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Extracorporeal Shock Wave Lithotripsy 25 Years Later: Complications and Their Prevention

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Abstract

Objective: We review the pathophysiology and possible prevention measures of complications after extracorporeal shock wave lithotripsy (ESWL).
Methods: A literature search was performed with the Medline database on ESWL between 1980 and 2004.
Results: ESWL application has been intuitively connected to complications. These are related mostly to residual stone fragments, infections, and effects on tissues such as urinary, gastrointestinal, cardiovascular, genital, and reproductive systems. Recognition of ESWL limitations, use of alternative therapies, correction of pre-existing renal or systemic disease, treatment of urinary tract infection, use of prophylactic antibiotics, and improvement of ESWL efficacy are the most important measures of prevention. Decrease of shock wave number, rate and energy, use of two shock-wave tubes simultaneously, and delivery of two shock waves at carefully timed close intervals improve ESWL efficacy and safety.
Conclusion: ESWL is a safe method to treat stones when proper indications are followed. The need for well-designed prospective randomised trials on aetiology and prevention of its complications arises through the literature review.

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1. Introduction

Since its first presentation in West Germany in the early1980s [1], extracorporeal shock wave lithotripsy (ESWL) has revolutionized the treatment of urinary lithiasis. ESWL has gained rapid acceptance worldwide because of its ease of use, noninvasive nature, high efficacy in treating kidney and ureteral stones, and wide availability of lithotriptors. ESWL acts via a number of mechanical and dynamic forces on stones such as cavitation, shear, and spalling [2]. The most important force is thought to

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Table 1 – Complications after ESWL for urinary stones

Immediate	Delayed
Related to stone fragments	Renal Function?
Infectious	Hypertension?
Tissue effects	Fertility?
• Renal (haematoma, haemorrhage)	
• Cardiovascular	
• Gastrointestinal	
• Genital system	
• Foetus	

be cavitation [2]. The destructive forces generated when the cavitation bubbles collapse are responsible for the ultimate stone fragmentation. However, they can also cause trauma to thin-walled vessels in the kidneys and adjacent tissues [3], which result in haemorrhage, release of cytokines/inflammatory cellular mediators, and infiltration of tissue by inflammatory response cells. These may lead to short-term complications and to formation of scar and possible chronic loss of tissue function (Table 1).

In this review we present an overview of the post-ESWL complications, their potential mechanisms and predisposing factors, and various ways to prevent them. A thorough Medline search was performed to review various types of papers such as clinical trials, randomised controlled trials, reviews, meta-analysis, editorials, and letters to the editor. Combinations of the following keywords were used: ESWL; complications; stone fragmentation; failure; residual stones; obstruction; steinstrasse; infection; renal anatomy; renal function; hypertension; vascular; cardiac; gastrointestinal; children; fertility; and pregnancy. We reviewed 3,937 abstracts and read 220 papers in full. Ninety-three of these are sited in the reference list.

2. Complications related to stone fragments

Incomplete fragmentation, residual stone fragments, steinstrasse, and obstruction are among the problems urologists confront when ESWL fails to completely fragment the stone treated (Table 2).

Growth of residual fragments <4 mm has been documented in 21%–59% of patients who underwent ESWL [4,5]. Streem et al demonstrated a 43% risk of having a symptomatic episode or needing an intervention, or both, after a mean 26-month follow-up in patients with residual calculi ≤4 mm [6]. With increasing renal persistence of residual fragments, the probability of stone clearance seems to decrease [5]. However, the location of residual fragments does not significantly influence stone clearance rate [5].

Table 2 – Complications of ESWL related to stone fragments

Possible predisposing factors	Possible prevention measures
Hard stones	Alternative therapy for hard and large stones (PCNL, sandwich therapy)
Large stones	Stenting when treating large stones
Lower pole stones	Improve ESWL efficacy
Increased number of stones	
Impaired renal anatomy	
Increased shock wave rate	
Decreased shock wave energy	

2.1. *Predisposing factors*

Predisposing factors to ESWL failure are stone composition, size, location, and number, as well as renal morphology and shock wave rate and energy [7,8]. The fragmentation rate of cystine and calcium oxalate monohydrate stones is low [9]. The ESWL success rate decreases as the stone size increases. Chaussy et al. in 1984 reported a stone-free rate of 91% for stones less than 2 cm [1]; stone-free rates for stones 2–3 cm are 50%–70% and decrease further for staghorn stones [10]. The success rate of ESWL is lower for lower pole calculi than for other stone locations [11]. Lingeman et al. reported stone-free rates of 29% for patients with lower pole calculi of 11–20 mm and 20% for those with calculi >20 mm [11]. The presence of multiple stones has also been related to a higher recurrence of stones after ESWL [1–4]. ESWL is effective for stones in the ureter, although less effective than initial treatment than ureteroscopy [12]. The stone-free rate seems to be related to stone location. For proximal ureteral stones there has been a higher success rate (65%–81%) than for lower ureteral stones (58%–67%). ESWL should be considered as initial treatment in cases such as stones <10 mm [12].

Shock wave rate affects stone fragmentation in vitro and in vivo, improved ESWL efficiency occurring at slower rates [13]. Similarly, progressive increase in lithotripter output voltage improves stone comminution in vitro [14]. However, only two clinical studies [15,16] have addressed the effect of varying shock wave rate on the efficiency of stone fragmentation. The authors confirmed the positive effect of lowering shock wave rates in treating ureteral stones, which indicates the necessity of large randomised clinical trials.

New generation types of the same lithotriptor design or lithotriptors of different design show variable fragmentation ability. Portis et al. [17]

evaluated the HM3 and Lithotron devices, which both use electrohydraulic power sources. The overall success rate was 83% and 63% for the two machines, respectively. Graber et al. [18], in a prospective randomised study that compared the Dornier HM3 and the Lithostar Plus (an electromagnetic lithotripter) revealed that 91% and 65% of patients had residual fragments <2 mm, respectively. However, other studies showed no significant difference when various piezoelectric lithotriptors [19] or electrohydraulic and electromagnetic lithotriptors [20] were compared. These studies were longitudinal trials, many of which did not include retreatment rates or auxiliary procedures after ESWL, which made a meta-analysis of the data difficult.

Despite major concerns about potential hazards of ESWL in the growing child, highly satisfactory results are being reported. Overall stone-free rates are initially 37%–52%, and increase to 57%–100% in long-term follow-up after ESWL [21,22]. ESWL monotherapy for staghorn calculi in children results in a stone-free rate of 73.3% after an average of two ESWL sessions [23]. Stone disintegration and clearance after ESWL in children is easier and earlier than in adults. This is probably because shock waves are transmitted with little loss of energy through the small bodies [24]. Other contributing factors could be the composition of stones and the shorter duration of uropathology in children. In addition, the paediatric ureter is shorter and more elastic and distensible; thus, it permits easier transmission of stone fragments and prevents ureteral impaction [25,26].

2.2. *Prevention*

Complications related to stone fragments can be prevented by realizing the limitations of ESWL for large stone burdens and by using PCNL or ESWL followed by PCNL and repeat ESWL (sandwich therapy), as an alternative. Overall steinstrasse occurs in 1%–4% of patients who undergo ESWL [7]. The rate increases in 5%–10% of patients with large stone burdens (>2 cm^2) [27] and in up to 40% of patients with partial or complete staghorn calculi [28].

Stenting before ESWL reduces complications caused by residual stone fragments, especially when a large stone is treated [29]. However, stents do not decrease the incidence of steinstrasse after lithotripsy of small to moderate-sized stones [27], so small calculi rarely require ureteral stenting. Recently, Okeke et al. [30] successfully used a ureteral access sheath combined with ESWL to facilitate passage of stone fragments in patients with large stone burdens when PCNL was contraindicated.

More importantly, to alleviate stone fragment problems, ESWL must become more effective. In vitro, in vivo, and preliminary clinical studies indicate that using two confocal, opposing shock wave sources triggered simultaneously could lead to an increased stone comminution compared to using one shock wave tube [31]. Similarly, delivery of two shock wave sessions at carefully timed close intervals may increase the exposure of stone to disintegrative forces and lead to increased stone fragmentation [31]. Finally, Heimbach et al. in an in vitro model showed that chemolytic solutions may provide a useful adjunctive modality for improving the efficacy of stone comminution during shock wave lithotripsy [32]. Certainly, more experimental and clinical data are warranted before these adjuncts and improvements in ESWL become established.

3. Infectious complications

3.1. *Incidence and severity*

The renal trauma and vascular disruption associated with ESWL may allow bacteria in urine to enter the bloodstream. Moreover, when infected calculi are destroyed, bacteria are released from the stone into the urine and may be absorbed systemically [2]. As a consequence, bacteriuria, bacteraemia, clinical urinary tract infection (UTI), urosepsis, perinephric abscess formation, endocarditis, candidal and Klebsiella endophthalmitis, candidal septicaemia, tuberculosis, and (rarely) death have been reported after ESWL [2] (Table 3).

Bacteriuria has been found in 7.7%–23.5% of patients who undergo ESWL, including 7.7% in a group of patients without infection-related stones [2,33]. Clinical UTI is more common in patients with struvite stones, multiple or complex stones, or who undergo periprocedural stone or urologic manipulation [2,34]. The rate of bacteraemia after ESWL is reportedly as high as 14% [33] converted into sepsis

Table 3 – Infectious complications following ESWL

Possible predisposing factors	Possible prevention measures
Pre-existing UTI	Treatment of pre-existing UTI
Infected calculi	Early diagnosis of UTI
Multiple stones	Prophylactic antibiotics when predisposing factors are present
Staghorn stones	Prophylactic antibiotics for all?
History of recurrent UTIs	
Urinary obstruction	
Instrumentation at the time of ESWL	

in <1% of cases, although for staghorn calculi, the rate is elevated to 2.7% [10]. The risk of sepsis increases when urine culture is positive before ESWL or in the presence of urinary obstruction [35].

3.2. *Diagnosis and prevention*

Patient symptoms, erythrocyte sedimentation rate (ESR), white blood count (WBC), and urine and blood cultures are all helpful in detecting post-ESWL bacteriuria and bacteraemia. However, these studies become positive when patient symptoms are already established. C-reactive protein (CRP) measurement on the first and third days after ESWL is useful for early diagnosis of complications, before urine and blood cultures become positive [36]. Whether early antimicrobial empiric therapy based on CRP results will prevent these serious complications remains unclear.

The role of routine prophylactic antibiotics is controversial. Pearle and Roehrborn [37], in a meta-analysis of randomised controlled trials, indicated that routine prophylactic antibiotics in all patients who undergo ESWL is efficacious and cost effective in decreasing the need for inpatient treatment of urosepsis. However, several studies, including randomised controlled trials [38], have demonstrated no advantage of prophylactic antibiotics in patients without preoperative UTI or infection stones [38,39]. Preoperative antibiotics should be given to patients with infection-related stones (staghorn and struvite calculi), positive urine cultures, or a history of recurrent UTIs and to those who undergo instrumentation at the time of ESWL [2,34,37,39].

4. Tissue effects of ESWL

4.1. *Renal complications*

Renal complications can be subdivided into early effects on kidney anatomy that lead to haematuria and haematoma formation, and late complications that affect kidney function and cause systemic hypertension (Table 4).

Histopathological examination of human and animal kidneys showed endothelial cell damage to midsized arteries, veins, and glomerular capillaries immediately after ESWL [40,41]. Thin-walled arcuate veins in the corticomedullary junction are especially vulnerable to shock wave exposure and are related to haematuria and haematoma [40]. The lesion is usually a focal process; most of the renal parenchyma is unaffected [40,41].

ESWL-induced acute renal damage may also result in severe injury to the nephron, microvasculature, and the surrounding interstitium [42]; renal tubules and vessels are more vulnerable than renal blood flow to discharge energy [43]. These injuries may be related to the long-term effects of ESWL on renal function.

4.2. *Effects on renal anatomy*

The most common clinical manifestation of renal trauma is gross haematuria that spontaneously resolves in a few days. Symptomatic intrarenal, subcapsular, or perirenal fluid collections and haematomas are rare and occur in <1% of patients who undergo ESWL [44]. However, when computerized tomography or magnetic resonance imaging is

Table 4 – Possible renal effects of ESWL

Effect	Possible predisposing factor	Possible prevention measures
Acute		
Damage to vascular endothelium	Pre-existed hypertension	Use of different types of lithotriptor
Damage to nephron, renal tubules, and interstitium	Pre-existed renal disease	Decrease shock wave number, rate, and energy
Loss of corticomedullary demarcation	Increased shock wave number, rate, and energy	Use of two shock wave tubes
Increased excretion in urine of metabolites indicating renal damage	Increased patient age	Delivery of two shock-waves at carefully timed close intervals
Haematuria		
Haematoma		
Decrease in GFR		
Decrease in effective RPF		
Chronic		
New onset of hypertension?	Increased shock-wave number, rate, and energy	Decrease shock-wave number, rate, and energy
Perirenal Fibrosis	Increased patient age	
Loss of renal function		

performed routinely after ESWL, the haematoma rate may increase to 20%–25% [44].

Haemorrhage and haematomas may be related to the type of lithotripter used [45,46]. The HM3, which uses electrohydraulic energy, delivers more energy per shock wave into the kidney and causes more trauma than the Lithostar Plus machine that uses an electromagnetic source [45]. The Lithostar apparently exerts a greater pressure on the renal capsule, which may account for the higher incidence of subcapsular haematoma compared to EDAP LT-01 piezoelectric machine [46].

Potential risk factors for haematoma formation are bleeding diathesis, the use of drugs with antiplatelet activity, hypertension, obesity, diabetes mellitus, and the number and intensity of shock waves. In the setting of electrohydraulic lithotripsy none of these factors have been consistently proved to be a risk, although hypertension remains a plausible factor [47]. The probability of haematoma increased significantly with patient age during electromagnetic lithotripsy, but was not associated with increasing mean arterial pressure at treatment or any other factor [44].

Treatment of the haematomas is conservative in most cases. The most likely outcome is spontaneous radiographic resolution of the haematoma within two years without clinically evident adverse effects on blood pressure or renal function [48]. However, a decrease in renal blood flow has been reported and associated with acute renal failure and hypertension when there is bilateral involvement or in patients with a solitary kidney [49]. These high-risk patients should be closely followed up.

4.3. *Renal function after ESWL*

Biochemical evidence of renal injury is apparent immediately after ESWL. Blood and urine markers such as renin, creatinine, N-Acetyl-b-D-glucosaminidase (NAG), b-galactosidase (BGAL), b-2-microglobulin (B2M), and proteinuria return to near-normal levels within a few days [41,50,51].

Studies on animals and humans [52,53] reveal a reduction of glomerular filtration rate (GFR) and renal plasma flow soon after ESWL, especially when pyelonephritis coexists [54]. However, ESWL does not affect GFR over the long-term, and immediate renal damage appears to resolve over days to a couple of months [52,53].

Renal function remains unaffected when ESWL is applied to specific clinical situations. Definitive treatment of urolithiasis after relief of obstruction in patients with renal insufficiency further improves renal function [55]. There are several conflicts in the literature about the possibility of the detrimental effect of shock waves on children's growing kidneys. Significant alterations of renal growth in children after ESWL were observed in a long-term study, although the authors could not determine whether these alterations were secondary to the ESWL treatment or to some underlying conditions that are intrinsic to paediatric kidneys with urolithiasis [56].

Shock wave energy induces transient functional damage of tubular function in children [57] and the renal vasoconstriction induced by ESWL is greater in small kidneys than in large ones [58]. On the other hand, assessment of long-term effects of ESWL on GFR in children by renal scintigraphy revealed no significant decrease in mean ipsilateral and total GFR [59] Other long-term follow-up studies could show no parenchymal damage in children who underwent ESWL [21,60]. This evidence supports the concern that has been raised about potential damage to epiphyseal growth centres in children; no long-term skeletal deformities to date having been demonstrated [61].

There is evidence that shock wave lithotripsy damage to the kidney is reduced when cavitation is suppressed [62]. Minimizing the voltage and number of shocks may decrease the deleterious effect [62]. Animal and cell-suspension studies as well as human studies have shown that slowing of the shock wave rate may reduce the level of tissue injury [63]. Experimental studies showed that animals treated with two shock wave tubes showed decreased renal damage than animals treated with a single tube [64]. Additionally, delivery of two shock waves at carefully timed close intervals of microseconds led to reduced renal trauma and improved stone comminution in a porcine model [31]. Prospective trials are clearly necessary to exclude any long-term deleterious effects of ESWL and depict ways to prevent them.

4.4. *ESWL and hypertension*

The incidence of newly diagnosed hypertension after lithotripsy was initially reported to be 8% [65–67]. This does not differ from the incidence of new onset hypertension in the general population, which is approximately 6% [68].

Systolic hypertension per se has not been shown to be increased after ESWL, but diastolic hypertension has been found in multiple studies [65,66,69]. Diastolic hypertension may be a dose-related phenomenon; an increasing number of shock waves correlates with more severe diastolic hypertension [69]. These preliminary surveys were of uncertain validity because of their retrospective nature, the lack of a non-ESWL control group, and a low response rate (up to 33%).

To further elucidate the possible long-term association between ESWL and hypertension, Lingeman et al. [67] retrospectively surveyed 961 patients who were treated for stone disease. Eighty percent of the patients received therapy that exposed them to shock waves; the rest were treated with percutaneous surgery or ureteroscopy and consequently were not exposed to shock waves and served as controls. Follow-up blood pressures were measured one year after treatment. In patients treated with ESWL the annualized incidence of hypertension (2.4%) did not differ significantly from that in control patients (4.0%). Moreover, patients who were exposed to ESWL showed no correlation between the incidence of hypertension and the laterality of treatments, the number of shock waves administered, the voltage applied, or the power index. There was a statistically significant rise in diastolic blood pressure (DBP) after treatment with ESWL. The annualized incidence of new onset hypertension in ESWL patients four years later was 2.1% compared with 1.6% in non-ESWL patients (not significant). A statistically significant difference in the annualized mean DBP was identified in the ESWL-treated patients compared to the non-ESWL patients at all time intervals following treatment. This change in blood pressure remained statistically significant even after other statistically significant risk factors such as pretreatment blood pressure, gender, age, and factors such as years since treatment, direct shock wave exposure to the kidney, and multiple shock wave sessions were controlled for [70].

Patients over the age of 60 may develop hypertension at a higher rate than the control population, which can be predicted by increased intrarenal resistive indices [71]. Janetschek et al. demonstrated a 45% incidence of new-onset hypertension after ESWL in a small group of patients older than 60 (mean follow-up, 26 months) [71]. Close postoperative screening for hypertension in the ESWL patients older than 60 seems reasonable.

The true cause of hypertension after ESWL is probably multifactorial, and whether there is a direct causal link is unclear. Blood pressure is more commonly affected by either renin-mediated [50] or renin-independent [72] mechanisms. Recent studies indicated that renal stone disease rather than the type of treatment significantly increases blood pressure during a follow-up period of 24 months [73].

Most of the preceding studies were retrospective and did not stratify patients into at-risk groups or exclude patients with pre-existing hypertension, renal disease, or other risk factors for renal injury after ESWL. Randomised controlled trials failed to reveal any evidence that ESWL causes changes in blood pressure [68,74,75]. Furthermore a recent study indicated that extracorporeal lithotripsy for kidney stones may be responsible for a drop in blood pressure, possibly because the intrarenal metabolism is altered. This decrease was related to the number and the power of the shock waves applied [76].

4.5. *Cardiovascular complications during ESWL*

Cardiac arrhythmias during ESWL are not uncommon; the incidence is 11%–59% [77]. They usually represent minor, unifocal premature ventricular contractions. Morbid cardiac events [77] or biochemical evidence of myocardial injury [78] are extremely rare. The incidence can be reduced with gating of the shock wave to the electrocardiogram pulse [77]. Ungated ESWL can be performed, but the incidence of arrhythmia increases [79]. No correlation is demonstrated between ventricular premature contractions and patient age, gender, heart disease, stone size and location, presence of a ureteral catheter or nephrostomy tube, mode of anaesthesia, number of shock waves, or types of lithotriptors [77].

ESWL may be performed safely on patients with pacemakers with appropriate precautions [80]. The treatment should be approved and supervised by a cardiologist. Dual-chamber pacemakers should be reprogrammed to the single-chamber mode, and single-chamber rate-responsive devices should have the activity mode programmed off. Patients with the latter type of pacemaker implanted in the abdomen should not have ESWL if the device will be close to shock-wave focal point F2 [81].

Although several patients had abdominal aortic aneurysmal rupture after ESWL [82], experimental and clinical data indicate that patients with aortic and renal aneurysms can be treated safely and without complications [83]. Major vein thrombosis after ESWL has been reported but is rare [84,85]. The exact mechanism is unclear, but it can be precipitated by haematological disorders [85].

4.6. *Gastrointestinal injury secondary to ESWL*

In a recent review, 62 of 3,423 (1.81%) patients experienced a documented gastrointestinal injury (GI) complication after ESWL [86]. Small bowel and colon perforation, ureterocolic fistula formation, GI anastomosis dehiscence, cecal ulcers, colon erythema, bruising and haematomas, bleeding per rectum, pancreatitis and peripancreatic haematoma and abscess formation, liver and spleen subcapsular haematomas, and ileus have been reported in case studies [86]. Two studies specifically examined the incidence of GI injury after ESWL. The first included 40 patients tested with pre- and postprocedural endoscopy, of whom 32 (80%) sustained gastric or duodenal erosions [87]. The second study included 54 patients who were screened with guaiac testing, of whom 2 (3.7%) converted positive after lithotripsy [88].

These adverse effects were associated with the increase in the number and energy of shock waves delivered but also with patient position. Most GI perforations occurred when the patient was prone and received shock-waves that exceeded the U.S. Food and Drug Administration recommended numbers [86]. The exact pathophysiology is not yet clear, but spallation, heat injury, and cavitation are possible injury mechanisms [86]. Prospective randomised studies are needed to determine the exact incidence of GI injury during ESWL and to determine its true clinical impact on patients.

5. Effects of ESWL on fertility and pregnancy

There is enough evidence from experimental and clinical studies that ESWL does not have severe permanent effects on testicular and ovarian function [89,90]. Consequently, male and female fertility are not affected by ESWL [89,90]. Pregnancy is the only absolute contraindication to ESWL because of the potential disruptive effects of the shock wave energy on the foetus that are found in numerous experimental studies [91]. These animal studies are supported by clinical reports of spontaneous miscarriages secondary to ESWL [89]. However, there are case reports of successful delivery of healthy babies with no detectable malformations or chromosomal anomalies, despite the inadvertent application of ESWL during pregnancy [92]. One possible explanation is that embryotoxic or teratogenic sequelae do not occur when shock waves are focused outside the uterus [93]. Further research is necessary to determine whether this procedure can ever be performed safely during pregnancy.

6. Conclusions

ESWL is a safe method to treat stones in the urinary tract when proper indications are followed. Today, 25 years after its implementation, various side effects have been reported and studied, but most are rare and do not hamper the effectiveness of this technique. Preventive measures can be taken to minimize the frequency of these side effects.

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Editorial Comment

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The authors present an interesting review article summing up the experience of the literature with the complications and potential preventing factors of extracorporeal shock wave lithotripsy. They address in a meticulous manner, controversial issues like ‘‘stenting or not stenting’’, ‘‘prophylactic antibiotics’’, ‘‘renal trauma’’, etc.

Twenty five years of clinical experience with extracorporeal shock wave lithotripsy has proved and established its safety and efficacy. Nevertheless, there is an ongoing debate among investigators pertaining to its acute and chronic effects. In the beginning of the 80’s the first Dornier HM3 lithotriptor was introduced and indeed revolutionised the management of lithiasis. Nevertheless, progress with extracorporeal shock wave lithotripsy has been unexpectedly slow since then.

Current lithotripters have not reached the potential of the original electrohydraulic device and provided inferior fragmentation rates compared with the original generation. The industry, in an attempt to minimise morbidity, compressed energy and reduced the size of the lithotriptor focal zone [1]. The theoretical aim was to strike the stone harder and expose less tissue to the potential deleterious effects of shock waves. Nevertheless, third generation lithotripters proved to have lower efficacy than the original HM3 but with an increased rate of side effects. Stone fragmentation rates were not improved and many authors reported higher re-treatment rates. In addition, success rates declined the larger the stone and the further the stone progressed distally within the ureter, leading to a continuous increase in alternative methods (i.e. ureteroscopic procedures) for the removal or ureteral stones [2,3].

The authors finally conclude that there is a need for well designed prospective randomised trials on the aetiology and prevention of treatment related complications. Furthermore, future research for the development of new generation lithotripters, that will be safe for the patients but will also provide a more effective fragmentation rate, is deemed necessary.

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