ORIGINAL ARTICLE

Effect of Different Analgesics on Pain Relief During Extracorporeal Shock Wave Lithotripsy

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Abstract

Bacground/aim: The aim of this study was to compare three drugs for pain relief during shock wave lithotripsy (SWL).

Materials and Methods: Seventy six male patients that were treated for renal stones with SWL were included in this study. They were randomized into four groups. A different treatment protocol was used for each group. Intramuscular (IM) diclofenac 75mg was given in group 1 (n=20), dexketoprofen, 50mg, IM in group 2 (n=20) and hyoscine 10 mg plus paracetamol 500mg, orally in group 3 (n=20). In group 4 (control, n=16) saline solution was given 30 min before SWL. Pain during SWL was assessed using the 10-score linear visual analogue pain scale (VAS) and was compared among groups. Age, weight, height, body mass index (BMI), stone size, stone location, duration of SWL, total shock waves performed and mean energy level (kV) for each patient were recorded. A p value of <0.05 was considered statistically significant.

Results: The mean patients' age was 45.4 ± 12.9 years. The highest VAS value was observed in Group 4 (8.4 ± 1), and the lowest in Group 1 (6.25 ± 2.2). Statistically significant difference was noted only when Group 1 and Group 4 were compared. The remaining groups provided similar results and there were no significant statistical differences according to VAS values. Other parameters were similar in all groups.

Conclusion: In conclusion, this study shows that reducing the pain with a single dose injection of intramuscular diclofenac sodium before SWL is superior compared to others. Hippokratia 2014; 18 (2):107-109.

Key words: shockwave lithotripsy, diclofenac sodium, dexketoprofen, hyoscine-N-butyl bromide plus paracetamol

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Introduction

Shock wave lithotripsy (SWL) has become a common treatment option for urolithiasis, as it has high efficacy and a low complication rate. It can be performed under day surgery conditions in selected centers. SWL-related pain is the complaint that patients express mostly intraoperatively and reducing this pain is inevitable for effective stone breaking and good results. Therefore, to reduce and to prevent the pain, local, parenteral or oral non-steroidal anti-inflammatory agents (NSAIDs) and/or opioid agents are applied with various ways in the clinical setting[1,2]. There is no consensus on this issue in the literature[3]. Management of stones with SWL in adults is done in an outpatient setting to enable patients recover earlier and make them able to perform daily activities as soon as possible. However, due to the administration of analgesics (eg. opioids), complications such as bradycardia, hypotension, respiratory depression, nausea, vomiting and pruritus may occur. Therefore, patients have to stay in the hospital. In clinical practice, diclofenac sodium is among the most widely used NSAIDs with lower side effects than opioids, especially with regard to hemodynamic instability and respiratory depression. It is associated, however, with mild gastrointestinal disturbances and occasional hypersensitivity reactions[1-3].

In this prospective randomized study, we aimed to compare the efficacy of diclofenac sodium, dexketoprofen trometamol and combination of hyoscine-N-butyl bromide plus paracetamol in pain management during SWL.

Materials and Methods

A total of 76 male patients treated for renal stones with SWL were included in this study. The patients were randomized into four groups and a different treatment protocol was used for each group in order to control pain during SWL. In group 1 (n=20), diclofenac sodium 75 mg (Dik-

loron, Deva Medical, Turkey) intramuscularly (IM); in group 2 (n=20), dexketoprofen trometamol 50 mg (Arveles, Ibrahim Ethem Ulugay, Menarini Group, Italy) IM; in group 3 (n=20), hyoscine-N-butyl bromide 10 mg plus paracetamol 500mg (Molit Plus, Turkey) orally; and in group 4 (control; n=16), 2 ml of saline solution were given IM 30 min before the procedure. A third-generation lithotriptor (Dornier, Compact Sigma, Germany) was used for SWL. Exclusion criteria were signs and symptoms of urinary tract infection, ingestion and/or injection of any analgesic drug within 3 days before the procedure, allergy to study drugs, moderate to severe hydroureteronephrosis, presence of multiple and/or bladder and/or radiolucent stones. The study was approved by the Ethics Committee and informed consent was obtained from all patients.

All procedures were applied by the same urologist. Pain was assessed with the 10-score linear visual analogue pain scale (VAS) during SWL and was compared between groups. Age, weight, height, body mass index (BMI), stone size, stone location, duration of SWL, total shock waves performed and mean energy level (kV) for each patient were recorded. BMI was calculated for each patient by dividing weight in kilograms by height in square meters.

For statistical analyses, SPSS version 11.5 (SPSS Inc., Chicago, IL, USA) was used. One-way analysis of variance test was used to compare parametric variables. Nonparametric variables were analyzed with the chi-square test. A p value of <0.05 was considered statistically significant.

Results

The mean patients' age was 45.4 ± 12.9 years. Patients' mean age, BMI, stone size and side, shock waves and energy level values within each group are presented in Tables 1 and 2. In the studied patients, there was no difference in terms of age, stone size, stone location and BMI values among the groups. No additional medication was required to relieve excessive pain. Also, the groups were statistically similar in terms of shock waves and kw values between each other (p>0.05, all parameters). The highest VAS value was observed in Group 4 (8.4 ± 1), while the lowest in Group 1 (.25 ± 2.2). While a significant difference was found in terms of VAS values between Groups 1 and 4 (p = 0.02), they were similar between Groups 2, 3, and 4, although lower in Groups 2 and 3 (6.9 ± 2.0 and 6.7 ± 2.3, respectively) (Table 3). Groups 2 and 3 were similar statistically; however VAS score was lower in Group 3. There were no drug-related complications including nausea and vomiting in any of the patients.

Discussion

Table 1: Comparison of mean age, stone size and localization, shock waves, body mass index (BMI), energy level for each groups during shockwave lithotripsy.

	Group1	Group2	Group3	Group4	p value
Mean Age	40.9 ± 13.3	44.2 ± 11.6	49.2 ± 11.9	42.1 ± 17.4	0.247
Side (Left/Right)	13/7	15/5	12/8	9/7	0.108
Stone Size (mm^2)	111.3 ± 71.8	92.3 ± 78.8	169.6 ± 132.3	139.4 ± 99.1	0.08
Shock Waves	2735 ± 460	2980 ± 514	2840 ± 484	2700 ± 578	0.332
BMI	27.0 ± 4.1	27.0 ± 4.2	28.3 ± 4.8	26.2 ± 4.4	0.534
Energy Level (kW)	2.98 ± 0.49	3.09 ± 0.45	2.77 ± 0.92	2.93 ± 0.68	0.482

BMI: Body mass index.

Table 2: Stone location in each group (stone location was similar in all groups).

Location and Number (%)	Group 1	Group 2	Group 3	Group 4
Renal pelvis 26 (34.2)	6	7	7	6
Inferior calix13 (17.1)	4	3	3	3
Medium calix 3 (3,9)	1	-	1	1
Superior calix 1 (1.3)	-	-	1	-
Pelvic urether 17 (22.3)	5	5	3	4
Lumbar urether 6 (7.9)	1	2	1	2
Subrenal urether 10 (13.1)	2	2	3	3

Table 3: Visual analoque scale (VAS) scores of all Groups.

Group 1	Group 2	Group 3	Group 4	p value
6.25 ± 2.2*	6.9 ± 2.0	6.7 ± 2.3 $^{+}$	8.4 ± 1.5	0.02

*p= 0.01 when compared to Group 4, $^{+}$p= 0.08 when compared to Group 4.

SWL has become a routine procedure for the management of urinary stones. One of the factors affecting the success of breaking urinary stones with SWL is patients' pain during the course of the procedure. Although SWL-related pain has been reduced with new generation devices, it remains a serious problem for the patients. To reduce SWL related pain clinically, various medications and various methods have been utilized and new studies are being done. Different analgesic agents including opioids (morphine, pethidine, and fentanyl), NSAIDs (diclofenac, propofol, ketorolac, and piroxicam), local anesthetic agents, and a number of combinations have been used during SWL with various analgesic techniques (general anesthesia, regional anesthesia, subcutaneous and intravenous (IV) injections, patient-controlled analgesia, monitored anesthesia care, cutaneous cream)[4-7]. There is no consensus on this issue. For this reason, while planning this study, we aimed to show the effects of three different drugs on SWL related pain by virtue of VAS scoring system. Because Oh et al, stated that pain can vary according to age, gender and stone, in this study, male patients were chosen and gender as a factor was not assessed[8]. Also, because there was no statistical difference among the groups in terms of age, stone size and side, shock wave and its power, BMI index, factors which were related to stone, age, weight and SWL device were also similar. Moreover, although there are some studies on SWL-related pain and diclofenac sodium and dexketoprofen in the related literature, we were unable to find any reports on the combination of hyoscine-N-butyl bromide plus paracetamol.

The goal of pain management is to relieve pain while keeping side effects to minimum. Diclofenac sodium is an NSAID. NSAIDs are effective analgesics without undesirable side effects associated with opioids such as sedation, respiratory depression, nausea and vomiting, . They inhibit the synthesis of prostaglandins which are responsible for pain, fever, and vasodilatation in response to trauma[3,9]. Dexketoprofen has been shown to possess comparable efficacy and better tolerability over ketoprofen in several clinical studies. Earlier published studies have shown the efficacy and safety of parenteral dexketoprofen in postoperative pain following major orthopedic surgery, renal colic, and acute low back pain[10]. Hyoscine-N-butyl bromide is an anticholinergic and antispasmodic agent which is routinely used for patients with acute renal colic. Furthermore, in addition to this antispasmodic effect, the form of hyoscine-N-butyl bromide plus paracetamol, which has a painkiller feature, has been introduced by adding paracetamol.

Of the studies on reducing SWL-related pain, Tokgoz et al, applied dexketoprofen and diclofenac 30 minutes before SWL, and VAS scores of patients who had been given dexketoprofen was decreased[3]. In Eryıldırım et al's study, it was found that diclofenac was more effective than eutectic mixture of local anesthetics (EMLA) cream[4]. In the study of Gupta et al, patients who were given diclofenac an hour before SWL were compared with patients that were given EMLA, and VAS scores of the latter group found to be lower[7]. Also, the study of Saita et al, showed that the patients who used intramuscular ketorolac and tamadol gave better responses than topical Luan (gel containing lidocaine 1%)[5]. In contrast to the literature, in our study, VAS scores of the patients who were given only diclofenac were statistically lower compared with control and other groups. The results related with the use of dexketoprofen were found to be worse compared to the literature. Though mixture of hyoscine-N-butyl bromide plus paracetamol, which is used for SWL-related pain for the first time in the literature reduces VAS scores, its ananlgesic effect seems to be less compared with diclofenac. This is because reaching a peak concentration of paracetamol in this combination takes twice time compared to dexketoprofen and diclofenac (the former 30-60 minutes, the latter 28-30 minutes). If hyoscine-N-butyl bromide plus paracetamol had been given an hour instead of half an hour before SWL operation, it might have been better than dexketoprofen and diclofenac. For this reason, the present results should be supported with future studies.

In conclusion, our study shows that pain relief with a single dose injection of intramuscular diclofenac sodium 30 minutes before SWL is more effective compared with dexketoprofen and mixture of hyoscine-N-butyl bromide plus paracetamol.

Conflict of Interest

Authors declare no conflict of interest.

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