

What's new for the clinician?

- Excerpts from and summaries of recently published papers

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Compiled and edited by V Yengopal

1. The effect of pre-anaesthesia with a needle-free system versus topical anaesthesia on injection pain of the inferior alveolar nerve block: a randomized clinical trial

S Yıldırım, M Tokuç, MN Aydın. The effect of pre-anaesthesia with a needle-free system versus topical anaesthesia on injection pain of the inferior alveolar nerve block: a randomized clinical trial. Clin Oral Invest. 2020; 24: 4355-61.

INTRODUCTION

A common pain control method used in children and adults is the application of a local anaesthesia prior to treatment. Among local anaesthesia methods, the inferior alveolar nerve block (IANB) is frequently used to ensure pain control prior to procedures such as restoration of mandibular primary and permanent molar teeth, endodontic treatments, and surgical interventions.¹

The IANB method consists of three stages of administration of the anaesthetic solution: inserting the needle through the alveolar mucosa, placing the needle into the target location, and finally, depositing the anaesthetic solution at the target location.

A number of studies have shown that techniques that allow for a painless method of inserting the needle through the alveolar mucosa often contributes to much more relaxed child who is less anxious and displays a more positive dental behaviour throughout the dental procedure.

Various methods have been investigated for preventing the pain of an IANB, such as applying topical anesthetics prior to the injection, warming or buffering the solution prior to administration, using a computer-controlled anaesthesia delivery system such as the Wand system, and employing modern devices, like DentalVibe that uses vibration and the two-stage injection technique.¹

Comfort-in™ (Korea), one of the more recent dental devices, was developed to administer local anaesthesia using a needle-free injection method. The developers of this system claim that it is an easy to use, virtually pain-free, needle-free jet injector system, which eliminates the fear, pain, and danger of needles from the injection process.

Common uses include insulin injections, use in dental clinics, vitamin injections such as methyl B12, men who have erectile dysfunction (ED), hormone therapy, growth hormones, IVF treatments, allergy shots, etc. As much as 25% of adults and up to 75% of children have needle-phobia. Needle phobia contributes to situations where adult patients delay or forego treatment altogether, and physicians and other professionals such as dentists are left in an awkward position of having to cause pain.

The Comfort-in™ system is a patented device using the "liquid jet" system to inject the anaesthetic solution rapidly (one-third of a second) from a 0.15 mm hole with high pressure. Yıldırım and colleagues (2020) reported on a trial that sought to compare the effectiveness of pain control between a needle-free system and topical anaesthesia applied prior to inferior alveolar nerve block (IANB).

MATERIALS AND METHODS

This was a randomized, controlled cross-over clinical trial with 60 children, aged 6–12 years. Healthy, cooperative (exhibiting "positive" and "absolutely positive" behaviour on the Frankl Behaviour Scale (FBS)) children requiring IANB for dental treatments (restorative and endodontic procedures) on their bilateral mandibular primary or permanent molars were included in the study.

Veerasamy Yengopal: BChD, BScHons, MChD, PhD, Community Dentistry Department, School of Oral Health Sciences, University of Witwatersrand, Medical School, no. 7 York Road, Parktown 2193, South Africa.
ORCID Number: 0000-0003-4284-3367
Email: veerasamy.yengopal@wits.ac.za

All patients had previous experience with infiltration anaesthesia but not IANB. Based on medical history, children under medication or who were found to have a chronic disease or history of allergy were excluded.

Dental treatments with IANB were administered to bilateral mandibular molars of each patient in two separate sessions at 1-week intervals. Before IANB, topical anaesthesia was applied in one session and needle-free injection was applied in the other session as pre-anaesthesia.

The first pre-anaesthesia method was randomly assigned to each patient with a computer-assisted program. The operator was asked to select the side to do the first treatment before the researcher revealed the pre-anaesthesia method to be applied, to avoid possible operator bias. In this study, all anaesthesia procedures and dental treatments were performed by the same operator.

Before initiating treatment, each patient underwent age-appropriate behaviour management. All dental equipment was introduced using the “tell-show-do” technique. Injection was described to patients using reframing methods (for instance, using euphemistic phrases such as “putting the tooth to sleep”).

One hundred twenty IANB injections were performed in total. Patients were divided into two groups, according to the two pre-anaesthesia procedures, prior to IANB.

- **Topical anaesthesia group (TA):** The IANB injection site was dried, and topical anaesthetic spray containing 10% lidocaine (Xylocaine) was applied with a cotton pellet for 60s.
- **Comfort-in™ injection system group (CIS):** Before application, patients were given a demonstration of the popping sound produced by the device during the injection. The Comfort-in™ system was prepared according to the manufacturer’s recommendation, and 0.1 mL of 4% articaine hydrochloride with 1/100,000 epinephrine (Ultracaine) was drawn into the needle-free syringe using filling adapters.

The device was placed at the IANB injection site, and the anaesthetic solution was injected into the mucosa by pressing the button on the back of the device. Subjective and objective pain assessments were performed during Comfort-in™ application.

Waiting 5 min after the pre-anaesthesia procedure, IANB injections were administered to each patient with a 27-gauge dental needle using a standardized approach. The effectiveness of pre-anaesthesia methods on injection pain during IANB was assessed subjectively and objectively in the “needle insertion” and “solution deposition” phases.

The Wong-Baker PRS was used for subjective assessment. The pain level of patients is judged according to face images ranging from smiling to crying with ratings between 0 and 5: 0 signifies “no hurt” and 5 indicates “hurts worst”.

The Face, Legs, Activity, Cry, Consolability (FLACC) scale was used for objective assessment. This scale consists

of five parameters - facial expression, legs, activity, crying, and consolability. The rater scores each parameter from 0 to 2 points by observing the patient. Total scores range from 0 to 10. A score of 0 means “no pain,” scores between 1 and 3 mean “mild pain,” 4 to 6 indicate a “medium level of pain and discomfort,” and scores of 7 and above indicate “severe pain and discomfort”.

At the end of the second session, after IANB injection, patients were asked which pre-anaesthesia method they preferred, and their answers were recorded.

RESULTS

60 children - 33 girls (55%) and 27 boys (45%) - who were 6 - 12 years of age (8.37 ± 0.26) were included in this study. On both scales, significantly higher pain ratings were observed in the **Topical anaesthesia group (TA)** group during needle insertion ($p < 0.01$) and solution deposition ($p < 0.01$) when compared to the **Comfort-in™ injection system group (CIS)** group.

On the FLACC scale, the number of “no pain” ratings was higher in the CIS group than in the TA group for both needle insertion (CIS, 36; TA, 1) and solution deposition (CIS, 32; TA, 1). In contrast, the number of “severe pain” ratings was lower in the CIS group than in the TA group for needle insertion (CIS, 1; TA, 2) and solution deposition (CIS, 1; TA, 5).

Similarly, according to the Wong-Baker PRS, the number of “no hurt” ratings was higher in the CIS group than in the TA group for needle insertion (CIS, 27; TA, 2) and solution deposition (CIS, 29; TA, 3). The number of “hurts worse” ratings was lower in the CIS group than in the TA group for needle insertion (CIS, 1; TA, 2) and the same for solution deposition (CIS, 1; TA, 1).

There was no statistically significant difference in terms of patient preference. While 50% ($n = 30$) of the children preferred CIS, the remaining half ($n = 30$) preferred TA. No significant gender difference was found in patient preference. Seventeen (56.7%) of 33 girls preferred the use of the CIS before IANB, while 13 (43.3%) of 27 boys chose the CIS.

There was a statistically significant association between age and patient preference ($p < 0.001$). A negative association was found between age and scale ratings, except in the TA group in which no association was found between age and PRS ratings both for needle insertion and for solution deposition phases ($p > 0.05$).

CONCLUSIONS

The researchers concluded that in both the objective and subjective pain assessments, the needle-free system reduced the injection pain of undergoing IANB. Both methods (CIS and TA) were equally preferred by the patients.

Implications of practice

Before using the results of this trial, clinicians should note the inclusion criteria used (Healthy, cooperative (exhibiting “positive” and “absolutely positive” behaviour on the Frankl

Behaviour Scale (FBS)) children requiring IANB) and also note that patients had no preference in terms of TA or the CIS.

Reference

1. Yıldırım S, Tokuç M, Aydın MN. The effect of pre-anaesthesia with a needle-free system versus topical anaesthesia on injection pain of the inferior alveolar nerve block: a randomized clinical trial. *Clin Oral Invest.* 2020; 24: 4355-61.

2. Comparison of two vasoconstrictors on glycemic levels in diabetic patients

D Meneses-Santos, KS Amorim, ACGC Dantas, et al. Comparison of two vasoconstrictors on glycemic levels in diabetic patients. *Clin Oral Invest.* 2020; 24; 4591-6.

INTRODUCTION

Diabetes mellitus (DM) is common among patients attending for dental treatment. The most common forms of DM are Type 1 and Type 2. Type 1 DM (DM1) is an autoimmune disease destroying pancreatic β cells, leading to poor insulin production.¹ Type 2 DM (DM2) has multifactorial causes, it is usually associated with obesity, hypertension, and dyslipidemia, and affects both β cell function and insulin tissue sensitivity.

Fear and anxiety are common factors associated with dental care. The dental anaesthesia, an essential procedure for performing dental treatment, may generate pain; it is also associated with anxiety, odontophobia, and can lead to changes in corticosteroid secretion and sympathomimetic hormones, which can act as hyperglycemic agents. In diabetics with altered insulin metabolism, stress may be a factor to potentiate hyperglycemia. Thus, oral surgery requires special care, including stress control and the use of safe and effective anaesthetic solutions.

Some authors have reported an increase in blood glucose levels after the administration of local anesthetics containing adrenaline as vasoconstrictor.¹ The recommended anesthetics in these patients may be 3% mepivacaine without vasoconstrictor or 3% prilocaine with 0.03 IU/mL felypressin.¹

Felypressin is indicated in non-controlled diabetic patients because it does not activate α - nor β -adrenergic receptors.¹ However, it presents some disadvantages, such as deficient hemostasis control and short pulpal anaesthesia.

Meneses-Santos and colleagues (2020) reported on a trial that sought to evaluate glycemic levels in controlled diabetic patients before, during, and after extraction using 2% lidocaine with 1:100,000 epinephrine and 3% prilocaine with 0.03 IU/mL felypressin.

MATERIALS AND METHODS

This was a double-blind parallel controlled clinical trial which sought to evaluate changes in physical parameters and glycemic levels in diabetic patients undergoing two anaesthetic protocols during tooth extractions. All patients

were diabetic controlled by oral medication (oral hypoglycemic agents and insulin). Inclusion criteria were patients over 18 years of age, DM controlled by medication, requiring a tooth extraction in the mandible, with an indication of the intra-alveolar technique.

Exclusion criteria were any significant medical condition (besides DM), alcoholic individuals, patients on drugs that affect the central nervous systems, patients who reported the use of drugs that might interfere with pain sensitivity within 15 days prior to the surgery, and those who reported pregnancy, lactation, odontophobia, or hypersensitivity to local anesthetics or non-steroidal anti-inflammatory drugs (NSAIDs).

The participants were randomly divided into two groups: Lido/Epi group (20 patients), who were anesthetized with 2% lidocaine with 1:100,000 epinephrine (Alphacaine®), and Prilo/Fely group (20 patients), who were anesthetized with 3% prilocaine with 0.03 IU/mL felypressin (Prilonest®).

The present study was conducted in three phases. In phase I, the degree of anxiety was assessed in all participants before the surgical procedure by applying the Corah Dental Anxiety Scale. Subsequently, the basal physical parameters, such as systolic (SBP) and diastolic (DBP) blood pressure, heart rate (HR), blood oxygen saturation (SpO₂), and glycemic levels by capillarity were evaluated. Glycemic levels were determined by using a glucometer (Accu-Chek® Active).

In phase II, the baseline physical parameters were measured and in both groups, patients received a *Passiflora incarnata* capsule (500 mg orally, 1 h before the start of the surgical procedure) for anxiety control. The physical parameters were measured 30 min after the capsule administration. At the time of surgery, 3.6 mL of lido/epi or prilo/fely was administered by an inferior and buccal alveolar nerve block. At this point, the timer was triggered up to 60 min after the anaesthesia. Physical parameters were measured at different surgical moments: during incision, during tooth removal, during suture, and 30 and 60 min after anaesthesia. Furthermore, the investigator and operator responsible for the surgery evaluated the degree of

anxiety, both of them did answer the same questionnaire at the end of each surgical procedure. In the postoperative period, sodium dipyrone 500mg every 6h for 48h was prescribed.

In phase III, performed 8 days after the tooth extraction and during suture removal, the side effects resulting from the medication used in this study were evaluated using a questionnaire.

RESULTS

Forty participants were included in this study. No differences were observed between the study groups in age, weight, gender, time of surgery gender, surgery sides, and the initial anxiety level. All surgical procedures were completed before 30min. The majority of the sample was low-anxiety level patients.

The use of lido/epi induced a significant increase in systolic blood pressure (SBP) during the “incision” period in comparing to “basal,” “anaesthesia,” and “60 min after anaesthesia” periods. The last period showed lower SBP than that in the “tooth removal” period. No differences were found in the other periods.

Prilo/fely caused increased SBP during “suture” when compared with “basal,” “30 min after anaesthesia,” and “60 min after anaesthesia” periods. Markedly, when lidocaine was used, SBP peaks greater than 160mmHg were observed in eight (40%) patients during the incision, six (30%) during tooth removal, five (25%) during suturing, four (20%) after 30 min of anaesthesia, and three (15%) at the end of the procedure. None of the patients presented these peaks at the baseline.

When prilo/fely was used, these peaks were observed in two (10%) patients during the baseline, eight (40%) during the incision, nine (45%) during tooth removal, nine (45%) during suturing, six (30%) after 30 min of anaesthesia, and three (15%) at the end of the procedure.

No differences among the periods were observed considering SpO₂ for both lido/epi ($p=0.94$) and prilo/fely ($p=0.91$). Levels of HR did not show differences ($p>0.05$) between basal values and those obtained in other periods for both local anesthetics despite the sporadic fluctuations.

There was a marked reduction in blood glucose caused by Lido/Epi, from 30 min of *P. incarnata* administration until the last period when compared to the baseline value. Although less pronounced, prilo/fely also significantly decreased glucose, starting at the “tooth removal” period until the last period when compared to the baseline.

Six episodes of increased blood glucose above the initial measurements (5.0% of 120 measurements) were observed when lido/epi was used, but prilo/fely caused 28 (23.3%) episodes.

In general, no improvement or worsening was observed between the initial anxiety and the anxiety reported on the day of surgery. Besides that, no difference between the perception of the operator and researcher was seen about the anxiety declared by the patient.

CONCLUSIONS

The researchers concluded that 3.6 ml of lidocaine 2% plus 1:100,000 epinephrine or prilocaïne 3% plus felypressin presented safe for controlled diabetic patients. The use of lidocaine associated with epinephrine did not increase glycemic levels, but led to a decrease over time when associated with an anxiety reduction protocol, offering some advantage over prilocaïne plus felypressin for diabetic patients.

Implications for practice

Diabetes is a major public health problem in our communities and the safe use of local anaesthesia for these patients contributes to maintenance of healthy glycaemic levels during dental treatment.

Reference

1. Meneses-Santos D, Amorim KS, Dantas ACGC, et al. Comparison of two vasoconstrictors on glycemic levels in diabetic patients. *Clin Oral Invest.* 2020; 24; 4591-6.