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# EFFICACY AND SAFETY OF RETROGRADE INTRARENAL SURGERY (RIRS) FOR RENAL STONE CLEARANCE: A PROSPECTIVE INTERVENTIONAL STUDY.

*[1]Nikhil Ranjan, [2]Kumar Dheeraj, [2]Rakesh Kumar, [2]Gaurav Babelay**
*[1]Assistant Professor, Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.*
*[2]Senior Resident, Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.*



## Abstract

### Background

The management of kidney stones has advanced with the development of minimally invasive techniques like Retrograde Intrarenal Surgery (RIRS). RIRS, which employs flexible ureterorenoscopy and laser lithotripsy, is a highly promising and safe method for the removal of stones, even in complicated cases. Recent technological improvements have expanded its use, particularly for larger stones (> 2 cm), which were previously treated through percutaneous nephrolithotomy.

### Aims

This study seeks to assess the safety and efficacy of RIRS for renal stone clearance in adults. Key objectives include evaluating the success rate of stone removal and analyzing perioperative factors such as surgical duration, complications, and recovery.

### Methods

Conducted at IGIMS, Patna, this interventional investigation was performed on 20 adult patients with kidney stones over one year. The surgery utilized a Holmium laser for stone fragmentation, with post-procedural evaluation through X-ray imaging. Data on stone clearance rates, procedure time, complications, and recovery were collated to examine the procedure's safety as well as effectiveness.

### Results

The study included 20 patients with a greater proportion of males and a mean age of 33.4 ± 10.6 years. The stones were mainly located in the middle calyx (40%) and lower calyx (20%), with an average size of 1.06 ± 0.36 cm. RIRS achieved a 100% stone-free rate, with an average surgical duration of 90 ± 18.7 minutes and an average duration of hospitalization (approx. 4.6 days). Complications were minimal, with 90% classified as Grade I and 10% as Grade II. A second RIRS session was required in 10% of cases, and 20% of patients needed a postoperative blood transfusion.

### Conclusion

RIRS proved to be a promising treatment for renal stones, demonstrating high stone clearance rates with minimal complications. This technique offers a dependable alternative to traditional treatments, providing shorter hospital stays and manageable recovery outcomes.

**Keywords:** *Retrograde Intrarenal Surgery (RIRS), Renal Stones, Stone Clearance, Holmium Laser.*
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***Corresponding Author:*** *Gaurav Babelay*
***Email:*** *gaurav.babelay@gmail.com*
*Senior Resident, Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.*

## Introduction

The therapeutic management of renal stones has rapidly revolutionized with the advent of minimally invasive surgical techniques, offering patients more treatment choices and serving as alternatives to conventional open surgery [1,2]. Endoscopic methods, such as Extracorporeal Shock Wave Lithotripsy (ESWL) and Percutaneous Nephrolithotomy (PCNL), are becoming recognized as the standard procedures for removing kidney stones, owing to their advantages like quicker recovery times and fewer complications compared to traditional surgery [3-5]. Among these techniques, Retrograde Intrarenal Surgery (RIRS) has gained considerable recognition, especially for stones smaller than 2 cm. RIRS, which utilizes flexible ureterorenoscopy combined with laser lithotripsy, is now considered an efficient primary protocol for removing kidney stones in various patient populations, including those with complex conditions such as pediatric patients or those with anatomical anomalies [6-10].

With technological advancements, including the development of next-generation flexible ureteroscopes, Holmium lasers, and Thulium fiber lasers, RIRS has extended its capabilities to treat larger stones (greater than 2 cm), which were once managed primarily by PCNL. These innovations have enhanced the versatility of RIRS, enabling accurate stone fragmentation and removal with minimal damage to surrounding tissue [11,12]. The

increased adoption of RIRS has also been linked to shorter hospital stays, reduced postoperative discomfort, and faster recovery times, making it a preferred choice among both urologists and patients [13-15]. This study aims to assess the effectiveness and safety of RIRS in adult patients, focusing on stone clearance rates and associated perioperative outcomes.

## Aim of the study

This study seeks to scrutinize the effectiveness as well as safety of RIRS in clearing kidney stones in adult patients. The main objective is to evaluate the short-term stone clearance rate after the procedure. Secondary objectives include examining important perioperative factors, such as surgical duration, complication rates based on the Clavien-Dindo classification, postoperative pain intensity, hemoglobin (Hb) reduction, and the duration of hospitalization.

## Methods

### Study Setting

This research was conducted at the Indira Gandhi Institute of Medical Sciences (IGIMS), employing a prospective interventional design to examine the outcomes of RIRS in participants with renal stones. Eligible participants for RIRS were selected from the outpatient department (OPD), admitted for the procedure, and subsequently monitored for follow-up assessments.

### Study Population

The study involved 20 adult patients diagnosed with renal stones, all of whom underwent Retrograde Intrarenal Surgery (RIRS) at IGIMS, Patna. The study was conducted over one year, from November 2022 to November 2023.

### Inclusion Criteria

Participants eligible for inclusion met the following requirements: kidney stones measuring < 1.5 cm in diameter, aged over 18 years, and either male or female. The size of the stones was confirmed using non-contrast computed tomography (NCCT) before the procedure.

### Exclusion Criteria

Patients with chronic renal failure (CRF), and coagulopathy, who were on antiplatelet therapy, had an active urinary tract infection (UTI), or exhibited abnormalities in the kidney anatomy were not part of this investigation. These exclusions were made to ensure an accurate evaluation of RIRS outcomes without external confounding factors.

### Study Method

Eligible patients were admitted from the outpatient department (OPD) and underwent comprehensive preoperative evaluations, including CT urography or NCCT KUB with intravenous pyelography (IVP), and standard laboratory tests. Patients were administered general anesthesia and asked to lie in the lithotomy position. A cystoscope was first used to insert the Roadrunner guidewire in the ureter. A 10F, 40 cm ureteric access sheath was then inserted above the guidewire under C-arm guidance. Retrograde pyelography (RGP) was conducted through the access sheath to visualize the urinary tract. A flexible ureteroscope (Flex-X2) was advanced through the access sheath to the target calyx under C-arm guidance. A Holmium laser fiber (200 μm) in dusting mode was placed via the working channel of the ureteroscope to fragment the stones. Stone clearance was verified through C-arm imaging, and a Double-J (DJ) stent was used to complete the procedure.

### Study Design

This observational study was prospective and designed to take place at IGIMS, Patna, on 20 adult patients with renal stones over a one-year duration. Data on stone clearance, operative time, complications, postoperative pain, hemoglobin (Hb) levels, and hospital stay were collected for analysis.

### Data Collection

Data gathered included operative time, complications grouped according to the Clavien-Dindo system, postoperative pain scores, pre- and post-procedural hemoglobin (Hb) levels, and duration of hospitalization. Postoperative stone clearance was evaluated using an X-ray of the kidney, ureter, and bladder during follow-up to confirm the procedure's success.

### Statistical Analysis

Descriptive statistics helped to analyze categorical variables, while continuous variables were expressed as mean ± standard deviation (SD). Stone clearance rates as well as complication data were noted, and the outcomes were contrasted against standard RIRS benchmarks to assess the effectiveness of the procedure.

## Results

This study observed a majority male population with a ratio of 4:1, with a mean age of 33.4 years. Most stones were located in the middle calyx (40%) and lower calyx (20%), with a mean size of 1.06 ± 0.36 cm. Patients with multiple stones made up 30% of the cases, while 70% had single stones. Preoperative DJ stenting was required for 40% of patients, and the majority of cases (80%) were primary indications for RIRS. These characteristics reflect a typical demographic profile for renal stone cases requiring intervention, with most cases amenable to a single-stone approach (Table 1).

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**Table 1: Patient characteristics and demographic profile (n=20)**

| Parameter | Value |
|---|---|
| Age (years) | 25-45 (Mean: 33.4 ± 10.6) |
| Sex Ratio (Male: Female) | 4:1 |
| Stone Size (cm) | 0.7 - 1.5 (Mean: 1.06 ± 0.36) |
| Stone Location | Pelvis: 4 (20%) |
| | Middle Calyx: 8 (40%) |
| | Lower Calyx: 4 (20%) |
| | Upper and Lower Calyx: 2 (10%) |
| | Middle & Lower Calyx: 2 (10%) |
| Multiple Calyces | 4 (20%) |
| Number of Stones | Single: 14 (70%) |
| | Multiple: 6 (30%) |
| Preoperative DJ Stenting | 8 (40%) |
| Indication for RIRS | Primary: 16 (80%) |
| | Residual Post-ESWL: 4 (20%) |

All 20 patients successfully underwent ureteral access sheath placement, and the mean operation time was 90 min. Duration of hospitalization averaged 4.6 days, with a 100% SFR achieved. In this study, a mere 10% of patients only needed a second RIRS session within the same admission and postoperative complications were minimal, with 90% classified as Grade I (Clavien-Dindo) and only 10% as Grade II (Clavien-Dindo). These results suggest that RIRS is effective and has a high safety profile in achieving complete stone clearance with minimal complications and short hospital stays. The need for additional sessions and blood transfusions in a few cases highlights manageable risks within this patient population (Table 2).

**Table 2: Intraoperative and Postoperative Outcomes (n=20)**

| Parameter | Value |
|---|---|
| UAS Placement | Possible in 20 (100%) |
| Operation Time | 40 - 110 min (Mean: 90 ± 18.7 min) |
| Hospital Stay | 3 - 8 days (Mean: 4.6 ± 1.9 days) |
| Stone-Free Rate (SFR) | 100% |
| Need for Second RIRS Session | 2 (10%) |
| Postoperative Blood Transfusion | 4 (20%) |
| Clavien-Dindo Complication Rate | Grade I: 18 (90%) |
| | Grade II: 2 (10%) |

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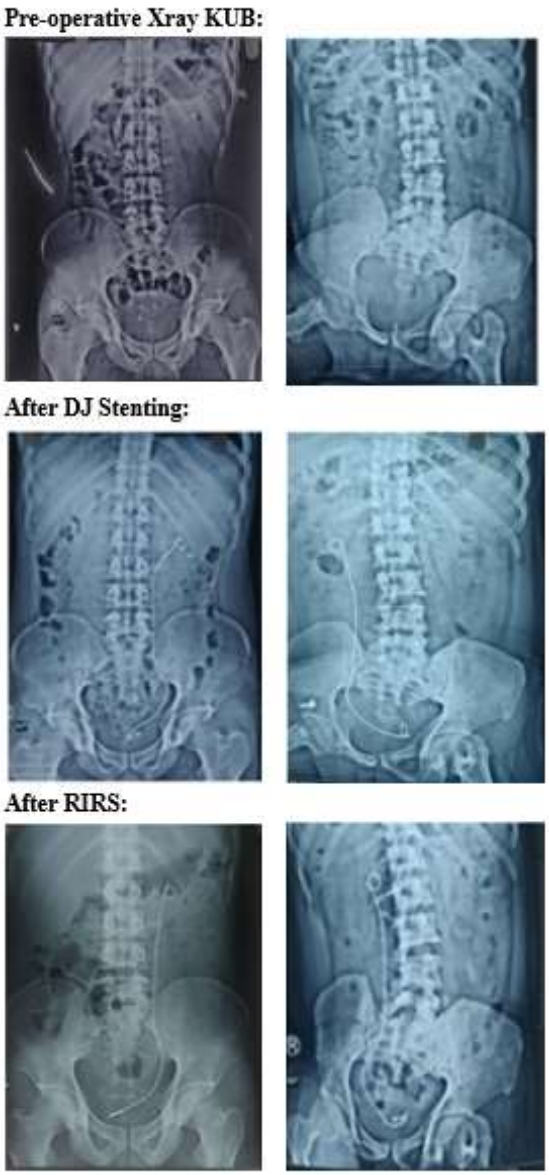


**Figure 1: X-ray results of 6 patients undergoing RIRS.**

## Discussion

Although in 10% of cases, we needed a second RIRS within the same admission, our research achieved a 100% stone-free rate (SFR) following RIRS for renal stones < 2 cm (1.5 cm) surpassing earlier investigations, which reported SFRs ranging from 69.7% to 89.2% [16, 17]. The location, size, and composition of the renal calculi were capable of affecting the SFR, with a prior study involving 66 RIRS cases indicating that lower pole stones, a higher total stone burden, and multiple stones contributed towards lower SFR [16].

In this study, the location of the renal calculi had no significant impact on the SFR, aligning with the findings of Perlmutter et al., wherein no notable variations in SFR based on stone location [18]. Specifically, for lower-pole stones, the SFR remained 100%, which is notably higher than the 50% SFR for lower-pole stones under 1 cm reported by Pearle et al. [19].

Additionally, the SFR in this study was unaffected by whether RIRS was carried out as a primary or secondary procedure. Primary RIRS was performed in 80% of the cases, while secondary RIRS, after post-ESWL, was performed in 20% of the cases. This indicated that RIRS is equally effective in achieving complete stone clearance regardless of prior treatments. While some studies suggest that ESWL and RIRS have similar effectiveness for lower-pole stones under 1 cm [19], secondary RIRS may involve more challenging cases, which could influence the success rate.

With a 100% SFR in this study, 80% of patients become stone-free in a single setting, while 20% of patients require a second setting within the same admission. The consistently high success rate supports the effectiveness

of both primary and secondary RIRS procedures. Although we did not assess differences in stone composition or density between primary and secondary cases, this could provide additional insights into the outcomes. Previous studies have utilized non-contrast spiral CT to examine stone characteristics and link them to composition and hardness [20]. Future research incorporating stone composition data could offer a more comprehensive understanding of these factors.

Regarding complications, this study recorded a Grade II complication rate of 10%, which is relatively low compared to other studies, such as the one by Lim et al., which reported a 6% complication rate [4,5,16]. The complications in our study were mostly minor & the majority of which fall under Clavien-Dindo Grade I (90% of cases) and II (10% of cases) issues, with no major adverse effects, thereby demonstrating that RIRS has a success rate and a reduced complication rate.

Although Blood transfusion rates were higher (20% cases), this reflects our learning as this is a new modality to us as this has not been reported in earlier studies [21,22]. Excessive manipulation of instruments causes damage to calyces & renal parenchyma, prolonged lasing time causes continuous mucosal bleed & high irrigation pressure causes capsular or parenchymal damage. These are some reasons associated with blood loss.

The study's high SFR could be attributed to the selective inclusion criteria, as it only involved patients with kidney stones < 15 mm and normal renal anatomy. Moreover, the use of an X-ray renal system to assess residual stones may have limitations in detecting smaller fragments when compared to CT imaging. Additional limitations include the relatively small sample size and the focus on short-term SFR, without assessing long-term outcomes. While further research is recommended, the results of this study suggest that RIRS should be considered as a first-line therapeutic approach for renal calculi in appropriate cases.

## Conclusion

This study demonstrated that RIRS is highly efficient and safe for the treatment of renal calculi, with a 100% stone-free rate as well as minimal post-surgical adverse effects. The protocol was effective in all patients, with an average surgery duration of 90 min and an average duration of hospitalization of 4.6 days. In this study, most of the complications were mild (Grade I), with only a small proportion requiring additional interventions. These findings suggest that RIRS is a highly efficient, minimally invasive option for renal stone management, offering excellent stone clearance rates and a favorable safety profile. Moreover, on account of its increased rates of success and reduced rates of complication, RIRS is a promising protocol that can serve as a first-line therapeutic option for the treatment of renal calculi.

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