

Analgesia For ESWL: Comparing Two Analgesia Techniques. A Double Blind Randomized Study.

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Citation

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Abstract

Analgesia for ESWL: Comparing to analgesia techniques. A double blind randomized study.

Objectives: In this prospective double blind randomized study we compared the efficacy of topical diclofenac gel with or without intramuscular diclofenac sodium injection for analgesia during outpatient ESWL procedure.

Materials and methods: This study was conducted in a tertiary health center in North India. Fifty patients who underwent ESWL for renal stones and upper ureteric stones were included in the study. These patients were randomized into two groups: In first group (group G) 25 patients received topical diclofenac gel 5 gm, 30 minutes before ESWL. The gel was applied to a 15 x 20 cm area of skin overlying the kidney to be treated, these patients were also given intramuscular injection of distilled water as placebo. In second group (group C) another 25 patients were applied topical diclofenac gel as in group G, in addition these patients were administered 75 mg of diclofenac sodium intramuscularly 30 minutes before procedure. The total number of shocks, energy level and status of fragmentation was noted in each case. After completion of the procedure patients were evaluated for pain intensity using visual analogue scale (VAS) and compared between two groups.

Results: There was no statistically significant difference between patient age, weight, sex ratio, number of stones, size of stones and ESWL parameters like energy level and number of shocks in two study groups. Mean VAS score in group C was 24 ± 20.361 mm and in group G was 42.40 ± 20.722 mm with P value of 0.004.

Conclusion: Topical application of diclofenac gel in combination with intramuscular injection of diclofenac sodium ensures superior analgesia during ESWL as compared to topical application of diclofenac gel alone and the use of diclofenac is safe for analgesia during ESWL.

INTRODUCTION

In the past urolithiasis used to be treated by open stone surgery. The treatment of urolithiasis has been revolutionized with the introduction of extracorporeal shock wave lithotripsy (ESWL) due to its simplicity, noninvasive nature, efficacy, and minimal morbidity^{1, 2}. Acoustic shock waves breakdown stones into sand-like fragments that may then be excreted. Main problem with this procedure is pain, several medications and methods have been used to control the pain felt during ESWL. The efficacy of the procedure can be improved by attenuating the pain and anxiety that may occur during ESWL. Newer generation lithotripters are less painful than their prototypes. Thus, the trend in anesthesia for ESWL has shifted from general and regional analgesia towards sedative analgesic techniques³. For this reason, topical local anesthetics, non-steroidal anti-inflammatory agents (NSAIDs), parenteral and sometimes opioid agents given via PCA pumps (patient-controlled analgesia) are being used. There is no consensus on the

analgesia protocol. The major issue is to provide the sufficient analgesic efficacy with minimum side effects. Although the usage of opioid analgesics is an appropriate alternative to control the pain that can be felt during ESWL. However, opioid analgesics have complication potentials such as significant respiratory depression, bradycardia, hypotension, nausea, vomiting, pruritis and prolonged recovery time^{4, 5}. Therefore the reliable alternative for pain management might be NSAIDs. In this double blind randomized control study we compared the efficacy of diclofenac gel versus diclofenac gel along with paraneural diclofenac injection for analgesia during outpatient ESWL.

MATERIAL AND METHODS

After approval by the institutional ethics committee 50 patients with stones in the kidney and upper ureter attending the outpatient department of urology in a tertiary referral health center were included in this prospective double blind randomized control study. Patients were investigated as per

the protocol. Informed written consent was obtained from each patient. Adult patients with renal stones two cm or less in diameter in renal pelvis or calyces and upper ureter stone, non-impacted and less than one cm in diameter in functioning renal unit, patients with no distal obstruction and no history of allergy to diclofenac sodium were included in this study. Patients having history of drug or alcohol abuse, history of acid peptic disease, documented urinary tract infection and pregnant patients were excluded from the study. On arrival to the lithotripsy unit, the procedure was well explained to all the patients and they were advised not to move during the procedure. They were instructed to ask for analgesic drugs for intolerable pain or discomfort. These patients were randomly allocated to one of the two treatment groups. In first group, (group G i.e. diclofenac gel only) 25 patients received topical diclofenac gel 5 gm 30 minutes before ESWL. The gel was applied to a 15 x 20 cm area of skin overlying the kidney to be treated (site of entry of shock wave). The patients were also given intramuscular injection of distilled water as placebo. In second group (group C i.e. combined diclofenac gel and intramuscular diclofenac sodium injection) 25 patients were applied topical diclofenac gel as in group G, in addition these patients were administered 75 mg of diclofenac sodium injection intramuscularly 30 minutes before procedure. The stones were localized fluoroscopically. Patients with renal stones were treated in supine position and those having upper ureteric stone overlying transverse process were treated in prone position. Shocks were delivered at low energy level at the beginning of lithotripsy which was gradually increased to recommended energy level. The number of shocks varied from 1800 to 4000 during a treatment session. The total number of shocks, energy level and status of fragmentation was noted in each case. At the end of procedure any change in appearance at the site of shock head coupling was noted. After completion of the procedure, patients were evaluated for pain intensity using visual analogue scale (VAS) of 100 mm (0-extremely comfortable, 100-extremely uncomfortable). After the completion of the procedure the patients were discharged when they satisfied the institutional discharging criteria. At discharge patients were advised to drink plenty of fluids to produce 2-3 L/day urine output and to attend clinic in case of colicky pain not responding to oral medication, fever or hematuria. After 3 weeks X-ray KUB was taken to see the degree of stone disintegration and clearance. In case of significant residual fragment patient was advised second session of ESWL.

Statistical Analysis

All statistical calculations were performed using the statistical package for social sciences (SPSS) for windows version 15, proportions and percentages were used to summarize categorical variables. The Chi-square test was used to investigate statistical significance of these categorical variables. The relationship between pain intensity measured by VAS and body weight, energy level, number of shocks were analyzed using Pearson correlation co-efficient. Values were expressed as means \pm SD unless otherwise specified. As the data was non symmetric, the non parametric Mann-Whitney test was used to see the significant difference between descriptive variables. Differences were considered statistically significant when P value was < 0.05 .

RESULTS

Two study groups were comparable with respect to demographic factors, stone characteristics like size and number of stones and ESWL parameters like energy level and number of shocks (table 1).

Table 1

Comparison of patients, stones and ESWL parameters between group C and G

S.No.	Factors	Group C	Group G	P value
1	Mean age in years	43.52 \pm 15.83	35.44 \pm 12.88	0.056
2	Mean body weight in kg	62.52 \pm 11.73	65.20 \pm 13.043	0.376
3	Sex ratio (male:female)	16:09	21:04	0.107
4	Mean number of stones	1.08 \pm 0.277	1.16 \pm 0.473	0.126
5	Mean size of stones in mm	12.16 \pm 4.589	9.72 \pm 4.248	0.058
6	Mean energy level in KV	3.60 \pm 0.500	3.36 \pm 0.653	0.126
7	Average number of shocks	3168.00 \pm 432.743	3175.60 \pm 384.665	0.764
8	Mean VAS score in mm	24.00 \pm 20.361	42.40 \pm 20.722	0.004
9	Extra-analgesia required (Number of patients)	0	2	0.149
10	VAS score 0 mm (Number of patients)	8	2	.034

VAS- Visual analogue score, KV- Kilovolt

In group C out of 25 patients 23 had unilateral and 2 had bilateral stone disease. Among 23 patients having unilateral stone disease 12 had stones on left side and 11 on the right side. In group G out of 25 patients 24 had unilateral and 1 had bilateral stone disease. Among 24 patients having unilateral stone disease 11 had stones on left side and 13 on the right side. There was no statistically significant difference in number of shocks and energy level between 2 groups (table 1). VAS score in group C ranged from 0 - 60

mm and mean VAS score was 24 ± 20.361 mm. VAS score was 0 mm in 8 patients. VAS score in group G ranged from 0 - 80 mm and mean VAS score was 42.40 ± 20.722 mm. VAS score was 0 mm in 2 patients. There was statistically significant difference with respect to VAS score in two groups. P value was 0.004. Extra analgesia was demanded by 2 patients in group G and none in group C (table 1). There was no difference in stone clearance between two groups as extra analgesia was provided on demand. We correlated body weight, size of stones, energy level and number of shocks with VAS score using Pearson correlation co-efficient in both the groups (table 2). In group C there was no significant correlation between body weight, size of stones, energy level and number of shocks with VAS score. In group G there was significant correlation between number of shocks and VAS score but correlation between body weight, size of stones and energy level with VAS score was not significant.

Table 2

Correlation matrix in group G and C.

S.No:	Correlates in group G	Pearson correlation	P value
1	Body weight and VAS score	-0.108	0.609
2	Energy level and VAS score	0.00	1.00
3	Number of shocks and VAS score	-0.191	0.362
4	Size of stones in mm and VAS score	0.193	0.356
S.No:	Correlates in group C	Pearson correlation	P value
1	Body weight and VAS score	-0.48	0.819
2	Energy level and VAS score	0.271	0.19
3	Number of shocks and VAS score	0.438	0.028
4	Size of stones in mm and VAS score	0.078	0.712

VAS- Visual analogue score.

Patients in group C and group G were divided according to the size of stones into 2 categories, size of stone <1 cm and >1 cm. In group C 12 patients had stone size <1 cm and mean VAS score was 26.25 ± 22.975 mm and 13 patients had stone size >1 cm and mean VAS score was 21.92 ± 18.319 mm and P value was 0.580. In group G 21 patients had stone size <1cm and mean VAS score was 40.48 ± 21.846 mm and 4 patients had stone size >1cm and mean VAS score was 52.50 ± 9.574 mm and P value was 0.260. P value is statistically not significant for VAS score in any of group C and G irrespective of stone size (<1 cm or >1 cm).

DISCUSSION

For treatment of urinary stones extracorporeal shock wave lithotripsy (ESWL) is one of the major treatment alternatives⁶. Success of ESWL in treatment of urinary

stones depends on three different groups of variables:

1.Related to stones, 2.Related to patients and 3. Related to operator
7. Patient compliance is crucial for optimal stone fragmentation and compliance is closely related with pain management during ESWL. The pathogenesis of pain in ESWL is still poorly understood but is considered to be multifactorial. The cutaneous superficial skin nociceptors and visceral nociceptors such as periosteal, pleural, peritoneal, and/or musculoskeletal pain receptors are two important components responsible for causing pain during ESWL ⁸<http://www.ncbi.nlm.nih.gov/pubmed/9693241>. Patient related factors and several physical variables including the type of lithotriptor, size and site of stone burden, location of the shockwave front, cavitation effects, shock wave peak pressure, size of focal zone and area of shock wave entry at the skin are additionally responsible for pain ⁹. ESWL treatment was very painful with first-generation lithotriptors and general or regional anesthesia was needed during the procedure. With the development of second and third generation lithotriptors, the procedure became less painful. Therefore, nowadays, general anesthesia has been replaced by intravenous sedatives, narcotic analgesics, NSAIDs and topical anesthetics. The avoidance of a general anesthetic during ESWL is advantageous reducing the morbidity and potential mortality and allowing treatment on an outpatient basis, indirectly reducing cost. Although many techniques have been described for the pain management during ESWL, there is no consensus on protocol. In addition, Oh et al demonstrated that pain during ESWL may be well tolerated in some patients. Their studies showed that 64.4% of patients did not agree that analgesics should be recommended to other patients during ESWL ¹⁰. The aim while using these agents is to provide optimum analgesia with minimum side effects. Predicting the analgesic drug requirements prior to ESWL is very difficult. The opioid analgesics used during ESWL may cause vomiting, nausea, bradycardia, bronchospasm, respiratory depression, etc.¹¹. To prevent such side effects, certain centers have used NSAIDs or topical anesthetic cream. Previously, the aim of using these agents was to reduce the dose of opioid analgesics, while with time they started to be used alone for pain management. NSAIDs like diclofenac sodium provide pain relief by their anti-inflammatory effect caused by prostaglandins synthesis inhibition and are effective via oral, intramuscular and rectal routes. It is an effective analgesic with lower side effects than opioids especially with regard to hemodynamic instability and respiratory depression¹². However, it is

associated with mild gastrointestinal disturbances, occasional hypersensitivity reactions and sometimes coagulation disorders because of cyclo-oxygenase inhibition 13. Saita et al suggested that intramuscular analgesia along with topical application of Luan (gel containing lidocaine 1%) provide better analgesia than intramuscular analgesia alone during ESWL 14. EMLA cream was used for analgesia, but was found to be less effective as compared to dimethyl sulfoxide with lidocaine 15. Lidocaine 1% by local infiltration is considered an effective and inexpensive agent that can be applied with minimal morbidity for analgesia during ESWL. It couldn't be used as a monotherapy but it effectively reduced the need for patient controlled analgesia 16. Parkin et al concluded in their study that there was no significant difference in pain score in patients who received diclofenac alone or a combination of diclofenac and patient controlled analgesia, that is alfentanil. However, patients were more satisfied with pain relief when using a patient controlled analgesic pump. They suggested that patient should be given the option of a patient controlled analgesia pump during ESWL, especially when presenting for second or subsequent treatment 17. Rane et al in their study showed the efficacy of diclofenac cream as topical analgesia in lithotripsy as it decreases opioid requirements when compared to placebo 18. In our study when intramuscular diclofenac sodium along with diclofenac gel was applied no patient required extra-analgesia. This shows that intramuscular diclofenac sodium injection along with diclofenac gel provide better analgesia than diclofenac gel alone. No patient in our study had any adverse drug reaction. This shows that the use of diclofenac was a safe medication for analgesia during ESWL.

CONCLUSION

In conclusion, we observed that topical application of diclofenac gel in combination with intramuscular diclofenac sodium injection ensures superior analgesia during ESWL as compared to topical application of diclofenac gel only and the use of diclofenac is safe for analgesia during ESWL.

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