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Research Article

A randomized study to compare extracorporeal shockwave lithotripsy with or without intravenous anaesthesia

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ABSTRACT

Background: The lifetime prevalence of kidney stone disease is estimated at 1-15%. The various treatment options available for urinary calculus disease are open surgery, ureterorenoscopy, percutaneous nephron-lithotomy retrograde intra-renal surgery & extracorporeal shock wave lithotripsy. The aim of the study was to study whether performing extracorporeal shockwave lithotripsy (ESWL) under intravenous anesthesia can reduce no. of sessions by increasing intensity of shockwaves and its comparison with ESWL under local anesthesia and also to study the safety of higher intensity shock waves.
Methods: The nucleus of this prospective study done between March 2011 to February 2015 was 60 patients with renal or upper ureteric solitary calculus less than or equal to 2 cm in size, in which ESWL is elected as the treatment. These were randomized into one of the two groups with 30 patients in each - Group I: in which patients underwent ESWL under IV anesthesia & group II: in which patients underwent ESWL under local anesthesia.
Results: For age group, P value of age difference of the two groups was 0.6 and not significant. During the study it was found that there was statistically significant reduction in number of sessions required for complete stone clearance in Group I. In group I the average number of shock waves used was 3800, whereas in group II it was 5967. The P value of difference between the means was extremely significant (P =0.003). Time taken for clearance of stone in group I was 1 month in 22 patients and 3 months in 8 patients with the average being 1.53. In group II time taken for clearance was 1 month in 9 patients and 3 months in 21 patients and the mean was 2.4.
Conclusions: The use of total intravenous anesthesia (TIVA) for ESWL reduces the number of sessions significantly by allowing higher intensity and number of shock waves & improved fragmentation due to regular and controlled respiratory excursions, and immobility of the patient, leading to significantly less wastage of shockwaves when compared to ESWL without TIVA.

Keywords: Ureterorenoscopy, Percutaneous nephron-lithotomy, Intravenous anesthesia

INTRODUCTION

Throughout history of medicine perhaps no technological advance was produced a more revolutionary effect than extracorporeal shockwave lithotripsy (ESWL). Lithotripsy is the brainchild of engineer of Dornier laboratories in West Germany. They observed that during high-speed flight, shock wave generated by collision with raindrops caused pitting on the metal surface of supersonic aircrafts. Beginning in 1969 and funded by the German Ministry of defence, Dornier began studies of the effect of shock waves on living tissue Dr. Christian Chaussey and his colleagues at Munich with technologist of Dornier lab succeeded in using this principle to treat kidney stone by developing Lithotripsy machine. ESWL was approved by FDA in 1984. It is a technique by which

stone can be broken by shock waves generated outside body and focussed on the stone. ESWL is a simple, safe and effective technique in which renal and ureteric calculi are pulverized in vivo by shockwaves into smaller fragments which body can expel spontaneously along with urine ESWL has become the preferred tool in the Urologist's armamentarium for treatment of urinary calculi in appropriate cases because it is minimally invasive. Intodaysera, the first treatment of choice for most of the urinary calculi is ESWL.[1] The introduction of ESWL by Chaussy in 1980 had revolutionized the management of urinary calculi.[2] Analgesics commonly used during ESWL include opioids, sedative hypnotics, nonsteroidal anti-inflammatory drugs (NSAIDS), and local anesthetic creams such as EMLA.[3] A relaxed, cooperative patient during treatment is paramount in maintaining stone targeting for optimal fragmentation. Therefore, it is essential to choose an appropriate analgesic with minimal adverse effects.[4,5] Despite reports of various studies comparing different analgesic techniques during ESWL, guidelines for pain management during the procedure are not established.

METHODS

The nucleus of this prospective study was 60 patients with renal or upper ureteric solitary calculus less than or equal to 2 cm in size, in which ESWL is elected as the treatment. These were randomized into one of the two groups with 30 patients in each - Group I: in which patients underwent ESWL under IV anesthesia & group II: in which patients underwent ESWL under local anesthesia. The study period was March 2011 to February 2015 in tertiary care center.

Exclusion criteria

Pregnancy, Uncontrolled Coagulopathy, Urosepsis, Stone with distal obstruction, Non-functioning kidney, Body habitus, morbid obesity.

1. Deformity -orthopedic or spinal (prevents proper positioning),Stone in kidney (>2cm),Stone in calycealdiverticulae with narrow infundibulum, Renalectopia or malformation (Horseshoe kidney or pelvic kidney)
2. Complex intrarenal drainage (infundibulum stenosis)
3. Poorly controlled HTN
4. GI disorder (exacerbated after ESWL)
5. Poor functioning kidney
6. Febrile UTI
7. Severely moribund patient unfit for IV anesthesia
8. Lower infundibulopelvic angle (LIP angle) <90 for lower polar calculi

A complete clinical history and physical examination was carried out in all patients and routine investigations were done.

Imaging study done was USG KUB, X-ray KUB, IVP or CECT

Procedure

ESWL was done on Dornier Compact Delta Lithotripter at Lithotripsy center, SGRH.

The intensity and frequency of shocks varied as per individual patient tolerability during the procedure in Group II. The number of shock waves used in group I was between 3500 with maximal or sub maximal intensity depending on stone fragmentation. In group II the number of shock waves varied from 2500 to 3500 depending on patient's tolerability.

Patients were called for follow up on day 3 of the procedure for USG to rule out perinephric hematoma. Follow up x-ray KUB was done at 1 week, following which a further session of ESWL was given if clinically significant stone burden still persisted. The time interval between two sessions was minimum 14 days. The following parameters during the procedure and follow up were observed:

(a) *Intraoperative details*

No of shocks

1. Intensity
2. Frequency(60 – 80/min)
3. Need for local or IV/IM analgesia (group II)
4. (Those patients in-group II who do not tolerate the procedure –
   i. Additional application of EMLA/IV analgesia was required).
5. Fragmentation
6. Treatment duration
7. Any difficulty/complication due to anesthesia (Group I).

(b) *No of sessions required*

(c) Operative & post-operative complications including pain, hematuria, perinephric hematoma, injury to other organs.

(d) *Pain score*

Using visual analog scale (1 to 10) - Post operative pain score was taken 15 minutes of the procedure, since this was the time of recovery from anesthesia.

(f) *Duration required for complete stone clearance*

Anesthesia

We used I.V anesthesia in Group I, which included I.V Midazolam to allay anxiety, Fentanyl (1 –2 ugm/Kgbwt) and propofol (1 –1.5 mg /kgbwt) as bolus followed by

infusion for maintenance (1 mg / Kgbwt/hr). The effect of anesthesia disappears 10 minutes after discontinuing the infusion. Continuous monitoring of ECG, SPO2 and vitals was done during the procedure. The patient was orally allowed 3 hours after the procedure as a day care case.

The patients in group II were given IV/IM analgesic along with local application of EMLA cream (eutectic mixture of prilocaine and lignocaine hydrochloride) 45-60 minutes prior to the procedure. All the patients who completed the treatment were entered in the study and assessed at 1 and 3 months with a plain film of the Kidneys, Ureter and Bladder / USG KUB.

Final outcome was defined as stone free or residual fragments 4 mm or less. Analysis was made according to stone size, location, number of sessions per stone, number of shock waves per stone and maximum intensity of shock waves used & cost implication in the two groups. The analgesia /anesthesia requirements during each treatment, safety of higher intensity shockwaves and safety of total intravenous anesthesia and complication were also been analyzed. Patients were asked to maintain 6 hours of Nil per Oral (NPO) on the day of ESWL. On arrival in lithotripsy unit, all patients were explained about the procedure, written informed consent was taken. They were advised not to make any movement during the procedure (group II). They were also instructed to inform for intolerable pain or discomfort during the procedure (group II).

Group I patients received supplemental Oxygen inhalation via mask. Monitoring included that of blood pressure every 5 minutes by automated noninvasive method and continuous monitoring of pulse oximetry and electrocardiogram. An intravenous line was opened with normal saline (1 liter bag). All patients received injection Diclofenac sodium 50- 75 mg STAT (those with weight <50 kg received 50 mg and those above 50 kg received 75 mg) 15 minutes before the procedure to counter intra and post procedural pain (group II). All patients also received Injection Ondensetron 4mg and Injection Gentamicin (60-80)/Amikacin (500 mg)-stat, just prior to ESWL. Fluoroscopy/ultrasound guided localization of stone was done. After localization in group II shock waves were started at lower intensity for first few hundred shocks and gradually increased to maximum as tolerated. Fragmentation of stone was monitored under fluoroscopy/ ultrasound. After completion of the procedure, patients were transferred to the recovery room. In recovery room patients vitals were monitored and any other complication like nausea / vomiting were noted. In group I, I.V fluids were continued till 4 hours after the procedure with continuous vitals monitoring whereas in group II the patients were orally allowed shortly after the procedure. When the patient was fully conscious, well oriented and could walk without assistant, they were discharged with all the necessary advice.

Statistical analysis

All the parameters were statistically analysed. Mean and standard deviations were calculated. 't'- test was used as test of significance to test difference of mean values between the two groups. A two tailed p-value <0.05 was considered to indicate a significant difference.

Ethical considerations

Informed consent was obtained from all the subjects prior to induction of labour. Permission was taken from the hospital authority to conduct the study in the hospital. Secrecy and confidentiality was maintained.

RESULTS

A total of 60 cases of solitary renal or upper ureteric calculi were studied. They were randomly divided in two groups, 30 patients in each group. Patients in Group I underwent ESWL under total intravenous anesthesia and those in group II underwent the procedure in local anesthesia. The data were recorded and analysed as follows.

Age distribution

In regards to age distribution, in group I minimum age was 9 yrs. and maximum 64 yrs. with mean age of 37.5 yrs.; whereas in group II minimum and maximum age was 18 yrs. and 59 yrs. respectively with a mean age of 36 years (Table 1).

P value of age difference of the two groups was 0.6 and not significant.

Table 1: Age distribution.

	Minimum age in yrs.	Max. age in yrs.	Mean
Group I	9	64	37.5
Group II	18	59	36

Sex distribution

In group I 11 (36.67%) were females and 19 (63.33%) were males; whereas in group II 4 (13.33%) were females and 26 (86.67%) were males (Table 2).

Table 2: Sex distribution.

	Males	Females	Total
Group I	19	11	30
Group II	26	4	30

Side and location of stones

16 stones were located on the left and 14 were located on right in group I .Of the right sided 1 was middle calyceal ,

2 were inferior calyceal, 8 were pelvic and 2 were upper ureteric; whereas on the left side 4 were inferior calyceal, 6 were pelvic and 6 were upper ureteric. In group II 14 were on right and 16 on the left. On the left side 1 was inferior calyceal, 9 were pelvic and 6 were upper ureteric and on the right 1 was middle calyceal, 4 were pelvic and 9 were upper ureteric (Table 3).

Table 3: Size and location of stones.

		Sup. calyx	Middle calyx	Inferior calyx	Renal pelvis	Upper ureter
Group I	right		1	2	9	2
	left			4	6	6
Group II	right		1		4	9
	left			1	9	6

Preoperative stenting

The number of patients stented prior to ESWL in group I were 1 (3.33%) of the total 30, whereas in group II 8 (26.67%) of the total 30 were stented (Table 4).

Table 4: Comparison of Preoperative Stenting.

	Stented	Non stented	Total
Group I	1	29	30
Group II	8	22	30

Stone size

Regarding the stone sizes, in Group I minimum stone size was 6mm, maximum 20 mm and the average was 11mm; whereas in Group II the minimum stone size was 7mm, maximum 20 mm and average being 10.56mm. P value of the difference between the mean stone sizes was not significant (P= 0.52) (Table 5).

Table 5: Comparison of Stone Sizes in the Two Groups.

	Minimum size (mm)	Maximum size (mm)	Mean
Group I	6	20	11
Group II	7	20	10.56

Number of sessions

In Group I the average number of sessions was 1.06; whereas in group II the average number of sessions was 2.2. Maximum number of sessions in group I was 3 in one patient whereas in Group II it was 6 in one patient. P value of difference between the mean scores was extremely significant (p= 0.0001) (Table 6).

Shock wave intensity

In group I minimum intensity used was 3 and maximum was 5, the average was 4.33; whereas in group II also the minimum intensity was 3 and maximum was 5, the mean was 3.53. P value of difference between the two means was extremely significant (p=0.0001).

Although the maximum intensity of shock waves in both the groups was same but the number of cases which could be treated with maximum intensity was higher in group I (n=11) versus group II (n=2) (Table 7).

Table 6: Number of sessions.

	Minimum	Maximum	Mean
Group I	1	3	1.06
Group II	1	6	2.2

Table 7: Comparison of intensity of shockwaves.

	Minimum intensity	Maximum intensity	Mean
Group I	3	5	4.33
Group II	3	5	3.53

Procedure related pain

In group I there was no pain during the procedure due to anesthesia. In post procedure period minimum score of two was present in 18 patients and a maximum score of 5 was seen in 1 patient, the average pain score was 2.47. The score of 8 in two of the patients in group I was present in the evening of ESWL under total intravenous anesthesia not 15 minutes after the procedure. In group II preoperatively and postoperatively the maximum and minimum pain scores were 8, 4 & 5, 2 respectively. The average post procedure pain in group II was 3.43.

P value of the difference between the mean postoperative scores in the two groups was extremely statistically significant (p=0.0001) (Table 8).

Total number of shock waves for stone fragmentation

In group I the minimum number of shock waves used was 3500 and maximum was 10500 (3 sittings).The average number of shock waves used was 3800. In group II

minimum number of shock waves used were 2500 and the maximum was 15000 (6 sittings) the mean being 5967.

The P value of difference between the means was extremely significant (P =0.003).

Post operatively the patients were discharged on the same day, few hours after the ESWL in group II and same day in the evening once the patient was fully conscious, accepting orally and ambulatory in group I (Table 9).

Table 8: Comparison of Pain scores in the two groups.

Pain score (per procedure)	No of Patients	Pain Score (post procedure)	No of Patients
4	2	2	4
5	12	3	13
6	9	4	9
7	1	5	4
8	6		

Table 9: Comparison of average no. of shockwaves in both groups.

Shock waves	
Group I	Group II
3800	5967

Complications

No significant complications occurred in the two groups in the postoperative period either due to ESWL or due to intravenous anesthesia. There was no incidence of perinephric hematoma, gross hematuria, and fever. Two patients in group I had an episode of severe pain in the evening of ESWL, was diagnosed to have steinstrasse, but could be managed conservatively and no surgical intervention were needed.

Table 10: Comparison of complications in both groups.

Complications	Group I	Group II
Mild Hematuria	All	All
Significant Hematuria	None	None
Perinephric Hematoma	None	None
Fever	None	None

DISCUSSION

Extracorporeal shock wave lithotripsy is considered the treatment of choice for majority of urinary calculi in appropriate cases as it is minimally invasive. Pain experienced during ESWL is considered to be multifactorial including type of lithotripter used, frequency, voltage, age, and sex of patient. Recent developments have made ESWL more effective, with minimal morbidity, making it possible to perform ESWL in an outpatient setting without the need for general or spinal anaesthesia. Though avoidance of general anaesthesia is beneficial to the patients, there is significant concern regarding jeopardizing treatment outcomes due to use of less potent analgesic methods. In this study the percentage number of females in group I was higher (36.67%) whereas in group II was 13.33%. Although the sex distribution also did not make a difference in the two groups. In our study the number of stones on both the sides was coincidentally equally distributed for side but not for location Irrespective of the status of the stenting, no difference in results was observed in the two groups .Sinha M et al did a study of ESWL between stented and non-stented groups.[6] They found no significant difference between the stone free rate in the two groups. They also did not find statistical difference between the average number of sessions per patient, retreatment rates and number of shock waves in both the stented and non-stented groups: all were higher in the stented group. They concluded that the insertion of DJ stent did not add to the results and this additional procedure may not be necessary. In a study by Ahmed El-Assamy et al to evaluate the outcome of ureteral stents for solitary ureteral stones 2 cm or less, in moderately or severely obstructed systems using SWL concluded-pre-treatment stenting provides no advantage over in situ SWL for significantly obstructing ureteral calculi & can be given safely as the primary treatment.[7] In our study the minimum, maximum and average stone size in groups I & II were 6mm, 20mm, 11mm and 7mm, 20 mm, 10.56 mm respectively. The two groups were comparable. There was one patient in each group with stone of size 20 mm. The one treated under TIVA was fragmented in single sitting with 5000 shock waves, while the one treated without TIVA took 6 sessions and required 15000 shock waves. So as per our study stones till size of 20 mm can be effectively treated with ESWL, with better and early clearance in group I in which the patients are treated with ESWL under TIVA. Dr. Rassweiler JJ et al established that, the first line treatment for renal stones is ESWL, till the stone size is less than 30 mm.[3,8] Nestor J Lalak et al performed a prospective study to evaluate the short term results of patients undergoing SWL with Dornier Compact Delta lithotripter for all renal calculi between April 1999 to May 2000 with total 500 patients. The overall stone free rates of stones ,<10 mm, 10-20 mm, and >20 mm at 1 and 3 months were 62% & 76%; 53% & 66% and 41% & 47 % respectively. The effectiveness quotient for calculi <10 mm, 10-20 mm and > 20 mm was 60%, 51% and 31% respectively. The final outcomes for stones < 10 mm, 10-20 mm & >20 mm at 1 and 3 months was 90& 93%; 73 & 84% and 57 & 675 respectively. Oral analgesia was given routinely, however additional intravenous analgesia was required in 22% of treatments. No serious complications were seen.

Courtney Lee et al evaluated the impact of the type of anesthesia on treatment efficacy using a comparison of general anesthesia and monitored anesthesia care (MAC) with intravenous sedation for patients undergoing ESWL on the Medstone STS lithotripter and concluded that the overall stone free rate was better with general anesthesia than MAC.[9] Stone free rates were not affected for stones < or = to 10 mm. The type of anesthetic impacted stone free rate in the upper calyx. This study helps define that population that may benefit best from the use of general anesthesia: those with stones >10 mm or in an upper calyx. General anesthesia may decrease excursion of the calculus out of the focal area secondary to breathing or patient movement ·In our study in Group I the average number of sessions required for the clearance of stone was 1.06 whereas in group II the average number of sessions was 2.2 which was double that in group I. This finding points towards the efficacy of ESWL for stone fragmentation under total intravenous anesthesia. We couldn't find any study comparing number of sessions needed for stone clearance. In our study, although, the maximum and minimum intensity used in the two groups was same, the maximum intensity of 5 could be used in more than five times the cases than in group II which led to better fragmentation and clearance in group I. This supports the use of TIVA for ESWL. Also in the TIVA group use of lower intensity also led to better fragmentation due to better focussing, because of less respiratory excursions and the elimination of the need of gradual escalation of the shock waves as required in the patients in group I. There were no untoward complications noted with the use of higher intensity of shock waves pointing to the safety of higher intensity during TIVA. Again we could not find studies which compared the intensity of shock waves in patients treated with or without anesthesia. In our study the average number of shock waves in group I and II were 3800 and 5967. Thus our study supports the use of total intravenous anesthesia as it significantly reduces the overall shock wave requirement, benefitting the patient & also by reducing the wear and tear of the lithotripter machine, thus increasing the longevity of the machine. We could not find any other study mentioning the advantage of TIVA in terms of reduced number of shock waves required. In group I there was no pain during the procedure and the average post procedure pain was 2.47. Two patients in group I had pain score of 8 in the evening of the day of the procedure which was due to colic and could be managed conservatively. In group II per and post procedure average pain score was 8.23 and 3.43 respectively. P value of difference between the mean scores in the pre procedure group was extremely significant both in the pri & post procedure period. This supports the use of TIVA for ESWL, as in this modern era every procedure should be as pain free as possible, without increased morbidity and complications. Yilmaz et al[10] in their study also found that prilocaine infiltration decreases the additional need of analgesic drugs and concluded that prilocaine infiltration alone can be used for analgesic purpose efficiently and safely during ESWL with minimal morbidity. In their study of 114 patients randomized to two groups-groups I received intramuscular injection diclofenac sodium & group II received prilocaine infiltration. Pain score for group II was statistically lower compared with pain score of group I. In our study no significant complication was seen in the two groups with no incidence of significant hematuria, fever or perinephric hematoma. Mild hematuria was seen in all the cases. Two patients in group I had an episode of severe pain in the evening of ESWL and was diagnosed to have colic. This was managed conservatively and no additional surgical intervention was needed. There was no morbidity or side effects attributable to I.V anesthesia. This supports the safety of TIVA for ESWL with no increased morbidity in comparison to ESWL without TIVA. G G Tailly et al in their study concluded that I.V administration of a combination of alfentanil and propofol via a PCA device is an elegant and safe method of Analgesio sedation for SWL.[11] Patient satisfaction is high and side effects are uncommon, faster turnover of patients is possible. Monk et al - studied various combinations under "sedative – analgesic technique'' and found, that, short acting agents such as the narcotic alfentanil& the sedative hypnotics Midazolam &Propofol allow most ESWL treatment with any lithotriptor, with improved recovery profile & calculi fragmentation .Sorensen and Colleagues (2002) found that of the patients treated with the DoLi 50 lithotriptor, those who received IV anesthesia experienced a significantly greater stone free rate than did those patients who underwent intravenous sedation-the possible explanation for these findings is the more controlled respiratory excursions that are conferred by the general anesthetics.[12] In our study the average time required for clearance of stones in group I & II was 1.53 months and 2.4 months respectively. The number of patients cleared in 1 month was 22 in group I and 9 in group II.

Although stone clearance was achieved in all patients in both the groups irrespective of the anesthesia used, the duration of treatment i.e. the number of sessions was higher in group II under local anesthesia as seen in other studies.[13]

Recently, the use of dimethyl sulfoxide (DMSO) in combination with lidocaine has been reported to provide better pain control during ESWL as compared to EMLA cream, due to local anesthetic effect along with diuretic, anti-inflammatory, muscle relaxant, and hydroxyl radical scavenger effects of DMSO.[14,15] However, large scale randomized controlled trials are required for validating its use.

CONCLUSION

The use of total intravenous anesthesia (TIVA) for ESWL reduces the number of sessions significantly by allowing higher intensity and number of shock waves & improved fragmentation due to regular and controlled respiratory excursions, and immobility of the patient, leading to

significantly less wastage of shockwaves when compared to ESWL without TIVA. TIVA decreases the total number of shock waves required for full fragmentation of stones. TIVA is cost effective as early & efficient fragmentation can be achieved using less number of shock waves. The use of total intravenous anesthesia (TIVA) for ESWL reduces the number procedure.

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