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Comparative study of attenuation of needle prick pain of spinal anaesthesia by local infiltration analgesia versus EMLA skin patch

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ABSTRACT

Introduction: Needle prick pain is a distressing event for a patient receiving spinal anaesthesia. A 'Needle piercing the spine' might be physically and mentally traumatizing for many patients. This may lead to unwanted panic and anxiety during the procedure of spinal anaesthesia. To avoid this distressing needle prick pain, many clinicians have resorted to the practice of giving injections of local anaesthetic or local application of EMLA cream or patch at the site of spinal puncture beforehand for anaesthetizing the skin and subcutaneous tissues.

Methods: A prospective cohort study was done. Those enrolled patients were assessed by an expert anesthesiologist, who was not part of the research team, and he prescribed patients either EMLA cream or regular standard lignocaine infiltration anaesthesia and labelled them as Group E and Group L respectively. The pain score was assessed using a Visual Analogue Scale.

Result: A total of 64 patients were enrolled in the study-33 in Group E and 31 in Group L. Both groups had an almost similar number of patients who had a similar extent of surgery. Univariate analysis showed that the mean pain score (VAS) was significantly higher in Group E patients compared to that in Group L, $p<0.001$. The multivariate analysis had similar findings after controlling confounding factors in multiple regression analysis.

Conclusion: Local 2% lignocaine injection achieved significantly more pain reduction during spinal needle insertion compared to the application of an EMLA patch before spinal anaesthesia.

KEYWORDS: EMLA, Lignocaine, VAS, Visual Analogue Scale, Needle insertion, Spinal Anaesthesia

INTRODUCTION:

No other speciality is more concerned with relieving pain than the practice of anesthesiology. Anesthesiologists continue to strive towards making surgical procedures 'less painful and more comfortable' for the patients so that their surgical experience becomes less traumatizing physically and mentally.Spinal anaesthesia is a form of neuraxial anaesthesia that has been widely used worldwide for surgical procedures involving the abdomen, pelvis and lower limbs. Its utility is proven in abdominal surgeries like inguinal hernioplasty, appendectomy, haemorrhoidectomy, hydrocele etc. The procedure of spinal anaesthesia is very simple, requires minimal amounts of drugs/equipment, and has minimal effects on the Respiratory, cardiovascular, Renal, Endocrine and central nervous systems [1–3]

Spinal anaesthesia involves giving an injection of local anaesthetic drugs into the intrathecal space. Usually, this injection is achieved with a thin and slender 26 g Quinke's needle. This procedure is usually tolerated well by most patients. Still, for many patients, it can be the most distressing event during the whole procedure of spinal anaesthesia. To avoid this distressing needle prick pain, many clinicians have resorted to the practice of giving injections of local anaesthetic at the site of spinal puncture beforehand for anaesthetizing the skin and subcutaneous tissues. This method abolishes the needle prick pain of actual injection of spinal anaesthesia [3, 4]. EMLA cream (eutectic mixture of lignocaine 2.5% + prilocaine 2.5%) acts by diffusing through the intact skin to block the neuronal transmission from dermal receptors 5. EMLA cream has been widely used for skin anaesthesia during procedures such as arterial cannulation, venous cannulation, excision of dermal warts, myringotomy, circumcision, and skin grafting etc. [5–9].

Local infiltration anaesthesia involves the placement of local anaesthetic into the subcutaneous plane, in the area to be anaesthetized. Lignocaine is the most commonly used local anaesthetic used for local infiltration anaesthesia. Commonly used concentrations are 1% and 2% [10]. The 100 mm visual analogue scale (VAS) score is routinely used to measure pain intensity after surgery which ranges from zero (no pain) to 10 (maximum pain) [11]. This study used the VAS score to assess the difference in pain perception of insertion of a spinal needle for spinal anaesthesia between patients who received EMLA patches or who received local lignocaine injections before spinal anaesthesia.

MATERIAL AND METHODS:

A prospective cohort study was conducted from June 2021 to June 2022 at Noor Hospital Indian Institute of Medical Science and Research, Warudi, Jalna. The consecutive patients with American society of anaesthesiologists' physical status (ASA) 1 and 2 who were posted for elective abdominal and lower limb surgeries under spinal anaesthesia, were included in the study. Those who had an allergy to drugs such as bupivacaine lignocaine, pentazocine, midazolam etc were excluded. Also, patients with pre-existing serious systemic illnesses like cardiac disease, uncontrolled Diabetes, Hypertension, Asthma etc were excluded from the study. Patients enrolled for the study were assessed by an expert anaesthesiologist, who was not part of the research team, who prescribed patients either EMLA cream or regular standard lignocaine infiltration anaesthesia and labelled them as Group E and Group L respectively.

Study procedure: Patients of Group E were applied a 5 X 5cm patch of EMLA cream over L 3-4 level of the lumbar spine on the back of the patient and covered with an occlusive dressing, about one hour before arrival at the operating room by the anaesthesiologist who did not participate in the care and evaluation of the patients on the postoperative visit. Patients of Group L were given local infiltration analgesia under all aseptic precautions with a 2 ml injection of 2% lignocaine at L3-4 level of the lumbar spine, 5 min before giving spinal anaesthesia by the same anesthesiologist. Under all aseptic precautions, Spinal anaesthesia was given in L3-4 inter space in a sitting position with a 26 G Quinke's needle.

Follow-up: One anesthesiologist who did not know patients' groups evaluated patients' pain and physical withdrawal responses like verbalization, and arching of back or leg or arm movement. The patient was taught to rate his/her pain score on a scale of 0 to 10 (0 for no sensation at all and 10 for the worst pain). The primary objective of the study was to evaluate patients' responses to pain in these two groups from the insertion of the spinal needle to the removal of the spinal needle from the skin using a visual analogue scale.

Statistical analysis: Data were entered and checked in MS excel 2021. The findings were presented as percentages for qualitative variables and mean with standard deviation for continuous variables. The effect of treatment on VAS scores was analyzed using multiple regression analysis for controlling other confounding variables (Age, Sex and operation performed).

RESULT:

A total of 64 patients were enrolled in the study- 33 in Group E and 31 in Group L. The mean age was not significantly different in both groups but Group E had more male patients (27) while only 14 were in Group L, p<0.002. Both groups had an almost similar number of patients concerning type and extent of surgery, p>0.05.Table 1

Variables	Group E (EMLA) n=33	Group L (Lignocaine) n=31	Significance p-value
Age in years, Mean (SD)	39 (14.7)	37.9 (12.7)	p=0.73
Gender			
Male	27	14	p=0.002
Female	06	17	
ASA physical status			
I	13	15	p=0.52
II	20	16	
Extent of Surgery			
Minor	1	2	p=0.43
Intermediate	7	6	
Major	25	23	
Type of Surgery			
General Surgery	30	19	p=0.09
Orthopedics	0	4	
Obstetric/Gynecology	0	7	
Urology	2	0	
Others	1	1	

Table 1: Sociodemographic and preoperative data of both treatment groups

Table 2 shows that out of 33 patients in Group E, 14 patients had an inguinal hernia, 10 had an acute or chronic appendectomies and four patients had Umbilical and Supraumbilical Hernia. While in Group L, 10 patients had an inguinal hernia and 6 had acute or chronic appendicitis. The remaining others had orthopedics or gynecological

conditions.

Diagnosis	Group E n=33	Group L n=31
Inguinal Hernia	14	10
Umbilical And Supraumbilical Hernia	4	1
Acute or Chronic Appendicitis	10	6
UV Prolapse and Fibroid Uterus	0	4
Pregnancy Complication	0	3
Implant Tibia and Fibula	0	2
Fracture Midshaft Femur	0	1
Osteochondroma	0	1
Hydrocele	2	2
Vesical Calculus	2	0
Varicose Vein	1	1

Table 2: Distribution of different diseases between Group E (EMLA) and Group L (Lignocain).

The majority of patients had general surgical operations in Group E compared to half of the patients in Group L. Orthopedics or gynecological operations were done in Group L wherein three pregnancies were delivered by LSCS Table 3 .

Surgical Operations	Group E n=33	Group L n=31
Hernioplasty	15	10
Umbilical Hernioplasty	3	1
Open Appendicectomy	10	6
Vaginal Hysterectomy	0	4
LSCS	0	3
Implant Removal	0	2
ORIF for lower extremity	0	1
Excisional Osteotomy	0	1
Eversion of Sac or Orchidectomy	2	2
Cystolithotomy	2	0
Stripping and Ligation	1	1

Table 3: Type of Operations performed in both groups (Group E and Group L)

The patient's response to pain from the insertion of the spinal needle to the removal of the spinal needle from the skin was recorded using a visual analogue scale (VAS). Univariate analysis showed that the mean pain score (VAS) was significantly higher in Group E patients compared to that in Group L, p<0.001. The patients in Group E reported higher VAS as shown in Figure 1.

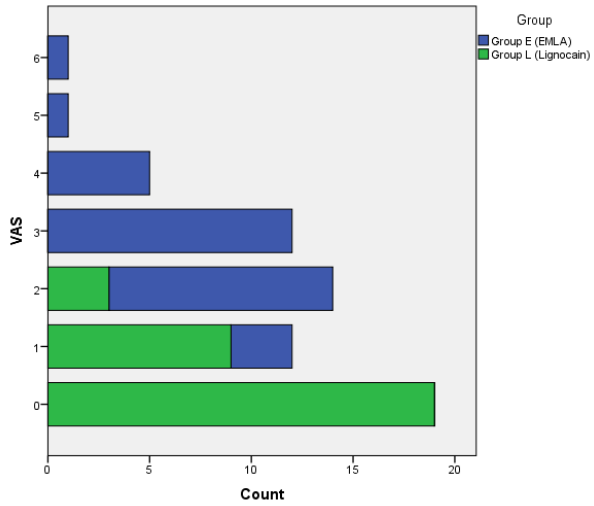

Figure 1: Comparison of VAS score count between EMLA and Lignocain groups

The multiple regression model with all four predictors (Groups, Age, Sex and operations performed) produced R^2 = .595, F (4, 63) = 24.3, p < .001. As can be seen in the summary regression Table, only VAS scores had a significant association, indicating patients from Group E (EMLA) had higher VAS scores compared to that of Group L, after controlling for the other variables in the model. No other factor had a significant VAS difference in the model Table 4.

Multiple Regression Model	Standardized Beta Coefficients	p-value
Age	0.009	0.916
Sex	-0.074	0.412
Groups (E and L)	-0.762	<0.001
Operation Performed*	0.053	0.514

Dependent Variable: VAS. *Operations performed coded 1 to 11 as given in table 3.

Table 4: Regression Summary table of VAS difference between Group E and Group L

DISCUSSION:

Needle prick pain of spinal anesthesia is the most distressing event during the whole spinal anesthesia procedure. In this study, we compared the patients' response to pain using a visual analogue scale between two groups

of patients (Group EMLA who have been applied a 5 X 5cm patch of EMLA cream over L 3-4 level of the lumbar spine about one hour before spinal anaesthesia and other Group L who were given local infiltration analgesia with a 2 ml injection of 2% lignocaine at L3-4 level of the lumbar spine, 5 min before giving spinal anaesthesia). We found that patients in Group E had more painful responses (higher VAS) compared to patients in Group L.

S Sharma et al. [12] in the comparative study between EMLA patch application and 3 ml 1% lidocaine before spinal needle insertion for postpartum tubal ligation operation reported significantly lower pain score (VAS) in the EMLA group than in the lidocaine group, $p < .001$. This contrasting finding may be because we assessed pain in intermediate to major surgical procedures with various diagnoses. Furthermore, another similar study by Z. Koscielniak-Nielsen et al. [1, 13] reported significantly lower pain scores in the EMLA group compared to the injection 2% lignocaine group.

There are many studies which reported similar findings to this study. A clinical trial by Katsushi Doi et al. [14] found that an EMLA patch one hour before epidural insertion in elective cesarean delivery could not reduce pain during epidural insertion. Similarly, Baek et al. [15] reported no significant difference in patients for deep local anaesthesia for transforaminal epidural injections. This study had similar findings as that of Elson J and Paech M [16] in double-blind RCT in women for elective caesarean section showed that those who received EMLA and saline infiltration had significantly higher pain scores compared to those who received 1% lignocaine infiltration.

There are now many newer modalities like INJEX™ technology, known as the ”Needle-free” drug delivery system, which reduces pain more compared to local injection [17].

How much the VAS score relates to clinical improvement is another question which has both subjective components from the patient’s perception and objective components from the doctor’s clinical assessment. Some studies such as by Bodian C et al. [18] pointed to the need for grouping the measured scores of VAS into categories (<30, 31 to 70 and >70) that were more appropriate to assess clinical relevance. Variability in outcome measures of various studies and clinical trials makes the evaluations of the efficacy, effectiveness and usefulness of different pain reduction techniques difficult. Nevertheless, the present study showed that we could not completely rely on the application of the EMLA patch and this finding is supported by many previous studies [13–16]. Slow and variable absorption of EMLA cream through intact skin into the deeper nerve endings can be one of the reasons for its relatively less pain relief in comparison to local infiltration anaesthesia.

CONCLUSION:

This comparative study found that a 2% lignocaine injection had better pain reduction of needle insertion for spinal anaesthesia than applying an EMLA patch in different settings and among patients posted for surgical, orthopaedic, renal or gynaecological operative procedures. After controlling other confounding factors such as age, sex and type of operations performed, the multiple regression model showed significantly higher VAS of pain during needle insertion in Group E (EMLA) compared to that of Group L who received 2% lignocaine injection before spinal anaesthesia. Hence, we conclude that lignocaine 2% infiltration at the site of giving spinal anaesthesia is a superior mode of anaesthesia for attenuating needle prick pain of spinal anaesthesia.

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