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Research Article

Comparative Evaluation of Analgesic Effect of 4% Articaine with 2% Lignocaine in Surgical Extraction of Mandibular Third Molar: A Randomised Prospective Clinical Trial

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Abstract

Background: Surgical extraction of impacted third molar is one of the most common surgical procedure performed by a maxillofacial surgeon [1]. To provide a pain-free treatment to patients, numerous local anesthetic agents has been used by surgeon. However, gold standard has been lignocaine hydrochloride [2]. In spite of introduction in 1976, articaine is not renowned in dentistry. In this randomised clinical trial, we aimed to determine the safety and efficacy of articaine in comparison with lignocaine for surgical extraction of impacted mandibular third molar.

Method: The study was done in the department of OMFS on 50 patients of age between 18 and 40 years of both genders receiving either 4% articaine hydrochloride (HCl) with 1: 100,000 epinephrine or 2% lignocaine HCl with 1: 200,000 epinephrine. Drug volume, onset of anaesthesia, duration of anaesthesia and duration of postoperative analgesia intake with post-extraction sequels were evaluated for both groups with follow up till 7 post operative days. The parametric and non-parametric test used to analyse data using SPSS Statistics 21.0 program.

Result: 50 patients included in the study out of which 19 were female and 31 males, underwent surgical extraction performed by the same oral surgeon. Age range was 18 to 60 with a peak incidence in the age group of 18-30 years. The author found statistically significant difference between study groups in relation to mean volume (articaine - 2.07 ± 0.37 ml and lignocaine - 3.48 ± 0.85 ml, P value-0.00).

Conclusion: The efficacy of 4% articaine is comparable with that of 2% lignocaine and hence, can be used as an alternative to lignocaine in surgical extraction of mandibular third molar.

Keywords: Local Anesthesia; Lignocaine; Articaine

Introduction

The pursuit to make dentistry as painless as possible has been started since long. Management of pain during oral and maxillofacial surgical procedures has always been critical and an area of continued interest. Among various method used to control pain while performing dental procedure, local anesthetic agent is the backbone of pain control [3]. The era of local anesthesia started with introduction of ester-type local anesthetic, in 1886, followed by procaine in 1904 [2]. In the search for a compound with low allergy and faster onset, an amide-type local anesthetic Lignocaine was discovered by Lofgren and Lundquist in 1942. This anesthetic agent revolutionized dental practice and soon became a gold standard drug against which all other local anesthetics were compared (4). Over the years, many new drugs have been researched. Among these, Articaine has additional benefits of long duration of action and superior effectiveness as compared to others drugs [5]. Articaine (d, l- 4-methyl- 3 - [2 - (propylamine)- propionamido]-2 - thiofene carboxylic acid, methyl ester hydrochloride), is an intermediate-potency, short-acting local anaesthetic with a fast onset of action [6]. It is classified as an amide but differs from other LA solution due to the presence of a thiophene ring instead of a benzene ring [7]. It is metabolised in plasma (hydrolysis by plasma esterase) and liver (hepatic microsomal enzymes) [6]. This study aimed to compare safety and efficacy of articaine with lignocaine in surgical extraction of mandibular third molar with lignocaine.

Materials and Methods

Single blind simple randomized prospective clinical trial study was carried on 50 patients that were referred to the out-patient department of OMFS, Goa Dental College and Hospital, Bambolim, Goa, India. The study was approved by the Institute Review Board. l patiets icuded I the study frapproval and written informed consent.

Patients between age group of 18 to 60 years with moderately difficult impaction according to Pederson's difficulty index were included in the study. Subjects with any bleeding disorder, pregnant or lactating mothers, allergic to local anaesthesia, took analgesics 24 hours prior, ASA III and IV were excluded.

Patients were divided into two groups by simple randomization of 1:1 allocation ratio

- **Group A:** 4% Articaine HCl with 1: 100,000 epinephrine
- **Group B:** 2% Lignocaine HCl with 1: 200,000 epinephrine.

Routine laboratory investigations were carried out for all patients prior to the procedure. Perioral and intraoral site were prepared using betadine scrub and solution respectively. LA was injected for the regional anesthesia of the inferior alveolar nerve, lingual nerve, and long buccal nerve.

Subjective and objective sign of local anesthesia was assessed before surgical extraction of mandibular third molar. Standardized technique was used for extraction in all patients. A single surgeon carried out all the procedure. Variables were recorded were, Drug volume in ml and any additional injections.

- Onset of anaesthesia (s) = Time of soft tissue anesthesia - time of injection
- Duration of anaesthesia (min) = Time of loss of numbness - time of achieving anesthesia
- Duration of postoperative analgesia intake (min) = Difference between the end of surgery and the ingestion of the first analgesic tablet for pain relief.

Intraoperative and postoperative pain = Measured using a Visual Analogue Scale (VAS) which is divided into 6 units as shown in figure 1.

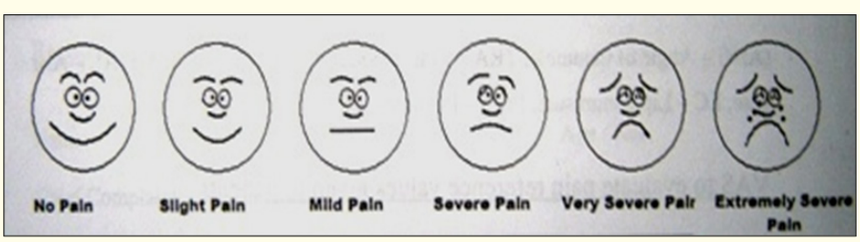

Figure 1

Swelling assessed by a modification of 3 - line measurements using 5 fixed points (lateral canthus of eye, oral commissure, soft tissue pogonion, posterior-most point on tragus, angle of mandible) on surgical site of face with measuring tape in millimetre. The average of these lines recorded as the amount of swelling (S).

Mouth opening: Measured from the mesioincisal angle of the maxillary central incisor to the mesioincisal angle of the ipsilateral mandibular central incisor using Vernier calliper.

Statistical analyses performed using IBM SPSS Statistics 25 program. Parametric and non-parametric tests, including t-test, Spearman's rho, Kruskal-Wallis, Mann-Whitney U, and Wilcoxon's signed-ranks tests were used to analyse inter and intragroup differences. Statistical significance set at $P < 0.05$.

Results

On compilation of data, it is found that, in total of fifty patients male to female ratio was 31:19 with an age range of 18 to 60. Peak incidence was 18 to 30 years.

Table 1 and figure 2 elucidates the mean volume of articaine administered is 2.07 ± 0.37 ml and of lignocaine is 3.48 ± 0.85 ml. This difference was statistically significant ($P = 0.00$).

Local anesthesia	N	Mean (SD)	Range	Median(Q1-Q3)	Mann Whitney U Test	
					U statistic	p-value
Group A	25	2.07 (0.37)	1.7- 2.7	2 (1.7- 2.5)	42	0.00*
Group B	25	3.48 (0.85)	2- 5	3.5 (3- 4)		

Table 1: Comparison of volume between the study groups.

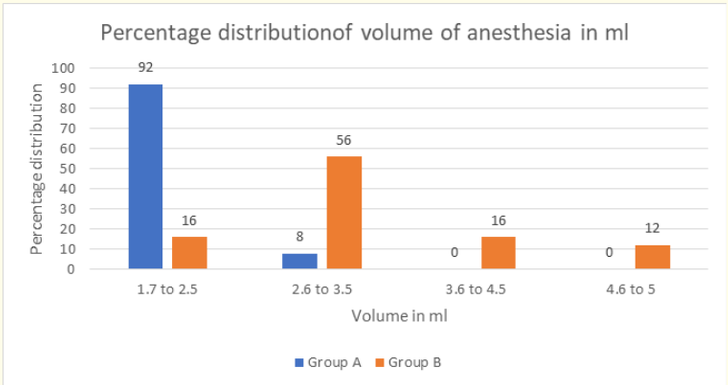

Figure 2: Graph showing volume of anesthesia for the two groups.

Table 2 illustrates the mean onset time of articaine is 99.72 ± 56.71 s and of lignocaine is 97.84 ± 44.01 s and this difference was statistical insignificant.

Table 3 and 4 demonstrates that though the mean duration of anesthesia and post-extraction of analgesia intake for articaine was longer than lignocaine, the difference was statistical insignificant.

Local anesthesia	N	Mean (SD)	Range	Median(Q1-Q3)	Mann Whitney U Test	
					U statistic	p-value
Group A	25	99.72 (56.71)	45- 284	80 (59.5- 117)	302.50	0.84
Group B	25	97.84 (44.01)	45- 205	90 (59- 127.5)		

Table 2: Comparison of onset of anesthesia (seconds) between the study groups.

Local anesthesia	N	Mean	SD	Mean Difference	95% CI of the Difference		t	df	p-value
					Lower	Upper			
Group A	25	222.52	71.63	7.04	-29.77	43.85	0.384	48	0.70
Group B	25	215.48	57.01						

Table 3: Comparison of duration of action anesthesia (min) between the study groups.

Local anesthesia	N	Mean (SD)	Range	Median (Q1-Q3)	Mann Whitney U Test	
					U statistic	p-value
Group A	25	287.80 (83.39)	150-480	283 (215- 355.50)	224.50	0.08
Group B	25	247.00 (82.71)	110- 420	230 (194- 289)		

Table 4: Comparison of duration of post-extraction analgesia intake (min) between the study groups.

Table 5 demonstrates comparison of pain using visual analogue scale on range of (0-5), there was no significant difference (P > 0.05) between the two groups.

Table 6 illustrates, comparison of swelling on post-extraction in which day 3 comparison among two group showed significance difference (P = 0.031) on applying t-test.

Swelling	Local Anesthesia	N	Mean	SD	Mean difference	95% CI of the Difference		t	df	P value
						Lower	Upper			
Baseline	Group A	25	12.12	0.71	-0.18	-0.58	0.22	-0.91	48	0.368
	Group B	25	12.30	0.69						
Day 1	Group A	25	12.31	0.93	-0.19	-0.68	0.31	-0.76	48	0.454
	Group B	25	12.49	0.80						
Day 3	Group A	25	12.42	0.80	-0.49	-0.93	-0.05	-2.23	48	0.031*
	Group B	25	12.91	0.75						
Day 7	Group A	25	13.56	7.36	1.24	-1.74	4.21	0.84	48	0.407
	Group B	25	12.32	0.68						

Table 5: Comparison of Swelling (cm) between both the study groups.

Trismus	Local Anesthesia	N	Mean	SD	Mean difference	95% CI of the Difference		t	df	P value
						Lower	Upper			
Day 1	Group A	25	46.70	5.24	6.71	10.55	3.51	3.50	48	0.001*
	Group B	25	39.99	7.99						
Day 3	Group A	25	33.98	7.78	3.86	8.99	8.99	1.52	48	0.136
	Group B	25	30.11	10.09						
Day 7	Group A	25	46.91	7.34	6.57	10.86	10.86	3.08	48	0.003*
	Group B	25	40.34	7.75						

Table 6: Comparison of Trismus (mm) between the study groups.

Table 7 elucidates, no significant difference in trismus was noted in two groups for trismus on the 3rd day following extraction. However, there was a significant difference on applying t-test in trismus between two groups on the post extraction day 1 (P = 0.001) and day 7 (P = 0.003).

VAS	Local Anesthesia	N	Mean(SD)	Range	Median (Q1-Q3)	Mann Whitney U Test	
						U statistic	p-value
Day 1	Group A	25	0.32(0.48)	0- 1	0 (0-1)	267	0.06
	Group B	25	0.72 (0.74)	0- 3	1 (0- 1)		
Day 3	Group A	25	1.12 (1.13)	0- 4	1 (0-2)	337	0.64
	Group B	25	1.12 (0.88)	0- 3	1 (0.5- 2)		
Day 7	Group A	25	0.08 (0.40)	0- 2	0 (0-0)	356.5	0.85
	Group B	25	0.16 (0.47)	0- 2	0(0- 0)		

Table 7: Comparison of VAS between the study groups.

0	No pain	The patient feels well.
1	Slight pain	If the patient is distracted, he or she does not feel the pain.
2	Mild pain	The patent feels the pain even if concentrating on some activity.
3	Severe pain	The patient is very disturbed but nevertheless can continue with normal activities.
4	Very severe pain	The patient is forced to abandon normal activities.
5	Extremely severe pain	The patient must abandon every type of activity and feel the need to lie down.

Table 8: Visual Analogue Scale.

Discussion

Pain can be a demoralising factor in the patient seeking dental treatment. In theory, local anesthetic with a more prolonged duration of action is the best remedy for pain control. Since, management of pain and inflammation is a critical part of patient care, it is advisable to use an anesthetic that has a longer duration of action [8]. Over the years, many new drugs have been researched with lignocaine as a gold standard. Among these, Articaine has additional benefits of long duration of action and superior effectiveness as compared to others drugs [5].

In the present study, patient's age, gender was statistically insignificant among the groups. The mean volume of articaine injected to achieve inferior alveolar nerve block, lingual nerve block and long buccal nerve block was 2.07 ± 0.37 ml and lignocaine was 3.48 ± 0.85 ml. On applying Mann Whitney U test, the p value was 0.00 indicating significant difference between two groups. The volume of lignocaine was ranged from 2-5 ml to achieve complete nerve block whereas only 1.7-2.7 ml of solution of articaine was required for the same. This was correlates with the study of Malamed., *et al.* (2.5-4.2 ml for articaine and 2.6 - 4.5 ml for lignocaine) [9].

Onset of anesthesia relies on a number of factors, namely intrinsic properties of the drug, anesthetic technique used and pKa value. Shorter latency is reported with a lower pKa value. 4% Articaine shows shorter latency period (pKa = 7.8) than 2% Lidocaine (pKa = 7.9) [10]. In this study, though the data was statistically insignificant (P > 0.05), the articaine group had an early onset 99.7 ± 56.71 s as compared to lignocaine which was 97.84 ± 44.01 s. This result is in concurrence with the study conducted by Shruthi

Saralaya., *et al.* [8]. and Natalia Martínez-Rodríguez., *et al.* [11]. On the contrary, in the study conducted by Berwal V., *et al*, the mean onset for articaine was 57.21 ± 9.87 s and for lignocaine is 84.50 ± 10.68 s with statistically significant difference between the two groups [12].

The duration of action of anaesthesia is related to many factors such as degree of protein binding of the solution, injection site or concentration of vasoconstrictor present in the anesthetic solution. Articaine has a high protein binding percentage among amide local anesthetics. This is comparable to other ultra-long-acting local anesthetics such as bupivacaine, ropivacaine and etidocaine suggesting a longer duration of the anesthetic effect of articaine [10]. The duration of the anaesthetic effect was recorded till the disappearance of numbness in the lower lip. The mean duration of action of anesthesia for articaine was 222.52 ± 71.63 min whereas for lignocaine was 215.48 ± 57.01 min. Although lignocaine had a shorter duration of action as compared to articaine, there was insignificant difference between two groups (P = 0.7). The findings were in conformity with the study by Kimmo Vähätalo., *et al*, where no statistically significant differences were found in duration of action of anesthesia [13]. Duration of action of anesthesia recorded by Natalia Martínez-Rodríguez., *et al.* was greater for articaine i.e., 4 hours 6 min ± 2 hours 28 min as compared with 3 hours 33 min ± 2 hours 35 min for lidocaine but this difference was not statistically significant [11]. Study conducted by Berwal V., *et al,* concluded that the mean duration of action of anesthesia for articaine is 233 ± 57.13 min, whereas for lignocaine it is 190 ± 36.24 min with significant difference between the two groups [12]. Similarly, A. Rebolledo., *et al.* found statistically significant difference in the duration of articaine's anesthetic effect (57 - 416 min) and lignocaine (74 - 336 min) [10].

Peak of postoperative pain occurs in first 8 - 12 hours, thus use of local anesthetic solutions with longer duration is justified. This will reduce the consumption of analgesic in the postoperative period. In the present study, average duration of post-extraction analgesia intake for Articaine was 287.8 ± 83.39 min (range 150-480) in comparison to Lignocaine which was 247 ± 82.71 min (range 110-420). However, this difference was statistically insignificant (P = 0.08). Our finding differs with study done by Shruthi Saralaya., *et al*, who reported statistically significant longer duration of analgesia in subgroup of articaine (236.25 ± 80 min) than lignocaine (152.86 ± 20 min) [8]. There are no other studies which demonstrate the relation between difficulty index of the tooth extracted with postoperative analgesia intake.

Amin Naghipour., *et al*, reported significantly less facial swelling with articaine as compared to lignocaine during the follow-up period [14]. A similar finding was noted in the articaine group and this difference was statistically significant on post-extraction day 3 (P = 0.031) in this study.

Maximum mouth opening post extraction in group A was 46.70 mm and 46.91 mm and for group B it was 39.99 mm and 40.34 mm on day 1 and day 7 respectively. This finding showed a significant difference statically. Amin Naghipour., *et al*, found significantly higher maximum mouth opening in articaine group on 3 and 7 days after surgery than in lignocaine [14].

Measuring pain on a VAS showed, there were no significant difference (P > 0.05) between groups. However, Amin Naghipour., *et al,* showed that articaine causes significantly lesser pain than lignocaine on the post-extraction day 1 (P = 0.03) [14].

No systemic adverse reactions were observed with the local anesthetic solution in the present study. Inclusion of only moderately difficult impacted tooth is limitation of this study which can be corrected by further conducting a study with categorising the difficulty of impaction.

In present study it is found that, a smaller volume of articaine was required to achieve profound anesthesia as compared to lignocaine. Though, Articaine had longer duration of analgesia compared to lignocaine but it is statistically insignificant. Extent of post-extraction sequalae such as pain, swelling and trismus was comparatively less in Articaine, this could help patients reducing fear and anxiety during the treatment. The efficacy of 4% articaine is comparable with that of 2% lignocaine hence, can be used as an alternative to lignocaine in surgical extraction of mandibular third molar. However, numerous factors of variability exist, further controlled clinical trials are essential to bring valuable contribution to research topic.

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Declaration of Interests

There is no conflict of interest.

Ethical Standard

Ethical approval taken by the Institutional Review Board (GDCH/IEC/III-2020 (6)-PROV).

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