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Comparison Of The Efficacy Of Extracorporeal Shockwave Lithotripsy (ESWL) With Retrograde Intrarenal Surgery (RIRS) On Clinical And Patient-Reported Outcomes Among Patients With Renal Stones: A Randomized Controlled Study

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Abstract

Background: Management of intermediate-sized renal calculi (10–20 mm) remains debated. While extracorporeal shock wave lithotripsy (ESWL) offers a non-invasive outpatient option, retrograde intrarenal surgery (RIRS) achieves higher stone-free rates (SFR) but requires anesthesia and hospitalization. This randomized controlled trial compared both modalities in terms of efficacy, safety, retreatment, and patient-reported outcomes.

Patient and Methods: A total of 176 adults with 10–20 mm renal calculi were randomized (block randomisation, SNOSE technique) into RIRS (n=88) or ESWL (n=88). Primary outcome was SFR, defined as absence of residual fragments >3 mm on non-contrast CT. Secondary outcomes included complications (Clavien–Dindo), retreatment, auxiliary procedures, hospital stay, time to normal activity, and validated health questionnaire scores.

Results: Complete clearance was 76.1% (RIRS) vs. 67% (ESWL). When residual fragments ≤3 mm were considered insignificant, SFR was 93.2% vs. 87.5% ($p=0.324$). Retreatment was required in 1.1% vs. 51.1% ($p<0.05$). Auxiliary procedures were needed in 5.7% vs. 12.5%. Complications were low in both groups, with Grade 1 events more common in RIRS (9.1%) and Grade 3a events exclusive to ESWL (3.4%). Operative time was longer for RIRS (70 vs. 45 min), but hospital stay and return to activity favored ESWL ($p<0.05$). Median reduction in health score was greater with ESWL (7 vs. 5, $p<0.05$).

Conclusions:RIRS provides higher definitive clearance and minimizes retreatment, while ESWL remains relevant due to its non-invasive nature, shorter recovery, and superior early patient-reported outcomes. Treatment should be individualized, integrating both objective and patient-centered endpoints.

INTRODUCTION

Urolithiasis affects 7%–13% of the global population [1], and ESWL and RIRS remain the principal treatments for renal calculi measuring 1–2 cm. ESWL is favoured for its non-invasive, outpatient nature and minimal anaesthesia requirements. In contrast, advances in flexible ureteroscopes and LASER technology have made RIRS a highly effective alternative with superior single-session stone-free rates (SFRs) [2]. However, most comparative studies focus exclusively on lower-pole stones, where anatomical constraints inherently reduce ESWL efficacy and may overstate the relative advantage of RIRS. In real-world practice, many patients achieve comparable cumulative clearance with ESWL after multiple sessions, emphasising the need for broader evaluation across all intrarenal stone locations.

Increasingly, procedural success is assessed not only by stone-free and retreatment rates but also by patient-reported outcomes reflecting recovery, comfort, and overall satisfaction. Validated PROM tools such as the 7D5L questionnaire provide structured assessment of these domains and are increasingly used in stone disease [3]. Cost and resource utilisation also influence treatment choice. Extracorporeal Shock Wave Lithotripsy is generally more economical as an outpatient procedure performed without anaesthesia or theatre time, although repeated sessions may increase cumulative costs. In contrast, Retrograde Intrarenal Surgery offers higher single-session clearance but incurs greater costs related to anaesthesia, disposable instruments, and short hospitalisation.

Although RIRS is increasingly used for stones ≤ 2 cm, treatment decisions in many settings continue to depend on availability, expertise, and affordability rather than robust evidence. Except for lower-pole stones, where RIRS consistently outperforms ESWL, current guidelines do not clearly favour either modality, and existing randomised

trials remain limited. To address this gap, we conducted a single-centre randomised trial comparing RIRS and ESWL across all calyceal locations, incorporating both clinical and patient-reported outcomes to provide a comprehensive patient-centred evaluation.

MATERIALS AND METHODS

This was a prospective, randomised, controlled trial conducted at our tertiary centre between September 2023 and March 2025. The protocol was approved by the Institutional Ethics Committee (JIP/IEC-OS/2023/08/123), adhered to the Declaration of Helsinki, and was registered prospectively with the Clinical Trials Registry of India (CTRI/2025/04/084708). Written informed consent was obtained from all participants, and symptomatic adults (≥ 18 years) with renal calculi measuring 10mm – 20 mm on non-contrast CT were included in this study. The study was designed to evaluate both clinical outcomes and patient-reported symptom improvement following intervention. Inclusion was therefore restricted to symptomatic patients to ensure a uniform indication for treatment and to allow meaningful assessment of pre- and post-procedure PROM changes. Exclusion criteria were distal obstruction, calyceal diverticulum, congenital anomalies, BMI > 29, pregnancy, active urinary tract infection, serum creatinine > 3 mg/dL, and solitary kidney.

The authors confirm the availability of, and access to, all original data reported in this study. The authors declare that they used ChatGPT (version 5.2) for language editing, grammar correction, and improving clarity and readability of the manuscript. The authors confirm that they have reviewed and take full responsibility for the accuracy, originality, and integrity of the content.

Sample Size and Randomisation

Both ESWL and RIRS were provided free of cost within our academic tertiary-care setting; therefore, financial considerations did not influence treatment allocation. Patients were counselled that both modalities are established standard-of-care options for 10–20 mm renal calculi, and the concept of randomization was explained prior to enrolment. Written informed consent was obtained, and patients retained the right to withdraw prior to intervention.

The sample size was calculated for a superiority design, assuming a 25% difference in stone clearance, a 5% significance level, and 90% power, yielding 79 participants per group. This was increased to 88 participants per group (total 176) to account for dropouts. Sample size was calculated using the formula for comparison of two independent proportions:

$$n = [(Z\alpha/2 + Z\beta)^2 \times \{P1(1 - P1) + P2(1 - P2)\}] / (P1 - P2)^2$$

where P1 and P2 represent expected stone clearance rates in the two groups, Zα/2 corresponds to the two-sided 5% significance level, and Zβ corresponds to 90% power.

Randomisation was computer-generated in variable block sizes of 4 and 6, with allocation concealed using sequentially numbered, opaque, sealed envelopes (SNOSE). Envelopes were maintained by the outpatient nursing officer and opened sequentially after patient consent, ensuring allocation concealment. (Fig. 1)

Interventions

- **RIRS arm**: Patients underwent ureteral stenting 2 weeks prior. RIRS was performed under general anaesthesia with a 7.5 Fr flexible ureterorenoscope, using a Holmium: YAG laser (8–12 W) for fragmentation. A 5 Fr DJ stent was placed postoperatively and removed after 2 weeks.

Pre-stenting was adopted as a uniform protocol to standardize ureteral access and minimize intraoperative complications. Although RIRS can be performed without pre-stenting in selected cases, a standardized approach was implemented to reduce procedural variability within the randomized framework. As this study was conducted in an academic tertiary-care centre where procedures were performed under consultant supervision in a teaching environment, protocol standardization was considered important to ensure procedural safety and consistency across operators.

Operative time for RIRS was calculated from scope insertion to completion of the procedure and did not include the separate pre-stenting procedure.

- **ESWL arm**: Performed as an outpatient using Dornier Compact Delta III lithotripter under mild IV sedation. Each session delivered 2500–3000 shocks (energy level 1–11, frequency 60–120/min). A maximum of three sessions was permitted. ESWL was an outpatient procedure and patients were given same-day discharge.

Patients were followed up at 1 week for complications and 2 weeks for stone clearance, complications, and PROMs. Patients were instructed to complete the questionnaires on two occasions to evaluate patient-reported outcome measures. Initially, before the procedure, patients were asked about the preceding seven days. The subsequent occasion, following the treatment, was when patients returned for a follow-up scan. For patients undergoing ESWL, the health questionnaire was administered only after completion of all planned treatment sessions. Patients with residual stones after three ESWL sessions were counselled for alternative treatment (RIRS/PCNL). (Fig. 2)

No prophylactic stenting was performed in the ESWL arm; stents were inserted only if clinically indicated as auxiliary intervention.

Outcome Definitions

Follow-up NCCT scans were reviewed by consultant radiologists, and residual fragment measurements were based on formal radiological reporting.

- **Stone-Free Rate (SFR)**: Defined as the absence of any residual stone fragments > 3 mm on follow-up non-contrast CT. Residual fragments ≤ 3 mm were considered clinically insignificant and categorised as stone-free, consistent with prior trials.
- **Patient-Reported Outcomes (PROMs)**: Evaluated using a validated health questionnaire, 7D5L health questionnaire [3] administered pre-procedure and at follow-up (after all ESWL sessions or after the definitive RIRS procedure). The questionnaire objectively measured changes in mobility, self-care, usual activity, pain/discomfort, anxiety/depression, cognition and social participation.
- **Retreatment Criteria**: Retreatment was defined as the need for an additional session of the same modality (repeat ESWL or RIRS) due to incomplete clearance, persistent symptoms, or complications.
- **Need for Auxiliary Procedure**: Defined as the requirement of an additional intervention other than the initially assigned modality, such as DJ stent insertion or URSL performed to facilitate stone clearance or manage

procedure-related complications.

- **Complication Assessment**: All adverse events were graded according to the Clavien–Dindo classification in line with established urological reporting standards.[4]

Statistical Analysis

Categorical variables (sex, site, size categories, comorbidities, and outcomes) were expressed as frequencies and percentages, and compared using the Chi-square test. Continuous variables (age, stone size, BMI, HU) were summarised as mean ± standard deviation or median (interquartile range), depending on distribution assessed by the Kolmogorov–Smirnov test. Intergroup comparisons were made using the independent *t*-test or Mann–Whitney *U* test, as appropriate. Statistical analyses were performed using SPSS v. 31.0 (IBM Corp., Armonk, NY), with $P < 0.05$ considered statistically significant.

RESULTS

A total of 176 patients were analysed, with 88 in each arm. Baseline characteristics were largely comparable between the groups (Table 1). Although patients in the RIRS arm were older (48.3 ± 11.9 vs. 41.5 ± 10.4 years; $P < 0.05$), sex distribution and BMI did not differ significantly. The prevalence of comorbidities showed a statistically significant difference, with a higher proportion of comorbidity-free patients in the ESWL group ($P < 0.05$); however, this imbalance is likely due to chance within the randomisation process. Renal function was similar between groups, with median creatinine levels of 0.95 and 0.90 mg/dL, respectively ($P = 0.825$). Stone laterality and distribution across upper, middle, and lower calyces and pelvis were well balanced ($P = 0.12$). Median stone size was identical (1.4 cm), and most stones were radio-opaque in both groups. Stone density, measured by Hounsfield units, was comparable where median HU was 1010 (range: 720–1350) in RIRS and 995 (range: 800–1250) in ESWL (P = 0.402) indicating similar fragmentation difficulty. The proportion of primary vs. recurrent stone formers also did not differ. Overall, the demographic and stone-related variables demonstrate that both groups were well matched at baseline, providing a reliable foundation for comparing clinical outcomes.

Perioperative parameters differed significantly between groups (Table 2). The mean procedure time was higher for RIRS (70 min) compared with ESWL (45 min; $P < 0.05$). Correspondingly, the median time to resume normal activity was longer following RIRS (5 vs. 4 days; $P < 0.05$). All ESWL patients were discharged within 24 hours, whereas 12.5% of RIRS patients required postoperative stay beyond one day ($P < 0.05$). Strict no-residual clearance was 76.1% in the RIRS group and 67% in the ESWL group. When clinically insignificant fragments ≤ 3 mm were included, the final stone-free rate was 93.2% for RIRS and 87.5% for ESWL ($P = 0.324$), the latter representing cumulative clearance after all prescribed ESWL sessions rather than a single sitting. Retreatment requirements were markedly different: only 1 patient (1.1%) in the RIRS arm required repeat intervention, whereas 45 patients (51.1%) in the ESWL arm did (P < 0.05). Consequently, nearly all RIRS cases were completed in a single session (98.9%), whereas ESWL required two or three sessions in 49% of cases ($P < 0.05$).

Complications were infrequent in both groups. In the RIRS arm, 78 patients (88.6%) had no complications, 8 (9.1%) developed Grade I events (fever in 3 and hematuria in 4), and 2 (2.3%) experienced Grade IVa urosepsis requiring intervention without mortality. In the ESWL arm, 83 patients (94.3%) had no complications, 2 (2.3%) had Grade I events (hematuria or severe flank pain), and 3 (3.4%) developed Grade IIIa steinstrasse requiring intervention. The overall difference in complication distribution was not statistically significant (p = 0.251, Fisher's exact test).

In the RIRS group, 5 patients (5.7%) required auxiliary procedures, compared to 11 patients (12.5%) in the ESWL group. The difference was not statistically significant ($P = 0.116$). Among those requiring additional interventions in the ESWL arm, the most common were placement of DJ stents (3 cases), followed by secondary RIRS (7 cases) and ureteroscopic lithotripsy (1 case). A small number of patients in the RIRS group also underwent repeat ESWL sessions (5 cases) to achieve clearance. Overall, the majority of patients in both groups did not require auxiliary procedures (94.3% in RIRS vs 87.5% in ESWL).

The median reduction in patient-reported health score was greater in the ESWL group (7 vs. 5; $P < 0.05$), indicating a higher subjective burden during the treatment course.

DISCUSSION

Management of 10–20 mm renal calculi requires balancing efficacy and invasiveness. RIRS offers higher stone-free rates and fewer retreatments, whereas ESWL remains attractive because of its non-invasive outpatient nature. Our study compared both modalities using objective and patient-reported outcomes for a comprehensive assessment.

In our study, RIRS patients were older than ESWL patients (48.3 vs. 41.5 years; $P < 0.05$), likely due to chance imbalance despite SNOSE-based block randomisation, as age has not been shown to influence efficacy in prior RCTs [5, 6]. The sex distribution was comparable and clinically insignificant. BMI was similar between groups (24.5 vs. 25; $P = 0.984$). To avoid confounding from obesity-related reductions in ESWL efficacy and technical difficulties during RIRS, patients with a BMI greater than 30 were excluded. ESWL patients more frequently had no comorbidities, while RIRS patients more often had one or more comorbidities ($P < 0.05$), reflecting random variation; the comorbidity burden affects perioperative tolerance rather than stone clearance. Baseline creatinine was comparable (0.95 vs. 0.90 mg/dL). Abdel-Khalek et al. [7] proposed a multivariate model identifying patient and stone characteristics influencing ESWL outcomes. Patients with creatinine levels greater than 3.0 mg/dL were excluded to ensure an unbiased comparison.

Stone distribution was comparable ($P = 0.12$), although lower-pole stones were more frequent in the Retrograde Intrarenal Surgery arm (46.6% vs. 31.8%), likely representing a chance finding. Stone location is a key determinant of success, as ESWL has lower clearance rates for lower-pole stones because of gravity-dependent fragment clearance and unfavourable anatomy. In contrast, RIRS remains effective but requires greater scope deflection and incurs higher costs.

Prior studies confirm the superiority of RIRS in this setting [8, 9]. The median stone size was identical (1.4 cm), a crucial factor, as increasing stone size reduces ESWL efficacy, whereas RIRS maintains higher single-session success rates [4, 5, 6, 9]. Median HU was ~ 1000, a threshold beyond which ESWL success declines; El-Nahas et al. [5] and Pareek et al. [10] identified HU > 900–1000 as predictive of ESWL failure, while RIRS outcomes remain unaffected. In our study, stone density was not a selection criterion. The observed median HU values around 1000 likely reflect the predominance of calcium oxalate stones, which are common in our region. Published studies report renal stone densities typically ranging from 600 to 1200 HU depending on composition, with calcium oxalate stones frequently exceeding 900 HU. [8] In our RCT, stone site, size, and density—the principal determinants of success—were well balanced, with relatively high HU likely contributing to lower ESWL clearance.

Although Retrograde Intrarenal Surgery is increasingly performed as an outpatient procedure,

short postoperative observation was routinely practiced in our institution, contributing to longer hospital stays. RIRS was associated with longer operative times (70 minutes vs. 45 minutes), delayed return to normal activity (5 days vs. 4 days), and a higher rate of postoperative stays exceeding one day (12.5% vs. 0%; $P < 0.05$). These findings reflect the greater procedural burden of RIRS related to anaesthesia, ureteral access, and stent placement compared with the non-invasive outpatient nature of ESWL. Similar findings have been reported by Bosio et al. [6] and Singh et al. [8], supporting the advantage of ESWL in procedural efficiency, early recovery, and resource utilisation, particularly in working-age patients and resource-limited settings.

Fragments ≤ 3 mm were considered clinically insignificant in line with contemporary randomized trials and the recent 2025 updated systematic review and meta-analysis [9], where most studies adopted similar thresholds.

Strict no-residual clearance numerically favoured Retrograde Intrarenal Surgery; however, when clinically insignificant fragments (≤ 3 mm) were included, the difference narrowed and overall stone-free rates became comparable. This approach aligns with contemporary reporting standards and reflects real-world clinical relevance. Several studies by Salem et al. [11], Vilches et al. [12], and Zhang et al. [13] have reported higher single-session clearance rates with RIRS, particularly for lower-pole stones. However, longer follow-up has shown improved outcomes with ESWL after repeat sessions. Meta-analyses consistently favour RIRS for single-session efficacy, although comparisons are limited by heterogeneous definitions and follow-up protocols.

Our study showed significantly lower retreatment rates with Retrograde Intrarenal Surgery, with reintervention required in only 1.1% of patients compared to 51.1% in the ESWL group. Similar findings were reported by Salem et al. [11], Pearle et al. [14], and Wiseman et al. [15] (PURE-1), where ESWL retreatment rates ranged from 25% to 60%, while RIRS remained below 10%. However, RIRS requires a staged pathway with pre-stenting and stent removal, whereas ESWL is typically performed without instrumentation. Thus, although RIRS reduces unplanned repeat interventions, the overall treatment course differs between modalities.

Auxiliary procedures were required in 5.7% of RIRS and 12.5% of ESWL patients ($P = 0.116$), with more than 85% in both groups requiring no further intervention. The most common was secondary RIRS (7 cases), followed by placement of DJ stents (3 cases) and Ureteroscopic lithotripsy (1 case). Prior studies by Kumar et al. [4], Singh et al. [8], and Vilches et al. [12], as well as meta-analyses by MacLennan et al. [9], consistently report higher auxiliary procedure rates with ESWL, underscoring the advantage of RIRS as a single definitive treatment.

Complications after ESWL are usually minor, including hematuria, flank pain, and infection, with rare steinstrasse or hematoma [16]. Retrograde Intrarenal Surgery may cause mucosal trauma, stent-related discomfort, or infection related to raised intrarenal pressures, although most events are minor [17]. Imaging studies have shown renal parenchymal volume changes after Percutaneous Nephrolithotomy, but this was not central to the present RIRS versus ESWL comparison [18]. RIRS has minimal long-term functional impact, with operative time being the main predictor [19], while ESWL may cause transient microvascular injury without significant long-term renal damage, particularly in children [20].

Both RIRS and ESWL demonstrated low and predominantly minor complication rates in our study (11.4% vs. 5.7%), consistent with previous trials and meta-analyses. RIRS complications mainly included transient fever, hematuria, and occasional urosepsis, whereas ESWL complications were typically steinstrasse, flank pain, or mild hematuria, all managed conservatively. Reported complication rates vary across studies (RIRS 11%–38%, ESWL 5%–26%) without consistent statistical differences, likely reflecting variations in stone size, patient selection, and

reporting criteria [6, 9, 14, 15]. Overall, serious complications are uncommon, and the safety profiles differ more in type than severity: RIRS carries procedural risks under anaesthesia, whereas ESWL involves minor repeated risks across sessions. Therefore, although both are safe for 10–20 mm renal calculi, treatment decisions should also consider efficacy, retreatment rates, and patient-reported outcomes.

Table 3 synthesizes key evidence from prior studies comparing stone clearance, retreatment, auxiliary procedures, and complications between ESWL and RIRS, and our results are consistent with these data. While access to ESWL may vary across regions, in centers where a lithotripter is available, its outpatient delivery, avoidance of anesthesia, and ability to treat a high patient volume may provide practical advantages over operative approaches.

Table 3
Comparative summary of clearance, retreatment, auxiliary procedure rates and complications in various ESWL vs RIRS studies

Variable	Category	Median (Q1,Q3)		Statistical Significance (P-value)
		RIRS	ESWL	
Age		48.27 (± 11.87)	41.49 (± 10.38)	P < 0.05
Sex	Male	60 (68.2)	53 (60.2)	0.271
	Female	28 (31.8)	35 (39.8)	
BMI		24.5 (23, 26)	25 (23, 26)	0.984
comorbidities	No	30 (34.1)	46 (52.3)	P < 0.05
	1	42 (47.7)	33 (37.5)	
	2	14 (15.9)	5 (5.7)	
	3	2 (2.3)	4 (4.5)	
Creatinine		0.95 (0.8, 1.1)	0.9 (0.8, 1.08)	0.825
side	Right	42 (47.7)	48 (54.5)	0.37
	Left	46 (52.3)	40 (45.5)	
Stone site	Upper pole	13 (14.8)	18 (20.5)	0.12
	Middle pole	19 (21.6)	17 (19.3)	
	Lower pole	41 (46.6)	28 (31.8)	
	Pelvis	15 (17)	25 (28.4)	
Stone size		1.4 (1.3, 1.5)	1.4 (1.2, 1.5)	0.318
Stone radio-opacity	Radio Opaque	73 (83)	71 (80.7)	0.696
	Radiolucent	15 (17.0)	17 (19.3)	
HU		1010 (900, 1180)	995 (900, 1127.5)	0.402
Stone-formers	Primary	78 (88.6)	73 (83)	0.28
	Recurrent	10 (11.4)	15 (17)	

Patients undergoing Retrograde Intrarenal Surgery often report faster symptom relief and greater confidence in stone clearance, although stent-related discomfort may offset this benefit. In contrast, Extracorporeal Shock Wave Lithotripsy is valued for its non-invasive, anaesthesia-free nature and minimal disruption to daily activities, despite requiring multiple sessions [21, 22].

In our study, validated PROMs showed greater median improvement after ESWL (7 points) than RIRS (5 points; P < 0.05), suggesting faster subjective recovery despite higher definitive clearance with RIRS. Stent-related discomfort may partly explain the delayed return to activity and lower PROM improvement in the RIRS group. These findings highlight the importance of patient experience alongside radiological outcomes.

Limitations include short follow-up (2 weeks), which may underestimate final ESWL clearance compared to longer follow-up protocols and also precludes assessment of long-term recurrence and renal functional changes; absence of stone composition analysis; lack of formal cost-effectiveness evaluation; single-centre design; and potential operator variability inherent to a teaching institution. Larger multicenter studies with longer follow-up and economic evaluation are needed to define the optimal patient selection between RIRS and ESWL.

CONCLUSION

Management of renal calculi measuring 10–20 mm should be individualised. RIRS offers superior single-session clearance with minimal retreatment, while ESWL remains a safe, non-invasive option with faster recovery and outpatient convenience. Incorporating patient-reported outcomes highlights that procedural success extends beyond stone clearance alone. Optimal treatment selection should therefore balance efficacy, safety, resource utilisation, and patient preference to deliver truly patient-centred care.

Declarations

Author Contribution

S.B and KS wrote the Amin manuscript text and collection and analysis of the data and S.G, R.M, S.K, R.P prepared graphs and figures and helped in data collection and analysis.All authors reviewed the manuscript.

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Tables

Table 1: **Baseline demographics and stone parameters**

Variable		Median (Q1,Q3)		Statistical Significance
	Category	RIRS	ESWL	(P-value)
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side	Right	42 (47.7)	48 (54.5)	0.37
	Left	46 (52.3)	40 (45.5)	
Stone site	Upper pole	13 (14.8)	18 (20.5)	0.12
	Middle pole	19 (21.6)	17 (19.3)	
	Lower pole	41 (46.6)	28 (31.8)	
	Pelvis	15 (17)	25 (28.4)	
Stone size		1.4 (1.3, 1.5)	1.4 (1.2, 1.5)	0.318
Stone radio-opacity	Radio Opaque	73 (83)	71 (80.7)	0.696
	Radiolucent	15 (17.0)	17 (19.3)	
HU		1010 (900, 1180)	995 (900, 1127.5)	0.402
Stone-formers	Primary	78 (88.6)	73 (83)	0.28
	Recurrent	10 (11.4)	15 (17)	

Table 2: **Perioperative and clinical outcomes**

Variable	Category	RIRS n (%)	ESWL n (%)	Statistical Significance
Mean procedure time		70 (60, 80)	45 (45, 50)	P**<0.05**
Time to return to normal Activity		5 (5,7)	4 (3,4)	P<0.05
Post operative hospital stay	£ 1 day	77 (87.5)	88 (100)	P<0.05
	> 1 day	11 (12.5)	0 (0)	
Residual calculus size	No residual calculus	67 (76.1)	59 (67)	0.324
	Less than or equal to 3 mm	15 (17)	18 (20.5)	
	More than 3 mm	6 (6.8)	11 (12.5)	
Stone Free Rate		93.2 %	87.5%	
complications	Grade 0	78 (88.6)	83 (94.3)	P<0.05
	Grade 1	8 (9.1)	2 (2.3)	
	Grade 3	0 (0)	3 (3.4)	
	Grade 4	2 (2.3)	0 (0)	
Need for retreatment	No	87 (98.9)	43 (48.9)	P<0.05
	Yes	1 (1.1)	45 (51.1)	
Total no. of RIRS/ESWL sessions	1	87 (98.9)	45 (51.1)	P<0.05
	2	1 (1.1)	28 (31.8)	
	3	0 (0)	15 (17)	
Need for auxiliary procedure	No	83 (94.3)	77 (87.5)	0.116
	Yes	5 (5.7)	11 (12.5)	
Median Reduction in Health Score		5 (4, 6)	7 (6,8)	P<0.05

Table 3: Comparative summary of clearance, retreatment, auxiliary procedure rates and complications in various ESWL vs RIRS studies

Study (Year)	Stone Clearance		Need for Re-treatment		Auxiliary Procedures		Complications	
	RIRS	ESWL	RIRS	ESWL	RIRS	ESWL	RIRS	ESWL
Pearle et al. 2005	72%	65%	6%	27%	-	-	21%	23%
Salem et al. 2013	97%	57%	3%	43%	-	-	17%	23%
Kumar et al. 2013	86%	74%	11.1%	61.1%	11%	20%	11.1%	6.6%
Singh et al. 2014	-	-	5.7%	65%	8%	45%	-	-
Vilches et al. 2015	71%	48%	8%	56%	8%	16%	37.5%	16.1%
Zhang et al. 2019	92%	73%	7%	49%	7%	23%	17%	6.7%
Bosio et al. 2022	48%	24%	9%	41%	12%	25%	20%	26.5%
Wiseman et al. 2024	72%	36%	12%	46%	9.1%	27%	20%	13%
MacLennan et al. 2025	-	-	~10%	~50%	~10%	40-50%	-	-
Our RCT	93.2%	87.5%	1.1%	51.1%	5.7%	12.5%	11.4%	5.7%

Figures

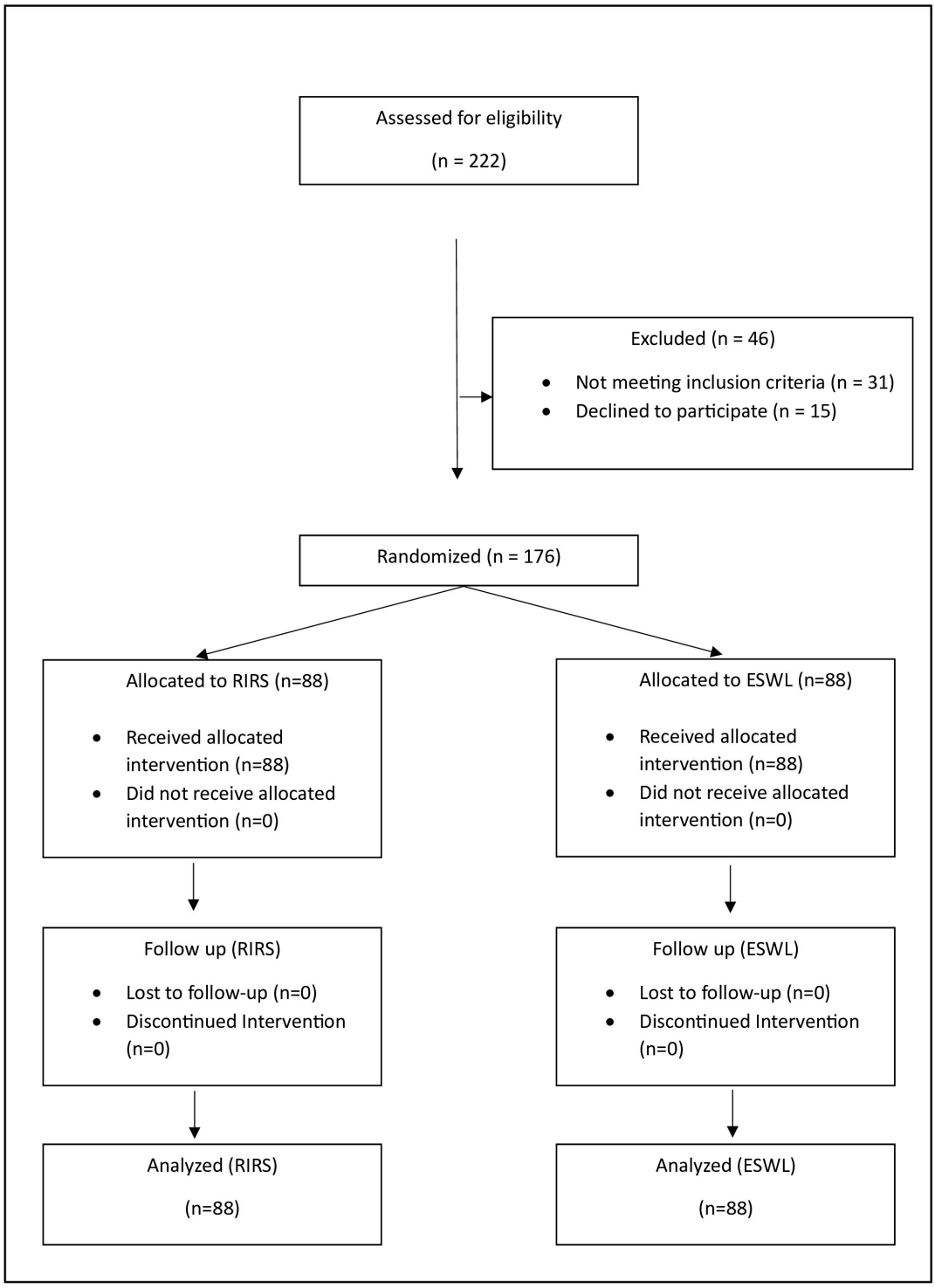


Figure 1

CONSORT Flow Diagram of Study Participants

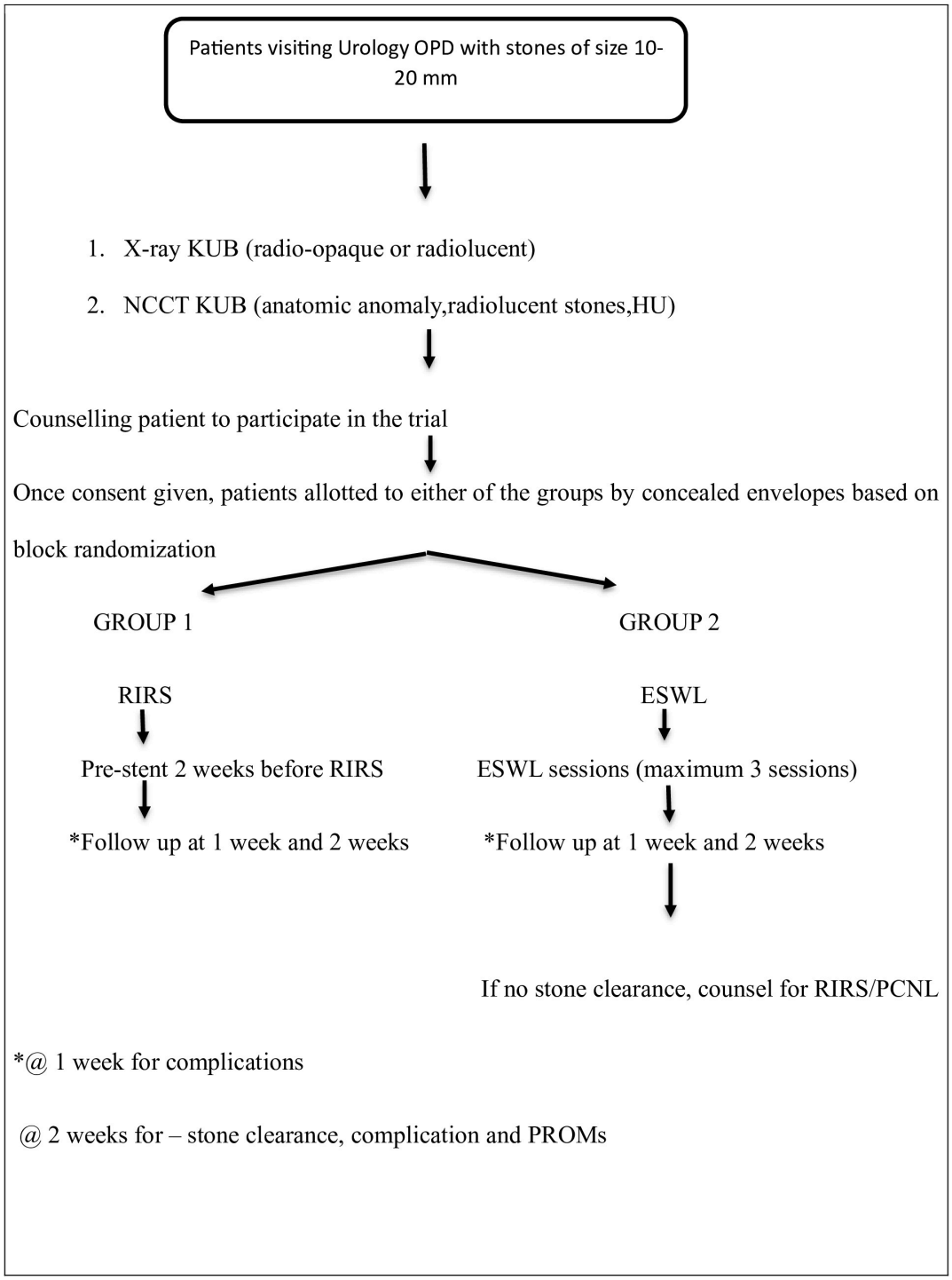


Figure 2

Flow chart for the study