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Dental anaesthesia for children – effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial[☆]

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Abstract

Local anaesthesia in dentistry is usually given by conventional injection through a syringe. In this randomised, single-blind, split-mouth clinical study we evaluated the perception of pain and changes in heart rate in children being given dental local anaesthesia using a computer-controlled device compared with that given using a traditional syringe. Participants were in good general health with no contraindications to local anaesthetics. One half of each maxilla was anaesthetised using each technique, the order having been randomly selected according to a computer-generated sequence. The hypothesis was that the controlled anaesthetic flow rate results in virtually imperceptible injections. The outcomes were the perception of pain and the heart rate. Seventy-six children aged from 5–12 years old participated in this study. The mean (SD) pain score of the conventional injection was 5.51 (2.46) and the mean (SD) heart rate was 2.72 (6.76), which were significantly higher than those of the computerised delivery system, which were 4.74 (2.8) and 0.34 (7.3) ($p=0.04$). More patients anaesthetised with the traditional syringe technique required a second injection ($n=21$). These results suggest that dental anaesthesia given to children with a computer-controlled delivery system reduced pain better than that given with a conventional syringe.

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Keywords: Child; Heart Rate; Dental Anesthesia; Anesthesiology; Pain; Tooth Extraction

Introduction

The number of children who attend the dentist prophylactically has decreased as a consequence of parental carelessness, poor economic conditions, or both, and children now attend

the dentist with conditions such as pulpitis or a dental abscess, which make the sessions more stressful. Local anaesthesia and control of pain and stress are among the most challenging elements for such children, as fear of injections is common.^{1–4} Pain arises from the mechanical trauma of insertion of a needle into the site of an injection as the tissues suddenly distend,^{5–7} but local infiltration by conventional syringe injection is still the most common way of giving a dental anaesthetic.

A precision-metered dental injection system called Wand[®] (Milestone Scientific) has now become available (Fig. 1), which is a computer-controlled local anaesthetic delivery system that provides a precise flow-rate of injection regardless of the resistance of the tissues. The flow of anaesthetic is

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Fig. 1. The computer-controlled local anaesthetic delivery system.

computer-controlled, and initiated by exerting pressure on a foot pedal.^{5,7} Continuous positive pressure yields a constant anaesthetic drip that precedes the needle during its insertion. All techniques of local intraoral anaesthesia are possible with the Wand[®], and while there is considerable evidence of the benefits of using computer-controlled delivery systems in adults, only moderate evidence exists regarding its use in children.^{8–11}

Our hypothesis was that, as with adults, a controlled flow rate would result in a virtually pain-free injection, so the aim of this single-blind, split-mouth study was to compare the traditional syringe technique with the computer-controlled Wand[®] anaesthetic system to evaluate perception of pain (assessed with Numerical Visual Rating Scale (NVRS)),¹² and heart rate, in children who required at least two teeth to be extracted from opposite sides of the maxilla.

Patients and Methods

We designed a parallel, single-centre, single-blind, split mouth, active control study that was stratified according to age (5–12 years, with balanced randomisation) and was done in the Paediatric Dentistry Unit of the Catholic University

of the Sacred Heart, Rome, Italy, from March 2016 – March 2017. The participants were in good general health and had no contraindications to local anaesthesia. Exclusion criteria were: any patients with a medical condition that could alter the perception of pain, or any patient who had taken an antibiotic or anti-inflammatory drug during the month immediately preceding the procedures.

The study was done in accordance with the declaration of Helsinki and it was approved by the local Ethics Committee. A detailed informed written consent form was signed by each patient's parent or guardian before every procedure. Patients were informed that both a computer-controlled, and traditional syringe, techniques would be used for their dental procedures. No patient had previously experienced the Wand[®] injection technique.

Measurements

The NVRS was shown to the patients and explained before the injections. It is a 10-point pain scale (in which 0 means no pain and 10 means the worst pain possible) based on the Visual Rating Scale and Numerical Rating Scale that were used for adults in a previous report.¹² It was easier for the children to understand and for this reason was preferred to other scales. Heart rate was assessed using a pulse oximeter before and after the injection.

Procedures

The sample size was calculated from a power analysis based on the results of previous studies^{12,13} to detect at least a one grade difference on the NVRS with an SD of 0.85, and a difference in heart rate of at least 4 bpm with an SD of 3 bpm between groups. The α and β values were set as 0.05 and 0.90, respectively, and the sample size was calculated to be 30 subjects for each group. One half of the maxilla of each patient was anaesthetised with the Wand[®] system, and the other half by a conventional syringe, in two different sessions to avoid lasting effects. In both sessions patients were blindfolded with a sleeping mask so that they could not see which anaesthetic delivery system was being used. The anaesthetic was given by the same trained operator (RP), and the order in which the techniques were used had been randomly selected.

Simple randomisation was used taken from a random computer-generated sequence. The number generated indicated the technique that was to be used at the first session: odd numbers for the traditional technique and even numbers for the computer-controlled technique. Generation of the random numbers, enrolment of participants, and their assignment to the intervention was done by an author not involved in the clinical procedures (AC).

In both halves the intraligamentary technique, and the same amount of anaesthetic (one cartridge), were used. In both techniques pressure was applied using the handle of the dental mirror as distraction for palatal injections, before

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