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Comparison of Conventional Percutaneous Nephrolithotomy and Endoscopic Combined Intrarenal Surgery with Respect to Efficacy and Safety in Complex Renal Stone

Dr. Prabhav Agarwal[1], Dr. Vikram Satav[2], Dr. A Mulay[3], Dr. Vilas Sabale[4], Dr. Shashikant Asabe[5], Dr. Ashish Gavade[6*]

[1]Resident, Dr D.Y. Patil Medical College and Research Centre and Hospital, Dr D.Y. Patil Vidyapeeth Pimpri, Pune.
[2]Professor, Dr D.Y. Patil Medical College and Research Centre and Hospital, Dr D.Y. Patil Vidyapeeth Pimpri, Pune.
[3]Professor, Dr D.Y. Patil Medical College and Research Centre and Hospital, Dr D.Y. Patil Vidyapeeth Pimpri, Pune.
[4]Professor and HOD-Dr D.Y. Patil Medical College and Research Centre and Hospital, Dr D.Y. Patil Vidyapeeth Pimpri, Pune.
[5]Professor, Dr D.Y. Patil Medical College and Research Centre and Hospital, Dr D.Y. Patil Vidyapeeth Pimpri, Pune.
[6]Resident, D.Y. Patil Medical College and Research Centre and Hospital, Dr D.Y. Patil Vidyapeeth Pimpri, Pune.*

Corresponding author:** **Dr. Ashish Gavade
ADDRESS: Dr D.Y. Patil Medical College and Research Centre and Hospital, Dr D.Y. Patil Vidyapeeth Pimpri, Pune.
Email: pie.agarwal@gmail.com

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Abstract

Background: When PCNL and RIRS alone are unable to completely clear complex renal calculi, a combination of the two modalities was tested. Endoscopically Combined Intra Renal Surgery (ECIRS) is name given to this procedure afterwards. It excludes the drawbacks of multi-puncture PCNL and simultaneously provides much higher stone free rates. ECIRS is a relatively new tool in the arsenal of urologists, and as of right now, there isn't much information available in developing nations.
Methods: A Comparative Observational study where 40 patients were split into two groups of 20, one for ECIRS and the other for prone PCNL. Both groups' surgical times, stone removal rates, potential complications, and other post-operative results were compared.
Results: The majority of the patients (26) were men between the ages of 36 and 45, and both the group's age and gender were similar. The average calculus size was 2.43 cm for the ECIRS group and 2.60 cm for the prone PCNL group. Mean duration of the surgery was 85.24 & 88.12 min in ECIRS and prone PCNL group respectively. In the ECIRS group, the stone-free rate was considerably greater with lesser requirement of additional punctures and blood transfusions. More ancillary procedures prone PCNL patients' hospital stays were observed, as well. Post-operative S. urea and S. creatinine, fever, pain, post-operative complications were comparable.
Conclusion: In view of the findings of the study, ECIRS seems to be a better

CC License CC-BY-NC-SA 4.0	option in comparison to prone PCNL in terms of effectiveness and safety. **Keywords**: Ancillary procedures, Retrograde Intra Renal Surgery (RIRS), ECIRS, PCNL, stone free rate (SFR).

1. Introduction

Complex renal stones are characterized by many regardless of stones, anatomical/functional problems whether the stones are peripheral or branching, affecting about 10% of the population worldwide [1]. Renal calculi are usually asymptomatic until they reach a large size because of their pelvicalyceal anatomy. Some of these may be enlarged to occupy the complete pelvicalyceal system. The most difficult forms are staghorn stones, which have branching properties and usually have heavy stone loads and fill the renal pelvis and one or more calyces. [2]. Conventional percutaneous nephrolithotomy (PCNL) and endoscopic combined intrarenal surgery (ECIRS) are two surgical options available for breaking down complex renal stones.

PCNL is the most effective choice of treatment for staghorn calculi, according to the AUA regulations [3] and has been the recommended treatment since its introduction in 1976, having partial and whole staghorn stone stone-free rates (SFRs) of 98.5% and 71%, respectively [4]. Valdivia Uria proposed in 1987 that the supine decubitus position is a possible setting for PCNL, and revealed identical results and problems to PCNL was carried out while lying flat, with possible improvements in the administration of anesthesia and ergonomics [5]. Furthermore, the risk of colon perforation, which caused PCNL to be performed in the prone position, was found to be decreased in the supine position [5]. However, in circumstances where the stone burden is high, PCNL is not the only choice.

Dr. CM Scoffone invented ECIRS in 2008 and performed the procedure in the Galdakao-Modified Supine Valdivia (GMSV) position, which is an adaptation of the prone position [6]. ECIRS sought to improve one-step urolithiasis resolution while minimizing the number of access tracts. ECIRS is a recent addition to the urologist arsenal and there is still no agreement on whether ECIRS is superior in terms of surgical time, hospital stay, or even stone-free rate or problems.

We undertook this study to examine the differences between the two methods, evaluate their effectiveness in terms of stone clearance, complications and recovery time, analyze their respective benefits and drawbacks and determine which method is more suitable for breaking down complex renal stones. By doing so, we aim to provide a comprehensive understanding of these two surgical approaches and offer valuable insights to guide clinical decision-making.

2. Materials and Methods

A Comparative observational study was conducted at our tertiary care hospital in Pune. Pregnant women, patients with positive culture growth and with coagulopathies were excluded whereas patients who were > 18 years and had complex renal stones in the form of staghorn calculus, multiple stones and those associated with anatomical and functional abnormalities were included in the study.

Ethical approval was taken prior the enrollment. The patient was informed and explained in detail about the study, after which the patient's written consent was obtained in their preferred locallanguage. The data was collected and entered with a specially designed Performa, consisting of pre-anesthetic evaluation, essential laboratory investigations, and pre- and post-operative subjective and objective measures.

The patients were allocated into groups of two. Patients in the first group underwent prone PCNL, while ECIRS was performed in the other. A comprehensive pre-operative evaluation, which included basic patient characteristics, history, routine blood tests, urine tract radiograph (KUB plain film), urine system,color ultrasoundand abdominal CT (NCCT and CECT with reconstructive images) to confirm single or multiple stones, was performed. Intraoperative findings were noted during the procedure in relation to the number of punctures in PCNL, time taken for the procedures, efficacy, and complications of the procedure. The patient was closely monitored and assessed following the procedure. Postoperative blood testing included CBC, serum creatinine and electrolytes, blood urea, in both the groups. The Clavien technique was used to classify surgical complications.

Prone PCNL:
General anesthesia was used during the surgery. Retrograde ureteral catheterization was performed in the lithotomy posture. The desired calyx was punctured in the prone position. Teflon dilators were used to dilate the tract, and an Amplatz sheath (14F - 28F as needed) was inserted. Depending on the stone load and diameter of the tract, a rigid Storznephroscope (standard 18F or miniperc 12F) was used for Nephroscopy, and an EMS lithoclast or holmium laser was used for stone fragmentation. Fluoroscopy and nephroscopy together confirmed that no stones were present during surgery. A nephrostomy and double-J stent were placed in each patient.

ECIRS
General Anesthesia was used for performing ECIRS. The patients were placed in a 15-degree tilted modified Barts supine position. First, after stent removal semi-rigid ureteroscopy was performed to passively dilate ureters. Second, a size (10/12 Fr) ureteral access sheath of 10/12 Fr size was passed over the guidewire up to the upper ureter. A flexible ureterorenoscope (f-URS) was placed within the ureteral access sheath. Under fluoroscopic and f-URS guidance, calyceal puncture was performed. Teflon dilators were used to dilate the tract, and an amplatz sheath (14F–28F as needed) was inserted. Depending on the stone load and diameter of the tract, a rigid Storznephroscope (standard 18F or miniperc 12F) was used for nephroscopy, and an EMS lithoclast or holmium laser was used for stone fragmentation. Intraoperative stone-free status was confirmed using a combination of fluoroscopy and flexibleureteroscopy. A nephrostomy and a double-J stent were placed in each patient.
Follow-up of patients:
To determine the SFR, after three months of surgery an NCCT scan was done. The absence of residual stones or the presence of asymptomatic, clinically trivial residual pieces of 4 mm or less after three months of surgery were utilized to calculate the success rate.

Statistical analysis
The mean and standard deviation were used to present the quantitative data whereas quantitative and categorical data were displayed as proportions and absolute numbers. The statistical study was built on Student's t-tests for continuous data and chi square test for categorical variables. The significance test was conducted using the chi square method. For comparison of quantitative outcome measures, the student t test was utilized. Based on a Z-test with a 95% level of significance, the final interpretation was made. A Statistics were considered significant at a P value of 0.05. The statistical analysis was performed using the SPSS program, version 20.0.

3. Results

Forty patients were split into two groups of 20, one for ECIRS and the other for prone PCNL. Most patients (n=15) were between the ages of 36 and 45 (37.50%), followed by those between the ages of 26 and 35 (n=11; 27.50%), 46 to 55 years (n=6, 15%), 16 to 25 years (n=3, 7.50%), 56 to 65 years (n=3, 7.50%), and 66 to 75 years (n=2; 5.00%). 80% of the individuals studied were between the ages of 26 and 55. Most of the patients (26 / 65.00%) were male. When comparing the P-values for both groups, age and gender were insignificant.
The average stone size was 2.43 cm in the ECIRS group and 2.60 cm in the prone PCNL group. Statistics showed that the P-value was 0.49, which was not significant. (Table 1)

	ECIRS group	prone PCNL	P-value
Number of patients requiring additional punctures	Nil	4	0.004
Stone Free Rate	90%	80%	0.024
Mean Hb drop	0.37gm/dl	0.61gm/dl	0.043
Mean post-operative S. creatinine difference	0.19	0.21	0.41
Ancillary Procedures	2	4	0.023
Mean duration of hospitalization (days)	4.42	4.79	0.032
Incidence of fever	1	2	0.52
Patients with post op pain on smiley scale ≦**5**	18	14	0.087
Mean post-operative TLC	9.87	10.75	0.287
Time on average from position (mins)	85.24	88.12	0.176
Time on average after a puncture (mins)	55.32	57.28	0.296
Time on average before puncture (mins)	29.92	30.84	0.198

4. Discussions

Stone disease of the urinary system is a major health problem and can lead to urosepsis, blockage, and gradual kidney damage. Therefore, complete stone removal is necessary to preserve renal function, relieve blockage, and get rid of the infection's source.
The results of this study's evaluation of 40 patients who had urolithiasis were compared to those of individuals who underwent ECIRS or conventionally prone PCNL and determined that ECIRS was superior to PCNL in terms of residual stones, number of punctures, fall in haemoglobin, and ancillary procedures.
The majority of the patients (n = 15) were male (65%), 26 were in the range of 36–45 age, and 12 were in the ECIRS group and 14 were in the prone PCNL group. With 6 in the prone PCNL group and 8 in the ECIRS group, 14 patients (or 35% of the population) were female. Both groups compared similarly in terms of age and gender. Similar research was conducted

on 149 patients with staghorn calculi by Singla M et al. [7] where 118 males and 31 women, had a mean age of 39.8 years.

The mean stone size was 2.43 cm in the ECIRS group and 2.60 cm in the prone PCNL group. The P value was 0.49, which was not significant. This means that the average stone size in both groups was comparable.

There was a significant difference between the two groups in the number of participants in the current study for punctures needed. In contrast to none in the ECIRS group, four patients in the prone PCNL group required more than one puncture. It was found that the P value was 0.004. The findings of our study are equivalent to those of most of the authors. In their systematic study of 666 patients who underwent ECIRS, **Cracco et al. [8]** concluded that in most instances, only a single tract is sufficient. Prospective research by **Scoffone et al.** [6] in 2008 that included 127 patients with ECIRS likewise found that 98.4% of patients used a single tract. Like this,

In some instances, the stone may only have been partially removed, leaving left over stones. Remaining stones were present in our investigation in 2 (10%) ECIRS patients and 4 (20%) prone PCNL patients. At 0.024, the p value was significant. The SFR in investigations by **Cracco et al. [8]** was similar. SFRs of 82% to 97% were recorded in 666 patients who underwent ECIRS. In prospective research by **Scoffone et al. [6]** in 2008, which included 127 patients, the SFR was 82 percent, with 98.4 percent of patients having a single tract.

A significant sign of a patient's post-operative morbidity is post-operative discomfort. 90% of patients in the ECIRS group had a smiling scale score of less than 5, compared to 70% in the group with prone PCNL. The remaining patients made up 30% of the prone PCNL group and 10% of the ECIRS group, experienced higher pain intensities of more than 5. When the P value for the two groups was compared, it was not significant. It is clear that the patients in the prone PCNL group have had more discomfort as a result of the increased number of punctures.

The preoperative Hb of both groups was similar. In comparison to the ECIRS group, the post-operative Hb of the prone PCNL group was statistically lower. This suggests more blood loss in multi-tract prone PCNL when both procedures are compared with a P value of 0.043. The mean Hb drop was 0.37 gm% and 0.61 gm% in ECIRS and in the prone PCNL group, respectively. Similar results were seen in the multiple studies where they concluded given that ECIRS is often performed through a single tract, the reduced bleeding risk of ECIRS—which is illustrated by the confined hemoglobin drop and the decreased TRs, 0.5%–3% versus 6.1%–7% for the typical prone PNL and 4.3% for the supine—is evident and entirely understandable. [9,10,11,12]

The total leucocyte count did not differ significantly between the two groups when the results of the operations were compared. The mean difference in change in creatinine levels between the two groups was likewise not statistically significant. No statistically significant differences between the two procedures' mean increases in creatinine values were found by Akman et al. [13], who evaluated 413 patients having multiple-tract PCNL.

Two patients in the prone PCNL group and one patient in the ECIRS group experienced a transitory fever for 48 hours after surgery. With a P value of 0.52, the comparison was not significant. There was no detectable difference in the incidence of postoperative fever in a systematic review by Liu C et al. [14].

In ECIRS and Prone PCNL, holmium laser lithotripters were utilized in 9 and 6 patients, respectively, whereas pneumatic lithotripters, or lithoclast, were employed in 15 and 14 patients, respectively.

The mean time of operation from position was 88.12 minutes for the prone PCNL group and 85.24 minutes for the ECIRS group. The time from location is comparable between the two

groups, according to the P value of 0.176. Six trials were included in a thorough analysis by Y H Liu et al. [15] that found no discernible difference in operational time.
The prone PCNL group's average length of stay was 4.79 (SD: 0.80) days compared to 4.42 (SD: 0.53) days in the ECIRS group. Prone PCNL patients stayed longer in the hospital, and the difference was statistically significant. It is a highly variable parameter because it strongly depends on regional hospital protocols**. Y H Liu et al. [15]** in their meta-analysis of six studies did not observe any difference in the duration of hospitalisation between the two procedures. In our study, the number of complications with prone PCNL was slightly higher attributable to a greater number of punctures, leading to a greater drop in haemoglobin and a greater need for ancillary procedures. This could have possibly led to an overall increased duration of hospitalisation in our study.
In total, 2 patients in the ECIRS group and 4 patients in the prone PCNL group required ancillary procedures. P value came in at 0.023. The remaining two patients in the prone PCNL group had undergone second stage PCNL, while two patients in the ECIRS group and two patients in the prone PCNL group underwent RIRS. In comparison to the ECIRS group, the prone PCNL group had a much higher demand for ancillary operations. This finding of ours is in accordance with the findings of **Cracco et al.** [8] in their systematic reviews and meta-analyses. They concluded that ECIRS apparently implies less need for ancillary procedures. Even with heavy stone loads, it is a flexible process for one-step total removal.

Due to several issues, including the need for two surgeons and two endovison systems, extra expense, and perhaps longer operating times, ECIRS is still not widely used. However, these worries need to be re-examined because the benefits of ECIRS, such as the removal of potential complications like blood transfusion and the improved SFR, which reduces the need for supplemental therapies and the expenses connected with them, exceed their drawbacks to a greater extent.

5. Conclusion

With the introduction of supine PCNL and tools like mini-PCNL, ultra-mini, and micro-mini, prone PCNL has been steadily evolving over the past 40 years at a very quick rate. In addition, the introduction of smaller diameter high-quality digital flexible ureteroscopes with high-quality images has revolutionised the RIRS. As observed in this study, when treating complicated renal stones, ECIRS is more successful and safer than standard prone PCNL. Because ECIRS has a higher SFR, it requires fewer ancillary procedures and a shorter hospital stay, reducing the overall cost burden, fewer overall complications, fewer access tracts, minimizing renal parenchymal loss, and requiring fewer transfusions than conventional prone PCNL. The requirement of two endovision systems, two surgeons, a flexible ureteroscope, and a compulsory laser might increase the cost, but to some extent, the benefits of ECIRS may exceed the drawbacks.
We suggest further research by recruiting more participants and contrasting ECIRS with the prone position when carrying out the PCNL technique.

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