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ORIGINAL ARTICLE

Perioperative and long-term results of retroperitoneal laparoscopic pyelolithotomy versus percutaneous nephrolithotomy for staghorn calculi: a single-center randomized controlled trial

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Abstract

Purpose To compare the perioperative and long-term outcomes of retroperitoneal laparoscopic pyelolithotomy (RLP) and percutaneous nephrolithotomy (PCNL) for the treatment of staghorn calculi.

Methods From May 2011 to March 2017, eligible patients with staghorn calculi were randomly assigned to two groups: RLP and PCNL. Patients underwent the operations prospectively. Subsequently, a follow-up protocol was performed. Perioperative data related to the efficacy, safety and long-term outcomes (stone recurrence and functional changes in the affected kidney) were comparatively analyzed between the two groups.

Results Overall, 105 patients underwent surgical treatment, including 51 in the RLP group and 54 in the PCNL group. There was no difference in demographics or stone characteristics between the two groups. The single-session stone-free rate (SFR) was higher (88.2% vs. 64.8%), the mean hemoglobin drop was lower (0.4 ± 0.3 vs. 1.7 ± 0.9 g/dL), the rate of postoperative fever was lower (5.9% vs. 20.4%), but operative time was longer (135.7 ± 35.5 vs. 101.9 ± 41.2 min) and the total cost was more expensive (5546 ± 772 vs. 3861 ± 402 USD)in the RLP group than in the PCNL group (all $p < 0.05$). The mean increase in the split function (8.3 ± 3.1 vs. 4.2 ± 2.4 mL/min) and the rate of improvement of the affected kidney (56.3% vs. 35.3%) were significantly higher in the RLP group than in the PCNL group at 1 year after surgery (both $p < 0.05$). However, the rate of stone recurrence was similar between the groups at a mean follow-up of 47.3 ± 18.6 months.

Conclusions PCNL remains the first-line treatment for most cases of staghorn calculi. Nevertheless, in some selected cases with the extrarenal and dilated pelvis, RLP can be considered as an alternative management of staghorn calculi, which was associated with a high single-session SFR, low rates of complications, and better functional preservation of the affected kidney.

Keywords Staghorn stones · Laparoscopy · Pyelolithotomy · Nephrostomy · Percutaneous · Treatment outcome · Long-term · Glomerular filtration rate

Introduction

Staghorn calculi are defined as large and branched stones that occupy all or part of the renal pelvis and extend into at least one of the renal calices [1]. Without surgical intervention, this condition may lead to urosepsis and progressive deterioration in renal function [2]. In the current guidelines, percutaneous nephrolithotomy (PCNL) is recommended as the first-line therapy for staghorn calculi [1, 3]. However, some PCNL-related complications, such as fatal urosepsis and severe hemorrhage, continue to occur to patients [4, 5].

A laparoscopic technique is gradually being accepted as an alternative minimally invasive approach for managing complex renal stones [6]. Two recent meta-analyses both suggested that compared with PCNL, laparoscopic pyelolithotomy (LP) seemed to be more advantageous for managing large renal pelvic calculi; for example, LP had a higher stone-free rate and was associated with lower rates of blood

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loss and postoperative fever [7, 8]. A few studies of small sample sizes have shown that the single-session stone-free rate (SFR) and safety of LP are excellent in staghorn calculi [9–11]. However, the role of LP in staghorn calculi requires further exploration. In addition, only limited evidence is available to compare the long-term outcomes of LP versus PCNL in staghorn calculi. In this randomized clinical trial, we compared the efficacy and safety of RLP and PCNL for the treatment of staghorn calculi, including perioperative and long-term results.

Patients and methods

Study protocols

An open-label, randomized, controlled trial was conducted in patients presenting with staghorn calculi in our department from May 2011 to March 2017. The study protocol was designed by professional staff and approved by our hospital's Medical Ethics Committee. All participants signed an informed consent form before enrollment. The following inclusion criteria were used to select patients: (1) older than 18 years old, (2) firstly diagnosed as unilateral staghorn calculi, (3) an extrarenal and dilated pelvis, and (4) demonstrated understanding of the purpose and risks of the study and volunteered for participation in it. Participants were excluded if they had urinary calculi outside the affected kidney, congenital urinary anomalies, solitary kidney, urinary tumors, other chronic renal disease or a history of urinary or ipsilateral retroperitoneal procedures.

All eligible patients with staghorn stones were randomly allocated to two groups who underwent RLP or PCNL. Preoperative routine laboratory tests were performed in all patients and included a complete blood count, blood chemistry and urinalysis and urine culture. In addition, differential single renal function was evaluated by 99mTc-DMSA scan. Five-day antibiotic therapy was required for patients in whom a UTI was diagnosed by urine culture before the operation. All procedures were performed by the same surgical team, and the surgical team did not participate in the follow-up of patients or the assessment of outcomes.

The data collected from each group included patient age and gender, hypertension, diabetes, body mass index (BMI), stone size [evaluated with non-contrast computerized tomography (NCCT) scan (length $\times$ width $\times$ π $\times$ 0.25)], stone number, glomerular filtration rate (GFR) of the affected kidney, preoperative UTI, operative time, drop in hemoglobin, postoperative hospital stay, total cost for treatment and stone composition, which were analyzed by an infrared spectroscopy (LIIR-20, Lanmode Scientific Instrument Co. Ltd., China). In addition, perioperative complications were recorded. NCCT was performed on postoperative day 2 to assess single-session SFR. If patients without residual fragment or residual fragments $\leq$ 4 mm were diagnosed as stone-free status. When residual calculi larger than 4 mm were found, extracorporeal shock wave lithotripsy (SWL), flexible ureterorenoscopy (F-URS) or repeat PCNL was considered. Stone-free status was reevaluated by CT scan 3 months postoperatively and defined as completely stone-free or residual fragments smaller than 4 mm. The primary endpoint was single-session SFR. The secondary endpoint was postoperative complications.

A follow-up protocol was performed to evaluate stone recurrence and functional alterations in the affected kidneys in the two groups. Patients with stone-free status at postoperative 3 months were assessed for stone recurrence during the follow-up period. The protocol included urinalysis, kidney–ureter–bladder X-ray (KUB) and urinary ultrasonography every 3 months for patients with residual fragments $<$ 4 mm and every 6 months for patients without residual fragment. Stone recurrence was defined as the occurrence of new stones or the growth of residual fragments. If necessary, NCCT was required to determine an appropriate second intervention. Functional alterations in the affected kidneys were assessed by 99mTc-DMSA renal scan at 1 year after surgery. A change of more than 5% from the preoperative differential GFR was regarded as either improvement or deterioration in the function of the affected kidney.

Surgical techniques

RLP was performed under general anesthesia with the patient in a modified lateral decubitus position. A 3-port retroperitoneal laparoscopy was done. Operative access was the same as that described by Gaur [9]. After the retroperitoneal space was revealed, the renal pelvis was fully exposed. Subsequently, a longitudinal pyelolithotomy incision was performed according to the shape and size of the calculi. The primary stone was removed integrally with laparoscopic graspers. Subsequently, a 14-Fr flexible nephroscopy was introduced via the dorsal trocar to examine the pelvocalyceal system at least twice. Residual stones in the renal pelvis can been flushed out with 8-Fr catheter introduced via the dorsal trocar or directly removed with laparoscopic graspers. The calyces stones were smashed by a laser lithotripter or removed with a ZeroTip™ Nitinol Stone Retrieval Basket under the flexible nephroscopy. After the clearance of residual stones was confirmed with ultrasonography, a 5-Fr Double-J catheter was inserted into the ureter and removed with cystoscopy about 1 month later in the outpatient clinic. The renal pelvis was closed with a running 4-0 absorbable suture.

The operative procedure for PCNL for staghorn calculi is briefly described as follows. Under general anesthesia, a

5-Fr ureteral catheter was inserted while the patient was in the lithotomy position. Percutaneous access was obtained under ultrasonic guidance with the patient in the prone position. After dilation was performed with serial dilators up to 24 Fr, a 22-Fr working access sheath was placed into the collecting system. Stone was fragmented by a ultrasound lithotripter under a rigid 18-Fr nephroscope. The fragments were actively flushed out with continuous irrigation backflow through access sheath. After PCNL, a 16-Fr flexible nephroscopy was used to inspect all calyces carefully at least twice via the working access. Any residual stone fragments were smashed by a laser lithotripter or removed with a ZeroTip™ Nitinol Stone Retrieval Basket. Ultrasonography was performed to confirm stone clearance. At the end of the procedure, a 5-Fr Double-J catheter was inserted into the ureter and removed with cystoscopy about 1 month later in the outpatient clinic. A 14-Fr nephrostomy tube was inserted into the calyceal system and routinely removed 4 days after surgery.

Statistical analysis

Statistical analyses were performed with Statistical Package for the Social Sciences, version 16 (SPSS Inc., Chicago, IL). Independent sample *t* tests were used to compare quantitative values and all qualitative factors were analyzed using Chi-squared tests. A P value less than 0.05 was considered statistically significant.

Results

A total of 116 consecutive eligible patients were involved in the study, and 105 patients underwent surgical intervention, including 51 cases in the RLP group and 54 cases in the PCNL group. There were no significant differences between the two groups in preoperative parameters, including demographic data, stone characteristics and GFR of the affected kidney (all $p > 0.05$) (Table 1).

The perioperative clinical data obtained in the RLP and PCNL groups are shown in Table 2. Statistical analyses showed that the mean hemoglobin drop was lower (0.4 ± 0.3 vs. 1.7 ± 0.9 g/dL), the rate of postoperative fever was lower (5.9% vs. 20.4%), the single-session SFR was higher (88.2% vs. 64.8%) and the complete SFR was higher (76.4% vs. 51.9%) in the RLP group than in the PCNL group (all $p < 0.05$). One patient selectively underwent renal artery embolization due to uncontrolled bleeding and two cases had urosepsis in the PCNL group. However, RLP required a longer operative time (135.7 ± 35.5 vs. 101.9 ± 41.2 min, $p = 0.031$), and more expense (5546 ± 772 vs. 3861 ± 402 USD; $p = 0.000$). In addition, postoperative hospital stay (5.3 ± 1.8 *vs.* 4.7 ± 2.4 days; $p = 0.233$), the rates of prolonged urine leakage (11.8% vs. 3.7%) and blood transfusion (3.9% vs. 16.7%), and SFR at 3 months postoperative (92.2% vs. 85.2%) were not significantly different between the two groups (all $p > 0.05$).

Table 1 Demographics and stone characteristics

	RLP ($n = 51$)	PCNL ($n = 54$)	p value
Age (years)	55.3 ± 14.8	53.7 ± 12.5	0.376
No. gender (%)			0.687
Male	35 (68.7)	39 (72.2)	
Female	16 (31.3)	15 (27.8)	
BMI (kg/m^2)	24.95 ± 4.57	25.80 ± 4.70	0.411
Stone size (mm^2)	1377 ± 518	1259 ± 658	0.256
No. stone number (%)			0.658
Solitary renal stone	29 (56.9)	33 (61.1)	
Multiple renal stones	22 (43.1)	21 (38.9)	
No. stone composition (%)			
Calcium oxalate	12 (23.5)	13 (24.1)	0.948
Struvite	11 (21.6)	11 (20.4)	0.880
UA	9 (17.6)	10 (18.5)	0.908
CaPh	6 (11.8)	8 (14.8)	0.646
Cystine	3 (5.9)	4 (7.4)	0.754
Mixed	10 (19.6)	8 (14.8)	0.515
No. hypertension (%)	8 (15.7)	10 (18.5)	0.700
No. DM (%)	5 (9.8)	4 (7.4)	0.661
No. preoperative UIT (%)	15 (29.4)	17 (31.4)	0.818

The long-term outcomes observed in the two groups are shown in Table 3. As shown in the flow diagram in Fig. 1, 99 patients (48 in the RLP group and 51 in the PCNL group) finished the assessment of GFR of the affected kidney before surgery and at 1 year after surgery. The mean increase in the split function (8.3 ± 3.1 vs. 4.2 ± 2.4 mL/min; $p = 0.025$) and the rate of improvement (56.3% vs. 35.3%; $p = 0.036$) were significantly higher in the LP group than in the PCNL group. The rate of deterioration was not significantly different between the two groups. To evaluate postoperative stone recurrence, 93 patients (47 in the RLP group and 46 in the PCNL group) with stone-free status at 3 months after surgery completed a mean follow-up of 47.3 ± 18.6 months (range 15–79 months). The long-term results suggested that there were no significant differences in the rate of stone recurrence (25.5% vs. 39.1%; $p = 0.161$), the rate of new stone recurrence (17.5% vs. 28.6%; $p = 0.253$) or regrowth of residual fragments (71.4% vs. 72.7%; $p = 0.952$) between the two groups.

Discussion

The primary aim of the management of staghorn calculi is to completely remove the stones, eradicate the causative organisms, preserve renal function and prevent stone

Table 2 Intraoperative and postoperative parameters

	RLP (*n* = 51)	PCNL (*n* = 54)	*p* value
Operative time (min)	135.7 ± 35.5	101.9 ± 41.2	0.031
Drop in hemoglobin[a] (g/dL)	0.4 ± 0.3	1.7 ± 1.3	0.007
Postoperative hospital day (days)	5.3 ± 1.8	4.7 ± 2.4	0.233
Costs (USD)	5546 ± 772	3861 ± 402	0.000
Single-session SFR (%)	45 (88.2)	35 (64.8)	0.005
Complete SFR	39 (76.4)	28 (51.9)	0.009
Residual fragment (< 4 mm)	6 (11.8)	7 (12.9)	0.852
SFR at 3 months postoperative (%)	47 (92.2)	46 (85.2)	0.262
Complete SFR	40 (78.4)	35 (64.8)	0.123
Residual fragment (< 4 mm)	7 (17.6)	11 (20.4)	0.367
Postoperative complications (%)			
Prolonged urine leakage	6 (11.8)	2 (3.7)	0.120
Postoperative fever (> 38.5 °C)	3 (5.9)	11 (20.4)	0.029
Postoperative blood transfusion	2 (3.9)	7 (13.0)	0.098
Selective renal artery embolization	0 (0)	1 (1.9)	0.329
Second-session surgical intervention	6 (11.8)	17 (31.5)	0.015
Repeat PCNL	0	12	
ESWL	4	3	
F-URS	2	2	
Urosepsis	0 (0)	2 (3.7)	0.165

Table 3 Results of long-time follow-up

	RLP	PCNL	*p* value
% Stone recurrence during follow-up (N/T)	25.5 (12/47)	39.1 (18/46)	0.161
%Stone recurrence in CSF (N/T)	17.5 (7/40)	28.6 (10/35)	0.253
% Regrowth of residual fregment (N/T)	71.4 (5/7)	72.7 (8/11)	0.952
No. function alteration of affected kidney	48	51	
Preoperative GFR (mL/min)	37.1 ± 15.9	38.8 ± 17.3	0.634
GFR of postoperative 1 year (mL/min)	46.2 ± 17.6	42.9 ± 19.3	0.118
GFR alteration (post–pre) (mL/min)	8.3 ± 3.1	4.2 ± 2.4	0.025
No. GFR improvment (%)	27 (56.3)	18 (35.3)	0.036
No. GFR deterioration (%)	3 (6.3)	6 (11.8)	0.340

CSF complete stone free, *N* number of positive cases, *T* total number of evaluated cases

recurrence [1]. While PCNL remains the undoubted cornerstone of management strategies in patients with staghorn calculi, frequent complications, such as severe hemorrhage and infectious complications (postoperative fever and urosepsis), continue to baffle urologists. El-Nahas et al. [12] retrospectively analyzed the complications associated with PCNL in 241 staghorn calculi patients. The overall complication rate was 27%, including 40 cases (16%) that required blood transfusion, five cases (2%) that required angiographic embolization and one patient who died due to uncontrolled hemorrhage. Lei et al. [13] evaluated 284 patients with staghorn calculi who were treated with PCNL and reported that postoperative fever was observed in 27.1% of those patients, and 1.8% of the patients developed septic shock despite the use of preoperative general antibiotic therapy based on urine culture results. In this study, seven cases (13.0%) in the PCNL group required blood transfusion due to perioperative bleeding, and one case (1.9%) was treated by renal angiographic embolization because of postoperative uncontrolled bleeding. In addition, 11 cases (20.4%) had postoperative fever, and two cases (3.7%) had severe urosepsis in the PCNL group. In these cases, the pathogenesis of perioperative hemorrhage is primarily correlated with the rupture of the renal parenchyma, vessel injury caused by parenchymal puncture and dilation of the access tract and intraoperative excessive nephrostomy sheath bending [4]. Consequently, the surgeon's technique and experience, the occurrence of multiple punctures, the parenchymal thickness, the size of the access tract, and the stone burden are considered risk factors for post-PCNL hemorrhagic complications [14, 15].

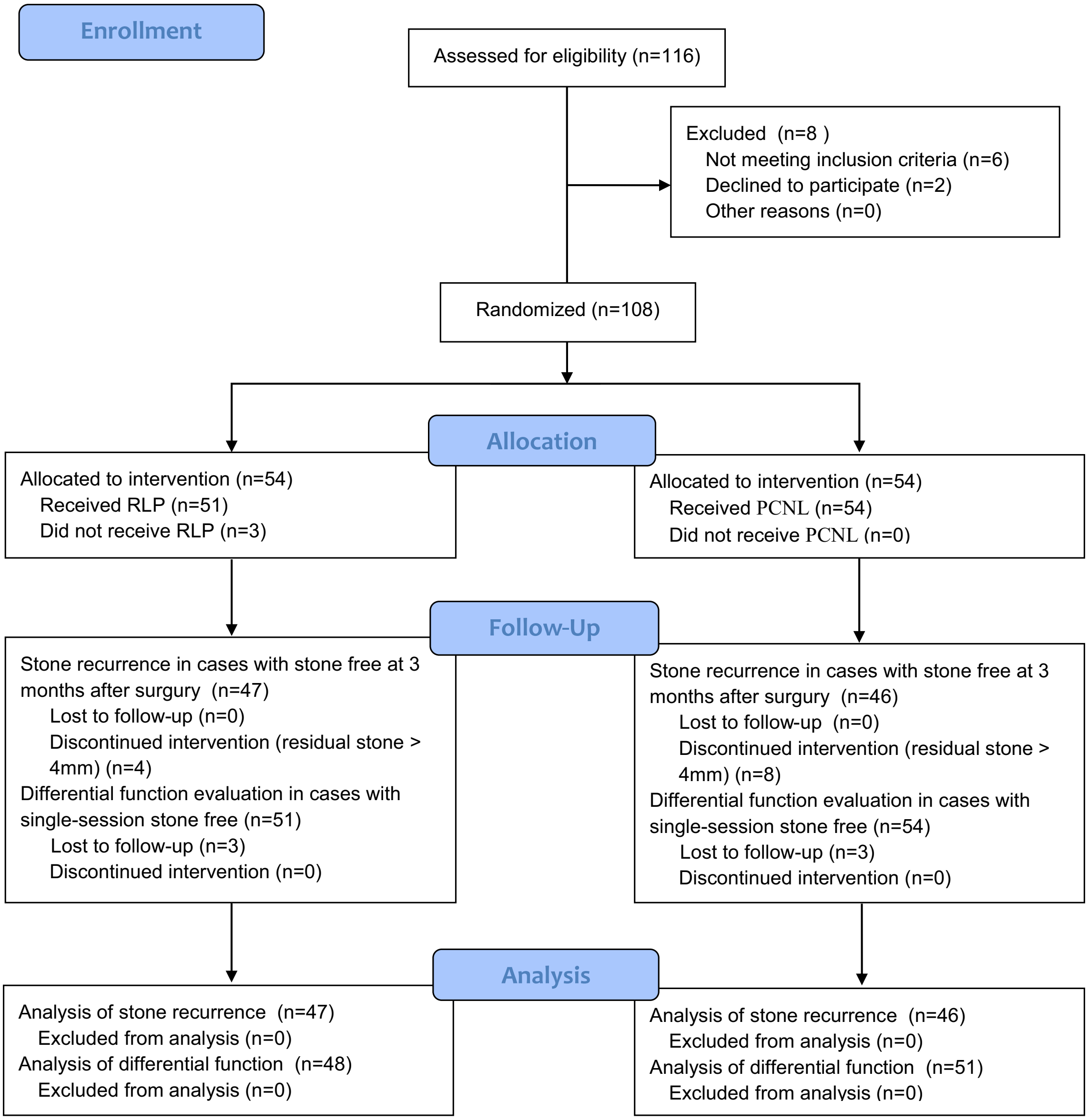

Fig. 1 Flow diagram of the trial

In addition, infectious complications following PCNL have been associated with bacteria and endotoxins originating in disintegrated stones and infected urine that are released in irrigation fluid and then absorbed into the systemic circulation via pyelovenous-lymphatic and pyelotubular backflow and forniceal rupture caused by high intrapelvic pressure during stone-breaking procedures [16]. Moreover, positive preoperative urine and stone cultures have been identified as important risk factors for post-PCNL fever and sepsis [17, 18].

Theoretically, RLP for staghorn calculi seems to provide some advantages. Stones are often extracted integrally via pyelolithotomy without damaging the renal parenchyma or increasing intrapelvic pressure. This reduces the risk of severe perioperative hemorrhage and infectious complications as well as the rate of residual stones. This hypothesis is supported by two previous studies that showed that the single-session SFR was 86–100% and the rate of perioperative complication rates was low in staghorn calculi patients treated with LP [9, 11]. Unfortunately, few studies have focused on the efficacy and safety of LP versus PCNL in staghorn calculi, although two recent meta-analyses systematically assessed the effectiveness and safety of LP and PCNL in large renal pelvic calculi. Third, statistical analyses have suggested that RLP is associated with significantly smaller decreases in hemoglobin, a lower rate of postoperative fever and a higher SFR than are observed in PCNL [7, 8]. In the present study, 105 cases of staghorn calculi were randomly assigned to undergo RLP or PCNL. Similar perioperative results were obtained with regard to blood loss, postoperative fever, blood transfusion and the single-session SFR between the RLP and PCNL groups. In addition, there was a high rate of required second-session surgical intervention due to residual stones > 4 mm in the PCNL group. However, the required operative time was longer in the RLP group than in the PCNL group; we suggest that this effect might be primarily associated with the fact that the entire pelvocalyceal system is assessed and an additional lithotomy is performed with the flexible cystoscope during RLP.

To date, only a few studies have evaluated the long-term outcomes of PCNL for renal stones, especially with regard to stone recurrence and the effect of the procedure on renal function. El-Nahas and colleagues [19] evaluated changes in renal function in 71 affected kidneys that were stone-free after PCNL for staghorn calculi. At the last follow-up (mean, 3.5 ± 2.3 years), the GFR of the affected kidneys had improved or deteriorated in 12 cases (17%) and six cases (8.5%), respectively. In the present study, we used the same method and found better outcomes: the differential GFR improved in 39.4% of patients and deteriorated in 8.8% of patients. We hypothesized that the differences in results observed between these two studies might be associated with differences in inclusion criteria or the time points at which postoperative assessments were obtained. To avoid the influence of second interventions and residual recurrence on renal function, only post-PCNL patients who were single-session stone free and without stone recurrence or second intervention at 1 year after surgery were submitted to renal radioisotope scans. In addition, two groups evaluated the influence of PCNL on total renal function. Akman and colleagues [20] analyzed 265 cases in which staghorn calculi was treated with PCNL and reported that deterioration occurred in 20.4% of cases during a mean follow-up of 37.3 ± 25.4 months. Teichman and colleagues [21] investigated 177 cases treated for staghorn calculi using PCNL. After a mean follow-up of 7.7 years, 28% of the patients were identified as having postoperative renal deterioration. It should be noted that the standards for functional deterioration were different between the two studies. In the former, deterioration was confirmed according to changes in the chronic kidney disease stage based on the estimated GFR obtained before the operation and at the last postoperative follow-up visit. In the latter, deterioration was defined as an elevated serum creatinine level (> 1.2 mg/dl), decreased total creatinine clearance (< 40 ml/min or > 30% of preoperative values) or need for dialysis.

There is scant evidence indicating that there is a difference in the effects of LP versus PCNL on renal function. Basiri and colleagues [22] assessed 60 patients with large renal pelvic stones who underwent transperitoneal LP or PCNL. At 3 months after surgery, the GFR of the affected kidney had improved more in the LP group than in the PCNL group. This effect was thought to be associated with harm to the kidney parenchyma and complications caused by PCNL, such as massive hemorrhage. Similar results were obtained in our study. The mean increase in the split function and the rate of improvement of the affected kidney were significantly higher in the LP group than in the PCNL group at 1 year after surgery. There was no significant difference in the rate of GFR deterioration between the two groups.

With regard to the long-term effect of PCNL on stone recurrence in staghorn calculi, El-Nahas et al. [19] reported that recurrent stones occurred in 25% of cases with complete stone-free status and that regrowth occurred in 65% of patients with residual stones during a post-PCNL follow-up period of 4.8 ± 2.3 years. Akman et al. [20] found that stones recurred in 31.2% of cases with stone-free status and that stone size increased in 63.2% of cases with residual stones during a 37.3 ± 25.4-month post-PCNL follow-up. In addition, the authors noted that recurrent UTI and DM increased the risk of post-PCNL stone recurrence. Unfortunately, our literature review revealed no data related to stone recurrence as an outcome after LP for staghorn calculi. In the present study, similar long-term results were found in the PCNL group and there were no significant differences in stone recurrence between the PCNL and RLP groups.

This study has some limitations. Risk factors for stone recurrence and the functional deterioration of the affected kidney were not evaluated in this study. Another limitation is that the differential GFR was not measured during the entire follow-up period and we, therefore, could not analyze trends in changes in the renal function of affected kidneys after surgery. In addition, this was a single-center clinical trial and future larger multicenter studies will be needed to achieve more convincing results.

Conclusion

The current evidence suggests that RLP has some advantages in the management of staghorn calculi in selected cases with the extrarenal and dilated pelvis. Compared to PCNL, RLP was associated with a higher single-session SFR and lower rates of hemorrhage and postoperative fever. Our long-term results suggest that RLP better preserved the affected renal functions. Nevertheless, it should be noted that RLP is not usually a repeatable procedure and more expensive than PCNL, which should be taken into account when choosing the approach. In addition, the inherent limitations of this trial prevented us from achieving definitive conclusions. Nevertheless, PCNL remains the first-line treatment for most cases of staghorn calculi. Further, randomized controlled multicenter clinical trials are needed to improve our understanding of the role of RLP as a treatment for staghorn calculi.

Author contributions YX: project development, data collection, manuscript writing. CBH: project development. QWL: project development. PXW: data collection, data analysis. JXZ: data collection, data analysis. WHF: project development, data collection, manuscript writing.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical approval All procedures performed in studies involving human participants were conducted in accordance with the ethical standards of the institutional and/or national research committee and the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study protocol was approved by the local ethics committee (No. 2010-0031).

Informed consent Informed consent was obtained from all individual participants included in the study.

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