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Original Article

A Comparison of Minimally Invasive Surgery Ureterolithotomy and Transurethral Lithotripsy in Combination with Retrograde Intrarenal Surgery: A Randomized Clinical Trial

Seyed Mohammad Kazem Aghamir¹, Mohammad Hafez Khorrami², Mohammad Saatchi³, Hamidreza Zia¹, Seyed Naser Seyedesmaeili^{1*}

¹Urology Research Center, Tehran University of Medical Sciences, Tehran, Iran

²Department of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran

³Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

HIGHLIGHTS

- Laparoscopic ureterolithotomy is an effective and safe surgical procedure.
- Laparoscopic ureterolithotomy is the minimally invasive strategy.
- This method is suggested when previous therapeutic approaches were unsuccessful in patients with larger ureteral stones.

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*Corresponding Author:

Seyed Naser Seyedesmaeili

Email: drnaser1982@gmail.com

Address: Urology Research Center (URC), Sina Hospital, Hassan Abad Sq., Tehran, Iran

ABSTRACT

Introduction

The establishment of good efficacy and safety of non-invasive methods in comparison with conventional methods would be the result of a higher ability for decision-making about the best therapeutic approach in patients with large ureteral calculi. Accordingly, this study was carried out to compare the efficacy of minimally invasive surgical ureterolithotomy (MISU) versus Transurethral Lithotripsy (TUL) plus Retrograde Intrarenal Surgery (RIRS) in patients with ureteral stones larger than 15 mm.

Methods

In this single-blind randomized clinical trial, 74 consecutive patients with ureteral stones larger than 15 mm attending to Urology Clinic, Sina Hospital, and Tehran, Iran in 2017 were enrolled. Patients were randomly assigned to undergo minimally invasive surgical ureterolithotomy or TUL plus RIRS. Then the cases with remained stones over 2 mm after treatment were recognized by imaging and stone-free rate (SFR) was determined and compared across the groups.

Results

Longer hospital stay, larger Apotel Infusion dose, and longer operation time were seen in the MISU group (P -value ≤ 0.00). The stone-free rate was 94.6% and 97.3% in TUL plus RIRS and MISU groups, respectively (P -value = 1.00). The rates of adverse effects were alike across the groups (P -value = 0.95) with considering fever that was higher in TUL plus RIRS group.

Conclusions

Laparoscopic ureterolithotomy is an effective and safe surgical procedure for minimally invasive strategy when first-line therapeutic approaches were unsuccessful in patients with larger ureteral stones.

Keywords: Ureteral Stone; Management; Minimally Invasive Surgery

Introduction

Urinary stones are common in about ten percent of the population at some stage in their lifetime worldwide (1, 2) with an estimated annual incidence rate of ureteral stones of nearly 500 per 100,000 populations (3). However, there is an increasing trend globally (4). Multiple therapeutic

procedures such as extracorporeal shock wave lithotripsy (ESWL), transurethral lithotripsy (TUL), percutaneous nephrolithotripsy (PCNL), open ureterolithotomy, and laparoscopic ureterolithotomy are suggested to treat ureteral stones (5). Treatment modalities are generally selected according to stone size and location, and the

patient's preferences and comorbidities (6). Nowadays, there are many alternative strategies for the treatment of ureteral stones when determining the best treatment by the minimal urological treatment philosophy (7). There is an increasing trend for use of minimally invasive management of ureteral stones due to the high rate of efficacy besides the low rate of adverse effects (8, 9). Laparoscopic removal of ureteral stones is a minimally invasive surgical method (10, 11). Treatment with the best approach of non-invasive methods in comparison with conventional methods such as TUL would result in higher patient safety and satisfaction. However, utilization of the TUL method accompanying with retrograde intrarenal surgery (RIRS) may result in an increased success rate (12, 13). Accordingly, for better decision-making and selection of best therapeutic approach, this study was carried-out to compare the efficacy of minimally invasive surgical ureterolithotomy (MISU) versus TUL plus RIRS in patients with ureteral stones larger than 15 mm.

Methods

The study was run under the ethics committee supervision of Tehran University of Medical Sciences after receiving the IRCT code (IRCT20190624043991N12), and All patients signed the informed consent before enrolling. In this single-blind randomized clinical trial, 90 consecutive patients with ureteral stones larger than 15 mm referring to Sina Hospital in 2017 were enrolled. After an informed consent form was received from each patient, computed tomography (CT) scan was done and the largest stone measurement was determined and recoded and those patients with ureteral calculi larger than 15 mm were included. The patients currently under medical therapy or other surgical approaches for stone management, those with stones smaller than 15 mm, subjects with TUL alone procedure without subsequent RIRS, and also patients that were impossible to be followed-up were excluded. After exclusion, 74 patients have remained for assignment.

This study was approved by the local ethical committee and the Helsinki Declaration was respected across this clinical trial. Patients were randomly assigned to undergo minimally invasive surgical ureterolithotomy or TUL plus RIRS. Both groups received antibiotic as cefalotin with three daily doses and after urine culture was negative, the patients were enrolled. Then the cases with remained stones over 2 mm after treatment were recognized by imaging and stone-free rate (SFR) was determined and compared across the groups.

Data analysis was performed among 74 subjects including 37 patients in MISU and 37 subjects in TUL plus RIRS group. Data analysis was performed by SPSS (version 19.0) software [Statistical Procedures for Social Sciences; Chicago, Illinois, USA]. Chi-Square, Fisher, and Independent-Sample-T tests were used and were

considered statistically significant if the P values were less than 0.05.

Results

The mean age (standard deviation) was 47.3 (\pm 3.5) and 47.4 (\pm 3.4) years in MISU and TUL plus RIRS groups, respectively (P-value = 0.89). The mean stone size (standard deviation) was 22.1 (1.2) and 22.9 (1.4) mm in MISU and TUL plus RIRS groups, respectively (P-value = 0.21). The ureteral stone was right-sided in 18 cases (48.6%) in each group.

Longer hospital stays and larger Apotel Infusions dose and longer operation length were seen in the MISU group (Table 1). As shown in Figure 1 the stone-free rate was alike across the groups (P-value = 1.00). Among 37 cases in the MISU group, there were two patients with stone migration during operation. Among them, one was removed by ureteroscope and basket via ureteral incision site. In another patient with migration in the MISU group, a Double-J stent was placed and ESWL was done. In TUL plus RIRS group there were two cases with the remained stone of five mm diameter that both had spontaneous stone passage after six months. The rates of adverse effects (according to Calvin Score System) were alike across the groups (P-value = 0.957) except for the fever with a higher rate in TUL plus RIRS group (Figure 2).

Discussion

In this interventional study, the efficacy and safety of two surgical modalities for patients with ureteral stones larger than 15 mm, were compared. It was found that the laparoscopic (MISU) group had longer operation accompanied by a longer hospital stay and more analgesic consumption. The stone-free rate was alike across the groups and also complications had the same rate between the two groups except for postoperative fever that had a higher rate in TUL plus RIRS group. The remained stones in the MISU group required intervention to be passed from the ureter, but the stones in TUL plus RIRS were passed spontaneously.

A meta-analysis by Kallidonis et al (14) revealed a significantly higher stone-free rate for MISU in comparison with ureteroscopic lithotripsy in large upper ureteral stones. Similarly, they reported longer operative and hospitalization time in patients under treatment with the MISU method. In a study by Falahatkar et al., (15) among sixty patients with ureteral stones larger than 10 mm, the stone-free rate was 95 percent and 100 percent for those under MISU and TUL groups, respectively without a significant difference as well as our study. Also similar to our findings, the analgesic dose was significantly lower in the TUL group.

In the study by Ozturk et al., (12) the stone-free rate

Table 1. Hospital stay, apotel dose, and operation length across the groups

Variable	Group		P-value
	MISU	TUL plus RIRS	
Hospital Stay (day)	2.9 ± 0.8	1.6 ± 0.7	0.00
Apotel Dose (mg)	139.2 ± 37.5	62.2 ± 24.7	0.001
Operation Length (minutes)	97.03 ± 11.8	52.9 ± 5.9	0.00

was 96 percent and 79 percent for RIRS and MISU groups, respectively. In our study, these rates were 94.6 percent and 97.3 percent in TUL plus RIRS and MISU groups, respectively. The presence of the difference between our results and their findings is related to the important role of urologist experience in laparoscopic procedures such as MISU. The study by Aboutaleb et al., (16) revealed a stone-free rate of 59 percent and 86 percent for ESWL and MISU in patients with ureteral stones larger than 15 mm. In their study, the complications had the same rate across the groups as well as our study. Feyaerts et al. also reported similarly promising results for the MISU method inpatient with proximal ureteral stones that showed a low rate of adverse effects (17).

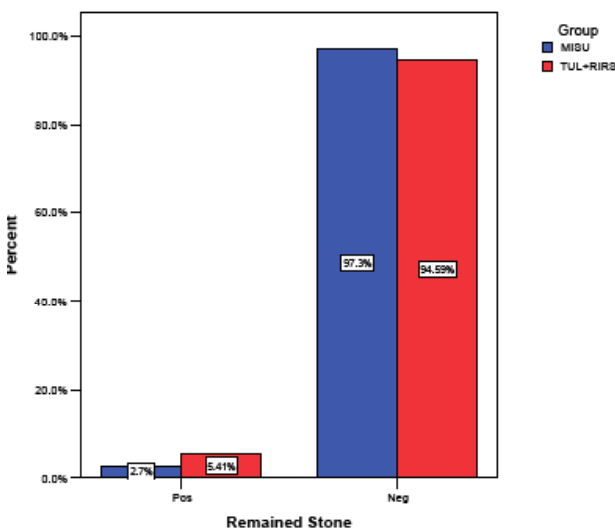


Figure 1. The stone-free rate across the groups

Conclusions

Totally, according to the obtained results, it may be concluded that laparoscopic ureterolithotomy is an effective and safe surgical procedure for minimally invasive strategy when first-line therapeutic approaches were unsuccessful in patients with larger ureteral stones. However further interventional studies with a larger sample size are required to attain more definite results about the best therapeutic approach for patients with large ureteral stones.

Authors' contributions

SMKA is the principal surgeon and who suggests this novel method, HZ and MHK are urologists who run the project and provide the data and SNS wrote the manuscript. MS analyses the data. HZ and MS edited the manuscript. All authors reviewed the results and approved the final version of the manuscript.

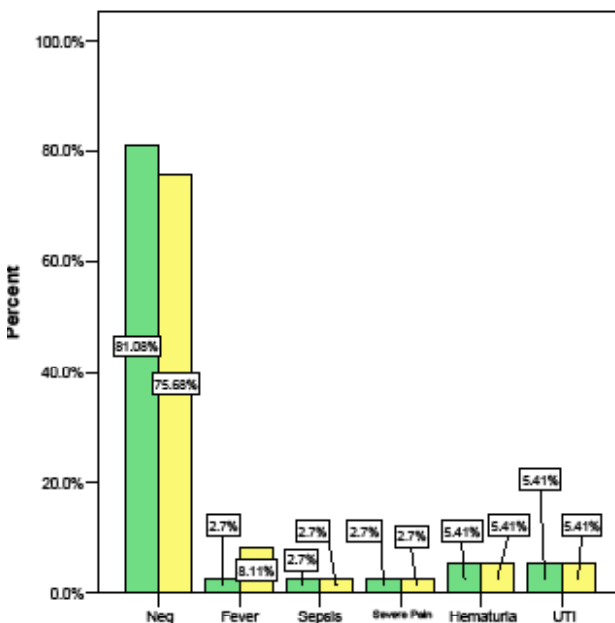


Figure 2. Therapeutic adverse effects across the groups

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Conflict of interest

All authors claim that there is no competing interest in this case report of surgery.

Funding

There was no founding.

Ethical statement

The study was performed prospectively under the Tehran University ethical committees after receiving the IRCT code (IRCT20190624043991N12). All patients signed informed consent before enrolling the study.

Data availability

Data will be provided by the corresponding author on request.

Abbreviations

ESWL	Extracorporeal shock wave lithotripsy
MISU	Minimally invasive surgical ureterolithotomy
PCNL	Percutaneous nephrolithotripsy
RIRS	Retrograde intrarenal surgery
SFR	Stone free rate
TUL	Transurethral lithotripsy

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Author (s) biosketches

Aghamir SMK, Associate Professor, Urology Research Center, Tehran University of Medical Sciences, Tehran, Iran.

Email: mkaghamir@tums.ac.ir

Khorrani MH, PhD, Department of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran.

Email: khorraniimohammadhatef@gmail.com

Saatchi M, PhD, Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

Email: m.saatchi65@gmail.com

Seyedesmaeili SN, PhD, Urology Research Center, Tehran University of Medical Sciences, Tehran, Iran.

Email: dr.seyedesmaeili@gmail.com

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