

# Clinical Assessment of Preemptive Analgesia on Success of Pulpal Anesthesia and Postendodontic Pain in Children with Irreversible Pulpitis: A Randomized Comparative Study

Nasrin A Gori<sup>1</sup>, Megha C Patel<sup>2</sup>, Rohan K Bhatt<sup>3</sup>, Kaushal R Joshi<sup>4</sup>, Foram C Patel<sup>5</sup>, Kaksha B Choksi<sup>6</sup>

## ABSTRACT

**Introduction:** Optimal pain management of symptomatic pulpitis in formative years goes a long way in developing a positive dental attitude. Efforts should be made to increase the success of anesthesia, thus diminishing negative dental experiences. The aim of the study was to assess the efficacy of preemptive analgesia on the success of pulpal anesthesia following inferior alveolar nerve block (IANB) in children with symptomatic irreversible pulpitis and on reducing postendodontic pain.

**Materials and methods:** The research design was an *in vivo*, three-group, parallel, quadruple-blind study. A total of 75 patients were randomly allocated to one of the three groups—group I: ibuprofen, group II: combination of ibuprofen and paracetamol, and group III: multivitamin (placebo). Premedication was given 45 minutes before treatment, and patients received IANB in a standardized manner. Pain during pulpectomy was recorded using the face, legs, activity, cry, consolability (FLACC) scale and postoperatively using Wong–Baker’s pain rating scale (WBPRS) at 4, 12, and 24 hours. Success was measured if the pain felt was of no or mild intensity.

**Results:** Success of IANB was 64% for ibuprofen, 72% for the combination group, and 40% for the placebo group, with no statistically significant difference between all groups ( $p = 0.06$ ) on the FLACC scale. At 4 hours postoperatively, a significant difference ( $p = 0.02$ ) was found among groups with more children experiencing no or mild pain in groups I and II and the highest number of rescue medications taken by the placebo group.

**Conclusion:** Ibuprofen and a combination of ibuprofen and acetaminophen as preemptive analgesics had no significant effect on the success rate of IANB, although it was effective in reducing pain at 4 hours postoperatively.

**Keywords:** Inferior alveolar nerve block, Postendodontic pain, Preemptive analgesia, Pulpal anesthesia, Symptomatic irreversible pulpitis.

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## INTRODUCTION

The internal association for the study of pain defines pain as an unpleasant sensory and emotional experience linked to confirmed or possible tissue injury.<sup>1</sup> Inflammation of pulp due to tooth decay or dental trauma is a leading cause of dental pain. Pain patterns and pain perception differ in children than in adults. In children, pain assessment is a difficult task as they may report discomfort even though they do not feel pain or may not report pain when they feel it. Unaddressed pain heightens anxiety and fear, which enhances pain perception.<sup>2</sup>

Odontalgia is the most common form of orofacial pain.<sup>3</sup> Pain management is a prime part of pediatric dentistry, as pain and discomfort during and after treatment are reasons that children find dental treatment distressing. Pain experienced during treatment in children may lead to refusal of future dental appointments.

Inferior alveolar nerve block (IANB) is a common technique for anesthetizing mandibular molars in children and adults because of its depth and profundity of anesthesia.<sup>4</sup> The high rate of local anesthetic failure in teeth diagnosed with irreversible pulpitis is prostaglandin (PG)—induced sensitization of peripheral nociceptors caused by inflammation. Inflammation also induces changes in the central nervous system’s pain processing system. Lack of pulpal anesthesia, especially in children, results in fear and anxiety. In the past, it has been proposed that the administration of preemptive analgesic before IANBs may increase the efficacy of anesthesia.

There is a considerable link between pulp condition and postoperative pain, according to evidence. In the majority of

<sup>1–3,5,6</sup>Department of Pedodontics, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India

<sup>4</sup>Private Practitioner, Gandhinagar, Gujarat, India

**Corresponding Author:** Nasrin A Gori, Department of Pedodontics, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India, Phone: +91 8866348224, e-mail: gorinasrin511@gmail.com

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cases, postoperative pain is caused by an increase in inflammatory mediators such as PGs, which activate sensitive nociceptor cells in the periapical tissue.<sup>5</sup> In teeth with chronic irreversible pulpitis, pain is mostly due to lack of anesthesia, and pain after endodontic treatment is unpreventable; hence, palliative measures should be taken for patient management.

Preemptive analgesia is defined as an antinociceptive treatment that prevents altered processing of afferent input, amplifying postoperative pain. It reduces the onset of central sensitization, a process in which spinal neurons become more receptive to peripheral nociceptive input.<sup>6</sup> It inhibits or lowers the generation of chemical mediators that are important for nervous activation, such

as serotonin, histamine, and PGs. Nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol are the most widely utilized preemptive analgesics in dentistry, either alone or in combination, because they are both safe and quick-acting analgesics.<sup>6</sup> Ibuprofen is the most commonly used NSAID in dentistry. It works by inhibiting cyclooxygenase (COX), which causes enzyme synthesis and changes the inflammatory response. The ceiling effect is the drawback of ibuprofen.<sup>7</sup> It is that to obtain the desired analgesia, the medication must be used in conjunction with other drugs. Acetaminophen is another commonly used analgesic in dentistry to control pain. Acetaminophen's mechanism of action is more complex, with various theories suggesting that it works both centrally and peripherally to block COX activity and lessen pain perceptions. To the best of our knowledge, none of the previous studies has evaluated either the efficacy of preemptive analgesia on the success of pulpal anesthesia following IANB and postendodontic pain in children with symptomatic irreversible pulpitis. Hence, this study was designed.

## NULL HYPOTHESIS

We hypothesize that there will be no significant difference between the effect of preemptive analgesia, that is, ibuprofen, a combination of ibuprofen and acetaminophen and placebo (vitamin) on the success of pulpal anesthesia following IANB, and postendodontic pain in children treated for symptomatic irreversible pulpitis.

## MATERIALS AND METHODS

### Study Design and Patient Criteria

It was an *in vivo*, three-group, parallel, quadruple-blinded comparative study. The principal investigator involved in dental treatment, dental assistant, observer, and participants (children and parents/caregiver) were unaware of the preemptive analgesic used to ensure blinding. Before commencing the study, ethical approval was obtained from the Ethics Committee at Karnavati University. The subjects, as well as their parents, were told the whole procedure verbally, and written consent was given. Only subjects who gave informed written consent were included in this study. Patient screening was done by a single investigator who screened children aged 4–8 years old who were accompanied by parents or guardians to the outpatient department of the Department of Pediatric and Preventive Dentistry, Karnavati School of Dentistry. Mandibular primary molars with a clinical diagnosis of symptomatic irreversible pulpitis indicated for pulpectomy with moderate to severe pain (>10 seconds) after cold testing, children with Frankl scores 3 and 4 and modified child dental anxiety scale (MCDAS) score below 19, no intake of analgesics for 24 hours prior to treatment, tooth with no pathological mobility and periapical pathology were included. Children with systemic disease, allergic to local anesthesia (LA) and drug used, uncooperative and anxious patients, and radiographs showing resorption and furcation involvement were excluded from the study.

### Clinical Procedure

Preoperative phase: 75 patients were allocated to either an experimental or control group using computerized randomization. Details of medications used in the study—group I: ibugesic suspension (100 mg/5 mL, Cipla), group II: ibugesic plus suspension (ibuprofen 100 mg + paracetamol 162.5 mg/5 mL, Cipla), and group III: multivitamin syrup (Morvin). A computer-generated

randomization list was used for randomization and allocation concealment. Clinical and radiographic examinations were performed before treatment. Preoperative pain of the child was recorded using Wong–Baker's pain rating scale (WBPRS) after explaining it to participants in their mother tongue language and in age-appropriate terms. The heart rate of the child was measured with a pulse oximeter while he/she was waiting in the waiting room. The drug dosage was calculated based on the patient's weight. Medication was given 45 minutes prior to the pulpectomy. Prior to the LA administration, the heart rate of the child was recorded.

Intraoperative phase: Topical anesthesia in the form of gel (2% lidocaine hydrochloride; Xylocaine®) was applied with a cotton applicator tip for 1 minute at the injection site. To achieve soft tissue anesthesia and pulpal anesthesia, IANB was administered in a standardized manner with 2% lidocaine containing 1:100,000 by using a 27-gauge needle. For standardization, 1.8 mL of anesthetic solution was deposited at a rate of 1 mL/minute in all cases. Around 15 minutes after IANB, the patient was probed for subjective signs, that is, tingling and numbness of the lower lip and tongue. A cold test was also used to confirm anesthesia. The sample was excluded from the study if subjective signs for IANB were not recorded and responded to cold test, that is, felt pain or discomfort. In order to complete the treatment in patients with moderate to severe pain, supplemental anesthesia was given, and the sample was excluded from the study. Prior to the pulpectomy, heart rate was recorded. The pulpectomy was performed by a single operator on all children. If the face, legs, activity, cry, consolability (FLACC) score was >3 (moderate to severe pain) during any of the pulpectomy steps, namely caries excavation, access opening, and pulp extirpation, intrapulpal anesthesia was given, and the treatment was completed. After obturation, the heart rate was recorded again, and the child was asked to report their level of perceived pain using WBPRS.

Postoperative phase: Both parents and children were instructed to avoid lip or cheek biting as the effect of anesthesia will keep the area numb for a specific time. They were informed to use analgesic rescue medication (syrup ibugesic 10 mg/kg/5 mL) only if they have pain sensation of more than mild discomfort, as reported by WBPRS. To assess the success of preemptive analgesia on postendodontic pain, Wong–Baker scale (video calling to the child/parent) at 4, 12, and 24 hours was recorded.

Success criteria: On the FLACC scale, a score of  $\leq 3$  (relaxed to mild discomfort) for all steps, that is, caries excavation, access opening, and pulp extirpation, and on WBPRS, a score of  $\leq 3$  (no to mild pain) following obturation was considered as success of IANB. Success was scored if the patient had no or mild pain on the WBPRS scale for postendodontic pain.

### Statistical Analysis

Data was assessed using Statistical Package for the Social Sciences (SPSS) version 22. Chi-squared and Fisher's exact test were employed to determine the association between the two groups wherever applicable. Intragroup comparison according to time interval was made by using the Friedman test. Intergroup comparison was done by using the Kruskal–Wallis test. The level of significance was kept at 5%.

## RESULTS

The study included 75 children, both male and female. The mean age [ $\pm$ standard deviation (SD)] of the participants in group I (ibuprofen) was  $5.40 \pm 1.47$ ; in group II (combination of ibuprofen

and paracetamol), was  $6.24 \pm 1.42$ , and that for group III (placebo) was  $6.04 \pm 1.48$  ( $p = 0.11$ ). There was no significant association with respect to gender ( $p = 0.95$ ) and type of tooth treated, that is, first or second mandibular molar ( $p = 0.67$ ).

In all the groups, the mean heart rate was maximum prior to medication ( $108 \pm 12.07$ ), ( $109.40 \pm 10.53$ ), and ( $111.96 \pm 11.33$ ) and was minimum after obturation ( $99.40 \pm 11.29$ ), ( $97.96 \pm 11.83$ ) and ( $101.24 \pm 11.73$ ) for groups I, II, and III, respectively. In the intergroup comparison, there was no statistically significant difference ( $p > 0.05$ ) at different time intervals. However, when compared to intragroup, it represented a highly statistically significant difference ( $p < 0.001$ ) (Table 1).

Table 2 shows that the mean FLACC score was maximum during pulp extirpation, followed by access opening and caries excavation in all three groups. When compared to the intergroup, a highly statistically significant difference was found among the three groups only during access opening ( $p = 0.002$ ).

Table 3 showed that the premedication with ibuprofen gave an overall 64%, a combination of ibuprofen and paracetamol gave 72%, and multivitamins gave a 40% success rate of IANB on the FLACC scale, though the difference was not significant statistically ( $p > 0.05$ ).

Before medication ( $p = 0.72$ ), the mean pain scores recorded using the Wong–Baker pain scale (WBPS) were  $5.68 \pm 1.49$ ,  $6.04 \pm 1.74$ , and  $5.68 \pm 1.49$ , and after obturation ( $p = 0.003$ ), it was  $1.68 \pm 1.49$ ,  $1.20 \pm 1.73$ , and  $2.72 \pm 1.40$  for groups I, II, and III, respectively. Figure 1 depicts the success rate of IANB at the end of the pulpectomy procedure (i.e., after obturation). According to WBPRS, the premedication in group I gave an overall 76%, group II gave 80%, and group III reported a 52% success rate. It was rated for patients having no or mild discomfort only. On intergroup comparison, there was no statistical significance ( $p = 0.08$ ).

Table 4 shows that at 4 hours, 20% of patients in group I, 4% in group II, and 32% in group III had severe pain. A statistically significant difference ( $p = 0.04$ ) was found at 4 hours postoperatively but not at 12 and 24 hours.

Table 5 depicts that 28% of children in group I, 20% of children in group II, and 48% of children in group III consumed rescue medication at 4 hours. The analgesic intake postoperatively was found to be significant ( $p = 0.02$ ) only at 4 hours.

## DISCUSSION

Pain is a multidimensional sensory experience that is unpleasant (Pozos-Guillén) and has strong cognitive and emotional components.

The American Pain Society has stated pain as the fifth vital sign. If child pain management in dental clinics is not absolute, they will instill a negative attitude toward dentists and dental treatment. This can cause apprehension about returning to the dentist for future treatments, even years after the first bad experience.

The major problem encountered by dentists using IANB during endodontic treatment of mandibular molars, both primary and permanent with symptomatic irreversible pulpitis, is lack of profound anesthesia. A hot tooth is usually difficult to manage as local anesthetics usually fail.

The term "hot tooth" is used to describe a pulp that has been diagnosed with irreversible pulpitis and with spontaneous moderate to severe pain. Various strategies have been tried in order to increase the efficacy of LA, which include the usage of alternative anesthetics,<sup>7</sup> supplemental injections,<sup>8</sup> modification of adrenaline ratio,<sup>9</sup> changing anesthetics volume,<sup>10,11</sup> different chemicals, and additives are used in anesthetics and addition of medications in anesthetics or administration of preemptive analgesia.<sup>12–14</sup>

Previous studies have investigated the efficacy of oral premedication with ibuprofen, paracetamol, and placebo in children following the extraction of teeth either under LA or general anesthesia (Giath Gazal; Johnny Kharouba; and Nabih Raslan). In pediatric dentistry, knowledge regarding the effect of preemptive analgesia on the success of pulpal anesthesia following IANB with irreversible pulpitis and postendodontic pain in children is scarce. Therefore, to bridge the gap in the literature, this study was conducted.

Huynh and Yagiela<sup>15</sup> demonstrated that the most commonly recommended analgesics in dentistry for acute pain relief are NSAIDs, acetaminophen, and various opioid-containing analgesic combinations. NSAIDs acts as an anti-inflammatory and analgesic by blocking the COX enzyme that produces PGs; this will inhibit the release of inflammation-inducing PGs.<sup>16</sup> Ibuprofen is a propionic acid derivative. It is an efficient anti-inflammatory and analgesic agent in dosages ranging from 10 mg/kg/day to a maximum of 40 mg/kg/day.<sup>17</sup> It blocks COX-1 and COX-2 enzymes, which are responsible for the synthesis of PGs responsible for mediating pain, fever, and inflammation. It has a strong affinity for plasma proteins (90–99%), reaches peak plasma concentration 30 minutes after administration, and has a serum half-life of 1.2–2 hours.<sup>18</sup> As premedication, ibuprofen is the favorable drug of choice because of its lower latency time. However, the major drawback of ibuprofen is the "ceiling effect."

**Table 1:** Comparison of mean heart rate at different time intervals and among groups

Time intervals	Group I (n = 25); mean $\pm$ SD (median)	Group II (n = 25); mean $\pm$ SD (median)	Group III (n = 25); mean $\pm$ SD (median)	p-value
Prior to medication (T1)	108 $\pm$ 12.07 (105.0)	109.40 $\pm$ 10.53 (111.0)	111.96 $\pm$ 11.33 (115.0)	0.42
Prior to LA (T2)	107.12 $\pm$ 12.53 (100.0)	109.08 $\pm$ 11.69 (110.0)	109.16 $\pm$ 12.54 (110.0)	0.41
Prior to pulp therapy (T3)	108.24 $\pm$ 13.15 (101.0)	108.20 $\pm$ 12.98 (104.0)	109.80 $\pm$ 10.98 (114.0)	0.71
During caries excavation (T4)	105.84 $\pm$ 13.94 (100.0)	106.20 $\pm$ 11.69 (105.0)	108.40 $\pm$ 11.82 (100.0)	0.61
During access opening (T5)	106.72 $\pm$ 12.37 (105.0)	107.60 $\pm$ 13.02 (110.0)	108.32 $\pm$ 12.86 (105.0)	0.96
During pulp extirpation (T6)	104.52 $\pm$ 12.38 (100.0)	102.52 $\pm$ 12.32 (100.0)	107.20 $\pm$ 13.57 (100.0)	0.51
After obturation (T7)	99.40 $\pm$ 11.29 (95.0)	97.96 $\pm$ 11.83 (98.0)	101.24 $\pm$ 11.73 (100.0)	0.65
p-value	<0.001	<0.001	<0.001	

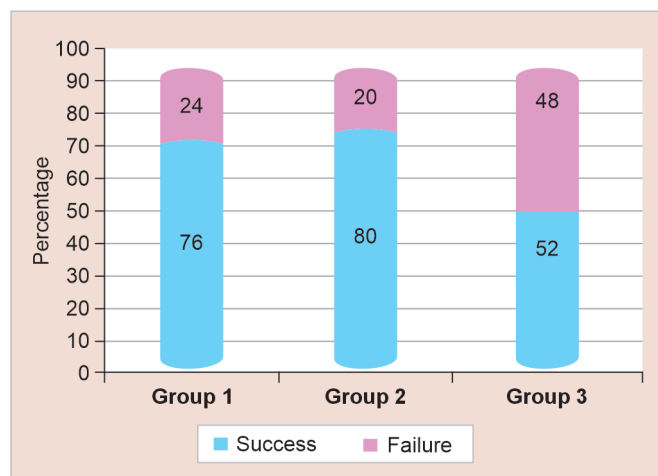
**Table 2:** Comparison of mean FLACC pain score at different time intervals among groups

Time intervals	Group I (n = 25); mean ± SD (median)	Group II (n = 25); mean ± SD (median)	Group III (n = 25); mean ± SD (median)	p-value
During caries excavation	0.88 ± 1.05 (1.00)	0.84 ± 1.03 (1.0)	1.04 ± 0.84 (1.00)	0.50
During access opening	1.44 ± 1.16 (1.00)	1.32 ± 1.03 (1.00)	2.44 ± 1.39 (2.00)	0.002*
During pulp extirpation	2.00 ± 1.47 (2.00)	1.92 ± 1.58 (0.0)	2.80 ± 1.44 (3.00)	0.07
p-value	<0.001**	<0.001**	<0.001**	

\*p <0.05 significant; \*\*p <0.001 highly significant

**Table 3:** Comparison of the success rate of inferior alveolar nerve block among groups according to the FLACC scale

Time intervals	Pain intensity	Group I (n = 25) (%)	Group II (n = 25) (%)	Group III (n = 25) (%)	p-value
During caries excavation	Success (no/mild pain)	24 (96.00)	24 (96.00)	25 (100.00)	1.00
	Failure (moderate/severe pain)	1 (4.00)	1 (4.00)	0	
During access opening	Success (no/mild pain)	23 (92.00)	24 (96.00)	19 (76.00)	0.13
	Failure (moderate/severe pain)	2 (8.00)	1 (4.00)	6 (24.00)	
During pulp extirpation	Success (no/mild pain)	19 (76.00)	20 (80.00)	16 (64.00)	0.51
	Failure (moderate/severe pain)	6 (24.00)	5 (20.00)	9 (36.00)	
Overall (all time interval)	Success (no/mild pain)	16 (64.00)	18 (72.00)	10 (40.00)	0.06
	Failure (moderate/severe pain)	9 (36.00)	7 (28.00)	15 (60.00)	



**Fig. 1:** The success rate of inferior alveolar nerve block among groups according to WBPS after obturation; proportions were compared by; <sup>a</sup>Chi-squared test; p > 0.05 not significant

Paracetamol, often known as tylenol, is the deethylated active metabolite of phenacetin. Paracetamol's exact method of action is unknown. It is proposed that in order to lower pain, it acts both centrally and peripherally to block the activity of COX.<sup>19</sup> It increases the pain threshold but has a weak peripheral anti-inflammatory component. It is good and promptly acting antipyretic. Expected hypotheses postulated for the difference between its analgesic-antipyretic and anti-inflammatory action is its poor ability to inhibit COX in the presence of peroxides, which are generated at sites of inflammation but are not present in the brain. The meta-analysis by Pierce and Voss<sup>20</sup> have demonstrated that both ibuprofen and paracetamol are equally safe in both pediatric and adult patients.

A placebo is an inert substance that does not contain an active drug ingredient and is usually in the form of a tablet, pill, or

other dose form. Research suggests that placebos can affect the COX pathway, implying an intricate set of mechanisms, including enzymatic activity, that can be activated by psychosocial stimuli like patients' expectations of improvement and various therapeutic rituals.<sup>21,22</sup> Therefore, in this study, ibuprofen and a combination of paracetamol and ibuprofen (to overcome the ceiling effect of ibuprofen and the weak anti-inflammatory action of paracetamol) were used as preemptive analgesics and compared to a multivitamin that served as the placebo group.

The perception of pain is a complex process. Many previous studies in literature have examined the relationship between dental fear and anxiety (DFA) and pain. Lauth<sup>23</sup> discovered that highly anxious patients had lower pain thresholds compared to low anxious patients. Vassend<sup>24</sup> reported the positive correlations between dental anxiety and pain. Eli et al.<sup>25</sup> concluded that the level of state anxiety is the best predictor of pain. Hence, in our study, the MCDAS scale was used to evaluate the level of anxiety about dental treatment in children. The child's behavior was evaluated using Frankl's behavior rating scale. An anxious or uncooperative patient will have a lower pain threshold, which might cause difficulty in obtaining a sufficient effect of analgesics. Therefore, children with Frankl scoring 3 or 4 and MCDAS scores below 19 were included in our study to standardize the preoperative conditions of an individual that might have affected the outcome of our study.

For treating mandibular primary and permanent molars, a mandibular block is the preferred local anesthetic technique. The foremost advantage is the depth of anesthesia achieved by mandibular block. Infiltration anesthesia is not commonly used in anesthetizing mandibular molars because the denser bone will not allow adequate dissemination of anesthetic.<sup>26</sup> A total of 2% lidocaine HCL with 1:100,000 epinephrine was chosen as the anesthetic agent in this study because of its greater potency at low concentrations, the latency of lidocaine varies from 2 to 3 minutes, duration of the anesthetic, safe to use as it has low toxicity and allergenic property. It is assumed that lip numbness after IANB is



**Table 4:** Comparison of proportions of pain score by Wong–Baker pain scale postoperatively at different time intervals among groups

Time intervals	Pain intensity	Group I (n = 25) (%)	Group II (n = 25) (%)	Group III (n = 25) (%)	p-value
At 4 hours	No pain	5 (20%)	15 (60%)	4 (16%)	0.04
	Mild pain	13 (52%)	5 (20%)	9 (36%)	
	Moderate pain	2 (8%)	4 (16%)	4 (16%)	
	Severe pain	5 (20%)	1 (4%)	8 (32%)	
At 12 hours	No pain	17 (68%)	20 (80%)	15 (60%)	0.49
	Mild pain	6 (24%)	3 (12%)	5 (20%)	
	Moderate pain	1 (4%)	2 (8%)	1 (4%)	
	Severe pain	1 (4%)	0 (0%)	4 (16%)	
At 24 hours	No pain	18 (72%)	21 (84%)	17 (68%)	1.00
	Mild pain	7 (28%)	4 (16%)	7 (28%)	
	Moderate pain	0 (0%)	0 (0%)	0 (0%)	
	Severe pain	0 (0%)	0 (0%)	1 (4%)	

**Table 5:** Analgesic intake postoperatively among groups

Time intervals	Intake	Group I (n = 25) (%)	Group II (n = 25) (%)	Group III (n = 25) (%)	p-value
At 4 hours	Yes	7 (28.00)	5 (20.00)	12 (48.00)	0.02
	No	18 (72.00)	20 (80.00)	13 (52.00)	
At 12 hours	Yes	2 (8.00)	2 (8.00)	5 (20.00)	0.14
	No	23 (92.00)	23 (92.00)	20 (80.00)	
At 24 hours	Yes	0	0	1 (4.00)	1.00
	No	25 (100.0)	25 (100.0)	24 (96.00)	

suggestive of pulpal anesthesia. The study by Saha et al.<sup>27</sup> reported that despite reporting lip numbness in all patients 15 minutes after IANB, some of the patients experienced pain during access cavity preparation. This indicates that lip numbness is not an absolute indicator of pulpal anesthesia. Therefore, in this study, cold testing was also done to determine pulpal anesthesia. In our study, all the patients reported lip numbness and a negative cold test 15 minutes after IANB. Therefore, none of the patients were excluded from the study. These findings of our study were similar to the study by Saha et al.<sup>27</sup> and Aggarwal et al.<sup>28</sup>

Pain can be measured by physiological parameters such as assessing heart rate, blood pressure, respiratory rate, oxygen saturation, or salivary cortisol.<sup>1</sup> Heart rate is a direct measure of physiological arousal, and its increase is attributed to stress and pain during dental procedures. In this study, the mean pulse rate in all three groups was found to be at its maximum prior to medication, that is, the initial waiting period before the pulpectomy procedure. The drop in heart rate over time could be ascribed to lower pain and anxiety levels as a result of medication and behavior modification strategies. Elevation in heart rate before the pulpectomy procedure could possibly be due to needle phobia.

“Pain has a direct influence on behavior.” Pain can be evaluated by observing changes in patient behavior.<sup>29</sup> FLACC is a validated scale, and it is indicated in children unable to intensify their level of pain. It can be used in children aged 2 months to 7 years. The child’s legs and body are uncovered, and legs and activity are noticed for 1–5 minutes or longer.<sup>30</sup> Hence, FLACC was used in our study to assess the pain objectively by an observer blinded to the preemptive medication used for that child.

Results showed that the FLACC pain score was the lowest during caries excavation, then it gradually increased during access opening and pulp extirpation in intergroup comparison; statistical significance was found only during access opening.

According to the literature, activation of the C-fibers (such as deep cavity preparation and high-intensity thermal/chemical stimuli) causes amplification due to neurokinin action, particularly substance P (SP). Sensory neuron activity is affected differently by changes in pulpal blood flow. SP, a neuropeptide released from afferent nerves, causes vasodilation and endothelial cell contraction, allowing plasma extravasation and mastocyte degranulation, resulting in neurogenic inflammation of the tooth pulp. Histamine is released by mastocyte granules, which enhances vascular processes and activates nociceptors. SP can activate lymphocytes, granulocytes, and macrophages to generate cytokines by binding to their receptors. PGE2 and thromboxane are inflammatory mediators produced by SP-stimulated macrophages, as well as the proinflammatory cytokines interleukin (IL) 1, IL-6, and tumor necrosis factor. All of these chemical activities eventually support the synthesis and release of additional SP, perpetuating the vicious cycle and raising pain sensitivity even more.<sup>31</sup> Hence, this can explain the increase in FLACC score in our study from caries excavation to pulp extirpation.

Inferior alveolar nerve block (IANB) was considered successful if there was no pain or mild pain at any point of the pulpectomy procedure, that is, caries excavation, access opening, and pulp extirpation. More children reported less pain in the preemptive analgesic group. The marginal increase in success rate in the combination group could be due to the synergistic effect of ibuprofen and paracetamol. However, there was no statistically significant difference between the three groups according to FLACC scoring. The results of our study are supported by the Ianiro et al. study<sup>32</sup> conducted in an adult population.

Self-reporting pain is the gold standard for pain assessment. WBPRS was used to evaluate children’s pain. In our study, WBPRS was used at different time intervals during the pulpectomy procedure and postoperatively. Our findings mention that children

have reported more success of IANB with the Wong–Baker scale when compared to the FLACC scale on completion of pulpectomy procedure. It can be explained by the fact that pain is subjective in nature. The different reporting as compared to FLACC might be due to the social, cognitive, and communication abilities of the children, the clinic setting, and who is asking the questions. Also, when children are asked to quantify pain over an extended period of time, they are more likely to report biased results.

Our secondary aim was to study the efficacy of preemptive analgesia in reducing postendodontic pain in children with symptomatic irreversible pulpitis. It is suggested that patients with severe preoperative endodontic pain experience more postoperative pain. Postendodontic pain is mainly due to inflammatory mediators that activate nociceptors. Postoperative pain, 24 hours following endodontic treatment, is intense. Therefore, postoperative pain was evaluated at 4, 12, and 24 hours. Our findings showed that patients comparatively had more pain experience at 4 hours in all groups than at 12 and 24 hours. None of the patients with preemptive analgesia had pain at 24 hours. Overall, groups I and II needed a smaller number of rescue medications, which can be explained by the fact that preemptive analgesics function by inhibiting COX enzymes and preventing the generation of new PG molecules; however, they have no effect against existing mediators in circulation.

In all groups, the majority of patients had consumed rescue medication 4 hours after the pulpectomy procedure. Chemical mediators that had already activated the nociceptors as a result of the initial inflammatory reaction or discomfort experienced by children as a result of LA administration or rubber dam clamp insertion may have caused the need for extrarescue medication at 4 hours. Also, it might be possible that supplemental intrapulpal injections have masked the actual need for postoperative pain.

### Limitation of the Study

The pain perception is influenced by variable factors. The number of dental visits, previous negative experiences, and parent's DFA were not accounted for in our study.

### CONCLUSION

The following conclusion can be drawn:

- In children with symptomatic irreversible pulpitis, the success of IANB was reported more with a combination of ibuprofen and acetaminophen group followed by ibuprofen and placebo group, though the difference was not statistically significant.
- Preemptive analgesics were found to be effective in reducing pain at 4 hours after the pulpectomy procedure but not at 12 or 24 hours when compared to the placebo.

### ORCID

Nasrin A Gori  <https://orcid.org/0009-0004-0370-7965>

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