

Effectiveness of EMLA Cream Local Application vs Placebo for Pain Relief in ESWL - A Prospective Study

Dr Griffin M¹, Dr Sivasankar M^{2*}, Dr Arjun P A³, Dr Aswin V⁴, Dr V Kamaraj⁵, Dr N Muthulatha⁶, Dr Ginu Mathew⁷

¹Associate Professor, Department of Urology, Saveetha Medical College Hospital

^{2*}Associate Professor, Department of Urology, Saveetha Medical College Hospital

³Assistant Professor, Department of Urology, Saveetha Medical College Hospital

⁴Third Year Resident of Urology, Department of Urology, Saveetha Medical College Hospital

⁵Professor, Department of Urology, Saveetha Medical College Hospital

⁶Professor, Department of Urology, Saveetha Medical College Hospital

⁷Consultant, Department of Critical Care Medicine, MGM Hospital

Corresponding Author

Dr. Sivasankar M

ABSTRACT

ESWL is a procedure commonly used for the treatment of urolithiasis. Usage of appropriate agents for analgesia in ESWL is still not standardised and a number of studies have been conducted for this purpose. We attempted to determine whether usage of EMLA cream is effective in ESWL for pain relief. Our study investigated the effectiveness of EMLA cream alleviates pain in a population of 170 patients divided into two comparable populations, one in which EMLA was used and another with placebo. We inferred that usage of EMLA is very effective for pain management during ESWL with additional benefits of being cost effective, easy application and better patient acceptability.

Keywords: ESWL, Pain relief, EMLA cream, Double J stenting

Introduction

Extracorporeal shock wave lithotripsy (ESWL) is one among the many different interventions used for the treatment of urinary tract lithiasis. Patient cooperation during the procedure is necessary for the correct application and success, making proper analgesic administration crucial(1). Pain from ESWL has a multifactorial origin. Parietal pain originates from the continuous impact of shock waves on cutaneous nociceptors. Visceral pain results from increase in intrapelvic pressure and renal capsule distension; as a result of stimulation of periosteal, pleural, peritoneal and musculoskeletal nociceptors(2, 3). Other factors include individual differences, the type of lithotripter, site and size of the stones, and pressure of shock waves(4).

During ESWL, general anaesthesia, regional anaesthesia, intravenous anaesthesia and sedation can be administered. Commonly used analgesics during ESWL include opioids, sedatives, nonsteroidal anti-inflammatory drugs (NSAIDS), and anesthetic topical creams (6). It has been shown that opioids provide adequate analgesic control but cause marked risk of side effects. Several studies using opioids such as fentanyl, alfentanil, sufentanil and remifentanil have been conducted(7, 8).The use of local anaesthetics during ESWL has been demonstrated to be effective in achieving analgesia. Since 1986, various studies have been reported on the use of infiltrative or topical local anaesthetics for analgesic purposes (2, 3, 4, 5).

The most appropriate analgesia, which offers pain-free treatment, minimal side effects and cost-effectiveness, needs to be established.

Objectives

“Eutectic mixture of local anesthetic” (EMLA) is a type of topical cream that includes lidocaine (2.5%) and prilocaine (2.5%). This cream has a skin-penetrating depth of 4mm and onset time of 10–20 minutes, and provides pain relief for up to 60 minutes. In our prospective study, the effectiveness of EMLA cream application in the effectiveness of ESWL was studied with respect to pain reported by the patient, which was assessed by the Numerical Rating Scale.This study was conducted on patients with urolithiasis reporting to the Department of Urology, Saveetha Medical College from September of 2018 to April 2020.

Inclusion Criteria

Patients diagnosed as having renal or proximal ureteric calculi that underwent ESWL at Saveetha Medical College from September 2018 to April 2020.

Exclusion Criteria

- Patients with deranged renal function tests
- Patients with coagulopathy
- Patients under 16 years of age
- Pregnant women and nursing mothers
- Patients with local anaesthetic allergies

Materials and Methods

After the approval of the Ethics Committee of Saveetha Medical College and the informed consent of patients, a total of 170 patients with urolithiasis between 17-70 years of age who were scheduled to

undergo elective ESWL using the Dornier® lithotripter (Dornier MedTech, Germany) were enrolled in the study.

Both In-situ ESWL and patients on whom Double J stenting was done prior to the procedure were included in the study. Both those on whom ESWL was being performed for the first time as well as those on whom it was being done for the second time were included in the study.

The patients were divided into two groups by simple random technique.

At least 30 minutes before ESWL, a placebo cream was applied to a 100 cm² outlined skin area corresponding to the presumed entrance of the shock waves in the first group. In the second group, 30 gm. EMLA cream (1 gm. contains 25 mg. lidocaine and 25 mg. prilocaine) were applied to a 100 cm² outlined skin area corresponding to the presumed entrance of the shock waves.

ESWL was performed using a Dornier Lithotripter SII. ESWL was allowed to proceed for a maximum of 2500 shocks. The intensity of shocks was also kept standard at a setting of 4.

Patients were then asked to rate their pain as a score between 0 to 10 using the Numerical rating scale to indicate the pain intensity that was experienced during the ESWL procedure with zero being the least pain and ten being the maximum.

Variables evaluated included the patient's sex, age, body mass index, size of the stones, number of stones, location of stones (renal pelvis, upper, middle or lower calyceal, proximal ureteric), Hounsfield Units of the stones, whether ESWL was done In-situ or post Double J stenting, pain score before and after application of EMLA cream.

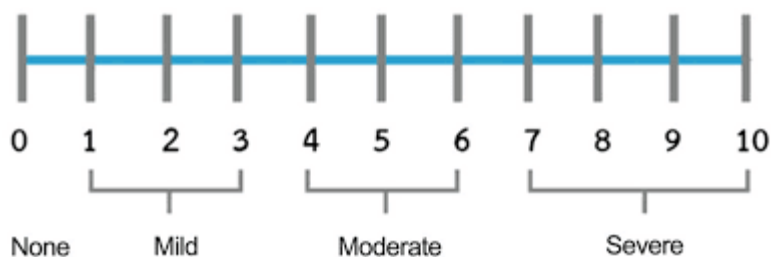


Figure 1. Numerical rating scale

Results

All 85 patients in both the groups who underwent ESWL procedure were studied by demographic characters, BMI, stone characteristics. Pain score allotted to each patient was tabulated and studied.

Patients in this study were in the age group of 17 – 70 years. Mean age of patients was 41.59 years in study group and 41.21 years in control group with standard deviation of 11.34 and 12.43 respectively. P value obtained by unpaired t test analysis (0.206) which was not significant with respect to age (p value 0.837).

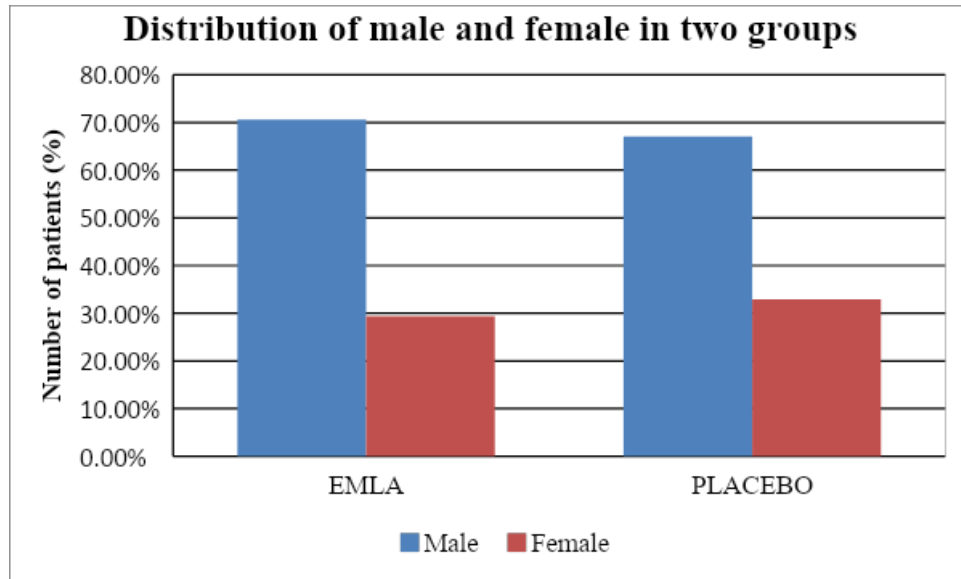


Chart 1. Sex distribution of study population

Majority of the patients were males in both the groups. However, gender distribution between the two groups was not significant (p value 0.619)

Table 1. Comparison of pain relief between two groups by t- test for two independent groups

Group	N	Mean ± Std. Deviation	Mean Difference ±S.E.M.	t(d.f.)	p value
EMLA	85	3.45±.523	2.565±0.085	30.053(168)	0.0001*
PLACEBO	85	6.01±.587			

ResultThis table 2 shows the Mean ± Std. Deviation of numerical rating scale in EMLA and PLACEBO is 3.45±.523 and 6.01±.587 respectively. By t test for two independent groups the Mean Difference ±S.E.M (2.565±0.085) between these two groups is significant, p<0.01. Therefore the adequacy of pain relief in EMLA groups is significant lower than the Placebo group.

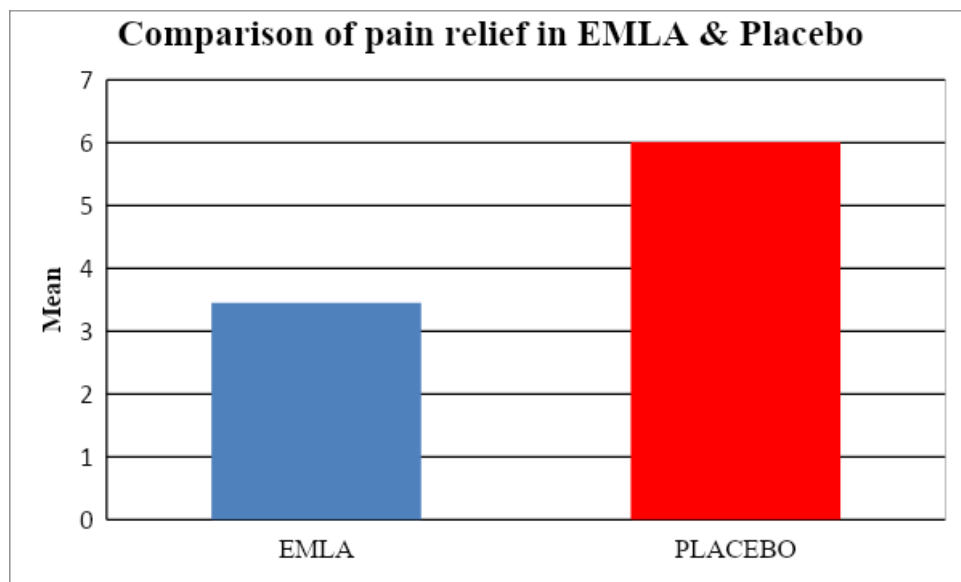


Chart 2. Comparison of adequacy of analgesia in ESWL vs. Placebo by numerical rating scale

Table 2. Comparison of different parameters in two groups

SEX	EMLA	PLACEBO	Pearson Chi-Square(d.f.)	p value
Male	60(70.6%)	57(67.1%)	.247(1)	.619 ^{NS}
Female	25(29.4%)	28(32.9%)		
LOCATION				
Renal Pelvis	4(4.7%)	5(5.9%)	7.729(7)	.357 ^{NS}
Upper pole	27(31.8%)	25(29.4%)		
Middle pole	13(15.3%)	19(22.4%)		
Lower pole	23(27.1%)	18(21.2%)		
Proximal ureter	18(21.2%)	13(15.3%)		
Upper, Lower pole	0(.0%)	3(3.5%)		
Middle, Lower pole	0(.0%)	1(1.2%)		
Renal Pelvis Middle, Upper, lower pole	0(.0%)	1(1.2%)		
LATERALITY				
Right	45(52.9%)	42(49.4%)	.212(1)	.645 ^{NS}

Left	40(47.1%)	43(50.6%)		
STENTING				
In situ	21(24.7%)	46(54.1%)	15.396(1)	0.0001*
Post DJ stenting	64(75.3%)	39(45.9%)		

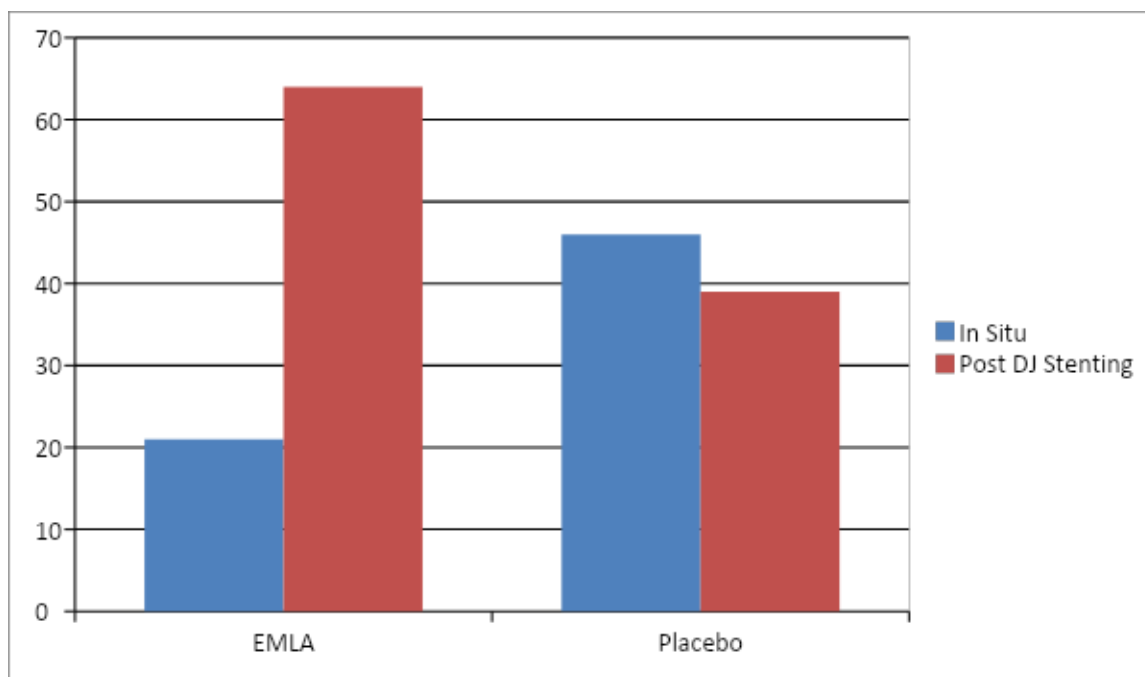


Chart 2. In situ ESWL vs Post DJ Stenting in study population

Discussion

ESWL is a commonly used treatment for patients with kidney and ureteric stones, offering a high efficacy and a low complication rate and is performed on an outpatient basis in most centres. ESWL uses acoustic shock waves to break up kidney stones, during which pain at the entry site of shock waves and deep visceral discomfort is experienced.

For this reason, there are numerous studies using opioids to overcome these side effects of ESWL. Although opioids are used extensively because of their high efficiency, their side effects such as bradycardia, hypotension, respiratory depression, sedation, nausea-vomiting, and itching can lengthen their hospital stay which has led clinicians to seek alternatives. Since 1986, various studies have been conducted on the use of local anesthetics for analgesic purposes during treatment(2, 3, 4). Local anesthetics were also shown to be effective in achieving analgesia during ESWL and only 5% of these

patients required general anesthesia. There are a number of studies concerning use of topical EMLA cream for this purpose(4,5,6). Even though the skin is where the pain is experienced most intensely as a result of the shock waves during the procedure and EMLA cream is effective in relieving pain, patients usually require additional analgesia since the pain related to ESWL has both cutaneous and visceral components (3, 4, 5).Barcena et al. conducted a study on 20 patients who had been unable to tolerate pain without IV analgesia during ESWL(10). In this study, 10 gm of EMLA cream was applied on the skin over the area of 64-100 cm², 60 minutes before the second session. Despite higher voltages, lower pain scores were found in patients for whom EMLA cream was used and only two patients required further analgesia. In addition, all patients required additional fentanyl in the first session without EMLA.In a study by Ganapathy et al(11), one group received 30 gram EMLA cream and the other group received a placebo 60-90 minutes before the procedure. All patients received 5 mcg/kg of alfentanil via a PCA machine with a lockout time of 3 minutes and no significant differences were noted in pain scores, side effects and duration of stay in the post anesthesia care unit between EMLA cream and placebo.In the present study, similar to those of Ganapathy and Terri , 10 gram of EMLA cream was applied to a 10x15 cm² area of skin 30 minutes before the procedure.We tried to assess how effective EMLA cream was. None of the patients had severe pain necessitating the administration of other analgesics or the termination of the procedure. Even though it has been suggested that topical anesthetics used for the elimination of cutaneous component of pain is not adequate for ESWL and is only in addition to opioids to reduce the dose of opioids used and their side effects, we demonstrated in this study that EMLA cream decreased pain effectively compared to a placebo during ESWL negating any need for opioid use.We do consider that further investigation of the use of EMLA cream alone or combined with other IV analgesia regimens will be able to substantiate the efficacy of EMLA cream.

Conclusion

EMLA is very effective for pain management during ESWL with additional benefits of being cost effective, easy application and better patient acceptability. EMLA can be used as topical application 30 minutes before the procedure to decrease the pain and increase effectiveness of ESWL.

Source of Support: Nil.

Conflict of Interest: None.

References

1. Burmeister MA, Brauer P, Wintruff M, Graefen M, Blanc I, Standl TG. A comparison of anaesthetic techniques for shock wave lith- otripsy: the use of a remifentanil infusion alone

- compared to in- termittent fentanyl boluses combined with a low dose propofol infusion. *Anaesthesia*. 2002;57(9):877-81.
2. Gupta NP, Kumar A. Analgesia for pain control during extra- corporeal shock wave lithotripsy: Current status. *Indian J Urol*. 2008;24(2):155-8.
 3. Basar H, Yilmaz E, Ozcan S, Buyukkokcak U, Sari F, Apan A, et al. Four analgesic techniques for shockwave lithotripsy: eutectic mixture local anesthetic is a good alternative. *J Endourol*. 2003;17(1):3-6.
 4. Coloma M, Chiu JW, White PF, Tongier WK, Duffy LL, Armbruster SC. Fast-tracking after immersion lithotripsy: general anesthesia versus monitored anesthesia care. *Anesth Analg*. 2000;91(1):92-6.
 5. Aeikens B, Fritz KW, Hoehne E. Initial experience with local anesthesia in extracorporeal shock wave lithotripsy. *Urol Int*. 1986;41(4):246-7.
 6. Demir E, Kilciler M, Bedir S, Erten K, Ozgok Y. Comparing two local anesthesia techniques for extracorporeal shock wave litho- tripsy. *Urology*. 2007;69(4):625-8.
 7. Beloeil H, Corsia G, Coriat P, Riou B. Remifentanil compared with sufentanil during extra- corporeal shock wave lithotripsy with spontaneous ventilation: a double-blind, randomized study. *Br J Anaesth*. 2002;89(4):567-70.
 8. Medina HJ, Galvin EM, Dirckx M, Banwarie P, Ubben JF, Zijlstra FJ, et al. Remifentanil as a single drug for extracorporeal shock wave lithotripsy: a comparison of infusion doses in terms of an- algesic potency and side effects. *Anesth Analg*. 2005;101(2):365-70, table of contents.
 9. Tiselius HG. Cutaneous anesthesia with lidocaine-prilocaine cream: a useful adjunct during shock wave lithotripsy with an- algesic sedation. *J Urol*. 1993;149(1):8-11.
 10. Barcena M, Rodriguez J, Gude F, Vidal MI, Fernandez S. EMLA cream for renal extracorporeal shock wave lithotripsy in ambu- latory patients. *Eur J Anaesthesiol*. 1996;13(4):373-6.
 11. Ganapathy S, Razvi H, Moote C, Parkin J, Yee I, Gverzdys S, et al. Eutectic mixture of local anaesthetics is not effective for extra- corporeal shock wave lithotripsy. *Can J Anaesth*. 1996;43(10):1030- 4.