

# Mini- Percutaneous Nephrolithotomy, Retro-grade Intra-renal Surgery, and Extra-corporeal ShockWave Lithotripsy for Treatment of Mediumsized, HighDensity, NonLower Pole, Renal Stones: A Prospective, Randomized, Comparative Study

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## Abstract

**Background :** Treatment options for medium in size renal stones, including shockwave litho-tripsy (SWL), flexible intra-renal (RIRS), and percutaneous nephrolithotomy (PNL), remain debated.

**Aim:** The current study contrasts between the efficacy of mini-PNL, RIRS, and SWL in the management of high in density renal stones.

**Methods:** This randomly allocated, prospective trial involved 247 individuals with single stone that is not lower calyceal (between 1 and 2 cm) and a density of  $\geq 1000$  Hounsfield Unit. The individuals were randomly assigned to undergo mini-PNL (no.= 82), RIRS (no.= 84), or SWL (no.= 81). stone-free rate (SFR) was the primary endpoint, while operation time, fluoroscopy time, hospital stay, and complications were considered as secondary endpoints.

**Results:** Analysis finally comprised 82 individuals in the mini-PNL section, 84 in the RIRS section, and 81 in the SWL section. The median age was 39 y, the median BMI was 26.9. The highest SFR was observed in the mini-PNL section (95.1%), followed by RIRS (90.5%) and SWL (33.3%). SFR was far greater in mini-PNL and RIRS sections than SWL ( $p < 0.001$ ). The SWL section had the shortest operative time, while RIRS exhibited the lowest fluoroscopy time ( $p < 0.001$ ). Complication rate was highest in the RIRS section (46.4%), followed by mini-PNL (22.0%) and SWL (17.3%).

**Conclusion:** Mini-PNL and RIRS are significantly more effective than SWL in the management of renal stones that are medium in size, high in density, and not in lower pole. Mini-PNL provides highest single-session SFR, while RIRS minimizes fluoroscopy exposure and hospital stay. Treatment selection should be individualised based on patient factors and institutinfected urinary systemonal resources.

**Keywords:** Mini-PNL; RIRS; SWL; Renal Stones; Stone-Free Rate; Complications; Operative Time

## 1. Introduction

U rinary tract calculi are a common benign urological condition that affects about 12% of the general population, with a recurrence rate of nearly 50%.<sup>1</sup> Treatment of medium in size renal stones remains a subject of debate, with options including shockwave litho-tripsy (SWL), flexible intra-renal surgery (RIRS), and percutaneous nephrolithotomy (PNL).<sup>2</sup>

While SWL is a non-invasive and generally well-tolerated procedure, it tends to have a lower the rate of stone-free (SFR) and often requires multiple sessions or additional

procedures. Factors such as body masses index, size of stone, the location, stone-to-skin distance, and densityof stone influence success of SWL.<sup>3</sup>

PNL is believed to be the standard method for treating kidney stones, with rate of success exceeding 90 %.<sup>4</sup> The advent of miniaturised PNL (mini-PNL) has further enhanced using technique percutaneously, particularly in stones smaller than 2 cm.<sup>5</sup> Mini-PNL offers the benefits of reduced bleeding and postoperative pain while maintaining high Free rate of stones , which range from 96–100%.<sup>6</sup>

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RIRS has become a successful substitute for treating large stones in the kidney, achieving Free rate of stones up to 92%.<sup>7</sup> Studies suggest that RIRS is particularly advantageous for lower calyceal stones, demonstrating more free rate of stones and lesser rates of retreat in comparison to other modalities.<sup>8</sup>

Although SWL offers the shortest operating time and hospital stay, it is associated with the lowest SFR, higher retreat rates, and an increased need for additional procedures.<sup>9</sup> Given these considerations, the optimal treatment choice for medium in size, high in density renal stones remains unclear.

This study hypothesizes that stone density is a crucial factor influencing treatment outcomes. Taking into account this parameter, we aim to determine whether mini-PNL or RIRS demonstrates superior efficacy in terms of SFR while maintaining an acceptable morbidity profile.

## 2. Patients and methods

In current prospectively, randomised, comparative research has done in urology Department at Al-Azhar hospitals of University, Cairo, Egypt, since November 2021 till May 2024. Prior to inclusion, each participant provided written informed consent. and the reasearch received approval from local institinfected urinary systemonal review board before enrolment of the patient.

Research enrolled non-pediatric individuals with a single, not in the lower renal pole stone, ranging from 1 to 2 cm in diameter, with a heightened density ( 1000 Hounsfield Units) as determined by contrast-free computerized tomogram (NC-CT). Individuals were excluded if they were pregnant, had morbid obesity, significant ortho-deformity, coagulation disorders, an actively infected urinary system, stones located within a calyx, diverticular stones, malformed anatomy of the kidney, or obstruction beyond the stone. Additionally, individuals with synchronised pathologies requiring simultaneous procedure or those with advanced hydronephrosis were also excluded.

The individuals were classed by stone size and randomly allocated to one of three sections of treatment: mini-PNL, RIRS, or SWL. Randomisation was performed using a blocked technique to ensure a balanced section allocation. Before treatment, all individuals had a full preoperative assessment, including a comprehensive history of medical importance, clinical assessment, basic laboratory tests, and radio-studies such as abdominal ultrasound (USG), plain abdominal radiograph (KUB), and NCCT. If a more detailed assessment of the

calyceal anatomy was needed, contrast imaging (IVU or contrast-enhanced CT) was performed.

In the mini-PNL section, the operations were generally done under anaesthesia, and all of those steps were guided by fluoroscopy. A mini-nephroscope (Karl STORZ, 12 Fr., 22 cm) was used, and fragmentation of stones was achieved by using a lithotripter of a Ho: YAG-laser or pneumatic lithotripter. In the RIRS section, the procedures were done under anaesthesia, generally or spinally. A flexible ureteroscope (OUT Medical, 8.6 Fr., 905 mm length) was used, and stone fragmentation was performed using a lithotripter of a Ho: YAG-laser. A J-J ureteral stent was routinely placed at the end of the operation. In the SWL section, procedures were performed by a third-generation Dornier lithotripter (Dornier SII, Wessling, Germany) using narcotics or analgesia medication and fluoroscopic guidance. The operation was terminated once sufficient stone fragmentation (stones < 4 mm) was achieved or after 3500 shockwaves were received. On the basis of postoperative imaging, the procedure was repeated for a maximum of three sessions if necessary.

Follow-up imaging, including KUB or NCCT, was conducted at one and three months post-procedure to assess the status of being free of stones. For individuals who required additional treatment, stone-free status was determined on the final imaging results.

The SFR was the primary endpoint and was defined as the absence of fragmented stones >4 mm on follow-up imaging. Secondary endpoints included operation time, time of fluoroscopy, residence at the hospital, hemoglobin drop rate, requirements of transfusion of blood, need for another session of treatment, the need for auxiliary procedures, and complication rates. Classification of Complications was done using the Modified Classification System of Clavien (MCCS). Operative time was measured differently between the three treatments: for mini-PNL, it was determined from anaesthesia induction to fixation of the nephrostomy tube; for RIRS, from anaesthesia induction to urethral catheter placement; and for SWL, from sedation induction to the end of the SWL session.

Data were analyzed using version 25 of the SPSS program (SPSS Inc., USA). The analysis followed the intention-to-treat principle, with a per-protocol analysis specifically at the Free rate of stones. Descriptive statistics were calculated, and normality tests were performed for quantitative variables. Continuous data were presented as mean  $\pm$  SD or with median and the interquartile range (IQR), with section comparisons conducted by tests like the ANOVA or Kruskal-Wallis H. Pairwise comparisons were done using independent t-tests or Mann-Whitney U tests, as

appropriate. Preoperative and postoperative comparisons of numerical variables were assessed using the Wilcoxon signed rank test. Categorical data were expressed as percentages and frequencies, with comparisons made using the Chi-square test or Fisher's exact test, as applicable. A p-value of less than 0.05 is considered statistically significant.

### 3. Results

Initially, the study comprised 255 individuals, 85 individuals randomly assigned to each treatment section. However, postoperative follow-up was incomplete for 3 individuals in the mini-PNL section 1 in the RIRS section, and 4 at SWL section. As a result, the final analysis comprised 247 individuals: 82 in mini-PNL section, 84 in RIRS section, and 81 in SWL section.

The study population median age was 39.0 y (IQR: 14.0), and the bodies masses indices (BMI) median was 26.9 (IQR: 4.0). Most of individuals were classified as overweight, representing 59.5% (147/247) of the total sample. The stone median size was 1.7cm (IQR: 5.0), with all individuals with radiopaque stones as observed on KUB films. The median stone density, assessed by NCCT, was 1220.0 HOUNSFIELD UNITS (IQR: 452.0). Most stones (72.9%) were at renal pelvis. A baseline data summary is in [Table 1](#).

Table 1. Basic data for each section.

	MINI-PNL (N=82)	RIRS (N= 84)	SWL (N= 81)	P - VALUE
AGE, YEARS, MEAN±SD	42.8±9.1	39.3±13.4	42.4±13.8	0.076
GENDER, N (%)				
MALE				
FEMALE				
BODIES MASSES INDICIES, MEAN ± SD	26.8±2.2	27.4±3.2	27.6±3.7	0.649
SIZE OF STONE IN MM BY MEAN±SD	16.2±3.3	16.5±2.3	16.2±1.2	0.084
SITE OF STONE, NO. (%)				0.508
THE PELVIS	60 (73.2)	57 (67.9)	63 (77.8)	
THE UPPAR CALYX	9 (11.0)	8 (9.5)	8 (9.9)	
THE MEDDLE CALYX	13 (15.9)	19 (22.6)	10 (12.3)	
STONE SIDE, N (%)				
RIGHT KIDNEY				
LEFT KIDNEY				
STONE DENSITY, HOUNSFIELD UNITS,	1254.9±212.6	1272.2±235.0	1302.7±219.6	0.548

MEAN±SD

Regarding operative time, the SWL section demonstrated a significantly lower median operative duration (65.0 minutes; IQR: 25.0) compared to the mini-PNL section (75.0 minutes; IQR: 23.0,  $p < 0.001$ ) and the RIRS section (77.5 minutes; IQR: 40.0,  $p$  value = 0.001) (Figure 1). The time of the fluoroscopy was shorter significantly in RIRS section, a median duration of 1.3 min (IQR: 0.6), compared to the mini-PNL section (3.0 minutes; IQR: 0.3) and the SWL section (2.5 minutes; IQR: 0.1), Figure 2 shows the p-value of less than 0.001.

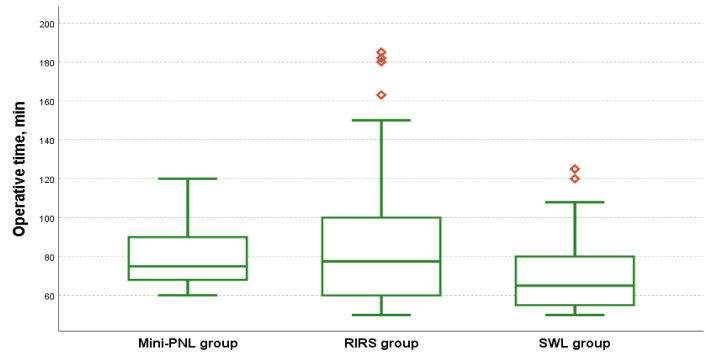


Figure 1. Box plot demonstrating the full time of operation in mini-PNL, RIRS, and SWL sections.

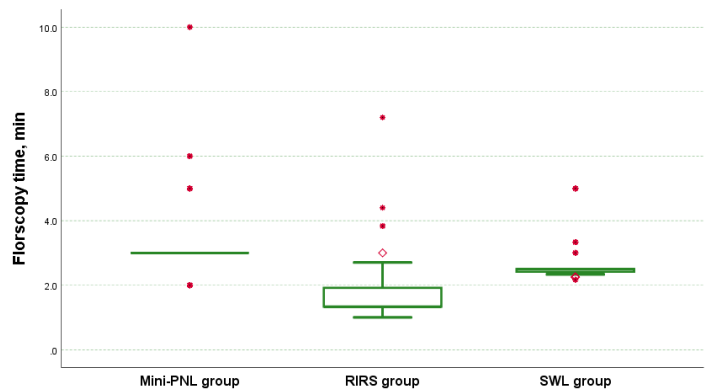


Figure 2. Box plot showing the time of fluoroscopy in mini-PNL, RIRS, and SWL sections.

The rate of freeness of stones was highest in that mini-PNL section, with 78 out of 82 individuals (95.1%) achieving stone-free status, followed by the RIRS section, where 76 out of 84 individuals (90.5%) were stone-free. The SWL section demonstrated a significantly lower SFR, with only 27 out of 81 individuals (33.3%) achieving complete stone clearance. Statistical analysis confirmed that rate of clearance from stones was higher significantly in both mini-PNL and RIRS sections in comparison to the SWL section ( $p$  less than 0.001). differences were not significant between the mini-PNL and RIRS sections in terms of SFR ( $p = 0.733$ ).

rates of complication varied between treatment sections. The RIRS section showed a significantly more complication rate overall in comparison to the mini-PNL section ( $p = 0.002$ ) and SWL section ( $p$  less than 0.001). However, differences were not significant statistically noticed in rates of complication between the mini-PNL and SWL sections ( $p = 0.580$ ). The complications intraoperatively and postoperatively and their MCC grades were plotted in Table 2.

Table 2. The complications intraoperatively and postoperatively and their MCC grades.

MINI-PNL SECTION			
	MCC Grade	Number (82)	%
OVERALL		18	22.0
INTRAOPERATIVE:		1	2.9
BLEEDING NEEDS TRANSFUSION OF BLOOD	2	1	2.9
THE PERFORATION OF RENAL PELVIS	3 b	1	2.9
POSTOPERATIVE:		18	22.0
POSTOPERATIVE FEVER	2	13	15.8
TRANSIENT BLEEDING	1	4	4.9
AFTER REMOVAL OF NP TUBE URINE LEAKAGE TRANSIENTLY	1	7	8.5
RIRS SECTION			
	MCC Grade	Number (84)	%
OVERALL		39	46.4
INTRAOPERATIVE:		2	2.9
PERFORATION OF THE P/C SYSTEM	3b	2	2.9
POSTOPERATIVE:		39	46.4
POSTOPERATIVE FEVER	2	19	22.6
HAEMATURIA	1	5	5.9
IRRITATIVE LUTS	1	17	20.2
ACUTE PYELONEPHRITIS	2	7	8.3
SWL SECTION			
	MCC Grade	Number (81)	%
OVERALL (ALL POSTOPERATIVE)		14	17.3
RENAL PAIN	1	8	9.9
HEMATURIA	1	3	3.7
IRRITATIVE LUTS	1	2	2.5
STEINSTRASSE	2	2	2.5
STEINSTRASSE	3b	1	1.2
STONE MIGRATION TO LOWER URETER	3 b	1	1.2
ACUTE PYELONEPHRITIS	2	2	2.5

The complications number exceed the cases number, as some individuals experienced > 1 complication.

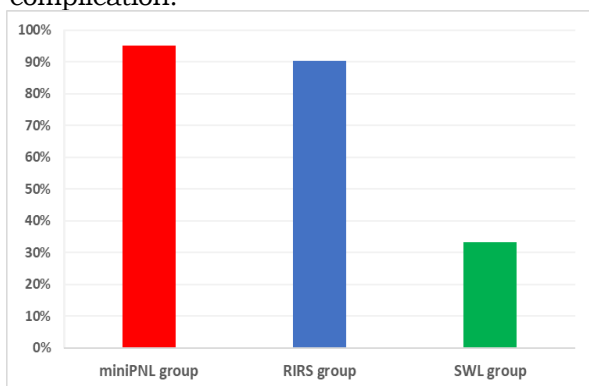


Figure 3. Bar chart demonstrating the stone-free rate in the 3 groups (intention-to-treat analysis).

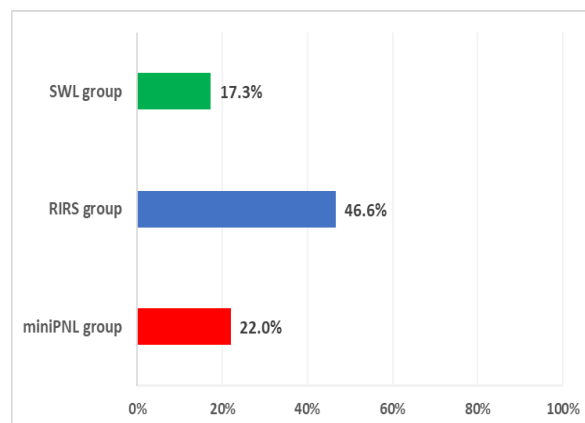


Figure 4. Bar chart demonstrating the overall complication rate in the 3 g

#### 4. Discussion

Renal stone treatment options include SWL, RIRS, and PNL, which are available in standard, mini, or ultra-mini variants, as well as laparoscopy and open operation. The optimal approach must be individualised based on patient characteristics, stone properties, renal anatomy, and the available resources in the treating facility. According to European guidelines, stones not in the lower pole of the kidney measuring 1 to 2 cm can be effectively managed using SWL, PNL, or RIRS.<sup>2</sup> However, the efficacy of these treatments varies significantly according to stone composition and density, which remains a critical factor in directing the most satisfactory therapy modality.

The free rate of stones after SWL for stones of medium size in the kidney range is between 66%. 4% and 83%<sup>10</sup>, higher success rates observed in the not in the lower pole stones.<sup>11</sup> Several factors influence SWL outcomes, including stone size, density, and patient BMI.<sup>12</sup> The effectiveness of SWL is significantly higher for stones with high density. Previous studies have reported a Free rate of stones of 44.6% and 54.5% for stones with densities >1000 HOUNSFIELD UNITS, and as low as 20.2% for stones > 750 HOUNSFIELD UNITS in density.<sup>13,14</sup> Given these limitations, alternative treatments such as PNL and RIRS are often preferred for high-density stones. PNL, particularly in its miniaturised form, offers high stone clearance rates but is more invasive than SWL. RIRS, on the other hand, provides a less invasive alternative while maintaining high efficacy, particularly for stones that are resistant to SWL due to density or location. Despite the availability of these modalities, the selection of the optimal treatment remains controversial, particularly for medium-sized, high-density stones not in the lower pole of the kidney. This prospective, randomised research aimed to address this uncertainty by categorizing the efficacy and safety of mini-PNL, RIRS, and SWL in



individuals with not in the lower pole stones > 10 mm and with a stone-density more than 1000 HOUNSFIELD UNITS.

The findings of this study demonstrate that both RIRS and mini-PNL are more efficient than SWL in achieving a stone-free condition, with a reasonable complication profile. Compared to mini-PNL, RIRS showed advantages with regard to reducing radiation exposure and less time in the hospital. Mini-PNL achieved a higher rate of immediate stone clearance. At 3 months of follow-up, the Free rate of stones for mini-PNL, RIRS, and SWL was 95.1%, 90.5% and 33.3%, respectively, confirming the superiority of the former two techniques over SWL.

PNL has consistently demonstrated the best effective rates in the treatment of stones, regardless of size. For example, a research study comparing PNL and SWL in the treatment of solitary renal pelvic stones measuring 2 to 3cm found that PNL achieved significantly higher SFR (95.3%) compared to SWL (75%). Additionally, retreatment and secondary procedure rates were considerably higher in the SWL section (75. 4% and 2 5%, respectively) than in the PNL section (5. 3% and 4.7 %, respectively).<sup>15</sup> A recent Cochrane review<sup>16</sup> showed that no significant differences in treatment success for kidney stones based on size (< 2 cm vs. ≥2cm) or site (inferior calyx vs. not in the inferior calyx). However, variations in the reported Free rate of stones between studies may result from differences in the term "stone-free," the type of image used, and the timing of assessment. To ensure consistency, our study used CT scans at 3 months for post-treatment evaluation. The comparable Free rate of stones of 90.5% and 95.1% observed in the RIRS and mini-PNL sections further support the effectiveness of these techniques over SWL.

A prospective randomised study comparing mini-PNL and RIRS for larger stones (20–30 mm) demonstrated a significantly shorter operative time for mini-PNL (59.71 minutes) compared to RIRS (80.43 minutes,  $p < 0.001$ ), highlighting the efficiency of mini-PNL in managing larger stones more rapidly. The prolonged operative time for RIRS in this study likely reflects the technical challenges associated with navigating and fragmenting larger stones through a retrograde approach.<sup>17</sup> In our study, the time of operation mean in the SWL section was significantly lower (69.0 minutes) in comparison to mini-PNL (78.5 minutes) and RIRS (87.0 minutes). This is consistent with previous findings, as SWL typically requires less procedural time due to its non-invasive nature and reliance on external shock waves for stone fragmentation. Non-effective differentiation was found between mini-PNL and RIRS regarding operative time,

suggesting that for medium-sized stones, both procedures offer comparable efficiency. This similarity may be attributed to advances in endoscopic technology that have streamlined the stone removal process in both approaches.

Exposure to fluoroscopy remains a critical concern in endourological procedures. A previous study contrasting mini-PNL and RIRS for 2:3cm stones in the kidney found a significantly shorter fluoroscopy time in the RIRS section (5.8 minutes) in comparison to the mini-PNL section (8.1 minutes).<sup>17</sup> This aligns with our findings, where fluoroscopy time was significantly shorter in the RIRS section compared to mini-PNL, SWL sections. The reduced fluoroscopy time in RIRS highlights its advantage in minimising radiation exposure, which is a significant consideration in modern urological practice.

A study analysing 322 consecutive RIRS procedures reported a rate of complication of about 26.1%, with complications classified as Clavien Grade I section (67.7%), Grade II section (22.7%), Grade IIIb section (7.2%), and Grade IVb section (2.4%). Significant predictors of the severity of the complication include positive urine culture pre-operatively and prolonged time of operation .<sup>18</sup> In our research, we found that the complication rate was about 46. 4%, with postoperative fever being the most frequent complication, occurring in 22.6% of cases. Most cases of fever were managed conservatively with antipyretics and did not require antibiotic modification, which matches previous research on post-procedural complications. Irritative symptoms of the lower part of the urinary system(LUTS) were ordered as a second-degree complication, affecting 20.2% of individuals. J J ureteral stents as a routine likely contributed to LUTS incidence; however, symptoms were generally self-limiting, requiring only reassurance and observation. The incidence of stent-related LUTS in this research was less than reported in past research, possibly due to the administration of tamsulosin, an alpha-blocker. More severe complications, classified as Clavien Grade 3b, were rare, occurring in only 2.9% of the cases, with PC system perforation being the most significant complication. These cases were conservatively managed by extending the duration of double J ureteral stenting.

Although it is a prospective randomised trial, our study has several limitations. The absence of a cost analysis prevents a comprehensive evaluation of the economic impact of mini-PNL, RIRS, and SWL. Without cost-effectiveness data, it is challenging to assess financial feasibility, particularly in resource-limited settings. Additionally, generalizability is limited by possible selection bias and external validity concerns, which can affect the eligibility of the results for

more diseased people.

#### 4. Conclusion

In conclusion, both mini-PNL and RIRS demonstrate superior efficacy over SWL for the management of medium-sized, high-density renal stones, not in the lower pole renal stones. Although the Free rate of stones was comparable between mini-PNL and RIRS, mini-PNL achieved a higher SFR in one session, reducing the need for retreatment and rehospitalisation. However, mini-PNL was engaged in increased bleeding and a longer duration of residence at the hospital. Given these findings, treatment selection must be individualized based on patient factors, procedural risks, and institutional resources. Future research should incorporate cost-effectiveness analyses and longer duration in clinical visits to further refine management recommendations for this patient population.

#### Disclosure

The authors have no financial interest to declare in relation to the content of this article.

#### Authorship

All authors have a substantial contribution to the article

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#### Conflicts of interest

There are no conflicts of interest.

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