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EFFECT OF PRE-WARMING OF LOCAL ANESTHESIA ON REDUCING PAIN PERCEPTION DURING INJECTION IN CHILDREN: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

INTRODUCTION: Local Anesthetic (LA) administration is crucial to maintain pediatric patients' cooperation. A promising modality to decrease pain during injection is to Pre-warm the LA solution.

OBJECTIVES: The main study objective is to evaluate the effectiveness of Pre-warming of LA solution to body temperature (37°C) and (40°C) in pain perception during injection in contrast to LA at Room Temperature (RT). The study also aims at evaluating if pre-warming would yield better results when used during Maxillary Infiltration (MI) versus Inferior Alveolar Nerve Block (IANB) techniques.

MATERIALS AND METHODS: The study was a triple blinded randomized controlled clinical trial (RCT) that included 72 children 5-7 years old having at least one primary molar requiring dental treatment. Participants were randomly allocated to three groups according to the temperature of LA; Group I (Control) received LA at RT, Group II received LA pre-warmed to 37°C and Group III received LA pre-warmed to 40°C. Each group was further sub-divided into two sub-groups; (A) and (B) according to the required injection technique. Subgroup (A) received MI and Subgroup (B) received IANB. Pain perception was evaluated physiologically, objectively and subjectively using Heart Rate (HR), Sound, Eye, Motor (SEM) scale and a Maunuksela modified face pain scale (FPS), respectively. All Normality was first tested for all quantitative variables using descriptive statistics, plots (Q-Q and boxplots), and normality tests. All variables showed normal distribution, so means and standard deviation (SD) were calculated and parametric tests were used. Two-way ANOVA was performed to assess the influence of groups and subgroups on HR and SEM scores. Adjusted means, standard error (SE), and 95% confidence intervals (CI)s were calculated. Meanwhile, comparisons of ordinal variables (FACES scale) were performed using Kruskal Wallis H test (between main groups), and Mann-Whitney U test (between subgroups). Significance level was set at p-value <0.05. Data were analyzed using IBM SPSS for Windows (Version 26.0).

RESULTS: 72 children; 35 boys and 37 girls, participated in the study. Pre-warmed groups experienced significantly less pain manifested as significantly lower HR (P=0.04) and SEM (P=0.03) scores compared to RT group. Adjusted mean (SE) for group I, group II and group III regarding HR was 112.79 (2.93), 102.33 (2.93) and 107.19 (2.93) respectively, and regarding SEM was 5.08 (0.34), 3.88 (0.34) and 3.96 (0.34) respectively. There was no significant difference in FPS scores between the three study groups (P>0.05). There was no significant difference between results of MI and IANB sub-groups.

CONCLUSION: Pre-warming of LA provided significantly lower pain perception during LA injection in children compared to LA at RT according to physiologic and objective testing methods.

KEYWORDS: Pre-Warming, Local Anesthesia, Pain, Articaine, Maxillary Infiltration, Inferior Alveolar Nerve Block.

RUNNING TITLE: Local Anesthetic pre-warming effect on child pain perception.

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INTRODUCTION

In Pediatric Dentistry, successful behavior guidance is critical towards obtaining cooperation of young patients (1). Together with Tell, Show and Do, Modeling and Desensitization, a fundamental step is

successful administration of LA to ensure a pain free visit (2).

According to a study performed by Vika and Skaret in 2008 (3), it was found that children's anxiety towards dental visits was attributed mainly to the LA administration procedure rather than the treatment itself, leading the child to refuse the treatment altogether.

Therefore, pediatric dentists have long searched for methods to achieve the goal of a painless LA injection technique. Such methods are operator controlled like decreasing the injection speed and tissue compression before the injection. Other methods are instrumental and include application of topical anesthetics, using computer-controlled methods like the Wand, intraligamentary injections, using buffered anesthetic solutions, using vibratory devices like Dental Vibe, cooling the injection area and warming of the LA prior to injection (4-11).

In 1967, Boggia was the first to describe in literature the technique of pre-warming of LA cartridges (12). It was proposed as a method of decreasing pain during solution injection. In 2011, Hogan et al. performed a systematic review on dermal and subcutaneous injections. It was noted that during the study, pain reaction decreased when cartridges were pre-warmed prior to injection. Due to that observation, the authors recommended trying that method in dentistry as well (13). These same findings were also observed in plastic and ophthalmic surgeries (14-16).

The exact mechanism of action behind that theory is unclear. However, several possible mechanisms have been described in literature. The first theory is that nerve endings are sensitive to cold stimuli, and hence a warm solution would lead to less stimulation and therefore less pain sensation. A warm solution would also increase the rate of nerve block onset and thus prevents the propagation of pain signals before the nociceptive stimulus is entirely expressed and appreciated (17). Another theory is related to the dissociation constant (pKa) of the LA. The pKa values are inversely related to temperature; the warmer the LA solution, the less the pKa value would become. This leads to more active deionized form of the solution to penetrate through the nerve membrane, leading to rapid expression of the anesthetic action and also less pain during injection (18). According to Powell, pKa of lignocaine is 7.57 at 40°C and 7.92 at 25°C. Therefore, warming of lignocaine would lead to faster onset and higher quality of anesthesia (19). Defrin reported that thermal pain threshold was above 42.1°C and below 27.6°C in cutaneous sensation (20). According to these findings, Yang et al reported that temperatures within this range would induce less degree of pain (21). Although the thermal pain threshold of intraoral tissues is not stated clearly in the literature, this could serve as an additional explanation to why warmer injections would decrease the pain sensation.

Various studies have been conducted to evaluate the efficacy of that method in lowering injection pain for pediatric patients receiving dental treatment (5, 22, 23). However, they were limited to using that technique only during MI or IANB Techniques or pre-warming to a single temperature. To the best of our knowledge, no controlled clinical trials could be secured that attempted observing whether this technique achieves best results when used in MI in comparison to IANB or attempted pre-warming to different temperatures and comparing pain perception in each of them.

Therefore, as part of the endless endeavor of achieving a painless injection technique for our young patients, the aim of this study is to compare the difference in pain perception between using un-warmed LA solution in contrast to pre-warming the LA to different temperatures during MI and IANB techniques in children.

The null hypothesis for this study is that there will be no significant difference in pain perception of children during injection of room temperature LA solution in comparison to pre-warmed LA solution.

MATERIALS AND METHODS

The study in hand was a triple blinded randomized controlled clinical trial that was performed in Pediatric Dentistry Department in the Faculty of Dentistry, Alexandria University, Alexandria, Egypt. The study protocol was approved by the Research Ethics Committee of Faculty of Dentistry, Alexandria University, Egypt (IRB No. 001056 - IORG 0008839). All research activities abided by the Declaration of Helsinki and other ethical guidelines adopted by the Research Ethics Committee of Alexandria University Faculty of Dentistry. The research protocol was registered on ClinicalTrials.gov with ID number NCT06519838.

Sample size estimation

Sample size was estimated assuming 80% study power and 5% alpha error. Kurien et al. (5) reported mean (SD) Sound, Eye, Motor scores after using pre-warmed and room temperature anesthesia solutions, which were used to calculate mean (SD) SEM scores**.** Aravena et al. (22) reported mean (SD) pain level using visual analogue scale= 15.0 (14.67) and 35.3 (16.71) when 42°C warmed and room temperature solutions were used, respectively. The minimum sample size was calculated to be 11 per group, increased to 12 to make up for procedural problems. The total required sample size= number of groups × number per group= 6 × 12= 72 patients (24).

Inclusion criteria

Participants chosen for the study were 5-7-year-old patients having at least one carious primary molar requiring dental treatment under the effect of LA. Patients must be healthy with ASA 1 or 2 Classification (25) and with Frankl Classification 3-

4 (26). Informed consent was obtained from all patients' legal guardians prior to participation.

Exclusion criteria

Patients excluded from participation in the study were those having previous negative dental experience, patients complaining of cellulitis or infection spreading in the fascial spaces, patients who have received analgesics within the previous 12 hours before receiving the required dental treatment, patients with any Intellectual Impairment and patients with a history of allergy from any of the components of the dental anesthetic carpule (5).

Study design

The setup, design and reporting were carried out according to CONSORT guidelines (27). Patients who fulfill the inclusion criteria were assigned randomly (28) using a computer generated list of random numbers to one of the three arms of the study (Figure 1); Group I (n= 24) was a Control Group receiving LA solution at RT, Group II (n= 24) was a Test Group receiving LA solution pre-warmed to 37^0C and Group III (n= 24) was a Test Group receiving LA solution pre-warmed to 40^0C. Each of the three groups was further subdivided into 2 subgroups; A and B, Sub-group (A) received MI and Sub-group (B) received (IANB).

Blinding

The Dentist administering the LA (Researcher) was blinded to the temperature of the LA solution being administered. The research supervisor was also blinded to the groups to which every participant belongs. The participants were also blinded to the temperature of the LA they received.

Allocation Concealment

Each patient participating in the study was assigned a serial number which was used in his/her allocation. These numbers were written in similar sheets of paper with the group to which each child is assigned and placed inside opaque envelopes containing the respective names of the patients. An individual independent of the study was assigned the role of securing the envelopes and opening them only at the time of the session so that the group to which the patient is assigned is concealed from the outcome evaluator.

Technique used to pre-warm Local Anesthesia

A baby bottle warmer (Phillips Avent®, Amsterdam, Netherlands Model SCF 355) was chosen to pre-warm the LA. The researcher carried out a trial using 10 LA carpules to determine how to use the baby bottle warmer to achieve the required temperatures. One hundred and fifty ml of water at (21^0C) was added to the heating compartment of the device. The LA cartridge was placed at the bottom of the heating compartment. The device was plugged in and the control gauge was set at the "Express milk warming setting for contents up to 180ml/6oz" mark. Results of the trials showed that the contents would reach 37^0C and 40^0C after 120 and 130 seconds respectively.

Examiner reliabilty and caliberation

An experienced Dental Assistant received training followed by intra-examiner reliability test in how to use a Pulse Oximeter to record heart rate and was responsible for recording the baseline HR and HR after the injection. The dental assistant was also responsible for using the baby bottle warmer to pre-warm the LA to the designated temperatures, assembling the LA syringe and handing it to the dentist. The research dentist carrying out the patients' treatment was responsible for recording the patient's answer to a face scale (29) modified from the Maunuksela et al scale (30). An impartial, blinded research supervisor was responsible for interpreting the results for the SEM scale (31) through watching recorded videos of the procedure and underwent intra-examiner reliability testing to insure an acceptable degree of reliability. Intraclass correlation Coefficient (ICC) (32) for the S, E, M and total SEM scores was calculated, ranging from 0.84 to 0.92, indicating excellent reliability.

Study outcomes

Pain perception was assessed throughout the study using the following three methods:

A. Physiologic method

Heart rate (HR) was used as a physiological indicator of pain (33). A pulse oximeter was used to record and measure the patient's heart rate. A baseline reading was obtained before the LA administration and another reading was obtained directly after the injection was carried out.

B. Objective method

Sound, Eye, Motor (SEM) Scale (31) was used as an objective method to assess pain during LA administration. It comprises the following parameters: Sound, Eye and Bodily movements. These were independently assessed by an impartial, blinded research supervisor through watching recorded videos of the procedure. The slightest changes in the sound, eye movement and bodily movement of the patient were categorized as one of the following levels; comfortable, mild, moderate, and severe discomfort and hence given a grade of 1, 2, 3 or 4 respectively. The final SEM score was calculated by adding the grades of the three parameters.

C. Subjective method

To assess pain subjectively during LA administration, a modified face scale (29) from the Maunuksela et al scale (30) was used. It consists of three schematic faces with different facial expressions for happy and sad faces representing: Satisfaction, Indifference or Dissatisfaction. Each patient was trained on using the scale by modelling and then requested to think of the last time she/he went through a painful experience and to choose the facial expression that best relates his/her current experience of discomfort to the previous one.

Statistical analysis

All data was collected; descriptive quantitative values were summarized using mean and standard

deviation, while count and percentage were used for qualitative values. The data was represented by suitable tables and graphs. Comparing between normally distributed data occurred using T- and Paired T-tests, while for not – normally distributed data, Wilcoxon signed-rank and Mann-Whitney U tests were used. All statistical analyses were performed with statistical Package for Social Sciences (SPSS) software version 25 (SPSS Inc., Version 25.0, Chicago, IL, USA). The significance level was set at P <0.05.

RESULTS

Demographic characteristics of the study groups

Table (1) shows the demographic characteristics of the study groups. The study included 35 boys and 37 girls, with a mean age of 6.24 ± 0.78 years. No significant difference was detected between the study groups in age and sex, neither in MI subgroup (p=0.10 and 0.89) nor in IANB subgroup (p=0.40 and 0.64).

Results of pain assessment using heart rate

Table (2) shows Two-way ANOVA with repeated measures to assess the influence of group and subgroup on the HR. The highest adjusted mean (SE) was recorded in the room temperature group (112.79, SE=2.93) with a 95% CI of 106.94 to 118.65. On the other hand, 37^{0}C group had the lowest adjusted mean (102.33, SE=2.93) with a CI ranging from 96.48 to 108.19. These were statistically significant when compared to room temperature (p=0.04). The 40^{0}C group had an average adjusted mean (107.19, SE=2.93) and a CI of 101.33-113.04.

When comparing between both sub-groups, MI and IANB had comparable means (108.43 and 106.44 respectively) and confidence intervals that are overlapping, which indicates non-statistically significant difference (p=0.56).

Results of pain assessment using SEM score

Table (2) shows results for Two-way ANOVA test used to assess the influence of group and subgroup on the SEM score. Room temperature group exhibited the highest adjusted mean (5.08, SE=0.34, CI ranging from 4.41 to 5.76). Both 37^{0}C and 40^{0}C groups had significantly lower means (3.88, SE=0.34 and 3.96, SE=0.34 respectively) and non-overlapping CIs with the room temperature group, which suggests a statistically significant difference (p=0.03).

The sub-group analysis showed similar adjusted means between MI and IANB sub-groups (4.25, SE=0.28 and 4.34, SE=0.28 respectively) and the CIs greatly overlapped, which indicates non-significant difference (p=0.77).

The previous analysis regarding HR and SEM indicate that pre-warming to 37^{0}C and 40^{0}C had a significant impact on lowering SEM and HR scores in comparison to room temperature. However, sub-group analysis was statistically non-significant.

Results of pain assessment using modified face scale

Table (3) shows results for comparisons of Face scale between the study groups. In MI sub-group, differences between the three study groups was non-significant (p=0.18). Differences were also non-significant in IANB sub-group (p=0.09).

When comparing between both sub-groups within each temperature group, p values for RT, 37^{0}C and 40^{0}C groups were 0.63, 0.51 and 0.51 respectively, indicating non-significant difference between both sub-groups. Figure (2) shows faces scale results in the three study groups.

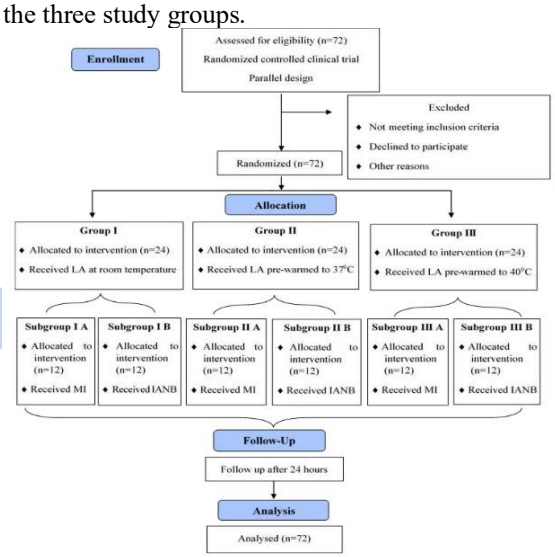

Figure (1): Study plan flowchart

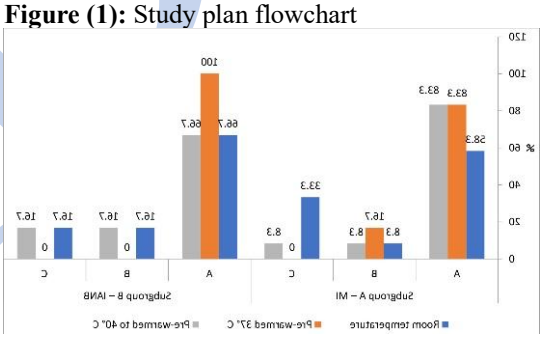

Figure (2): FACES scale in the three study groups.

Table (1): Demographic characteristics of the study groups

Sub group			Room temperature	Pre-warmed 37° C	Pre-warmed to 40° C	P value
MI	Age: mean (SD)		6.08 (0.90)	6.67 (0.65)	5.92 (0.79)	0.10
	Gender: n (%)	Male	6 (50%)	**5 (41.7%)**	**5 (41.7%)**	0.89
		Female	6 (50%)	**7 (58.3%)**	**7 (58.3%)**	
IANB	Age: mean (SD)		6.08 (0.90)	**5.92 (0.79)**	**6.75 (0.62)**	0.40
	Gender: n (%)	Male	7 (58.3%)	**7 (58.3%)**	**5 (41.7%)**	0.64

		Female	5 (41.7%)	**5 (41.7%)**	**7 (58.3%)**	

Table (2): Two-way ANOVA with repeated measures to assess the influence of group and subgroup on the HR and SEM score

Factor			**Adjusted mean (SE)**	**95% CI**	**P value**
HR	**Group**	**Room temperature**	112.79 (2.93) **a**	106.94, 118.65	**0.04***
		Pre-warmed 37° C	102.33 (2.93) **b**	96.48, 108.19	
		Pre-warmed to 40° C	107.19 (2.93) **ab**	101.33, 113.04	
	Subgroup	**MI**	108.43 (2.39)	103.65, 113.21	0.56
		IANB	106.44 (2.39)	101.66, 111.23	
SEM score	**Group**	**Room temperature**	5.08 (0.34) **a**	4.41, 5.76	**0.03***
		Pre-warmed 37° C	3.88 (0.34) **b**	3.19, 4.55	
		Pre-warmed to 40° C	3.96 (0.34) **b**	3.28, 4.64	
	Subgroup	**MI**	4.25 (0.28)	3.70, 4.80	0.77
		IANB	4.34 (0.28)	3.81, 4.91	

SE: Standard Error, CI: Confidence interval
HR values were adjusted to different Timepoints
Model F= 425.97, p <0.001*
HR: P value of interaction group*subgroup= 0.82
SEM score: P value of interaction group*subgroup= 0.93
*statistically significant at p-value <0.05

Table (3): Comparisons of FACES scale between the study groups

		Room temperature	**Pre-warmed 37° C**	**Pre-warmed to 40° C**	**P value 1**
		N (%)			
MI	**A**	7 (58.3%)	10 (83.3%)	10 (83.3%)	0.18
	B	1 (8.3%)	2 (16.7%)	1 (8.3%)	
	C	4 (33.3%)	0 (0%)	1 (8.3%)	
IANB	**A**	8 (66.7%)	12 (100%)	8 (66.7%)	0.09
	B	2 (16.7%)	0 (0%)	2 (16.7%)	
	C	2 (16.7%)	0 (0%)	2 (16.7%)	
P value 2		0.63	0.51	0.51	

P value 1: Kruskal Wallis H test was used
P value 2: Mann-Whitney U test was used

DISCUSSION

Pediatric dentists have long used different techniques to achieve the goal of a less painful LA injection procedure for their young patients. These techniques have ranged from decreasing injection speed and using topical anesthetics, to using buffered LA solutions and computer-controlled devices such as the Wand. The study in hand aims to evaluate the effectiveness of yet another promising modality to achieve that goal; Pre-warming of the LA solution to lower pain perception during injection in children.

In this study, a baby bottle warmer (Phillips Avent®, Amsterdam, Netherlands) was used to pre-warm LA to the desired temperatures. This method of pre-warming was successfully used in previous researches (6,13,22). Study took place in the months April to June when normal room temperatures ranged from 25^0C to 31^0C. Air conditioners were used to keep room temperature at 23^0C.

Although it is recommended to keep local anesthetic cartridges at room temperature according to the manufacturer's instruction, there are reports indicating that local anesthetics can withstand autoclave sterilization (34) and that epinepherine can tolerate temperatures reaching 51.7^0C without molecular degradation (35).

A parallel study design was preferred over a split mouth design for this study due to several reasons. One of the major drawbacks of Split mouth design is needle anticipation by the child during the second visit which would act as a confounding factor. Another drawback of split mouth design is recall bias where patients would fail to show up for a subsequent visit. To overcome any inter-operator variations, the same operator carried out all injection procedures and the subsequently needed dental treatments (24).

In this study, LA solution was pre-warmed to two different temperatures; 37^0C and 40^0C. Gümüş H. et al. pre-warmed LA to 37^0C and compared it to LA at room temperature (RT) (23). In other studies, the researchers pre-warmed LA to either 41^0C (5) or 42^0C (22) and compared them to LA at RT. None of the aforementioned studies attempted pre-warming to different temperatures and comparing them to each other alongside the comparison with LA at RT. This was therefore attempted in our study; where LA was pre-warmed to 37^0C and 40^0C, to determine if pre-warming to temperatures higher than body temperature would yield less pain perception during injection. Moreover, this study compares this technique when used in Maxillary Infiltration (MI) versus Inferior alveolar nerve block (IANB). IANB is considered to be one of the most painful injections experienced by dental patients (36). According to Sharaf, Block anesthesia was significantly more painful than buccal infiltration anesthesia, and behavior of children 3-5 years old sometimes turned negative following the block injection (37). This was also concluded from the study conducted by Aditya et

al., which included participants of a higher mean age of 16 years (38). Therefore, to give a more comprehensive outcome to evaluate the pre-warming technique, it was considered beneficial to utilize different temperatures and also compare the effect of pre-warming when used during MI versus IANB.

Since pre-school children can't give an accurate description and precise indication to the pain level they're experiencing, three different methods have been selected in this study to measure pain reaction, namely Heart Rate (Physiologic method) (33), SEM scale (Objective method) (31) and Face scale (Subjective method) (29). These methods have been used in previous studies as pain indicators. However, they have been very rarely combined altogether in one study to evaluate LA injection pain.

Results of this study indicate that pre-warming to 37^0C or 40^0C yielded positive clinical effects regarding HR and SEM scores. Lower HR values and lower SEM scores were recorded in pre-warmed groups in comparison to RT group and results were statistically significant. There was no difference in Face scale scores either clinically or statistically between the three study groups. Moreover, no statistically significant difference was found between 37^0C and 40^0C groups, indicating that variations in the degree of pre-warming did not have an effect on pain reaction. There was also no statistically significant difference between MI and IANB scores, indicating that pre-warming is equally effective in both injection techniques.

Heart rate and SEM score results in this study come in accordance with various other studies. Kurien et al. (5) reported significantly lower SEM scores in their study which included 60 patients aged 6-12 years. Lower SEM scores were also reported by Hassan et al. in their study which included 80 children aged 6-12 years (39). Gumus et al. (23) also reported significantly lower Face, Legs, Activity, Cry and Consolabilty (FLACC) and HR scores in their study which included 100 children aged 5-8 years requiring MI injections for their dental procedures.

Various explanations can be offered to why pre-warmed LA solution is less painful during injection than that at RT. Nerve endings are more sensitive to cold stimulations than warm ones, thus a warmer LA solution would stimulate nerve endings to a lesser degree than a cooler one. A warm solution would also increase the rate of onset of the block and thus prevents the propagation of pain signals before the nociceptive stimulus is entirely expressed and appreciated (17). Moreover, warm LA solutions have lower pKa values and lead to an increase in membrane fluidity. This leads to more active deionized form of the solution to penetrate through the nerve membrane, leading to rapid expression of the anesthetic action and also less pain during solution injection (18). According to Powell, pKa of lignocaine is 7.57 at 40°C and 7.92 at 25°C. Therefore, warming of lignocaine would lead to faster onset and higher quality of anesthesia (19). Defrin reported that thermal pain threshold was above 42.1°C and below 27.6°C in cutaneous sensation (20). According to these findings, Yang et al reported that temperatures within this range would induce less degree of pain (21). Although the thermal pain threshold of intraoral tissues is not stated clearly in the literature, this could serve as an additional explanation to why warmer injections would decrease the pain sensation.

Faces pain scale results in this study come in agreement with those reported by Ram et al (6), who reported Non-significant Visual-Analog scale (VAS) results in their study which included 44 children aged 6-11 years. However, these results come in disagreement with those reported by Aravena et al. (22), who reported significantly different VAS scores in their study which included 72 patients aged 18-35 years. Significantly lower VAS scores were also reported by Hassan et al. in their study (39). Kurien et al. (5) and Gumus et al. (23) used the Wong Baker Face pain scale as their subjective method of measuring pain and reported significantly different results. The variations in outcomes reported when using subjective methods can be attributed to the different age groups. Older patients can better muster their emotions and report their feelings more accurately. Moreover, the researcher in the study at hand reported that patients tended to choose the smiling face in FPS, even though it was clear that they felt discomfort during the injection procedure. According to Beyer et al. (40), subjective pain indicators such as face scale are not the gold standard for measuring pain anymore and that objective methods such as SEM and HR are more reliable and consistent and are therefore more preferred.

Current study limitations include the need to include a wider age group than the one selected and a wider range of child cooperation degree to include also uncooperative children of Frankl scale 1 & 2. Another study limitation is the lack of thorough behavior assessment of children participating in the study.

Therefore, the null hypothesis of this study was partially rejected since significant difference in pain perception was only found in results of the HR and SEM but not in the results of the facial pain scale.

These study findings carry the advantages of providing evidence of efficacy of pre-warming technique in reducing injection pain perception. This would benefit as a valuable clinically applicable tool to make dental interventions more acceptable to young patients, and therefore increase their compliance and cooperation in a dental setting. However, possible adverse effects of using this technique is the possible degradation of molecular structure and thermal injury to patients if the

anesthetic solution is not closely monitored during warming and allowed to reach excessively high temperatures.

CONCLUSION

In conclusion, the study results indicate that pre-warming greatly decreased pain perception during injection when compared to LA at room temperature, with equal efficiency when used during MI and IANB injections.

These findings would encourage the usage of the pre-warming technique – which is easily achieved using different warming methods that can be found in all practices – as a modality to make the LA injection step a less stressful one for young patients.

CONFLICT OF INTEREST

There was no conflict of interest.

FUNDING STATEMENT

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