Original Research Paper UROLOGY

"EFFECTIVENESS OF EMLA CREAM LOCAL APPLICATION ON ESWL – A PROSPECTIVE RANDOMISED STUDY"

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ABSTRACT

Introduction and Objectives: Since ESWL is painful, the role of EMLA cream during ESWL as a local anesthesia has been studied
Materials and Methods:A prospective study was done on 60 patients who underwent ESWL at INU in 2016. Patients were divided into study group (EMLA cream) and control group (Ultrasound gel) each comprising of 30 patients. Topical application (EMLA or Ultrasound gel) was applied 20 minutes prior to procedure and patients were evaluated for pain using universal pain score.
Results: Mean pain score assessed by Universal pain score was 4.2 in EMLA cream group (study group) and 6.7 in Ultrasound gel group (control group) which was highly significant (p value 0.001).
Conclusion:EMLA is very effective for pain management during ESWL with additional benefits of being cost effective, easy application and better patient acceptability.

KEYWORDS Extra corporeal short wave lithotripsy (ESWL), EMLA cream, Universal pain score

INTRODUCTION:
Extracorporeal shock wave lithotripsy (ESWL), the most commonly used procedure for the treatment of kidney stones, is painful based on the power of the acoustic shock waves applied (1). Though believed to be multifactorial, the pathogenesis of the pain during ESWL remains to be elucidated.

The cutaneous superficial skin nociceptors and visceral nociceptors such as periosteal, pleural, peritoneal and/or musculoskeletal pain receptors are held responsible for the pain (2, 3). Other imperative factors include individual differences, the type of lithotripter, site and size of the stones, and pressure of shock waves (2, 4).

During ESWL, general anaesthesia, regional anaesthesia, intravenous anaesthesia or analgesia and sedation can be administered (5, 6). For this purpose, several studies using opioids such as Fentanyl, Alfentanil, Sufentanil, and Remifentanil have been conducted (7, 8). Since 1986, various studies have been reported on the use of infiltrative or topical local anesthetics for analgesic purposes.

The use of local anesthetics during ESWL has been demonstrated to be effective in achieving analgesia (9, 10). The most appropriate analgesia, which offers pain-free treatment, minimal side effects, and cost-effectiveness, remains to be established.

In our prospective study effectiveness of local application of EMLA Cream (Eutectic mixture of Xylocaine and prilocaine) during ESWL was evaluated using universal pain score.

MATERIALS AND METHODS:
This was a prospective case control study done from November 2015 to May 2016 at Institute of Nephro Urology (INU), Bangalore

INCLUSION CRITERIA
Patients diagnosed as renal or ureteric calculi who underwent ESWL at Institute of Nephrourology, Bangalore between November 2015 to May 2016.

EXCLUSION CRITERIA

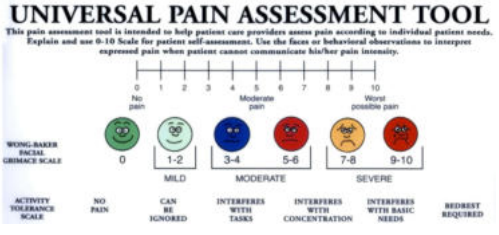
- Patients whose procedure was abandoned.
- ESWL done under general anesthesia.
- Children below 3 years.

A total of 60 patients were selected. Patients were randomly divided into 2 groups:

- Patients undergoing ESWL with local EMLA cream application (Study Group) – 30 patients
- Patients undergoing ESWL with local Ultrasound jelly application (Control Group) – 30 patients

Topical application was applied 30 minutes prior to the procedure and patients were evaluated for pain during ESWL using universal pain score. Pain score, on a scale of 10 was given to each patient based on activity tolerance scale

Figure 1: Universal pain assessment tool



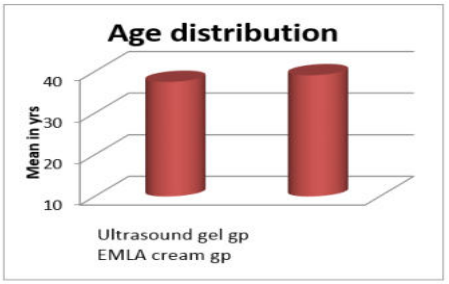
RESULTS:
All 60 patients in both the groups who underwent ESWL procedure were studied by demographic characters, creatinine levels, and stone fragmentation index (partial or completely fragmented). Pain score allotted to each patient was tabulated and studied.

Patients in this study were in the age group of 18 – 77 years. Mean age of patients was 39.1 years in study group and 37.5 years in control group with standard deviation of 13.81 and 12.67 respectively. P value obtained by unpaired t test analysis (0.477) which was not significant with respect to age (p value 0.635).

Table 1: Age distribution

Group	No. of cases	Mean age in yrs	Standard deviation=SD	Unpaired t	P value
Ultrasound jelly (Control group)	30	37.5	12.67	0.477	0.635 NS
EMLA cream (Study group)	30	39.1	13.81		

Figure 2: Age distribution

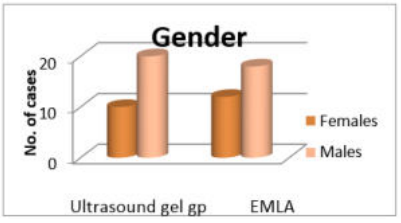


Majority of the patients were males in both the groups. However, gender distribution between the two groups was not significant (p value 0.789)

Table 2: Gender distribution

Group	Females	Males	Chi square df=1	P value
Ultrasound jelly (Control)	10	20	0.072	0.789 NS
EMLA cream (Study)	12	18		

Figure 3: Gender distribution

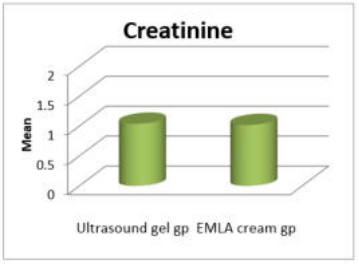


Mean creatinine level was 1.02 in study group and 1.04 in control group which did not vary significantly between the two groups (p value 0.703).

Table 3: Creatinine levels

	Group	No. of cases	Mean	SD	Unpaired t	P value
Creatinine	Ultrasound jelly (Control)	30	1.04	0.156	0.383	0.703 NS
	EMLA cream (Study)	30	1.02	0.179		

Figure 4 : Creatinine distribution

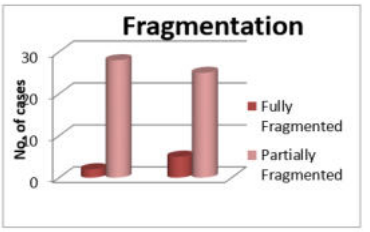


Seven patients had fully fragmented stones after ESWL procedure, 5 in case group and 2 in control group which was not statistically significant (p value 0.424) after Fisher exact test analysis.

Table 4: Stone fragmentation index

Group	Fully Fragmented	Partially Fragmented	Fisher Exact Test p
Ultrasound jelly (Control)	2	28	0.424 NS
EMLA cream (Study)	5	25	

Figure 5: Stone fragmentation index distribution



Minimum and maximum pain scores in each group is as shown in the table below. Median and mean values were obtained and tabulated.

Table 5: Mean Pain Score

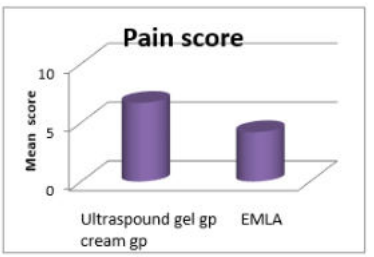
Group	Pain score			
	Minimum	Maximum	Median	Mean
Ultrasound jelly (Control group)	4	8	7	6.7
EMLA cream (Study group)	2	6	4	4.2

Mean pain score assessed by Universal pain score was 4.2 in EMLA cream group (study group) and 6.7 in Ultrasound gel group (control group) which was highly significant (p value 0.001, Mann Whitney Z test).

Table 6: p value

	Group	No. of cases	Median Pain score	Mean Pain score	Std. Deviation	Mann Whitney Z	p
Pain score	Ultrasound jelly (Control)	30	7	6.7	0.952	6.307	<0.001 HS
	EMLA cream (Study group	30	4	4.2	0.935		

Figure 6: p value



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 centers. 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 (13).

For this reason, there are numerous studies using opioids (1, 13, 14). Even though 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 (9). Local anesthetics were also shown to be effective in achieving analgesia

during ESWL and only 5% of these patients required general anesthesia (9). There are a number of studies concerning the use of topical EMLA cream for this purpose (9, 13). Even though the skin is where the pain is experienced most intensely as a result of the shock waves during the procedure (6, 14) 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 (2, 3).

Barcena et al. (15) conducted a study on 20 patients who had been unable to tolerate pain without IV analgesia during ESWL. In this study, 10 gr of EMLA cream was applied on the skin over the area of 64-100 cm 2 ,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 (16), 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 (6, 16), 10 gram of EMLA cream was applied to a 10x15 cm area of skin 30 minutes before the procedure.

We tried to assess how effective EMLA cream was. No 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 can provide a more comfortable analgesia by reducing the use of opioids and their side effects, we demonstrated in this study that EMLA cream decreased pain compared to a placebo during ESWL

We do consider that the investigation of the use of EMLA cream alone or combined with other IV analgesia regimens will be able to give further insight into 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.

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Nil.

Conflicts of interest:
No conflicts of interest.

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