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Ultrasound-guided percutaneous nephrolithotomy for the treatment in patients with kidney stones

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Abstract

Background: In this study, we aimed to explore the effect of ultrasound-guided percutaneous nephrolithotomy (UGPN) for the treatment in patients with kidney stones (KS).

Methods: We randomly assigned 86 patients with KS to a UGPN group or a control group, each group comprising 43 patients. Patients from the UGPN group underwent UGPN whereas those from control group underwent fluoroscopic-guided percutaneous nephrolithotomy (FGPN). The primary outcome included the stone-free rate. Secondary outcomes included complication rates, operative time, and length of hospitalization.

Results: UGPN did not show better efficacy than the FGPN procedure in decreasing stone-free rate (UGPN group 79.1% vs control group 69.8%, $P=.45$), operative time (UGPN group 108.4 ± 31.7 minute vs control group 113.2 ± 34.5 minute, $P=.50$), and length of hospitalization (UGPN group 2.7 ± 1.3 days vs control group 3.1 ± 1.5 days, $P=.19$). Additionally, no complications, except fever (UGPN group 4.7% vs control group 9.3%, $P=.41$) and hemoglobin slightly reduced (UGPN group 7.0% vs control group 11.6%, $P=.46$) were noted in patients from both groups in this study.

Conclusions: To summarize, we demonstrated that both UGPN and FGPN techniques showed similar efficacy and complications when used for the management of KS.

Abbreviations: FGPN = fluoroscopic-guided percutaneous nephrolithotomy, KS = kidney stones, PN = percutaneous nephrolithotomy, UGPN = ultrasound-guided percutaneous nephrolithotomy.

Keywords: complication, effect, fluoroscopic, kidney stone, percutaneous nephrolithotomy, ultrasound

1. Introduction

Kidney stones (KS), which are very commonly detected in patients presenting with urological problems, can seriously affect health and quality of life in those affected.[1–4] In the absence of effective treatment, they can cause significant morbidity such as urinary tract infections, flank pain, hydronephrosis, and even decreased renal function. Reportedly, the global prevalence of KS ranges between 10% and 15% worldwide.[1–4] It has been reported that about 13% of men and 7% of women in the United States will develop KS during their lifetime.[5] Notably, an amount >$2 billion is expended annually on the treatment of this condition.[6] In China, its prevalence in survey studies varied from 1.61% to 20.45%.[7,8]

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M-nL and WS contributed equally in this study.

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Percutaneous nephrolithotomy (PN), an important treatment strategy for the management of large, complex KS[9] is widely accepted as a safe and cost-effective intervention because of its high success rate and low morbidity.[10,11] A PN can be performed using several positions including the prone, flank, supine, and its modified position.[12] To date, fluoroscopic-guided PN (FGPN) is a very popular treatment in patients with KS. However, adverse effects associated with the procedure limit its usefulness. Therefore, in this study, we investigated the efficacy of ultrasound-guided PN (UGPN) as an alternative method to treat KS and simultaneously minimize hazards of radiation exposure among the surgical team.[12,13]

In this study, we conducted a randomized controlled trial to assess the effect of UGPN in Chinese patients with KS in complete supine position. We hypothesized that UGPN would be superior to FGPN in terms of efficacy in the management of KS.

2. Methods

This study was approved by the Medical Ethical Committee of Daqing Oilfield General Hospital. It was operated at this hospital from January 2015 and April 2017. Eighty-six eligible patients with KS were randomly assigned to receive either UGPN or FGPN at a 1:1 allocation ratio.

2.1. Inclusion and exclusion criteria

Our study included men and women with KS, aged 18 to 70 years. All patients were required to meet the diagnostic criteria for KS. Additionally, it was necessary that the KS should measure at least 2 cm in diameter, and these KS presented as the diverticular, pelvic, staghorn, middle, and lower caliceal stones with hydronephrosis. Exclusion criteria were pregnant women or those who were breastfeeding, presence of renal and urinary tract anomalies, multiple KS in complete staghorn and upper caliceal stones without hydronephrosis.

2.2. Randomization and blinding

Randomization schedule was conducted by a statistician using the SAS software (version 8.1; SAS Institute, Inc., Cary, NC). The stratified block randomization method was used for the randomized numbers. All patients, outcome assessors, and data analysts were masked to the allocation assignment.

2.3. Participants and recruitment

All patients were recruited from Daqing Oilfield General Hospital. After clinical assessment, 86 patients who qualified for inclusion in the study were equally allocated to either the UGPN or the control group. All researchers had been trained regarding the administration of the intervention before the study initiation. All patients were subsequently informed about the research and provided signed informed consent before the study.

2.4. Intervention

Before this study, we had experience of successfully conducting 41 patients with KS by UGPN, and 36 patients with KS by FGPN. Thus, it is easy for operators to find the correct route to the site of stone by using both ultrasound and fluoroscopy. The procedure was performed in a complete supine position in all patients from both groups. In the UGPN group, ultrasonography was performed using a 3.5-MHz transducer to identify the location of the kidneys, KS, and urinary tract dilation and to check for residual stones at the end of surgery. Caliceal puncture was performed using an 18-gauge access needle that was attached to the side of the ultrasound probe. This was passed into the appropriate calix through the fornix. After successful puncture of the caliceal system, a 0.035-in. J-tipped guidewire was introduced into the targeted calix. Under the ultrasonographic guidance, a 30 F Amplatz sheath was passed into the target calix after dilation of the nephrostomy tract using a one-shot 28 or 30 F Amplatz dilator. An FGPN was performed in patients belonging to the control group. Contrast material was injected through the ureteral catheter after ureteral catheterization, and an 18-gauge needle was passed under fluoroscopic guidance. All procedures such as guidewire insertion, nephrostomy tract dilation, Amplatz insertion, and stone removal were similar to the procedures performed on patients belonging to the UGPN group, except that all those operations were performed under fluoroscopic guidance.

2.5. Outcome measurements

The primary outcome was the stone-free rate, which was determined using abdominal radiography and renal ultrasonographic evaluation performed a month after the treatment. The success rate was defined as KS $\leq$3.5 mm in stone-free patients and in those with residual stones. The secondary outcomes were complication rates, operative time, and length of hospitalization.

2.6. Statistical analysis

All the outcome data were analyzed by the SAS software (version 8.1; SAS Institute, Inc.) using the intention-to-treat approach. The sample size was calculated based on the stone-free rate with $\alpha = 0.5$, $\beta = 0.8$, and assuming a 20% drop-out rate. Therefore, the required sample size of this study was estimated to be 86 patients, each group 43 patients. Chi-square tests were used to analyze the categorical data, and *t* test or Mann–Whitney *U* test were used to analyze the continuous data. The statistical significance level was set at $P < .05$.

3. Results

One hundred fifty patients were selected initially (Fig. 1). We excluded 64 patients from our study because they did not meet

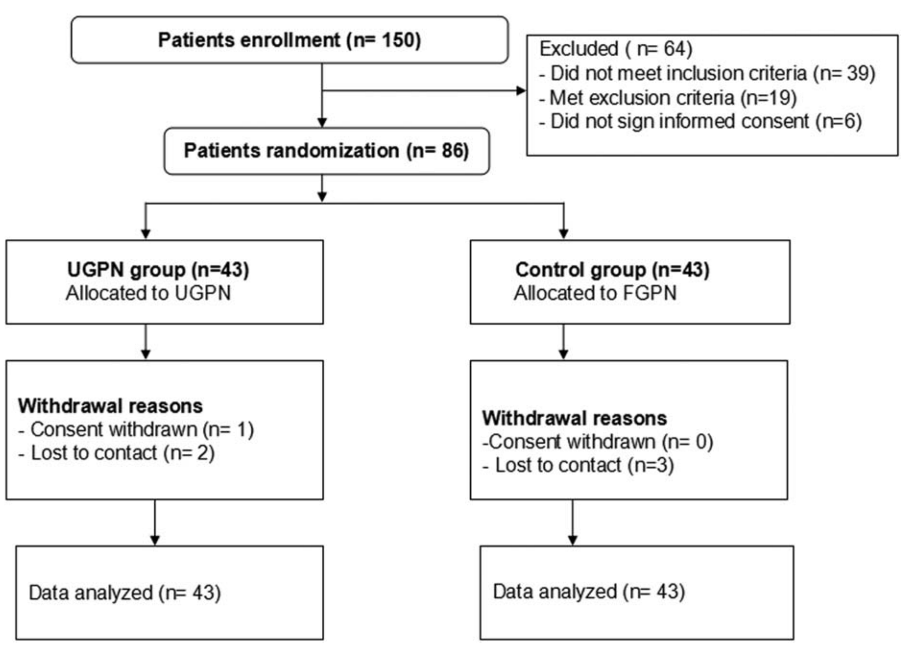

Figure 1. Flow of study selection.

Table 1

Patients demographics and characteristics at baseline.

Characteristics	UGPN group (n=43)	Control group (n=43)	P
Mean age, y	42.9 (11.3)	45.1 (12.7)	.40
Sex			
Male	29 (67.4)	32 (74.4)	.71
Female	14 (32.6)	11 (25.6)	.71
BMI, kg/m^2	24.2 (1.8)	24.5 (2.0)	.46
Stone diameter, mm	29.4 (3.7)	30.1 (3.5)	.37
Number of stones	1.8 (0.6)	1.9 (0.7)	.48
Stone location			
Renal pelvis	15 (34.9)	17 (39.5)	.66
Inferior calyx	11 (25.6)	10 (23.3)	.80
Middle calyx	5 (11.6)	4 (9.3)	.76
Renal pelvis and inferior calyx	7 (16.3)	6 (13.9)	.73
Renal pelvis and middle calyx	1 (2.3)	3 (7.0)	.33
Inferior and middle calyx	4 (9.3)	3 (7.0)	.69
Hydronephrosis			
Mild	16 (37.2)	14 (32.6)	.65
Moderate	25 (58.1)	26 (60.7)	.83
Severe	2 (4.7)	3 (7.0)	.46
Side			
Right	31 (72.1)	27 (62.8)	.36
Left	12 (27.9)	16 (37.2)	.36

Data are present as mean ± standard deviation or number (%).
BMI = body mass index, UGPN = ultrasound-guided percutaneous nephrolithotomy.

inclusion criteria, and did not sign informed consent. Therefore, 86 patients were included in our study and were randomly allocated to the UGPN and control group, each group comprising 43 patients. Among the included patients, 6 patients withdrew from the study (Fig. 1).

The baseline demographics and characteristics are summarized in Table 1. No significant differences were found between 2 groups regarding the age, sex, body mass index, stone diameter, number of stones, stone location, hydronephrosis, and the attached side (Table 1).

Results of primary and secondary outcomes are listed in Tables 2 and 3. No statistically significant difference in stone-free rate was observed between the groups (79.1% in the UGPN, and 69.8% in the control group (P=.45, Table 2)). Additionally, the operative time did not significantly differ between patients from the UGPN and control groups (UGPN 108.4 ± 31.7 minute vs control group 113.2 ± 34.5 minute, P=.50, Table 2), and no significant difference was observed in terms of length of hospitalization between the groups (UGPN 2.7 ± 1.3 days vs control group 3.1 ± 1.5 days, P=.19, Table 2). Furthermore, no complications were reported in either group, except fever (4.7% in the UGPN and 9.3% in the control group, P=.41, Table 3) and hemoglobin slightly reduced (7.0% in the UGPN and 11.6% in the control group, P=.46, Table 3) reported in patients from both groups.

Table 2

Outcome measurements comparison between 2 groups.

Outcomes	UGPN group (n=43)	Control group (n=43)	P
Stone-free rate			
Stone free	34 (79.1)	31 (69.8)	.45
Residual stone	9 (20.9)	11 (30.2)	.45
Operative time, min	108.4 (31.7)	113.2 (34.5)	.50
Duration of hospital stay, d	2.7 (1.3)	3.1 (1.5)	.19

Data are present as mean ± standard deviation or number (%).
UGPN = ultrasound-guided percutaneous nephrolithotomy.

Table 3

Complications comparison between 2 groups.

Complications	UGPN group (n=43)	Control group (n=43)	P
Fever	2 (4.7)	4 (9.3)	.41
Hemoglobin slightly reduced	3 (7.0)	5 (11.6)	.46
Pneumothorax	0 (0)	0 (0)	—
Colon injury	0 (0)	0 (0)	—
Metabolic abnormalities	0 (0)	0 (0)	—
Sepsis	0 (0)	0 (0)	—
Deep venous thrombosis	0 (0)	0 (0)	—
Blood transfusion	0 (0)	0 (0)	—

Data are present as number (%).
UGPN = ultrasound-guided percutaneous nephrolithotomy.

4. Discussion

Three previous studies have reported the efficacy of UGPN among the Iran population. In 1 study, UGPN was performed using the flank position to treat patients with KS, and this procedure was compared with the FGPN procedure performed in patients using a prone position.[14] The study included 60 patients who were randomly allocated them to 2 groups, each group comprising 30 patients.[14] The study results demonstrated that UGPN performed using the flank position provided easier access to calculi through the pyelocaliceal system[14] and was associated with higher success rates and fewer complications.[14] Another study was a randomized controlled trial that compared the success and complication rates of UGPN versus FGPN using standard prone technique.[15] The results of this study demonstrated that UGPN was presented a safe and effective technique showing promising success and complication rates[15] and that it could minimize the hazards of radiation exposure among the surgical team members and also decreases the incidence of postoperative fever.[15] A separate study has compared complications and outcomes of UGPN and FGPN using a complete supine position to perform the procedure.[16] It included 51 patients with renal stones who were randomly allocated such that 26 patients underwent UGPN, and 25 patients underwent the FGPN procedure.[16] The results of this study showed that both UGPN and FGPN demonstrated similar outcomes. Moreover, ultrasonography could be a useful alternative to fluoroscopy during this surgery.[16]

In this study, we investigated the efficacy of UGPN versus FGPN to treat patients with KS using the complete supine position. We included 86 patients with KS who were eligible for inclusion in our study. These patients were randomly assigned equally to 2 groups and underwent UGPN or FGPN. We utilized the stone-free rate as the primary outcome, and complication rates, operative time, and length of hospitalization as the secondary outcomes to assess the efficacy of the UGPN procedure. The results of our study did not confirm our hypothesis that UGPN resulted in better treatment outcomes than the FGPN procedure in treating patients with KS. Our results showed that UGPN did not demonstrate greater efficacy in terms of stone-free rate, complication rates, operative time, and length of hospitalization than that observed with the use of FGPN.

Limitations of our study: Our study was performed at a single center and included a relatively small sample size, which could have affected our results. Our study only included a 1-month follow-up, which is a relatively short-term follow-up to conclusively validate our findings. Our study was performed in China and included only Chinese patients, thus these results might not show general applicability.

5. Conclusion

The results of this study demonstrated that both UGPN and FGPN showed similar efficacy and complication rates. However, long-term clinical trials with longer follow-up evaluations are warranted to validate our findings.

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