Original Article

The Effect of Medical Clowns on Pain and Anxiety Levels during Inferior Alveolar Nerve Block Injection in Children: A Randomized Controlled Trial in an Iranian Clinical Setting

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ABSTRACT

Background: Pain and anxiety during inferior alveolar nerve block injections are common challenges in pediatric dentistry; therefore, effective behavioral interventions such as medical clowning may help reduce children's distress during dental procedures.

Purpose: This study aimed to evaluate the effect of medical clowns on pain and anxiety during inferior alveolar nerve block injections in children aged 6–12 years in a private pediatric dental clinic in Iran.

Materials and Method: In this prospective, randomized controlled trial, 66 healthy children requiring bilateral mandibular pulpotomy were enrolled. Each child attended two sessions: a baseline session (standard care) and an intervention session. In the second session, children were randomly assigned to either a control group (standard care) or an intervention group (standard care + medical clown). Anxiety was assessed subjectively using the Venham picture test (VPT) and objectively via HR measurement. Pain was assessed using the visual analogue scale (VAS). Data were analyzed using SPSS ver. 24 with paired and independent t-tests, Mann-Whitney U test, and calculation of effect sizes (Cohen's d) with 95% confidence intervals.

Results: The findings indicated that the mean pain scores (VAS) increased significantly from baseline in both groups (p Value=0.001) but did not differ significantly between groups post-intervention (p=0.13, d=0.37, 95% CI: -0.15 to 0.88). In contrast, anxiety scores (VPT) were significantly lower in the clown therapy group compared to controls after the intervention (p= 0.04, d= 0.40, 95% CI: 0.02 to 0.87). Furthermore, the mean heart rate increased significantly within both groups (p= 0.001) but showed no substantial between-group difference post-intervention (p= 0.90, d= 0.03).

Conclusion: The use of medical clowns significantly reduced self-reported anxiety in children during IANB injections but did not significantly affect perceived pain levels. Medical clowning presents a viable, non-pharmacological strategy for anxiety management in pediatric dental settings, particularly in cultural contexts where such interventions are novel.

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Introduction

Dental anxiety and fear of pain are prevalent challenges in pediatric dentistry, often precipitated by the local anesthetic injection itself [1]. A strong correlation exists between a child's anxiety and perceived pain intensity, which can compromise treatment outcomes [2]. There-

fore, identifying effective non-pharmacological techniques to manage anxiety and pain is crucial.

The inferior alveolar nerve block (IANB) is a common but anxiety-provoking procedure in pediatric dentistry [3]. Therefore, targeted interventions are necessary to effectively divert their attention from the treatment process. Distraction techniques, such as auditory, audiovisual, tactile, olfactory, and gustatory distraction, are increasingly used to manage children's behavior during dental treatments [4]. Medical clowns are trained professionals who use humor, play, and music to reduce psychological distress and improve cooperation during medical procedures [5-6]. Evidence suggests their effectiveness in reducing preoperative anxiety and postoperative pain in hospital settings [5-7].

While studies like Aggarwal *et al*. [8] have demonstrated the benefits of medical clowns in pediatric dentistry for general behavior management, their application during specific, high-anxiety procedures such as IANB injections in routine clinical settings remains underexplored. Furthermore, within the Iranian cultural context, medical clowns are a relatively novel concept, and specific cultural attitudes towards them might influence their acceptance and efficacy. No prior study has investigated its impact within this specific cultural and clinical setting. This study is the first to evaluate the effect of medical clowns on both pain and anxiety during IANB injections in a pediatric dental setting in Iran, addressing a significant gap in the literature.

Materials and Method

Study Design and Ethics

This single-center, parallel-group, prospective randomized controlled trial was conducted at a private pediatric dental clinic in Zahedan, Iran, and approved by the Ethics Committee of Zahedan University of Medical Sciences (IR.ZAUMS.REC.1399.307) and registered in the Iranian Registry of Clinical Trials (IRCT20201026049-144N1). The study adhered to the principles of the *Helsinki Declaration* and was reported following Consolidated Standards of Reporting Trials (CONSORT) guidelines. Written informed consent was obtained from all parents/guardians.

Participants

Sixty-six healthy children (ASA physical status I) aged 6-12 years, with a Frankl behavioral rating score of 2 or 3, who required pulpotomy and stainless-steel crown placement on both mandibular second primary molars, were enrolled. Exclusion criteria included poor cooperation (Frankl score 1), previous traumatic dental experience, cognitive or developmental impairments, known coulrophobia (fear of clowns), or any contraindication to local anesthesia.

Sample Size and Randomization

The sample size was calculated as 33 participants per group, based on the previous study [9] (α=0.05, β=0.80, effect size=0.5). Participants were allocated to either the control or intervention group using block randomization (block size of 4) via a computer-generated random sequence (www.randomizer. org), stratified by age and sex to ensure group comparability. The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE), which were opened only at the beginning of the child's second session by a research assistant not involved in outcome assessment.

The flow of participants through the study is summarized in the CONSORT diagram (Figure 1).

Clinical Procedure and Intervention

The study comprised two separate treatment sessions for each participant, spaced two weeks apart.

First Session (Baseline)

This session established a baseline for all children under standard care conditions, with no clown intervention. After a brief familiarization, anxiety was assessed in the waiting area using the Venham picture test (VPT) by a dental intern. Baseline heart rate (HR) was recorded via a pulse oximeter (Oxy 300; Microlife AG, Widnau, Switzerland). A single experienced pediatric dentist

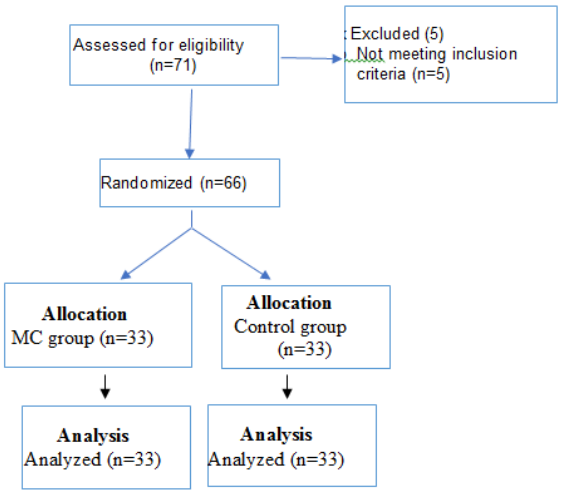

Figure 1: CONSORT flow diagram of the study process

performed the IANB injection using a standardized protocol: application of topical anesthetic (20% benzocaine, Benzotop, DFL, Rio de Janeiro, Brazil) for two minutes, followed by a slow injection (over one minute) of 1.8mL of 2% lidocaine with 1:80,000 epinephrine (Daroupakhsh, Tehran, Iran) using a 30G long (C-K Dental, Gyeonggido, South Korea) needle. Standard behavioral management techniques (Tell-Show-Do, voice control) were used. Immediately post-injection, HR was re-measured, and the child completed the completed the VPT and the visual analogue scale (VAS) for pain. To minimize distraction, parents were asked not to be present during the procedure.

Second Session (Intervention)

Children were randomized into two groups as Control and Intervention.

The Control Group (n=33) received identical standard care as in the baseline session.

In the Intervention Group (n=33), before the dental procedure, the children spent 15 minutes in a separate room with a trained medical clown. The clown, an experienced performer in full character costume, used age-appropriate interactive techniques such as magic tricks, storytelling, and puppet play. The clown then accompanied the child to the operatory and remained present until the IANB injection was completed. The same sequence of assessments (VPT, HR, and VAS) was repeated.

The self-reported anxiety was measured by using the VPT. The VPT is a self-report measure designed to assess situational anxiety in young children. The test works by presenting children with stylized cartoon figures that depict various emotional states. Children are then asked to select the figure with which they most identify at that moment. This picture selection task is designed to be easily understood and accepted by children as young as three years old [10].

The self-reported pain was measured by using the VAS. The VAS is typically presented as a 10cm (or 100mm) horizontal line. This line is commonly anchored with "no pain" at one end and "worst pain imaginable" at the other, allowing for a score ranging from 0 to 10 [11]. The VAS is considered a valid and reliable scale for pain measurement in clinical practice [12].

The physiological anxiety was measured by participant's HR (beats per minute) using pulse oximetry. A dental student, blinded to the group allocation of each child, recorded all outcome measures (VPT, VAS, and HR) during the second session. The operating dentist could not be blinded due to the nature of the intervention.

Statistical Analysis

Data were analyzed using SPSS software (Version 24.0). Normality was assessed using the Shapiro-Wilk test. Quantitative data were presented as mean ± standard deviation (SD). Between-group comparisons of continuous variables were performed using independent samples t-test (for normally distributed data) or Mann-Whitney U test (for non-normal data). Within-group comparisons (baseline vs. post-intervention) were assessed using paired samples t-test or Wilcoxon signed-rank test. Categorical data were compared using the Chi-square test. To provide clinical relevance beyond statistical significance, effect sizes were calculated using Cohen's d (with 95% confidence intervals) for key between-group comparisons. A two-tailed p Value of < 0.05 was considered statistically significant.

Results

All 66 enrolled children completed the study. As shown in Table 1, there were no significant differences between the control and intervention groups regarding age (p= 0.82) or gender distribution (p= 0.44), confirming successful randomization.

The comparisons of clinical outcomes are detailed in Table 2. For pain levels (VAS), scores increased significantly from baseline within both the control (p= 0.001) and intervention (p= 0.001) groups. However, no significant difference in pain scores was observed between the two groups after the intervention (p= 0.13). The effect size was small (Cohen's d= 0.37, 95% CI: -0.15 to 0.88).

For anxiety (VPT), scores at baseline were compara-

Table 1: Comparison of demographic characteristics between the two groups

Characteristic	Control (n=33)	Intervention (n=33)	p Value
Age (Years)			
Minimum	6	6	
Maximum	11	12	
Mean±SD	7.91±1.57	7.82 ± 1.61	0.82*
Gender, n(%)			
Male	13 (39.4)	10 (30.3)	0.44**
Female	20 (60.6)	23 (69.7)	

n: Number; SD: Standard Deviation. *Independent t-test; **Chi-square test

Table 2: Comparison of pain, anxiety, and heart rate between the two groups before and after the intervention

Variable/Group	Baseline (Mean±SD)	After (Mean±SD)	Within Group*	Between Groups**	Effect Size
		Pain (VAS)			
Intervention	1.94 ± 2.26	3.03±2.88	0.001	0.13	0.37
Control	2.36 ± 1.93	4.03±2.47	0.001		
Anxiety (VPT)					
Intervention	2.00 ± 2.14	2.64±2.40	0.002	0.04	0.40
Control	2.21 ± 1.60	3.48±1.79	0.001		
Heart Rate					
Intervention	103.00±12.37	119.45±11.78	0.001	0.90	0.03
Control	99.30±15.13	119.82±11.28	0.001		

VAS: Visual Analogue Scale; VPT: Venham Picture Test; SD: Standard Deviation, *Paired t-test;**Independent t-test

ble between groups (p= 0.60). Post-intervention, the anxiety score was significantly lower in the intervention group compared to the control group (p= 0.04), with a moderate effect size (Cohen's d = 0.40, 95% CI: 0.02 to 0.87). Anxiety increased significantly from baseline within both groups (Control: p= 0.001; Intervention: p= 0.002) (Table 2).

The findings also revealed that the mean HR increased significantly from baseline within both groups (p= 0.001 for both) but showed no significant difference between groups after the intervention (p= 0.90, d= 0.03) (Table 2).

Discussion

This randomized controlled trial demonstrated that the presence of a medical clown during IANB injections led to a significant reduction in self-reported dental anxiety among children aged 6–12 years in an Iranian clinical setting (p=0.04, Cohen's d=0.40), representing a moderate effect size. This finding is consistent with a growing body of evidence supporting the anxiolytic role of clown therapy in pediatric healthcare. Previous studies in hospital environments, such as those by Vagnoli *et al*. [7] and more recent meta-analyses [5-6], have consistently reported reduced preoperative anxiety and improv-ed cooperation when medical clowns are present. In dental practice specifically, Aggarwal *et al*. [8] found that medical clowning positively influenced behavior and reduced anxiety during various dental procedures, though their study did not focus exclusively on injection-related anxiety. Our results extend these findings by confirming that the benefit persists even during a brief, high-stress stimulus like the IANB injection, and within a cultural context where such an intervention is relatively novel.

However, contrary to some reports from general medical settings [13-14], medical clowning in our study did not significantly reduce self-reported pain during the injection (p= 0.13, Cohen's d=0.37). The small effect size observed suggests that while there may be a trend toward pain reduction, it lacks both statistical significance and meaningful clinical impact in this context. This discrepancy may be explained by several factors. First, the nature of dental injection pain is acute, sharp, and highly localized, which may be less amenable to cognitive distraction compared to prolonged or dull procedural discomfort. Studies on clown therapy during venipuncture [9] have shown mixed results regarding pain reduction, suggesting that the type and timing of pain modulate the efficacy of distraction. Second, the psychological construct of pain in children is complex and often conflated with anxiety [2]. While our intervention reduced the affective component (anxiety), the sensory-discriminative component (pain intensity) may have remained unchanged due to the salient physical sensation of the needle. Third, cultural familiarity with medical clowns may influence their perceived effectiveness. In Iran, where clown therapy is not yet integrated into mainstream pediatric care, children may not associate the clown's presence with pain relief as strongly as in cultures where hospital clowns are more common.

An intriguing finding was the dissociation between the reduction in subjective anxiety (VPT) and the lack of effect on the physiological measure of anxiety (HR). While children in the clown group reported feeling less anxious, their HRs increased to a similar extent as those in the control group (p= 0.90, Cohen's d=0.03), indicating a negligible effect size on autonomic arousal. This phenomenon has been observed in other distraction studies and may reflect the limitation of HR as a pure marker of emotional anxiety in acutely stressful situations. The sympathetic arousal triggered by the injection might be largely impervious to cognitive-emotional distrac-

tion, even when the child feels psychologically supported. Alternatively, the clown's presence might have modulated higher-order cognitive appraisal of the threat without significantly altering autonomic reactivity. This divergence underscores the importance of using multi-modal assessment in pediatric anxiety research, as different measures may capture distinct facets of the stress response.

When compared to other non-pharmacological interventions for managing dental anxiety in children- such as virtual reality [1], audio-visual distraction [4], or tell-show-do, medical clowning offers a unique, human-centered, and interactive form of engagement. Unlike passive distractions, a trained clown can dynamically adjust interactions based on the child's reactions, providing personalized emotional support. This may explain why it was effective in reducing anxiety with a moderate and clinically relevant effect size, despite the brevity of the procedure. However, its lack of impact on pain and the small, non-significant effect size suggest that for maximally invasive steps like injections, a multi-modal approach combining clown therapy with topical anesthetics or vibration devices might be more comprehensive.

Strengths and Limitations

Key strengths of this study include its rigorous randomized controlled design, use of concealed allocation and blinded outcome assessment to minimize bias, inclusion of a within-subject baseline control, and focus on a specific, high-anxiety dental procedure within an understudied cultural setting. These elements enhance the internal validity and clinical relevance of our findings.

Several limitations should be acknowledged. First, the operator could not be blinded to the group allocation, which may have introduced performance bias, though the standardized injection protocol aimed to mitigate this. Second, we did not assess parental anxiety, which is a known confounder in pediatric dental anxiety [15-16]. Future studies should measure and control for parental stress to better isolate the clown's effect. Third, the sample size, though adequate for detecting moderate effects, may have been underpowered to identify smaller differences in pain scores, as reflected in the wide confidence interval for pain effect size (95% CI: -0.15 to 0.88). Fourth, the generalizability of our findings may be limited to children with moderate dental cooperation (Frankl 2-3) and to similar cultural contexts where clown therapy is unfamiliar. Finally, the long-term effects of clown-assisted visits on future dental attitudes were not evaluated- a worthwhile direction for further research.

Conclusion

The use of medical clowns significantly reduced self-reported anxiety in children during IANB injections but did not significantly affect perceived pain levels. Medical clowning presents a viable, non-pharmacological strategy for anxiety management in pediatric dental settings, particularly in cultural contexts where such interventions are novel.

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Author Contributions

- F. A: Conceptualization, Methodology, Writing- Review & Editing
- N.N: Data Collection, Writing – Original Draft
A.P: Formal analysis

Language editing assistance was provided using Ai; all content, analysis and conclusions were generated, reviewed and verified by the authors.

Ethical Approval

This study was approved by the Ethics Committee of Zahedan University of Medical Sciences (IR.ZAUMS.REC.1399.307)

Data Availability

The data supporting this study's findings are available from the corresponding author upon reasonable request.

Conflict of Interest

The authors declare no conflict of interest.

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