The influence of buffered and conventional anesthetic solutions on the pain level in children during an inferior alveolar nerve block injection: randomized Clinical Trial

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Objectives: The purpose of this study was to assess pulse rate as a physiological pain assessment during inferior alveolar nerve block injection using buffered anesthetic solution (lidocaine 2% epinephrine 1/80,000 with sodium bicarbonate 8.4%) and conventional anesthetic solution (lidocaine 2% epinephrine 1/80,000) to treat bilateral mandibular primary molars.

Materials and Methods: Forty patients were included in the study sample to perform 80 inferior alveolar nerve block injections with split-mouth technique in patients aged 6-10 years with bilaterally infected mandibular primary molars. A fingertip oximeter was used to measure the pulse rate before and during anesthesia.

Results: The pulse difference before and during anaesthesia was evaluated using the student's t-test for independent samples for both the buffered anaesthetic solution and the standard anesthetic solution groups. At P = 0.05, there was a statistically significant difference in favor of the buffered anesthetic solution.

Conclusions: This study discovered an alleviation in pain during the injection of buffered anesthetic solution over conventional anesthetic solution.

Keywords: Anaesthesia, Lidocaine, Buffered lidocaine, Inferior alveolar nerve block injection, Pain, Inferior Primary molars, Pulse.

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تقييم تأثير كل من المحلول المخدر المقلون والتقليدي على مستوى الألم أثناء إجراء حقنة إحصار العصب السني السنخي السفلي عند الأطفال (دراسة سريرية مضبوطة معشاة)

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الملخص:

هدف البحث: هدفت هذه الدراسة لقياس معدل النبض كمشعر فيزيولوجي لتقييم الألم أثناء التخدير باستخدام المحلول المخدر المقلون (ليدوكائين 2% أدرينالين 1/80.000 مع بيكربونات الصوديوم 8.4%) مقارنة مع المحلول المخدر التقليدي (ليدوكائين 2%أدرينالين 1/80.000) أثناء إجراء حقنة إحصار العصب السني السنخي السفلي في سياق معالجة الأرحاء السفلية المؤقتة.

المواد والطرائق: تألفت عينة الدراسة من أربعين مريض لإجراء 80 حقنة إحصار العصب السني السنخي السفلي وفق تقنية الفم المشطور لمرضى بأعمار 7 – 10 سنوات لديهم أرحاء سفلية مؤقتة مصابة ثنائية الجانب، تم اختيار المحلول المخدر الذي سوف يتم البدء به عشوائياً مع الأخذ بعين الاعتبار الشكوى الرئيسية للمريض. تم قياس النبض قبل البدء وأثناء التخدير باستخدام جهاز قياس الأكسجة الإصبعي (Pulse Oximeter).

النتائج: تمت مقارنة معدل فرق النبض قبل البدء وأثناء التخدير لكل من مجموعتي المحلول المخدر المقلون والمحلول المخدر التقليدي باستخدام اختبار ت ستودنت للعينات المستقلة (Independent T Student). لوحظ وجود فرق دال إحصائياً لصالح مجموعة المحلول المخدر المقلون حيث بلغت قيمة P value=0.000.

الاستنتاج: وجدت هذه الدراسة انخفاض معدل الألم باستخدام المحلول المخدر المقلون مقارنة مع المحلول المخدر التقليدي الذي أبدى معدل ألم أعلى أثناء إجراء حقنة إحصار العصب السني السنخي السفلي في سياق معالجة الأرحاء السفلية المؤقتة عند الأطفال.

الكلمات المفتاحية: تخدير ، ليدوكائين، محلول مخدر مقلون، حقنة إحصار العصب السني السنخي السفلي، الألم، أرحاء مؤقتة سفلية، معدل النبض.

Introduction

Pain management is key to the success of dental treatment, especially in children, as controlling pain helps reduce anxiety and stress in anxious children (Khatri et al., 2021, p. 81). In 1992, Malamed described a technique for alkalinizing the anesthetic solution by adding 8.4% sodium bicarbonate to the anesthetic solution immediately before injection. This aims to increase the pH of the anesthetic solution, which in turn increases the proportion of effective anesthetic molecules and facilitates the infiltration of the anesthetic solution into the nerve fiber, thus reducing pain during injection (Khatri et al., 2021, p. 81). The pH of pure anesthetic solutions without a vasoconstrictor range from 5 to 6, while the pH of anesthetic solutions containing a vasoconstrictor ranges from 3.3 to 5.5 (Logothetis, 2013, p. 50). Anesthetic solutions containing a vasoconstrictor, such as epinephrine, have a low pH due to the presence of antioxidant agents like sodium bisulfite, which are used to increase the shelf life of the anesthetic solution (Malamed, 2020b, p. 350). The vasoconstrictor (epinephrine) can be added to the anesthetic solution directly before injection without adding antioxidants; however, such solutions have a short shelf life and oxidize quickly, turning yellow and brown (Malamed, 2020b, p. 351). A low pH is associated with several drawbacks:

- Pain during injection, manifesting as a tingling or burning sensation, which is the most common complaint from patients.
- Relatively slow onset of pulpal anesthesia.
- Suboptimal effectiveness in the presence of infection (Logothetis, 2013, p. 51).

When injecting the anesthetic solution, tissue fluids raise the pH of the anesthetic solution to a physiological pH (pH = 7.4). However, raising the pH of an acidic anesthetic solution requires more time after injection, leading to a delay in the onset of local anesthesia (Malamed, 2020b, p. 351). Several behavioral and pharmacological techniques have been proposed to alleviate pain and discomfort during injections, such as applying topical anesthetics, distraction techniques, warming the anesthetic solution, regulating the injection rate, and alkalinizing the anesthetic solution (Vafaei et al., 2019, p. 65). Alkalinizing (raising the pH) the anesthetic solution to a physiological pH immediately before injection increases the effective anesthetic molecules and has several advantages:

- Reduction or elimination of pain during injection.
- Increased patient comfort.
- Faster onset of anesthesia.
- Reduced tissue damage following injection (M.M *et al*., 2019, p. 93).

Therefore, raising the pH of the anesthetic solution to a level close to pH = 7.4 is ideal for increasing the effectiveness of the anesthetic solution safely (Malamed, 2020c, p. 364). Alkalinizing the anesthetic solution also provides an additional benefit due to the formation of carbon dioxide (CO_2), which directly enhances the effectiveness of the anesthesia by inhibiting nerve stimulation and indirectly by increasing the effective anesthetic molecules (Vent et al., 2020, p. 30).

The aim of the study

The aim of this research is to evaluate the pulse rate during the administration of inferior alveolar nerve block injections using an alkalinized anesthetic solution (2% Lidocaine with 1/100,000 Epinephrine and 8.4% Sodium Bicarbonate).

Materials and Methods

This study is designed as a controlled, randomized clinical trial. The required sample size for an alpha level of 5% and a study power of 95% was forty children (eighty injections), following a split-mouth design.

Inclusion Criteria

1. Children aged 7 to 10 years.
2. Cooperative children according to the Frankl Scale (positive or definitely positive).
3. Children requiring bilateral pulpal treatment (pulpotomy or pulpectomy) for temporary lower molars.

Exclusion Criteria

1. Children with systemic diseases or an allergic reaction to any component of the local anesthetic.
2. Children with only one affected molar.
3. Presence of signs of pulp necrosis (e.g., fistula, abnormal mobility, associated abscess, radiographic periapical lesion).

Procedures

1. Obtain written consent from parents before enrolling children in the study, and assess the child's behavior, accepting only those classified as positive or definitely positive according to the Frankl Scale.
2. Randomly assign patients to receive either the traditional anesthetic solution (2% Lidocaine with 1/80,000 Epinephrine) or the alkalinized anesthetic solution (2% Lidocaine with 1/80,000 Epinephrine plus 8.4% Sodium Bicarbonate) using a lottery system.

3. Conduct clinical and radiographic examinations to confirm the indication for bilateral pulpal treatment (pulpotomy or pulpectomy) for the temporary molars.
4. Add 8.4% Sodium Bicarbonate to the anesthetic solution (2% Lidocaine with 1/80,000 Epinephrine) in a 1:10 ratio.
5. In the first session, administrate either the alkalinized or traditional anesthetic solution according to the randomization, considering the child's main complaint.
6. Measure the child’s pulse rate before starting the treatment using a finger pulse oximeter (Figure 2). Pulse Oximeter (Alpha, Germany)
7. Apply topical anesthesia with Benzocaine gel (Sky-CAINE GEL, SKYDENT, USA) for one minute (Figure 1).
8. Administer the inferior alveolar nerve block injection according to the randomization.
9. Measure the child’s pulse rate during anesthesia.
10. The second session was scheduled one week later to treat the molar on the opposite side.
11. The independent samples t-test was used to compare the difference in pulse rate between the pre-anesthesia and during-anesthesia phases between the two groups using the statistical software SPSS version 20.0 (SPSS Inc., Chicago, IL, USA)

Results

The study sample included forty patients for the treatment of symmetrical lower temporary molars using a split-mouth design. The traditional anesthetic solution group received 40 injections, and the alkalinized anesthetic solution group received 40 injections. The anesthetic solution used in the first session was selected according to randomization using a lottery system. Pulse rates were recorded before and during anesthesia (Tirupathi & Rajasekhar, 2020, p. 71). A statistically significant difference was observed in the pulse **rate** before and during anesthesia between the traditional anesthetic solution group and the alkalinized anesthetic solution group, favoring the alkalinized solution. The t-test value for independent samples was 5.220, and the corresponding p-value was 0.000, which is less than the significance level of 0.05. This statistically significant difference is in favor of the alkalinized anesthetic solution group, where the mean difference in pulse rate was 0.05, which is lower and better than the mean difference in pulse rate in the traditional anesthetic solution group, which was 11.05. This is illustrated in Table 2.

Figure 1. Benzocaine 20%

Figure 2. Pulse Oximeter

Figure 3. Sodium Bicarbonate 8.4%

Table 2. Results of the Statistical Anal

Follow-up	Study group	n	Mean	SD	t-value	DF	P-Value	Result
Pulse Differences: During Anesthesia - Before Starting	Non-Buffered anesthetic solution	40	11.05	8.688	5.220	78	0.000	There are significant differences.
	Buffered anesthetic solution	40	0.05	10.107				

Discussion

Local anesthesia is defined as the loss of sensation in a specific area of the body through the inhibition of nerve endings or the suppression of nerve signal transmission (Malamed, 2004, p. 150). The pH of commercially available anesthetic solutions containing a vasoconstrictor range between pH = 3.5 and 5, and thus, injecting an anesthetic solution with a low pH can lead to pain or a burning sensation (Tirupathi & Rajasekhar, 2020, p. 70). Anesthetic solutions are unstable in an alkaline state, which is why it is recommended to raise the pH of the anesthetic solution using sodium bicarbonate (Figure 3) immediately before injection. Although the alkalinized anesthetic solution has been discussed in various medical literatures, only a few studies have investigated its effectiveness in the context of dental treatments (Tirupathi & Rajasekhar, 2020, p. 71). The addition of sodium bicarbonate to raise the pH of the anesthetic solution to approximately pH = 7.4 brings the pH close to the pKa value of the anesthetic (lidocaine). This balance between charged and uncharged molecules facilitates the rapid diffusion of the anesthetic into tissues, resulting in less pain during injection (Chopra et al., 2016, p. 55). Mixing sodium bicarbonate with an acidic anesthetic solution (lidocaine with epinephrine) increases the number of free lidocaine molecules capable of crossing nerve fibres. It enhances the ability of the anesthetic to bind to sodium channels (Tavana, 2013, p. 62). Sodium bicarbonate acts as an alkalizing agent and is effectively used to treat acidosis resulting from chronic kidney diseases (Tavana, 2013, p. 63). The study included 40 patients for the treatment of symmetrical lower temporary molars, employing a split-mouth design with a total of 80 inferior alveolar nerve block injections (40 injections using the traditional anesthetic solution and 40 injections using the alkalinized anesthetic solution). Split-mouth trials are commonly used in clinical dentistry as they significantly reduce individual variability, thus increasing the power of the conducted study (Qin et al., 2020, p. 45). The type of anesthetic solution used in the first session was randomly selected (by lottery), considering the side of the child's complaint, adhering to CONSORT 2010 guidelines in this study. The inferior alveolar nerve block was chosen due to its importance as one of dentistry's most crucial injection techniques, second only to infiltration anesthesia (Malamed, 2020d, p. 400). The inferior alveolar nerve block has a higher success rate in children than adults due to the location of the mandibular foramen, which is more lateral and lower than the occlusal plane (Malamed, 2020a, p. 335). The importance of the inferior alveolar nerve block lies in achieving adequate depth of anesthesia and the ability to anesthetize several teeth in one half of the jaw in a single session (Elbay et al., 2016, p. 70). Lidocaine hydrochloride is one of the most commonly used local anesthetics and has been considered the gold standard since its clinical introduction in 1941, compared to newer local anesthetic solutions (M.M et al., 2019, p. 93). Topical anesthetics are widely used to alleviate pain caused by needle penetration into tissues (Vafaei et al., 2019, p. 65). Several studies have evaluated the pain associated with injecting anesthetic solutions using the inferior alveolar nerve block technique in the context of dental treatments or extractions in adults, showing reduced pain during injection when using alkalinized anesthetic solutions. For example, a study by V.M. Kashyap and colleagues in 2011 showed a significant reduction in pain among patients who received anesthesia with an alkalinized anesthetic solution compared to those who received traditional solutions (Kashyap et al., 2011, p. 66). There are few studies that have addressed the effectiveness of the local anesthetic solution in children. A randomized controlled clinical study by researcher Kurien and colleagues in 2018, using the split-mouth technique, showed results on this topic. This is consistent with the results of the following studies: (M.M et al., 2019), (Kurien et al., 2018), (Tavana, 2013). The results of this study differed from those of the study conducted by (Chopra et al., 2016), and this difference is attributed to the variation in the study conditions and the differences in evaluation criteria.

Conclusions

The results of our current study showed a reduction in pain during injection using the buffered anesthetic solution compared to the traditional anesthetic solution (2% lidocaine with 1/80,000 adrenaline and 8.4% sodium bicarbonate) in children during the treatment of lower primary molars. It is recommended to conduct further studies to assess the effectiveness of the buffered anesthetic solution in children with Molar Incisor Hypo-mineralization (MIH).

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