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Comparison of single tooth anaesthesia by computer-controlled local anaesthetic delivery system (C-CLADS) with a supraperiosteal traditional syringe injection in paediatric dentistry

ABSTRACT

Aim *In recent years, new technologies for local anaesthetics delivery have emerged as alternative methods to the traditional syringe injection. The aim of this study was to compare the efficacy of traditional syringe buccal infiltration to the Computer-Controlled Local Delivery System (C-CLADS's) STA-Intraligamentary (Single Tooth Intraligamentary Anaesthesia) on the molars of both arches in paediatric patients, focusing on anaesthetic effect onset and effect over time.*

Materials and methods *Subjects consisted of 50 paediatric patients aged 5–13 years , randomly divided into 2 groups of 25. Efficacy and onset of anaesthesia were evaluated at time 0 and after 10, 20, and 40 minutes with a pulp tester.*

Results *Percentages of complete anaesthetic effect at time 0, 10', 20' and 40' were respectively as follows: 88% and then 96% at all following time points for STA-Intraligamentary delivery system, and 56%, 64% 76% and 72% for conventional syringe (0', p: 0.025; 10', p: 0.005; 20', p:0.024; 40', p:0.024) with a cumulative Odd Ratio (OR): 7.72 (CI95% 1.49-39.9).*

Conclusion *The STA-Intraligamentary injection offers a statistically relevant longer anaesthetic effect and a more constant duration over time. Clinical relevance: The STA-Intraligamentary injection has a high safety and comfort, and a faster onset with a more predictable outcome compared to the traditional anaesthetic technique.*

Keywords *Computer-Controlled Local Delivery System; Intraligamentary anaesthesia; Local anaesthesia;Pain perception; STA System; Traditional syringe.*

Introduction

The fear of local anaesthesia performed with needle-injection is recognised as a major cause for patients' avoidance of dental treatments. Difficult and traumatic childhood dental treatment experiences are often the cause of the subsequent anxiety and worries that develop further on [Guinot Jimeno et al., 2014; Klaassen et al., 2003; Majstorovic and Veerkamp, 2005]. Pain control in the treatment of children and adolescents is of great importance in order to avoid that anxiety and fear of dental treatment may in the future affect the oral health of the patient. Accordingly, among the dental procedures, needle injection is thought to be one of the most painful [Krochak e Friedman 1998] and dentists use different techniques to reduce pain: some use topical anaesthetics for mucosa before injection [Fukayama et al., 2002]. Some try to puncture the mucosa very softly, while others administer local anaesthetics very slowly. Nonetheless, none of these methods offered the solution for complete elimination of puncture and injection pain. Even though it is well known that slow injection of local anaesthetics is less painful than a rapid one, this is very difficult to achieve with a traditional syringe, as a palm-thumb grasp requires a greater force to inject the anaesthetics and it is necessary to adjust the pressure according to the density of the tissues. It is thus practically impossible to deliver the anaesthetics at a constant, slow flow rate using a conventional syringe [Hochman et al.,1997].

Local anaesthesia offers a painless dental treatment, but the injection itself is often associated with disruptive behaviour. Computer-Controlled Local Anesthetics Delivery System (C-CLADS) overcomes the drawbacks of a traditional syringe in dentistry– specifically in paediatric dentistry .

The aim of this study was to compare the efficacy of a computerised system for administration of local

FIG. 1 Traditional syringe and WandTM reduced disposable handpiece.

FIG. 2 Injection sight for STA-Intraligamentary anaesthesia.

anaesthesia with a traditional delivery of local infiltration anaesthesia using a conventional syringe, focusing on the onset time and the anaesthetic effect over time, and the relative comfort perceived by the child during the anaesthetic procedure.

Efficacy of anaesthesia was evaluated with a pulp tester measuring the presence, or rather lack, of sensitivity.

Materials and methods

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study has been carried out independently and without funding. There is no conflict of interest for any of the authors. Informed consent was obtained from all individual participants. Naturally, since the subjects involved in the study were minors, the formal authorization was obtained from the parents.

Subjects consisted of 50 patients between the ages of 5 and 13, each requiring local anaesthesia for dental treatments of a single tooth, visited at the Department of Paediatric Dentistry of the University of Rome Tor Vergata, between January and April 2015.

Patients were randomly divided into two groups of 25 each, and assigned to receive either the STA-intraligamentary injection or, in the control group, the traditional anaesthetic infiltration.

In each group, anaesthesia was administered to 10 permanent teeth and 15 primary teeth. In both the maxilla and the mandible, the sample teeth were primary and permanent molars, requiring restorative treatments or extractions. The same anaesthetic solution, 2% xylocaine with epinephrine 1:100,000, and the same dosage (½ of a 1.8 ml anaesthetic cartridge) was used for each tooth in both groups. Such dosage was chosen according to the C-CLADS usage protocols, based on the recommendations of the STA System™ operating manual, administering half drug volume for paediatric patients, and detected precisely for the C-CLADS because of its real-time audio-visual feedbacks. The injection for the C-CLADS was administered using a disposable handpiece with a bonded 30 G ½ inch needle, whereas, for the control group, a traditional syringe with a 27 gauge 1 inch needle (Fig. 1) was used.

Regarding the injection technique, the STA-Intraligamentary injection was performed by breaking the Wand™ handpiece to its shortest length, bending the bonded needle to a 45° angle, and by gently placing it with the bevel oriented toward the tooth at the bottom of the sulcus until the resistance of the periodontal ligament was felt, according to the instructions of DPSTM Technology (Fig. 2). The insertion sites were always two for each tooth –distal-lingually and mesial-lingually in the mandible and distal-buccally and mesial-buccally in the maxilla, always beginning from the distal position – delivering ¼ of a cartridge in approximately 1 minute per site. The infiltration injection in the control group was performed using the traditional method, placing the needle in the buccal fold and administering half of a cartridge in a single injection site in approximately 50 seconds.

All the selected teeth were vital: before dental treatment pulp tester scores ranged from 43 to 67 for the permanent molars and from 41 to 65 for the primary molars.

Efficacy of anaesthesia for each tooth was evaluated with a pulp tester using electric pulp stimulation, and recording for each tooth the value at which patients felt the stimulus after delivery of the anaesthetic at times: 0 minutes, 10 minutes, 20 minutes, and 40 minutes. The complete anaesthetic effect was reached if no sensation was felt at maximum value (80) recorded by the pulp tester.

Statistical analysis

Baseline children's clinical characteristics were reported as mean and standard deviation or frequencies and percentages for continuous and categorical variables, respectively.

The normal distribution of groups age was analysed by the Shapiro-Wilk test. Then we used the unpaired t test to verify a possible difference between STA-Intraligamentary injection and the control group.

The effect of treatment was tested by using a binary variable (pain sensation vs no pain sensation). Comparisons were investigated through suitable contrasts between STA-Intraligamentary injection and the control group. We used the Mann-Whitney test for non parameter

variables, including differences from time 0′ to 10′, 20′ and 40′. Finally we applied a general linear model for repeated measures obtaining a odds ratio which indicates the global outcome performance (STA-Intraligamentary injection versus the traditional delivery system).

A p-value lower than 0.05 was considered as significant. All analyses were performed using SPSS for Windows (SPSS, Chicago, IL, USA).

Results

Table 1 shows the clinical characteristics of the participants. Age and gender were similar in the two groups of paediatric patients. Table 2 summarises the results.

For all teeth (25 molars), at baseline and after 10, 20 and 40 minutes, the estimated positive response percentages to the anaesthetics administration were observed as follows: 56%, 64%, 76% and 72% for the control group and 88%, 96%, 96% and 96% in STA-Intraligamentary system group (p value respectively, 0′, p: 0.025; 10′, p: 0.005; 20′, p:0.024; 40′, p:0.024). We then used a general linear model for repeated measures which offers an outcome performance global odds ratio. In comparison to conventional syringe, the STA-Intraligamentary system achieves the anaesthetic effect (outcome) with an odd ratio of 7.72 (95%CI: 1.49-39.9) (Fig. 3).

Figures 4 and 5 show the results of a sub-analysis including only permanent teeth (10 molars) and primary teeth (15 molars). As the charts indicate, the result is confirmed only for permanent teeth (chart 2: 0′, p: 0.085; 10′, p: 0.043; 20′, p: 0.043; 40′, p:0.016) with a global odd ratio of 2.12 (95% CI: 1.02-32.13), whereas no significant differences emerged for primary teeth. In fact, Figure 5 shows a tendency towards a statistical significance for primary teeth at times 0′ and 10′, such that the observed positive responses to the anaesthetics administration were as follows: 66,67% for the control group and 93,33% in STA-Intraligamentary system group.

In addition, we observed a higher rate of absence of anaesthetic effect using the conventional syringe as compared to the STA delivery method. No anaesthetic effect was registered in 13.33% of the primary teeth and in 40% of the permanent teeth with conventional syringe versus 6.67% of the primary teeth and 0% of permanent teeth with STA-Intraligamentary system (Fig. 6).

In contrast, as displayed in Figure 7, we registered a collateral numbness of the lip in 80% of cases using the conventional syringe, whereas no undesired collateral

	STA-Intraligamentary (n° 25)	Conventional syringe (n° 25)	p
Age (Y)	8.8	8.7	0.852
Sex (M/F)	14/11	12/13	0.389

TABLE 1 Baseline demographic characteristics of the patients according to treatments.

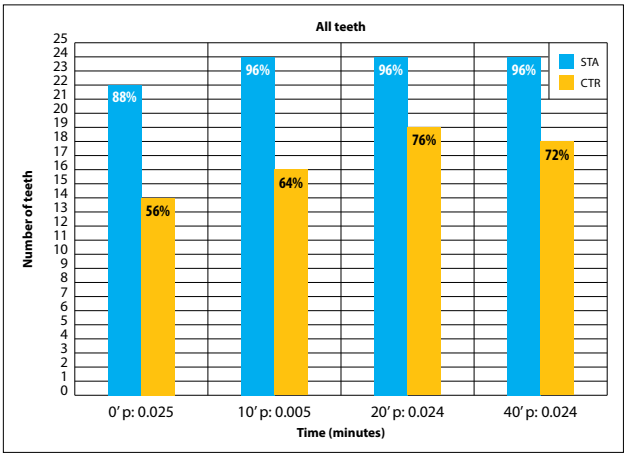
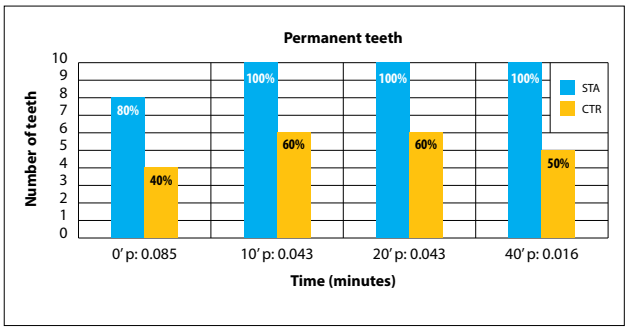


FIG. 3 Complete anaesthetic effect over time for all teeth.

	Primary	Conventional syringe	STA-Intraligamentary System
Complete anaesthetic effect	All teeth	No sensation was felt in 56% of cases at time 0. The percentage increased to 64% al 10′, and to 76% at 20′, and decreased to 72% at 40′	No sensation was felt in 88% of the cases at time 0. The percentage increased to 96% at 10 minutes, and remained constant throughout (measurement times 20′ and 40′)
	Lack of anaesthetic effect	No sensation was felt in 40% of cases at time 0. The percentage increased to 60% al 10′, remained constant at 20′, and decreased to 50% at 40′	No sensation was felt in 80% of the cases at time 0. The percentage increased to 100% at 10 minutes, and remained constant thereafter (measurement times 20′ and 40′)
	Collateral numbness of the lip	No sensation was felt in 66.67% of cases at time 0. The percentage stayed at 66.67% of cases at time 10′ and increased to 86.67% at 20′ and 40′.	No sensation was felt in 93.33% of the cases at time 0, remaining unvaried throughout (93.33% at measurement time points 10′, 20′ and 40′)
Patient disruptive behaviour**	Permanent	40%	0%
	Primary	13.33%	6.67%
Collateral numbness of the lip	All Teeth	80%	0%
Patient disruptive behaviour**	All Teeth	88%	0%
*All teeth: 25; Permanent teeth: 10; Primary teeth: 15 **Due to pain perception and/or psychological impact, as judged by the operator			

TABLE 1 Summary of results.



GIG. 4 Complete anaesthetic effect over time in permanent molars.

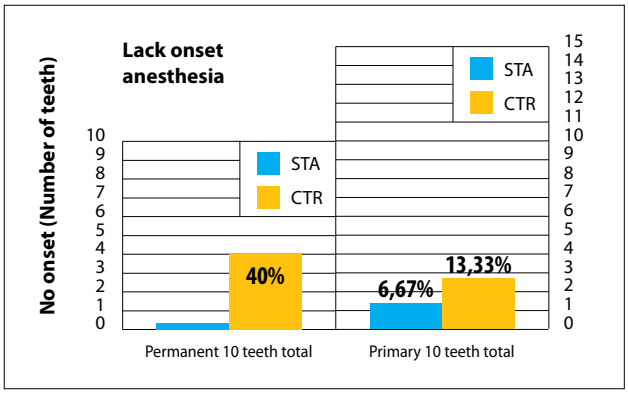


FIG. 6 No anaesthetic effect reached.

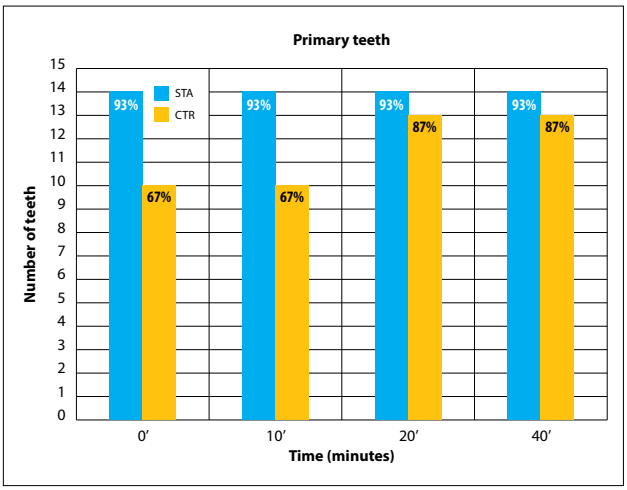


FIG. 5 Complete anaesthetic effect over time in primary molars.

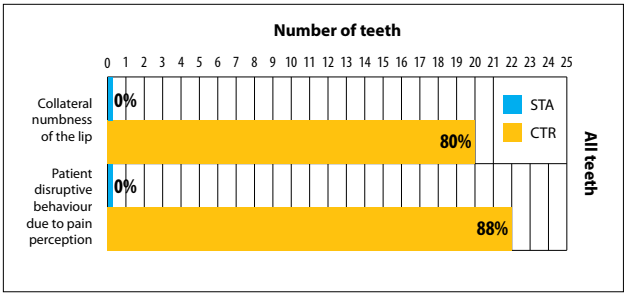


FIG. 7 Collateral numbness of lip and patient disruptive behaviour.

numbness cases were recorded using STA-Intraligamentary system. Finally, as judged by the operator, 88% of the patients treated with the conventional syringe showed a disruptive behaviour due to pain perception, while this happened in 0% cases when the anaesthesia was administered with the STA-Intraligamentary system (Fig. 7).

Discussion

This work shows that, compared to the traditional syringe supraperiosteal buccal infiltration, the STA-Intraligamentary delivery system guarantees a more complete onset of anaesthesia with a faster, longer and more constant duration over time. Interestingly, this positive effect observed for all teeth was confirmed by a sub-analysis including permanent teeth, but not primary teeth, which, in any case, showed a tendency towards statistical relevance. Consequently, this tendency shown by primary teeth at times 0' and 10' is a crucial aspect to be investigated more specifically in further studies and with different populations. Our opinion is that, also on primary teeth, from a clinical point of view the use of the STA-Intraligamentary delivery system could reduce the onset time of complete anaesthetic effect.

Regarding efficacy, our results seem to confirm previous reports. Taking into consideration also the post-operative effect, Ashkenazi et al. described an interesting long-term effect of the STA-Intraligamentary injection delivered by C-CLADS to primary molars on their corresponding permanent tooth buds (78 children aged 4.1-12.8 years, 166 primary molars, time-spam of 0.5 to 8 years post-treatment). The authors concluded that, although the intraligamental injection administered by C-CLADS and high pressure syringe are injected in the same site, the C-CLADS injection does not damage the underlying permanent dental bud [Ashkenazi et al., 2010]. Actually, when the operator acts with the traditional syringe, the high syringe pressures can cause tissue damage, as evidenced by histologic, animal, and human studies [Pashley et al., 1981; Pertot and Dejou, 1992; Albers and Ellinger, 1988]. The result of such tissue damage is also an increased pain perception reported by dental patients [White et al., 1988; Miller, 1983].

Our main findings confirm the large evidence in dental literature; patients expressed a marked preference for intraligamentary injection using C-CLADS, compared to the inferior alveolar block injection and/or buccal infiltration [Gibson et al., 2000; Öztas et al., 2005; Elbay et al., 2015]. Our paediatric patients did not show signs of discomfort during and after treatment (0% as compared to the 88% disruptive behaviour when using the traditional syringe). Furthermore, a higher number of patients reported discomfort due to collateral numbness of the lip after conventional anaesthesia

(80%), compared to the computerised technique (0%). Therefore we demonstrate that the STA-Intraligamentary technique can significantly reduce disruptive behaviours in a population of children, who are typically more difficult to manage. Of note, the significant reduction of pain-induced disruptive behaviour in the children will eventually result in a lifelong benefit to the dental patients as adults [Gibson et al., 2000; Öztas et al., 2005]. In our work, the disruptive behaviour was discretionally assessed by the practitioner (estimating verbal as well as non-verbal reactions, such as body and face tension, aggression, agitation, tears, moans, etc.), while the undesired collateral numbness was evaluated through an active interaction with the patient (applying pressure on the tissues surrounding the anaesthetised tooth and stimulating the patients' verbal and non-verbal feedback).

Issues concerning the use of traditional syringes are connected to its possible blockage or leakage of the solution which may occur during injection [Dower e Barniv, 2004] and can result in an inadequate duration of the anaesthetic effect; for this reason clinicians report a difficulty in assessing that the right dose of anaesthetic has been delivered. From the patient's point of view, increased tissue damage/pain perception is reported.

The main limitation to our work is the relatively small sample size. This is due in particular to the young age of participants. However, the 2 groups were well balanced in terms of age and gender. As expected, 40% (4 out of 10) of the permanent teeth of the control group in which a complete anaesthetic effect was not reached (pulp tester value = 80) were, specifically, lower molars. In order to proceed with the required dental treatments, in 3 of the 4 cases, the entire anaesthetic cartridge was delivered with traditional syringe infiltration to obtain complete anaesthesia. To anaesthetise the fourth case, it was necessary to use the mandibular nerve block.

Conclusions

In conclusion, the computerised single tooth technique allows significantly higher control of the various components that lead to a successful anaesthesia. The STA-Intraligamentary technique provides the clinician with multiple benefits that, as evidence shows, cannot be achieved using the standard dental syringe infiltration technique. Due to the increased comfort, operating speed and safety permits the modified intraligamentary injection to be performed as a primary injection with associated rapid onset and increased duration of anaesthesia.

This paper is important to paediatric dentists because:

- The STA-Intraligamentary delivery system, has a faster onset, a more predictable outcome, and a longer and more constant duration over time, less collateral numbness, without distinction between upper and lower molars;
- The traditional syringe buccal infiltration has a significant lower molars fallibility degree, whereas the C-CLADS presents consistent results in both arches, providing a valid alternative to the inferior alveolar nerve block.

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