## EFFECT OF INJECTION SITE PRE-COOLING ON PAIN PERCEPTION IN PATIENTS ATTENDING A DENTAL CAMP AT LIFE LINE EXPRESS: A SPLIT MOUTH INTERVENTIONAL STUDY

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#### Abstract

**Background and aim.** To determine the effect of pre-cooling injection site on pain perception in patients attending a dental camp at lifeline express, Habibganj.

**Methods.** A split mouth interventional study assessed the effect of pre cooling the injection site in patients (n=33) requiring bilateral buccal infiltration prior to extraction. One side of the patient's mouth received the intervention after the injection site was pre cooled with ice for 3 minutes along with topical Lidocaine, while the other mouth side of the same patient received only topical Lidocaine and served as control group. A structured proforma assessed the demographic characteristics and risk factors that influence pain perception in patients. Mann-Whitney U tests and Wicoxon rank sum test were used for statistical analysis. Statistical significance was defined at P<0.05.

**Results.** The results revealed a significant difference in pain perception between control and intervention group as assessed using both Heft-Parker Visual Analog Scale (median score 3.0 and 1.0) and Sound Eye Motor scale (median score=1.0 and 0.0) (P<0.01). For both the scales the assessed and self reported variables Gender, Location, Chief Complaint, Region and Arch were found to be statistically significant. **Conclusion.** Pre cooling injection site reduced pain perception in patients.

Keywords: pain perception, mouth injection site, anesthetic, local, lidocaine

### Introduction

Pain is considered to be the major reason for seeking dental treatment, although it is also considered to be a major reason for avoiding it. Injection of local anesthesia is one of the most feared or anxiety-inducing stimuli in dental practice [1]. Fear of injection creates a barrier and interferes with the dental treatment whereas a successful anesthesia always relieves anxiety and apprehension in patients, particularly those undergoing surgical procedures. A number of methods are available to reduce pain associated with injection of Local Anesthesia, for example the application of topical anesthesia (ex. Lidocaine) [2],

Manuscript received: 08.07.2016 Received in revised form: 08.09.2016 Accepted: 27.09.2016 Address for correspondence: upendrazzz@gmail.com warming the local anesthetic agents [3]. buffering the local anesthetics [4-6], adjusting the rate of the infiltration by reducing the speed of injection [7], counter-irritation [8], distraction techniques [9], vibrating the surrounding tissue while administering the injection, applying pressure to the injection site, and use of a mechanical delivery system [10,11].

Another recommended method that can be effectively, efficiently and economically employed to reduce the pain perception among patients undergoing dental procedures is cooling or pre cooling the injection site. Alleviating pain during dental treatment helps in developing trust in the dentist and dental procedures and can also result in improving the oral hygiene of the patients. This technique has been used in sprains, burns, fractures, bruises, insect bites, and sports injuries [12, 13]. Previous literature suggests that ice has been used to relieve pain from a local anesthetic injection, control postoperative pain, and prevent edema. A study conducted by Faezeh Ghaderi [14] found pre cooling the anesthesia site to be effective in reducing the pain perception among pediatric patients. Literature on the efficiency of pre cooling the injection site among adults and patients of other age groups is sparse and deficient. Dental camps in this regard serve as an effective medium in dealing with a vast number of patients with varied age groups in short intervals of time; due to compromised periodontal and oral conditions one of the most commonly encountered treatment in dental camps is extraction. Life Line Express in India has been rendering health services throughout the country. The dental coach of Life Line Express provides free dental services to rural and deprived sections, people of all age groups being the beneficiaries. The present study was thus aimed at comparing the pain perception with and without pre cooling the injection site using Heft Parker Scale and Sound, Eve and Motor (SEM) Scale in patients attending dental camp at life line express. The study also evaluated the risk factors that can influence the pain perception during injection in patients.

# Materials and method *Study design*

The present study utilized a split-mouth interventional study design that evaluated the efficacy of pre-cooling injection site on pain perception in patients attending a dental camp at lifeline express.

## Ethical approval

Permission to conduct study in Life Line Express was obtained. Patients fulfilling the eligibility criteria were treated in the operating area, seated on a dental chair. Ethical approval was obtained from Institutional Review Board of Sri Aurobindo College of Dentistry Indore.

## Eligibility criteria

The participants included patients attending dental camp at Life Line Express Habibganj who needed bilateral infiltration of local anesthetics for dental extractions. Patients included in the study were willing to undergo extraction, were prior informed about the treatment and intervention procedure, provided written informed consent before conducting the study. To ensure comparability among subjects patients with same complaint, similar region, arch and mobility were included. Subjects with allergy to anesthesia or anesthetic procedure, intellectual disability, psychiatric disorders, dental abscesses or fistulas and vestibular tenderness in the procedural site were excluded from the study.

## Study setting and location

The study was carried out in the dental coach of life line express Habibganj camp, Madhya Pradesh India.

## Interventions

The present study used a pre tested structured proforma that recorded the socio demographic characteristics and risk factors that might influence patient's pain perception. The characteristics included selfreported variables like patient age, gender, residence, chief complaint, arch and region affected, past medical history and personal history. The assessed variables included mobility of teeth, temporo mandibular joint dysfunction and socio economic status, which was assessed using Prasad Scale; the patients were divided into different classes ranging from Class I – Class IV [15]. The chief intervention included in the study was ice cubes. One half of patient's mouth received the intervention in which the injection site was pre cooled with ice for 3 minutes along with topical Lidocaine (2 sprays) while other half of same patient received only topical Lidocaine( sprays) and served as control group. The appropriate time of application of ice ranges from 2-5 minutes [16], in the present study the application was done for 3 minutes. Thus in the present study patients who needed bilateral infiltration for extraction randomly received topical anesthesia on one side prior to injection and topical anesthesia and pre cooling with ice cubes for 3 min prior to injection. The dental extractions with and without pre cooling were performed in different appointments. A strict sterilization protocol was followed during the intervention procedure,

## Outcomes

The study assessed the effect of pre cooling the injection site on pain perception in patients which was based on the patient's rating to Visual Analog scale like Heft-Parker and objective assessment by Sound. Eye and Motor scale after the interventions. In the first appointment patients were intervened with Lidocaine spray and pre cooling with ice before injection and in the subsequent appointment the other half of the same patient was intervened with Lidocaine spray prior to injection for infiltration, allocation of appointments was randomly done for different patients, some of them received pre cooling first while the others received only Lidocaine prior. Their response to pain was noted by asking them to point about how much pain they felt during the injection procedure using heft parker visual analog scale (scale 1) and objectively assessing the pain using SEM scale (scale 2). The Heft Parker Visual Analog Scale is a pre tested analog scale that has range from 0 -170 mm with intervals at 0, 23, 36, 54, 85, 114, 144 and 170 mm coinciding with faint, weak, mild, moderate, string, intense and maximum possible pain. The objective assessment was done by SEM scale which has score ranging from comfort to severe discomfort based on Sounds, Eye and Motor parameters which were assessed during the time of injection of site. Patient's enrollment, allocation and analysis is shown in figure 1.

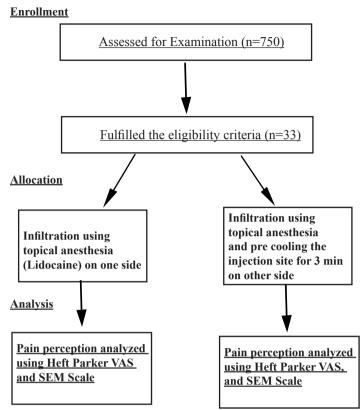


Figure 1. Enrollment, allocation and analysis of study patients.

#### Sample size

Sample size estimation is based on pilot study which was conducted in a total of 10 patients fulfilling the same eligibility criteria whose results are not included in study. The event rate obtained from pilot study in interventional and control group signified a sample size of 26. The sample size was further evaluated by G power Analysis and after evaluation for compensation for losses due to attrition the present study is based on 33 patients who fulfilled the eligibility criteria.

### Statistical methods

Data collected was entered in Excel and was analyzed to determine the normality of distribution by Kolmogrov- Smirnov test and Shapiro Wick Test using SPSS version19.0.Mann Whitney U test and Wilcoxon Rank Sum test were employed to determine the association between the variables. P value < .05 was considered statistically significant. For analysis purpose the variable age group was dichotomized into 60 years or less and more than 60 years. Socio- Economic status into Class1, 2 and 3, 4 and mobility into Grade 1, 2 and 3, root stumps. The variables Past Medical History, TMJ dysfunction, smoking, smokeless tobacco and alcohol consumption habit were categorized into present and absent, whereas other variables like Gender, Chief Complaint, Area of Chief Complaint, Region, were subsequently categorized into Male/Female, Loosening/Decay, Maxilla /Mandible and Anterior/ Posterior. The scores of Heft Parker VAS

were coded as 0, 1, 2, 3, 4, 5, 6, 7 respectively coinciding with the scores of 0, 23, 36, 54, 85, 114, 144, 170 mm of the scale. Similarly the scores of SEM scale were coded 0, 1, 2, 3 coinciding with the grades of comfort, mild, moderate and severe discomfort.

### Results

Table I shows the details of the structured proforma inclusive of the demographic factors and risk factors that influence pain perception, the majority of patients belonged to age group 31-60 years. Almost three fourths of the participants were male. Most of the participants belonged to Class II Socio- Economic Status. More than half of patients resided in urban areas and complained of loose teeth. Most participants reported an absence of past medical history, TMJ dysfunction, smoking, smokeless tobacco and alcohol intake. The mandible was the area of chief complaint in two thirds of the participants. The posterior region was more commonly affected than the anterior region. There were more patients with extraction of root stumps patients with mobile teeth. There was a significant difference in pain perception between control and intervention group as assessed using both Heft-Parker Visual Analog Scale and SEM scale (p value < .001) (Table II) (Figure 2). There was a statistically significant difference (p = .02) in pain perception after pre-cooling using Heft Parker Visual Analog Scale between participants with and without medical history. Similarly after pre-cooling patients with posterior region involvement perceived less pain as compared to those who had anterior involvement and the difference was statistically significant (p=.048). For both

Table I. Socio-demographic	characteristics	of patients (N=33).
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Age of participants	(·······
Age in years	Number (%)
0 to 30 years	5 (15.2)
31 to 60 years	20 (60.6)
Over 60 years	8 (24.2)
Gender of participants	
Male	24 (72.7)
Female	9 (27.3)
Socio-economic status of participants	
Class 1	2 (6.1)
Class 2	12 (36.4)
Class 3	8 (24.2)
Class 4	11 (33.3)
Residence of participants	
Urban	18 (54.5)
Rural	15 (45.5)
Chief complaints	
Loosening of teeth	18 (54.5)
Decay of teeth	15 (45.5)
Past medical history	
Present	2 (6.1)
Absent	31 (93.9)
Area of chief complaints	
Maxilla	11 (33.3)
Mandible	22 (66.7)
Region affected	
Anterior	12 (36.4)
Posterior	21 (63.6)
Mobility of teeth	
Grade 1	2 (6.1)
Grade 2	7 (21.2)
Grade 3	11 (33.3)
Root stumps	13 (39.4)
TMJ dysfunction	
Present	1 (3.0)
Absent	32 (97.0)
Alcohol intake	
Present	1 (3.0)
Absent	32 (97.0)
Smokeless tobacco intake	
Present	8 (24.2)
Absent	25 (75.8)
Smoking	
Present	6 (18.2)
Absent	27 (81.8)

the scales the assessed and self reported variables Gender, Location, Chief Complaint, Region and Arch were found to be statistically significant with a higher pain perception in the control group than the intervention group. (Table III and IV).

SCALES	CONTROL GROUP N=33 Median (Inter- quartile range) score	INTERVENTION GROUP N=33 Median (Inter- quartile range) score	P-VALUE
Heft Parker Visual Analog Scale	3.0 (2.0-3.0)	1.0 (0.0-1.0)	<0.001*
SEM Scale	2.0 (1.5-2.0)	0.0 (0.0-1.0)	<0.001*
*P value < 0.05			

3 2.5 Scale 1 Control 2 Scale 1 1.5 Intervention 1 Scale 2 Control 0.5 0 Scale 2 0 Intervention Intervention Intervention Control Control

**Figure 2.** Showing the difference in median scores as assessed using Heft Parker Visual Analog Scale (Scale1) and SEM Scale (Scale 2)

 Table III. Comparison of pain perception scores according to the scale 1 using pre cooling and without pre-cooling effect.

Variables	Categories (N=33)	Control (Mean+ S.D)	Intervention (Mean+ S.D)	P value
	Male	2.33+1.28	.81+.60	.001
Gender	Female	2.44+1.23	.67+.35	.014
	Urban	2.83+.98	.67+.53	.001
Location	Rural	2.60+1.4	.73+.50	.001
Chief	Loosening	3.00+.97	.94+.60	.001
Complaint	Decay	2.40+1.40	.50+.40	.001
	Anterior	3.08+1.08	1.17+.54	.003
Region	Posterior	2.52+1.20	.43+.22	.001
	Maxilla	3.18+.87	.91+.61	.003
Arch	Mandible	2.50+1.34	.59+.39	.001
*P value < 0.05				

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Variables	Categories (N=33)	Control (Mean+ S.D)	Intervention (Mean+ S.D)	P value
Gender	Male	2.43+.65	.47+.58	.001
	Female	1.78+.97	.44+.23	.016
Location	Urban	1.89+.58	.44+.62	.000
Location	Rural	2.34+.93	.43+.23	.001
Chief Complaint	Loosening	3.00+.97	.94+.27	.001
	Decay	2.40+.40	.40+.50	.002
Region	Anterior	1.92+.79	.67+.49	.004
	Posterior	1.95+.74	.69+.58	.001
Arch	Maxilla	2.27+.46	.65+.52	.002
	Mandible	1.77+.81	.41+.17	.001

**Table IV.** Comparison of pain perception scores according to the scale 2 using pre cooling and without pre-cooling effect.

\*P value < 0.05

#### Discussion

In the present study 33 patients who needed bilateral buccal infiltration for extraction of teeth were examined. Participants received bilateral topical anesthesia of Lidocaine and in addition the injection site was pre cooled using ice for 3 minutes on one side. The study design was a split mouth interventional study and apart from being the same participant they were matched for region, mobility and arch. The results of the present study indicate a significant difference in pain perception when the injection site was pre cooled as compared to the site which only received topical anesthesia. Patients expressed and assessed lower pain perception in the site that was pre cooled prior to injection compared to the other. The results of the present study are in line with the study conducted by Faezeh Ghaderi [14] who investigated pain perception in 50 healthy pediatric patients and reported that cooling the injection site before infiltration of local anesthetics in the buccal mucosa for 1 min, reduced pain perceived by pediatric patients. The results of the present study also correspond with the study carried out on cooling the skin prior to surgery of inguinal hernias. Chan et al. [13] used a laser system with a cooling device to treat 37 patients with nevus of Ota removal. They reported that cooling the site of injection resulted in less pain perception by their patients. However, the difference was not statistically significant and they did not specify the objective criteria used to evaluate pain. Furthermore, Kuwahara and Skinner [17] and Goel et al. [12] in different studies, reported reduction in pain perception by application of ice on injection site. The results of the present study also support the results reported by Harbert [18], who applied ice to reduce pain perception associated with palatal injections. The results of the present study are in accordance with the findings obtained by the study of Kosaraju et al. [19], but, their evaluation were not elaborated on an objective scale. That is difficult to evaluate a feeling such as pain

perception precisely just using the subjective scale (VAS) for assessment. Aminabadi et al. [20], reported the efficacy of 2-min application of ice prior to infra-alveolar nerve block injection in decreasing perception of pain. The finding would have been more reliable if each single subject has been considered to be as a case and control simultaneously. A number of theories have been put forward to explain the mechanism of effect of injuries and induction of analgesia at a local level, which include decreasing tissue metabolic rate and vasoconstriction leading to a decrease in the inflow of inflammatory mediators and a decrease in edema. This might explain the successful application of topical cooling to reduce bruising, bleeding, and edema in sports injuries and after orthopedic surgeries. Local cooling is also believed to slow or eliminate pain signal transmission and to retard neuromuscular transmission. In addition, cooling muscle tissue reduces its tone via a reduction in the activity of muscular spindles. Topical cold application stimulates myelinated A fibers, activating inhibitory pain pathways, which in turn raises pain threshold. Cold has also been demonstrated to work at the spinal level to inhibit stretch reflex and reduce muscle spasm. The results of the present study support the idea that topical cooling amplifies pain threshold to stimuli such as needle stick during local anesthetic injection and helps patient management during dental procedures. For both the scales the assessed and self reported variables Gender, Location, Chief Complaint, Region and Arch were found to be statistically significant with a higher pain perception in control group than the intervention group The results of the present study are in line with previous studies which have also shown that pain perception was positively influenced by female gender, rural place of residence, younger age of patient [21]. The present study has some limitations too, firstly as the present study was carried out in a dental camp which is flooded with patients and the manpower constraint prevented us to carry out blinding procedure. Hence the principal investigator himself assessed pain perception which might have created bias in reporting of scales. Secondly, in order to ensure comparability a strict eligibility criteria was followed which restrained the investigator from randomization. The results of the present study can be generalized with caution, due to limitations and smaller sample size although the patients included belonged to all age groups. However, the association between risk factors and pain perception should be further examined and noted due to the limited sample size of the present study.

### Conclusion

Based on the present study it can be concluded that pre cooling the site for 3 minutes reduced pain perception during injection. The intervention of pre-cooling the injection site before local anesthesia can serve as effective, inexpensive and reliable methods in alleviating pain especially in patients with fear and anxiety during dental procedures. This is in particular helpful in patients of dental camps where we have limited knowledge about the past history of patients.

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