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RCT on the Effectiveness of the Intraligamentary Anesthesia and Inferior Alveolar Nerve Block on Pain during Dental Treatment

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1 ABSTRACT

Objective: To compare the effectiveness and complications of intraligamentary anesthesia (ILA) with conventional inferior alveolar nerve block (IANB) during injection and dental treatment of mandibular posterior teeth.

Materials and Methods: In this randomized, prospective clinical trial, 72 patients (39 males, 33 females) patients scheduled for dental treatment of mandibular posterior teeth, were randomly allocated to ILA group (n=35) received ILA injection or IANB group (n=37) received the conventional IANB. Our primary outcome was to assess pain and stress (discomfort) during the injection and dental treatment, using the Numeric Rating Scale (NRS) from 0 to 10 (0 = no pain, 10= the worst pain imaginable). Whereas; recording 24 hours postoperative complications were our Secondary outcomes.

Results: Patients in ILA group reported significantly less pain during injection when compared with IANB group (p=0.03). While pain during dental treatment was similar in both groups (p=0.2). Patients in both groups also reported similar law values of discomfort during treatment (p= 0.7). Although no signs of nerve contact or any other postoperative complications were observed, five patients in IANB group (none in ILA group) reported temporary irritations

Conclusion: This study showed equivalent effectiveness of both intraligamentary anesthesia and conventional inferior alveolar nerve block, for pain control during routine dental treatment of mandibular posterior teeth. Nevertheless, ILA showed significantly less pain during injection. No major postoperative complications in both groups were observed.

Clinical Relevance: ILA could be considered as an effective alternative for routine dental treatment.

Key Words: local anesthetic, dentistry, pain, Inferior alveolar nerve block, RCT

2 INTRODUCTION

Pain is relevant problem in dental treatment [1], making the administration of local anesthetics a necessary and routine measure for various dental procedures [2]. Unfortunately, pain, side effects and a widely common fear of the injection are also relevant issues in dentistry [3], often resulting in missed or delayed appointments [4]. Regarding local anesthesia for mandibular teeth, two alternative techniques are well established: inferior alveolar nerve block (IANB) or local intraligamentary anesthesia (ILA) at the treated tooth. For decades, IANB has been considered as gold standard for blocking the hemimandible [5], especially in posterior mandibular permanent teeth. It provides adequate anesthesia for one side of the mandibular teeth and gingival mucosa, the body and inferior ramus of the mandible, and the anterior two-thirds of the tongue and floor of the mouth effectively [5,6].

The evidence suggests that IANB is relatively painful, and has a comparatively higher failure rate [7]. It also has a technique-immanent risks, such as transient or even persistent damage to the lingual and/or the inferior alveolar nerve [8]. Moreover, it may provoke intravascular injections, hematoma, muscle injury, and trismus [9]. In addition, IANB is associated with an increased risk of burning sensations and/or bite injuries, especially in children and patients with mental disorder due to the long duration of the soft tissue anesthesia which exceeds the dental treatment time considerably. In consequence, an alternative, local and tooth-based anesthetic technique is demanded [9], which ILA could present.

A considerable number of literatures on ILA as alternative technique for IANB were generated over the last years [12,15]. ILA only requires an injection directly into the periodontal space of the tooth with relatively high pressure. The injected solution spreads to the cancellous bone adjacent to the tooth to be anesthetized [10,11]. Among the advantages of this technique are the rapid onset of action, a reasonable duration of 30-49 min, which is in line with standard dental treatment, as well as a low and safe amount of anesthetic solution (about 0.2 ml for each root) [12]. It is of high safety in pediatric patients, patients with bleeding disorders as well as in medically compromised patients [9,13,14]. On the other hand, ILA has its own limitations, especially because it is applied for single teeth and bacteremia is reported [12]. Also, the question of (reversible) damage of periodontal tissue, bone and even root resorption is discussed [12]. In some procedures such as extractions, this is not relevant at all. In summary, current research views ILA as possible good alternative to IANB for dental routine procedures [12,15]. Therefore, the aim of this study was to evaluate the effectiveness of ILA versus IANB for dental treatment of mandibular posterior teeth.

3 MATERIALS AND METHODS

This prospective randomized comparative clinical trial was conducted in the integrated clinical course in the dental school of the University of Greifswald, Germany after the approval of the local ethics committee of the medical faculty in Greifswald (No. BB 174/18) in a period from December 2018 to June 2019. It was also registered in ClinicalTrails.gov (ID: NCT04563351). The sample size calculation using "G*power version 3.1" (Heinrich-Heine-University / Germany) was based on the following estimates: T-test for means (difference between two independent means), effect size 0.7, α error 0.05 and power (1-ß error) 0.9. It resulted in a samples size of 36 patients in each of the two groups (IANB & ILA).

3.1 Inclusion and Exclusion Criteria

The patients requiring regular dental treatment in permanent mandibular posterior teeth under local anesthesia were recruited with an age range of 18 to 50 years. Patients were not included if they had a clinical or radiographic sign of acute abscess, pus or peri-radicular pathology. Also, patients with a systemic disease requiring special considerations during their dental treatment or patients with contra-indications for any of the components of the anesthetic solution (allergy to articaine, epinephrine, and sulfite) were excluded.

3.2 Clinical Treatment and Outcome

Only one tooth per patient was included in the study. A computer-generated random number list with allocation concealment was used to assign patients to one of the two groups (ILA vs. IANB, see CONSORT diagram, Figure 1). The dental practitioners (GDPs) or the students performing the treatment and evaluating the effectiveness of the anesthesia were blinded to the form of anesthesia which was administered by the clinical instructors of the course being also dental practitioners (GDPs) or other dental students in the 4th and 5th academic year in the integrated clinical course in the dental school of the University of Greifswald. The distributions of different experience level of clinical instructors, dental students in 4th and 5th year were recorded and analysed. The intensity of pain as well as stress during the injection of the local anesthesia and during the dental procedure was assessed by using the Numeric Rating Scale (NRS 0-10).

For the inferior alveolar nerve block, the patient was placed comfortably in a supine position on the dental chair. The start of the anesthetic procedure was done without using topical anesthesia. The IANB injection was administered with cannulas of 38 mm in length and a gauge of 0.4 mm (Sopira Carpule, Heraeus Kulzer GmbH Hanau, Germany). The patients were anesthetized with Ultracain DS Forte 1:100.00 (Sanofi Aventis, Germany), the active ingredient being articaine in 1.7 ml ampules (1 ml equal to 40 mg articaine hydrochloride and 0.012 mg epinephrine hydrochloride, which is included as a vasoconstrictor). Once the bone was contacted, 1.5 ml of anesthetic solution was injected slowly [16,17]. Subsequently the needle was detached for approximately 1 cm and an addition of 0.3-0.5 ml of local anesthetic solution was injected to anesthetize the lingual nerve [6].

For the intraligamentary anesthesia, three different syringe systems were used with randomized selection: Softjet syringe (Henke-Sass Wolf, Tuttlingen, Germany), Citojet syringe (Sopira, Heraeus Kulzer GmbH Hanau, Germany), Ultrajet syringe (Sanofi-Aventis, Frankfurt am Main, Germany). The patients were also placed in a supine position and the dentist administered the ILA injection without using topical anesthesia with cannulas of 12 mm in length and a gauge of 0.30 mm (Sopira Carpule, Heraeus Kulzer GmbH Hanau, Germany). Also, Ultracain DS Forte 1:100.000 (Sanofi Aventis, Germany) was used from 1.7 ml ampules. The needle was navigated through the gingival sulcus with the bevel towards the alveolar bone and away from the root surface, at an angle of 30°-40° to the long axis of the tooth and 2– 3 mm into the periodontal ligament space between root and alveolar bone. For each root, 0.2 ml of local anesthetic was injected over at least 20 seconds according to Endo et al. (2008) as well as Bender and Taubenheim (2014) [14].

The intensity of pain during the injection of the LA and during the dental treatment was the primary outcome, assessed by the patient using the Numeric Rating Scale (NRS) 0-10 (0 representing no pain at all and 10 representing the worst pain imaginable). The secondary outcomes were postoperative complications, temporary irritation and the duration of the anesthesia (when the feeling of numbness had disappeared) being assessed after 24 hours by calling the patient.

CONSORT Flow Diagram

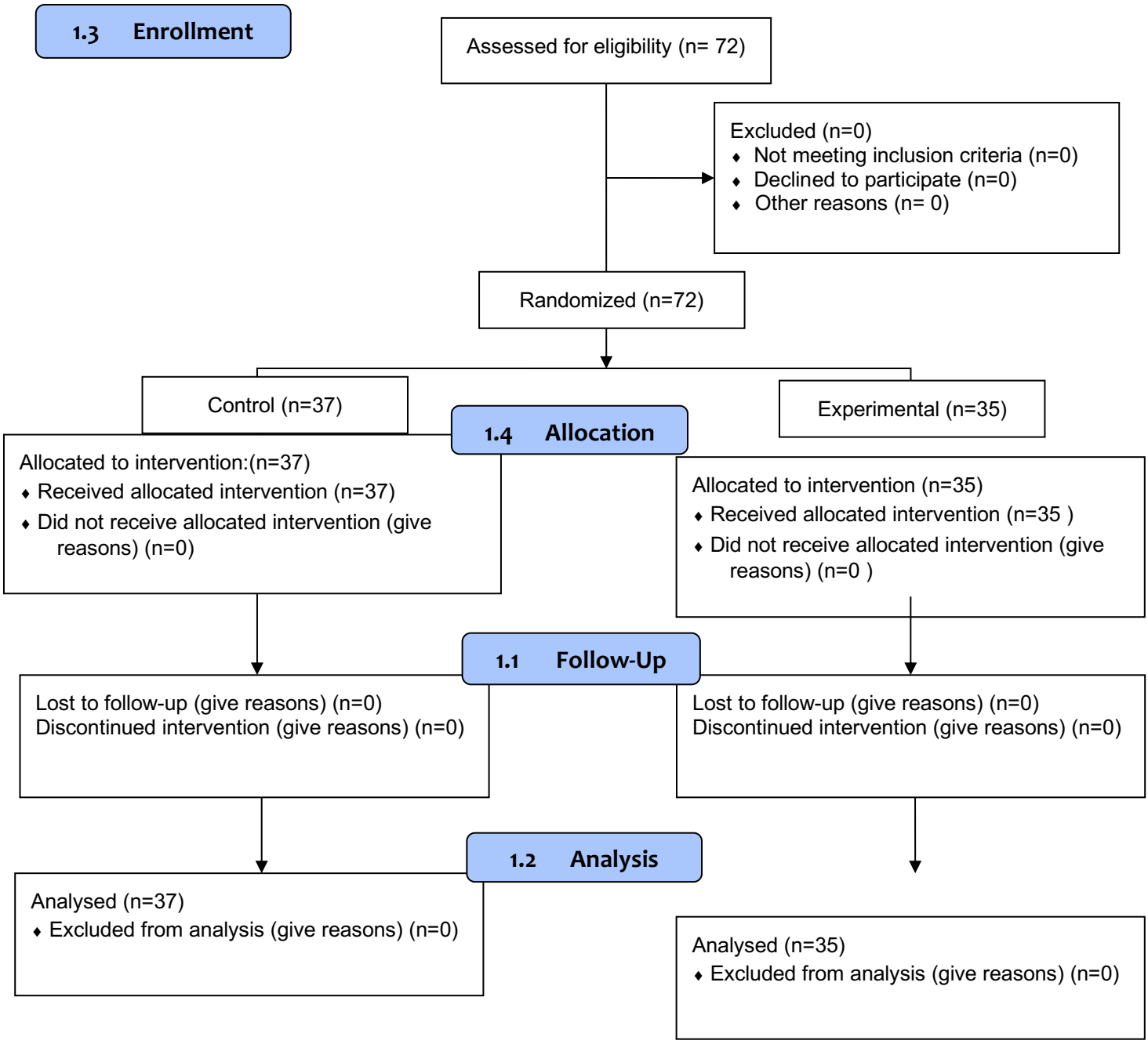

Fig. 1 Show the CONSORT diagram

3.3 Statistical Analyses

Skewedness, quartiles and standard deviations were checked for the distribution of the data. For the descriptive analysis of categorical data, absolute and relative frequencies were calculated. For continuous data, minimum, maximum, median and mean values. Categorical data were visualized via bar charts and consistent data via boxplots. For further explorative data analysis, Kolmogorov-Smirnov test was employed to test for a difference among ILA and IANB. In cases of p-values <0.05, Mann-Whitney-U test and Kruskal-Wallis H, and in cases of p-values >0.05, Students' t-test and one-way Annova for independent samples were employed for the main analysis between ILA and IANB. In addition, the data for the different ILA syringes systems were compared in a sub analysis. The influence of categorical variables was shown with chi square tests and cross tables. A significance level was set at 0.05. All analyses were carried out using SPSS Statistics version 22 (IBM, Armonk, NY, USA).

4 RESULTS

Seventy-two adult patients (39 males, 33 females) were enrolled and participated in this study. They were randomizer located in two groups, IANB group (37 teeth were treated in 37 patients) and ILA group (35 teeth were treated in 35 patients). Both groups showed similar distributions of patients' age, body mass, gender, treated teeth and experience level of clinical instructors (Table 1). The performed treatments for IANB group were endodontic treatment (26%), caries removal (23%), and preparation of crown or inlay (23%, Table 2). For ILA group, they were replacement of old fillings (26%) and caries removal (23%, Table 2). The amount of local anesthesia that had been applied was significantly lower for ILA (p=0.00, Figure 2).

Table 1. Distribution of patients` age, body mass, gender, treated teeth and different experience level for clinical instructors, dental students in 4th and5th year for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA)

	IANB group	ILA group	P value
Age (Years), Mean (SD)	41.2 (12.1)	44.4 (16.4)	0.3
BMI (Kg/m^2), Mean (SD)	25.9 (4.4)	26.1 (5.9)	0.8
Gender, pat. No. (%)			0.3
Male	22 (59.5%)	17 (48.6%)	
Female	15 (40.5%)	18 (51.4%)	
Treated teeth. No. (%)			0.47
Molars	29 (78.3%)	26 (74.2%)	
Premolars	8 (21.6%)	9 (25.7%)	
Experience level No. (%).			0.9
Clinical instructor (GP)	8 (21.6%)	8 (22.8%)	
Dental students in 5th year	20 (54.0%)	18 (51.4%)	
Dental students in 4th year	9 (24.3%)	9 (25.7%)	

SD= standard deviation. GP= general practitioner

Table 2. Distributions of clinical treatment of permanent mandibular posterior teeth for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA)

Type of clinical treatment	IANB group	ILA group
caries removal (%)	23%	23%
endodontic treatment (%)	26%	18%
preparation of crown or inlay (%)	23%	15%
insertion of crown or inlay (%)	8%	12%
replacement of old filling (%)	17%	26%
extraction of single tooth (%)	3%	6%

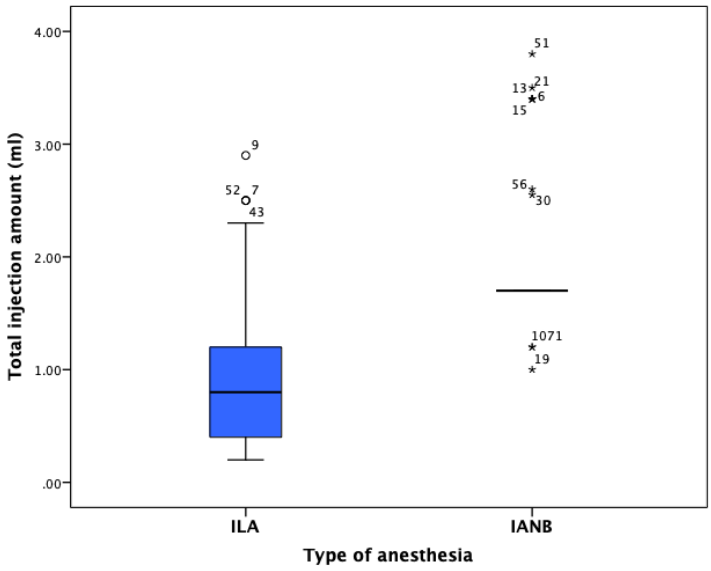

Fig. 2 *The total injection amount (ml) of local anesthetic solution during the entire procedure for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA).*

4.1 Pain of Injection and During Treatment

The pain of injection and during treatment assessed on the numeric rating scale (NRS) showed lower pain scores during the injection and treatment reported by the patients in ILA and IANB groups (Table 3). However, ILA showed significantly less pain during the injection than IANB (p=0.03), while both techniques were similarly effective in pain control during the dental treatment (p=0.2). In cases of ILA, 6 (17%) patients reported high scores of pain (>5) during treatment and 2 (5.7%) patient during the injection, for IANB 2 (5.4%) patients reported high scores of pain (>5) during the injection (Figure 3).

The patient´s discomfort during treatment was very low and similar in both groups indicating mostly satisfactory local anesthesia (p=0.7), but the distribution showed considerable variation within patients of both groups. One patient in each group rated the experience as unpleasant (>5, Figure 3).

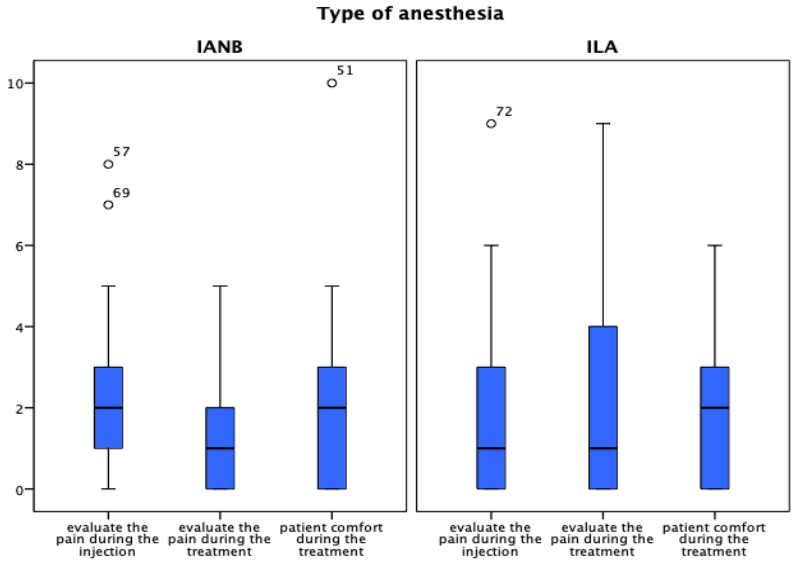

Fig. 3 *Assessment of the differences between pain of injection, pain during treatment, and unpleasantness of treatment for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA) by using a 10-point segmented numeric rating scale (NRS).*

Table 3. The median pain score during injection, treatment and patient's comfort for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA) by using a 10-point segmented numeric rating scale (NRS)

Pain Score	IANB group	ILA group	P value
Pain score during injection (0-10); median (IQR)	2(2)	1 (3)	0.03
Pain score during treatment (0-10); median (IQR)	1(2)	1(5)	0.2
Patient comfort during the treatment (0-10); median (IQR)	2(3)	2(3)	0.7

IQR= Interquartile range

4.2 Frequency of Complications or Irritations

In general, IANB had a longer time of local anesthesia than ILA (p=0.00, Figure 4). No sign of detrimental nerve contact or other complications were observed in any patient. However, one case with IANB reported difficulty during talking for one day after the anesthesia, other three more cases reported pain at the site of injection, and one case reported pain around the ear after the injection. On the other hand; no signs of any complication including soft tissue necrosis were observed with ILA technique.

4.3 Comparison of different ILA syringes

In two cases using Softjet syringes (16.6%) and Ultrajet (18.1%), high scores of pains (>5) during following dental treatment were reported. For Citojet syringes, two patients (18%) reported high score of pain (>5) during the injection and the subsequent treatment were reported. Still, the comparison of the pain parameters for the three different ILA syringes showed a very similar outcome (Table 4, Figure 5). The comparison of the patient's comfort during treatment resulted in an equivalent outcome with overall low degrees of unpleasantness (p=0.7, Table 4). Only one patient rated the experience as unpleasant (>5) for Softjet syringes (Figure 5).

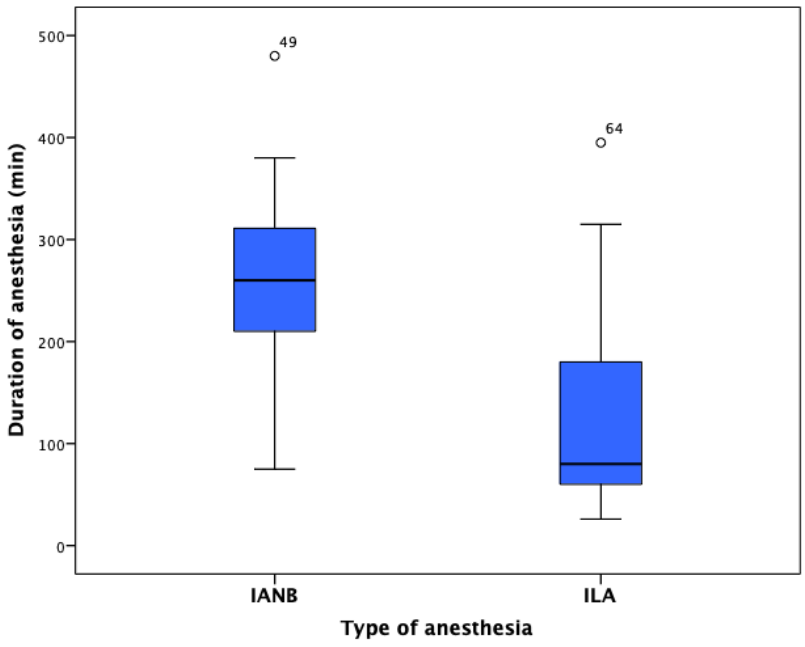

Fig. 4 *The duration of soft tissue anesthesia (min) for inferior alveolar nerve block (IANB) vs. for intraligamentary anesthesia (ILA).*

Table 4. Median pain score during injection, treatment and patient comfort for different intraligamentary syringe systems (Softjet, Citojet, Ultrajet) by using a 10-point segmented numeric rating scale (NRS)

Pain Score	Softjet	Citojet	Ultrajet	P value
Pain score during injection (0-10); median (IQR)	0.5 (3)	1.5(4)	1(3)	0.6
Pain score during treatment (0-10); median (IQR)	0(2)	1.5(4)	2(4)	0.3
Patient comfort during the treatment (0-10); median (IQR)	3(2)	3(3)	3(2)	0.7

IQR= Interquartile range

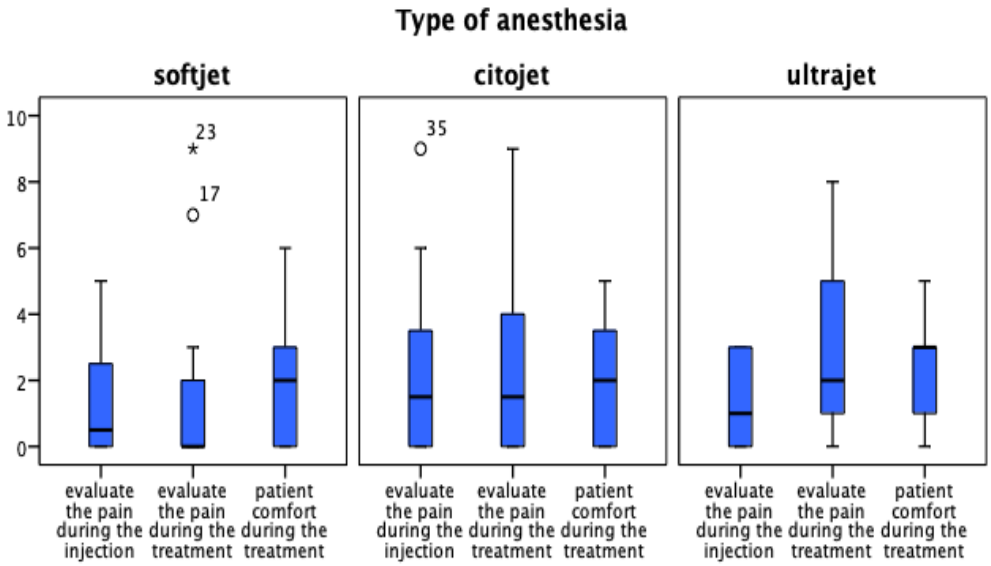

Fig. 5 *Assessment of the differences between pain of injection, pain during treatment, and unpleasantness of treatment for different intraligamentary syringe systems (Softjet, Citojet, Ultrajet) by using a 10-point segmented numeric rating scale (NRS)*

5 DISCUSSION

The results of this study indicate that ILA is at least as efficient as IANB in terms of effective pain control and the degree of unpleasantness for routine dental treatment as proposed by other studies and meta-analysis [5,12,15]. Similar to our study Kämmerer et al [12]. reported an injection pain score of 1.55 ± 1.18 (mean ± SD) for mechanical (PDL-S) application and a 1.85 ± 1.22 (mean ± SD) computer-controlled (CCLAD) in 22 cases of ILA Vs 3.05 ± 1.99 (mean ± SD) in 20 cases of IANB (p=0.005). Three years later the same Authors in another study confirmed the superiority of ILA and found a mean injection pain score of 2.19 ± 1.8 (mean ± SD) for ILA Vs 3.65 ± 1.9 (mean ± SD) for IANB ($p < 0.00$) [12,15].

Although our study as well as other previously mentioned studies had reported a clear superiority of ILA over IANB for injection pain control, "regardless of the type of syringe systems used", both anesthetic techniques showed no statistically significant differences concerning the success rate, the depth of the block as well as pain scores during the subsequent dental treatment.

As the pain recognized by the patient is the most important reason for anxiety or phobia of dental treatment and the main aspect in the evaluation of the effectiveness of local anesthetic techniques [12,15]. Thus, pain assessment is crucial during dental treatment and the most commonly used tool is the numeric Rating scale (NRS) from 0 to 10 as it is a highly reliable and appropriate for dental environment [18].

On contrast to our result, Dumbrigue et al. reported that the injections of ILA were associated with more pain and discomfort to the patient compared with IANB, however, the authors did not consider each extracted tooth as an independent sample [18]. Several intraligamentary injections were required in the same quadrant, which may be a reason for the great patients´ discomfort during the injections with ILA. Moreover, Dumbrigue et al used pistol type syringes without safety pressure limiting mechanism, and the injection takes place rapidly under higher pressure than appropriate which increase the injection pain certainly [10]. Thus, the results of such studies with small sample size (16 patients, 45 teeth) should be taken cautiously. It must also be emphasized that the comparisons between different studies are difficult due to variable procedural factors possibly associated with pain experience during the administration of local anesthetic such as, the type or the amount of local anesthetic solution, temperature of the injection solution, injection rate, site of injection as well as the experience of the dentist.

In addition, our study is in agreement with Kämmerer et al [12], study found no statistically significant difference in both groups regarding patient satisfaction (comfort) and over all pain experienced during the entire treatment course.

Our study confirmed ILA as a reliable alternative technique to IANB with the superiority of the following: The amount of local anesthesia for ILA was small and carries no risk of systemic toxicity with accidental intravascular injection [9,14]. As ILA mostly wearing off at the end of the dental treatment with no residual regional anesthesia (as in case of LANB), due to the sensitivity of the lower lip for considerable time after the dental treatment. - These reduces the risk of unwanted side effects such as lip biting in children or patients with mental disabilities who have higher risk of bite or thermal injury as reported in our and other previous studies [9,14], in addition it also reduces the risk of temporary unpleasant reductions of mastication and speech.

6 CONCLUSION

ILA has shown to be a safe and reliable method of local anesthesia for treatment of lower premolars and molars, with a success rate comparable to IANB without complications and temporary irritations. Thus, ILA can be considered as an effective alternative to IANB for routine dental treatment to reduce known side effects of IANB.

7 COMPLIANCE WITH ETHICAL STANDARDS

7.1 Conflict of interest

The authors declare that they have no conflict of interest.

7.2 Informed consent

Informed consent was obtained from all individual participants included in the study.

7.3 Funding information

No funding was obtained.

7.4 Ethics approval

All procedures involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Approval of the local ethics committee of the medical faculty in Greifswald (No. BB 174/18).

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9 APPENDIX

Patienteninformation

Vergleich der Wirksamkeit der intraligamentären Injektionstechnik und der Leitungsanästhesie bei der Behandlung von Unterkiefermolaren

Sehr geehrte Patientin, sehr geehrter Patient,
vielen Dank, dass Sie sich für eine Teilnahme an dieser Studie interessieren.

Einleitung

Zur zahnärztlichen Behandlung ist häufig die lokale Ausschaltung der Schmerzempfindung mittels Lokalanästhesie nötig.

Bei Ihnen soll eine Behandlung eines Molaren (Backenzahn) im Unterkiefer vorgenommen werden.

Derzeit werden unterschiedliche Lokalanästhesietechniken bei der Behandlung von Unterkiefermolaren verwendet.

Ziel dieser Studie ist die Reduktion von Schmerzen und Komplikationen während der Behandlung von Unterkiefermolaren mit den verschiedenen Anästhesietechniken.

Vorgehensweise

Die Teilnahme an dieser Studie ist freiwillig hat keinen Einfluss auf die Entscheidung des Zahnarztes über die Art der Behandlung. Es geht ausschließlich um den Vergleich der beiden Anästhesietechniken und welche in Zukunft die primäre Technik der Schmerzausschaltung darstellen sollte.

Dazu wird Ihr Zahnarzt u.a. Angaben zur benötigten Menge an Anästhesiemittel und der Dauer bis zum Wirkeintritt notieren und Sie werden nach der Behandlung um eine Einschätzung gebeten, wie sie die Behandlung empfunden haben. Sie werden nach 24 Stunden angerufen und nach eventuell aufgetretener Komplikation gefragt.

Risiken/bekannte Nebenwirkungen

- Die Lokalanästhesie stellt ein sicheres Verfahren zur Schmerzausschaltung dar.

- Obwohl beide Techniken im Alltag in der Praxis durgeführt werden, gibt es trotzdem Nebenwirkungen und Risiken.

a) Bei einer **Leitungsanästhesie** im Unterkiefer wird das Betäubungsmittel in die Nähe des Hauptastes des Nervs platziert. Damit kann eine Hälfte des Unterkiefers inklusive Zunge und Lippe bis ca. 4 Stunden betäubt werden.

Bei der Leitungsanästhesie muss zur vollständigen Rückkehr normaler Reaktionen mit mehr als 2,5 Stunden gerechnet werden.

Schwerwiegende Beeinträchtigungen durch Läsion des N. mandibularis oder

des N. lingualis mit langanhaltenden Parästhesien oder sogar jahrelang

bestehender Parese sind nicht auszuschließen.

b) Bei einer **intraligamentären Anästhesie** wird das Anästhetikum in den Spalt zwischen Zahn und Kieferknochen, den sogenannten Parodontalspalt platziert. Diese ist für die kurzzeitige Betäubung von ca. 30 min eines einzelnen Zahnes bzw. unterstützend für die o.g. Methoden geeignet. Für größere Eingriffe kann hiermit keine ausreichend lange und ausgedehnte Anästhesie erreicht werden.

Bei der intraligamentären Anästhesie, die angeblichen Schäden, die durch die Applikation ins Parodont am Zahnhalteapparat entstehen könnten wie zum Beispiel Zerreißungen am parodontalen Ligament aufgrund des Injektionsdruckes und Gewebeschädigung durch den ungewollten Transport von Plaque in die tieferen Regionen des Parodonts bei der Injektion. So könne es nachfolgend zur Taschenbildung kommen.

Es wurden auch viele histologische Untersuchungen durchgeführt, dass es nach

intraligamentärer Anästhesie zwar zu minimalen, kurzzeitigen entzündlichen Veränderungen, aber zu keinen dauerhaften Schäden am Zahnhalteapparat kommt.

- Über die Risiken und Nebenwirkungen wurden/werden sie auch von Ihrem/Ihrer

  Behndler/in aufgeklärt.

Datenschutz

Während der Studie werden medizinische Befunde und persönliche Informationen von Ihnen erhoben und in der persönlichen Akte niedergeschrieben oder elektronisch gespeichert. Die für die Studie wichtigen Daten werden zusätzlich in pseudonymisierter Form gespeichert, ausgewertet und gegebenenfalls weitergegeben. Pseudonymisiert bedeutet, dass keine Angaben von Namen oder Initialen verwendet werden, sondern nur ein Nummern- und/oder Buchstabencode, evtl. mit Angabe des Geburtsjahres. Die Daten sind gegen unbefugten Zugriff gesichert und werden vertraulich behandelt.

Wenn Sie vor Studienende aus der Studie ausscheiden, werden keine weiteren Informationen über Sie im Rahmen der Studie erhoben. Alle bereits erhobenen Daten werden gelöscht.

Weitere Einzelheiten, insbesondere zur Möglichkeit eines Widerrufs, entnehmen Sie bitte der Einwilligungserklärung, die separat abgedruckt ist.

Behördliche Zulassung der Studie

Die Studie wurde von der Ethik-Kommission in Greifswald überprüft und positiv bewertet.

Weitere Informationen

Sollten Sie Fragen haben, steht Ihnen Ihr behandelnder Prüfarzt für weitere Fragen gerne zur Verfügung.

Universitätsmedizin GREIFSWALD
Zentrum für Zahn-, Mund- und Kieferheilkunde
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Vergleich der Wirksamkeit der intraligamentären Injektionstechnik und der Leitungsanästhesie bei der Behandlung von Unterkiefermolaren

Patientennummer: _____ **Datum:** _____

Alter: _____ **Geschlecht: männl.** ____ **weibl.**____

Gewicht: : _____ **Große:**_____ **Telefonnr.:** _____

Schmerzen vor Behandlungsbeginn? □ **ja** □ **nein**

Schmerzmittel vor Behandlungsbeginn? □ **ja** □ **nein**

Wenn ja, welche Schmerzmittel? _____

Letzte Einnahme vom Schmerzmittel vor der Behandlung? Datum:_____ Uhrzeit_____

Begleiterkrankungen? _____ **Begleitmedikation**_____

Sind allergische Reaktionen auf Lokalanästhetika bekannt? □ **ja** □ **nein**
Wenn ja, welche? _____

Sind allergische Reaktionen auf Stabilisatoren, z.B. Sulfit bekannt? □ **ja** □ **nein**
Wenn ja, welche? _____

Behandler: _____

Ausfüllen durch Anästhesie-geber:

Zu Behandelnde Zähne _____ **Indikationen** _____

Bitte die verwendete Technik wählen

Material für ILA = Intraligamental - Anästhesie	**SoftJect- Citojet-Ultrajet**	**4 %ige Articainhydrochlorid- Lösung mit 1 : 100.000 Adrenalinzusatz**	
Material für die Leitungsanästhesie des N. alveolaris inferior	**Handelsübliche Aspirations-Spritze**	**4 %ige Articainhydrochlorid- Lösung mit 1 : 100.000 Adrenalinzusatz**	

Startzeit der Behandlung / Injektion: _____ **Ende der Behandlung:** _____

Injektion initial **Methode** ☐ **Leitungsanäs** ☐ **Intralig. T-A** **Menge ..... ml**	**Anästhesieeintritt / Überprüfung**						**Entscheidung über Anästhesie: Behandlungsbeginn möglich**				
	Sondierung Anästhesie ausreichend			Kälte/Wärme-Test Anästhesie ausreichend:			Ja jetzt		Nein später		
	ja		nein	ja		nein	ja		nein		
	unverzüglich		nach 1 Minute ausreichend		nach …… Minuten ausreichend						
	ja	nein	ja	nein	ja	nein					
1.Nachinjektion erforderlich **(der gleichen Technik)** Uhrzeit l__l__l:l__l__l **Methode** ☐ **Leitungsan.** ☐ **Intralig.Anäst.** **Menge ..... ml**	**Anästhesieeintritt / Überprüfung**						**Entscheidung über Anästhesie: Behandlungsbeginn Möglich**				
	unverzüglich		nach 1 Minute ausreichend		nach …… Minuten ausreichend						
	ja	nein	ja	nein	ja	nein	ausreichend		Nicht ausreichend		
							ja		nein		
2.Nachinjektion erforderlich **(einer anderen Technik)** Uhrzeit l__l__l:l__l__l **Methode** ☐ **Leitungsan.** ☐ **Intralig.Anäst.** **Menge ..... ml**	**Anästhesieeintritt / Überprüfung**						**Entscheidung über Anästhesie: Behandlungsbeginn Möglich**				
	unverzüglich		nach 1 Minute ausreichend		nach …… Minuten ausreichend						
	ja	nein	ja	nein	ja	nein	ausreichend		Nicht ausreichend		
							ja		nein		
Injektionsmenge gesamt	**Initial**		**Nachinjektion**		**2. Nachinjektion**		**Gesamtmenge**				
	……..ml		**..……..ml**		**…….ml**		**……..ml**				

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Vergleich der Wirksamkeit der intraligamentären Injektionstechnik und der Leitungsanästhesie bei den Behandlungen von Unterkiefermolaren

Patientennummer: _____

Sehr geehrte Patientin, sehr geehrter Patient,

wir möchten für Sie auch in Zukunft eine qualitativ hochwertige Zahnbehandlung gewährleisten. Sie können uns dabei helfen, indem Sie sich einen Augenblick Zeit nehmen, um diesen Fragebogen auszufüllen.

Bitte bewerten Sie die folgenden Fragen mit den für Sie zutreffenden Antworten in einer Skala von null bis zehn.

1. Wie bewerten Sie den Schmerz während der Injektion?

Kein Schmerz										**stärkster vorstellbarer Schmerz**
0	1	2	3	4	5	6	7	8	9	10

2. Wie bewerten Sie die Schmerzen während der Behandlung?

Kein Schmerz										**stärkster vorstellbarer Schmerz**
0	1	2	3	4	5	6	7	8	9	10

3. Wie bewerten Sie Ihren Komfort während der Behandlung?

sehr angenehm			**angenehm**		**moderat**		**unangenehm**		**sehr unangenehm**	
0	1	2	3	4	5	6	7	8	9	10

Vielen Dank für Ihre Mitarbeit!!!

Ausfüllen durch den Zahnarzt

Der Patient / die Patientin wurde gebeten, bei jeglichen Anzeichen von Beeinträchtigungen oder Veränderungen ihres Zustandes / Befindens das Behandlungsteam sofort zu informieren.

- Dauer der Anästhesie: nachgelassen um: Uhrzeit l__l__l:l__l__l
- Komplikationen 24 Stunden nach der Behandlung / Sind nach der Behandlung Komplikationen aufgetreten und wenn ja, welche? ……..

Dokumentation erfolgt durch: ……

Universitätsmedizin GREIFSWALD
Zentrum für Zahn-, Mund- und Kieferheilkunde

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Einwilligung & Datenschutz

Vergleich der Wirksamkeit der intraligamentären Injektionstechnik und der Leitungsanästhesie bei der Behandlung von Unterkiefermolaren

Ich bin in einem persönlichen Gespräch durch den Studienarzt ausführlich und verständlich über Wesen, Bedeutung, Ablauf, Risiken und Tragweite der Studie aufgeklärt worden.

Ich habe eine Kopie der Patienteninformation und Einwilligungserklärung ausgehändigt bekommen, diese gelesen und verstanden.

Ich hatte die Gelegenheit, mit dem Studienarzt über die Durchführung der Studie zu sprechen. Alle meine Fragen wurden zufrieden stellend beantwortet.

Möglichkeit zur Dokumentation zusätzlicher Fragen seitens der Patientin/des Patienten oder sonstiger Aspekte des Aufklärungsgesprächs:

Ich hatte ausreichend Zeit, um meine Entscheidung zu überdenken und frei zu treffen.

Mir ist bekannt, dass ich jederzeit und ohne Angabe von Gründen meine Einwilligung zur Teilnahme an der Studie zurückziehen kann (mündlich oder schriftlich), ohne dass mir daraus Nachteile entstehen.

Ich stimme zu ☐, ich stimme nicht zu ☐,

dass ich erneut kontaktiert werde, um weitere Daten zur Krankheitsanamnese/-verlauf zu erheben.

Ich bin damit einverstanden, dass ich keine Rückinformationen über die Ergebnisse der Studie erhalte.

Datenschutz:

Mir ist bekannt, dass bei dieser Studie personenbezogene Daten über mich erhoben, gespeichert und ausgewertet werden sollen. Die Verwendung der Daten erfolgt nach gesetzlichen Bestimmungen und setzt vor der Teilnahme an der Studie folgende freiwillig abgegebene Einwilligungserklärung voraus, das heißt ohne die nachfolgende Einwilligung kann ich nicht an der Studie teilnehmen.

Ich erkläre mich weiterhin einverstanden, dass im Rahmen dieser Studie personenbezogene Daten, über mich erhoben und in Papierform sowie auf elektronischen Datenträgern in pseudonymisierter Form im … aufgezeichnet werden. Soweit erforderlich, dürfen die erhobenen Daten anonymisiert (verschlüsselt) weitergegeben werden.

Die für die Datenverarbeitung verantwortliche Person der Studie ist Prof. Dr. Christian Splieth, Walther-Rathenau-str. 42, 17457 Greifswald. Telefon: 03834 867136, Email: splieth@uni-greifswald.de

Datenschutzbeauftragter der für die Datenverarbeitung verantwortlichen Person der Studie ist Prof. Ulf Glende, Projekt 29 GmbH & Co. KG, Ostengasse 14, 93047 Regensburg, E-Mail: datenschutz-umg@uni-greifswald.de.

Ich bin auf das Beschwerderecht bei einer Datenschutzaufsichtsbehörde hingewiesen worden. Die Datenschutz-Aufsichtsbehörde der Studienleitung lautet: Der Landesbeauftragte für Datenschutz und Informationsfreiheit Mecklenburg-Vorpommern, Werderstraße 74a, 19055 Schwerin, E-Mail: info@datenschutz-mv.de.

Ich bin darüber aufgeklärt worden, dass ich jederzeit die Teilnahme an der Studie jederzeit und ohne Angabe von Gründen gegenüber dem ZZMK Universitätsmedizin Greifswald widerrufen kann. Im Falle des Widerrufs werden meine Daten gelöscht.

Ich erkläre mich damit einverstanden, dass meine Daten nach Beendigung oder Abbruch der Studie mindestens zehn Jahre aufbewahrt werden. Danach werden meine personenbezogenen Daten gelöscht, soweit nicht gesetzliche Aufbewahrungsfristen entgegenstehen.

Ich habe vom datenschutzrechtlichen Einsichts- und Korrekturrecht bezüglich meiner personenbezogenen Daten Kenntnis genommen. Ich bin auf das Recht hingewiesen worden, Auskunft (einschließlich kostenfreier Überlassung einer Kopie) über mich betreffende personenbezogene Daten zu erhalten sowie ggf. deren Berichtigung oder Löschung zu verlangen.

Schließlich erkläre ich auch meine Einwilligung für die wissenschaftliche Veröffentlichung der Forschungsergebnisse unter Beachtung der datenschutzrechtlichen Bestimmungen.

Ich bin einverstanden, dass ich an der oben genannten Studie freiwillig teilnehme.

Ein Exemplar der Patienteninformation und -einwilligung habe ich erhalten. Ein Exemplar verbleibt im Prüfzentrum.

.....
Name der Patientin / **des Patienten** in Druckbuchstaben

.....
Datum Unterschrift

Ich habe das Aufklärungsgespräch geführt und die Einwilligung des Patienten eingeholt

.....
Name der Studienärztin / **des Studienarztes**

.....

Datum Unterschrift

10 EIDESSTATTLICHE ERKLÄRUNG

Hiermit erkläre ich, dass ich die vorliegende Dissertation selbständig verfasst und keine anderen als die angegebenen Hilfsmittel benutzt habe.

Die Dissertation ist bisher keiner anderen Fakultät, keiner anderen wissenschaftlichen Einrichtung vorgelegt worden.

Ich erkläre, dass ich bisher kein Promotionsverfahren erfolglos beendet habe und dass eine Aberkennung eines bereits erworbenen Doktorgrades nicht vorliegt.

Datum Unterschrift

11 LEBENSLAUF

BERUF Zahnarzt

BERUFSERFAHRUNG

01.01.2020	Kinderzahnärztliche Tätigkeit In einer Praxis in Berlin
01.07.2019-30.12.2019	Kinderzahnärztliche Tätigkeit In einer Kinderpraxis in Berlin
01.11.2015–01.10.2016	Zahnarzt und wissenschaftlicher Mitarbeiter Future Universität, Kairo (Ägypten) Abt. Orale Radiologie
01.11.2015–01.10.2016	Zahnärztliche Tätigkeit Dr. Gihan Omer Zahnklinik, Kairo, Ägypten

SCHUL- UND BERUFSAUSBILDUNG

24.01.2020-27.11.2021 Das ZK-Curriculum: Grundausbildung in Kinderhypnose, Kommunikation und Verhaltensführung

Oktober 2019 Master of Science Kinderzahnheilkunde, Universität Greifswald

03.07.2020-04.07.2020 des 15. Kongresses der Europäischen Akademie für Kinderzahnmedizin (16 Punkte)

02.12.2019-02.12.2019 Fortbildung: Moderne Kariestherapie mit Curodent Repair
Frau. Dr.AnjaWenger

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16.01.2018-18.01.2018 Fortbildung: CAD/CAM Technology & All Keramik Restauration
im ZZMK Universitätsmedizin Greifswald, Abt, Poliklinik für Zahnärztliche Prothetik

November 2017 Deutsche Zahnärztetag 2018 in Frankfurt (16 Punkte)

24.10.2018-24.10.2018 Fortbildung: Moderne Diagnostik und Therapie im Frühstadium der Karies
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05.10.2018-06.10.2018 Fortbildung: Der unkooperativene Patient (Verhaltensführung? Sedierung? Lachgas? Oder Narkose?)
im ZZMK Universitätsmedizin Greifswald, Abt. Präventive Zahnmedizin und Kinderzahnheilkunde

23.06.2018-23.06.2018 Fortbildung: Vollkeramik in aller Mund
im ZZMK Universitätsmedizin Greifswald, Abt. Poliklinik für Zahnärztliche Prothetik

25.05.2018–26.05.2018 Fortbildung: Implantat Prothetik mit praktischen Übungen (Mini-Implantate)
im ZZMK Universitätsmedizin Greifswald, Abt. Poliklinik für Zahnärztliche Prothetik

11.04.2018–11.05.2018 Fortbildung: Wurzelbehandlungen mittels Endomikroskop
an der Future Universität, Kairo (Ägypten) Abt. Poliklinik für Endodontologie

17.01.2018-17.01.2018 Fortbildung: CA DIGITAL - der Partner in der digitalen Kieferorthopädie
im ZZMK Universitätsmedizin Greifswald, Abt. Poliklinik für Kieferorthopädie

31.01.2018–16.02.2018 Fortbildung: Kieferorthopädischen Propädeutik und Prophylaxe
im ZZMK Universitätsmedizin Greifswald, Abt. Poliklinik für Kieferorthopädie

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November 2017 Deutsche Zahnärztetag 2017 in Frankfurt (16 Punkte)

20.10.2017–21.10.2017 Fortbildung: Zahnbehandlung mittels Lachgassedierung
im ZZMK Universitätsmedizin Greifswald, Abt. Präventive Zahnmedizin und Kinderzahnheilkunde

13.09.2017-14.09.2017 Fortbildung: "The in-vitro ICDAS Training Course in caries detection and assess ment for ICCMS"
im ZZMK Universitätsmedizin Greifswald, Abt. Präventive Zahnmedizin und Kinderzahnheilkunde

10.03.2016-10.03.2016 Fortbildung: "Sinus lift technique with crestal & lateral approach's &surgical Placement of B&B implants"
an der Future Universität, Kairo (Ägypten), Abt. Oralchirurgie

November 2015 Approbation als Zahnarzt in Ägypten

01.09.2014–31.08.2015 Praktisches Jahr
im Universitätsklinikum, Future Universität, Kairo (Ägypten)

01.09.2009–23.07.2014 Bachelorabschluss in Mund- und Zahnmedizin mit Auszeichnung: sehr gut
Future Universität, Kairo (Ägypten)

2009 Allgemeines Abitur

PERSÖNLICHE FÄHIGKEITEN

Sprachkenntnisse

- Deutsch (C1 Niveau)
- Englisch (B2 Niveau)
- Arabisch (Muttersprache)

- Sichere EDV-Kenntnisse (Microsoft Word/Excel/PowerPoint)

Nov 2018 (Modul-6.b) ‘‘Praxis- & Qualitätsmanagement Stress bei Kindern und Jugendlichen“ in Hamburg

Okt 2018 (Modul-6.a) ‘‘Wissenschaftliches Arbeiten IV Fallpräsentation II” in Jena

Juni 2018 (Modul-5.c) ‘‘Wissenschaftliches Arbeiten III‘ im ZZMK Universitätsmedizin Greifswald

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März 2018 (Modul-5.a) ‘‘Kinder mit chronischen Krankheiten’’ in Hannover Fach und Sachkunde in Strahlenschutz

Feb 2018 (Modul-4.b,c) “Endodontologie und pharmakologische Therapie/Dentale Traumatologie‘ ‘in Oldenburg

Jan. 2018 (Modul-4.a) “Restaurative Kinderzahnheilkunde“ im Universitätsklinikum Mainz

Nov 2017 (Modul-3.d) “Wissenschaftliches Arbeiten II und Fallpräsentation“, im Universitätsklinikum Leipzig

Okt 2017 (Modul-3.c) “Schmerz, Schmerztherapie und Sedierung bei Kindern und Jugendlichen“, im ZZMK Universitätsmedizin Greifswald

Sep 2017 (Modul-3.b) ‘‘Modernes Kariesmanagment incl. Individualisierter Prävention‘‘ Zahnklinik an der Universität Berlin

Aug 2017 (Modul-3.a) ‘‘Epidemiologie, Gruppen- und Kollektivprophylaxe, Gesundheitsökonomie ‘‘ Zahnklinik an der Universität Hamburg

Juli 2017 (Modul-2.c) ‘‘Orofaciale und dentale Entwicklung, Kieferorthopädie, CMD bei Kindern und Jugendlichen‘‘ Zahnklinik an der Universität Leipzig

Juni 2017 (Modul-2.b) “Orale Erkrankungen”, und “Oral Radiologie“ im Universitätsklinikum Tübingen

Mai 2017 (Modul-2.a) “Wachstum und Entwicklung ,Kinderpsychologie, Verhaltungsmanagement und Pädiatrie“, in Bremen

April 2017 (Modul-1.b) “Ethik, Biostatistik und wissenschaftliche Schreiben“, in der Zahnklinik des Universitätsklinikums Köln

März 2017 (Modul-1.a) “Grundlagen der evidennzbasierte Zahnmedizin“, im ZZMK Universitätsmedizin Greifswald

12 ACKNOWLEDGMENT

Firstly, I would like to thank my thesis advisor Professor Christian Splieth of the Pediatric Dentistry Department at Greifswald University. Beside accepting my proposal from the beginning and supporting me throughout my research work, he gave me a strong motivation to finish the research, despite all the huge challenges I faced, he made everything easy for me from the first day I came to Germany, his doors were always open for help.

I would also like to acknowledge OA. Alkilzy, Dr. Sohnel and OA. Welk for their full support during collecting my sample in the Integrative Clinical Course in the Dental School of the University of Greifswald. Also, I am gratefully indebted to the students in the 4th and 5th academic year for their help and for their support.

My thanks also go to the colleagues in Pediatric Dentistry Department in Greifswald University and especially for my colleague Mohamed Abudrya as the second reader of this thesis. And I am grateful for his comments and corrections.

I must express my very profound gratitude to my sister Dalia and her husband Osama and all of my brothers Moustafa, Mohanad and Ahmed, who helped me a lot during my study.

Last but not least, words are powerless to express my gratitude to my mother Mrs. Manal Alagami and my father Prof. Dr. Roshdi Youssef, for believing in me from the first day and for providing me with endless support and continuous encouragement throughout my years of study and through the process of researching and writing this thesis. This accomplishment would not have been possible without them.

Clinical Oral Investigations
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ORIGINAL ARTICLE

RCT on the effectiveness of the intraligamentary anesthesia and inferior alveolar nerve block on pain during dental treatment

Bahaa R. Youssef[1] · Andreas Söhnel[2] · Alexander Welk[3] · Mohamed H. Abudrya[1] · Mohamed Baider[1] · Mohammad Alkilzy[1] · Christian Splieth[1]

Received: 2 October 2020 / Accepted: 7 January 2021

Abstract

Objective To compare the effectiveness and complications of intraligamentary anesthesia (ILA) with conventional inferior alveolar nerve block (IANB) during injection and dental treatment of mandibular posterior teeth.

Materials and methods In this randomized, prospective clinical trial, 72 patients (39 males, 33 females), scheduled for dental treatment of mandibular posterior teeth, were randomly allocated to ILA group ($n = 35$) received ILA injection or IANB group ($n = 37$) received the conventional IANB. Our primary outcome was to assess pain and stress (discomfort) during the injection and dental treatment, using the numeric rating scale (NRS) from 0 to 10 (0 = no pain, 10= the worst pain imaginable), whereas recording 24-h postoperative complications was our secondary outcomes.

Results Patients in ILA group reported significantly less pain during injection when compared with IANB group ($p = 0.03$), while pain during dental treatment was similar in both groups ($p = 0.2$). Patients in both groups also reported similar law values of discomfort during treatment ($p = 0.7$). Although no signs of nerve contact or any other postoperative complications were observed, five patients in IANB group (none in ILA group) reported temporary irritations.

Conclusion This study showed equivalent effectiveness of both intraligamentary anesthesia and conventional inferior alveolar nerve block, for pain control during routine dental treatment of mandibular posterior teeth. Nevertheless, ILA showed significantly less pain during injection. No major postoperative complications in both groups were observed.

Clinical relevance ILA could be considered as an effective alternative for routine dental treatment.

Trial registration NCT04563351

Keywords Local anesthetic · Dentistry · Pain · Inferior alveolar nerve block · RCT

Introduction

Pain is a relevant problem in dental treatment [1], making the administration of local anesthetics a necessary and routine measure for various dental procedures [2]. Unfortunately, pain, side effects, and a widely common fear of the injection are also relevant issues in dentistry [3], often resulting in missed or delayed appointments [4]. Regarding local anesthesia for mandibular teeth, two alternative techniques are well established: inferior alveolar nerve block (IANB) or local intraligamentary anesthesia (ILA) at the treated tooth. For decades, IANB has been considered as gold standard for blocking the hemimandible [5], especially in posterior mandibular permanent teeth. It provides adequate anesthesia for one side of the mandibular teeth and gingival mucosa, the body and inferior ramus of the mandible, and the anterior two-thirds of the tongue and floor of the mouth effectively [5, 6].

The evidence suggests that IANB is relatively painful and has a comparatively higher failure rate [7]. It also has a technique-immanent risk, such as transient or even persistent damage to the lingual and/or the inferior alveolar nerve [8]. Moreover, it may provoke intravascular injections, hematoma,

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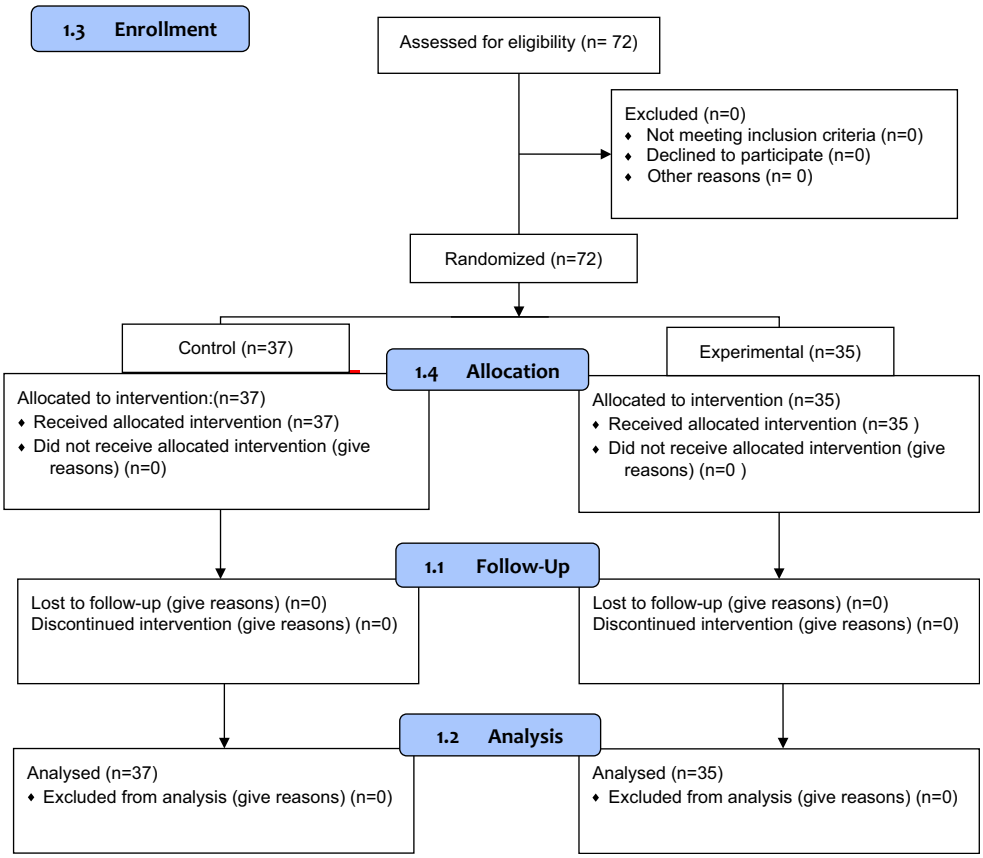

Fig. 1 Show the CONSORT diagram

muscle injury, and trismus [9]. In addition, IANB is associated with an increased risk of burning sensations and/or bite injuries, especially in children and patients with mental disorder due to the long duration of the soft tissue anesthesia which exceeds the dental treatment time considerably. In consequence, an alternative, local, and tooth-based anesthetic technique is demanded [9], which ILA could present.

A considerable number of literatures on ILA as alternative technique for IANB were generated over the last years [10, 11]. ILA only requires an injection directly into the periodontal space of the tooth with relatively high pressure. The injected solution spreads to the cancellous bone adjacent to the tooth to be anesthetized [12, 13]. Among the advantages of this technique are the rapid onset of action, a reasonable duration of 30–49 min, which is in line with standard dental treatment, as well as a low and safe amount of anesthetic solution (about 0.2 ml for each root) [10]. It is of high safety in pediatric patients, patients with bleeding disorders as well as in medically compromised patients [9, 14, 15]. On the other hand, ILA has its own limitations, especially because it is applied for single teeth and bacteremia is reported [10]. Also, the question of (reversible) damage of periodontal tissue, bone, and even root resorption is discussed [10]. In some procedures such as extractions, this is not relevant at all. In summary, current research views ILA as possible good alternative to IANB for dental routine procedures [10, 11]. Therefore, the aim of this study was to evaluate the effectiveness of ILA versus IANB for dental treatment of mandibular posterior teeth.

Materials and methods

This prospective randomized comparative clinical trial was conducted in the integrated clinical course in the dental school of the University of Greifswald, Germany, after the approval of the local ethics committee of the medical faculty in Greifswald (No. BB 174/18) in a period from December 2018 to June 2019. It was also registered in ClinicalTrails.gov (ID: NCT04563351). The sample size calculation using "G*power version 3.1" (Heinrich-Heine-University/Germany) was based on the following estimates: *T* test for means (difference between two independent means), effect size 0.7, α error 0.05, and power (1-ß error) 0.9. It resulted in a samples size of 36 patients in each of the two groups (IANB and ILA).

Inclusion and exclusion criteria

The patients requiring regular dental treatment in permanent mandibular posterior teeth under local anesthesia were recruited with an age range of 18 to 50 years. Patients were not

Table 1 Distribution of patients' age, body mass, gender, treated teeth, and different experience level for clinical instructors and dental students in the 4th and 5th year for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA)

	IANB group	ILA group	*p* value
Age (years), mean (SD)	41.2 (12.1)	44.4 (16.4)	0.3
BMI (Kg/m^2), mean (SD)	25.9 (4.4)	26.1 (5.9)	0.8
Gender, pat. no. (%)			0.3
Male	22 (59.5%)	17 (48.6%)	
Female	15 (40.5%)	18 (51.4%)	
Treated teeth. no. (%)			0.47
Molars	29 (78.3%)	26 (74.2%)	
Premolars	8 (21.6%)	9 (25.7%)	
Experience level no. (%).			0.9
Clinical instructor (GP)	8 (21.6%)	8 (22.8%)	
Dental students in the 5th year	20 (54.0%)	18 (51.4%)	
Dental students in the 4th year	9 (24.3%)	9 (25.7%)	

SD, standard deviation; *GP*, general practitioner

included if they had a clinical or radiographic sign of acute abscess, pus, or peri-radicular pathology. Also, patients with a systemic disease requiring special considerations during their dental treatment or patients with contra-indications for any of the components of the anesthetic solution (allergy to articaine, epinephrine, and sulfite) were excluded.

Clinical treatment and outcome

Only one tooth per patient was included in the study. A computer-generated random number list with allocation concealment was used to assign patients to one of the two groups (ILA vs. IANB, see CONSORT diagram, Fig. 1). The dental practitioners (GDPs) or the students performing the treatment and evaluating the effectiveness of the anesthesia were blinded to the form of anesthesia which was administered by the clinical instructors of the course being also dental practitioners (GDPs) or other dental students in the 4th and 5th academic year in the integrated clinical course in the dental school of the University of Greifswald. The distributions of different experience level of clinical instructors, dental students in the 4th and 5th year were recorded and analyzed. The intensity of pain as well as stress during the injection of the local anesthesia and during the dental procedure was assessed by using the numeric rating scale (NRS 0–10). For the inferior alveolar nerve block, the patient was placed comfortably in a supine position on the dental chair. The start of the anesthetic procedure was done without using topical anesthesia. The IANB injection was administered with cannulas of 38 mm in length and a gauge of 0.4 mm (Sopira Carpule, Heraeus Kulzer GmbH Hanau, Germany). The patients were anesthetized with Ultracain DS Forte 1:100.00 (Sanofi-Aventis, Germany), the active ingredient being articaine in 1.7-ml ampules (1 ml equal to 40 mg articaine hydrochloride and 0.012 mg epinephrine hydrochloride, which is included as a vasoconstrictor). Once the bone was contacted, 1.5 ml of anesthetic solution was injected slowly [16, 17]. Subsequently, the needle was detached for approximately 1 cm and an addition of 0.3–0.5 ml of local anesthetic solution was injected to anesthetize the lingual nerve [6].

Table 2 Distributions of clinical treatment of permanent mandibular posterior teeth for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA)

Type of clinical treatment	IANB group	ILA group
Caries removal (%)	23%	23%
Endodontic treatment (%)	26%	18%
Preparation of crown or inlay (%)	23%	15%
Insertion of crown or inlay (%)	8%	12%
Replacement of old filling (%)	17%	26%
Extraction of single tooth (%)	3%	6%

For the intraligamentary anesthesia, three different syringe systems were used with randomized selection: Softjet syringe (Henke-Sass Wolf, Tuttlingen, Germany), Citojet syringe (Sopira, Heraeus Kulzer GmbH Hanau, Germany), and Ultrajet syringe (Sanofi-Aventis, Frankfurt am Main, Germany). The patients were also placed in a supine position and the dentist administered the ILA injection without using topical anesthesia with cannulas of 12 mm in length and a gauge of 0.30 mm (Sopira Carpule, Heraeus Kulzer GmbH Hanau, Germany). Also, Ultracain DS Forte 1:100.000 (Sanofi-Aventis, Germany) was used from 1.7-ml ampules. The needle was navigated through the gingival sulcus with the bevel towards the alveolar bone and away from the root surface, at an angle of 30°–40° to the long axis of the tooth and 2–3 mm into the periodontal ligament space between root and alveolar bone. For each root, 0.2 ml of local anesthetic was injected over at least 20 s according to Endo et al. (2008) as well as Bender and Taubenheim (2014) [15].

The intensity of pain during the injection of the LA and during the dental treatment was the primary outcome, assessed by the patient using the numeric rating scale (NRS) 0–10 (0 representing no pain at all and 10 representing the worst pain imaginable).

The secondary outcomes were postoperative complications, temporary irritation, and the duration of the anesthesia (when the feeling of numbness had disappeared) being assessed after 24 h by calling the patient.

Statistical analyses

Skewedness, quartiles, and standard deviations were checked for the distribution of the data. For the descriptive analysis of

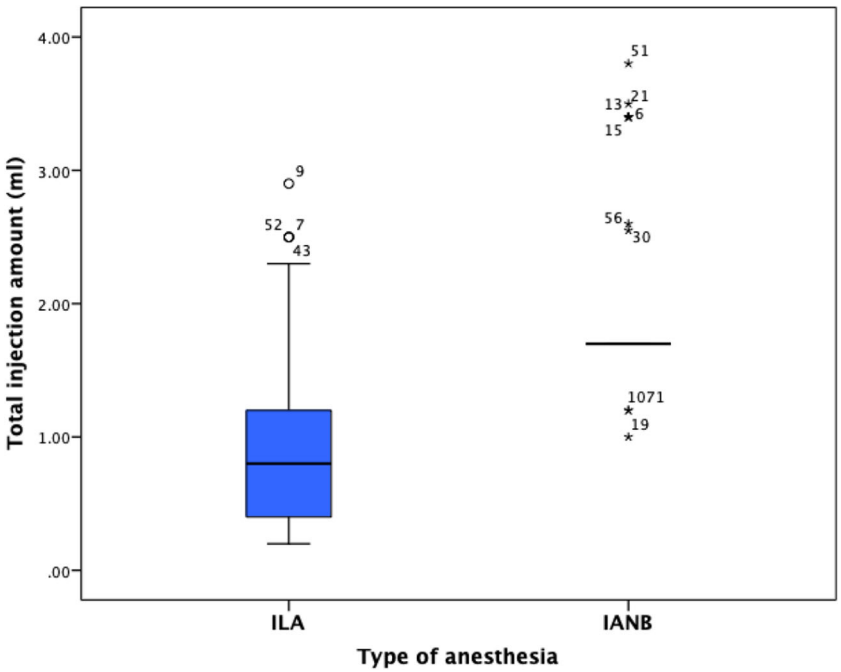

Fig. 2 The total injection amount (ml) of local anesthetic solution during the entire procedure for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA)

categorical data, absolute and relative frequencies were calculated. For continuous data, minimum, maximum, median, and mean values. Categorical data were visualized via bar charts and consistent data via boxplots. For further explorative data analysis, Kolmogorov-Smirnov test was employed to test for a difference among ILA and IANB. In cases of p values < 0.05, Mann-Whitney U test and Kruskal-Wallis H, and in cases of p values > 0.05, Student's t test and one-way ANOVA for independent samples were employed for the main analysis between ILA and IANB. In addition, the data for the different ILA syringe systems were compared in a sub analysis. The influence of categorical variables was shown with chi-square tests and cross tables. A significance level was set at 0.05. All analyses were carried out using SPSS Statistics version 22 (IBM, Armonk, NY, USA).

Results

Seventy-two adult patients (39 males, 33 females) were enrolled and participated in this study. They were randomizer located in two groups, IANB group (37 teeth were treated in 37 patients) and ILA group (35 teeth were treated in 35 patients). Both groups showed similar distributions of patients' age, body mass, gender, treated teeth, and experience level of clinical instructors (Table 1). The performed treatments for IANB group were endodontic treatment (26%), caries removal (23%), and preparation of crown or inlay (23%, Table 2). For ILA group, they were replacement of old fillings (26%) and caries removal (23%, Table 2). The amount of local anesthesia that had been applied was significantly lower for ILA ($p = 0.00$, Fig. 2).

Pain of injection and during treatment

The pain of injection and during treatment assessed on the numeric rating scale (NRS) showed lower pain scores during the injection and treatment reported by the patients in ILA and IANB groups (Table 3). However, ILA showed significantly less pain during the injection than IANB ($p = 0.03$), while both techniques were similarly effective in pain control during the dental treatment ($p = 0.2$). In cases of ILA, 6 (17%) patients reported high scores of pain (> 5) during treatment and 2 (5.7%) patients during the injection; for IANB, 2 (5.4%) patients reported high scores of pain (> 5) during the injection (Fig. 3).

The patient's discomfort during treatment was very low and similar in both groups indicating mostly satisfactory local

Table 3 The median pain score during injection, treatment, and patient's comfort for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA) by using a 10-point segmented numeric rating scale (NRS)

Pain score	IANB group	ILA group	p value
Pain score during injection (0–10); median (IQR)	2 (2)	1 (3)	0.03
Pain score during treatment (0–10); median (IQR)	1 (2)	1 (5)	0.2
Patient comfort during the treatment (0–10); median (IQR)	2 (3)	2 (3)	0.7

IQR, interquartile range

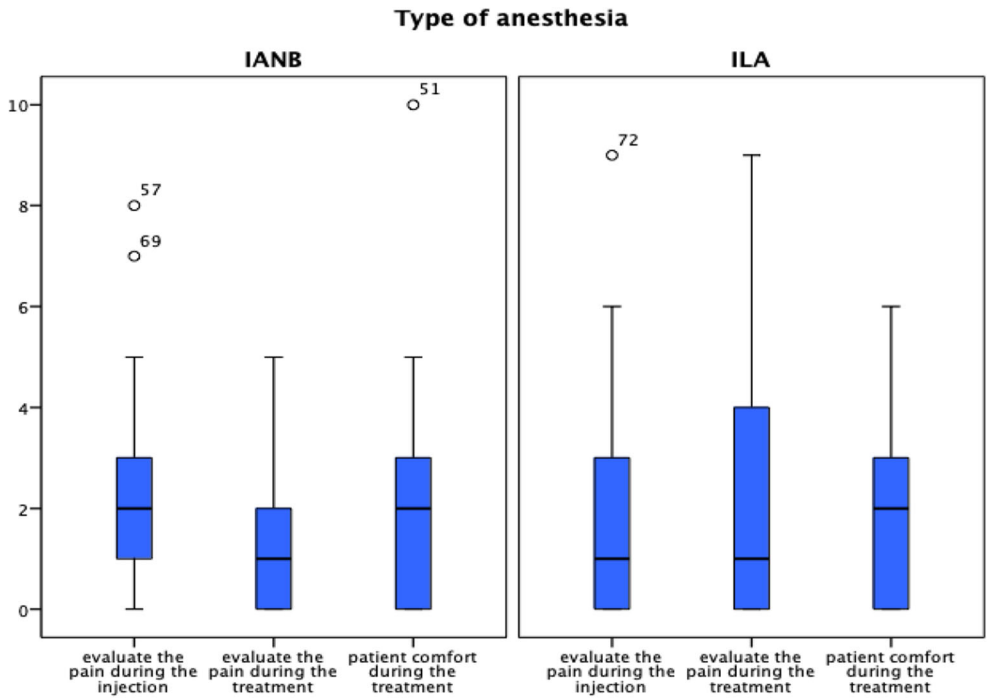

Fig. 3 Assessment of the differences between pain of injection, pain during treatment, and unpleasantness of treatment for inferior alveolar nerve block (IANB) vs. intraligamentary anesthesia (ILA) by using a 10-point segmented numeric rating scale (NRS)

anesthesia ($p = 0.7$), but the distribution showed considerable variation within patients of both groups. One patient in each group rated the experience as unpleasant (> 5, Fig. 3).

Frequency of complications or irritations

In general, IANB had a longer time of local anesthesia than ILA ($p = 0.00$, Fig. 4). No sign of detrimental nerve contact or other complications were observed in any patient. However, one case with IANB reported difficulty during talking for 1 day after the anesthesia, other three more cases reported pain at the site of injection, and one case reported pain around the ear after the injection. On the other hand, no signs of any complication including soft tissue necrosis were observed with ILA technique.

Comparison of different ILA syringes

In two cases using Softjet syringes (16.6%) and Ultrajet (18.1%), high scores of pains (> 5) during following dental

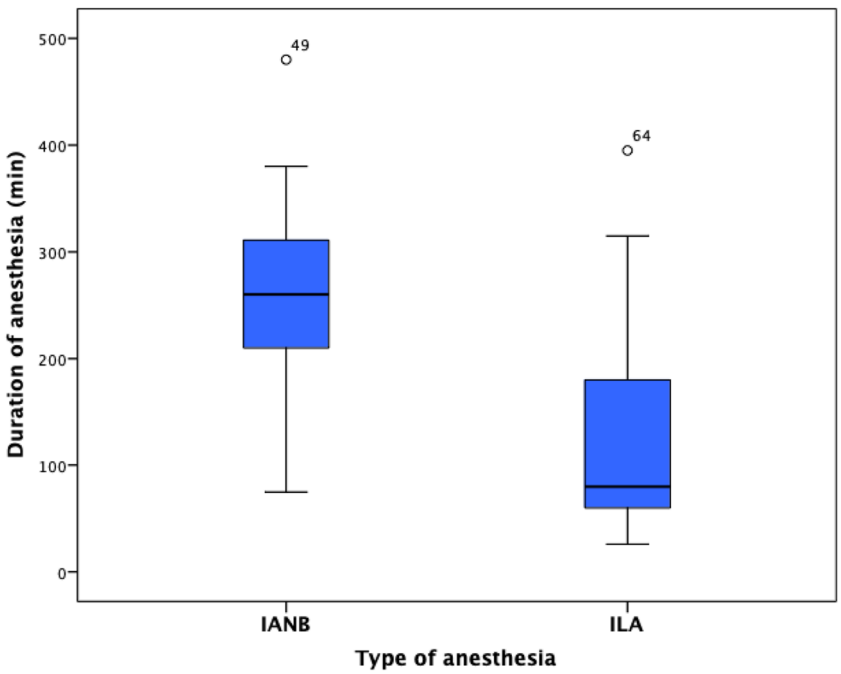

Fig. 4 The duration of soft tissue anesthesia (min) for inferior alveolar nerve block (IANB) vs. for intraligamentary anesthesia (ILA)

Table 4 Median pain score during injection, treatment, and patient comfort for different intraligamentary syringe systems (Softjet, Citojet, and Ultrajet) by using a 10-point segmented numeric rating scale (NRS)

Pain score	Softjet	Citojet	Ultrajet	*p* value
Pain score during injection (0–10); median (IQR)	0.5 (3)	1.5 (4)	1 (3)	0.6
Pain score during treatment (0–10); median (IQR)	0 (2)	1.5 (4)	2 (4)	0.3
Patient comfort during the treatment (0–10); median (IQR)	3 (2)	3 (3)	3 (2)	0.7

IQR, interquartile range

treatment were reported. For Citojet syringes, two patients (18%) reported high score of pain (> 5) during the injection and the subsequent treatment were reported. Still, the comparison of the pain parameters for the three different ILA syringes showed a very similar outcome (Table 4, Fig. 5). The comparison of the patient's comfort during treatment resulted in an equivalent outcome with overall low degrees of unpleasantness ($p = 0.7$; Table 4). Only one patient rated the experience as unpleasant (> 5) for Softjet syringes (Fig. 5).

Discussion

The results of this study indicate that ILA is at least as efficient as IANB in terms of effective pain control and the degree of unpleasantness for routine dental treatment as proposed by other studies and meta-analysis [5, 10, 11]. Similar to our study, Kämmerer et al. [10] reported an injection pain score of 1.55 ± 1.18 (mean ± SD) for mechanical (PDL-S) application and a 1.85 ± 1.22 (mean ± SD) computer-controlled (CCLAD) in 22 cases of ILA vs. 3.05 ± 1.99 (mean ± SD) in 20 cases of IANB ($p = 0.005$). Three years later, the same authors in another study confirmed the superiority of ILA and found a mean injection pain score of 2.19 ± 1.8 (mean ± SD) for ILA vs. 3.65 ± 1.9 (mean ± SD) for IANB ($p < 0.00$) [10, 11].

Although our study as well as other previously mentioned studies had reported a clear superiority of ILA over IANB for injection pain control, "regardless of the type of syringe systems used", both anesthetic techniques showed no statistically significant differences concerning the success rate, the depth of the block, and pain scores during the subsequent dental treatment.

As the pain recognized by the patient is the most important reason for anxiety or phobia of dental treatment and the main aspect in the evaluation of the effectiveness of local anesthetic techniques [10, 11], thus pain assessment is crucial during dental treatment and the most commonly used tool is the numeric rating scale (NRS) from 0 to 10 as it is a highly reliable and appropriate for dental environment [18].

On contrast to our result, Dumbrigue et al. reported that the injections of ILA were associated with more pain and discomfort to the patient compared with IANB; however, the authors did not consider each extracted tooth as an independent

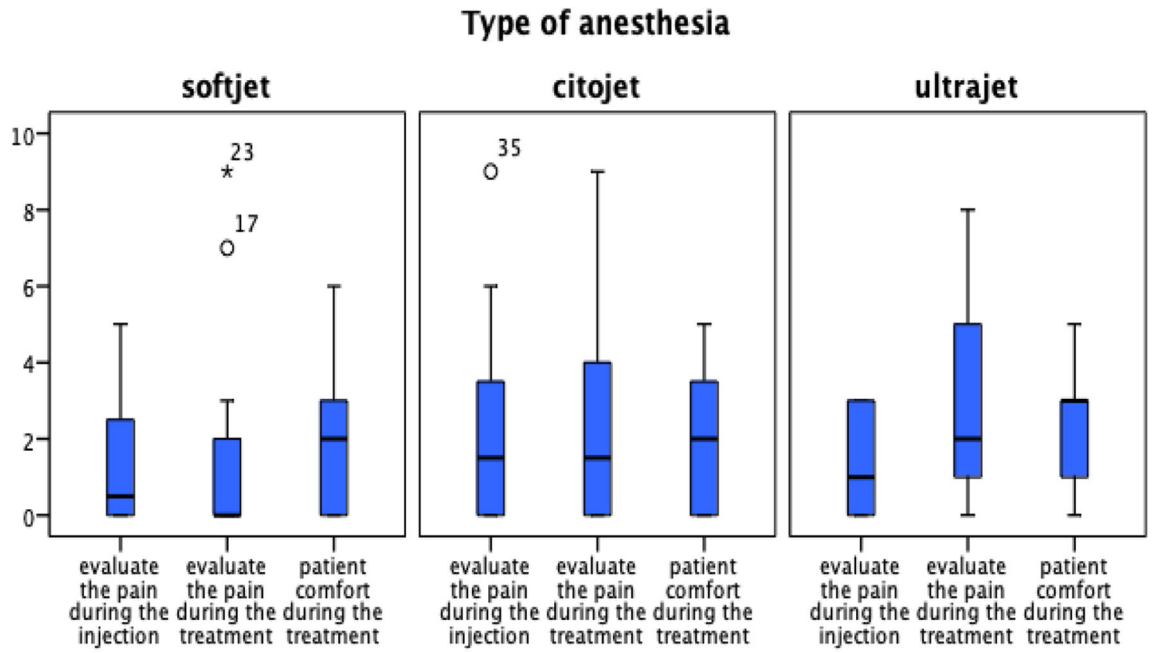

Fig. 5 Assessment of the differences between pain of injection, pain during treatment, and unpleasantness of treatment for different intraligamentary syringe systems (Softjet, Citojet, and Ultrajet) by using a 10-point segmented numeric rating scale (NRS)

sample [18]. Several intraligamentary injections were required in the same quadrant, which may be a reason for the great patients' discomfort during the injections with ILA. Moreover, Dumbrigue et al. used pistol type syringes without safety pressure limiting mechanism, and the injection takes place rapidly under higher pressure than appropriate which increase the injection pain certainly [12]. Thus, the results of such studies with small sample size (16 patients, 45 teeth) should be taken cautiously. It must also be emphasized that the comparisons between different studies are difficult due to variable procedural factors possibly associated with pain experience during the administration of local anesthetic such as, the type or the amount of local anesthetic solution, temperature of the injection solution, injection rate, site of injection, and the experience of the dentist.

In addition, our study is in agreement with Kämmerer et al.'s [10] study which found no statistically significant difference in both groups regarding patient satisfaction (comfort) and over all pain experienced during the entire treatment course.

Our study confirmed ILA as a reliable alternative technique to IANB with the superiority of the following: the amount of local anesthesia for ILA was small and carries no risk of systemic toxicity with accidental intravascular injection [9, 15]. As ILA mostly wearing off at the end of the dental treatment with no residual regional anesthesia (as in case of LANB), due to the sensitivity of the lower lip for considerable time after the dental treatment, this reduces the risk of unwanted side effects such as lip biting in children or patients with mental disabilities who have higher risk of bite or thermal injury as reported in our and other previous studies [9, 15]; in addition, it also reduces the risk of temporary unpleasant reductions of mastication and speech.

Conclusion

ILA has shown to be a safe and reliable method of local anesthesia for treatment of lower premolars and molars, with a success rate comparable to IANB without complications and temporary irritations. Thus, ILA can be considered as an effective alternative to IANB for routine dental treatment to reduce known side effects of IANB.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

Ethics approval All procedures involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This has been approved by the local ethics committee of the medical faculty in Greifswald (No. BB 174/18).

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