

EFFICACY OF INTRALIGAMENTARY ANAESTHESIA FOR MANDIBULAR MOLAR EXTRACTION: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

To evaluate the efficacy of intraligamentary anaesthesia for mandibular molar extraction as an alternative to inferior alveolar nerve block (IANB), a randomized controlled clinical trial was carried out. With simple random sampling, consenting participants were assigned to one of three groups receiving intraligamentary injection with pressure syringe (ILPS), IL with non-disposable dental anaesthesia syringe (ILDAS) and the control group receiving inferior alveolar nerve block. IANB was found to be significantly less painful during administration than other two techniques. No significant difference was found for repeat anaesthesia in the three techniques. For number of cartridges used, no significant difference was found between ILDAS and IANB, but a significant difference was found when compared with ILPS. All extractions were successful with Mean Treatment Time 10.1 minutes. Extractions were completed in significantly shorter duration with ILDAS. Anaesthetic technique was switched to IANB in 20% (n=8) cases of ILPS, and 10% (n=4) cases of ILDAS. It is concluded that intraligamentary anaesthesia (ILA) can be used as an alternative to inferior alveolar nerve block for extraction of mandibular molars where IANB cannot be performed or not indicated. The pressure syringe is not better than the non-disposable dental anaesthesia syringe for delivery of ILA.

KEYWORDS: Intraligamentary injection, Inferior alveolar nerve block, anaesthetic efficacy, mandibular molar extraction, pain on injection, pressure syringe.

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INTRODUCTION

To win patient's confidence, a dental surgeon's first and most important task is to gain competency in performing painless local anaesthesia administration and hence painless surgical procedure.¹

Periodontal ligament anaesthetic technique/Intraligamentary anaesthesia (ILA) was first introduced in the 20th century in France. ILA is a form of intraosseous injection in which anaesthetic solution injected with high pressure into the periodontal ligament space enters the cancellous bone around the tooth. It was described to cause less discomfort and having minimal complications if correctly administered. A short onset of action and small quantity required for this technique, leads to reduced risk of systemic toxicity. It has not been recommended for procedures in infected and inflamed tissue.²⁻⁴

The documented advantages of ILA include achieving single tooth soft tissue and pulpal anaesthesia without the need of a regional block. As extractions cannot be performed bilaterally with Inferior Alveolar Nerve Block (IANB) technique, the ILA allows extractions to be performed on both sides. ILA has also been said to have an advantage in paediatric patient as it reduces the risk of self-inflicted trauma caused by residual soft tissue anaesthesia. ILA technique being less invasive than IANB and at the same time believed to be equally effective makes it advantageous in patients where injection in deep tissue may lead to uncontrolled

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bleeding for example in haemophilic patients and as a supplemental technique for IANB and is found more effective than infiltration anaesthesia.^{3, 4, 5, 6}

Dalla et al used ILA to teeth mesial and distal to a single implant gap for the purpose of implant insertion. They reported successful implant insertion in 39 out of 40 patients with low mean pain score and no significant complication.⁷

Thilak et al presented advances in local anaesthesia delivery including Computer controlled local anaesthetic delivery system (CCLAD), Vibrotactile devices, Jet injection, Safety dental syringe and Intraosseous anaesthesia.¹

Pressure syringes used for ILA make it easier to perform, but at the same time, it may cause a discomfort to the patient because of a quick entry of solution in a narrow space. These syringes inject a specific quantity of anaesthetic drug, and this overcomes the resistance offered by the narrow PDL space.⁸

Dental extraction is the most common procedure undertaken in the department of Oral Surgery, and inferior alveolar nerve block (IANB), is the local anaesthesia technique primarily used for extraction of lower posterior teeth. The complexity of technique and possibility of anaesthetic failure leads to multiple needle penetrations which is a painful experience for the patients. In addition, IANB technique, many times, becomes impossible to perform in fearful adult and paediatric patients, those with restricted mouth opening or intellectual disability. As already mentioned above, certain coagulation defects contraindicate administration of IANB due to its depth of penetration into the tissues that may lead to fatal consequences in case of uncontrolled bleeding. Because of these shortcomings of IANB, the authors realized a need to investigate the effectiveness of an alternative anaesthesia technique for such situations.

Salem and co-workers investigated the knowledge of undergraduate students and interns about the ILA as an alternative to IANB and concluded that there is a need to improve their knowledge regarding its indications and limitations.⁹

Reddy et al¹⁰ and Shiraz et al¹¹ in their survey concluded that despite majority of dental students and dental practitioners have knowledge of ILA, this technique is only used after failure of IANB.

Shabazfar et al¹² performed a meta-analysis of prospective and retrospective studies during the period 1979-2012 comparing IANB and ILA utilizing the tool to assess risk of bias in these studies. They reported a lack of precision among the criteria used in these studies and therefore did not label one technique more effective than the other.

The objective of our study was to evaluate the efficacy of ILA for posterior mandibular molar extraction as an alternative to inferior alveolar nerve block (IANB) so that it can be used in cases where IANB is either

difficult to perform or not indicated.

The Null Hypotheses of our research were

Intraligamentary anaesthesia (ILA) is not an alternative to inferior alveolar nerve block (IANB) for extraction of mandibular molars.

The pressure syringe is not better than the non-disposable dental anaesthesia syringe (DAS) for delivery of ILA.

The Alternate Hypotheses of our research were

Intraligamentary anaesthesia (ILA) is an alternative to inferior alveolar nerve block (IANB) for extraction of mandibular molars.

The pressure syringe is better than the non-disposable dental anaesthesia syringe (DAS) for delivery of ILA.

METHODOLOGY

Study Design

A randomized controlled clinical trial was conducted by the Oral & Maxillofacial Surgery department, Hamdard University Dental Hospital, Karachi. Duration of study was 12 months. Using relevant research¹³, sample size was calculated with Openepi software version 3 at the confidence level 95%, margin of error 5%, and power of study 80%. Total sample size was calculated to be 105 (35 samples per group). For enhanced validity of the study, a sample size of 120 was considered (40 samples/group).

Eligibility Criteria

Inclusion Criteria

Age 18 years and above

Both genders.

Teeth selection: Mandibular first and second molars needing extraction under local anaesthesia.

Healthy patients or those with well controlled systemic disease.

Patients consenting to participate in the study.

Exclusion criteria

Patients younger than 18 years.

Mandibular third molars, acutely inflamed or infected first and second molars.

Pregnant patients and those with poorly controlled systemic disease.

Mentally handicapped patients.

Patients not consenting to participate in the study.

Procedure

Simple random sampling by lottery method was used to assign participants consenting for the study to one of three groups (A, B, C) and to one of two operators (AB, MN). A written informed consent was signed by all study participants (Annexure 1a and b). The variables were recorded on a specially designed form (Annexure 2).

Group A received intraligamentary injection using pressure syringe (ILPS) with 27-gauge needle. In case of unsuccessful anaesthesia after 1 minute, the same modality was repeated once. Second failure of the same technique was considered an indication for inferior alveolar nerve block (IANB). Group B received intraligamentary injection with disposable dental anaesthesia syringe (ILDAS) with 27-gauge needle. In case of unsuccessful anaesthesia, the same modality was repeated once. Second failure of the same technique was considered an indication for IANB. Group C received inferior alveolar nerve block anaesthesia (IANB) and anaesthesia was checked after 6 minutes.

Lidocaine 2% in 1.8 ml cartridge was used for dental anaesthesia regardless of the technique.

Primary outcome measures included pain on injection and local anaesthesia success checked by using Numeric Pain Rating Scale (NPRS).

Secondary outcome measure was successful completion of extraction within 30 minutes, without changing the intervention.

ClinicalTrials.gov ID: NCT05122819 (Annexure 3)

ERB approval: Ethical Review Board of Hamdard University Ref: HCM&D/1990/2021, dated 30th Dec 2021 (Annexure 4).

Statistical Analysis

Using SPSS version 23, data was analysed by using Independent Sample T test (P-value=0.05). Frequencies of age, gender, tooth mobility, pain and tenderness before extraction were calculated. Difference between the three techniques was analysed in terms of time taken for LA administration, pain on injection, pain after first LA administration, repeated anaesthesia, cartridges used, and duration of procedure.

RESULTS

Total number of teeth extracted were 120. Table 1 shows preoperative status of the teeth extracted. It includes age, gender and teeth distribution, preoperative pain status of teeth to be extracted and time taken for administration of individual LA techniques.

Table 2 shows frequencies variables used for primary outcome measures. It includes pain on injection,

effectiveness of anaesthesia after first LA administration, anaesthesia repeated, number of cartridges used, duration of procedure in three LA techniques used.

Table 3 shows the results of Secondary outcome measures. It includes difference between the three techniques in terms of time taken for la administration, pain on injection, pain after first la administration, repeated anaesthesia, cartridges used, and duration of procedure.

DISCUSSION

With the null and alternate hypotheses presented in the introduction section a randomised controlled clinical trial was performed comparing the efficacy of ILA performed with pressure syringe (ILPS), ILA performed with conventional dental anaesthesia syringe (ILDAS), and IANB, with all three techniques using 27-gauge needle, for the extraction of mandibular molars.

Shabazfar et al in their meta-analysis between 1979-2012 found seven studies fitting their inclusion criteria and the limitations they found in one or more of those studies included, absence of hypotheses, information about the number of operators, inconsistency in information about failure of anaesthesia, inadequate number of participants, and therefore inconsistent data for the variables selected.¹²

While searching for local research, we were able to find only two studies which were questionnaire-based surveys about knowledge of undergraduate and postgraduate students regarding intraligamentary anaesthesia.^{11, 14} In our study we have addressed these limitations by presenting hypothesis, sampling according to sample size calculations and analysis of anaesthetic failures.

Local anaesthesia was injected buccally and lingually in the periodontal space at three points, i.e. mesial, middle, and distal. This technique leads to pulpal anaesthesia when the anaesthetic solution injected against resistance, penetrates the cancellous bone through socket wall perforations.³ Anticipated time of onset is believed to be 30 seconds. Duration of anaesthetic effect is expected to be in the range of 5-55 minutes.⁸ We considered first anaesthetic check after 1 minute of anaesthesia administration.,

Histological studies on animal tissue after ILA show widespread diffusion of local anaesthetic solution into the surrounding bone explaining the clinical evidence of its effectiveness.¹⁵

In our study, ILA with pressure syringe significantly took more than 1 minute for administration, when compared with the other two techniques. We were unable to find any research regarding this variable.

No research was found that compared two different techniques for ILA with IANB like ours. Kammerer et al¹⁶ reported ILA administered with pressure syringe to be a dependable alternative technique to IANB for

TABLE 1: PREOPERATIVE STATUS OF THE TEETH EXTRACTED

AGE	GENDER			TOOTH	
18-28	18.3 (n=22)	Males	49.2 (n=59)	LLSM*	16.7 (n=20)
29-39	20.8 (n=25)	Females	50.8 (n=61)	LLFM*	35 (n=42)
40-50	30.8 (n=37)			RLFM*	29.2 n=35)
51-60	15 (n=18)			RLSM*	19.2 n=23)
61 and above	15 (18)				
FIRM TEETH				ASYMPTOMATIC TEETH	
88.3 (n=106)				Pain free	71.7 (n=86)
				Non-tender	74.2 (n=89)
TIME TAKEN FOR LA ADMINISTRATION					
	ILPS*	ILDAS*	IANB*	Total	
1 minute or less	14	31	38	83	
more than 1 minute	26	9	2	37	

*LLFM: left lower first molar

*RLFM: right lower first molar

*RLSM: right lower second molar

*ILPS: intraligamentary injection with pressure syringe

*ILDAS: intraligamentary injection with disposable dental anaesthesia syringe

*IANB: inferior alveolar nerve block

TABLE 2: FREQUENCIES OF PRIMARY OUTCOMES MEASURES

Pain On Injection				
	ILPS	ILDAS	IANB	Total
no pain	0	0	5	5
mild pain	21	23	31	75
moderate pain	17	17	4	38
worst possible pain	2	0	0	2
Pain After First La Administration				
	ILPS	ILDAS	IANB	Total
no pain	18	29	25	72
mild pain	10	5	11	26
moderate pain	4	4	4	12
worst possible pain	8	2	0	10
Anestheisa Repeated				
	ILPS	ILDAS	IANB	Total
No	26	27	33	86
Yes	14	13	7	34
Cartridges Used				
NUMBER	ILPS	ILDAS	IANB	Total
1	26	26	27	79 (65.8%)
2	8	11	12	31 (25.78%)
3	6	2	1	9 (7.5%)

Duration Of Procedure				
	ILPS	ILDAS	IANB	Total
upto 6 min	13	24	0	37
7-10 min	8	9	19	36
11-15 min	13	2	13	28
more than15 min	6	5	8	19
Mean Treatment Time				
	ILPS	ILDAS	IANB	Overall
	9.1	8.4	12.53	10.1

*ILPS: intraligamentary injection with pressure syringe

*ILDAS: intraligamentary injection with plunger

*IANB: inferior alveolar nerve block

TABLE 3: RESULTS OF SECONDARY OUTCOME MEASURES

Duration of procedure			Pain on injection		
ILPS* vs IANB*	0.01	significant	ILPS vs ILP	0.088	Not significant
ILDAS* vs IANB	0.01	significant	ILDAS vs IANB	0.01	significant
Pain after first la administration			Anesthesia repeated		
ILPS vs IANB	0.002	significant	ILPS vs ILDAS	0.642	Not significant
ILDAS vs IANB	0.334	Not significant	ILDAS vs IANB	0.002	significant
ILPS vs ILDAS	0.03	significant	ILPS vs IANB	0.01	significant
Cartridges used			Duration of procedure		
ILPS vs IANB	0.011	significant	ILPS vs IANB	0.013	significant
ILDAS vs IANB	0.402	Not significant	ILDAS vs IANB	0.275	Not significant

*ILPS: intraligamentary injection with pressure syringe

*ILDAS: intraligamentary injection with plunger

*IANB: inferior alveolar nerve block

extraction of lower molars with the advantages of lower pain on injection, rapid onset, and short duration of action. Youssef and coworkers¹⁷ also reported IL injection pain lower than that of IANB. In contrast, we found IANB to be significantly less painful during administration as compared to the other two techniques. In this regard, no significant difference was found between IL anaesthesia administered with either of the two techniques. In addition, Kammerer et al¹⁶ reported no significant difference between ILA and IANB for the need to repeat anaesthesia injection. This finding agrees with ours as we found a non-significant difference with IANB. In addition ILA with non-disposable dental anaesthesia syringe was found to be significantly more effective after single administration as compared to ILA with pressure syringe.

Kammerer et al¹⁶ also reported a significantly less quantity of local aesthetic solution required for ILA compared to IANB. In our study, generally 65.8% extractions were completed with single cartridge, 26.7% with two cartridges, and 7.5% with three cartridges. When the three techniques were compared, no significant difference was found between ILDAS and IANB,

but a significant difference was found when compared with ILPSA.

Lower pain on injection, reduced onset of action and success rate superior to that of IANB have also been reported by Pradhan and co-workers.¹³ All extraction were successful in our study with Mean Treatment Time 10.1 minutes. The studies included in the meta-analysis by Shabazfar et al¹² showed mean treatment time less than 30 minutes. Among the three techniques compared in our study, extraction procedure was completed in significantly shorter duration with ILDAS. Anaesthetic technique was switched to IANB in 20% (n=8) of ILPS group and 10% (n=4) of ILDAS group.

Limitations of the Study

Our research targeted only the adult patients 18 years and above because of reluctance of performing an injection technique which may be ineffective in patients who already lack cooperation. But we find published studies done with paediatric population for endodontic procedures and extraction of primary molars.^{18,19,20}

Both the operators found the pressure syringe difficult to use and encountered shattering of cartridge because of excessive pressure. The manufacturing quality may be the reason for this adverse experience.

Another limitation was that we did not record duration of anaesthesia so that we could compare this variable between the three techniques. Future research exploring the duration of anaesthesia and complications like dry socket may be more helpful and recommended in understanding the advantages of ILA over IANB.

CONCLUSION FUTURE RECOMMENDATIONS

Intraligamentary anaesthesia (ILA) can be used as an alternative to inferior alveolar nerve block for extraction of mandibular molars where IANB cannot be performed or not indicated.

The pressure syringe is not better than the non-disposable dental anaesthesia syringe (DAS) for delivery of ILA. We recommend that in the oral surgery clinics, in addition to IANB, students should be trained to practice this alternative technique so that they can more confidently use it when needed.

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