Original Article

Comparative Evaluation of Anaesthetic Efficacy of Intra-ligamentary 4% Articaine with and without Oral Pre-operative Ibuprofen in Mandibular First Molars with Irreversible Pulpitis - An *in-vivo* Randomized Control Trial

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Abstract

Context: Effective pain management is important during endodontic therapy. **Aims:** The aim of our study was to evaluate the anesthetic efficacy of 4% articaine using intra-ligamentary injection technique with and without premedication in irreversible pulpitis of mandibular 1st molar teeth using visual analog scale (VAS). **Settings and Design:** Present randomized control trial was conducted on 100 patients within the age group between 20 and 50 years, divided into four groups as follows group 1A for male, 1B for female where intra-ligamentary anesthesia with 4% articaine was given. Group 2A for male, 2B for female where pre-medication of Ibuprofen 400 mg orally given before intra-ligamentary anesthesia. **Materials and Methods:** In control group, 0.2 ml of 4% Articaine was deposited into the mesio-buccal, disto-buccal, mesio-lingual, and disto-lingual line angle of the mandibular first molar. Test group patients were administered with premedication before injection. **Statistical Analysis Used:** Clinical data were compared between the groups by Student's paired *t*-test. *P* value was ≥ 0.05 were considered statistically non-significant, and $P \leq 0.05$, was considered statistically significant. Mean values between the groups were compared using Chi-square test and proportions between two groups were compared using two sample z-test. **Results:** Mean preoperative pain VAS score in groups 1 and 2 was statistically non-significant ($P > 0.05$). At pulp, the mean VAS score in Group 1 and 2 was statistically significant ($P < 0.05$). The maximum pain score in both the groups was statistically significant ($P < 0.05$). No significant difference between men and women regarding success rates of two comparison groups. **Conclusions:** premedication with ibuprofen 400 mg increases the anesthetic efficacy of 4% articaine.

Keywords: Articaine, Ibuprofen, Intra-ligamentary anesthesia, Pre-medication.

Introduction

Effective pain management represents a unique opportunity to integrate pharmacological, procedural, and behavioral skills in pain control to grateful patients.[1] literature has shown that Inferior alveolar nerve block failures significantly more with irreversible pulpitis as it is often difficult to obtain complete pulpal anesthesia in mandibular molars.[2] The thick cortical plate of the mandible and the nerves supplying the mandibular teeth are thought to be the attributing factors.[3] To overcome these problem intra-ligamentary injection technique along with the administration of non-steroidal anti-inflammatory drugs (NSAIDs) during endodontic procedures has been tried.[4,5] It has also been suggested that 4% Articaine may be more successful than Lidocaine in achieving anesthesia. Considering these factors, the aim of our present study was to evaluate and compare the anesthetic efficacy of 4% Articaine using intra-ligamentary injection technique with and without

Access this article online

Website: www.jrad.co.in

DOI: https://doi.org/10.53064/jrad.2022.13.3.166

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Received: Jan. 12, 2022; **Accepted:** Feb. 16, 2022; **Published:** Mar. 06, 2022

How to cite this article: Tiwari P, Sisodia S, Mishra UK, Bhardwaj A, Pal PC, Ali Syed G. Comparative Evaluation of Anaesthetic Efficacy of Intra-ligamentary 4% Articaine with and without Oral Pre-operative Ibuprofen in Mandibular First Molars with Irreversible Pulpitis - An *in-vivo* Randomized Control Trial. J Res Adv Dent 2022;13(3):102-108.

oral premedication in adult patients with irreversible pulpitis of mandibular 1st molar teeth using visual analog scale (VAS). In our knowledge, till date, no other clinical trials have compared the anesthetic efficacy of 4% articaine administered through intra-ligamentary technique in adult patients after oral premedication using Ibuprofen.

Materials and Methods

This present randomized control clinical trial was conducted with a sample size of 100 patients within the age group between 20 and 50 years, who were selected from the outpatient department with symptomatic irreversible pulpitis in mandibular first molars indicated for root canal therapy. Inclusion criteria included a positive response to cold testing with endodontic ice stick and an electric pulp tester, absence of any periapical radiolucency on radiograph except for a widened periodontal ligament space, ability of the subject to understand the use of pain scales, and with general good health. None of the participants was taking any medication that would alter pain perception in the past 24 h. Patients with systemic disorders, Pregnant and lactating mothers, known allergic to articaine and/or NSAIDs, Patients having active pain in more than 1 mandibular molar in the same quadrant, Swelling associated with the tooth in question/ Non-vital teeth were excluded from this study. Ethical clearance was obtained from the University ethical review committee to conduct this clinical trial. The University Ethical Committee approved the consent form and experimental protocol (IEC NoIEC/MDCRC/2017-20/01010). Informed consent was signed by every subject who fulfilled the inclusion criteria and agreed to participate voluntarily, after thorough explanation of the nature, risk, and benefit of the clinical investigations and associated procedure. The patients were explained the pain scale and the procedure and were asked to rate their pre-treatment pain on Heft-Parker VAS.[6] Patients were instructed to point to the position on the scale to indicate how much pain they are currently feeling. The far left end marked "0 mm" indicates "No pain" and the far right end marked "170 mm" indicates "Maximum possible pain." The VAS scale was categorized as: no pain corresponds to 0 mm, mild pain is defined as >0 mm and ≤54 mm, moderate pain is defined as >54 mm and <114 mm, and severe pain is defined as ≥114 mm.[7,8]

All the participants were randomly allocated using coin toss method into two groups i.e. Group 1 and Group 2, which was further be divided into two subgroups with 25 patients in each subgroup as follow:

Group 1A (Male): Intra-ligamentary anesthesia with 4% Articaine.

Group 1B (Female): Intra-ligamentary anesthesia with 4% Articaine.

Group 2A (Male): Intra-ligamentary anesthesia with 4% Articaine, 1 h after administering Ibuprofen 400 mg orally.

Group 2B (Female): Intra-ligamentary anesthesia with 4% Articaine, 1 h after administering Ibuprofen 400 mg orally.

Procedure for Group 1-In 50 patients topical anesthetic gel was applied with a cotton tip applicator on to the injection site for 60 s. Then, the needle was inserted into the gingival sulcus to a depth of 1–2 mm, at 30° to long axis of the tooth at the mesio-buccal line angle, disto-buccal line angle, mesio-lingual line angle, and disto-lingual line angle of the mandibular first molar. It was made to rest firmly in the sulcus and remained fixed during the injection process. Needle bevel faced the root surface. As soon as the needle got fixed in the sulcus the injection was begun. The injection pressure was created by pressing the thumb or index finger smoothly onto the dosage lever (Medesy®; Italy) (Figure 1). Pressure was then transmitted to the plunger, which empties the anesthetic containing cartridge (Figure 2). 0.2 ml solution of 4% Articaine with 1:100,000 epinephrine was deposited into the periodontium of each line angle by maintaining the needle position for about 10–15 s. After 7 min of injection, the patients were again be asked to rate their pain on Heft-Parker VAS. The involved tooth was isolated with rubber dam and conventional access opening was initiated using endodontic access bur no 2. Patients were instructed to raise their left hand if any pain is felt during the procedure. If pain was felt during the treatment, the procedure immediately was stopped and was asked to rate the pain on Heft-Parker VAS. The extent of access preparation and/or instrumentation was

Figure 1: Armamentarium including dosage lever

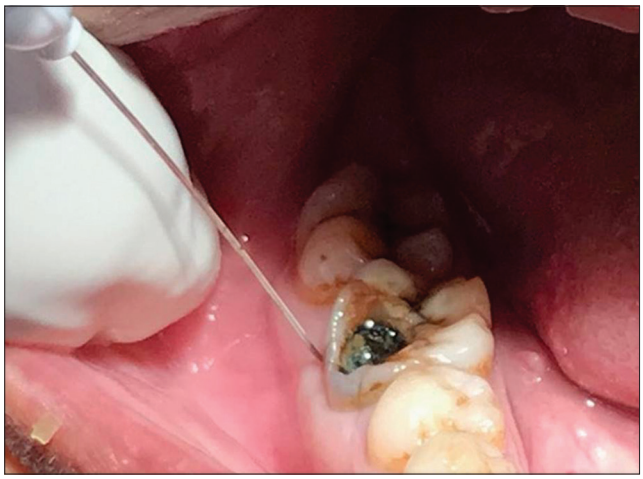


Figure 2: Injection procedure

recorded as within dentin/within pulpal space/during insertion of 1st instrument in the canal till the working length using apex locator. The success was defined as "no pain" (0 mm) or "weak/mild pain" (>0 mm and ≤54 mm) during endodontic access preparation and file insertion. The failure was defined as "moderate pain (>54 mm and <114 mm)" or "severe pain (≥114 mm)" during access preparation/during first File insertion till working length. The findings were recorded using Microsoft Excel Sheet for statistical evaluation.

In Group 2-A total of 50 patients were given tablet Ibuprofen-400 mg, orally; after 1 h of which they were given local anesthesia with 4% articaine 1:100,000 epinephrine. Rest of the procedure was repeated the same as in Group 1.

Statistical analysis

Clinical data were compared between the groups with the help of Student's paired *t*-test. If $P \geq 0.05$, the difference observed was considered statistically non-significant, and $P \leq 0.05$, it was considered statistically significant. In this present study, the mean values between the groups were compared using chi-square test and proportions between two groups were compared using two sample z-test. The statistical software SPSS 20.0.0 was used for analysis. The data were represented as tables and graphs.

Results

Age

Considering the age of the patients, in Group 1, there were 20 (40%) patients in the age group 20–30 years, 15 (30%) in the age group 31–40 years, and 10 (20%) in the age group 41–50 years. In Group 2, there were 21 (42%) patients in the age group 20–30 years, 19 (38%) in the age group 31–40 years, and 7 (14%) in the age group 41–50 years. Thus, majority of the patients in this study were young between the age group 20–40 years (Table 1 and Graph 1).

Table 1: Distribution of patients according to age group

(*n*=100)	Group		Total
	Group 1	Group 2	
Age group (years)			
<20			
Count	5	3	8
% Within group	10.0%	6.0%	8.0%
20–30			
Count	20	21	41
% Within group	40.0%	42.0%	41.0%
31–40			
Count	15	19	34
% Within group	30.0%	38.0%	34.0%
41–50			
Count	10	7	17
% Within group	20.0%	14.0%	17.0%
Total			
Count	50	50	100
% within Group	100.0%	100.0%	100.0%

n=Total sample size

Mean pain scores preoperatively, at 7 min after injection, and different tooth location in Group 1 and Group 2 was recorded. In this present study, Heft Parker VAS scale was used for pain scoring. In Group 1, the mean preoperative pain VAS score was 147.16 (±10.47) mm, while it was 146.70 (±13.44) mm in Group 2. There was no statistically significant difference between the two mean pain scores ($P > 0.05$). 7 min after giving injection no pain was reported in both the groups. During the procedure, the VAS score was again measured at dentine, at pulp, and during the file insertion. In Group 1, the mean VAS score at dentine was 8.30 (±28.62) mm, while in Group 2, it was 3.20 (±15.96) mm, there was no statistically significant difference between the two mean pain scores ($P > 0.05$). At pulp, the mean VAS score in Group 1 was 32.88 (±62.75) mm, while in Group 2 it was 13.14 (±30.88) mm. which was statistically significant ($P < 0.05$). During file insertion in mesio-buccal and mesio-lingual canals pain according to VAS scale was 53.42 (±53.04) mm and 55.84 (±55.06) mm respectively in Group 1 and it was 43.54 (±50.02) mm and 42.34 (±48.71) mm respectively in Group 2. Both the findings were not statistically significant ($P > 0.05$). In distal canals in both Group 1 and 2 pain was 53.92 (±52.97) and 32.94 (±47.35), respectively, and it was statistically significant ($P < 0.05$) (Table 2 and Graphs 2 and 3).

Comparison of pain score in test groups

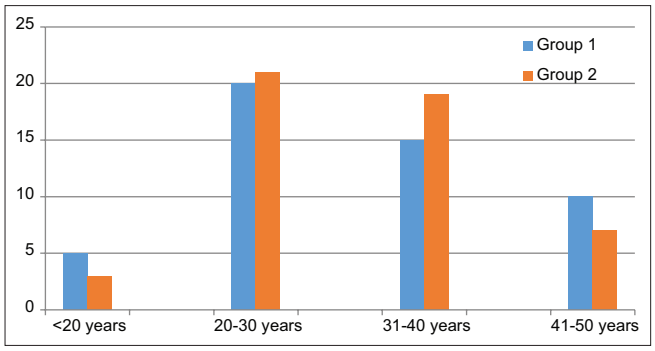
On comparison of grading of pain from no pain to severe pain, 6% participants was having no pain, 20% had mild pain, 18% had moderate, and 56% had severe pain in Group 1. While in Group 2, 14% had no pain, 34% had mild pain, 36% had moderate and 16% had severe pain. The pain score between the two groups was statistically significant ($P < 0.05$). In Group 1 maximum 56% of patients had severe pain and in Group 2 maximum 36% of patients were of moderate pain (Table 3 and Graph 4).

Comparison of number of unsuccessful pain control in test groups: Unsuccessful cases are defined as no pain relief, having moderate to severe pain even after administration of anesthesia and premedication. In Group 1, only 4% of patients had moderate pain and 4% had severe pain at dentine, while

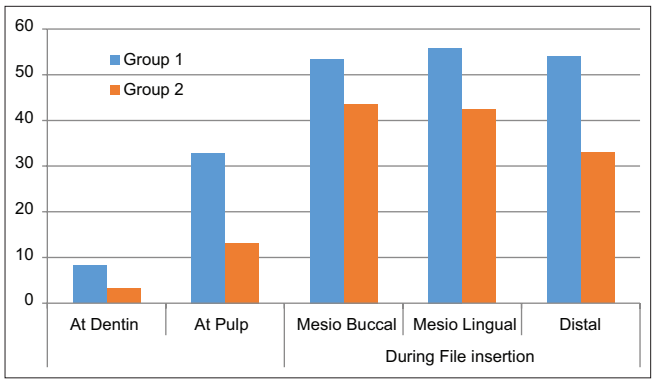
Table 2: Mean pain scores preoperatively, at 7 min after injection and different tooth location in Group 1 and Group 2

(*n*=50)	Group 1	Group 2	*t*-value	*P*-value
Pre-operative pain	147.16±10.47	146.70±13.44	0.191	0.849
After 7 min of administering Injection	0.00	0.00	-	-
During procedure				
At Dentin	8.30±28.95	3.20±15.96	1.091	0.278
At Pulp	32.88±62.75	13.14±30.88	1.998	0.048*
During file insertion				
Mesio buccal	53.42±53.04	43.54±50.02	0.958	0.340
Mesio lingual	55.84±55.06	42.34±48.71	1.298	0.197
Distal	53.92±52.97	32.94±47.35	2.088	0.039*

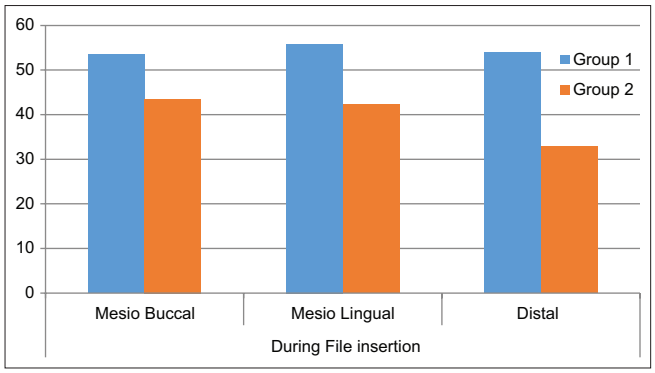
n=Sample size, *t*-value=Student's *t*-test value, *P* value=Probability Value, $P \leq 0.05$ considered statistically significant, (*) statistically significant



Graph 1: Age wise distribution of patients



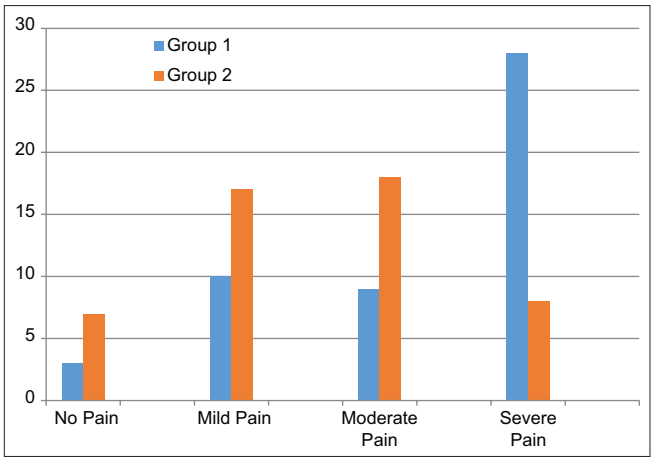
Graph 2: Mean pain scores at different tooth location in Group 1 and Group 2



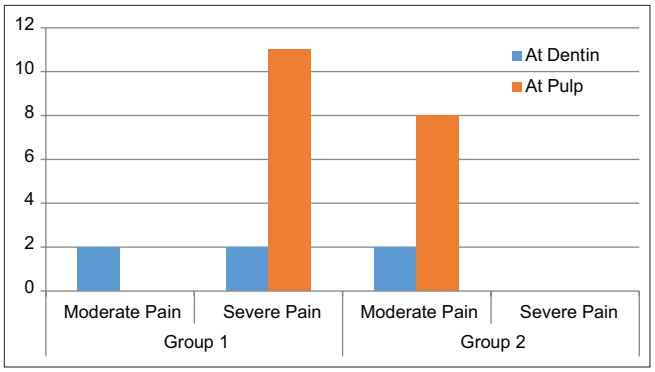
Graph 3: Mean pain scores preoperatively, at 7 min after injection mesio-buccal, mesio-lingual and distal canal during file insertion in Group 1 and Group 2

22% of patients had severe pain at pulp and 24% had moderate pain and 26% severe pain during file insertion. In Group 2 Similarly, 4% had moderate pain at dentine, while 8% had moderate pain at pulp there was no severe pain at dentine and pulp in this group, 16% had moderate and 16 % severe pain during file insertion (Table 4 and Graphs 5 and 6).

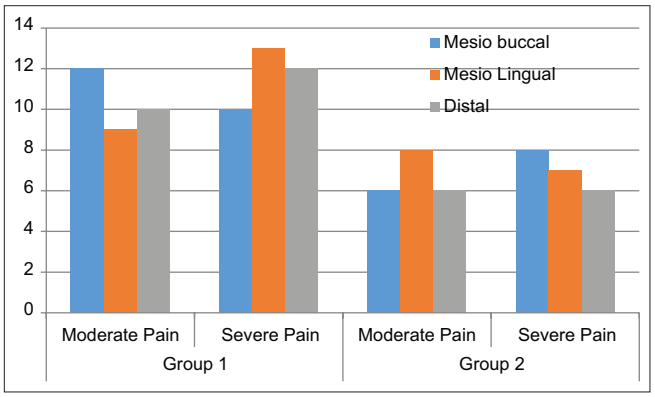
Two sample z-tests to compare sample proportions were done to calculate the significance between Group 1 and Group 2 for each type (moderate pain and severe pain). When moderate pain was compared between the two groups, the z value obtained was 3.41, with a $P < 0.05$, thus shows there was statistically



Graph 4: Comparison of pain score in test groups



Graph 5: Comparison of number of unsuccessful pain control in test groups at dentin and pulp



Graph 6: Comparison of number of unsuccessful pain control in test groups

significant difference between the number of patients having moderate pain in both the groups. When severe pain was compared between the two groups, the z value obtained was 3.41, with a $P < 0.05$, thus, shows that there was statistically significant difference present between the number of patients having severe pain in both the groups. Thus in patients with unsuccessful pain control in both the groups, significant difference was there in the number of patients having moderate pain and severe pain in both the groups (Table 5).

Comparison of pain score in between male and female of Group 1: Intra-group comparison of pain score in male of female patients of Group 1 showed total 3 male patients had moderate pain and 15 had severe pain in this group while six female patients had moderate pain and 13 had severe pain. There was no statistical difference between mean pain score of male and female patients in this group ($P > 0.05$) (Table 6 and Graph 7).

Table 3: Comparison of pain score in test groups

(*n*=50)	Group		Total	Chi-square value	*P*-value
	Group 1	Group 2			
Pain					
No pain					
Count	3	7	11	17.526	0.001*
% Within group	6.0%	14.0%	10.0%		
Mild Pain					
Count	10	17	27		
% Within group	20.0%	34.0%	27.0%		
Moderate Pain					
Count	9	18	27		
% Within group	18.0%	36.0%	27.0%		
Severe Pain					
Count	28	8	36		
% Within group	56.0%	16.0%	36.0%		
Total					
Count	50	50	100		
% Within group	100.0%	100.0%	100.0%		

n=sample size, *P* value=Probability value, $P \leq 0.05$ considered statistically significant, (*) statistically significant

Table 4: Comparison of number of unsuccessful pain control in test groups

(*n*=50)	Group 1		Group 2	
	Moderate pain (54–113%)	Severe pain (>114%)	Moderate pain (54–113%)	Severe Pain (>114%)
At Dentin	02 (4)	02 (4)	02 (4)	00
At Pulp	00	11 (22)	08 (16)	00
During File Insertion	24	26	16	16
Mesio buccal	12 (24)	10 (20)	06 (12)	08 (16)
Mesio Lingual	09 (18)	13 (26)	08 (16)	07 (14)
Distal	10 (20)	12 (24)	06 (12)	06 (12)

n=sample size

Table 5: Two sample z-test to calculate the significance between Group 1 and Group 2 for each type (moderate pain and severe pain)

	Group 1	Group 2	Z	*P*-value
Moderate pain	9/37	17/25	–3.41	0.001*
Severe pain	28/37	08/25	3.41	0.002*

n=sample size, Z value=Pearson's Correlation coefficient, *P* value=Probability value, $P \leq 0.05$ considered statistically significant, (*) statistically significant

Comparison of pain score in between male and female of Group 2: Intra-group comparison of pain score in male of female patients of Group 2 showed seven male patients had moderate pain and 4 had severe pain in this group while 11 female patients had moderate pain and 4 had severe pain. There was no statistical difference between mean pain score of male and female patients in this group ($P > 0.05$) (Table 7 and Graph 7).

Comparison of pain score in between males of two groups: Inter-group comparison between the male patients of Group 1 and Group 2 showed in Group 1, a total of 3 had moderate pain and 15 had severe pain while in Group 2, total 7 had moderate pain and only 4 had severe pain. The mean pain scores between the male patients of both the groups were statistically significant ($P < 0.05$) (Table 8 and Graph 8).

Comparison of pain score in between females of two groups: Inter-group comparison between the female patients of Group 1

Table 6: Comparison of pain score in between male and female of Group 1

Group 1	Pain				Chi-square value	*P*-value
	No pain	Mild pain (0–53)	Moderate pain (54–114)	Severe pain (>114)		
Gender						
Male	3	4	3	15		
Female	0	6	6	13	4.543	0.208
Total	3	10	9	28		

n=sample size, *P* value=Probability value, $P \leq 0.05$ Considered statistically

Table 7: Comparison of pain score in between male and female of Group 2

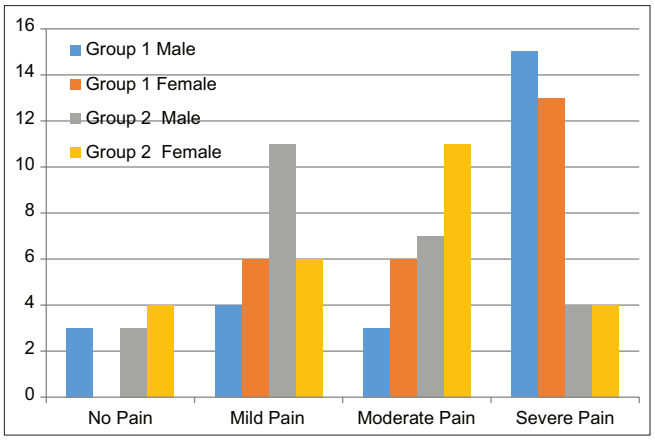
Group 2 (*n*=50)	Pain				Chi-square value	*P*-value
	No pain	Mild pain (0–53)	Moderate pain (54–114)	Severe Pain (>114)		
Gender						
Male	3	11	7	4		
Female	4	6	11	4	2.502	0.475
Total	7		18	8		

n=sample size, *P* value=Probability value, $P \leq 0.05$ considered statistically significant

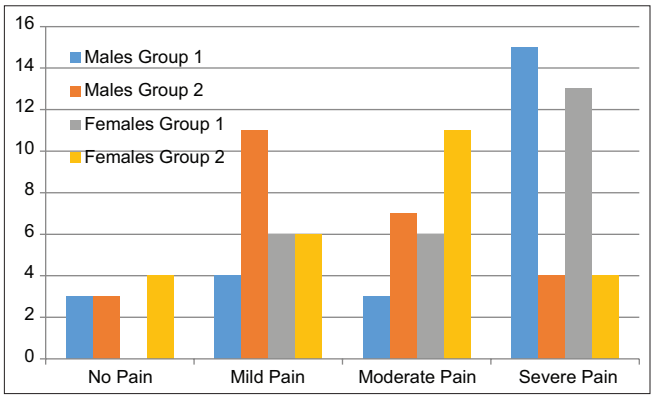
Table 8: Comparison of pain score in between males of two groups

Males	Pain				Chi-square value	*P*-value
	No pain	Mild pain	Moderate pain	Severe pain		
Group						
Group 1	3	4	3	15		
Group 2	3	11	7	4	11.235	0.011*
Total	6	15	10	19		

P-value=Probability value, $P \leq 0.05$ considered statistically significant, (*) statistically significant



Graph 7: Comparison of pain score in between male and female of Group 1 and Group 2



Graph 8: Comparison of pain score in between male-male and female-female of two groups

Table 9: Comparison of pain score in between females of two groups

Females	Pain				Chi-square value	*P*-value
	No pain	Mild pain	Moderate pain	Severe pain		
Group						
Group 1	0	6	6	13		
Group 2	4	6	11	4	10.235	0.017*
Total	4	12	17	17		

P-value=Probability value, $P \leq 0.05$ considered statistically significant, (*) statistically significant

and Group 2 showed in Group 1, total of 6 had moderate pain and 13 had severe pain while in group 2, total of 11 had moderate pain and only 4 had severe pain. The mean pain scores between the male patients of both the groups were statistically significant ($P < 0.05$) (Table 9 and Graph 8).

Discussion

Few scientific studies have shown oral premedication or prophylactic, resulted in increased success rate as it reduced the nociception activation by reducing the level of inflammatory mediators, providing added analgesic effect.[5] It has been hypothesized that premedication with NSAIDs would affect the success rate of local anesthetic in patients with irreversible pulpitis. Efficacy in achieving deep anesthesia with premedication of Ibuprofen and acetaminophen/codeine has been evaluated. Currently, articaine is available as a 4% solution containing 1:00,000 or 1:200,000 adrenaline.[9] Plain articaine was approved for clinical use by US Food and Drug Administration in March 2006.[10] Clinical trials have shown articaine to be safe and effective which accounts for its increased use as local anesthetic agent while performing endodontic treatments.[11] Effective pain management is important for successful endodontic procedures. To overcome the pain during dental procedures different techniques, material and medicaments are routinely used during treatment.[12] In case of inflamed pulp of irreversible pulpitis, using only the local anesthetic agent fails to obtain profound anesthesia since in these cases, inflammation and infection lower the pH of surrounding tissue thereby providing inadequate pain control.[13] It has been found in literature, that such patients have 8 times more chances of failure of local anesthesia as compared to patients with normal pulp.[14,15] Various mechanisms have been explained by researcher regarding failure of local anesthetics in inflamed pulp which can be explained due to tachyphylaxis of anesthetic solutions; decreased local pH; activation of nociceptors including tetrodoxin receptors. Study of Byers *et al.* in 1990 Hargreaves *et al.* in 2002 have led to realization that the terminals of peripheral nerves literally grow ("sprout") into areas of inflammation in dental pulp and periradicular tissue.[16,17] In our present study mandibular first molars were used as these are the first permanent tooth to erupt in the oral cavity and has the highest incidence of dental caries leading to irreversible pulpitis.[18] We have used intra-ligamentry injection technique because profound pulpal anesthesia is difficult to achieve on a solitary tooth with the conventional nerve block technique. In contrary, periodontal ligament injection provides pulpal and soft tissue anesthesia in a localized area of the mandible without producing extensive soft tissue anesthesia.[3] The success of the intra-ligamentary injection as primary and supplemental in achieving pulpal anesthesia has been reported to be from 18% to 100% because it allows placement of a local anesthetic solution directly into the cancellous bone adjacent to the tooth to be anesthetized.[19] Clinical studies have reported high failure rate after with nerve block (44–81%).[20] Articaine in comparison to other local anesthetics has shown to have better hard and soft tissue diffusion.[21] Chemically, Articaine is an amide local anesthetic; differs from other agents of its group as it contains a thiophene ring as well as an additional ester ring.[22] Its greater lipid solubility action is due to the presence of thiophene ring, which facilitates diffusion across the lipid-rich nerve membrane to access target receptors. The plasma half-life of articaine is known to be 20 min.[19] Articaine was chosen in our present clinical trial because when compared to lidocaine they both have same maximum dose of 500 mg for the adult patient, seven cartridges of 4% articaine solution would be effective compared to 13 cartridges of 2% lidocaine.[23] It also shown to provide longer duration of anesthesia when compared to lidocaine.[22,23]

Analgesic medications are indicated for the relief of chronic/acute pain, post-operative pain and for controlling adjunctive intraoperative pain.[24] Ibuprofen is a propionic acid derivative and an effective analgesic and anti-inflammatory agent. By decreasing the level of inflammatory mediators they reduce the nociceptor activation.[25] Ibuprofen has found to increases the depth of anesthesia. Significantly lower tooth sensitivity level after ibuprofen premedication therapy may be because of the effect of NSAIDs on blocking the COX pathways and decreasing the prostaglandin level, resulting in significant inhibition of stimulated nerve activity.[13] In our study result showed that patient on premedication with Ibuprofen 1 h before LA, showed less pain than without medication which was in accordance with the study conducted by Modaresi *et al*., Ramachandran *et al*.[5,13] On the contrary Jena *et al*. found more success rate with ketorolac than ibuprofen.[26] Lapidus *et al*. concluded that there is moderate evidence to support ibuprofen 600 mg prior to LA.[27] Aggarwal *et al*. found that preoperative administration of ibuprofen or ketorolac has no significant effect.[25] In this present study, majority of the patients in both the groups were between 20 and 40 years of age. The maximum pain score in both the groups was measured as the maximum pain the patient had felt during the procedure, i.e., at dentine, at pulp or during the insertion of first instrument in the canal till the apex. We also found no significant difference between male and female regarding the success rate within the same group, which is in accordance with study done by Yadav *et al*.[28] So within the limitations of this study, it can be found that the oral premedication with ibuprofen 400 mg increases the anesthetic efficacy of 4% articaine. So, for the benefit of patient care by reducing the pain in clinical practice we can use premedication with NSAIDs before the LA administration.

Conclusions

Results of this study showed that the mean pain score in both the groups was comparable. The maximum pain score in both the groups was statistically significant ($P < 0.05$). Within the limitations of the present study, it is concluded that the premedication with ibuprofen 400 mg increases the anesthetic efficacy of 4% articaine as compared to 4% articaine given without premedication. It can also be concluded that no significant difference between men and women regarding success rates of two comparison groups.

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