Retrograde Intrarenal Surgery Versus Ultrasound- Guided Shock Wave Lithotripsy for Treating 1-2 cm Radiolucent Lower Calyceal Stones

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Abstract

Objectives: To compare the safety and efficacy of retrograde intrarenal surgery (RIRS) and ultrasound-guided (US-guided) shockwave lithotripsy (SWL) for the treatment of radiolucent lower pole calculi of 1- 2cm.

Materials and Methods: This prospective randomized study was performed at our tertiary care urology institute of Banha University Hospitals; cases were randomized either to undergo RIRS (group A) or US-guided SWL with triple focus system (group B). The safety and effectiveness of both therapies were compared using new criteria for stone-free rate (SFR): Grade A (absolutely stone-free), Grade B (≤2mm fragments), and Grade C (> 2mm up to 4mm fragments), fluoroscopy time, operative time, auxiliary procedures, retreatment, and complications.

Results: Out of 100 patients, 92 were eligible for this study. RIRS had a higher SFR of 88.9% compared to SWL,72.3% (P=0.045). Also, Stone-free classification significantly differed between the studied groups (P < 0.001), with grade A being significantly higher in group A. conversely, grades B and C were lower in group A. On the other hand, operative and fluoroscopy times were significantly reduced with SWL (P = 0.004 and < 0.001, respectively). While complications did not significantly differ between the 2 groups (P = 0.340), a significant distinction was observed in terms of the Clavien-Dindo classification.

Conclusion: RIRS is an effective and safe option for treating radiolucent lower calyceal stones of ≤ 2cm, with a greater SFR and lower need for auxiliary operations. However, Sono SWL is a cost-effective alternative that can achieve a comparable success rate after retreatment sessions.

Keywords: Retrograde Intrarenal Surgery; Lower Calyceal Stones; Radiolucent; Shock Wave Lithotripsy; Ultrasound-Guided.

INTRODUCTION

Lower calyceal renal calculi comprise 25–35% of all kidney calculi, and calculi up to 2 cm in diameter might be difficult to manage. [1] Despite the fact that most asymptomatic lower pole calculi may be handled without therapy, about 25 percent of stones may necessitate intervention. [2] Retrograde intrarenal surgery (RIRS) and shock wave lithotripsy (SWL) are the favored treatments for renal calculi between 1 and 2 centimeters in diameter. [3] SWL is a generally accepted treatment for urinary stones. However, a growing trend in the treatment of kidney calculi involves the implementation of minimally invasive endoscopic techniques, such as flexible ureteroscopy (FURS). Despite this tendency, for renal stones measuring less than 2 centimeters, SWL remains one of the most favored approaches. [4]

SWL has a lower complication and does not necessitate the use of anesthesia during treatment. However, the success rates of SWL for achieving stone-free status vary greatly. [5]

Accurate visualization of the radiolucent stone is crucial for the success of SWL for the precise focusing of shock waves. This visualization is usually achieved through the use of ultrasonography (US), which is safe and does not expose the patient to any radiation. In addition to active monitoring during the procedure. It is recommended to comply with the idea of reducing radiation exposure to the minimum feasible amount, as low as reasonably achievable (ALARA). [6] Considered an appealing therapeutic alternative for kidney stones of intermediate size, RIRS is characterized by a high stone-free rate (SFR) and the absence of substantial complications often associated with percutaneous nephrolithotomy (PCNL). [4] As far as we know, there have been only a few studies that compared the efficacy of RIRS, SWL, and mini PCNL for moderate-sized lower calyceal radiolucent calculi. Our study utilized a less invasive approach for managing radiolucent lower pole stones of 1-2 cm in size, employing RIRS and piezoelectric US-guided SWL to reduce the risk of complications.

The study aimed to compare the safety and efficacy of RIRS and US-guided SWL for the treatment of radiolucent lower pole calculi of ≤ 2cm.

MATERIALS AND METHODS

Study design and participants

This prospective randomized study was conducted in our tertiary care urology institute of Banha University hospitals between February 2022 and November 2023 after obtaining ethics approval and informed consent from all participants. Closed envelopes were used for randomization. The study recruited cases with radiolucent lower calyceal calculi who were treated by either RIRS or SWL. All cases underwent full history taking, clinical examination, routine laboratory investigations, and radiological examinations, including pelviabdominal ultrasonography, intravenous pyelography (IVP), non-contrast spiral CT, and plain abdominal radiograph of the kidneys, ureters, and bladder (KUB).

Inclusion criteria were patients of both sexes with an age > 15 years, a single radiolucent lower calyceal stone measuring 1 to 2 cm, an infundibulo-pelvic angle by IVP more than 45º, and previous failure of oral chemolysis. Exclusion criteria included active urinary tract infection, severe comorbidities, renal stones in the anomalous kidney, distal ureteric obstruction, declining renal function, BMI > 35, and uncorrected coagulopathy.

The analysis included patient demographics, perioperative data (including stone site, size, side, density, fluoroscopy time, Visual Analogue Scale (VAS) for pain, hospital stay, operative time, auxiliary procedure rate, re-treatment rate), 1-month SFR measured by non-contrast CT, and complications.

SWL Procedure

The SWL procedure involved the utilization of a piezoelectric lithotripter (Richard Wolf, piezolith 3000 plus, Germany) with an integrated ultrasound system and with *triple focus sizes localization* (*F1*=2mm, *F2*=4mm, *F3*=8mm). This outpatient procedure involved the use of an integrated ultrasound device to locate and monitor the stone. Fluoroscopy was briefly employed solely to confirm the radiolucency of the lower calyceal stone. The shockwave rate consisted of 90 pulses/minute, with a maximum of 3000 shockwaves for each session, and we started with a small focus size (F1) till stone fragmentation, then F2 and F3 were set for complete disintegration. To manage pain, patients received pain relief medications, with proper intravenous hydration fluids and diuretics. Following the procedure, patients were monitored for several hours. Two weeks later, a pelvi-abdominal ultrasound was conducted to evaluate stone fragmentation and clearance, while a non-contrast CT scan was conducted four weeks later to determine SFR. In cases where incomplete clearance was observed, SWL was repeated, with a maximum of three sessions allowed and a two-week interval between each session. ***(Figure 1)***

RIRS procedure

The RIRS procedure involved the use of a single-use digital flexible ureteroscope (**LithoVue, Boston Scientific, USA**). General anesthesia was delivered while the patient was positioned in the lithotomy position. A guide wire was introduced into the pelvicalyceal system by cystoscope, subsequent to which a retrograde study by ureteric catheter was conducted. Sequential ureteral dilation was performed using dilators up to 16 F, and in cases of non-dilatable ureter, a JJ stent was inserted pre-procedure for two weeks. Subsequently, following the insertion of a safety guide wire, a 12/14 F ureteral access sheath (UAS) was positioned over the guide wire and into the proximal ureter. The pelvicalyceal system was subsequently examined using flexible ureteroscopy, and the stones were in situ treated with a Holmium: YAG laser (Lumenis®) operating at low energy and high frequency (0.6–1.2 J, 15–20 Hz) via a dusting approach. A nitinol tipless basket was used to eliminate the larger stone bits. A JJ stent was implanted following a retrograde study that was conducted before the conclusion of the procedure. **(Figure 2)**

Postoperative follow-up

The study defined residual stones as fragments bigger than 4mm, evaluated by non-contrast CT with 2mm cuts one-month following RIRS or SWL in all patients, and stone-free data was classified into three grades: Grade A (absolutely stone-free), Grade B (≤2mm fragments) and Grade C (> 2mm up to 4mm fragments). Auxiliary procedure was defined as the use of a treatment other than the primary treatment, such as SWL or ureteroscopy in the RIRS group. Retreatment was defined as the necessity for a second session of the same treatment modality. The study analyzed the hospital stay, VAS, complications, 1-month SFR, retreatment rate, and auxiliary procedure rate between the two groups.

Statistical methods

SPSS version 28 (IBM, Armonk, New York, United States) was used for the analysis of the data. G*power software version 3.1.9.2 was used to calculate the sample size based on a pilot study conducted as a part of this study. The pilot reported a stone-free rate of 60.9% and 93.3% in the SWL and RIRS groups, respectively. The determined overall sample size comprised 90 cases (45 per group). Alpha and power were adjusted at 0.05 and 0.8, respectively. In order to evaluate the normality of quantitative data, the Shapiro-Wilk test and direct data visualization techniques were implemented. Categorical data were presented as numbers and percentages. The manner in which the quantitative data were summarised varied depending on their normality of distribution, mean and standard deviation, or medians and ranges. The Chi-square test or Fisher's exact test was employed for comparing categorical data. For comparing data between groups, the Mann-Whitney U test was utilized for non-normally distributed variables, and the independent t-test was applied to normally distributed variables. Multivariate logistic regression analysis was conducted to predict residual stones and calculate odds ratios along with 95% confidence intervals. A two-tailed p-value<0.05 was deemed statistically significant.

RESULTS

Among the 100 randomized patients, a total of 8 patients (8%) had withdrawn from the study. Within Group A (RIRS), 5 out of 50 patients (10%) were lost to follow-up, while in Group B (SWL), 3 out of 50 patients (6%) were lost to follow-up. Consequently, the analysis was carried out on a total of 92 patients, comprising 45 cases in Group A and 47 cases in Group B **(Figure 3)**.

The demographic data analysis revealed no significant variation between both groups **(Table 1).** operative time and fluoroscopy time were significantly reduced with the SWL group compared to the RIRS group (54 ±6 minutes vs. 60 ±12 minutes, P = 0.004; and 5 ±2 seconds vs. 88 ±24 seconds, P< 0.001, respectively). Among the cases in the RIRS group, only six individuals had JJ insertion prior to the procedure. Additionally, the average number of shocks administered in the SWL group was 2851 ±190 **(Table 1)**.

The SWL group exhibited significantly shorter hospital stays (4 ±1 hours vs. 30 ±10 hours, P < 0.001) and a lower SFR (72.3% vs. 88.9%, P = 0.045) compared to the RIRS group. Stone-free classification significantly differed between the studied groups (P < 0.001), with grade A being significantly greater in group A in comparison to group B (67.5% vs. 5.9%, respectively). In contrast, grades B and C were lower in group A (25% and 7.5%, respectively) than in group B (38.2% and 55.9%, respectively). The SWL group reported significantly higher scores on the VAS for pain (median = 4 vs. 2, P < 0.001). Although no significant variation was found in complications between both groups (P = 0.340), a significant distinction was observed in terms of the Clavien-Dindo classification (P = 0.041). The findings indicate that a higher percentage of cases in the SWL group (62.5%) were classified as grade I compared to the RIRS group (50%). Conversely, a higher percentage of cases in the RIRS group (50%) were classified as grade II compared to the SWL group (18.75%). None of the patients in the RIRS group were classified as grade III, whereas three patients (18.75%) in the SWL group were classified as grade III. Among these patients, two experienced complications related to obstructing steinstrasse after SWL; They underwent ureteroscopy with JJ insertion after failed medical treatment. Another patient presented with persistent loin pain two weeks after SWL and required JJ insertion following unsuccessful medical treatment. Within the SWL group, a greater proportion of cases need auxiliary procedures, with 8 patients (17%), compared to the RIRS group, with 3 patients (6.7%) (P = 0.126). The most frequent auxiliary procedure in the SWL group was ureteroscopy with JJ insertion, which was performed for 4 patients (2 patients developing steinstrasse and 2 patients with lower ureteric stones post SWL after unresponsiveness to medication). In contrast, RIRS was performed for 3 patients who were shifted to this procedure after SWL failure, inspite of retreatment. Finally, JJ insertion was performed for a patient presented with persistent pain 2 weeks after SWL. The auxiliary procedures in the RIRS group consisted of SWL on 2 patients (66.7%) and URS on a patient with a mid-ureteric stone (33.3%). The rate of retreatment was much greater in the SWL group as opposed to the FURS group, with 9 patients (19.1%) versus 2 patients (4.4%) requiring retreatment (P = 0.03) **(Table 2)**.

A multivariate logistic regression analysis was conducted to predict the occurrence of residual stones, taking into account all relevant variables and adjusting for age and gender. The analysis identified significant predictors related to the risk of residual stones. RIRS was found to be related to a reduced risk of residual stones (OR = 0.310, 95% CI = 0.099 – 0.971, P = 0.044). Furthermore, stone size was identified as a significant predictor, indicating that larger stone size increases the risk of residual stones (OR = 12.199, 95% CI = 1.597 – 93.194, P = 0.016). Also, it was discovered that stone density was a significant predictor, suggesting that higher stone density is associated with an increased risk of residual stones (OR = 1.008, 95% CI = 1.001 – 1.016, P = 0.046) **(Table 3).**

DISCUSSION

Lower calyceal stones pose a significant therapeutic challenge. Also, concerning the management of radiolucent renal stones, no specific surgical guidelines exist. [3, 7] There are two minimally invasive treatment options available for the treatment of stones up to 2 cm: SWL and RIRS. However, factors including stone density, stone size, and anatomical abnormalities can affect the effectiveness of SWL. [8] Ultrasonography plays a crucial role in SWL success by accurately visualizing radiolucent stones and allowing precise localization of shock waves. [4] Importantly, the use of ultrasonography in stone localization and management eliminates the risk of radiation exposure and enables continuous active monitoring during treatment. [9]

The advancements in RIRS have generated interest due to its ability to remove stones with fewer complications and lower recurrence rates, albeit requiring anesthesia. [10]

Therefore, this study was conducted to compare the effectiveness, safety, and SFR of RIRS and sono SWL in treating lower calyceal radiolucent kidney calculi measuring < 2 cm.

Our study revealed insignificant differences between both groups regarding age, gender, stone side, stone density, stone size, and stone number. In the RIRS group, only six patients received JJ insertion prior to the procedure, while the SWL group received an average of 2851 ±190 shocks. The SWL group also showed significantly reduced fluoroscopy time ($P < 0.001$) and operative time ($P = 0.004$). These findings align with Vilches *et al.* [11] and Kumar *et al.* [4] trials, which reported that the RIRS group has significantly longer surgical duration in comparison to the SWL group ($p < 0.05$). However, this contrasts with El-Nahas *et al.* [12] and Kumar *et al.* [13] findings, where the operational time of the SWL group was longer than that of the RIRS group, but the difference was not significant ($P = 0.31$). No significant variations were found in complications between both groups ($P = 0.340$). However, a notable disparity was observed in the Clavien-Dindo classification. The SWL group had more patients classified as grade I (pain), while the RIRS group had more patients classified as grade II (fever or UTI). Among the SWL group, only three cases were classified as grade III. This finding aligns with previous studies by Kumar *et al.* [4], Singh *et al.* [8], Bas *et al.* [14], Resorlu *et al.* [15], Ozturk *et al.* [16], and El-Nahas *et al.* [12], which also reported on complications in the SWL and RIRS groups. Our study's results showed that the two groups did not differ significantly in terms of the incidence of complications. Furthermore, according to Singh *et al.* [8], most complications in the two groups were categorized as Clavien grade I or II. The current study did not identify a significant variation in residual stone size between both groups ($P = 0.267$). Significant residual fragments (> 4 mm) were detected in 8% of patients following RIRS and 8% following SWL, according to previous research by El-Nahas *et al.* [12]. In the present study, the rate of auxiliary procedures in the SWL group was 17%, which was higher than the rate of the RIRS group, which was 6.7%, despite the fact that this difference failed to attain statistical significance ($P = 0.126$). Among the patients who required an auxiliary procedure in the SWL group, the most frequent procedure was URS and JJ insertion (50%), followed by RIRS (37.5%) and JJ insertion (12.5%). In contrast, the most frequent auxiliary procedure in the RIRS group was SWL (66.7%), followed by URS (33.3%). The trial performed by Kumar *et al.* [13] and El-Nahas *et al.* [12] also found that SWL required a higher number of auxiliary procedures than RIRS, but the variation was not statistically significant ($P > 0.05$). Similarly, Bozzini *et al.* [17], Kumar *et al.* [4], and Singh *et al.* [8] found that RIRS had a significantly lower rate of auxiliary procedures in comparison to SWL. In contrast to the RIRS group, the SWL group had a significantly elevated VAS ($P < 0.001$). These findings are consistent with Javanmard *et al.* [18] trial, which reported that cases in the RIRS group had lower VAS scores for postoperative pain and required fewer analgesics after the surgery. In our study, a multivariate logistic regression analysis was conducted to predict the likelihood of residual stones. The results indicated that RIRS was related to a lower risk of residual calculi ($P = 0.044$), while stone size was related to a higher risk of residual calculi ($P = 0.016$) and stone density was related to a higher risk of residual calculi ($P = 0.046$). SWL is a recommended treatment option due to its affordability, non-invasive nature, and shorter procedure duration. It is widely accepted and associated with lower radiation exposure. However, it is important to note that SWL is related to lower SFR and higher rates of retreatment. On the other hand, RIRS has emerged as a viable treatment alternative for calculi ranging from 1 to 2 cm, RIRS has demonstrated higher success rates. However, it should be noted that RIRS is an invasive procedure, more expensive, and requires anaesthesia.

CONCLUSIONS

RIRS is the preferred choice for the initial treatment of radiolucent lower calyceal stones measuring 1-2cm due to its higher success rate and reduced need for additional procedures and retreatment. However, Sono SWL is a cost-effective alternative that can achieve a similar success rate after multiple retreatment sessions.

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Conflicts of interest: There are no conflicts of interest.

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Table1: Patient characteristics, preoperative finding and Operative characteristics of the studied groups.

		Group A (RIRS) (n = 45)	Group B (SWL) (n = 47)	P-value
Age (years)	Mean ±SD	36 ±13	38 ±13	0.362
Sex				
Males	n (%)	25 (55.6)	30 (63.8)	0.982
Females	n (%)	20 (44.4)	17 (36.2)	
Stone side				
Right	n (%)	21 (46.7)	20 (42.6)	0.692
Left	n (%)	24 (53.3)	27 (57.4)	
Stone size (cm)	Mean ±SD	1.6 ±0.3	1.5 ±0.3	0.657
Stone density (HU)	Mean ±SD	309 ±74	336 ±61	0.052
JJ insertion before procedure	n (%)	6 (13.3)	-	-
Operative time (min)	Mean ±SD	60 ±12	54 ±6	**0.004***
Fluoroscopy time (sec)	Mean ±SD	88 ±24	5 ±2	**<0.001***
Number of shocks	Mean ±SD	-	2851 ±190	-
Hospital Stay (hour)	Mean ±SD	30 ±10	4 ±1	**<0.001***

*: significant p-value at < 0.05.

Table 2: Outcome and postoperative finding in the studied groups

		Group A RIRS (n = 45)	Group B SWL (n = 47)	P-value
Stone free rate				
Free	n (%)	40 (88.9)	34 (72.3)	**0.045***
Residual	n (%)	5 (11.1)	13 (27.7)	
Stone free classification**				
Grade A	n (%)	27 (67.5)	2 (5.9)	**< 0.001***
Grade B	n (%)	10 (25.0)	13 (38.2)	
Grade C	n (%)	3 (7.5)	19 (55.9)	
Size of residual (mm)	Mean ±SD	9 ±1	8 ±2	0.267
Pain score (VAS)	Median (min-max)	2 (1 - 6)	4 (1 - 7)	**<0.001***
Complications				
Complications	n (%)	14(31.1)	16 (34)	0.340
Fever	n (%)	3 (6.7)	2 (4.3)	
Pain	n (%)	7 (15.6)	11 (23.4)	
Steinstrasse	n (%)	0 (0)	2 (4.3)	
Urinary tract infection	n (%)	4 (8.9)	1 (2.1)	
Clavian-Dindo classification				
Grade I (pain)	n (%)	7 (50)	10 (62.5)	**0.041***
Grade II	n (%)	7 (50)	3 (18.75)	
Grade II (fever)	n (%)	3(21.4)	2 (12.5)	
Grade II (UTI)	n (%)	4(28.6)	1 (6.25)	
Grade III	n (%)	0 (0)	3 (18.75)	
Grade III (Steinstrasse)	n (%)	0 (0)	2 (12.5)	
Grade III (Persistent pain need JJ insertion)	n (%)	0 (0)	1 (6.25)	
Auxiliary procedure	n (%)	3 (6.7)	8 (17)	0.126
Type of auxiliary procedure				
ESWL	n (%)	2 (66.7)	0 (0)	-
JJ	n (%)	0 (0)	1 (12.5)	
JJ + URS	n (%)	0 (0)	4 (50)	
RIRS	n (%)	0 (0)	3 (37.5)	
URS	n (%)	1 (33.3)	0 (0)	
Retreatment	n (%)	2 (4.4)	9 (19.1)	**0.004***

UTI: urinary tract infection, URS: Ureteroscopy, RIRS: retrograde intrarenal surgery, VAS: visual analog scale *: statistically significant as P value <0.05; **Percentages were calculated based om the total patients who achieved stone-free status

Table 3: Multivariate logistic regression analysis to predict residual stones

	OR (95% CI) †	P-value
RIRS procedure	0.310 (0.099 - 0.971)	**0.044***
Stone side	0.945 (0.326 - 2.738)	0.917
Stone size (cm)	12.199 (1.597 - 93.194)	**0.016***
Stone density	1.008 (1.001 - 1.016)	**0.046***

OR: Odds ratio; 95% CI: 95% confidence interval; † Adjusted for age and gender; RIRS: flexible ureteroscopy, *: statistically significant as P value <0.05.

Figure legends:

Figure 1: A) The piezoelectric lithotripter with an integrated ultrasound system (Richard Wolf, piezolith 3000 plus, Germany). B) localization of radiolucent lower calyceal stone by ultrasound.

Figure 2: A) Retrograde study revealed prescence of lower calyceal stone. B) Introducing of flexible ureteroscopy through access sheath. C) Dusting of stone by a Holmium: YAG laser (Lumenis®).

Figure 3: Flowchart of the studied groups.

Figure 1

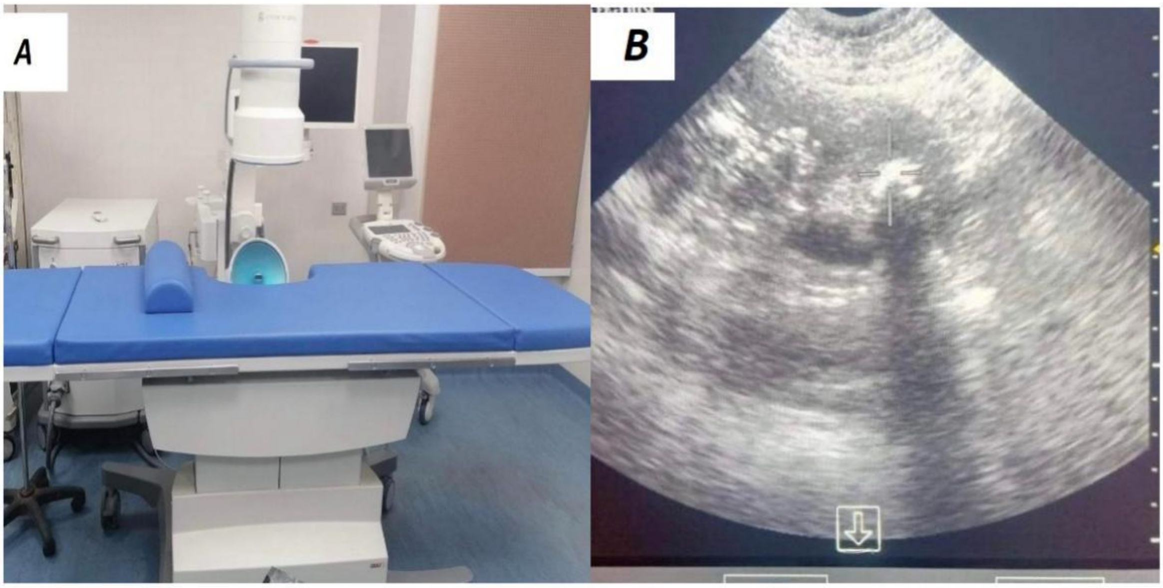


Figure 2

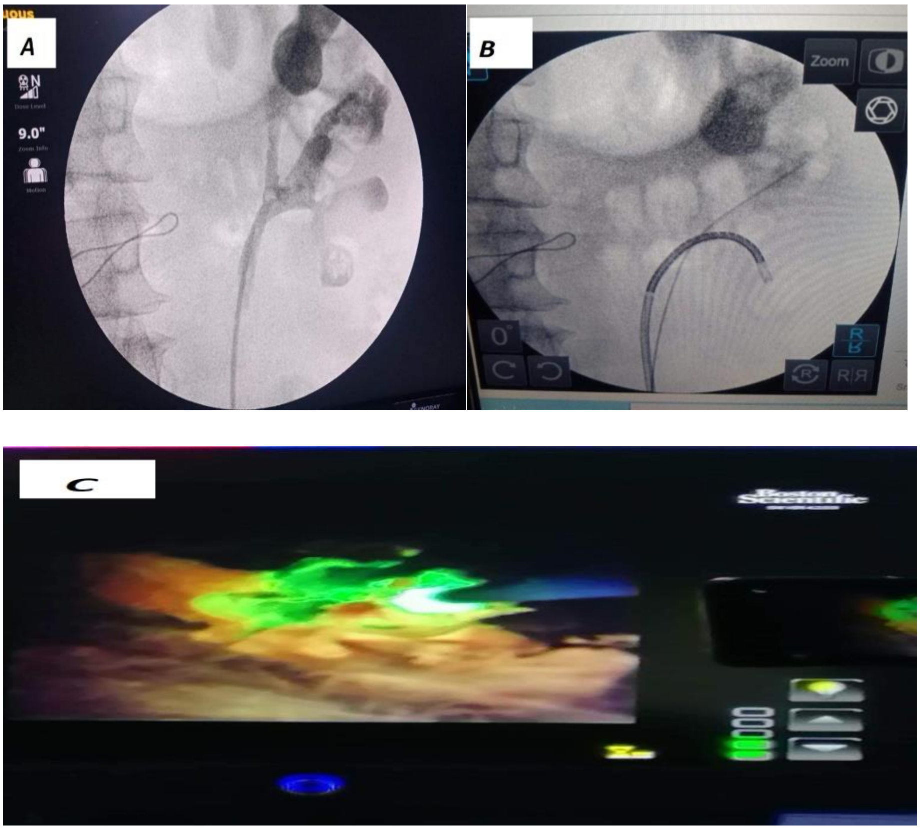
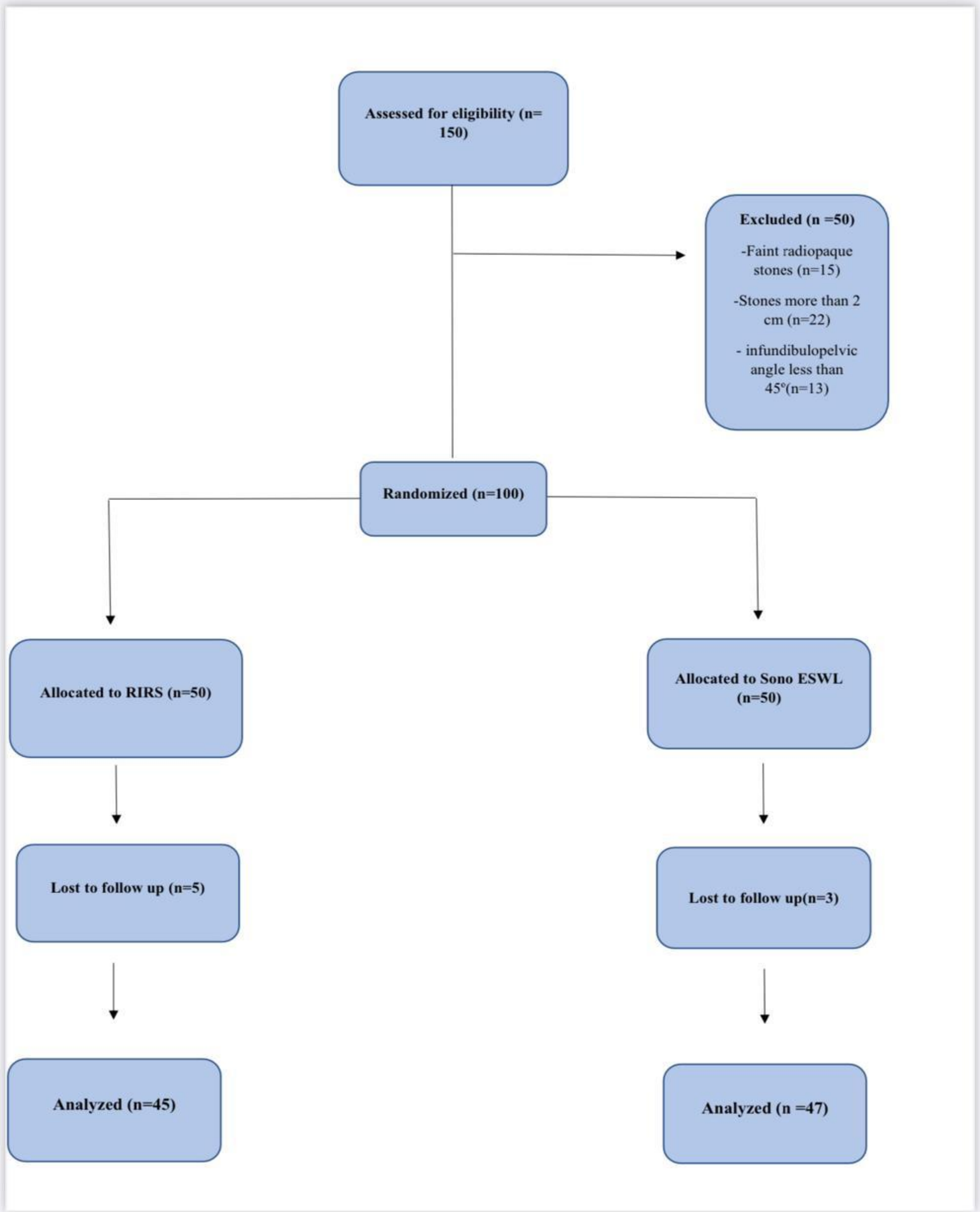


Figure 3



Assessed for eligibility (n= 150)
Excluded (n =50)
-Faint radiopaque stones (n=15)
-Stones more than 2 cm (n=22)
- infundibulopelvic angle less than 45°(n=13)
Randomized (n=100)
Allocated to RIRS (n=50)
Allocated to Sono ESWL (n=50)
Lost to follow up (n=5)
Lost to follow up(n=3)
Analyzed (n=45)
Analyzed (n =47)