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Semi-closed-circuit vacuum-assisted mini percutaneous nephrolithotomy in the pediatric population: the initial experience of two tertiary referral centers

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ABSTRACT

Background

Percutaneous nephrolithotomy (PCNL) is the gold-standard for complex renal stones treatment in the pediatric population. While the miniaturization of PCNL reduces the risk of bleeding, it can hinder surgical and functional outcomes. The aim of the study is to assess the safety and feasibility of semi-closed-circuit vacuum-assisted Mini-PCNL (vmPCNL) in pediatric patients.

Methods

From January 2017 to December 2018, we prospectively collected data on consecutive vmPCNLs from two European tertiary referral centers. The procedure was performed with the ClearPetra® access sheath equipped with a lateral arm connected to the aspiration system (pressure setting ~ 120-150 cmH_2O) by a 200 ml plastic stone collector. Pre-, intra- and post-operative data and costs were analyzed. The stone-free rate (SFR) was defined as absence of residual fragments > 4 mm with either ultrasound or kidney, ureter, and bladder x-ray.

Results

Eighteen vmPCNLs were performed in 16 renal units of 13 children. The median age was 119 months (IQR: 97-160) and the weight was 29 Kg (IQR: 25-40). The median cumulative stone size was 32 mm (22-46) with 8 (44.4%) cases of staghorn stones. The OT was 128 min (IQR: 99-167). The basketing was unnecessary in 6/18 (33%) cases. Neither intra-operative complications nor blood transfusions occurred. Post-operative fever was observed in 5/18 (27.8%) cases; in one case a double J ureteral stent was placed for concomitant hydronephrosis. The SFR was 81.3% (13/16), rising to 93.8% (15/16) after ancillary procedures. The materials costs of a vmPCNL (734.8 €) were comparable to mini-PCNL using a reusable set (710.7 €).

Conclusions

The vmPCNL seems to be sustainable, safe and feasible for kidney stones treatment in the pediatric population.

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INTRODUCTION

Surgical treatment of pediatric kidney stones has changed over the years [1]. Percutaneous nephrolithotomy (PCNL) was firstly introduced in 1976 and it still has a leading role despite many technological advancements in retrograde approaches [2-4]. According to the EAU guidelines, PCNL remains the first surgical option for renal stones > 20 mm (~300 mm^2), for lower pole caliceal stones > 10 mm and for staghorn or multiple stones [5]. It ensures a higher stone-free rate (SFR) than shockwave lithotripsy (SWL) and retrograde intra-renal surgery (RIRS), despite presenting a higher rate of major complications and a higher decrease of post-operative hemoglobin levels [6].

In order to reduce PCNL morbidity, Jackman et al. introduced the Mini-PCNL in 1998, reporting encouraging results in terms of complication rate reduction. Their findings were subsequently confirmed by several randomized controlled trials (RCTs) [7]. Although mini-PCNL (nephrostomy tract size < 20 Fr) may reduce the number of major complications (haemorrhage in particular), some authors argue that it may decrease the SFR, lengthen the operative time (OT), and increase the number of post-operative urinary tract infections (UTI) [8,9].

Endourological research is currently focusing on regulating intra-renal pressures, especially, to reduce the risk of infection. During surgery, irrigation flow and irrigation pressures tend to be increased in order to achieve better visibility [10]. Increased intrarenal pressures can provoke the deterioration of the renal parenchyma, and cause pyelorenal backflow, fluid reabsorption, and bacteremia [11]. Novel systems to control and limit the increase of intra-renal pressures, like a semi-closed-circuit vacuum-assisted mini-PCNL (vmPCNL) system, may potentially reduce the number of post-operative complications and overcome some of the above-mentioned limitations of a minimally invasive approaches [12].

The aim of the study is to report our initial experience using a vmPCNL system for renal stone treatment and to assess its safety and efficacy in pediatric patients.

MATERIALS AND METHODS

We prospectively collected data from two European tertiary referral centers: Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico (Milan) and Fundació Puigvert (Barcelona). From January 2017 to December 2018, we enrolled to the study all consecutive < 18 years old at the time of surgery undergoing a vmPCNL. Patients' data and surgical outcomes were retrospectively analyzed. The study was conducted in accordance with the Declaration of Helsinki (1964) and its later amendments. The study was approved by the Institutional Review Board. All patients signed an informed consent at the time of hospitalization to share anonymously clinical information for research purposes.

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Data collection

Pre-operative patient data included demographic variables (e.g. age, sex), medical history and stone characteristics, like cumulative stone size (evaluated as sum of largest stones diameter) and stone location, assessed by a non-contrast computed tomography (CT) scan or ultrasound (US) and kidney-ureter-bladder x-ray (KUB).

The analyzed intra-operative parameters were: OT, number of punctures required, intraoperative complications, and exit strategy.

The collected post-operative parameters were: length of hospital stay, post-operative complications (graded by the Clavien-Dindo classification), SFR, and the need for auxiliary procedures [13]. The stone-free status was assessed one month after surgery by means of two radiological exams, ultrasound (US) and kidney, ureter, and bladder (KUB) x-ray, and defined as the absence of residual fragments > 4 mm after one month from surgery.

Equipment and procedure

Before starting the procedure, we administered antibiotic prophylaxis with a third-generation cephalosporin. In case of positive pre-operative urine culture, a targeted antibiotic therapy was scheduled prior to surgery on the basis of the urine culture antibiogram. After general anaesthesia, patients were positioned in Valdivia-Galdakao modified position. The first step was to gain ureteral access. It is our practice to use a 4.8 or 6 Fr open-ended ureteral catheter.

As for the nephrostomy access sheath, we used the ClearPetra® system (Well Lead Medical Co., Ltd., China), which is shown in Figure 1. This device is available in different measures: internal diameters range from 10 to 22 Fr and lengths can range from 13 to 21 cm. In Milan the 16-Fr x 13-cm access sheath was adopted, while in Barcelona surgeons preferred the 14-Fr x 13cm system.

A fluoroscopy-guided (+/- ultrasound) renal puncture was performed by the urologist. The tract was dilated in one-shot via the ClearPetra 16Fr access sheath. When the 14 Fr ClearPetra was used a progressive dilation by means of 8-10-12 Fr fascial dilators (Cook, Bloomington, IN, USA) was performed.

We used a 12 Fr nephroscope (Karl Storz SE & Co. KG, Germany; length: 22 cm; working channel 6.7 Fr) for the 16 Fr ClearPetra, and a 9.5 Fr semirigid ureteroscope (Karl Storz SE & Co. KG, Germany; length: 34 cm; working channel 5 Fr) was used for the 14 Fr ClearPetra.

The sheath is equipped with a lateral arm connected to the aspiration pipe which is linked to a 200 ml plastic bottle. The stone collection bottle has a valve that permits the aspiration of the fluids in the aspiration system without losing stone fragments. The aspiration strength can be adjusted in three ways. The first one is through a valve on the connecting tube. The second one is through an oval window on the lateral arm of the sheath that can be completely or partially closed by the connecting

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tube. The third way is closing the oval window on-demand with a finger to temporarily increase the aspiration. The ClearPetra system is therefore characterized by a continuous inflow and a suction-controlled outflow.

For estimation purposes, we considered our system as a closed one and estimated the involved variables. In accordance to Bernoulli's principle, the aspiration pressure should be $p=-133\ cmH_2O$ for the 16-Fr nephrostomy sheath/12-Fr nephroscope kit, and $p= -143\ cmH_2O$ for the 14-Fr nephrostomy sheath/9.5-Fr ureteroscope kit (Figure 2; Appendix A). To allow a continuous flow of fluid with controlled intrarenal pressure of 15 cmH_2O as demonstrated by Zanetti et al. [14], the aspiration was set at ~ 120-150 cmH_2O. Lithotripsy was performed with the Holmium:YAG laser (365-550 µm fiber) with a frequency and energy setting of 10-20 Hz and 1-1.5 J, respectively. Litholapaxy was achieved by slowly drawing back the nephroscope inside the sheath until the opening of the lateral aspiration arm was reached. A red stripe on the sheath marks the limit for the nephroscope retraction. Baskets or forceps were not routinely used, except for stones located distant to the tip of the access sheath and/or located in difficult-to-reach positions (e.g. stones located in an upper calyx and renal access through a middle/lower calyx). Flexible nephroscopy was finally performed in case of doubt of residual fragments.

The exit strategy varied according to the specificity of the scenario. A nephrostomy tube was usually left in place and removed after 24-48 hours. If the procedure was free from complicatons, and no large residual fragment was detected intraoperatively, the nephrostomy tube was not positioned. Instead, an indwelling ureteral catheter was kept in place for 1–2 days and subsequently removed. The bladder catheter was always left in place for at least 24-48 hours.

Analysis of materials costs

All costs for standard materials and material specific of the procedure were analysed. The cost of the ClearPetra® system was compared to the cost of standard mini-PCNL (MIP set, Karl Storz SE & Co. KG, Germany), which was amortized on the average number of pediatric PCNL performed in the last two years.

Statistical analysis

As for the statistical analysis, we estimated the median and interquartile range (IQR) for each quantitative variable, whereas for qualitative variables we reported the occurrence of the various outcomes. Data were stored and analyzed using Microsoft Excel (Microsoft Corporation, Washington, USA).

RESULTS

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Thirteen patients (8 males, 5 females) with a median age of 119 months (IQR: 97-160) and a median weight of 29 Kg (IQR: 25-40) were recruited for the study (Table 1). We performed 18 vmPCNLs in 16 renal units - 10 right (55.6%) and 8 left (44.4%). Two patients had a pre-planned two-stage vmPCNL due to stone burden. In one additional case the decision to perform a second-look procedure was made intraoperatively due to the prolongation of the OT. Eight procedures (44.4%) were carried out on staghorn stones. Fifteen (83.3%) surgeries were performed for multiple renal stones. Six (33.3%) patients were pre-stented, 2 (11.1%) had a nephrostomy tube prior to the intervention and 2 (11.1%) had both. The median cumulative stone size was 32 mm (IQR: 22-46) and was significantly higher in the population from Milan (37 mm vs 19 mm; p=0.02). Seven out thirteen patients (53.8%) presented with comorbidities; among them some were predisposed to stone recurrence (e.g. primary hyperoxaluria type 1, cystinuria etc.). One patient had been submitted to a Cohen's ureterovesical reimplantation. No pre-operative blood test revealed anemia or a significant alteration of the renal function. One out of 18 cases presented with a positive pre-operative urine culture and underwent a 7-day-long antibiotic therapy before performing vmPCNL.

Surgical procedure

The median OT was 128 min (IQR: 99-167; Table 2). In 13 (72.2%) cases, a single tract dilation was performed; in 4 cases two tracts were necessary, whereas 3 tracts were only necessary in a single case. A lower-calyx dilation was used in 14 (58.3%) surgeries, while a first mid-calyx approach was preferred in 7 (29.2%) procedures. A dilation of the upper calyx was performed in 3 (12.5%) vmPCNLs. Stone removal was achieved only via suction in 6/18 (33%) of cases. At the end of the procedure, a nephrostomy tube was positioned in 83.3% (15/18) of cases. A double-J stent was positioned in 3 (16.7%) cases. All vmPCNLs were completed without intraoperative complications.

Outcomes

Fever (5/18; 28%) was the most frequent post-operative complication. Two (11%) patients experienced a renal colic after nephrostomy closure or removal. Six (33.3%) patients presented a minor complication (Clavien-Dindo $\leq$ II) during post-operative course. One (5.6%) patient underwent post-operative double-J ureteral stent positioning due to fever and hydronephrosis after catheter removal (Clavien-Dindo IIIa).

The stone composition was as follows: 3 calcium monohydrate oxalate, 3 calcium monohydrate oxalate and calcium carbonate, 2 cystine, and 5 phosphate-based infectious stones.

The median post-operative stay was 3 days (IQR: 3-6 days). No patient required blood transfusions.

The SFR was confirmed in 13/16 renal units (81.3%). The SFR rised up to 93.8% (15/16) after ancillary procedures, such as second-look vmPCNL (n=1) or RIRS (n=2). The patient affected by

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primary hyperoxaluria presenting with a bilateral urolithiasis, was subjected to one left-sided and two right-sided vmPCNLs. Stone-free status was only obtained in the right kidney.

Analysis of materials costs

The average cost of a mini-PCNL performed with vmPCNL or mini-PCNL using a reusable set was 734.8 € and 710.7 €, respectively (Table 3). The vmPCNL costed 24.1 € (+3,4%) more per surgery. The ClearPetra® system costed 256.2 € per surgery while standard mini-PCNL set 134.12 €. The standard materials costed 478.6 € for vmPCNL and 576.5 € for mini-PCNL using a reusable set, reflecting the less frequent use of the basket in vmPCNLs.

DISCUSSION

In this study assessing the utility of vmPCNL in the pediatric population affected by complex stones, we demonstrated that this system was safe and feasible in the selected population.

Pediatric urolithiasis presents with different challenges from those encountered in the adults. In the pediatric age, stone formation is often associated with anatomical abnormalities, metabolic disorders, and UTIs, all factors that can increase recurrence risk [15,16]. Pediatric patients can be treated with minimally invasive techniques. However, children with large stone burdens, complete renal staghorn calculi, SWL-refractory stones, dilated or obstructed kidneys are best treated with PCNL.

In order to decrease the morbidity associated with PCNL, over the last few years miniaturized PCNL techniques have gained increased popularity [17]. The miniaturization of the technique may be particularly beneficial in the pediatric population. It has been demonstrated that the renal injury following dilation is significantly wider when the tract is more than 22 French. A tract dilation of 16 French generates a renal fissure of a diameter of 4.4/6.28 mm in cadaveric/porcine model. On the other hand, a tract dilation of 24 French (standard-PCNL size) generates a renal fissure of 7.49/12.53 mm, almost doubling the diameter of a mini-PCNL and tripling the total dilation area [18]. These findings explain why the tract dilation size is associated with hemorrhagic complications. The impact of a tract dilation on a pediatric kidney, which mean longest diameter is 9 cm in 10-year-old patients, is even more significant. However, their superiority in terms of safety and efficacy compared to conventional PCNL is still under debate.

The smaller tract size may be associated with decreased SFRs and, because of poor fluid drainage, elevated intra-renal pressures for a longer OT with respect to standard PCNL, increase the risk of infective complications [19,20].

In children with stones larger than 2 cm, Saad et al. showed that mini-PCNL has a higher SFR than RIRS (71% vs 95.5%, p=0.046), but it is nonetheless associated to higher radiation exposure, longer

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hospital stay and more complications [21,22]. The rate of fever in the PCNL group was twice the one of the RIRS group.

To improve the clinical outcomes related to mini-PCNL, research is currently focusing on avoiding high intra-renal pressures [23]. vmPCNL system may control and limit intra-renal pressures above the physiological limit of 30 mmHg, beside reducing the dissemination of stones in the pyelocaliceal system during lithotripsy [12,14].

To the best of our knowledge, our study is the first to describe the use of a vmPCNL system in the pediatric population. Our study demonstrated the feasibility of a vmPCNL approach in pediatric patients. No intra-operative complications were recorded. During the post-operative period, no blood transfusions were required, and 5 procedures were complicated by fever, with onset usually happened on the first 24 hours.

Rashid et al. reported an initial SFR after Mini-PCNL for complex staghorn stones in children of 78%, which increased to 89% after a few ancillary procedures [24]. Their median OT was 91 min (range 55–130 min). Our SFRs (81.3 and 93.8%) were comparable to the ones reported in the literature. The SFR might be significantly conditioned by patients' predisposing factors to stone formation (Table 1), which were present in 53.8% (7/13) of patients enrolled in our study. Moreover, the stone burden was significant (median cumulative stone size = 32 mm). The vmPCNL seems a sustainable procedure as total cost per procedure is slightly higher than a mini-PCNL using a reusable set. Moreover, the average cost of a vmPCNL resembles the costs reported in literature for percutaneous surgeries, ranging from 562.79 € to 749.39 € [25]. Our study presents several limitations. To start with, the study design is associated with a low level of evidence, as it is not a comparative study. The sample was relatively small. Both pre-operative stone burden and post-operative status assessment were heterogeneous and not performed with the most accurate radiological exams. Indeed, radiological assessment should be performed by CT imaging, as US has a low sensitivity and inability to properly measure stone size [26]. This is in contrast with the pursuit of limiting radiation exposure in children. Which is why we preferred to assess the SFR with US and KUB x-rays limiting radiation exposure. As a result, SFR might have been overestimated. We reported only the largest stone diameter instead of the entire stone volume [27]. The cumulated stone size uses only one dimension, and this may limit its reliability, especially in case of complex stone shape and stones > 20 mm [28,29].

According to our experience, the continuous aspiration was associated with a clear vision during the procedure. Considering our high-risk population, the limited incidence of infectious complications in our series may be associated with the low intra-renal pressures, warranted by the aspiration system.

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Moreover, the facilitated litholapaxy and the absence of fragments scattering, guaranteed by the vmPCNL, may decrease OT and the need for disposable devices.

CONCLUSIONS

The use of a vmPCNL system seems to be a sustainable, safe and feasible procedure for kidney stones treatment in the pediatric population. Further multi-institutional RCTs are mandatory to test our initial hypothesis and to compare clinical outcomes of mini-PCNL using a reusable set versus vmPCNL.

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TABLES

Table 1. Baseline characteristics of the population

Parameters	Values
No. patients	13 - 8 Milan (61.5%) - 5 Barcelona (38.5%)
No. renal units	16
No. vmPCNLs	18
Sex	- Males: 8 (61.5%) - Females: 5 (38.5%)
Age (months) median (IQR)	119 (97-160)
Weight (Kg) median (IQR)	29 (25-40)
BMI (Kg/m^2) median (IQR)	17.7 (16.4-18.3)
Type of stone	- Staghorn: 8 (44.4%) - Multiple: 15 (83.3%)
Stone side	- Right: 10 (55.6%) - Left: 8 (44.4%)
Cumulative stone size (mm)* median (IQR)	32 (22-46)
No. patients with comorbidities	7 (53.8%) - Primary hyperoxaluria type 1 (7.7%) - Cystinuria: 2 (15.4%) - Bladder exstrophy: 1 (7.7%) - Distal renal tubular acidosis: 1 (7.7%) - Bilateral ureteral reimplantation according to Cohen: 1 (7.7%) - Kabuki syndrome: 1 (7.7%) - Posterior urethral valves: 1 (7.7%) - Gastroschisis: 1 (7.7%)
Pre-operative condition	- Ureteral DJ stent: 6 (33.3%) - Nephrostomy tube: 2 (11.1%) - Ureteral DJ stent + nephrostomy tube: 2 (11.1%)
Pre-operative hemoglobin (g/dL) median (IQR)	13.2 (12.1-13.7)
Pre-operative creatinine (mg/dL) median (IQR)	0.7 (0.5-1.1)
Pre-operative sodium (mEq/dL) median (IQR)	140 (138-142)
Pre-operative potassium (mEq/dL) median (IQR)	4.6 (4.3-4.7)
Pre-operative calcium (mg/dL) median (IQR)	9.8 (9.6-9.9)
Pre-operative uric acid (mg/dL) median (IQR)	3.9 (3.4-4.2)
Positive pre-operative urine culture (%)	5.6 (1/18) - Pseudomonas aeruginosa

* Cumulative stone size was evaluated as sum of largest stones diameter
BMI = body mass index; IQR = inter-quartile range; vmPCNL = semi-closed-circuit vacuum-assisted Mini-PCNL.

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Table 2. Intra- and post-operative data of the patients submitted to vmPCNL

Parameters	Values
Operative time (min) median (IQR)	128 (99-167)
Tract location	Upper calyx: 3 (12.5) Middle calyx: 7 (29.2) Lower calyx: 14 (58.3)
Tract	Single: 13 (72.2) Multiple: 5 (27.8)
Intra-operative complications (%)	0
Exit strategy	- Nephrostomy tube: 15 (83.3%) [in one case: two nephrostomy tubes] - Tubeless: 3 (16.7%) - double-J ureteral stent: 3 (16.7%) - single-J ureteral catheter: 5 (27.8%)
Stone composition	- Calcium oxalate monohydrate: 3 (23.1%) - Calcium oxalate monohydrate and calcium carbonate: 3 (23.1%) - Cystine: 2 (15.4%) - Phosphate-based infectious stones (e.g. struvite, carboapatite): 5 (38.5%)
Fever (%)	27.8 (5/18)
Blood transfusion (%)	0
Complications according to Clavien-Dindo classification (%) **- Grade I-II** **- Grade IIIa**	 - 33.3 (6/18) - 5.6 (1/18)
Hospital stay (days) median (IQR)	3 (3-6)
Post-operative hemoglobin (g/dL) median (IQR)*	12.1 (11.3-13.2)
Post-operative creatinine (mg/dL) median (IQR)**	0.61 (0.52-0.86)
Post-operative CRP (mg/L) median (IQR)**	3.3 (1.8-4.8)
Stone-free rate (%)	81.3 (13/16)
Stone-free rate after ancillary procedures (%)	93.8 (15/16)

vmPCNL = semi-closed-circuit vacuum-assisted Mini-PCNL; CRP = C-reactive protein; IQR = inter-quartile range

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Table 3. Analysis of the disposable and reusable materials cost for mini-PCNL, stratified for mini-PCNL using a reusable set (standard) and vacuum-assisted mini-PCNL (excluding endoscopes)

Materials	Quantity	Price (€)	Standard mini-PCNL (€)	Vacuum-assisted mini-PCNL (€)
Ureteral catheter	1	10.0	10.0	10.0
Hydrophilic wire	2	24.3	48.6	48.6
Basket	1	146.2	146.2	48.3
Laser fiber*	1	888.2	88.8	88.8
Nephrostomy set	1	73.2	73.2	73.2
Irrigation set**	1	136.1	78.4	78.4
Contrast	1	29.3	29.3	29.3
Lubrication	2	1.9	3.8	3.8
Gowns/gloves	5	2.5	12.7	12.7
Draping	1	62.0	62.0	62.0
Miscellaneous	/	23.6	23.6	23.6
PCNL set***	1	1475.3	134.1	/
ClearPetra	1	256.2	/	256.2
Total	/	/	710.7	734.8

* Depreciation calculated on 10 procedures
** Depreciation calculated on 4 procedures
***Depreciation calculated on the number of pediatric PCNLs performed in the last 24 months

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TITLES OF FIGURES

Figure 1. A) The ClearPetra® system (Well Lead Medical Co., Ltd., China), is shown. A plug is put over the external access to prevent the medium from flowing out. The sheath is equipped with a lateral arm connected to the aspiration system through a 200 ml plastic bottle, which collects stone fragments. B) The pressure vent on the lateral arm is used to regulate aspiration and the red stripe on the sheath is the mark for endoscope retraction. D) Lapaxy is performed by slowly drawing back the nephroscope inside the sheath until the red stripe on the sheath, thus aspiring the fragments in the lateral arm.

Figure 2. Estimation of the pressures involved in the employed system. The entire circuit was considered as closed for estimation purposes. Bernoulli's principle states the total pressure is a constant in the system and derives from the sum of static and dynamic pressures. In the example shown, we considered the 16-Fr nephrostomy sheath and 12-Fr nephroscope, evaluating the aspiration pressure in $p = -13.013 Pa = -133\ cmH_2O$. To estimate the pressure with a 9.5-Fr ureteroscope and a 14-Fr nephrostomy sheath, the values of r_1 and r_2 were modified accordingly, obtaining a final aspiration pressure $p = -14.00 Pa = -143\ cmH_2O$.

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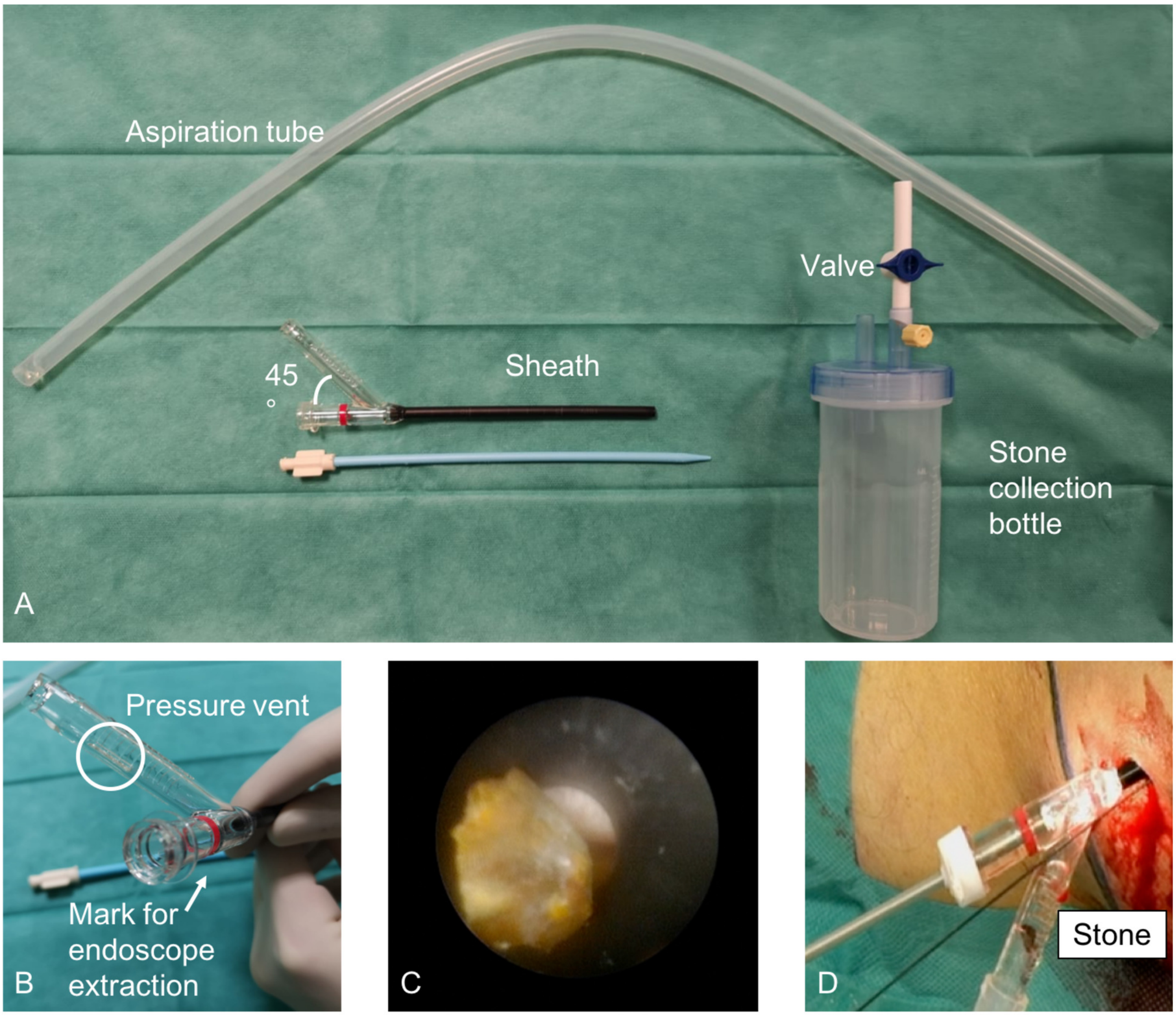

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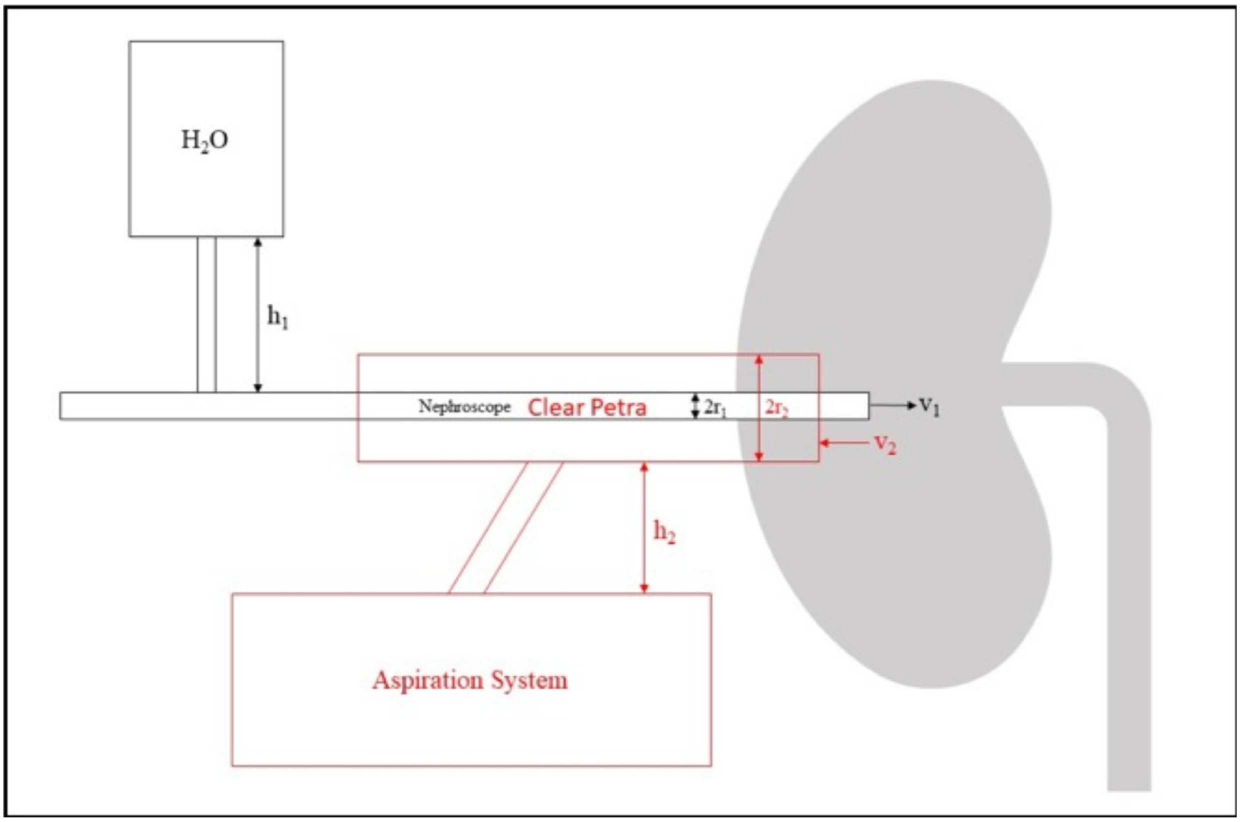

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