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Proposal Title: Effect of preoperative oral administration of Ibuprofen and Acetaminophen on the anesthetic efficacy of buccal infiltration during vital pulpotomy of mandibular primary molars: A Prospective, Double-blinded, Randomized Controlled Trial

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Introduction:

Pain is one of the most unpleasant sensations that human beings may experience throughout their lives. Pain control, particularly in children, is a vital part for a successful dental treatment. Optimal pain control measures result in building up trust and facilitate the entire procedure [(1)].

Effective pain control while delivering dental treatment is considered as the keystone of pediatric behavior management. The mandibular block is the local anesthesia technique of choice when treating mandibular primary or permanent molars. A number of disadvantages, however, have been associated with this technique. The duration of anesthesia makes the uncomfortable numb feeling last long after the end of dental treatment, often resulting in lip or tongue biting [(2)]. Furthermore, triggering a successful mandibular block involves a degree of difficulty rendering the injection stressful for both the clinician and the patient. Thus the administration of the anesthetic agent is still considered the most painful part of most dental procedures [(3)].

Investigators have tested other techniques where infiltration anesthesia was used successfully to restore maxillary teeth but has been avoided in the mandibular molar regions because of denser bone that does not allow adequate dissemination of the anesthetic [(2)]. Some studies assessed the effectiveness of mandibular infiltration in restoring primary molars in children and concluded that infiltration anesthesia was successful [(4, 5)].

Generally, pain assessment is very subjective; it can be only indirectly measured in children through verbal self-report or observation of behaviors that suggest pain [(6)]. There are several pain scale indicators that can be used with children, including the FACES pain scale and the Wong-Baker FACES scale [(7, 8)].

Researchers have studied different ways to have better anesthesia in permanent teeth. Premedication with analgesic agents has been proposed as alternatives with controversial results [(9)]. Numerous analgesics are used for pain control ranging from opioids to non-narcotic analgesics including acetaminophen (Flavol) and non-steroidal anti-inflammatory drugs (NSAIDs) (Brufen). NSAIDS block the cyclooxygenase enzyme in the pathway that produces prostaglandins, resulting in lower levels of inflammation-inciting prostaglandins [(10, 11)]. Although the action of acetaminophen is unknown, it has been suggested that it interferes with inflammation by diminishing the synthesis of prostaglandins (possibly PGF2); and also alters the transmission of pain by acting directly on an unknown site in the brain [(12, 13)].

Objective:

The purpose of this double-blinded, randomized, prospective study will be to determine the effectiveness of buccal infiltration during vital pulpotomy in mandibular primary molars in relation to two different analgesic premedications.

Methodology

Recruitment/Study setting:

A total of 60 healthy children will be recruited from the outpatient clinic of the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Ain Shams University. One author will screen and recruit all the patients in the study.

Inclusion and Exclusion Criteria

Preoperative periapical radiographs will be obtained for all subjects prior to inclusion in the study and participation will be based on the following eligibility criteria for children:

Of age group 7–9 years

Without systemic or mental disorders.

Who could be categorized as cooperative according to ***Wright's classification*** for child behavior

Ability of child to understand the use of pain scales;

Having at least one lower second primary molar with deep caries indicated for pulpotomy;

Absence of any periapical or furcation radiolucency on radiographs,

Absence of any signs of internal or external resorption on radiographs,

A vital coronal pulp on access opening.

Exclusion criteria include any allergic reactions, sensitivity, or contraindications to any tested drugs or history of bleeding problems. Patients who had taken analgesics within 12 hours before administration of the study drugs or those having active pain, pulpitis or abscess related to the designated mandibular molar will not be included. Children with special health care needs or any systemic problems will be excluded from our study as well.

Ethical Considerations:

Patients who failed to fulfill the eligibility criteria of the study will receive any necessary dental treatment in the outpatient clinic. Parents of eligible children will be informed about the nature of the procedure, the purpose of the study, any possible discomfort or risks and a signed informed consent will be obtained from them prior to enrollment.

Interventions:

Subjects meeting the inclusion criteria will be divided into three groups (24 patients/group) and will be given one of the following three drugs:

- Brufen syrup (Ibuprofen BP 100 mg/5 ml, an orange-coloured, orange-flavoured, syrupy suspension)
- Fevano Syrup (Paracetamol 200 mg/5ml. an orange-coloured, mango flavoured)
- Sansovit Iron (Multivitamin +Iron, an orange-coloured, orange-flavoured) as a control

All solutions will be placed in medicine bottles and will be randomly assigned 3-digit numbers by one of the authors to ensure blinding. To ensure randomization and allocation concealment, children will be randomly assigned to the three groups using computer-generated numbers. The numbers of patients in each group will be written on paper which will be then kept in a sealed opaque envelope. Each child will be asked to choose one of the envelopes and thus assignment to one of the three groups will be based on the chosen number.

Each child will then receive an age-dosed volume of the assigned drug 1 hour before starting the treatment. Before taking the drug, the patients will be asked to rate their pain using **Wong Baker FACES** pain assessment tool. For all subjects, the anesthetic solution will be 4% Articaine with adrenaline 1:200 000. Topical anesthesia will be applied for 2-3 min on previously dried mucosa before administration of the solution. The solution will be injected by the same clinician by using self-aspirating syringes and 27 gauge, short needles.

Children will be asked about lip numbness every 3 minutes for 10 minutes. Ten minutes after injection, removal of caries and coronal access will be performed. Patients will be asked to rate any pain felt during treatment using the same assessment tool.

A pilot study will be conducted in a group of 10 children to assess for feasibility and success of combining buccal infiltration with the tested analgesic premeditations.

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