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ORIGINAL SCIENTIFIC ARTICLE

Comparison of two computerised anaesthesia delivery systems: pain and pain-related behaviour in children during a dental injection

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Abstract
Aim The purpose of this study was to investigate whether there is a difference in pain and distress response of the child when using two different computer-controlled local analgesic delivery systems, the Sleeper One® and the WAND®, and whether this was influenced by the anxiety level of the child.
Methods This randomised controlled trial was conducted among 112 children (56 girls) aged 4–6 years (mean age 66 months, SD 9 months). All children needing at least one dental visit using local analgesia were randomly assigned to either the Sleeper One® or the WAND®.
Results During the injection phase, children expressed the same amount of disruptive behaviour using the Sleeper One® or the WAND® (Mann–Whitney U test, $p > 0.05$). The average injection time of the Sleeper One® (mean 2.49 min, SD 0.56) was significantly shorter than that of the WAND® (mean 3.20 min, SD 0.61; Mann–Whitney U test, $p < 0.001$).
Conclusion No significant difference was found in pain and distress reaction of the child between the WAND® and the Sleeper One®. The average delivery time of the Sleeper One® was shorter.

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Keywords Dental anxiety · Local analgesia · Computer-controlled local anaesthetic delivery system (CCLAD) · Sleeper One® · The WAND®

Introduction

Dental visits are often associated with pain. Even local analgesia, though meant to reduce pain, can be painful or can at least create discomfort, thereby opening the pathway of anticipation anxiety caused by conditioning mechanisms as described by Davey (1989). Despite the use of topical analgesia, the delivery of local analgesia solutions and the injection in traditional infiltration procedures can be uncomfortable (Locker et al. 1999; Roghani et al. 1999; Meechan 2002; ten Berge et al. 2002a, b).

Pain is described by the International Association for the Study of Pain (IASP 1997) as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.' Pain experienced by the patient during injection can be twofold. First, tissue damage occurs during the actual perforation of the mucosa by the needle, and second, pressure is built-up by the infiltration of the injection fluid, which causes pain (Baart and Brand 2008). As a consequence, there is a constant search for ways to avoid the invasive and often painful nature of the injection, particularly in paediatric dentistry.

Two new systems to deliver local analgesic injection, which were developed to address the shortcomings of the traditional infiltration procedures, are the computer-controlled local analgesic delivery systems (CCLAD), the Sleeper One® and the WAND® (Milestone scientific 1998). Using a CCLAD, the amount of analgesic fluid injected over a given period of time is regulated, thus the pressure

remains low which may reduce the pain. Furthermore, in case of very young children using a CCLAD, the local analgesic fluid can be directly injected in the cancellous bone adjacent to the tooth to be anaesthetised (Versloot et al. 2004). This in contrast to the traditional infiltration methods (buccal infiltration, mandibular nerve block, etc.) in which the fluid is injected in soft tissue, resulting in mucosal numbing and self-biting of soft tissue.

A study by Versloot and co-workers (2005) indicated that low anxiety children receiving local analgesia with the WAND® displayed less muscle tension, less verbal protest and less movement than children receiving local analgesia with the traditional syringe during the first 15s of the injection. However, highly anxious children did not benefit, maybe because the prolonged injection time creates additional discomfort for the child. Further research is needed to aim at the reduction of this time-related discomfort during local analgesia. The Sleeper One® is a new type CCLAD with a permanent analysis of resistance system that regulates the injection according to the density of the tissue. This leads to a faster average delivery time than the WAND® and a higher comfort is expected as a result. In addition, the Sleeper One® has a double-bevelled needle, which assumedly makes it easier to penetrate the bone in comparison with the needle of the WAND® (see Fig. 1).

Therefore, the aim of this study was to investigate whether there was a difference in pain and distress response of children when using the WAND® compared to the Sleeper One®, and whether this is influenced by the anxiety level of the child. Because of the improvements of the Sleeper One®, it is hypothesised that this CCLAD is superior in reducing the pain and pain-related behaviour in children in comparison to the WAND®.

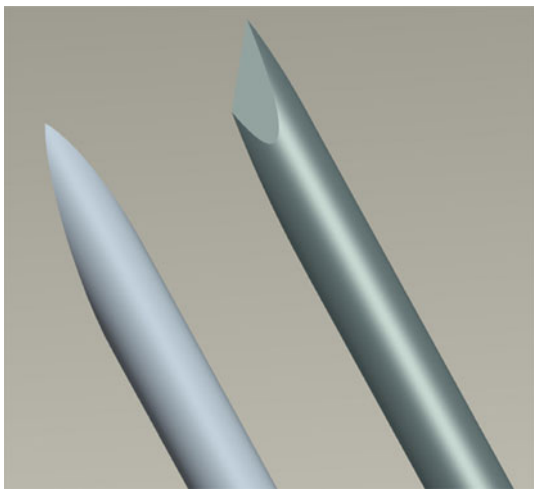

Fig. 1 *Left*: single-bevelled needle, WAND®. *Right*: double-bevelled needle, Sleeper One®

Materials and methods

Subjects

This study was conducted among 118 children (59 girls) aged 4–6 years (mean age 66 months, SD 9 months). Children were selected as a convenience sample of referred patients treated in three paediatric dental practices by four dentists in total. The reasons for referral were heterogeneous. Most children were referred because of behavioural management problems and extensive caries. Other reasons included young age, (dental) developmental disorders and their family dentist feeling uncomfortable when treating children.

To be included in the study, the child had to be scheduled for a routine restorative dental treatment session requiring local analgesia. Children who followed special education were excluded. Data were collected during two periods of 4 months. Parents were not present during the treatment sessions as a consequence of the practices' treatment protocols. The study was approved by the medical ethical committee of the VU medical centre Amsterdam, the Netherlands (ref NL30999.029.10). Written parental consent was obtained before the treatment.

Procedure

After consent, each child was assigned to the use of either the WAND® or Sleeper One® based on a randomisation list generated by SPSS (SPSS, 17,0: Chicago, IL, USA). After placing topical analgesia on the injection site according to the manufacturer's instruction, local analgesia was administered using either the WAND® or the Sleeper One®. A fixed amount (0.6 ml) of analgesic (articaine) was given intra-osseously, both in the maxilla and in the mandible. For this, the needle was inserted in the cortical bone below the interdental papilla at a 45° angle and with gentle clockwise and counter-clockwise movements pushed into the bone. After the patient had received the analgesia and the child was calm (i.e. after a sip of water), the dental assistant presented the modified Wong-Baker Faces Pain Rating Scale (Fig. 2). Introducing the scale was performed using a fixed protocol to avoid variation during the introduction.

The treatment session was video-taped from the moment the child entered the treatment room until the end of the local analgesia delivery. These video tapes were rated by two observers, not taking part in the treatment of the children. The observers were aware of the type of CCLAD used. Both observers were extensively trained using video recordings of other treatments not included in the study until an almost perfect agreement was reached (Cohen's Kappa 0.94). The tapes during this calibration session were scored independently and compared. In case of

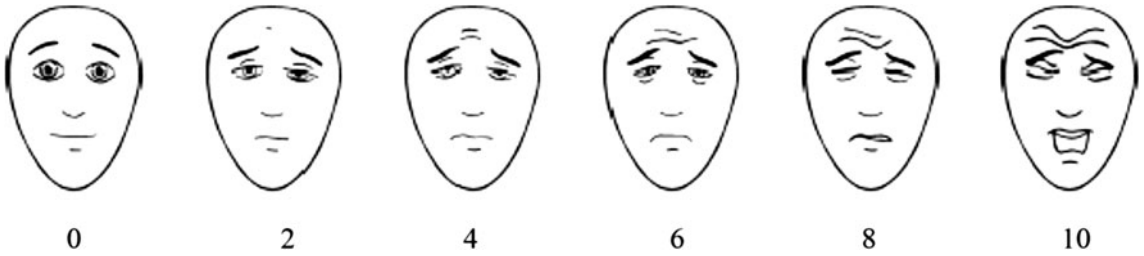

Fig. 2 Faces Pain Scale-Revised (FPS-R) 0–10

disagreement, the tape was discussed until mutual agreement was reached.

Measurements

Pain-related behaviour

The video tapes were recorded on five different pain-related behaviours as being present or absent during each 15 s interval of the injection phase: (1) body movement: movement of more than 15 cm of an extremity or turning of the body, (2) muscle tension: clear tension in the hands (white knuckles) or tension of the body or face, (3) crying or screaming, including groaning, (4) verbal protest and (5) bodily resistance, when it was needed to hold the child (Versloot et al. 2005). The frequency of each behaviour during all 15 s intervals was divided by the total number of intervals scored.

Distress

Because a child's response to dental stimuli and its behaviour in dentistry are often a mixture of anxiety and pain (Versloot et al. 2008) and because these two concepts are difficult to separate, it was decided to assess distress behaviour as well. Distress behaviour was measured using Venham's (modified) clinical rating of anxiety and cooperative behaviour. The scale consists of 6 points (0 relaxed, 1 uneasy, 2 tense, 3 reluctant, 4 resistance and 5 out of contact or untreatable) (Venham et al. 1980). The highest Venham score (peak Venham) of each treatment session was used for analysis (Veerkamp et al. 1995).

Self-reported pain

The Faces Pain Scale-Revised (FPS-R) was used as a self-report measure to assess the intensity of the child's pain during local analgesia (Hicks et al. 2001). The FPS-R was shown to be appropriate to assess the intensity of children's acute pain from age 4 or 5 years onward. The scale consists of six faces that represent the child during the injection, expressing different levels of pain/distress from 1 (no pain) to 6 (worst pain possible) (Chapman and Kirby-Turner 2002) (see Fig. 2). Each child was raised the following standard question: "These faces show how much something can hurt. This face *(point to most-left face)* shows no hurt. The faces show more and more hurt *(point to each from left to right)* up to this one *(point to most-right face)*—it shows very much pain. Point to the face that shows how much making the tooth fall asleep hurts (the injection) (just now)."

Dental anxiety

The parent was asked to complete the parent version of the Dental Subscale of the Children's Fear Survey Schedule (CFSS-DS) on behalf of their child to assess the level of dental anxiety of the patient. The questionnaire consists of 15 items with a 5-point scale per item, from 1 (not afraid at all) to 5 (very afraid). The total score varies from 15 to 75 points. Previous research has indicated that scores under 32 are non-clinical, scores from 32 to 38 are 'borderline range' and scores of 39 and higher are registered as 'clinical range' of dental fear (ten Berge et al. 2002a, b). In the present study, a distinction was made between children scoring lower than 32 (low anxiety) and 32 or higher (high anxiety) (ten Berge et al. 2002a).

Statistical analysis

Differences in age and CFSS-DS between the Sleeper One® and the WAND® were assessed by independent *t*-tests. Differences in gender and dental experience with previous analgesia injections between the Sleeper One® and the WAND® were assessed by Chi-square tests. Differences in pain-related behaviour, distress, FPS-R and dental anxiety between the two groups were analysed with the Mann–Whitney *U* test. For all tests, the chosen level of significance was $p < 0.01$. A number of 100 children in total were enough to detect medium effect sizes with a power of 80 %. Calculations were performed using SPSS 18.0 (SPSS, 18.0: Chicago, IL, USA).

Results

Five children had to be excluded because of technical difficulties with the filming equipment or with the

Table 1 Randomisation check

	Total group ($n = 112$)				
	Sleeper One® ($n = 52$)		WAND® ($n = 60$)		
	Mean	SD	Mean	SD	p
Injection time	2.49	0.56	3.20	0.61	<0.001**
Age (months)	65.3	9.1	66.5	9.4	0.473
CFSS-DS	31.0	10.1	31.4	9.3	0.664
			%	%	p
Gender (% boys)			57	43	0.131
Previous dental injection (% yes)			39	47	0.535

** Significant difference Mann–Whitney U test $p < 0.01$

prescribed analgesia system, and one patient was excluded because he was found to attend special need education. The exclusion of these children resulted in 112 children in the analyses. When the density of the cortical bone was too high, intra-ligamentary injection was given, which occurred in six patients.

No difference was found regarding age, gender, dental anxiety level and experience with previous dental analgesic injections between participants in the Sleeper One® and the WAND® group (see Table 1). Furthermore, no differences were found between the four dentists on the variables mentioned above. The average injection time of the Sleeper One® (mean 2.49 min, SD 0.56) was significantly shorter than that of the WAND® (mean 3.20 min, SD 0.61; Mann–Whitney U test, $p < 0.001$) (Table 1).

In Table 2, the mean scores (and SD) for the proportion of pain-related behaviours, the peak Venham score and the FPS-R are shown for the total group and for low and high anxiety children separately. There appeared to be no difference between the Sleeper One® and the WAND® for all variables, neither for the total group nor for low and high anxiety children.

Discussion

This study was conducted among 112 children, which should be enough to measure clinically relevant differences in pain, pain-related behaviour and distress during treatment. However, there were neither differences in children's subjective pain ratings during local analgesia nor in their observed pain-related behaviour and distress response. Furthermore, this result pertained to both the total group of children and to low and high anxiety children separately. Thus, the type of computer-controlled local analgesic delivery system does not seem to influence the reaction of the child, neither of the low anxiety child nor of the high anxiety child.

For this study, two CCLAD's were selected that differ with respect to the average delivery time and in appearance of the needle. Indeed, the delivery time of the Sleeper One® was shorter than of the WAND®. It might be that in the long term, this will result in a reduced anticipation anxiety, but this was not assessed in the present study.

Despite the instruction given to the dentists at the start of the treatment to use 0.6 ml analgesia fluid, this instruction was not followed for every treatment. In particular in the Sleeper One® group, the dentists tended to give more, because the analgesia ran quicker. The WAND® used more time and tended to stop earlier. If the instructions were followed, the difference in average time would be larger and the discomfort in the WAND® group might increase (Versloot et al. 2005). The fact that in some children the prescribed amount of analgesic fluid was not given does not seem to have influenced the results.

Conclusions

There was no significant difference in reaction of the child using the Sleeper One® or the WAND®. The use of the Sleeper One® might be preferred over the WAND® since

Table 2 Proportion of pain-related behaviour, peak Venham score and FRP-S in relation to type of CCLAD used (WAND® vs. Sleeper One®)

	Total group ($n = 112$)				p	High anxiety ($n = 48$)				p	Low anxiety ($n = 64$)				p
	Sleeper One® ($n = 52$)		WAND® ($n = 60$)			Sleeper One® ($n = 21$)		WAND® ($n = 27$)			Sleeper One® ($n = 31$)		WAND® ($n = 33$)		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Muscle tension	0.41	0.39	0.42	0.38	0.765	0.62	0.40	0.47	0.40	0.230	0.27	0.31	0.35	0.34	0.267
Crying	0.17	0.31	0.25	0.34	0.220	0.35	0.36	0.32	0.39	0.696	0.06	0.19	0.17	0.28	0.041
Verbal protest	0.07	0.17	0.07	0.15	0.507	0.07	0.12	0.09	0.18	0.871	0.07	0.19	0.06	0.12	0.443
Body movement	0.03	0.06	0.09	0.18	0.165	0.04	0.06	0.14	0.23	0.198	0.02	0.06	0.04	0.12	0.574
Resistance	0.01	0.05	0.07	0.22	0.070	0.03	0.08	0.11	0.28	0.436	0.00	0.00	0.04	0.16	0.044
Peak Venham (0–5)	0.96	0.86	1.42	1.15	0.842	1.48	0.87	1.56	1.22	0.943	0.61	0.67	1.25	1.08	0.691
FPS-R (0–10)	3.42	4.16	4.10	3.97	0.265	5.43	4.61	4.52	4.17	0.234	2.06	3.25	3.53	3.70	0.220

the average local analgesia time of the Sleeper One® was significantly shorter.

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