Learning Curve for Endoscopic Combined Intra-Renal Surgery Using Vacuum-Assisted Device

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Abstract
Introduction: The aim of the study was to provide data related to endoscopic combined intra-renal surgery learning curve using minimally invasive techniques with vacuum-assisted devices. Minimal data exist on the learning curve for these techniques. ***Methods:*** We conducted a prospective study monitoring the training of a mentored surgeon learning ECIRS with vacuum assistance. We use varied parameters for improvements. After collection of peri-operative data, tendency lines and CUSUM analysis were used to investigate the learning curves. ***Results:*** 111 patients have been included. Guy's Stone Score 3 and 4 stones 51.3% of all cases. The mostly used percutaneous sheath was 16 Fr (87.3%). SFR was 78.4%. 52.3% patients were tubeless, and 38.7% achieved trifecta. High-degree complication rate was 3.6%. Operative time improved after 72 cases. We observed a decrease of complications throughout the case series, with improvement after 17 cases. In terms of trifecta, proficiency was reached after 53 cases. Proficiency seems achievable in a limited number of procedures, but results did not plateau. Higher number of cases might be necessary for excellence. ***Discussion:*** A surgeon learning ECIRS with vacuum assistance can obtain proficiency in 17–50 cases. The number of procedures required for excellence remains unclear. Exclusion of more complex cases might positively affect the training, re-ducing unnecessary complications.

Introduction

Despite a long history since its initial description, PCNL still remains a challenging procedure and therefore Extracorporeal Shock Wave Lithotripsy (ESWL) and Retrograde Intra-Renal Surgery (RIRS) are preferred due to their lower risk of complications, including bleeding, infections, and pain [1]. Its complexity might discourage junior specialists from getting involved with PCNLs. On the other hand, experienced surgeons might be unmotivated in adopting "modernized techniques" as it may be associated with suboptimal results during the initial learning.

The percutaneous tract size is one of the important factors influencing peri-operative bleedings [2] and pain [3]. Jackman et al. and Helal et al. in 1997 described for the first time "mini-PCNL" in children using a 11–15F sheath [4]. It was then extended to adults and nowadays is widely diffused [5]. Recently, many refinements have been introduced, and minimally invasive PCNLs with vacuum-assisted devices (VDs) [6, 7] seem to reduce operative times (OTs) and maintain a low (the) intra-renal pressure [8]. Moreover, supine positions for PCNLs have been adopted [9], facilitating also the endoscopic combined intra-renal surgery (ECIRS) [10]. Outcome comparison between different techniques remains lacking, and the choice is left to endourologists. Currently, no data exist in regard to learning curves (LCs) for ECIRS and its combination with VDs. Herein, we describe peri-operative outcomes of this approach, and we also discuss the LC of a mentored surgeon learning ECIRS.

Materials and Methods

Study Population

We conducted a prospective, observational, non-interventional, single-center study on consecutive patients who have undergone ECIRS and completed at least 3 months of follow-up. The study was conducted after local ethical approval.

Inclusion criteria were patients aged >18, stones >20 mm of cumulative stone diameter or smaller if unsuitable for RIRS or ESWL. Miniaturized PCNL was defined as <22 Fr. We used ClearPetra© percutaneous sheath (Wellead, Guangzhou, China) as VD.

Exclusion criteria included pregnant patients or aged under 18, stone in caliceal diverticula or secondary to pyelo-ureteric junction obstruction (confirmed by MAG-3 renogram). An unenhanced CT scan of the abdomen/pelvis (NCCT) had to be performed within 3 months before surgery. Baseline demographic/pre-operative data included age, sex, age-adjusted Charlson comorbidity index, laterality, cumulative stone diameter (mm), stone volume in mm^3 (the formula $0.785 \times \text{length} \times \text{width}$) [11], skin-to stone distance (mm), number of calices involved (1, 2, 3, or staghorn), mean stone density (HU, evaluated in CT scan bone window), stone location (renal pelvis, lower pole, interpole, upper pole, or multiple sites), presence and degree of hydronephrosis (absent, mild, moderate, severe), previous treatment on the same kidney (SWL, ureteroscopy, PCNL, or multiple treatments).

Stone complexity has been reported using two different STONE nephrolithometric nomograms, specifically the Guy's Stone Score (GSS) [12] (cases divided into 4 subgroups) and the STONE Score [13] (cases divided into low complexity scoring 4–5, medium complexity scoring 6–8, and high complexity scoring >8). Intra-operative data included maximum tract diameter (Fr), number of punctures, level of upper puncture (below 12th rib, below 11th rib, below 10th rib), utilized drainages (both ureteric stent and nephrostomy, only ureteric stent named as tubeless, avoidance of any drainage named as totally tubeless), fluoroscopy time (FT), OT calculated from insertion of scope into the urethra to completion of drainage(s) placement. Moreover, achievement of trifecta for PCNL was reported (avoidance of nephrostomy tube placement, absence of residual fragments equal or greater than 2 mm, and absence of complications equal or greater than 1 according to Clavien-Dindo [CD] classification) [14].

Post-operative data included length of stay (LOS) expressed as days from treatment to decision to discharge, stone biochemistry, complications within 30 days from surgery (defined accordingly to CD score modified for PCNLs [15]). The stone-free rate (SFR) was verified at 2–3 months post-operatively with NCCT. The cut-off for residual fragments was 2 mm as this would include existing Randall's plaques.

Cumulative stone diameter, stone surface, and stone volume have been calculated and agreed by two experienced fully trained urologists not involved with the surgeries and blinded from clinical results. All patients have been contacted at 30 days post-operatively for assessment of complications. If present, they have been graded in agreement by two trained urologists. The assessment of residual fragments has been carried out by a trained radiologist blinded from operations results. In this study, data and outcome presentation have been conducted in agreement with International Alliance of Urolithiasis (IAU) Consensus on standardized reporting outcomes of PCNLs [16].

Surgical Technique/Peri-Operative Work-Out

Procedures were conducted in modified Galdakao supine Valdivia position [10]. After initial retrograde pyelogram, a ureteric access sheath was placed. A preliminary retrograde flexible ureteroscopy was then carried out to assess the caliceal system. Once the ideal calix was identified, the percutaneous puncture was carried out using a combination of ultrasound and X-rays with an 18 G needle. The puncture and the dilatation were retrogradely assisted (Endovision). In all cases, when technically possible, a percutaneous safety guidewire was placed into the ureter. The ClearPetra© percutaneous sheath was inserted over a second guidewire after preliminary single-step dilation. The sheath size varied from 14 Fr to 22 Fr, and the decision on the appropriate sheath caliber was determined in consideration of case complexity and stone size. In case of a 14 Fr sheath, the percutaneous scope was 8 Fr (Karl Storz©, Tuttlingen, Germany). In case of 16 Fr sheath, a 12 Fr Karl Storz© nephroscope was used. In case of a 22 Fr sheath, the scope was Karl Storz® 18 Fr. Lithotripsy was carried out with Ho-YAG laser for 14 Fr and 16 Fr ECIRS (in the first case, a 365 micron fiber was used, 550 microns for the latter). In terms of laser setting, the maximum power never exceeded 40 Watts, and the irrigation was cold with a pressure of 190 mm Hg generated by automated infusion pump. ClearPetra® was connected to aspiration with a negative pressure of 150 mm Hg. In case of 22 Fr ECIRS, Shockpulse© lithotriptor (Olympus©, Shinjuku, Tokyo, Japan) was used with a 10.2 Fr probe. At completion of lithotripsy, all calices were assessed both percutaneously and retrogradely to identify residual fragments. Residual fragments not accessible percutaneously were relocated with the flexible ureteroscope ("pass-the-ball" technique). In case of fragments unsuitable for repositioning, we evaluated whether to perform an additional percutaneous puncture or treat them in place with a flexible scope, used either retrogradely or antegradely. After complete stone clearance, the ureter was re-assessed. A ureteric double-J stent was inserted in all cases, and decision was made whether to place a percutaneous nephrostomy tube. Reasons for placement were need to re-access the urinary tract,

Table 1. Baseline characteristics of the 111 patients undergone ECIRS with VD

Variable	
Patients, *n* (%)	111 (100.0)
Age, median (IQR), years	58 (49.5–67.0)
Gender, *n* (%)	
Male	66 (59.5)
Female	45 (40.5)
Age-adjusted CCI, *n* (%)	
0	35 (31.5)
1	58 (52.3)
2	13 (11.7)
≥3	5 (4.5)
Stone side, *n* (%)	
Right side	47 (42.3)
Left side	64 (57.7)
Horseshoe kidney, *n* (%)	3 (2.7)
Maximum stone diameter, median (IQR), mm	20.0 (17.0–30.0)
Stone size, median (IQR), mm^2	314.0 (200.0–463.5)
Stone volume, median (IQR), mm^3	14,130 (2956–33,493)
Hydronephrosis, *n* (%)	
None	47 (42.3)
Mild	40 (36.0)
Moderate	17 (15.3)
Severe	7 (6.3)
Skin-to-stone distance, median (IQR), mm	98.0 (83.5–116.0)
Calyces involved, *n* (%)	
1–2	60 (54.1)
3	25 (22.5)
Staghorn	26 (23.4)
Stone density, median (IQR), HU	900.0 (602.0–1109.5)
Stone location, *n* (%)	
Upper calyx	5 (4.5)
Interpole calyx	2 (1.8)
Lower calyx	8 (7.2)
Renal pelvis	42 (37.8)
Multiple	54 (48.6)
Prior treatment, *n* (%)	
None	31 (27.9)
ESWL	18 (15.4)
URS	1 (0.9)
PCNL	6 (5.4)
Multiple	56 (50.9)
Guy's scoring system, *n* (%)	
1	31 (29.9)
2	23 (20.7)
3	43 (38.7)
4	14 (12.6)
STONE score, *n* (%)	
Low complexity	18 (16.2)
Medium complexity	64 (57.6)
High complexity	29 (26.2)
Positive pre-operative culture, *n* (%)	7 (6.3)
Pre-operatively stented/nephrostomized, *n* (%)	
No	100 (90.1)
Stented	7 (6.3)
Nephrostomized	4 (3.6)
Maximum tract diameter, *n* (%)	
14 Fr	7 (6.4)
16 Fr	96 (87.3)
22 Fr	8 (7.3)

Table 1 (continued)

Variable	
Punctures, *n* (%)	
1	103 (92.8)
2	7 (6.2)
Level of puncture, *n* (%)	
Below 11th rib	6 (5.4)
Below 12th rib	105 (94.6)
Fluoroscopy time, median (IQR), s	148.0 (102.5–289.5)
Operative time, median (IQR), min	95.0 (75.0–125.0)
Stone biochemistry, *n* (%)	
Calcium oxalate	62 (55.9)
Calcium phosphate	18 (16.2)
Cystines	1 (0.9)
Struvite	5 (4.5)
Urates	18 (16.2)
LOS, median (IQR), days	2.0 (2.0–4.0)
Tubeless, *n* (%)	58 (52.3)
Stone free, *n* (%)	
Overall	87 (78.4)
GSS 1	26 (83.8)
GSS 2	19 (82.6)
GSS 3	33 (76.7)
GSS 4	9 (64.3)
Achievement of trifecta, *n* (%)	43 (38.7)

suspension due to the presence of thick pus, rupture of caliceal system, or cases believed at risk for post-operative infections. The threshold for operative suspension was 2 h, and uneventful tubeless procedures were discharged at post-operative day 1.

Surgical Mentoring and Training Process

The mentored surgeon was a fully trained urology consultant who had previously performed >150 prone PCNLs (combination of both standard and mini) and >300 RIRS. During this study, he has been assisted in the first 10 ECIRSs by a senior consultant fully trained in ECIRSs, who participated in all the surgical steps.

After 10 cases, the supervisor was unscrubbed but present for additional 10 procedures. Subsequently, the surgeon-in-training was left free to operate independently. All procedures have been carried out with the support of two urologists who were expert in RIRS. The learning process was supported by recording and reviewing endoscopic/fluoroscopic images. Focus was made on main surgical aspects including patient's positioning, renal access/tract preparation, lithotripsy technique, Endovision principles, drainage placement, etc. Videos/images have been analyzed with the supervisor for 20 procedures. Subsequently, analysis was not mandatory and only carried out in the event of unexpected difficulties and/or complications.

Definition of Outcomes

Aim of this study was to evaluate the LC of a mentored single surgeon during ECIRS with VD. As surrogates of surgical adequacy/improvement, we monitored the SFR, complication rate (CR), LOS, OT, FT, and trifecta achievement.

Statistical Analysis

Descriptive analysis included frequencies and proportions for categorical variables. Medians and interquartile range (IQR) were reported for continuous variables. Alternatively, means and standard deviation were reported. For investigated parameters, LC was calculated for the entire case series and then divided into low complexity cases (GSS 1/2) and high complexity cases (GSS 3/4). A graphical description together with tendency line was performed to cumulatively represent the study cohort. Cumulative sum (CUSUM) analysis was performed for continuous variables such as OT and FT for proficiency evaluation. CUSUM analysis is a graphical method of quality control that examines consecutive series of procedures to determine trends in changes over time. Basically for continuous variables, the CUSUM curve runs randomly at or above a horizontal line at an acceptable level of performance ("no slope" situation). However, the CUSUM curve slopes upward and will eventually cross a decision interval when an operation is performed at an unacceptable level. These are horizontal lines drawn across a CUSUM chart. The degree of the slope is a measure of consistency and surgeon's progress in mastering a specific technique: the greater the slope, the slower the progress. Technique acquisition can be routinely assessed when the curve eventually flattens ("no slope" situation). Since the surgeon is competent from the beginning of the program, this point was accepted as the case number where proficiency was obtained [17, 18]. Statistical analyses were performed using R version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria, 2020).

Fig. 1. Moving average of cumulative SFR among the entire cohort. The stippled line indicates the slope of the median value.

Results

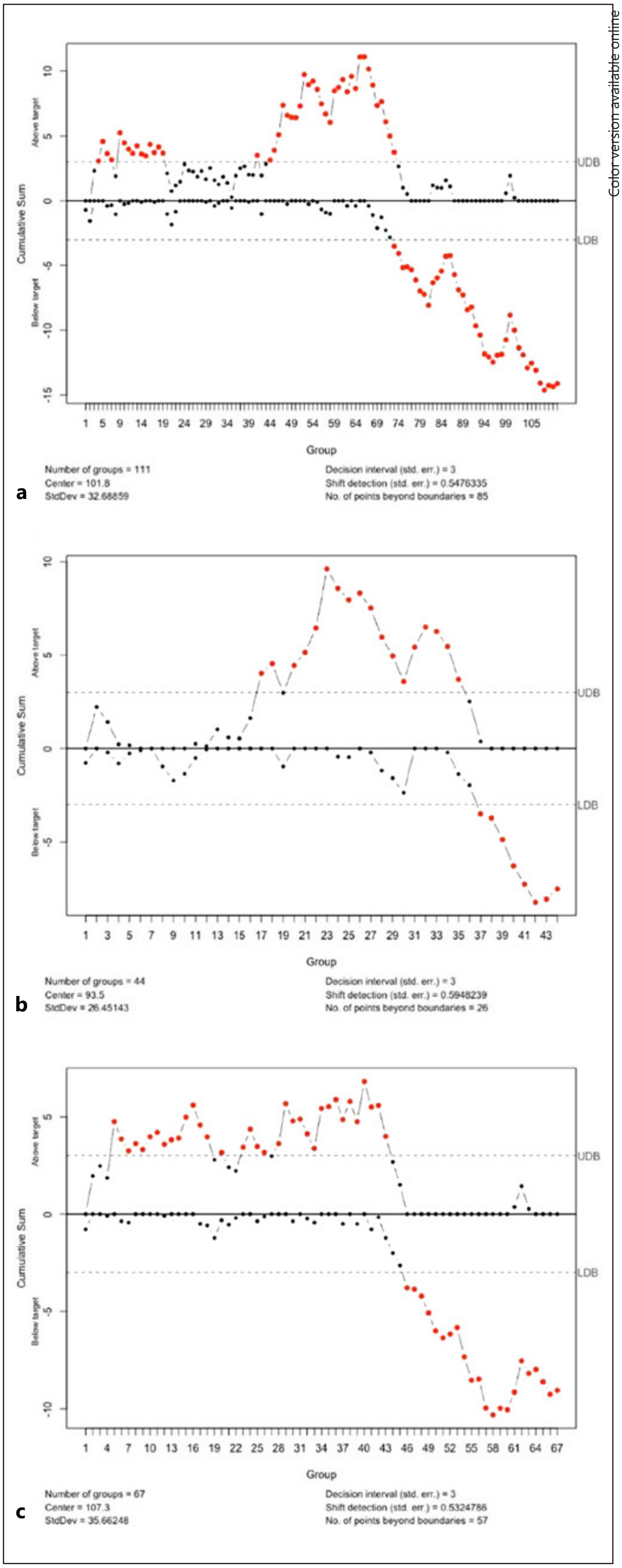
During the study period, a total of 119 procedures have been carried out. In the final analysis, 111 patients fulfilled inclusion/exclusion criteria and have been included in the study (median age 58 years, IQR 49.5–67.0). Four out of 8 excluded patients had different post-operative imaging modalities, 2 patients were lost at follow-up, and the remaining two parts of peri-operative data were missing.

Table 1 reports patients' baseline characteristics and peri-operative data. Overall, GSS 3/4 stones represented 51.3% of all cases. The mostly used percutaneous sheath was 16 Fr (87.3%). In terms of surgical outcomes, the overall SFR was 78.4%. 58 (52.3%) patients were tubeless, and 43 patients (38.7%) achieved trifecta.

Supplementary Table 1 (for all online suppl. material, see www.karger.com/doi/10.1159/000528785) reports intra-/post-operative complications. In 2 cases, the procedure was prematurely stopped, with 1 case of hydrothorax (case 7) requiring chest drainage and 1 bleeding managed conservatively (case 41). No procedures have been stopped for failed access.

We observed 4 high-grade complications (3.6%), including two ICU admissions (for sepsis and hydrothorax, cases 3 and 7), 1 (0.9%) re-intervention under general anesthesia for a dislodged ureteric stent (case 16), and 1 (0.9%) angio-embolization for arterial bleeding (case 21). Transfusion rate was 1.8%. Figure 1 reports correlation between LC and SFR. Improvement results became consistent after case 31 (online suppl. Fig. 1a–c).

LC for OT and FT is shown in Figures 1 and 2a–c, respectively. OT results became consistent after 72 cases, and improvements resulted faster in simpler cases (for GSS 1/2, OT reduction was observed after 36 cases and for GSS 3/4 after 45 cases). Regarding FT, improvement was observed after 46 cases. Looking into GSS 1/2, improvement was observed after 21 cases and for GSS 3/4 cases after 25 procedures (Fig. 3a–c). Details are shown in online supplementary Figure 2a–c and 3 a–c. In terms of LOS, it decreased after 37 cases. At the beginning of training period, LOS of GSS 1/2 had a mean of 3.6 days versus 4.2 days for GSS 3/4. At the end, LOS was 2.5 days for all cases (online suppl. Fig. 4a–c). Correlation between LC and overall CR is analyzed in online supplementary Figure 5a–c. We observed a decrease of complications



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throughout the case series, with a significant improvement after 17 cases. At the beginning, GSS 3/4 presented a higher CR, but at the end the results were comparable to GSS 1/2. In terms of trifecta, consistent results were reached after 53 cases (online suppl. Fig. 6a, b, c).

Discussion

This is the first study investigating outcomes of ECIRS VD. It also represents the first paper exploring ECIRS's LC, using a large variety of parameters for surgical proficiency and quality.

PCNLs continue to represent an important option, their number has increased from 6.07% in 2007 to 7.24% in 2014 [19], with mini-PCNL corresponding to 33–45% of all procedures [20]. Monitoring quality of training and surgical proficiency remain therefore necessary.

Our data provide important information on surgical exposure to obtain proficiency during ECIRS. They suggest that CR improves quickly (17 procedures), while SFR requires approximately 30 cases, OT and FT approximately 40–45 cases. The last parameter to improve is trifecta (>50 cases). These results can support novice surgeons for an adequate case selection. For all parameters, LC did show a constant trend of improvement, but a plateau was not observed. This fact might suggest that higher surgical volumes are necessary to obtain excellence.

At the beginning of the case series, outcomes of GSS 3/4 resulted worse than GSS 1/2. At the end of study period, results of both groups were similar. This is also shown by steeper curves of GSS 3/4, demonstrating a more significant improvement. This could suggest that surgeons at initial training phases should be exposed only to simpler cases, avoiding unnecessary complications. Looking into complications, GSS 3/4 cases seemed to have unfavorable results, presenting a 75% CR compared

Fig. 2. a CUSUM chart for operative time among the entire cohort (n = 111). Consistency (no slope) is being reached about after 33 cases presenting the potential target number for technical proficiency of ECIRS. **b** CUSUM chart for operative time among patients harboring Guy's score 1–2 (n = 44). Consistency (no slope) is being reached about after 20 cases presenting the potential target number for technical proficiency of ECIRS. **c** CUSUM chart for operative time among patients harboring Guy's score 3–4 (n = 67). Consistency (no slope) is being reached about after 35 cases presenting the potential target number for technical proficiency of ECIRS.

to 21% of GSS 1/2 (overall CR was 51% at the beginning of the study). However, we underline that only 4 high-degree complications have been recorded. Majority of events were graded as CD 1–2, including 17 post-operative fevers (15.3%) and 5 sepsis (4.5%). Eleven episodes of fever and 3 episodes of sepsis occurred during the initial 50 cases.

In our opinion, longer OTs and incorrect management of intra-renal pressure (due to suboptimal utilization of ClearPetra) might have led to these results. The acronym ECIRS was first used in 2008 (10), although at the beginning it was sparsely described; recently, it has been more widely adopted as demonstrated by the increased number of published papers [21] and by its introduction in the European Association of Urology guidelines [22]. Publications in this regard are still very limited, and the comparison with prone PCNLs is controversial.

Its key element is the simultaneous antegrade/retrograde approach, and the retrograde ureteroscopy has an active role in the caliceal system assessment and stone clearance. This also reduces the need for fluoroscopy as several steps (tract preparation, guidewire placement, final assessment for eventual residual fragments) can be monitored endoscopically.

Currently, there are two different VD systems for PCNL. The most described is the 14 Fr super-mini PCNL, introduced by Zeng G et al. [6]. In case of stones <2 cm, SFR ranged from 93% to 96% [23, 24].

Guddeti et al. [25] compared prone 14 Fr super-mini PCNL with standard PCNL for stones <20 mm. They showed comparable SFR, but the super-mini PCNL was associated with longer OT, lower post-operative bleedings, pain, and shorter LOS.

Recently, an 18 Fr device has been introduced (enhanced super-mini PCNL). In the treatment of 2–5 cm renal stones, if compared to traditional 18 Fr PCNL, it provided significant benefits in terms of OT (34.9 min vs. 49.6 min, $p < 0.001$), intra-operative renal pressure

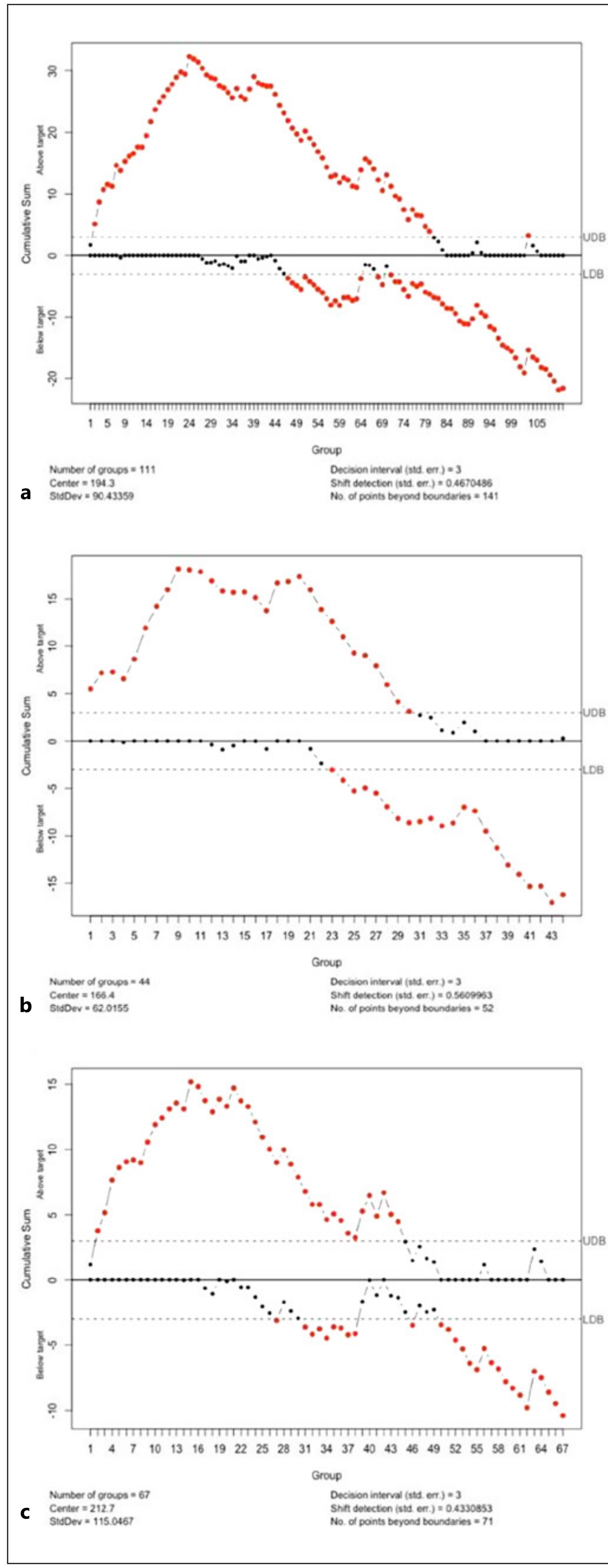

Fig. 3. a CUSUM chart for fluoroscopy time among the entire cohort ($n = 111$). Consistency (no slope) is being reached about after 43 cases presenting the potential target number for technical proficiency of ECIRS. **b** CUSUM chart for fluoroscopy time among patients harboring Guy's score 1–2 ($n = 44$). Consistency (no slope) is being reached about after 20 cases presenting the potential target number for technical proficiency of ECIRS. **c** CUSUM chart for fluoroscopy time among patients harboring Guy's score 3–4 ($n = 67$). Consistency (no slope) is being reached about after 40 cases presenting the potential target number for technical proficiency of ECIRS.

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(12.03 mm Hg vs. 17.7 mm Hg, $p < 0.001$), and LOS (2 days vs. 3 days, $p = 0.008$), maintaining comparable SFRs [26].

Similar results were shown by Montanari et al. using the ClearPetra® disposable system. Using the 16 Fr sheath, the SFR was 87% with an overall CR of 25.4% and high-degree complications of 5.8% [27]. This technique was able to maintain a low intra-renal pressure, with a mean value of 15.3 cm H_2O and pressure >40 cm H_2O in 2.45% of cases.

In literature, data on LC for PCNLs are limited. Tanriverdi et al. [28] published a case series of 30 Fr-prone PCNLs carried out by a single surgeon with no previous experience. Competence was achieved after 60 cases, measuring OT (from 2.4 to 1.5 h) and FT (from 17.5 to 7 min). They could not observe improvements in terms of SFR and CR. Regarding supine PCNLs, Jang et al. [29] presented a series of 53 patients undergone 30 Fr PCNLs showing achievement of proficiency after approximately 36 cases. As proficiency parameter, they could identify only the OT (from 97 to 72 min), while SFR, CR, and LOS did not differ.

Moreover, Schilling et al. [30] investigated the LC for prone mini-PCNL. In this study, an untrained surgeon had longer OT (108 vs. 58 min) and FT (4.6 vs. 2.8 min), lower SFR (60 vs. 89.9%), and higher re-treatment rate (31.4 vs. 10.2%) but not longer hospitalization compared to an experienced surgeon. Proficiency was achieved after 35 cases.

A limitation of this study is that it reports results of a single surgeon, previously trained in a recognized fellowship program and with prior experience in prone PCNLs but not with super-mini PCNLs. Our results may not be applicable to novice urologists or senior urologists unfamiliar with percutaneous surgery, but it provides important data for the transition from prone to supine PCNL/ECIRS. In this study, VD-assisted procedures have been investigated, while other traditional forms of minimally invasive PCNLs without active suction have not been considered. Certainly, different surgical steps remain identical including the caliceal puncture, tract dilatation and preparation, caliceal system navigation in lithotripsy; therefore, we believe our data can be realistically considered valid also for other types of mini-PCNLs. However, we need to acknowledge that some differences exist between the two techniques in terms of stone extraction and regulation of the inflow/outflow. In our opinion, this does not represent a substantial difference, but certainly further investigations might be necessary in the future on this regard.

Lastly, we cannot state whether the surgeon-in-training obtained equivalent or superior results compared to prone PCNLs and we could not compare with other surgeons. In this context, it is unclear whether excellence has been achieved. These limitations should be addressed in further studies, evaluating LC of multiple surgeons at different levels of seniority.

Conclusions

This is the first study describing the utilization of a VD during ECIRS. Its LC seems comparable to prone techniques. While proficiency can be achieved in 17–50 cases, excellence might require a significantly higher surgical volume. Exclusion of complex operations might optimize the LC.

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Statement of Ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all individual participants involved in the study. The Ethics Committee of the San Bassiano Hospital in Bassano del Grappa approved the study, study number 183, approved on February 17, 2022.

Conflict of Interest Statement

The authors declare that they have no conflicts of interest.

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Author Contributions

Conception and design and drafting of the manuscript: Giorgio Mazzon; acquisition of data: Davide Brusa; analysis and interpretation of data: Giorgio Mazzon, Francesco Claps, Federico Germinale, and Davide Brusa; critical revision of the manuscript for important intellectual content: Giorgio Mazzon, Simon Choong, Adara Caruso, Marco Pirozzi, Alessandro Antonelli, Maria Angela Cerruto, and Antonio Celia; statistical analysis: Francesco Claps.

Data Availability Statement

The dataset can be requested from the corresponding author and is available. All data generated or analyzed during this study are included in this article and its online supplementary material files. Further inquiries can be directed to the corresponding author.

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