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Comparative Study of Stone Pulverization and Clearance Rate between Patients Treated by ESWL Under Spinal Anesthesia in Comparison with ESWL Under Sedation and Analgesia

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Summary:

This interventional (quasi) comparative clinical study was conducted on patients with renal stone to find out the stone pulverization and clearance rate in patients treated by ESWL under spinal anesthesia and treated by ESWL under sedation and analgesia.

Selected patients were grouped as 'Group-A' for ESWL under spinal anesthesia & 'Group-B' for ESWL under sedation & analgesia. Immediate stone clearance was much higher in Group-A (96.7%) than that of Group-B (66.7%). Although both groups demonstrated 100% clearance after 3rd follow up. In this study different numbers of shock waves were given for stone pulverization as some stones were soft, hard or very hard. Under sedation and analgesia patients could not tolerate more shock waves and stayed long time on table in targeted position due to pain. But under spinal anesthesia more shock waves application was possible. This study outcome suggest that ESWL under spinal anesthesia is a better option than ESWL under sedation and analgesia.

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Introduction:

Stone formation in the kidney is one of the oldest and widespread disease known to human beings. Calculi have been found in the pelvis, in the bladder of an Egyptian mummy estimated to be in 4800 BC[1]. The history of stone disease implies that many diverse factors might be involved in its causation like heredity, environment, age, sex, urinary infection, metabolic diseases, and dietary excesses or deficiencies[2].

It has been estimated that in United Kingdom the incidence of urinary stone disease is about 2-3%. Male to female ratio is 3:1. Stone disease is also common in Bangladesh, more in northern part of the country[3]. Revolutionary changes occurred in the field of management of renal stone in last 20 years[4]. Treatment of stone disease moved dramatically from an open operative procedure to endoscopic, minimally invasive and non-invasive methods[2]. Among those non invasive procedures ESWL is more popular. Treatment of renal stone depends on stone size, composition, position, degree of obstruction, presence of infection, single kidney, abnormal anatomy and functional status of the kidneys[1]. Management of renal and ureteral calculus disease has dramatically changed after Introduction of extracorporeal shockwave lithotripsy (ESWL) in 1980[4]. Success of ESWL depends on stone size, composition, location, excretory function of the kidneys, position of the patient, shock wave lithotripsy rate and energy level.

Principle:

The abrupt release of energy in a small space (air or water) generates high-energy amplitudes, which is called shockwaves. The physical laws of acoustics regulate the propagation and transmission of shockwaves through water or media of similar density (e.g. soft tissues). The passage of a shockwave through substances of differing acoustic impedance generates compressive stresses at the boundary surface. If the tensile strength of the encountered object (e.g. a stone) is overcome by the produced stress, the anterior surface of the stone crumbles. Part of the energy of the shockwave crossing to the posterior surface of the stone is reflected, causing fragmentation and ultimately implosion of the stone by increasing the tensile stress on the fragment. The ultimate goal of ESWL is the creation of stone fragments that are smaller than 1 mm, which can pass spontaneously and painlessly from the urinary tract[4].

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ESWL under sedation and analgesia causes pain which hampers proper fragmentation. When patient gets pain, he/she moves & target become displaced. Also energy can not be increased due to excessive pain. Even adequate number and rate of shock wave can not be exerted due to pain. On the basis of the result of the study done in different parts of the world, the present study also has been designed to compare the effectiveness of stone pulverization and clearance rate between patients treated by ESWL under spinal anesthesia in comparison with ESWL done under sedation and analgesia.

To my knowledge, no such study has been conducted in Bangladesh. Hence, this study has been designed to find out the stone pulverization and clearance rate in patients treated by ESWL under spinal anesthesia or treated by sedation with analgesia.

Materials & Methods:

Type of study

It is an interventional quasi experimental study.

Place of study

Department of Urology

National Institute of Kidney Diseases & Urology

Sher-E-Bangla Nagar, Dhaka-1207, Bangladesh.

Duration of study

July 2005 to July 2006.

Study population

Patients presenting with loin pain and / or haematuria due to renal stone at the Urology Outpatient Department of National Institute of Kidney Diseases & Urology and fulfilling patient's selection criteria mentioned below were included as study population.

Sampling technique & sample size

Sampling technique: Random sampling (Lottery Method)

Sample size was taken conveniently.

Sample size: 100

Group A (ESWL under spinal anesthesia): 50 patients

Group B (ESWL under sedation & analgesia): 50 patients

A total of 120 patients were considered for inclusion, but 10 were excluded before randomization. 110 patients were randomized by lottery into two groups namely group-A for 'ESWL under spinal anesthesia' and group-B for 'ESWL under sedation & analgesia'. After randomization four patients in the group A were withdrawn from the study by own and six (four in group-A, two in group-B) failed to attend follow-up visits. Thus total 100 patients, 50 in each group completed this study.

Patient's Inclusion criteria

1) Renal stone size < 3 cm
2) Well excreting kidneys without any congenital anomalies of the genitourinary tract.
3) For inferior calyceal stone wide infundibulopelvic angle (> 45^0).

Patient's exclusion criteria

1. Acute urinary tract infection
2. Uncorrected bleeding disorders
3. Pregnancy
4. Uncorrected obstruction distal to the stone
5. Orthopedic or spinal deformities
6. Renal ectopia, or renal malformations (including horseshoe and pelvic kidneys)

Procedure

From July 2005 to July 2006 one hundred patients of renal stone were selected according to inclusion and exclusion criteria from the urology outpatient department of National Institute of Kidney Diseases and Urology. Diagnosis was confirmed by history, physical examination, USG, plain X-ray KUB region and IVU. Size of the stone was measured by scale from 100% film of digital X-ray. After sampling of patients, group-A were selected for ESWL under spinal anesthesia and Group-B were selected for ESWL under sedation and analgesia. Follow up given at three weeks interval. Digital plain X-ray KUB, Urine culture and sensitivity, and in some cases USG were done. In group-B 50 mg pethidine given intravenously in all cases. One anesthetist was present in all cases in both groups. Re-ESWL done in all cases of residual stone. Four patients in group-A needed second session ESWL under spinal anesthesia. Twenty patients in group-B needed second session ESWL under sedation and analgesia. Only one patient needed third session ESWL in group-A and five patients in group-B for complete clearance. All data were collected in a pre-designed and pre-tested data collection

sheet. Data were processed and analyzed using software SPSS-12. Results were correlated with other study done in different parts of the world.

Observations and Results:

Total 100 subjects were selected for the study, 50 were in Group-A and 50 were in Group-B. The findings of the study derived from data analysis are presented below:

IVU findings:

Mean size of the stone of group A patients observed in IVU was 2.01 (±.58) cm and group B patients was 1.97 (±.61) cm. Mean stone size of all the present study population was 1.99 cm. Statistically no significant difference was observed (p>.05). The results shown in Table I, demonstrates that most of the stone were within 21 – 25 mm(32%), & 16-20 mm (30%) in Group-A and 16-20 mm (28%), & 21-25 mm (26%) in Group-B

Table-I

Size of the stone

Size of the stone in mm	Group	
	Group A	Group B
5-10	3 (6%)	4 (8%)
11-15	7 (14%)	8 (16%)
16-20	15 (30%	14 (28%)
21-25	16 (32%)	13 (26%)
26-30	9 (18%)	11 (22%)
Total	50 (100%)	50 (100%)

Position of the stone are shown in Table II. Statistically no significant difference was observed in terms of position of the stone (p>.05).

Table-II

Position of the stone of both groups on IVU

Position of the stone	Group A	Group B	df	p value
Upper calyx	16 (32%)*	15 (30%)	3	.979
Middle calyx	14 (28%)	15 (30%)		
Lower calyx	6 (12%)	5 (10%)		
Pelvis	14 (28%)	15 (30%)		
Total	50 (100%)	50 (100%)		

Energy level:

Most of the stones were pulverized at energy level 7 and 8 in group A and 6 and 7 in group B. Due to excessive pain energy level could not be exerted beyond 7 in group B. In group A energy level could be exerted at 8 in 16 patients. Statistically significant difference was observed in terms of energy level of both groups (p<.0001). These results are shown in Table III.

Table-III

Energy level for complete pulverization in both groups

Energy level	Group		df	p value
	Group A	Group B		
5	0 (.0%)*	10 (20%)	3	.0001
6	11 (22%)	32 (64%)		
7	23 (46)	8 (16%)		
8	16 (32)	0 (0%)		
Total	50 (100)	50 (100%)		

Number of session:

Complete clearance of stone occurred in 46 patients in group A and 30 patients in group B after 1st session. In group A only 3 patients needed 2nd session but in group B 2nd session needed for 15 patients. In group A only one patient needed 3rd session but in group B 3rd session needed for 5 patients for complete clearance of stone. Mean number of session for full clearance of stone of group A was 1.1 ±.364 and group B was 1.5±.678 (p<.001).

These results are shown in Table IV.

Table-IV

Total number of session for full clearance of stone of both groups

No. of session	Group		df	p value
for full clearance	Group A	Group B		
1	46 (92%)	30 (60%)	2	.001
2	3 (6%)	15 (30%)		
3	1 (2%)	5 (10%)		
Total	50 (100%)	50 (100%)		

Side effects:
In the operation table no patients of group A had experienced pain whereas 15 (30%) patients of group B had experienced excessive pain (p<.0001).

Nausea was reported significantly high in group B than group A (p=.046). Vomiting and steinstrasse observed more in patients of group B and haematuria more in group A. Statistically no significant difference was observed in terms of vomiting, steinstrasse and haematuria between groups. Side effects due to anesthesia and analgesia were observed only in the patients of group A. Out of all patients only two patients of group A had hypotension and headache. These results are shown in table V and VI.

Table-V

Side effects due to operation procedure (ESWL)

Side effects due	Group		p value
to operation	Group A	Group B	
Pain	0 (.0%)	15 (30%)	.0001
Nausea	2 (4%)	8 (16%)	.046
Vomiting	1 (2%)	4 (8%)	.359
Steinstrasse	2 (4%)	4 (8%)	.674
Haematuria	10 (20%)	6 (12%)	.275

Table-VI

Side effects due to anaesthesia and analgesia

Side effects due	Group		p value
to anaesthesia	Group A	Group B	
Hypotension	2 (4%)	0 (.0%)	.475
Headache	2 (4%)	0 (.0%)	.475

Complete clearance of stone: (Seen by 100% film of digital plain X-ray of KUB region).

In 1st follow up complete clearance of stone was seen in 46 patients of group A and 30 patients of group B. In 2nd follow up 3 patients of group A and 15 patients of group B showed complete clearance of stone. In 3rd follow up one patient in group A and 5 patients in group B showed complete clearance of stone. Significant difference was observed statistically (p=.001). These results are shown in table VII.

Table-VII

Complete clearance of stone in follow up.

Follow up for	Group		df	p value
clearance of stone	Group A	Group B		
1st follow up	46 (92%)	30 (60%)	2	.001
2nd follow up	3 (6%)	15 (30%)		
3rd follow up	1 (2%)	5 (10%)		
Total	50 (100%)	50 (100%)		

Discussion:
Total 100 patients were selected for this study, 50 were in Group-A and 50 in Group-B. Age range for group A was 21 to 89 years and in Group-B was 21 to 87 years. The mean age (± SD) of Group-A and Group-B were 46.06 ± 15.85 and 44.98 ± 14.71 years respectively. Mean size of the stone of group A patients observed in IVU was 2.01 (±.58) cm and of group B patients was 1.97 (±.61) cm (p>.05). Mean stone size of this present study was 1.99 cm. One British study showed mean stone size found 9 ± 4 mm and 1.07 cm[6], which does not correlate with this study. Present study demonstrates that most of the stone were within 21 – 25 mm (32%) in Group-A followed by 16-20 mm (30%) and 16-20 mm (30%) in Group-B.

IVU showed that statistically no significant difference was observed in terms of position of stone (p>.05).

In this study different numbers of shock wave were given for stone pulverization as some stone were soft, hard and very hard. Under sedation and analgesia patients could not tolerate more shock wave and stay long time on table in targeted position due to pain. But under spinal anesthesia more shock wave application was possible. In Group-A highest numbers of shock wave (3000 – 3500) were given in 20 (40%) patients. In Group-B highest numbers of shock wave (2000 – 2500) were given in 24 (48%) patients. Statistically significant difference was observed in terms of given shock wave of both groups (p=.0001). Mean shock wave was applied for group A 2810 ±436.12 and group B 2215± 476.52. (mean shock wave for all patient was 2512.5 ± 544). The mean number of shock waves was 2879 ±1415; (median of 3000; range of 900-5600) in a British study

conducted by Ather[6]. Das G et al found that for the complete clearance of stone a mean of 1200 shocks (range 100-4000) was needed at each procedure[5]. It is revealed that most of the stones were pulverized at energy level 7 and 8 in group A and 6 and 7 in group B. Due to excessive pain energy level could not be exerted beyond 7 in group B. In group A energy level could be exerted at 8 in 16 patients (p=.0001).

From the present study it is revealed that complete clearance of stone has occurred in 46 patients (92%) in group A and in 30 patients (60%) in group B after 1st session. In group A only 3 patients needed 2nd session but in group B 2nd session needed in 15 patients. In group A only one patient needed 3rd session but in group B 3rd session needed for 5 patients for complete clearance of stone. In group A subsequent sessions were also performed accordingly under spinal anesthesia and in group B under sedation and analgesia (p=.001). Mean number of session for full clearance of stone of group A was 1.1 ±.364 and group B was 1.5±.678[6].

In the operation table no patients of group A of present study had complaints of pain whereas 15 (30%) patients of group B had complaints of pain (p=.0001).

Nausea was reported significantly high in group B than group A (4% vs 16%,p=.046). However vomiting, Stainstrasse and haematuria rates were similar in both groups.

In a study in King Abdul Aziz University Hospital, Saudi Arabia, 2006 May. 64 patients underwent ESWL under spinal anesthesia and they showed that successful stone fragmentation and clearance was 90%[7].

Another study published in Canadian Journal of Anesthesia in 1997, which was done in the Department of Anesthesiology, Hadassah University Hospital, Jerusalem, Israel. That study showed that ESWL was done in continuous spinal anesthesia and successful pulverization and clearance rate was 95%[8].

In another study published in BJU in 2001, which was done in the department of urology, King Abdul Aziz Hospital, Saudi Arabia. That study showed that when ESWL was done under sedation and analgesia successful pulverization and clearance rate was 64%[9].

All these studies show that they are comparable with my study in terms of outcome in the form of stone pulverization and clearance rate. As far as outcome is considered it is seen that both study group experienced a favourable result. But in relative terms the outcome of Group-A was much better than that of Group-B. However data required validation by other studies conducted around the world on the same issue. The present study is by far the first study conducted in Bangladesh.

Conclusion:

From this study it is concluded that ESWL under spinal anesthesia permits more total shock wave and desired energy level which is more effective for pulverization and clearance of renal stone than ESWL under sedation and analgesia. So ESWL should be done under spinal anesthesia to make it more effective and tolerable to the patient.

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