Journal of Oral Research

ORIGINAL ARTICLE

Effect of warming anaesthetic solutions on pain during dental injection. A randomized clinical trial.

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Receipt: 09/08/2015 **Revised:** 09/23/2015
Acceptance: 10/08/2015 **Online:** 10/08/2015

Abstract: Objective: To determine the effectiveness of warming anesthetic solutions on pain produced during the administration of anesthesia in maxillary dental infiltration technique. Material and Methods: A double-blind cross-over clinical study was designed. Fifty-six volunteer students (mean age 23.1±2.71 years) of the Dental School at Universidad Austral de Chile (Valdivia, Chile) participated in the study. Subjects were given 0.9ml of 2% lidocaine with 1:100.000 epinephrine (Alphacaine®; Nova DFL - Brazil) by two punctions at buccal vestibule of lateral incisor. Warm anesthesia at 42°C (107.6°F) was administered in a hemi-arch; and after one week anesthesia at room temperature (21°C; 69.8°F) and at a standardized speed was administered at the contralateral side. The intensity of pain felt during injection was registered and compared using visual analog scale (VAS) of 100mm (Wilcoxon test $p<0.05$). Results: The use of anesthesia at room temperature caused a VAS-pain intensity of 34.2±16.6mm, and anesthesia at 42°C a VAS-pain intensity of 15.7±17.4mm ($p<0.0001$). Conclusion: The use of anesthesia at 42°C resulted in a significantly lower pain intensity perception during injection compared with the use of anesthesia at room temperature during maxillary infiltration technique.

Keywords: *Local anesthetics, Pain, Injection, Warming, Temperature.*
DOI: *10.17126/joralres.2015.060.*

Cite as: *Aravena PC, Barrientos C & Troncoso C. Effect of warming anaesthetic solutions on pain during dental injection. A randomized clinical trial. J Oral Res 2015; 4(5): 306-312.*

INTRODUCTION.

The use of local anesthesia in dentistry is a critical aspect because of the fear and anxiety the injection of anesthetic solution causes in patients[1,2]. This is also one of the main reasons why patients avoid regular checkups with their dentists[3]. Among the methods used to manage this situation we find the use of troncular injections, injection speeds below 1 tube per minute[4,5], and the compression of the tissue surrounding the puncture site[5]. However, all these methods are operator-dependent and may be ineffective in a local infiltration technique.

One way of reducing the perception of pain during injection is to warm local anesthetic solutions. Experiments of pain perception during the injection of anesthetic solutions at 10°C, 18°C, 37°C and 42°C in the trigeminal area have shown a linear relationship between increased temperature of the anesthetic solutions and a reduction in the perception of pain during injection[6]. Also, previous reports have shown effectiveness of warming anesthetic solutions in areas of the head and the perception of lower intensity of pain during injection using 2% procaine and 1:80.000 epinephrine at 42°C in plastic surgery[6], 2% lidocaine and 1:200.000 epinephrine at 37°C in cataract surgery[7], and 1% lidocaine and 1:100.000 epinephrine between 40°C to 54.4°C in dermatology[8].

In dentistry there are conflicting reports. Rogers *et al.*[9] showed that in dental students warm anesthetic injections were significantly more comfortable than injections at room temperature. However, Oikarinen *et al.*[10] reported that patients under local anesthetic injection at room temperature and at body temperature experienced the same feeling as if both solutions had been at body temperature. Also, Ram *et al.*[11] conducted a study in children, comparing the effect of warming anesthetic solutions at 37°C and at room temperature (21°C) in relation to the control of pain and anxiety during dental treatment. They did not find statistically significant differences in subjective pain sensation during the warm anesthetic injection and the injection performed at room temperature.

A recent systematic review[12] evaluates the effectiveness of warming anesthetic solutions in pain control during injection into different areas of the body. The review suggests to perform an analysis of the effect of warming anesthetics in dental infiltrative anesthesia and incorporate this technique in pain control during the injection of dental anesthesia. The benefit of significantly reducing pain during anesthetic injection would likewise help reduce anxiety levels, identified by patients as one of the main reasons they avoid visiting the dentist[3,13,14]. It would also provide a more comfortable treatment and promote a better dentist-patient relationship.

The aim of this research is to determine the effectiveness of the use of anesthesia at 42°C (107.6°F) in reducing the perception of pain during dental anesthetic injection, compared to use of anesthesia at room temperature (21°C; 69.8°F) in maxillary dental infiltration technique, taking into account the positive results reported by Alonso *et al.*[6] using anesthesia at 42°C.

MATERIALS AND METHODS.

A clinical randomized double-blind cross-over study as indicated by CONSORT[15] guidelines was conducted between the 10th and 21st of June 2015. This study was reviewed and approved by the Research Ethics Committee of the School of Medicine at Universidad Austral of Chile (No. 11/05/2015).

Population and sample size

Volunteer students of the School of Dentistry at Universidad Austral de Chile in Valdivia, Chile, participated in the study. They had an ASA I status (American Society of Anesthesiologists), and were between 18 and 35 years. Regardless of sex, they did not have dental pain or infection at the puncture site and accepted to participate in the study after reading and signing the informed consent.

To avoid pharmacological influences on pain perception, students under pharmacological treatment with nonsteroidal analgesics (NSAIDs), such as benzodiazepines or antidepressants as inhibitors of serotonin reuptake, among others, were excluded.

Sample size calculation was based on the results reported by Alonso *et al.*[6], whose study on 136 patients showed a difference of 2.6 points on the visual analog scale (VAS) in reducing pain using local anesthesia at temperatures between 18°C and 42°C. Considering a level of significance of 5%, power of 80% and effect size of a standard deviation of 0.4 points on the VAS scale to design a cross-over clinical study, a minimum of 42 subjects to receive treatment was estimated ("EpiTools Epidemiological Calculators", Australian Biosecurity Cooperative Research Centre, Australia).

Temperature control of the anesthetic tube

To warm the anesthesia a researcher (C.B.) conducted a pilot study with 50 anesthesia cartridge. For this, a baby-bottle warmer (Phillips Avent®) similar to the one used in previous studies was chosen[6,11,12]. To avoid water contact with the rubber plunger, the tube was placed inside a sealed plastic bag and then put into the warmer with 300ml of cold water. Using the maximum power of the warmer, the desired temperature of 42°C was achieved in the cartridge during 3 minutes and 50 seconds. Temperature of the liquid was checked removing the rubber plunger of one of the tubes and inserting a digital thermometer. After that time, the warmer was turned

off while maintaining the temperature of the anesthetic solution with the use of the built-in thermostat and by checking temperature with a mercury thermometer. To maintain the other anesthetic solution at room temperature, the thermostat of the dental practice room was adjusted to 21°C while anesthetic tubes were left outside of the storage drawer for 24 hours. The temperature of the anesthetic solution was checked removing the rubber plunger and inserting a digital thermometer in one of the cartridge chosen randomly.

Randomization and use of anesthetic solution

Simple randomization was used from a number pattern generated by the "RANDBETWEEN" function of Microsoft Excel 2013 (Windows Corporation®, 2013), choosing the first injection on the dominant side of the subject (left/right) with anesthetic solution warmed at 42°C in those volunteers that in order of attention coincided with an even number; and the solution at room temperature (21°C) in those volunteers with an odd number of attention respectively. A researcher (C.B.) warmed the tubes and made the masking of the sequence, preparing the carpule syringe before the selection of the anesthetic tube (according to randomization) in the clinical area behind the dental chair.

Regarding the infiltrative anesthetic technique for the anterior superior alveolar nerve, a second investigator (C.T.) with over 7 years experience in dental anesthetic techniques performed the anesthetic administration according to the steps and the technique described by Malamed[4]. For this purpose, the voluntary patient was placed in supine position in the dental chair and the point of injection was located into the apical mucobuccal fold between teeth #6 and #11 using a short needle gauge 30G (Septoject XL, Septodont®) and injecting 0.9ml (half tube) of anesthetic solution (Nova DFL Alphacaine100®; Brazil) at a rate of 0.15ml/s[16].

Immediately after injection, a second researcher (C.B.) showed the patient a visual analog scale (VAS) of 100mm (0=no pain to 100=unbearable pain) asking "how much pain did you feel during the administration of anesthesia?".

The value indicated by the patient's finger or by verbal communication with respect to the perceived pain intensity during puncture and injection of the anesthetic solution was recorded. After the first injection, a washout period of 1 week was estimated and the second puncture was performed by injecting the contralateral side of the jaw with the anesthetic solution at the temperatures established in the sequence described above.

Data analysis

Data were tabulated in a spreadsheet Google Drive®. For each patient age, sex (male/female) and type of anesthesia used was recorded (42°C or room temperature).

One of the researchers (P.A.) performed the calculation of average, standard deviation (±SD) and median of the data. Temperature groups (42°C and room temperature) were considered as independent variable, and the level of pain perceived during anesthetic injection as dependent variable.

To check the effectiveness of warming at 42°C versus anesthetic solution at room temperature (21°C), the parametric behavior of the pain values in both groups of study was analyzed by Shapiro Wilk test.

Then, the median VAS of the total number of subjects in both groups was compared, using the appropriate test according to the distribution of values (t-test or Wilcoxon, $p<0.05$) with statistical package STATA 10.0 (STATA Corp., USA).

RESULTS.

There were 58 participants, only 2 of them did not return after a week of washout for unknown reasons (Figure 1). Fifty-six subjects (35 men) with an average age of 23.05±2.71 years (range 19-33 years; men: 23±2.8 years; women: 23±2.4 years) were analyzed. The normal distribution of the records of pain in both groups proved to be nonparametric ($p<0.0001$).

The level of pain perceived according to VAS for the 42°C group averaged 15.7±17.4mm and a median of 10mm; and for room temperature an average of

Figure 1. Flowchart of study.

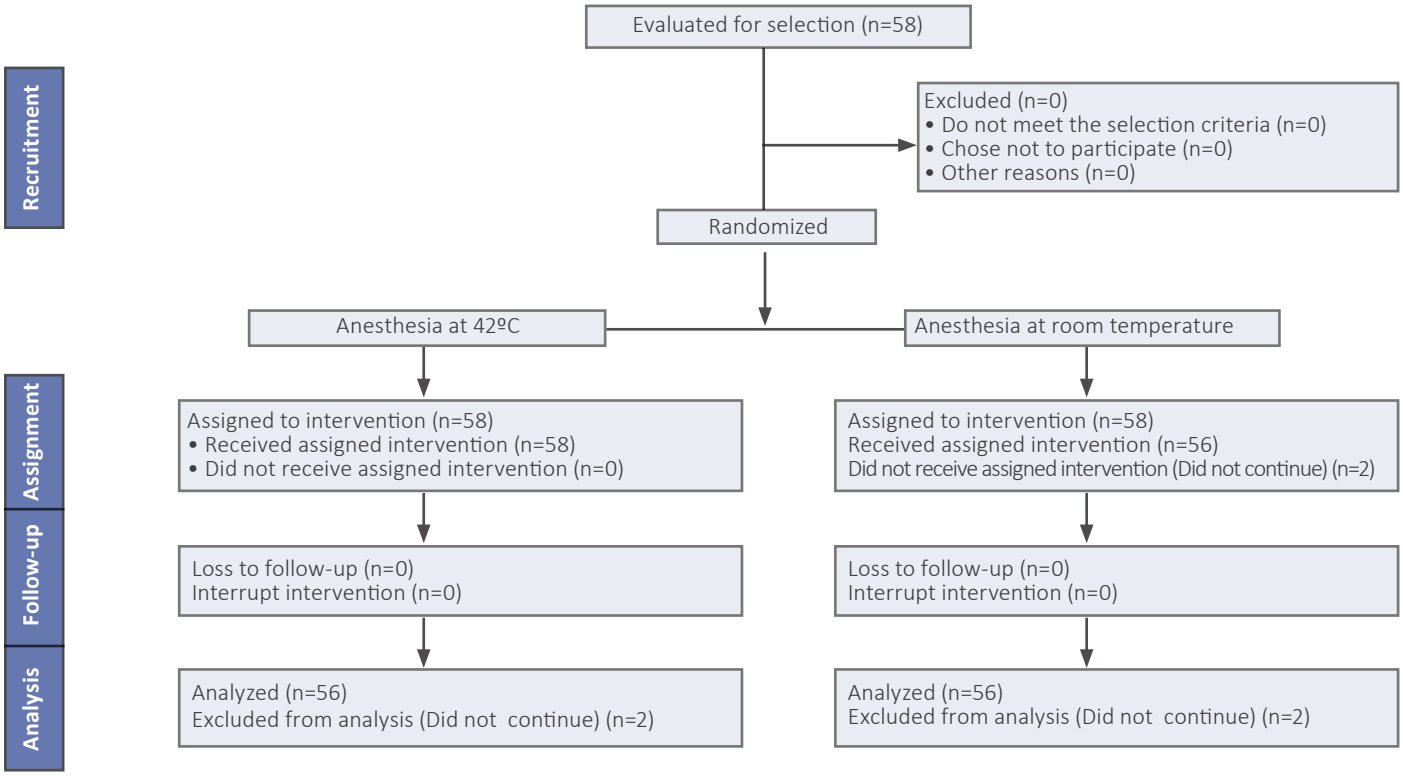
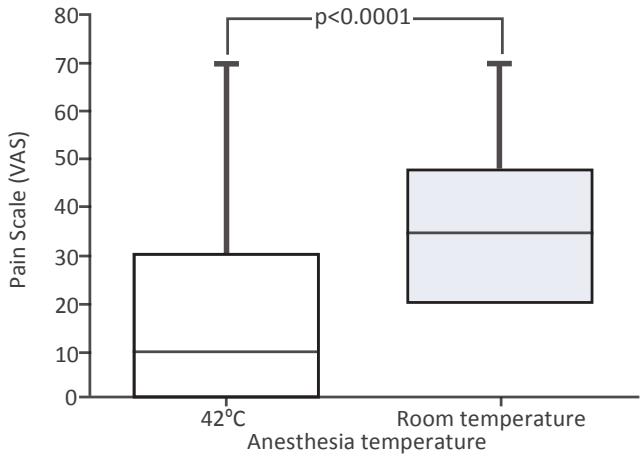


Table 1. Level of pain perceived by the group studied according to the visual analog pain scale.

	Level of pain according to Visual Analog Scale (in mm)						
Group	Average	±	Median	Min	Max	95% IC	p[1]
42°C	15.71	17.14	10	0	40	1.44-2.44	0.0001
21°C- Room temperature	34.28	16.60	35	0	70	2.88-3.79	

1. Wilcoxon's test (p<0.05)

Figure 2. Average (standard error) of pain perceived by the groups studied according to visual analog scale (VAS) (Wilkoxon's test p<0.05)



34.2±16.6mm and a median of 35mm; showing an average difference of 18.5mm on the VAS scale that was statistically significant between both groups (p<0.0001) (Table 1) (Figure 2).

DISCUSSION.

The use of anesthesia at 42°C caused significantly less pain compared to the use of anesthesia at room temperature during the injection of local anesthesia in the maxillary infiltration technique. These results are a contribution to the different mechanisms used in dentistry to manage pain and anxiety in patients during dental treatment.

A reduction in the perception of pain by injecting anesthetic solutions at temperatures equal to or greater than the body has been shown in different areas of medicine[5,7]. It dentistry it is particularly important since most dental procedures require local anesthesia. This aspect is critically important if we consider that most patients show fear and anxiety to undergo dental treatment[3] because of the injection of anesthetic solutions[13,14]; feelings that in many cases even lead them to put off or cancel their appointments.

These results are consistent with clinical trials in which volunteer subjects are tested using the split-mouth technique. Rogers *et al.*[9] showed that in dental students between 22 and 32 years of age, the use of anesthesia was more comfortable at body temperature than at room temperature. Eche-Herrera[17] analyzed the effect of warming anesthetic solution at body temperature in 38 volunteer students and how it helped reduce pain perception during injection of anesthesia in the mandibular nerve block technique, showing that the use of anesthesia at body temperature achieved average VAS values of 6.63mm versus 12.8mm at room temperature ($p<0.05$). These results were also complemented with a verbal response scale, where 100% of students who received anesthesia at body temperature reported a "less than expected" type of pain ($p<0.05$).

However, there are other reports that have not shown a positive effect. Oikarinen *et al.*[10] reported that the use of anesthesia at body and at room temperature produced the same feeling. In a cross-over clinical trial, Ram *et al.*[11] studied the reaction of children between 6 and 11 years to anesthetic solutions used at 37°C and at room temperature (21°C) in relation to pain and anxiety perceived during a vestibular infiltration technique, an interpapillary technique and a mandibular nerve block technique. Their results showed no statistically significant differences in pain sensation during the injection of anesthetic solutions at both temperatures.

While there are reports from different medical fields that show that the warming of the anesthetic solution reduces the perception of pain during injection[12], in dentistry there are few reports in electronic databases that allow researchers to compare the results of this study appropriately, since there are many other variables associated to the anesthetic technique (anatomical location, infiltration or troncular technique), dentist (years of experience, injection speed) and patient's own perception (previous experiences of anesthetic injections, subjective perception of pain).

At the other extreme, some studies even suggest that warming anesthetic tubes may cause drug and vasoconstrictor degradation, reducing their effectiveness[4,18]. However, this information is inconclusive because of the lack of technical reports in electronic databases that test the condition of anesthetic compounds in the tube after being exposed to different temperatures.

Limitations of this study are related to variables that depend on both the patient and the dentist. It is important to keep in mind that the subjects studied were healthy volunteers and do not necessarily represent the population that requires local anesthesia. Moreover, the description of a subjective variable such as pain by VAS varies among people, mainly because of the different experiences patients have had in relation to dental treatments[3,13,14].

However, this scale is recognized as a valid and reliable method for clinical use[19]. Although it is advisable to manage fear and anxiety through proper cognitive behavioral therapy[20] guided by the patient's previous experience and the use of distraction methods (verbal, auditory and visual)[21] during anesthetic injection in a less traumatic way and at low speed[16].

CONCLUSION.

Warming the anesthetics cartridge at 42°C showed a reduction in pain during injection of anesthetic in the maxillary infiltration technique compared to the use of anesthesia at room temperature.

These results provide an easy and repeatable method using domestic portable equipment such as incubators or baby-bottle warmers[6,11,12] to treat patients with negative or traumatic past experiences associated with anesthetic injections, producing a lower perception of pain during dental injection and reducing the levels of pain and anxi-

ety during dental treatments[3,13,14].

Further analyses are suggested in patients with pulp diseases, as well as analyses based on the physiological and pharmacological principles that may help explain this clinical outcome.

ACKNOWLEDGEMENTS.

The authors would like to thank Dr. Pamela Sotelo-Hitschfeld of the Institute of Physiology at Universidad Austral de Chile; Dr. Cesar Coronado-Gallardo of the Morphofunction Department at Diego Portales University of Santiago, Chile; Biochemist José Vicente González and all the volunteer students from the School of Dentistry at Universidad Austral de Chile.

This research is based on a thesis written as a requirement of C.T. and C. B. to obtain the degree of Bachelor of Dental Surgery and Dentistry at Universidad Austral de Chile, September 2015.

Efecto del calentamiento del anestésico sobre el dolor durante la inyección dental. Ensayo clínico aleatorio.

Resumen: Objetivo: Determinar la efectividad del calentamiento de anestesia en la reducción del dolor producido durante la administración de anestesia dental en técnica infiltrativa maxilar. Material y método: Se diseñó un estudio clínico doble ciego de brazos cruzados. Participaron cincuenta y seis estudiantes voluntarios (23.1±2.71 años) de la Escuela de Odontología de la Universidad Austral de Chile (Valdivia, Chile). Se les administró 0.9ml de lidocaína 2% con epinefrina 1:100.000 (Alphacaine®; Nova DFL - Brasil) mediante 2 punciones en el fondo de vestíbulo a nivel del incisivo lateral superior. En una hemi-arcada se administró anestesia a 42°C (107.6°F) y luego de una semana se les administró anestesia en el lado contralateral a temperatura ambiente (21°C; 69.8°F) con una velocidad estandarizada. Se comparó la intensidad de dolor percibida durante la inyección mediante escala visual análoga (EVA) de 100mm (prueba de Wilcoxon $p<0.05$). Resultados: El uso de anestesia a temperatura ambiente provocó un dolor promedio EVA de 34.2±16.6mm y la anestesia a 42°C un dolor promedio EVA 15.7±17.4mm ($p<0.0001$). Conclusión: El uso de anestesia a 42°C generó una percepción de dolor significativamente menor durante la inyección del anestésico en comparación a su uso con temperatura ambiente en la técnica infiltrativa maxilar

Palabras clave: *Anestesia local,Dolor, Inyección, Calentamiento, Temperatura.*

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