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Assessing the efficiency of extracorporeal shockwave lithotripsy for stones in renal units with impaired function: a prospective controlled study

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Abstract The objective was to determine the efficiency of extracorporeal shockwave lithotripsy (ESWL) in clearing stones from renal units with impaired function. Thirty-five patients with poorly functioning kidneys determined by intravenous urogram and ^{99m}technetium diethylene triamine pentacetic acid renal dynamic scan underwent ESWL. Stone clearance was assessed at 3 months and compared with that in normally functioning kidneys. The study group was divided into two subgroups. Those with split glomerular filtration rate (GFR) of the concerned kidney between 10 and 20 ml/min were in group 1. Group 2 consisted of patients with split GFR between 20 and 30 ml/min. A control group (group 3) was formed from patients with urolithiasis and normally functioning kidneys. The overall retreatment rate was 84.4%. The overall stone clearance rate in the study group was 34.2% while it was 57.7% in the control group. The stone clearance rate in group 2 was 40%. The difference in stone clearance rate between the study and control groups was statistically significant ($P=0.023$) but that between group 2 and the control group was not ($P=0.159$). The incidence of steinstrasse between the study group 2 and control group was not statistically significant ($P=0.408$). The clearance rate for ureteral stones was comparable in all the three groups. The stone-free rate and rate of steinstrasse for renal stones in kidneys with moderately impaired function were comparable to normally functioning kidneys. However, kidneys with severely impaired function had poor results. The clearance rate for ureteral stones was not influenced by the impairment of renal function.

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Introduction

With its low morbidity and acceptable success rate, extracorporeal shockwave lithotripsy (ESWL) has become the preferred treatment for stone disease by patients and urologists [1]. The majority of renal calculi less than 2 cm are treated by ESWL as the first-line management [2]. In situ ESWL of proximal ureteral calculi has high success rate [3–5]. Customarily ESWL is believed to result in poor stone clearance rates in kidneys with impaired function, as adequate post-procedural urine flow is fundamental to successful fragment passage [6]. Bhatia et al. [7] reported satisfactory results with ESWL of renal and ureteral stones in chronic renal insufficiency (CRI). However, no study has methodically evaluated the clearance of calculi in kidneys with impairment due to diverse causes such as obstructive nephropathy and medical renal disease. There is a need to assess the efficiency of ESWL in such kidneys and correlate it with their degree of impairment. This would allow more accurate estimation of their stone clearance rate, thus enabling objective decision making in individual patients. We report our prospective study designed to evaluate clearance rate of calculi from poorly functioning renal units or their proximal ureters with ESWL and correlate this with a quantitative assessment of their function.

Materials and methods

All patients undergoing ESWL from January 2003 to June 2005 were eligible for inclusion in the study. Pre-procedure investigations included a complete haemogram, renal function profile, coagulogram, urine culture, electrocardiogram if age more than 40 years, intravenous urogram (IVU) if serum creatinine <2 mg%, ultrasonography (USG) and ^{99m}technetium diethylene triamine pentacetic acid (^{99m}Tc DTPA) renal dynamic scan if appearance of the nephrogram phase was delayed beyond 5 min on IVU. Inclusion criteria included patients with unilateral single stones less than 2 cm in size in the pelvis or calyces and less than 1 cm in the upper ureter (above the pelvic brim), appearance of nephrogram phase beyond 5 min on IVU and split glomerular filtration rate (GFR) less than 30 ml/min (calculated by the method of Gates) on the treated side [8]. Patients were excluded if they presented with acute renal failure or if they already had stents or nephrostomies in place, which could confound the results of renal scintigraphic studies. ESWL was done with the third-generation lithotripter Karl Storz modulith SLK (Karl Storz, Germany) in prone position with a specified range of 3,000–3,500 shocks at 20 kV. All treatments were unilateral.

Ultrasonography and X-ray of kidney, ureter and bladder were repeated 1 week after ESWL. Retreatment was offered at this time if there was no fragmentation or a residual fragment greater than 4 mm in maximum diameter persisted. Imaging was repeated at 1 month after the second ESWL session. Patients with no fragmentation were offered alternative treatments at this time. Those with fragments larger than 4 mm were offered a third ESWL session at least 1 month after the second session. Stone clearance was evaluated at 3 months after the first treatment. Successful treatment was defined as stone-free status.

The study group was divided into two subgroups. Those with split GFR of the concerned kidney between 10 and 20 ml/min were in group 1. Group 2 consisted of patients with split GFR between 20 and 30 ml/min. The mean GFR in groups 1 and 2 was 14.27 ± 2.82 and 25.18 ± 3.14 ml/min. A control group (group 3) was formed from patients with urolithiasis and normally functioning kidneys (based on IVU) with all other criteria remaining the same.

Data are expressed as mean ± standard error of mean. Statistical analysis was performed with the chi square and unpaired student's *t* test where appropriate. *P* value less than 0.05 was considered significant.

Results

A total of 36 patients were enrolled in the study. One patient failed to return for assessment at 3 months and was withdrawn. The mean age of the entire study population was 48.9 ± 9.9 years. The demographic data in respect of the three groups are given in Table 1. The three groups were statistically comparable with regard to age, sex, stone site and size.

Serum creatinine was more than 2 mg% in 25.7% of patients. Mean serum creatinine in patients with CRI in groups 1 and 2 was 4.1 and 2.9 mg%, respectively. No patient required dialysis before or after ESWL. Bilateral double J stents were placed in all patients with CRI and bilateral urolithiasis ($n=5$) before treatment but after ^{99m}Tc DTPA renal dynamic scan. A period of 2–3 weeks was allowed for the serum creatinine levels to settle down and remove the confounding variable of acute obstruction in this group of patients. Among these patients all except one had serum creatinine more than 2 mg% at the time of ESWL. All were hypertensive. In four of them there was evidence of renal medical disease also. The dominant cause of renal insufficiency in all of them was deemed to be obstructive uropathy. In four of these patients the serum creatinine showed improvement at 3 months. Of these, two had pelvic and two had impacted ureteral calculi, which showed clearance at 3 months. Therefore 55.5% of patients with serum creatinine above 2 mg% showed no improvement in their renal parameters. No patient with renal medical disease obtained stone-free status or showed reduction of serum creatinine at 3 months.

Impacted upper ureteral calculi (defined as complete obstruction on the IVU) were present in 14.2% of patients in the study group and 7% in the control group. No attempt was made to bypass impacted ureteric calculi before treatment. All patients with impacted stones in the study group were stone free at 3 months while four of five patients with impacted stones in the control group became stone free at 3 months.

Eleven patients had bilateral urolithiasis and nine had recurrent stones. Five patients with CRI had bilateral stones.

Three patients in group 1 required only one session of ESWL, six required two sessions and five patients required three to achieve satisfactory fragmentation. Four patients in group 2 required one session, nine required two sessions and seven underwent three sessions. One did not show any fragmentation after two sessions and was referred for alternative treatment. Eleven stones were fragmented satisfactorily after a single session in group 3 while 35 and 25 underwent two and three sessions of ESWL, respectively. One stone in this group too did not show fragmentation. The overall retreatment rate was 84.4%.

The average number of shockwaves per session in groups 1–3 was 3,090, 3,115 and 3,379, respectively.

Stone-free rates at 3 months according to the stone location are given in Table 2.

The overall fragmentation rate for the study group was 97.1% as compared to 98.5% for group 3. The overall stone clearance rate in the study group was 34.2%. The difference in stone clearance rates between the study and control groups was statistically significant ($P=0.023$) but did not reach significance between groups 1 and 2 ($P=0.41$). Importantly though on subgroup analysis the clearance rate between groups 2 and 3 did not reach statistical significance ($P=0.159$) while that between groups 1 and 3 was significant ($P=0.028$).

Within the study group while the rate of clearance of renal stones was 25.9%, that of ureteral calculi was 62.5%. This difference was statistically significant. The

Table 1 Patient and stone characteristics

	Group 1 ($n = 15$)	Group 2 ($n = 20$)	Group 3 ($n = 71$)
Sex			
Male/female	9/6	13/7	41/30
Age (mean ± standard deviation, years)	48.3 ± 12.2	49.4 ± 8.2	53.2 ± 14.6
Stone location (mean stone size)			
Upper calyx	4 (1.8 cm)	3 (1.9 cm)	18 (1.5 cm)
Middle calyx	2 (1.5 cm)	3 (1.2 cm)	17 (1.7 cm)
Pelvis	6 (1.9 cm)	9 (1.8 cm)	27 (1.9 cm)
Upper ureter	3 (0.9 cm)	5 (0.8 cm)	9 (0.8 cm)
Mean stone size (cm)	1.4	1.3	1.3
Chronic renal insufficiency	6	3	Nil
Impaction	2	3	5

Table 2 Stone clearance rates

	Group 1	Group 2	Group 3
Renal stones	16.6% (2/12)	33.3% (5/15)	56.4% (35/62)
Ureteral stones	66.6% (2/3)	60% (3/5)	66.6% (6/9)
Total	26.6% (4/15)	40% (8/20)	57.7% (41/71)

difference between renal and ureteral stone clearances in normally functioning kidneys was not statistically significant.

The complications observed were mild haematuria in 80 patients (68.9%), nausea and vomiting in 4 (3.4%), renal colic in 5 (4.3%) and steinstrasse in 18 (15.5%) patients. Five patients in group 1, four in group 2 and nine in group 3 developed steinstrasse. While the incidence of steinstrasse between group 1 and the control group was statistically significant ($P = 0.049$) it did not reach statistical significance between groups 2 and 3 ($P = 0.408$).

Discussion

There are two issues with the use of ESWL in kidneys with impaired function. The first is whether ESWL is as effective in these kidneys due, presumably, to low urine flow at least in some cases [6, 9], as it is in normal kidneys, and the second is whether these kidneys are more susceptible to the harmful effects of shockwaves [10]. This study attempted to address the first concern, though as a secondary end point we measured the serum creatinine at 3 months post-ESWL in patients with CRI.

Renal calculus disease results in CRI in 10–15% of patients in this country [11]. Mebel et al. [12] reiterate that every calculus causing obstruction can have disastrous effect on the kidney especially when connected with pyelonephritis and recommend early surgery taking the greatest care of the parenchyma, particularly when treating patients with reduced renal function. In order to salvage the renal function most authors recommend aggressive surgical management in these patients [11–13]. However, damage to renal parenchyma may occur during surgery for stone removal [11]. The role of ESWL in the treatment of calculi in kidneys with impaired function has not been fully explored [7]. Though some authors have reported the effects of ESWL on kidneys with renal insufficiency, the stone clearance rate for such kidneys has remained relatively unnoticed [13, 14] and few studies have attempted to characterize its effectiveness based on the level of renal impairment. Most reports which have assessed the effect and efficacy of surgical treatment or ESWL on urolithiasis in kidneys with insufficiency have expressed renal function in terms of serum creatinine or global creatinine clearance [7, 14]. Thus they lose the possibility of detecting even a severe unilateral renal dysfunction that is compensated by the contralateral kidney [10].

There is apprehension about the long-term adverse effects of ESWL. Chandhoke et al. [14] did not find any convincing evidence to suggest that ESWL results in long-term deterioration of renal function in patients with CRI or a solitary kidney. They concluded that the choice between ESWL and percutaneous nephrolithotomy should be based on the stone composition, stone location and stone burden, rather than on the pre-existing renal function or presence of a solitary kidney. In their study on the effects of newer generation lithotripsy upon renal function, Gupta et al. [15] were convinced of the safety of a second-generation lithotripter. ESWL was successful in 9 of 15 patients with residual calculi in poorly functioning kidneys in the study by Singh et al. [16]. In contrast Gambaro et al. [10] feel that both percutaneous and extracorporeal urological methods for the treatment of renal stones may lead to some chronic deterioration of renal function, particularly in recurrent stone formers treated with multiple therapeutic sessions. They argue that although still speculative, concerns exist about the effect of ESWL on small or pathological kidneys. Eterovic et al. [17] feel that ESWL impairs kidney function as compared to pyelolithotomy, which by virtue of not invading the renal parenchyma improves the renal function. They also voice unease regarding the effects of ESWL on the untreated kidney.

As compared to normal kidneys the clearance of calculi in kidneys with impaired function was significantly less in our study. The 3-month stone-free rate with ESWL in renal insufficiency was 68% in the study by Bhatia et al. [7] who used routine ureteral JJ stenting in all their patients. Singh et al. [16] reported clearance rates of 60% in such kidneys with residual calculi after pyelonephrolithotomy and percutaneous nephrolithotomy. The low clearance rate in our study (34.2%) may be due to lack of routine stenting in our patients or the fact that they were untreated rather than residual stones. Also the proportion of ureteral stones in our study (14.6%) was lower than that in the study (29%) by Bhatia et al. [7]. Appreciably, however, the difference in stone-free rate for kidneys with GFR between 20 and 30 ml/min and normally functioning kidneys was not statistically significant. This is in contrast to the clearance rate of kidneys with GFR between 10 and 20 ml/min and normal kidneys. Thus efficiency of ESWL in kidneys with moderately impaired function is probably comparable to that in healthy kidneys. However, among those kidneys with impaired function we were not able to prove any significant difference between the two groups. We feel this may be due to the small number of cases in these groups, which did not allow the results to reach statistical significance.

Surprisingly the clearance rate for ureteral calculi was significantly higher as compared to renal stones in our study. A significant proportion of ureteral stones in our study was impacted (62.5%) and presumably the reduction in GFR was predominantly due to this. Satisfactory clearance rates have been obtained with unstented ESWL of impacted ureteral stones in other studies [3, 18]. Gilbert et al. [19] have reported significant improvement in GFR after ESWL in patients with previously obstructed kidneys. Thus the impact of renal dysfunction on stone clearance is minimal in this group of patients.

The incidence of steinstrasse varies from 2 to 10% in normally functioning kidneys [20–22]. In our study it was 34.6 and 14.5% in the groups with impaired function and normal function, respectively. However, subgroup analysis revealed similar probability of steinstrasse between moderately impaired kidneys (group 2) and normal kidneys. The higher incidence in group 1 may be due to inadequate fragment passage owing to low urinary flow. Steinstrasse may occur despite the presence of stents [21]. This effect may be accentuated in the presence of renal impairment [9]. Steinstrasse can result in persistence of obstruction, hydronephrosis and infection [6]. The risk of renal damage in already compromised kidneys is multiplied manifold.

Poor results in patients with renal medical disease in our series have been corroborated by others [7]. Serum creatinine showed improvement in patients with CRI and impacted ureteral calculi that were cleared. Though most authors reporting the effect of treatment of urolithiasis in patients with CRI find improvement in renal parameters after treatment [13, 16], a significant proportion of our patients did not achieve such improvement. This may be due to the concurrent presence of renal medical disease in some of them and the poor clearance rate in group 1.

Conclusion

The efficacy of ESWL in poorly functioning kidneys is not established. Our results show that the clearance rate of renal stones in moderately impaired kidneys was not significantly different from normal kidneys. Thus ESWL should be used as the first line of management in suitable stones for this group of patients. The clearance rate for kidneys with GFR between 10 and 20 ml/min was poor and such patients should undergo alternative treatment modalities or if ESWL (being the least invasive) is attempted in these patients the threshold for shifting to an alternate treatment should be low. The incidence of steinstrasse was also substantially higher in severely impaired kidneys but not in moderately impaired ones. The clearance rates of ureteral stones were not affected much by the apparent impairment of renal function. Though we stratified our patients into two groups according to their split renal function the differences between them were not statistically significant despite apparently superior results in patients with better renal function. Given the small number of patients in this report we recommend a larger study for the corroboration of these findings.

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