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Effect of Sleeper One® 5 anesthesia device on heart rate

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Abstract

Aim: This study compares the pulse parameter values before, during, and after anesthesia using computer-assisted local infiltration anesthesia and traditional local infiltration anesthesia methods in children.

Materials and Methods: The study included 100 children aged 7-11 who applied to the pediatric dentistry clinic. During the initial session, the children underwent intraoral examinations. The children were divided into two groups randomly. Traditional local infiltration and computer-assisted local anesthesia were applied to treat dentin caries in the maxillary primary molar teeth. The heart rate of the patients was measured using a pulse oximeter device.

Results: The average age of the patients was 8.21±1.00 years, with 48 (48.0%) male and 52 (52.0%) female. The average heart rate (HR) was found to be 99.28±14.68. At the end of the study, 61 (61.0%) of the patients preferred the computer-assisted anesthesia method, and 39 (39.0%) preferred the traditional method. A notable distinction exists between the pre- and post-anaesthesia heart rate values associated with each anesthesia technique, indicating significant variations when comparing different methods of anesthesia ($p<0.001$). No significant differences were observed between the two methodologies across all measured values ($p>0.05$).

Conclusion: Although there was no significant difference in heart rate parameters, 61% of the patients preferred the computer-controlled local anesthesia method, which showed effectiveness in reducing anxiety. Further studies are required to confirm these results using modern local anesthesia devices.

Introduction

Dental anxiety and fear of dental treatment in children is a global public health problem that leads to neglect of dental care in many countries [1]. In studies conducted in various countries, the prevalence of childhood dental anxiety in Turkey ranges between 21.3% and 23.5% [2]. It has been reported that the percentage varies between 2.5% and 20% in other countries [3]. It is common for dental treatments that involve procedures such as local anesthesia applications to elicit fear and anxiety in patients. The resulting physiological reactions can make the experience even more unpleasant. That is why dental professionals must prioritize patient comfort and well-being. By addressing dental fear and anxiety, such as sedation or other relaxation techniques, dental professionals can help patients feel more at ease and improve their overall experience [4]. Local anesthesia is frequently used in dentistry to prevent pain, but it can cause anxiety and fear in pediatric patients, making it difficult to manage their behavior [5]. During local infiltration anesthesia, using long needles, venting the syringe visibly, and administering inappropriate doses of anesthetics can trigger anxiety and fear of pain in children [6]. Several methods have been proposed to alleviate pain during injections, including topical anesthetics, warming the anesthetic solution to body temperature, and extending the injection time [7].

Local anesthesia devices have gained popularity in recent years. Various systems for administering local anesthesia include computer-aided applications, electronic dental anesthesia, intraoral lidocaine tape, jet injectors, and vibration devices [8]. Computer-controlled local anesthesia application systems are devices designed to reduce pain and anxiety. Excessive pressure and rapid injection of

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anesthetic solution cause pain during injection [9]. In computer-controlled anesthesia systems, an injection is administered gradually and at a speed controlled, eliminating the need for pressure. This device makes dental anesthesia more comfortable and painless for patients and pediatric dentists [10,11].

Sleeper One® 5 (DHT, Cholet, France) is a lightweight handpiece with an easy-to-grip design, wireless foot pedal, and control unit. It has a resistance analysis system that regulates the injection according to tissue density, and the foot pedal controls the injection speed. The device's hand unit allows for monitoring the amount of solution applied and the resistance to the solution, featuring three pre-programmed injection rates. The most important feature of Sleeper One® 5 is its double-curved needle, which makes it easier to penetrate bone (Figure 1) [12].

Figure 1. Sleeper One® 5 anesthesia device.

This study aims to evaluate using heart rate as a parameter for selecting anesthesia in children and detecting dental anxiety and fear. The study will compare the effectiveness of infiltrative anesthesia using classical dental syringes versus the Sleeper One® 5 anesthesia device. The study's null hypothesis is that there is no difference between patients' heart rate measurements during buccal infiltration anesthesia performed with the traditional technique and the Sleeper One® 5 device.

Materials and Methods

The study received approval from the Afyonkarahisar Health Sciences University Clinical Research Ethics Committee (decision numbered 2021/85) and the Ministry of Health Turkey Pharmaceuticals and Medical Devices Agency (decision numbered E-68869993-511.06-365560). All patients included in the study were treated according to the ethical principles of the Declaration of Helsinki. The study has been presented according to CONSORT guidelines for reporting trials.

Sample size determination

Patient groups were selected based on specified criteria from applicants to the pediatric dentistry department clinic between October 2021 and May 2022. The analysis for this study was conducted using the G*Power 3.1 software [13]. Drawing on power analyses from analogous research, the minimum sample size was established at 88 patients, ensuring a 95% confidence interval with an achieved power of 80%. After detailed anamnesis and clinical and radiographic examinations, 100 patients (48 boys and 52 girls) were deemed appropriate for inclusion in the study.

Study population

A total of 100 patients, 48 (48.0%) males and 52 (52.0%) females, aged between 7 and 11, participated in the study voluntarily. The patients were randomly divided into two groups based on their preference for green or yellow.

The inclusion criteria

Individuals included in the study:

- Systemically healthy
- Score 3 or 4 on the Frankl scale, [14]
- Have caries in their upper jaw primary molars that have not reached the pulp and require treatment.

The exclusion criteria

Individuals excluded in the study:

- Who had a systemic disease,
- Children who were allergic to the anesthetic agent that would be used,
- Children who had an acute infection,
- Children or their guardians who refused to participate in the study,
- Patients who were unable or unwilling to attend the follow-up sessions.

Study design

Cross-over and split-mouth designs were used in the research. Patients were randomly divided into two groups according to their preference for green or yellow. It was determined that the green color represents traditional infiltration anesthesia, and the yellow color represents anesthesia performed with the help of computer technology using Sleeper One® 5. An independent researcher who was not involved in the study asked the participants to choose a color to ensure a double-blind randomization procedure. After each participant selected a color, they were informed about the relevant anesthesia technique and the groups were randomly assigned. Both anesthesia methods were administered to every patient (Figure 2). One hundred participants were thoroughly informed about the details of the study. Additionally, each participant completed the patient consent form to provide consent.

Clinical protocol

The first appointment

The first appointment is the session wherein child underwent an oral examination and became familiar with the environment and treatment. In this session, the children's heart rate was measured using a pulse oximeter (Yongkang, Xuzhou, China) before the intraoral examination with the help of HR determination.

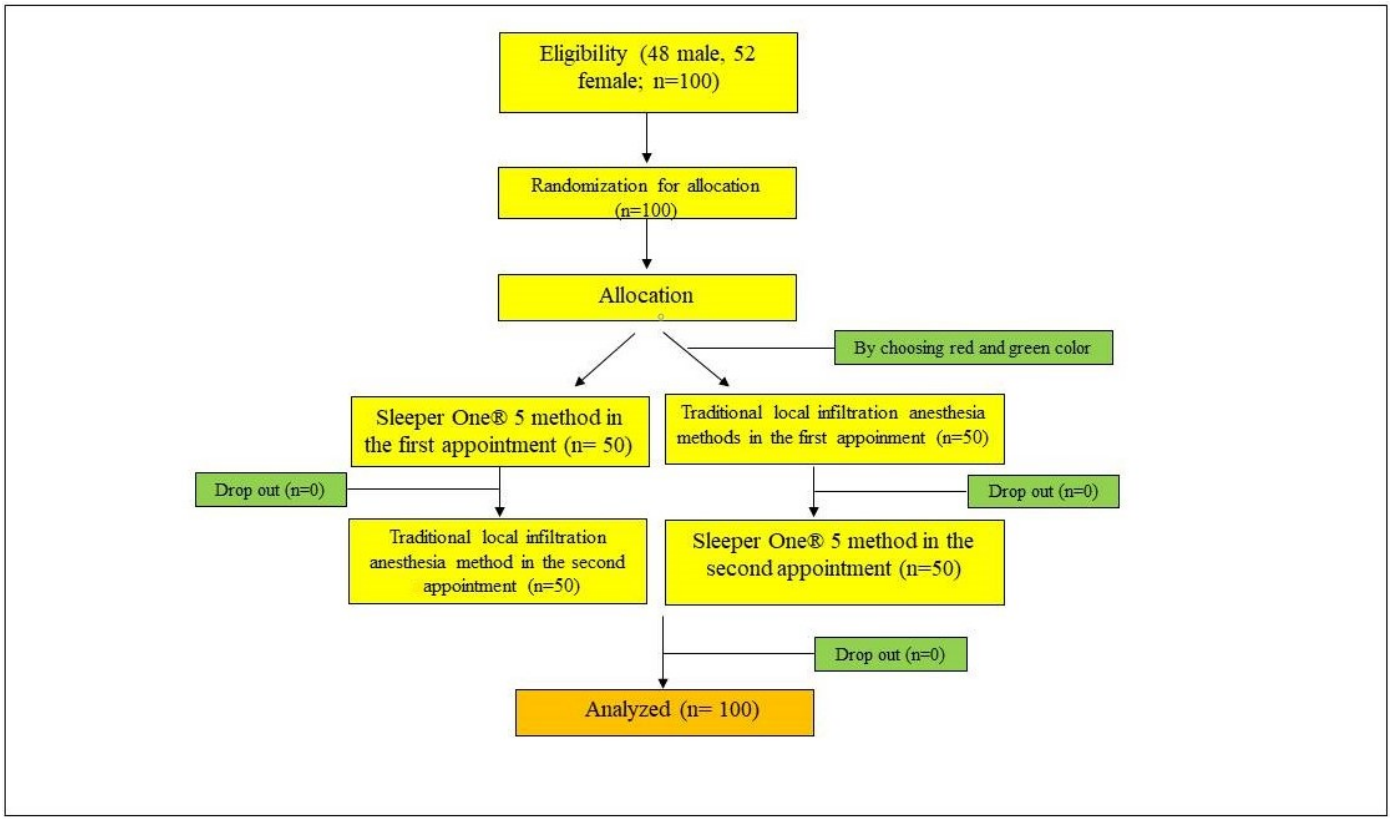

Figure 2. The study flowchart follows CONSORT guidelines for clinical trials.

Figure 3. Sleeper One® 5 anesthesia device.

The second appoinment

A randomly selected anesthesia method was applied in this session. At the start of the session, a topical anesthesia sprays containing 2% lidocaine (Locanest spray, Axiva İlaç San. ve Tic. AŞ., İstanbul, Türkiye) was applied for 1 minute. Afterward, Sleeper One® 5 was used for children who chose the yellow color. At the same time, traditional local anesthesia was administered to children who chose the green color with a two-cc classic dental injector (Berika Teknoloji Medikal İml. İth. İhrc. Ticaret LTD. ŞTİ., Konya, Türkiye). During local anesthesia, 4% articaine was used as the active ingredient along with 1 part in 100000 epinephrine content mixed in Ultracaine DS Forte capsule (Hoechst Marion Roussel,Germany). In the buccal infiltrative injection, 1.5 cc of local anesthetic solution were injected into the tissue at 60 seconds using the traditional method. However, the Sleeper One® 5 device took 145 seconds. After removing the caries and opening the cavities, teeth that required restorative treatment were restored.

The third appointment

After applying a 1-minute topical anesthetic, the anesthesia method used in the first session was changed to a different one. Local anesthesia was used for restorative treatment of decayed teeth in the other half of children's maxilla. The child was made to sit on a chair at the start of the three sessions. Afterward, the necessary information was given to the child, and then the finger apparatus of the pulse oximeter was attached to the index finger of the left hand. The apparatus remained on the finger until the end of the procedure (Figure 3). During the first session, only one measurement was recorded. However, four heart rate (HR) values were recorded in the second and third sessions. The first measurement was taken before starting the anesthesia, the second measurement was taken when half of the anesthetic capsule was reached, the third was taken immediately after the anesthesia procedure, and the fourth was taken one minute after the anesthesia process had ended. It was recorded that a single patient had 9 HR values in total. All the values were combined and averaged to produce a single value for statistical analyses.

Statistical analysis

Statistical analyses were conducted using IBM SPSS Statistics version 20.0 (IBM SPSS®, Chicago, USA). Each individual heart rate measurement was treated as a distinct statistical entity. Quantitative heart rate data

Table 1. Comparisons of repeated measurements for the conventional anesthesia method.

Variables	Mean±SD	95% CI for Mean (Lower Bound-Upper Bound)	p value
1. Heart Rate Measurements	98.18±14.31	95.34-101.02	**<0.001[a]**
2. Heart Rate Measurements	95.29±15.89	92.14-98.44	
3. Heart Rate Measurements	96.86±15.96	93.69-100.03	
4. Heart Rate Measurements	103.20±13.27	100.57-105.83	

SD: Standard Deviation, CI: Confidence Interval, [a]: Analysis of Variance in Repeated Measurements test.

Table 2. Comparisons of repeated measurements for the computer-assisted anesthesia method.

Variables	Mean±SD	95% CI for Mean (Lower Bound-Upper Bound)	p value
1. Heart Rate Measurements	99.82±14.52	96.94-102.70	**<0.001[a]**
2. Heart Rate Measurements	95.17±15.35	92.12-98.22	
3. Heart Rate Measurements	96.80±15.03	93.82-99.78	
4. Heart Rate Measurements	101.52±13.43	98.86-104.18	

SD: Standard Deviation, CI: Confidence Interval, [a]: Analysis of Variance in Repeated Measurements test.

Table 3. The comparison between computer-controlled anesthesia methods and traditional anesthesia methods for each measurement value.

Variables	Traditional		Computer-Controlled		p value
	Mean±SD	95% CI for Mean (Lower Bound-Upper Bound)	Mean±SD	95% CI for Mean (Lower Bound-Upper Bound)	
1. Heart Rate Measurements	98.18±14.31	95.34-101.02	99.82±14.52	96.94-102.70	0.094[b]
2. Heart Rate Measurements	95.29±15.89	92.14-98.44	95.17±15.35	92.12-98.22	0.927[a]
3. Heart Rate Measurements	96.86±15.96	93.69-100.03	96.80±15.03	93.82-99.78	0.968[a]
4. Heart Rate Measurements	103.20±13.27	100.57-105.83	101.52±13.43	98.86-104.18	0.157[a]

SD: Standard Deviation, CI: Confidence Interval, [a]: Paired-t test, [b]: Wilcoxon Sign Rank test.

were summarized using standard deviation and median (with minimum and maximum values), while qualitative data were presented as the number of patients along with their corresponding percentages. To compare heart rates between traditional and computer-assisted anesthesia techniques, the paired t-test was employed for normally distributed dependent quantitative variables, whereas the Wilcoxon signed-rank test was applied for non-normally distributed variables. For assessing variance across multiple measurements, the ANOVA test for repeated measures was utilized. A p-value threshold of <0.05 was established to denote statistical significance.

Results

Out of the total number of patients in the study (n=100), 48 (48.0%) were male and 52 (52.0%) were female. The mean age of the patients was 8.21±1.00 years. The average HR was calculated to be 99.28±14.68. At the end of the study, 61 out of 100 patients chose computer-assisted anesthesia, while 39 chose the traditional method.

Table 1 compares the repeated measurements obtained using the traditional anesthesia method. A significant difference was found in HR between the traditional anesthesia procedure ($p<0.001$). The HR measurements were taken at four different stages. It has been determined that there are considerable variations between certain pairs of measurement times. Significant differences were observed between certain dual measurement times: 1^{st}-2^{nd}, 1^{st}-4^{th}, 2^{nd}-3^{rd}, 2^{nd}-4^{th}, and 3^{rd}-4^{th}. The p-values were 0.001, <0.001, 0.041, <0.001, and <0.001, respectively.

In Table 2, comparisons were made for the computer-assisted anesthesia method, and a significant difference was found for HR ($p<0.001$) among repeated measurements. It has been determined that there are considerable variations between certain pairs of measurement times. Significant differences were observed between certain dual measurement times: 1^{st}-2^{nd}, 1^{st}-3^{rd}, 2^{nd}-4^{th}, and 3^{rd}-4^{th}. The p-values were 0.001, $=0.019$, 0.001, and <0.001, respectively.

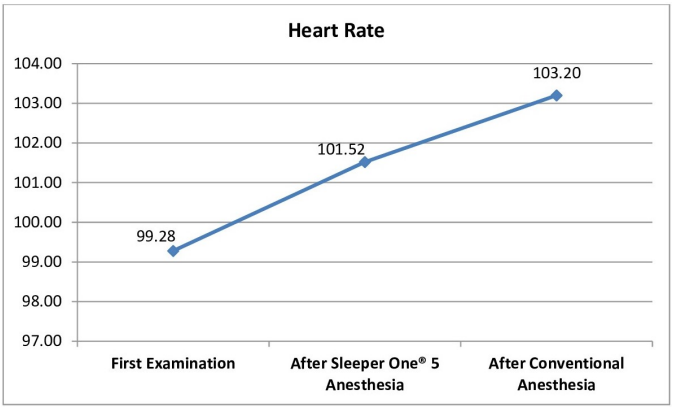

Figure 4. Comparison of heart rate measurement during examination and measurements of anesthesia methods.

In Table 3, traditional anesthesia and computer-assisted methods were compared separately for each measurement value, and no significant difference was found between the two anesthesia methods for any measurement value ($p>0.05$) (Figure 4).

Discussion

The results of the study showed that although higher heart rate values were observed with the traditional method of administering local anesthesia during the upper jaw buccal infiltration technique as compared to the Sleeper One® 5 device at all measurement times, this difference was not statistically significant. It was found that the null hypothesis of the study was valid.

It is recommended to control the injection speed and the pressure applied to the tissues during injection, but manual control of this situation may be difficult in local anesthesia applications. Based on these considerations, The Wand® (later versions called Wand Plus® and CompuDent®) (Milestone Scientific, Livingston, New Jersey, USA), Quicksleeper® (Dental HiTec, Cholet, France), Sleeper One® 5 (Dental HiTec, Cholet), France) and Comfort Control Syringe® (Dentsply International, York, PA, USA) have been developed. [15,16] The Sleeper One® 5 device is controlled by a wireless foot pedal with three injection speeds. This device's asymmetrical triple-beveled needle detects tissue resistance, and the anesthetic dose and application rate are controlled to avoid exceeding the pain threshold [17]. In our study, we used disposable plastic dental syringes with a needle diameter of 0.40 mm and a length of 4-5 cm. On the other hand, the needle used in Sleeper One® 5 has a diameter ranging from 0.27-0.36 mm (30-27 Gauge) and a length of 0.9-1.2 cm. The Sleeper One® 5 injection device has a thinner and shorter needle than plastic dental syringes.

Dental anxiety in children is influenced by various physical and emotional factors such as age, gender, past dental experiences, family socioeconomic status, and parenting style. Some of the reasons why people experience fear and anxiety when it comes to dentistry are related to the tools used by the dentist, the procedures involved during the dental treatment, the sight of a syringe or the injection process, and the use of an aerator [18].

There are various methods to measure dental anxiety and fear, including observation-based techniques, psychometric scales, and physiological and projective measurements [19]. Physiological measurements use specialized equipment to indirectly obtain information about the severity of a patient's fear and anxiety by measuring pulse and blood pressure. In the current study, the researchers utilized physiological measurement techniques and preferred measuring HR through pulse oximetry due to its ease of clinical application. To eliminate the risk that a very short-term increase in HR may affect the general health of patients with cardiac disease, patients with any systemic disease were not included in our study. Dental fear and anxiety can cause an increase in cortisol levels, resulting in higher levels of catecholamines, which can lead to elevated blood pressure and heart rate [4,20].

During dental treatments, HR increases due to anxiety, such as during injections. In studies evaluating HR, baseline HR values are measured before treatment and compared to subsequent values [15,21]. Rosenberg et al. conducted a study on 58 children, aged between 3 and 12, to investigate the relationship between heart rate (HR) and anxiety. Contrary to some studies that highlight HR as an important factor in measuring anxiety, Rosenberg et al. argued that HR cannot be a determinant of anxiety [22,23].

The treatment programs in our study consisted of three sessions with appointments scheduled 7-10 days apart. In a study by Wogelius et al. regular dentist visits without invasive treatment can prevent mild dental anxiety in children [24]. On the other hand, a study conducted by Hembrecht et al. revealed that children exhibited more anxious behavior in the second injection session with both The Wand and Sleeper One® 5 devices when compared to the first session. They suggested that this situation could be attributed to a conditioning effect resulting from repeated dental appointments [25].

Pulse oximeters are non-invasive devices that measure blood oxygen saturation and do not require calibration for HR measurement. The measurement is typically taken with a probe that is placed on the finger.It measures only the amount of oxygen present in the arteries during each heartbeat. Pulse oximetry may cause dental anxiety even in anxiety-free children and may produce inaccurate results [26]. It is important to consider any limitations that may have influenced the results obtained during their use.

Both computer-assisted anesthesia and traditional anesthesia techniques increased HR, with no significant difference found between them, according to a previous study [27,28].

This study measured heart rates four times during injections with both anesthesia methods. Significant differences were found. When comparing computer-assisted anesthesia devices to traditional anesthesia, the difference in average heart rate is insignificant. Computer-assisted anesthesia devices have an average heart rate of 98.32, and traditional anesthesia has an average heart rate of 98.38. HR increased after anesthesia in both methods, and there was no statistically significant difference between them.

One limitation of our study was that some patients had a phobia of the dental syringe. The sight of the needle caused behavioral disorders in some patients and made treatment difficult. One of the limitations of addressing dental anxiety is that it is not solely related to the use of a needle and anesthesia. Dentist anxiety is a common phenomenon that can be affected by a variety of factors. The sounds in the clinic environment, the behavior of other children receiving treatment, and even small details such as the dentist's coat can contribute to a person's anxiety level. It is important to keep in mind the limitations of this study when analyzing the results. Although physiological methods are important in evaluating pain and anxiety in school-age children, this study only evaluated the HR parameter. It should be noted that while HR can support physiological tests for anxiety and fear, it may not be enough on its own.

Conclusion

When anesthesia techniques are compared, heart rate values are considered, and there is a significant difference between each anesthesia technique's pre and post-anesthesia values. Our proposed study found no statistically significant difference in average heart rates between the two methods, leading us to accept the null hypothesis. 61% of patients preferred the anesthesia method performed with the Sleeper One® 5 devices for future dental procedures, while 39% preferred traditional anesthesia. However, further studies are necessary with a larger sample group of children using the Sleeper One® 5 anesthesia device to confirm the results obtained.

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Conflict of interest

The authors have no specific funding or other conflicts of interest to disclose.

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Ethical approval

This study received approval from the Afyonkarahisar Health Sciences University Clinical Research Ethics Committee (decision number: 2021/85).

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