

## Kidney stones over 2 cm in diameter-between guidelines and individual approach

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### Abstract

The prevalence of urolithiasis has been observed to increase during last decades. Kidney stones over 2 cm in diameter are the common urologic problem. European and American Associations of Urology has published guidelines on Urolithiasis and presented the most effective tools to treat large stones. On the other hand many experienced endourologic centres choose other modalities from their armamentarium. All treatment methods are characterized by their efficacy and safety which are usually inversely proportional. It is crucial for patients and physicians to find a golden mean. Percutaneous lithotripsy is still considered treatment of choice with more than 95% efficacy. Less invasive retrograde intrarenal surgery is also less effective, but burdened with lower complication rate. Extracorporeal shockwave lithotripsy is feasible in paediatric patients with acceptable stone free rates. Open surgery (pylolithotomy and anatomic nephrolithotomy) are almost obsolete techniques. All methods have their pros and cons. Physicians should share decisions regarding treatment modalities with patients.

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**Key words:** Kidney stones; Percutaneous lithotripsy; Shockwave lithotripsy; Retrograde intrarenal surgery; Pylolithotomy; Anatomic lithotomy

**Core tip:** There are various modalities for treatment of kidney stones over 2 cm in diameter. Guidelines indicate the most appropriate methods. Percutaneous lithotripsy is considered first line treatment while retrograde intrarenal surgery or shockwave lithotripsy are optional approaches. Apart from guidelines physicians should share decisions regarding optimal treatment with patients.

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### INTRODUCTION

Nephrolithiasis is one of the most common diseases afflicting mankind. It has been reported in various medical writings since antiquity. In United States its prevalence has doubled since the sixties being now between 2% and 7%. Similarly in countries of Western Europe like Germany, Spain and Italy its prevalence has also been rising<sup>[1,2]</sup>. It has recently been shown that the real prevalence might even be higher reaching 8.4%. Men are afflicted more frequently than women (10.6% vs 7.1%). Racial differences are evident. The most commonly afflicted are white males. African-American females develop least likely urinary stones, while other races are in-

between<sup>[3]</sup>.

Urolithiasis manifest itself clinically mostly between 30 and 50 years of patients' age. The risk of recurrent renal colic after the first stone episode is roughly 15% during the first 3 years and grows up to 50% for the next 7 years<sup>[4,5]</sup>. In patients with more than one stone diagnosed during their first renal colic this ratio might increase to 75%. After every urolithiasis treatment, the patients should be stratified and accordingly assign to low or high risk group of stone recurrence. Urolithiasis promoting factors as patients' age, recurrent stone formers, familial urolithiasis, calcium hydrogenphosphate (brushite), uric acid, cystine, and so called infection stones have to be analysed and appropriately considered for the further management. This group requires thorough metabolic evaluation and a close follow-up. However, only in 20% of the patients a systemic disease predisposing to stone formation can be identified<sup>[6]</sup>.

Over the last centuries a significant shift in stone location has been observed from the lower to the upper urinary tract. A disease considered previously as male ailment is now gender blind. Metabolic diseases such as obesity and diabetes are strongly associated with urolithiasis. It seems that diet and lifestyle play an important role in disease development<sup>[7]</sup>. Nephrolithiasis might be an effect of other systemic diseases such as: inherited and acquired renal tubular acidosis, primary and secondary hyperparathyroidism, gout, various neoplasms, primary hyperoxaluria, gastrointestinal diseases, sarcoidosis, recurrent/persistent urinary tract infection, metabolic syndrome and cystinuria. Some anatomical abnormalities of the urinary tract are also associated with lithogenesis and comprise: horseshoe kidney, ureteropelvic junction obstruction, medullary sponge kidney, calyceal diverticulum and vesicoureteral reflux<sup>[8]</sup>. Urinary tract infections play an important role in stone formation and thus need a special clinical attention and management. As it can be seen in the example of staghorn calculi, most of them have an infectious origin and consist of magnesium ammonium phosphate-struvite or carbonate apatite-dahlite or ammonium urate<sup>[9,10]</sup>.

The aim of our study was to present and compare several treatment methods that can be offered for patients with renal stones over 2 cm in diameter.

Medline was search for articles published between 1977 and 2013. The following keywords were entered: "kidney stone", "Percutaneous nephrolithotripsy", "extracorporeal shockwave lithotripsy" and "retrograde intrarenal surgery". Only English written papers were included. Only papers most relevant for the purpose of this review were included.

## DO WE HAVE TO TREAT KIDNEY STONES?

Until now this crucial question remains at least partially unanswered. What is the appropriate clinical management for small asymptomatic calyceal stones, that do

not grow? For all other renal stones active treatment is recommended. Referring to this, Guidelines on Urolithiasis of the European Association of Urology changed in 2011. Previously, active stone removal had only been recommended for calculi > 6 mm. In accordance to the literature, a rate of spontaneous passage was estimated to be 1% in comparison to smaller stones (*i.e.*, < 3 mm) when almost all stones can be expelled<sup>[11]</sup>. Currently guidelines state that all stones over 15 mm in diameter should be removed. This recommendation is based on a trial revealing, that there are no differences between active and conservative approach in asymptomatic calyceal kidney stones < 15 mm in diameter in terms of stone free rate, symptoms, quality of life and renal function<sup>[12]</sup>. Therefore patients who elect observation instead of active treatment of their kidney stones should be informed about the possible course of the disease. In that situation, in three years 77% of asymptomatic patients with kidney calculi will progress and 26% will require active treatment. Moreover, lower pole stones grow more frequently than middle and upper pole stones (61% *vs* 47%). The rate of growth is positively correlated with uric acid concentration in serum and urine<sup>[13]</sup>. Therefore individual approach for each patient is advised with abovementioned consideration and taking into account other clinical information obtained from patients history (*e.g.*, occupation, *etc.*). For that reason, even small asymptomatic calyceal stones should be actively treated in jet pilots, travelers, *etc.*

There is no such question in terms of larger stones. Staghorn calculi inevitably lead to unresolved/persistent urinary tract infections with loss of renal parenchyma, chronic pyelonephritis and eventually loss of kidney function<sup>[9,14-17]</sup>. Untreated large stones may also cause life-threatening urosepsis which in some circumstances requires intensive care management or even nephrectomy.

## METHODS OF TREATMENT

Renal stone treatment has gone through significant changes over last decades from mainly open surgeries to minimally invasive ones. The treatment modality depends mainly on stone size, hardness and position within the kidney. The last Guidelines on Urolithiasis of the European Association of Urology (EAU) recommend endourology as a treatment option for renal calculi over 20 mm in diameter stating simultaneously superiority of percutaneous lithotripsy (PNL)<sup>[8]</sup>. However, optional approaches in large stones are feasible and comprise retrograde intrarenal surgery (RIRS) with flexible (fRIRS) or semirigid ureterorenoscopes (rRIRS), endoscopic combined intrarenal surgery (ECIRS), shockwave lithotripsy (SWL) and exceptionally open surgery (pylolithotomy and anatomic nephrolithotomy).

### **PNL and open surgery**

Until the last year, PNL had been the gold standard in the treatment of renal stones over 2 cm in diameter. Still

this technique is being chosen among other methods as first line therapy for large renal calculi. It remains also an alternative for smaller stones formed by cystine, brushite and whewellite which are usually very hard and associated with lower stone free rates when treated with different modalities. It was shown that stone density over 970 Hounsfield units on non-contrast computed tomography are efficiently destructed by SWL in 38% in comparison with softer stones where such ratio reached 96%<sup>[18]</sup>. Usually 3-5 ineffective sessions with SWL also should prompt physician to offer more invasive methods to the patient.

There are many different PNL techniques. None appears to be more efficient than the others. The procedure can be conducted in prone and supine position. Originally PNL was described in prone position with specially invented metal dilators<sup>[19]</sup>. This kind of patient positioning offers an unlimited access to the kidney even in terms of a multi-track approach. Subsequently supine position was proposed by Valdivia Uría *et al*<sup>[20]</sup> to improve direct anesthesiological access to the patient's chest and to minimize the vena cava-syndrome. A further miniaturization of the equipment allowed to perform PNLs in children<sup>[21,22]</sup>. As standard PNL procedures are performed with 28-Fr or 30-Fr channel mini PNL offers smaller sheaths between 12-Fr and 20-Fr. Unfortunately ultrasonic disintegration is technically unfeasible in these systems. The next step of miniaturization called ultra-mini-PNL (UMP) has been shortly presented<sup>[23]</sup>. The procedure is carried out using a 3.5-F telescope and special inner and outer sheaths. After puncturing the kidney, tract dilatation up to 13-F is performed. Stones are disintegrated with a 365- $\mu$  holmium laser fibre and actively evacuated by creating an eddy current of saline in the instrument shaft. Further miniaturization has allowed to disintegrate stones with the so called "all-seeing needle" (4.8-Fr). Using this, micro PNL device, renal stones can be disintegrated but neither actively extracted nor washed out. Concerning the size of the instrument, it can be excellently used in paediatric urology<sup>[24,25]</sup>.

To make PNL more convenient for patients tubeless (without nephrostomy) and totally tubeless (without nephrostomy and ureteral catheter) variations of procedure were proposed. Conventional PNL comprise insertion of nephrostomy tube after completion of surgery. This allows free drainage of clots and remnant stones as well acts as hemostat when closed for a short period after procedure. However, hospitalization and operation times are significantly longer in comparison with tubeless procedures<sup>[26-29]</sup>.

Over the last three decades PNL has supplanted pyelolithotomy and anatomic nephrolithotomy in treatment of larger stones mostly due to its significantly decreased invasiveness with only marginally worse efficacy. The last comparison between open stone surgery and percutaneous nephrolithotomy was performed in the late 90's and showed that pyelolithotomy or nephrolithotomy was superior in terms of SFRs<sup>[30,31]</sup>. Despite in-

ferior SFRs, PNL replaced open surgery in treatment of large kidney calculi. The reason for that might have been the acceptance of SFRs in favour of lower complication rate during PNL compared to the open approach. Due to continuous increase of expertise in PNL, both methods seem to have similar efficacy (see Table 1). Another endoscopic alternative in treatment of large renal stones might be a laparoscopic approach. As a minimally invasive procedure, PNL similar SFRs burdened with longer operative times were documented<sup>[32]</sup>. It is worth emphasizing that PNL is not free from complications. The most common are infections occurring in up to 35% of patients. Significant bleeding at 7.8% and mortality rates at up to 0.5% were estimated<sup>[33,34]</sup>.

### Shockwave lithotripsy for large renal stones

In 1984 first SWL machine was introduced for the treatment of kidney stones. Dornier Human Model 1 was a prototype while model number 3 was the first generation lithotripter that was widely used in the clinic<sup>[35,36]</sup>. First interventions were performed under general anaesthesia. The patient was positioned in a large basin filled with degassed fluid. Until now HM-3 Dornier has had the highest known efficacy throughout all shockwave lithotripters.

The mechanism of stone fragmentation is based on a rule that focused ultrasound waves can cause hard object disintegration through tear forces, spallation, cavitation and squeezing<sup>[35,37-41]</sup>.

With only 45%-60% stone free rate SWL efficacy in kidney stones over 2 cm in diameter may be consider as disappointing<sup>[42,43]</sup>. In older studies SFRs up to 70% with low complications rate were reported<sup>[44]</sup>. Fortunately, significantly higher SFRs reaching 85% can be achieved in paediatric patients<sup>[45-47]</sup>. In comparison PNL in children shows the same treatment efficacy as in adults. PNL stone free rates in this group ranges from 68% to 100%<sup>[48,49]</sup>.

In conclusion SWL in patients with stones over 20 mm in diameter is inappropriate except paediatric patients, where an individual approach should always be aimed.

### RIRS

Continuously mastered lithotripsy through natural body orifices (as ureteroscopy) has nowadays allowed to achieve satisfactory results with low complication rates. Although lower SFRs in comparison to PNL, natural orifice transluminal endoscopic surgery (NOTES) is characterized by low morbidity rates, pain and hospitalization times<sup>[50]</sup>. RIRS may be done using flexible (fRIRS) and semirigid instruments (rRIRS). Flexible ureterorenoscopy is characterized by a small shaft calibre, usually less than 10-F. In stones over 2 cm prolonged operation times can be observed (mean 82.5 max up to 215 min). Excellent SFRs above 90% are reported in centres with profound experience in urinary stone management and high case load. It was shown that 1.6 procedures per patient are needed to

**Table 1** The summary of procedures feasible in treatment of renal stones over 2 cm in diameter

	Stone free rate <sup>2</sup>	Complications rate <sup>3</sup>	Ancillary procedures	Operating room time, min
Open surgery <sup>[30,31]</sup>	71%-84%	46%	-	130
PNL <sup>[26-29,32,34]</sup>	75%-98%	0%-33%	9%-33%	52
ESWL <sup>[42-47]</sup>	45%-60%-adults 85%-children	6%	18%	50-70
fRIRS <sup>[50,51-56]</sup>	90%	8%-10%	3%-13%	82-94
rRIRS <sup>[50,54]</sup>	Aug-81%	8%-15%	12%-5%	85-98

<sup>1</sup>Data from 1986; <sup>2</sup>Including insignificant small stone fragments; <sup>3</sup>Including minor and major complications. PNL: Percutaneous lithotripsy; ESWL: extracorporeal shockwave lithotripsy; RIRS: Retrograde intrarenal surgery.

achieve superior results in terms of RIRS treatment<sup>[51,52]</sup>. Complication rates were calculated to occur in 10% of patients while major complications contribute approximately to half of them<sup>[53]</sup>. Instrument costs for flexible ureterorenoscopy are high and appear to be a limiting factor. Due to a very fragile laser fibres which is frequently bent within the working channel of the instrument, its breakage and a consecutive damage of the scope might occur. On contrary, the latest comparison of costs between PNL and fRIRS revealed a vast economic advantage towards ureteroscopy (\$ 19845 *vs* \$ 6675) at least in the United States health care system<sup>[53]</sup>.

The main disadvantages of NOTES-based techniques using semirigid ureterorenoscopes in comparison to fRIRS is their inability to disintegrate stones in lower and middle calyces, potentially high renal fluid pressure, limited intraoperative manoeuvrability and occasional inability to pass the scope through a tight ureter. The main advantage is the ability to pass stone extraction devices through wide working channels and high irrigation flow significantly improving visibility. In the last years we observe many efforts to increase the disintegration rate while lowering the morbidity<sup>[54,55]</sup>. However, even with this improvements reported SFRs are lower in comparison to fRIRS (90% *vs* 81.8%)<sup>[50,51,53,54,56]</sup>. On the other hand the number of ancillary procedures is inferior for rRIRS (see Table 1)<sup>[51]</sup>. The costs for rRIRS are lower than for fRIRS strongly depending on scope damages during procedure.

One of the most important questions regarding urolithiasis therapy has still to be answered. "Can we achieve high stone free rates with low morbidity only in experienced institutions specialized in urinary stone treatment or is it also feasible for all centres?".

## HOW TO ASSESS TREATMENT SUCCESS?

The answer seems to be simple at first sight—lack of stones after the procedure. In most cases stone free status is estimated on the basis of ultrasound and X-ray, rarely on computed tomography (CT). It was shown that results documented by CT and ultrasound + X-ray may tremendously differ (62.3% *vs* 20.8%) in the same treatment group<sup>[57]</sup>. Noncontrast enhanced computer tomography (NCCT) has become a new diagnostic stan-

dard for evaluation of acute flank pain. Its sensitivity for identifying urinary stones was estimated by 96%<sup>[58]</sup>. Sensitivity of ultrasound for identifying renal stones over 5 mm is also 96%<sup>[59]</sup>. X-ray is used mainly due to its high specificity (80%-87%) in detection of urolithiasis<sup>[60]</sup>. Taking into consideration the abovementioned facts one may think that X-ray and ultrasound could be equal to CT in identifying significant residual stones (> 4 mm). Indeed this is not true. Park *et al*<sup>[57]</sup> in their study shown that almost 50% of stones over 4 mm in diameter are visible on NCCT and are not visualized on X-ray (mean size 7.4 mm). These facts strongly support the need for performing NCCT to assess residual stones after lithotripsy. It is also very difficult to compare the results of studies where other than NCCT diagnostic methods of efficacy were applied.

The definitions of stone SFRs are various. Some authors conservatively consider a stone free status as a renal pelvis free of any remaining fragments. Some are more liberal and treat insignificant stones as no stones at all. That concept of insignificant stone is based on statistics which states that almost all stones < 3 mm are freely expellable. On the other hand, some data suggest, that even small persistent calculi might accelerate stone formation and significantly shorten recurrence free intervals.

At last, appropriate scheduling for postoperative evaluation and imaging is crucial. It was shown that up to 25% of patients may become stone free when assessed 1 mo postoperatively in comparison to a group examined one day after a rRIRS intervention<sup>[50]</sup>.

## WHICH TECHNIQUE SHOULD BE CHOSEN FOR KIDNEY STONES OVER 2 CM?

The last EAU guidelines on urolithiasis recommend endourology for the treatment of > 2 cm renal calculi<sup>[8,9]</sup>. Nowadays, a wide spectrum of procedures and therapeutic modalities is available and allows the surgeon to offer an individualized treatment strategy to the patients taking into account all relevant clinical and patient-related parameters. The patient should also be well informed about advantages and disadvantages of each option and be involved in the decision making process. While many

patients choose PNL as widely established standard for treatment of a > 2 cm kidney stone, others may benefit from less invasive procedures accepting lower efficacy and necessity for ancillary procedures. The summary of abovementioned procedures is given in Table 1.

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