatment modalities were discussed with the patients. In the remaining patients, it was done as a salvage procedure for failed cases of URS/ESWL.

The mean operative time was 29.90±5.07 mins. in Group I (MIU) versus 115.25±20.99 mins. in Group II (LU). The reason for shorter time in Group I was experienced surgeon and high volume of cases (>150 MIU). The minimum time taken was 22 mins and the longest was 42 mins, one reason being the high BMI of the patient and periurereritis. The reason for mean of 115.25±20.99 mins. in Group II (LU) was attributed to the initial learning curve of the surgeon. The result was statistically significant with P value less 0.05.

The mean blood loss in patients was 46.75±10.17 ml in Group I (MIU) versus 81.00±25.27 ml in Group II (LU) which was statistically significant with P<0.001. The range of minimum and maximum blood loss in Group I and II was 30 ml-70 ml and 40-120 ml respectively. The mean VAS score was 3.95±1.23 at 24 hrs in Group I (MIU) versus 4.20±1.74 in Group II (LU). The increased VAS score in group II (LU) was due to pneumoperitoneum, more dissection, and increased operative time. The 48 hrs VAS scale demonstrated a better VAS score for Group II vs. Group I probably because of the skin/muscle incision pain in Group I. The analgesia requirement was initially more for LU but later on, decreased as compared to MIU group. The p-value was insignificant. Table 1 shows the Complications in the two groups studied with the majority of the patients having no intra-operative and post-operative complications viz. 75% in MIU and 60% in LU. In Group I (MIU) two patients each had haematuria (transient) and fever (<100oF) which was managed conservatively. One patient had a wound infection. In group II haematuria and ileus were present in 3 patients each and 2 patients developed fever which was managed conservatively. No patient required any intervention or blood transfusion. Complications were recorded and graded (all < II) using the Dindo-modified Clavien classification of surgical complications. The mean drain removal was 2.15 days (range 1-3 days) in Group I (MIU) versus 3.15 days (range 2-4 days) in Group II (LU). Most of the patients in Group I had their drain removed by day 2 - 55% Vs. 10% in Group II. All MIU patients had the drain removed by day 3 compared to 75% of patients in LU. The reason for early drain removal in MIU was minimal dissection. No patient had the drain beyond day4. The mean hospital stay in the two groups - 4.05 days (range 2-7 days) in Group I (MIU) versus 4.95 days (range 4-7 days) in Group II (LU). The reason for the difference was the duration of drain removal and associated complications which were more in Group II (LU). With experience, an improvement in results is expected. By day 10 it was observed that 80% of MIU Vs. 85% of LU patients could return to work. The mean return to work was 8 days (range 5-11 days) in Group I (MIU) versus 8.96 days (range 7-12 days) in Group II (LU). The result (P=0.661) was not significant. The mean scar size in the Group I – MIU patients was 4.75 cm (range of 4-5.5 cm). 95% of patients of Group I had scar length of less than 5 cm.

Table 1: Complications in two groups studied

Complications	Group I- MIU (n=20)		Group II-LU (n=20)	
	No	%	No	%
Absence	15	75.0	12	60.0
Presence	5	25.0	8	40.0
Haematuria	2	10.0	3	15.0
Fever	2	10.0	2	10.0
Ileus	0	0.0	3	15.0
Wound infection	1	5.0	0	0.0

P=0.311, Not significant, Chi-Square test

Table 2: Comparison of study variables in two groups studied

	Group I - MIU	Group II - LU	P value
Age in years	36.25±8.48	36.10±9.68	0.959
Stone size	19.55±2.93	20.95±2.33	0.102
BMI (kg/m2)	22.66±2.15	24.09±1.98	0.035*
Operative time	29.90±5.07	115.25±20.99	<0.001**
Blood loss	46.75±10.17	81.00±25.27	<0.001**
VAS 24 hr	3.95±1.23	4.20±1.74	0.603
VAS 48hr	2.80±1.11	2.55±1.15	0.487
Drain removal	2.15±0.67	3.15±0.59	<0.001**
Hospital stay	4.05±1.39	4.95±0.83	<0.001**
Return to work	8.00±1.92	8.95±1.57	0.095+
Stone clearance	100.00±0.00	100.00±0.00	-

DISCUSSION

The treatment options for the ureteric calculus includes various options depending upon the stone size, site, co-morbidities, surgeon and patient preference. ESWL, URSL and PCNL are the preferred modalities for treatment of ureteral stones and offer considerable advantages over open ureterolithotomy (OU) [9,12]. Still, there are situations when OU is required in patients with complex calculus disease, large impacted calculus or in presence of anatomic and physiologic anomalies, as per the Guidelines of the European Association of Urology[12,13,14]. After the initial description of laparoscopic ureterolithotomy in 1979 by Wickham [14], and with the advancements in technique and experience, laparoscopy has become a highly effective modality in the treatment of large impacted/ complicated ureteral stones.[14,16,20,30]

Due to scarcity of complex and large ureteric stones nowadays, there are only a few studies that actually compared the laparoscopic and open techniques of ureterolithotomy in prospective design. Most of the previous laparoscopic studies are un-randomised and not actually comparative [17,20,21,30].There is no randomised trial study in the literature that compares minimal access/incision ureterolithotomy (MAU/MIU) with transperitoneal laparoscopic ureterolithotomy (LU).

The concept of MAU was proposed by Frang D et al in 1996 as a new minimally invasive ureterolithotomy utilising a 4 cm long skin incision[10]. Many authors popularized MAU as an alternative to other options in large impacted/ failed procedure with varying results. The main factors were less morbidity, better cosmesis, less analgesics and early return to work, although initially there is longer operative time as compared to conventional open ureterolithotomy .[23,24,31]

The last two decades saw laparoscopic ureterolithotomy gaining popularity among urologists. Laparoscopic ureterolithotomy can either be retroperitoneal or transperitoneal. In the present study laparoscopic transperitoneal ureterolithotomy was used in all patients because this is a familiar approach, provides a good working space, and identification of anatomical landmarks are easier. The main limiting factor with this approach is the intraperitoneal adhesions due to previous abdominal surgeries, but we did not encounter any major difficulty in operating on such patients. Several authors have recommended the transperitoneal route for ureterolithotomy.[9,20,30]

In the present study (n=40), the mean age of MIU and LU was 36.23 ± 8.48 years and 35.52 ± 10.93 years respectively which was statistically insignificant. Most of the patients were in the age group of 30-39 years. The mean age of patients in various studies were (in years)- Garg et al [30] (OU-42.56 , LU-39.78), Bayar at el [32] (OU-44.5, LU-44), Meitei et al [31] (MIU-44.97), Sharma et al [23] (MIU-38). The Male to Female ratio in the present study was MIU M:F= 9:11, LU M:F= 8:12. The stones in our study were equal in MIU right: left 10:10 and in LU right: left 9:11. Regarding the site of ureteric stone MAU- Upper Ureter 11 (Rt-6, Lt-5) and Middle Ureter 9 (Rt-4, Lt-5). In the study by Sharma et al [23] (Upper ureter-30, Lower ureter-69) and Garg et al [30] (Upper ureter-15, Lower ureter-10) were noted.

The mean size of stone in our study was 19.55 ± 2.93 mm for MIU and 20.95 ± 2.32 mm for LU. The average size of stone in various studies was - Garg et al 30 (OU-2.5 mm , LU-2.3 mm), Meitei et al 31 (MIU-18 mm), Sharma et al 23 (MIU-12 mm), El-Moula MG26 (LU-18 mm). Therefore our mean stone size was similar to most studies. The size of stone varied from 15 mm – 26 mm in MAU and 15mm-24mm in

case of LU. Various studies have documented that the results with MAU and LU are better in non-obese patients. The BMI (Body Mass Index) of the two groups viz. Group I (MIU) - 22.66±2.15 Vs. Group II (LU) - 24.09±1.98 with the p-value= 0.035. BMI has more role in MIU than LU. Many studies in literature lack BMI. Bayar et al 32 reported mean BMI of 26 (OU) vs. 24.7 (LU) and El feel et al 25 study had mean BMI of 28.7 for LU. Moreover, most of the population in this North-East India has normal BMI suited for both.

The mean operative time in our study was 29.90±5.07 mins. in Group I (MIU) versus 115.25±20.99 mins. in Group II (LU). The mean operative time for MIU/MAU by Sharma et al [23] and Meitei et al [31] was 28 mins and 25.39 mins respectively. The mean operative time in LU by Al-Sayyad et al [29], El-Feel et al [25], Garg et al [30] and Matias et al [28] were 107 mins.,145 mins,60 mins. and 145 mins. respectively. Laparoscopic ureter dissection, endo-suturing and laparoscopic DJS take up more time during the initial learning curve of the surgeon. Higher volume centers tend to have lesser operative time.

The mean intra-operative blood loss in patients was 46.75±10.17 ml in Group I (MIU) versus 81.00±25.27 ml in Group II (LU) which was statistically significant with **P<0.001**. The mean blood loss for MIU was 50 ml by Sharma et al [23] study . The mean blood loss for LU in various studies of Al-Sayyad et al [29], El-Feel et al [25], Garg et al [30] and El-Moula et al[26] was 60.5 ml, 62 ml and 60.84 ml and 90.6 ml. The mean VAS score in our study was 3.95±1.23 at 24 hrs in Group I (MIU) versus 4.20±1.74 hrs. in Group II (LU). Most literature did not measure VAS scores. The mean VAS score in Garg et al [30] study was 6.2/ 4.8 at 24 and 48 hours respectively for OU ;and 3.1/2.4 at 48 hours respectively for LU. One reason for higher VAS was larger incision compared from <5 cm incision of MIU.

Our study's mean drain removal time was 2.15 days in Group I (MIU) versus 3.15 days in Group II (LU). The mean drain removal time in MIU study by Meitei et al [31] and Sharma et al [23] was 3 and 5 respectively. The mean drain removal time in LU study by Garg et al [30] and Matias et al [28] was 3.6 and 7.2 days.

The mean hospital stay was 4.95 days (range 4-7 days) and return to work 8.96±1.57 days (range 7-12 days) for LU in the present study. The mean hospital stay and return to work for LU by Al-Sayyad et al [29] and Bayar G was 2.6days/7.3 weeks and 2.9/24 days respectively. The mean hospital stay was 4.05±1.39 days (range 4-7 days) and return to work 8.00±1.92 days (range 7-12 days) for MIU in the present study The mean hospital stay and return to work for MIU by Sharma et al [23] and Meitei et al [31] was 2/16 days and 3/16 days respectively.

The mean scar length in the MIU patients in the present study was 4.75 cm which is cosmetically acceptable, has minimum morbidity and good patient acceptance. The mean scar length in the study by Meitei et al [31] and Sharma et al [23] was 4.78 cm and 4.5 cm respectively. Both the procedures (MIU and LU) have their merits and demerits. No one procedure can be offered to all patients. The merits of LU is minimal scar, lesser analgesic requirement, early return to work ,dealing with bilateral calculi/ or additional procedure e.g. Laparoscopic cholecystectomy. The demerits include longer duration of hospital stay, steep learning curve, higher cost, higher chances of bowel injury, and chances of ileus and post op adhesions. The merits of MIU is short operating time, no need for GA, cost effectiveness, lesser morbidity and easy learning curve. The demerits being scar, more analgesia requirement and not suitable for bilateral cases. In the present study we prefer MIU over LU in most of the cases due to its various advantages as an alternative to LU in large impacted/complicated stones in non-obese patients.

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