

Evaluation of Effect of Pre-operative Sublingual Oral Medication of Ketorolac-dt On Anaesthetic Efficacy of Inferior Alveolar Nerve Block With Lignocaine In Patients With Irreversible Pulpitis : A Prospective, Randomized Clinical Trial.

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ABSTRACT:

INTRODUCTION:

Inferior alveolar nerve block (IANB) with lignocaine local anesthesia in patient with irreversible pulpitis as shown better result. It was hypothesized that sublingual oral premedication with NSAID like ketorolac DT might improve the success rates of IANB.

METHOD :

Sixty adult patient who were not aware of this clinical study participated. patient divided into 3 groups on a random basis and randomly given oral premedication half an hour before IANB of 2% lignocaine with 1:200000 epinephrine. Endodontic procedure was

initiated 15 minutes of IANB. Pain during treatment was recorded by using HP visual analog scale.

RESULT:

Statistical Analysis with T test showed that placebo gave 29% success rate, control group gave 23% and premedication with ketorolac DT gave 39%. There was no significant difference between each group.

CONCLUSION:

Preoperative sublingual oral administration of ketorolac DT has slight significant affect on success rate of IANB in patient with irreversible pulpitis.

Key Words:

INTRODUCTION:

Local anesthesia is an essential requirement for endodontic treatment procedure.^{1,2,3} Inferior alveolar nerve block is commonly employed technique for pulpal anesthesia of mandibular teeth.. IANB has a high failure rate, ranging from 7-77% success rate is very low in case of irreversible inflamed pulpal tissues. Various hypothesis have been suggested for this high failure rate which include various anatomic variations, accessory innervations, decrease local pH, central core theory, unpredictable spread of anesthetic solution, activation of nociceptors.^{2,3}

Inflammatory mediators such as prostaglandins cause altered response of peripheral nociceptors and raise threshold of nociceptors by sensitizing them to bradykinins and histamines.

Non-steroidal anti-inflammatory drug (NSAIDs) inhibit PG synthesis by inactivating cyclooxygenase (COX) pathway. They also have effect on central pathway of hypothalamic PG system involved in nociception. Hence, it has been hypothesized that premedication with NSAIDs like ketorolac will influence the success of local anesthesia in patient with irreversible pulpitis.^{4,5}

Various methods of administration of Ketorolac have been tried which included oral premedication, buccal infiltration, intramuscular and intra nasal. ketorolac tromethamine in highly water soluble and it is only NSAIDs that can be delivered by via intraoral premedication. ketorolac inhibits the enzyme cyclooxygenase pathway that converts arachidonic acid to thromboxane, prostacyclin and prostaglandin. The bioavailability of ketorolac is approximately 80-100% following oral administration. Sublingual administration might improve more faster rate of bioavailability.^{7,8}

Purpose of this study is to evaluate the effect of oral premedication of ketorolac DT of anesthetic success rate in terms of pain during endodontic procedures.

MATERIALS AND METHODS:

Sixty healthy adult patients aged between 18-45 year who met the

inclusion criteria were invited to participate in this study from Department of conservative dentistry and endodontics, Sharavathi Dental college Shimoga, were included in this prospective, randomized, clinical study.

This study was approved by the ethics committee of the institution. Oral and written questionnaire determined the patients information, health condition, and preoperative pain. Informed written consent was obtained from each patient.

INCLUSION CRITERIA:

1. The patients having pain in a mandibular molar (visual analog scale >54) with prolonged response to cold test. (lingering pain for more than 45 seconds)
2. Absence of any periapical radiolucency.
3. Medical history to know the ability to understand consent forms and pain record scales.

EXCLUSION CRITERIA:

1. Known allergy, sensitivity to NSAIDs or local anesthetics.
2. History of active peptic ulcer, bleeding problems or anticoagulant use, active asthma, decreased renal or liver function, pregnancy or breastfeeding.
3. Patients who had taken NSAIDs, antidepressants, or sedatives within 24 hours before the root canal treatment (RCT).
4. Patients experiencing pain in more than 1 mandibular teeth.
5. Patients where the first injection of IANB did not produce lip numbness.

Before initiating the treatment, the patients were asked to rate their pain on a 170-mm Heft-Parker visual analog scale (HP-VAS 1984) marked with no pain on one side and maximum pain on the other side without millimeter marks. The scale was divided into 4 categories.

1. 0 = no pain

2. 1–54 mm = mild pain
3. 55–114 mm = moderate pain
4. >114 mm = severe pain

Preoperative radiographs were obtained. Patients were provided with an explanation of the treatment procedure and they were instructed about how to use the pain scales. sixty packages including questionnaires, consent forms, 2 sterile packs including a self-aspirating syringe were provided. A trained post graduate dental student who was blinded regarding the treatment procedures administration of oral ketorolac DT (Exir Pharmaceutical Company, Boroojerd,Iran) and placebo treatment were undertaken and randomly divided all the patients into 3 groups of 20 patients each and gave oral administration of drug half an hour before the procedure.

To ensure blinding, neither the operator nor the assistant had any knowledge about the chosen medication. All the patients received a standard IANB injection that used 1.8 ml 2% lignocaine with 1:200,000 epinephrine after negative aspiration. An injection rate of 1 mL/min was used for each injection. The pulp anesthesia was evaluated every 5 minutes by using an analog electric pulp tester (EPT) (Parkell Inc, Edgewood, NY).

The endodontic procedure was commenced 15 minutes after the initial IANB if the patient had lip numbness and 2 consecutive negative responses to the EPT. Otherwise the patient was excluded from the study. The patients' age, gender, pain on percussion, and initial pain before starting the treatment were evaluated and compared between the groups. If the patient felt pain during the caries and dentin removal(CDR), access cavity preparation (ACP), and canal length measurements(CLM) stages, then the level of pain was recorded by using the HP-VAS. When the full lip numbness appeared, the involved teeth were isolated with a rubber dam, and a conventional access opening was initiated. Patients were instructed to raise their hands if any pain was felt during the procedure. In case of pain during the treatment, the procedures was stopped, and patients were asked to rate the pain on HP VAS. The extent of access preparation and/or instrumentation was recorded as "within pulpal space" and "instrumentation of canals". The success was defined as "no pain" or "weak/mild" pain during endodontic access preparation or instrumentation. Whenever an extra injection was applied because of severe pain, the patient's pain score was recorded, and that patient was excluded from the remainder of the study. Successful anesthesia was defined as the absence of pain or only mild pain present during any of the stages of treatment. The findings were recorded on a Microsoft Excel sheet(Microsoft Office Excel 2003;Micrisift Corp,Redmond,WA) for statistical evaluation. In this study the role of related factors were evaluated between 3 groups. The data were statistically analyzed by using Mann-Whitney U and C tests. The significance level was set at $P < .05$.

RESULT:

60 Adult patient with average age 18-45 years participated in this protective randomized clinical trail study. Out of 60 patients 5 patient did not have profound anesthesia at 15 minutes and were excluded from study. There was no statistical difference between the age and distribution of teeth. The evaluation of % of patient with successful anesthesia is in table 1.

Control group gave 20% success rate.

Placebo group gave 23% success rate.

Premedication with ketorolac DT gave 36% success rate.

No significant difference between 3 groups.

TABLE 1. Evaluation of % of successful anesthesia in controlled and test groups

	CONTROL GROUP	CONTROL PLACEBO	KETOROLAC DT
SUCCESSFULL ANESTHESIA	8 of 20 (40%)	9 of 20 (45%)	12 of 20 (60%)

TABLE 2. Need for additional injection during various stages of root canal treatment.

GROUPS	STAGES OF PROCEDURE		
	CDR	ACP	CLM
CONTROL	2(6%)	7(23%)	8(24%)
PLACEBO	3(8%)	6(21%)	8(24%)
KETOROLAC	1(9%)	3(10%)	7(23%)

ACP, access cavity preparation; CDR, caries and dentin removal; CLM, canal length measurements.

There was no significant difference($P < 0.05$) between the groups

DISCUSSION

Ketorolac is pyrrolo-pyrrole derivative NSAID with potent analgesic and modest anti-inflammatory activity.it inhibits PG synthesis and relieves pain by peripheral mechanism. Ketorolac is rapidly absorbed after oral administration. Ketorolac is frequently used in postoperative, dental and acute musculoskeletal pain. Sublingual drug is placed under the tongue or crushed in the mouth and spread over the buccal mucosa. Only lipid soluble and non-irritating drugs can be so administered. Absorption is relatively rapid-action can be produced in minutes. Though it is somewhat inconvenient, one can spit the drug after the desired effect has been obtained. The chief advantage is that the liver is bypassed and drugs with high first pass metabolism can be absorbed directly into systemic circulation.^{8,9,10}

The inferior alveolar nerve block (IANB), commonly (but inaccurately) referred to as the mandibular nerve block, is the second most frequently used (after infiltration) and possibly the most important injection technique in dentistry. Unfortunately, it also proves to be the most frustrating, with the highest percentage of clinical failures even when properly administered.^{2,11,12}

IANB is an effective tool in management of mandibular endodontic procedures by reversibly interrupting the propagation of inferior alveolar nerve impulses. IANB might provide successful anesthesia in 70% of uninflamed pulp, but the success rate drastically decreases to 30% or even less in patients with irreversible pulpitis.^{2,3,5-10} The literature suggests activation of nociceptors by inflammatory mediators such as PGs as a major cause of increased incidence of failure of IANB in patients with irreversible pulpitis.¹⁵⁻²⁰

Our investigation aimed to determine the best anesthetic combination with or without ketorolac premedication in symptomatic mandibular molars. The mean initial pain rating was not significantly different for patients in both groups.

The IANB in posterior teeth shows no difference between placebo

and ketorolac, but ketorolac has increased success in inflamed irreversible pulpitis. Lip numbness, the clinical indicator of successful block, does not guarantee successful pulpal anesthesia. Also pulp tests showed poor reliability because 80% of mandibular teeth with a negative response after an IANB. Therefore the current study uses pulpal access and instrumentation to determine the success of anesthesia. 13-15

The augmenting an IANB with ketorolac increases the success rate. This may bring up the point that sublingual ketorolac DT with an IANB could be a reliable choice of anesthesia.

The most common explanation for the decrease in the success rate in inflamed pulp can be the activation of nociceptors by inflammation. Inflammatory mediators reduce the threshold for activation of nociceptor neurons. The inflammatory process is mediated via prostaglandins, which act by sensitizing nerve endings to bradykinins and histamines and hence enhance the pain and tenderness of inflammation. Oral ketorolac is completely absorbed, with a mean peak plasma concentration occurring at an average of 15 minutes after single 10 mg dose. In present study, oral premedication was given half an hour before the procedure to allow ketorolac to achieve a satisfactory plasma concentration. Because NSAIDs reduce nociceptor activation by decreasing the level of inflammatory mediators, it is hypothesized that premedication with NSAIDs would affect the success rate of local anesthesia in patients with IP. Efficacy in achieving deep anesthesia with premedication of placebo and ketorolac was evaluated with the help of an electric pulp tester, which concluded the strong enhancing effect of oral NSAIDs in improving the anesthesia in teeth with IP. In another study, preoperative administration of ibuprofen or ketorolac improved the success rate of IANBs in patients with IP during access cavity preparation. These authors did not evaluate the success or failure rate on the basis of pain during root canal instrumentation. 10-15

In our study, administration of anesthesia and ketorolac combination for caries removal, access preparation and pulp space instrumentation was evaluated. The primary outcome of present study indicated that when oral premedication was given higher success rate of lignocaine IANB. A similar result was observed when only an articaine IANB (48%) and a lidocaine IANB (40%) with oral premedication of ketorolac were given. This higher success rate may be because of the sufficient premedication time (1 hour) and both BI and LI administration. In recent study by Kanna et al (10) on mandibular teeth with IP, buccal infiltration with articaine after a lidocaine IANB had a success rate of 84%. The higher success rate in their study could be caused by a higher volume of the anesthetic solution used (2.0 mL) for the infiltration injections and also the fact that they used the electric pulp test for success measurement and not VAS rating during access opening and instrumentation.

IANBs were administered half an hour after premedication with ketorolac DT. We waited 15 minutes after the IANB which was based on time suggested by previous studies. Therefore, impact of the anesthesia was maximized in our study.

In conclusion, premedication with ketorolac significantly increased the anesthetic efficacy of lignocaine IANB in mandibular molars with irreversible pulpitis.

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