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Anaesthetic efficacy of 4% articaine compared with 2% mepivacaine: a randomized, double-blind, crossover clinical trial

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Abstract. The aim of this study was to evaluate the clinical efficacy of 4% articaine (Ar4) compared to 2% mepivacaine (Me2), both in combination with 1:100,000 epinephrine, in a unique soft tissue model. This was a randomized, double-blind, crossover clinical trial. The anaesthetic was applied to the lower lip using a computerized local delivery system. The following were evaluated: blood flow, thermal sensation, pressure and proprioception, extent of anaesthesia, gradual elimination, and the final duration of the effect of the anaesthesia. Seventy-two volunteers completed all parts of the study. Significant differences, which indicated better effectiveness of Me2 compared to Ar4, were observed in the following tests: reduction in blood flow (larger in the Me2 group); anaesthetized area at 30 min (larger in the Me2 group); pressure tests; temperature tests after 20 min; fine and discriminatory proprioception tests after 20 min. The volunteers' perception of anaesthesia at 30, 40, 50, and 60 min was superior for Me2 at all recorded time points. The duration of anaesthesia was also superior for Me2. The overall performance of Me2 was superior to Ar4, implying that Me2 provides a more effective anaesthesia in terms of depth, extent, and duration.

Key words: articaine; mepivacaine; local anaesthesia; clinical efficacy; clinical trial.

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Local anaesthetic solutions are some of the most commonly used drugs in dentistry. However, there are differences in the potency and pharmacokinetic parameters of the many drugs that are available, which account for the variations in onset, depth, and duration of anaesthesia. These differences should guide professionals in the selection of a particular anaesthetic[1,2].

Few studies have compared the clinical efficacy of articaine with that of mepivacaine[3–7]. Allegretti et al. compared the efficacy of three anaesthetic solutions in the treatment of irreversible pulpitis of

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the mandibular molars: 4% articaine, 2% lidocaine, and 2% mepivacaine, all in combination with 1:100,000 epinephrine[4]. No statistically significant differences in the anaesthesia success rate were found; however, 2% mepivacaine performed a little better than 4% articaine. Colombini et al. reported that 4% articaine (with 1:100,000 epinephrine) had a longer anaesthetic effect and could improve postoperative pain control after surgery for impacted lower third molars compared to 2% mepivacaine (with 1:100,000 epinephrine)[3]. Gazal found that 4% articaine (with 1:100,000 epinephrine) had better potency and a more rapid onset of action, as well as earlier lip and tooth numbness, compared to 2% mepivacaine (with 1:100,000 epinephrine) for mandibular first molar pulp anaesthesia through inferior alveolar nerve block[5]. Odabaş et al. compared the efficacy of 4% articaine with 1:200,000 epinephrine to that of 3% mepivacaine without a vasoconstrictor for paediatric anaesthesia, and observed that the two solutions presented the same efficacy; however, articaine with the vasoconstrictor showed a longer duration of anaesthesia than mepivacaine without a vasoconstrictor[6]. Said Yekta-Michael et al. compared 4% articaine with 3% mepivacaine, both without a vasoconstrictor, and observed that mepivacaine provided a longer duration of analgesia to the anaesthetized tooth and had a stronger influence on the thermal and mechanical test parameters investigated at all measurement times[7].

Articaine is classified as an amide because of the linkage of its intermediate chain – a thiophene ring instead of a benzene ring. A second molecular difference between articaine and other amide local anaesthetics is the extra ester linkage incorporated into the articaine molecule, which results in the hydrolysis of articaine by plasma esterases. The result is that articaine has a half-life of only 20 min compared with 90 min for lidocaine and other amides that require hepatic clearance. Articaine also possesses a high vasodilatory property; because of this, it is mostly used in association with a vasoconstrictor to increase its anaesthetic efficacy[7,8]. Mepivacaine is an amide-type local anaesthetic that is used widely in dentistry and which has a similar structure to that of bupivacaine. Mepivacaine is metabolized in the liver and, in contrast to other local anaesthetics, has a mild vasodilatory effect[7,9]. Despite claims regarding the superiority of articaine compared with mepivacaine[3,5], the relevant literature indicates that articaine is equally as effective or less effective when compared statistically to mepivacaine[4–6].

The aim of this study was to evaluate the clinical efficacy of 4% articaine compared to 2% mepivacaine, both in combination with 1:100,000 epinephrine, using a unique soft tissue method not related to surgical trauma or the intense pain associated with pulpitis, or subject to variations in technique. The null hypothesis was that the two anaesthetics – 4% articaine and 2% mepivacaine – would present similar behaviour, since they are both classified in the intermediate potency and duration group. The alternative hypothesis was the superiority of 2% mepivacaine for the parameters of clinical anaesthesia assessed, since it may provide a more pronounced vasoconstriction due to the lower vasodilatory property of the anaesthetic, as well as a greater depth and duration of anaesthesia, regardless of the differences between the anaesthetic concentrations.

Materials and methods

This study was a randomized, double-blind, crossover clinical trial. The objective was to compare two commercially available anaesthetic solutions: 2% mepivacaine with 1:100,000 epinephrine (Me2) and 4% articaine with 1:100,000 epinephrine (Ar4) (Mepiadre and Articaíne, respectively; DFL, Rio de Janeiro, Brazil).

Sample selection and sample size calculation

All subjects signed a consent form to participate in this study. Initial examinations were performed on 100 adult volunteers (age range 18–35 years), of whom 72 were included in the study sample. The decision to use this number of subjects was reached after a sample size calculation based on the mean differences obtained in 10 patients tested using the same protocol in a pilot study, which was conducted to calibrate the researcher; alpha was set at 5% and power at 80% (Bioestat 5.3; Instituto Mamirauá, Tefé, Brazil).

The inclusion criteria were good systemic health (American Society of Anesthesiologists status 1 (ASA 1)), a history of previous use of dental local anaesthetics, and willingness to participate in the study. Volunteers were excluded if they presented a systemic illness, any gastrointestinal, cardiovascular, or kidney disease, an infection or inflammation at the site of proposed anaesthetic application, a history of hypersensitivity to the drugs tested (Ar4 or Me2) or any component of the anaesthetic solutions, a history of hypersensitivity to any other drug or food, any use of analgesics, anti-inflammatory drugs, sedatives, tranquilizers, or other drugs that could modify the perception of anaesthesia, a history of psychiatric illness, or were pregnant or breastfeeding.

Randomization, sequence generation, and volunteer allocation

The volunteers were assigned randomly to one of two study groups using a six-sided die; if a 2, 4, or 6 was thrown, the subject was assigned to group 1; if a 1, 3, or 5 was thrown, the subject was assigned to group 2. By drawing lots, it was decided that mepivacaine would be designated 'anaesthetic 1' and articaine would be designated 'anaesthetic 2'. The labels were removed from the anaesthetic tubes to avoid operator or patient detection; the tubes were marked as '1' or '2' and stored according to the manufacturer's recommendations. A third person, who was not directly involved in the research protocol, was responsible for blinding of the clinical procedures.

Initially, the subjects in group 1 received anaesthetic 1 and the subjects in group 2 received anaesthetic 2. After a 7-day wash-out period, the crossover study was performed: group 1 subjects received local infiltration with anaesthetic 2 and group 2 subjects received local infiltration with anaesthetic 1. The research flowchart is shown in Fig. 1.

Clinical sequence and procedures

After signing the informed consent agreement, and before any anaesthetic infiltration, the volunteers were blindfolded and received the test sequence to establish the baseline parameters. The tests were selected in order to evaluate blood flow, thermal stimuli and acute pressure (type A-delta nerve fibres), superficial touch (type A-beta nerve fibres), deep/diffuse pressure and temperature (type C nerve fibres), and proprioception stimuli (type A-alpha nerve fibres). After local anaesthesia, the anaesthetic diffusivity test was performed to assess the area of anaesthesia. All tests were repeated at 3 min (T3), 10 min (T10), 20 min (T20), and 30 min (T30) after the application of the anaesthetic. The lower lip was chosen, as the peri-oral region is one of the areas with the highest density of peripheral receptors. These receptors act through the lemniscal system and generate a highly discriminative somatic sensitivity, which results in the ability to accurately identify

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