

Blood pressure changes following extracorporeal shock wave lithotripsy in Kirkuk province

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Abstract

Background and objectives: : Hypertension has been reported as a possible sequela of extracorporeal shock wave lithotripsy. The aim was to determine, in a clinical trial, the effect of extracorporeal shock wave lithotripsy (ESWL) on blood pressure

Methods: This study included 216 patients, aged (12-65) years, with asymptomatic renal stones that underwent ESWL in lithotripter unit/ Azadi teaching hospital –Kirkuk Province. Blood pressure was recorded randomly using a standardized protocol. Patients undergoing ESWL received a mean (\pm SD) of 3608.8 (\pm 475.9) shocks over a mean (6.81) of sessions on one lithotripter. Patients were then followed-up by assessing their blood pressure. Data were analyzed on an intention to treatment basis.

Results: At randomization (13.42) % of the study group were hypertensive. Of (320) patients referred to the study, (258) were recruited based on the inclusion and exclusion criteria. A total of (216) patients (83 % of patients included) completed follow up, (137) (63.42%) were male and (79) (36.57%) were female. The mean follow-up period was (15.03) months. In the present study there was no association between mean diastolic and systolic blood pressure before and after ESWL.

Conclusion: : In the present study there was no evidence that ESWL causes changes in BP. More randomized control trials are needed to demonstrate the relationship between ESWL and hypertension.

Keywords: : ESWL, hypertension, clinical trial

Introduction

Since its first presentation in West Germany in the early 1980¹, 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 and high efficacy in treating kidney and ureteral stones. ESWL acts via a number of mechanical and dynamic forces on stones such as cavitation, shear, and spalling.² When it was first introduced, there was virtually no information available regarding the potential adverse effects of shock waves. It was widely believed that shock waves had minimal, if any, effect on tissues as they passed through the body.³ However, the existence of both short- and

long-term damage to the renal parenchyma after ESWL is well documented.^{4,5} In 1986, Peterson and Finlayson⁶ first suggested the possibility of a relationship between ESWL and changes in blood pressure (BP). They described three patients who became hypertensive or had worsening of hypertension immediately following ESWL. Ischemic changes in the kidney secondary to ESWL might create alternations in systemic blood pressure similar to changes occasionally noted following renal trauma.⁷ Subsequently, Lingeman reported that 8.2% of 243 patients who were normotensive became hypertensive after ESWL.⁸ The mean follow-up time was 1.5 years with an annual incidence of 5.5%. William et al⁹ and Montgeomery et al¹⁰ reported similar results thereafter, with a de novo

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hypertension rate of about 8%. Other institutions, however, showed new-onset hypertension rates of only 3.1- 4% among patients receiving ESWL during 1- 5 years of follow-up, which are similar to that among the general population.¹¹⁻¹³ Controversy about changes in BP after ESWL has continued ever since.

Methods

Patients who received treatment for urolithiasis at Azadi Teaching Hospital- Kirkuk Province between February 2010 and August 2011 were targeted for follow up. Of 320 patients referred to the study, 258 were recruited based on the inclusion and exclusion criteria. A total of 216 patients (83 % of patients included) completed follow up, 137 (63.42%) were male and 79 (36.57%) were female. Hypertension was defined as a systolic BP of ≥ 140 mmHg or a diastolic BP of ≥ 90 mmHg or if patients were being prescribed for antihypertensive drugs.¹⁴ Patients were included if they were asymptomatic or minimally symptomatic with single or multiple renal stones less than 15mm in size. Patients were excluded if they had symptoms of loin pain or colic requiring strong analgesics, bleeding disorder or anticoagulant therapy, pregnancy, medullary sponge kidney, radiolucent stones, patients with stag horn calculus and obesity (body weight >100 kg). The baseline BP was measured by the investigator according to a standardized protocol using a mercury sphygmomanometer on the patient's right arm with the patient seated; the pressure was raised to above the disappearance of a palpable radial pulse and then the cuff deflated gradually while auscultating the appearance of the first Korotkoff sound and disappearance of the fifth Korotkoff of the pulse in the brachial artery after 5 min of rest. The baseline BP was designated as an average of two measurements taken 5 min apart. Patients were treated using the Richarzo Wolf Lithotripter (Piezolith-3000, Germany). Each patient was treated according to the proto-

col of the respective units. The mean (\pm SD) 3608.8 (± 475.9) of shocks were administered per patient at a mean power level of 16.8 (range, 4) over a mean of sessions 6.81 (range, 6). Follow up was performed by KUB at two weeks interval to evaluate result of ESWL. Data from the final follow-up were used for the analysis on an intention-to-treat basis. The univariate relationship between each continuous outcome variable (systolic or diastolic BP) and treatment was examined using the t-test (for normally distributed data). The analysis was carried out using SPSS (Statistical Package for Science Services) version 16 computer software. The confounding variables were: age, sex, previous stones (yes, no), ESWL before randomization (yes, no), normotensive or hypertension at baseline.

Results

Of the 320 patients referred to the trial, 62 were not eligible, declined to take part, or withdrew from the study before the baseline data were collected after randomization Table (1). Baseline data were available for 216 patients while the follow up of forty two patients were not completed. The mean (\pm SD) of age was 39.9 (± 12.4) years in the study group. The distribution of diastolic blood pressures before and after ESWL were not different significantly (T test, $p=0.14$) and the same applies to the distribution of systolic blood pressures before and after ESWL (T test, $p=0.22$) Table (2). At baseline, 187 patients were not hypertensive (86.57%) and 29 patients were hypertensive (13.42%). Fifty five patients had received previous ESWL for renal calculi; ten of these patients were hypertensive compared with 161 (74.53%) of those who had not previously had ESWL Table (3 and 4). The hypertensive group had a significant fall in mean diastolic and systolic blood pressure (89.66 ± 12.95 , 85.52 ± 10.2 mmHg) (141.38 ± 19.58 , 134.83 ± 15.72 mmHg) respectively, $P < 0.05$. In normotensive group there was a significant

increase in mean systolic blood pressure (114.4 ± 15.24 , 117.06 ± 11.52), $p < 0.01$, while diastolic pressure was not significantly decreased (78.07 ± 11.14 , 77.87 ± 8.14), $P = 0.693$. In ESWL group there was no association between mean diastolic and systolic blood pressure before and after ESWL ($(80.73 \pm 13.17$, 80.36 ± 9.01 mmHg ($P = 0.72$)), (119.64 ± 21.77 ,

121.45 ± 12.68 mmHg ($P = 0.33$)), respectively. Also there was no association between mean diastolic and systolic blood pressure before and after ESWL in patients that not undergone previous ESWL ($(79.25 \pm 11.64$, 78.39 ± 8.72 mmHg ($P = 0.13$)), (117.52 ± 17.03 , 118.76 ± 13.81 mmHg ($P = 0.08$)), respectively

Table 1: reasons for not participating in the trial (% of 320 referrals)

Reasons	Number (%) of referrals
Symptoms of lion pain	20 (6.2)
Pregnancy	4 (1.2)
Medullary sponge kidney	15 (4.6)
Obesity	9 (2.8)
Large stone (> 15 mm)	14 (4.3)

Table 2: Mean diastolic and systolic blood pressure measurements for the study group before and after ESWL

Blood pressure category mean±SD	Before ESWL	After ESWL	P value
Diastolic pressure	79.63 ± 12.04	78.89 ± 8.82	$p = 0.14$
Systolic pressure	118.15 ± 18.63	118.98 ± 13.77	$p = 0.22$

Table 3: Mean (\pm SD) BP according to whether patients had hypertension or not. The baseline and follow-up for hypertensive group and normotensive group with the number included and the mean age for each group

Blood pressure category	cate-	No (%)	Mean age in years \pm SD	Diastolic mmHg	Systolic mmHg
Hypertension		29 (13.42)	49.83 \pm 10.68		
Base line				89.66 \pm 1 2.95	141.38 \pm 19.58
Final				85.52 \pm 10.2	134.83 \pm 15.72
P value				P= 0.001	P= 0.009
Normotension		187(86.57)	38.36 \pm 11.98		
Base line				78.07 \pm 11.14	114.4 \pm 15.24
Final				77.87 \pm 8.14	117.06 \pm 11.52
P value				P= 0.693	P= 0.001

Table 4: Mean (\pm SD) BP according to whether patients had undergone previous ESWL, the baseline and follow-up for the patients that undergone previous ESWL and those that not undergone previous ESWL.

Variable & number.	Hypertensive.n. (%)	Diastolic mmHg	Systolic mmHg
Previous ESWL (n=55)	10(18%)		
Baseline		80.73 \pm 13.17	119.64 \pm 21.77
Final		80.36 \pm 9.01	121.45 \pm 12.68
P value		P= 0.72	P= 0.33
No previous ESWL (n=161)	19(11%)		
Baseline			
Final		79.25 \pm 11.64	117.52 \pm 17.03
P value		78.39 \pm 8.72 P= 0.13	118.76 \pm 13.81 P= 0.08

Discussion

The development of ESWL has dramatically changed the management of upper urinary tract calculi. While broadly regarded as a safe and effective means of treating upper tract calculi, two independent retrospective uncontrolled studies suggested that ESWL had a small but measurable deleterious effect on BP (Lingeman and Kulb)⁸ and Newman et al.¹⁵. These findings were supported by further retrospective studies reported by Williams et al.⁹ and by Montgomery et al.¹⁰ However, deleterious effects on BP have not been a universal finding¹⁶⁻²⁰ and there is considerable controversy as to the role of ESWL in the development of either diastolic or systolic

hypertension. The prevalence of hypertension in this study before treatment was 13.42%; the mean age of the hypertensive patients was 49.83 years while the mean age of the study group was 39.9 years. The mean age of the population in the study is comparable with that in another study by Yokoyama et al.¹⁹ The prevalence of baseline hypertension is consistent with that reported by Montgomery et al.¹⁰ and Yokoyama et al.¹⁹, although lower than that reported by Lingeman.²¹ A small proportion of patients were on antihypertensive treatment and it is possible that drug-induced reduction in blood pressure in these patients may have influenced the study outcome. In the present study no overall increase in diastolic

and systolic blood pressure was observed, similar result was seen in other studies Yokoyama et al¹⁹ and Vaughan et al.²⁰ In an attempt to explain the failure of some studies to identify effects of ESWL on BP, it has been suggested by Lingeman²¹ that the authors failing to detect an effect was due to fewer shock wave administration. However, Yokoyama et al¹⁹ reported a dose-related effect of ESWL on diastolic BP; the number of shock waves used in the present study (mean 3608.8, SD 475.9) was lower than other studies. Indeed. There was no apparent relationship between the number of shock waves with either the development of hypertension or BP values. Zwergel et al²² demonstrated that the lithotripter might be a risk factor for post-ESWL hypertension. He noted that the incidence of hypertension was 5.8% with electrohydraulic lithotriptors (Donier HM3) and 2.9% with piezoelectric generators (Wolf Piezolith) 4 months after SWL. This might have been due to different sizes of the focal area, which is 15 × 120 mm for the Dornier HM3 vs. 2 × 12 mm for the Wolf Piezolith. In the present study the lithotripter used was piezoelectric generators. The piezoelectric generator probably causes less renal contusion. The general trend in newer lithotripters (second and third generation ones) is to decrease the device's focal volume and increase the peak positive pressure, since it was hypothesized that high peak positive pressure and a smaller focal zone may produce fewer deleterious effects on renal tissues. Zanetti et al¹³ prospectively studied 52 solitary kidneys treated with SWL. After 12 -56 months of follow up, hypertension was noted in only 1 previously normotensive patient, establishing a new onset hypertension rate of 4%, which is similar to that of the general population.

Conclusion

Data from this study provide no evidence that exposure to ESWL increases the risk of becoming hypertensive over an average follow-up of approximately 15 months.

Recommendations: Further long-term surveillance of blood pressure is essential to demonstrate the relationship between ESWL and blood pressure.

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