



Effects of Acetaminophen and Ibuprofen on Pulpal Anaesthesia Immediately after Pulpectomy of Primary Maxillary Molars

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ABSTRACT

Introduction: This study aimed to evaluate the effects of acetaminophen and ibuprofen on pulpal anaesthesia immediately after pulpectomy of primary maxillary molars. **Methods and Materials:** In this placebo-controlled, double-blind clinical trial, 60 children (aged 5 to 9) were referred to the Department of Pediatric Dentistry, Yazd Dental School; for primary maxillary molar pulpectomy. Local anaesthesia and analgesic drugs were used for the pre-operative stage. A five-face scale was considered to evaluate pain reaction during the pulp therapy. Pain scores were determined when the dental procedure was complete. The Kruskal-Wallis and Mann-Whitney U tests were finally used at the confidence level of 95%. **Results:** Use of analgesics before pulpectomy in children can reduce pain score compared to placebo group ($P < 0.001$) and increase the effectiveness of pulpal anesthesia. Additionally, ibuprofen exhibited lower pain scores compared to acetaminophen although the difference was not statistically significant. **Conclusions:** Pre-operative use of ibuprofen and acetaminophen might be a useful way to achieve analgesia during pulpectomy of primary maxillary molars in children.

Keywords: Acetaminophen; Analgesia; Child; Ibuprofen; Pain; Pediatric Dentistry; Pulpectomy

Introduction

Pain control in dentistry, especially in children, is very necessary, and is primarily done by use of local anesthesia [1]. Complete anesthesia in teeth with inflamed pulp may be difficult, because threshold of pain perception reduces in the inflamed tissues [2]. Morphologic and biochemical changes in the inflamed nerves lead to deactivation of local anesthetic solutions [3]. The anesthetic agent may be unable to prevent pain during such dental treatments such as access preparation or pulp extirpation, because the lower-speed fibers are not anaesthetized [4].

In children, optimal anesthesia in teeth with irreversible pulpitis may not be entirely achieved [5]. Significantly higher amounts of prostaglandins in the teeth with irreversible pulpitis can cause decreased nerve responses to anesthetic agents [6].

The first drug to consider is acetaminophen. It is very safe if used in therapeutic doses. Its favorable risk/benefit balance makes it the

analgesic of choice for acute postoperative dental pain in adults and children. Caution must be exercised in patients with a history of liver disease or alcoholism because its excessive dose can lead to irreversible liver damage. Long-term use should be avoided as it may lead to renal toxicity [7]. Non-steroidal anti-inflammatory drugs (NSAID) have been consumed increasingly as analgesics, not just as anti-inflammatory agents. They are used for reducing mild to moderate pain in children. Traditional NSAIDs block prostaglandins which protect gastric mucosa and regulate renal blood flow. Moreover, they can inhibit the platelet aggregation [8].

Pain, during pulp therapy, may cause distress for the child, parents and dental professionals [9]. In addition to local administration of anesthetics, systemic administration of analgesics is occasionally necessary to help control pain. These analgesics may be administered pre-operatively or post-operatively in association with the dental procedure that may cause pain for the child [2].

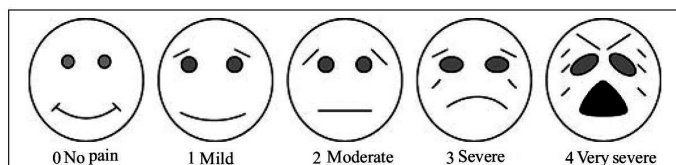


Figure 1. Five-face scale for pain intensity measurement

Use of systemic analgesic drugs along with local anesthetic agents may produce a synergistic effect in reducing pain, especially in the teeth with inflamed tissues. This hypothesis confirmed in several studies in adults [10]. Batawi [11], assessed the efficacy of diclofenac compared to acetaminophen on children's pain perception under general anesthesia after dental treatment. He found that diclofenac is more effective than acetaminophen, especially after painful procedures. In another research, Primosch Re *et al.* [12] in 1995 compared the effect of preoperative ibuprofen, acetaminophen and placebo on pain score in children after tooth extraction. They found that analgesics were not superior to placebo administration. Kharouba *et al.* [13] compared postoperative pain among children who received paracetamol, ibuprofen or placebo, prior to tooth extractions and revealed that administration of paracetamol or ibuprofen appeared to reduce the pain following pulpotomy in children. Kharouba *et al.* [14] revealed that usage of preemptive intravenous paracetamol provides lower pain scores compared to post-treatment administration in children underwent dental rehabilitation under general anesthesia.

There are many controversial reports about the efficacy of analgesics in children [15, 16]. Some studies showed the analgesic administration after tooth extraction in children had beneficial pain relief properties over placebo [15-18]. Nonetheless, we couldn't find studies about the effect of the pre-operative use of analgesics on pain control during pulp therapy in children.

Pain assessment in children is difficult, because of their limited ability to recognition. Two approaches were used in the previous studies: parental report or self-report. Self-report measures (*e.g.* visual analogue scale) are more reliable than parental report [19].

In 2016 Ashley *et al.* [20] conducted a review study about efficacy of preoperative analgesics. They stated that it is not possible to determine whether premedication is beneficial in pain relieving in different pediatric dental procedures, or not. They claimed that further studies are required to assess the efficacy of premedication in children and adolescents undergoing dental treatments.

Based on the above, this study aimed to evaluate the effects of acetaminophen and ibuprofen on pulpal anaesthesia immediately after pulpectomy of primary maxillary molars.

Materials and Methods

This placebo-controlled, double-blind clinical trial was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran (ethics code no. 79291) and registered in the Iranian registry of clinical trial under the ID number: IRCT2014111017935N3. This study was conducted in full accordance with ethical principles, including the Declaration of Helsinki.

The present study was carried out on 60 children (22 boys, 38 girls), aged between five to nine, who were referred to Yazd dental school for primary maxillary molar pulp therapy in 2015-2016. The sample size was calculated 20 subjects in each group based on similar studies [15], ($\alpha=0.05$ and $\beta=0.2$, SD: 0.5, mean difference 0.45 for pain score).

Children with a history of systemic diseases (renal, hepatic or gastro-intestinal diseases); prolonged bleeding; platelet disorders; hypersensitivity or allergy to analgesics or any drugs used in this study, also patients using any analgesic drugs in last 5h, and anxious or uncooperative children were excluded from the study.

A checklist was designed to inform parents about the purpose of the study, risks and benefits; and to obtain their informed consent. For each child, dental history was completed and their weight and age were recorded. Intraoral examinations were done by one practitioner. The eligible teeth for the study were primary maxillary molars with spontaneous pain. The selected teeth did not show any pain because of percussion or palpation, and/or any signs of fistula or abscess formation. A periapical radiograph was taken from each participant and the ones with external or internal resorption, and furcation or periradicular radiolucency were excluded from the study.

Patients assigned in to three treatment groups in a blind, parallel method based on the table of random digits. The drugs prepared in the number coded bottles by pharmacist, have same color and flavor and was administered one h before the dental procedure by a nurse based on the patient's weight. Both the practitioner and the child parents were blinded to the type of the solution. In the first group, an oral suspension of ibuprofen (100 mg/5 mL, HAKIM Pharmaceutical Company, Tehran, Iran) was administered in the dosage of 10 mg/kg/dose. In the second group, children had acetaminophen elixir (120 mg/5 mL, HAKIM Pharmaceutical Company, Tehran, Iran) in the dosage of 15 mg/kg/dose. In the third group (control group), a placebo solution was administered.

Parents were not present at the time of the dental procedure including the injection. One h after the administration of the

drug, the dental procedure began using 20% benzocaine gel (Benzotop 200mg/g; DFL, Industria e Comerico S.A, Rio de Janeiro, Brasil) as the topical anaesthesia on the injection site.

Lidocaine with 1:80000 adrenaline (Daropaksh Company, Tehran, Iran) was injected for local anaesthesia. After 10 min, a pedodontist performed pulpectomy. A broach was used to extirpate pulp from each canal. Endodontic files were used 1 mm to 2 mm shorter than the radiographic apex. Normal saline solution was used to rinse and remove debris from the canals. Then, the appropriately sized paper points were selected, and the canals were dried and then filled with zinc oxide eugenol (ZOE) paste (Dental Products Ltd Kemdent Works, Purton, Swindon Wiltshire, SN5 4HT, United Kingdom).

Pain score was recorded using a five-face visual analogue scale (VAS), which provided good validity. Immediately after pulpectomy, VAS score was explained for the child. Participants were asked to choose one of the five cartoon faces (Figure 1) that better expressed their feelings during pulpectomy [15]. Five-face scores were used as a self-report scale after the treatment to determine the feeling of the participants during pulp therapy. The teeth were restored with amalgam or a stainless steel crown (SSC) in the next session.

Statistical analysis

The age, weight and gender of children were analysed using ANOVA and chi-square analysis. The Kruskal-Wallis and Mann-Whitney U tests were used at a confidence level of 95% to analyse pain scores. All statistical analyses were conducted using SPSS software (SPSS version 11.0.0, SPSS, Chicago, IL, USA) at a significant level of 0.05.

Results

Sixty children (22 boys and 38 girls) were eligible to participate in this study (Figure 2). The average age and weight of the children were 6.37 ± 1.11 and 21.1 ± 4.18 respectively. The children were randomly assigned to three groups (20 subjects to ibuprofen group, 19 subjects to acetaminophen group and 21 subjects to placebo group). Totally, 34 first and 26 second primary maxillary molars were treated.

There was no significant difference in the average age, average body weight and gender amongst three study groups ($P=0.25$, $P=0.84$ and $P=0.34$ respectively) (Table 1).

There was significant differences in VAS pain score among three study groups ($P<0.001$).

The children, who received ibuprofen and acetaminophen pre-operatively, reported significantly lower pain scores compared to placebo group. Although there was not a significant difference between acetaminophen and ibuprofen ($P=0.75$) groups, the average VAS pain score in ibuprofen group was lower.

Table 2 demonstrates the frequency of each scale in three experimental groups. Totally, 19 percent of children in placebo group reported score 4 for pain intensity, while frequency of the same score in ibuprofen and acetaminophen groups were 0 % and 5.3 %, respectively. The percentage of score 0, according to test solution group, was reported as follows: ibuprofen (70 %), acetaminophen (68.4 %), and placebo (9.5 %). Thus, it seems that patients in placebo group selected higher scores of pain intensity after dental treatments.

Table 1. Mean (SD) of comparison demographic data and VAS score amongst the three groups

	Ibuprofen	Acetaminophen	Placebo	P-value*
Age (years)	6.70 (1.20)	6.31 (1.14)	6.11 (1.01)	0.252
Weight (kg)	21.60 (4.76)	21.05 (3.71)	20.85 (4.09)	0.845
Male to female ratio	0.33	0.90	0.61	0.345
VAS (score)	0.45 (0.82)	0.73(1.24)	1.90 (1.22)	0.000

* Significant level <0.05

Table 2. Frequency of each VAS score amongst the three groups

	VAS score					Total
	0	1	2	3	4	
Ibuprofen	14 (70.0%)	4 (20.0%)	1 (5.0%)	1 (5.0%)	0 (0%)	20 (100%)
Acetaminophen	13 (68.4%)	1 (5.3%)	3 (15.8%)	1 (5.3%)	1 (5.3%)	19 (100%)
Placebo	2 (9.5%)	6 (28.6%)	9 (42.9%)	0 (0%)	4 (19.0%)	21 (100%)
Total	29 (48.3%)	11 (18.3%)	13 (21.7%)	2 (3.3%)	5 (8.3%)	60 (100%)

CONSORT 2010 Flow Diagram

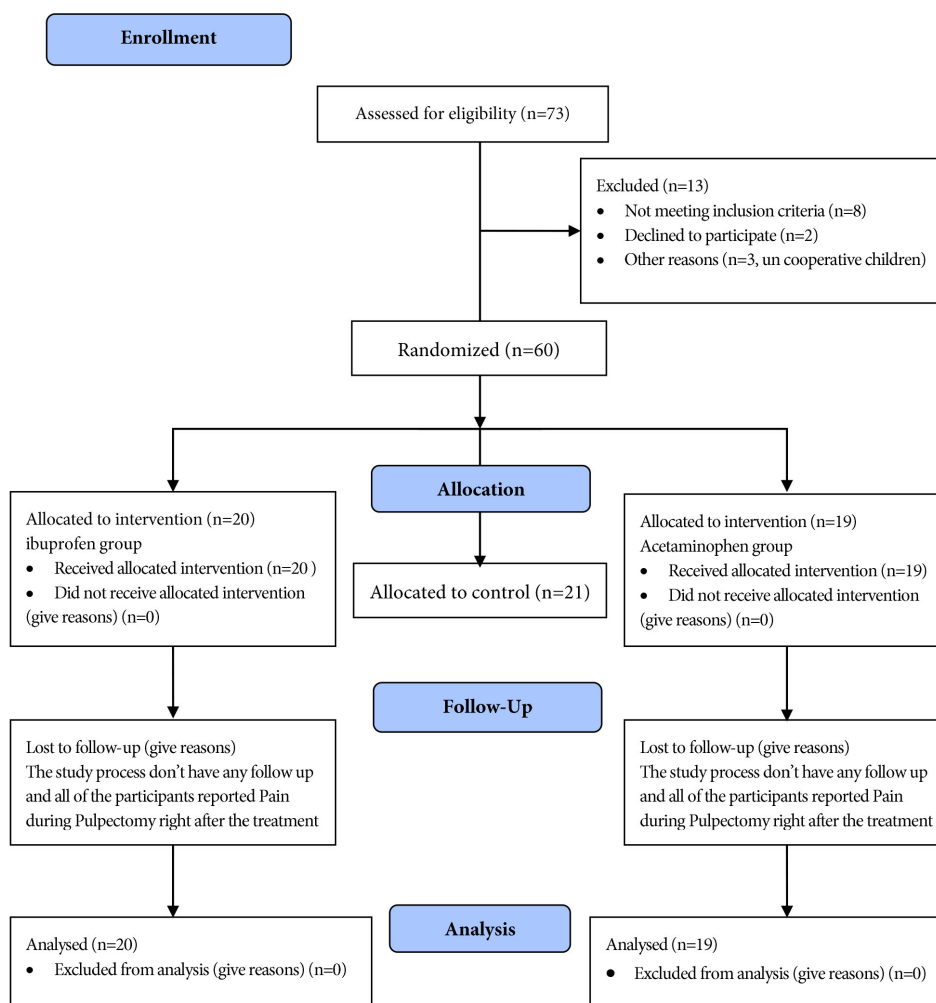


Figure 2. Flowchart of the included patients into the study

Discussion

The results of present study indicated that ibuprofen and acetaminophen, when given pre-emptively, decreased intra-operative pain in the pulp therapy of primary maxillary molars. Hence, pre-operative use of ibuprofen and acetaminophen might be a useful way to achieve analgesia during the pulpectomy of primary maxillary molars in the mentioned group of children.

Use of systemic analgesic drugs along with local anesthetic agents may lead to a synergistic effect in reducing pain especially in teeth with irreversible pulpitis. Irreversible pulpitis in primary dentition can cause spontaneous pain and accomplishing sufficient dental anesthesia may be difficult in some cases especially during pulp excavation [2, 21]. While the efficacy of systemic analgesics has been confirmed in pulp treatment of adults, no study assessed the efficacy of these drugs after

pulpectomy in children with irreversible pulpitis; although pulp therapy is a common and painful procedure in children.

The results is in accordance with the study of Shafie *et al.* [22] found premedication with ibuprofen is an effective method to reduce pain following pulpotomy and SSC placement in primary teeth. Also there exist some studies in children where the effectiveness of analgesics after tooth extraction is assessed. Bygin *et al.* [15] demonstrated that use of ibuprofen and acetaminophen compared to placebo can reduce post-extraction pain in children. Gazal *et al.* [17] compared the effectiveness of different oral analgesics in reducing pain in children following extraction of teeth under general anesthesia. Both the ibuprofen alone and acetaminophen/ibuprofen combination groups compared to usual dose of acetaminophen had lowered pain score in a significant manner. Moore *et al.* [18] revealed that both ibuprofen and acetaminophen with codeine provided significant post-extraction

pain relief in children compared to placebo. Unlike the study of Primosch *et al.* [12] revealed that preoperative administration of acetaminophen or ibuprofen had no significant beneficial effect in reducing post extraction pain over placebo. As the child pain was assessed based on the parental report this discrepancy may be related to the parental attitude toward the child's pain.

Several studies in adults have found the pre-operative administration of analgesics to be effective in reducing pain after different dental procedures [2, 16, 23, 24]. It was shown that pre-medication therapy before local anesthesia injection is an effective method for achieving a deep anesthesia during root canal treatment in teeth with irreversible pulpitis [2, 10]. Ramazani *et al.* [25] concluded that prophylactic use of ibuprofen is an effective pain relieving agent on post endodontic pain of molars with irreversible pulpitis compared with zintoma. In another study by Mokhtari *et al.* [26] ibuprofen and indomethacin significantly reduced the postoperative pain in comparison with placebo during treatment and 8 h after treatment. Mehrvarzfar *et al.* [27] found that pretreatment PDL injection of dexamethasone can reduce the severity of post-treatment pain in patients with irreversible pulpitis.

Modaresi *et al.* [2] reported that the use of analgesics could improve the success rate of inferior alveolar nerve block (IANB) in the teeth with inflamed pulp during endodontic treatment. Parirokh *et al.* [10] also demonstrated that premedication with analgesics significantly increased success rate of IANB during the endodontic treatment.

This study is in accordance with the results reported by Modaresi *et al.* [2] and Parirokh *et al.* [28] that were obtained by using different analgesic agents before pulp treatment in adults. Previous studies have used tooth sensitivity level (pulp tester scale) to measure depth of anesthesia, but this test is not reliable in children. In the study by Parirokh *et al.* [28] each patient recorded pain score on a visual analogue scale, during access cavity preparation and root canal instrumentation. In this study visual analogue scale was used as well to measure pain during pulp therapy. Several visual analogue pain scales exist, but the five-face scale is the easiest one for younger children. Self-report visual analogue scales measure the effects of analgesia in children [19].

Generally, assessment of the effects of analgesics on pain relief is difficult in pediatric dentistry. One reason is children's limited ability to understand assessment instructions and to articulate description of pain [17, 29]. In the present, to measure pain score, the five-point pain scale with picture of faces was used. The same scale has been used in previous studies for pain measurement [15, 17].

In this study, the mean VAS score for ibuprofen and acetaminophen was significantly lower than placebo. These findings confirm the efficacy of these drugs in decreasing the intra-operative pain. Significantly lower VAS after ibuprofen

premedication therapy may be due to its blocking effect on the cyclooxygenase (COX) pathways. Ibuprofen decreases the prostaglandin level and inhibits the stimulated nerve activity [30]. Additionally, ibuprofen resulted in lower pain scores compared to acetaminophen after pulp therapy. This is probably due to the anti-inflammatory properties of ibuprofen, which results in lower pain scores [31]. But the difference was not significant in this study and it shows that both drugs are effective in reducing pain during pulp therapy procedure when compared with placebo. Acetaminophen has analgesic and antipyretic properties. If there is any contraindication to use a NSAID, acetaminophen is the analgesic of choice [32].

Only upper primary molars were enrolled in this study. This enrollment was due to the unpredictability of the success in IANB anaesthesia in mandibular teeth; which might have some effects on the results [33].

Age and gender characteristics may influence the reports of pain [12, 17]. Girls often demonstrate a lower pain tolerance [34]. In this study, there was no significant difference amongst the groups on gender, age and body weight. The effect of these variables on the mean pain score was minimized by random sampling.

This study demonstrated that pre-emptive analgesic prescription could be considered as a routine and rational pain prevention strategy in primary maxillary tooth pulp therapy in children. If further studies proved this effectiveness, it could eliminate the need for supplementary injections such as intra-pulpal and periodontal ligament (PDL) injections which are very painful and may cause unpleasant experience in children [2].

Further studies with a larger sample size and the use of other physiological scores _such as heart rate and blood pressure_ with pain-score measurement, before and after treatment, may be considered beneficial to get more reliable evidence.

Conclusion

The present study suggested that pre-operative administration of ibuprofen or acetaminophen before the administration of local anesthetics might be an effective way of achieving deep analgesia during the pulpectomy of primary maxillary molars with irreversible pulpitis in children.

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Conflict of Interest: 'None declared'.

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