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The Efficacy and Safety of Lidocaine 1% by Local Infiltration as a Monotherapy in Extracorporeal Shock Wave Lithotripsy

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Abstract:

Background and Aims: Extracorporeal shock wave lithotripsy (ESWL) represents first line therapy for the majority of urinary tract calculi and requires anesthesia. The purpose of this study is to prospectively evaluate the analgesic effects and safety of lidocaine 1% by local infiltration as a monotherapy during renal ESWL and ensure stone clearance after the procedure.

Methods: One hundred patients with renal stones, aged 18 to 65 years, were randomly allocated into two groups; 49 patients in group 1 received intramuscular injection of 20 mg Ketorolac tromethamine, 20 minutes before start of the procedure and 51 patients in group 2 received Lidocaine 1% by local infiltration (5mg/kg) into the 30 cm^2 area after localizing the stones site, 10 minutes before the session. A visual analog scale, (0 to 100 mm) was used to evaluate pain every 10 minutes.

Results: The visual analog scores for group 2 were significantly lower than (group 1) at 10, 20, 30 and 40 minutes till end of the procedure, ($p < 0.001$). The mean requirements of supplemental fentanyl analgesia (µg) were significantly decreased in group 2 than group 1, (3.34 ± 7.32 versus 15.72 ± 6.41, $p<0.001$). All patients in group 2 were discharged earlier, 1 hour after the end of the procedure while 13 patients (26.5%) in group 1 had delayed discharge. No significant difference was detected between the two groups with regards to complete stone clearance after 1 month, no. of shocks, voltage power or duration of procedure. No patient in group 2 reported neurological side effects of local anesthesia.

Conclusions: Lidocaine 1% by local infiltration cannot be used alone for pain relief but effectively reduced the analgesic needs and minimized hospital stay after renal ESWL, without affecting stone clearance.

Keywords: Anesthetics, Cyclooxygenase 2 Inhibitors, Kidney Calculi, Local, Pain

Introduction

Extracorporeal shock wave lithotripsy (ESWL) has been introduced by Chaussy and his co-workers (1). ESWL represents first line therapy for the majority of urinary tract calculi. Renal and ureteral calculi are crushed into small fragments by shock waves and then pass spontaneously as small fragments. ESWL is a non-invasive procedure and requires anesthesia less than other treatment modalities. Majority of patients undergoing lithotripsy are outpatients and discharged on the same day of procedure (2). During the procedure patients experience sharp, stinging pain produced by the impact of the shock waves at the cutaneous entry site. Due to this sharp pain,

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patient may move leading to the need of repeated radiographic localization of the stone(s) for an effective lithotripsy. Effective ESWL requires a co-operative patient who should remain immobile on the lithotripsy table till the end of procedure. Thus local anesthetic infiltration can achieve this goal with minimal side effects. Different analgesic drugs like opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), ketamine in conjunction with sedative agents like propofol, benzodiazepines are used (3) for this purpose. However, occasionally, discharge is delayed due to persistent sedation, nausea and vomiting (4). The aim of our study was to evaluate the analgesic efficiency and safety of local infiltration of lidocaine 1% (5mg / kg) as a monotherapy during renal ESWL when compared with intramuscular (I.M.) 20 mg Ketorolac tromethamine and ensure satisfactory stone clearance after the procedure.

Materials and Methods

This prospective study was done from April 2006 to January 2008 and involved patients with renal stones attending the ESWL unit, Urology Department, Assiut University Hospital, Egypt. One hundred patients with radiopaque, single kidney stones smaller than 20 mm, detected by x-ray of the kidneys, ureters, and bladder, abdominal ultrasonography, and intravenous urography; were included in this study. The stone size was determined according to the maximal stone diameter. Exclusion criterion consisted of bleeding disorders, peptic ulcer, active urinary-tract infection, analgesic/ narcotic dependency, history of an allergic reaction to NSAIDs, age above 70 years or below 18, body mass index less than 20 or more than 30 kg/m^2, and cardiovascular or respiratory illness. Patients with psychiatric problem and who were unable to co-operate with the investigation were also excluded. After providing informed consent, which was approved by our local ethical committee in Assiut University Hospitals, the enrolled patients underwent a detailed clinical evaluation, including family and dietary history, baseline hematologic and biochemical tests, urine microscopy, urine culture with sensitivity, and 24-hour urine analysis. Each patient was instructed on the use of standard 100 mm visual analogue scale (VAS) before the procedure to enable understanding and co-operation of this investigation during and after the procedure. All patients had eight hours of fasting prior to ESWL.

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. At the beginning of the procedure, all the patients received 40 mg IV furosemide, after routine preoperative evaluation and placement of an intravenous catheter. Patients were treated in the supine position. They were randomized into two groups, the treatment regimens were included in closed envelopes to be picked randomly. Patients in (group 1, n=49) as a control received I.M. 20 mg Ketorolac tromethamine; 20 minutes prior to the procedure. Those in (group 2, n=51) received a Lidocaine 1% by local infiltration (5mg/kg) into the 30 cm^2 area in diameter, around the posterior axillary line, beginning just above the last rib downwards and including intradermal (producing pea d'orange), subcutaneous, muscular and periosteal infiltration, which was performed with a single needle entry, after localizing the stones site & size. ESWL was started 10 minutes after the infiltration. Shockwave lithotripsy was performed by ESWL Machine (BMA-MOBITRIP-MT- 1RX), with ellipsoid reflector with shockwave coupling of water cushion (Electrohydraulic lithotripsy) with C-arm (Philips BV25). Patients who had pain during the procedure received 0.25-µg/kg intravenous (I.V.) fentanyl, which was repeated on demand and was recorded. The patients were monitored in the ESWL room, and mean arterial blood pressure, pulse,

respiratory rate and oxygen saturation measurements were recorded (MARQUETT, SOLAR 8000, patient monitor, London, U.K). The visual analog scale (VAS) was assessed at every 10 minutes till the end of ESWL. The scale consisted of a 100 mm long horizontal line ranging from completely no pain to (the Ut-most pain). Facial expressions were put above the line to express satisfaction visually. All patients received this scale preoperatively and were asked to mark the line at a point that matched their pain severity. With a ruler, the number of millimeters was measured and converted to points. An investigator who was unaware of the study drug assessed the patients. All patients received supplemental oxygen via nasal prongs (2 lit/min) and also received 1 gram intravenous first generation cephalosporin. All patients were asked to report and were interrogated continuously for early symptoms of local anesthetic toxicity including lightheadedness, lip or tongue numbness, drowsiness, fatigue, nausea, and dizziness (5, 6). Group 2 was evaluated in terms of skin lesions at the end of the procedure.

At the end of the procedure, the number of shockwaves, their power and the total duration of shockwave treatment were recorded. After completion of the procedure, patients were transferred to the recovery room where patients' vitals and any complications were noted. One hour after the end of the maneuver, the patients were discharged with routine therapy and instructions if they fulfilled our local discharge criteria which mandate that the patient is fully conscious; he can walk to the bathroom and void, has no nausea or vomiting and is hemodynamically stable. The stone clearance rate after one month was compared between the two groups.

Statistics

The data was analyzed using the Statistical Package for the Social Services for Windows (SPSS version 16) Inc., Chicago, IL, USA. Most of data were presented as mean ± Standard deviation (SD). For analysis of variables between the two groups, the Student's t-test was used for the statistical evaluation of the age, weight, height of the patients, ESWL duration, size of stones, number of shocks, voltage, VAS values, and additional analgesic requirement parameters. ANOVA repeated measures were used to confirm changes of pain score by time. The Clearance of stone after 1 month was assessed by number of reported complete or incomplete clearance as the patients' frequency.

Results

A total of 100 patients with kidney stones, including 55 males, aged 18 to 65 years, were randomly allocated into two groups. The stone size ranged was from 8 to 20 mm, a total of 2500 to 3300 shocks were applied to the patients. The ESWL duration range was from 29 to 42 minutes. The age, sex, height, weight, stone size, and number of shocks and voltage values of both groups are presented as mean ± Standard deviation (SD), no statistically significant differences were observed between the two groups, (Table 1).

VAS scores were significantly lower in group 2 than group 1 at 10, 20, 30 and 40 minutes, ($p < 0.001$) (Figure 1). The mean requirement for supplemental fentanyl analgesia (µg) was markedly decreased in group 2 than group 1 (3.34 ± 7.32 versus 15.72 ± 6.41, $p<0.001$) (Table1). We confirmed the significant lowered pain score in group 2 than group 1 by using (ANOVA repeated measures; $p < 0.001$, and supplemental analgesia amount, $p= 0.010$), while both age, sex and body weight had insignificant difference between the two groups. In group 2, nine patients (17.6 %) had experienced considerable pain (during lithotripsy) and received minimal additional analgesia but without a delay in discharge, while 43 patients (87.8%) had received larger doses of I.V. analgesia and 13 of them; (26.5%) from group 1 had delayed discharge more than one hour to fulfill

the discharge criteria as they had sedation resulting from I.V. fentanyl increments. All patients in group 2 were discharged 1 hour earlier after the end of the procedure. In group 2, we observed the following: tolerable burning pain at the site of injection which started at the beginning of injection and disappeared within 2 minutes and was reported in all group 2 cases, bruises at the site of injection which disappeared within one week.

No patient in group 2 had reported lightheadedness, lip and tongue numbness, drowsiness, fatigue, nausea or dizziness. Also, there were no reported arrhythmias or hemodynamic instability in both the groups. No significant difference was detected between the two groups with regards to complete stone clearance after 1 month and 44 patients in group 1 (89.8 %) had complete clearance of the stone after 1 month versus 45 patients (88.2 %) in group 2. Incomplete clearance data are presented in Table 1.

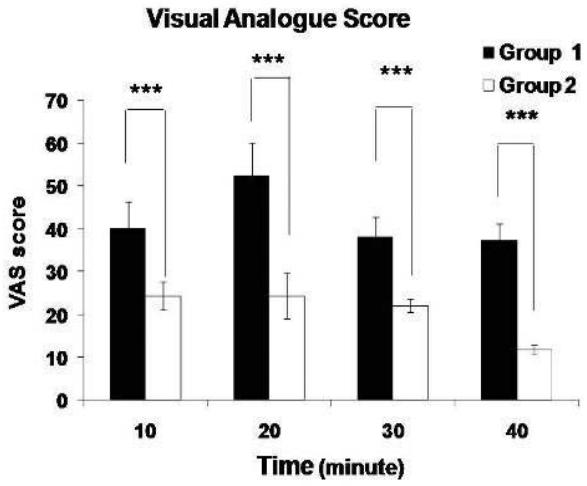

Figure 1. Comparison of the pain scores with intramuscular Ketorolac tromethamine (group 1) and Lidocaine 1% by local infiltration (5mg/kg); (group 2) during renal ESWL. Visual Analogue score (0-100 mm scale) measured every 10 minutes till end of the procedure. **ESWL,** extra-corporeal shockwave lithotripsy.Values are presented as mean ± SD
*** P< 0.001

Table 1. Patients, Stone and Extracorporeal Shock Wave Lithotripsy characteristics

Variable	Group 1 (n = 49)	Group 2 (n = 51)	P value
Gender (M/F)	27/22	28/23	0.984
Mean age ± SD (years)	35.95 ± 9.73	35.51 ± 10.23	0.825
Mean weight ± SD (kg)	71.63 ± 9.82	75.147 ± 11.51	0.104
Mean height ± SD (cm)	169.20 ± 12.16	169.21 ± 10.69	0.996
Mean stone size ± SD (mm)	10.37 ± 0.86	10.36 ± 0.87	0.940
Mean No. of shocks ± SD	2945.97 ± 26.37	2947.66 ± 27.09	0.753
Mean voltage ± SD (kV)	20.33 ± 1.14	20.23 ± 1.21	0.686
Mean ESWL duration ± SD (minute)	35.55 ± 3.20	35.57± 3.16	0.980
Outcome of ESWL			
Mean supplemental fentanyl ± SD (µg)	15.72 ± 6.41	3.34 ± 7.32	<0.001
Clearance of stone after 1 month			
Complete clearance, number (%)	44/49 (89.8)	45/51 (88.2)	
Incomplete clearance, number (%)	6/49 (12.2)	5/51 (9.8)	

ESWL, extracorporeal shockwave lithotripsy; **kV,** Kilovolt

Discussion

In our study we found that Lidocaine 1% by local infiltration was effective and safe when used for analgesia in renal ESWL and reduced the need for supplemental analgesia markedly. However, it cannot be used as a monotherapy. A wide variety of outpatient anesthetic techniques have been successfully used for ESWL. NSAIDs are among the agents used for analgesic purposes during ESWL (7). Ketorolac tromethamine is a NSAID in the family of heterocyclic acetic acid derivatives, often used as an analgesic, antipyretic and anti-inflammatory. The anti-inflammatory effect revealed through prostaglandin synthesis is thought to facilitate stone removal by inducing ureteral relaxation. As these drugs, however, may cause coagulation disorders because of cyclooxygenase enzyme inhibition and hepatotoxicity, peptic ulcers, and a decrease in kidney blood flow, we sought to find a better treatment option with minimal side effects (8). Fentanyl is a strong synthetic narcotic agent, and its intravenous application during ESWL has a wide use (9). Nonetheless, it can slow respiration by depressing the central nervous system and resulting in hypotension, and bradycardia (10). Lidocaine hydrochloride is an amide group local anesthetic that temporarily blocks the transfer of stimulus through nerve fibers by inhibiting the passage of sodium ions from nerve membrane into the cell. The effect starts from 1 to 2 minutes up to 1.5 to 2 hours. It is similar to prilocaine in terms of efficiency and duration of effect. Many studies have been done on the use of anesthetics for pain control during ESWL. Most of these studies have been related to topical lidocaine/prilocaine use (11-13). The eutectic mixture of local anesthetic (EMLA) cream, which contains lidocaine and prilocaine, reduces the anesthesia requirement prominently during ESWL. A combination of topical agents and short-term active intravenous agents can minimize the amounts of these agents to be used. EMLA alone has been reported as an effective and reliable alternative in two studies (12, 13). However, because EMLA must be used 45 to 60 minutes before ESWL to be effective, it poses a time problem and thus it is not practical for use as a quick pain relief tool. In contrast, the fact that the treatment session can start 1 to 2 minutes after lidocaine infiltration, it is considered an important advantage of Lidocaine. On the other hand, in the study by Rasmussen and Dahl (14) related to subcutaneous local anesthetic use, no difference was found between lidocaine infiltration and suppository naproxen in terms of morphine, pain score and additional analgesic requirements.

Pain scores were found significantly lower in patients received dimethyl sulfoxide (DMSO) with lidocaine than those who received EMLA cream (15). Moreover, Yilmaz et al (16) found in their study that prilocaine infiltration decreases the additional need of analgesic drugs and concluded that prilocaine infiltration alone can be used for analgesic purposes efficiently and safely during ESWL with minimal morbidity.

Lidocaine was used at a dose of (5mg/kg) via intravenous infusion over 30 minutes for treatment of neuropathic pain by many authors and had a proven safety at that higher level than the conventional dose as long as the patient is monitored and asked to report early symptoms of toxicity, and if the anesthesiologist is ready to deal with toxicity (17, 18).

In our study, we sought to determine whether the use of this local anesthetic alone to avoid the complications of NSAIDs could ensure that the patient leaves the treatment area within shorter time and minimal morbidity. We found that Lidocaine was more effective in pain control during ESWL than NSAIDs. The additional analgesic requirement during the process was lowered markedly when compared with that needed with the use of NSAIDs. Another advantage of the Lidocaine infiltration approach is that patients do not need an accompanying person as they do after intravenous analgesic sedation.

Conclusions

Lidocaine 1% by local infiltration is considered an effective and inexpensive agent that can be applied with minimal morbidity during renal ESWL. It couldn't be used as a monotherapy but it effectively reduced the need for analgesia. It can hopefully minimize the duration of stay in the recovery room following the procedure; without affecting stone clearance.

Conflict of Interest

None declared.

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