

Protocol and Statistical Analysis Plan

Title: Effect of the DentalVibe injections system on pain during local anesthesia injections in children
(0661-17-FB)

PI: Jennifer Marshall, DDS
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Summary

The purpose of this study is to compare self-reported pain scale measurements using the Wong-Baker FACES pain rating scale from an experimental group (local anesthesia injection with DentalVibe system) and a control group (traditional local anesthesia injection with DentalVibe system turned off) in children. Eligibility: Children age 5-11 years old who require local anesthesia for bilateral dental treatment at UNMC pediatric dental clinic. Children must understand and speak English. Interventions and evaluations: Each patient will have two separate restorative appointments where the DentalVibe will be used during local anesthetic injections. One appointment the DentalVibe will be turned on and one appointment the DentalVibe will be turned off. After each injection the child will be shown the Wong Baker FACES Pain Rating Scale and asked to pick a face associated with their level of hurt during the injection. Follow-up: All children will be followed up with any necessary recommended dental treatment.

Purpose, Background and Rationale

The purpose of this study is to compare self-reported pain scale measurements using the Wong-Baker FACES pain rating scale from an experimental group (local anesthesia injection with DentalVibe system) and a control group (traditional local anesthesia injection with DentalVibe system turned off) in children.

An important aspect of behavior guidance in pediatric dentistry is the control of pain during dental procedures. There can be anxiety and discomfort associated with some dental procedures. Anxious patients feel more pain than less anxious patients.¹ Dental procedures can be carried out more effectively if a child is not in pain. The use of local anesthetic is generally indicated when teeth require restorative treatment or extraction. Dental injection is the dental procedure that produces the greatest negative response in children.² If a child experiences pain during a dental procedure, their future as cooperative dental patients may be damaged.³ Children who have traumatic dental experiences are more likely to avoid the dentist as an adult.^{4,5}

Different techniques have been proposed to decrease pain and anxiety during local anesthetic administration. Distraction by use of audiovisual glasses have been shown to reduce the pain associated with the injection of local anesthesia.⁶ Another study showed cooling the injection site before local anesthetic injections reduced pain perceived by pediatric patients.⁷ The Wand, a computer delivery system that provides precise injection flow rate, can provide less painful injections when compared to the conventional local anesthesia in pediatric patients.⁸

According to the Gate theory, proposed by Wall & Melzack in 1965, pain can be reduced by activation of nerve fibers that conduct non-noxious stimuli.^{9,10} Vibration stimulus can decrease pain during dental local anesthetic administration.^{11,12} Numerous devices have been developed to cause stimulation of the mechanoreceptors during injections to reduce pain.

The Vibraject is a device that attaches to a traditional dental syringe and transfers vibrating stimulus to the needle. In the study by Roeber, the Vibraject did not provide any benefit over a conventional approach to anesthesia injections in children. This may have been due to the vibrations targeting the wrong location.^{13,14} The Gate Theory suggests pain can be blocked by pressure or vibration to the surrounding tissue but not necessarily the exact same tissue where the nociceptive stimulus is directed. In contrast, the DentalVibe targets tissues surrounding the injection site, so it might produce better pain relief.

More recently the DentalVibe has been proposed to reduce pain during local anesthetic administration. The device is handheld and delivers vibration to the tissues around the injection site. This device can replace the dental mirror or operator's finger to acts as a check and/or lip retractor. The DentalVibe allows for no changes in the traditional local anesthetic injection technique, patient position and time involved. In the study by Ching, the use of the DentalVibe injection system significantly reduced pain associated with infiltration injections of local anesthesia in adolescents.¹⁵ Studies of its use in children have had mixed results.¹⁶⁻¹⁷ The study by Raslan & Masri did not show significant reduction in pain with use of the DentalVibe. This study was conducted on subjects in a similar age group but only subjects with positive or absolute positive on the Fankl behavior rating scale were included. This raises the question of the influence of the DentalVibe on subjects with various levels of cooperation.¹⁸

This study will be a systematic replication of the study by Ching. The population will be younger and subjects will not be excluded for poor behavior. The purpose of this study is to compare self-reported pain scale measurements from an experimental group (local anesthesia injection with DentalVibe) and a control group (traditional local anesthesia injection with DentalVibe system turned off) in children ages 5-11.

Subjects

The justification for the inclusion of children in this research is that typically children experience discomfort during local anesthetic administration during dental appointments. 30 subjects between ages 5-11 should be an adequate number of subjects to complete the research. A power analysis will be performed to verify the total number of subjects needed to complete the research in order to achieve the scientific objectives of the study.

Inclusion Criteria

The specific inclusion criteria are children between the ages of 5-11 who require dental treatment that requires bilateral local anesthesia on the maxilla or mandible. Subject must understand and speak English.

Exclusion Criteria

The specific exclusion criteria are that no children with the presence of medically or developmentally compromising conditions (autism, cerebral palsy, moderate/severe asthma); history of chronic disease (seizure disorder, cardiac disorder, hematological disease, endocrine disorder, liver disease, renal disease) and currently taking medication which contraindicated the use of local anesthesia. Non-english speakers will also be excluded. Subjects who require oral sedation or general anesthesia for treatment due to behavior or medical history will be excluded.

Methods

This study will be a systematic replication of the Ching study. The differences will be:

Age range of the subjects

Subjects will not exclude subjects with negative Frankl behavior ratings

All subjects will receive nitrous during both restorative appointment due to the age of the subjects.

Administration of nitrous oxide is commonly practiced in pediatric dentistry with patients of this age group. From McDonald & Avery (2016) eighty-five percent pediatric dentist use inhalation of nitrous

oxide and oxygen. It is used to reduce anxiety, produce analgesia, and enhance effective communication between a patient and health care provider.

Up to 50 children between the ages of 5-11 years will participate in this randomized, controlled, split-mouth study. There will be no gender restrictions used in this study. Participants will be recruited from a continuous sample of patient seen at the UNMC pediatric dental clinic and will be selected based on their need for dental treatment. Each child will have 2 separate dental appointments. Written consent will be obtained from parent or guardian prior to first restorative appointment. Verbal consent will be obtained prior to second restorative appointment. Dr. Marshall will be the provider for every patient. The same dental assistant will be used for each appointment. All treatment will be completed in the same private quiet room. Both Dr. Marshall and the dental assistant will wear the same color scrubs and black lab jackets during all appointments. One appointment patient will receive local anesthetic dental injection with the DentalVibe turned on and at one appointment the child will receive local anesthetic dental injection with the DentalVibe off. Used strictly as a check/lip retractor. The child will be randomly assigned via a random number generator to either the DentalVibe on or off during the initial appointment. During the DentalVibe turned on appointment, the DentalVibe will be introduced to each child to make him/her familiar with the vibration sensation. All patients will receive 5 mins of O₂, then N₂O will be titrated up to 50%N₂O/50%O₂.

When appointment is complete the child will receive 5 mins of 100% O₂. At both restorative appointment a cotton tip applicator with 20% Benzocaine topical anesthetic gel (Patterson) will be administered for 1 min. 2% Lidocaine HCl with 1:100,000 epinephrine (Patterson Dental) will then be deposited using a medium-length (0.4mm) with 27-gauge short needles. Local anesthetic injections will be referred to as sleepy juice. Buccal and lingual infiltration will perform on the maxilla. Mandibular blocks will be performed on the mandible. One cartridge of local anesthetic will be used at each appointment. After administration, patient will be shown the Wong Baker FACES pain rating scale and asked to rate the amount of discomfort experienced during the injection by pointing to the face or number.

The following manuscript will be used:

Each face represents a person who has no hurt, or some hurt, or a lot of hurt.

Face 0 doesn't hurt at all.

Face 2 hurts just a little bit.

Face 4 hurts a little bit more.

Face 6 hurts even more.

Face 8 hurts a whole lot.

Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain. Touch the face of the hurt you felt when I gave you the sleepy juice.

After child has rated pain Dr. Marshall will continue with restorative treatment. The same process will be followed at the second appointment. Appointments will be scheduled 3-4 weeks apart.

The statistical methods to analyze the data will likely be a combination of measures of central tendency, descriptive stats, t-tests and correlations using SPSS version 2.2.

Risk

Potential risks are minimal. There is considered to be no more risk to a child beyond what is normally associated with local anesthetic injections. All potential participants will still require dental treatment requiring bilateral local anesthetic administration in the dental clinic. The only change in procedure for

consenting individuals will use the DentalVibe injections system to aid in local anesthetic administration. The DentalVibe system acts as a cheek and/or lip retractor which is often performed with the dental mirror or operator's fingers. Dr. Marshall will monitor the subject's behavior by observation. This will help ensure the safety of the subjects.

Monitoring/Auditing/Analysis

Dr. Houser will conduct procedural checks in which the dentist (PI) implementing the procedures will be monitored to ensure appropriate consent is obtained and treatment protocol is being followed. The procedural fidelity checks will occur weekly.

Dr. Jennifer Marshall will perform ongoing data and safety analysis. She will administer the local anesthetic with the DentalVibe injections system and present the Wong-Baker FACES pain rating scale to the children after local administration.

Data analysis will occur every time a child is administered anesthetic. Data analysis will occur when the child is asked to evaluate his/her own pain rating.

Benefits

The potential benefits to the subject that may reasonably be expected from participation in the research is that less pain may be felt during local anesthesia injection. Potential benefits to society include the possibility of identification of an effective device to reduce pain during local anesthetic injections in children. This could lead to better behavior and more positive experiences in the dental clinic.

Recruitment

All subjects will be new or existing patients of the UNMC pediatric dental clinic. Research staff will have ethical access to potential subjects because Dr. Marshall has a clinical relationship with the potential subjects. Participants will be recruited from a continuous sample of patients who are scheduled for new patient or recall appointments at the UNMC Pediatric Dental Clinic. The children's parent or guardian will be informed of the research. If parent/guardian chooses to have their child participate, the research will be further explained. A treatment appointment will then be made with Dr. Marshall. If the parent/guardian chooses not to have their child participate, a treatment appointment will still be scheduled with Dr. Marshall or one of the other providers.

Informed Consent

The location where informed consent will be obtained in the consultation room located in the UNMC pediatric dental clinic. The environment will be conducive to discussion. The consultation room is a private and quiet room located behind closed doors. Dr. Marshall will be the only person involved in the process of consenting the parent or guardian about their child's participation in this study. Her responsibility will be to properly inform the parent or guardian about the research. Approximately 10-15 minutes will be allotted to the process of consent. The process of consent for parents or guardians who are likely to be more vulnerable to coercion or undue influence may include but are not limited to appointment of a subject advocate, involvement of the subject's family or friends, counselors or other confidants, reading the consent to the parents or guardians, and use of teaching aids. Dr. Marshall will question the parents or guardian concerning his/her understanding of all the elements of informed consent. At the second treatment appointment Dr. Marshall will get verbal consent for the child to continue to participate in the study before starting the appointment. During the appointment when the DentalVibe injection system is turned on, the DentalVibe will be introduced to each child to make

him/her familiar with the vibration sensation prior to use during local anesthetic injections. Tell-show-do will be used as a behavior guidance technique during all dental appointments.

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