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Original Research

Anaesthetic efficacy of 2% lignocaine without adrenaline in patients with irreversible pulpitis in mandibular molars undergoing vital pulp therapy: A prospective, randomized, double-blind study

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ABSTRACT

Introduction: This exploratory, prospective, randomised, double-blind clinical investigation's main objective was to assess the effectiveness of pulpotomy treatments for mandibular molars with irreversible pulpitis using 2% lignocaine with and without epinephrine.

Methods: The subjects were split into two groups at random. The Heft Parker Visual Analogue Scale was used to capture the subject's self-reported pain reaction before the study began (pre HP VAS scores). All subjects received a standard IANB along with buccal infiltration of either plain 2% lignocaine (test group) or 2% lignocaine with 1:1000,000 epinephrine (control group). The level of pain was assessed using the HP VAS scale once again following caries excavation and pulp exposure (Post HP VAS Scores), and a full pulpotomy was carried out by amputating the pulp to the canal orifices level. Following this haemostasis was attained and MTA (ProRoot; Dentsply, Tulsa, OK, USA) capping done. Temporary restorations were given immediately. Patients were recalled after 2 weeks for a permanent restoration.

Results: The variance analysis (one way ANOVA) and post hoc Tukey LSD statistical investigation revealed a significant distinction in success rates between the two trial groups (p-value = 0.037).

Conclusions: In mandibular molars with irreversible pulpitis receiving critical pulp treatment, IANB and buccal infiltration with 2% lignocaine without epinephrine can be taken into consideration as suitable substitutes for producing pulpal analgesia.

***Keywords:** 2% Lignocaine without Epinephrine, Irreversible pulpitis, Randomized control trial, Pain management, Pulpotomy.*

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INTRODUCTION

Possibly the single most crucial foundation upon which endodontic therapy rests is effective local anaesthesia. Contrarily, administering local anaesthetic is the most frequent reason for patient worry, and dental practitioners continue to have major doubts about their ability to successfully manage pain while minimizing suffering.[1] Many clinicians still believe that performing absolute anaesthesia on mandibular teeth with persistent pulpitis is an impossible task.[2]

The American Association of Endodontists (AAE) states that irreversible pulpitis refers to an inflamed pulp that cannot heal and for which root canal therapy is recommended. This definition does not accurately reflect the pulp's histopathological state.[3] Pulpitis was categorized by Hashem and colleagues as mild, severe, reversible, and irreversible.[4] A new categorization for clinical pulp diagnosis with related treatment techniques was offered as initial, mild, moderate, and severe pulpitis, building on the idea of minimally invasive endodontics. This opens the door to minimally invasive procedures in which the inflammatory tissue is cut out, leaving behind healthy, less-inflamed tissue that may heal.[5]

Anesthetizing teeth with irreversible pulpitis has posed a challenge during root canal procedures. Many strategies have been proposed which include changing the anaesthetic solution or the anaesthetic technique. In an effort to keep the anaesthetic agent at the injection site for a longer period of time, doctors may increase the anaesthetic volume or the adrenaline concentration (1:50,000).[6] Time-honoured supplemental injection techniques like intraligamentary, intraosseous, pulpal, mandibular buccal infiltration with Articaine have been devised to improve the adequacy of IANB.[7,8,9]

Even though only a small number of these methods were successful, none were discovered to significantly increase the prevalence of pulpal anaesthesia in mandibular molars with permanent pulpitis. When injected into regions with already inflamed pulps and periradicular spaces, local anesthetics including vasopressors that have an intrinsic low pH are particularly difficult to anaesthetize.[10,11]

There are limited studies on the anaesthetic efficacy of lignocaine without adrenaline for teeth undergoing pulpotomy procedures that have irreversible pulpitis. The amide anaesthetic lignocaine, often referred to as lidocaine, has a rapid start of action and a short duration of anaesthesia.[12] It was projected that a straightforward procedure using a well-known anaesthetic (2% lignocaine without adrenaline) may give efficient pulpal anaesthesia in the event of irreversible pulpitis in mandibular molars. The primary goal of this exploratory, prospective, randomised, double-blind clinical trial was to determine if pulpotomy treatments with 2% lignocaine with or without epinephrine for mandibular molars with irreversible pulpitis were successful.

MATERIALS AND METHODS

In this study, mandibular molars with irreversible pulpitis were treated during pulpotomy operations with 2% lignocaine without adrenaline in IANB and buccal infiltration. Protocols for the trials followed the CONSORT declaration.[13] The study protocol was authorized by the Institutions Review Board of Rajah Muthiah Dental College and Hospital of Annamalai University (RMDCH/IEC/01/2019/04). The study subjects provided written, fully informed consent. The Clinical Research Registry of India gave the study the registration number CTRI/2022/02/040254. Between March 2019 and February 2020, healthy adult volunteers between the ages of 18 and 30 who visited the outpatient department reported active pain in the mandibular molar that measured 54 mm on the longer reaction to cold evaluation with a frozen stick (1,1,1,2 tetrafluoroethane; Hygenic Corp, Akron, OH) and a battery-powered pulp tester (Digitest; Parkell, Farmingdale) using the Heft-Parker Visual (HP VAS).

Women who were pregnant or nursing, people taking medications that alter pain perception, people with systemic disorders categorized as IV by the American Society of Anesthesiologists, and anyone with a history of problems from local anesthetics were also excluded from the research.

There were two different test groups scheduled for the investigation. The people were randomly assigned to one of the 2 groups. G Power Analysis was performed to determine the sample size from a pilot study with 30 participants (version 3.0.10). According to a power analysis, 146 participants were needed to accurately detect a correlation value of 0.83 in an objective measure that was constant with a probability value of 5%. The study error was estimated to be 0.10 inches. Each group had 73 participants. Prior to surgery, each subject was asked to rate their degree of pain on the HP VAS scale. Their HP VAS pain levels were then communicated (Pre HP VAS scores).

Randomization and Masking

Using a 1:1:1 randomization ratio, the participants were split into two research groups (software version 1.0, May 2004). Two experienced physicians who were calibrated and blinded to the treatment groups administered the anaesthetic injections. Group A participants received IANB and 2% lidocaine buccal injection without adrenaline, whereas Group B patients are administered IANB with 1:100,000 epinephrine. After the area has been suctioned, 1.8 solution mL are given at a rate of 1 milliliters. All injections are administered using the syringe-provided, 27-gauge long needles. To keep the operators separate, the study complied with acknowledged standards. Patients who required several doses of anaesthesia were excluded from the study.

After giving the local anaesthetic to both the test and control groups, the treatment was begun after determining whether the lips were numb. During the pulpotomy surgery, patients were instructed to report any pain or discomfort. Before excavating cavities, the crown was cleaned with 5% NaOCl after isolating the rubber dam. Using a hygienic high-speed diamond bur and water cooling, a full pulpotomy was carried out, with the pulp being severed to the height of the canal orifices. The viability was demonstrated by the appearance of bleeding pulp tissue from all channels.

The pain level was again measured using the HP VAS scale following caries excavation and pulp exposure. The residual tissue was treated with a cotton pellet wet with 2.5% NaOCl for 2 minutes, followed by a dry cotton pellet, and the bleeding time was noted. After attaining hemostasis, MTA (ProRoot; Dentsply, Tulsa, OK, USA) was mixed in accordance with the manufacturer's instructions and applied to the floor of the pulp chamber and the orifices of the root canals to a thickness of about 2-3 mm. The coating of MTA was then covered with a moist cotton pellet to help it set. A temporary filling was used following the pulp capping treatment, and it was replaced after two weeks with a resin composite repair (Z250, 3M, ESPE, St. Paul, MN, USA). In a small number of cases involving 3-wall cavities, selective cusp covering with resin composite was carried out. Following the installation of the last restoration, a postoperative periapical radiograph was taken.

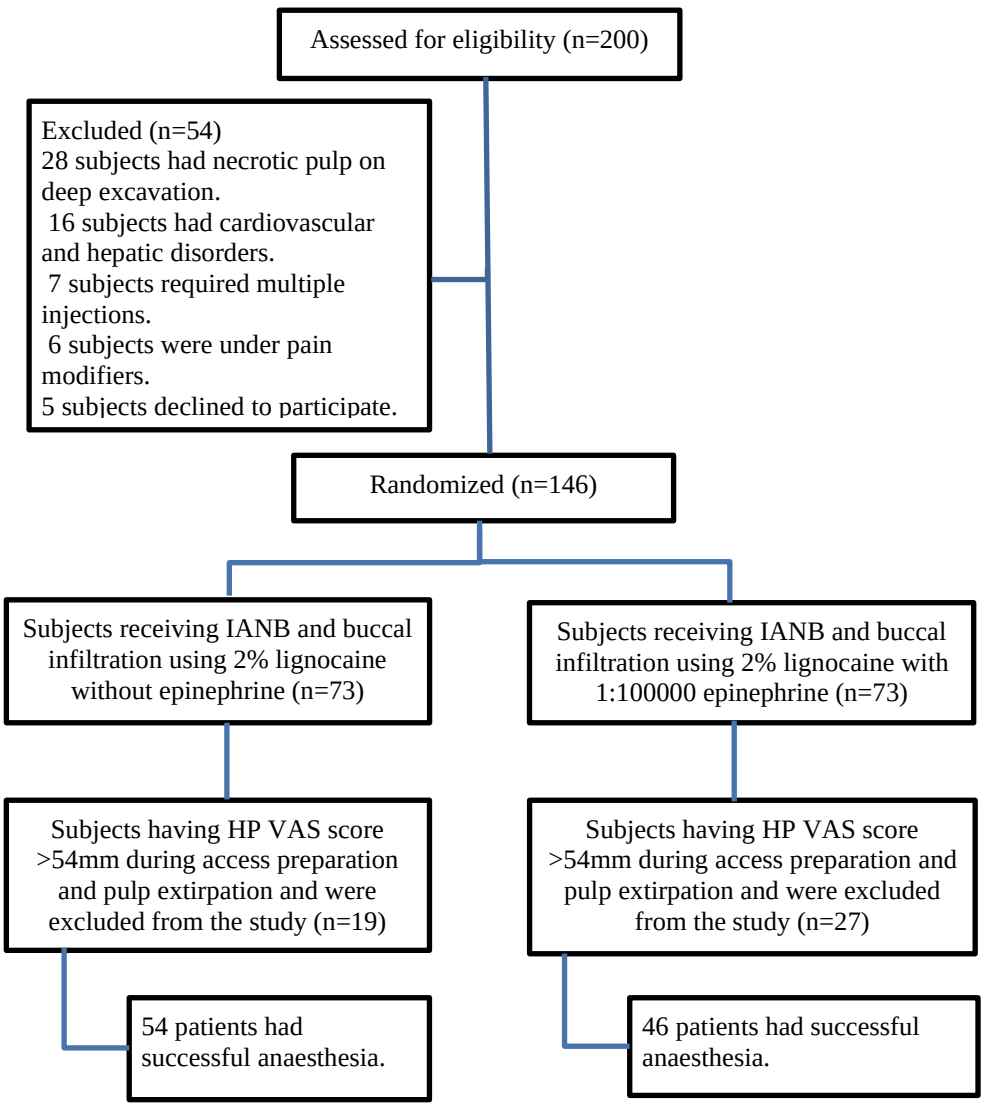
If there was no moderate or minor aches after the pulpotomy procedure, it was considered successful. The sedation was deemed unsuccessful, the therapy was halted, and those participants were eliminated from the report's further analysis if the HP VAS score for the study subject's self-reported pain during the operation is substantially less than 54 mm.

The investigation used the Windows SPSS application 15 (SPSS Inc, Chicago, IL). Descriptive statistics were used to analyse the data, and one-way variance analysis (one-way ANOVA) and post hoc Tukey LSD were carried out.

RESULTS

The CONSORT process flow shows how many people decided to sign up for the study overall and how many people finished it (Figure 1).

Figure 1: Consort flow chart



The study's volunteers, who ranged in age from 18 to 30, included 146 patients in total—80 males and 66 women (Table I).

Table I: Demographics of the study population

Attributes		N* (146)	%
Age Group (years)	18-21	46	31
	22-25	50	34
	26-30	50	34
Gender	Male	80	55
	Female	66	45
Height (cm)	140-160	71	49
	161-180	75	51
Weight (Kg)	40-65	69	47
	66-90	77	53

*N – Total number of participants

Table II illustrates the distribution of the sample group according to the three age brackets (18–21, 22–25, and 26–30), as well as the preliminary (Pre HP VAS) and concluding (Post HP VAS) mean pain ratings. An intragroup comparison of the mean pain scores did not differ significantly regarding age.

Table II: Pain scores across age groups

GROUP A	18-21	22-25	26-30	p- Value
	62.36 ± 8.89	67.45 ± 13.6	Initial (Pre HP VAS)	0.422
Final (Post HP VAS)	2.46 ± 0.26	2.69 ± 0.53	2.48 ± 0.38	0.209
GROUP B	**18-21**	**22-25**	**26-30**	**p- Value**
Initial (Pre HP VAS)	64.73 ± 12.16	64.3 ± 9.35	64.31 ± 13.4	0.994
Final (Post HP VAS)	2.81 ± 0.75	2.68 ± 0.53	2.88 ± 0.85	0.758

Following the two anaesthetic methods, no adverse responses were noted. No significant differences in the initial and final mean pain scores with respect to gender were found in an intragroup comparison (Table III).

Table III - Pain scores across gender

GROUP A	Male	Female	p- Value
Initial (Pre HP VAS)	63.75 ± 10.69	66.60 ± 12.30	0.366
Final (Post HP VAS)	2.54 ± 0.25	2.58 ± 0.59	0.719
GROUP B	**Male**	**Female**	**p- Value**
Initial (Pre HP VAS)	65.88 ± 11.98	62.7 ± 11.72	0.379
Final (Post HP VAS)	2.84 ± 0.73	2.77 ± 0.75	0.743

According to Table IV, of the 73 participants in each group, 74% in group A were able to achieve effective anaesthesia, as opposed to 63% in group B. In an intergroup analysis, there was a statistically significant difference in the final mean pain scores (Post HP VAS) (p-value = 0.037).

Table IV - Percentage of successful anaesthesia and final mean pain scores across for 146 patients

Groups	N	%	Mean ± S.D*	p- Value
GROUP A (n =73)	54	74	2.55 ± 0.43	0.037
GROUP B (n =73)	46	63	2.81 ± 0.73	

*Mean ±standard deviation

DISCUSSION

This study's objective was to determine how well 2% lignocaine without adrenaline worked as an anaesthetic on mandibular molars with irreversible pulpitis during pulpotomy surgery. For problematic adult permanent teeth with carious exposure, root canal therapy (RCT) is typically the preferred course of action and has a favourable prognosis. RCT is also linked to a few side effects, such as calcification in the root canal, uncommon canal shapes (such as C-shaped canals), dilations, and an unusual number of canals. It is well known the RCT renders teeth non-vital and causes the removal of a substantial amount of tooth structure, and thus leaves teeth brittle and prone to fractures.[14] Like in the current trial, vital pulp therapy is a straightforward, affordable, and conservative treatment. The success of essential pulp therapy procedures depends on the methodology utilized, the pulp tissue's inflammatory status, the length of observation, the success criteria, and the kind (biocompatibility) of pulp therapy agent used.[15]

The current study's findings showed that both groups' pain scores significantly decreased after receiving anaesthesia. Age and gender were not anticipated to have much of an impact on the outcomes (Table 1 and Table 2). The final HP VAS pain scores, however, significantly varied between the two groups (Table 3).

There were more number of anaesthetic failures using 2% lignocaine with 1:100000 adrenaline in the current study (63%). These results are similar to previous literature which also shows a failure to achieve profound pulpal anaesthesia in patients with irreversible pulpitis.[9] Several hypothesis have been given for the failure of local anaesthetics ranging from anatomical causes like difficulty to place the tip of the needle in the sulcus colli and accessory innervations to mandibular teeth, inflammation-induced tissue acidosis may cause 'ion trapping' of local anaesthetics,[16,17] activation of nociceptors by inflammation or local acidosis leading to the development of TTX resistant resulting in central sensitization which causes an exaggerated response to even mild stimuli like administration of local anaesthetics[18] and finally patient anxiety.[17]

The local pH theory is significant and has two effects. The first one claims that local anaesthetics with lower pKa values are probably more successful in treating people who have irreversible pulpitis and its accompanying pain and have naturally acidic tissue pH. Second, a transient change in tissue pH may enhance clinical anaesthesia.[18,19,20] pH of the anaesthetic solution at the time of injection determines the onset of analgesic effect of any local anaesthetic. Commercially available lignocaine without adrenaline has higher pH. Thus, it will have more molecules in unionized form and good lipid solubility. So, the solution is absorbed easily, has an earlier onset, and has good potency.[21,22] This can prove beneficial in minimally invasive endodontic procedures like pulpotomy which can benefit from early onset of action for maximum pain reduction during removal of most of the inflamed pulp leaving the remaining pulp to heal. Similar thinking is explored in a study by Lammers et al. that uses 3% mepivacaine plain to enhance anaesthesia and lessen injection pain during inferior alveolar nerve block.[23,24] Meechan and Day found that when given into the maxillary premolar buccal sulcus of people, plain lidocaine caused less discomfort than lidocaine with epinephrine.[25]

It is often a challenge to quantify and standardize pain objectively across group of individuals. To measure the severity of pain and to establish if a patient's pain has changed after an intervention are the two main roles of pain scales. HP VAS used in the current study was found to be easy to understand, highly reproducible and methodologically sound. The HP VAS does not have gender bias and is apt for use in clinical pain trials. The Heft-Parker scale combines six categorical explanation words with irregular spacing into a 170-mm horizontal line.[26]

No postoperative complications, other than pain, were reported by volunteers in the present study. To determine the timing of the peak effect and duration of anaesthesia of 2% lignocaine without adrenaline in moderate to severe irreversible pulpitis an investigation of longer duration is warranted. Furthermore, the effect of 2% lignocaine without adrenaline on teeth with irreversible pulpitis in the maxillary arch and mandibular incisors is yet to be determined. However, the risk of complications attributable to the presence of anaesthetic formulations with vasoconstrictors is high in patients with cardiovascular disease. Usage of 2% lignocaine without adrenaline may prove to be beneficial in these circumstances.

CONCLUSION

According to the study's findings, IANB and buccal infiltration using 2% lignocaine without epinephrine were statistically significantly different from IANB and buccal infiltration using 2% lignocaine with 1:100000 epinephrine when used to anaesthetize mandibular molars with irreversible pulpitis during pulpotomy procedures. 2% simple lignocaine is a common anaesthetic choice for minimally invasive endodontic procedures including vital pulp treatment in teeth with irreversible pulpitis.

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Conflicts of interest - There are no conflicts of interest.

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