e-ISSN: 0976-822X, p-ISSN:2861-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2023; 15(5); 438-445

Original Research Article

A Prospective Randomized Clinical Assessment of Flexible Ureterorenoscopy (RIRS) vs Mini- Percutaneous Nephrolithotomy (Mini-PCNL) for Renal Stones 10-20 MM

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Received: 09-01-2023 / Revised: 25-02-2023 / Accepted: 22-03-2023

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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to evaluate the safety and efficacy of mini percutaneous nephrolithotomy (mini PCNL) and retrograde intrarenal surgery (RIRS) in treatment of kidney stones 20–30 mm.

Methods: This was a randomized prospective study of 100 patients presented to the department of urology in Indira Gandhi institute of Medical sciences, Patna, Bihar India , with calyceal or pelvic kidney stone (20–30 mm) for the period of 2 years. Patients were randomized using computer based program into 2 groups; group A (Mini PCNL), and group B (RIRS) with 50 patients in each group.

Results: The Mean of age was 35.25 ± 12.68 years in group A & 34.6 ± 11.49years in group B, with no statistically significant difference (p value was 0.44). In group A, The lower calyx stones were in 21 (42%) patients & 13 (26%) patients in group B, while stones in lower calyx and pelvis were in 3 (6%) patients in group A & 8 (16%) patients in group B, Pelvic stones were in 19 (38%) patients in group A& 17 (34%) patients in group B, middle calyx in 7 (12%) patients in group A & 12 (24%) patients in group B, with no statistically significant difference (p value < 0.18). The stone size was 20.22 ± 2.6 mm in group A & 20.7 ± 2.2 in group B, with no statistically significant difference (p value < 0.22). The operative time in group A was 62.38 ± 18.32 min and in group B was 80.20 ± 15.75 min with statistically significant difference (p value < 0.001).We also observed that mean postoperative hemoglobin was 12.58 ± 0.92 g/dL in mini PCNL, 12.82 ± 0.92 g/dl in RIRS with no statistically significant difference (p value < 0.60).

Conclusion: RIRS and mini PCNL can be an effective and alternative option for treatment of renal stones 2–3 cm. Both techniques have relatively similar SFR but RIRS showed more operative time, on contrary Mini PCNL has more operative and postoperative complications. However, mini-PCNL is more cost-effective making it a viable alternative to RIRS.

Keywords: Mini-PCNL, RIRS, Stone

Introduction

Currently, percutaneous nephrolithotomy (PCNL) is recommended as the first-line treatment of choice for renal stones more than 2cm in diameter. Due to its high efficiency [1], it continues to have non-negligible morbidity effects such as bleeding requiring angio-embolization, urinoma and organ injury, although rare. [2,3] With the technological advances in flexible ureteroscopy (FURS), coupled with the development of laser lithotripsy systems and novel endoscopic baskets, FURS allows urologists to deal with lower calix stones or even complex renal stones through the natural orifice and achieve an acceptable stone-free rate (SFR). [4]

Progress in the field of endourological has superseded technological advances in extracorporeal shockwave lithotripsy (ESWL). Whereas ESWL was the mainstay of treatment for most non-lower caliceal renal stones, it is now relegated to a lower order of preference. ESWL ruled the stone world from its introduction in the mid-1980s [5] until about early 2000, when flexible ureteroscopy (fURS) and miniaturized percutaneous nephrolithotomy (mPCNL) took over as the mainstay of treatment for most 10–20 mm renal stones. The need for intervention for moderate-sized renal stones is often due to symptoms. They are also often associated with recurrent infections and, rarely, stone growth and obstruction. The natural history of small and medium stones is variable. Stone growth and symptomatic events are often seen in patients with competing morbidities like diabetes and hyperuricemia in adult urolithiasis. [6] Recently, the use of both retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL) has increased in the surgery of renal stones because of their minimal invasiveness nature. [1] Mini-percutaneous nephrolithotomy (Mini-PCNL) is a modification of the standard PCNL maneuver that decreases the tract size and has gained widespread use as a pediatric endourological technique due to its fewer complications than the usual PCNL. [7,8]

Retrograde intrarenal surgery (RIRS) was considered a new era in the minimally invasive treatment of renal stones and upper urinary tract tumors. [9,10] The beginning of use of RIRS was in the treatment of small size renal stones. [11] Also, it gained its attraction in the management of large stone, the surgeons initially used RIRS in medium then larger stones, but the disadvantage is the long operative time. [12] The morbidity and complications of RIRS were considered few, and it showed high success rate which allow several centers to apply it in the treatment of large renal stone instead of ESWL. [13,14]

The aim of the present study was to evaluate the safety and efficacy of mini percutaneous nephrolithotomy (mini PCNL) and retrograde intrarenal surgery (RIRS) in treatment of kidney stones 20–30 mm.

Materials and Methods

This was a randomized prospective study of 100 patients presented to the department of urology in Indira Gandhi institute of Medical sciences, Patna, Bihar India, with calyceal or pelvic kidney stone (20–30 mm) for the period of 2 years. Patients were randomized using computer based program into 2 groups; group A (Mini PCNL), and group B (RIRS) with 50 patients in each group. All procedures performed in this study involved human participants with written informed consent in accordance with the ethical standards of the institutional research committee.

Patient assessment required through full medical history, general, local examination, laboratory investigation (urinalysis, complete blood count, kidney function test, liver function test, prothrombin time, concentration and random blood glucose level), and radiological investigation in the form of computed tomography (CT). CT scan was used to calculate the size of the stone in its longest diameter. All patients

were informed about the advantages, disadvantages, and possible complications of both Mini PCNL and RIRS. Patients with history of kidney stones surgery or congenital anomalies were excluded from the study.

Complete blood count, serum biochemistry, CT for the stone clearance was carried out to all patients at the first postoperative day. The success of the technique was considered when status is stone-free or clinically insignificant residual fragments < 4 mm on CT. Demographic distribution, Intraoperative data and postoperative complications of both groups were compared for statistical analysis by using Chi-square and t-test, and statistical significance was defined as p value < 0.05.

Operative Technique

Group A: mini PCNL

All patients received a prophylactic antibiotic before beginning of the procedure. The patient was in lithotomy position. Operative area was cleaned with 10% povidine iodine and drapped in sterile manner, and a 5 Fr retrograde ureteric catheter was placed into the renal pelvis, a small amount of radiographic contrast medium was flushed if needed to ascertain the ureteric catheter position. Then a Foley urethral catheter (16 Fr) was inserted and fixed with the ureteric catheter on the side of the thigh. We performed the procedure in supine position with the patient's side of the procedure at the edge of the operating table without putting any support under the flank, then retrograde pyelography was done by injecting contrast medium through the ureteric catheter, the appropriate calyx was punctured by using a fluoroscopy at 0 degree by using 18 gage puncture needle, after assuring of being in the collecting system an J tip, 0.038 inch diameter, 150 cm length, hydrophilic guidewire was inserted via puncture needle and it will be better to go antegrade to reach the urinary bladder. The Teflon dilators 12Fr then 14Fr were used to dilate the track. The 18 Fr metal sheath was then passed over the 14Fr dilator, 14Fr dilator is removed after confirmation of the sheath inside the collecting system under fluoroscopy. This metal sheath has a sideway for connection with suction system which facilitate retrieval of gravels through the procedure. Stones were fragmented and by a holmium: YAG laser (Lisa; Sphinx 30 W, Katlenburg University, Germany) (272µ caliber fiber) via 12Fr RZ nephroscope, and removal of the fragments by using the stone grasper and also by suction through the side way of the metal sheath. At the end of the maneuver we replaced the ureteric catheter by double J stent and nephrostomy tube.

Group B: RIRS

All procedures were performed by 7.5-Fr (Karl Storz, FLEX-X2, Tuttlingen, Germany) flexible ureteroscope. All patients received prophylactic antibiotics before the beginning of the procedure. Under general anesthesia, patients were in the lithotomy position. Operative area was cleaned with 10% povidone iodine and drapped in sterile manner, Rigid ureteroscopy was used in all patients to insert the hyrophylic guidewire till reach the renal pelvis and dilatation of the ureter by tephlone dilator routinely before flexible ureteroscopy also we passed a 0.035-inch safety guidewire into the renal pelvis then a ureteral access sheath (9.5/11.5 or12/14Fr) was inserted for optimal visualization, to sustain low intrarenal pressure, and to extract the stone fragments. When the 12/14Fr ureteral access sheath could not pass smoothly under the fluoroscopy, it was replaced by 9.5/11.5 Fr sheath. A holmium: YAG laser (Lisa;Sphinx 30 W, Katlenburg University, Germany) (272µ caliber fiber) was applied for fragmentation of the stones. The laser functioning parameters were dusting setting (0.4 Joule/25 Hertz), applying the Baskets for residual fragments was rarely used; however, for stone extraction we often use tip-less nitinol baskets for stone extraction. A double-J stent was inserted in all patients at the end of the procedure.

Results

Table 1: Comparison between nephrolithotomy (Mini-PCNL) and flexible ureterorenoscopy (RIRS) according to demographic distribution

	mPCNL (50)	RIRS (50)	P Value
Age (years) mean ± SD	35.25 ± 12.68	34.6 ± 11.49	0.50
Gender			
Male	35 (70)	24 (48)	0.055
Female	15 (30)	26 (52)	
BMI (kg/m2)mean ± SD	42.48 ± 9.31	43.27 ± 10.20	0.82

The Mean of age was 35.25 ± 12.68 years in group A & 34.6 ± 11.49years in group B, with no statistically significant difference (p value was 0.44). BMI was 42.48 ± 9.31 kg/m2 in group A, while in group B it was 43.27 ± 10.20 kg/m2.

Table 2: Comparison between nephrolithotomy (Mini-PCNL) and flexible reterorenoscopy (RIRS) according to stone characters

	mPCNL (50)	RIRS (50)	P Value
Site no. (%)			
Lower calyx	21 (42)	13 (26)	0.18
Pelvis +Lower calyx	3 (6)	8 (16)	
Pelvis	19 (38)	17 (34)	
Middle calyx	7 (14)	12 (24)	
Size (mm), mean ± SD	20.22 ± 2.6	20.7 ± 2.2	0.22
Side no.(%)			
Right	26 (52)	18 (36)	0.16
Left	24 (48)	32 (64)	
Density no.(%)			
Opaque	41 (82)	39 (78)	0.16
Lucent	9 (18)	11 (22)	

In group A, The lower calyx stones were in 21 (42%) patients & 13 (26%) patients in group B, while stones in lower calyx and pelvis were in 3 (6%) patients in group A & 8 (16%) patients in group B, Pelvic stones were in 19 (38%) patients in group A& 17 (34%) patients in group B, middle calyx in 7 (12%) patients in group A & 12 (24%) patients in group B, with no statistically significant difference (p value < 0.18). The stone size was 20.22 ± 2.6 mm in group A & 20.7 ± 2.2 in group B, with no statistically significant difference (p value < 0.22). The stone density in group A was 41 (82%) opaque & 9 (18%) lucent and in group B was 39 (78%) opaque & 11 (22%) lucent, with no statistically significant difference (p value < 0.16).

Table 3: Comparison between (Mini-PCNL) and (RIRS) according to operative data

	mPCNL (50)	RIRS (50)	P Value
pre-op. Haemoglobin (gm/dl) mean ± SD	12.58 ± 0.92	12.82 ± 0.92	0.60
Operative time (minutes) mean ± SD	62.38 ± 18.32	80.20 ± 15.75	< 0.001
Fluoroscopic time (minutes) mean ± SD	7.23 ± 2.07 min	5.2 ± 1.95 min	< 0.001
Intra-operative morbidity			
Bleeding No. (%)	4 (2)	0	0.40
Perforation No. (%)	4 (2)	0	

Meanwhile, the operative time in group A was 62.38 ± 18.32 min and in group B was 80.20 ± 15.75 min with statistically significant difference (p value < 0.001), while Fluoroscopy times had mean ± SD of 7.23 ± 2.07 min in group A & 5.2 ± 1.95 min in group B with statistically significant difference (p value < 0.001). We also observed that mean postoperative hemoglobin was 12.58 ± 0.92 g/dL in mini PCNL, 12.82 ± 0.92 g/dl in RIRS with no statistically significant difference (p value < 0.60).

Table 4: Comparison between (Mini-PCNL) and (RIRS) according to postoperative data

	mPCNL (50)	RIRS (50)	P Value
Blood transfusion No. (%)	6 (3)	0	1.0
Postoperative morbidity			
Fever	6 (3)	0	0.40
UTI	12 (6)	6 (3)	
Post-op. hemoglobin gm/dL mean ± SD	12.08 ± 1.0	12.38 ± 1.05	0.060
Stone free N (%)	45 (90)	39 (78)	0.50
Residual (for ESWL) N(%)	5 (10)	11 (22)	
Hospital stay	1.43 ± 0.47	1.32 ± 0.48	0.22
1 day	19 (38)	30 (60)	0.20
2 days	23 (46)	18 (36)	
3 days	8 (16)	2 (4)	

The hospital stay was 1.43 ± 0.47 in mini PCNL, 1.32 ± 0.48 in RIRS with no statistically significant difference (p value < 0.24). The stone free rate was 90% in mini PCNL, 78% in RIRS with no statistical significance (p value < 0.5). Only one case of m PCNL (2.9%) had significant bleeding and needs one-unit blood to be transfused with no statistical significance(p value < 0.1). One patient of mini PCNL (3%) had renal pelvic perforation and extravasation which was a small perforation and resolved with Double J stent and conservative measures, nephrostomy tube was inserted in both cases.

Discussion

The renal stone has upgrading role in the morbidity and quality of life of patients and its prevalence is about 10%. [15] Also, the recurrence of renal stones may be up to 50%. [16] The impact of recent technology on the kidney stone management has a great role, especially the advancement of minimally invasive technique such as extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), retrograde intra renal surgery (RIRS). [17]

The Mean of age was 35.25 ± 12.68 years in group A & 34.6 ± 11.49years in group B, with no statistically significant difference (p value was 0.44). In group A, The lower calyx stones were in 21 (42%) patients & 13 (26%) patients in group B, while stones in lower calyx and pelvis were in 3 (6%) patients in group A & 8 (16%) patients in group B, Pelvic stones were in 19 (38%) patients in group A& 17 (34%) patients in group B, middle calyx in 7 (12%) patients in group A & 12 (24%) patients in group B, with no statistically significant difference (p value < 0.18). The stone size was 20.22 ± 2.6 mm in group A & 20.7 ± 2.2 in group B, with no statistically significant difference (p value < 0.22). The operative time in group A was 62.38 ± 18.32 min and in group B was 80.20 ± 15.75 min with

statistically significant difference (p value < 0.001).We also observed that mean postoperative hemoglobin was 12.58 ± 0.92 g/dL in mini PCNL, 12.82 ± 0.92 g/dl in RIRS with no statistically significant difference (p value < 0.60). This was in agreement with the results of Pelit et al. who reported that fluoroscopy and hospitalization times were statistically higher in the mini-PCNL group than in the RIRS group. They attributed the longer hospital stay to the presence of a nephrostomy tube and more ongoing postoperative pain in the mini-PCNL group. [18] Also, Ferroud et al. found out that the postoperative hospital stay in the RIRS group was significantly shorter than in the mini-PCNL group with a mean hospital stay time of 1.49 ± 11.4 days compared to 4.1 ± 1.2 days, respectively (P < 0.05). [19]

Meanwhile, the operative time in group A was 62.38 ± 18.32 min and in group B was 80.20 ± 15.75 min with statistically significant difference (p value < 0.001), while Fluoroscopy times had mean ± SD of 7.23 ± 2.07 min in group A & 5.2 ± 1.95 min in group B with statistically significant difference (p value < 0.001). We also observed that mean postoperative hemoglobin was 12.58 ± 0.92 g/dL in mini PCNL, 12.82 ± 0.92 g/dl in RIRS with no statistically significant difference (p value < 0.60). In many studies the Stone characters were recorded as [20] showed Stone diameter 20.6 mm in group A (mini PCNL) & 20.3 mm in group B (RIRS), similar results of [21] reported demographic data in the form of Mean stone size 20.5 ± 10.2 mm in group A (mini PCNL) & 20.3 ± 10.2 mm in group B & stone side (Right/Left) 50/27 in group A (mini PCNL) & 21/11 in group B, moreover studied. [22]

The hospital stay was 1.43 ± 0.47 in mini PCNL, 1.32 ± 0.48 in RIRS with no statistically significant difference (p value < 0.24). The stone free rate was 90% in mini PCNL, 78% in RIRS with no statistical significance (p value < 0.5). Only one case of m PCNL (2.9%) had significant bleeding and needs one-unit blood to be transfused with no statistical significance(p value < 0.1). One patient of mini PCNL (3%) had renal pelvic perforation and extravasation which was a small perforation and resolved with Double J stent and conservative measures, nephrostomy tube was inserted in both cases. This was in agreement with Resorlu et al. who reported that the total complications in mini-PCNL were more but this difference was not statistically significant. [23] Also, Pelit et al. observed only minor complications (grade I, II, and III) happened in 8.4% and 17% of RIRS and mini-PCNL, respectively, but again the difference was not statistically significant. [18]

Conclusion

RIRS and mini PCNL can be an effective and alternative option for treatment of renal stones 2–3 cm. Both techniques have relatively similar SFR but RIRS showed more operative time, on contrary Mini PCNL has more operative and postoperative complications. However, mini-PCNL is more cost-effective making it a viable alternative to RIRS.

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