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Ideal Analgesia in Day Care Extra Corporeal Shockwave Lithotripsy for Renal Stones: A Single Centre Randomised Controlled Study

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Abstract: Extracorporeal shock wave lithotripsy (ESWL) is the main day care treatment modality for small renal stones. Good pain relief with least sedative effect is one of the main criteria for an effective day care ESWL. The aim of this study was to compare efficacy of Meperidine with Pentazocine in day care ESWL. One hundred patients with treated with ESWL were randomized into two groups. Group-EM received EMLA cream with injection meperidine 1 mg/kg body weight; Group-EP received EMLA cream with injection pentazocine 0.8mg /kg body weight. Pain during ESWL was assessed using visual analogue pain scale (VAS). Age, weight, height, body mass index (BMI), stone size, stone location, duration of ESWL, total shock waves performed, mean energy level (kV)and stone fragmentation were analysed for each patient. 47 patients in EM group and 46 patients in EP group were analysed. Both groups were similar w.r.t respect to age, sex, BMI and stone burden. Patients in EM group perceived less pain (VAS score 3.17 ±1.06 vs 3.63 ±1.72) and could tolerate higher energy shocks (3.09 ± 0.45 vs 2.93± 0.68). Number of shocks used was less (though it did not achieve statistical significance) in EM group compared to EP group (2980 ± 514 vs 3340± 348) with a shorter duration of procedure (49.67±10.63 mins vs 55.68±6.54mins). Both overall stone clearance and clearance after 1st session of ESWL was better in the EM group [(78.72% vs 71.74%) and (57.44% vs 52.17%)]. EM group had higher satisfaction rate (72.34% vs 63.04%). Meperidine group had significantly lower respiratory rate (9.19±1.11 vs 13.18±1.13), however no patients had respiratory depression, all had normal post-procedure oxygen saturation. Reducing the pain with a single injection of meperidine is good day care analgesia and is superior to pentazocine when used along with EMLA.
Keywords: Day care ESWL, analgesia, EMLA cream, meperidine, pentazocine.

INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) is the main outpatient treatment modality for urinary tract calculi of size less than 1.5 cm. Success rate of ESWL depends on many factors; patient factors, stone characteristics, anatomical abnormalities in kidneys and the type of lithotripter used. One of the most important factors in effective ESWL is patient's pain perception/ discomfort to shock waves.

Analgesia and anaesthesia are provided to control the cutaneous, somatic, and visceral pain associated with ESWL. Primary goal of analgesia in ESWL is to provide adequate analgesia, make the patient calm and quiet and minimise movement of patients during shock wave delivery; as for a successful ESWL, shockwave must be targeted on and over the stone.

Currently majority of the ESWL 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 and also make it cost effective.

The ideal day care analgesic, offering optimal pain control, minimal side effects, and cost-effectiveness is still elusive. Analgesics commonly used during ESWL include opioids, sedative hypnotics, nonsteroidal anti-inflammatory drugs (NSAIDS), and local anaesthetic creams such as EMLA [1-4]. Although opioids provide effective analgesia, they are associated with significant complications- respiratory depression, bradycardia, hypotension, nausea, vomiting, and prolonged recovery time-requiring active monitoring of patient for potential adverse effects. Diclofenac sodium, one of the most widely used NSAIDs, has lower side effects than opioids, especially with regard to hemodynamic instability and respiratory depression but

it is associated with gastrointestinal disturbances and occasional hypersensitivity reactions [5]. Combination therapy (oral NSAID and occlusive dressing of EMLA, DMSO with lidocaine) offers an effective alternative mode for achieving analgesia with minimal morbidity. This therapy avoids the need for general anaesthesia, injectable analgesics, and opioids along with their side effects. Though avoidance of general anaesthesia is beneficial to patients, there is a significant concern regarding jeopardizing treatment outcomes due to use of less potent shock waves.

Therefore, it is essential to choose an appropriate analgesic with good efficacy but minimal adverse effects. Despite reports of various studies comparing different analgesic techniques during ESWL guidelines for pain management during the procedure are still not established.

In this prospective randomized study, we aimed to compare the efficacy of single dose intravenous Meperidine to one of the most commonly used and effective analgesic - iv pentazocine, in adjunct with EMLA cream.

MATERIALS AND METHODS

A total of 100 patients with renal stones treated with ESWL were included in this study. A third-generation lithotripter (Dornier, Compact Sigma, and Germany) was used for ESWL. Solitary non-radiolucent renal stone, less than 15 mm in size (up to 10 mm for lower calyceal stone) who agreed for the procedure after proper counselling were included in the study. Patients with multiple stones, stones with HU value of more than 1000 (if CT was done), associated ureteric stone, history of prior failed ESWL, associated moderate to severe hydro nephrosis, uncorrected coagulopathy and patients on antiplatelets (which could not be withdrawn), were excluded from the study. Non-co-operative patients, children below 18 years, morbidly obese patients, neuro-psychiatric patients, patients who are on chronic NSAID therapy or who received pain killers within 3 days of study and the patients who are allergic to the drugs used were also not considered for the study. Patients with active UTI were treated and included in the study only after they had a sterile urine culture report.

Institutional ethics committee approval was taken before enrolling patients. Total 100 patients of either sex, aged between 18 to 55 years, with BMI less than 30, were included in this study. All the patients were explained beforehand about the procedure, possibility of pain during/after the procedure and the possible complications of ESWL. All the patients gave written informed consent.

Procedure

Patients were randomised into two groups (EM vs EP/ EMLA-Meperidine vs EMLA-pentazocine) using a computer-generated randomisation table. Neither the patient nor the resident giving shock waves were aware about the group of the patient. EMLA cream was applied over the back as a thick layer, 60 mints before the procedure. An occlusive dressing was placed over the cream for better absorption. Patients were observed for any local allergic reaction to EMLA. If there was any local reaction, it was wiped off, other methods of analgesia were administered and the patient taken out of study group.

Before starting ESWL an 18 Gauge intravenous line was secured, inj ondansetron 4mg given slowly, multipara monitor attached (Phillips intelliview MP-30). Group-EM received i.v meperidine 1mg/kg. Group-EP received i.v pentazocine 0.8 mg/kg. All patients received ESWL in supine position, under both USG and fluoroscopy guidance. All patients received shocks at a frequency of 60 per minute, shocks were started from minimum energy level and gradually increased to next higher energy level after the patient tolerated few hundred shocks. All procedures were done by a single urology resident.

Patients were explained about the 10-score linear visual analogue pain scale (VAS) score before the procedure. Pain was assessed every 10 minutes and SOS during ESWL. Patients were instructed to denote the pain intensity by raising their fingers equal to the VAS score they feel about the pain. If the patient experienced much pain then shocks were withheld for few minutes and restarted at a lower energy. The final score was taken as the "mean" of all the scores.

Average around 3000 shocks were targeted in all patients. Patient who had good fragmentation before the target value, were completed with less number of shocks. The patients who had substantial/good but incomplete fragmentation at 3000 were given more shocks depending of patients' tolerance and discretion of the treating resident. Patients who did not have good fragmentation at 3000 shocks were posted for second session later on. At the end of the procedure all data regarding number of shocks, energy level received, duration of ESWL, pain score, tolerability, stone fragmentation and need for any repeat ESWL session were recorded. All patients were advised X-ray KUB and USG KUB at 3 weeks after ESWL for stone clearance. Stone free status was defined as having no residual stone with diameter 4 mm or more.

STATISTICAL ANALYSIS

Results were presented as the mean ±Standard deviation (SD). Data were analyzed using SPSS-16.0 for Windows (SPSS, Inc., Chicago, IL USA). Statistical analyses of the means of continuous variables were performed with the Student's *t*-test and Mann-Whitney test. Categorical variables were analyzed using chi-square tests. Bivariate, multivariate, regression model and the Pearson Correlation Tests were used for

correlation among variables. A probability level of p <0.05 was considered significant.

RESULTS

Total of 100 patients were included in the study, 50 in each group. Both the groups were statistically same with respect to age, sex, body weight, BMI, stone size and laterality (table 1). One patient in each group developed skin reaction to EMLA and were excluded from the study. Two patients in the EM group and 3 patients in the EP group could not tolerate pain, they were given TIVA to complete the procedure and were excluded from the study in final result analysis. Finally, 47 patients in the EM group and 46 patients in the EP group were analysed for the study. All these patients were done in day care basis only.

Table-1: Demographic data of the patients and stone parameters

Variables	EM (n=50)	EP (n=50)	P value
Age (years)	28.98±17.78	30.408±15.65	0.178
Sex (M:F)	25: 21	24: 23	0.241
Weight (Kg)	51.52± 10.95	52.1±8.15	0.142
ASA (I: II)	40: 6	40: 7	***.481***
BMI	27.3 ± 4.8	26.2 ± 4.4	0.704
Side (Rt/Lt)	22/28	26/24	0.623
Stone Size (mm)	11.2±3.73	10.4±4.82	0.073

Parameters of ESWL in the form of number of shocks given, energy level tolerated by the patient, procedural duration and stone fragmentation/clearance were analysed (Table 2). Number of shocks needed for stone fragmentation was less in EM group compared to EP group, though it did not reach statistical significance (2980 ± 514 vs 3340± 348; p value 0.591) with a shorter duration of procedure in EM group (49.67±10.63 mins vs 55.68±6.54mins; p value……).

Analysis of pain perception revealed less VAS score in patients of EM group compared to EP group (3.17 ±1.06 vs 3.63 ±1.72; p value 0.001). This was also corroborated by the finding of higher energy level tolerability in patients who received Meperidine (3.09 ± 0.45 vs 2.93± 0.68; p value 0.0031). (Table 2)

Stone clearance rate was analyzed and was found to be higher in EM group. Both overall success rate and clearance after 1st session of ESWL was better in the EM group [(78.72% vs 71.74%) and (57.44% vs 52.17%)].

Table-2: Showing the ESWL parameters, pain perception and success rate

Variables		EM (n=47)	EP (n=46)	P value
Shock Waves		2980 ± 514	3340± 348	0.591
Energy Level (kW)		3.09 ± 0.45	2.93± 0.68	0.003
Procedure duration		49.67±10.63	55.68±6.54	0.031
Pain score	VAS score	3.17 ±1.06	3.63 ±1.72	0.001
	Wong-Baker	3.05 ±0.31	3.57 ±0.51	0.001
Tolerability	Yes	47 (95.91%)	46 (93.88%)	0.001
	No	02 (4.08%)	03 (6.12%)	---
Stone clearance		37 (78.72%)	33 (71.74%)	0.001
Per session	1st session	27 (57.44%)	24 (52.17%)	0.001
	2nd session	07 (14.89%)	06 (13.04%)	0.001
	3rd session	03 (6.38%)	03 (6.52%)	------
Failure rate		10 (21.27%)	13 (28.26%)	0.001

Analysis of the respiratory parameters during the procedure revealed a significantly lower respiratory rate in patients who received inj Meperidine (9.19±1.11 vs 13.18±1.13), however no patients in the study had any respiratory depression (defined as rate less than 8/ min) and all the patients had normal oxygen saturation after the procedure. (Table 3).

More patients in the group EM had nausea, but none of them had any vomiting. Also, there were more number of patients in EM group who experienced itching. Patient satisfaction score analysis revealed a higher satisfaction rate in patients of EM group (72.34% vs 63.04%). (Table 3)

Table 3: Results of Respiratory parameters and adverse events

Variables		EM (n=47)	EP (n=46)
Mean RR		9.19±1.11	13.18±1.13
Respiratory depression (RR <8/min)		0%	0%
Oxygen saturation after procedure		96.99 ±0.76	97.64 ±0.73
PONV	Nausea	04 (8.51%)	03(6.52%)
	Vomiting	0%	0%
Pruritus		07(14.89%)	05(10.86%)
Patients Satisfaction score	Excellent	34 (72.34%)	29 (63.04%)
	Good	9 (19.14%)	9 (19.57%)
	Fair	2 (4.26%)	5 (10.87%)
	Poor	2 (4.26%)	3 (6.52%)

DISCUSSION

ESWL has become a routine day care procedure for the management of urinary stones. Stone-free (SF) rates, for stones less than 2 cm, vary widely from 55% to 90% [6]· Many factors influence ESWL success rates, including the type of lithotripter used, patient characteristics such as BMI and age, as well as stone characteristics, such as size, location and hardness [6].

Treatment of urolithiasis has been revolutionized with the introduction of extracorporeal shock wave lithotripsy (ESWL) due to its simplicity, efficacy, non-invasive nature and minimal morbidity [7,8]. Pain experienced during ESWL is considered to be multifactorial: age and sex of the patient, type of lithotripter used, frequency and voltage [9]. Recent developments have made ESWL more effective with minimal morbidity, making it possible to perform ESWL in an outpatient setting without the need for general or spinal anaesthesia [10,11]. Though avoidance of general anaesthesia is beneficial to patients, there is a significant concern regarding jeopardizing treatment outcomes due to use of less potent analgesic methods [12]. Analgesics commonly used during ESWL include opioids, sedative hypnotics, nonsteroidal anti-inflammatory drugs (NSAIDS), and local anaesthetic creams such as EMLA [8,12,13].

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 [14,15].

Pain causes tachypnoea which in turn causes increased respiratory movement of the kidneys. Without good pain control, the number of shock waves focused on the stone decreases, resulting in a lower fragmentation rate during the first session. Therefore, reduced perception of pain during the ESWL is essential for targeting and optimal fragmentation of stones during the ESWL[16]· According to the European Association of Urology guidelines for urolithiasis, suitable analgesia is recommended because of its effect on treatment results by limiting pain-induced movements and excessive respiratory excursions as well as improving patients' comfort.

To reduce ESWL related pain, various medications and various methods have been utilized and new studies are being done. Different analgesic agents including opioids (morphine, pethidine, pentazocine and fentanyl), NSAIDs (diclofenac, ketorolac and piroxicam), local anaesthetic agents, and a number of combinations have been used during ESWL with various analgesic techniques (general anaesthesia, regional anaesthesia, subcutaneous and intravenous injections, patient-controlled analgesia, monitored anaesthesia care, cutaneous cream) [17-19].

Chaussy and Thuroff showed that the need for analgesia during the ESWL depends on the lithotripter used, the stone location, age, gender, and the number of shock waves performed [20]. While treatment with the third-generation piezoelectric lithotripters has been described as painless by some [21], practically it is less painful and actually 28% patients experienced severe pain when undergoing treatment without anaesthesia [22].

Tokgoz *et al*. applied dex-ketoprofen and diclofenac 30 minutes before ESWL. VAS scores of patients who had been given dex-ketoprofen was less [23]. In Eryıldırım et al's study, it was found that diclofenac was more effective than eutectic mixture of local anaesthetics (EMLA) cream [1]. Also, the study of Saita et al, showed that the patients who used intramuscular ketorolac and tramadol gave better responses than topical Luan (gel containing lidocaine1%) [2]. The fentanyl-propofol combination has been proven as an effective IV analgesic option, but has significant adverse effects [18,24].

The avoidance of a general anaesthetic during ESWL is advantageous reducing the morbidity and potential mortality and allowing treatment on an outpatient basis, indirectly reducing cost. Regional anaesthesia has utilized intrathecal lidocaine and sufentanil during ESWL [25-28]. These techniques are,

however, more time consuming to perform and results in prolonged recovery due to residual sympathetic blockade. Intrathecal sufentanil is a safer and an effective alternative to lidocaine, resulting in early ambulation and discharge, ability to void, most likely due to preservation of motor and sensory function [27]. However, its use results in undesirable pruritis in addition to requirement of active patient monitoring [25,27].

NSAIDS like diclofenac sodium provide pain relief by their anti-inflammatory effect caused by prostaglandins synthesis inhibition and are effective via oral, IM, and rectal routes. It is an effective analgesic with lower side effects than opioids especially with regard to hemodynamic instability and respiratory depression [19]. However, it is associated with mild gastrointestinal disturbances, occasional hypersensitivity reactions, and sometimes coagulation disorders because of cyclo-oxygenase inhibition [28].

The EMLA cream, a eutectic mixture of lignocaine (2.5%) and prilocaine (2.5%) for topical use, has also been used in ESWL as an occlusive dressing due to its local anaesthetic effect and its action like a coupling medium [29]. It can penetrate to a depth of 4 mm through intact skin after 60 mins of application [30,31]. Though some reports have found EMLA cream to be an ineffective analgesic agent without any opioid-sparing effect [33], others have found it to be a good alternative to other analgesics because of its simplicity and non-invasiveness, avoiding the side effects of IM or IV analgesic agents [30-36]. It reportedly reduces opioid requirement by 23% during ESWL. EMLA to be applied 45-60 min before the procedure to achieve its maximum effect [29]. Interestingly, most studies evaluating EMLA cream during ESWL did not use it as an occlusive dressing. This may have been the reason for their un-favourable results with pain control [29].

We performed a prospective randomized doubleblind study comparing the efficacy of intravenous Meperidine with iv Pentazocine, one of the commonly used and effective analgesic in ESWL. Both the groups received EMLA cream application 1 hour before. Efficacious analgesia was achieved during the procedure in both the groups, but pain relief was better in patients who received Meperidine. This group of patients could tolerate higher shock energy waves during ESWL due to better pain control with Meperidine.

The stone fragmentation/clearance was significantly better in Meperidine group even with a lesser number of shocks. The reason for this is two: First, the patients with inj Meperidine had better pain control and could tolerate shocks with higher energy level. Second, these patients had lesser respiratory rate resulting in more number of shocks targeting right on the stone. Lesser respiratory rate in the meperidine group was presumably because of better pain control and inherent sedative property of meperidine. So, more number of targeted shocks with higher energy could do the tricks.

There is common fear of respiratory depression with Meperidine. In our study although there was less respiratory excursion with meperidine, none of the patients had any respiratory depression or hypoxia. Nonetheless we emphasise that ESWL with Meperidine should be a supervised procedure with all resuscitation measures available at hand.

More number of patients had nausea and pruritus with meperidine, but none of the patients had any vomiting or any other serious side effects. In spite of this minor complications patients were more satisfied with Meperidine and EMLA, probably because of much better pain control and a higher stone clearance rate.

We know that this study has limitation in the form of small number of patients and not determining the HU of the stone in all the patients. This is a pilot project and with this initial encouraging result we will continue the study on more number of patients.

CONCLUSION

Combined use of topical EMLA and intravenous meperidine is an effective method of analgesia in extracorporeal shock wave lithotripsy. Good stone clearance rate, high patient satisfaction without any significant complication makes it an ideal and safe agent for ESWL performed in day care setting.

Conflict of Interests

The authors declare that they have no conflict of interests as pertains to the materials or methods specified in this study or the data presented in this paper.

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