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Research Article

The Effect of Pre-Operative Ketorolac Tromethamine Administration during Single Visit Root Canal Treatment of Mandibular Molars with Acute Irreversible Pulpitis on Intra-/Post-Operative Pain

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Abstract

Introduction: Mandibular molar teeth with acute irreversible pulpitis pose challenges during root canal treatment (1) success of local anesthesia (2) post-operative pain. The primary aim of this study was to assess the effect of pre-operative ketorolac tromethamine oral administration on intra-/post-operative pain. Secondary objective was to evaluate the effect of different anesthetic solutions and irrigants on the same.

Materials and Methods: 128 patients with irreversible pulpitis associated with carious mandibular molar teeth were enrolled. All patients were administered 10 mg of ketorolac tromethamine prior to local anesthestic injections. The local anesthetics used were 2% lignocaine and 4% articaine. Three irrigation solutions were used - saline, 3% sodium hypochlorite and dexamethasone. Pain was assessed using a 10-point Visual Analog Scale.

Results: The mean intra-operative pain scores for the lignocaine and articaine groups were 2.43 (± 2.37) and 3.19 (± 3.01), respectively. The post-operative pain incidence in the lignocaine and articaine groups was 23.8% (15 patients) and 39.7% (25 patients) (P = 0.057) respectively. Sodium hypochlorite irrigation in the lignocaine group had the lowest mean 24 hr post-operative pain score of 0.57 ± 0.21 whereas in the articaine group, it had the highest mean 24 hr post-operative score of 1.36 ± 1.76.

Conclusion: In conclusion, the combination of pre-operative ketorolac with lignocaine was effective in controlling post-operative pain. Single visit root canal treatment with pre-operative ketorolac tromethamine and lignocaine inferior alveolar nerve block and additional injections combined with sodium hypochlorite or dexamethasone irrigation was very effective in the management of symptoms associated with acute irreversible pulpitis in mandibular molar teeth.

Keywords: *4% Articaine; 2% Lignocaine; Buccal Nerve Infiltration; Inferior Alveolar Nerve Block; Intra-Ligamentary Injection; Ketorolac Tromethamine; Root Canal Irrigants; Single Visit Root Canal Treatment*

Introduction

A mandibular molar tooth with acute irreversible pulpitis is one of the most disconcerting situations to be encountered in an endodontic clinic [1]. Treatment options for these situations are limited to either emergency access opening or prescribing potent analgesics [1]. Achieving satisfactory anesthesia and reducing the incidence of post-treatment discomfort are the difficulties encountered in clinical treatment of these teeth [1]. Multiple strategies have been explored for attaining profound anesthesia and to control post-operative pain in these situations [2]. Pre-operative use of analgesics has been the most investigated strategy in the literature [2,3]. However, there is a lack of scientific evidence regarding the efficacy of oral pre-operative analgesics in controlling both the intra-operative and post-operative pain following single visit root canal treatment for mandibular teeth with acute irreversible pulpitis. An earlier report from the concluded that pre-operative ketoro-

lac tromethamine was not effective in reducing the intra-operative pain for mandibular molar teeth with acute irreversible pulpitis when inferior alveolar nerve blocks (IANB) with both lignocaine and articaine anesthetic agents were used. However, pre-operative ketorolac tromethamine was effective in reducing post-operative pain in the lignocaine anesthetic group [4]. Furthermore, pre-operative ketorolac tromethamine prior to single visit root canal treatment showed no significant difference in post-treatment pain between the different irrigation groups [4]. These findings are in agreement with reports on the role played by root canal irrigants in controlling post-operative pain in teeth with acute irreversible pulpitis being inconclusive [5-8].

A literature search has shown that there is a gap in understanding about the efficacy of pre-operative ketorolac tromethamine in improving the success of local anaesthetics and for the management of post-operative pain following single visit root canal treatment in mandibular molar teeth with acute irreversible pulpitis. Furthermore, no scientific evidence is available on the role played by different local anesthetic agents on post-treatment pain following single visit root canal treatment.

Aim of the Study

The present study was planned with the primary aim to compare the anesthetic efficacy of lignocaine and articaine IANB with additional injections for single visit root canal treatment for mandibular molar teeth with acute irreversible pulpitis following pre-operatively administered oral ketorolac tromethamine. A second objective was to explore the efficacy of these two different local anesthetics in controlling post-operative pain following single visit root canal treatment when employed with three different root canal irrigants.

Materials and Methods

A sample size of 126 patients was calculated to be sufficient to detect clinical data difference (alpha error of 0.05, power of 95% and effect size 0.4) (G power 3.1.9.2. software, Germany). The period of study was from November 2018 to January 2020 and 128 patients were recruited. After gaining approval from the institutional ethics committee [CSICDSR/IEC/0052/2018] and the trial was registered with the Clinical Trial Registry of India [CTRI/2019/10/021597]. The patients (or where appropriate, parents or guardian) were informed about the nature of the treatment and the study, and they were asked to sign an informed consent form. The methodology adopted for this study is similar to a previous experiment in the authors' department with the same operator.

Patients referred to the Department of Conservative Dentistry and Endodontics with pain due to acute irreversible pulpitis from carious mandibular first and second molar teeth requiring root canal treatment were evaluated as possible candidates for this study. Subjects aged between 13 and 70 years with no intake of medications for pain relief in the previous 10 days prior to treatment were included in the study. All patients reported mild to severe pain that was continuous, spontaneous, radiating, nocturnal or throbbing in nature. All teeth included in this study responded to cold pulp sensibility testing (Endo-Frost, Coltene Whaledent, Switzerland) with exaggerated pain, with or without lingering. They also had tenderness on percussion. In addition, profuse bleeding was evident upon gaining access into the pulp chamber. The teeth included in the study also did not have any evidence of periapical bone changes in the pre-operative periapical radiographs.

Exclusion criteria were teeth with poor periodontal or restorative prognosis, patients with systemic ailments or conditions hindering single visit root canal treatment, patients not willing to participate in the post-operative recall evaluation, any anatomic variation such as extra roots or root canals, C-shaped roots, and patients with a history of allergy.

In the period from November 2018 to April 2019, 64 patients underwent single visit root canal treatment with 2.5 mL of 2% lignocaine containing 1:80,000 adrenaline (Lignox, Warren Pharmaceuticals, Mumbai, India) for an inferior nerve alveolar nerve block (IANB) plus a 1.5 mL buccal infiltration and 0.1 to 0.2 mL intra-ligamentary injection using the same anesthetic agent (lignocaine group). The intra-ligamentary injections were given at four sites for each tooth on the buccal and lingual sides. From May 2019 to January 2020, another 64 patients underwent single visit root canal treatment using 2.5 mL of 4% articaine with 1:100,000 adrenaline (Septodont Healthcare Pvt Ltd, Raigod, India) for an inferior alveolar nerve block (IANB) plus buccal infiltration and intra-ligamenta-

ry injections as described above (articaine group). Subjects were allotted to three different irrigation groups - saline, sodium hypochlorite, or dexamethasone. Allocation to the irrigation groups was done by block randomization according to pre-operative pain intensity (mild, moderate or severe). Randomisation was done by a dentist who was not involved in the study. Figure 1 explains the methodology flowchart.

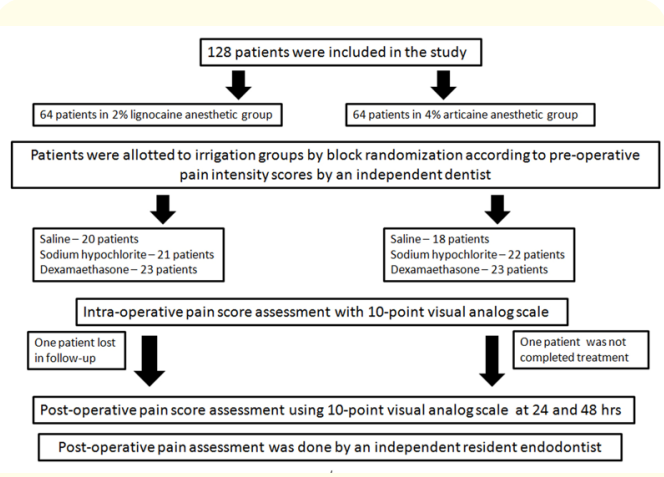

Figure 1: Flowchart of methodology of the experiment.

All the root canal procedures were done by a single operator blinded to the irrigation allotment. The levels of pre-, intra- and post-operative pain at 24 hrs and 48 hrs for each patient were recorded using a 10-point visual analog scale (VAS). The participants indicated the intensity of their pain by choosing a number using the following values: levels 1 - 3, mild pain; levels 4 - 7, moderate pain; and levels 8 - 10, severe pain. All patients in this study were given a 10 mg of ketorolac tromethamine tablet (Dr. Reddy's Laboratories Ltd, Solan (HP) India) which was taken orally 45 mins prior to local anaesthetic administration.

An intra-dermal injection of 0.2 mL of the local anesthetic agent to be used was given prior to the IANB in order to rule out any allergy to the anaesthetic agents. Local anesthesia with 2.5 mL of 2% lignocaine containing 1:80,000 adrenaline or 4% articaine with 1: 100,000 adrenaline was administered seven minutes prior to commencing the root canal procedure. Cold pulp sensibility tests and percussion evaluations were performed after enquiring about the level of lower lip numbness and before the access opening was initiated. Responses to these tests were also recorded. If sufficient anesthesia was not attained, an additional IANB with the same anesthetic agent was administered.

Working length was determined using a Root ZX Mini Apex Locator (J Morita, Kyoto, Japan) and Aurum Profiles (Meta Biomed, Co. Ltd, Incheon, Korea) were used for root canal preparation according to the manufacturer's instructions with an Endomate DT motor (NSK Inc.,Tochigi, Japan). Canal lubrication and smear layer management were done with EDTA (10%) and carbamide peroxide (15%) (Endoprep RC, Anabond Stedman Pharmaceuticals, Chennai, India). Depending on the participant's allotment to the irrigation groups, saline (NS 500 mL, Sodium chloride 0.9%, Fresenius Kabi, Pune, India Pvt. Ltd), 3% sodium hypochlorite (Septodont Healthcare India Pvt. Ltd, Raigad, India) or dexamethasone sodium phosphate (Dexalab Inj 2 mL, Laborate Pharmaceuticals, Sahib (H.P), India) were used as irrigants during the root canal preparation procedures. In all cases, 2 mL of saline with 2% povidone-iodine (Puradine, Leeford Healthcare ltd, Mumbai, India) was used as the initial irrigant and this was followed by the interventional irrigation solutions - saline, sodium hypochlorite or dexamethasone, according to the group allocation- as mid-treatment rinses using 1.5 mL for each canal. Then, a final irrigation of each canal was performed with 2 mL of saline with 2% povidone-iodine solution. Initial irrigation of the root canal was done after glide path establishment upto size 20 or 25K-file (Mani, Co., Tokyo, Japan). Mid-treatment rinses and final irrigation were employed after the use of rotary instruments. A total of 6 mL of irrigation solution was used in each canal during the treatment. The interventional irrigation solutions were delivered inside the root canal using a side-vented 25-gauge needle (RC Twents, Prime Dental Products, Mumbai, India) with a standard syringe. The needle was inserted as far apically into the canal as possible but without any binding within the canal. Gentle force was used on the syringe to deliver the irrigant, and the needle was moved up and down inside the canal to assist with irrigant flow and to ensure no binding of the needle to the canal walls.

Patients were given instructions that if pain was felt at any stage of the root canal procedure they were asked to raise their left hand.

The intensity of this intra-operative pain was recorded and patients were re-assessed about the need for either supplementary intra-ligamentary or intra-pulp anesthesia, or an additional IANB. If supplementary local anesthetic was required, the same anaesthetic agent used for the original IANB was employed.

After completion of the root canal preparation, apical patency was checked using a size 10 K-file (ManiCo., Tokyo, Japan). Root canal preparation was completed to an apical preparation size of either 6% size 20 or 25. Root canal filling was done using a greater taper single gutta percha point (DiaDent Group, Seoul, Korea) with zinc oxide eugenol-based cement (Prime Dental Products, Thane, India). The occlusion was not relieved in this study. A post-operative radiograph was taken to ensure the canals were filled to the working length and there was no extrusion of filling material into the periapical tissues. Analgesics were prescribed but the patients were advised to only take them in the event of significant pain.

The post-operative pain levels and the need for analgesics were recorded after 24 and 48 hrs by telephoning each patient to question them. The post-operative pain enquiry was done by a resident endodontist who was blinded to the study groups. If analgesics were required, the patients were questioned about which medication they had used, the dosage, how often they had taken them and whether they were effective.

Statistical analysis was performed using IBM SPSS software version 23 (IBM Corp., Washington, USA). The normality of pre-, intra-and post-operative pain scores were checked by the Shapiro-Wilk test. The data were skewed and deviated from normal distribution - therefore, the comparison of these values for the different irrigation groups was done by non-parametric Mann-Whitney U and Kruskal-Wallis tests. The level of significance was set at 5%. A logistic and an ordinal regression analysis was performed to assess the factors influencing the intensity of intra- and post-operative pain, respectively. A stepwise protocol was used to statistically enter and exclude factors from the regression model for a better global fit.

Results

A total of 128 patients (40 males and 88 females, aged between 13 to 70 years) participated in the study. The overall mean pre-operative pain score was 6.60 (± 1.72) while the means for the lignocaine and articaine groups were 6.43 (± 1.60) and 6.78 (± 1.82), respectively. Females in the articaine group had significantly higher pre-operative pain scores (7.13 ± 1.79) than males (5.68 ± 1.64).

The mean intra-operative pain score was 2.43 (± 2.37) and 3.19 (± 3.07) respectively for the lignocaine and articaine groups and there was no significant difference (Mann-Whitney test). Gender difference did not exhibit significant association for intra-operative pain score [males - 3.07 (± 2.99) and females - 2.68 (± 2.60)] (Mann-Whitney test) (Figure 2). Intra-operative pain occurrence was similar in both the anesthesia groups at around 75%. Supplementary anesthesia was required for 4 patients (6.3%) and 8 patients (12.5%), respectively, for the lignocaine and articaine groups with no significant difference (Mann-Whitney test). The mean intra-operative pain scores for patients requiring supplemental anesthesia was 7.36 ± 3.38. The mean intra-operative pain scores for those patients requiring supplemental anesthesia in the lignocaine and articaine groups were 6.50 ± 3.10 and 7.85 ± 3.67 respectively (with no significant difference in the Mann-Whitney test). Overall, males [7 (17.5%)] had a significantly higher need for supplemental anesthesia (P = 0.034) compared to females (Mann-Whitney test) (Table 1). The need for an additional IANB had no significant difference (Mann-Whitney test) for the two anesthetic groups -zero and three (3.7%) patients for the lignocaine and articaine groups respectively (Mann-Whitney U test). One female patient in the articaine group with a pre-operative pain score of 8 had the root canal treatment terminated on the day of the appointment and it was completed during a subsequent appointment because of excessive intra-operative pain, even after additional an IANB. Prior to access cavity preparation, none of the teeth responded to the cold pulp sensibility test and only one tooth in the lignocaine group had pain on percussion after the anesthetic had been administered. Logistic regression analysis of the requirement for supplementary anesthesia in both groups revealed that none of the pre-operative variables had a significant role.

There was no significant difference in post-operative pain occurrence and the mean scores at 24 and 48 hrs between the three irrigants in both anesthetic groups (Kruskal-Wallis test) (Table 2). The articaine group higher had post-operative pain incidence and scores than the lignocaine group for all three irrigants. Sodium hypochlorite irrigation in the lignocaine group had the lowest mean 24 hr post-operative pain score of 0.57 ± 0.21 whereas in the artic-

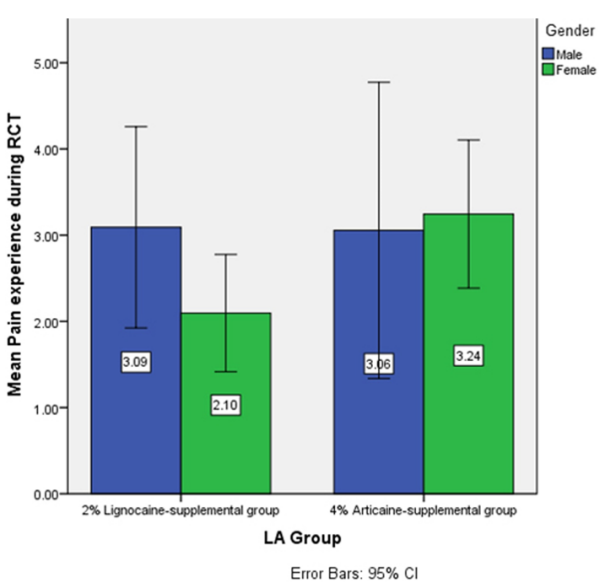

Figure 2: Bar graph showing the intra-operative pain scores for males and females in the two local anesthetic groups.

	Supplemental injection requirement [Mann-Whitney test Asymp.Sig. (2-tailed)]		Total
	Yes	No	
Male	7 (17.5%) (P = 0.034)	33 (82.5%) (P = 0.034)	40
Female	5 (5.7%) (P = 0.034)	83 (94.3%) (P = 0.034)	88

Table 1: *Gender difference for supplemental injection requirement.*

aine group, it had the highest mean 24 hr post-operative score of 1.36 ± 1.76.

Post-operative pain incidence was much higher in the articaine group [25 patients (39.7%)] (*P* = 0.057) (Mann-Whitney test) compared to the lignocaine group [15 patients (23.8%)] and it was very near to being statistically significant (Table 3). No significant difference was observed with regard to analgesic requirement between the two anaesthetic groups (Mann-Whitney test) (Table 3). No significant difference in mean post-operative pain scores at 24 and 48 hrs was observed between the two anesthetic groups (Mann-Whitney U test) (Figure 3). The articaine group had the highest mean post-operative pain score at 24 hrs of 1.23 ± 1.72 (Figure 3). The lignocaine group exhibited the lowest mean post-treatment score at 48 hrs of 0.23 ± 0.75 (Figure 3). Females in the articaine group experienced significantly (P = 0.030) (Mann-Whitney test) higher post-treatment pain scores at 24 hrs (1.55 ± 1.87) compared to males (0.44 ± 0.92) (Figure 4B). No significant difference was noticed in post-operative pain at 48 hrs between the genders (Figure 4A and 4B). Logistic regression analysis showed that the post-operative pain incidence was not significantly associated with any of the pre- or intra-operative factors in both anesthetic groups. However, female gender in the articaine-supplemental group was close to being significant (P = 0.054) for post-operative pain occurrence in the logistic regression analysis. Logistic regression analysis for post-operative pain occurrence in all 128 patients showed that only the local anesthetic variable played a significant role (P = 0.037).

				Post-operative pain incidence		Post-operative pain 24hrs VAS score	Post-operative pain 48hrs VAS score
				Yes	Mean	No	Mean
Local anesthetic groups	Lignocaine group	Irrigant groups	Saline	4 (20%)	16 (80%)	0.95 ± 1.53	0.30 ± 0.80
			Dexamethasone	7 (31.8%)	15 (68.2%)	1.09 ± 1.71	0.27 ± 0.93
			Sodium hypochlorite	4 (19%)	17 (81%)	0.57 ± 1.20	0.14 ± 0.47
	Articaine group	Irrigant groups	Saline	8 (44.4%)	10 (55.6%)	1.11 ± 1.45	0.27 ± 0.75
			Dexamethasone	8 (34.8%)	15 (65.2%)	1.21 ±1.95	0.69 ± 1.52
			Sodium hypochlorite	9 (40.9%)	13 (59.1%)	1.36 ± 1.96	0.13 ± 0.46

Table 2: *Post-operative pain score at 24 and 48 hrs among the three different irrigation groups in the two local anesthetic groups. Kruskal-Wallis test showed no significant difference.*

Yes		Post-operative pain [Mann-Whitney test Asymp. Sig. (2-tailed)]		Post-operative analgesics	
		No	Yes	No	
Local anesthetic groups	Lignocaine group	15 (23.8%) [P = 0.057]	480 (76.2%) [P = 0.057]	18 (28.6%)	45 (71.4%)
	Articaine group	25 (39.7%) [P = 0.057]	38 (60.3%) [P = 0.057]	23 (36.5%)	40 (63.5%)

Table 3: *Comparisons of post-operative pain incidence and analgesics requirement for the two local anesthetic groups.*

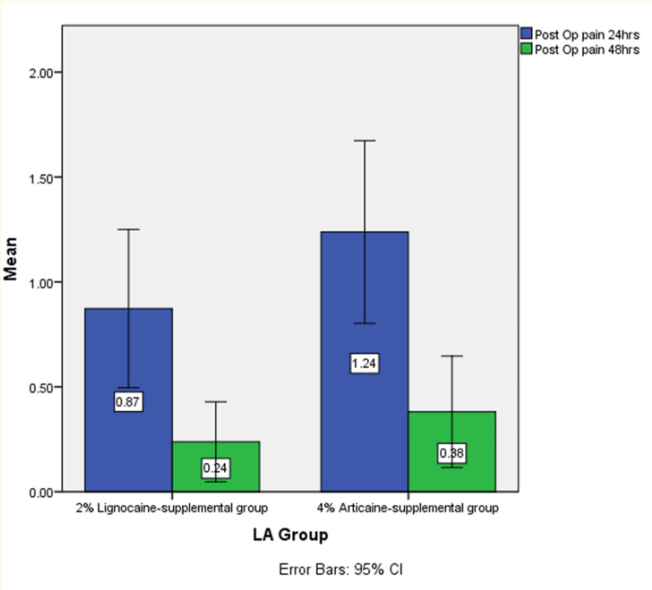

Figure 3: Bar graph showing the post-operative pain scores at 24 and 48 hrs for the two local anesthetic groups.

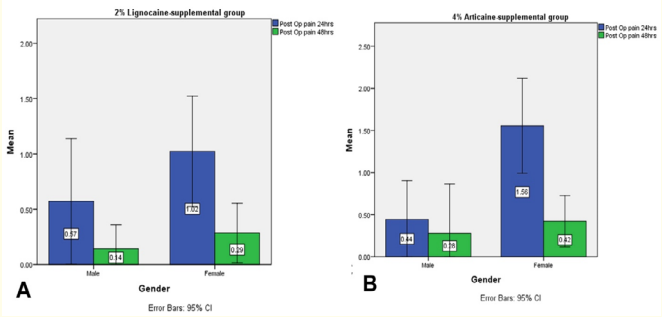

Figure 4: A. Bar graph representing the post-operative pain scores between the two genders at 24 and 48-hrs in lignocaine group. B. Bar graph representing the post-operative pain scores between the two genders at 24 and 48-hrs in articaine group.

Discussion

The primary aim of this study was to evaluate the anesthetic efficacy of lignocaine and articaine IANB with buccal infiltrations and intra-ligamentary injections for single visit root canal treatment for mandibular molar teeth following pre-operatively administered oral ketorolac. A secondary objective was to explore the efficacy of these two different local anesthetics in controlling the post-operative pain following single visit root canal treatment when used with three different root canal irrigants. Only mandibular molar teeth with acute irreversible pulpitis were included in the study. All patients in the present study were given oral ketorolac pre-operatively as a previous report showed that this was effective in controlling the post-operative pain occurrence with lignocaine anesthetic [4]. Intra-operative pain incidence was around 75% with no significant difference between the lignocaine and articaine group groups and this was far less than an earlier report regarding pre-operative ketorolac with IANB only where it was 91.3% [4]. This observation of improved anesthetic success in the present study shows that the extra injections played a key role compared to pre-operative ketorolac administration. The present results with no significant difference in mean intra-operative pain scores between the lignocaine and articaine groups is in accordance with another earlier trial and a review report [2,4]. In previous study from the authors' department with lignocaine and articaine IANB only, the mean intra-operative pain score was 4.27 which were far higher than the mean intra-operative score of 2.81 in the present study. This again underlines the importance of the additional injections in achieving successful anaesthesia rather than the pre-operative analgesic intake.

Males in the present investigation had a significantly higher requirement for supplemental anesthesia similar to the previous report [4]. This was despite the females having significantly higher pre-operative pain score in the articaine group and also no gender

difference was exhibited in the mean intra-operative pain score in both the anesthetic groups. One possible explanation could be that the primary clinical operator in this study was a female which could have led the male patients to report a higher intensity of intra-operative pain compared to females. Both these results from the present and the previous reports highlight that intra-operative pain experience is highly gender subjective and could be influenced by the operator's gender.

Logistic regression analysis showed that none of the pre-access preparation variables played a significant role in the requirement of supplemental anesthesia in both anesthetic groups which was contrary to an earlier clinical trial [4]. The reason may be that the incorporation of the additional injections in both groups led to better anesthetic effects and possibly negated the influence of any pre-operative variables. The requirement for supplemental anesthesia may also have been influenced by hidden non-diagnosable factors such as anatomic variations in the nerve distribution/innervations or individual variations in pain threshold values. The increased level of anesthetic effect obtained in the present investigation compared to the previous study [4] can be noticed from the results where none of the teeth responded to cold pulp sensibility testing and, except for one tooth, no teeth had any percussion sensitivity prior to access preparation. This is in contrast to the previous trial [4] where the presence of pain prior to access preparation had a significant role in the intra-operative pain intensity. Also, only 12 patients (9%) required supplemental injections for lack of sufficient anesthesia compared to 27 patients (21.6%) in the authors' previous study where only an IANB injection was given [4].

Three different irrigants were selected for this study to understand whether different irrigation and anesthetic combinations have an influence on post-operative pain. However, there was no significant difference in post-operative pain incidence or scores between the three irrigants in both anesthetic groups. It was also noted that the articaine group had consistently higher post-operative pain incidence and scores in all three irrigations compared to the lignocaine group. This result of no significant difference among the three irrigants is comparable to an earlier review which concluded that there was insufficient evidence regarding the role played by different irrigants for post-operative pain [9]. Among the three irrigants, sodium hypochlorite had the least mean 24-hrs post-treatment score in the lignocaine group, whereas in the articaine group the same irrigant registered the highest mean 24-hrs post-operative score. This variation in post-operative pain score for sodium hypochlorite in the articaine group may due to the absence of central desensitization and anti-inflammatory effects with articaine which has been proven to be present with lignocaine [10]. It could be argued that for each of the irrigation sub-groups, the number of samples was low but the previous report from the authors' department with similar study methodology and with the same female operator also had the same results [4]. The present and the previous study span over a period of two years (June 2018 to January 2020) with 254 patients being treated [4].

Post-operative pain in the articaine group (39.7%) was much higher than in the lignocaine group and it was very close to being statistically significant. Logistic regression observation also displayed a significant association of articaine with post-treatment pain incidence among all the variables included in this study. Lignocaine has been shown to have central desensitization effects along with potent anti-inflammatory properties, and this may have helped to reduce the post-operative discomfort [10]. Whether articaine has this effect has not yet been investigated. To the authors' knowledge, no other investigations have been done to compare the post-operative pain incidence after single visit root canal treatment for mandibular molar teeth using lignocaine and articaine as local anaesthetic agents. Post-operative pain occurrence of 23.8% in the lignocaine group is comparable to the earlier study [4]. This again re-establishes the earlier reported conclusion that pre-operative ketorolac intake was more effective with lignocaine anesthetic combination than articaine [4]. To the authors' knowledge, no studies have investigated the role of pre-operative ketorolac tromethamine intake on post-operative pain incidence following root canal treatment so no comparison was possible. The mean 24-hrs and 48-hrs post-treatment pain scores of 1.05 ± 1.62 and 0.30 ± 0.91, respectively, is in accordance with earlier reports [4,11]. No significant difference in the 24-hrs and 48-hrs mean post-operative pain score was observed between the two local anaesthetic groups

and all patients who required analgesics for post-operative pain control had only one or two doses. An earlier observation without pre-operative ketorolac administration was that the mean post-treatment pain scores were similar to the present results [11]. The above mentioned factors underline the efficacy of single visit root canal treatment in alleviating the intensity of pre-operative symptoms of irreversible pulpitis, attenuating the importance of removal of the cause of the pain compared to other pharmacological means [1,12]. Articaine group had the highest mean post-treatment pain score in the current results as in the previous report [4] which questions the efficacy of its use in single visit root canal treatment. Females in the articaine group had significantly higher 24-hrs mean post-operative pain score, which was also observed with the regression analysis. This was in agreement with previous reports of increased post-operative pain associated with symptomatic teeth requiring root canal treatment [13-15]. As in this study, the females in the articaine group had significantly increased pre-treatment pain scores compared to the males. This was because the patient allotment in the present investigation was done according to the pain intensity to different irrigation groups and not to the two anesthetic groups. Female predilection for increased post-treatment discomfort in this study is contrary to the earlier result of no significant difference between the two genders [4]. This female association of increased post-operative pain has been earlier documented in other studies [13,16]. That the variable "gender" alone has a predilection for post-treatment pain is contradicted in this study because female association with post-operative pain was linked with significantly higher pre-treatment pain scores. Also, in any clinical studies on post-operative pain, the subjective component of the pain experience should never be forgotten. Regression analysis of post-operative pain occurrence failed to show any other pre-treatment variables having a significant role. This is because of better anesthetic effect obtained in the present study, contrary to the earlier investigation where intra-operative pain severity played a significant role in post-operative pain occurrence [4]. This also again reinstates the earlier suggested rationale that individual pain threshold values and subjective reporting of pain scores might have had a role in the post-treatment pain incidence.

Limitation of the Study

The limitations of this study are that a direct comparison with patients not having had pre-operative ketorolac intake was not done and allocation of patients was done to various irrigation groups and not based on the local anesthetic groups. Based on the results of this study, a new clinical study is being undertaken in the authors' department to assess the effects of using and not using pre-operative ketorolac administration prior to lignocaine and articaine local anesthetic injections and then 3% sodium hypochlorite irrigation of the root canals. A four group block random allocation of the patients is planned.

Conclusion

Additional infiltration and PDL injections were effective in reducing the intra-operative pain occurrence and intensity for mandibular molar teeth with acute irreversible pulpitis. Ketorolac tromethamine administration was effective in controlling post-operative pain incidence in the lignocaine anesthetic group. Articaine was not superior in achieving pulp anaesthesia compared to lignocaine, and it also had higher post-operative pain occurrence following single visit root canal treatment. Single visit root canal treatment with pre-operative ketorolac tromethamine and lignocaine IANB and additional injections combined with sodium hypochlorite or dexamethasone irrigation was very effective in the management of symptoms associated with acute irreversible pulpitis in mandibular molar teeth.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic		Item No	Checklist item	Reported on page No
	Title and abstract			
		1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1	
	Introduction			
Background and objectives		2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4	
	Methods			
Trial design		3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable	
Participants		4a	Eligibility criteria for participants	4, 5
	4b	Settings and locations where the data were collected	4	
Interventions		5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5 - 8
Outcomes		6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable	
Sample size		7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable	
Randomisation				
Sequence generation		8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Not applicable	
Allocation concealment mechanism		9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation		10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6

Blinding		11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not applicable
	11b	If relevant, description of the similarity of interventions	Not applicable	
Statistical methods		12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9	
Results				
Participant flow (a diagram is strongly recommended)		13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	10, Figure 1	
Recruitment		14a	Dates defining the periods of recruitment and follow-up	5, 6
	14b	Why the trial ended or was stopped	6	
Baseline data		15	A table showing baseline demographic and clinical characteristics for each group	Not applicable
Numbers analysed		16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10
Outcomes and estimation		17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10, 11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	
Ancillary analyses		18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11
Harms		19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion				
Limitations		20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability		21	Generalisability (external validity, applicability) of the trial findings	15
Interpretation		22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11 - 16

	Other information			
Registration		23	Registration number and name of trial registry	4
Protocol		24	Where the full trial protocol can be accessed, if available	http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=27074&EncHid=&userName=CSI%20College%20of%20Dental%20Sciences
Funding		25	Sources of funding and other support (such as supply of drugs), role of funders	Nil

**We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.*

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