Using vacuum-assisted ureteral access sheath in the treatment of complex steinstrasse

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**Abstract:**

**Introduction:** Steinstrasse is an iatrogenic condition resulting from upper urinary tract lithotripsy. Uncomplicated steinstrasse can be managed expectantly. Complex steinstrasse can pose a therapeutic challenge.

The vacuum-assisted ureteral access sheath (vaUAS) is similar to a conventional ureteral access sheath but has a side branch that can be connected to vacuum apparatus. This device seemed to be useful in the management of complex steinstrasse.

**Material and Method:** 35 patients with complex steinstrasse, defined as steinstrasse containing ≥4 stones or with an aggregate length of ≥1.5 cm, were treated in four tertiary medical centers using the vaUAS in this prospective and non-randomized study. The vaUAS was inserted into the ureter over a guidewire until the tip of the vaUAS was in contact with the lowermost stone fragment. A 7 Fr./8.4 Fr. semirigid ureteroscope and a holmium laser were used to pulverize the obstructing stone. All the stone fragments were aspirated either in the space between the scope and the sheath, or through the channel of the sheath by withdrawing the scope to the proximal of the aspiration port.

**Result:** All patients were steinstrasse-free at end of the procedure, as assessed visually and by KUB. At the three-month follow-up, 94.3% of patients were stone-free with or without a supplementary procedure. There were no perioperative complications. Five patients experienced postoperative fever and/or significant hematuria, and one patient had transient sepsis, a grade I and IV Clavien complication respectively.

**Conclusion:** vaUAS can be an effective adjunctive device in the management of complex steinstrasse.

## Introduction:

Steinstrasse is almost always an iatrogenic condition, although rare cases of spontaneous steinstrasse formation from innate renal diseases have been reported[1,2,3]. Prior to the advent of percutaneous nephrolithotomy and retrograde ureteroscopic lithotripsy, extracorporeal shock wave lithotripsy (SWL) was the exclusive cause of steinstrasse. Many reports have shown that a large stone burden, high stone attenuation value, and the location of the stone are the major risk factors[4,5,6,7] for steinstrasse formation. Minor steinstrasse can usually be managed with watchful waiting or retrograde ureteroscopic manipulation. Complex steinstrasse, however, poses a therapeutic challenge.

Vacuum assisted ureteral access sheath (vaUAS) has been commercially available for the past few years. The vaUAS differs from the conventional ureteral access sheath in that the vaUAS has an oblique side branch with an air vent (Figure 1-1). The side branch can be connected to a vacuum source. The air vent, in the form of a slit, is used to regulate the aspiration pressure (Figure 1-2). We have gained significant experience in using the vaUAS in the treatment of ureteral stones[8]. We felt that the vaUAS can be an effective tool in the treatment of complex steinstrasse; thus, we undertook this prospective, non-randomized study.

## Materials and Methods:

**2.1** Patients with complex steinstrasse (defined as a steinstrasse with ≥ four stone fragments or an aggregated longitudinal stone length of ≥ 1.5 cm) who failed expectancy therapy and decided to undergo surgical therapy were prospectively enrolled into this study. 35 patients were accrued from four tertiary medical centers in two provinces in China from January 2019 to September

2022. Patients were either initially treated at or referred to these medical centers after the treatment of the primary stones. Written consent was obtained from each of the patients and the study was approved by the respective Institutional Ethics Committees. All the steinstrasse cases were treated following a uniform protocol.

The size of the steinstrasse was measured by its longitudinal length from the uppermost end to the lowermost end, based on the patient's KUB or the coronal plane of the patient's CT scan. If the steinstrasse was not contiguous, the summation of each of the segments was used. Representative steinstrasse from each medical center is displayed in Figure 2, A-D.

Clinical data collected included the patient's age and gender, laterality and length of the steinstrasse, cause of the steinstrasse, pre- and postoperative CBC and serum creatinine, and urine analysis and urine culture. Operative data included prior stent placement, steinstrasse treatment time (defined as from the completion of the vaUAS insertion to its removal), postoperative stent placement, steinstrasse-free rate, immediate and final stone free rate, stone analysis, and perioperative or postoperative complications per Clavien grading system. The steinstrasse was evaluated either with KUB or CT scan prior to the surgery. KUB was performed immediately after surgery. Positive urine culture was treated with antibiotics according to the sensitivity tests. In addition, all patients received a single dose of prophylactic antibiotics one hour preoperatively. Patients with residual stones were treated with supplementary procedures at two to four weeks postoperatively. These included repeated SWL, repeated PCNL, and retrograde intrarenal surgery using flexible ureteroscopy. Non-contrasted CT or KUB with B mode ultrasound were used to assess residual stones at three-month follow ups. All the stones were sent for analysis.

**2.2** All procedures were performed under general anesthesia in lithotomy position. A Storz 7/8.4 Fr. semirigid ureteroscope was introduced into the ureter under direct vision. The lowermost stone fragment was visualized. A flexible tip guide wire was advanced laterally to the stone fragment under fluoroscopy until it entered the renal pelvis. If the patient already had a stent in place, the stent was partially retrieved, and the guide wire was passed into the renal pelvis through the lumen of the stent. Depending on the location and the length of the steinstrasse, either a 35-centimeter or 25-centimeter vaUAS (ClearPetra, Guangzhou, China) with a 12/14 Fr. inside diameter/outside diameter was selected for the procedure. The sheath was inserted over the guide wire until the tip of its obturator touched the stone fragment. The guide wire and the obturator were then removed. The side branch of the vaUAS was connected to a vacuum at 30-40 pKa. Either a 43-cm or 34-cm 7/8.5 Fr. (Storz, Germany) semirigid ureteroscope was used for the procedure. It should be noted that the vaUAS requires the scope to be at least three French smaller than the inside diameter and seven centimeters longer than the length of the sheath to be effective. The scope was inserted into the vaUAS through a sealing cap. The inflow of irrigation was delivered through the scope using a mechanical pump at 60 c.c./minute. The outflow of the irrigation was between the scope and the sheath and exited through the side branch. The aspiration pressure was set at 200 mmHg. The scope was advanced until the lowermost stone fragment was visualized. Since the obturator of the vaUAS has a 1.5-cm tapered tip that extends beyond the sheath itself, the sheath was further advanced under direct vision until it came in contact with the stone fragment. A 550-micron Holmium laser fiber was used for the lithotripsy. The lowermost stone fragment was treated using a high-frequency (25-30 Hertz) and low-energy (0.5-0.6 Watts) setting to achieve a “dusting” effect. The tiny disintegrated stone fragments would pass between the scope and the sheath, then exit through the side branch. Larger residual stone fragments that came into the sheath but were too large to pass between the scope and the sheath were managed by withdrawing the scope slowly to a point just beyond the bifurcation of the side branch. This maneuver opened up the full channel of the access sheath to allow the evacuation of the larger stone fragments. Once the leading and obstructing fragments of the steinstrasse were treated, the higher fragments of the steinstrasse would often migrate to the sheath. They were treated using the same technique. If there was a significant gap between segments of the steinstrasse, the guide wire was reinserted. The sheath was advanced with the obturator in place to the lowermost stone fragment of the next segment of the steinstrasse. The procedure was then repeated until the entire steinstrasse was treated. A double J ureteral stent was placed at the end in most of the procedures. We used the lithotripsy time as the operative parameter to compare with the length of the steinstrasse for statistical analysis. We found other operative parameters such as the time required for the placement of guidewire and sheath varied considerably from case to case, especially if a ureteral stent was in place. A stone basket was not needed in any of the procedures. Patients were discharged the next day. The double J was removed around one to four weeks later, either during the supplementary procedure or as an outpatient. Patients were scheduled for follow-ups at three months after steinstrasse treatment.

**2.3** Statistical analysis: All variables are expressed as means ± SD. Either the Linear Regression Analysis or the Wilcoxon Rank Sum Test was used to perform the intragroup comparison. $P$ value < 0.05 was deemed statistically significant. IBM® SPSS 26.0 software was employed for the task.

**Results:**

Preoperative and postoperative data are shown in Table 1 A&B. There were 21 males and 14 females. The mean age was 52.2 years old. Extracorporeal shock wave lithotripsy was the cause for 25 patients. The average length of the steinstrasse was 36.2 mm. The average lithotripsy time for the steinstrasse was 33.7 minutes. There was no correlation between the lithotripsy time and the length of the steinstrasse, $P = 0.197$. Linear Regression Analysis showed that there was no correlation between steinstrasse length and operative time. There was significant elevation of WBC postoperatively per Wilcoxon Rank Sum Test. All the steinstrasse were successfully cleared. 10 patients had residual renal stones prior to steinstrasse lithotripsy, and the residual stones remained after the procedure in eight patients. Two patients passed the stone spontaneously at their three-month follow-ups, four patients underwent supplementary procedures for the stones, and two patients with ≤ 4mm non-obstructing stones refused further therapy. The final stone-free rate after three months was 33/35 or 94.3%. There were six postoperative complications. Three patients had fever, including one patient who also exhibited chill and transient hypotension. Three patients had significant hematuria that required catheter drainage.

**Discussion:**

Complex steinstrasse can be a challenging condition to treat. No standard treatment has been described, although many treatments have been advocated. These treatments include watchful waiting, medical expulsive therapy[9,10], placement of ureteral stent, placement of percutaneous nephrostomy tube, repeat SWL[11.12], percutaneous nephrolithotomy (PCNL), retrograde ureteroscopic procedure with or without a pulsatile irrigation device, such as Water-Pik® or Davol Simpulse® irrigator[13,14,15], open ureterolithotomy, or any combination of the above options. There are several treatises in the literature discussing the surgical outcomes of steinstrasse treatment. Kim[11] et al and Sayed[12] et al reported management of steinstrasse using repeat SWL monotherapy to treat the obstructive leading fragment. In Kim's series, 20 out of 55 patients with steinstrasse did not pass spontaneously and underwent repeat SWL. 18 patients were treated successfully, and two patients underwent ureteroscopic or open ureterolithotomy. Sayed reported the outcomes of surgical treatment in 27 patients. 23% underwent repeat SWL, 19% underwent PCNL, 6% underwent retrograde ureteroscopy, and 4% underwent open surgery. Treating steinstrasse using repeat SWL will require longer follow-ups. Furthermore, SWL monotherapy would be cumbersome or unfeasible, for noncontiguous steinstrasse.

Feng C[13] et al reported 21 patients who underwent laser lithotripsy for steinstrasse. The steinstrasse length was 3.5 cm to 8.0 cm with an average of 5.5 cm. They reported 90.5% (19 out 21 patients) stone-free rate at one month. One patient required second SWL and one patient underwent open surgery. In their paper, the surgical technique was only briefly mentioned. It was unclear if they advanced the scope upward to treat every single fragment or whether the stone basket was used to retrieve some of the stones.

Rabbani[15] reported treatment of 24 patients with 1.5-cm to 6-cm steinstrasse using transureteral lithotripsy. They achieved 14/24 (58.3%) immediate success, 6/24 (25%) partial success, and 4/24 failure that required open ureterolithotomy.

Steinstrasse is mostly iatrogenic in etiology. In the past, SWL has been the major cause of steinstrasse. The incidence of steinstrasse following SWL was reported to be between 2-13%.

With the introduction of single-use digital ureteroscope and the tendency to treat larger and larger renal stones, there is likely to be an increase in the incidence of steinstrasse formation. It is well documented that preoperative placement of a double J stent can decrease the risk of steinstrasse formation[17,18,19]; nevertheless, the stone burden is the most important determinant[20]. There is a unique situation in China. The National Health Ministry has authorized the establishment of commercial free-standing SWL facilities to meet the need of this service, especially in rural areas. Consequently, there are numerous such facilities throughout China. The cost of treatment is quite low, in the range of 600-800 Ren Min Bi or the equivalent of 90-120 U.S. Dollars. Most of these facilities do not have the capability to insert ureteral stents. Often, they are not even staffed by urologists. As result, there are probably more incidences of complex steinstrasse per capita in China than in many other countries. To wit, only three out of the 25 patients in our series had preoperative stents placed. When complex steinstrasse occurs and does not resolve spontaneously, these patients are generally referred to the tertiary medical centers.

We have gained significant experience using vaUAS for the treatment of large ureteral stones. We felt the vaUAS can also be a valuable tool in the management of steinstrasse.

The vaUAS has a hydrophilic coating, which made its insertion relatively safe and easy. During the procedure, the irrigation fluid is delivered through the semirigid ureteroscope. The outflow of the irrigation fluid travels between the scope and the sheath, then exits through the side port. This setup creates a turbulent vortex in the space between the stone, the scope, and the sheath (Figure 1-3). The vortex tends to stir and trap the stone particles and the vacuum mechanism removes them. Furthermore, under continuous aspiration, the risk of retropulsion of the stone fragments was reduced.

We had excellent results using vaUAS for the treatment of complex steinstrasse. This technique resulted in 100% immediate success in clearing the complex steinstrasse.

There was no intent to treat any residual stones using flexible ureteroscopy during the steinstrasse procedure. The reason is monetary. As previously mentioned, the SWL is very inexpensive; conversely, RIRS using either digital or optical flexible scope will incur much higher cost. Most patients preferred to delay the treatment of residual renal stone for SWL.

The lithotripsy time was used to analyze the operative time. We found tremendous variation in the time required for insertion of the guidewire. For patients with previously placed stents, the insertion of the guidewire through the stent was quite simple. Contrary wise, inserting guide wires directly through unstented steinstrasse can be complicated and time consuming. We found that the lithotripsy time did not correlate with the length of the steinstrasse. Frequently, once the obstructive leading fragment was treated, the rest of the steinstrasse would simply move downward with vacuum and could be removed easily. The shortest lithotripsy time in our series was only eight minutes. Furthermore, there was a noticeable decrease in the lithotripsy time with experience.

We found a significant increase in postoperative WBC count. Three patients experienced postoperative fever, including one who also experienced chills and transient hypotension. We cannot fully explain the elevation of the postoperative WBC except that the seven positive preoperative urine cultures, despite appropriate antibiotic therapy, might play a role in the leukocytosis.

Three patients experienced significant hematuria that required catheter drainage. All the instances occurred in patients who had multi-segments of steinstrasse that required repeated upward advancement of the ureteral access sheath to reach the upper stones. Both the nature of the steinstrasse and the maneuverings required likely accounted for the hematuria.

The steinstrasse in our 35 patients encompassed all three of Coptcoat's[21] classifications. We found this classification had no impact on the procedure nor the outcome.

The weakness of this study is that it is not a randomized trial. However, with the high success rate of steinstrasse treatment using vaUAS, it is hard to justify a randomized trial.

**Conclusion:**

Using vaUAS in the treatment of complex steinstrasse is safe and effective. vaUAS can be a valuable adjunctive device in the treatment of complex steinstrasse.

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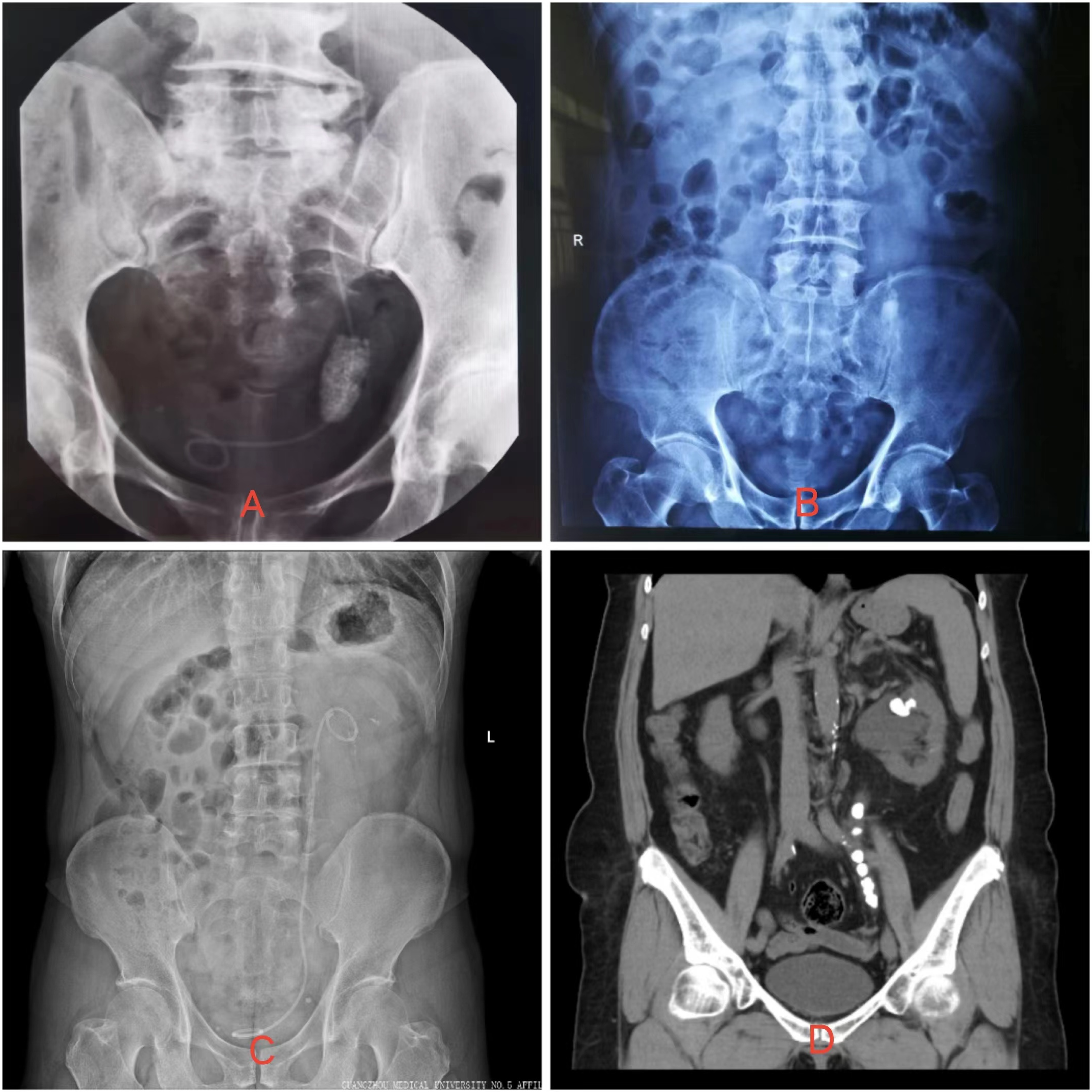
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Table 1-A: Preoperative data

| Variable | Value |
|---|---|
| Number of patients | 35 |
| Male/Female | 21/14 |
| Age, years, mean ±SD | 52.2 ±10 |
| Steinstrasse | |
| Left/Right | 18/17 |
| upper/middle/lower | 18/8/9 |
| Multiple segments | 3 |
| Length, mm, mean ±SD | 36.2 ±20.5 |
| The cause of steinstrasse | |
| SWL | 25 |
| PCNL | 6 |
| RIRS | 4 |
| Prior stent placement | |
| SWL | 3/25 (12%) |
| PCNL | 2/6 (33.3%) |
| RIRS | 2/4 (50%) |
| Positive urine culture, n | 7 (20%) |
| Residual renal stones before steinstrasse lithotripsy | 10 (28.6%) |

Table 1-B: Postoperative data

| Variable | Value | *P* |
|---|---|---|
| Lithotripsy time, min, mean ±SD | 33.7 ±12.2 | *P* = 0.197 |
| Steinstrasse Length, mm, mean ±SD | 36.2 ±20.5 | |
| Preoperative WBC, 10^9/L, mean ±SD | 7.9 ±2.3 | $P < 0.001$ |
| Postoperative WBC, 10^9/L, mean ±SD | 12 ±5.0 | |
| Preoperative Creatinine umol/L, mean ±SD | 93.3 ±35 | *P* = 0.775 |
| Postoperative Creatinine umol/L, mean ±SD | 96.3 ±36.9 | |
| Postoperative ureteral stent placement | 32/35 (91.4%) | |
| Steinstrasse free rate | 100% | |
| Residual renal stone after steinstrasse lithotripsy | 8 (22.9%) | |
| Spontaneous passage of residual renal stone | 2/8 (25.0%) | |
| Supplementary procedure for residual renal stone | 4/35 (11.4%) | |
| ESWL | 2 | |
| PCNL | 1 | |
| RIRS | 1 | |
| Final stone free rate | 33/35 (94.3%) | |
| Complication per Clavien Grade, n (%) | | |
| Grade I, fever | 2 (5.7%) | |
| significant hematuria | 3 (8.6%) | |
| Grade IVa, sepsis (fever, chill, transient hypotension) | 1 (2.9%) | |
| Stone composition, n (%) | | |
| Calcium oxalate | 19 (54.3) | |
| Uric acid | 1 (2.9%) | |
| Struvite | 2 (5.7%) | |
| Carbonate apatite | 1 (2.9%) | |
| Mixed Calcium oxalate/carbonate apatite | 12 (34.3%) | |