The Saudi Dental Journal (2023) **35**, 567–573

King Saud University

The Saudi Dental Journal

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ORIGINAL ARTICLE

Efficacy of inferior alveolar nerve block and intraligamentary anesthesia in the extraction of primary mandibular molars: A randomized controlled clinical trial

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Received 21 October 2022; revised 21 April 2023; accepted 16 May 2023
Available online 25 May 2023

KEYWORDS

Inferior alveolar nerve block;
Intraligamentary anesthesia;
Primary mandibular molars;
Pain;
Visual analog scale

Abstract *Objective:* The study aims to compare the effectiveness and quality of intraligamentary anesthesia (ILA) and inferior alveolar nerve block (IANB) for primary mandibular molar extraction.

Methods: This prospective, randomized clinical study included patients aged 5 to 13 years scheduled for primary mandibular molar extraction. A total of 208 participants were randomly allocated into two groups (n = 104 each group), IANB and ILA, who were administered 2% lignocaine with epinephrine 1:100,000. Patients rated their pain during injection and extraction (VAS pain score). Frankl's behavior rating score, quality of anesthesia as perceived by clinician, and duration of procedure were recorded. Demographic and other variables were analysed using Pearson x^2 test, Pearson correlation coefficient, Fisher exact test, or an analysis of variance, as appropriate.

Results: In patients who received IANB, the clinician reported a slightly better quality of anesthesia (p = 0.19) than those who received ILA (VAS score 1.3 ± 0.7 *Vs* 1.6 ± 0.4). Mean (±SD) score for pain during extraction were found be 1.7 (±0.6) for the IANB group and 1.8 (±0.5) for the ILA group. The clinician observed 46.2% of patients in the IANB group and 39.4% of patients in the ILA group had no discomfort during extraction. Frankl's behavior score was negatively cor-

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Peer review under responsibility of King Saud University. Production and hosting by Elsevier

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https://doi.org/10.1016/j.sdentj.2023.05.011

related with the quality of anesthesia and the time taken to complete the extraction (p = 0.017 and p = 0.053, respectively).

Conclusion: The efficacy of conventional ILA was similar to IANB, and thus ILA might be a good alternative to the IANB while extracting primary mandibular molars.

1. Introduction

Anesthetic injections are still the most common method practiced by dentists worldwide while performing restorative and dentoalveolar surgeries in dentistry to help pediatric patients receive painless treatment. When treating mandibular primary or permanent molars, especially in mixed dentition, the inferior alveolar nerve block (IANB) is often the local anesthesia technique of choice (Klingberg et al., 2017). Although IANB is proven to be effective, it has some drawbacks, such as being technique sensitive, the occasional need to separately anesthetize the lingual and long buccal nerves, and lip or tongue biting (Faizal and Vijayan, 2013).

Intraligamentary anesthesia (ILA) is commonly utilized to supplement mandibular anesthesia when the conventional IANB fails. However, ILA has been successfully utilized for single tooth extractions, especially in patients with bleeding tendencies or when there is concern for biting of lips or tongue postoperatively (Monteiro et al., 2020; Aggarwal et al., 2020). ILA benefits include rapid onset, 30–45 min duration of anesthesia lower systemic toxicity risk, less residual and soft tissue anesthesia, avoiding potential nerve injury, and no post-anesthesia complication like lip or tongue biting (Blanton and Jeske, 2003; Moore et al., 2011).

Ryalat et al. (2018) found that ILA provided greater pain relief than infiltration, and it may be recommended if infiltration fails to control pain. A four-site (mesiobuccal, mesiolingual, distobuccal and distolingual) ILA injection technique has been demonstrated to be a favourable alternative to the standard IANB (Lin et al., 2017). Anesthetic efficacy of ILA for extraction of maxillary molars and endodontic treatment of mandibular molars were researched in the past (Allen et al., 2002; Kaufman et al., 2005; Al-Shayyab, 2017), but the utility of ILA for extraction of primary mandibular molars is not fully explored. There is little data in the literature comparing ILA and IANB in pediatric patients (Tekin et al., 2012, Elbay et al., 2016, Haghgoo & Taleghani, 2015; Pradhan et al., 2017). The authors hypothesized that ILA will be as effective as IANB during the extraction of primary mandibular molars in children with mixed dentition.

This study was designed to compare the anesthetic efficacy and adequacy of ILA and IANB for primary molar extractions. A secondary objective of this study is to explore the relationship between the quality of anesthesia and the patient's behavior (Frankl's behavior rating) and their pain experience (VAS scale).

2. Methods

This prospective, blinded randomized clinical trial included patients aged 5 to 13 years who attended the dental clinic of a teaching hospital in Benghazi, Libya. Institutional and ethical approval was obtained from Benghazi University and all parents/legal guardians of participants signed an informed consent agreement. This study followed the guidelines of the Consolidated Standards of Reporting Trials (CONSORT). Patients presenting to the dental clinic for primary mandibular molar extraction were included in the study. A total of 208 participants were included in the study, who required extraction of mandibular primary molars. The radiographs were taken to ensure there is no pathology and to confirm the presence of a permanent successor. Among the variables collected are age, sex, chief complaint, offending teeth, diagnosis, quality of anesthesia, and Frankl's behavior rating. During enrollment, parents and patients were informed that they may receive an ILA or an IANB. Each participant's parent or legal guardian provided written informed consent.

Patients with irreversible pulpitis due to extensive or recurrent caries or failed pulp therapy, retained teeth, and orthodontic reasons were included. The study excluded those with an acute dentoalveolar infection, multiple carious teeth, allergies to lidocaine or anesthetic solutions, those who needed physical restraint, known medical conditions that compromised the general well-being, those who refused to take part, and those who took analgesics 12 h prior to the dental appointment.

2.1. Injection techniques with randomization

Following aspiration, 1.5 ml of 2% lidocaine HCl containing 1:100,000 epinephrine (Lignospan Special; Septodont, Kent, England) was deposited slowly at a rate of 1 ml/min using a 27-gauge short needle (0.4 × 21 mm; CK Dental, Orange, CA, USA) and one 0.3 ml cartridge for buccal nerve anesthesia was used (Meechan, 2002). After the needle was inserted, it was advanced until bony resistance could be felt. Aspiration was performed after reaching the target area, and the solution was slowly deposited (Fig. 1).

As described by Malamed (2013), ILAs are also applied with a 27-gauge short needle (0.04x38 mm) and syringe, similar to IANBs. The needle was inserted into the gingival sulcus of the tooth until resistance was felt. Approximately 0.2 ml of anesthesia solution was injected slowly over the course of the 20 s. By pressing the syringe handle firmly, back pressure was achieved and tissue blanching was observed (Fig. 2). For the ILA technique, 2% lidocaine with 1:100.000 epinephrine was used. Each patient received 0.8 ml of the solution (0.4 ml on the buccal and palatal sides and 0.4 ml on the proximal and distal sides of the tooth).

This study involved two clinicians in order to ensure blinding. Based on the diagnosis, one clinician (HAE) randomized participant allocation, to minimize recruitment bias, through

Fig. 1 Administration of inferior alveolar nerve block (IANB) for the extraction for lower primary molar.

Fig. 2 Administration of intraligamentary anesthesia (ILA) for the extraction of lower primary molar.

an easily accessible web-based randomization tool (https://www.randomizer.com). One independent clinician, not involved in the study, prepared sterile pouches containing the syringe and needle and marked them either A (IANB) or B (ILA). The second blinded clinician (MO) received one of the labelled pouches prior to administering the local anesthesia and dental extraction. Tooth extraction was completed using an elevator and forceps. At any point during the procedure where there was pain or the patient showed marked discomfort, the procedure was stopped and the case was considered a failure.

2.2. Anesthetic efficacy assessment

Three minutes after MO administered the local anesthetic, HEA asked the patient to rate their pain during injection on a 10-cm visual analog scale (VAS), with 0 representing no pain and 10 representing maximum pain (Katz and Melzack, 1999). Patients selected corresponding numbers and these were recorded in a data collection form. Following the dental extraction, the VAS was recorded again. We re-scored pain levels at injection and extraction on a 5-point Likert scale (0, none; 1, mild; 2, moderate; 3, severe; 4, worst).

Anesthesia quality was assessed using a 3-point rating scale based on patient reports of comfort, 1 "no discomfort", 2 "discomfort, no need for additional anesthesia" and 3 "discomfort with the need for additional anesthesia". This was done twice, once for anesthesia injection and once for tooth extraction. The clinician MO recorded the duration of the extraction procedure.

2.3. Behavior assessment

A behavioral rating scale developed by Frankl in 1962 was used by HEA to assess the participant's behavior in the waiting room when they were in the waiting room.

Definitely positive: Good rapport with the dentist, interested in dental procedures, laughing and enjoying.

Positive: Acceptance of treatment, at times cautious, willingness to comply with the dentist, at times with reservation, but the patient follows the dentist's directions cooperatively.

Negative: Reluctant to accept treatment, uncooperative, some evidence of a negative attitude but not pronounced (sullen, withdrawn).

Definitely negative: Refusal of treatment, crying forcefully, fearful, or any other overt evidence of extreme negativism.

For statistical analysis, each rating category was given a numerical value: "definitely positive" was 1, "positive" was 2, "negative" was 3, and "definitely negative" was 4. Following extraction, MO assessed the quality of the anesthesia using a modified method described by Sisk (Sisk, 1992).

2.4. Statistical analysis

Data were collected and analyzed by SK, a co-author who did not participate in clinical aspects. Data analysis was performed using SPSS version 15 for Windows (SPSS Inc) with a level of statistical significance set at $P < 0.05$. Demographic and other variables were analyzed using Pearson x^2 test, Pearson correlation coefficient, Fisher exact test, or an analysis of variance, as appropriate. Analysis of variance was used to compare outcome variables between groups.

Both VAS pain scores and behavior assessment (Frankl) were analyzed using Spearman's rho test. In order to test for differences between ILA and IANB for pain during the injection of anesthesia and during tooth extraction, Mann-Whitney U and Kolmogorov-Smirnov tests were used.

3. Results

A total of 208 participants were included in the study and were randomly divided into two equal groups ($n = 104$ per group), with a mean age of years 8.2 ± 1.7 (range, 5 to 12 years). The study included 121 boys and 87 girls, the ratio being (1.39:1). Most of the patients were in the age group of 5 to 7 years (43.2%) followed by 8 to 10 years (40.4%). Among all the mandibular primary molars, left first molars (42.8%) and right first molars (33.2%) were frequently extracted than the second molars. In more than half of the patients, advanced carious lesions (56.7%) which were unrestorable or the parents/patient declined restoration was the most common cause for extraction. No statistical differences were identified in the demographic data of the patients and parameters such as the age, sex, type of offending teeth extracted and reasons for extraction (Table 1).

3.1. Local anesthetic effectiveness

The variable means, SDs, and ranges are presented in Table 2. The average time taken to complete the extraction was 4 min (SD = 1.2) for the IANB group and 4.8 min (SD = 1.7) for the ILA group (p = 0.15). The failure rate for the IANB group was 14.4% (n = 15) and 19.3% (n = 20) ILA groups. Overall pain levels reported by the patients were low, and there were no significant differences between the two groups, during injection and extraction. In patients who received IANB, the clinician reported a marginally better quality of anesthesia than those who received ILA (1.3 ± 0.7 *Vs* 1.6 ± 0.4), but it was not statistically significant (p = 0.19). The clinician observed 46.2% of patients in the IANB group and 39.4% of patients in the ILA group had no discomfort during extraction (Table 3).

3.2. Behavior and VAS score analysis

Among 208 patients who were classified based on Frankl's behavior rating scale, 34.1% (n = 71) were graded as positive, 31.7% (n = 66) were graded as definitely positive, 21.2% (n = 44) were graded as negative and 13% (n = 27) as definitely negative. Analysis using the Mann-Whitney test revealed no significant difference between the two anesthetic techniques, indicating that there is no difference in pain levels during injection and extraction. The F-test result demonstrated no significant difference between the two techniques and VAS pain score during injection and during extraction. Similar observations were seen regarding Frankl's behavior scale and quality of anesthesia as reported by the clinician.

3.3. Correlation analysis

Table 4 presents Pearson correlation coefficients comparing the VAS pain scores results during injection and extraction as well as other parameters. Among all parameters investigated in the study, Frankl's behavior scale provided the highest correlations with VAS score during injection and extraction in both the groups, IANB and ILA. Frankl's behavior score was noted to be negatively correlated (nearly significant) with the quality of anesthesia as reported by the operating clinician (p = 0.017) and the time taken to complete the extraction (p = 0.053). All VAS scores were associated with each other, while the age of the patients was positively correlated with the VAS scores recorded during extraction in both groups.

4. Discussion

In our study, the VAS pain scores between IANB and ILA for the anesthetic injection were marginally, but not significantly, higher than the IANB group, while the VAS pain scores for extraction in the IANB group were marginally lower than ILA group. VAS pain scores were lower for patients receiving ILA than for those receiving IANB or infiltration methods in recent studies (Lin et al., 2017, Ryalat et al., 2018, Helmy et al. 2022). When using the conventional method for delivering the ILA injection, the clinician should be using higher pressure when compared to other anesthetic injections, and this could be the explanation for the higher VAS score in the ILA group during the injection. ILA is not frequently used in clinical practice because of possible shortcomings like pain and discomfort during injection and difficulty in needle positioning, the merits of ILA are the lesser dose of an anesthetic drug used, no undue residual soft tissue anesthesia, improved patient comfort and greater success in achieving anesthesia (Klingberg and Broberg, 2007).

Al-Shayyab noticed higher VAS scores in the ILA group than the infiltration group when extracting the posterior maxillary permanent tooth, and not advocating the use of ILA in adults (Al-Shayyab, 2017). In those studies which utilized a 0–10 VAS rating scale, the mean score for the ILA group ran-

Table 1 Characteristics of the study population.

		Group			
		IANB (%)	ILA (%)	Total (%)	p-value
		n = 104	*n = 104*	*n = 208*	
Sex					
	Male	62 (51.2)	59 (47.8)	121 (58.2)	0.866
	Female	42 (48.3)	45 (51.7)	87 (41.8)	
Age (years)					
	5–7	49 (54.4)	41 (45.6)	90 (43.2)	0.011
	8–10	37 (44.1)	47 (55.9)	84 (40.4)	
	11–13	18 (52.9)	16 (47.1)	34 (16.4)	
Offending tooth (primary molars)					
	Right first molar	42 (60.9)	27 (39.1)	69 (33.2)	0.603
	Right second molar	7 (35.0)	13 (65.0)	20 (9.6)	
	Left first molar	44 (49.4)	45 (50.6)	89 (42.8)	
	Left second molar	11 (36.6)	19 (63.3)	30 (14.4)	
Reasons for extraction					
	Extensive caries (Unrestorable)	69 (58.5)	49 (41.5)	118 (56.7)	0.824
	Failed restoration/pulp therapy	25 (40.3)	37 (59.6)	62 (29.8)	
	Orthodontics	8 (36.4)	14 (63.6)	22 (10.6)	
	Others	2 (33.3)	4 (66.6)	6 (2.9)	

Table 2 Comparison between IAN block and ILA and other dependent variables.

	IANB (n = 104) Mean ± SD	ILA(n-104) Mean ± SD	Range	p-value
Frankl*	2.4 ± 0.3	2.2 ± 0.7	0–3	0.193
Quality of anaesthesia*	1.1 ± 0.4	1.4 ± 0.5	0–2	0.193
Duration of extraction (mins) **	4.0 ± 1.2	4.8 ± 1.7	2–9	0.148
VAS pain (anaesthesia) **	1.3 ± 0.7	1.6 ± 0.4	0–4	0.164
VAS pain (extraction) **	1.7 ± 0.6	1.8 ± 0.5	0–4	0.419

VAS indicates visual analog scale.
* *t*-test.
** Mann-Whitney *U* test.

Table 3 Frankl's behavior rating in children and clinician's perceived quality of anesthesia achieved using IANB and ILA injections.

	IANB group n = 104 (%)	ILA group n = 104 (%)	Total n = 208 (%)	p-value*
Frankl behavior scale				
1	31 (29.8)	35 (33.6)	66 (31.7)	0.16
2	38 (36.5)	33 (31.7)	71 (34.1)	
3	20 (19.2)	24 (23.1)	44 (21.2)	
4	15 (14.4)	12 (11.6)	27 (13.0)	
Quality of anesthesia				
1	48 (46.2)	41 (39.4)	89 (42.8)	0.12
2	31 (29.8)	37 (35.6)	68 (32.7)	
3	25 (24.0)	26 (25.0)	51 (24.5)	

IANB Inferior Alveolar Nerve Block; ILA Intraligamentary Injection.
* There was no difference between the two groups (chi square test).

Table 4 Pearson correlation coefficients between the variables.

	Sex	Age	Frankl Score	Quality of Anesthesia	Duration of extraction	VAS injection (IANB)	VAS extraction (IANB)	VAS injection (ILA)	VAS injection (ILA)
Sex	1								
Age	0.19	1							
Frankl	−0.33	0.05*	1						
Quality of anesthesia	0.13	0.08–	0.13*	1					
Duration of extraction	0.18	0.06–	0.19*	0.15	1				
VAS injection (IANB)	−0.05	0.23	0.13	0.43	0.02	1			
VAS extraction (IANB)	0.02	0.13*	0.16*	0.22	0.06	0.51*	1		
VAS injection (ILA)	−0.19	0.10	0.19	0.08	0.10	0.17*	0.16*	1	
VAS extraction (ILA)	−0.15	0.01*	0.13*	0.16	0.02	0.50*	0.09*	0.64*	1

† VAS indicates visual analog scale; IANB Inferior Alveolar Nerve Block; ILA Intraligamentary Injection.
* Significance of Pearson's r at level 0.05 (2 tailed).

ged from 1.55 to 3.4 (Monteiro et al., 2020; Carugo et al., 2020; Kaufman et al., 2005; Mittal et al., 2019). The mean VAS scores recorded in our study after injection was 1.3 for IANB and 1.6 for ILA, which is within the range reported in the past.

In a survey among Bulgarian dental practitioners, it was observed that 75.91% of dentists use ILA in different types of dental treatment and they admitted that ILA was adequate in 32.9% and about 27.5% had complications related to ILA such as periodontitis, necrosis, and alveolitis (Lalabonova et al., 2005). It must be acknowledged that these studies were conducted on adult patients, making it unclear whether similar outcomes are likely to occur in pediatric patients as well.

Researchers have established that dental anxiety was more pronounced in younger children (4–6 years) and begins to decrease by 6 to 7 years by when they can cope up with dental situations (Klingberg et al., 2017; Klinberg and Broberg, 2007; Sharma and Tyagi, 2011). In our study, according to Frankl's behavior rating scale, 84 patients were categorized as "Negative" and 37 patients were categorized as "Definitely Negative", and most of them were treated under physical restraint when other strategies fail. We are not certain whether an exaggerated VAS pain score after the injection and extraction, considering the behavior management techniques used. In a group of 2–14-years old, Sharma and Tyagi found a significant improvement in Frankl's behavior rating score with every subsequent dental visit (Sharma and Tyagi, 2011). It can be assumed that if a positive and painless experience was created for children, they may have less anxiety in their future dental visits and can be very cooperative.

ILA increases the risk of endocarditis and therefore it is contraindicated (Shabazfar et al., 2014; Ashkenazi et al., 2006). In addition, there were some concerns of the use of ILA in pediatric patients such as damage to the unerupted permanent teeth, the crestal bone and cementum from needle trauma, which were later shown to be insignificant and reversible (Shabazfar et al., 2014; Ashkenazi et al., 2006). The decision to employ ILA should be based on child's medical history, duration and type of planned procedure.

5. Limitations

We are not certain that this study will really detect a difference between the two groups since no power analysis was performed a priori. In addition, there were no computer-assisted delivery systems or specialized syringes available for ILA in the study. Additionally, we only used single-tooth anesthesia for the extraction of primary mandibular molars. While VAS pain scores have been used to evaluate anesthetic efficacy in the past since they serve as a validated and meaningful metric, their use depends on the understanding and perception of patients, especially in children.

6. Conclusion

In the study, conventional ILA proved to be an effective alternative to IANB in extracting mandibular primary molars. Clinicians managing pediatric patients should consider this procedure because of its simplicity, short learning curve, low failure rates, and no possible post-injections.

Funding information

No funding was obtained.

Ethical approval

The study was in accordance with the ethical standards of the institutional research committee of Benghazi University and approval was obtained.

Informed consent

Written consent was obtained from all parents/legal guardians of participants enrolled in the study.

CRediT authorship contribution statement

Maraai Orafi: Investigation, Formal analysis, Visualization, Writing – original draft. **Halima Abd Elmunem:** Investigation, Data curation. **Subhashraj Krishnaraaj:** Conceptualization, Methodology, Writing – review & editing, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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