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COMPARISON OF TOPICAL LIDOCAINE-PRILOCAINE CREAM (EMLA) VERSUS LOCAL LIDOCAINE INFILTRATION FOR RADIAL ARTERY CANNULATION IN AWAKE PATIENTS

Anaesthesiology

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ABSTRACT

BACKGROUND: Radial artery cannulation is a commonly done invasive procedure in various major surgeries and intensive care settings. This study was aimed to compare the local infiltration of the lignocaine for radial artery cannulation versus EMLA cream application for providing analgesia for radial artery cannulation.**METHODS:** A prospective randomized study was done in which 101 patients were recruited. The patients who were posted for valve replacement and coronary artery by-pass surgery were included in the study. Patients were randomized into two groups to receive either topical EMLA cream 2 hours before the attempt of the radial artery cannulation or 0.5 ml of 2% lidocaine solution infiltration, 2 minutes before taking attempt for radial artery cannulation. The radial artery cannulation time, the number of cannulation attempts, patient pain score and operator satisfaction score were noted. **RESULTS:** The radial artery cannulation times and numbers of attempts were comparable in both the groups. The patient pain scores and operator satisfaction scores were statistically significant ($p<.05$) and better in the EMLA cream application group in comparison with lidocaine infiltration group.**CONCLUSION:** The EMLA cream application before the radial artery cannulation may ease an awake patient as well as operator both during the elective surgeries.

KEYWORDS

Radial Artery, Cannulation, Emla, Lignocaine

INTRODUCTION: In the present era anaesthesiologists are continuously striving to alleviate the pain during surgery. However, anaesthesiologist often has to take needle pricks and punctures to insert various invasive lines for hemodynamic monitoring purposes. These are often required before the induction of anaesthesia in high-risk cardiac patients posted for cardiac or noncardiac surgeries both. These invasive lines are usually taken under anaesthesia but in certain clinical circumstances due to patient morbidities, it is imperative to insert these invasive lines under awake conditions. This is basically been done to effectively manage the hemodynamic perturbations during induction of anaesthesia.

The painful invasive procedures usually include insertion of central venous catheters and invasive arterial lines.[1] The first attempt success rate of radial artery catheterisation (RAC) in an awake patient depends on cooperation by the patient which is directly proportional to the degree of analgesia provided by the anaesthesiologist during the procedure. The RAC is often preceded by application of local anaesthetic creams which is a combination of local anaesthetic that provides topical anaesthesia. [2-5]. EMLA (eutectic mixture of a local anaesthetic) cream is a mixture of Lidocaine-Prilocaine that allows topical cutaneous anaesthesia after being applied for certain amount of time under occlusive dressing. However, RAC is been more commonly done by providing local subcutaneous anaesthesia given in the form of infiltration of 1-2% lidocaine solution at the site of radial artery cannulation with 24-27 G needle. There are two prevalent methods of topical cutaneous anaesthesia for RAC and their selection often depends on institutional protocol and personal choices. In this study, we have tried to compare the two methods i.e. EMLA cream and local subcutaneous infiltration with 2% lidocaine for the relief of pain associated with radial artery cannulation in awake patients.

METHODS AND MATERIAL

This a prospective randomized parallel group single blinded study which was conducted after obtaining ethical committee approval. Patients, between the age group of 18-65 years of age, scheduled to undergo elective coronary artery bypass surgery and valve replacements surgery were included in this study. Exclusion criteria were patient refusal to participate in the study, abnormality in Allen's test, sensitivity or allergy to local anaesthetic, any significant arteriopathy in the radial artery, Raynaud's disease, atopic dermatitis, left radial arterial coronary by-pass graft and psychiatric disorders. A total of 150 patients were selected but only 101 consented for the study. After obtaining written informed consent from these 101 patients, a total of 101 patients were included in the study and were randomised by computer generated table into two groups, to receive either topical EMLA cream 2 hours before attempt of RAC (Group E) or 0.5 ml of 2% lidocaine infiltration at least 2 minutes before attempting RAC (Group I) in the operative room. The random allocation of patients was concealed in an envelope which was opened in operative room just before induction. The RAC was performed by an anaesthesiologist who has been performing RAC in our institute for more than five years. All patients were properly acquainted with Visual analogue scale (VAS) of pain and operator satisfaction scale during their preoperative visits. All patients were properly counselled about the anaesthetic technique and morning premedication was avoided in all patients.

In Group E patients EMLA cream followed by a cellophane dressing was applied on flexor aspect of both the wrists approximately 2 hours before shifting to the operative room. In Group I patient's petroleum jelly followed by a cellophane dressing was applied on flexor aspect of both the wrists approximately 2 hours before shifting to operative room.

All patients in both the groups were positioned for RAC by hyperextension of the wrist over a rolled gauze pack. All radial artery cannulation in both the groups was done by 22 G radial artery cannula. The number of attempts in which successful RAC was done was noted and procedure time (in seconds) was also noted by an independent observer.

The procedure time was defined by the time taken from the skin prick with cannula until the appearance of radial artery pressure tracing on the multi-parameter monitor.

Patient rating of pain during cannulation was recorded on the VAS scale (0-10) immediately after RAC by the independent observer. Ordinal rating of pain during RAC was also recorded as No pain= 0, mild= 1, moderate= 2 and severe pain= 3. Patient overall satisfaction was noted on the scale of 100. The same observer also recorded an operator satisfaction score (on a scale of 100) from the anaesthesiologist who performed RAC.

Primary outcome in our study were patient pain scores on both scales (VAS and Ordinal scale). The secondary outcomes were number of cannulation attempts, RAC procedure time, patient satisfaction scores and operator satisfaction scores.

STATISTICAL ANALYSIS

A pilot study was done to calculate effect size. The mean VAS pain scores in Group E and Group I were 3.0±1.5 and 4±1.5 (effect size =0.67). Hence using this effect size with minimum two-sided 95% confidence interval and 90 % power of the study, the required sample size in each of the Group E and Group I came out to be 49. Thus, we

included 50 patients in each study group [total size 100]. The sample size was estimated using software Power analysis and sample size version -16 (PASS-16, NCSS, LLC, USA). SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, New York, USA) was used for data analysis. All quantitative variables were estimated using mean and standard deviations (SD). Normality of data was tested and a variable was considered normally distributed when Z score of skewness was within ± 3.29. For normally distributed data, means were compared using Student's t-test. Pain VAS scores was not found to be normally distributed so Mann Whitney was used for intergroup comparison. Qualitative or categorical variables and percentages were compared using Chi-Square test. All statistical tests were two-sided and performed at a significance level of $\alpha = 0.05$.

RESULTS

A total of 101 patients (75 males and 26 females) were recruited in this study. In one patient operator was unable to do the RAC in both the hand so it was decided to proceed with femoral artery cannulation and that one patient was excluded from the study (Figure 1). The demographic profile of patients in both group E and group I were comparable. The pain scores on both VAS scale and Ordinal scale were significantly lower in Group E (p=0.013 and p=0.037 respectively) as shown in Table 1. The RAC procedure time and number of attempts were comparable in both groups (Table 1 & Figure 2).

Figure1: Showing patient recruitment & randomization

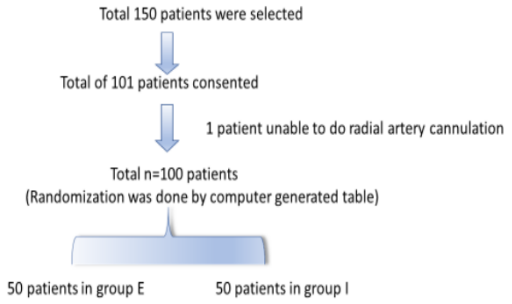

Table 1: Distribution of Clinical Values between Two Study Groups (N=100)

Variable´s	E (n=50)	I (n=50)	Total (N=100)	P Value
No. of Attempts				
One	34(68)	29(58)	63(63)	0.569
Two	13(26)	18(36)	31(31)	
Three	3(6)	3(6)	6(6)	
Patient rating pain during cannulation (Ordinal scale)				
No pain	5(10%)	0(0)	5(5)	0.037
Mild	18(36%)	13(26%)	31(31%)	
Moderate	22(44%)	26(52%)	48(48) %	
Severe	5(10%)	11(22%)	16(16) %	
$Cannulation (time in seconds)	18.42±2.48	19.32±2.58	18.87±2.56	0.078
$Operator Satisfaction Score	74.32±5.50	70.90±8.85	72.61±7.53	0.022
$Patient Overall Satisfaction	74.28±7.44	69.30±9.21	71.79±8.69	0.004
#Patient rating pain during cannulation VAS scale	3(2-4)	4(3-4)	4(3-4)	0.013

Presented in #Median (Interquartile range) and compared by Mann Whitney U test

/ $Mean ± Standard deviation and compared by Independent samples t test

/ Frequency (%) and compared by fisher exact test. P<0.05 significant

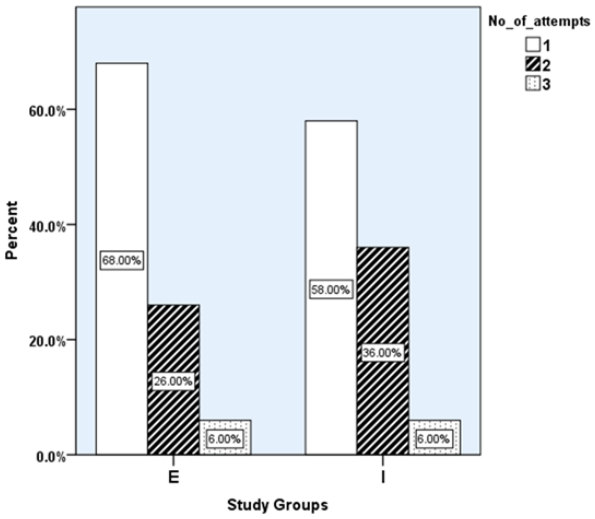

Figure 2: Number of radial artery cannulation attempt in both the groups

The operator satisfaction score was significantly better in group E in comparison to group I and patient satisfaction score were also significantly better in group E when compared with group I (p=0.022 and p=.004 respectively) as shown in Table 1 and Figure 3.

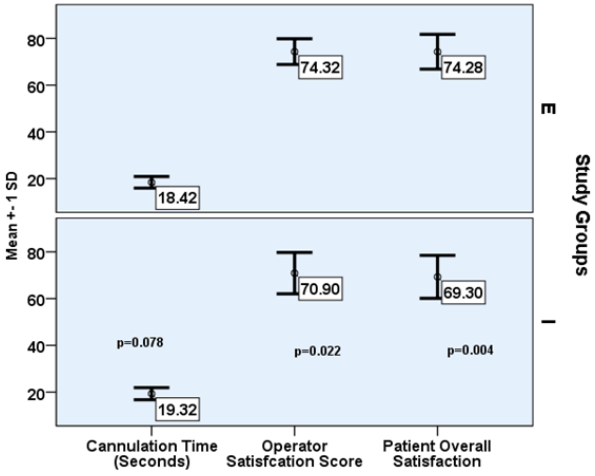

Figure 3: Showing cannulation time, operator satisfaction score and patient overall satisfaction.

DISCUSSION

The present study observed that the pain scores were significantly better in patients using EMLA cream (Group E) during RAC compared to patients receiving 2% lignocaine infiltration. We found no difference in the number of attempts of RAC and procedure time. However, satisfaction scores of both patients and operator anaesthetists were significantly higher in Group E.

Joly et al did a randomized trial in which they compared topical anaesthesia by EMLA cream with subcutaneous local lignocaine infiltration for radial artery cannulation in 538 patients posted for radial coronary angiography where they found failure rate and insertion time both were significantly lower in EMLA group in comparison to infiltration group.

In this study scoring of pain experienced by the patient during the radial artery cannulation was done on two scales namely VAS scale and ordinal scale by an independent observer. According to scales pain control was better and statistically significant in group E when compared with Group I. Measurement of pain experienced by the patient on two pain scales was done to ensure the adequacy of pain response measurement from the patient. Smith et al[4] did a double-blind comparison between three groups EMLA alone, EMLA and 0.9 % saline infiltration and 1% lidocaine infiltration, they found that median level of pain on 10 point scale was 2.5 in EMLA group vs 6 in

the placebo group.[4] We however did not use saline infiltration as the pain of needle prick for local or saline infiltration potentiates the pain of actual arterial canula prick and this is an inherent major advantage of using an EMLA cream over subcutaneous local infiltration. Hence to incorporate an additional needle prick to infiltrate saline after application of EMLA cream would have diluted the advantage of EMLA cream and might distort the level playing field while comparing in-between the two methods.

Olday et al did a prospective randomized study in one hundred cardiac surgery patients in which they compared topical 4% amethocaine gel (Ametop™) with 2% lidocaine infiltration for analgesia for radial artery cannulation and they found no significant difference between the given two methods of analgesia[7]. Patients in their study were premedicated with a benzodiazepine (BZD). BZD does not provide analgesia but however it is well recognized that a premedicated patient may perceive and recall pain differently in comparison to a non-premedicated patient. That is the reason why we have avoided morning premedication in our patients to avoid the issue of pain perceiving and recall in the operative room. Proper counselling of the patient and explanation of the technique in detail during pre-anaesthetic check-up helped us in the operative room and patient remain calm and compose during the whole procedure.

Different studied have been conducted previously to show the time which is required to produce topical anaesthesia by EMLA and they have concluded that 1-hour application of EMLA cream is insufficient.[2,3] Wahlgren etal studied the depth of cutaneous analgesia after application of EMLA cream and found that the Biopsy punch insertions with acceptable pain can be made to depths of 1 to 2 mm after 60 minutes, to 2 to 3 mm after 120 minutes, and to 6 mm after 3 to 4 hours of EMLA cream application [8]. Lee etal did Ultrasound evaluation of the radial artery for arterial catheterization in healthy anesthetized 195 pts and found that average depth of radial artery from skin is 1.99 ± 0.99 mm [9]. So, to achieve an analgesia depth of 2mm or more we waited approximately 2 hours before attempting for RAC.

The patients were blinded as there was application of petroleum jelly followed by cellophane dressing in group I patients. However double Blinding was not possible since we did not infiltrate saline in group E after application of EMLA cream. Moreover, post removal of EMLA cream the blanching or erythema of skin is characteristic which might have acted as a tell-tale sign[10,11].

Operator satisfaction score was better in Group E since the infiltration of local anaesthetic infiltration at puncture site usually cause swelling at the injection site or spasm of the artery which might interfere with the RAC.

The infiltration of 2% lignocaine causes transient but an extreme discomfort to a patient[7,10-15]. So when we compare the fear of one needle vs fear of two needles i.e. in group E only one prick (22G cannula needle prick) for RAC vs two pricks in group I for RAC (Lidocaine infiltration needle prick followed by 22G cannula prick), the visualisation of two-needle prick is psychologically more painful than one this might be the reason for lower pain score and better patient satisfaction score in group E.

Our study is a single blind study and double blinding was not done since we did not infiltrate saline in group E after application of EMLA cream, this is the major limitation of our study. The biggest issue with EMLA cream is the time delay which is mandatory to obtain adequate topical analgesia. Skin absorption of EMLA cream occurs by iontophoresis and is time-dependent and skin depth of anaesthesia usually reaches till 5 mm after 1.5 hours.

Measurement of pain experienced by the patient on two pain scales i.e. VAS and ordinal scale and the use of operator satisfaction score are the major strengths of our study. Although coronary artery bypass surgery and valve replacement surgeries were included in this study but the results of this study can be applied on all surgeries in which awake radial artery cannulation is required.

CONCLUSIONS:

The RAC for elective surgeries can be done with EMLA cream application 2 hours before the cannulation attempt and will ease the patient and operator both. The findings of our study suggest the anaesthesiologist to practice timely preoperative application of EMLA cream for radial artery cannulation in elective surgeries.

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