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The effect of oral analgesic premedication on the success rate of inferior alveolar nerve block for teeth with irreversible pulpitis: A randomized clinical trial

Negar Moghaddam[1], Ahmad Pirzadeh Ashraf[2], Fatemeh Bakhtiari[3], Fahime Mirzaali[3], Alireza Pournasrollah[3*]

Abstract

Objective: This study aimed to evaluate the effect of different premedication protocols on the success rate of the inferior alveolar nerve block (IANB) technique in mandibular molars with irreversible pulpitis.

Methods: Two hundred and ten participants were randomly assigned into three groups (n=70) and received one of the following premedications 30 minutes before IANB injection: dexamethasone, pharmapain (containing acetaminophen, ibuprofen, and caffeine), and a placebo lactose capsule. Pain severity was evaluated with the Heft–Parker visual analog scale (VAS) before and 15 minutes after the injection, during dentin removal, and when inserting files into the root canal. The IANB injection was considered successful if VAS values after 15 minutes implied no pain or mild pain.

Results: IANB success rates were comparable in the dexamethasone (51.4%), pharmapain (55.7%), and placebo (41.4%) groups (P=0.222). Pain severity at baseline, 15 minutes post-injection, and during dentin removal was comparable among the groups (P>0.05). However, when inserting endodontic files, the mean pain severity in the pharmapain group was significantly higher than the dexamethasone group (10.27 ± 1.71 versus 7.38 ± 2.24; P=0.002). No significant difference was observed between the placebo with any of the study groups (P>0.05).

Conclusions: Premedication with pharmapain (an anti-inflammatory agent) or dexamethasone (a corticosteroid) does not enhance the success rate of the IANB technique in mandibular molars with irreversible pulpitis compared to placebo. However, the use of dexamethasone was significantly more effective than pharmapain in reducing pain severity at inserting endodontic files.

Keywords: Anesthesia, Dexamethasone, Endodontics, Inferior alveolar nerve block, Irreversible pulpitis, Success rate

Introduction

Pain management is integral to a successful root canal treatment. The standard technique for pulpal anesthesia of posterior mandibular teeth is the inferior alveolar nerve block (IANB) (1). However, achieving profound pulpal anesthesia in mandibular posterior teeth with irreversible pulpitis can be challenging. Therefore, various studies have investigated the efficacy of supplemental injection techniques such as intraligamentary injection and buccal infiltration to increase the IANB success rate (2, 3).

Premedication with nonsteroidal anti-inflammatory drugs (NSAIDs) has been hypothesized to increase the efficacy of IANB in cases with irreversible pulpitis, by blocking the synthesis of specific prostaglandins that complicate the mechanism of action of the anesthetic drugs (4). The result of an umbrella review suggested that ibuprofen and acetaminophen are the most effective NSAIDs for dental pain relief (5). Although several studies have demonstrated increased IANB success rates following premedication with ibuprofen,

[1]Department of Endodontics, School of Dentistry, Tabriz University of Medical Sciences, Tabriz, Iran
[2]Department of Endodontics, School of Dentistry, Tabriz Branch, Islamic Azad University, Tabriz, Iran
[3]Department of Prosthodontics, School of Dentistry, Tabriz University of Medical Sciences, Tabriz, Iran

*Corresponding Author: Alireza Pournasrollah
Department of Prosthodontics, School of Dentistry, Tabriz University of Medical Sciences, Tabriz, Iran.
Email: a.pour.1391@gmail.com
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acetaminophen codeine, and indomethacin (6-8), other studies did not report any different results from the placebo group (9, 10). Pharmapain is a combination of 325 mg acetaminophen, 200 mg ibuprofen, and 40 mg caffeine. Caffeine is a mild stimulator of the central nervous system and causes vasoconstriction, which can lead to pain relief. Caffeine-containing analgesics are proven to be effective in alleviating dental pain (11).

Corticosteroids reduce inflammation by inhibiting leukotrienes and thus prostaglandin synthesis (4). Dexamethasone has a long action duration (24–36 hours) and shows the greatest anti-inflammatory effect among corticosteroids (12). Previous clinical trials showed that corticosteroids, especially dexamethasone, can be used effectively before IANB injection (13-15). Furthermore, the results of a systematic review showed that the administration of 4 mg dexamethasone can be effective for pain control in symptomatic irreversible pulpitis (16). According to Hegda et al. (15), premedication with prednisolone, dexamethasone, or ketorolac significantly increased the IANB success rate in patients with symptomatic irreversible pulpitis.

There are a few studies that compared the efficacy of taking corticosteroids and NSAIDs on the IANB success rate. Therefore, the current randomized clinical trial aimed to assess the efficacy of premedication with dexamethasone or pharmapain on the success rate of IANB in patients with irreversible pulpitis.

Materials and methods

The protocol of the current triple-blind randomized clinical trial was approved by the ethics committee of Tabriz University of Medical Sciences (Tbzmed.rec.1394.316). This study was registered in IRCT under the code IRCT2014040417 11SN1. The current clinical trial was conducted according to the CONSORT 2010 guidelines and the declaration of Helsinki.

Patients were provided with adequate information about the procedural steps and the possibility of discomfort and risks for participation. Patients were enrolled after obtaining informed written consent.

Sample size calculation

The sample size was calculated according to the results of a study by Aggarwal et al. (10). Considering an α=0.05, a study power of 80%, and a significant decrease of 20 units in pain severity; a sample size of 70 subjects per group, was deemed sufficient. We used the OpenEpi website for sample size calculation. Further details and formulas are available at http://www.openepi.com/ (17).

Inclusion and exclusion criteria

The sample consisted of healthy participants at least 18 years of age, with a definitive diagnosis of asymptomatic irreversible pulpitis in mandibular first or second molars and a normal view on periapical radiographs. The patients were selected from those referring to the Department of Endodontics, School of Dentistry, Tabriz University of Medical Sciences, Tabriz, Iran between May 2018 and March 2019.

The clinical diagnosis of irreversible pulpitis was based on the results of electric pulp testing and a cold test. A positive response to the electric pulp test ruled out pulpal necrosis. Irreversible pulpitis was confirmed when the patient responded to the cold test with persisting and progressive pain (for at least 10 seconds) with moderate to severe intensity (7).

Medically compromised patients, lactating or pregnant women, patients with nasal polyps, and those showing allergy to lidocaine, NSAIDs, and/or dexamethasone were excluded. The exclusion criteria also involved subjects who took any analgesic medication 12 hours before the treatment. The investigation also did not include teeth with periodontal ligament space widening, periapical radiolucency, and the presence of a crown on the tooth.

Patient allocation

Patients were randomly allocated to three study groups (n=70) and received one of the following medications 30 minutes before IANB injection: 1) one capsule of dexamethasone 0.5 mg (Hakim Pharmaceutical Company, Tehran, Iran); 2) one capsule of pharmapain 400 mg (Pharma Chemie Pharmaceutical Co, Tehran, Iran); and 3) a placebo lactose capsule. The capsules were prepared by a pharmacologist and they were all identical in terms of appearance.

The patient, the clinician who performed the endodontic treatment, and the evaluator were all blind to the group allocation (triple-bind randomized clinical trial).

Treatment procedure

The IANB injection was carried out with a dental syringe capable of aspiration and with a 27-gauge needle. The needle was inserted into the mucosa, and after contact with the mandibular bone, it was withdrawn 1–2 mm. Following achieving a negative

aspiration result, the anesthetic agent was deposited slowly. The anesthetic drug consisted of 2% lidocaine with 1:80,000 epinephrine concentration (Daroupakhsh, Tehran, Iran).

Fifteen minutes after injection, the anesthetic signs of soft tissues were evaluated. If the patient did not report lip numbness, the IANB technique was considered unsuccessful, and the patient was excluded from the study. When the IANB injection was successful, pain severity was assessed according to the cold test. Then, the tooth was isolated, and an access cavity was prepared. The patient was asked to report any pain during dentin removal for access cavity preparation. The pain level was also assessed at the time of the file insertion into the root canals. The endodontic treatment was completed according to the standard protocols and the patient was referred for restorative procedures.

Pain assessment

Pain severity was evaluated using the Heft–Parker visual analog scale (VAS) (18), which extends from 0 to 17 cm. In this index, 0 cm indicates no pain, values from 0 to 5.4 cm represent mild pain, those between 5.4 and 14.4 cm correspond to moderate pain, and values higher than 14.4 cm show severe pain. Pain intensity was evaluated before taking medications (baseline) and 15 minutes after IANB injection using VAS response to the cold testing. Also, the patient's pain severity was asked during dentine removal and when the endodontic files were inserted into the root canal.

The IANB injection was considered successful when the VAS value after 15 minutes ranged from 0 to 5.4 cm (no pain or mild pain) (9). The assessment of pain severity was performed by a researcher, who was blind to the group allocation.

Statistical analysis

The statistical analyses were conducted using SPSS 22.0 (IBM Corp., Armonk, N.Y., USA). The chi-square test was used to compare the IANB success rate among the groups. Since data regarding pain intensity was not normally distributed, the non-parametric Kruskal-Wallis test and Mann–Whitney U test were used to compare the pain intensity between the groups at different treatment stages. P-values less than 0.05 were considered statistically significant.

Results

A total of 210 consecutive patients participated in this study. No complication was reported in any subject within the first 48 hours after the treatment. The study sample included 32 (45.7%), 32 (45.7%), and 33 (47.1%) males in dexamethasone, Pharmapain, and placebo groups, respectively. There was no significant difference in gender distribution among the study groups (P=0.98).

The success rate of the IANB injection was 51.4%, 55.7%, and 41.4%, in the dexamethasone, Pharmapain, and placebo groups, respectively. The result of the chi-squared test did not reveal any significant differences between the three groups (P=0.222).

Table 1 represents the pain severity at different stages in each study group. At baseline, 15 minutes after IANB injection and during dentin removal, the pain severity was comparable between the groups (P>0.05; Table 1). However, pain perception differed significantly among the groups when the endodontic files were inserted into the root canal (P=0.002; Table 1). The mean pain severity in the pharmapain group (10.27 ± 1.71) was significantly higher than that in the dexamethasone (7.38 ± 2.24) group (P<0.05; Table 1). No significant difference was observed between the placebo (8.11 ±1.62) with pharmapain or dexamethasone groups (P> 0.05; Table 1).

Discussion

The study revealed that there was no statistically significant difference in the success rate of IANB injection following premedication with dexamethasone, Pharmapain, or a placebo capsule. Pharmapain exhibited the highest IANB success rate (55.7%) and the placebo group showed the lowest (41.4%). The findings of this study align with those of Kumar et al. (19), who

Table 1. Descriptice statistics of pain severity (cm) at different treatment stages in the study groups

	Baseline Mean ± SD	15 min after injection Mean ± SD	Dentin removal Mean ± SD	File insertion Mean ± SD
Dexamethasone	3.81 ± 3.80	0.50 ± 1.21	5.00 ± 1.97	7.38 ± 2.24[b]
Pharmapain	4.66 ± 4.26	0.54 ± 1.98	5.23 ± 0.44	10.27 ± 1.71[a]
Placebo	3.83 ± 3.56	0.48 ± 0.86	4.73 ± 1.12	8.11 ± 1.62[a,b]
P- value	0.35	0.12	0.31	0.002

SD: Standard deviation
Different lowercase letters indicate statistical differences between groups at P<0.05.

observed similar IANB success rates when comparing premedication with dexamethasone, ibuprofen, and placebo in patients suffering from symptomatic irreversible pulpitis. Interestingly, they found that the combination of dexamethasone and ibuprofen showed significantly more favorable results than the placebo or using the drugs alone. Ianiro et al. (8) also found no significant difference in IANB success rates after premedication by a combination of acetaminophen and ibuprofen versus a control group.

In contrast to the findings of this study, several studies have shown that preoperative administration of 400 mg or 600 mg ibuprofen was more effective than placebo in achieving anesthesia (6, 7, 21, 22). Elnaghy et al. (20) reported success rates of 54% and 58% for IANB premedicated with ibuprofen and dexamethasone respectively, which was significantly higher than the placebo group (32%). In the present study, the success rate for the placebo group was greater (41.4%) compared to the value reported by Elnaghy et al (20). They focused on emergency patients experiencing moderate to severe pain due to symptomatic irreversible pulpitis, whereas our study involved patients with asymptomatic irreversible pulpitis and mild pain. Therefore, variations in patient selection criteria, including the inclusion of patients with spontaneous pain or those showing prolonged pain during cold testing, may explain the differences in these findings. Shahi et al. (13) discovered that dexamethasone was more effective than either placebo or ibuprofen in enhancing the success of IANB, with their criteria for success being lip numbness. Our approach was different; we evaluated the pain response to the cold test after 15 minutes of IANB injection, and VAS values ranging from 0 to 5.4 cm (no pain or mild pain) were considered representative of the treatment success. This method aligns with methodologies used in other studies (6-10).

In the present study, none of the premedication strategies achieved complete anesthesia. The highest pain level was reported during the initial stage of canal preparation. Others have also indicated that the most intense pain was typically associated with file insertion (13). While the pain experienced at the baseline, after injection, and during dentin removal was comparable between the groups, at the file insertion stage, patients who received dexamethasone reported a significantly lower pain level compared to those who took Pharmapain. The pain level of the patients in the placebo group was not significantly different from those who received either dexamethasone or Pharmapain. Dexamethasone functions by inhibiting the formation of arachidonic acid and blocking both cyclooxygenase and lipoxygenase pathways. In contrast, ibuprofen acts later in the inflammatory process, specifically inhibiting cyclooxygenase enzymes and thus the production of prostaglandins (19). According to a systematic review by Jose et al. (23), oral corticosteroids such as dexamethasone, tend to offer better analgesic effectiveness than NSAIDs when used as premedication to alleviate post-endodontic pain.

The present study was not without limitations. Firstly, pain intensity was assessed based on the subjective VAS scale, which may vary among individuals, potentially introducing bias in interpreting the results. Secondly, we diagnosed pulpitis based on clinical findings, whereas the definitive standard for diagnosis is histological examination. This may have led to the inclusion of some participants whose condition did not meet the criteria for pulpitis.

Conclusions

The findings of the present study suggest that premedication with pharmapain (an anti-inflammatory agent) and dexamethasone (a corticosteroid) did not enhance the success rate of IANB injection. However, pain during the file insertion was significantly reduced in patients who took dexamethasone compared to those who took Pharmapain.

Conflict of interest

There are no conflicts of interest.

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