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A new variable emerges to guide the decision when choosing surgical options for renal stones larger than 20 mm

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Abstract. *Renal stones pose a significant health burden affecting many of the global population. When stones exceed 20 mm, invasive urological interventions become necessary. The study aimed to compare the effectiveness of percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS) in managing renal stones above 20 mm.*

Methods. This prospective interventional study was conducted over four years (June 2019 - June 2023) in multiple centers including Ghazi Al-Hariri Hospital, a Beirut private hospital, and a private clinic in Baghdad. A total of 240 patients with renal stones sized 20-40 mm were enrolled, excluding those with specific medical conditions. Patients were divided into two groups: 116 underwent RIRS and 124 underwent PCNL. The evaluation included sociodemographic and medical history, clinical and laboratory assessments, imaging studies, and follow-ups for three months post-surgery. Statistical analysis was performed using SPSS version 26.

Results. The mean surgical time was significantly lower in the RIRS group (83.51 ± 21.7 minutes) compared to the PCNL group (98.12 ± 22.1 minutes) ($p = 0.001$). The mean hospital stay was also significantly shorter in the RIRS group (1.9 ± 1.0 days) compared to the PCNL group (3.2 ± 1.3 days) ($p = 0.001$). The prevalence of minor complications (Clavien I) was higher in the RIRS group (15.5%) than in the PCNL group (6.5%) ($p = 0.037$). However, moderate to severe complications (Clavien II and III) were higher in the PCNL group (Clavien II: 10.5% vs. 3.4%, $p = 0.033$; Clavien III: 4.8% vs. 0%, $p = 0.016$).

The stone-free rate in the RIRS group was significantly higher among patients with longitudinal stones (93.8%) compared to globular stones (54.3%) ($p = 0.001$). No significant differences were detected in BMI ($p = 0.065$) and stone size ($p = 0.112$) between those with successful and unsuccessful procedures in the RIRS group.

Conclusions. Stone shape, especially longitudinal, is a crucial factor in choosing between RIRS and PCNL for renal stones >20 mm. RIRS offers advantages in surgical time, hospital stay, and minor complications, with higher success rates for longitudinal stones. Future research should focus on multivariate analyses considering stone size, shape, and configuration to determine the most effective treatment strategies for large stones.

Key words: *renal stones, percutaneous nephrolithotomy, retrograde intrarenal surgery, stone shape, stone-free rate, surgical time, hospital stay, complications.*

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Нова змінна у прийнятті рішення щодо вибору хірургічного лікування ниркових конкрементів розміром понад 20 мм

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Резюме. *Сечокам яна хвороба становить значний тягар для здоров'я багатьох людей у всьому світі. У разі збільшення розміру ниркового конкремента понад 20 мм, необхідні інвазивні урологічні втручання. Метою нашого дослідження було порівняти ефективність черезшкірної нефролітотомії (PCNL) і ретроградної інтраренальної хірургії (RIRS) у лікуванні ниркових конкрементів розміром понад 20 мм.*

Методи. Це проспективне інтервенційне дослідження проводилося протягом чотирьох років (червень 2019 – червень 2023) у кількох центрах, включаючи клініку Газі Аль-Харірі, приватну лікарню Бейрута та приватну клініку в Багдаді. У дослідженні прийняли участь 240 пацієнтів з нирковими конкрементами розміром 20-40 мм. Пацієнти були розподілені на дві групи залежно від методу оперативного втручання: RIRS (n = 116) та PCNL (n = 124). Порівнювали соціально-демографічний та медичний анамнез, клінічні та лабораторні маркери, результати візуалізуючих досліджень та спостереження протягом трьох місяців після операції. Статистичний аналіз проводився за допомогою SPSS версії 26.

Результати. Середній час хірургічного втручання був значно нижчим у групі RIRS (83,51 ± 21,7 хвилини) порівняно з групою PCNL (98,12 ± 22,1 хвилини) (p = 0,001). Середня тривалість перебування в стаціонарі також була значно коротшою в групі RIRS (1,9 ± 1,0 дня) порівняно з групою PCNL (3,2 ± 1,3 дня) (p = 0,001). Поширеність незначних ускладнень (Clavien I) була вищою в групі RIRS (15,5%), ніж у групі PCNL (6,5%) (p = 0,037). Однак помірні та важкі ускладнення (Clavien II і III) були частішими в групі PCNL (Clavien II: 10,5% проти 3,4%, p = 0,033; Clavien III: 4,8% проти 0%, p = 0,016).

Повну відсутність конкрементів у групі RIRS було досягнуто у 93,8% пацієнтів із поздовжніми каменями та у 54,3% хворих з глобулярними (p = 0,001). Не було виявлено істотних відмінностей в ІМТ (p = 0,065) і розмірі каменю (p = 0,112) між пацієнтами з успішною та неуспішною процедурою групі RIRS.

Висновки. Форма каменя, особливо поздовжня, є вирішальним фактором під час вибору техніки хірургічного втручання ниркових каменів >20 мм. RIRS має переваги щодо тривалості операції, перебування в стаціонарі та кількості ускладнень, з вищими показниками успішності (без каменів). Майбутні дослідження повинні зосередитися на багатофакторному аналізі з урахуванням розміру, форми та конфігурації каменю, щоб визначити найбільш ефективні стратегії лікування ниркових конкрементів понад 20 мм.

Ключові слова: *ниркові конкременти, черезшкірна нефролітотомія, ретроградна внутрішньониркова хірургія, форма каменя, ремісія, тривалість операції, тривалість перебування в стаціонарі, ускладнення.*

Introduction. A renal stone is a frequent urological condition that causes crystal agglomerates to grow in the urine tract and occasionally pass through it [1]. It is a major cause of morbidity and affects approximately 1–15% of the world's population resulting in a significant increase in treatment costs and substantial health challenges [2]. Calcium stones are the most common and include about 70 to 80% of the stones [3]. Obesity and metabolic syndrome are identified as risk factors for renal stones. Currently, it is known that renal stones increase the chance of developing other systemic conditions, including diabetes, cardiovascular disease, bone fractures, and chronic kidney disease. Conversely, kidney stones are also at risk due to these disorders. Kidney stone formation and these systemic diseases are probably caused by similar risk factors [4-6]. Regarding treatment, the majority of patients with stones less than 1 cm will pass the stones naturally with analgesic medication and oral stone lysis; however, patients with stones larger than 1 cm typically need more urological treatments [7]. Because of its exceptional success rate in removing large renal stones (> 2 cm), percutaneous nephrolithotomy (PCNL) has emerged as the standard procedure for treating these stones. However, minimally invasive procedures—particularly mini-PCNL and retrograde intrarenal surgery (RIRS)—are now the mainstay of stone therapy due to their reduced risk of complications [8, 9]. Checking the stone's size and shape is the first thing that most urologists do when they are looking at a renal stone to determine the most effective treatment for it. There is no doubt that the stone burden is the most important factor to consider when

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deciding [10]. However, the significance of stone shape is often undervalued, and mostly the measurement of calyceal extension is used to assess the complexity of the stone [11].

The location and size of the stone, the surgeon's experience, the accessibility of endoscopic tools, and the patient's preferences are all taken into consideration when choosing a course of therapy [12]. Open surgeries and laparoscopic approaches are still viable options for such big stones, but they are seldom used nowadays in current practice [13]. Despite PCNL's great efficiency, non-negligible morbidity effects persist, including organ damage (rare), urinoma, and bleeding that requires angioembolization [14]. Compared to PCNL, RIRS is less risky and has a lower morbidity rate; nevertheless, it also has a lower rate of stone removal. RIRS has made it possible for urologists to treat complicated renal stones or lower calyx stones through the natural orifice, contributing to an acceptable stone-free rate [12, 15].

This study aims to compare the effectiveness of PCNL and RIRS options in the management of renal stones above 20 mm.

Patients and methods. ***Study design, setting, and time.*** This was a prospective interventional study conducted in the Urology Department at Ghazi Al-Hariri Hospital for Surgical Specialties, a Beirut private hospital, and a private clinic in Baghdad, Iraq, during a period of four years from June 2019 to June 2023. The study protocol was approved by the Bioethics and Deontology Commission of Ibn Sina University (protocol number: 2024-1234, dated 15/01/2018); all patients provided written informed consent to participate in the study.

Study Population and Sample Size. The study included 240 patients who attended the Urology casualty department or private clinic and were diagnosed with renal stones of 20 - 40 mm in size with little or no calyceal extensions and were scheduled for either PCNL or RIRS. The diagnosis of renal stones was confirmed radiologically by ultrasound, plain abdominal (KUB), and/or non-contrast CT scan.

This study excluded patients with acute or chronic nephritis, nephrotic syndrome, obesity, concurrent ureteral or bladder stones, renal tumors, renal dysfunction, single kidney, and pregnant women.

Patients were informed about the potential for both treatments, as well as the benefits and drawbacks of each, and were then treated using the technique that best suited their needs and those of the medical community. All the patients signed an informed consent that allows us to review their medical records for research purposes, provided that the patient's anonymity and confidentiality of their medical records are maintained. They were divided into two groups:

- **RIRS group:** Included 116 patients who underwent treatment by flexible ureterorenoscopic lithotripsy.
- **PCNL group:** Included 124 patients who underwent treatment by percutaneous nephrolithotomy.

Workup. A total of 240 patients were evaluated following these steps:

- Complete sociodemographic, medical, and surgical history with assessment of height & weight to obtain Body Mass Index (BMI).
- Clinical evaluations were done using a complete medical history, physical examination, and routine laboratory tests (Complete blood count, coagulation, biochemistry).
- One week before surgery, a urine culture was collected. Five to seven days before surgery, patients whose cultures were positive were given antibiotics; the remaining patients received 1 g of ceftriaxone during the induction of anesthesia, preceded by a skin sensitivity test.
- Computed tomography (CT) and/or KUB radiography were done to evaluate stone characteristics and anatomical data.

Procedure.

RIRS group:

- Under general anesthesia, patients were positioned for dorsal lithotomy and given intravenous antibiotics.
- The ureteral access sheath (UAS) will be passed and scanned fluoroscopically over the zebra guide wire (0.038 mm) that was inserted using a semi-rigid 8 Fr KARL STORZ ureteroscopy.
- After removing the guidewire, a flexible ureteroscope (Innovex China with Insertion section diameter 2.9 mm / 8.7 Fr) passed through UAS.
- 230 μm fiber of KARL STORZ CALCULASE III 35-Watt holmium: YAG Laser used via ureteroscope to dust stones with an energy setting level of 0.7 J and pulse rates (30 Hz).
- A wire basket can be passed through the working channel to collect larger fragments, while 4 mm particles can pass naturally.
- In patients with tight ureters, Double-J stents were inserted, and the flexible ureterorenoscopy was delayed two weeks to take advantage of their passive dilation effect.
- The day after the intervention, the patient is typically released from the hospital.

PCNL group:

- Under general anesthesia, patients were positioned for dorsal lithotomy, given intravenous antibiotics, and a cystoscope was used to insert a ureteral catheter. The patients were then prone.
- The pelvicalyceal system is outlined by injecting contrast fluid through a ureteral catheter. This helps guide the needle's entry into the kidney from the skin with the aid of a fluoroscope.
- Once the needle is inserted, remove the stylet and note a urine drip. Then, a 0.9 mm (0.035-inch) bendable hydrophilic-coated guidewire is passed through the needle hollow and curled within the renal collecting system or even passed to the ureter.

- A metal ALKIN cannula is passed over the guidewire into the collecting system after the needle is removed. A guide metal rod entered the calyx through that cannula.
- A serial AMPLATZ dilator was guided by a guide rod into the targeted calyx until the last access sheath passed through the skin into the collecting system, where a Karl Storz nephroscope and pneumatic lithotripter broke the stone. Stone pieces were removed with forceps.
- After the procedure, a nephrostomy tube and urinary catheter were used to empty the bladder.
- Patients stay in the hospital for 2-3 days after the one- to three-hour procedure, depending on its intricacy. Drainage tubes are usually removed within 24–48 hours.

Evaluation. The third postoperative month was used to assess the effectiveness of the surgical procedure (% stone-free rate) using a non-enhanced abdominal CT scan. When there is no sign of stone remnants, or they are less than 4 mm, the area is deemed free of stones [**17**]. Postoperative fever was defined as a body temperature > 38 °C.

A modified version of the Clavien-Dindo grading system was employed to assess peri and postoperative complications. Surgical complications classified using the modified Clavien-Dindo method:

Grade I: Anything that departs from the anticipated healing process without the need for medicine or medical treatments such as surgery, endoscopy, or radiography. Drugs, including antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physical therapy are among the permitted pharmaceuticals.

Grade II: Pharmaceutically managed complications requiring the use of drugs other than those approved for complications of Grade I. Blood infusions and complete parenteral nutrition are also included.

Grade III: Challenges requiring endoscopic, radiologic, or surgical treatments.

- A: Operations not requiring general anesthesia.
- B: Operations requiring general anesthesia.

Grade IV: Challenges requiring acceptance to the critical care unit and are potentially fatal.

- A: Dysfunction of a single organ.
- B: Dysfunction of multiple organs.

Grade V: The patient passes away.

Statistical analysis. The data was analyzed using Statistical Package for Social Sciences (SPSS) version 26. The data is presented as mean, standard deviation, and ranges. Categorical data is presented as frequencies and percentages. An independent t-test (two-tailed) was used to compare the continuous variables accordingly. The Chi-square test was used to assess the association between categorical variables, while the Fisher exact test was used instead when the expected frequency was less than 5. A level of P – P-value less than 0.05 was considered significant.

Results. In this study, the age ranged from 23 to 59 years, with a mean of 39.62 ± 9.0 years. There were no statistically significant differences ($P \geq 0.05$) between study groups in age, BMI level, gender, stone size and number, Hounsfield units, and stone-free rate. We noticed that the shape of the stone was longitudinal in 69.8% of the RIRS group and 56.5% of the PCNL group, and this difference was statistically significant (P= 0.032).

The means of surgical time and hospital stay were significantly lower in the RIRS group than in the PCNL group, given that 17 (14.6%) patients experienced tight ureter and required ureteral stenting for a duration of two weeks, the retrograde intrarenal surgery (RIRS) was subsequently performed. However, each of them had hospital stays lasting no longer than 4-5 hours, and these hours were included in the overall hospital stay duration for RIRS. The prevalence of patients with complications graded as Clavien I (minor complications) was significantly higher in the RIRS group than in the PCNL group (15.5% versus 6.5%, $p = 0.037$). They complained of mild to moderate loin pain or discomfort, vomiting, or increased body temperature, and all responded well to analgesia, antiemetics, and antipyretics. The prevalence of patients with complications graded as Clavien II and III was significantly higher (10.5% versus 3.4% and 4.8% versus 0%, $p < 0.05$ respectively) in the PCNL group than in the RIRS group. In the RIRS group, three patients (Clavien II) had severe infection and pyrexia (urosepsis), which required intensive care and monitoring with very broad-spectrum antibiotic therapy covering culture and sensitivity results. One patient required re-admission a few days after discharge from the hospital because of severe pain and fever, and she responded well to high-potency analgesia and antibiotic therapy. In the PCNL group, seven patients required blood transfusions, two patients had a severe infective complication (urosepsis), and four patients required admission a few days after discharge from the hospital because of severe pain and fever, and they responded well to high potency analgesia and antibiotic therapy.

In PCNL patients with Clavien III, three patients required angioembolization (because of persistent bleeding), two patients converted to open surgery because of loss of access, and one patient required a secondary percutaneous procedure to evacuate a large perinephric urinoma a few days after surgery (Table 1).

Table 1

Comparison between study groups by certain characteristics

Variable	Study group		p-value
	RIRS	PCNL	
Age (Year)	38.65 ± 8.7	40.59 ± 9.3	0.096
BMI (kg/m^2)	25.85 ± 2.9	26.45 ± 3.1	0.122
Gender (M/F), n (%)	102 (87.9) / 14 (12.1)	114 (91.9) / 10 (8.1)	0.3
Stone size (mm)	23.31 ± 3.6	24.03 ± 2.7	0.081
Hounsfield units (Density)	1198.8 ± 164.3	1224.87 ± 126.4	0.17
Stone shape (Longitudinal / Globular)	81 (69.8) / 35 (30.2)	70 (56.5) / 54 (43.5)	0.032
Stone number (Single / Multiple)	105 (90.5) / 11 (9.5)	105 (84.7) / 19 (15.3)	0.171
Surgical time (mint.)	83.51 ± 21.7	98.12 ± 22.1	0.001
Stone free rate (%)	95 (81.9)	107 (86.3)	0.351
Hospital stay (Day)	1.9 ± 1.0	3.2 ± 1.3	0.001
Complication			
Clavien I	18 (15.5)	8 (6.5)	0.037
Clavien II	4 (3.4)	13 (10.5)	0.033
Clavien III	0 (0)	6 (4.8)	0.016
Total	22 (19.0)	27 (21.8)	0.589

The data is presented as M ± SD or proportion (%).

As shown in Table (2), the highest prevalence of stone-free rate (success procedure) in the RIRS group was seen significantly among patients who had a longitudinal shape of stone (93.8%, p = 0.001).

Table 2

Comparison of certain clinical characteristics according to stone-free rate in the RIRS group

Variable	Stone free rate in RIRS group		Total (%) (n = 116)	p-value
	Yes (%) n= 95	n (%) n= 21		
Stone shape				
Longitudinal	76 (93.8)	5 (6.2)	81 (69.8)	0.001
Globular	19 (54.3)	16 (45.7)	35 (30.2)	
BMI (Kg/m^2)	24.91 ± 2.7	26.2 ± 3.1		0.065
Stone size (mm)	24.13 ± 3.9	22.92 ± 3.2		0.112

No statistically significant differences were detected in BMI and stone size (p ≥ 0.05) between those with successful and those with unsuccessful procedures.

Discussion. Currently, PCNL is advised as the preferred initial treatment for renal stones larger than 20 mm [14]. Despite its great effectiveness, PCNL can still have non-negligible morbidity, such as organ injury, urinoma, and bleeding that requires angioembolization. Modern technology, such as laser lithotripsy and creative endoscopic baskets, permits treating complicated renal stones via the natural orifice [16, 17]. The current study observed that surgical time and hospital stay were significantly lower in the RIRS group. Similarly, the Cosmin et al. study revealed that surgical time and hospital stay were significantly longer for the PCNL group than for the ureteroscopy group (P<0.05) [14]. Also, the Giusti et al. study [18] and the Xuan et al. study [19] found that surgical time and hospitalization took longer for the PCNL group. Differently, He-Qun Chen et al. found that the RIRS group was identical to the PCNL group in surgical time (P = 0.1) [20]. Although the location, number, density, shape, and size of stones are important determinants for the difference observed, it should be remembered that complications might accompany the procedures as an explanation for the differences observed. Although smaller, less dense

stones require less time to operate on, patients with a stone burden approaching 40 mm, particularly those with high Hounsfield units (>1000 HU), need more time in PCNL. This finding is consistent with the findings of Hoa TQ et al, [21] but we still measured an average operating time of (98.12 ± 22.1) minutes for all stones larger than 20 mm. The duration of the surgical operation has an important role in the impact of complications. The risk of urosepsis secondary to RIRS is raised with the longer duration, and the requirement for blood transfusion secondary to hemoglobin decreases in patients receiving the PCNL treatment [18].

In this study, the prevalence of complications graded as Clavien I (mild to moderate loin pain or discomfort, vomiting, or fever) was significantly higher in the RIRS group than in the PCNL group (P= 0.037).; while complications graded as Clavien II and III were significantly higher in the PCNL group (P < 0.05). The LV G et al. study observed that both minor and major complications were significantly higher in the PCNL group [22]. Differently, the Cosmin et al. study reported a non-significant difference in minor complications between the RIRS and PCNL groups, but it was significantly higher in the PCNL group in Clavien III, IV [14].

On the contrary, Pieras and colleagues revealed no differences in the complications between both procedures [23], while the overall complication rate in the Cosmen et al. study was higher in the PCNL group but with an absence of statistical relevance (P>0.5). Also, there were further grade III and IV complications in the PCNL group (P < 0.05) [14]. The difference observed above is explained by different expertise levels in different centers, in addition to the stone characteristics, composition, and general condition of the patients. Infectious complications are more pronounced in the RIRS group because of the relatively high intrarenal pressure procedure in comparison with PCNL [24]. Moreover, vascular complications are more pronounced in the PCNL group because of the invasive nature of the procedure, which requires a violation of the kidney parenchyma to access the urinary collecting system [25].

In this study, the stone-free rate in the RIRS group was seen as significant among those with longitudinal stones (P= 0.001). There is no relation between BMI and stone size (P ≥ 0.05). Karalar et al. study reported that localization, type, and burden of stone were numerically significant determinants impacting the absence of stone status (P<0.05) [26]. In the same concern, Iqbal and co-authors revealed that PCNL can be done safely and effectually regardless of BMI level (P=0.7) [27]. Moreover, results from the Akbulut et al. study [28] and Şimşek et al. study [29] deduced that BMI and size of stone do not affect success rates post-PCNL. The potential reasons for different stone-free rates among studies are that fragment residues denote a cluster of clinically insignificant fragments, besides the intrinsic flaws in the existing RIRS methods and systems, such as the flexibility of ureterorenoscopy and the restricted working channels. Physiologically, we did not see any specific reasons why longitudinal stones are successfully treated with RIRS. However, from a physical and anatomical standpoint, longitudinal stones have a smaller surface area compared to globular stones. Additionally, the narrow working space during the procedure prevents excessive jerky movements during fragmentation. These characteristics make longitudinal stones well-suited for RIRS, even if they are large in size. Moreover, another important factor concerning the shape of the stone is that the stone takes the shape of the part at which it is impacted, according to the pelvic configuration, especially the intrarenal pelvis that influences the stone configuration. Which, in turn, makes it easier to be accessible by the RIRS and to be fragmented [30].

Our study has several limitations. One limitation of this study is the lack of stone analysis to determine the ease of fragmentation. Stone hardness was determined by measuring the density of stones using Hounsfield units obtained from computed tomography. The absence of supplementary tools such as cone baskets and high-quality company forceps hinders our ability to thoroughly remove all traces of stone from the surface. Consequently, we are often compelled to rely on fragments to extract smaller pieces. A sluggish learning curve indicates a scarcity and shortage of competent trainers. Furthermore, due to the absence of NCCT follow-up for all patients, the comparison between preoperative and postoperative imaging may be subject to bias and the assumption of stone-free status based on intraoperative imaging. The strength of our study lies in its large sample size, multi-center data, and the extensive surgical and endoscopic expertise of all authors.

Conclusions. Our study identifies a crucial factor influencing the choice between RIRS and PCNL for renal stones larger than 20 mm: stone shape, particularly longitudinal. RIRS offers advantages in surgical time, hospital stay, and minor complications compared to PCNL, which exhibits higher rates of moderate to severe complications. Moreover, RIRS demonstrates significantly higher success rates with longitudinal-shaped stones.

The results of this study highlight the increasing significance of RIRS as a safer and more efficient choice for treating large kidney stones. It emphasizes the need for customized approaches that consider the characteristics of the stones. Furthermore, It is suggested that future research should prioritize multivariate analysis that takes into account not only the size but also the shape and configuration of the stones. This will help determine the most effective management strategy, particularly for large stones.

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Authors contributions. MA collected the data, MA, MN, and TS wrote the first draft, and MA analyzed the data. All authors contributed to the design and conduct of the study, as well as the editing of the manuscript. All authors read and approved the final version of the manuscript.

Ethics approval. The authors declare that the article is original and has not been submitted anywhere else, and the Tables included in the article are original.

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