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Is it the injection device or the anxiety experienced that causes pain during dental local anaesthesia?

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Aim. The aim of this study was to investigate the influence of anxiety and type of dental injection, a plastic syringe or an electronic computerized device, on the pain perceived by children.

Design. Two dental injectors, a computerized device (Wand®, Milestone Scientific, Livingston, NJ, USA) and a traditional plastic syringe, were compared. Forty-one children, aged 9–13 years, who had registered for treatment in Marmara University, Istanbul, Turkey, were included in the study. Both anxious and non-anxious children were included in the study group. The Children's Fear Survey Schedule–Dental Subscale, Facial Image Scale, Spielberger's State Anxiety Index for Children, and heart rates were used to determine the anxiety levels. Participants were assigned to interventions by using random allocation. The first appointment was designed as an introductive familiarization session and injections were administered in the second and third sessions, with one or the other injector. The visual analogue scale was used for pain measurement after injections.

Results. No significant differences in injection pain scores were observed between the Wand and traditional plastic injector. Higher levels of pre-injection anxiety were found to be related to more severe pain reports by the children.

Conclusions. Anxiety plays an important role in the pain reaction of children, and was found to be more determinative in pain perception than the injection devices preferred.

Introduction

Pain is a highly complex and multidimensional phenomenon that energizes the organism, regardless of real or apparent tissue damage, to take action in relieving or alleviating its presence[1]. It is important to acknowledge that the pain sensation is not necessarily dependent on tissue damage; it may also be generated by conditioned stimuli such as the sound of the drill or a gentle touch of the needle during local anaesthetic injections[2].

Today there is no excuse for not using local anaesthesia during dental treatment, since it offers pain-free treatment, children's comfort and cooperation, and it allows the dental practitioner to perform his or her task better. This may, however, appear contradictory as it seems that it is the local anaesthetic injection that produces pain and anxiety in patients[3]. Thus, there has been a continual effort to search for techniques to make injections less painful. Some of these techniques are behavioural, such as reframing and using distraction and suggestions[4,5]. Other techniques have used instrumental approaches such as the application of topical anaesthetic gel or patches prior to injection, or electronic computerized devices such as the Wand® (Milestone Scientific, Livingston, NJ, USA). Furthermore, techniques have been suggested to ease the discomfort of intraoral injections, which have required a prolonged injection time or warmed-up anaesthetic solution. Neither, however, have been able to cope totally with the pain connected with injections[3,5–9].

There is a strong relationship between a child's dental anxiety and successful dental treatment[10], and also between anxiety and pain[11]. Painful dental operations cause fear, whereas fear and anxiety increases the amount of perceived pain[11]. A search of the paediatric dental literature for techniques to

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make injections less painful has not produced any research that has comprehensively evaluated the relationship between injection pain and dental anxiety as a confounding factor. In a previous pilot study where low and high anxious children were examined, it was found that the dental injector preference was influenced by anxiety levels[12]. Anxious children's injector preferences were significantly different from those of non-anxious children's. In the comparison of two injection devices, Versloot *et al*. aimed to differentiate the reactions of highly anxious children with those displaying low anxiety and reported anxiety-based differences in pain-related behaviours[13].

The aim of this study was to investigate the influence of anxiety and type of dental injection, a plastic syringe or an electronic computerized device, on the pain perceived by children.

Materials and methods

Participants

Patients accepted in the study were chosen from the children who had been registered for treatment at the School of Dentistry, Marmara University, Istanbul, Turkey, between February and August 2005. The selection criteria were mainly aimed at forming a study group that consisted of both anxious or non-anxious children. Children's Fear Survey Schedule–Dental Subscale (CFSS-DS) anxiety scores (≥ 32 indicating anxious children, < 32 non-anxious) were evaluated for this purpose. Additional criteria were: (i) being 9–13 years old, (ii) being healthy without any systemic or psychological problems, and (iii) having at least two carious teeth, one on each side of the maxilla (16 or A and 26 or J, where A denotes the right maxillary second primary molar and J the left maxillary second primary molar tooth)[14].

Of the children examined, the first 22 anxious and the first 23 non-anxious children who fulfilled the selection criteria participated in the study. Four children had to be excluded because two failed to return for the second session of treatment and two because their heart rate readings were spoilt (heart rate readings were out of the hidden camera's view). Out of the 41 children left (19 boys and 22 girls), the study group consisted of 19 anxious and 22 non-anxious children according to CFSS-DS anxiety scores.

The study was approved by the Ethical Research Committee of Marmara University Medical Faculty and parental consent for all children was obtained.

Measurements

Dental anxiety

CFSS-DS is a revised form of the Children's Fear Survey Schedule and consists of 15 items that are rated on a Likert scale, ranging from 1 (not afraid) to 5 (very afraid). Thus, the total score on the CFSS-DS can range from 15 to 75 and represents trait anxiety of children, including dental situations. Previous research has defined scores between 32 and 38 as 'mild dental anxiety and fear' and scores of 39 and higher as 'high dental anxiety and fear.' The reliability of CFSS-DS is high and it has a moderate validity[15].

The Facial Image Scale (FIS) is a self-report measure for state anxiety, and has two rows of nine faces ranging from 'very happy' to 'very unhappy.' The children are asked to indicate which face represents their feelings most at that moment in time. The scores of state anxiety range between 0.04 (non-anxious/happy) and 0.97 (very anxious/unhappy). FIS has a moderate validity, but no cut-off points have been mentioned for FIS in the literature[16].

Spielberger's State Anxiety Inventory for Children (SSAI-C) consists of 20 items that ask how a person feels now, and reflects situational factors that may influence anxiety levels. Scores range from 20 to 60 and the higher the score, the greater the level of anxiety.

Heart rate, as a physiological indicator of anxiety response[17,18], was recorded by using a pulse oximeter. It was placed on the index finger of the left hand and pulse rate was recorded continuously during the treatment sessions. All heart rate values (prior to injections) were then read and calculated from the videotapes recorded by a hidden camera mounted on the ceiling.

Fig. 1. Injectors used in the study.

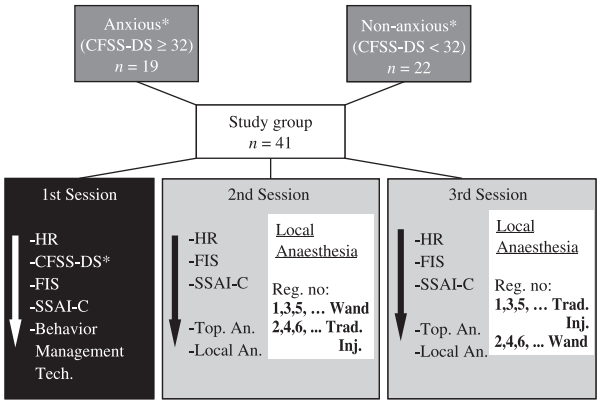

Fig. 2. Procedures followed in the study. HR, heart rate; CFSS-DS, Children's Fear Survey Schedule–Dental Subscale; FIS, Facial Image Scale; SSAI-C, Spielberger State Anxiety Inventory for Children; Reg; no., Registration number; Top. An., Topical Anaesthesia; Trad. Inj., Traditional injector.

Pain. The self-reported pain experience of the children was measured using the visual analogue scale (VAS). The scale resembled a coloured spectrum from white (no pain, 0) to red (severe pain, 10)[1].

Materials

Topical anaesthesia was applied (lidocaine, 10 mg/dose; Xylocaine spray, AstraZeneca, Södertälje, Sweden). Aticaine 4%, 1 : 100 000 epinephrine local anaesthetic solutions (Ultracaine DS Forte carpule and ampule, Hoechst Marion Roussel, Frankfurt, Germany), was used with both injections by using Set Inject traditional plastic injector (Tıbset Steril Tıbbi Aletler San. ve Tic. AS., Istanbul, Turkey) and the Wand® (Milestone Scientific, Livingston, NJ, USA) (Fig. 1). Needles measuring 30 gauge and 12 mm were used for both with either injection devices. Heart rate was measured using the by Nanox 2 pulse oximeter (Medlab medizinische Diagnosegeräte GmbH, Karlsruhe, Germany).

Procedure

Treatment was provided by the same experienced paediatric dentist in three sessions without the parents being present. All treatment was videotaped and the children were unaware that they were being recorded.

In the first session, preliminary anxiety levels and systemic and dental health history of the children were recorded, but no treatment was undertaken (Fig. 2). A combination of behavioural management techniques was used on the child to familiarize him or her with the dentist, the environment, and the proposed treatment. Preliminary anxiety levels of the children were determined by psychometric tests (CFSS-DS, FIS, SSAI-C) and physiological methods (heart rate) before any familiarization approach was undertaken while the children were sitting on the dental chair. Each child was randomly assigned to a study subgroup to receive either the Wand (odd number registration) or the traditional injector (even number registration) in the second session, with the other injection device administered in the third session. Injection devices were not demonstrated to children, but no special effort was made to hide them.

In the second and third sessions, before any treatment was undertaken, the children's preliminary anxiety levels were again determined by psychometric (FIS, SSAI-C) and physiological methods (heart rate). After 2 min of topical anaesthetic application by means of a cotton pellet, injections were performed either with the Wand or traditional injector and afterwards pain scores were measured using VAS.

All patients had maxillary infiltration injections with 1.5 mL anaesthetic solution. Tissue penetration was at the free gingival mucosa, below the targeted permanent first molar or

deciduous second molar. At the beginning of the injections, anaesthetic solution was injected very slowly with the plastic injector and the Wand was set in the slow rate mode. Gradually the injection rate was increased and the Wand was set to fast injection mode.

Statistical analysis

Statistical analysis was performed with the GraphPad Prisma version 3 program (GraphPad Software, San Diego, CA, USA). Cronbach alpha coefficients for the reliability of CFSS-DS and SSAI-C, sensitivity, specificity, positive predictive value, negative predictive value, accuracy, relative risk scores, receiver operating characteristic (ROC) curve, and cut-off score for FIS were calculated. Parameters were evaluated by unpaired *t*-test and Pearson χ^2 analysis. Significance was set at $P < 0.05$.

Results

The mean age for the study group was 10.78 ± 1.21 years. The mean age for the anxious children was 10.8 ± 1.2 and 10.8 ± 1.2 for the non-anxious ones ($P = 0.96$). CFSS-DS anxiety scores revealed a significant difference between the anxious (43.4 ± 7.5) and non-anxious (23.9 ± 3.8) children ($P = 0.0001$). Cronbach alpha coefficients for CFSS-DS and SSAI-C were calculated as 0.86 and 0.66, respectively.

No statistical differences were found in the distribution of boys and girls by the anxiety groups according to gender between anxious (12 girls, 7 boys) and non-anxious children (10 girls, 12 boys) ($\chi^2 = 1.28$, $P = 0.25$).

In the first session, the CFSS-DS was used to group the children as anxious or non-anxious, and also to determine a cut-off point for FIS. Sensitivity, specificity, positive predictive value, negative predictive value, accuracy, and relative risk scores for FIS were calculated and the cut-off score for non-anxious children was finally defined as ≤ 0.37, using the ROC curve. This cut-off value was used for grouping children as anxious or non-anxious depending on their state anxiety at the start of second and third sessions.

Results were evaluated in three categories: (i) pain and anxiety scores in *injector groups*, (ii) pain scores in *anxiety groups*, and (iii) anxiety scores in *pain groups*.

Pain and anxiety scores in injector groups

Mean VAS pain scores reported for the Wand and traditional injector in the second session were 0.4 ± 0.8 and 0.5 ± 0.9, respectively (Table 1a). For the third session, the scores were 0.5 ± 1,

Table 1. (a) Pre-injection anxiety scores and VAS pain scores related to injectors preferred in the second session.

2nd session Injectors	Anxiety and pain scores							
	n	FIS (0.04–0.97)	*n*	SSAI-C (20–60)	*n*	Heart rate	*n*	VAS (0–10)
Wand	22	0.2 ± 0.2	22	26 ± 6.4	22	92.5 ± 11.4	22	0.4 ± 0.8
Traditional	19	0.3 ± 0.2	19	27.5 ± 6.8	18	93.4 ± 13	19	0.5 ± 0.9
t		–0.55		–0.77		–0.23		–0.37
P		0.583		0.448		0.821		0.717

NS, unpaired *t*-test.

(b) Pre-injection anxiety scores and VAS pain scores related to injectors preferred in the third session.

3rd session Injectors	Anxiety and pain scores							
	n	FIS (0.04–0.97)	*n*	SSAI-C (20–60)	*n*	Heart rate	*n*	VAS (0–10)
Wand	20	0.2 ± 0.2	20	27.2 ± 6.9	20	93.5 ± 11.4	20	0.5 ± 1
Traditional	21	0.2 ± 0.2	21	23.1 ± 5.5	20	87.2 ± 12.9	21	0.4 ± 0.7
t		–0.29		2.14		1.63		0.48
P		0.773		0.039*		0.112		0.633

*$P < 0.05$, unpaired *t*-test. FIS, Facial Image Scale; SSAI-C, Spielberger's State Anxiety Index for Children; VAS, Visual analogue scale.

and 0.4 ± 0.7, respectively (Table 1b). No statistically significant difference of VAS pain score was noted between injectors for both sessions.

In the second session, mean delivery time with the Wand was 114.2 s and 116.8 s with the plastic injector ($P = 0.826$). In the third session the average time required for delivery was 132.2 s with the Wand and 97.3 s with the plastic injector ($P = 0.029$).

State anxiety scores before relevant injections are listed in Table 1. Number of patients (n) evaluated in 2nd and 3rd sessions showed variations due to some technical difficulties in heart rate readings and where the operator could not follow the study protocol. Higher anxiety scores were observed in the groups reporting higher VAS pain scores with the exception of FIS score in the third session. However, only one statistically significant measure, STAI-C in the third session, was noted.

Pain scores in anxiety groups

When children were grouped according to FIS anxiety score in the second and third sessions, anxious children (FIS > 0.37) were found to report higher pain scores than non-anxious children (FIS ≤ 0.37). However, statistically no significant difference of VAS pain score was noted between anxiety groups for both sessions (Table 2).

Table 2. Visual analogue scale (VAS) pain scores of the anxious and non-anxious children.

	2nd session		3rd session	
	n	**VAS**	***n***	**VAS**
Anxious	12	0.7 ± 0.9	7	0.7 ± 0.9
Non-anxious	29	0.4 ± 0.8	34	0.4 ± 0.8
t		0.96		0.77
P		0.343		0.446

NS, unpaired *t*-test.

Anxiety scores in pain groups

The children were grouped as the ones reporting pain or no pain, and their preliminary anxiety scores, assessed by different measures, are listed in Fig. 3. Children reporting pain were found to be more anxious than the ones reporting no pain, and significant differences in FIS and STAI-C anxiety scores were calculated in the second session. Mean heart rate values revealed no statistical difference between groups but again produced higher scores in the group reporting pain (Fig. 3a). Anxiety levels of the children reporting pain in the third session were again higher than the ones

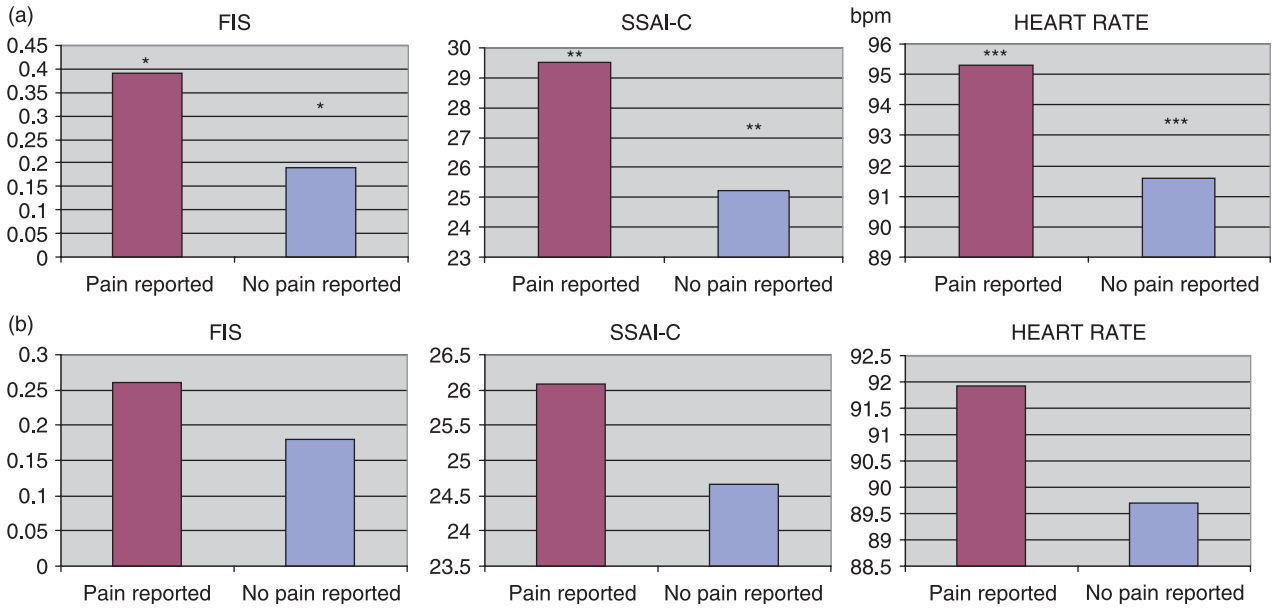

Fig. 3. (a) Second session: pre-injection anxiety scores and perceived pain. (b) Third session: pre-injection anxiety scores and perceived pain. **P* = 0.006 ***P* = 0.45 ****P* = 0.35 unpaired *t*-test; NS. unpaired *t*-test.

reporting no pain, but the differences were found to be nonsignificant (Fig. 3b).

Discussion

In the dental literature, there are a limited number of studies comparing the Wand with traditional dental injectors in children[3,6,9,12,19–23]. The injection site can also affect the level of pain perception[24], and this was taken into consideration when we compared our results with those of Asarch *et al*.[3], Gibson *et al*.[6], and San Martin-Lopez *et al*.[22]. Only the results of their work that was done utilizing maxillary buccal infiltration, as was done in this study, were used for comparative purposes.

For the VAS pain scores observed with the Wand/traditional dental injector, Asarch *et al*. and Gibson *et al*. reported painful injections with the Wand (4.4/3.4, $P > 0.05$, and 3.4/2.7, $P > 0.05$, respectively), whereas Lopez *et al*. performed less painful injections with the Wand (0.4/0.8, $P < 0.001$). In the present study, for the second session, injections with the Wand were less painful (0.4/0.5, $P > 0.05$), but were more painful (0.5/0.4, $P > 0.05$) in the third session.

To further understand the apparent contradictory results found above, the VAS pain scores of the anxiety groups were evaluated. In the anxious children, higher VAS pain scores were observed for both sessions. When the anxiety scores were further analysed, there was an interesting finding that showed that children with higher anxiety scores, using all the anxiety measures (except for FIS in session 3), were anticipating higher pain perception.

To better interpret these results, pain groups (children reporting pain and no pain) were further analysed and significant differences in preliminary anxiety levels were observed in the second session. In the third session however, the differences in preliminary anxiety levels were not statistically significant due to anxiety reduction from second to third session but anxiety levels were again higher in children reporting pain. The results demonstrate quite clearly that anxious children are more susceptible to pain perception than non-anxious children despite undergoing similar treatment in similar surroundings.

The relationships between anxiety/pain and anxiety/success of a dental appointment have been reported in the dental literature[10,11,25]. However, in clinical studies that compare the Wand with a traditional injector, the possible effect of preliminary anxiety on pain perception has not been given the important consideration it deserves. In the published pilot study of the present research[13], it was found that even the injector preferences of children were influenced by anxiety. Our pilot study findings were supported by Versloot *et al*.[12] who mentioned this relationship during dental injections and observed more disruptive behaviour in anxious children. In their recent study, Thompson *et al*.[26] suggest that those high in anxiety sensitivity may respond more negatively to specific types of pain.

The present study highlighted a greater pain response of anxious children to dental injections than non-anxious children and questions the reliability of pain studies comparing different injectors and techniques without considering preliminary anxiety levels.

Conclusions

Anxiety plays an important role in the pain perception of children, and was found to be a more determinative factor than the injection devices preferred. Further studies should however be undertaken to support and emphasize this finding. Furthermore, besides developing new injection devices, anxiety control through behavioural management techniques should be supported and encouraged for pain-free dental injections in children.

What this paper adds

- This study emphasizes the importance of anxiety in children's pain reaction during dental local anaesthesia.
- The study also suggests that further consideration needs to be given to subjects' anxiety levels in order to obtain more reliable results in pain studies comparing injectors and techniques.

Why this paper is important to paediatric dentists

- New injection devices should not be considered as the only competent mechanisms for pain-free dental injections in children.
- Anxiety control through behaviour management techniques should be a pre-requisite for all dental interventions in children.

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