Pre-operative analgesics for postoperative pain relief after dental treatment

NCT02393339

Research protocol 29.12. 2014

Background:

Patients associate dental treatment with pain. An experience of poorly managed pain related to dental procedure can cause avoiding looking for further treatment, and make patients more challenging to treat (1). The management of pain is of particular importance in pediatric dentistry where patient's perceptions of dental treatment are being established.

Pain control is routinely achieved through the use of local anesthetic (LA) solutions injected into the soft tissues during treatment. However, pediatric studies have shown that 38% of treated children still reported postoperative dental pain, with the highest being after root canal therapy, stainless steel crowns and extractions (2).

There may be a role for preoperative analgesics in the management of pain in children.

Several studies found that preoperative use of Ibuprofen and Paracetamol may provide a pre-emptive analgesic effect in pediatric patients following extraction treatments under local LA and following orthodontic separator placement without LA (3-5).

The use of preoperative analgesics postoperative pain in adults is well established in medicine. Use of preoperative oral analgesics for children undergoing dental treatment under general anaesthesia (GA) is also routine.

A Cochrane review conclusions from the available evidence couldn't determine whether or not preoperative analgesics are of benefit in pediatric dentistry for procedures under local anesthetic, and further randomized controlled clinical trials are needed (6).

Objective: to compare the efficacy of the pre-operative administration of Paracetamol and placebo in reducing postoperative pain after routine dental treatment in children.

Rationale: Use of preoperative oral analgesics for children undergoing dental treatment under GA is routine. Use of preoperative analgesics in children undergoing dental treatment with LA has the potential to reduce postoperative discomfort and pain. Prediction and treatment of post-operative pain should be an integral part of professional pediatric care.

Materials and methods:

This study will be a prospective, placebo-controlled, randomized, double-blind trial. 400 boys and girls 5-12 years old, healthy, in need of dental treatment with local anesthesia of Lidocaine 2% with adrenalin 1:100,000 in the Hadassah School of Dental Medicine will take part in the study. Exclusion criteria: preoperative pain, patients taking analgesics within 5 h prior to the dental treatment, allergic reaction or adverse effect to paracetamol, not available (by phone) at least 2 hours after treatment.

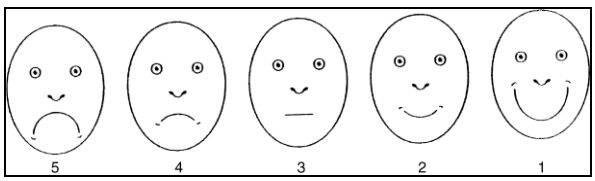
Study group: 200 children will receive paracetamol (15 mg/kg) 15 min before the dental treatment.

Control group: 200 children will receive placebo 15 min before dental treatment.

Randomization: every day a different unnamed but numbered bottle of medication/placebo (1-paracetamol or 2-placebo) will be available at the dental clinic. The bottles will look the same and will be marked 1 or 2. The patients will be assigned to the study group or the control according to the day of the treatment.

Blindness: the patient, the treating dentist, and the interviewer will be blind to the medication.

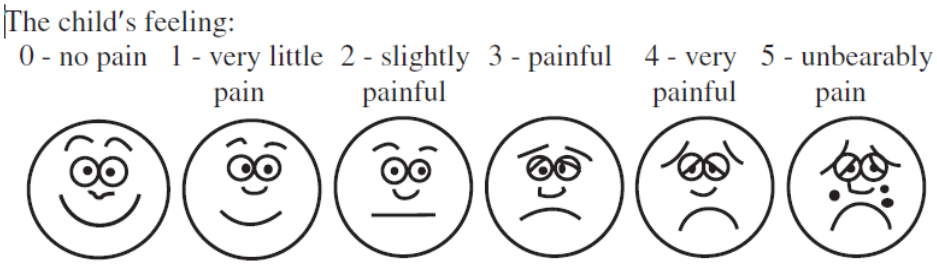
Data collection: age, gender, type of treatment, type of LA (infiltration /block), time of taking the preoperative analgesic, type of preoperative analgesics (1 or 2), time at the end of the treatment and baseline apprehension. Baseline anxiety will be recorded prior to the procedure using *Facial Image Scale (FIS)* (7). FIS is a valid means of assessing child dental anxiety status in a clinical context. It comprises a row of five faces ranging from very happy to very unhappy. Each face has a numerical value, from 1 to 5. The children will be asked to point at which face they feel most like at that moment, before the beginning of dental treatment.



Main outcome measure: one of the main investigators will interview the patient at three time points: immediately at the end of the treatment, one hour after taking the pre-operative analgesic and by phone 2.5 hours after taking the pre-operative analgesic. The patient and his parents will be asked if the child is crying (yes/no), complaining about pain (yes/no), needed a different kind of analgesics after the

treatment (yes/no). In addition, each child will describe his / her feelings regarding postoperative pain, using the *Wong-Baker Facial Rating Pain Scale* (8). This scale measures the unpleasantness or affective dimension of a child's pain experience, and is used with children aged 3–17 years old. The child is shown a set of six cartoon faces with varying facial expressions from smile / laughter to tears. Each face has a numerical value, from 0 to 5. The child selects the facial expression that best represents his / her experience of discomfort, the face 'which look like how you feel deep down inside, not the face you show to the world'. The facial pain scale shows good construct validity as a self-report pain measure.

The first two parts of the questionnaire (time 0, 1 h) will be answered in the clinic and the last part (time 2.5 h) by phone; the children will have the scale with the faces with them.



Statistical analysis plan

McNemar test - to analyze categorical variables difference (Wong-Baker Facial Rating Pain Scale) at two-time points. Chi-square and Fisher's exact test- for correlations between two categorical variables (between gender/ local anesthesia method/ baseline anxiety/ type of dental treatment/ type of behavior management technique/ Wong-Baker Facial Rating Pain Scale and group, and between type of behavior management technique/ type of dental treatment and Wong-Baker Facial Rating Pain Scale). Student's t-test was - for comparison of quantitive variables among two groups (participants' age, treatment length). Kruskal-Wallis test - for comparing different age groups and the Wong-Baker Facial Rating Pain Scale. Spearman's rank correlation coefficient - to assess the relationship between baseline anxiety and Wong-Baker Facial Rating Pain Scale.

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