



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

Urology

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KEYWORDS

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. However its effectiveness for the management of lower calyceal stones are not as effective as with upper pole and middle calyceal stones due to its high rate of residual fragments.

The factors that influence renal calculi management by shock wave lithotripsy are

Factors related to stone:

Size: 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. Shockwave lithotripsy is the preferred primary modality of treatment for stones upto 1cm and found to have equal efficacy with least morbidity when compared to Percutaneous Nephrolithotomy and Endoscopic procedures, in the form of Ureterorenoscopy (URS) or Retrograde Intra RenoScopy (RIRS) for stones up to 2cms.

Composition: Certain stones as Cystine, Brushite are the most resistant to ESWL and Uric acid and Calcium oxalate dihydrate are least resistant.

Density: It 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.

Location: 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. Various factors suggested for this decreased treatment outcomes are due to gravity dependent anatomy, Acute Infundibulo-pelvic Angle, longer length, narrow width of infundibulum etc.

Patient factors:

Patient's expectation,
Tolerance to the procedure,
Obesity and other co morbid illness
Skin to stone distance, etc.

Renal Anatomical Factors:

Abnormal anatomy as Horseshoe kidney, Renal ectopia, Ureteral duplication
Presence or absence of obstruction,
Calyceal diverticulum,
Lower pole location, etc

Technical factors :

Type of shock wave lithotripter,
Type of ancillary procedures available,

Role of stenting : The role of ureteral stenting on the outcome of ESWL is controversial. Stenting will be useful in cases of signs of obstruction

or sepsis. It wont affect the treatment outcome of shockwave lithotripsy.

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^{2,3}. This residual fragments will act as nidus for further stone formation. There is no standard non-invasive Auxiliary procedures which will facilitate the stone fragments 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^{6,7}.

Various adjuvant procedures described to improve stone clearance rates for lower calyceal stones were,

1. Shockwave lithotripsy done with the patient in Trendelenburg position (inversion),
2. Forced Diuresis by administering diuretics during the procedure,
3. 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^{8,9,10,11}.

We adopted the combination of Inversion (Trendelenburg 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.

AIMS AND OBJECTIVES

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

MATERIALS AND METHODS

Period of study:

February 2015 to January 2016

Study design:

Retrospective and prospective study

Source of patients:

This study was conducted at Institute of urology, at Government Rajiv Gandhi Government General Hospital and Madras Medical college, Chennai. Tamilnadu. All patients who were presented with isolated lower pole renal calculi were registered for this study. Institutional ethical committee approval obtained for the study and all the guidelines stipulated by the committee were followed.

Method of study:

All the patients enrolled were explained about their disease process and about necessary evaluation required. They were also explained

about various modalities of treatment available for lower pole renal calculi as shock wave lithotripsy, Percutaneous nephrolithotomy, endoscopic procedures and open surgeries and consent obtained from them for this study.

Patient evaluation:

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.

Subject selection:

All Patients presented with isolated lower calyceal stones.

Inclusion Criteria:

- All patients with symptomatic isolated lower calyceal stones of size between 5mm – 20mm and
- Patients with age above 18 years.

Exclusion Criteria:

- 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 Trendelenburg positioning, Forced diuresis,
- patients requiring Percutaneous Nephrostomy and DJ stenting.

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 Trendelenburg position(Inversion therapy) with Intra Procedural Forced Diuresis. Patients in Group B were managed by Routine Supine Positioned ESWL.

Patient preparation:

Bowel prepared with overnight laxatives and anti flatulents.

Patient position:

- Group A: Patient in Trendelenburg 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.

Analgesia :

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:

1. Done as out patient procedure.
2. Shock wave lithotripsy was done with Dornier Compact Delta II, which is based on electro magnetic shock wave generating principle.
3. Stones were localised by using Ultrasonography and / or fluoroscopy.
4. 2500 shocks were given per session

5. Energy intensity were kept between 4 and 5
6. Shockwaves with frequency at 60 shocks were given.

Post procedure:

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:

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.

Study 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: 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

Table2: 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

Table3: Distribution according to type of procedure and age:

In both groups majority of patients are between 21 to 50 years of age

	Procedure		Total
	Group A	Group B	
< 20yrs	4	2	6
	6.5%	3.6%	5.1%
21 – 30yrs	10	8	18
	16.1%	14.3%	15.3%
31 – 40yrs	22	20	42
	35.5%	35.7%	35.6%

41 – 50 yrs	12	14	26
	19.4%	25.0%	22.0%
51 – 60yrs	8	6	14
	12.9%	10.7%	11.7%
>60yrs	6	6	12
	9.7%	10.7%	10.2%
Total	62	56	118
	100.0%	100.0%	100.0%

Sex distribution

There were 51 males and 11 Females in Group A and 43 Males and 13 Females in Group B

Table 4: Distribution of subjects according to sex:

VARIABLE	COUNT	PERCENT
Male	94	79.7
Female	24	20.3
Total	118	100.0

Table 5: Distribution according to type of procedure and 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%

Table 6: Distribution of study subjects according to side of stone.

In both groups left sided stones predominates

VARIABLE	COUNT	PERCENT
Right	54	45.8
Left	64	54.2
Total	118	100.0

Table 7 : Distribution according to type of procedure and side of stone

	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 6 – 10 mm and the next predominant is in 11-15mm range

Table 8: Distribution of study subjects according to size of stone:

Variable	Count	Percent
6 – 10mm	59	50.0%
11 – 15 mm	45	38.1%
16 – 20 mm	14	11.9%
Total	118	100.0%

Both groups were matched according to their stone sizes

Table 9: Distribution according to type of procedure and size of stone

	PROCEDURE		TOTAL
	GROUP A	GROUP B	
6 – 10mm	31	28	59
	50.0%	50.0%	50.0%
11 – 15mm	25	20	45
	40.3%	35.7%	38.1%
16 – 20mm	6	8	14
	9.7%	14.3%	11.9%
Total	62	56	118
	100.0%	100.0%	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 10: 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%

In both Study and control groups there is no significant difference in stone attenuation values

Table: 11 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.

TREATMENT RESULTS

In Group A about 54.8% required only single sitting, but 21.2% and 24.2% patients required two and three sessions respectively

Table 12: Distribution according to number of sitting: Study Group (Group A)

VARIABLE	COUNT	PERCENT
Single	34	54.8%
Double	13	21.0%
Third	15	24.2%
Total	62	100.0%

In Group B only 37.5% required single session. 16.1 and 46.4% required two and three session respectively

Table 13: Distribution according to number of sessions of treatment: Control Group (Group B)

VARIABLE	COUNT	PERCENT
Single	21	37.5%
Double	9	16.1%
Third	26	46.4%
Total	56	100.0%

Table 14: 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

Almost half of patients (n=26) in Group B required Three sessions as it reflects significant residual stones is more in Group B

Table 15: 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 16: Distribution according to Insignificant Residual Stone Fragments:

Group	In significant 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 17: Distribution of study subjects according to treatment success rates

TREATMENT SUCCESS	COUNT	PERCENT
Yes	88	74.6%
No	30	25.4%
Total	118	100.0%

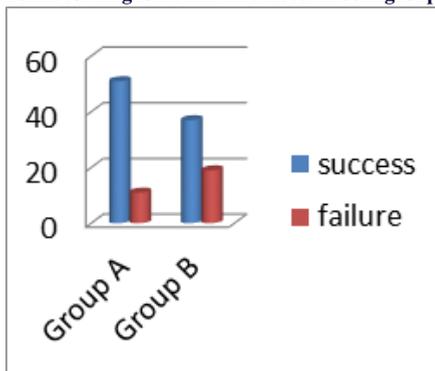


Table 18 : Distribution according to Type of Procedure and Treatment Success Rates

Success rate	Procedure		Total	P value
	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%	

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.

Distribution according to treatment success in both groups:



There is significant difference in number of patients got treated successfully at the end of 12 weeks.

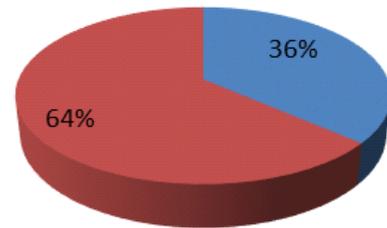
Complications

Among the total 118 patients, 43 patients (36.4%) had complications.

Table 19: Distribution of study subjects according to complications

VARIABLE	COUNT	PERCENTAGE
Complication	43	36.44
No complication	75	63.56
Total	118	100.0

■ complications ■ no complication

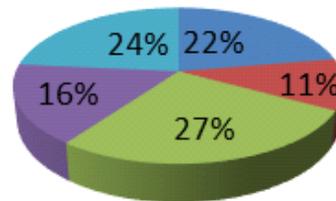


Among the complications , colicky pain is the commonest followed closely by hematuria and LUTS symptoms

Table 20: Distribution according to Type of complications

VARIABLE	FREQUENCY	PERCENTAGE
Haematuria	19	22.35
Fever, UTI	9	10.59
Colic	23	27.05
Steinstrasse	14	16.47
LUTS	20	23.54
Total	85	100.0

■ haematuria ■ Fever, UTI
■ Colic ■ Steinstrasse
■ LUTS



In terms of complications about 43.55% of patients in Study Group had complications, when compared to 28.57% of patients in Control Group.

Table 21: Distribution according to type of procedure and complications

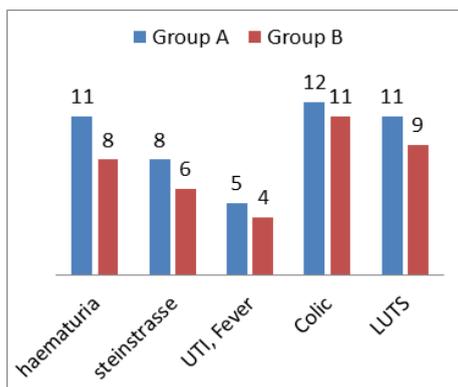
Complications	Procedure		Total
	Group A	Group B	
Yes	27	16	43
	43.55%	28.57%	36.44%
No	35	40	75
	56.45%	71.43%	63.56%
Total	62	56	118
	100.0%	100.0%	100.0%

Table 22: 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%	

Among all 118 patients about 23 (19.5%) patients had colic, 20 (16.9%) had LUTS, 19 (16.1%) had hematuria, 14 (11.9%) had steinstrasse.

Distribution according to type of complications in both Groups:



Among both groups there is no significant difference exists related to complications as suggested by non significant p values for each one of them.

STATISTICAL ANALYSIS OF RESULTS:

- Total number of patients with lower pole calculi, who met the inclusion criteria during my study period were 165.
- Among them 33 patients refused to participate in study.
- 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.

During the course of study, 14 patients, 9 from Group A and 5 from Group B were excluded as they didn't turn up for regular follow up. Hence in my study, total number of patients were effectively (n=118) which were segregated as 62 in study group and 56 in control group. 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. This signifies the presence of more significant residual fragments in Group B upto third session. (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 upto 12 weeks. (P value 0.04).

Overall success rate achieved is 74.6%. and patients who failed the management at the end of 12 weeks were shifted to other modalities of treatment. 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. Within both groups, stones with size less than 10mm, have higher stone free rates, shorter stone clearance time limit, lower retreatment rate, in terms of additional sessions, and less number of shock waves when compared to stones with size more than 10mm.

Regarding Stone Attenuation, in both groups stone with attenuation less than 500 HU have produced better results in terms of better stone clearance, less retreatment and less number of shock waves exposed. Also stones with stone attenuation value of more than 1000 HU had more retreatment and failure rates. 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 that order. Patients presented with colicky pain were managed conservatively with analgesics and evaluated with Ultrasonography. LUTS and Hematuria are the next predominant complications. Dysuria and increased frequency are predominant LUTS symptoms

recorded. Hematuria is usually mild and these patients are advised plenty of oral fluids. Only three cases required haematocrit evaluation as they presented with persistent hematuria. Steinstrasse occurred in 14 patients and about half of them required intervention in the form of stenting and or Ureteroscopic stone removal.

DISCUSSION

Combination of Trendelenburg 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 pole and middle calyceal 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 inefficient stone clearance rather than stone fragmentation.

This is due to dependent position of lower pole calices¹⁹. Various studies demonstrated this with computed tomography or Magnetic Resonance studies with oblique axis of lower pole calyx with 20-30 degree tilt^(22,23).

Other factors thought to cause this defective clearance are:

Anatomical factors like acute Infundibulo-pelvic angle, and infundibular length and width may have an impact on stone clearance^{21,22}. But more recent prospective studies have failed to demonstrate the significance of these anatomical factors in defective stone clearance from lower pole calices¹⁹. Also in realistic, the static images cannot accurately measure the dynamic pelvicalyceal system including the infundibulum^{21,23}. 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 exist which suggests to go for adjuvant procedures like, inversion, mechanical percussion, diuretics and repeat SWL treatment to improve clearance of lower pole calculi^{8,9,10,23}. Combination of all three was found to be 13 times more effective than observation alone²³.

In this study, we evaluated the combination of Inversion and Forced Intra Procedural Diuretics to improve the clearance rate of lower calyceal 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)¹¹, Albanis et al⁹, and by a recent study by Abul-fotouh ahmed et al (78.3% success rate)¹².

Retreatment rate achieved for Group A in our study is 45.2% which is much lower than that observed with Leong et al (90%)¹¹, Kupeli et al (79.4%)²⁸ and Abul-fotouh ahmed et al (73.9%)¹². 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

- This is a combined Prospective and Retrospective study, so proper randomisation is not possible.

- 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

1. Combination of Inversion with Intra Procedural Forced Diuresis significantly improves the Stone Clearance Rate of Lower Calyceal Stones during Extra Corporeal Shock Wave lithotripsy.
2. 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
 - Out patient 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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