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Effect of Premedication with Ibuprofen and Meloxicam on the efficacy of Inferior Alveolar Nerve Block in Irreversible Pulpitis

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Abstract
Pain relief in irreversible pulpitis cases with inferior alveolar nerve block is difficult, more-so in the case of mandibular molars. The present study evaluated the effect of premedication with non-steroidal anti-inflammatory drugs on local anaesthesia during endodontic therapy. In a prospective, randomised, double blinded clinical trial, 75 patients (25 per group) with symptomatic irreversible pulpitis were selected. They were given either placebo, 600 mg ibuprofen, or 7.5mg meloxicam an hour before local anaesthesia. Each participant recorded their pain score on a 10 centimetre visual analogue scale four times during the procedure. Pain was recorded: 1) before taking the analgesic, 2) 15 minutes after anaesthesia in response to an electric pulp test, 3) during access cavity preparation and 4) during biomechanical preparation. No or mild pain at any stage was reported as success. Data were analysed by the Kruskal-Wallis and one way analysis of variance tests. Ibuprofen and meloxicam showed significantly better results than placebo ($p<0.05$). The success rates were 92%, 88% and 60% for ibuprofen, meloxicam and placebo, respectively. There was no significant difference between ibuprofen and meloxicam ($p>0.05$). The study concludes premedication with ibuprofen and meloxicam significantly enhances the effectiveness of local anaesthesia in patients with irreversible pulpitis.

Keywords: *Anaesthesia, inferior alveolar nerve block, irreversible pulpitis, placebo, premedication.*

Introduction

Pain is the principal reason for seeking emergency endodontic treatment. For a successful endodontic treatment, absolute pain relief is an essential prerequisite[(1)]. Local anaesthesia is considered to be the major modality for dental pain control. For mandibular molars, inferior alveolar nerve block (IANB) is the most accepted method of local anaesthesia. However, it often fails to provide adequate pain relief. Several articles have reported the success rate of 75-90 % with inferior alveolar nerve block for uninflamed pulp[(2,3)]. The success rate further declines when the pulp is inflamed. The presence of pulpal inflammation has been reported to cause inferior alveolar nerve block failure in approximately 30%–45% of cases[(4)]. Hence, some researchers have suggested reducing the pulpal inflammation before injecting anaesthesia to make it more effective[(5)]. For dental pain, non-steroidal anti-inflammatory drugs (NSAIDs) have a long history of clinical use. Their over-the-counter availability

and efficacy in relieving pain and fever makes them popular drugs. Additionally, they have a low side effect profile at therapeutic doses. NSAIDs block the cyclo-oxygenase enzyme, thereby reducing prostaglandins[6]. This in turn, results in lower levels of inflammation. Numerous studies have found ibuprofen to be effective in relieving dental pain at various dosages, especially at doses of 600–800 mg [7-10]. However, according to Aggarwal V et al (11), neither ibuprofen nor ketorolac caused any improvement in the success of pulpal anaesthesia. So, the present study was aimed at reducing the confusion amongst endodontists about whether or not to use premedication with IANB.

In dentistry, there are rather few studies concerning the use of meloxicam and even fewer in endodontics. As meloxicam is a selective COX-2 inhibitor, it causes relatively less gastro-intestinal (GI) upset compared to other NSAIDs. It is widely used in the treatment of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and other rheumatologic conditions[12]. The current study was performed to compare the effect of placebo and premedication with ibuprofen and meloxicam, on the success of inferior alveolar nerve block in patients having symptomatic irreversible pulpitis.

Materials and Methods

Patient selection: This study was a randomised, double-blinded, placebo-controlled clinical trial focussing on pre-treatment oral administration of the NSAIDs ibuprofen (Brufen 600 mg, Abbott India Ltd., India) and meloxicam (Melflam 7.5 mg, Cipla Ltd., India). Endodontic pain was evaluated before and during endodontic treatment. Ethical clearance was taken from the Institutional Ethical Committee of Army College of Dental Sciences, Secunderabad, India. The study protocol was duly approved by the committee. Out of 83 patients clinically diagnosed with irreversible pulpitis, 75 were randomly selected to participate in the study. The participants were informed about the risks and benefits of the study, in detail. Written informed consent was obtained from each subject to participate in the study.

Healthy patients having symptomatic irreversible pulpitis with respect to a mandibular first or second molar and absence of periapical changes on a radiograph were included in the study. The exclusion criteria included a list of systemic and local factors. Systemic factors included a history of any systemic illnesses, allergies, a sensitivity to lignocaine with 1:80,000 adrenaline, a sensitivity to NSAIDs, a history of asthma, gastrointestinal ulcers, bleeding disorders, nursing or pregnant mothers, using anticoagulants and using any analgesics in the preceding twelve hours of treatment. Local factors were widened periodontal ligament space, presence of periapical radiolucency and non-restorable teeth / teeth with poor prognosis.

Randomisation Method

The clinical diagnosis of symptomatic irreversible pulpitis was given to patients exhibiting sharp or dull, intermittent or spontaneous pain in a mandibular molar of either side. The diagnosis was confirmed by a positive response to an electric pulp tester (Parkell, Inc., Edgewood, NY). Each participant was asked to complete a baseline 10 cm VAS and was allocated a random number. They were then asked to pick an envelope from a box for their allocation to groups. The opaque envelopes contained group codes, namely I, II, III. The drugs were kept in three identical coded containers in the form of capsules; of the same size and colour. All participants were given a capsule one hour before initiating the treatment; by a trained assistant who was blinded to the experiment. The capsules contained either a placebo of lactose powder (group I), 600 mg ibuprofen (group II), or 7.5 mg meloxicam (group III). Only a single dose of analgesic was administered before treatment. The patient, the assistant dispensing medicines and the principal operator were all unaware of the codes until the completion of the study.

Clinical procedure

VAS scores were recorded on a 10 cm scale and divided into four categories. No pain corresponded to 0 reading, mild pain >0 to less than equal to 3,

moderate pain was defined as being >3 and less than equal to 7 and severe pain was defined as >7. Pain was recorded four times during the entire procedure. First reading for pain was made before giving the placebo/premedication. Inferior alveolar nerve block was then given one hour later. Fifteen minutes after anaesthesia, a second reading was made in response to an electric pulp test. The third reading was made during access cavity preparation and fourth during root canal instrumentation.

Disposable 5 ml syringe and 27 gauge 1¼ inch needle were used to administer local anaesthetic. The operator performed blood aspiration before IANB was administered. If the aspiration was negative, then the anaesthetic solution, 1.8 ml of 2% lignocaine with 1:80,000 adrenaline (Xicaine, ICPA Health Products Ltd., India) was injected in each patient at a rate of 1ml per minute. Fifteen minutes after anaesthesia, patients were asked for subjective symptoms. If the patient did not report with profound lip anaesthesia, then IANB was considered a failure and patient was excluded from the study. However, all 75 patients in the present study reported lip numbness so none of them were excluded. After this, access cavity preparation was started and patients were asked to rate any pain experience. No or mild pain were classified as success, whereas moderate and severe pain were classified as failure of anaesthesia. All patients were monitored for 48 hours following the procedure.

Statistical analysis

One way analysis of variance (ANOVA) test was used to compare the data between the three groups. Comparison between groups at different steps was carried out using Kruskal-Wallis test. The data were analysed using the software SPSS version 21.0. The comparisons were considered significant if P-value was less than 0.05.

Results

No patients reported with any untoward event within 48 hours. No significant differences were found in the age and sex among the patients in the three groups (Table 1). Significant difference was found between the placebo and premedication groups but no significant difference was found between the ibuprofen and meloxicam groups (P-value >0.05). The P-value was 0.001 fifteen minutes after anaesthesia, 0.001 during access preparation and 0.01 during instrumentation being <0.05 at all steps and thus statistically significant (Table 2). On the basis of these findings, null hypothesis was rejected. Overall success rates for the placebo, ibuprofen and meloxicam groups were observed to be 60%, 92% and 88% respectively. The difference can be clearly appreciated in Fig. 1. Thus, according to the present study, the use of premedication before anaesthesia is recommended in irreversible pulpitis cases.

Table 1 Comparison of age, sex and baseline VAS scores between the groups (mean±SD)

Group	Placebo	Ibuprofen	Meloxicam	Total	P-value*
Age (years) (mean±SD)	34.12±11.11	32.68±9.69	36.56±10.57	34.45±10.45	0.421
Sex (Female: Male)	12:13	11:14	11:14	34:41	0.950
Baseline VAS score (mean±SD)	7.08±1.41	7.36±1.38	7.60±1.50	7.35±1.43	0.442

*P-value <0.05 : statistically significant
†VAS: Visual analogue scale
‡SD: Standard deviation

Table 2 Comparison of mean VAS scores before anaesthesia and steps during the procedure (mean±SD)

Group	Placebo	Ibuprofen	Meloxicam	P-value
Before anaesthesia (mean±SD)	7.08±1.41	7.36±1.38	7.60±1.50	0.442
15 mins after anaesthesia	2.04±1.17	0.84±0.80	1.04±0.79	0.001
During access preparation	2.44±1.55	0.96±1.2	0.88±1.2	0.001
During instrumentation	2.4±1.41	0.8±0.86	1.08±1.15	0.01

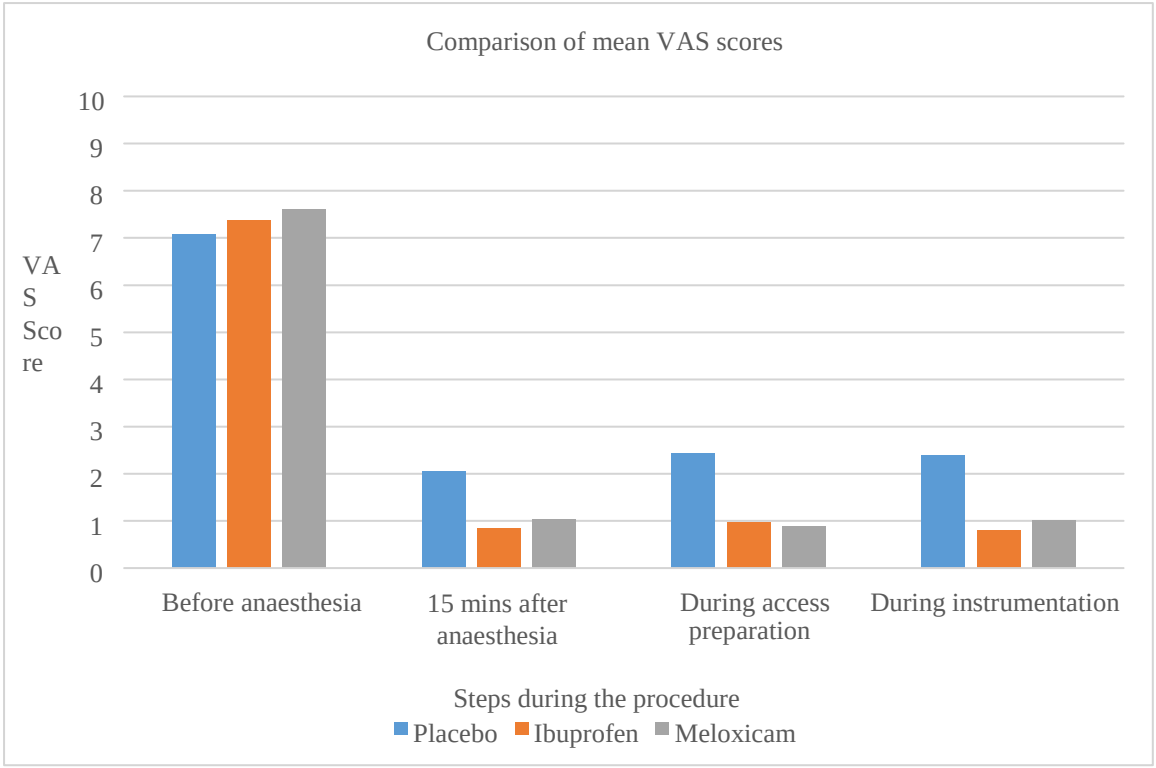

Figure 1: Comparison of mean VAS scores between placebo, ibuprofen and meloxicam groups

Discussion

The present study showed that premedication with NSAIDs (ibuprofen and meloxicam) notably improves the success rate of inferior alveolar nerve block in irreversible pulpitis cases. The age and sex of the patients were not significantly different in the three groups and so, did not affect the study results.

Pain is a highly subjective experience and can be influenced by numerous factors. These include physical, psychological, behavioural and cultural factors. So, it can be challenging to quantify and standardize pain across a group of individuals. Several clinical studies have used numeric and verbal self-rating scales in the past[13]. In a critical review of nursing and health care publications, a visual analogue scale (VAS) was found to be suitable for measuring pain intensity[14]. VAS comprises of a 100-mm line with 0 mm marking no pain and 100 mm marking maximum pain. It is highly reproducible and unaffected by gender[15]. On these grounds, the VAS was considered most suitable to measure intensity of pain in the present study.

In this study, 2% lignocaine with 1:80,000 epinephrine was used, being the most common local anaesthetic agent used in dentistry, with a long history of clinical success. It is also the agent used in most previous studies on the efficacy of anaesthetic techniques and solutions and allows comparison between results of these studies [16, 17].

Several previous studies have proved the anti-inflammatory effects of ibuprofen and indomethacin[10]. Seymour and Ward[18] evaluated various doses of ibuprofen (200mg, 400mg, 600mg) for the management of post-operative dental pain, and reported better results with 600mg ibuprofen.

Meloxicam has rarely been used in endodontic studies. Solis et al[19] demonstrated that patients receiving single dose of 15 mg preoperative meloxicam had a better postoperative analgesia compared with those given 100mg of diclofenac, after third molar extractions. Being a selective COX-2 inhibitor, it has a lower side effect profile. A lack of dose-response relationship for GI adverse effects allows for a flexibility in meloxicam dosage in the 7.5-15mg range. The decreased gastro-intestinal upset gives meloxicam an advantage over

other NSAIDs as it can be used for a wider range of patients. It provides adequate analgesia and has been successfully used in systemic conditions like osteoarthritis, rheumatoid arthritis, ankylosing spondylitis etc [12].

Several other investigations have proved the efficacy of premedication on IANB success rates for teeth with irreversible pulpitis[10,20]. However, Aggarwal V et al[11] in their study concluded that pre-treatment administration of ibuprofen or ketorolac did not improve the efficacy of anaesthesia. Inconsistent results in different studies could be attributed to variable methodology or operator-related factors.

In the current investigation, the overall success rates for the placebo, ibuprofen and meloxicam groups were 60%, 92% and 88% respectively. The current study suggests that combinations of analgesics are not required and that the use of only one anti-inflammatory drug is sufficient enough to produce adequate analgesia.

Although premedication with NSAIDs increased the efficacy of inferior alveolar nerve block, none of the drugs succeeded to produce 100% success. Therefore, we should also be prepared to use supplementary anaesthetic techniques to provide the patient with a painless experience during endodontic therapy.

Conclusion

The present study concludes that the use of NSAID premedication increases the efficacy of local anaesthesia in patients with irreversible pulpitis. However, to reach a consensus amongst dentists about whether to use or not to use premedication, more extensive studies need to be performed in future.

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