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ORIGINAL RESEARCH

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Comparison of computer controlled local anesthetic delivery and traditional injection regarding disruptive behaviour, pain, anxiety and biochemical parameters: a randomized controlled trial

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Abstract

The study herein evaluated the effects of infiltrative anesthesia administered *via* different ways. Resultantly, the pain and anxiety were monitored using psychometric, physiological and biochemical methods. Sixty children aged 7–11 years (8.73 $\pm$ 1.38) were included in the study. They were divided into 2 groups (n = 30): Traditional injection (control group), and computer controlled local analgesic delivery (CCLAD) (study group). Pulse, oxygen saturation (SpO_2), and salivary cortisol levels were recorded, and the scales data (Visual Analogue Scale (VAS), Wong-Baker Faces Rating Pain Scale (WBS), Modified Child Dental Anxiety Scale (MCDAS) and Face, Leg, Activity, Cry, Consolability Behavioral Pain Assessment Scale (FLACC)) were evaluated. The data were statistically analyzed. Age and gender had not much impact on the measured parameters ($p > 0.05$). SpO_2 values in both groups were not significantly different ($p > 0.05$). Pulse, VAS, WBS, MCDAS, FLACC and salivary cortisol values were increased after the anesthesia in control group ($p < 0.05$). WBS, MCDAS, FLACC and salivary cortisol values were decreased after the anesthesia in study group compared to the control ($p < 0.05$). It was inferred that computer controlled local analgesic delivery system could be preferred in pediatric patients because of reduced pain and anxiety.

Keywords

Anxiety; Dental anesthesia; Pain; Pediatric dentistry

1. Introduction

Anxiety is a complex behaviour pattern in the patients before or during dental treatment and is linked to the external and internal stimuli [1]. Anxiety is often associated to the painful stimulus. It may also increase the pain perception. The common anxiety-inducing factors in dental fear are dental needle phobia, lying in the dentist's chair, noises from high-vibration devices, pain during dental treatment, and the smell of materials or drugs used in the mouth [2]. The painful dental treatment experience, especially in pediatric patients, is the major cause of cooperation disorders and anxiety. In recent years, various computer-controlled dental anesthesia systems have been introduced to reduce the pain felt during dental anesthesia in dentistry [3]. CCLAD® (Milestone Scientific, Livingston, NJ, USA) was the first computer-controlled device introduced in mid-1990s. WAND® and the later versions of WAND PLUS® (Milestone Scientific, Livingston, NJ, USA) were also released. Dentsply introduced the Comfort Control Syringe® in 2001 (Midwest Dentsply, Des Plaines, IL, CCS). Quick Sleeper® and Sleeper One® (Dental Hi Tec, Cholet, France) are the currently released computer-controlled local anesthetic delivery devices [4]. Sleeper One® overcomes the shortcomings of traditional dental needles. It is a CCLAD system which provides precise injection flow rate and is independent of tissue resistance. The system maintains a constant positive pressure on the anesthetic solution flow. It is claimed that the anesthetic solution numbs the tissue in front of needle while penetration into bone occurs, thus providing a painless needle insertion. This is suggested for nerve block, infiltration anesthesia, intraosseous and intraligamentary injections. There are hand pieces and needle tips (9-12-16 mm) made in a special pen-like structure. The foot pedal provides convenience of aspiration, slow and fast injections. The slow burst mode is employed until the gingival anesthesia is completed. After soft tissue anesthesia, the anesthetic solution is completely injected by continuously pressing the pedal. Special needles (DHT, Intralig-S cartridge needle) have easier mucosal entry and painless penetration because of the same cutting feature of scalpel tip. The unique needles curved structure allows solution penetration by incising the tissue without tearing [5, 6].

Dental anxiety is evaluated through projective tests, psychometric techniques and physiological measurements. The techniques and scales used in pain diagnosis consider the

cognitive and social development, and experiential differences of children [7].

This study compares the pain and anxiety of patients experiencing traditional infiltration procedures or CCLAD. There are limited studies in literature investigating this topic [8, 9]. The cortisol being a physiological stress marker is measured as the unique aspect of this study. The study null hypothesis is that the different anesthesia techniques will have similar effects on pain and anxiety regarding all the measured parameters.

2. Materials and methods

2.1 Study population and design

The Consolidated Standards of Reporting Trials (CONSORT) statement was followed to design and report the current randomized clinical trial (RCT) (Fig. 1) [10]. The clinical procedures were executed according to the Declaration of Helsinki and good clinical practice guidelines. The anesthesia methods being employed and the complications might arise were stated in the child consent form. It was not mentioned which anesthesia method could be applied; however, both were explained. Moreover, it was explained that no stimulant would be used for taking saliva samples. Participants giving consent to these documents were included in the study.

Patients included in the study had active upper primary molar and the first permanent molar dental caries, not exceeding 1/3 of the dentin, not reaching the pulp, and no acute pain history. Periapical films (Kerr® Super-Bite X-ray, Kloten, Switzerland) were taken for the caries depth using radiographic film holder. Images were standardized according to the patient age with 0.8 s irradiation time (Planmeca Pro-x®, Helsinki, Finland), operated at 70 kv and 10 mA. Patients having congenital, acquired or systemic disease, previous dental treatment, acute infection and allergy to local anesthesia were excluded from the study.

Sixty patients were included using Win Epi 2.0 program (Agricultural University, Wageningen, Netherland) for power analysis with 95% confidence interval, 80% power and 5% significance level. Seventy-two patients were assessed for the study. Twelve were excluded because of not meeting the inclusion criteria. Participants included 32 girls and 28 boys aged 7 to 11 years. Computer generated the blocked randomization and was evenly distributed over the two groups. Codes were placed in invisible envelopes before the processing. The practitioner was blinded till administering anesthesia and also achieved allocation concealment. Sleeper One® (Dental Hitec, France) device training was given by Surmeli Dental Company (Istanbul, Turkey). The examiner took practical course on phantom jaws. The device was purchased and used for the first time in this study, and the calibration settings were made by Surmeli Dental® (Turkey).

The measurements taken before, during and after anesthesia performed in this study are shown in Fig. 2. The patients were divided randomly into 2 groups (n = 30). Control Group: Local infiltration anesthesia administered *via* the traditional injection; Study Group: CCLAD (Sleeper One®, Dental Hitec, France). A single physician ran the applications in a single-unit room where one anesthesia type was administered to each patient. The tell-show-do technique was employed in all participants. 10% Locanest™ lidocaine spray (Avixa Pharmaceutical Industry, Turkey) squeezed cotton pellets were placed for 60 s to the area. Conventional infiltrative anesthesia (Genject Brand Syringe (30G1, Genject Health Products, Turkey) + Ultracaine™ D-S forte ampule (Avixa Pharmaceutical Industry, Turkey)) was administered to the control group patients. Bone contact was taken by entering the stretched mucosa. The needle tip was withdrawn by 1 mm and 1.5–2 mL solution was injected into the tissue after aspiration. The infiltrative anesthesia was administered in the study group using the Sleeper One needle tip (Intralig-S 16 mm long and 30-gauge diameter) and Ultracaine™ D-S forte cartridge system. The device was programmed for the continuous slow mode. It was provided with over 1.8 mL by a server in every 2 s. The cavity was restored with Compoglass® compomer material (Ivoclar Vivadent, Schaan, Liechtenstein) after caries removal.

2.1.1 Assesment

The VAS (Visual Analogue Scale), WBS (Wong-Baker Faces Rating Pain Scale), and MCDAS (Modified Child Dental Anxiety Scale) scales were measured. The saliva was collected by the same rater (OA). Another evaluator recorded the physiological parameters (pulse and SpO_2) (GK). The videos recorded during anesthesia were analyzed by both investigators (OA, GK) for determining the destructive behavior index (FLACC).

2.1.2 Blinding

Blinding the practitioner and the patient was not possible regarding the device usage. However, blinding was achieved in the statistical evaluation while analysing the data.

2.2 Pulse and oxygen saturation measurements

Stress can increase the pulse and decrease the oxygen saturation due to increased oxygen consumption. Pulse and oxygen saturation measurements were employed as an anxiety indicator. The results could be obtained in short time for the physiological parameters [11] *via* Finger pulse oximetry (Contec Medical Systems, Qinhuangdao, China). Pulse and SpO_2 (oxygen saturation) values were recorded in triplicate from the right index finger; before (P1, SpO_2 1), during anesthesia (P2, SpO_2 2) and after (P3, SpO_2 3).

2.3 Pain and anxiety assessment scales

VAS (Visual Analogue Scale) and WBS (Wong-Baker Faces Rating Pain Scale) scales assessed the participants pain levels. The VAS values from 0 to 10 (0 no pain, 10 excruciating pain) were used to evaluate the patient's pain during (VAS 1) and after anesthesia (VAS 2) [12]. The patients were told about the scale, and asked to choose the number (line) representing pain level from the scale. The WBS scale had a series of six faces, from happy face at 0 indicating "no hurt", to a crying face at 10 symbolising "hurts worst" [13]. WBS was marked as the sequence of anesthesia before (WBS 1) and after (WBS 2). Both numerical (VAS) and visual (WBS) evaluations were made.

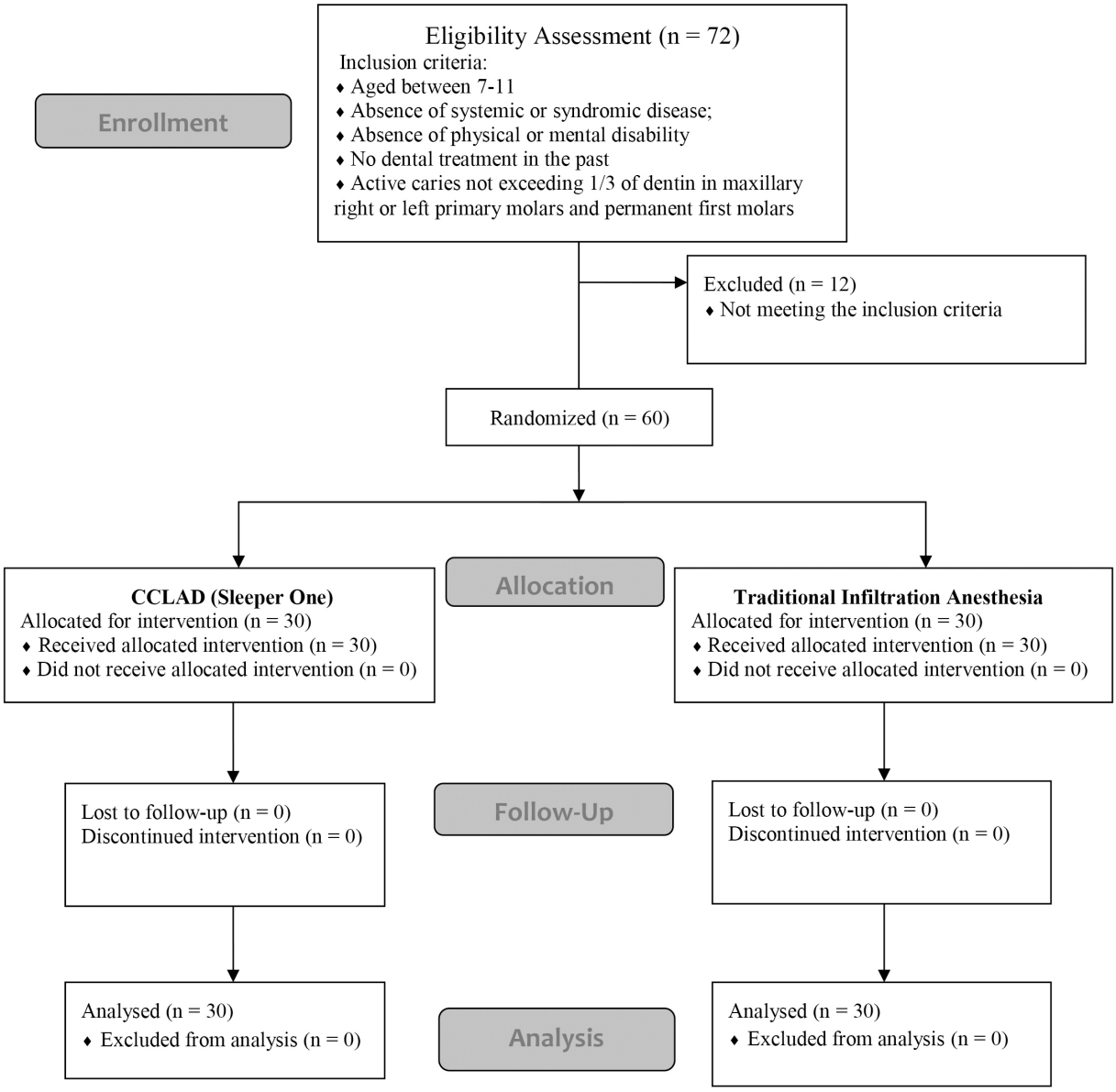

FIGURE 1. CONSORT flow diagram of the study. CCLAD: computer controlled local analgesic delivery.

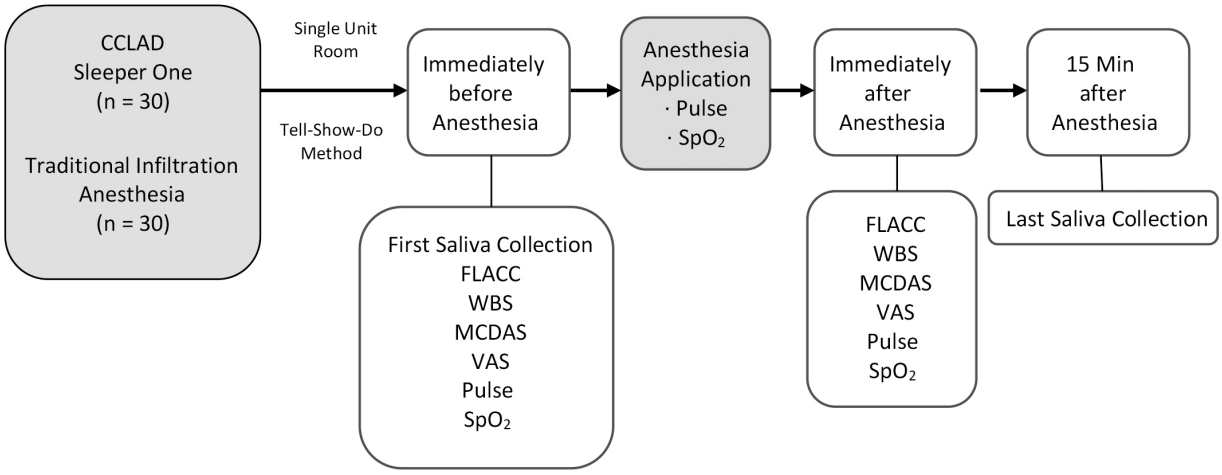

FIGURE 2. Flow diagram of different study phases. *Visual Analogue Scale (VAS); Wong-Baker Faces Rating Pain Scale (WBS); Modified Child Dental Anxiety Scale (MCDAS); Face, Leg, Activity, Cry, Consolability Behavioral Pain Assessment Scale (FLACC); computer controlled local analgesic delivery (CCLAD).

The MCDAS (Modified Child Dental Anxiety Scale) and FLACC (Face, Leg, Activity, Cry, Consolability Behavioral Pain Assessment Scale) scales evaluated the anxiety levels and patients fear. MCDAS consisted of 8 questions having both visual and numerical expressions. The MCDAS efficacy was accepted as a psychometric scale. It assessed the anxiety of children being afraid of certain dental procedure steps, such as local anesthesia, extraction, sedation and general anesthesia [14]. MCDAS values before (MCDAS 1), and after anesthesia (MCDAS 2) were calculated between 8 and 40 pertaining to this study. The FLACC scale included five categories: Face, Legs, Activity, Crying and Consolability. In this study, the facial expressions before (FLACC 1) and after anesthesia (FLACC 2) were marked on the scale. The results were classified as per the obtained scores: score 0 considered the patient as relaxed and comfortable, scores 1 to 3 as mild discomfort, scores 4 to 6 as moderate pain and 7 to 10 as severe pain [15].

2.4 Salivary cortisol measurements

The organism's stress response occurs in two ways. One is the sympathetic adreno-medullary system, and other is hypothalamic-pituitary-adrenal axis (HPA). The cortisol is secreted as a result of HPA activity and organism fights against stress. Cortisol thus has a role in behavioral and neuroendocrine responses towards stress. The salivary cortisol increases at the same rate as that of in plasma [16]. Cortisol was evaluated as a biochemical parameter in this study as it was secreted in response to the earliest stages of stress. The patient's dental procedures were performed at 08:30 as cortisol levels were higher in the morning hours. The teeth were brushed, patients were asked to rinse mouths with water, and spit into the saliva collection cup 15 min before applying anesthesia. Water was employed as a rinse solution to prevent hormone levels getting affected by anesthesia or chemicals in the mouth. Measurements were made using unstimulated saliva obtained without the stimulants usage such as paraffin. After anesthesia, the patient's mouth was rinsed with water and waited for 15 min. The collected unstimulated saliva was centrifuged at 5000 rpm for 10 min, transferred to Eppendorf tubes and stored at −20 °C. Saliva cortisol measurement was made using ELISA® kits (batch number, Catalog No: E1003Hu Salivary Cortisol Kit, BT LAB, Shangai, China).

2.5 Statistical analysis

SPSS (Statistical Package for Social Sciences, version 22.0, Chicago, IL, USA) program was utilised to analyse the data obtained in this study. The numerical variables of descriptive statistics of the data are given as mean and standard deviation, while categorical variables are depicted by the frequency and percentage analysis. Pulse, SpO_2, VAS, FLACC, MCDAS and salivary cortisol levels were examined with the Shapiro Wilk test, and the normal distribution test. It was found that the variables did not conform to the normal distribution ($p < 0.05$). The pulse and SpO_2 values were recorded in triplicate, and the statistical significance was set at 2% ($p < 0.02$) using the Bonferroni correction. Multiple comparison test was not performed as there was no difference in the cases ($p > 0.02$). Wilcoxon and Friedman tests were used in analysing these variables to compare the measurements obtained at different times in intra-group comparisons. Dunn's test was employed after the Friedman test. The Mann-Whitney U test compared the variables between control and study groups. The differences between categorical variables were analysed through Chi-square test. Spearman correlation analysis examined the correlations between variables. The significance level of $p < 0.05$ was used in the performed tests.

3. Results

53.3% patients in the study were females, 46.7% males and the mean age was 8.73 ± 1.38. There was no difference between the control and study groups regarding age and gender.

In the control and study groups, there was significant difference between the pulse values at different measurement times ($p < 0.05$). P3 was higher in the control than in study group ($p < 0.05$). P1 values were lower than P2 and P3 in the control group. No difference was found between P2 and P3 values in the control group ($p > 0.05$). P2 values were higher than P1 in study group ($p < 0.05$). No difference found between P1–P3 and P2–P3 values in study group ($p > 0.05$) (Table 1). SpO_2 values had no difference at different measurement times in control and study groups ($p > 0.05$). SpO_2 3 values were higher in the control than in study group ($p < 0.05$; Table 2).

In control group, there was difference between the first and last measurements of VAS, FLACC and MCDAS values ($p < 0.05$). There was difference between the first and last measurements of FLACC, and MCDAS values in study group ($p < 0.05$). No difference was found between the VAS 1 values of control and study groups ($p > 0.05$; Table 3). However, VAS 2 values were higher in the control than in study group ($p < 0.05$).

There was difference between the MCDAS values of both the groups ($p < 0.05$). MCDAS 1 values were lower in the control than in study group. MCDAS 2 values of the study group were lower than MCDAS 2 values of control ($p < 0.05$). There was significant difference between FLACC values of the groups ($p < 0.05$). FLACC 1 values were lower in the control than in study group. FLACC 2 values were lower in the study group than in control ($p < 0.05$) (Table 4).

In the control group, WBS 1 results; six of thirty patients reported "no pain", seventeen "very little pain", six "little pain" and one "significant pain". "Serious pain" and "unbearable pain" were not reported. WBS 2 results; one of thirty patients reported "no pain", one "very little pain", twelve "little pain", eleven "significant pain", three "severe pain" and two "unbearable pain". In the study group, WBS 1 results; fourteen of thirty patients reported "very little pain", thirteen "little pain" and three "significant pain". "No pain", "severe pain" and "unbearable pain" were not reported. WBS 2 results; four of sixty patients reported "no pain", seventeen "very little pain", six "little pain" and three "significant pain". No patients in the study group answered "severe pain" and "unbearable pain", and thus not scored.

There was a difference between the first and last measurements of cortisol (C) values in the control and study groups (p

TABLE 1. Patients' characteristics.

		Control Group	Study Group	*p*	Effect size
Gender n (%)					
	Girls	17 (56.67%)	15 (50%)	0.605	0.141
	Boys	13 (43.33%)	15 (50%)		
Age (Mean ± SD)		8.73 ± 1.36	8.73 ± 1.41	1.000	0.000

SD: Standard deviation.

TABLE 2. Pulse values analysis.

	Control Group		Study Group		*p*	Effect size
	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)		
P1	95.60 ± 5.51 (93.54–97.66)	96 (93–98)	97.37 ± 1.73 (96.72–98.01)	98 (96–98)	0.051	0.433
P2	100.63 ± 5.96 (98.41–102.86)	100 (96.75–105)	98.77 ± 1.77 (98.10–99.43)	98 (98–100)	0.344	0.423
P3	101.77 ± 8.09 (98.74–104.79)	100 (98–102)	97.97 ± 1.87 (92.27–98.66)	98 (96.75–100)	0.009*	0.647
Effect size	0.354		0.276			

**significant difference (p < 0.05, Mann-Whitney U test); P1: Pulse before anesthesia; P2: Pulse in anesthesia sequence; P3: Pulse after anesthesia; SD: Standard deviation; CL: Confidence limit.*

TABLE 3. Analysis of oxygen saturation values.

	Control Group		Study Group		*p*	Effect size
	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)		
SpO_2 1	97.77 ± 1.17 (97.33–98.20)	98 (98–98)	97.37 ± 1 (96.99–97.74)	98 (96–98)	0.168	0.367
SpO_2 2	98.13 ± 1.25 (97.67–98.60)	98 (98–98)	97.77 ± 1.04 (97.38–98.16)	98 (97–98)	0.099	0.313
SpO_2 3	98.50 ± 1.07 (98.10–98.90)	98 (98–100)	97.60 ± 0.93 (97.25–97.95)	98 (97–98)	0.002*	0.897
Effect size	0.109		0.061			

**significant difference (p < 0.05, Mann-Whitney U test); SpO_2 1: Oxygen saturation before anesthesia; SpO_2 2: Oxygen saturation in anesthesia sequence; SpO_2 3: Oxygen saturation after anesthesia; SD: Standard deviation; CL: Confidence limit.*

TABLE 4. Analysis of VAS, FLACC and MCDAS values.

	Control Group		Study Group		*p*	Effect Size
	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)		
VAS 1	2.07 ± 1.64 (1.45–2.68)	2 (0–5)	2.80 ± 1.45 (2.26–3.34)	3 (0–5)	0.062	0.471
VAS 2	5.20 ± 2.01 (4.45–5.95)	5 (0–10)	2.43 ± 1.59 (1.84–3.03)	2 (0–6)	0.001*	1.528
FLACC 1	1.17 ± 1.78 (0.5–1.83)	0 (0–6)	2.33 ± 2.43 (1.43–3.24)	2 (0–10)	0.019*	0.544
FLACC 2	5.27 ± 2.89 (4.19–6.35)	5 (1–10)	1.40 ± 1.85 (0.71–2.09)	1 (0–6)	0.001*	1.594
MCDAS 1	17.43 ± 4.08 (15.91–18.96)	18 (10–27)	21.90 ± 4.89 (20.08–23.72)	22 (15–33)	0.001*	0.992
MCDAS 2	22.40 ± 4.62 (20.67–24.13)	22 (11–32)	18.67 ± 5.14 (16.75–20.59)	18 (10–30)	0.003*	0.763

**significant difference (p < 0.05, Mann-Whitney U test); VAS 1: VAS score before anesthesia; VAS 2: VAS score after anesthesia; FLACC 1: Flacc score before anesthesia; FLACC 2: FLACC score after anesthesia; MCDAS 1: MCDAS score before anesthesia; MCDAS 2: MCDAS score after anesthesia; SD: Standard deviation; CL: Confidence limit.*

TABLE 5. Analysis of salivary cortisol values.

	Control Group		Study Group		*p*	Effect Size
	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)	Mean ± SD (95% Lower-Upper CL for Mean)	Median (Q1–Q3)		
C1	36.32 ± 13.14 (31.41–41.23)	35.15 (11.15–71.23)	37.92 ± 14.36 (32.55–43.28)	34.82 (18.63–69.67)	0.767	0.116
C2	51.15 ± 20.61 (43.46–58.85)	47.8 (24.91–96.79)	28.75 ± 8.82 (25.46–32.04)	30.16 (9.80–47.49)	0.001*	1.413

**significant difference ($p < 0.05$, Mann-Whitney U test); C1: Cortisol value before anesthesia; C2: Cortisol value after anesthesia; SD: Standard deviation; CL: Confidence limit.*

TABLE 6. Correlation analyses of VAS, FLACC, MCDAS, and C values after anesthesia.

Correlation (r)	VAS 2	FLACC 2	MCDAS 2	C2
VAS 2	1.000	0.788*	0.775*	0.458*
FLACC 2	0.788*	1.000	0.720*	0.345*
MCDAS 2	0.775*	0.720*	1.000	0.292*
C2	0.458*	0.345*	0.292*	1.000

**significant difference ($p < 0.05$, Spearman correlation analysis); ($0 < r < 0.2$, very low association); ($0.2 < r < 0.4$, low association); ($0.4 < r < 0.6$, medium association); ($0.6 < r < 0.8$, high association); VAS 2: VAS score after anesthesia; FLACC 2: FLACC score after anesthesia; MCDAS 2: MCDAS score after anesthesia; C2: Cortisol value after anesthesia.*

< 0.05). No difference found between the C1 values of control and study groups ($p > 0.05$). However, C2 values were higher in the control than in study group ($p < 0.05$; Table 5).

VAS, FLACC, MCDAS and cortisol values were positively correlated with each other after anesthesia. The highly positive correlations were found between VAS 2 and FLACC 2; VAS 2 and MCDAS 2; and MCDAS 2 and FLACC 2 values. A moderately positive correlation existed between VAS 2 and C2 values. A low degree of positive correlation was found between FLACC 2 and C2; and MCDAS 2 and C2 values (Table 6). Moreover, the gender and age had no significant effect on pain and anxiety ($p > 0.05$).

4. Discussion

Injections are the uncomfortable and painful procedures for patients. The scientists conduct research on techniques and devices for enhancing its acceptability. Sleeper One (Dental Hi-tec, France) is a computer-controlled device with advantages such as ease of use, less intimidating physical appearance of needle, no pressure needed throughout the injection, and guiding the injection site entry points.

Pain was assessed using VAS and WBS. Anxiety and behavior assessments were made *via* MCDAS and FLACC. The salivary cortisol levels were recorded for biochemical evaluation. Blood pressure and SpO_2 were employed for the physiological evaluations. This study compared the traditional dental injector and the Sleeper One® device. It was found that WBS, MCDAS, FLACC and salivary cortisol values decreased after anesthesia in the study group compared to control. In the study group, pulse values increased during the procedure and no significant difference was noticed in the VAS values. There was increase in pulse, VAS, WBS, MCDAS, FLACC and salivary cortisol values after anesthesia in the control group. No significant difference was obtained in SPO_2 values of both groups. Moreover, the age and gender had no significant effect on measured parameters. Yahyaoglu *et al.* [9] and Kuscu *et al.* [17] reported that pain and anxiety in dentistry were not related to gender. According to the results, the study null hypothesis was partially accepted.

In this study, an increase was observed in the pulse values of the patients after anesthesia with both techniques. However, no significant difference was indicated in the SpO_2 values. This might be linked to the possibility that recorded SpO_2 values were reflected on pulse oximeter screen later than the pulse values. This was one of the limitations of our study. Thoppedhamodhara *et al.* [18] reported changes in the pulse values after infiltrative anesthesia or nerve-blocking procedures through epinephrine solutions. Özer *et al.* [19] found pulse increase in the patients where infiltrative, intraosseous and mandibular anesthesia was applied. Goyal *et al.* [20] compared Wand and traditional anesthesia techniques for the teeth with extraction indications in 15 pediatric patients in India. It was reported that the pulse and SpO_2 values were similar between the groups. Smolarek *et al.* [21] compared the three anesthesia techniques; no difference was found between the groups pertaining to pulse, respiratory rate and SpO_2. In this study, no significant difference was indicated in the pulse and SPO_2 values for the two groups before and during anesthesia. However, lower pulse and SPO_2 values were obtained after anesthesia in the study group compared to control.

In this study, the VAS values after anesthesia were lower in the study group than in control. There were studies in literature that supported this result. Topaloglu Ak *et al.* [3], Mittal *et al.* [5] and Patil *et al.* [22] reported lower VAS values for the Sleeper One® and Wand® groups where they applied computer-controlled local anesthesia device and traditional injection infiltrative anesthesia. Sixou *et al.* [23] revealed that computer-controlled intraosseous anesthesia (QuickSleeper™ Dental Hi-tec, Cholet, France) was less painful than traditional

infiltration method. Tahmassebi *et al.* [24] and Shah *et al.* [25] employed the Wand, and reported similar Vas values in Wand group compared to the conventional injection group.

In this study, the WBS values obtained after anesthesia were lower in the study group than in control. Similar to the outcomes of this study, Thoppe-Dhamodhara *et al.* [18] and Garret-Bernardin *et al.* [26] reported that computer-assisted anesthesia methods caused lesser pain than the traditional methods. Smolarek *et al.* [21] compared the traditional methods, vibration-assisted traditional methods (DentalVibe®, Columbia Tech, Boston, USA), and computer-controlled anesthesia technique, Morpheus™ (Meibach Tech, São Paulo, Brazil). The lowest WBS values were obtained from the group wherein the traditional method was applied. The pain difference was related to the patient's age, cooperation level of patients participating in the study, technical sensitivity of applied method, or the dexterity of practitioner.

In previous studies, the employed scales and reported results were heterogeneous when anxiety levels of computer-controlled anesthesia and the traditional method were compared. In this study, anxiety caused by anesthesia techniques was measured using MCDAS. Similar to this study, Patini *et al.* [27] suggested that CCLAD reduced destructive behaviors in young children who were difficult to cooperate compared to the traditional method and created a positive experience for both the patient and physician.

Similarly, Thoppe-dhamodhara *et al.* [18] and Ucar *et al.* [15] reported lower FLACC values in the group anesthetized with Wand®, and low level of laser therapy on injection compared to the traditional method.

In literature, limited studies were found wherein the stress caused by anesthesia techniques was measured by cortisol. It had been reported that free cortisol in plasma could also be observed in saliva within 10–20 min after a stress is encountered. Cortisol levels increased in 40% patients anesthetized with traditional injector method and in 45% patients administered *via* computer-assisted anesthesia [8]. In this study, higher salivary cortisol values were recorded in the control group after anesthesia compared to study group.

The pain and anxiety are subjective and hence affected by the past experiences and sociocultural conditions. The patient and his/her family approach before and during the initiation of treatment hinders in standardizing the pain and anxiety. The crowded environment of hospital, the attitudes and behaviors of other children in waiting area may affect patients' behavior. It is the limitation of not only this study but also of other studies investigating pain and anxiety. The patients are therefore treated in single-unit rooms to minimise the impact of environmental factors. Moreover, increasing the number of scales is another measure. More comprehensive randomized controlled studies can be recommended for efficacy evaluation wherein various brands and devices are compared. More conducive information can thus be obtained pertaining to the efficiency of these systems and reliability of the results. Measures such as preventing variations between physicians and standardizing anesthesia techniques may increase the results reliance. Further studies must be conducted to incorporate current anesthetic techniques into routine dental practice and to support these findings.

5. Conclusions

Keep in view the data obtained from this study, it was concluded that the computerized anesthesia techniques have positive impact on pain and anxiety, and it brings changes in physiological and biochemical parameters. Computer-controlled anesthesia device can be recommended for pediatric patients as it reduces the pain and anxiety. The difference in pain caused by anesthesia techniques may be linked to the patient's age, cooperation of patients participating in the study, technical sensitivity of the applied method or the dexterity of practitioner. Evidence-based studies evaluating the psychological and physiological effects in large populations can minimize the pain and fear in pediatric patients regarding the dentist. Better recommendations can be in place to support the method efficacy and safety.

AVAILABILITY OF DATA AND MATERIALS

Medical and dental history, clinical data and associated dataset generated and/or analyzed for this study cannot be made publicly available as required consent to publish data were not given. However, the corresponding author can make de-identified data available on reasonable request.

AUTHOR CONTRIBUTIONS

All authors had full access to the data associated with this study and took full responsibility for the data integrity and accuracy. All authors contributed to the editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This randomized controlled prospective study protocol was approved by the Gaziantep University Clinical Research Ethics Committee (15 September 2021; 2021/219). All procedures performed in the studies involving human participants were in accordance with the tenets of the Declaration of Helsinki. All the study activities, benefits/risks of voluntary participation, and withdrawal from the study were verbally communicated to parents/guardians. Questions were asked to confirm that they understood the study. The written informed consent form was obtained from the participating children and their parents to participate in the study and publication of the results.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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