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International Journal of Current Research
Vol. 9, Issue, 02, pp.46194-46199, February, 2017

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

ROLE OF INVERSION THERAPY AND DIURETICS DURING EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY TO IMPROVE CLEARANCE RATE OF LOWER CALYCEAL STONES

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ARTICLE INFO

Article History:
Received 06th November, 2016
Received in revised form
26th December, 2016
Accepted 27th January, 2017
Published online 28th February, 2017

Key words:

Trendenlenburg,
Lower Calyceal Stones,
Percutaneous Nephrolithotomy.

ABSTRACT

Objectives: To combine Trendenlenburg Positioning of Patient and Intra Procedural Forced Diuresis during Shock Wave Lithotripsy to improve stone clearance rate for Lower Calyceal Stones. To compare the results obtained with that of Standard Supine Shock Wave Lithotripsy for Lower Calyceal Stones.

Methods: A prospective study was done in Institute of Urology, MMC, Chennai between February 2015 to February 2016. All patients presented with isolated lowerpole renal calculi of size between 7-20mm were registered. Total number of patients included are 132. Among them 33 patients refused to participate in the study and 14 patients who failed to follow up are excluded. All patients selected were allotted randomly in to two groups. Group A, comprising 62 patients who underwent ESWL with inversion therapy and intra-procedural diuresis Group B, comprising 56 patients, who underwent standard Supine ESWL and the data including number of sessions, success rate, and complications are all recorded and analysed.

Results: Both groups were comparable in terms of Demography (age, sex) and in terms of Stone Characteristics. Based on number of sessions for ESWL, there is a significant increase in number of third session required in Group B, when compared to Group A. (P value 0.044) Regarding treatment success, both Stone Free Rate and Insignificant Residual Fragments are significantly higher in Group A, from first follow up itself, which increased steadily up to 12 weeks. (P value 0.04). Overall success rate achieved is 74.6%. And Treatment success rate achieved with the study group (Group A) is 82.3%, when compared to 66.1% achieved with the control group. There is a significant difference between the two groups in terms of treatment success. (p value 0.044) In both groups the average stone size and stone density as measured by stone attenuation value correlates significantly. Regarding complications there is no significant difference exists between the two Groups. Among the complications, colic is the most common, followed closely by LUTS and hematuria, then steinstrasse and fever in the order.

Conclusion: Combination of Inversion with Intra Procedural Forced Diuresissignificantly improves the Stone Clearance Rate of Lower Calyceal Stones during Extra Corporeal Shock Wave lithotripsy. Though the results obtained are not as equivalent to that of Percutaneous Nephrolithotomy, ESWL with this combination of inversion with Forced Diuresis can be preferred for its specific advantages like Outpatient procedure, Non invasive intervention, No need for higher an aesthesia, No added cost and Can be repeated with least morbidity

Citation: Prabu, P. K. 2017. "Role of inversion therapy and diuretics during extracorporeal shockwave lithotripsy to improve clearance rate of lower Calyceal stones", *International Journal of Current Research*, 9, (02), 46194-46199.

INTRODUCTION

Extracorporeal shock wave lithotripsy has revolutionized the management of renal calculus disease. Today it is the preferred modality of treatment for most renal stones of size up to 2cm. Shock wave lithotripsy had attained widespread acceptance among both Patients and Urologists alike for it is, non invasive, safe, convenient, ease of the procedure, can be done under minimal anaesthesia as outpatient procedure and can be repeated.

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However its effectiveness for the management of lower calyceal stones are not as effective as with upper and mid pole calyceal stones due to its high rate of residual fragments The factors that influence renal calculi management by shock wave lithotripsy are Stone burden was perhaps the single most important factor determining success following shock wave lithotripsy. Thus as stone burden increases, stone free rate decreases and the rate of re-treatment and other ancillary procedures also increases. Composition of Certain stones as Cystine, Brushite are the most resistant to ESWL and Uric acid and Calcium oxalate dihydrate are least resistant. Density is measured as Stone Attenuation Value in Hounsfield Units (HU) in Computed Tomogram is an important factor considered in patients to be subjected for shock wave lithotripsy. Shock wave lithotripsy results for lower pole renal calculi was far inferior due to high rate of residual fragments, which itself will act as nidus for further stone development. Factors suggested for this decreased treatment outcomes are due to gravity dependent anatomy, Acute Infundibulo- pelvic Angle, longer length, narrow width of infundibulum, Patient's expectation, Tolerance to the procedure, Obesity and other co morbid illness, Skin to stone distance. Abnormal anatomy as Horseshoe kidney, Renal ectopia, Ureteral duplication, Presence or absence of obstruction, Calyceal diverticulum, Lower pole location, Type of shock wave lithotripter, Type of ancillary procedures available, Role of stenting. Among all the factors enumerated, stone size, composition, density and location are the prime factors that predict the outcome of shockwave lithotripsy.

For lower pole calculi, even though stone fragmentation rate is equivalent to upper and mid pole calculi, the clearance of stone fragments are far inferior when compared to other poles due to the factors as mentioned above. This leads to high rates of residual fragments which has been the cause for concern (Lingeman *et al*., 1994; Zanetti *et al*., 1991). This residual fragments will act as nidus for further stone formation. There is no standard non-invasive Auxiliary procedures which will facilitate the stonefragments clearance from lower pole calculi following shock wave lithotripsy. This lead to widespread acceptance of other modalities as PCNL or RIRS for its management, though they are invasive (Elbahnasy *et al*.; Carr *et al*., 1996). Various adjuvant procedures described to improve stone clearance rates for lower calyceal stones were, Shockwave lithotripsy done with the patient in Trendenlenburg position (inversion), Forced Diuresis by administering diuretics during the procedure, Mechanical Percussion after the procedure for varied period of time.

Any of these procedures either alone or in combination were tried with improved results for clearance of lower pole fragments following shock wave lithotripsy (Netto *et al*., 1991; Albanis *et al*., 2009; Chiong *et al*., 2005; Leong *et al*., 2014). We adopted the combination of Inversion (Trendenlenburg position with 30 degree head low tilt) with Intra Procedural Forced Diuresis during Shock Wave Lithotripsy as a means to improve clearance of lower pole stone fragments.

METHODS

This study was done prospectively at a tertiary care institute for a period of from February 2015 to February2016. Ethical clearance was taken from the Institute Ethics Committee prior to the start of the study. All patients who were presented with isolated lower pole renal calculi were registered for this study. A thorough and detailed patient history and physical examination was performed in all patients. All baseline investigations necessary as urine complete analysis, urine culture, complete blood count, blood sugar and basic renal function test as urea, serum creatinine and serum electrolytes were done in all patients. Ultrasonography, plain X-ray KUB, and Plain CT KUB were done in all cases, complimented by Contrast Enhanced Films were taken in selected cases where it deemed necessary. Stone size and stone attenuation values are calculated based on plain CT KUB. Largest dimension of stone in Non Contrast CT KUB is taken as stone size. All patients with symptomatic isolated lower calyceal stones of size between 7mm – 20mm and Patients with age above 18 years included in this study. Patients with Morbid obesity, Severe neurological diseases Cardio vascular diseases, Failed ESWL, Abnormal renal anatomy, (renal Ectopia, horseshoe kidney, bifid pelvis or duplex kidney) Uncontrolled coagulation disorders, Patients with medical co-morbidities which may prevent Trendenlenburg positioning, Forced diuresis, patients requiring Percutaneous Nephrostomy and DJ stenting excluded.

Randomization

Patients who met the inclusion criteria were randomly assigned to two treatment groups. To distribute patients efficiently between groups, stratified-blocked randomization was performed using computer random tables in a 1:1 ratio. Total number of patients with lower pole calculi registered in institute of urology, who met the inclusion criteria during my study period were 165. Among them 33 patients refused to participate in study. Among the remaining 132 patients were randomly divided by independent observer into two groups as Study Group (group A , comprising 71 patients) and Control Group (group B, comprising 61 patients).Totally 14 patients, 9 from Group A and 5 from Group B were excluded as they didn't turn up for regular follow up. Patients in Group A are managed by ESWL with the patient in Trendenlenburg position (Inversion therapy) with Intra Procedural Forced Diuresis. Patients in Group B were managed by Routine Supine Positioned ESWL

Study procedure Bowel prepared with overnight laxatives and anti flatulents.Group A Patient in Trendenlenburg position with an angle of 30 degree, head low position. This is combined with intravenous hydration using one litre of normal saline with 20 mg of Frusemide, which were started 30 minutes before the procedure and continued through out the procedure. So all patients in this group were catheterised. Group B Patient in Supine position. Patients in both groups were administered with inj. Pentazocine 30mg and inj, Promethazine hcl 25mg by intramuscular injection given 30 mins before the procedure.

Shock Wave Lithotripsy Technique done as outpatient procedure with Dornier Compact Delta II, which is based on electromagnetic shock wave generating principle. Stones were localised by using Ultrasonography and / or fluoroscopy, 2500 shocks were given per session, Energy intensity were kept between 4 and 5,Shockwaves with frequency at 60 shocks were given. All patients were observed for 2 to 3 hours after each session and then allowed to go home. Patients were sensitized about the complications as hematuria, Colic, dysuria etc before sending them home. They were advised to take adequate oral fluids, oral antibiotics, analgesics for 5 days. They were advised suitably to report for any complications

Follow-up and outcome measurements

Patients were evaluated at 4, 8, 12 weeks following ESWL session. During each follow up visit, patients were evaluated with history taking, physical examination, urine analysis, renal function tests, X-ray KUB and Ultrasonography. At the end of each follow up visit patient who presented with significant residual fragments (> 4mm) were subjected to repeat shock wave lithotripsy sessions to a maximum of 3 sessions. The primary end is stone free status at the end of 12 weeks, after the first session. For each group Number of ESWL sessions, time to stone clearance, total number of shock waves received, and all complications including hospital admission for complications were recorded, analysed and compared between two groups. Treatment success is defined as Stone Free Status or Insignificant residual fragments (size<4mm) at the end of 12 weeks Patients who are declared with treatment success are terminated from follow up. Patients who failed the above treatment were directed to other modalities as Percutaneous Nephrolithotomy and Endoscopic managements. A total of 14 patients 9 from study group and 4 from control group were excluded as they did not adhere to follow up schedules. So study effectively consists of 118 patients, 62 in Group A and 56 in Group B.

Statistical analysis

All datas were tabulated in Microsoft Excel sheet and analysed. Chi square test was used to identify association wherever needed. For all practical purposes P valve of < 0.05 were considered to be clinically significant.

OBSERVATION AND RESULTS

The study comprised of 118 patients of lower pole renal calculi divided into two groups as 62 patients in Group A (study group) and 56 patients in Group B (control group) (Table 1)

Table 1. Distribution of study subjects according to type of procedure

Variable	Frequency	Percentage
Group a	62	52.54
Group b	56	47.46
Total	118	100

Age Distribution

Age of the patients ranged from 19 years to 64 years and most of them are between 20 to 50 years of age (Table 2)

Table 2. Distribution of study subjects according to age

AGE	FREQUENCY	PERCENT (%)
< 20yrs	6	5.1
21 – 30 yrs	18	15.3
31 – 40 yrs	42	35.6
41 – 50 yrs	26	22
51 – 60yrs	14	11.9
>60yrs	12	10.2
Total	118	100.0

The age distribution show majority of the participants in both groups belonged to 31-40 age group (35.6%). The comparison of age distribution between the study group and control group showed no statistical significant difference (p-value >0.05). Hence both groups are comparable. (Table-2)

Table 3. Distribution of subjects according to sex

SEX	Procedure		Total
	Group A	Group B	
Male	51	43	94
	82.3%	76.8%	79.7%
Female	11	13	24
	17.7%	23.2%	20.3%
Total	62	56	118
	100.0%	100.0%	100.0%

There were 51 males and 11 Females in Group A and 43 Males and 13 Females in Group B (Table 3). Among the 118 study participants around 94 were males and 24 were females. The gender distribution shows the majority of participants in the study group were male (82.3%) and in control group were female (23.2%) but this difference was not statistically significant (p-value=0.158). Hence the both groups are comparable. (Table-3)

Distribution according to type of procedure and side of stone (Table 4)

	PROCEDURE		TOTAL
	GROUP A	GROUP B	
Right	28	26	54
	45.2%	46.4%	45.8%
Left	34	30	64
	54.8%	53.6%	54.2%
Total	62	56	118
	100%	100%	100%

There is no significant difference between study and control Groups regarding the laterality as left side predominates in both Groups.

Stone size distribution

In our study predominant stone size is between 7– 10 mm and the next predominant is in 11-15mm range (Table 5)

Table 5. Distribution of study subjects according to size of stone

Variable	Count	Percent
7– 10mm	59	50.0%
11 – 15 mm	45	38.1%
16 – 20 mm	14	11.9%
Total	118	100.0%

Stone density

In both groups the majority of stones are with attenuation value between 501- 1000 HU. In treatment failure cases the majority are in with HU > 1000.

Table 6. Distribution according to stone Density (Hounsfield Units)

STONE DENSITY	PROCEDURE		TOTAL
	GROUP A	GROUP B	
< 500	18	17	35
	29.0%	30.4%	29.7%
501 – 1000	37	33	70
	59.7%	58.9%	59.3%
>1000	7	6	6
	11.3%	10.7%	11.0%
Total	62	56	118
	100.0%	100.0%	100.0%

Table 7. Mean, Standard deviation for Stone Size and Stone Density

	Group	number	Mean	Std deviation	P value
Stone size	A	62	11.1290	3.94422	0.524
	B	56	11.5893	3.86018	
Stone density	A	62	768.0323	247.18865	0.598
	B	56	743.8571	249.27877	

In both Group A and Group B the mean stone size is 11.129 and 11.5893 and standard deviation are 3.944 and 3.860

respectively. In both Group A and Group B the mean stone density is 768.03 and 743.8571 with standard deviation of 247.18865 and 249.27877 respectively. Hence in both Groups both stone size and stone density are matched and P value is not significant.

Table 8. Distribution according to type of procedure and number of sessions

Sessions	Procedure		Total	P value
	Group A	Group B		
Single	34	21	55	0.040 By chi-square test
	54.8%	37.5%	46.6%	
Double	13	9	22	
	21.0%	16.1%	18.6%	
Third	15	26	41	
	24.2%	46.4%	34.7%	
Total	62	56	118	
	100%	100%	100%	

In group A more than 50% required only single session but in group B majority (62.5%) required more than one session. There is significant association seen in this difference as shown by the P value of 0.04

Table 9. Distribution of subjects according to stone free status

Group	Stone Free Status	Percent
Group A	43	69.35
Group B	25	44.64
Total	68	57.62

Table 10. Distribution according to Insignificant Residual Stone Fragments

Group	Insignificant residual stone fragments (< 4mm)	Percent
Group A	8	12.9
Group B	11	19.64
Total	19	16.10

Treatment outcomes

Over all treatment success was reported in 74.6% of patients comprising both study and control Group

Table 11. Distribution according to type of procedure and treatment success rates

Success rate	Procedure		Total	P valve
	Group A	Group B		
Yes	51	37	88	0.044 Chi square test
	82.3%	66.1%	74.6%	
No	11	19	30	
	17.7%	33.9%	25.4%	
Total	62	56	118	
	100%	100%	100%	

Table 12. Distribution according to type of procedure and complications

Complications	Procedure		Total	P value
	Group A	Group B		
Hematuria	11	8	19	0.610
	17.7%	14.3%	16.1%	
Fever, UTI	5	4	9	0.851
	8.1%	7.1%	7.6%	
Colic	12	11	23	0.969
	19.4%	19.6%	19.5%	
Steinstrasse	8	6	14	0.713
	12.9%	10.7%	11.9%	
LUTS	11	9	20	0.809
	17.7%	16.1%	16.9%	

In group A success rate was reported in 82.3% of patients at the end of 12 weeks. But in Group B success rate is seen only in 66.1% of patients. There is a significant association seen in treatment success rates as shown by the significant P value of 0.044. 19 (16.1%) had hematuria 14 (11.9%) had steinstrasse. Among both groups there is no significant difference exists related to complications as suggested by non significant p valves for each one of them

DISCUSSION

Combination of Trendenlenburg position (Inversion therapy) with Intra Procedural Forced Diuresis is an effective means for the improvement of clearance of lower calyceal stone fragments following Shock Wave Lithotripsy. Well established data are available describing the efficacy and safety of shock wave lithotripsy in primary treatment of upper and mid pole renal calculi up to 20mm, with favourable stone characteristics as stone attenuation less than 1000HU. But Till date there is considerable controversy exists in the management of lower pole calculi with similar characteristics, which is due to in-efficient stone clearance rather than stone fragmentation. This is due to dependent position of lower pole calices (Ather *et al*., 2003) Various studies demonstrated this with computed tomography or Magnetic Resonance studies with oblique axis of lower pole calyx with 20-30 degree tilt (Gerber, 2003; Pace, 2001). Anatomical factors like acute Infundibulo-pelvic angle, and infundibular length and width may have an impact on stone clearance (Knoll, 2003; Gerber, 2003). But more recent prospective studies have failed to demonstrate the significance of these anatomical factors in defective stone clearance from lower pole calices (Ather *et al*., 2003). Also in realistic, the static images cannot accurately measure the dynamic pelvicalyceal system including the infundibulum (Knoll *et al*., 2003; Pace *et al*., 2001). Recently there are studies available to suggest that stone size, but not the calyceal anatomy that determines the clearance. So the consistent factors identified so far, which determines stone clearance from lower pole calices after shock wave lithotripsy are Dependent position of lower pole calyx, Stone size and Stone density. So studies exists which suggests to go for adjuvant procedures like, inversion, mechanical percussion, diuretics and repeat SWL treatment to improve clearance of lower pole calculi (Netto *et al*., 1991; Albanis *et al*., 2009; Chiong *et al*., 2005; Pace *et al*., 2001). Combination of all three was found to be 13 times more effective than observation alone (Pace *et al*., 2001). In this study, we evaluated the combination of Inversion and Forced Intra Procedural Diuretics to improve the clearance rate of lower caliceal stones. The rationale behind this combination is to overcome the effect of dependency by 30 degree Trendelenburg position with diuretics to flush the fragments out of lower pole. In this study by combining the two, we achieved a success rate of 82.3%, at 12 weeks when compared to 66.1% success rate achieved with standard supine ESWL. This success rate is slightly higher than that achieved by Leong *et al* (76% success rate) (Leong *et al*., 2014), Albanis *et al*. (Albanis *et al*., 2009), and by a recent study by abul-fotouh ahmed *et al* (78.3% success rate) (Abul-fotouh ahmed, 2015). Re treatment rate achieved for Group A in our study is 45.2% which is much lower than that observed with Leong *et al* (90%) (Leong *et al*., 2014), Kupeli *et al* (79.4%) (Küpeli *et al*., 2005) and Abul-fotouh ahmed *et al* (73.9%) (Abul-fotouh ahmed *et al*., 2015). This may be due to better localization technique available with our lithotripter.

In our study mainly Ultrasound is used for stone localisation and fluoroscopy was used only as supplementation. This is not the scenario in other studies where their average fluoroscopy time is around 150seconds. Several studies have identified that small size stones and lower attenuation values as a predictor of success of ESWL. Our results agree with those results as our stone free rate for calculi less than 10mm is 90% and with stone attenuation value of less than 500 HU is over 90%. There is no significant difference related to complications among both the groups. Most of the complications are mild and managed conservatively.

Limitations

Two variables as Diuretics and Inversion are used to study the outcome. So it is difficult to predict which variable helped more to achieve the outcome. Only X-rays and Ultrasonography alone were used in follow up, which may not have better yield to identify smaller fragments when compared to Computed Tomography

Conclusion

Combination of Inversion with Intra Procedural Forced Diuresis significantly improves the Stone Clearance Rate of Lower Calyceal Stones during Extra Corporeal Shock Wave lithotripsy. Though the results obtained are not as equivalent to that of Percutaneous Nephrolithotomy, ESWL with this combination of inversion with Forced Diuresis can be preferred for its specific advantages like Outpatient procedure, Non invasive intervention, No need for higher anaesthesia, No need for any additional gadgets required to do this procedure, No added cost, Can be repeated with least morbidity

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