Effect Of Topical Application Of Anesthetic Agent On Pain Perception Among Patients And Degree Of Difficulty Among Healthcare Providers During Intravenous Cannulation: A Randomized Controlled Trial

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Abstract: Problem: Intravenous cannulation is one of the key procedures that is performed for patients; however, it causes pain and discomfort. Studies have shown feasibility and efficiency of various anesthetic and analgesic agents to reduce pain but it is still not implemented in daily practice. The current study aims to assess the effect of topical application of an anesthetic agent on the pain perception of patients and degree of difficulty for healthcare professionals. **Approach:** 120 patients who require intravenous cannulation at an emergency department of a tertiary care center were enrolled usinga consecutive sampling technique for therandomized controlled trial. The intervention group received an application of 2% lignocaine gelfive minutes before the procedure, while,control group received a placebo (ECG gel). After the procedure, the pain score from patients anddegree of difficulty score from the health care professionals were assessed. Inferential analyses were done using Chi-square test, Fisher's exact test, Mann-Whitney U test, and Kruskal Wallis test. **Findings:** There was a significant difference in pain perception between both groups. Participants in the intervention group mostly experienced mild pain or no pain (56.7% and 20% respectively), however, participants in control group mostly experienced moderate pain (56.7%) and severe pain (28.3%). However, there is no significant difference in the degree of difficulty experienced by healthcare professionals for both groups., **Conclusion:**The use of a topical anesthetic agent like 2% lignocaine gel before intravenous cannulation is recommended to reduce additional pain experienced by patients during the course of their treatment.

Keywords: Anesthetic agents, cannulation, health care provider, local anesthesia, pain perception

Introduction

Intravenous (IV) cannulation is one of the initial strategies forthe treatment of a patient, which has been followed since the bygone era[1,2] Around 80% of the patients who have been hospitalized worldwide, experience at least one peripheral IV cannula insertion, making IV cannulation one of the most common clinical procedures[3]Medication, fluids, nutrition, and blood products can all be administered peripherally or centrally, through the intravenous route. It assures almost complete drug bioavailability with minimal delay in its onset of action and hence brings out the most desired result.[1]However, intravenous cannulation may involve an unpleasant and very painful experience for the individual that can lead to fear and anxiety in both children and adults, which may trigger the autonomic system and hence cause vasoconstriction, making peripheral venous access even more difficult.[2,3]

Various methods have been tried to reduce the pain experienced during venipuncture including ice, distraction techniques, cough tricks, Valsalva maneuver, saline, different analgesics, as well as different forms and formulations of anesthetic agents. However, these studies yielded variable outcomes, and 2%lignocaine was considered to be one of the most effective agentsfor alleviating pain.[4,5]Even though few studies have shown the feasibility and efficiency of various anesthetic and analgesic agents to reduce pain during IV cannulation it is still not implemented in daily practice.This paper tries to show the effectiveness of the administration of a topical anesthetic agent on the reduction of pain during IV cannulation. This is a study with a good novelty that can be vital for bridging knowledge with practice. The study objective are to assess the effect of topical application of anesthetic agent on pain perception during IV cannulation and to compare the degree of difficulty experienced by health care professionals during IV cannulation with and without topical anesthetic agent. (Health care professionals: nurses, doctors and emergency technician).

Materials and Methods

Study design:

The Research design adopted for the present study on the effect of topical application of anaesthetic agent on pain perception among patients and the degree of difficulty among the healthcare providers during IV cannulation of a randomized controlled trial registered under the Clinical Trial Registry India (CTRI/2022/09/045599). The present study is a single-blinded, randomized controlled trial with a post-test design. The study setting was a tertiary care hospital providing services to the population of Puducherry and its neighbouring states (Tamil Nadu, Kerala, Karnataka, and Andhra Pradesh).

Sampling and randomization:

Using a consecutive sampling technique, patients seeking medical attention in the green zone of the Emergency Department at a tertiary care center with advice for IV cannulation were enrolled in the study(Figure 1). Patients with fractures of upper limbs, amputation of

upper limbs, any skin diseases,or known allergic reactions to 2% lidocaine gel were excluded from the study.

Block randomization with permuted blocks generated through a computer was used in this study. Participants were then randomized into two groups with the help of Serially Numbered Opaque Sealed Envelopes (SNOSE). Considering a minimum expected mean difference of 3 in the pain perception during IV cannulation between control and study groups, with a standard deviation of 5.

Sample size was estimated using formula for comparison of two means:

$$n \geq \frac{2[z_{1-\alpha/2} + z_{1-\beta}]^2 \sigma^2}{\delta^2}$$

here,

$z(1-\alpha/2)$ - critical value for corresponding level of confidence (95%)

$(1-\beta)$ – desired power

δ – mean difference in pain score after receiving intervention (3)

σ – standard deviation (5)

The Initial estimation of the sample size 50 in each group and corrected estimated sample (after considering loss) was round off to 60 (in each group) after considering 20 %attrition rate.

The sample size was estimated to be 120 by anticipating a minimum réduction of pain perception during IV cannulation (NRS score) by 3 after the application of 2% Lidocaine gel, at a 5% level of significance and 80% power.The participants were then randomized into two groups usingcomputer-generated permuted blocks of varying sizes by an independent statistician. Allocation concealment was done with the help of serially numbered opaque sealed envelopes.

Data Collection:

Inclusion criteria of the study was patients seeking care at Emergency Department, under green category by TRIAGE department, above the age of 18 years and patients for whom IV cannulation was advised. Exclusion criteria of the study was critically ill patients (patient shifted to yellow and red zone area), patients with fractures of both upper limbs, patient for whom both upper limbs are amputated, patients with any skin diseases, patients with known allergic reactions to 2% lidocaine gel. The withdrawal criteria was participants who develop any allergic reaction after the application of 2% lidocaine gel.

Following enrolment, participants' socio-demographic variables as well as Fitzpatrick skin typeand body mass index were collected.[6] Then, the healthcare professional who volunteers to perform IV cannulation for the selected patient assesses the visibility of the appropriate vein and the site for the insertion of a cannula**.** The investigator opened the sealed allocation envelope and applied the gel on the selected site based on their allocated group: 2% Lignocaine gel (Lox 2% Jelly; Neon Laboratories Limited, Mumbai, India) for the study group and ECG gel as a placebo for the control group.After five minutes the gel was rubbed

off with the help of a dry gauze piece and then with an alcohol swab; the healthcare professional then performed the IV cannulation procedure as per the standard protocol followed in the institute.Soon after the procedure, the patients were asked about their pain perception using a numerical rating scale (0-10), where 0 means no pain, whilst, 10 is the worst pain possible. A pain score of 1-3 is considered as mild pain, 4-6 as moderate pain, and 7-10 as severe pain. The data regarding the difficulty of IV cannulation was also collected from the healthcare professionals' right after the procedure, along with their demographic characteristics, experience, etc. The IV cannulation difficulty scale was modified from AF Jacobson's Intravenous Catheter Insertion Difficulty Scale and included six Likert items namely, visibility of proper veins, palpable veins, vein non-resistant to puncture, decreased movement of the patient, patient being cooperative, and IV cannulation success at the first attempt.[7]The Numerical Rating Scale is a standardized tool and the subject experts have approved the validity of the tool. However, the Modified AF Jacobson's Intravenous Catheter Insertion Difficulty Scale was modified by the investigator and got the content validity from 5 different experts from the Emergency Medicine and Nursing departments (one faculty from Emergency medicine and four Nursing faculties). Modifications were made based on the expert's suggestions.The reliability of the tool for measuring the degree of difficulty among healthcare professionals during IV cannulation was assessed by the Cronbach's alpha (internal consistency) method. The value was found to be 0.758.

Description of the Intervention

After taking consent from the participant he or she was enrolled in the study. The healthcare professional (Nurse/EMT staff/ Doctor) that is performing the IV cannulation, assessed for the visibility of the appropriate vein and the site for insertion of a cannula.Following this, the investigator opens the sealed envelope and applies the gel based on the group they are randomized to; 2% Lignocaine gel for the study group and ECG gel as a placebo for the control group. After 5 minutes, the gel was rubbed off with the help of a dry gauze piece and then with an alcohol swab. Following this, the healthcare professional performs the IV cannulation procedure as per institute protocol: A clean tray was arranged for IV cannulation, which contained a tourniquet, clean gloves, alcohol swab, IV cannula of different sizes, dynaplast, syringe with normal saline flush, and vacutainer tubes. Tourniquet was tied above the site of a previously identified vein. The site was cleaned with an alcohol swab. An appropriate cannula size is chosen and inserted in that particular vein and the line is then secured with a dynaplast.

Soon after the procedure, the patients were asked about their pain perception rating from 0 to 10 on the Numerical Rating Scale and the data regarding the degree of difficulty were collected from healthcare professionals, who performed the procedure by using Modified AF Jacobson's Intravenous Catheter Insertion Difficulty Scale.

The Institutional Ethics Committee and Research monitoring committee approved this study (JIP/CON/IEC/M.Sc./2021/MSN/6). It involves a minor increase over minimal risk or

low risk. Before enrolling in the study, the investigator took written informed consent from the participants after explaining the study's purpose and procedure in simple words in the participants' language. The data was collected anonymously and stored confidentially. The investigator ensured that the personal information obtained from the participants for the study would remain confidential throughout thestudy period and up to three years of publication. Participants were given all rights to withdraw from the study at any point of the study without explanation. ICMR guidelines for good clinical practice were followed throughout the study.

Statistics:

Data analysis was done using the IBM Statistical Package for Social Sciences(Version 25.0). Comparison of the categorical variables between the groupswas done using Chi-squaretest and Fisher's exact test. The relationship between the degree of difficulty and healthcare professionals' characteristicswas analysed using Mann Whitney U-test and Kruskal Wallis test based on the distribution of data.

Results

The participants of both groups were homogenous in terms of age, gender, occupation, skin type, and body mass index in both groups (P>0.05). The majority of the participants belong to the age group of 40-59 years in both study and control groups with 49.1% and 50.9% respectively. Most of the participants were male and a total of 88 participant's skin colour was classified under the type 5 category. (Table 1)

After the intervention, 34(56%) participants experienced mild pain, and 12(20%) participants experienced no pain in the study group. However, in the control group, the majority of the participants experienced moderate and severe pain with 56.7% and 28.3% respectively. A significant difference in the pain experienced by the study group and control group was observed (P<0.001). (Figure2)There is no statistically significant association between participants' characteristics and their pain perception during IV cannulation.

The baseline data collected from the healthcare personnel of both groups which include departments, experience, IV cannulation course attended, venflon size, IV insertion site, and number of attempts were homogenous and comparable with P≥ 0.05. In both groups, the dorsum of the hand was the most preferable site for IV cannulation. (Table 2)

The median degree of difficulty experienced by healthcare professionals during IV cannulations in the intervention group and control group was 5(4.67,5), with no significant difference (P-0.457).On assessing the relationship between the degree of difficulty and characteristics of healthcare professionals among the study group, the median difficulty score of healthcare professionals who have attended IV cannulation courses was 4.50(4.17,4.87), which was significantly lower than 5(4.67, 5) for those who have not attended a course (P-0.027). A significant difference was also noted in the difficulty level between different durations of experience for healthcare professionals. (Table 3).

Table 1: Comparison of participants' characteristics between groups

[1]Frequency (%) and Chi- square test; [2] Frequency (%) and Fisher's exact text; P≤ 0.05

Variables		Study group (60) n(%)	Control group (60) n(%)	P- value
Age (in years)[1]	18- 39	20 (54.1)	17 (45.9)	0.821
	40-59	26 (49.1)	27 (50.9)	
	>60	14 (46.7)	16 (53.3)	
Gender [1]	Male	34 (48.6)	36 (51.4)	0.711
	Female	26 (52.0)	24 (48.0)	
Occupation [2]	Unemployed	21 (43.8)	27 (56.3)	0.535
	Students	3 (42.9)	4 (57.1)	
	Daily wages	31 (57.4)	23 (42.6)	
	Regular employees	5 (45.5)	6 (54.5)	
Fitzpatrick skin type [2]	Type 3	0	1 (100)	0.677
	Type 4	17 (54.8)	14 (45.2)	
	Type 5	43 (48.9)	45 (51.1)	
Body mass index [2]	Underweight	3(27.3)	8(72.7)	0.157
	Normal	37 (48.7)	39(51.3)	
	Overweight	16 (55.2)	13 (44.8)	
	Obese	2 (100)	0	
	Extremely obese	2 (100)	0	

Table 2: Comparison of healthcare professionals' characteristics between groups

Variables		Study group (60) n (%)	Control group(60) n(%)	P-value
Department[1]	EMT	56 (49.1)	58 (50.9)	0.679
	Nursing	04 (66.7)	02 (33.3)	
Experience[1]	None (interns)	13 (65.0)	07 (35.0)	0.402
	≤2years	20 (57.1)	15 (42.9)	
	3-5years	18 (42.9)	24 (57.1)	
	6-7years	05 (41.7)	07 (58.3)	
	8-10years	04 (40.0)	06 (60.0)	
	>10years	0	01 (100)	
Intravenous cannula insertion site[1]	Left Cubital	04 (66.7)	02 (33.3)	0.274
	Right Cubital	04 (66.7)	02 (33.3)	
	Dorsum of the right hand	32 (48.5)	34 (51.5)	
	Dorsum of the left hand	16 (51.6)	15 (48.4)	
	Right radial	02 (100)	0	
	Left radial	01 (100)	0	
	Right forearm	01 (16.7)	05 (83.3)	
	Left forearm	0	02 (100)	
IV cannulation course attended[2]	Yes	06 (50.0)	06 (50.0)	1.000
	No	54 (50.0)	54 (50.0)	
Venflon size[1]	18 Gauge	27 (49.1)	28 (50.9)	0.558
	20 Gauge	0	02 (100)	
	22 Gauge	33 (52.4)	30 (47.6)	
Number of attempts[1]	1	59 (50.0)	59 (50.0)	1.000
	2	0	01 (100)	
	3	01 (100)	0	

Note: [1]Frequency (%) and Fisher's exact text; [2] Frequency (%) and Chi-square test; P≤ 0.05

Table 3: Relationship between degree of difficulty and characteristics of healthcare professionals among the study group

n= 60

Note: EMT-Emergency Medical Technician; IQR-Interquartile range; [1]Kruskal Wallis test; [2]

Characteristics of healthcare professionals		**Difficulty of IV cannulation** Median (IQR)	**P-value**
Department[1]	EMT	5.00 (4.67, 5.00)	0.451
	Nursing	5.00 (4.75, 5.00)	
Experience[1]	None (Interns)	4.83 (4.33, 5.00)	**0.013**
	≤ 2years	4.75 (4.41, 5.00)	
	3-5years	5.00 (5.00, 5.00)	
	6-7years	4.67 (4.41, 5.00)	
	8-10years	5.00 (5.00, 5.00)	
IV course attended[2]	Yes	4.50 (4.17, 4.87)	**0.027**
	No	5.00 (4.67, 5.00)	
Venflon size[1]	18 Gauge	5.00 (4.67, 5.00)	0.788
	22 Gauge	5.00 (4.50, 5.00)	
Intravenous cannula insertion site[1]	Left cubital	4.83 (4.67, 5.00)	0.510
	Right cubital	5.00 (4.49, 5.00)	
	Dorsum of the right hand	5.00 (4.71, 5.00)	
	Dorsum of the left hand	4.91 (4.25, 5.00)	
	Right radial	4.66 (4.33, 5.00)	
	Left radial	5.00 (5.00, 5.00)	
	Right forearm	4.17 (4.17, 4.17)	

Mann Whitney U test; P≤0.05

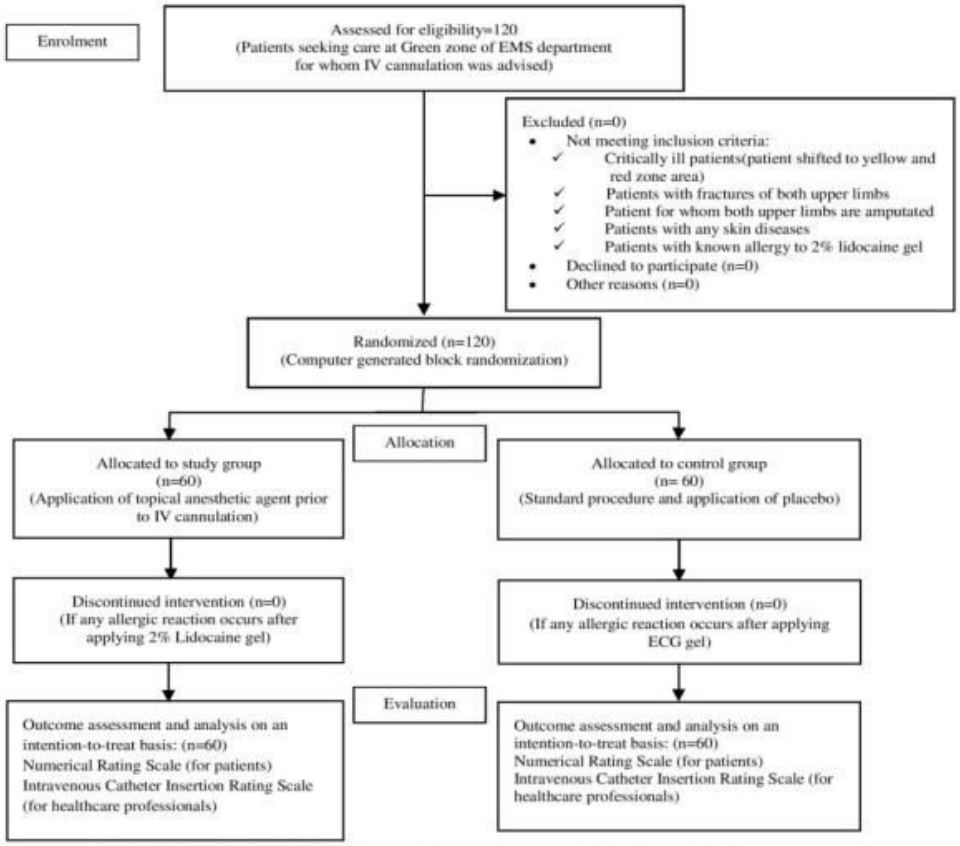

Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram

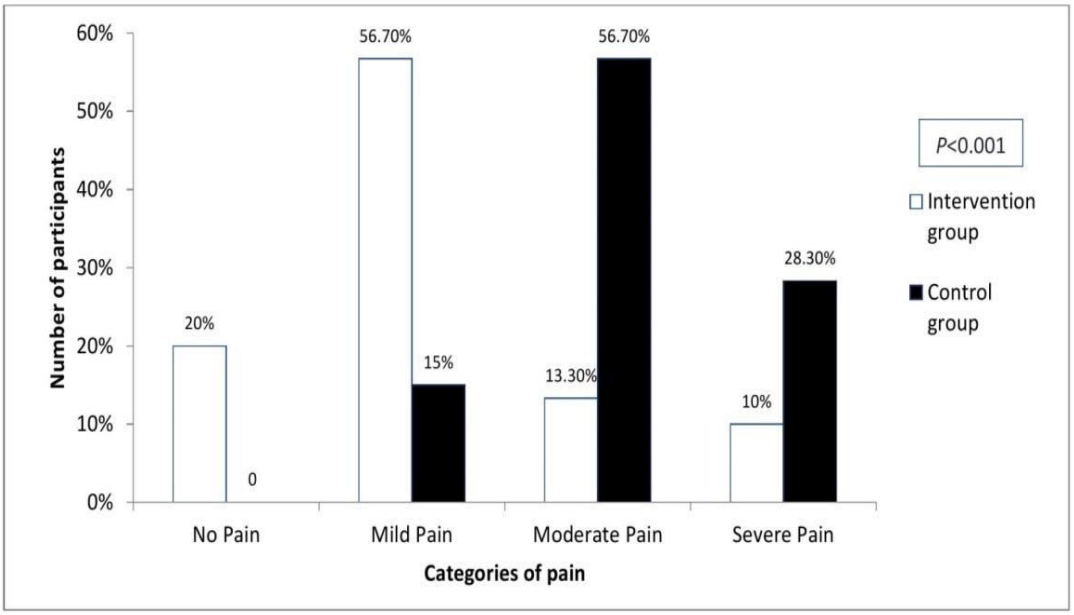

Figure 2: Comparison of participants' pain perception during IV cannulation between the groups

Discussion

"First do no harm" is a principle deeply embedded in medical practice, with patients' safety and well-being as the priority during patient care. Healthcare practitioners should make continuous efforts in order to minimize pain while providing safe and effective treatment for patients of all age groups. Understanding the pain and discomfort an individual undergoes during IV cannulation, the current study identifies a solution by applying a potent anesthetic agent, 2% lidocaine gel, before the procedure.The first objective of the study was to assess the effect of topical application of anesthetic agent on pain perception during IV cannulation.In this study, the pain score was assessed with the help of Numerical Rating Scale. Table 2.2 illustrates that there was a significant difference between pain perception among the participants in the study and the control group (P <0.001). The Numerical Rating scale has four categories: no pain, mild pain, moderate pain, and severe pain. All the participants (12; 100%) who have experienced no pain during the procedure belong to the study group. However, participants experiencing severe pain in the study group and control group were 26.1% and 73.9% respectively.A significant reduction in pain perception was noted among the participants receiving topical application of 2% Lidocaine gel in the current study. This finding is supported by a crossover study by McNaughton Candace et al. where IV insertion sites were pretreated with nothing, lidocaine cream, or injected-buffered lidocaine. The median pain scores during IV cannulation was significantly lower among the participants receiving lidocaine cream (3; IQR 2-5) and injected-buffered lidocaine (1; IQR 1-2), as compared to the participants without local anesthesia (7; IQR 4-8). However, the limitation of their study is that the participants were healthcare professionals and were not blinded to the pretreatment technique, which may cause the finding to be biased.[8]

A study was conducted by Burke SD et al among the patient admitted to the surgery unit, where a total of 148 samples were included in the study. Here, the intervention group was administered intradermal buffered lidocaine whereas the participants on the other arm were administered intradermal bacteriostatic normal saline. There was no significant difference in demographic characteristics between the two treatment groups as in the current study. Also, they have used the same tool i.e. Numerical rating scale which was also used in this study. The buffered lignocaine showed statistically significant superiority in reducing pain during IV catheterization as compared to bacteriostatic normal saline with P = 0.007[9].

Another study was conducted by Gupta D et al, wherein, participants were randomized into four different groups with the following interventions: plain lubricant cream (control group), EMLA (lidocaine and prilocaine) cream, Capsain ointment, and EMLA with Capsain ointment. It was observed that the incidence of participants responding to no pain was higher in EMLA group, Capsain group and EMLA with Capsain group. Subsequently, the severity of pain in the control group was higher than the other three groups (P <0.001, P<0.001, P<0.001). Side effects like stinging sensation and blanching were observed in EMLA, Capsain, and EMLA with Capsain group. However, in the current study no participants have shown any kind of side effect after applying the Lidocaine gel or ECG gel[6].In a similar study

conducted by Harris T et al, on the pre-cannulation use of a local anesthetic agent and factors affecting pain perception in the emergency department setting, it was found that there is no association between the pain perception and other factors like participants' age (P = 0.577), gender (P= 0.485), cannulator's experience (P=0.308) and size of the cannula (P= 0.377). This study has also concluded that, a slow subcutaneous injection of 0.1ml of lignocaine which was administered 30 seconds prior to cannulation, significantly reduces the pain perception of the participants[10].

The second objective of the study was to compare the degree of difficulty experienced by healthcare professionals during IV Cannulation with and without a topical anesthetic agent.

In this study, Modified AF Jacobson's Intravenous Catheter Insertion Difficulty Scale was used to assess the degree of difficulty experienced by healthcare professionals. Table 4.4 depicted that there is no significant difference in the difficulty score among the study [5.00 (4.67, 5.00)] and the control group [5.00 (4.67, 5.00)] with P = 0.457. However, in Table 5, an association between the degree of difficulty and baseline characteristics of healthcare professionals including work experience and previous IV course attended, among the study group has been seen with P = 0.013 and P = 0.027 respectively.The study shows that there is no significant difference in the degree of difficulty between the two groups. Hence, the administration of an anesthetic agent does not have an effect on the degree of difficulty while inserting a peripheral Intravenous catheter. It may be because of this one of the most commonly done procedures in their daily practice. Datema et alconducted a study in 2016 and described that there is no association between the application of an anesthetic agent and the degree of difficulty as disclosed in the current study. Furthermore, the study has also shown that there were no clinically or statistically significant differences between the two groups and all the vascular access were successful in the first attempt without any side effects. However,the current study has shown a significant difference statistically in terms of Pain perception between the study group and control group[11].No significant association was found between participants' characteristics and their pain perception. However, pain thresholds are known to vary on the basis of different factors. A study by Goudra BG et al. reported that IV cannula insertion on the antecubital fossa was significantly less painful in comparison to the dorsum of the hand (P<0.05).[12]

Limitation

The present study was conducted only in the Green zone of the Emergency Department, whichhas more stable patients as compared to the Yellow and Red zones. The size of the intravenous catheter used was notuniform for the current study, for which further analysis was not done related to pain perception. In addition, the sample size was quite small. Further research with a larger sample size including various departments of the hospital is recommended.

Conclusion

Application of topical anesthetic agent reduces the pain experienced by an individual during IV cannulation. However, it has no significant effect on the degree of difficulty level

experienced by the one who is performing the procedure. Hence,implementation of topical application of 2% Lidocaine gel prior to IV cannulation in clinical practices may help in reducing additional discomfort associated with patient care.

Conflicts of Interests: There is no conflict of interest.

Data Accessibility

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethical Issues: There are no ethical issues.

Research Highlights

1) What is the current knowledge?

Intravenous cannulation plays an important aspect in the emergency and continuation of care among the patient seeking care in the hospital. It is used for various purposes like sample collection, administration of medication, nutrients, and blood products as its bioavailability is 100%. However, an individual has to undergo a painful experience while getting an access to intravenous route.

2) What is new here?

Literature search reveals a limited number of studies on the effect of pre-treatment of skin with 2% Lignocaine gel prior to intravenous catheter insertion may reduce pain among the patient seeking care in a hospital.

Consent to Participate: Yes, Obtained**.**

Patients' Consent Form: Yes, obtained

Ethical Approval and/or Institutional Review Board (Irb) Approval

Institutional Ethics Committee (JIP/CON/IEC/M.Sc./2021/MSN/6) for human studies and Nursing Research Monitoring Committee (JIP/CON/NRMC/M.Sc./2021/MSN/7) approved the study. The study was also registered under the clinical trial registry of India, where the full protocol is available (CTRI/2022/09/045599). The procedures followed were in accordance with the ethical standards of the institution as well as the Declaration of Helsinki revised in 2013.

Data Availability Statement: The data set used in the current study is available on request from the College of Nursing, JIPMER through the corresponding author.

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