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RESEARCH

Evaluating the effect of using anti-stress balls as a distraction technique in reducing pain during inferior alveolar nerve block injection: a randomized clinical trial

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Abstract

Objective The aim of this study is to evaluate the effect of using anti-stress balls in reducing patients' pain during injection of the inferior alveolar nerve block (IANB).

Materials and methods In this randomized clinical trial, 32 individuals were divided into two groups. The conventional method of anesthesia injection was performed using IANB conventional injection technique. During the injection, individuals in the anti-stress ball group were asked to use the anti-stress ball as a distraction technique. For the control group, no supersede methods were used for pain control. Finally, both groups were asked to record their pain utilizing the numerical rating scale (NRS). The participants' vital signs were monitored before and after injection. Kolmogorov-Smirnov test, independent *T*-test, and Fisher's exact chi-square test were performed for statistical analysis ($\alpha = 0.05$).

Results Sixteen females and 16 males in the age range of 40 to 20 years old participated in this study. The mean pain score in the anti-stress ball group was significantly lower ($p < 0.001$). In both sexes, the pain score in the anti-stress ball group was significantly lower (males $p < 0.001$ and females $p = 0.001$). In addition, in all age ranges, the pain score in the control group was higher except for the above 35 years old participants ($p = 0.078$). Moreover, there were no significant differences in individuals' vital signs ($p > 0.05$).

Conclusion and clinical relevance Utilizing an anti-stress ball reduces patients' pain significantly during IANB in both sexes and individuals who are below 35 years without changing vital signs.

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Keywords Inferior alveolar nerve block · Anti-stress ball · Distraction technique · Pain

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Introduction

Pain is an uncomfortable feeling that is often caused by injury of the central neural system or intense and noxious stimuli affecting nociceptors in the peripheral neural system. Pain is the major reason for medical consultation in the USA, and for most medical conditions, it is an important symptom that is significantly associated with a person's quality of life and performance. Clinical treatments that required needle injection such as intravenous injection, phlebotomy, and intramuscular injection cause pain [1]. Moreover, pain during injection is one of the most important factors which leads to patients, including adults and children, avoiding to visit the dentist in the future [2, 3].

Pain has been described as a cognitive and sensory experience and varies between individuals based on various factors [4]. Many studies have shown that anxiety has a direct impact on lowering the pain threshold and increasing pain intensity [5–7]. Social support, hypnosis, emotional involvement in sports or war, using eye coverage, and distraction techniques play a significant role in reducing the intensity of pain or discomfort [8]. Cognitive refocusing is a method that makes distractions through tools and approaches that attract attention and leads to pain perception reduction by controlling fear. With this method, the perception of pain is reduced due to the increased mental concentration on more appealing stimuli [9]. Distraction techniques are safe and cost-effective strategies that can have a positive impact on reducing pain while performing dental procedures and leads to dental care quality improvement. A wide range of distraction methods can be found for reducing patient fear and pain cognition such as listening to music and video show distraction techniques that have a significant effect in reducing local anesthesia injection pain [10, 11]. Another type of distraction approach is using a small and soft anti-stress ball which is a simpler and less expensive approach for cognitive refocusing. In clinics, the use of anti-stress balls is used as a method to reduce patient anxiety and pain during injection [4, 12].

Previous studies determined the effect of distraction methods including anti-stress balls during medical procedures such as skin cancer excision, peripheral intravenous catheterization, intravitreal injections, venipuncture, and scaling and root planning. While some studies showed that utilizing an anti-stress ball and distraction techniques leads to less pain [12–16], others did not demonstrate any significant effect on the level of pain [4, 17]. Moreover, limited studies have been conducted on the evaluation of the effect of using the anti-stress ball in dental procedures. Torres-Gomez et al.[18] in 2021 showed that utilizing an anti-stress ball has no significant effect on patients' pain reduction during scaling and root planning. However, the effect of anti-stress balls as a distraction method for pain reduction during anesthetic injection has not been evaluated. The purpose of this study is to evaluate the effect of using anti-stress balls as a distraction technique in reducing pain and fear during injection of the inferior alveolar nerve block (IANB).

Method and materials

In this randomized clinical trial, individuals who attended dental school at Mazandaran University of Medical Sciences from August 2022 to November 2022 were selected. Based on the study by Girgin et al. [16] and the below-mentioned calculation, the sample size was a minimum number of 8 patients for each group.

$$n = \frac{(z_{1-\alpha/2}+z_{1-\beta})^2 \times (\sigma_1^2+\sigma_2^2)}{(\mu_1-\mu_2)^2} = 8.01$$
$$\alpha = 0.01,\ \beta = 0.1$$

Patients included in the study were informed before the examination, and an Informed Consent Form was signed by all participants. All procedures followed were in accordance with the principles stated in the Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and as amended most recently by the 64th World Medical Assembly, Fortaleza, Brazil, October 2013. In addition, all of the performed procedures were approved by the Ethical Committee of Mazandaran University of Medical Sciences (#4.1400.REC.MAZUMS.IR).

As inclusion criteria, the individuals who were healthy (ASA1) and were willing to participate in this study were included. For standardization of the psychological condition, which can affect individuals' pain perception [19], the GHQ-28 questionnaire was utilized. The reliability and validity of this questionnaire have been approved [20]. In addition, participants who were taking medications that alter their understanding of pain, patients with active infections at the injection site, and participants with respiratory and cardiovascular diseases were excluded from the study [19, 21]. The block technique with 8 blocks, of which each block has a size of 4, was performed for randomizing participants by utilizing the random allocation software 2.0 (Mahmood Saghaei, Isfahan, Iran) [22].

The patients rested for 10 min before injection to restore heart rate and blood pressure to normal levels. Afterward, a vital sign monitor (CMS 6000, Shenzhen, China) was attached to the patients, and heart rate, blood pressure, and respiratory rate were measured. The patients were in a semi-supine position (45 degrees) and were asked to open their mouths widely. Thereafter, oral mucosa was dried with a piece of gauze, and Benzocaine 20% topical anesthetics gel (Dentonics, NC, USA) was applied using the applicator in

the needle penetration zone (for 2 min). Afterward, 32 individuals were divided into two groups (16 individuals for each group); the first group utilized an anti-stress ball with a diameter of 7 cm (BB anti-stress ball, Iran) (Fig. 1), while the second group (control group) did not receive any distraction method. For performing the IANB injection procedure, a 25-mm gauge 30 needle (Transcodent, Schleswig-Holstein, Germany) was used. After initial penetration of mucosa, the needle was inserted into the tissue, while 0.4 ml of 2% lidocaine with 1:80,000 epinephrine anesthetic solution (Daroopakhsh, Tehran, Iran) was injected until it reached the mandibular bone. The rest of the anesthetic solution (1.4 ml) was injected into the injection site for 1 min.

Before and after the injection, patients' vital signs were monitored and recorded. These injection procedures were performed by an oral and maxillofacial surgeon with 10 years of experience on the deepest part of the pterygomandibular raphe. Afterwards, the participants reported their pain during the injection by employing a numerical rating scale (NRS) from 0 to 10 (from 0 which indicates no pain to 10 which indicates the worst pain possible).

Statistical analysis

Kolmogorov-Smirnov test, independent *T*-test, and Fisher's exact chi-square test were performed for statistical analysis by SPSS 22 (IBM, NY, USA) (p-value < 0.05 was considered significant).

Results

Thirty-two individuals from 20 to 40 years old participated in this study (16 individuals for each group). The demographic information is mentioned in Table 1. The demographic variables and participants' vital signs before injection were not significantly different between the two groups (p-value > 0.05).

Moreover, utilizing an independent *T*-test showed that the pain score of individuals who used an anti-stress ball was significantly lower than the control group (p-value $= 0.001$). In addition, in all sexes and age ranges, using the anti-stress ball reduced the pain score significantly except in individuals who were more than 35 years old (Table 2).

Using an independent *T*-test demonstrated that the patient's vital signs, including heart rate, systolic and diastolic blood pressure, and respiratory rate, were not significantly different before and after injection in the two groups (p-value > 0.05).

Discussion

The results of this study demonstrated that the individuals who utilized anti-stress ball distraction during the injection experienced less pain compared to those who did not use the anti-stress ball. In addition, the pain scores of all sex and age ranges were significantly higher in the control group compared to the anti-stress ball group except in individuals who were older than 35 years old. Moreover, monitoring participants' vital signs showed that there were no significant differences between individuals' vital signs before and after injection in both groups.

Dental fear is a constant challenge for doctors and patients, often interfering with the dentist's ability to provide care. This fear can force patients to avoid regular dental procedures. Using an anti-stress ball is a simple and inexpensive method for cognitive refocusing. In clinical settings, while the use of anti-stress guns is being evaluated as a method of reducing patient fear and pain during medical procedures, the use of anti-stress balls as a distraction technique for injection pain during dental anesthesia is rarely evaluated [4, 12]. Furthermore, dentists' awareness of the best methods for pain reduction can be lucrative for reducing patients' pain and fear during local anesthesia injections.

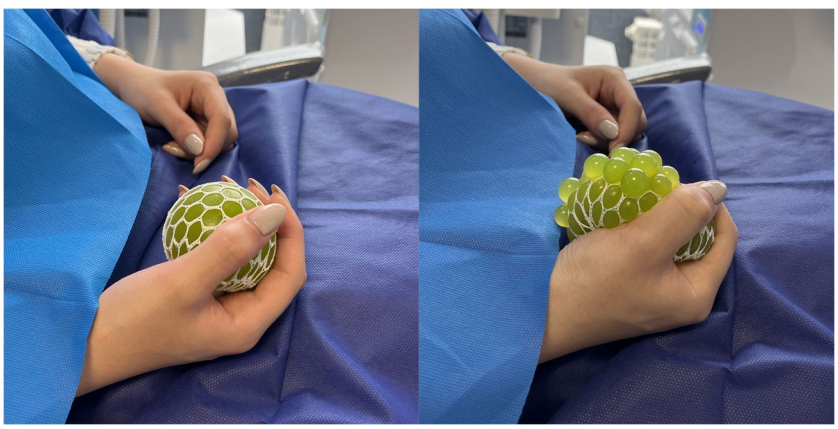

Fig. 1 Using the anti-stress ball

Table 1 Demographic and individual`s vital signs before injection information

			Utilizing anti-stress ball		
		Total	Yes	No	*p*-value
Sex (number)[1]	Male	16	8	8	> 0.999
	Female	16	8	8	
Age range (number)[1]	< 30	8	4	4	> 0.999
	30–35	16	9	8	
	35–40	7	3	4	
Heart rate (mean ± standard deviation (SD))[2]		82.25 ± 8.3	81.50 ± 6.89	83.00 ± 9.68	0.617
Systolic blood pressure (mean ± SD)[2]		119.00 ± 5.18	119.25 ± 4.12	118.75 ± 6.19	0.790
Diastolic blood pressure (mean ± SD)[2]		79.06 ± 5.88	79.38 ± 6.80	78.75 ± 5.00	0.769
Respiratory rate (mean ± SD)[2]		18.88 ± 1.41	19.00 ± 1.41	18.75 ± 1.44	0.624
GHQ-28 questionnaire score (mean ± SD)[2]		37.66 ± 1.31	38.13 ± 1.36	37.19 ± 1.11	0.056

[1]Fisher's exact chi-square test

[2]Independent *t*-test

Table 2 Individuals' pain score (mean ± SD) in different sexes and age ranges

		Utilizing anti-stress ball		
		Yes	No	*p*-value
Sex	Male	2.25 ± 0.71	4.63 ± 1.06	< 0.001
	Female	2.75 ± 1.04	4.75 ± 0.89	0.001
Age range (number)	< 30	2 ± 0.82	4 ± 0.82	0.013
	30–35	2.56 ± 0.89	5.25 ± 0.89	< 0.001
	35–40	3 ± 1.0	4.25 ± 0.5	0.078

According to the results of this study, using an anti-stress ball reduces IANB injection pain. Similarly, Hudson et al.'s [12] study in 2015 showed that utilizing an anti-stress ball and watching DVDs during surgery, which uses local anesthesia, significantly reduce patient pain and generally improve patient experience. In addition, the studies of Yilmaz and Güneş [14] in 2018 and Aykanat Girgin and Göl [16] in 2015 also demonstrated that using an anti-stress ball and other distraction methods are effective ways to reduce the pain of ambient catheterization and venipuncture.

On the other hand, in the study of Torres-Gomez et al. [18] in 2021, using an anti-stress ball as a distraction method did not lead to a significant reduction in individuals' fear during scaling and root planing with local anesthesia. In addition, Yanes et al.'s [17] study in 2018 showed that utilizing anti-stress balls did not reduce patient anxiety during skin cancer excision. Moreover, in Aydin et al.'s [4] study in 2016, using an anti-stress ball did not have a significant effect on reducing children's pain and anxiety during phlebotomy surgery. The cause of this incompatibility can be attributed to differences in studied procedures and population.

According to the results of this study for both sexes, there is a significant difference between the pain score in the two groups, and the pain score in the anti-stress ball group is lower significantly compared to the control group, which means that using an anti-stress ball in both sexes reduces pain. However, the study by Torres-Gomez et al. [18] in 2016 demonstrated that utilizing an anti-stress ball reduces pain and fear in females significantly more than in males. This difference is likely due to two reasons: first, the Torres-Gomez et al. [18] study aimed to identify strategies to help reduce pain during vitreous injection. Second, females outnumbered males in Torres-Gomez et al.'s [18] study, which could lead to a different result.

The results of this study showed that in all three age ranges, utilizing an anti-stress ball reduced the pain scores, but this difference is not significant in individuals who were above 35 years old. This finding can be explained by the fact that attracting and distracting the attention of people who are over 35 years old is harder than younger individuals.

Finally, while Moaddabi et al.'s [23] study in 2021 showed that blood pressure increased after an IANB injection, the results of the present study and another study by Moaddabi et al. [24] in 2023 demonstrated that this injection did not cause significant differences in participants' vital signs. Moreover, since there is no other study that has examined the vital signs before and after injection while using an anti-stress ball, it is not possible to compare the effect of utilizing an anti-stress ball on vital signs with other studies.

Due to not having the possibility to blind both operator and participants, one of the limitations of this study is

blinding. Moreover, individuals' lack of collaboration during performing the study is another limitation. For further studies, the authors suggest determining the effect of the anti-stress ball on pain reduction in other injection techniques to ensure that the anti-stress ball is suitable for reducing pain and fear during dental local anesthesia injections.

Conclusion

Utilizing an anti-stress ball reduces patients' pain significantly during inferior alveolar nerve block in both females and males who are 20–35 years old without altering their vital signs significantly.

Author contribution Parisa Soltani: conceptualization; methodology; project administration; data curation; methodology; validation; writing original draft; review and editing. Amirhossein Moaddabi: conceptualization; funding acquisition; supervision; methodology; writing original draft; review and editing. Mohammad Koochek Dezfuli: conceptualization; visualization; writing original draft; review and editing. Soodeh Ebrahimikiyasari: data curation; software; writing original draft; review and editing. Abolfazl Hosseinnataj: formal analysis; software; writing original draft; review and editing. Sandro Rengo: conceptualization; writing original draft; review and editing. Kioumars Tavakoli Tafti: conceptualization; methodology; validation; formal analysis; writing original draft; review and editing. Gianrico Spagnuolo: methodology; writing original draft; review and editing.

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Data Availability The datasets analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Declarations

Ethical approval All procedures followed were in accordance with the principles stated in the Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects," adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and as amended most recently by the 64th World Medical Assembly, Fortaleza, Brazil, October 2013. All procedures performed in the present study were approved by the Ethical Committee of Mazandaran University of Medical Sciences (#4.1400.REC.MAZUMS.IR).

Informed consent Patients included in the study were informed before the examination, and an Informed Consent Form was signed by all participants.

Competing interests The authors declare no competing interests.

References

1. Eisenberger NI, Lieberman MD (2005) Why it hurts to be left out. The social outcast: ostracism, social exclusion, rejection, and bullying, p. 109–127
2. Brahm CO et al (2012) Dentists' views on fearful patients. Problems and promises. Swed Dent J 36(2):79–89
3. Zhou X, Nanayakkara S (2022) Buccal infiltration with 4% articaine may be an alternative option to inferior alveolar nerve block with 2% lidocaine for pulp therapy in primary mandibular molars. J Evid Based Dent Pract 22(4):101801
4. Aydin D, Şahiner NC, Çiftçi EK (2016) Comparison of the effectiveness of three different methods in decreasing pain during venipuncture in children: ball squeezing, balloon inflating and distraction cards. J Clin Nurs 25(15–16):2328–2335
5. Kain ZN et al (2006) Preoperative anxiety, postoperative pain, and behavioral recovery in young children undergoing surgery. Pediatrics 118(2):651–658
6. Meulders A (2020) Fear in the context of pain: lessons learned from 100 years of fear conditioning research. Behav Res Ther 131:103635
7. Moaddabi A et al (2021) Effect of opaque eye coverage on anxiety in candidates for surgical removal of impacted third molars: a randomized clinical trial. Oral Surg Oral Med Oral Pathol Oral Radiol 132(3):267–272
8. Hoffmann B et al (2022) Management strategies for adult patients with dental anxiety in the dental clinic: a systematic review. Aust Dent J 67 Suppl 1(Suppl 1):S3-s13
9. Ruscheweyh R et al (2011) The effect of distraction strategies on pain perception and the nociceptive flexor reflex (RIII reflex). Pain 152(11):2662–2671
10. Appukuttan DP (2016) Strategies to manage patients with dental anxiety and dental phobia: literature review. Clin Cosmet Investig Dent 8:35–50
11. Barreiros D et al (2018) Audiovisual distraction methods for anxiety in children during dental treatment: a systematic review and meta-analysis. J Indian Soc Pedod Prev Dent 36(1):2–8
12. Hudson BF, Ogden J, Whiteley MS (2015) Randomized controlled trial to compare the effect of simple distraction interventions on pain and anxiety experienced during conscious surgery. Eur J Pain 19(10):1447–1455
13. Usichenko TI et al (2019) Mechanisms of "cough-trick" for pain relief during venipuncture: an experimental crossover investigation in healthy volunteers. Pain Res Manag 2019:9459103
14. Yilmaz D, Güneş ÜY (2018) The effect on pain of three different nonpharmacological methods in peripheral intravenous catheterisation in adults. J Clin Nurs 27(5–6):1073–1080
15. Gomez J et al (2016) Strategies for improving patient comfort during intravitreal injections: results from a survey-based study. Ophthalmol Ther 5(2):183–190
16. Aykanat Girgin B, Göl İ (2020) Reducing pain and fear in children during venipuncture: a randomized controlled study. Pain Manag Nurs 21(3):276–282
17. Yanes AF et al (2018) Effect of stress ball use or hand-holding on anxiety during skin cancer excision: a randomized clinical trial. JAMA Dermatol 154(9):1045–1049
18. Torres-Gomez J et al (2021) Management of dental anxiety via distraction technique. J Clin Exp Dent 13(4):e350–e356
19. Simons SH, Tibboel D (2006) Pain perception development and maturation. Semin Fetal Neonatal Med 11(4):227–231
20. Rashidi MA et al (2018) Evaluating general health status using Goldberg's General Health Questionnaire among the staff of

Ilam University of Medical Sciences in 2015. J Ilam Univ Med Sci 26(3):16–26
21. Ueno T et al (2008) Local anesthetic failure associated with inflammation: verification of the acidosis mechanism and the hypothetic participation of inflammatory peroxynitrite. J Inflamm Res 1:41–48
22. Saghaei M (2004) Random allocation software for parallel group randomized trials. BMC Med Res Methodol 4:26
23. Moaddabi A et al (2021) Comparison of the effects of articaine and lidocaine anesthetics on blood pressure after maxillary infiltration technique: a triple-blind randomized clinical trial. Int J Dent 2021:8894160
24. Moaddabi A et al (2023) Does a new modification of the two-step injection technique for inferior alveolar nerve block reduce pain compared to the conventional technique? A randomized clinical trial. Int J Dent 2023:5922663