Comparison of Safety and Efficacy of Laparoscopic Pyelolithotomy versus Percutaneous Nephrolithotomy in Patients with Renal Pelvic Stones: A Randomized Clinical Trial

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Purpose: A randomized clinical trial was designed to compare the efficacy, success rate and surgical complications of percutaneous nephrolithotomy (PCNL) and laparoscopic pyelolithotomy (LP).

Materials and Methods: Sixty patients with renal pelvic stones larger than 2 cm were randomly divided into two groups of LP and PCNL. All patients were followed up to three months after surgery using renal diethylenetriaminepentaaceticacid (DTPA) scan and determining the glomerular filtration rate (GFR).

Results: Mean operation time (149 ± 31 vs. 107 ± 26 min) and mean hospital stay (3.4 vs. 2.16 days) were significantly higher in LP, but mean hemoglobin drop (0.85 vs. 1.88 g/dL) and the rate of blood transfusion were significantly lower. Stone free rate was 90% and 86.6% for LP and PCNL, respectively (P =.59), while the changes in GFR were not statistically significant 3 days after surgery between two groups. Those in LP group showed better improvement in GFR at three months postoperatively. Improvement of the affected split kidney function was significantly higher in LP group (P =.04). No major complications were observed in both groups according to Clavien grading system.

Conclusion: PCNL remains the gold standard treatment for most large kidney stones, nevertheless, laparoscopic pyelolithotomy can be considered for selected cases especially in whom maximal preservation of renal function is necessary.

Keywords: kidney calculi; surgery; laparoscopy; nephrostomy; percutaneous; treatment outcome.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is accepted as the gold standard surgery for most patients suffering from large renal calculi. Despite the progressive advances in percutaneous approach, some concerns still remain about its complications such as immediate or late hemorrhage (due to arteriovenous fistula or pseudo aneurism), parenchymal loss and injury to the adjacent organs.[1] On the other hand, the effect of PCNL on renal function needs to be better clarified.[2,3] While, some studies have indicated that the effect of PCNL on glomerular filtration rate (GFR) and isotope uptake was not significant and there is no renal parenchymal injury,[2-6] more comparative studies with control groups (i.e. other surgical modalities) are still needed to evaluate this opinion.
With the evolution of laparoscopy, a new era in the field of stone removal surgery is developing. According to the findings of the previous studies that have assessed the outcomes and adverse effects of laparoscopic pyelolithotomy (LP), the definite indications for laparoscopic surgery of kidney stones have been limited to the following situations: 1) stones in extra-renal pelvis 2) failed PCNL and 3) stones associated with congenital renal anomalies such as ureteropelvic junction obstruction (UPJO).[7]
Theoretically, LP is assumed to preserve functional renal parenchyma, and there is a limited risk for immediate or late renal hemorrhage. Therefore, it might be an alternative for the patients in whom maximal preservation of renal parenchyma is necessary. In present study we aimed to compare the success rate and perioperative complications of LP versus PCNL. The main specific goal of the present study was to investigate the effect of these two modalities on renal function, as assessed by renal isotope scan and laboratory tests in short term follow-up period.

MATERIALS AND METHODS

Study Subjects

A randomized clinical trial was conducted in the patients with renal calculi referred to Labbafinejad medical center from September 2009 to February 2012. The study population consisted of 60 patients with one to 3 stones larger than 2 cm in extra-renal pelvis who were randomly divided into two groups of PCNL and LP. Simple randomization approach was used. The cutoff of 2 cm was considered appropriate for surgical intervention considering the literature.[8] All patients with a history of diabetes melli-

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tus, extracorporeal shock wave lithotripsy (SWL), retroperitoneal surgery and those with separate stone burden in different calyces or intra-renal pelvis were excluded from the study. All patients provided written informed consent before the study and the Medical Ethics Committee of Iranian Urology and Nephrology Research Center approved the study protocol.

All patients underwent routine laboratory tests including complete blood count, blood chemistry and urine analysis and urine culture preoperatively. To evaluate the impact of surgery on renal function, glomerular filtration rate (GFR) was measured preoperatively, at day 3 and three months after surgery. Estimated GFR was calculated using Cockcroft-Gault formula. To assess selective renal function, kidney scintigraphy with single–shot diethylenetriaminepentaacetic acid (DTPA) was done before operation and at three months postoperatively.

All perioperative and post-operative complications up to 3 months were recorded and classified according to the Clavien grading system.[9] Stone-free result (as the primary end point of the study) was defined as no residual fragments or a residual fragment smaller than 4 mm on the postoperative imaging profiles (ultrasonography and kidney-ureter-bladder X-ray).

Surgical Techniques

All PCNLs were performed under general anesthesia. First, a 5 French (F) ureteral stent was inserted using a semirigid cystoscope in lithotomy position. Desired calyces were then punctured using triangular method, under the guidance of fluoroscopy in the prone position. One-shot dilation technique was used as the regular approach for tract dilation up to 30 F and a pneumatic lithotripter was applied to break the calculi. A 16 F nephrostomy tube was inserted into the calyceal system at the end of the surgery and one-shot nephrostography would confirm that pyelocalyceal system was unharmed. At the first postoperative day, the nephrostomy tube was removed and if no urinary leakage was observed at the site of surgery, the ureteral stent was also withdrawn the day after.

LP was also performed under general anesthesia in modified lateral decubitus position. First, a 12 mm port was inserted at the umbilicus using open access approach.[10] Then three 5 (sub xiphoid), 10 (para rectal region parallel to umbilicus) and 5 mm (2 cm medial to anterior superior iliac spine) ports were inserted under direct vision. Whenever necessary, another 5 mm port was used for liver retraction in the patients with right kidney stones. All LPs were performed via a transperitoneal approach. After medial mobilization of colon and once renal pelvis and ureteropelvic junction were exposed, a longitudinal or circular incision was made on the renal pelvis, depending on the location and shape of the stone. Stones were removed from renal pelvis using grasper forceps and delivered via an Endobag. After suction- irrigation of renal pelvis (to wash out further tiny stone particles), a double J ureteral stent was passed through renal pelvis to the bladder. Finally, pelvis was closed using a 4-0 absorbable polyglactin suture in a running fashion. Foley catheter was removed 48 h after operation. Drain was removed when its daily output reached lower than 25 mL. Double J ureteral stent was removed under local anesthesia 4 weeks later.

Statistical Analysis

Regarding the power factor of 80% for the study and 95% confidence level, a sample size of 60 patients was calculated. The hypothesis of this study was that LP is as effective as PCNL in the selected group of patients. Thus, the primary end point of this study was to measure the mean success rate of the two groups and compare them together. Up to 20% difference in stone free rate of the two groups was accepted according to the previous studies. Multivariate analysis was used to reduce the effect of confounding factors. Independent sample *t*-test was used to compare quantitative values and all qualitative factors were analyzed using chi-squared and Mann-Whitney *U* test. Statistical analysis was performed by Statistical Package for the Social Science (SPSS Inc, Chicago, Illinois, USA) version 20.0. *P* value less than.05 was considered statistically significant.

RESULTS

The demographic characteristics of the patients are shown in **Table 1**. Mean age of patients in LP and PCNL groups were 38 ± 15.9 (range, 15-61) and 42 ± 14.3 (range, 17-72) years, respectively (*P* = .114). Mean stone size (as the largest diameter of the stone on computed tomography scan) was 3.6 cm and 3.3 cm in LP and PCNL groups, respectively (*P* = .356). Staghorn calculi (defined as stone burden in renal pelvis with extension to at least two cal-

Table 1. Demographic characteristics of the study groups.

Variables	Laparoscopy	PCNL	*P* Value
Mean age (year)	38.5 ± 15.9	42.1 ± 14.3	.114
BMI (kg/m^2)	26.1 ± 6.7	25.8 ± 7.3	.830
Side, No.			
Left	20	13	.426
Right	10	17	
Mean stone size (cm)	3.6 (2.8-4.4)	3.3 (2.7-4.2)	.356
Stone feature, no.			
Staghorn	12	9	.417
Non-staghorn	18	21	

Abbreviations: PCNL, percutaneous nephrolithotomy; BMI, body mass index.

Table 2. Intra operative and postoperative parameters and surgical complications in study groups.

Variables	Laparoscopy	PCNL	*P* Value
Mean operation time (min)	149 ± 31	107 ± 26	.01
Mean hemoglobin drop (g/dL)	0.85 ± 0.5	1.88 ± 1.2	.001
Blood transfusion, no.	1	4	.001
Conversion to open surgery, no.	1	0	.32
Mean hospital stay (day)	3.4 ± 1.2	2.16 ± 0.7	.025
Stone free rate (%)	90	86.6	.593
Postoperative complications			
Grade I	2	0	
Grade II	1	4	
Grade IIIa	0	2	.225
Grade IIIb	1	0	
Grade IV	0	0	
Mean change in total GFR (mL/min)			
3 days after operation	-5.2 ± 2.3	-7.2 ± 3.9	.379
3 months after operation	+14 ± 8.1	+6 ± 3.7	.05
Split function in DTPA scan			
Preoperative split function	42.5 ± 17.7	39.7 ± 8.6	.539
Postoperative split function	48.2 ± 15.2	43.5 ± 9.2	.741
Differential split function (post – pre)	5.7 ± 1.9	4.4 ± 1.3	.04

Abbreviations: PCNL, percutaneous nephrolithotomy; GFR, glomerular filtration rate; DTPA, diethylenetriaminepentaacetic acid.

yceal groups) were observed in 12 patients in LP group and 9 patients in PCNL group ($P = .417$).

Table 2 shows the intraoperative and postoperative parameters and surgical complications. Mean operation time was significantly higher in LP group than PCNL group (149 ± 31 min vs. 107 ± 26 min respectively, $P = 0.01$). Mean hospital stay was also lower in PCNL group than LP group (2.16 vs. 3.4 days; $P = .025$). The mean hemoglobin drop was significantly lower in LP group than in PCNL group (0.85 ± 0.5 vs. 1.88 ± 1.2 g/dL; $P = .001$). Of all patients, 5 required blood transfusion during surgery or after that. Among them 1 was in the LP group and 4 were in PCNL group ($P = .001$). Conversion to open surgery occurred in one patient in LP group due to injury to a branch of renal vein.

Stone free rate was 90% for LP group and 86.6% for PCNL group which did not indicate statistically significant difference ($P = .59$). Three patients in LP group had residual fragments that were managed with SWL. Four patients in PCNL group had residual fragments. Two patients underwent SWL and two other patients with complete staghorn stone underwent two sessions of PCNL.

Mean changes in GFR three days after the operation were - 5.2 ± 2.3 and - 7.2 ± 3.9 mL/min for LP and PCNL groups, respectively ($P = .379$). However, after 3 months the mean changes in GFR demonstrated a significant difference between two groups (+ 14 ± 8.1 mL/min for LP and + 6 ± 3.7 mL/min for PCNL group; $P = .05$). DTPA scan revealed that the mean increase in split function of the operated kidney 3 months after surgery was significantly higher in LP group (5.7 ± 1.9%) than PCNL group (4.4 ± 1.3%) ($P = .04$).

No major complications were seen in both groups. There was no case of urinary leakage in LP group. But in the PCNL group three patients needed to undergo double J ureteral stenting due to prolonged leakage of urine from the site of nephrostomy tube. In four patients in laparoscopic group, it was not possible to place a double J ureteral stent intra operatively, so they were followed as stentless pyelolithotomy, but since we did not observe any case of urinary leakage or other side effects, no further intervention was needed.

DISCUSSION

Although PCNL is considered as the gold standard treatment modality for most of large renal stones, with global increase in experience of laparoscopic surgery, there is an upward trend toward the usage of laparoscopy in stone removal surgery. However, sufficient findings regarding the efficacy and safety of laparoscopic pyelolithotomy are lacking. On the other hand, PCNL still has limitation in some situations like retrorenal colon and skeletal anomalies.[1] Nowadays, LP can be recommended for confined pelvic stones without extension to several renal calyces as an alternative to PCNL.

It is a fact that introduction of PCNL has led to a revolution in the field of stone surgery, but some concern still remains regarding its side effects. Colon injury and damage to the large blood vessels are some of the rare (less than 1%), but important PCNL complications. Immediate or late hemorrhage (4-20% and 1%, respectively) may also happen. Blood transfusion and prolonged hospital stay, or rehospitalization may occur due to the hemorrhage, which impose extra cost on the patient and the

health care system.[1] Radiation exposure during PCNL is another hazard for both the patient and physician.[11,12] Basiri and colleagues have reported few cases of neurologic complications including paraplegia and hemiplegia following PCNL.[13] Despite the fact that some of this hazards may happen during laparoscopy too (like visceral and great vessels injury), some urologists have proposed it as an appropriate alternative to PCNL in selected cases.[14] However, due to the potential side effects of laparoscopy, safety of LP needs to be assessed and compared to standard PCNL.

Earlier studies suggested LP for limited conditions such as solitary stone in extra renal pelvis and coexistence of congenital anomalies such as UPJO and pelvic kidney.[14-16] In 2005, Nambirajan and colleagues reported 18 patients with kidney stones who underwent laparoscopy. Several patients had coexisting anomalies such as UPJO, calyceal diverticulum and horse shoe kidney. Despite the relatively prolonged mean hospital stay in this case series (10.5 days) and small to moderate stone size (mean 1.3 cm length), Nambirajan and colleagues concluded that laparoscopic surgery would be effective for complex kidney stones and it could be an alternative to PCNL.[17] As laparoscopic surgery has been developing, several studies have reported a higher success rate for LP in extraction of more complex and staghorn stones.[18] Nouralizadeh and colleagues. al have reported 13 patients with large stones in extra renal pelvises who had underwent LP. Mean stone size and mean hospital stay were 5.1 cm and 4 days, respectively. Overall success rate was 84.6% and there was no major complication.[19] Another advantage of LP is that often stone is extracted in whole form, in contrast to PCNL, in which tiny stone particles can become a nidus for future stone formation.

Several studies have compared success rate, operation time, hospital stay and surgical complications of LP and PCNL. Study of 16 patients who had undergone LP by Meria and colleagues showed that operation time was longer in LP, but success rate and mean hospital stay were not significantly different between two groups.[20] In a cohort study by Tefekli and colleagues on two groups including 26 patients in each arm, operation time and hospital stay were significantly higher in LP group, but mean hemoglobin drop was less ($P = .024$). Stone free rate was similar between two groups.[21] Recently, Aminsharifi and colleagues have carried out another cohort study on 60 patients to compare LP and PCNL for solitary pelvic stones larger than 3 cm. According to their results, mean operation time was significantly higher in LP group ($P = .01$); but stone free rate and average treatment cost were significantly lower in LP group. In this study, no significant difference in mean hemoglobin drop was noted between LP and PCNL groups.[22]

There is a paucity of randomized clinical trials in the field of LP in the current literature. Wang and colleagues have reviewed 7 trials and a total of 176 and 187 patients who had undergone LP and PCNL for single pelvic stones.[23] They concluded that operation time and hospital stay were shorter in PCNL group; but decrease in hemoglobin level and rate of fever were lower in patients treated with LP. Similar to our results, the stone free rate was not different between two groups. Similar findings have been reported by Haggag and colleagues who compared a group of 10 LP cases with 40 PCNL cases.[24] Regarding the fact that all trials that were included in Wang's meta-analysis were not necessarily randomized, our study presents same results regarding the operation time, hospital stay, stone free rates and mean hemoglobin drop by conducting a randomized controlled research.

Our study showed a better improvement in renal function following LP at 3 months after surgery. It is believed that stone removal may result in renal function improvement due to several mechanisms. Stone extraction may lead to the improvement of postoperative renal function by relieving of urinary tract obstruction, possible infection and inflammation. Also, several studies have reported significant increase in GFR after PCNL,[2,4,6] but it can be assumed that this improvement is due to the resolution of stone burden rather than PCNL itself. In other words, all surgical approaches with acceptable success rate would have such impact on renal function. So, the effect of various surgical modalities (including PCNL and LP) on kidney function should be compared to withdraw a better conclusion. This is specially a matter of concern in the patients whose renal function is already impaired or maximal renal performance is necessary (those who are single kidney). Theoretically, PCNL may cause harm to the kidney parenchyma. This can happen by either direct injury to the renal tissue during tract dilation and lithotripsy, or indirect mechanisms like massive hemorrhage and vasoconstriction of kidney vessels. Moskovitz and colleagues has carried out a study on a series of 88 patients who had undergone PCNL by doing dimercaptosuccinic acid (DMSA) scan before and after PCNL. This study showed a decrease in functional volume of the treated kidney after PCNL ($P = .011$). Nevertheless, total isotope uptake was not significantly reduced.[3] Unsal and colleagues have reported a rate of 18% new focal cortical defects after PCNL. However, they reported that kidney function would preserve or often improve after PCNL.[5]

Giving the fact that total GFR is resultant of function of both kidneys and does not specifically show the impact of surgery on the affected kidney, we performed a DTPA scan before and after surgery in order to compare changes in split renal function. In both groups, GFR reduced within 3 days after surgery. This effect can be attributed to the impact of anesthetics, medications, intra and postoperative hemorrhage and parenchymal injury. Three months after surgery, while the burden of stone is removed and the effect of surgery and medications are nearly resolved; GFR increased and renal split function showed improvement in both groups. This is similar to the previous studies that indicated an improvement in renal function following PCNL. Nevertheless, our study shows that mean changes in total GFR and split function of the operated site were significantly higher in LP group at three months after surgery. Hence, LP can be assumed as a reasonable alternative for PCNL in the patients for whom preservations of renal performance is a matter of utmost importance.

Although the study population was not large enough to assess probable but rare complications, no major side effects were observed up to 3 months according to Clavien classification except that hemoglobin level and blood transfusion rate were higher in PCNL group. Larger and staghorn stones were independent risk factors for periop-

erative hemorrhage in both groups. There was one patient in LP group who underwent open surgery due to injury to the renal vein branch.

Our study has several limitations. The nature of laparoscopy prevents all stones from being extracted via pyelolithotomy. In fact only some kidney stones inside extra renal pelvis can be operated using LP. So we excluded many patients who had multiple staghorn stones in intra renal pelvis. With nowadays experiences with LP it can be solely recommended for selected cases. Another limitation is the small number of study population. It is necessary to carry out larger multi center studies to get more accurate results.

CONCLUSION

PCNL remains the gold standard treatment for most large kidney stones. Nevertheless, LP can be considered for selected cases in which maximal preservation of renal function is needed. While mean operation time and hospital stay is longer in LP, decline in hemoglobin level and rate of blood transfusion is significantly lower than PCNL. LP is not associated with radiation exposure and its success rate is comparable to PCNL. Further large scale studies are needed to get more accurate results, especially about the complications.

CONFLICT OF INTEREST

None declared.

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