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ORIGINAL ARTICLE

"Comparative study of conventional anesthesia technique versus computerized system anesthesia: a randomized clinical trial"

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Abstract

Objective The aim of the present study was to compare in terms of pain perception the use of conventional anesthesia and a computerized system.

Materials and methods Forty patients in need for extractions, dental restorative, or periodontal treatment bilaterally, were selected. Each patient served as his/her own control being subjected to two anesthesia techniques: conventional and electronically controlled anesthesia with Calaject® (Rønvig Dental MFG, Daugaard, Denmark). Each patient received both treatments in a blind way 1 week apart. The order was previously randomized. After performing the anesthesia (upper dental nerve, palatal posterior nerve, or inferior alveolar nerve), the patients evaluated their pain sensation with a visual analogue scale (VAS) (0–10). After treatment, the patients were asked about the presence of pain during the procedure. Finally, the patients selected their preference between the conventional and electronic anesthesia technique. Differences in assessment of pain's injection were analyzed using the Wilcoxon test and the Kruskal-Wallis test ($\alpha = 0.05$).

Results The mean general pain experienced was 3.73 (1.55 SD) for the conventional anesthesia, and 1.95 (0.53 SD) for computerized anesthesia. Statistical differences ($p < 0.05$) were found. There was no difference between the treatments (p value = 0.061). Most patients did not feel any pain during the treatment. Finally, 92.5% of the patients preferred the electronic system.

Conclusions Computerized anesthesia system produces significantly less pain compared with a conventional anesthesia syringe. Although both obtained sufficient anesthetic depth to perform treatments, the majority of patients chose electronic anesthesia as the most satisfactory.

Clinical relevance Computerized anesthesia devices are valid and more comfortable alternative to conventional anesthesia.

Keywords Calaject system · Computer-delivery anesthesia · Dental anesthesia · Electronic anesthesia · Local anesthesia · Pain

Abbreviations

SRP	scaling and root planning
RT1	restorative treatment in lower molars
RT2	restorative treatment in upper incisors
EXT	extraction of upper molars

Introduction

Pain is a subjective, personal, and individual experience. Given the same stimulus, there are people who perceive a lot of pain while others simply do not feel it. This is because the perception of the stimulus is the result of the interaction of multiple variables: biological, psychological, social, and cultural. Furthermore, the patient's pain perception can also be altered by their own prior treatment experiences [1]. Dental appointments often bring fear or any kind of stress to patients. This is because patients associate dental procedures with pain and discomfort. Generally, what patients really fear is the anesthetic procedure [2]. Despite of a careful anesthetic procedure, dental local anesthesia can cause pain. This pain occurs as a result of one or a combination of the following factors: soft tissue damage during penetration of the oral mucosa,

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pressure from the spread of the anesthetic solution and the distension of the tissues, or a rapid delivery of the anesthetic liquid of the syringe [3, 4].

Therefore, a comfortable anesthesia is essential to achieve patient's confidence in the operator. Throughout history, dentists have taken different measures to mitigate the discomfort associated with injections and increase patient satisfaction, such as the use of topical anesthesia [5], warming anesthesia solution to body temperature [6], adoption of alternative local anesthesia technique [7], or increasing injection time by the administration of local anesthesia [5, 8].

Although reducing the speed and pressure of the injection is the most effective method to reduce pain, manual control is quite laborious [9]. With the aim of improving this aspect, in the last few years, different computer-controlled anesthesia systems have been developed. The first system to appear was Wand® (Milestone Scientific, USA) in the year 1997. Later, more systems were developed such as Anaject® (Septodont, India), Stabident (Fairfax dental, USA), X-Tip® (X-Tip Technologies, USA), Intraflow® (IntraVantage, USA), Quicksleeper® (DHT, France), and CCS® (Comfort Control Syringe) (Denstply Sirona, USA). All of them present differences among themselves, in terms of design, shape, needle size and diameter, weight, or the possibility of aspiration. But all of them have in common is that the computer system controls the speed and pressure of the infiltration of the anesthetic solution, in order to reduce pain, discomfort, and anxiety of the patient [9, 10]. They dispense a constant flow rate of local anesthetic regardless of the location, density, and resiliency of the soft tissues at the injection site [11].

One of the recently introduced computerized anesthesia systems is Calaject® (Rønvig dental MFG, Daugaard, Denmark). It consists of a mobile unit with a built-in pressure indicator and a three button display to select the most suitable program in terms of different speeds and pressure. This unit is adapted to a pen-shaped container where the carpules and needles that serve as a syringe are placed. The control of anesthesia is performed with a pedal connected to the central unit, which emits sound messages as the anesthesia is administered.

This system incorporates three programs with pre-established speeds that regulate the flow and speed of the anesthetic liquid automatically. The first program releases a slow administration of the liquid and the second program begins with a slow administration during the first 10 s and after this time changes to a more rapid administration being ideal for the blockade of the inferior dental nerve. The third program administers the anesthesia more rapidly and can be useful for the reinforcement of the anesthesia.

A priori, the electronic anesthesia systems present advantages in terms of the pain suffered by the patients. This has been demonstrated in multiple studies, especially with the Wand® system, but there is not enough evidence regarding Calaject [10, 12–15].

The aim of the present study was to compare conventional anesthesia with computerized controlled anesthesia performed with Calaject system, in the following terms: pain sensation during the injection of anesthesia, effectiveness for performing painless dental treatments, and the preference of patients. The tested null hypothesis was that there were no statistically significant differences between the anesthetic technique with the Calaject system and the conventional syringe technique in terms of anesthesia effectiveness and pain sensation described by patients.

Material and methods

Trial design

A randomized controlled clinical trial was designed. Each patient served as their own control, so a split-mouth design was adopted.

Participants

Forty patients (16 men and 24 women, aged between 21 to 79 years) were selected from the clinic of Master in Restorative Dentistry Based on New Technologies, at the Complutense University of Madrid. All of them were informed about the objectives of the study and signed the corresponding informed consent form. The protocol was previously approved by the local ethics committee number 18/429-O_P and conducted in accordance with the Declaration of Helsinki and Good Clinical Practice.

Patients were in good health and presented the need for dental restorative, periodontal treatment, or extractions, bilaterally. The exclusion criteria are as follows: allergy to local anesthesia, pregnancy, and patients under treatment with opioid or psychotropic drugs. The selected patients were divided into four groups (ten patients in each), according to the treatment they needed:

- Restorative treatment in lower molars (RT1)
- Restorative treatment in upper incisors (RT2)
- Extraction of upper molars (EXT)
- Scaling and root planning in lower molars (SRP)

Restorative treatments consisted of caries elimination and cavity filling. According to the Black classification, class I and II fillings were made in the posterior sector and class III in the anterior sector, all without pulp involvement. The extractions were performed on upper molars affected by periodontal disease. All of them presented an "irrational to treat" prognosis [16]. None of them had previous symptoms or periodontal abscess. Scaling and root planning were performed in patients

with periodontitis in stage II and III, according to the last classification of periodontal diseases [17]. The treatment was performed in the lower quadrants using ultrasonic instruments and manual instrumentation with Gracey-type curettes.

Each patient served as their own control being subject to two anesthesia techniques: conventional and computerized controlled anesthesia with Calaject® (Rønvig dental MFG, Daugaard, Denmark). Each patient received the same treatment bilaterally 1 week apart. All appointments were made in the morning, from 9 a.m. to 1 p.m., trying to control this parameter as a confounding variable in patient's pain perception. The order of the application of the anesthesia was randomized using a smartphone application (Undecided, Deadmans Productions, NY, USA). To avoid bias, the patients were blind; they were unaware of the type of anesthetic technique that was being carried out. For this reason, an eye mask and headphones with predetermined music were placed, as the electronic system emits sound messages.

All the clinical procedures were carried out by the same operator. The clinician was a restorative dentistry specialist (S.B.D) with 10 years of clinical experience and trained in the use of both anesthetic techniques (Electronic and conventional). Prior to the anesthetic procedure, the area was not disinfected or prepared with any substance. Topical anesthesia was not applied either.

There were no complications or adverse effects during the anesthesia procedures.

Conventional anesthesia

Two different techniques were used for the conventional anesthesia. For the treatments in upper maxillary, infiltrative anesthesia technique was used. For the extraction of the molars, the upper dental nerve and the posterior palatal nerve were anesthetized. For restorations of the anterior teeth, the anterior dental nerve was blocked at the interincisal level. The area of insertion of the needle was the height of the mucobuccal fold above the apex for teeth. The needle was oriented with its bevel kept toward the bone; negative aspiration was ensured followed by deposition of the anesthetics.

For the treatments in the lower arch, the inferior alveolar nerve block (IANB) was carried out. The operator identified the anterior edge of the coronoid apophysis of the mandible with his thumb. The needle was inserted between the internal oblique edge and the pterygomandibular raphe about 1 cm above the occlusal surface in a direction coming from the opposite side, until the needle contacts the bone. After negative aspiration, the anesthetics were deposed. To mimic the computerized system with the conventional one, the operator performed a slow infiltration and tried to control the pressure.

A three-ring syringe (Pluraject, 3M, Maplewood, MN, USA) with 30G 0.3 × 30-mm needles (Octoplus, Clarben, Madrid, Spain) was used for conventional anesthesia. A solution of articaine with epinephrine (40 mg/ml + 0.01 mg/ml) (Artinibsa, Inibsa Dental SLU, Barcelona, Spain) delivered in conventional cartridges was selected.

Computerized control anesthesia

The electronic anesthesia technique was performed using the Calaject® system (Rønvig dental MFG, Daugaard, Denmark). This system uses the same needles and cartridges as a conventional syringe, mounted on their hand piece, with pen shape. The cap was removed, and the foot pedal is pressed once to remove air from cartridge. Therefore, the infiltration was activated through the foot control that was connected to the drive unit. Then the needle was inserted using the same technique than conventional techniques, both in the lower and the upper arch. Previously, the operator selected program II from the drive unit for all patients. This program started with 10 s of slow injection of the anesthetic solution and after that time the equipment automatically switched to the fastest pace until completely emptying the cartridge. The duration of infiltration was around 60 s according to the manufacturer. The system provides audible and visual feedback to the clinician. The audible signs indicated the injection speed and a scale of LEDs indicated the pressure that was being applied.

All injections were made with 1.8 ml of Articaine with epinephrine (40 mg/ml + 0.01 mg/ml) (Artinibsa, Inibsa Dental SLU, Barcelona, Spain) delivered in conventional cartridges. A 30G 0.3 × 30-mm needle (Octoplus, Clarben, Madrid, Spain) was used.

After the anesthesia, the necessary treatment was carried out. To ensure the correct effect of the anesthesia, all patients were treated after from the infiltration. Thus, an optimal anesthesia sensation was obtained. The duration of the treatments did not exceed, in any case, 60 min.

Patient assessment

Prior to starting the anesthetic procedure, the researcher explained the visual analogue scale (VAS) to the patient, to prevent confusions. This scale was divided into six non-equispaced levels, organized as follows: no pain (0–1), mild pain (1.1–3), moderate pain (3.1–5), severe pain (5.1–7), very severe pain (7.1–9), and unbearable pain (9.1–10).

Immediately after performing the anesthesia, the VAS (0–10) was presented to the patient, who was asked about the sensation of pain experienced during the infiltration. The patients selected the corresponding number and the researcher wrote it down in a data collection form.

After performing the dental procedure, the patient was asked if he had suffered pain during the procedure, and was given the option to select yes or no. To avoid possible bias, all data collection was carried out by a different operator.

At the second appointment, and after experiencing the two types of anesthesia, the patient was asked to express his preference between the first or second anesthesia.

Statistical analysis

The sample size used was calculated for 80% power, using software G power 3 version 3.1.9 (Heinrich-Heine-Universität Düseldorf, Düseldorf, Germany).

All data were collected in an Excel spreadsheet for Mac version 14.0, and a descriptive and inferential statistical analysis was carried out with the statistical software R and packages tidyverse and ggpubr.

After checking for normality, non-parametric tests were used. To study individual differences, the Wilcoxon test was applied, and the differences between groups were studied with the Kruskal-Wallis test. The level of significance was established at $\alpha = 0.05$.

Results

The 40 patients consisted of 24 women and 16 men ranging from 18 to 79 years (mean age of 45.65 ± 14.90). The teeth sample and their distribution by groups are represented in Table 1.

The pain scores given by patients to each of the anesthesia techniques are shown in Fig. 1 (general scores) and Fig. 2 (scores by treatment), and Table 2 summarizes the relevant statistics.

For hypothesis testing, the ratio of the pain scores was considered. Figure 3 shows the difference and the ratio of scores plotted against the total score given to both techniques by each patient. It can be seen that there's a tendency for the difference to increase as total score increases, whereas the ratio remains more constant. Correlation test was applied to both magnitudes, finding a statistically meaningful positive correlation between difference and total score (p value < 0.05, $R = 0.667$) and no statistically relevant correlation between the ratio and total score (p value $= 0.087$, $R = -0.274$). The ratio score distribution is shown in Fig. 4.

Shapiro-Wilk normality test reports a p value < 0.05; therefore, we cannot assume normality of the distribution. Wilcoxon test was applied to the ratio distribution, under the null hypothesis that the median was distributed around 100%. Statistically significant differences were found ($p < 0.05$), estimating that patients tend to give half the score to the computerized controlled anesthesia as compared with the conventional (pseudo-median = 50%, 95% CI = 45–58.33%). The null hypothesis was rejected. The results are summarized in Table 3.

In order to determine if there were differences in the pain perceived ratio with both techniques across the four different treatments, Kruskal-Wallis test was applied, showing no statistically significant differences (p value $= 0.061$).

Table 1 Distribution of the teeth sample by groups

Patient	Group	Quadrant/Tooth	
		Conventional	Computerized
1	SRP	Right	Left
2	SRP	Left	Right
3	SRP	Left	Right
4	SRP	Left	Right
5	SRP	Right	Left
6	SRP	Right	Left
7	SRP	Right	Left
8	SRP	Left	Right
9	SRP	Left	Right
10	SRP	Right	Left
11	RT1	4.6	3.6
12	RT1	3.7	4.6
13	RT1	3.6	4.6
14	RT1	3.5	4.6
15	RT1	4.5	3.4
16	RT1	3.7	4.7
17	RT1	4.5	3.4
18	RT1	4.6	3.5
19	RT1	3.7	4.7
20	RT1	4.4	3.5
21	RT2	1.1	2.1
22	RT2	1.2	2.2
23	RT2	2.2	1.1
24	RT2	2.1	1.2
25	RT2	2.2	1.3
26	RT2	2.3	1.2
27	RT2	1.2	2.2
28	RT2	1.1	2.2
29	RT2	2.3	1.3
30	RT2	2.2	1.2
31	EXT	1.8	2.6
32	EXT	2.6	1.7
33	EXT	2.8	1.8
34	EXT	2.6	1.7
35	EXT	1.6	2.7
36	EXT	1.7	2.8
37	EXT	2.8	1.7
38	EXT	1.8	2.7
39	EXT	2.6	1.6
40	EXT	1.7	2.7

Regarding the pain felt by the patients during the treatment, 90% of the patients treated with conventional anesthesia did not feel pain compared with 92% of those who were treated with computerized anesthesia. Finally, 92.5% of the patients preferred the digital anesthesia system. The rest of the patients had no preference for one system over the other.

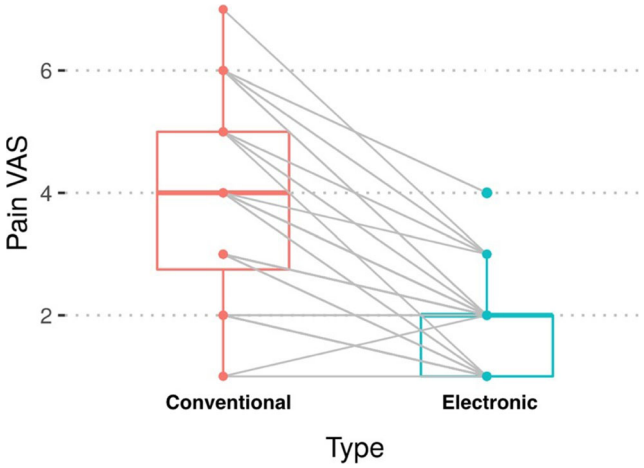

Fig. 1 Boxplot comparison of general perceived pain

Discussion

Reducing the pain of anesthesia is essential to minimize anxiety and fear, increasing patient confidence in professionals [18–20]. The aim of the present study was to compare conventional anesthesia with computerized controlled anesthesia performed with Calaject. From the obtained results, null hypothesis can be rejected. Statistically significant differences were obtained. Computerized controlled anesthesia group produced better results, both in the reduction of pain during the injection and improved effectiveness of anesthesia during treatment.

There is extensive scientific literature comparing traditional anesthesia versus computerized control injection systems, but the results must be assessed individually depending on the study design used, including injection locations and techniques applied. Assessment of pain is always very difficult

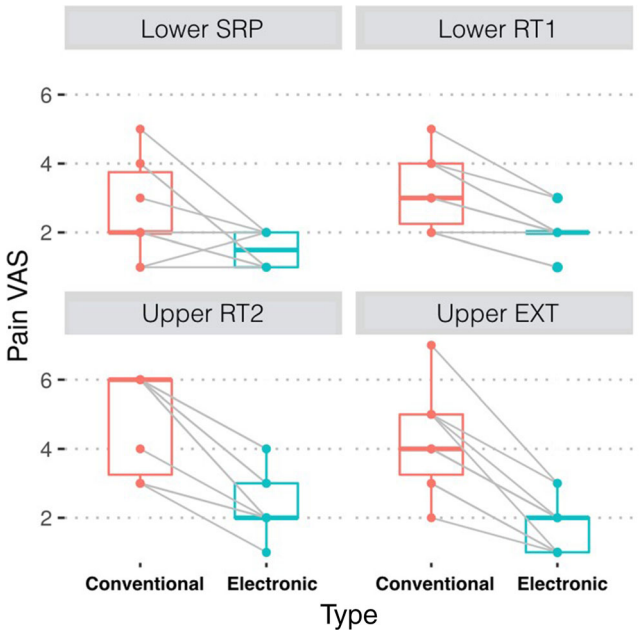

Fig. 2 Boxplot comparison of perceived pain by groups

Table 2 Mean and standard deviation of perceived pain

		Conventional		Computerized (Calaject)	
		Mean	SD	Mean	SD
General pain	$N = 40$	3.73	1.55	1.95	0.81
Lower molars (SRP)	$N = 10$	2.6	1.35	1.5	0.53
Lower molars (RT1)	$N = 10$	3.2	1.03	2.0	0.67
Upper incisors (RT2)	$N = 10$	4.9	1.45	2.5	0.97
Upper molars (EXT)	$N = 10$	4.2	1.40	1.8	0.79

to evaluate scientifically, as it is a subjective component, and it is influenced by many factors, such as anxiety, fear, and past experiences. There are many different methods to evaluate pain, but the "gold standard" is the self-report assessment [21]. We decided to use the visual analogue scale (VAS) method, since it is very easy to understand for the patient and also it seems to be the most reliable, sensitive, and comprehensible technique to assess pain from children of 8 years of age onwards [21, 22]. With the aim of increasing statistical power and avoid variability, a split-mouth design was adopted. This design allows the patients to be the case and the control simultaneously. Most studies that compare pain sensation after two different techniques of anesthesia use a split-mouth design [10, 12, 15, 18, 23–30]. Nevertheless, these designs might lead to some limitations, mainly that if the first stimulus causes much discomfort to the patient, then this could lead to an erroneous perception of the second stimulus, increasing or decreasing the real perception. In order to reduce possible errors, we randomized the procedures, performing the injections blindly and in two different appointments for the patient to have a clearance period.

At the statistical level, we decided to use the comparison of patient's ratio score. The reason being is that patients have different pain tolerance, here represented by the sum of the two scores given in total. When a test to the differences was applied, a p value together with an estimation of the magnitude of this difference was reported. For example, a difference of 2 points in VAS scale between both techniques is not very representative since some patients have scored 2 points in total, whereas some others have given 10. We considered an estimation of the ratio of the scores a more representative magnitude for the wide spectrum of patient's pain tolerance.

In general, articles that compared the computerized versus traditional anesthesia in adults showed beneficial results for the electronically controlled devices [10, 12, 14, 15, 18, 28–39]. Most papers focus on the study of the Wand system, as it was the first system released and therefore the most tested. These results are in concordance with our results, since we found significantly less pain with computerized controlled anesthesia for all anesthetic techniques studied.

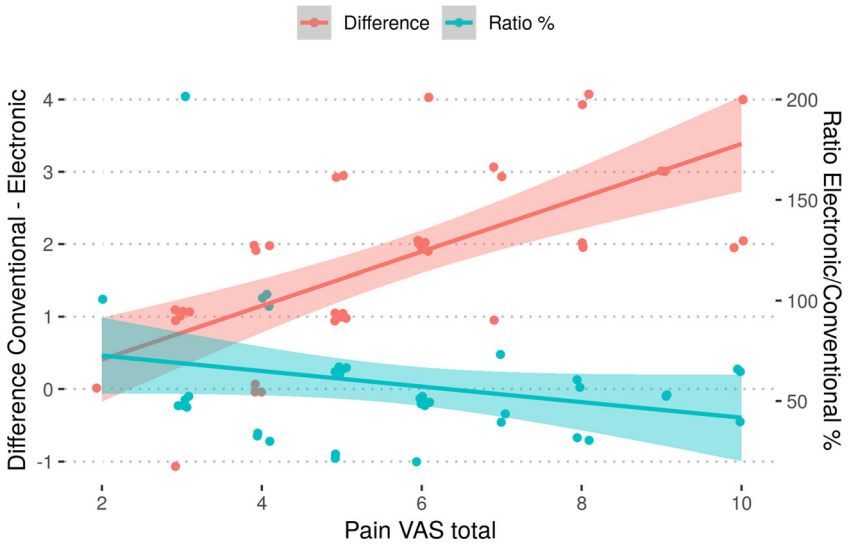

Fig. 3 Scatter plot of the patients difference (red) and ratio (blue) of scores versus the total score given. Jittering has been applied to avoid overplotting. The lines correspond to a linear regression applied to both sets, and the colored area represents the 95% confidence interval of the regression

According to our best knowledge, apart from this present study, there is only another one previous (Romero-Galvez et al.) [30] analyzation of the Calaject computerized system. In it, they found statistically significant differences between the two anesthesia procedures, evaluating by split-mouth the pain perceived by patients in the palatal area. This area is one of the most sensitive when anesthesia is applied, due to the nature of the tissue. Here, according to other studies, the electronic anesthesia systems have been shown to produce significantly less pain [13, 14, 32].

Similar results were found in the study of pain perceived in the inferior alveolar nerve block (IANB) [12, 29, 34, 36, 38]. Nussein et al. [13] and Kammerer et al. [34] divided the anesthetic procedure into two phases: insertion of the needle and infiltration of the solution. In the first phase, there were no significant differences between traditional and computerized anesthesia, but they reported less pain in the infiltration when they used the second method. These results are very consistent, since the device only controls the pressure and the rate of infiltration. Inserting the needle into the tissue is similar in both processes, as it is a manual process associated with the operator's manual skill.

Our study showed equal effectiveness of both anesthetic procedures, because most patients did not feel any pain during the corresponding treatments. Similar results were obtained by Al-Odaiba et al. [40], Campanella et al. [31], and Lee et al. [7]; all of whom reported that there was no difference in pain intensity experienced by conventional anesthesia and electronic anesthesia (Wand) during the restorative procedure. On the other hand, other authors found significant differences between the two anesthetic procedures, the computerized controlled anesthesia obtaining greater anesthetic depth [36, 38].

In general, electronic anesthesia systems have clear advantages in the adult population. On the contrary, when the study populations are children, the data are more inconsistent. There are many studies that do not find significant differences

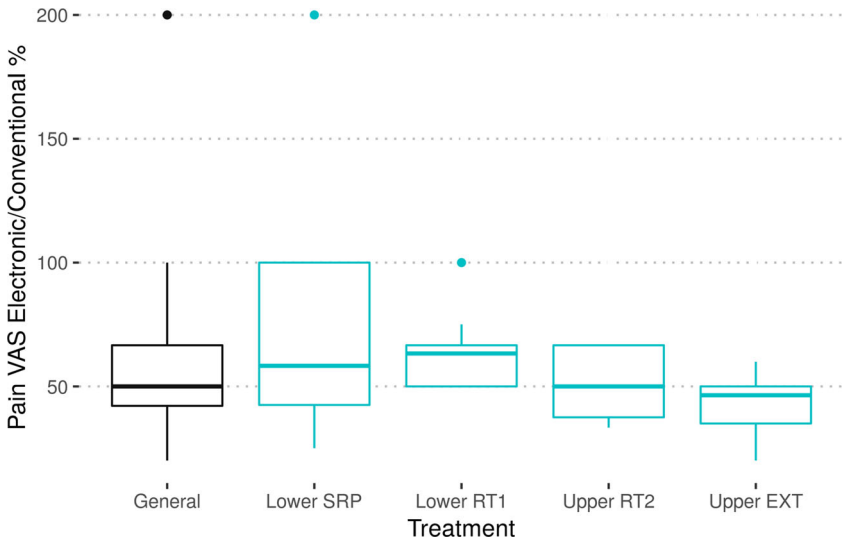

Fig. 4 Boxplots of the patients' scores ratio divided by treatment

Table 3 Statistical test applicated

	Mean	SD	Wilcoxon Test P Value
General Pain	58.45	30.59	< 0.05
Lower Molars (SRP)	75.67	52.75	0.27
Lower Molars (RT1)	63.50	15.76	< 0.05
Upper Incisors (RT2)	51.67	14.59	< 0.05
Upper Molars (EXT)	42.95	11.59	< 0.05

between the two methods of anesthesia, neither for perceived pain [26, 27, 41–44] nor for anxiety levels [41, 42]. Others find superior results for electronic anesthesia, but only in the pain perceived by the child [15, 24, 45–47], and significantly only in the palatal area [15, 48]. Patini et al. [49] reported better results for electronic anesthesia, both in pain and anxiety reported by the patient. Therefore, the results are less clear due to the fact that children are not completely objective with a self-assessment scale (VAS). Normally, the pediatric patient has greater fear of the dentist, needles, or simply the unknown. This is a main limitation in these studies. In addition, many studies use topical anesthesia, so the results should be taken with caution [50].

According to the results of this study, 92.5% of patients preferred anesthesia performed with a computerized controlled device, compared with conventional anesthesia. This preference and satisfaction were in agreement with the preceding studies done on computerized anesthesia delivery systems [40, 51, 52]. However, Grace et al. [53] claimed that traditional and computer-controlled anesthesia patients had equally good treatment experiences.

This study had limitations since only pain perception was measured. There are other factors that can be taken into account, such as anxiety and stress, since there are specific scales for this. Furthermore, the difference in latency time could also have been studied. Finally, this study could be carried out by comparing the Calaject system with another computerized anesthesia system. Therefore, new clinical studies are necessary to verify this computerized controlled anesthesia system.

Conclusions

Within the limitations of the present study, it can be concluded that computerized controlled anesthesia devices are a valid alternative to conventional anesthesia.

Calaject system produced significantly less pain compared with a conventional anesthesia syringe. These differences appeared in all the anesthesia techniques used: upper dental nerve, posterior palatal nerve, and the inferior alveolar nerve block (IANB).

Although both anesthesia systems (computerized and conventional) obtained sufficient anesthetic depth to perform the necessary treatments, the majority of patients chose electronic anesthesia as the most satisfactory.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

The permission note is enclosed with the authors' signatures.

Ethical approval All procedures performed in the present study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

The present study has the approval of the ethical committee of the "Hospital Clínico San Carlos" with the number (18/429-O_P).

Informed consent Informed consent was obtained from all individual participants included in the present study. They were informed verbally and in writing of the advantages and disadvantages of participating in the study.

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