

PROSPECTIVE STUDY TO COMPARE THE EFFICACY OF ANALGESIC AGENTS USED FOR THE PAIN MANAGEMENT DURING EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY

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ABSTRACT

BACKGROUND

Extracorporeal shock wave lithotripsy (ESWL) is well known for its non-invasiveness, effectiveness and minimal morbidity for the management of renal stones. Some generation of lithotripters were associated with significant pain, needing anaesthesia. In modern lithotripters, pain is insignificant making lithotripsy an outpatient procedure (day care).

AIMS

The present study is aimed to compare the clinical efficacy between four drugs.

METHODS AND MATERIALS

This was a prospective study of 1000 patients with normal BMI (25-30) who underwent ESWL in the Year 2012-15 at our institute. All the patients with renal stones were randomly divided into 4 groups. Dornier Compact Sigma lithotripsy machine was used in all the patients. Group A was given IM diclofenac sodium (1 mg/kg), 60 minutes before the procedure. In group B, 10 g of EMLA cream; and in group C, 15 g of diclofenac diethylamine gel; in group D placebo (electrode gel) was applied locally.

STATISTICAL ANALYSIS

Visual analogue scale (VAS) was used to assess the severity of pain for initial 5-10 minutes and after the procedure. A *P* value of less than 0.05 was considered to be statistically significant. Statistical analysis was done using one way ANOVA and results were compared between four groups.

RESULTS

All four groups were having comparable age, weight, stone size, number of shock waves delivered and maximum voltage used. In group A total 250 patients (M/F: 177/73), group B 250 patients (M/F: 129/121), group C 250 patients (M/F: 158/92), group D 250 patients (M/F: 162/88). With regard to pain scores, the responses were better in group B. According to location of the stones, majority of the stones were located in pelvis (41.5%), followed by upper (30.5%) and middle calyx (16.8%) and least in the lower calyx (11.2%). Overall stone free rate in our study was 75.5%, with least clearance in lower calyceal stones. 112 patients were stented prior to the procedure. Ureterscopy and RIRS (Retrograde intrarenal surgery) was done for residual stones after 3 sessions of SWL. Post ESWL complications like pyelonephritis, steinstrasse and renal stone migrating to ureter were 2%, 4.5%, 1.9% respectively.

CONCLUSIONS

With regard to pain scores, the EMLA cream provided better analgesic effect as compared to other groups. Oral NSAID and occlusive dressing of EMLA offers an effective mode for achieving analgesia with minimal morbidity. This therapy avoids the need for general anaesthesia, injectable analgesics, and opioids along with their side effects.

KEYWORDS

Pain, ESWL, Analgesic Agents, Stone Clearance.

HOW TO CITE THIS ARTICLE: Mulay A, Singh M, Kankalia SK, et al. Prospective study to compare the efficacy of analgesic agents used for the pain management during extracorporeal shock wave lithotripsy. *J. Evid. Based Med. Healthc.* 2016; 3(40), 1995-1997. DOI: 10.18410/jebmh/2016/443

Financial or Other, Competing Interest: None.

Submission 20-04-2016, Peer Review 05-05-2016,

Acceptance 14-05-2016, Published 19-05-2016.

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DOI: 10.18410/jebmh/2016/443

INTRODUCTION: Extracorporeal shock wave lithotripsy (ESWL) is well known for its non-invasiveness, effectiveness and minimal morbidity for the management of renal and ureteric stones.^{1,2} In modern lithotripters, pain is insignificant making lithotripsy an outpatient procedure (day care). ESWL has undergone significant development since

its first description by Chaussy.¹ General Anaesthesia was required earlier for original HM3 lithotripter causing intolerable pain.

Nowadays, with third generation piezoelectric lithotripters are described painless, but still some patients experience pain during treatment. Analgesics commonly used during ESWL include opioids, sedative hypnotics, non-steroidal anti-inflammatory drugs, and local anaesthetic creams such as EMLA, though opioids provide efficacious analgesia, they are associated with significant complications.

Therefore, it is essential to choose an appropriate analgesic with minimal adverse effects. Despite reports of various studies comparing different analgesic techniques during ESWL, guidelines for pain management during the procedure are not well established, so in order to establish appropriate analgesia, which offers pain free treatment, minimal side effects, cost effectiveness, we conducted this study. The present study was aimed to compare the clinical efficacy between four drugs, three of which are applied locally at the site of the entry of shock wave like 1) Eutectic mixture of local anaesthetic agents (EMLA) cream (2.5% lignocaine and 2.5% prilocaine), 2) Diclofenac diethylamine gel, 3) Diclofenac sodium which is given intramuscularly, 4) Electrode gel used as placebo.

SUBJECTS AND METHODS: This is a prospective study of 1000 patients with normal BMI (25-30) who underwent SWL in the Year 2012-15 at our institute. After obtaining ethical clearance and written consent from the patients, enrolled patients were evaluated in detail with clinical examination,

family history, biological and haematological tests, urine microscopy with culture and sensitivity.

An intravenous urogram (IVU) was done in all the cases to assess the anatomical and functional aspects of the urinary system along with stone characteristics like stone size and position.

Inclusion Criteria

- Renal stone of size less than 2 cm.
- No previous surgery.
- Bilaterally normal functioning kidneys on IVP.

Exclusion Criteria

- Stone size more than 2 cm.
- Age less than 18 years.
- Active UTI.
- Pregnancy.
- Coagulopathy.

Patients were divided into 4 groups by simple randomisation using the random number generator. Dornier Compact Sigma lithotripsy machine was used in all the patients. Group A was given IM diclofenac sodium (1 mg/kg) 60 minutes before the procedure. In group B, 10 g of EMLA cream; and in group C, 15 g of diclofenac diethylamine gel; in group D, placebo was applied locally 60 minutes before the procedure. Visual analogue scale (VAS) was used to assess the severity of pain. Statistical analysis was done using one way ANOVA and results were compared between four groups. A P value of less than 0.05 was considered to be statistically significant.

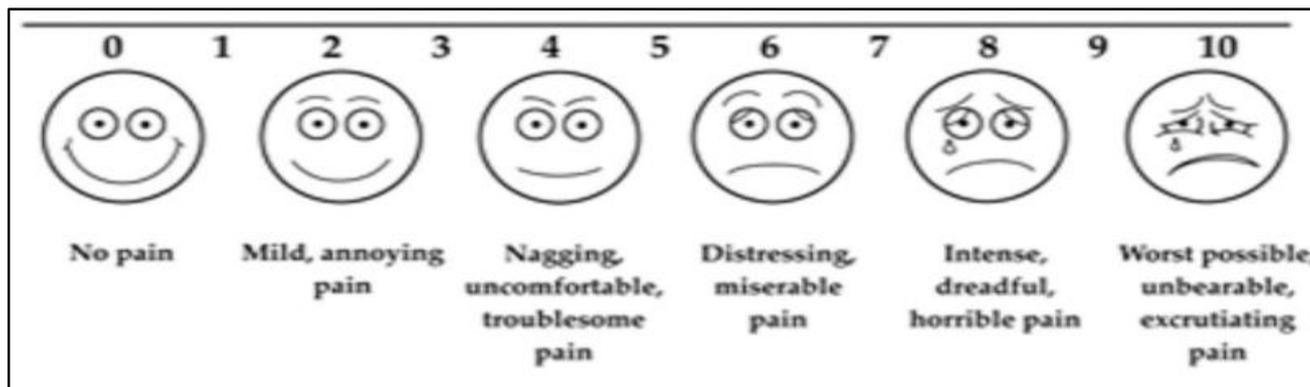


Fig. 1: Visual Analogue Scale

RESULTS: A total of 1000 patients were enrolled in this study. All the four groups were comparable with respect to age, weight, stone size, number of shock waves delivered and maximum voltage used.

Variables	Group A (Diclofenac Injection)	Group B (EMLA)	Group C (Diclofenac Gel)	Group D (Placebo)	P value
No. of Patients	250	250	250	250	-
Age	38.1±13.69	37.5±14.2	37.5±14.2	39.24±14.7	0.475
Sex (M:F)	177:73	129:121	158:92	162:88	-
Weight	61.0±8.2	58.6±9.4	58.3±9.9	58.5±8.9	0.002
Stone size	10.3±3.3	10.4±2.8	10.9±2.3	10.5±2.5	0.077
No. of shock waves	2580±408	2682±301	2800±322	2864±315	0.001
Used voltage	1-2	1-2	1-2	1-2	-

Table 1: Results

According to location of the stones, majority of the stones were located in pelvis followed by upper and middle calyx and least in the lower calyx. Overall, stone free rate in our study was 75.5% with least clearance in lower calyceal stones.

Stone Location	Upper Calyx	Middle Calyx	Lower Calyx	UPJ (Ureteropelvic Junction)
No. of Patients	305	168	112	415
Stone Free Rates	84%	75%	62%	81%

Table 2: Location of Stones and Stone Free Rates

112 patients were stented prior to the procedure. Ureterscopy and RIRS (Retrograde Intrarenal Surgery) was done for residual stones after 3 sessions of SWL.

Complications	No.	Percentage (%)
Pyelonephritis	20	2%
Steinstrasse	45	4.5%
Renal Stone migrating to ureter	19	1.9%

Table 3: Post ESWL Complications

Variables	Group A (Diclofenac injection)	Group B (EMLA)	Group C (Diclofenac gel)	Group D (Placebo)	P value
VAS SCORE	4.48±2.01	3.60±2.21	3.90±2.50	3.80±2.3	1

Table 4: Visual Analogue Score

DISCUSSION: Extracorporeal shock wave lithotripsy (ESWL) is noninvasive, has minimum morbidity, can be performed as an outpatient procedure. Various analgesic agents like opioids, NSAIDS, local anaesthetic agents and various other combination of drugs have been used. Kumar et al³ suggested that combination of oral diclofenac and occlusive dressing of EMLA provides adequate analgesia for SWL. Basar et al⁴ showed that EMLA cream was more effective in controlling pain during ESWL. Tritrakarn et al⁵ showed that EMLA is a safe, effective method to reduce pain during SWL. In our study, we used intramuscular injection, locally applied gel, topical cream, electrode gel as placebo and comparisons were made among these, and found EMLA cream provides more effective pain control.

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