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Original Article

Articaine 4% Containing 1% Magnesium Sulphate Versus Articaine 4%For Inferior Alveolar Nerve Block in Cases with Irreversible Pulpitis: Randomized Clinical Study

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Abstract

Aim: to access the success rate of inferior alveolar nerve block (IANB) with 4% articaine (1/100000 epinephrine) containing 1% magnesium sulphate ($MgSO_4$) in cases suffering from acute irreversible pulpitis (AIP) related to mandibular molars.

Subjects & methods: 50 patients suffering from (AIP) were carefully selected, then divided into two groups, the first one (control) injected with 1.8 ml articaine (1/100000 epinephrine) by IANB while the second group (Test) injected with 1.8 ml articaine (1/100000 epinephrine – 1% $MgSO_4$). Lip numbness was considered a check for anesthetic success within 15 minutes. During the access cavity preparation and initial files placement, the pain scores were recorded according to Heft Parker Visual Analog Scale HP-VAS, Success was defined as the ability to access and instrument the tooth without pain (visual analogue scale rating of 0) or mild pain (visual analogue scale rating less than or equal to 54 mm). Then all data were analyzed by Chi-Square and T-Test, comparisons were considered significant if $P < .05$.

Results: the success of the test group ($MgSO_4$ group) was 85% while it was 55% for the control one.

Conclusion: mixing 4% articaine (1/100000 epinephrine) with 1% $MgSO_4$ had a positive effect on IANB success in patients with (AIP) related to the mandibular molars.

Keywords: 4% articaine, Magnesium Sulphate, Lower Molars, Acute Irreversible pulpitis.

Introduction

Malamed reported that the most popular injection technique for anesthesia the lower molars is the inferior alveolar nerve block IANB [(1)]

Clinical trials in patients with AIP related to the lower molars reported 40 – 80% failure in obtaining profound anesthesia by IANB [(2, 3, 4)]. This failure could be due to activation of special receptors on the terminal peripheral nociceptors like tetrodotoxin(TTX) and capsaicin- sensitive transient receptor potentialvanilloid type 1(TRPV1) [(5, 6)]

Accordingly, many studies and clinical trials are directed toward augmentation of IANB success in patients with AIP through different methods by introducing different types of anesthetic solutions [(4)], alternative injections [(7,8)] premeditation before IANB [(9)] and addition of an adjuvant to the anesthetic agent [(10)].Articaine is derived from thiophane so articaine is more lipid soluble. Therefore,

allowing more anesthetic solution diffusing through the nerve membranes raising its potency and anesthetic effect [11].

Magnesium sulphate ($MgSO_4$) is used as a supplemental in many fields of general anesthesia like cardio v Vascular Surgery, epilepsy treatment…. Etc. [12] Narang et al reported that $MgSO_4$ had superior anesthetic and analgesic actions, thus mixing $MgSO_4$ to lignocaine in local anesthesia for upper limb surgery as an intravenous single dose [13]. Reinjection of $MgSO_4$ before IANB increases the success rate of mandibular anesthesia [14]

There are no clinical trials evaluating $MgSO_4$ combined with articaine as a single dose (one cartridge)

Aim of the study

Add mixture of 1% $MgSO_4$ with 4% articaine (1/100000 epinephrine) in one cartridge to investigate the anesthetic effect during routine endodontic treatment in patients with AIP related to the mandibular molars. The null hypothesis was that there is no difference between the administrations of both local anesthesia.

Materials and methods:

the ethics committee of the Faculty of Dentistry, Kafrelsheikh University, Egypt approved this study. All the patients participated in this study informed about all procedures in this study and signed a written approval. A pilot study ($n = 5$ per group) was done to obtain estimates for sample size calculation. The minimum sample size was calculated as 25 per group using sampling software (G power version 3.1.9.2). The alpha error was left at 5% and statistical power of 80% and expected dropout rate was 10% in each group. Root canal treatments in our study took place between June and October 2022. A total of 50 patients had been come to the department of endodontics, Kafrelsheikh University were selected, these patients were suffered from AIP. The diagnosis was based on pain characters, signs and symptoms and confirmed with clinical examination and thermal tests.

Inclusion criteria: participants were an age range from 20-50 years, reported symptoms of AIP related to lower molars. They suffered painful response to endo-ice spray which persisted after removal of the spray, and have intact periodontal ligament space as revealed in periapical radiograph.

Exclusion criteria: patients taking antidepressant medication, opioids, beta blocker or premedicated before clinical diagnosis, pregnant or lactating women, patients with systemic diseases like diabetic patients and patients reported no lip numbness after IANB.

Preparation of the anesthetic solution: 0.18 ml was drawn from a cartridge of Articaine HCl 4% with epinephrine 1:100,000 (Artpharmadent, Artpharma Co., Cairo, Egypt) by the aid of insulin syringe then the capsule was reloaded with 0.18 ml of $MgSO_4$ solution 10% weight-volume (El Gomhouria Company,Tanta, Egypt) with continuous agitation of the cartridge to avoid precipitation of the $MgSO_4$. 1% $MgSO_4$ anesthetic cartridge was obtained (for IANB injection to the test group). For the control group, substitution of the subtract 0.18 ml from the articaine cartridge with the same volume sterile distilled water with a final concentration of 1.8% articaine.

This study was given a parallel design with the allocation ratio of 1:1 articaine/ articaine containing 1% magnesium sulphate for each primary and final outcome.

Initially, the selected patients were divided into 2 groups of men and womens, who were then classified randomly into 2 subgroups of articaine or articaine containing 1% magnesium sulphate by using random allocation software (Microsoft excel 2019). All participants (Patient, nurses and clinicians) were blinded to patient allocation. a blinded nurse enrolled all participants and assigned

them to intervention. There were equal numbers of articaine and articaine containing 1% magnesium sulphate cartridges available that had been covered and given a code. Codes were recorded in a list and kept in opaque envelopes with nonparticipating personal. Cartridges were given randomly and in equal numbers according to the subgroups of articaine or articaine containing 1% magnesium sulphate. All the injections were given by the same clinician.

The injection was done by the standard IANB; aspiration before administrating the anesthetic solution, then injection was done as slow as possible. All the injections were done using a 27 gauge, 1.5-inch needles (CK ject- Korea) mounted to aspirating dental syringe.

Checking for IANB success was assessed by profound lip numbness within 15 minutes (Shai et al, 2018) [(15)]. If the patient reported absence of lip numbness, the patient was excluded from the study.

For patients with successful IANB, The patients were ordered to rate any discomfort or pain either during the access opening or canals negotiations by the initial files on a Heft-Parker Visual Analogue Scale (VAS) [(2)] as primary outcome. Root canal treatment was initiated and access cavity preparation was done under rubber dam isolation (Nic Tone Romania). VAS data collection was divided into 4 categories. No pain corresponded to 0 mm. Mild pain was defined as >0mmand#54 mm, which included the descriptors of faint, weak, and mild pain. Moderate pain was defined as >54 mm but <114 mm. Severe pain was defined as any score >114 mm that included the descriptors of strong, intense, and maximum possible where additional intrapulpal anesthesia was injected. Negotiation of the canals was done by 10 size K file (Mani Inc., Japan). Cleaning and shaping of the root canal system was performed subsequently using M3 pro gold rotary files (United Dental-China) and NaOCl 5.25% irrigant(CLOROX-Egypt), sterile cotton pellet was placed, and closed dressing given using Orafil-G (Prevest, India). Figure 1 shows the Consort flow diagram of this randomized controlled clinical trial. Post-operative instructions were given to all the patients along with the prescription of an anti-inflammatory drug(diclofenac sodium 50 mg, cataflam, Novartis), to be consumed only if pain arises. On the subsequent visit, the endodontic therapy was completed

Statistical analysis

SPSS, statistical package for the social science was used for analysis of baseline and outcome data (age, sex, initial pain score, and IANB success) (significant level was set at $P< 0.05$)

The chi-square test was used to analyze sex difference and the success of IANB between the control group and $MgSO_4$ group. T-test was used for analysis of age and difference of pain scores.

Results:

after the exclusion of 8 patients, a total of 42 patients participated in this study. 17 patients received 1.8 ml articaine (1/100000 epinephrine) (control group) and 25 patients were injected with (1% $MgSO_4$ – 4% articaine) (1/100000 epinephrine) (Test group)

Table 1 presented the sex, age and preoperative pain scores. There was no significant difference between the test and the control groups regarding these variables.

The success of IANB for the test group was 85% based on HP-VAS scores and 55% for the control group, with a confirmed statistical significant difference between the two groups.

Discussion:

This study was done to investigate the adjunctive effect of $MgSO_4$ added to 4% articaine in order to obtain an effective pulpal anesthesia in patients of hyperemic irreversible pulpitis. All the mandibular molars included in this study were confirmly diagnosed (acute irreversible pulpitis) based on signs, symptoms and sensitivity tests.

Eight patients were excluded from this study (16%) due to IANB failure. These patients reported absence of lip numbness [(15)].

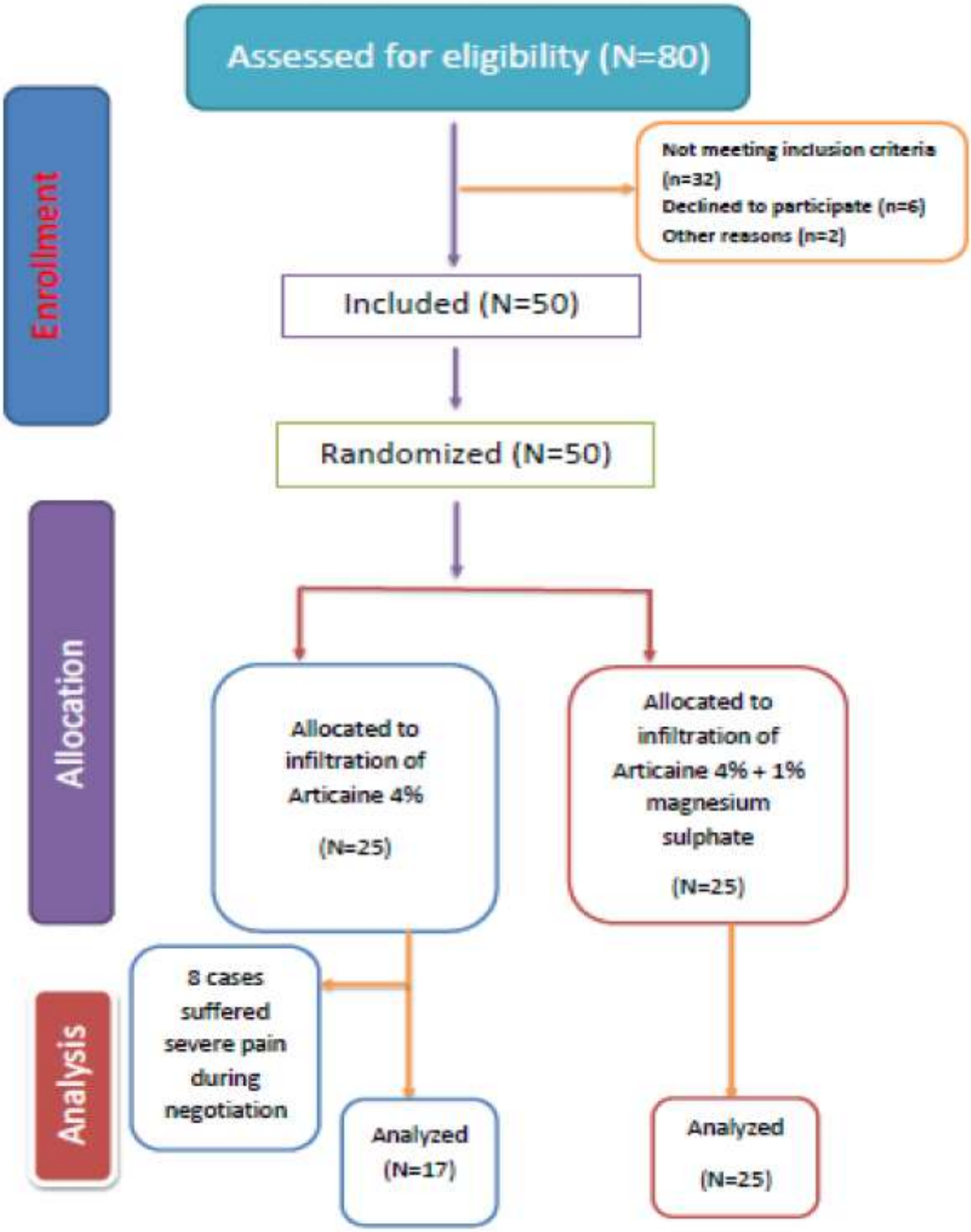

Figure 1: Consort flow diagram

Table 1: Comparison of the effect of $MgSO_4$and control group in achieving anaesthesia using IANB in patients with AIP

	$MgSO_4$ (n=25)	**Control group (n=17)**	**P value**	**95% confidence interval of the difference in means**
Sex	♀ 15 60% ♂ 10 40%	♀ 7 41% ♂ 10 59%	> 0.99	
Age ± standard deviation	37 years (± 10)	40 (± 12) years	0.209	(-10.10, 2.55)
Preoperative pain scores	140 mm (± 14)	145 (± 12)	0.350	(-4.3, 10.33)
Pain during access or initial files penetration ± standard deviation	20.33 mm (± 20.22)	65.33 mm (± 20.22)	< 0.001	(-48.55, -30.77)

Articaine was tested as the local anesthetic agent of choice as it is a commonly used anesthetic agent nowadays and proved more effective than the lidocaine type for IANB. [16, 17, 18, 19]

IANB failure may be due to wrong delivery of the anesthetic agent nearer to the nerve before it enters the mandibular foramen, also failure has been reported sometimes due to technical errors (unexperienced dentist), anatomical variations or the severity of the inflammation [20, 21, 6]

Adjuvant anesthetic agents and methods have been used in an attempt to improve IANB success especially for the mandibular molars with acute irreversible pulpitis, magnesium sulphate ($MgSO_4$) which is a naturally occurring mineral is one of these trial manners. Yentis et al reported that magnesium plays an important role in controlling the calcium (Ca) influx into the neurons. [22] Vastani et al, 2013 confirmed the ability of magnesium to lower the peripheral nerve excitability and increasing the local anesthetic agent diffusion to the nerve cells [23].

The effect of adding $MgSO_4$ to 4% articaine to achieve deeper pulpal anesthesia of mandibular molars was confirmed by this study (85% success compared to control group 55%)

Sex, age and the degree of the initial pain scores were not significantly different between $MgSO_4$ group and the control one.

Our results agreed with two trials that admixed Mg to ropivacaine and prilocaine to block the axillary brachial plexus getting a profound sensory block. [24, 25]

Regarding the safety of adding $MgSO_4$ in this study there were no comments about any adverse effect following the IANB [24, 25].

Assessment tool of the primary outcome was in accordance with Aggarwal et al and Simpson et al who evaluated the success of adequate pulpal anesthesia by pain levels during the access opening and instrumentation with the initial files using HP-VAS scores (no pain: 0 mm – mild pain ≤ 54 mm) [26, 27]

The maximum dosage of $MgSO_4$ used here is lesser than the adverse range and is safer for endodontic procedures as adverse drug reactions occur only when the serum magnesium level exceeds 6-7 mmol/kg.

Goyal et al, El Hamid, Lee et al administrated doses of 150 mg Mg as a supplemental to obtain nerve blocks, all them recorded a

significant increase in rate of success and none of them reported any adverse effects. [28, 29,30]

In our study, $MgSO_4$ concentration (1%) in accordance with Makherjee et al, Muthiah et al, Youssef et al; there are no previous studies in the literature on the action of Mg as a supplemental to articaine[31, 32,10] . However, Shetty et al [33] injected $MgSO_4$ 50% in patients with AIP one hour before the standard IANB and a statistically significant increase in success of IAN block was ensured.

In the previous study; Shetty et al [33], these patients received two separate injections which is assumed to cause patient discomfort thus in the present study the authors added the $MgSO_4$ in the same cartridge used for IANB to limit it to one injection.

$MgSO_4$ is safe and cheap, also showing chemical stability when combined with 4% articaine [34]

.This study was limited to vital pulp with acute irreversible pulpitis and articaine anesthesia ,additional studies are required in different pulp states and using different types of anesthesia.

Conclusion

Addition of 1% $MgSO_4$ to 4% articaine (1/100000 epinephrine) increased the success rate of IANB for mandibular molars with irreversible pulpitis. However, more researches with larger number of patients, more concentrations and longer time follow-up to confirm the safety concept of mixing $MgSO_4$ with 4% articaine should be carried out before its routine clinical application.

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