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# Is retrograde intrarenal surgery for the treatment of renal stones with diameters exceeding 2 cm still a hazard?

Guido Giusti, MD,<sup>1</sup> Silvia Proietti, MD,<sup>1</sup> Lorenzo G. Luciani, MD,<sup>2</sup>  
Roberto Pescechera, MD,<sup>1</sup> Antonella Giannantoni, MD,<sup>3</sup>  
Gianluigi Taverna, MD,<sup>1</sup> Giuseppe Sortino, MD,<sup>1,4</sup> Pierpaolo Graziotti, MD<sup>1</sup>

<sup>1</sup>Department of Urology, IRCCS Humanitas Clinical and Research Center, Milan, Italy

<sup>2</sup>Department of Urology, Santa Chiara Hospital, Trento, Italy

<sup>3</sup>Department of Urology, Santa Maria della Misericordia Hospital, Perugia, Italy

<sup>4</sup>Department of Urology, G. Rodolico Hospital, Catania, Italy

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**Introduction:** Major kidney stones have traditionally been treated with percutaneous nephrolithotomy. However, retrograde intrarenal surgery (RIRS), which until a few years ago was considered inappropriate for this purpose, is becoming a viable, attractive alternative. The aim of the current study was to assess the efficacy and safety of RIRS combined with holmium laser lithotripsy for the treatment of stones > 2 cm in diameter in a large series of patients, reporting complications according to the Clavien–Dindo classification.

**Materials and methods:** By retrospective analysis,

we identified a total of 162 patients who were affected by stones greater than 2 cm in diameter and who had undergone RIRS. We reviewed demographic and stone characteristics, intraoperative and postoperative outcomes, and complications.

**Results:** The mean stone size was 2.7 cm ± 0.6 cm. The primary, secondary, and tertiary stone-free rates were 66%, 80.9%, and 87.7%, respectively. The mean number of procedures per patient was 1.48. The complication rates according to the Clavien–Dindo classification were Clavien I in 20.4% of patients, Clavien II in 0%, Clavien III in 4.9%, Clavien IV in 0.6%, and Clavien V in 0%.

**Conclusions:** As an alternative to standard procedures for the treatment of renal calculi greater than 2 cm in diameter, RIRS is safe and effective, with a low complication rate.

**Key Words:** renal stones, endourology, flexible ureteroscopy, complications

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## Introduction

In 1976, Fernstrom revolutionized the surgical approach to urolithiasis by introducing percutaneous nephrolithotomy (PCNL);<sup>1</sup> since then, the management of renal stones has continued to evolve as efforts have been made to improve the stone-free rate (SFR) while reducing the invasiveness of the procedure and complications. The advent of extracorporeal shock wave lithotripsy (ESWL) in the late 1980s brought the utility of PCNL into question, owing to

its invasiveness, but it soon became clear that ESWL could not be considered a panacea for all stones. ESWL provides SFRs as high as 54%, but the retreatment rate is high for large stones<sup>2</sup> and for stones located in the lower calices with unfavorable radiographic anatomy.<sup>3</sup>

In 2013, the European Association of Urology's Guidelines on Urolithiasis for the first time listed retrograde intrarenal surgery (RIRS) as a viable option for the treatment of all kidney stones, including stones larger than 2 cm in diameter, in experienced hands in high-volume centers.<sup>4</sup> In the last few years, advancements in the endourological armamentarium together with the downsizing of flexible ureteroscopes, the advent of digital technology, and the increasing number of requests for minimally invasive procedures have made the use of RIRS for renal calculi increasingly attractive, even for stones larger than 2 cm in diameter. According

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Address correspondence to Dr. Silvia Proietti, Department of Urology, IRCCS Humanitas Clinical and Research Center, Via Manzoni, 56, 20089, Milan, Italy

to several recent retrospective reports, the retrograde approach to large renal calculi, which was considered inappropriate until few years ago, is becoming a viable and attractive alternative to PCNL.<sup>5-12</sup> In a recent meta-analysis of data on the use of RIRS for stones larger than 2 cm, Aboumarzouk et al showed that the SFR is comparable to that of PCNL; indeed it demonstrates a SFR of 93.7% for flexible ureteroscopy. Moreover, the authors reported for RIRS an overall complication rate of 10.1% (major complications in 4.8% of patients and minor complications in 5.3% of patients).<sup>13</sup>

Herein we present our retrospective series of RIRS with laser lithotripsy for intrarenal calculi larger than 2 cm; we describe the details of our technique and present results and complications.

## Materials and methods

From our database, we retrospectively identified patients with renal stones larger than 2 cm in diameter, regardless of position in the collecting system, who had been treated with RIRS by a single surgeon, from April 2006 to February 2012. The inclusion criteria were as follows: either sex, age 18-80 years, and renal stones with diameters between 2 cm and 4 cm. Exclusion criteria were as follows: pregnancy, urinary tract abnormalities (i.e., horseshoe and ectopic kidney, caliceal diverticulum, duplex reno-ureteral district), and positive urine culture. Note that we also offered our patients PCNL as an alternative treatment option and clearly specified that the percutaneous approach is still recommended as the first treatment option by the most important international guidelines. Informed consent was obtained from all patients, and the possible need for a staged procedure in order to obtain satisfactory stone clearance was mentioned.

We reviewed demographic and stone characteristics, intraoperative and perioperative outcomes, and complications related to the procedure. Routine preoperative work up included history, physical examination, urinalysis, urine culture, hematocrit, serum creatinine evaluation, and plain abdominal CT scan. Operative time was calculated from the time of endoscope insertion to the completion of stent placement. The Clavien classification of complications modified by Dindo was used.<sup>14</sup>

The day after the procedure, a kidney-ureter-bladder radiograph was obtained, and we used ultrasonography (US) for radiolucent stones. When there was a significant residual stone, the patient was discharged and immediately scheduled for a second-look procedure within 2 weeks. If clearance was satisfactory, the patient was discharged with a 2 week prescription for

0.4 mg of tamsulosin to facilitate spontaneous passage of debris<sup>15</sup> and a 6 week prescription for potassium citrate and magnesium; in case of radiolucent stones it was administered potassium citrate associated with potassium bicarbonate. The patient was advised to force fluids and sleep on his or her side with the operative side up. Solifenacin (5 mg daily) was used throughout the stenting period, in the absence of contraindications.

The JJ stent was removed either by the patient at home by means of gentle traction on the strings left in place or on an outpatient basis by means of flexible cystoscopy. At the 1 and 3 month follow up visits, all patients underwent US to rule out the presence of residual stone fragments and hydronephrosis. Stone free rate was defined as residual fragments up to 2 mm in maximum diameter detected on ultrasound.

## Technique

Before the procedure, patients are given intravenous antibiotics, usually gentamicin. Under general anesthesia, patients are positioned in a modified lithotomy position with the ipsilateral leg straightened to reduce the psoas bulge and in Trendelenburg's position with operative side up to prevent migration of stone fragments into the lower pole calices. Instead of starting with the cystoscope, we perform a quick first-look ureteropyeloscopy with a semirigid scope with the dual purpose of passively dilating the ureteral orifice under direct vision to facilitate placement of the ureteral access sheath (UAS) and carrying out initial lithotripsy with a larger, more effective laser probe.

Consequently, the procedure starts with the insertion of the semirigid ureteroscope into the bladder so that a hydrophilic nitinol core guide wire can be passed into the renal pelvis as a safety guide to ensure permanent access to the collecting system. A second guide wire is passed up the ureter to guide the progression of the semirigid ureteroscope.

In the case of pelvic stones, once the renal pelvis is entered and the stone visualized, a 550 mm holmium laser fiber set at low energy (0.2 J-0.6 J) with a high pulse rate (15 Hz-40 Hz) is introduced, and stone vaporization begins. Once the residual fragments are no longer reachable with the semirigid instrument, and in the case of caliceal stones, we retrieve the semirigid instrument in order to proceed with the flexible scope.

Initially, only 7.5 Storz Flex-X2 (STORZ, Tuttlingen, Germany) and Gyrus-ACMI DUR-8 Elite (ACMI Corp, Southborough, MA, USA) fiber optic flexible scopes were available at our institution. However, since March 2011, the Storz Flex-XC (STORZ) digital flexible ureteroscope has also been available to us.

We routinely place a 12-14 F UAS (Flexor 12-14F, Cook Medical, Bloomington, IL, USA) to the level of the proximal ureter alongside a safety guide wire in order to avoid prolonged intrarenal high pressure, which is associated with a risk of pyelo-venous backflow and damage to the ureter due to repeated passes for extraction of fragments. In the case of a narrow or uncompliant ureter, we shift to a smaller UAS (Flexor 9.5-11.5F, Cook Medical), which accommodates only the Storz Flex-X2 fiber optic scope. In cases in which placement of the UAS is impossible, we attempt a sheathless procedure, keeping in mind all the attendant limitations of that procedure. Active pressure irrigation is always used to keep the operative field clear.

In the case of lower caliceal stones, we always attempt to displace the stone into a more accessible upper calyx by tipless basketing or grasping (N-Circle 1.7 F tipless megabasket, Cook Medical, or 1.9 F Zero Tip basket, Boston Scientific, Natick, MA, USA). When stone relocation is not possible, lithotripsy is carried out in situ until fragments become suitable for repositioning into a favorable upper calyx.

Once stone fragments are visualized, a 200 mm laser fiber is inserted with the above mentioned power setting in order to proceed with fragmentation. When stone fragments appear to be less than 2 mm in diameter, on the basis of mobility with irrigation and using the laser fiber and the guide wire as visual size gauges, the procedure is considered terminated. Larger fragments are extracted by extensive basketing (N-Gage 1.7 F tipless basket, Cook Medical). Our policy is not to exceed an operative time of 2.0 h.

At the end of each procedure, the UAS is removed under visual control and a 6 Fr JJ stent is routinely placed. In uneventful procedures, without any detection of ureteral lesion, we leave the tether in place to allow for self removal within 3 to 5 days. In the remaining cases, traditional stenting is performed. In case of mucosal ureteral lesion we leave the stent 1 week, in presence of muscular ureteral injury 2 weeks and in case of adventitia lesion 3 weeks. In addition when the patients are scheduled for following endoscopic procedures, we leave the stent until the next surgery.

## Results

On retrospective analysis, we identified 162 patients: 88 males and 74 females. Demographic and stone characteristics are reported in Tables 1 and 2, respectively.

Intraoperative and postoperative data are shown in Table 3. All stones could be reached ureteroscopically; no inaccessible ureter has been encountered. Among the primary procedures, a 12-14 F UAS was placed in

**TABLE 1. Demographic characteristics of patients (n = 162)**

Gender, n (%)	
Male	88 (54.3)
Female	74 (45.7)
Age (y), mean $\pm$ SD	55.9 $\pm$ 11.4
BMI (kg/m <sup>2</sup> ), mean $\pm$ SD	27.8 $\pm$ 3.1
Previous treatments, n (%)	65 (40.1)
ESWL	40 (24.7)
PCNL	18 (11.1)
ESWL + PCNL	7 (4.3)
Pre-procedure stent placement, n (%)	48 (29.6)
BMI = body mass index; ESWL = extracorporeal shock wave lithotripsy; PCNL = percutaneous nephrolithotomy	

129 patients (79.6%), a 9.5-11.5 F UAS was placed in 17 patients (10.5%), and in the remaining 16 patients (9.9%), the ureter was not negotiable, and the procedure was carried out sheathless. Among the iterative procedures, all but two ureters were negotiable with a 12-14 F UAS.

Ninety-nine patients underwent only a single procedure (61.1%), 48 patients (29.6%) underwent a second-look procedure, and 15 patients (9.3%)

**TABLE 2. Stone characteristics**

Stone size (cm), mean $\pm$ SD	2.7 $\pm$ 0.6
Stone composition, n (%)	
Calcium oxalate	78 (48.1)
Uric acid	25 (15.4)
Apatite	32 (19.7)
Struvite	15 (9.3)
Mixed	12 (7.5)
Hounsfield units, mean $\pm$ SD	1050 $\pm$ 235
Stone location, n (%)	
Renal pelvis	60 (37)
Upper calyx	8 (4.9)
Mid calyx	7 (4.3)
Lower calyx	22 (13.6)
Renal pelvis + upper calyx	15 (9.3)
Renal pelvis + mid calyx	16 (9.9)
Renal pelvis + lower calyx	34 (21)
Number of stones, n (%)	
Single	97 (59.9)
Multiple	65 (40.1)

TABLE 3. Intraoperative and postoperative outcomes

Use of UAS, n (%)	146 (90.1)
OR time per procedure (min)	83.4 ± 17.4
Total OR time per patient (min)	129.4 ± 33
ΔHCT	1.8 ± 0.2
ΔCreatinine	0.8 ± 0.5
Length of hospital stay (days)	1.9 ± 0.1
Primary SFR	107/162 (66%)
Secondary SFR	131/162 (80.9%)
Tertiary SFR	142/162 (87.7%)
Mean no. of procedures per patient	1.48
Stent removal, n	240
By cystoscope	99
Removed by patient	141

UAS = ureteral access sheath; SFR = stone-free rate

underwent a third procedure. Note that two patients refused the third procedure because they were already asymptomatic and free of upper urinary tract infection and/or obstruction, despite the presence of significant residual fragments.

A final renal US (1 month after the final procedure) demonstrated SFRs after 1, 2, and 3 stages of 66%, 80.9% and 87.7%, respectively. Note that the tertiary SFR might have exceeded 87.7% if two patients had not refused a third procedure because they were already asymptomatic despite the presence of residual fragments. Apart from one, all patients with residual stones are asymptomatic and free of upper urinary obstruction and/or infection. All residual stones

were less than 1 cm in the maximum diameter and, except one in the middle calyx, were located in the lower calyx.

All uncomplicated procedures were carried out on an overnight regimen. Complications according to the Clavien–Dindo classification are shown in Table 4. We did not find any difference in complications and SFR between “naïve” patients for stones treatment compared to 40% of patients who underwent anamnestically prior surgeries (PCNL, ESWL or both).

## Discussion

In recent years, tremendous advances in flexible ureterorenoscopy have been made, due both to important refinements in newer-generation digital flexible ureteroscopes and to the greater effectiveness of the disposable endourological armamentarium together with the recent advent of intracorporeal holmium laser lithotripsy.

Even though flexible ureteroscopy has for years been considered merely as a diagnostic tool, acceptance of RIRS as a powerful therapeutic treatment option has become increasingly widespread. In a recent meta-analysis of data on the use of RIRS for stones with diameters of > 2 cm, the authors reported an average SFR of 93.7% for a mean stone size of 2.5 cm, with an average of 1.6 procedures per patient and a mean operative time of 82.5 minutes; results were better in patients with stones between 2 cm and 3 cm than in patients with larger stones.<sup>13</sup> Our outcomes were similar those of the meta-analysis: we achieved a final SFR as high as 87.7% with a mean OR time of 83.4 minutes and requiring 1.48 procedures per patient. According to other previous reports about RIRS,<sup>13</sup> our final SFR is absolutely comparable to that of PCNL.

TABLE 4. Complications by Clavien–Dindo grade

Grade	Patients with complications, n (%)	Type of complications
Clavien 0	120 (74.1)	None
Clavien I	33 (20.4)	Fever; hematuria without clot retention; acute urine retention; UTI without readmission; prolonged pain
Clavien II	0 (0)	None
Clavien III	8 (4.9)	URS for steinstrasse; balloon dilation for ureteral stenosis
Clavien IV	1 (0.6)	Septic shock requiring ICU stay
Clavien V	0 (0)	None

UTI = urinary tract infection; URS = ureteroscopy; ICU = intensive care unit



In a matched-pair analysis, Akman et al compared PCNL and RIRS for the management of 2-4 cm stones and reported that SFRs after a single session were 73.5% and 91.2% for RIRS and PCNL respectively. Overall complication rates in the PCNL group were higher, but the differences were not statistically significant. The length of the hospital stay was significantly shorter in the RIRS group ( $p < 0.001$ ).<sup>16</sup>

In a literature review of PCNL complications, Seitz et al reported Clavien I grade in 11.4% of cases, Clavien II in 7.1%, Clavien III in 4.1%; Clavien IV in 0.6% and Clavien V in 0.04%.<sup>17</sup> The most common complications of PCNL include bleeding requiring blood transfusion in 1-12% of patients, fever in 2.8-32.1%, and septicemia in 0.9-4.7%.<sup>18</sup> Even though in most cases, PCNL is still considered the gold standard procedure for removal of large stones with a high SFR in a single treatment, the procedure is burdened by more important and potential life-threatening complications than RIRS.

It is remarkable that high SFRs have been achieved with RIRS at a mean number of 1.6 procedures per patient as reported by Aboumarzouk et al<sup>13</sup> and 1.48 procedures per patient in our study; this number of procedures is quite high if related to PCNL in which about of 95% SFR is achieved after single session.

This concept is crucial and should be stressed. RIRS and PCNL represent two different ways to solve the same problem. RIRS is less invasive, given the endoluminal nature of the procedure, but in some cases, multiple hospital visits and anesthesia are required. In contrast, PCNL is much more effective in a single stage but is more invasive and carries a higher risk of hemorrhagic and other major complications. A radical change in mentality will be needed if endourologists are to accept the idea of a multistage procedure. If the idea is accepted, satisfactory and repeatable outcomes can be achieved by means of RIRS. In addition, detailed and honest patient counseling is of paramount importance so that patients have all the necessary information to allow them choose the procedure that best fits their expectations. If informed consent is obtained in a cursory manner, patients can experience disappointment and regret as they schedule second- or third-look procedures. In addition, as malpractice payments related to endourology continue to rise,<sup>19</sup> the possibility of legal action is something to be aware of.

Moreover, in their meta-analysis of RIRS outcome data, Aboumarzouk et al<sup>13</sup> reported minor complications in 4.8% of cases and major complications in 5.3% of patients. However, there is some bias in these findings because complications were not mentioned in 1 of the 9 studies included in the meta-analysis. In addition, in another of the studies, information about

complications was not clearly reported, so those data were left out of the calculation. Of the nine studies, four that reported complication information were conducted with a small number of patients. None of the studies precisely specified how complications were categorized as minor or major. As a matter of fact terms such as "minor" and "major" have not been standardized; therefore an objective comparison of complications among different studies is difficult. The modified Clavien classification system is a uniform, reproducible and standardized system representing a compelling tool for quality assessment and allowing a comparison data from different sources and systems.

Therefore, in an effort we considered any deviation from normal postoperative course as a complication and the most to standardize reporting of outcomes, we classified complications according to the Clavien-Dindo classification. In our study 19.6% of complications were classified as Clavien I-II and 5.5% as Clavien III-IV. These values are higher than previously reported values, and we attribute that to the fact that dangerous complication of ureteroscopic manipulation of renal calculi remains urinary infection, and the occurrence of urosepsis can be as high as 4.9%.<sup>20</sup> In our study, one patient developed septic shock requiring a 4 day stay in the ICU, even though the preoperative urine culture was negative. Even with placement of a UAS, pressure irrigation can sometimes lead to an excessive increase in intrarenal pressure ( $> 50$  mmHg), which has the potential to cause pyelo-lymphatic and pyelo-venous bacterial back-flow.<sup>21</sup> Moreover, the preoperative bladder urine culture is known to be a poor predictor of infection in the stone or in the upper tract urine.<sup>22</sup> In addition, neither preoperative nor intraoperative antibiotic therapy can control endotoxemia, which can result from the release of endotoxins contained within the stone structure during its fragmentation.<sup>23</sup>

To minimize the septic complication rate, the following criteria have to be rigorously adhered to: 1) operate only on patients with sterile urine, 2) always try to place a UAS, 3) always irrigate with caution while checking the continuous outflow from the UAS, 4) do not exceed a operative time of 2 hours, and 5) carefully observe patients in the first 6 postoperative hours (90% of these rare but potential lethal complications occur within 6 hours).<sup>24</sup>

Despite we used modified Clavien scale, we believe that the use of this system in reporting RIRS complications needs a reliable validation through a large prospective multicenter study before being accepted as undisputed tool for the reporting of complications in this aforementioned procedure among urological community.

Our study has some limitations, one being that it is a purely retrospective study. However, it is one of the largest involving a series of patients who underwent RIRS for kidney stones larger than 2 cm in diameter at a high-volume center performed by single experienced endourologist.

In addition, the US images obtained before and after the procedure were not sufficiently comparable to allow us to precisely determine SFRs; the fact that we did not conduct postoperative CT scans could call our outcomes into question. However, we are concerned about radiation exposure to our patients, who likely to experience recurring stones. An unenhanced CT scan results in a significant radiation exposure of 8.6 mSv,<sup>25</sup> and radiation hazard is known to be directly proportional to cumulative radiation exposure time. As a consequence, US is our favorite imaging tool for patient follow-up: we find that it provides reliable information about eventual residual fragments and/or hydronephrosis without the need for exposure to radiation.<sup>26</sup>

Despite these limitations of the study, it is interesting because it is the first to classify RIRS complications according to the Dindo-modified Clavien classification. Prospective randomized multicentric studies comparing RIRS to PCNL for treatment of stones larger than 2 cm in diameter are needed if the advantages and disadvantages of the two techniques are to be more precisely evaluated.

## Conclusion

We conclude that the reduced invasiveness of RIRS compared to PCNL is definitely not outweighed by a reduction in its effectiveness and, as a consequence, RIRS represents a significant step forward in the treatment of urolithiasis. □

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