ANESTHETIC PROPERTIES OF TWO SOLUTIONS ADMINISTERED BY A COMPUTERIZED INJECTOR USING THE ALVEOLAR CREST SPONGY BONE AREA TECHNIQUE: A RANDOMIZED CLINICAL TRIAL

PROPRIEDADES ANESTÉSICAS DE DUAS SOLUÇÕES ADMINISTRADAS POR UM INJETOR COMPUTADORIZADO USANDO A TÉCNICA DA ÁREA DO OSSO ESPONJOSO DA CRISTA ALVEOLAR: UM ENSAIO CLÍNICO RANDOMIZADO

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ABSTRACT: Most dental procedures require the use of local anesthetics. The Morpheus™ anesthetic computerized injector (Morpheus™ injector) provides painless needle insertion and satisfactory anesthesia with lower volumes of local anesthetic. The use of the intraseptal Alveolar Crest Spongy Bone Area (ACSBA) anesthesia technique with the Morpheus™ injector is an alternative to painless treatment. Thus, the objective of this study was to evaluate the anesthetic properties of the ACSBA technique using two different anesthetics, lidocaine and articaine. This randomized, split-mouth, triple-blind clinical trial included 31 volunteers who required restorative treatment of the lower first molars. In two sessions, 2% lidocaine with 1:100000 epinephrine and 4% articaine with 1:100000 epinephrine solutions were administered using the ACSBA technique. Patient physical parameters, pain perception, and degree of anxiety as well as anesthetic properties were evaluated. There were no statistically significant differences between the groups or time points for systolic (p = 0.928) and diastolic (p = 0.450) blood pressure or heart rate (p = 0.624). Moreover, there were no statistically significant differences between the treatments for needle insertion (p = 0.741) or anesthetic deposition (p = 0.810). Both of the anesthetic protocols had a 9.7% failure rate. The Mann-Whitney test showed no statistically significant differences between the groups in anesthesia latency (p = 0.758) or duration (p = 0.791). Articaine and lidocaine were safe drugs, and there was no change in their influence on the evaluated physical parameters. Articaine was similar to lidocaine for anesthesia duration with means of 70.7 and 61.1 min, respectively. The intraseptal ACSBA anesthesia technique was effective, provided sufficient anesthesia duration to perform medium-term dental procedures with articaine and lidocaine, and produced painless anesthesia that provided greater patient comfort.

KEYWORDS: Articaine, Dental Anesthesia, Lidocaine, Local Anesthesia, Tooth Pulp.

RESUMO: A maioria dos procedimentos odontológicos requer o uso de anestésicos locais. O injetor computadorizado de anestésico Morpheus™ (injetor Morpheus™) fornece inserção de agulha indolor e anestesia satisfatória com volumes menores de anestésico local. O uso da técnica de anestesia intraseptal Alveolar Crest Spongy Bone Area (ACSBA) com o injetor Morpheus™ é uma alternativa ao tratamento indolor. Assim, o objetivo deste estudo foi avaliar as propriedades anestésicas da técnica ACSBA usando dois anestésicos diferentes, lidocaína e articaína. Este ensaio clínico randomizado,
de boca dividida e triplo-cego incluiu 31 voluntários que necessitavam de tratamento restaurador dos primeiros molares inferiores. Em duas sessões, soluções de lidocaína a 2% com epinefrina 1:100.000 e articaína a 4% com epinefrina 1:100.000 foram administradas pela técnica ACSBA. Parâmetros físicos do paciente, percepção da dor e grau de ansiedade, bem como propriedades anestésicas foram avaliados. Não houve diferenças estatisticamente significativas entre os grupos ou momentos para pressão arterial sistólica (p = 0,928) e diastólica (p = 0,450) ou frequência cardíaca (p = 0,624). Além disso, não houve diferenças estatisticamente significativas entre os tratamentos para inserção da agulha (p = 0,741) ou deposição de anestésico (p = 0,810). Ambos os protocolos anestésicos tiveram uma taxa de falha de 9,7%. O teste de Mann-Whitney não mostrou diferenças estatisticamente significativas entre os grupos na latência da anestesia (p = 0,758) ou duração (p = 0,791). A articaína e a lidocaína foram drogas seguras e não houve alteração de sua influência nos parâmetros físicos avaliados. A articaína foi semelhante à lidocaína para duração da anestesia com média de 70,7 e 61,1 min, respectivamente. A técnica de anestesia intraseptal ACSBA foi eficaz, proporcionou duração anestésica suficiente para realizar procedimentos odontológicos de médio prazo com articaína e lidocaína e produziu anestesia indolor que proporcionou maior conforto ao paciente.


1. Introduction

The use of drugs to avoid pain is essential for dental office procedures. However, the administration of local anesthetics often causes anxiety and may be associated with pain in some patients. It is extremely important to evaluate a patient’s anxiety level before deciding on the best treatment because of the strong influence of a patient’s psychological state on the treatment outcome\textsuperscript{1,2}. Moreover, the fear of anesthetic injection may prevent
patients from seeking dental treatment. This fear is often related to the sensation of needle penetration and pain during injection³.

Lidocaine is the gold standard and most used local anesthetic in dentistry. Articaine is a newer dental anesthetic that is growing in the market. Articaine has been shown to be an excellent anesthetic for infiltrative techniques due to its high tissue diffusion capacity⁴. However, there are still reservations and controversies regarding the use of articaine because it is a local anesthetic with a shorter clinical follow-up time².

With the development of new technologies in the second half of the 1990s, electronically controlled anesthesia injection systems were created to control anesthetic flow and avoid pain during injection⁵-⁷. In 1995, the electronic Morpheus™ anesthetic computerized injector (Morpheus™ injector) was created. The Morpheus™ injector offers techniques that cannot be reproduced manually. One such technique is the intraseptal Alveolar Crest Spongy Bone Area (ACSBA) anesthesia technique, which is a mandibular anesthesia alternative that does not require an inferior alveolar nerve block (IANB). Recent research has demonstrated the applicability and efficiency of the Morpheus™ injector, which has provided new techniques and painless patient anesthesia⁸-¹⁰.

In 2016, Naichuan et al.¹¹ conducted a systematic review which suggested that articaine was a safer anesthetic than lidocaine in all of its applications. However, there are no studies in the literature concerning the use of articaine as an electronically controlled anesthesia. In 2002, Meechan¹² studied anesthetic properties and found that slower anesthetic injection was associated with greater anesthetizing power, leading to longer duration. A few studies have addressed the efficacy of the intraseptal technique¹³. The most recent studies, which did not use computerized devices, indicated low success rates of conventional intraseptal anesthesia as well as the unfeasibility of deep pulpal anesthesia¹⁴,¹⁵.
To date, the literature only comprises studies that have compared the use of lidocaine with different techniques. Thus, the objective of this study was to evaluate the anesthetic properties of 4% articaine (1:100000 epinephrine) and 2% lidocaine (1:100000 epinephrine) using the ACSBA technique and a Morpheus™ computerized system.

2. Material and Methods

2.1 Ethical Aspects

This randomized, split-mouth, triple-blind clinical trial was approved by the Research Ethics Committee of the Federal University of Sergipe (UFS) under the CAAE 77732117.3.0000.5546 and opinion no. 2488821 following Regulatory Requirements and Standards according to Resolution (CNS 466/2012). This clinical trial was also approved by the Brazilian Register of Clinical Trials under the registration no. RBR-59G3WF.

The sample calculation considered that the two treatments were split-mouth studies with an expected 20% difference in mean anesthetic durations and a standard deviation of approximately 30%. Thirty-one patients were required for a test power of 95% with a significance level of 5%. This study used BioEstat 5.0 statistical software (Mamirauá Institute, Belém, PA, Brazil).

This study included 31 volunteers who were treated at the UFS Dental Department in Aracaju, Sergipe, Brazil. The volunteers required medium depth class I restorations in the first right and left lower molars due to dentin exposure. The patients had healthy second right and left lower molars, no history of pain or trauma, and were reactive to electrical stimulation produced by an Electric Pulp Tester (EPT). The study did not include pregnant women, patients with a history of mental illness, drug dependence, abusive alcohol consumption, odontophobia, or ASA III and IV, or patients under analgesic drug treatment. The volunteers who decided to participate in the
study signed an informed consent form. A split-mouth randomization list was created using www.sealedenvelope.com, which generated two groups (protocol 1 and protocol 2). Furthermore, mandible laterality and different anesthetics were assigned for each protocol, allowing all volunteers to be anesthetized.

2.2 Clinical Protocol

This study was conducted in two sessions with an interval of at least two weeks between sessions. One researcher was responsible for randomization, equipment assembly with either articaine or lidocaine, and
informing the operator about the side to be anesthetized during the session. Opaque adhesive labels with the corresponding protocol number were placed on the anesthetic tubes because the technique dispensed the aspiration. A single experienced operator was responsible for performing the technique using the injection device.

Patient vital signs, including blood pressure (BP), heart rate (HR), and peripheral oxygen saturation, were measured before, during, and after anesthesia. The operator was responsible for verifying anesthesia efficacy, latency time, and duration using the EPT. The Corah scale was used at the initial consultation to evaluate anxiety, and the visual analog scale (VAS) was used after the anesthetic procedure to measure patient-reported pain during the anesthetic procedure.

Both of the protocols used the intraseptal ACSBA anesthesia technique with different anesthetics (i.e., lidocaine or articaine). Using a Morpheus™ injector equipped with an extra-short 30-G needle, the ACSBA technique involved the injection of 1.2 ml of anesthetic at an angulation of 45° into the gingival papilla near the vestibular area in the distal region of the targeted dental unit (i.e., 36 or 46). During this process, the Morpheus™ injector provided a controlled injection rate. The puncture point was equidistant from the adjacent teeth and located at the center of the vertical axis between the vertex and base of the gingival papilla.¹⁶

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¹⁶ Figure 2
The final restorative dental unit procedures were performed using an adhesive system (Ambar Universal FGM, Joinville, SC, Brazil) and composite resin (Filtek-Z350; 3M-ESPE, São Paulo, SP, Brazil) following the manufacturers’ recommended guidelines. The procedures lasted no longer than 10 min, and the procedure time was used for EPT testing to verify the anesthetic duration.

2.3 Evaluation of Pain Perception

At the end of each session, the VAS was applied to evaluate injection pain sensitivity. The VAS consisted of a 10-cm line, upon which there was a “no pain” indication on the left extreme and “worst possible pain” indication on the right extreme\textsuperscript{17}. Each volunteer was instructed to mark a vertical line on the VAS at the site that best indicated the pain or discomfort felt during anesthesia. For each moment evaluated, the pain felt by the volunteer was measured from the right extreme to the place marked on the VAS. A digital caliper was used to measure the distance from the “0” mark to the place marked by the volunteer.

2.4 Evaluation of Anxiety Level

Volunteer anxiety level was evaluated using the Corah scale as well as physical parameters during two distinct phases, Phase I (baseline) and Phase II (day of intervention). Phase I occurred during the initial consultation, which was one week before the first scheduled intervention day. Phase I used the 1969 Corah Anxiety Scale, which consisted of a questionnaire with four questions that had five alternative responses, to evaluate the patients’ dental treatment-associated feelings, signs, and reactions. In this questionnaire, each alternative response received a score from 1 to 5. Based on the total score, the patients were classified according to their anxiety level\textsuperscript{18}. The
questionnaire terminology was adapted to the needs of the study. HR and BP were evaluated during the initial consultation with the patient at rest. These measurements served as baseline data for the physical parameters used to evaluate anxiety. Phase II occurred on the day of intervention. For Phase II, patient anxiety level was evaluated by a researcher through BP and HR measurements.

2.5 Evaluation of Anesthesia Efficacy, Latency, and Duration

To evaluate the latency time, the EPT, which had two < 80-mA stimuli, was used after applying the anesthesia protocols. If there was no pain, the anesthesia was considered to be successful and the latency time was recorded. If, after 10 min and five EPT cycles, the patient still exhibited a positive response to the electrical stimulus, the anesthesia was considered to have failed.

Once a negative stimulus response was established and the anesthesia was considered to be successful, the anesthetic duration was monitored. Two 80-mA stimuli were applied at 10 min cycles until there was a positive stimulus response, which established the complete pulpal anesthetic duration.

2.6 Statistical Analysis

The data underwent distribution and normality analyses to select the appropriate statistical tests. To verify normality and variance (homoscedasticity), numerical variables were subjected to the Shapiro-Wilk and Bartlett tests, respectively. A descriptive analysis was performed to obtain the demographic profile of the sample. Percentage analysis was used to determine sex, race, and success rate distributions. The Kruskal-Wallis test was used to analyze systolic and diastolic BPs. Analysis of variance
(ANOVA) was used for HR analysis. The Mann-Whitney test was used to measure latency time, anesthetic duration, and VAS pain scores. All tests were significant at a level of 5%. BioEstat 5.0 (Mamirauá Institute), SPSS 17 (SPSS, Inc., Chicago, IL), and GraphPad Prism 7.0 (GraphPad Software, La Jolla, CA) statistical software were used for the analyses.

3. Results

Of the 31 study volunteers, there were 18 women and 13 men (Table 1). The mean age of the volunteers was 24 ± 2.9 y. The race distribution consisted of 11 pheodermic, 14 leucodermic, and six melanodermic volunteers. Regarding the anxiety measured by the Corah scale, most volunteers were mildly anxious (n = 17) or a little anxious (n = 12). Of the remaining volunteers, one was moderately anxious, and the other was extremely anxious.

<table>
<thead>
<tr>
<th>Race</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leucoderma</td>
<td>14</td>
<td>45,2</td>
</tr>
<tr>
<td>Pheoderma</td>
<td>11</td>
<td>35,5</td>
</tr>
<tr>
<td>Melanoderma</td>
<td>6</td>
<td>19,3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corah scale</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>A little anxious</td>
<td>12</td>
<td>38,8</td>
</tr>
<tr>
<td>Mildly anxious</td>
<td>17</td>
<td>54,8</td>
</tr>
<tr>
<td>Moderately anxious</td>
<td>1</td>
<td>3,2</td>
</tr>
<tr>
<td>Extremely anxious</td>
<td>1</td>
<td>3,2</td>
</tr>
</tbody>
</table>

Figures 3 and 4 display the impact of the two anesthetic types on the systolic and diastolic BPs, respectively, at three study time points (i.e., before, during, and 30 min after anesthesia). Kruskal-Wallis analysis of the BP data showed no statistically significant differences between the anesthetic types and time points for the systolic (p = 0.928) and diastolic (p = 0.450) BPs.
Figure 3 displays the impact of the two anesthetic types on HR. ANOVA showed no statistically significant differences between the anesthetic types and time points for HR (p = 0.624).
VAS data analyses and Mann-Whitney testing showed no statistically significant differences between the anesthetic treatments for needle insertion \( (p = 0.741) \) and anesthetic deposition \( (p = 0.810) \).

Table 2. Means, standard deviations, and \( p \) values of the VAS scores during needle insertion and local anesthetic deposition of the two anesthetic types

<table>
<thead>
<tr>
<th></th>
<th>Articaine</th>
<th></th>
<th>Lidocaine</th>
<th></th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle insertion</td>
<td>Mean</td>
<td>Standard deviation</td>
<td>Mean</td>
<td>Standard deviation</td>
<td></td>
</tr>
<tr>
<td>Articaine</td>
<td>0.42</td>
<td>0.68</td>
<td>0.62</td>
<td>0.53</td>
<td>0.741</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>0.19</td>
<td>0.5</td>
<td>0.25</td>
<td>0.53</td>
<td>0.810</td>
</tr>
</tbody>
</table>

*Statistically significant difference \( (p < 0.05) \).

Both of the anesthetic protocols had failure rates of 9.7% \( (3/31) \).

Figures 6 and 7 display the anesthesia latency and duration, respectively, for the two anesthetics. Mann-Whitney testing showed no statistically significant differences between the anesthetic treatments for anesthesia latency \( (p = 0.758) \) and duration \( (p = 0.791) \).
4. Discussion

In this study, we used a Microcontrolled Digital Pulp Tester™ (MIDIART Informática Ltda., []) to measure anesthesia success and duration. For many years, electrical stimuli have been used to measure anesthesia efficacy and techniques\textsuperscript{19}. Bjorn stated that dental anesthetic studies favor electrical stimuli because they provide control, allow for precise measurements, and are easily applied. Also, compared to other stimuli, electricity is better able to simulate physiological signals\textsuperscript{20-22}. 

Figure 6

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{articaine_lidocaine_graph.png}
\caption{Comparison of Articaine and Lidocaine effectiveness.}
\end{figure}

Figure 7

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{duration_graph.png}
\caption{Comparison of Articaine and Lidocaine duration.}
\end{figure}
Even minimally invasive dental treatments should provide the greatest comfort possible to patients. Unfortunately, oral anesthesia is still frightening to patients, causing uneasiness, fear, and anxiety\textsuperscript{23}. Although the goal of anesthesia is to provide a painless treatment, the anesthetic application itself results in an initial painful experience\textsuperscript{24}. The volunteers in this study had low levels of anxiety measured by the Corah scale\textsuperscript{18}. This result may be due to the volunteers knowing that they would be treated with computerized equipment or a technique promising painless anesthesia, which made them feel calmer and more relaxed\textsuperscript{25}.

In the present study, a 20% benzocaine topical anesthetic was applied prior to needle insertion for the infiltrative ACSBA anesthesia technique. However, many studies have shown that the administration of topical anesthetics before needle insertion has low efficacy\textsuperscript{24,26-28}. Meibach Tech, which is the manufacturer of the Morpheus\textsuperscript{TM} injector, also dispenses with the use of topical anesthesia in its instructions\textsuperscript{16}. Despite this, we decided to use topical anesthesia to avoid any reactions that could increase anxiety levels and, consequently, reduce the pain threshold\textsuperscript{24,29}.

The use of the ACSBA technique with the Morpheus\textsuperscript{TM} injector is an excellent alternative for anesthetizing and treating a single mandibular dental unit, which, previously, had only been possible with mandibular nerve block\textsuperscript{16}. This technique also produces satisfactory pulp anesthesia with smaller anesthetic amounts\textsuperscript{16}. Lidocaine is considered the gold standard local anesthetic, which makes it an excellent control for our study. Articaine has a high capacity for tissue diffusion and penetration and its use is increasingly growing in the dental anesthetics market\textsuperscript{2}. However, 4% articaine is still contraindicated for regional nerve block (i.e., IANB) because of the risk of complications, such as paresthesia\textsuperscript{2,30,31}. Despite this contraindication, 4% articaine is more effective compared to 2% lidocaine for IANB\textsuperscript{32} and may also be presented as a safe anesthetic\textsuperscript{11}. Considering the aforementioned studies, it is worth emphasizing the importance of our results, in which articaine
treatment produced physical parameter values similar to those of lidocaine, confirming its safety as described by Naichuan11.

In addition, our study provides a safe and effective way to use 4% articaine for inferior molar anesthesia with the ACSBA technique. This technique avoids the risk of paresthesia reported in the literature for inferior and lingual alveolar nerve blocks because it is not a regional anesthetic block technique and avoids unpleasant sensations, such as lip, tongue, and inferior hemiarcade anesthesia2,30,31. The technique used in our study provided greater comfort to the patients and only anesthetized the tooth to be treated.

In our study, the success rate of the ACSBA technique for both of the anesthetics was 90.3%, which is a high success rate compared to the success rates of IANB (80–85%) and vestibular anesthetic infiltration of the mandible with 4% articaine (65%)2,33-35. This technique is also easily reproducible. There have been variations in IANB success rates with lidocaine, which was caused by greater alveolar blade density, inferior alveolar nerve anatomical position variability, and difficulties in executing block techniques2.

With the vestibular infiltration technique, deposition occurs far from the target and the injection is uncontrolled and fast36. The ACSBA technique is superior to this technique because its slow and continuous intraseptal injection process provides diffusion facilitated by the cortical bone. The differences in anesthetic deposition between these techniques are directly related to the anesthesia success and duration because a smaller amount of the anesthetic is lost due to diffusion and absorption by other structures, including other tissues and blood vessels37. Throughout the injection procedure, the ACSBA technique with the Morpheus™ injector slowly and continuously deposits the anesthetic at a site that is closer to the target16. Such a technique follows the excellent anesthetic technique principles recommended in the literature2.

Anesthesia latency time and duration were similar for both of the study protocols, and there were no statistically significant differences between the
groups. The durations of approximately 60 and 70 min for lidocaine and articaine, respectively, are superior to the duration of mandibular infiltrations and equivalent to that of mandibular nerve blocks\textsuperscript{2,30,37}.

The VAS was used to evaluate pain\textsuperscript{38}. In most cases, we achieved painless or very close to zero pain treatments, and there were no statistically significant differences between the anesthetics or time points evaluated for needle insertion and anesthetic deposition. These results were expected because the technique used followed all of the literature recommendations for painless anesthesia, such as slow, continuous, and constant anesthesia. These results also corroborate previous studies of the electronic Morpheus\textsuperscript{TM} injector, which showed its efficacy for painless anesthesia application\textsuperscript{8-10}. The manufacturer of the Morpheus\textsuperscript{TM} injector reported that it causes no pain\textsuperscript{16}. The ACSBA technique used in our study is also strongly recommended for patients with mouth opening limitations due to its easy application, which does not require optimal mouth opening.

A study limitation is the use of articaine at the commercially available concentration (i.e., 4% articaine), which precludes a more reliable comparison from a pharmacological standpoint. However, this concentration was the effective clinical concentration available on the market. Future studies should compare 2% lidocaine with 2 and 4% articaine to eliminate the potential influence of articaine concentration on the results.

5. Conclusions

Regarding anesthetic safety, 4% articaine (1:100000 epinephrine) and 2% lidocaine (1:100000 epinephrine) were of equivalent safety, and they did not influence the physical parameters evaluated. For anesthesia duration, articaine was similar to lidocaine with means of 70.7 and 61.1 min, respectively.
The intraseptal ACSBA anesthesia technique was effective, provided sufficient anesthesia duration to perform medium-term dental procedures with both of the anesthetics studied, and produced painless anesthesia, which provided greater patient comfort.

Acknowledgments

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