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Incidence of Infectious Complications after Extracorporeal Shock Wave Lihotripsy and the Role of Routine Prophylactic Antibiotics

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Original Research Article

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Abstract: Infection is the one of the most important complication after extracorporeal shock wave lithotripsy (ESWL). Role of antibiotics after ESWL is controversial. We did the study to know the incidence of infectious complications following ESWL and need for post procedural antibiotics in low risk patients. We did a prospective, observational; cohort study from April 2015 to November 2016.Total 162 patients were taken who were advised to undergo ESWL in our Out Patient Department (OPD) for renal or ureteric calculus/calculi. Urine culture was performed 5 days before and 7 days after the procedure. No patients (without any risk factors or negative pre-procedural urine culture) received any post-procedural antibiotics. Total 144 patients were enrolled in the study with median age of 37.58 ± 10.67 years. Among 144 patients, 127 patients (88.2%) had sterile urine culture done 7 days after ESWL. Only in 17 patients (11.8%) patients, urine culture was positive. Out of these 17 culture positive patients, 14 patients(9.7%) had no symptoms(asymptomatic bacteriuria), 3 patients(2.1%) had urgency, frequency, burning micturition, dysuria(symptomatic UTI) and none of the patients developed urosepsis. In our study, we found stone size to be an independent factor for developing infection. The incidence of infectious complications after extracorporeal shock wave lithotripsy is low in patients without risk factors. So, routine antibiotic prophylaxis is not justified without defined risk factors such as positive urine culture before ESWL, an external bladder catheter or nephrostomy tube and a history of infectious stones or recurrent urinary tract infections. Patients with larger stones (>1cm) are more at risk for post-ESWL bacteriuria and, thus, for a possible infectious complication.
Keywords: extracorporeal shock, bacteriuria, antibiotic

INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) is commonly performed a non-invasive treatment of urinary tract stones using an acoustic shock wave. But it is not without complications. Some of these complications are infectious, such as asymptomatic bacteriuria, urinary tract infection and sepsis [1-3].

The incidence of UTIs after shockwave lithotripsy is reported to range from 0% to 28% without antimicrobial prophylaxis [4-7]. A meta-analysis of contemporary randomized controlled trials examined the utility and cost-effectiveness of antimicrobial prophylaxis for shockwave lithotripsy and demonstrated, in individuals with sterile pre-procedure urine cultures, a reduction in the rate of UTIs after shockwave lithotripsy from 5.7% to 2.1%. Until September 2012 the AUA recommended antibiotic prophylaxis in patients treated with SWL based on the meta-analysis of Pearle and Roehrborn [1].

Several studies have been performed questioning the need for antibiotic prophylaxis in this intervention. New evidence that emerged in recent years led to a change in these recommendations [2, 8-9]. Though Campbell-Walsh Urology (11th ed) [10] still recommends antimicrobial prophylaxis for ≤ 24hrs for patients without risk factors undergoing ESWL, today the AUA and EAU agree in not recommending generalized antibiotic prophylaxis, although they recommend it when associated factors exist that could increase the risk of infection [11-13] There is no agreement between the AUA and EAU about the risk factors that should be considered for prophylactic antibiotics.

So, it is important to know the exact incidence of bacteriuria and urinary tract infection after ESWL in patients without risk factors and this will help us to

decrease antibiotic use and, therefore, minimize the consequences resulting from it, such as the development of resistant bacteria, the risk of adverse reactions and the economic cost of antibiotic treatment. Thus primary aim of our study is to determine the exact incidence of infection related complications after ESWL in patients without any risk factors and secondary aim is to determine the risk factors associated with the infectious complications.

MATERIALS AND METHODS

We designed a prospective, observational, cohort study in the Department of Urology, Calcutta National Medical College & Hospital, and Kolkata, India. Study population was patients attending Urology out Patients Department (OPD) in our hospital and advised to undergo ESWL. It was done between April 2015 to November 2016.Total 162 patients were taken out of which 18 patients lost to follow-up. So total number of patients studied was 144.Ethical committee clearance was taken from appropriate authority.

Patients advised to undergo ESWL in our OPD who met the inclusion criteria of our study and had a radiographically documented renal/ureteric calculus underwent complete pretreatment evaluation. Pre ESWL Straight X-Ray KUB and IVU/NCCT KUB, blood parameters like Complete blood count (CBC), blood sugar, serum creatinine, bleeding & clotting time (BT&CT). Post ESWL Straight X-ray KUB was done one month after the procedure. Urinalysis (routine & microscopic examination) and culture were done 5 days before and 7 days after ESWL. Inclusion criteria were age more than 18yrs, negative urine culture before ESWL. Exclusion criteria were patient loss to follow up, no urinary culture within 7days of ESWL, urological manipulations during or after ESWL, patient with external bladder catheter or nephrostomy tube, history of infectious stone, history of recurrent urinary tract infections, patients with chronic corticosteroid use, immunodeficiency, and urinary tract anomalies.

Parameters studied at the beginning of the study were prior pathological conditions, lithiasis size (largest diameter in long axis), stone number and location, whether Double J Stent inserted before ESWL for obstructive uropathy or urosepsis. During the study information were collected regarding no of shock waves and power used, whether complete stone fragmentation achieved or not. Final parameters (after ESWL) reviewed lithiasis fragmentation, renal colic after ESWL (defined as colic pain on the treated side requiring continuous oral or intravenous analgesia, stone residues greater than 5mm on follow up X-ray, urine culture (more than 10^5 CFU /ml considered positive),symptomatic urine infection (defined as dysuria, burning micturition, voiding frequency and/or urinary urgency with a positive urine culture, urinary sepsis (defined as symptomatic urine infection plus systemic inflammatory response syndrome).

All the patients were explained about the procedure and written valid informed consent was taken from each subject. Detailed history was obtained & thorough clinical examination was done. Pre-treatment ultrasonography & Straight X-ray KUB were done in every patient supplemented by intravenous urography/ NCCT in selected patient. Stone size was determined by corroborating ultrasound dimension with measurement of the maximum dimension of the stone in scout KUB film. Routine investigations like Complete blood count, Blood Sugar, Urea, Creatinine, Bleeding Time (BT), Coagulation Time (CT) were done.

Urine Routine & Culture was done 5 days before the procedure and 7 days after the procedure. If the urine culture was positive before the procedure, antibiotic was given according to sensitivity report to make the urine sterile.

SWL was performed with Dornier Compact Sigma lithotripters, with the patient in the supine position. The stone was localized using biplanar fluoroscopy. The shockwave power was started at 14 kV and increased gradually up to 20 kV. For patient safety, the maximal number of shockwaves was 2500. The shockwave frequency was 60/min. The patients were discharged from the hospital on the same day of treatment and patients were asked to follow-up which with Urinalysis and culture & sensitivity report which was done 7days after the procedure. Plain X-ray KUB film was done 1month after the procedure to detect fragmentation, stone clearance and residual fragment, if any. If significant (>5mm) residual fragments were still seen, they were instructed to undergo a second session. Informed written consent was taken from every patient.

All statistical analyses is performed using SPSS®Software, version 20.0. Categorical variables are expressed as number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes. Continuous variables are expressed as Minimum, Maximum, Mean and Standard Deviation and compared across the 2 groups using Mann-Whitney U test. An alpha level of 5% has been taken, i.e. if any p value is less than 0.05, it has been considered as significant.

RESULTS

A total of 162 patients were enrolled in the study. Out of these, 18 patients did not follow-up with urinalysis and culture report after 7 days. So total 144 patients were finally considered for the study.

In our study, mean age of the patient is 37.58 years (± SD 10.67 years) with the range from 19 years to 72 years.

Out of 144 patients, 107 patients were male and 37 patients were females with 74.3% and 25.7% respectively.15 patients (10.4%) were hypertensive, 10 patients (6.9%) were diabetic and 6 patients (4.2%) underwent SWL with DJ stent in situ.

The mean size of stone in our study is 9.48mm(± 2.41 SD),with a range from 6mm to 17mm.104 patients (72.2%) had stones of ≤1cm and 40 patients (27.8%) had stones >1cm. Out of 144 patients, 125 patients (86.8%) had renal stones in different locations and 19 patients (13.2%) had stones in ureter. Out of 144 patients, 132 patients (91.7%) had single calculus, 10 patients (6.9%) had two calculi and 2 patients (1.4%) had 3 calculi. Mean number of shock waves in our patients was 1531.69 ± 231.79(SD) with range from 600 -2500. Most of our patients were given shock waves at a power of 14-20 kV with an escalating dose protocol without any renal protective pause. Table 1 shows stone and treatment characteristics of 144 patients.

Among 144 patients, 127 patients (88.2%) had sterile urine culture done 7 days after ESWL. Only in 17 patients (11.8%) patients, urine culture was positive. Out of these 17 culture positive patients, 14 patients(9.7%) had no symptoms(asymptomatic bacteriuria),3 patients(2.1%) had urgency, frequency, burning micturition, dysuria(symptomatic UTI) and none of the patients developed urosepsis. Table 2 shows the isolated organisms in patients with positive urine culture.

Stone fragmentation were noted in 138 patients (95.8%) and 6 patients (4.2%) did not have evidence of stone fragmentation on post-ESWL X-ray KUB.

We analyzed the risk factors (see Table 3) that might be associated with the increased chance of positive post-ESWL urine culture. Risk factors analyzed were age, sex, diabetes, hypertension, stone size, and stone location, number of stones, residual fragments and presence of Double J stent. We found that increased stone size was associated with positive urine culture but we did not find any significant association with elderly age or double J stent as found in some studies [13].

Table-1: Stone and treatment characteristics

	No of pts (percentage)
Stone location	
Calyx	104(72.2)
Pelvis	19 (13.2)
Multiple location	2 (1.4)
Ureter	19 (13.2)
Stone number	
One	132(91.7)
Two	10(6.9)
Three	2(1.4)
Stone size	
≤ 1cm	104(72.2)
> 1cm	40(27.8)
No. of shock waves	
< 1500	14 (9.7)
1500-1999	123(85.4)
2000-2500	6 (4.2)
>2500	1(0.7)
Energy	
14-18 kV	3 (2.1)
14-20 kV	141 (97.9)

Table 2 Urine Culture Results

Results	No. of pts (%)
Negative	127 (88.2%)
Positive	17 (11.8%)
E.coli	13 (9%)
Klebsiella	1 (0.7)
Proteus mirabilis	1 (0.7)
Staph. aureus	2 (1.4%)

Table-3: Risk factor analysis

	No. of pos urine culture/ Total no. of pts (%)	RR(95% CI)	p Value
Gender			
M	11/107 (10.28)	0.86(0.59-1.23)	0.335
F	6/37 (16.22)		
Age			
≤ 50 yrs	14/129(10.85)	1.87(0.59-5.95)	0.299
>50 yrs	3/15 (20)		
Diabetes mellitus			
Yes	1/10 (10)	0.83(0.11-6.15)	0.854
No	16/134 (11.28)		
Hypertension			
Yes	1/15(6.67)	0.53(0.07-3.81)	0.515
No	16/129(12.4)		
Stone size			
≤1cm	6/104(5.77)	2.83(1.76-4.56)	≤0.001
>1cm	11/40 (27.5)		
Stone no.			
1	15/132 (11.36)		
2	2/10(20)		0.626
3	0/2(0)		
Stone position			
Calyx	10/104(9.62)		
Pelvis	5/19(26.32)		0.202
Multiple	0/2(0)		
Ureter	2/19(10.53)		
Residual fragment(<5mm)			
Yes	2/14(14.29)	1.25(0.3-5.09)	0.762
No	15/130(11.54)		
Double J stent			
Yes	2/6(33.33)	3.74(0.74-18.88)	0.095
No	15/138(10.87)		

DISCUSSIONS

ESWL is minimally invasive, efficacious therapy for most renal and upper ureteric stones. However infection related complications are one of the most important complications encountered in post ESWL patients. Numerous studies have been done to estimate the incidence of infectious complications and, therefore, determine whether antibiotic prophylaxis is necessary [14-18].

Various incidences of infectious complications have been published. Bacteriuria has been found in 3.1%–23.5% of patients who undergo ESWL [9, 19-20]. In Campbell-Walsh Urology (11th ed, 2016), the range is described as 0%-28% without antimicrobial prophylaxis[20]. The occurrence of post-ESWL urinary infections (positive urine cultures) is 14% globally [21]. Our study confirms low incidence of infectious related complications after ESWL. In our study, we find overall infection rate of 11.8% with 9.7% patients presented with asymptomatic bacteriuria, 2.1% presented with symptomatic urinary tract infection and none developed urosepsis. Our rate of infection is low and most of the urine culture positive patients had no symptoms. But it is higher than Alejandra Mira Moreno *et al*. who described the

incidence rate of infectious complications of 5.8%, of which 4.6% presented with asymptomatic bacteriuria, 1.2% presented with a clinical profile of urinary tract infection and none presented with sepsis [22]. Lu *et al*. in their meta-analysis, mentioned rates of about 5% for asymptomatic bacteriuria and 1% for sepsis [8]. Our slightly higher rate may be due to the fact that we did not give any prophylactic antibiotic therapy to any patient before or after lithotripsy session which is given in some study [9]. It may also be due to poor local hygiene and nutritional status of the patient, chronic smoking or associated coexistent infection.

Therefore, it seems clear that in patients without associated risk factors and a negative urine culture before SWL antibiotic prophylaxis is not indicated. This coincides with the latest AUA and EAU guideline recommendations [23, 24].

On the other hand, there is no agreement in the literature about which factors should be considered risk factors for prophylactic treatment in this patient group. The table no.4(below) shows the risk factors considered by the AUA and EAU.[22,25] Few groups have directly analyzed factors associated with infection after ESWL.

In the study by Alejandra Mira Moreno et al, patient age (>65 yrs) was an independent risk factor for post-SWL bacteriuria [23]. In their study, they also found in-situ DJ stent as a risk factor in univariate analysis, but not on multivariate analysis.

In our study, we considered factors that may be related to positive urine culture after ESWL. The factors that are considered are like age, sex, comorbidities like hypertension, diabetes, Double J stent in-situ, stone parameters like location, number, size, side(right/left),stone fragmentation, residual fragment, shock wave characteristics like number of shock waves, power of shock wave, and visual analogue scale(VAS) score. We found that increased stone size (>1cm) as a risk factor to be associated with post lithotripsy bacteriuria on univariate analysis. However, the role of prophylactic antibiotic in the patients with larger stones (>1cm) is up for discussion and needs further study with larger number of patients as the incidence of symptomatic urinary tract infection and serious complication like urosepsis is very low. No other factors are found to be significantly associated with positive urine culture after ESWL.

Table-4: AUA & EUA risk factors

AUA	EUA
Advanced age	Internal stent placement
Urinary tract anatomical anomalies Indwelling catheter	Urinary tract anatomical anomalies
Poor nutritional status	Nephrostomy tube
Smoking	Infectious stone
Chronic corticosteroid use	
Immunodeficiency	
External catheters	
Colonized endogenous/exogenous material	
Distant coexistent infections	
Prolonged hospitalization	

CONCLUSIONS

The incidence of infectious complications after extracorporeal shock wave lithotripsy is low in patients without risk factors. So, antibiotic prophylaxis is not justified without defined risk factors such as positive urine culture before ESWL, an external bladder catheter or nephrostomy tube and a history of infectious stones or recurrent urinary tract infections. Patients with larger stones (>1cm) are more at risk for post-ESWL bacteriuria and, thus, for a possible infectious complication.

Limitations

Our study has some limitations.

First, study population was small.

Second, we had no comparison group with prophylactic antibiotic treatment. It would have been useful to determine whether the rates of bacteriuria and symptomatic urinary tract infection were similar or not.

Third, we could not determine the risk factors associated with symptomatic infections and serious events. This analysis was not possible due to the low incidence of these events.

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