Efficacy of Low Dose Intraligamental Local Anesthesia Technique for the Extraction of Maxillary Molars of Grade II Mobility: A Double-Blind Randomized Clinical Trial

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Abstract

Objective this study aimed to investigate the efficacy of intraligamentary anesthetic technique in the extraction of grade II mobility maxillary molars compared to the infiltration technique. **Materials and methods:** Sixty patients were randomly allocated either to local infiltration or intraligamentary anesthesia prior to the extraction of a grade II mobility maxillary molar. Pain during anaesthesia and during extraction was recorded using the visual analogue scale (VAS) in addition to its duration. Data were collected and analyzed using t-test for continuous data, a chi-square test for categorical data and two-sample Wilcoxon rank-sum (Mann-Whitney) test for pain scoring scale analysis. **Result:** Results showed that there was no statistically significant difference between both groups regarding pain scores during anesthesia and pain scores during extraction. However, there was a statistically significant difference in the duration of anesthesia between both groups with limited duration observed in the intraligamentary group. **Conclusion**: Intraligamental anesthesia is an efficient alternative to infiltration anesthesia in extraction of grade II maxillary molars.

KEY WORDS: intraligamental, grade II mobility, local anaesthesia

Introduction

Local anesthesia is an essential component in dentistry, with millions of injections administered worldwide every year. While generally considered a safe invasive procedure, adverse effects are possible. Infiltration anesthesia, which interrupts pain perception in the injection area, may lead to temporary loss of sensitivity and partial or complete loss of facial muscle function during the anesthesia [1]. This can result in temporary limitations in patients' daily activities, such as speaking and eating, as well as an increased risk of bite and burn injuries. Consequently, various techniques have been developed to mitigate these undesirable side effects while maintaining the same level of efficacy and depth of anesthesia [2, 3].

The intraligamentary periodontal technique, also referred to as non-trephinating intraosseous injection which is introduced by Chompret [4], is a method of intraosseous injection that delivers local anesthesia to the cancellous space in the bone through the periodontal ligament (PDL), resulting in a quick onset of action [5, 6]. This technique is advantageous in situations where there are anatomical variations and helps to prevent injury to soft tissues.

The intraligamental technique (ILT) offers certain benefits to both patients and dentists due to its limited anatomical range and short duration of action, which is approximately 30 minutes. Unlike other techniques, patients undergoing dental procedures with ILT experience no postoperative restrictions on their daily activities or occupational obligations, such as speaking, eating, or drinking. Furthermore, the localized anesthetic effect of ILT enables treatment of different regions, such as both left and right mandibular molars, in a single session. As the onset of the anesthetic effect is almost immediate after injection, preventing the delay between the administration of anesthesia and the commencement of treatment [7].

Lastly, the intraligamental technique offers a notable reduction in the overall amount of anesthetic solution and vasoconstrictor supplement required compared to other anesthetic methods. Moreover, intraligamental anesthesia is particularly beneficial for treating "high-risk patients" who may have cardiovascular diseases or are undergoing anticoagulation therapy [8].

Therefore, the purpose of this study was to test the null hypothesis that there is no difference in the effectiveness and the duration of intraligamental local anesthetic injection and buccal infiltration for the extraction of maxillary molars of grade II mobility.

Material and methods

1. Ethical Consideration

The protocol of the present study was reviewed and accepted by the Review and Ethics Committee of the Faculty of Dentistry of Minia University. The study protocol was then registered on clinicaltrials.gov with an identification number NCT05875350. All patients signed a written informed consent form after being informed the detailed steps, benefits, risks and the possible adverse effects of the proposed intervention.

2. Study Design and Study Settings

A 1:1 parallel armed randomized controlled clinical trial comparing the efficacy and the duration of intraligamentary anesthesia to the routine local anesthetic technique which took place at the oral and maxillofacial department of the Faculty of Dentistry at Minia University in Egypt. Randomization was performed by generating a random sequence using Microsoft Excel software where both groups A and B were equally and randomly distributed. Participants were allocated by choosing one card of a set of prepared cards with a series of numbers from 1 to 60 and the sequenced intervention was then retrieved from the excel sheet. All study participants as well as the outcome assessor were blinded to the study group intervention.

3. Eligibility Criteria

Inclusion criteria comprised the recruitment of healthy patients (class I category according to the American society of anesthesiologists) of an age range between 20 and 60 years old, of both genders who were seeking dental extraction of maxillary molar teeth diagnosed with grade II mobility. However, patients having teeth that require trans osseous extraction or were considered badly broken down with no enough coronal structure were excluded from the study. Alcoholic individuals, patients on drugs that affect the central nervous systems, or patients who reported the use of drugs that might interfere with pain sensitivity were also excluded. Pregnant or lactating women as well as patients who reported any hypersensitivity to local anesthetics or non-steroidal anti-inflammatory drugs (NSAIDs) were not enrolled into the study.

4. Grouping

Sixty healthy participants were randomly divided into two equal groups: group A (n=30), were anesthetized with a standard buccal infiltration of 1.8 ml of the anesthetic solution while group B (n=30), were anesthetized with intraligamental injection of 0.8 ml of the anesthetic solution. Articaine hydrochloride 4% with adrenaline 1:200000 (ArtPharma Dent, inc, Egypt) was the anesthetic solution used for both groups.

5. Intervention

Infiltration Technique

The infiltration was administrated using standard local anesthetic syringe with a 30 gauge needle 20–25 mm needle; articaine hydrochloride 4% with adrenaline 1:200000 (ArtPharma Dent, inc, Egypt) was deposited over a period of 30 seconds. At least two minutes elapsed before testing for the effect of the anaesthesia.

Intraligamental technique

The intraligamental technique was administered using ligajet intraligamentary jet injector (Micro Mega Company) containing articaine hydrochloride 4% with adrenaline 1:200000 (ArtPharma Dent, inc, Egypt) and a 30 gauge needle Injection was administrated at the buccal, lingual, mesial and distal aspect of the tooth to be extracted. Deposition of a minimal dose of 0.2 ml LA was done at each of these sites. The needle was inserted at an angle of 30-40 degrees with respect to the long axis of the tooth and should reach a sub gingival depth of about 2 to 3 mm [9].

The extraction was then performed after anesthetic injection in both groups, in an atraumatic manner while performing a stress reduction protocol during the procedure.

6. Outcome Measure

After the administration of anestheisa the patient was asked about the intensity of the pain experienced during injection as well as assessing objectively the profoundness of the anaesthesia while separating the gingiva and during the application of forceps to the tooth. Pain was assessed using the Visual Analogue Scale (VAS) scoring system. The duration of anesthesia was also calculated by recording the time at which maximum objective symptoms of anesthesia were obtained and the patient was then instructed to wait and note the time at which all anesthetic symptoms had disappeared.

7. Statistical Analysis

All the data were collected using a Microsoft Excel sheet, and Stata software (version 8) was used for statistical analysis. Two sample T-test was used for numerical data while chi-square test was employed for categorical data analysis for normally distributed data. Two-sample Wilcoxon rank-sum test (Mann Whitney) was also used for the analysis of pain scores.

Results

Results show that both age and gender (Tables 1 and 2) have no statistically significant difference between infiltration and intraligamentary groups at p=0.524 and 0.602, respectively. Neither pain during anesthesia nor pain during extraction (Tables 3 and 4) showed statistical significant difference between both groups at p=0.219 and 0.225, respectively. Results also showed that there was a statistical significant difference between both groups in anesthesia duration with a decreased mean duration of intra-ligamentary group of 23.63 (4.335) seconds compared to the mean duration of the infiltration group of 81.20 (13.29) seconds at p < 0.001 (Table 5).

Table 1: Two-sample T-test showing mean age among groups

Two-sample t-test with unequal variances						
Group	Obs	Mean	Std. err.	Std. dev.	95% conf. interval	
Infiltration	30	37.90	2.421	13.26	32.95	42.85
Intra-ligamentary	30	35.87	2.054	11.25	31.67	40.07
Combined	60	36.88	1.580	12.24	33.72	40.04
Diff	2.033	3.175	-4.326	8.392		
Diff = mean(1)- mean(2)					t =0.640	
H0 diff = 0					Satterthwaite's Degrees of freedom = 56.50	
Ha diff < 0		Ha diff != 0			Ha diff > 0	
Pr (T< t) = 0.738		Pr(|T|>|t|) = 0.524			Pr(T> t) = 0.262	

Table 2: Chi-square test showing Gender distribution among groups

	Gender		
Group	Female	Male	Total
Infiltration	18	12	30
Intra-ligamentary	16	14	30
Total	34	26	60
Pearsonchi2(1) = 0.272	Pr = 0.602		

Table 3: Two-sample Wilcoxon rank-sum (Mann-Whitney) test comparing pain during anesthesia between groups

Two-sample Wilcoxon rank-sum (Mann-Whitney) test			
Group	Obs	Rank sum	Expected
Infiltration	30	835	915
Intra-ligamentary	30	995	915
Combined	60	1830	1830
Unadjusted variance 4575			
Adjustment for ties -342.2			
Adjusted variance 4233			
H0 pa(grp=1) = pa(grp=2)			
Z = -1.230			
Prob > |z| = 0.219			
Exact prob = 0.217			
P pain (grp=1) > pain (grp==2) = 0.411			

Table 4: Two-sample Wilcoxon rank-sum (Mann-Whitney) test comparing pain during extraction between groups

Two-sample Wilcoxon rank-sum (Mann-Whitney) test			
Group	Obs	Rank sum	Expected
Infiltration	30	839	915
Intra-ligamentary	30	991	915
Combined	60	1830	1830
Unadjusted variance 4575			
Adjustment for ties -650.9			
Adjusted variance 3924			
H0 pain(grp=1) = pain(grp=2)			
z= -1.213			
Prob > |z| = 0.225			
Exact prob = 0.258			
P pain(grp=1) > pain(grp=2) = 0.416			

Table 5: T-test showing difference in duration of local anethesia between groups

Two-sample t-test with unequal variances for anesthesia duration between groups						
Group	Obs	Mean	Std. err.	Std. dev.	95% conf. interval	
Infiltration	30	81.20	2.427	13.29	76.24	86.16
Intra-ligamentary	30	23.63	0.791	4.335	22.01	25.25
Combined	60	52.42	3.955	30.64	44.50	60.33
diff		57.57	2.553		52.38	62.75
Diff = mean(1) - mean(2)					t = 22.55	
H0 diff = 0				Satterthwaite's degrees of = 35.10		

Ha diff < 0 Pr(T< t) =1.00	Ha diff != 0 Pr(| T|>|t|)=0.00	Ha diff > 0 Pr(T > t) = 0.00

Discussion

Effective pain management is crucial for the success of any oral surgical procedure. Nevertheless, the administration of local anesthesia (LA) has been identified as the sole source of perceived pain during dental procedures, and the associated anxiety and fear of receiving this injection are frequently cited as reasons for avoiding dental treatment [10]. To ensure success in the most frequently performed dental procedure, tooth extraction, appropriate anesthesia is imperative.

Local infiltration is widely considered the preferred technique for limited maxillary anesthesia, as it is relatively easy to perform, unaffected by collateral innervations, and enables rapid and efficient diffusion of the local anesthetic solution through the porous maxillary bone with its thin bony cortex [11]. In the current study, in infiltration technique, articaine Buccal infiltration was used, eliminating the need for the painful palatal anesthesia which has been proven by many studies to be effective to anaesthetise maxillary teeth for extractions without the need for extra palatal injection [12,13].

On the other hand, the intraligamental technique is known to offer a substantial reduction in the total quantity of anesthetic solution and vasoconstrictor supplement required in comparison to other anesthetic methods. Additionally, intraligamentary anesthesia is particularly beneficial in the treatment of patients at risk suffering from cardiovascular diseases [8]. Furthermore, it is advised for use in tooth extraction cases with irreversible pulpitis to provide superior pain management [14]. The initial clinical evaluation of intraligamental anesthesia found that success rates varied from 60% for endodontic procedures to 100% for periodontal procedures and tooth extraction [4]. Additionally, prior research has established that achieving pulp anesthesia with infiltration anesthesia or nerve-block techniques is more challenging in the presence of irreversible pulpitis or compromised teeth compared to healthy ones [15-19].

Articaine was employed in the current investigation as a secure and efficient local anesthetic for routine dental procedures in patients of all ages. A meta-analysis conducted by Martin et al., in 2021, revealed that articaine was more likely to achieve successful anesthesia than lidocaine in maxillary and mandibular infiltration anesthesia, as well as mandibular block anesthesia for both asymptomatic and symptomatic teeth [20]. Also, articaine showed a significantly greater success rate compared to lidocaines and mepivacaines for supplemental buccal infiltrations [21]. Furthermore, it has demonstrated a quicker onset and longer duration of anesthesia than lidocaine for buccal infiltrations [22]. It has not been reported earlier that articaine might be associated with any high frequency anesthetic-related adverse effects and is considered an efficient and safe local anesthetic used in treating children of ages of three and four [23].

The current study employed a double-blind design to minimize the potential for bias. This was accomplished by ensuring that both injection techniques and extraction procedures were indistinguishable. Moreover, neither the clinicians who assessed pain and duration nor the study participants were aware of the assigned anesthetic technique. This approach was intended to decrease threats to validity and prevent potential situational and inter-operator variability from impacting study outcomes [24].

The present clinical trials utilized a self-reported Visual Analog Scale (VAS) to assess pain scores [25, 26]. Such self-reported scales have been demonstrated to be valid and reliable, in addition to being easy to use and placing minimal demands on almost all patients [27]. When evaluating pain, validation and consistency indices for these scales can be leveraged to rank them hierarchically [28]. The VAS is typically considered to be more sensitive and valid than the Verbal Rating Scale (VRS), potentially due to the larger number of response categories [29].

Our results did not reveal a statistically significant difference in pain during anesthesia between the two groups, which is consistent with previous research [30, 31] indicating that intraligamental injection yields pain scores similar to those of infiltration anesthesia. However, this finding contradicts Al-shayyab's study [32], which compared intraligamental injection with local infiltration (buccal and palatal injection) for extracting a single permanent tooth in the posterior maxilla, and found that pain experienced during infiltration injection was significantly less than during intraligamental injection. Al-shayyab attributed this result to the number of free nerve endings in the area of needle insertion, which has been linked to pain perception. While the submucosa has fewer nerve endings, the PDL contains many. This discrepancy between studies may be due to the fact that the teeth examined in the present study had grade II mobility, which indicates that less pressure was exerted within the PDL than in the healthy teeth included in the earlier described study.

Similarly, the results demonstrated that there was no statistically significant difference in pain scores during extraction between the two groups, indicating that intraligamental anesthesia was equally effective as infiltration anesthesia, despite using a lower dose of anesthetic solution, which is consistent with Elbay et al.'s findings [33]. They found that intraligamental anesthesia achieved satisfactory anesthesia while reducing injection pain compared to conventional local infiltration anesthesia.

The afformentioned results could be due to the deposition of local anesthetic (LA) solution into the coronal part of the periodontal ligament, which then reaches the alveolar bone through fenestrations and marrow spaces, specifically targeting the surrounding tissues of the designated tooth and direct surrounding structures. Additionally, the type and concentration of the anesthetic agent used in this study might play a role. Articaine has been shown to have a significantly higher rate of anesthetic success than lidocaine for supplemental mandibular infiltrations following failed mandibular block anesthesia to anesthetize symptomatic teeth. Numerous reviews have found articaine to be superior to lidocaine for achieving anesthetic success and pain control in symptomatic teeth [34, 35]. Paxton and Thome, and Yapp et al. [36, 37] conducted literature reviews of articaine, both recognizing a general trend of articaine outperforming lidocaine in anesthetic efficacy.

The findings also revealed a statistically significant difference between the two groups regarding the duration of anesthesia, with intraligamental anesthesia wearing off faster than infiltration anesthesia. According to Smith et al. [38], intraligamentary injection was a preferred primary technique for short-duration anesthesia and limited anesthesia of the soft tissues for single tooth extractions. Although it is commonly used for mandibular extractions to avoid nerve blocks, it can also be employed for maxillary teeth due to its rapid onset of action, adequate duration of anesthesia, and rare systemic toxicity.

It was also noted that traditional techniques require a 1.8 ml of anesthetic solution, even with good operator skills and proper anesthetic technique, for infiltration anesthesia. However, in the present study, only 0.2 ml of anesthetic solution was required to be deposited at each side of the tooth of a total of 0.8 ml of the solution, providing similar efficacy and faster wearing off of local anesthesia.

Conclusion

The intraligamentary injection technique can be used effectively to anaesthetize maxillary molars, as a primary technique for extraction of maxillary posterior teeth with grade II mobility using a lower dose of anesthesia.

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