

LINGUAL SUPPLEMENTATION MAY NOT BE REQUIRED AFTER ARTICAININE BUCCAL INFILTRATION ANESTHESIA FOR LOWER MOLAR EXTRACTION: A CLINICAL COMPARATIVE STUDY.

La suplementación lingual opcional después de la anestesia por infiltración bucal con articaína para la extracción de molares inferiores: un estudio clínico comparativo.

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ABSTRACT:

Purpose: To investigate the anesthetic effectiveness of buccal infiltration (BI) versus buccal plus lingual infiltration (BI+LI) of 4% articaine for intra-alveolar extraction of erupted mandibular molar teeth

Material and Methods: Eighty patients were included in this prospective clinical study. They were randomly divided into 1 of 2 equal groups: the 1st group received BI of 4% articaine 1.8 ml and LI of 0.5 ml, while the 2nd group received 4% articaine 1.8 ml BI plus 0.5 ml LI of normal saline. Another 1.8 ml articaine BI was given if initial anesthesia was inadequate. Outcome variables included pain, which was rated by patients at 3 intervals using visual analogue scale, and lingual anesthesia and patients' satisfaction which were measured using 5-score verbal rating scale. Data analyses used were descriptive statistics, *t*-test, χ^2 test, and Pearson's correlation coefficient. *p*-value value less than 0.05 was considered significant

Results: There were 46 females and 34 males and the mean age was 35.3 years. All outcome variables were comparable between the two study groups (*p*=0.05). Anesthesia was successful in 78% and 88% of cases in the (BI) and (BI+LI) groups respectively with no significant difference (*p*=0.2392). The mean articaine volume used was 2.5 ml and 2.87 ml respectively without significant difference (*p*=0.090).

Conclusion: The anesthetic efficacy of (BI) alone and (BI+LI) of 4% articaine was comparable. When given in an adequate dose, articaine (BI) alone could be justified as an anesthetic option for the intra-alveolar extraction of mandibular molar teeth.

KEYWORDS:

Anesthesia, dental; Clinical study; Tooth extraction; Molar; Anesthesia, local; Carticaine

RESUMEN:

Objetivo: Investigar la efectividad anestésica de la infiltración bucal (BI) versus la infiltración bucal más lingual (BI+LI) de articaína al 4% para la extracción intraalveolar de molares mandibulares erupcionados.

Material y Métodos: Ochenta pacientes fueron incluidos en este estudio clínico prospectivo. Se dividieron aleatoriamente en 1 de 2 grupos iguales: el primer grupo recibió BI de articaína al 4% 1,8 ml y LI de 0,5 ml, mientras que el segundo grupo recibió articaína al 4% 1,8 ml BI más 0,5 ml LI de solución salina normal. Se administró otro BI de articaína de 1,8 ml si la anestesia inicial era inadecuada. Las variables de resultado incluyeron el dolor, que los pacientes calificaron en 3 intervalos mediante una escala analógica visual, y la anestesia lingual y la satisfacción de los pacientes, que se midieron mediante una escala de calificación verbal de 5 puntos. Los análisis de datos utilizados fueron estadística descriptiva,

prueba t, prueba χ^2 y coeficiente de correlación de Pearson. Se consideró significativo el valor del valor de p inferior a 0,05.

Resultados: Hubo 46 mujeres y 34 hombres y la edad media fue de 35,3 años. Todas las variables de resultado fueron comparables entre los dos grupos de estudio ($p=0,05$). La anestesia fue exitosa en el 78% y 88% de los casos en los grupos (BI) y (BI+LI) respectivamente sin diferencia significativa ($p=0,2392$). El volumen medio de articaína utilizado fue de 2,5 ml y 2,87 ml respectivamente sin diferencia significativa ($p=0,090$).

Conclusión: La eficacia anestésica de (BI) solo y (BI+LI) de articaína al 4% fue comparable. Cuando se administra en una dosis adecuada, la articaína (BI) sola podría estar justificada para la extracción intraalveolar de molares mandibulares

PALABRAS CLAVE:

Anestesia dental; Estudio clínico; Extracción dental; Diente molar; Anestesia local; Carticaína.

INTRODUCTION.

Profound anesthesia is an essential demand in dentoalveolar surgery.^{1,2} To fulfill this demand, different local anesthetic formulations and techniques are now available to oral surgeons. For the extraction of mandibular molars, inferior alveolar nerve block (IANB) is widely accepted as the gold standard anesthetic technique.³ Because of the thick buccal and lingual cortical plates of the adult posterior mandible, infiltration technique in this region has been overlooked for many years.⁴ However, the introduction of articaine - a relatively new amide local anesthetic with improved diffusion profile - into dental practice spurred interest in its use as infiltration in the posterior mandible (p274).⁵

Superiority of articaine over lidocaine in mandibular buccal infiltration (BI) has been already reported.^{6,7} According to literature, a primary BI of

4% articaine 1.8 ml opposite to the mandibular first molar in healthy asymptomatic volunteers offered successful pulpal anesthesia in 50% to 87% of cases.⁶⁻⁹ Anesthetic efficacy of 4% articaine BI was also comparable to that obtained by 2% lidocaine IANB, both in asymptomatic subjects and in patients with irreversible pulpitis.^{8,10,11} The effect of additional lingual infiltration (LI) in the mandibular molar region was found to be of little or no clinical value.^{8,12}

In mandibular molar extraction setting, BI plus LI of articaine showed comparable anesthetic efficacy to that of IANB, with a success rate of 67% to 100% and an average total dose of infiltrated articaine of 1.9 to 3.1 ml.¹³⁻¹⁶ The same infiltration protocol was adopted for the extraction of lower third molars with a success rate range of 56% to 93% and an average articaine volume of 2.1 to 3.7 ml.¹⁷⁻¹⁹

Without supplemental lingual infiltration, successful anesthesia could be achieved by only BI in 25% and 57% of cases when 1.8 ml and 2.2 ml of articaine were used, respectively.^{20,21} Wide variation exists among studies regarding study design, methodology, success criteria definition, and articaine dosage. No study was found investigating the anesthetic efficacy of additional LI following articaine BI for the extraction of mandibular molars. More evidence about the necessity of supplemental LI is required to provide helpful suggestions in this clinical setting.

The aim of the present study was to investigate the effect of additional LI on the success rate of BI of 4% articaine 1.8 ml for mandibular molar extraction. Specifically, we aimed:

- 1) to evaluate pain perception 8 minutes after articaine injection and during extraction, and
- 2) to compare the anesthetic sufficiency and the success rate between (BI) and (BI plus LI) of articaine in adult patients requiring mandibular molar extraction.

MATERIALS AND METHODS.

The null hypothesis was that BI plus LI of articaine will offer significantly higher pain control than BI alone. A prospective clinical study was planned to recruit patients requiring mandibular molar extraction under local anesthesia from those referred to the Department of Oral and Maxillofacial Surgery, College of Dentistry, Mosul university. All interventions in the present study were compatible with the guidelines and statement of the Declaration of Helsinki (2013). Research proposal was displayed and discussed by the ethical committee in the department and was approved by the scientific committee in the Department of Oral and Maxillofacial Surgery with the reference number: SCOMS-2- 15/11/2018.

Patients were invited to participate in the study protocol after offering them a brief verbal description about the aims of research, giving them the right to accept or refuse, and the right to withdraw at any point of the procedure. In addition,

they were supplied with all necessary information about data and measurements that would be required throughout the procedure. Once they accepted to participate, informed consent was obtained from all patients.

To be included in the study, patients should be healthy adults with 1 erupted mandibular molar tooth indicated for intra-alveolar extraction under local anesthesia, have negative history of any systemic disease, not allergic to articaine, not taking any medication that may affect pain assessment, and be compliant enough to follow the given instructions. Patients excluded were those under 18 years of age, unable to tolerate tooth extraction under local anesthesia, unwilling to give informed consent, were pregnant, had systemic diseases, and those with local infection in the extraction site.

Once the patient met the inclusion criteria, he was given a brief explanation about the study and his task in the sequential process of data collection. Patients' demographic data like name, gender, dental history, and indication for extraction were recorded in a case form specific to the study.

According to the results of previous studies,^{1,2} sample size was calculated. In order to obtain a pain difference of 20% between the two study groups, with a level of significance equal to 0.05 and a study power of 80%, the required number of patients per group was 39. So, we planned to include a total of 80 patients for both groups in the final analysis.

The type of treatment received was the predictable variable in the study. Patients were randomly divided into 2 groups: treatment group in which each patient received BI of 4% articaine 1.8 ml with epinephrine 1:100,000 (Ubistesin Forte, 3M ESPE, Seefeld, Germany) followed by LI of articaine 0.5 ml; and placebo group in which each patient received BI of 4% articaine 1.8 ml followed by LI of normal saline 0.5 ml. Randomization of patients' allocation to treatments was achieved by computer-generated numbers in a 1:1 ratio. All anesthetic injections were delivered by a surgeon with 20 years of experience (the first author) who

was uninvolved in the study measurements, so that a double blind effect was achieved in which both patient and operator were unaware of the type of treatment given. Extractions were performed by the second author who was blind to the type of anesthetic given.

The main outcome variable measured was pain. The degree of anesthesia achieved was evaluated by pinprick testing of the lingual tissues using a 5-score verbal scale (0, nil; 1, mild; 2, tolerable; 3, moderate; 4, severe). The level of how much patients were satisfied with overall treatment was rated on a similar scale (0, miserable; 1, poor; 2, acceptable; 3, good; 4, excellent). Both pain and satisfaction scales has been validated and reported by previous studies.^{1,2,22}

Patients were requested to indicate the level of pain perceived during extraction on a 10-cm visual analog scale (VAS-10), ranging from score 0 "no pain" to score 10 "maximum pain".^{6,23} Other variables were also registered like perceived numbness of the lip and lingual mucosa, and duration of the extraction.

The anesthetic technique involved local injections buccally and lingually. Buccal injections were given at the depth of the vestibule along the axis of the target tooth using a 27-gauge needle assembled to a loaded dental syringe. A complete cartridge (1.8 ml) of articaine solution was slowly infiltrated. For the LIs, a sterile disposable insulin syringe (1 ml capacity) was utilized to deliver 0.5 ml of either articaine or normal saline. Timer was set at 8 minutes and patients were asked to report lip and lingual numbness whenever perceived. At the end of the timer cycle, the initial analgesia was assessed by examining the lingual gingiva around the tooth using the pinprick test. Whenever pain perceived by the patient was rated as higher than 'mild' (score, 1), an additional cartridge of articaine was injected buccally and the patient was left for another 5 minutes before reattempting the procedure.

All extractions were performed using a standardized procedure in the morning period

(between 9 and 12 AM) and at the same clinic. An intra-alveolar forceps extraction technique was performed after making some luxation to the molar by a dental elevator. Immediately after extraction and appropriate wound toilet, the patients were asked to indicate the level of pain they perceived during treatment and their satisfaction score on the relevant scales. Duration of the extraction was recorded in minutes. If unacceptable pain or discomfort was experienced at any point of the procedure, the intervention was stopped and the case was reported as 'failure', excluded from the final analyses, and managed after giving appropriate anesthetic supplementation.

Data of all cases were incrementally collated onto an electronic Excel spreadsheet throughout the study period. Statistical analyses were performed using the Statistical Package for Social Sciences, version 12 (SPSS, Chicago, IL). A descriptive analysis was displayed for all variables under study. To show comparison and correlation, *t*-test, chi-square (χ^2) test, and Pearson correlation coefficient were used as appropriate. *p*-values <0.05 were considered significant.

RESULTS.

All patients received the intended treatment and completed the study; neither protocol shift was noted nor adverse incidents were reported. The study extended over 6 months (from November 2018 to May 2019) and included a total of 80 patients who were randomly divided into 2 equal groups. There was a 57% (n= 46) female majority and a 43% (n= 34) male minority, with a total mean age of 35.3 years (range 21-69 y). The teeth most commonly extracted were first molars (n= 55; 69%), while the most common associated pathology was periapical lesion (n= 57; 71%). The average time taken for extraction was 1.4 minutes in general. Statistical comparison showed no significant differences in patients' demographics, type of teeth extracted, associated pathology, and duration of the procedure between the 2 study groups (Table 1).

Figure 1. Number of successful and failed cases.

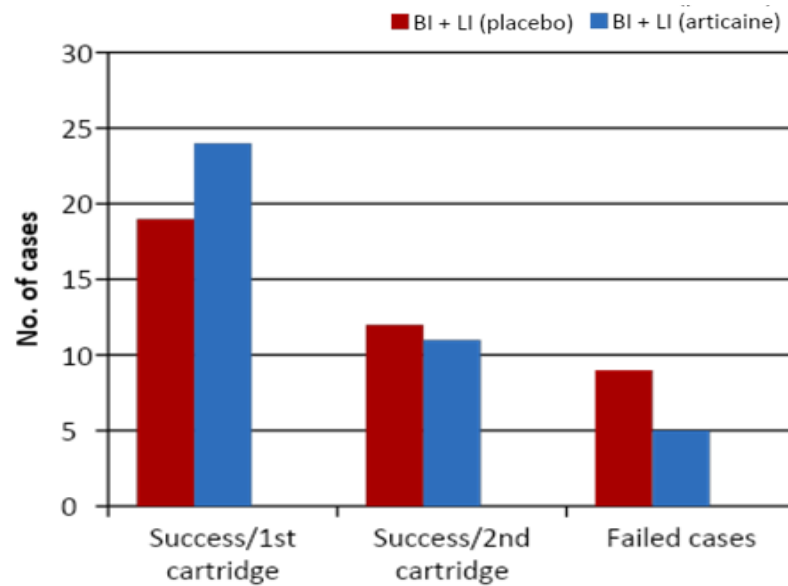


Table 1. Patients' data and operative variables.

Variable		BI + Articaine LI (n=40)	BI + Placebo LI (n=40)	Total (n=80)	p-value
Age (years)		34.1 (11.1)	36.6 (10.8)	35.3 (10.9)	0.315 ^a
Gender	Male	20	14	34	0.174 [†]
	Female	20	26	46	
Type of teeth	First molar	28	27	55	0.896 [†]
	Second molar	10	10	20	
	Third molar	2	3	5	
Associated pathology	Apical lesion	25	32	57	0.206 [†]
	Periodontitis	8	5	13	
	Extensive caries	7	3	10	
	Extraction time (min)	1.4 (1.0)	1.3 (0.7)	1.4 (1.1)	

Data are presented as mean (standard deviation) or as number. ^aT test. [†] Chi square (χ^2) test.

Table 2. Comparison of pain perception between the 2 study groups.

Variable	BI + Articaine (n=40)	LI BI + Placebo LI v(n=40)	Total (n=80)	T-value	p-value [†]
Onset/lip numbness (minutes)	1.2 (0.6)	1.3 (0.7)	1.2 (0.6)	-0.667	0.507
Pin-prick test score	0.6 (0.5)	0.8 (0.4)	0.7 (0.5)	-1.683	0.096
Pain/extraction (VAS-10)*	0.8 (0.8)	1.1 (0.7)	1.0 (0.8)	-1.708	0.092
Satisfaction score*	3.4 (0.7)	3.1 (0.8)	3.3 (0.8)	1.906	0.060

Data presented as mean (Standard Deviation). [†]: T test. ^{*}: Failed cases excluded (5 cases in the articaine group and 9 cases in placebo group).

Table 3. Comparison of pain perception between the 2 study groups.

Variable	BI + Articaine LI	BI + Placebo LI	χ^2 -value	<i>p</i> -value [†]
Lip numbness	40 / 40	40 / 40	1.00	1.00
Lingual tissue numbness	38 / 40	5 / 40	54.758	0.001 >
Pain free extractions	14 / 40	10 / 40	0.9524	0.3291
Successful extractions	35 / 40	31 / 40	1.3853	0.2392

†: Chi square (χ^2) test .

Both pre-extraction pinprick test scores and pain during extraction scores were lower in the articaine group as compared to the placebo group, but the differences were not significant ($p= 0.096$ and 0.092 , respectively). However, a significant correlation between the two sets of scores was found for the entire study population ($r= 0.662$; $p<0.01$).

Pain-free extractions (VAS score, 0) were reported by 14 and 10 patients in the articaine and the placebo groups, respectively ($\chi^2= 0.9524$; $p=0.3291$). Similarly, patients reported higher satisfaction scores in the articaine than in the placebo group but no statistical differences were found between the 2 groups ($p= 0.060$). The mean satisfaction scores were 3.4 (range, 2-4), and 3.1 (range, 1-4), respectively.

In the articaine group, 24 (60%) extractions were successfully completed after the first BI of articaine (1.8 ml), further 11 (27.5%) extractions were made possible after supplemental BI (1.8 ml), and 5 (12.5%) cases failed (Figure 1). On the other hand, 19 (47.5%) extractions in the placebo group were successful after initial BI, 12 (30%) extractions were completed after repeat articaine BI, and 9 (22.5%) cases failed. The total success ratio in the articaine and placebo groups was 87.5% and 77.5%, respectively.

Comparison of the success profile between the 2 groups revealed no significant differences ($\chi^2=$

1.3853, $p= 0.2392$). The mean total amount of local anesthetic given in the articaine and placebo groups was 2.87 ml and 2.5 ml, respectively, again without significant difference ($t= 1.722$, $p= 0,090$).

DISCUSSION.

With the beginning of the new century, infiltration anesthesia by articaine for dental treatments in the mandible has got growing popularity among the researchers, which was reflected on the dental practice to variable extents. Although the effectiveness of supplemental LI has not been previously investigated in molar extraction setting, it is well known that the LI causes more discomfort to the patient than the BI - at least due to the order effect -, puts the lingual nerve at potential risk of trauma, and calls for using an increased volume of the anesthetic agent.^{20,23,24}

The main finding of the present study was that both placebo-controlled (BI) and (BI + LI) of 4% articaine showed comparable anesthetic efficacy scores for mandibular molar extraction. Our primary hypothesis that combining BI and LI would provide more significant pain control than BI alone, was rejected. According to this, BI alone of 4% articaine in an adequate dose could be justified as a primary anesthetic technique for the extraction of lower molars.

Articaine has gained reputation of improved diffusion profile because of its physicochemical

properties like having a relatively high concentration (4%), containing thiophene rather than benzene group in its chemical structure, and possessing a relatively low pKa.²⁵

These features made articaine the most suitable local anesthetic for infiltration anesthesia. However, in the mandibular molar region, there are some anatomical factors that may challenge the diffusion superiority of articaine. The thickest cortical buccal and lingual plates of the mandible were found at the molar region.²⁶ In order to act effectively, articaine must penetrate the cortical and trabecular bone and come into contact with the nerves supplying the teeth.

According to a previous study using cone beam computerized tomography, patients with buccal cortical thickness of ≤ 2 mm had successful anesthesia after the initial shot (1.6 ml articaine BI).²⁷ Of course, this parameter can't be accurately predicted in the clinical practice, and the need for a second cartridge has to be tailored to the level of anesthesia achieved by the first one.

In the present study, the need for a second cartridge to succeed was comparable in the BI with and without LI (31% and 39% of cases, respectively), supporting what has already been reported that the main pulpal anesthesia was achieved by the BI, and that the LI had only a little clinical value.^{12,23,28}

Comparing the success rates of mandibular (BI) and (BI + LI) of articaine in the present study to those reported by past studies,^{13-16,20} we can see comparable figures. This agreement may be related to the similarities among different studies regarding extraction technique, type of teeth extracted, study population, and criteria of success.

Unlike IANB, infiltration anesthesia in the lower molar area seems to be dose dependant.^{9,17,29} Malamed has early reported that the mean articaine volume required to achieve anesthesia was 2.5 ml.³⁰ In the present study, 2.5 ml was the mean articaine volume required in the BI group, while in the BI + LI group the figure was

2.87 ml, which falls within the dosage range reported by other studies (1.9-3.1ml).¹³⁻¹⁹ This is quite different from the dose required for lower premolar extraction, where profound anesthesia could readily be achieved with 1.8 ml of articaine BI with or without supplemental LI.² It appears that BI of one full articaine cartridge would not provide predictable anesthesia of the lower molars, and a second articaine shot would frequently be required to enable for successful extractions. Trying to determine the minimal anesthetic volume that would give the best clinical effect seems to be a tricky task due to variation of the cortical thickness according to age, gender, and local anatomy; further investigation is needed in this domain.

Mandibular LI has previously been shown to be less effective than the BI.^{8,23,28} This difference could be related to the relatively thick lingual cortical bone in the molar region, the absence of lingual anatomical openings (like the mental foramen in the buccal side), and the different distribution patterns of anesthetic solution between buccal and lingual sides. Once it is injected, the anesthetic solution tends to spread downward and backward into the floor of the mouth offering little amount available at the injection site for enough time to produce the desired effect.²⁴ Variable doses for LI were used in the previous studies, ranging from 0.3 ml to 0.9 ml.^{14,15,17} In the present study, we injected 0.5 ml lingually as we thought that this would suffice to demonstrate the effect of LI. Although the success rate was higher in the articaine than in the placebo groups, the difference was not significant. Whether or not increasing the volume of lingually infiltrated articaine would improve its anesthetic effectiveness is worthy of more research.

Interestingly, lip numbness was reported in 100% of our patients. The most reasonable explanation of this effect is the diffusion of articaine anteriorly toward the nearby mental foramen. Articaine BI at the mandibular molars seems to achieve an effect via a modified mental nerve block and/or local diffusion.³¹

It is useful to mention that lip numbness should not be considered a true sign of dental anesthesia after BI.

Expectedly, numbness of the lingual mucosa was found more common in the BI + LI group (95%) than in the BI group (13%). Previous studies reported lingual mucosa numbness after articaine BI alone in 23% and 0% of cases.^{6,7,8} According to pinprick test scoring, articaine BI could achieve lingual anesthesia in variable levels. Lingual numbness after BI of articaine means that some of the local anesthetic could pass through the alveolar bone into the lingual tissues resulting in lingual nerve anesthesia.

However, secured anesthesia that is required for the extraction of lower molars could be achieved without feeling of lingual numbness by patients. Omitting the LI would be in favor of the patient, provided that the BI has achieved the desired pain control; it is unlikely that patients would prefer prolonged unpleasant lingual numbness if given the option.

Regarding pain perceived during the extraction, which was the main outcome variable in the present study, patients in both study groups reported little discomfort (mean score 1, on VAS-10), which is lower than that mentioned in earlier studies.^{14,16} This discomfort level was accepted by the authors because 'pressure feeling' by the patient should always be expected during molar extraction, and because of the high satisfaction scores given by the patients in both groups.

According to many anesthetic profile studies in healthy volunteers, the profound anesthesia declined sharply after 30 minutes of articaine BI opposite to the mandibular first molar.⁶⁻⁹ Without further supplementation, this duration may not be adequate for long procedures. In our study, no extraction took more than 4 minutes, and thus, BI protocol could be considered suitable for routine intra-alveolar extraction of the lower molars.

A limitation of the current study is lack of monitoring the anesthetic duration of articaine injections. Further research is required to study

the effect of supplemental LI on the duration of anesthesia after mandibular molar extraction. Another limitation is the use of a small dose for (LI). Increasing the amount of articaine given lingually might have improved the success rate in (BI + LI) group

CONCLUSION.

The anesthetic efficacy of both placebo-controlled (BI) and (BI + LI) of 4% articaine was comparably successful for the intra-alveolar extraction of mandibular molar teeth. When given in an adequate dose, the articaine BI alone provided successful anesthesia in 77.5% of the cases, negating the need for supplemental LI, with ultimately less anesthetic volume and less discomfort.

Omitting the LI could be justified as an option for the exodontist after articaine BI anesthesia of mandibular molars. Future research with larger samples is needed to confirm these results and to evaluate the minimal effective dose of articaine BI for the extraction of mandibular molars.

Conflict of interests:

The authors declare that they have no conflict of interest.

Ethics approval:

The study was approved by the scientific committee in the Department of Oral and Maxillofacial Surgery with the number: SCOMS-2- 15/11/2018

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Authors' contributions:

Omer W. Majid: Conceptualization; Investigation; Methodology; Data analysis; Supervision; Writing and editing of manuscript.

Zaid A. Muhammad: Investigation; Data curation; Project management.

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