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ORIGINAL RESEARCH

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Local anesthesia with SleeperOne S4 computerized device *vs* traditional syringe and perceived pain in pediatric patients: a randomized clinical trial

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Abstract

Local anesthesia is performed in dentistry before clinical procedures to avoid pain. Children can show fear at the sight of the needle and pain at its insertion. To make local anesthesia more comfortable, the use of computer-controlled local anesthetic delivery (CCLAD) systems has been developed to control the flow rate of the anesthetic solution injected through the needle. The aim of the present research is to evaluate and compare the discomfort felt by patients using a traditional syringe and the CCLAD system SleeperOne®, by considering pain, size sensation, bitterness, and vomit. 30 patients were included in the study and randomly assigned to traditional anesthesia or CCLAD. After injection, patients were assessed for the abovementioned outcomes. A Visual Analogue Scale (VAS) from 0 to 10 scores was used. As far as pain is concerned, statistically lower mean values were found in the Trial group ($p < 0.05$). Instead, concerning size, bitterness and vomit perceptions, no statistically significant differences were found between the groups ($p > 0.05$). Linear regressions were calculated considering technique, quadrant, dental arch, tooth, dentition, sex, and age as independent variables. The technique has shown to have a significant influence on pain ($p < 0.05$), with lower values for SleeperOne® device. Pain resulted significantly influenced by the type of dentition ($p < 0.05$), with higher scores for deciduous one. Moreover, perceived pain decreased with the increase of the age of patients ($p < 0.05$). At last, bitterness perception scores resulted to be higher for primary first molars ($p < 0.05$). SleeperOne® device seems to be a valid support for the reduction of pain related to anesthetic injection, especially in children. Further studies should evaluate CCLADs' uses combined with lidocaine preanesthetic as well as with conscious sedation through nitrous oxide in order to determine possible synergistic effects between these procedures.

Keywords

Local anesthesia; Pediatric patients; Pedodontics; SleeperOne; Computerized local anesthesia device; Visual analogue scale

1. Introduction

In dental practice, local anesthesia is a fundamental step in order to avoid pain sensations during the clinical procedures. Despite the necessity to recur to anesthesia, the fear exerted before injection usually represents a concern for many patients [1]. Many adults can show anxiety before local anesthesia, but this procedure is usually more worrying for children. In pedodontics, several procedures require anesthetization, like pulpotomies, root canal treatments, and extractions. The fear of a child during the administration of local anesthesia starts at the sight of the needle to the pain at the moment of the needle insertion [2].

In order to reduce anxiety without resorting to general anesthesia, various techniques are at disposal for clinicians, like the use of lidocaine-based preanesthetics (typically in form of spray or cream to be applied on the site before the injection) and conscious sedation (*i.e.*, the use of a sedation machine delivering a mixture of oxygen and nitrous oxide, this latter exerting a slight sedative and analgesic effect) [3].

In more recent years, in addition to those mentioned above, a new approach has been developed consisting of the use of computer-controlled local anesthetic delivery (CCLAD) systems [4, 5]. The concept behind these systems is to incorporate a computer technology to control the flow rate of the anesthetic solution injected through the needle. The first of these devices was introduced in 1997 and since then different models have been marketed by different Manufacturers. The working principle of CCLAD is to reduce pain by controlling anesthetic injection speed, which allows the continuous administration

of a small amount of anesthetic at a slow speed. In this way the onset of the anesthetic effect already occurs during administration itself, as the tissue is already anesthetized [6]. The basic concepts of CCLAD are:

• Reduction of pain sensation by speed control of anesthetic injection.

• Introduction of a small amount of anesthetic liquid at a slow speed [6].

One of the latest CCLAD systems available on the market is represented by SleeperOne® (Dental Hi Tech, Messina, Italy). This device consists of an electronic control unit, a pedal, and an injection pen. This latter is very light, and, thanks to its pen grip, it offers precision to perform anesthesia effectively and comfortably [4, 7–9].

The aim of the present research is to evaluate and compare the discomfort felt by patients undergoing local anesthesia on primary first or second molars using a traditional syringe and the CCLAD system SleeperOne®, considering pain, size sensation, bitterness, and vomit. The null hypothesis of the study is that no significant differences occur between the two anesthetic methods.

2. Materials and Methods

2.1 Study design

This was a single-center, split-mouth, randomized controlled trial with a 1:1 allocation ratio.

2.2 Participants

Pediatric patients aged 5–15 years addressing for dental care to the Unit of Orthodontics and Pediatric Dentistry, Section of Dentistry, Department of Clinical, Surgical, Diagnostic and Pediatric Sciences, University of Pavia, Pavia, Italy were asked to participate in the study if meeting the inclusion criteria as follows:

• presence of dental caries requiring filling with local anesthesia on first or second primary molar

• presence of dental caries requiring filling with local anesthesia on the contralateral primary molar

• score 4 of Frankl scales for children behavior during dental procedures [10]

The following exclusion criteria were considered:

• gingivitis

• dental abscesses, facial traumas/injuries

• drugs (non-steroidal anti-inflammatory drugs, paracetamol, antibiotics)

2.3 Interventions

The split-mouth design consisted of local anesthesia administration with articaine 4% + adrenaline 1/100,000 vial (Septanest, Septodont, Saint Maur des Fossés, France) and with the same 30G-9 mm needle (Dental Hi Tec, ZI de l'Appentière, Mazières-en-Mauges, France) for both groups. As local anesthesia was performed by a single trained operator no calibration was needed. Each patient had a tooth allocated to the trial group and its contralateral was assigned to the control group.

Supraperiosteal anesthesia with articaine 4% + adrenaline 1/100,000 vial (Septanest, Septodont, Saint Maur des Fossés, France) was performed as follows:

—in the Trial group, SleeperOne® computerized device and DHT needle (30G-9 mm); a slow injection was performed both on the vestibular and lingual sides; the DHT needle was used with an insertion angle of 15° between the needle and the mucosa, according to manufacturer's instructions. The speed was slow and steady, with 2 second of pause every 4 seconds;

—in the Control group, a traditional syringe (0480-1, ASA Dental, Massarosa, LU, Italy) with a standard 30G-9 mm needle (needle (Dental Hi Tec, ZI de l'Appentière, Mazières-en-Mauges, France); a slow injection was performed both on the vestibular and lingual sides (Fig. 1).

As there is no clinical procedure that can be repeated twice for the calibration procedure, Cohen's kappa coefficient was not calculated.

2.4 Outcomes

After the local anesthesia infiltration, patients assessed pain, size related to the device, bitterness and vomit perceptions using a VAS (visual analogue scale) administered by a neutral observer, containing a combination of Numeric Rating Scale (0–10, where 0 means "no perception", 10—"the worst possible perception") and Wong-Baker Faces Pain Scale, including pictures of facial expressions with correlating numbers of 0–10 (0 being "no perception" and 10 being "the worst perception") [11]. The combination helps younger patients to choose the correct score.

2.5 Sample size

Sample size calculation (alpha = 0.05; power = 95%) for two independent study groups and a continuous primary endpoint was performed concerning the primary outcome "VAS scale for pain". An expected mean of 2.6 with an expected mean difference of 1.7 and a standard deviation of 1.84 were hypothesized [12]; therefore, 30 teeth per group were required and a total of 30 patients for the split-mouth design study had to be enrolled.

2.6 Randomization and blinding

Using a block randomization table, the data analyst generated a randomization sequence, considering a permuted block of 30 teeth, due to the split-mouth design of the study. After the random assignment of the Trial treatment for one quadrant, the contralateral one was allocated to Control treatment. Based on previously prepared sequentially numbered, opaque, sealed envelopes (SNOSE), patients were divided into two groups: group A, in which the left quadrant (upper or lower) was allocated to Trial group and the right one to the Control group, and group B, in which quadrants were inverted.

Patients were blinded, hiding the devices and using them from behind their head. The operator could not be blinded. The data analyst, instead, was blinded.

2.7 Statistical analysis

Statistical analysis was performed with R Software (R version 3.1.3, R Development Core Team, R Foundation for Statistical

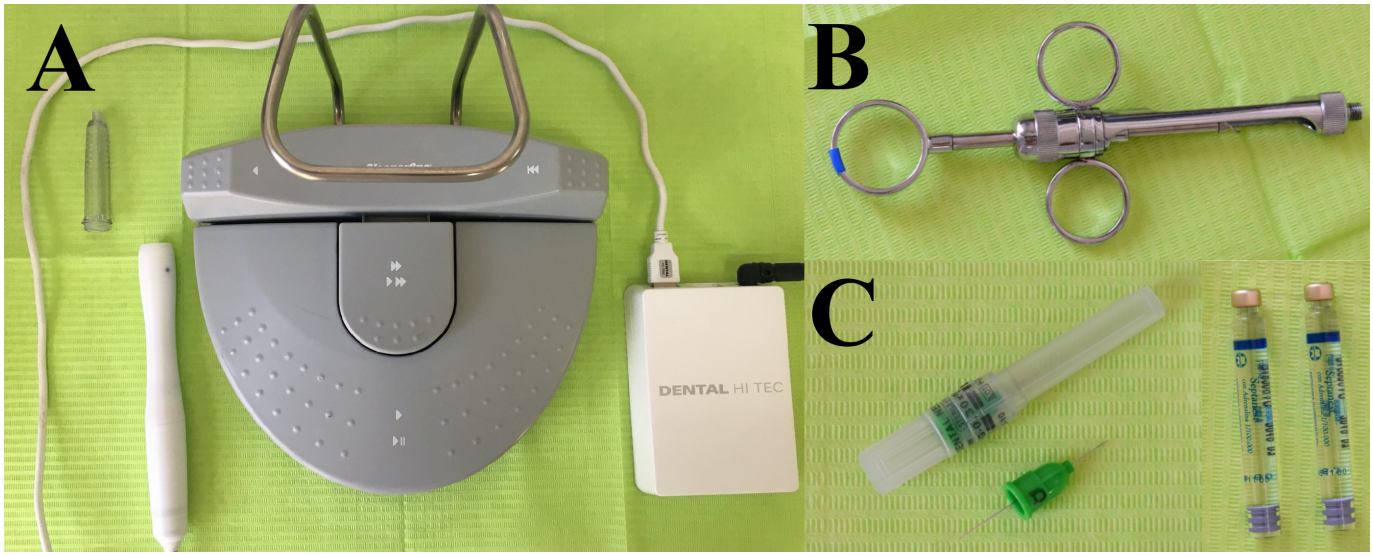

FIGURE 1. Materials used in the study. (A) SleeperOne® device; (B) traditional syringe; (C) needle; (D) local anesthetic vials.

Computing, Wien, Austria). Descriptive statistics (mean, standard deviation, minimum, median, and maximum) were calculated for each variable. Data normality of distributions was assessed with the Kolmogorov-Smirnov test. Subsequently, Student's *t* test was performed to compare VAS scores of pain, size, bitterness and vomit between the two groups. Linear regressions were performed to assess if technique, quadrant, dental arch, tooth, dentition, sex and age independent variables could influence pain, size, bitterness and vomit perceptions. Significance was predetermined for $p < 0.05$.

3. Results

30 patients were recruited for the study. They all fulfilled the inclusion criteria and accepted to participate in the study, they all received the allocated interventions, and none was excluded from analysis. The baseline characteristics of the study sample are shown in Table 1.

TABLE 1. Baseline demographic data of the study sample.

	Age (yr)	
Demographic characteristics	Mean ± SD	Range
Male (n = 16)	8.52 ± 2.44	5–14.75
Female (n = 14)	8.57 ± 2.57	5–14.75

SD: Standard Deviation.

The mean age of the participants at the beginning of the study was 8.57 ± 2.59. The CONSORT flow chart of the study is shown in Fig. 2. As regards the teeth included in the study, 17 were lower primary first molars, 15 lower primary second molars, 14 upper primary first molars and 14 upper primary second molars.

As regards pain values, a statistically significant difference between the two groups was assessed, with a lower mean score for the Trial group ($p < 0.05$). Instead, as far as size, bitterness and vomit perceptions are concerned, no statistically significant differences were found between the groups ($p > 0.05$) (Table 2).

Linear regressions were calculated considering technique, quadrant, dental arch, tooth, dentition, sex and age as independent variables and are shown in Table 3. Tables 4,5,6 explain the regressions outcomes. The technique has shown to have a significant influence on pain ($p < 0.05$), with lower values for SleeperOne device compared to the traditional syringe. Pain resulted significantly influenced by the type of dentition ($p < 0.05$), with higher scores for the deciduous one and lower for the mixed one (Table 4). Moreover, perceived pain decreased with an increase of the age of patients ($p < 0.05$) (Table 5). At last, bitterness perception was significantly influenced by the type of tooth on which local anesthesia was performed ($p < 0.05$), with higher scores for primary first molars and lower scores for primary second molars (Table 6).

4. Discussion

Delivery of pain-free dentistry is crucial for reducing fear and anxiety thus allowing the operator to perform the procedures and increasing acceptance of future dental treatments, especially in children [13, 14]. General anesthesia can be used to facilitate dental treatment, mainly in case of children or patients with special needs. When performing procedures under general anesthesia, dentists should perform a pre-operative assessment and ensure that the patients are aware of rare but potentially severe risks associated with this procedure (*i.e.*, anaphylaxis and death). These precautions ensure optimal patient management and reduce the frequency of morbidities associated with this form of sedation. Morbidity and mortality due to dental treatment performed under general anesthesia were investigated, and the mortality rates were surprisingly high comparing to other medical procedures performed under general anesthesia; therefore, although this latter is sometimes the only method to treat certain patients, maintaining specific

TABLE 2. VAS scores for pain, size, bitterness and vomit variables.

Variable	Groups	Mean	SD	Min	Median	Max	*p* value*
Pain							
	Control	3.77	2.28	0.00	4.00	10.00	$p < 0.0001$
	Trial	2.20	1.85	0.00	2.00	8.00	
Size							
	Control	1.37	1.56	0.00	1.00	6.00	$p = 0.6293$
	Trial	1.63	2.28	0.00	1.00	10.00	
Bitterness							
	Control	3.37	2.85	0.00	2.00	10.00	$p = 0.5311$
	Trial	3.83	3.16	0.00	3.50	10.00	
Vomit							
	Control	0.13	0.43	0.00	0.00	2.00	$p = 0.6203$
	Trial	0.23	0.97	0.00	0.00	5.00	

**: paired t test. SD: Standard Deviation.*

TABLE 3. *p* values of linear regressions for the variables considered in the study.

	Independent variable						
Dependent variable	Technique	Quadrant	Dental arch	Tooth	Dentition	Sex	Age
Pain	0.005*	0.2200	0.1780	0.0687	<0.0001*	0.2220	0.0005*
Size	0.6000	0.8830	0.8950	0.0725	0.5973	0.4292	0.2055
Bitterness	0.5500	0.9030	0.8510	0.0099*	0.9090	0.7200	0.5143
Vomit	0.6087	0.8730	0.9640	0.0657	0.5930	0.4650	0.8630

**: denotes significant p value ($p < 0.05$).*

TABLE 4. Means and standard deviations of pain levels among the groups in deciduous and mixed dentition.

	Deciduous dentition	Mixed dentition
Trial	6.00 ± 2.00	1.78 ± 1.28
Control	6.29 ± 2.14	3.00 ± 1.73

TABLE 5. Means and standard deviations of pain levels among the groups in age ranges 5–10 years and 10–15 years.

	5–10 years	10–15 years
Trial	3.44 ± 2.34	2.11 ± 1.56
Control	3.53 ± 2.37	2.11 ± 1.56

indications for dental treatment under general anesthesia is required [15].

Conscious sedation was found as a safer alternative for reaching a level of consciousness enabling dental treatment in those patients who are unable to receive treatment in normal dental clinic settings. However, even this technique is not risk-free considering that a maximum percentage of 70% N_2O_2 is regarded as safe to avoid side effects including sickness, vomit, and alteration of consciousness [16].

In any case, local anesthesia (LA) remains the most common pain-free approach. However, it remains challenging due to the uncomfortable sensations felt at the moment of the injection. The aim of the present research was to evaluate and compare the discomfort felt by patients when performing local anesthesia using a traditional syringe or a CCLAD system (SleeperOne®). Specifically, pain, size sensation, bitterness, and vomit have been assessed. The null hypothesis of the study has been rejected only for pain, whereas the other variables did not show significant differences between the groups. In fact, lower pain values resulted from the injection through SleeperOne® compared to the traditional syringe. As expected, no significant variations were found neither for the size sensation nor for the sense of bitterness and vomit. Among the other components, SleeperOne® is composed of an injection pen which certainly assures a more comfortable grip for the operator but does not particularly differ as far as size is concerned if compared to a traditional syringe. For the same reason, the sense of vomit was not influenced by the anesthetic system. Finally, as obvious, the sense of bitterness referred was similar between the groups since the anesthetic solution used was the same. However, this latter parameter was assessed in order to evaluate the presence of any difference of sense of bitterness depending on the specific tooth anesthetized.

Performing linear regressions considering technique, quad-

TABLE 6. Means and standard deviations of bitterness levels among the groups divided per tooth.

	Lower IV	Upper IV	Lower V	Upper V
Trial	4.75 ± 3.69	5.00 ± 2.50	1.88 ± 1.73	3.67 ± 3.44
Control	5.19 ± 3.75	1.91 ± 1.81	2.86 ± 1.66	3.20 ± 2.83

rant, dental arch, tooth, dentition, sex, and age as independent variables, pain resulted significantly influenced by the type of dentition with higher scores for the deciduous one and lower for the mixed one. Accordingly, perceived pain decreased with the increase of the age of patients, which could also be explained by the higher propensity for older children to undergo anesthetic procedures compared to the younger ones. Finally, although bitterness perception did not significantly vary between the groups, it resulted to be influenced by the type of tooth on which local anesthesia was performed, with higher scores for primary first molars and lower scores for primary second molars. This could be related to a different positioning of the patient during the anesthesia procedure, with a major drop of anesthetic solution at the base of the tongue (where papillae for bitterness are mainly located) in case of anesthetization of primary first molars, but this aspect deserves to be further evaluated with future studies.

Previous randomized clinical trials have been conducted to evaluate and compare the pain induced by CCLAD systems with respect to traditional anesthesia. In these studies, the methodology most frequently used to determine the effects of anesthesia was Visual Analogue Scale (VAS), as well as indices that assess facial or bodily responses, like Sound, Eye, Motor scale (SEM), Face Legs Activity Cry Consolability (FLACC), Facial Image Scale (FIS), and Faces pain Rating Scale (FRS) [17–19]. Among the papers reporting CCLAD to be effective, Feda *et al.* [20] and Mittal *et al.* [21] compared infiltration anesthesia on buccal and palatal sides. In the former study, children's pain was measured by SEM scale in a cohort of 40 children who received both anesthetic techniques alternatively on two different visits. The children's pain perception scores resulted to be lower using the CCLAD compared to the traditional injection as in the current study, moreover the prolonged injection time required for delivering the CCLAD injection had no negative impact on the subjects. Similarly, in the latter study, children were randomly assigned to two groups, one receiving buccal and palatal infiltration injection with CCLAD and the second using a traditional syringe, respectively. VAS score and SEM scale were assessed, and the Authors reported that patients experienced significantly less pain of injection with the computerized method during palatal infiltration, whereas pain was not significantly lower during buccal infiltration. In addition to that, heart rate increased during both buccal and palatal infiltration in traditional and computerized local anesthesia with no statistically significant differences. Therefore, it can be stated that, despite a sense of fear associated with both CCLAD and traditional anesthesia, the use of the former significantly reduces pain perception, in particular on the palatal side. In fact, compared to the buccal mucosa, which is soft and fluid, dense palatal mucosa is put under significant pressure during administration of anesthesia; therefore, particularly in this latter case, CCLAD offers particular advantages. Therefore, the results mentioned above confirm those obtained in the present report, although no differentiation between the assessment of pain on the vestibular and buccal side was conducted.

Patil *et al.* [22] assessed the perceived pain in children when performing palatal anesthesia using a CCLAD system (Wand) and the conventional technique. A total of 30 children undergoing bilateral palatal anesthesia were included in the study according to a split-half design. The children were asked to indicate their intensity of pain response on a visual analogue scale (VAS) after administration of anesthesia by the CCLAD system and the conventional technique. No difference resulted from the two techniques, anyway the CCLAD system was more accepted by females compared to males. It should be considered that, since the only palatal infiltration has been conducted in the study mentioned above, no direct comparison can be performed with the results of the current report, where pain evaluation has been conducted after realizing both palatal and buccal anesthetization.

O'Neal *et al.* [23] randomly assigned 130 adults to a maxillary lateral incisor infiltration with a CCLAD system (Dentapen®) and a traditional syringe at two separate appointments. The pain felt at solution deposition resulted significantly lower for the former injection method with the Dentapen® device (16% experienced moderate pain) with respect to the traditional syringe (39% experienced moderate pain), in accordance with the results of the current study. Overall, 75% of subjects preferred the Dentapen injection over the conventional injection.

In the study by Flisfisch *et al.* [24] twenty adult patients reporting at least two tooth-neck defects each in different quadrants were treated with local buccal infiltration anesthesia. Using a split-mouth design, one quadrant was anesthetized with a conventional syringe, while the other with CCLAD. The time elapsed between time of injection and time of disappearance of numbness was registered. Participants were asked to mark on a VAS their visual impression of the device as regards anxiety-inducement, their sensation of mucosal puncture, pain at the time of the administration, and pain perception during treatment for the two different methods along with future preference immediately after treatment and after reflection time. The level of anxiety-inducement and pain during administration resulted to be three times higher using the conventional syringe, a value even higher compared to the current study where pain with the conventional syringe resulted to be about 1.5 higher than with CCLAD. There was no difference in mean sensation of mucosal puncture, nor a statistically significant correlation between the duration of administration and the time until disappearance of numbness. Once anesthesia was administered, no pain during treatment was detected using either method. Patients' preference of methods changed significantly with time in favor of CCLAD.

According to these results, the Authors conclude that patients' preference of CCLAD over the conventional anesthesia with the syringe, even more so after reflection time, can imply the preference of CCLAD for clinicians, too, in order to enhance patients' and clinicians' comfort.

Riba-Roca *et al.* [25] conducted a randomized, split-mouth and simple blind clinical trial to compare pain experienced after injection with two different CCLAD systems. Twenty patients received two palatal injections in the same session using Dentapen® on the former side and STA Wand® on the contralateral side. Pain perception assessed through a VAS scale resulted to be similar with both devices, specifically most participants referred to mild pain (80%) and none experienced severe pain. In their study, pain was measured using a 10-cm numeric rating scale (NRS) and the results obtained were 2.40 for the STA Wand® and 2.35 for Dentapen®, respectively. Although in the current study a different scale was used, a correspondence between the NRS and the VAS scale can be assumed. Considering that in the present report a value of 2.2 of VAS was obtained in patients exposed to anesthetization with the CCLAD system, these results are comparable to those of Riba-Roca and colleagues.

Further randomized clinical trials have been assessed leading to similar results of those obtained in the present study [26–28]. Moreover, it has also been shown that CCLAD induces lower pain than conventional inferior alveolar nerve block anesthesia [29].

The results obtained in the current work also confirm the findings of recent reviews and meta-analyses. For instance, Pozos-Guillén and colleagues [5], concluded that Wand® caused significantly lower pain than the conventional injection. In the subgroup by pain scale analysis, the Facial Image Scale and Wong-Baker Faces Pain Scale showed a significant difference in favor of the CCLAD system. In general, the reviewed evidence shows that less perceived pain and anxiety occur when the local anaesthetic technique is performed with a CCLAD system than with the traditional technique.

In the review conducted by Carugo *et al.* [30], pain perception in pediatric patients when using a CCLAD compared to the traditional injection was evaluated. Seven clinical studies regarding paediatric patients and using split-mouth designs or group division were included. The age ranged from 5 to 17 years old, compatible with the inclusion criteria considered in the present report. Pain and fear parameters were measured by visual analogue scales, behavioural scales, heart rate and satisfaction questionnaires. The Authors concluded that substantial heterogeneity between clinical trials was observed, leading to difficult comparisons. Computerised devices have proved to be effective in reducing pain during anaesthesia, facilitating the clinical and psychological approach to the paediatric patient. However, the Authors suggest that further research with anxious subjects and patients under 4-year-old should be conducted, since no evidence was found in the literature. Considering that even in the current report only children older than 5-years old have been recruited, it can be hypothesized that the positive action exerted by CCLAD systems on pain reduction could not be generalized to younger children.

Concerning the relationship between pain levels and other variables like type of dentition, site of injection, and age of the patient, the review by Kwak and colleagues [6] found no correlation with the age, whereas no definitive conclusion could be stated for the other parameters. As evidenced by the Authors, children are generally more afraid than adults when receiving an injection, independent of using CCLAD or conventional local anesthesia with syringe. This could also justify why lower pain values were assessed in the present research for older children with mixed dentition with respect to younger children with deciduous teeth. In any case, there are limitations in the objective assessment of the potential correlations between local anesthesia effects and pain in children.

Further limitations of this study include not considering the dental procedure performed which can highly influence the pain perceived [31]. Additionally, no pre-anesthetic procedure was performed in the cohort recruited. The application of lidocaine in the form of spray or cream could have lowered the pain felt at the time of the insertion of the needle, independently of the method of anesthesia chosen. Further randomized clinical trials are required to evaluate whether using a pre-anesthetic could reduce the significant difference as regards the pain experienced with traditional injection and using CCLAD. Moreover, the effects of CCLAD should be evaluated on permanent teeth for the different anatomy and innervation that could alter anesthetic diffusion. Also, the present report tested the device with patients who presented a Frankl Score of 4. It would be interesting to perform the same type of study with patients with lower compliance. Additionally, surgical interventions deserve to be investigated, such as teeth extractions for orthodontic purposes, labial and lingual frenulotomy/frenulectomy and the removal of oral mucoceles. Finally, the influence of recurring to conscious sedation with nitrous oxide before anesthesia and throughout the entire clinical procedure should be also evaluated. On the basis of these considerations, every effort should be made to determine the best protocol to reduce anxiety and pain during dental clinical procedures, especially in young patients.

5. Conclusions

CCLAD devices show the advantage of controlling the speed of the anesthetic injected into tissues, thus they have been proposed as an alternative to the traditional syringe to reduce pain during the anesthetic procedure. The outcomes of this study confirm that the use of CCLAD in children causes less pain whereas no influence is exerted on the perception of size, bitterness, and vomit. Additionally, higher pain scores were assessed in younger children with deciduous teeth with respect to older ones with mixed dentition. Bitterness perception was significantly influenced by the type of tooth on which local anesthesia was performed.

CCLAD devices seem to be a valid form of support for the reduction of pain related to anesthetic injection, especially in children. Further studies should evaluate their use combined with lidocaine preanesthetic as well as with conscious sedation through nitrous oxide in order to determine a possible synergistic effect between these procedures.

AUTHOR CONTRIBUTIONS

MCV—designed the research study. RA and CC—performed the research. MP and SG—wrote the manuscript. AS—analyzed the data and revised the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

All procedures performed in this study were in accordance with the Declaration of Helsinki (1964) and its later amendments, and it was approved by the Unit Internal Review Board (2022-0706). The protocol was registered on clinicaltrials.gov (NCT: NCT05531435). Informed consent was obtained from a parent or guardian; assent was obtained from the minor. Patients could withdraw from the study whenever they wanted without compromising the agreed treatment.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Simone Gallo, Maurizio Pascadopoli, Andrea Scribante are serving as the Editorial Board members of this journal. We declare that Simone Gallo, Maurizio Pascadopoli, Andrea Scribante had no involvement in the peer review of this article and have no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to APG.

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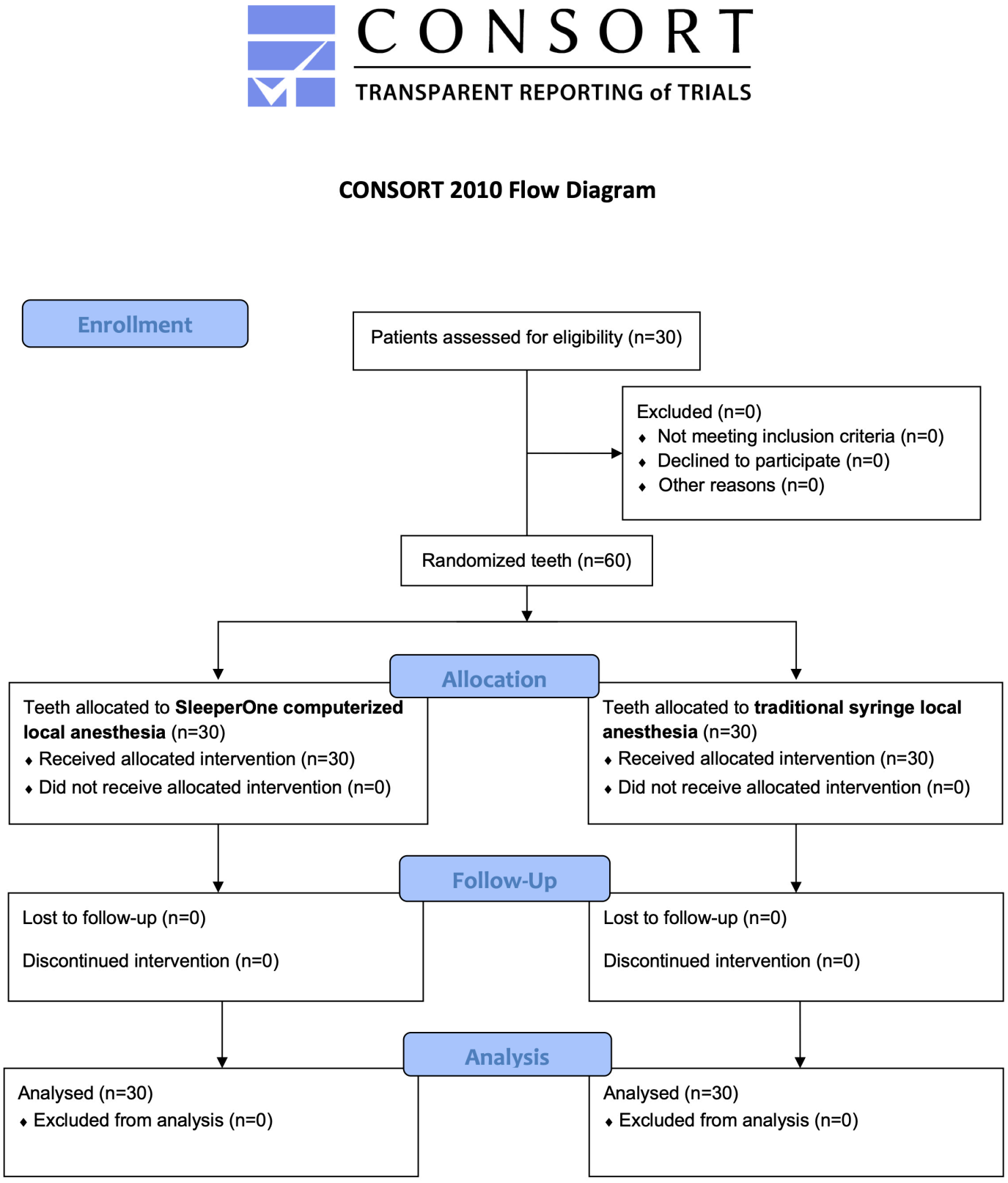

FIGURE 2. CONSORT flow chart of the study.