

The effect of eye massage and nature sounds on children's blood pressure during dental anesthesia as a parameter for dental anxiety: A Randomized Clinical Trial

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Aim: Anxiety is one of the main problems encountered in pediatric dentistry that directly affect children's behavior and cooperation during dental procedures. Dental anesthesia is known to be the most stressful inducing procedure for children. Anxiety usually triggers the sympathetic systems leading to an increase in blood pressure and pulse rate. Studies have shown the efficacy of massage intervention in reducing anxiety by shifting the response from a sympathetic response to a parasympathetic one. Thus, this study evaluates the effect of eye massage device and nature sounds on children's blood pressure during dental anesthesia.

Materials and methods: 70 children aged between 8 and 10 years whose dental treatment required an IANB injection participated in this randomized controlled clinical trial. They were randomly divided into two groups: Group A: eye massage with natural sounds, and Group B: (control group): traditional behavior management techniques. Changes in children's blood pressure was used as a physiological scale and a biomarker for anxiety and was measured two times at rest and after receiving dental injection using a digital blood pressure monitor.

Results: diastolic and systolic blood pressure significantly decreased in group A compared with the control group ($p < 0.05$).

Conclusion: Eye massage and natural sounds can effectively reduce children's blood pressure during dental anesthesia indicating a reduction in anxiety, with the two interventions combined having the best relaxation effect on children.

Keywords: dental anxiety, dental anesthesia, massage, nature-based intervention

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Introduction

The Biopsychosocial Model of Illness emphasizes the unity of mental, emotional, social, and physiological factors in its contribution to illness and recovery. Anxiety is one of the emotional factors that predict the patient's ability to cope with pain, comprehend instructions, and adhere to medical advice¹.

State anxiety (an acute form of anxiety experienced in a particular and temporary situation)² is of particular interest because illness itself and health care procedures may produce a state of anxiety that can interfere with patient outcomes³. Reducing patient anxiety is fundamental. Anxiety can delay healing, increase pain and blood loss, interfere with sleep, and increase the need for analgesics and other medications⁴.

Dental anxiety in children is a prevalent issue that can significantly impact their willingness to seek dental care and their overall oral health⁵. Research indicates that the prevalence of dental anxiety among children ranges from 5% to 30%⁵, with various factors influencing its severity, including age, gender, previous dental experience, and parental anxiety⁷. Dental anesthesia can indeed trigger anxiety in patients, impacting their physiological and psychological responses during dental procedures⁸. Research indicates that anxiety levels are often heightened in anticipation of anesthesia, which can lead to increased pain perception and cardiovascular changes⁹. Severe preoperative anxiety has been linked to significant increases in heart rate and blood pressure during local anesthesia administration¹⁰.

Massage interventions have shown promise in reducing anxiety among dental patients, particularly during procedures that typically induce stress¹¹. Research indicates that various forms of massage, including acupoint massage and progressive muscle

relaxation, can significantly alleviate anxiety levels¹¹. A study involving 100 patients undergoing oral implant surgery demonstrated that acupoint massage combined with touch therapy significantly reduced anxiety, as measured by the Modified Dental Anxiety Scale (MDAS), compared to routine care.¹²

On another hand, Natural sounds have been shown to significantly reduce anxiety in dental settings. Research indicates that auditory stimuli, including nature sounds, can create a calming environment, thereby alleviating patient anxiety during dental procedures¹³. The calming effects of nature sounds were comparable to those of music, indicating their potential as a therapeutic tool in dental practices.¹³

Therefore the aim of the study was to Assess the effect of eye massage and nature sounds on children's anxiety through observing changes in blood pressure during dental anesthesia.

Materials and methods

Study design

The study was designed as a two-armed randomized clinical trial in which a total of 105 children who visited the Department of Pediatric Dentistry at Damascus University participated in this study. A written consent was obtained from the children's guardians before their enrollment. The study was carried out between February 2023 to September 2023 and was conducted in accordance with the precepts stipulated in the Declaration of Helsinki. The study was registered with the clinical trial registry of the United States National Institutes of Health (NIH) at ClinicalTrials.gov (NCT05592587). Ethical approval for the conduct of this study was obtained (No. 2371) from the Institutional Ethical Review Board of the Faculty of Dentistry, Damascus University. CONSORT

guideline was implemented to report this randomized clinical trial.

Sample collection

The sample size was determined with G-power software v3.1.9.7 and based on similar previous studies¹⁴ and the power of the study was set at 95%. A total of 70 children aged 8-10 years with no previous experience with dental anesthesia and needed dental treatment in the mandibular arch including administration of IANB injection, were included in this study. Children with communication disabilities, vision, and hearing disorders, and who refused to put the device on were excluded from the study. Furthermore, children who suffered from acute dental pain or scored negative or absolutely negative on Frankel behavioral scale were also excluded.

Study protocol

Children were randomly distributed into two groups (35 participants in each group), using the website service www.random.org as follows:

- 1- Group A: using the vibrating eye massage device combined with natural sounds and the application of topical anesthesia (20% benzocaine gel) before receiving the IANB injection.
- 2- Group B: (control group): Using basic behavior guidance techniques (tell-show-do, positive reinforcement, verbal distraction) with the application of topical anesthesia (20% benzocaine gel) before receiving the IANB injection

For group A: After the child was seated comfortably on the dental chair, both diastolic and systolic blood pressure were measured at rest using a digital blood pressure monitor. Subsequently, the child was introduced to the eye massage device and a brief simple explanation of how the device work were provided for them. The child was

given the device to familiarize with its vibration before applying it to their eyes. The child was also informed about the natural sounds that the device produces. After this, the device was applied to the child's eyes with both vibration (intermittent pattern) and natural sounds (mixed sounds) turned on. Meanwhile, the region of injection was topically anesthetized with 20% benzocaine gel for 1 min (GINGICaine, Belpoint County, CA, USA), followed by the administration of the IANB injection using 1.8 ml of 2% lidocaine along with 1:100,000 adrenaline (Xylocaine, Dentsply, PA, USA). After receiving the injection, the device was turned off and removed from the child's eyes and both diastolic and systolic blood pressure were measured again.

For group B: the control group received the same dental injection using the same technique without using the eye massage device, however, traditional methods of behavioral management were applied. The technique (Tell-Show-Do) and verbal distraction were followed when applying the topical anesthesia and administering the injection and both diastolic and systolic blood pressure were measured at rest and after receiving the injection.

2.4 A background on the used device:

The Comfort Eye Massage Device (Maxcare, China) is a glasses-shaped device with an adjustable head strap. The inner surface of the glasses contains 20 massage magnetic points that rest on the forehead, temple, nasal bridge and bony margins that form the orbit without touching the eyelid. An internal audio system is fixed inside the device that produces natural sounds, and it includes three sound options: bird sounds, water sounds, or mixed birds and water sounds. Connected to the glasses is a remote control that contains 4 buttons: one to turn on the device and control the volume, one for the timer, one to switch between sounds, and one to switch between

the three vibration patterns: continuous, intermittent, and alternating.

In this study, the intermittent vibration pattern was applied for children in group A following the manual instruction of the device that indicates the usage of intermittent vibration for gentle massage purposes while the other two options are used for deep strong meditation. A mix of both bird and water sounds was chosen from the device for children in group A to listen to during the procedure to ensure the highest effect.

Statistical analysis

The data was analyzed using SPSS software (version 22.0, IBM, USA). Descriptive statistics including means, frequencies, and percentages were summarized regarding the age, gender, and children's type of behavior according to Frankel of the 70 participants. The Kolmogorov–Smirnov test was conducted to assess the normal distribution of the data, the results indicated that the data followed a normal distribution. Consequently, independent sample T-Test was utilized to analyze the mean difference of both diastolic and systolic blood pressure between the two groups. A P-value of less than 0.05 was considered significant

Results

A total of 70 children, (41 boys and 29 girls, mean age 8.7 ± 0.7) participated in this study. No statistically significant difference was found between the three groups with regard to mean age, gender, and Frankel behavioral scale (Table 1).

Children who received the eye massage with nature sounds intervention during dental anesthesia showed a decrease in both diastolic and systolic blood pressure with a mean change of $(-7.03 \pm 5.45, \text{ and } -7.13 \pm 5.54 \text{ respectively})$. However, an increase in both diastolic and systolic blood

pressure was noted for children in the control group with a mean change of $(5.56 \pm 9.65 \text{ and } 8.1 \pm 9.55 \text{ respectively})$ (Table 2) (Table 3)

A statistically significant difference was found between the two groups regarding both diastolic and systolic blood pressure (P-value = 0.000) which indicates that children who received the massage with nature sounds intervention were more relaxed and less anxious after dental anesthesia. (Table 2) (Table 3)

Table 1: Sample description: one-way ANOVA test used for age comparison, and Kruskal-Wallis test used for gender and Frankel behavior scale comparison.

| Variables | | Group A | Group B | P-value |
|-----------|------------------------|------------|-----------|---------|
| Age | Mean (SD) | 8.6 (0.84) | 8.7 (0.7) | 0.79 |
| Gender | Male: n (%) | 20 (57) | 21 (60) | 0.65 |
| | Female: n (%) | 15 (43) | 14 (40) | |
| Frankel | Positive: n (%) | 30 (86) | 32 (91.4) | 0.33 |
| | Definitely positive: n | 5(14) | 3 (8.6) | |

Table 2: Independent sample T-Test to compare the mean difference in diastolic blood pressure between the two groups

| | J: Mean DBP before injection (SD) | I: Mean DBP after injection (SD) | Mean Differences | | t | P-Value |
|---------|--|---|------------------|------|--------|---------|
| | | | Mean(I-J) | SD | | |
| GroupA | 68.17 | 61.14 | -7.03 | 5.45 | -6.782 | 0.000* |
| Group B | 63.50 | 69.06 | 5.56 | 9.65 | -6.782 | |

*p- Value is significant at < 0.05

Table 3: Independent sample T-Test to compare the mean difference in systolic blood pressure between the two groups

| | J: Mean SBP before injection (SD) | I: Mean SBP after injection (SD) | Mean Differences | | t | P-Value |
|--------|---|---|------------------|------|--------|---------|
| | | | Mean(I-J) | SD | | |
| GroupA | 106.3 | 99.17 | -7.13 | 5.54 | -7.703 | 0.000* |
| GroupB | 103.4 | 111.5 | 8.1 | 9.55 | -7.703 | |

*p- Value is significant at < 0.05

Discussion

Dental anxiety relates to the fear, stress, or dread induced before, during, or after dental treatment, and is one of the most common problems encountered in the dental setting¹⁵. Thus, managing children's anxiety is considered standard practice for pediatric dentists due to its essential role in providing children with optimum dental care and ensuring they develop a positive perspective on dental treatments.

Dental anxiety significantly impacts blood pressure (BP) during dental procedures, often leading to elevated readings¹⁶. Research indicates that anxiety can trigger physiological responses, including increased BP and heart rate, particularly in patients undergoing treatments like tooth extractions, oral surgery, or simply receiving dental anesthesia^{16,17,18}, this could be attributed to the fact that anxiety increases the activity of the autonomic nervous system which activates the circulation and respiratory system¹⁹. A study found that 44.4% of patients reported dental anxiety, with 60% exhibiting high BP before treatment²⁰. Another investigation revealed that 77.3% of patients experienced anxiety, correlating with significant BP fluctuations during their dental visits²¹. Thus, in this study changes in blood pressure were chosen to be measured as a physiological biomarker that correlates with anxiety.

Children aged 8-10 years were enrolled in this study because School-aged children possess the ability to communicate effectively, express their emotions, and build relationships with the dentist^{22,23}. Local anesthesia is a significant source of anxiety in pediatric dentistry, primarily due to the fear associated with needle use and the pain of injections²⁴ with the IANB injection being reported as one of the most painful dental injections²⁵. Children's anticipation of pain from injections can exacerbate their anxiety, making it crucial for dentists to manage these

expectations effectively²⁶. Therefore, this study chose to evaluate the efficacy of massage and nature sounds during IANB injection due to its relation to producing high levels of anxiety that allow it to be observed through the changes in blood pressure ratings. Massage is a complementary alternative medicine described as the manipulation of soft tissues for therapeutic purposes applied manually or through specialized devices to specific parts of the body¹¹. Studies have shown that massage therapy can significantly lower heart rate, respiratory rate, and blood pressure, which are indicators of physiological stress²⁷. This is in accordance with the results of this study that showed a significant decrease in blood pressure for children who experienced eye massage which indicates lower stress and anxiety level compared to those in the control group.

Another study involving patients undergoing oral implant surgery demonstrated that acupoint massage combined with touch therapy led to a notable decrease in anxiety, as measured by the Modified Dental Anxiety Scale (MDAS). The intervention group reported lower anxiety and pain levels compared to the control group, highlighting the effectiveness of this approach¹². While these findings are promising, it is essential to consider that individual responses to massage can vary, and further research is needed to establish standardized protocols for its use in dental anxiety management.

Sounds and music stimulate the involuntary centers in the central nervous system. initially transmitted to the higher levels of the brain, where they influence emotional and abstract thought before eliciting a physiological response²⁸. A systematic review by Buxton et al.²⁹ regarding the health benefits of natural sounds demonstrated that exposure to natural sounds improves health outcomes and decreases stress and annoyance, indicating that water sounds, such as running water or waterfalls,

had the highest impact on health and positive feelings, while bird sounds had the greatest effect on alleviating stress and annoyance. Thus, in this study a mix of birds and water sounds were chosen for children to listen to during the dental injection procedure.

Nature-based sounds (N-BS) have been linked to lower heart rates, blood pressure, and anxiety levels in patients under mechanical ventilation, indicating a cumulative effect over time³⁰. In patients undergoing coronary artery bypass graft surgery, exposure to natural sounds resulted in significantly reduced anxiety levels preoperatively³¹. In current study, children who received eye massage with nature sounds were significantly more relaxed and less anxious than those in control group as their blood pressure readings significantly decreased during the procedure compared to those in control group. This could be attributed to the simultaneous effect of both massage and nature sounds on overall health and well being that led to the significant drop in blood pressure readings during dental anesthesia.

Study limitations

The effect of nature sounds interventions alone were not studied, and only cooperative children who were not previously subjected to dental anesthesia were included in this study. Another limitation would be the short period in which the device was implemented for, while testing it during other dental procedure that takes longer time such as restorative treatment, would further enrich the results.

Conclusion

Eye massage and nature sound can effectively reduce children's blood pressure during dental anesthesia, ensuring a more relaxed and less anxious procedure.

Authors' contributions

A D: Research concept and design, Collection and/or assembly of data, Writing the article. A D: Research concept and design, Collection and/or assembly of data, Writing the article. B J; Data analysis and interpretation, Writing the article; L M: Research concept and design, Final approval of the article research, B N: Research concept and design, Final approval of the article.

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Conflicts of interests

The authors declare no conflict of interests

Data availability

All data generated or analyzed during this study are included in this published article.

Ethical approval

Ethical approval was obtained from the institutional ethics committee of Damascus University (No. 2371). All methods were carried out in accordance with all relevant guidelines and regulations and Declaration of Helsinki. The study was registered with the clinical trial registry of the United States National Institutes of Health (NIH) at ClinicalTrials.gov (NCT05592587).

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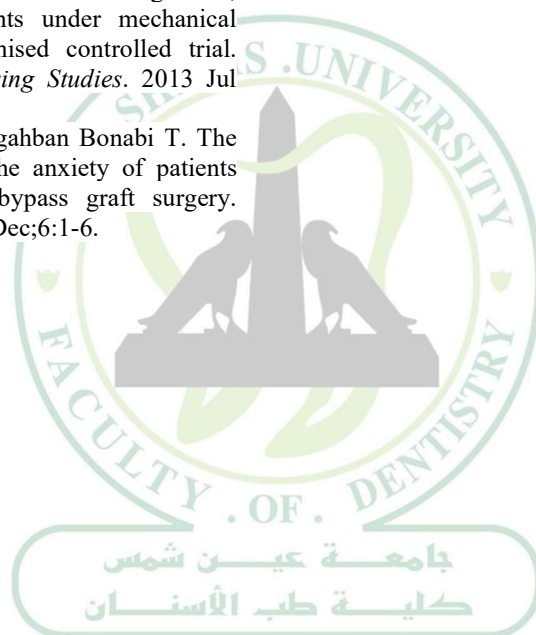
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