National and Kapodistrian University of Athens

School of Health Sciences — Department of Dentistry

Study Protocol

A Randomized Controlled Trial of the Acceptance of Two Computer-Controlled Anaesthetic Delivery Systems in Paediatric Patients

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A randomized controlled trial of the acceptance of two computer-controlled anaesthetic delivery systems in paediatric patients.

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Αναπληρώτρια Καθηγήτρια και Διευθύντρια Εργαστηρίου Παιδοδοντιατρικής, Σχολή Επιστημών Υγείας, Τμήμα Οδοντιατρικής ΕΚΠΑ

Introduction

Treating children with minimal discomfort and pain has always been a very important goal in the practice of paediatric dentistry. Pain causes dental anxiety in children which will result in uncooperative behaviors that will reduce the probability of tolerating treatment and will increase treatment duration. It may also cause avoidance behaviors, that might interfere with child's future dental treatment. Local anaesthesia produces a localized temporary loss of sensation, infused by a topically applied or injected agent, without depressing the level of consciousness. Injection of local anaesthetic agents is one of the most important stimuli causing fear and anxiety in children requiring dental treatments. New methods of computerized controlled anaesthetic delivery systems such us the Wand STA ^{R} (Milestone Scientific, USA) and the SleeperOne^{R} (Dentalhitec, France) may reduce the pain during dental anaesthesia, and chance the appearance of the conventional syringe which has been combined in the patients' mind with pain and fear. (P. Ashley et al 2021, Andrea Prol Castelo et al 2023)

SleeperOne achieves intraosseous anaesthesia by direct placement of the anaesthetic solution in the cancellous bone adjacent to the tooth scheduled for dental treatment, leaving the surrounding soft tissues unaffected. With a 3-programmed injection adjustable speed option, that the device is providing, allows the operator to perforate and inject the anaesthetic solution without pain and trauma depending on the type of anaesthesia performed. The system ensures a regular injection independent of the density of the infiltrated tissue, without the operator having to exert any muscular effort and t is light and easy to use. SleeperOne has several advantages such as the reduced volume of anaesthetic used, the decreased anaesthetic duration and the decreased discomfort sensation, allowing the clinician to work in multiple quadrants. Sleeper One is mostly used in young children, up to the age of 9, since the bone is easier to be perforated only by the precure of the handle without the need of any other. (Violaine Smaïl-Faugeron et al 2019, F. S. Ludovichetti et al 2022)

Wand consists of a computer base unit and a foot pedal, which controls the injection speed of 0.005 mL/s with low pressure application, while increased pressure activates a faster injection of 0.03 mL/s (1 cartridge per minute). The pen-like design of the hand piece gives the operator greater precision and allows for faster onset and higher anaesthetic success. Computer control of the delivery instrument reduces injection pain and enhances patient comfort. A latest version, the WAND STA (Single Tooth Anaesthesia), provides visual and audible feedback while continuously monitoring the pressure of the solution throughout the injection. Automatically controls, regulates flow rates and pressure during the injection and delivers the anesthetic solution at a precise and consistent rate below the patient's pain threshold. Consistent flow maximizes injection predictability. (Vincenzo Campanella et al 2018, N. Carugo et al 2020)

Although WAND STA and SleeperOne are both computerized controlled anaesthesia systems they work in a different way. The SleeperOne has an age restriction because it's an intraosseous anaesthesia in comparison to WAND STA which is not an

intraosseous anaesthesia and any type of intaligamental or infiltration anaesthesia can be performed. There is also a great difference in the appearance of those two computerized controlled anaesthetic delivery systems. Even though both have a foot petal and a cable connecting the hand piece with the devise, WAND STA has a smaller hand piece which makes it easier to use.
There is a high number of reports in the literature about the Wand system since it is the oldest computer controlled anaesthetic delivery system in comparison with the Sleeper One which is a newer. When these systems are compared with conventional anaesthesia, they show greater acceptance from young patients, but no significant difference in pain during anaesthesia (Andrea Prol Castelo et al 2023, Mohammad I Al-Obaida et al 2019). According to Garret-Bernardin et al (2017), most of the patients found the injection with the traditional syringe to be more painful than the injection with the Wand. In the study of Versloot et al (2005), no significant differences were found in the pain-related behaviors for the Wand and the traditional injection, although the pain-related behaviors tended to occur less often before an injection using the Wand. Up to now, there is no literature that compares the two computerized systems.

Aim

The aim of this study is to evaluate the acceptance of two computerized controlled anaesthetic delivery systems, the WAND STA and the SleeperOne, used in children.

Materials and Methods

Study Design:
This is a randomized, single blind, controlled, split-mouth clinical trial comparing the two systems. Half of the patients will undergo Wand STA during the first visit and SleeperOne during the second, while the other half will undergo SleeperOne first and Wand STA second. The study will be conducted in the Paediatric Dentistry Postgraduate Clinic School of Dentistry National and Kapodistrian University of Athens. The legal guardians of all of the patients will complete and sign an informed consent form for study participation. Patients will be blinded not knowing which anaesthetic system is used.

Registration in RCT registry: The study will be registered in the clinicaltrials.gov.

Trial Design

Randomized single blinded controlled clinical trial Each patient will be served as their own control group, so a split-mouth design will be adopted.

Participants

All the patients and the guardians will be informed about the objectives of the study and will sign an informed consent form. Patients will be randomly selected from the Postgraduate Peadiatric clinic at the National and Kapodistrian University of Athens, Department of Dentistry that fit the inclusion criteria.

Inclusion criteria:

- aged 4-9 years old
- non-contributary medical history
- at least one tooth that needs the same treatment in each side of the same jaw
- teeth that require the same restorative treatment and/or pulp treatment, or extraction, should have a normal periodontium and no periapical pathology (confirmed with periapical radiographs)

Exclusion criteria

- Patients older than 9 years or younger that 4 years old
- history of psychiatric/developmental illness or allergies
- patients using any type of analgesic medication in the preceding 12 h
- patients with a history of unpleasant dental treatment experiences will be excluded

Arms/Groups and Interventions

Sample:

The sample size was calculated using the G*Power, with the power calculated at 80.1%, effect size=0.3 and a=0.05 considering The Visual Analogue Scale as the primary outcome. A sample size of 72 patients was estimated. This will be carried out by an operator who is not involved in the process. The randomization of the sample will be based on the age of the patients. Single sequence of random assignments, known as simple randomization, computer generated numbers will be used to allocate the first anesthesia method to be used in each patient.

Procedures

Pre-anaesthesia: Before using the computerized controlled anaesthetic delivery system, a topical anaesthetic gel will be applied using a cotton pellet to the dry mucosa of the injection site. The topical anaesthetic gel active ingredient is 20% Benzocaine is Gluten free and contains Xylitol and Vitamin E (Iolite topical anesthetic gel, Dharma Research, Inc., USA). Basic behavioral management techniques such us tell show do will be applied to all children based on their age and development stage. For both of the anaesthetic systems the anaesthetic solution of choice will be articaine 1:200,000 (Septanest, Septodont, France).

During anaesthesia: the vital sings will be monitoring with an oximeter (see below) and the face, legs, activity, cry, consolability (FLACC) scale will be used to record behavior.

Post-anaesthsia: after injection the patients will be asked to evaluate their pain or discomfort with the help of the Visual Analogue Scale and the Wong-Baker visual scale. All procedures will be done by a single operator and all assessments by a single examiner, blinded for the type of anesthesia system.

Outcome Measures

Acceptance of the anaesthesia system will be evaluated using objective and subjective methods. It will be measured the heart rate with an oximeter and the anxiety and the behavior of the patients will the help of scales.

A. Subjective:

1. The Visual Analogue Scale will be used to evaluate pain, discomfort, and anaesthetic efficacy right after injection. Prior to starting the anaesthetic procedure, the researcher will explain the visual analogue scale (VAS) to the patient, to prevent confusions. Immediately after performing the anaesthesia, the VAS will be presented to the patient, who will be asked about the sensation of pain experienced during anesthesia. The patient's assessment corresponding number will be noted in a data collection form.
2. The FLACC scale will be used to record behavior during the application of the anaesthesia. The FLACC pain scale is a system that assess pain levels in children who have limited or no expressive communication. The assessment will be done by the operator and the corresponding number of the scale, will be noted in a data collection form.
3. Discomfort will be assessed right after the anesthesia by asking the child to point at the picture from the Wong-Baker visual scale that best corresponds to the pain sensation. This self-assessment tool will be explained to the patient, to be able to choose the face that best illustrates the physical pain they are experiencing. The patient's assessment corresponding number will be noted in a data collection form.

B. Objective:

Pulse rate, blood pressure and oxygen saturation rate fluctuations will recorded throughout the anaesthesia procedure as objective indicators of the efficacy of the methods used before, during and after both types of computerized controlled anaesthesia.

Outcome variables

1. The Visual Analogue Scale is divided into six levels, organized as follows: no pain (0–1), mild pain (1.1–3), moderate pain (3.1–5), severe pain (5.1–7), very severe pain (7.1–9), and unbearable pain (9.1–10).
2. The FLACC scale will be evaluated with the help of a diagram that shows the categories for scoring. Zero, one or two points are given to each of five categories: face, legs, activity, cry and consdability. Each category is scored on the 0-2 scale, which results in a total score of 0-10. (0 is relaxed and comfortable, 1-3 is mild discomfort, 4-6 moderate pain, 7-10 severe discomfort of pain or both).
3. The vital sings will be measured with a digital pulse oximeter.
4. The Wong–Baker Faces Pain Rating Scale is a pain scale that shows a series of faces ranging from a happy face at 0, or "no hurt", to a crying face at 10, which represents "hurts like the worst pain imaginable". Based on the faces and written descriptions, the patient chooses the face that best describes their level of pain. There are 6 faces in the Wong-Baker Pain Scale. The first face represents a pain score of 0, and indicates "no hurt". The second face represents a pain score of 2, and indicates "hurts a little bit". The third face represents a pain score of 4, and

indicates "hurts a little more". The fourth face represents a pain score of 6, and indicates "hurts even more". The fifth face represents a pain score of 8, and indicates "hurts a whole lot"; the sixth face represents a pain score of 10, and indicates "hurts worst".

Sponsor/Collaborators
This study will be partially sponsored by Estetika (Wand STA).

Statistical analysis
The sample size used was calculated for 80.1% power, using software G*Power. Statistical analyses will be done using t-test for normally distributed continuous variables and Mann Whitney U test for not normally distributed continuous variables.

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