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The Efficacy and Safety of Using a Stone Cone During Ureteroscopic Pneumatic Lithotripsy

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Abstract

Background: Ureteroscopic fragmentation and extraction of ureteric stones is one of the most efficient minimal invasive treatment modalities. One of the drawbacks of this procedure, which occurs mainly during the fragmentation of upper ureteric stones, is the migration of proximal stones.

Objectives: To study the efficacy and safety of the Stone cone in preventing proximal stone migration during ureteroscopic pneumatic lithotripsy.

Patients and Methods: A retrospective data set of forty patients (25 male and 15 female), with symptomatic upper ureteral stones of greater than 7 mm in size, was collected from patients' records. Patients were allocated into two equal groups: Group A (interventional group) underwent ureteroscopic pneumatic fragmentation using a stone cone, and Group B (control group) underwent ureteroscopic fragmentation without using a stone cone. The data on pre-operative patients, the stones dealt with, and the results of the procedure in both groups were all stated.

Results: Pre-treatment patients and stone data (including patient age, gender, stone size, opacity, laterality, duration of symptoms, and degree of pelvicalyceal system dilatation) were comparable in both groups, with no statistically significant difference. The mean stone size was 12.7 mm in group A and 12.5 mm in group B. Stone migration occurred in 0 % in group A and 35% in group B (p=0.004), which led to a stone-free rate of 90% in group A and 60% in group B (p=0.028). Complications were minimal and comparable in both groups, and they were all amenable to conservative treatment.

Conclusion: Use of a stone cone as a ureteric occlusive device was reasonably safe, helped prevent proximal stone migration, and led to statistically significant improvement in stone-free rate during pneumatic lithotripsy.

Keywords: Ureteroscope, Renal Stone, Pneumatic Lithotripsy, Efficacy, Safety.

Introduction

The urinary tract consists of four parts, including the kidneys, ureters, bladder, and urethra. The ureters act as narrow muscular channels that transport urine from the renal pelvis to the bladder. This narrow and delicate anatomy contributes to the deposition and formation of urinary tract stones (1). Urinary tract stones affect 5–12% of people throughout their lives, and recurrence rates are close to 50.0%. Stone development is more than twice as common in males as in males (2). Ureteric stone usually presents with a sudden onset of severe flank pain, which is colicky in nature, and most commonly presents in emergency rooms. Intracorporeal lithotripsy via ureteroscopy has become the preferred treatment for ureteric stones during the past three decades (3,4). The preferred method for surgically treating ureteric stones has historically been ureteroscopy. A safer and more effective method for treating stones in any part of the ureter has emerged with the invention of small-caliber semirigid and flexible ureteroscopies, along with the introduction of better equipment. Global complication rates, particularly those of ureteral perforations, have decreased to less than 5% due to growing experience, and the incidence of long-term issues like stricture formation is 2.0% or lower (5). The development of intracorporeal lithotripters, such as ultrasonic, electrohydraulic, pneumatic, and laser lithotripters, coincided with advancements in rigid and flexible ureteroscopies. These advancements allowed for effective stone fragmentation using contemporary ureteroscopic equipment. Among the indications for using URS for a ureteric stone are the stone is larger than 7 mm, insufficient pain alleviation even with analgesics, the stone is less than 7 mm, when the medical expulsive therapy has failed, the possibility of sepsis or pyonephrosis, and unilateral obstruction in a single kidney or bilateral ureteric obstruction. After ureteroscopic removal, the predicted stone-free percentage is 90–100% for distal ureter stones and 74.0% for proximal ureter stones. The development of innovative gripping tools, pneumatic and laser lithotripters, and efficient semi-rigid and flexible ureteroscopes is responsible for the high success rate of ureteroscopic stone extraction (6,7). Nevertheless, the irrigant's propulsion effect or, more commonly, the application of kinetic energy employed for stone breakdown are two minor concerns that restrict the success of ureteroscopic stone manipulation. These issues include the possibility of upward migration or retropulsion of the stone (7). Retropulsion rates range from 2 to 60.0% (8,9,10). Furthermore, because proximal ureteric stones have a larger retropulsion rate than those placed distally in the ureter, this large variance in migration rate is mainly attributable to the stone's location. Stone cones and N-traps are examples of ureteric occlusion devices that have been developed as a remedy for this retropulsion. During intracorporeal lithotripsy, the stone cone and N-Trap are intended to prevent the retropulsion of ureteric calculi and facilitate the secure removal of stone fragments. Furthermore, the ureteric guide wire can be replaced with a stone cone, preserving continuous ureteric access and reducing the need for extra disposables (11,12). This study aimed to study the efficacy and safety of the stone cone in preventing ureteral stone migration during ureteroscopic pneumatic lithotripsy.

Patients and Methods

Study design: In this retrospective study, medical records of forty patients (25 males, 15 females) were reviewed over a period of 2 years. All patients were assessed by history taking, physical examination, and laboratory investigations (urinalysis, complete blood count, blood sugar, and renal function tests). Imaging studies, including KUB, ultrasound, and native computerized tomography (CT) scan, helped assess stone size, site, opacity, and degree of hydronephrosis.

Inclusion and exclusion criteria: The inclusion criteria were being older than 20 years and having a stone with a longest diameter of more than 7 mm located in the upper ureter. The Exclusion criteria include the presence of ureteral stricture distal to the stone, clinical evidence of sepsis, coexistence of kidney stones, lower ureteric stone, ureteric stone in a single kidney,

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and significant renal impairment.

Procedures: Patients were distributed equally into two groups. Group A (interventional group) underwent ureteroscopic fragmentation using a stone cone, and Group B (control group) underwent ureteroscopic fragmentation without using a stone cone. In both groups, an 8-9.5 Fr semi-rigid ureteroscope with a 5 Fr working channel was used, a pneumatic lithotripter was employed for stone fragmentation, and the stone cone used in group A was 3 Fr in size.

Stone cone technique: All patients underwent ureteroscopy under general or spinal anesthesia, and all of them received a single dose of broad-spectrum antibiotics parenterally at the time of induction of anesthesia. Patients were placed in lithotomy position; the ureteroscope was passed into the ureter with the aid of a 0.035-inch guide wire. After reaching the stone with the semi-rigid ureteroscope, in group A patients, the stone cone was advanced through the working channel of the ureteroscope until it reached beyond the stone, and the stone should be seen between the two black lines on the Stone Cone sheath. Coaxial traction on the Stone Cone sheath allows the cone to reform, and it should act as a barrier between the stone and the pelvicalyceal system. The ureteroscope is then taken out and reinserted beside the Stone Cone device to the level of the calculus, and the pneumatic lithotripsy probe is introduced to fragment the stone. Once the stone has been sufficiently fragmented, residual fragments are removed by a ureteric grasper. Continuous low-pressure fluid irrigation was necessary to maintain visibility of the stone and was used in both groups. In group B patients, fragmentation of the stone was also performed using the pneumatic lithotripter, but without the Stone cone. At the end of the procedure, a 5 Fr JJ stent was inserted over the guide wire and left indwelling for 4-6 weeks. A Foley catheter was inserted for all the patients and kept for 2 days. Parenteral antibiotics were continued for two days postoperatively, and if no fever occurred, they were replaced by oral antibiotics for 5-7 days. KUB was taken on the same or next day (before discharge) to check the state of stone fragmentation and the position of the JJ stent. Most of our patients were discharged on the same operation day (after complete recovery) and asked to return after two weeks for follow-up. This follow-up usually includes a history review, physical examination, and an ultrasound or KUB or native CT scan to check for any residual stone pieces & complications. The procedure was considered successful in either group if no proximal stone migration occurred and if the stone was fragmented completely. Stone-free status is defined as complete clearance of stone fragments at the time of JJ stent removal, without the need for auxiliary procedure. The recorded post-operative data were: the degree of fragmentation (complete or incomplete), stone-free rate, proximal stone migration, and any complications related to the intracorporeal lithotripsy or Stone cone.

Statistical Analysis

The data were analyzed using Epi Info™ version 7, a statistical software developed by the Centers for Disease Control and Prevention (CDC), Atlanta, USA [https://www.cdc.gov/epiinfo/index.html]. Continuous data are presented as means and standard deviations. Student's t-test (two-tailed) was used to compare them between study groups. Categorical data are shown in frequency and percentage tables. Pearson's chi–squared test was used to assess the statistical association between categorical variables. A p-value less than 0.05 was considered significant.

Results

Demographics and clinical characteristics: Pre-treatment parameters, including the demographic and clinical characteristics, were compared between Group A (interventional group) and Group B (control group) (Table 1).

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The mean age (± SD) of total respondents was 35.2 (± 7.6). The mean age in Group B (36.4±8.6 years) was higher than that in Group A (33.9±6.5 years). Most of the participants were males, with a higher percentage in Group A (65%) compared to Group B (60%). The Majority of stones were radio-opaque (87.5%), and Right-sided (22, 55.0%), especially among the interventional group (13, 65% vs. 9, 45%). The mean duration of impaction was longer among the Group A individuals (10.1±20.5 weeks vs. 5.2±3.3 weeks in Group B), with an overall mean of 7.7±14.7 weeks. Both interventional and control groups similarly exhibit mild and moderate P.C.S. dilatation. Findings of the independent t-test (t) and chi-square test showed that all parameters had no statistically significant differences when compared between the two groups (Table 1).

Table 1. Pre-treatment parameters, comparison between study groups (Number = 40).

Parameters	Categories	Group A	Group B	Total	p- value
Age (years), Mean ± SD		33.9±6.5	36.4±8.6	35.2±7.6	0.306 ^{t}
Age groups, No. (%)	<30 years	5 (20.0)	3(20.0)	8 (20.0)	0.688
	30 - 39 years	12 (48.0)	9 (60.0)	21(52.5)	
	40+ years	8 (32.0)	3 (20.0)	11(27.5)	
Gender, No. (%)	Male	13 (65)	12 (60)	25 (62.5)	0.744
	Female	7 (35)	8 (40)	15 (37.5)	
Stone laterality, No. (%)	Left	7 (35)	11 (55)	18 (45)	0.204
	Right	13 (65)	9 (45)	22 (55)	
Stone opacity, No. (%)	Radio-opaque	17 (85)	18 (90)	35 (87.5)	0.633
	Radio-lucent	3 (15)	2 (10)	5 (12.5)	
Duration of impaction (weeks), Mean ± SD		10.1±20.5	5.2±3.3	7.7±14.7	0.304 ^{t}
Degree of P.C.S. dilatation, No. (%)	Mild	7 (35)	7 (35)	14 (35)	0.907
	Moderate	9 (45)	10 (50)	19 (47.5)	
	Sever	4 (20)	3 (15)	7 (17.5)	

PCS: pelvicalyceal system, SD: standard deviation, t independent t-test, chi-square test.

The outcomes of the intervention procedure: Average stone size was compared between Group A (12.7±3 mm) and Group B (12.5±3.2 mm) using an independent t-test prior to surgical intervention (Table 2). Findings were almost similar in both groups, with no statistically significant difference (0.841).

Table 2 illustrates the outcomes of the intervention procedure among patients in group A and group B. Chi-square tests showed that the successful fragmentation was higher (90%) in group A compared to group B (60%), with a statistically significant difference (p-value = 0.028). Stone migration was reported only in group B (35%), with a significant difference (p-value = 0.004). The highest stone-free rate (90.0%) was in group A compared to 60.0% in group B, indicating a significant difference (p-value = 0.028). However, complications were similar between groups (30% in group A vs. 25% in group B) with no significant difference (p-value = 0.723). Out of forty cases, 11 (27.5%) were reported complications, mainly bleeding and post-operative fever (Table 3).

Table 2: Results of treatment with comparison between study groups (Number = 40).

Parameters	Group A	Group B	Total	p-value
Average Stone size (mm), Mean ± SD	12.7±3	12.5±3.2	12.6±3.1	0.841ᵗ
Successful fragmentation, No. (%)	18 (90)	12 (60)	30 (75)	0.028*
Stone migration, No. (%)	0 (0)	7 (35)	7 (17.5)	0.004*
Stone free rate, No. (%)	18 (90)	12 (60)	30 (75)	0.028*
Complications, No. (%)	6 (30)	5 (25)	11 (27.5)	0.723
* Significant by chi-square test.				

Table 3. Complications of treatment according to study groups (Number = 40).

Complication	Group A	Group B	Total
Bleeding	3 (15)	2 (10)	5 (12.5)
Perforation	1 (5)	0 (0)	1 (2.5)
Post-Operative Fever	2 (10)	3 (15)	5 (12.5)
Total	6 (30%)	5 (25%)	11 (27.5%)

Findings of bivariate analysis: Bivariate analysis was performed to assess the relationship between stone migration and various studied parameters. A significant reduction in stone migration was seen when using the stone cone (no cases of stone migration), compared to 35% of cases had migration when stone cone was not used, with a statistically significant correlation (p-value = 0.004) suggesting that using a stone cone significantly reduces the risk of stone migration. Other parameters, including the stone size (p-value = 0.426), PCS dilatation (p-value = 0.101), and duration of impaction (p-value = 0.772), did not show significant correlations (Table 4).

Table 4. Correlations between stone migration and different parameters (Number = 40).

Parameters	Categories	Stone migration			p-value
Observation No. (%)		Yes 7(17.5)	No 33(82.5)	Total	
Stone size (mm), Mean ± SD		13.7±4	12.4±2.9	12.6±3	0.426 ᵗ
Degree of PCS dilatation, No. (%)	Mild	0 (0)	14 (100)	14 (100)	0.101
	Moderate	5 (26.3)	14 (73.7)	19 (100)	
	Sever	2 (28.6)	5 (71.4)	7 (100)	
Duration of impaction (weeks), Mean ± SD		6.9±4.6	7.8±16.1	7.7±14.7	0.772 ᵗ
Use of stone cone, No. (%)	Used	0 (0)	20 (100)	20 (100)	0.004*
	Not used	7 (35)	13 (65)	20 (100)	
PCS: pelvicalyceal system, mm: millimeter, SD: standard deviation, * significant by chi-square test, t independent t-test.					

Association between stone-free rate and different parameters: The chi-square test and the independent t-test were employed to find out the relationship between the stone-free rate and different parameters (Table 5). The stone-free rate was 95.5% in the right kidney compared to 50.0% in the left kidney, with a statistically significant difference (p-value = 0.001), indicating that kidney stones in the left kidney were harder to clear than those in the right kidney. In terms of stone migration, about 90.9% of non-migrated stones succeeded in becoming stone-free, while 100% of cases with stone migration were unsuccessful in becoming stone-free,

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suggesting a highly significant correlation (p-value < 0.001). The stone-free rate was significantly higher among patients who underwent a stone cone procedure (90.0%) compared to those without a stone cone procedure (p-value = 0.028), indicating the effectiveness of the stone cone procedure in improving kidney stone clearance. Sociodemographic factors (age, gender), stone size, stone opacity, duration of impaction, and PCS dilatation showed no significant difference (Table 5).

Table 5. Association between stone-free rate and selected clinical parameters (Number = 40).

Parameters	Categories	Stone free			p-value
Observation		Yes 30 (75)	No 10 (25)	Total 40 (100)	
Age (years), Mean ± SD		34.1±6.5	38.3±10.1	35.2±7.6	0.242 ᵗ
Gender, No. (%)	Male	18 (72)	7 (28)	25 (100)	0.572
	Female	12 (80)	3 (20)	15 (100)	
Stone Laterality, No. (%)	Left	9 (50)	9 (50)	18 (100)	0.001*
	Right	21 (95.5)	1 (4.5)	22 (100)	
Stone size (mm), Mean ± SD		12.5±2.8	12.8±3.9	12.6±3.1	0.845 ᵗ
Stone opacity	Radio-opaque	26 (74.3)	9 (25.7)	35 (100)	0.783
	Radio-lucent	4 (80)	1 (20)	5 (100)	
Duration of impaction (weeks), Mean ± SD		8.2±16.8	5.9±4.2	7.7±14.7	0.490 ᵗ
Degree of PCS dilatation, No. (%)	Mild	13 (92.9)	1 (7.1)	14 (100)	0.146
	Moderate	12 (63.2)	7 (36.8)	19 (100)	
	Sever	5 (71.4)	2 (28.6)	7 (100)	
Stone migration, No. (%)	Yes	0 (0)	7 (100)	7 (100)	<0.001*
	No	30 (90.9)	3 (9.1)	33 (100)	
Use of stone cone, No. (%)	Yes	18 (90)	2 (10)	20 (100)	0.028*
	No	12 (60)	8 (40)	20 (100)	

SD: standard deviation, *significant by chi-square test, t independent t-test.

Discussion

The past three decades have witnessed noticeable developments in the field of renal and ureteral stone management. The procedures ranged from simple medical treatment to relief of pain, open surgery intervention, to more advanced, specific, and minimally invasive techniques such as the extracorporeal shock wave lithotripsy (ESWL) and the Ureteroscopy (URS) (13,14). Several studies confirm the highly effective achievement of stone-free rates up to 95.0% using the URS technique (14,15,16). Although the success rate differs with the size and position of the stone (14), one of the main challenges in the upper ureter stones were the proximal migration during fragmentation, especially when processing pneumatic lithotripsy (15,16). To alleviate this, urologists have adopted the Lithotripsy laser instead of pneumatic and ureteral occlusive devices, which improve the outcomes by preventing the stone migration in the renal pelvis (12). This study evaluated the effectiveness of using a stone cone as an occlusive device to prevent stone migration in a trial to improve the stone-free rate. To reduce the cost and also due to the lack of a laser machine or flexible URS, the stone cone was preferred. The results of the surgical intervention, indicated a significantly higher successful fragmentation (90.0% versus 60.0%, p=0.028), stone migration (0.0% versus

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35.0%, p=0.004), and stone free rate (90.0% versus 60.0%, p=0.028) among patients who had underwent ureteroscopic pneumatic fragmentation with using of stone cone compared to without using stone cone suggesting a strong protective effect. These findings are consistent with recent evidence reported by Saeed Pansota et al. (11), who conducted a prospective study among 94 patients with proximal ureteric stones sized 7–15 mm. They reported a significantly higher stone clearance using the Stone Cone (93.6% vs. 70.2%, p = 0.003). Raphael and Danagogo (17) reported a 100% stone clearance after lithotripsy for proximal ureteric stone under ureteroscopy, indicating that the stone cone is a safe device. The mean stone size in our samples was 12.6 ± 3.1 mm, which was comparable to those reported by Raphael and Danagogo (17), and less than those reported by Alameddine et al. (18). The more the duration of stone impaction, the more inflammatory process around the stone, which usually leads to more difficult stone manipulation. Consequently, the above-mentioned histological changes most likely affect ureteroscopy instrumentation, leading to an inability to deal with stones proximal to the level of ureteric obstruction. Ansari et al. (19) reported that the stone-free rate was improved among stented patients compared to those who had not been stented. Moreover, the duration of stone impaction was neither a statistically significant factor affecting stone migration nor affecting the stone-free rate between the two groups. Furthermore, we studied the factors affecting stone migration, and the main correlation was obviously with the use of the stone cone in group A. All cases with migration failed to become stone-free, whereas 90.9% of non-migrated stones were successfully cleared (p < 0.001). Although there was a difference in stone migration regarding the degree of PCS dilatation, it was statistically nonsignificant. Overall stone free rate was 75.0% in our series (90.0% in group A versus 60.0% in group B), while it was 95.0% to 100% in Raphael and Danagogo (17), 89.0% in Alameddine et al. (18), 100.0% in Kapoor et al. (20) and 95.5% in Sen et al. (21) and related to the high incidence of stone migration in group B (35.0%). In this study, there was a statistically significant stone-free rate in the right kidney (95.5%) compared to the left-sided (50.0%) (p = 0.001), raising the challenge to clear stones from the left kidney. However, this positive correlation between stone-free rate and stone laterality is actually of no clinical importance. The use of the stone cone and its introduction through URS was easy and safe, especially with building experience, and the whole procedure, with or without using the stone cone, was, in general, with minimal complications. Although the sample size was relatively small, the study showed statistically significant differences in the main results, such as stone-free rates and stone migration between patients who received the stone cone and those who did not. These findings suggest that the study has sufficient power to identify clinically related effects, especially concerning the interest of using the stone cone in improving the success of the surgical procedure. Additionally, retrospective studies often serve as a basis for future prospective studies or help guide hypothesis generation and design for larger randomized trials. This study contributes to real evidence of the effectiveness and safety of the stone cone devices during ureteroscopy.

Conclusion

The study demonstrates that the use of a stone cone significantly improves stone-free rates and reduces stone migration. Patients in the interventional group (Group A) had a higher stone-free rate compared to the control group. Stone migration was reported exclusively in the control group, reinforcing the role of the stone cone in preventing migration. Other factors, including age, gender, stone size, and duration of impaction, were not significantly associated with treatment success. Ureteroscopic pneumatic lithotripsy for ureteric stones is still a valid treatment option. Use of a stone cone as a ureteric occlusive device was reasonably safe and was helpful in preventing proximal stone migration, and led to statistically significant improvement in stone-free rate during pneumatic lithotripsy.

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Ethical clearance: This study was conducted following the Declaration of Helsinki. The ethical committee approval was obtained from the Iraqi Board for Medical Specialization, Ministry of Higher Education and Scientific Research, Iraq (Reference No. 3712).

Conflict of interest: None.

Use of Artificial Intelligence: The authors declare that they did not use artificial intelligence for creating or preparing this manuscript.

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فعالية وسلامة استخدام Stone Cone أثناء تفتيت الحصوات الهوائي بالمنظار

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الملخص

الخلفية: يُعدّ تفتيت واستخراج حصوات الحالب باستخدام المنظار من أكثر طرق العلاج طفيفة التوغل كفاءة. ومع ذلك، فإنّ أحد العيوب الرئيسية لهذا الإجراء، خاصة أثناء تفتيت الحصوات في الجزء العلوي من الحالب، هو هجرة الحصوات إلى الأعلى.

الأهداف: دراسة فعالية وسلامة استخدام **Stone Cone** في منع هجرة الحصوات العلوية أثناء تفتيت الحصوات الهوائي بالمنظار.

المواد والطرق: تمّ إدراج أربعين مريضًا (٢٥ ذكرًا و١٥ أنثى) يعانون من حصوات علوية في الحالب يزيد حجمها عن **7** مم في هذه الدراسة. تمّ تقسيم المرضى عشوائيًا إلى مجموعتين متساويتين:

- المجموعة **(A) المجموعة التدخلية :**خضع المرضى لتفتيت الحصوات الهوائي بالمنظار باستخدام **.Stone Cone**
- المجموعة **(B) مجموعة الضبط :**خضع المرضى لتفتيت الحصوات الهوائي بالمنظار دون استخدام **.Stone Cone**

تمّ تسجيل البيانات الأولية للمرضى، وخصائص الحصوات، ونتائج الإجراء لكلا المجموعتين.

النتائج: كانت البيانات الأولية للمرضى وخصائص الحصوات (بما في ذلك عمر المريض، الجنس، حجم الحصوة، الكثافة الشعاعية، الجهة المصابة، مدة الأعراض، ودرجة توسع حوض الكلية) متشابهة في كلا المجموعتين دون فروق ذات دلالة إحصائية. بلغ متوسط حجم الحصوات ١٢,٧ مم في المجموعة A و١٢,٥ مم في المجموعة B. لم تحدث أي حالات لهجرة الحصوات في المجموعة A (0%)، بينما حدثت في ٣٥٪ من المرضى في المجموعة B، مما أدى إلى تحقيق معدل خلو من الحصوات بنسبة ٩٠٪ في المجموعة A مقارنةً بـ ٦٠٪ في المجموعة B. كانت المضاعفات طفيفة ومتماثلة في كلا المجموعتين، وتمّت معالجتها جميعًا بشكل تحفظي.

الاستنتاج :يُعتبر استخدام **Stone Cone** كجهاز انسداد للحالب آمنًا إلى حدٍ كبير، ويساعد في منع هجرة الحصوات العلوية، مما يؤدي إلى تحسن ملحوظ من الناحية الإحصائية في معدل خلو المرضى من الحصوات أثناء التفتيت الهوائي بالمنظار.

الكلمات المفتاحية : منظار الحالب، حصى الكلى، تفتيت الحصوات الهوائي، الفعالية، السلامة

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