Pesquisa Brasileira em Odontopediatria e Clínica Integrada 2021; 21:e0132
https://doi.org/10.1590/pboci.2021.060
ISSN 1519-0501 / eISSN 1983-4632

ORIGINAL ARTICLE

Efficacy of Higher Gauged Needles or Topical Pre-Cooling for Pain Reduction during Local Anesthesia Injection: A Split-Mouth Randomized Trial

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Academic Editor: Alidianne Fábia Cabral Cavalcanti

Received: 15 June 2020 / **Review:** 04 December 2020 / **Accepted:** 07 January 2021

How to cite: Gadicherla S, Mahandwan M, Xuan SQY, Pentapati KC. Efficacy of higher gauged needles or topical pre-cooling for pain reduction during local anesthesia injection: a split-mouth randomized trial. Pesqui Bras Odontopediatria Clín Integr. 2021; 21:e0132. https://doi.org/10.1590/pboci.2021.060

ABSTRACT

Objective: To evaluate the efficacy of pre-cooling and the use of higher gauged needles in reducing pain during local anesthetic infiltration. **Material and Methods:** We conducted a split-mouth randomized controlled trial among 70 patients who require bilateral maxillary local anesthetic (LA) injections for dental treatment. After applying the topical anesthetic, each participant received four local anesthetic injections, two on buccal and two palatal sides. At each visit, the participants received one buccal and one palatal infiltration based on the randomization. On the buccal aspect, participants received LA with a 26G needle injection on one side (control) and a 31G needle (test) on the contralateral side. On the Palatal aspect, participants either received LA with a 31G needle on one side (control). In contrast, the opposite side was preceded by topical ice application (iced cotton swab) before LA with a 31G needle (test). Both the visits were spaced with a gap of 7-10 days based on the participants' feasibility. Participants were asked to rate the pain on a visual analog scale independently for buccal and palatal LA injections. **Results:** On the Buccal aspect, the mean pain scores were 2.74 ± 1.26 and 2.11 ± 1.26 for control and test groups, respectively (p=0.002). On the Palatal aspect, the mean pain scores were 4.14 ± 1.49 and 4.3 ± 1.80 for control and test groups, respectively (p=0.295). **Conclusion:** Significant lower pain scores were reported with higher gauge needles (31G) when compared to traditional (26G) needles on the buccal aspect. No significant difference was seen with pre-cooling the injection site on the palatal aspect when used with higher gauged needles (31G).

Keywords: Dental Anxiety; Pain; Local Anesthesia; Visual Analog Scale.

Introduction

The primary cause of fear and anxiety towards dental treatments is pain. It is a subjective feeling that arguably exists only in the individual that feels it. The International Association for the Study of Pain (IASP) defines it as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" [1]. Pain can be associated with the administration of local anesthesia (LA) or the dental treatment itself. The pain or discomfort related to chair-side treatments can be limited by LA injection, which itself can be a painful experience for the patient.

Pain is sensed through free nerve endings, nociceptors, which pick up painful stimuli and transmit them to the higher order. Depending on the type of stimulus, the afferent signals pass through either A-delta pain fibers or C-fibers. A-delta fibers are myelinated axons that convey sharp and momentary pain signals. For example, the pain perceived by the initial prick of the needle. C-fibers comprise of slow conducting, unmyelinated axons and are characterized by dull and diffuse pain [2]. They respond to thermal, chemical, and mechanical stimulation. For example, the pain felt while depositing the LA solution into the target site is caused by chemical irritation and distension of tissue space. The ultimate goal of dental practitioners is to reduce the painful experience related to LA's insertion and administration.

Adopting evidence-based techniques to reduce pain during LA administration is crucial for both patients and oral health care professionals. Previous research reported a variety of factors like the use of sharp needles [3], topical LA [4], higher gauge needles [3,5], warming the LA, altering the pH [6], a slower rate of administration [7], ice application at the target site [8,9], use of vibration for reduction of pain during administration of LA [10,11]. Higher gauge needles are thinner in diameter compared to lower gauge needles. The former stimulates fewer nociceptors when inserted into the tissue by creating a smaller puncture wound, thereby triggering less pain [12,13]. Pre-cooling the target tissue by use of ice causes a drop in the local tissue temperatures, slowing down the conduction of painful stimuli and making the LA administration a smoother experience.

Given the above factors, we aimed to evaluate two factors, pre-cooling with topical ice pressure and the use of higher gauge needles to reduce pain during LA administration. The study's first objective was the comparison of pain during maxillary buccal LA infiltration with traditional or higher gauge needles. The second objective was comparing pain during maxillary palatal LA infiltration with a higher gauge needle or higher gauge needle with pre-cooling the tissue.

Material and Methods

Study Design and Ethical Clearance

We conducted a split-mouth randomized, single-blind study among patients who required administration of LA infiltration. This study was conducted among the patients visiting oral and maxillofacial surgery at our center. The protocol was approved by the Kasturba hospital and Kasturba Medical College institutional ethics committee (IEC: 338/2019). The protocol was registered with the clinical trial registry of India (CTRI/2019/08/020545). Informed consent was obtained from all patients before the procedure. No changes were implemented to the protocol after the commencement of the trial.

Data Collection

Patients requiring bilateral maxillary posterior tooth extractions were included. Highly anxious patients, medically compromised, presence of severe periapical pathology were excluded. Highly anxious

patients were excluded based on one of the questions ("If you were about to have a local anaesthetic injection in your gum, above an upper back tooth, how would you feel") from the Modified Dental Anxiety scale. The sample size was calculated based on the previous study's estimates [3], which yielded an effect size of 0.4. At the power of 90% and an alpha value of 5%, a total of 61 was required, which was rounded to 70 subjects considering an attrition rate of 10%.

Consented and eligible patients were explained about the protocol. The patient was seated in the supine position with their mouth open. A topical lignocaine gel (Lox-2% Jelly, Neon Laboratories Ltd., Mumbai, India) was applied onto the proposed site of injection and left for 2 minutes before the injection of LA. Buccal infiltration of LA was administered either with disposable syringes housed with 26G 1.5-inch needle (Unolok, Hindustan Syringes and Medical Devices Ltd., India) (Control) or U-40 insulin disposable syringe with thin 31G 8 mm ultrashort needle (Dispovan, Hindustan Syringes and Medical Devices Ltd., India) (Test). Similarly, palatal infiltration LA injection was administered using U-40 insulin disposable syringe with a thin 31G 8mm ultrashort needle with (Test) or without topical pre-cooling of the tissue (Control). Topical pre-cooling of the tissue was done using iced cotton buds. Randomization of techniques was done using a coin toss method for buccal and palatal LA injections independently by one of the investigators.

Administration of the Local Anesthesia

The intervention was planned in two visits with a gap of 7-10 days based on the feasibility of the patient. At each visit, two infiltrations (one buccal and one palatal) based on the randomization. The buccal infiltrations were given at the approximate location of the apex of the tooth to be extracted. 1mL of the local anesthetic solution was deposited into the desired site. The infiltrations were given in the same manner for both the 26G conventional needle and syringe and the 31G insulin needle and syringe. The greater palatine nerve block was used for palatal LA. The landmarks for the greater palatine nerve block are the junction of the maxillary alveolar process and the palatine bone and the greater palatine foramen from which the greater palatine nerve traverses. The greater palatine foramen was located by running the index finger against the hard palate at the junction of the maxillary alveolar process, and the palatal bone distally until a depression in the tissue was felt. The needle was slowly advanced until the palatine bone was contacted. Aspiration was done, and if negative, 0.5mL of the local anesthetic solution was deposited to achieve a profound nerve block. The side which requires topical pre-cooling of the tissue, the process was similar except that the tip of the iced cotton bud was gently contacted onto the site of injection for a minute, and the topical local anesthetic solution was deposited in the same manner as described above. Universal precautions were followed throughout the process. A single trained clinician did the administration of LA for all the infiltrations.

Pain Assessment

The pain was assessed using the Visual Analogue Scale (VAS) for pain, which consisted of 1 to 10 rating with 1 being no pain and 10 being unbearable pain [14,15]. The patient was asked to circle or mark the most appropriate number depending on the degree of pain that they experienced during the administration of LA. The response for pain was recorded after 5 minutes after each injection by an evaluator unaware of the intervention. There was a significant gap between the recording of pain assessment and injection on buccal and palatal aspects.

Statistical Analysis

All the analysis was done using SPSS version 18. A p-value of <0.05 was considered statistically significant. Comparison of mean VAS scores was done using Paired t-test. The effect size was calculated by Cohens d for the paired test. Two-way repeated-measures ANOVA was conducted to simultaneously assess the effect of gender and experimental treatment. Two-way repeated-measures ANCOVA was conducted to assess the effect of age on pain.

Results

A total of 70 participants were enrolled, out of which more than half were females (58.6%) (Figure 1). Participants were enrolled from August to November 2019. All the participants enrolled had finished both interventions. The trial was stopped after the required sample size was achieved as per the protocol.

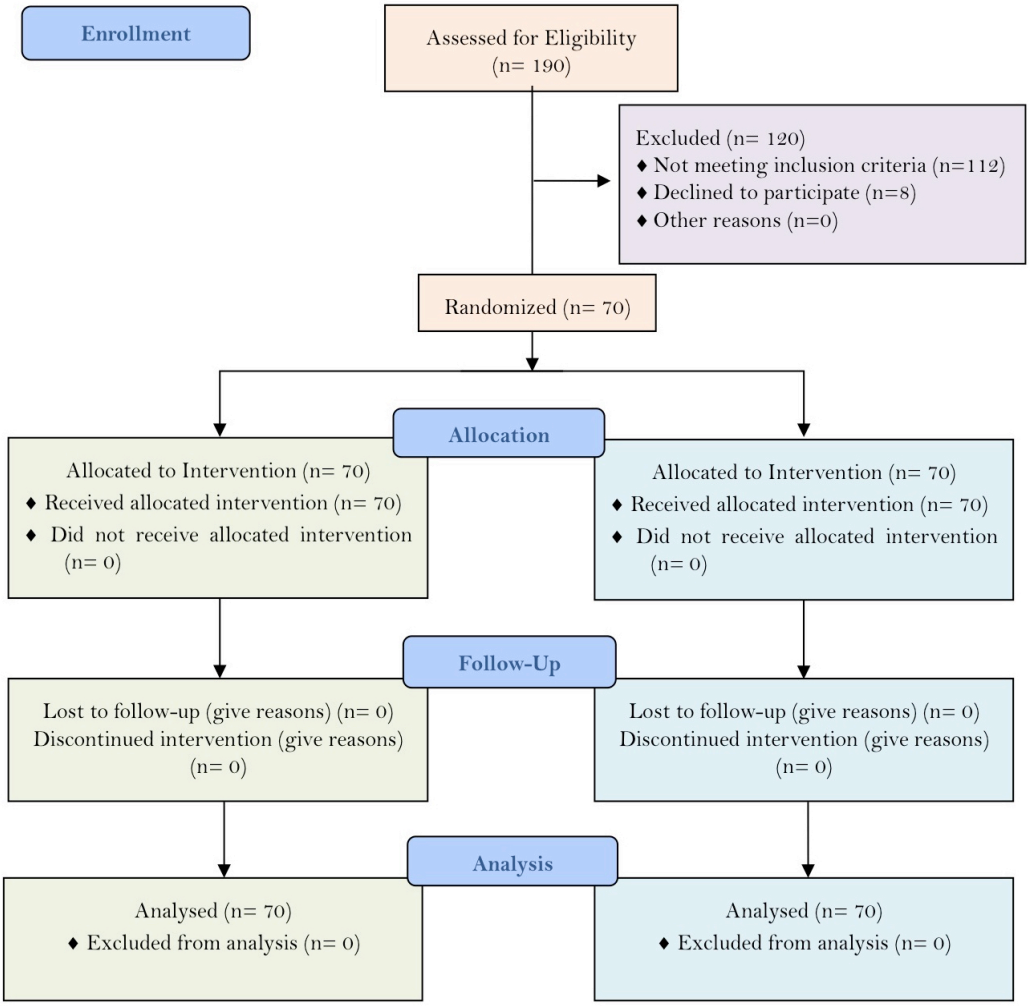

Figure 1. CONSORT 2010 Flow Diagram.

Regarding gender distribution, 41.4% were male and 58.6% were female. The mean age of the participants was 24.77 ± 8.65. Overall, it was seen that the test protocol was significantly less painful than the control protocol for buccal infiltration (p=0.002). No significant difference was seen between test and control techniques on the palatal aspect (p=0.295) (Table 1). VAS scores were categorized as mild (1-4), moderate (5-7), and severe (8-10). Comparison between test and control on buccal (p>0.99) and palatal (p=0.275) infiltration showed no significant difference (Table 2).

Table 1. Comparison of pain scores between test and control methods.

Location	Control	Test	p-value	Effect Size
	Mean (SD)	Mean (SD)		
Buccal	2.74 ± 1.26	2.11 ± 1.26	0.002	0.38
Palatal	4.14 ± 1.49	4.30 ± 1.80	0.295	0.13

Table 2. Distribution of pain severity scores.

Pain Scores	Buccal Control	Buccal Test	Palatal Control	Palatal Test
	N	N	N	N
No Pain	0	0	0	0
Mild	64	65	46	40
Moderate	6	5	23	28
Severe	0	0	1	2

Two-way repeated-measures ANOVA was conducted to assess the effect of gender and experimental treatment simultaneously. The model revealed a significant difference in the pain scores on the buccal side between the test and control (p=0.001). No significant interaction was seen with gender and pain score (p=0.15). A similar analysis was conducted on the palatal side. No significant difference in the mean pain scores on the palatal side between test and control was seen (0.33). No significant interaction was seen with gender and pain score (p=0.764).

Two-way repeated-measures ANCOVA was conducted to assess the effect of age on pain. The model revealed no significant difference in the pain scores on the buccal side between test and control (p=0.104), and no significant interaction was seen between age and pain score (p=0.524). A similar analysis was conducted on the palatal side. No significant difference in the mean pain scores on the palatal side between test and control was seen (0.51), and no significant interaction was seen between age and pain score (p=0.736). None of the participants reported any adverse effects.

Discussion

Our study evaluated the role of higher gauge needles in the reduction of pain during the administration of LA. Many studies have been reported on the concept of minimizing pain using higher gauge needles with substantial ambiguity in the findings. Our study showed that buccal LA injections with test methods were significantly less painful than the control method, similar to the previous studies [3]. A higher gauge needle is thinner in diameter, thus stimulating lesser nerve endings than the conventional needle. Previous studies showed no significant difference with different gauge sizes [16-18]. This difference could be due to variation in sample participants (dentists) [16], minimal difference in the comparison groups of needle gauge (25 *versus* 27) [18], differences in the self-reported pain assessment.

On the palatal side, we found that no significant difference was seen with or without topical pre-cooling of the tissue using higher gauge needles. The VAS score for most individuals was much higher on the palatal side than its buccal counterpart, although it was administered with higher gauge needles. The palatal mucosa is much more adherent to the underlying bone and allows very little room for tissue expansion during anesthetic solution administration. Although the use of pre-cooling was shown to be effective in reducing the pain using conventional needles [8,19-21], the reduction when used concomitantly with higher gauge needles was not statistically significant. Precooling the tissue was shown to be effective due to the decreased pain

receptor sensitivity, nerve firing threshold, slow down cellular metabolic rates, and synaptic activity. It also reduces blood flow and inflammation [22].

Clinicians could use higher gauge needles or pre-cooling of the tissue to reduce pain during palatal injections to administer LA. Similarly, higher gauge needles can be used to administer LA wherever feasible to reduce the pain during the administration of LA. However, pain is subjective and can vary with different population groups. Hence, any intervention that could reduce perceived pain can be adopted in clinical practice. The reduction of pain in our study was minimal, and it could be achieved with minimal alteration in the required armamentarium. Clinicians can implement these techniques when there is no access or availability of other methods.

The fact that palatal injections are painful, discouraged us from including a separate group using a conventional needle. On the other hand, the buccal vestibule is more accommodating for tissue expansion, leading to less pressure build-up and pain.

The strengths of this study include randomized split-mouth design and self-reported pain assessment. Overall assessment of pain rather than the differential assessment of pain related to needle penetration and LA deposition were some of the limitations. It is generally recommended that 1/3rd of the needle remains visible in order to remove the needle in case of needle breakage. However, with the use of ultrashort needles, it is not possible to implement such guidelines. Clinicians should be aware and cautious while using ultrashort needles for LA. There is a possibility of reduced incidence of medical emergencies secondary to the pain during LA's administration with the use of ultrashort needles. Future studies should also evaluate hemodynamic parameters and other proxy indicators to assess the pain and discomfort during the administration of LA.

Conclusion

Significant lower pain scores were reported with higher gauge needles (31G) when compared to traditional (26G) needles on the buccal aspect. No significant difference was seen with pre-cooling the injection site on the palatal aspect when used with higher gauged needles (31G).

Authors' Contributions

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All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.

Financial Support

None.

Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

Acknowledgements

We thank all the participants for their patience and co-operation during this research. We thank all the non-teaching staff of department of Oral Surgery for their help during the study.

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