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Research Article

Comparative Evaluation of the Efficacy of Intra-ligamentary Injection of 20 mg Piroxicam Versus 4% Articaine in Management of Endodontic Pain in Patients with Symptomatic Irreversible Pulpitis in Mandibular Molars: A Randomized Controlled Clinical Trail

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Abstract

This clinical study was conducted to compare between intra-ligamentary injection of 20 mg Piroxicam and 4% Articaine after inferior alveolar nerve block injection in patients with symptomatic irreversible pulpitis of mandibular molar teeth treated in a single-visit root canal treatment as regards to their ability to control pain during access cavity preparation, instrumentation and at 6, 12, 24, 48-hrs post-operatively using Numerical Rating Scale (NRS).

The study design was a double blinded randomized clinical trial as study participants and assessor didn't know which intervention has been received. Twenty patients complaining from symptomatic irreversible pulpitis in posterior mandibular teeth were included. After thoroughly careful clinical and radiographic examination, patients were randomly assigned into two equal groups (n=10) Group P, where patients received intra-ligamentary 20 mg Piroxicam, or Group A, where patients received intra-ligamentary 4% Articaine. Root canal treatment was performed in single-visit using RaCe Rotary NiTi files, then Obturation was then done using modified single cone technique with resin sealer.

Pain was assessed pre-operatively, during access cavity preparation, instrumentation, at 6, 12, 24 and 48-hrs post-operatively, in addition the need of supplemental anesthesia and post-operative analgesic intake were recorded.

Results showed similarity between the two groups regarding age, gender distribution, tooth type and pre-operative pain, there was significant reduction in pain in both groups, however, there was statistically significant reduction in post-operative pain intensity in the Piroxicam group during instrumentation and at 6, 12 and 24-hrs compared to the Articaine group, however there was no statistically significant difference between the two groups at 48-hrs post-operatively. Moreover, there was significant increase in pain with the Articaine group during instrumentation.

There was also a statistically significant difference between the two groups regarding the supplemental intra-pulpal anesthesia and post-operative analgesic intake, where the Articaine group showed higher percentage of the needed supplemental intra-pulpal anesthesia and post-operative analgesic intake.

It could be concluded that: Intraligamentary injection of Piroxicam showed a significant success in reducing intra and post-operative pain compared to Articaine. Articaine can be used as a successful supplemental technique during early stages of treatment.

Keywords: Piroxicam; Articaine; Intra-Ligamentary Injection; Post-Operative Endodontic Pain; Mandibular Molars

Introduction

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. The International Association for the Study of Pain (IASP) amplified this definition specifically to insure clarity of concepts and terms used to define pain [1].

Pain accompanying irreversible pulpitis is quite challenging and sometimes difficult to be controlled, hence pain control is considered an important key for success of the treatment. Endodontic pain management encompasses all aspects of treatment, preoperative pain control including accurate diagnosis and anxiety reduction, intraoperative pain control depending on effective local anesthetic and operative techniques while postoperative pain management involve a variety of pharmacologic agents [2].

Pain management strategies includes local anesthetic agents, different anaesthetic techniques, analgesics, antibiotics and anti-inflammatory drugs [3]. Adequate local anaesthesia eliminates most of the pain during the treatment, but obtaining complete anesthesia especially in posterior mandibular teeth with irreversible pulpitis is much more difficult than teeth with uninflammed pulp because nerves in inflamed tissue have altered resting potential and lowered excitability threshold, so local anesthesia is not sufficient to prevent impulse transmission [3,4].

Post-operative pain is a common finding after endodontic treatment, its incidence ranges from 3% to 58% in single and multi-visit treatment. It may be due to microbial, mechanical or chemical injury to the periapical tissues [5,6]. Post-operative endodontic pain intensity increases during the first 48-hrs and gradually decrease until disappear after 7 - 10 days [7,8].

Advances in local anesthesia and modern pharmacology in addition to various supplemental anesthetic techniques as intra-ligamentary, intra-osseous and infiltration techniques allow dental practitioners to deal effectively with the patient experiencing odontogenic pain and in most cases exceed their expectations [9]. Intra-ligamentary injection of local anaesthesia was reported to be an effective and easy way to control severe pain during endodontic treatment mainly in mandibular teeth [10].

Piroxicam is a non-selective, oxicam derivative, long acting and potent Non-steroidal anti-inflammatory drug, it has a half-life of 50 hrs in the plasma, the onset of action of oral piroxicam is 2 - 4 hrs [11]. But it has been anticipated that injectable piroxicam could produce more rapid onset of action [12]. It could favourably overcome the intense pain up to 48 hrs following the treatment [11]. It has been also postulated that the intraligamentary injection enables the application of anti-inflammatory agents in the periapical intraosseous region [13,14]. Thus, intra-ligamentary injection of NSAIDs may be effective as an adjuvant drug to support the action of local anesthetics.

To our knowledge, there was lack of studies investigating the effect of intra-ligamentary injection of Piroxicam to control endodontic pain.

Purpose of the Study

Thus, the purpose of this study is to compare the effect of intra-ligamentary injection of 20 mg Piroxicam and 4% Articaine in preventing intra-operative and post-operative endodontic pain after single-visit root canal treatment of mandibular molar teeth with symptomatic irreversible pulpitis.

Materials and Methods

Trial design

The trial design of this study was a prospective, parallel, Randomized clinical trial (RCT). The clinical trial involves research using human volunteers, called participants, the participants were allocated randomly to receive one of several interventions (two in our current study) according to the research plan.

Ethical consideration

The protocol for this parallel designed trial was reviewed and approved by the ECs [Ethical Committees], Faculty of Dentistry, Cairo University, with respect to scientific content and compliance with applicable research and human subjects' regulations. Site-specific informed consent forms, participant education, recruitment materials, other requested documents and any subsequent modifications were also reviewed and approved by the ethical committee. The treatment procedures, aim of the study, possible side effects, and treatment alternatives were thoroughly explained to all the participants.

Sample size

This study was planned to include independent cases and controls with one control per case. The study was planned with 8 participants in control group and 8 participants in intervention group, based on probability of Type 1 error 0.05 and power at 0.9. The expected dropout rate in this experiment was 10% hence the total sample size was 10 interventional subjects and 10 control subjects.

Participants

Eligibility criteria

The inclusion criteria for participants were healthy and medically free patients. Patients suffering acute symptomatic irreversible pulpitis in either mandibular first or second molar teeth with no periapical involvement. Teeth that could be treated endodontically in single-visit. Patients able to understand numerical rating scale and sign the informed consent. Patients with age range between 20 - 45. The case was excluded if Patients hypersensitive to Piroxicam or any other non-steroidal anti-inflammatory drug, Pregnant or lactating females. Patients with history of peptic ulceration, had taken analgesics in the 12-hrs preceding the injection, having acute pain in more than one molar, suffering pathosis in the area of injection.

Setting and location

Participants' selection was done from patients attending or referred for root canal treatment to post- graduate clinic students in the Department of Endodontics, Faculty of Dentistry, Cairo University, Egypt.

Randomization

Twenty numbers were generated by the center of Evidence-Based Dentistry, Faculty of Oral and Dental Medicine, Cairo University and randomly allocated to either intervention or control group in Excel [Microsoft Office Excel 2010] using block randomization and printed on a table, each participant was a letter P for intervention and A for control with 10 participants in each group. To ensure allocation concealment, the table was kept only with the co-investigator so that the intervention to be allocated was unknown by the operator until the patient was entered into the study.

Blinding

The labels on the carpules were removed and they were masked with paper with a mark of P or A by the assistant supervisor and were given to the operator. This research was a double blinded study, where the patient (participant) and the operator who was also the outcome assessor were blinded.

Endodontic procedure

Patients who were eligible to the trial criteria and accepted to enter the trial were asked to mark his/her level of pain on the pre-operative NRS (Numerical rating scale) in the pain diary. The treatment was planned to be performed in a single visit that didn't exceed 1-hr and fifteen minutes. Lidocaine topical anesthesia (Lidocaine ointment USP, 5%, Septodont, France). was applied at the site of injection. Each patient in both intervention and control groups received Inferior Alveolar Nerve Block (IANB) for mandibular molars using a side loading aspirating syringe and 27-guage long needle (C-K ject, 27 gauge Long Disposable Dental Needles. Ultra Sharp, Tri-Bevel Point, Color-Coded Plastic Hub, Korea) with one carpule of 1.8 ml of 4% Articaine HCl with 1:100,000 epinephrine local anesthetic solution (Artinibsa 4% carpule. inibsa, Spain). After gentle contact with bone, the needle was withdrawn 1 mm, aspiration was performed and if there was no blood aspirated, injection was performed. Injection of the anesthetic solution was done over one minute period of time. Ten to fifteen minutes post-injection, the patient was asked if there was lip numbness as a subjective sign of IANB success, if not, the patient was excluded from the trial. Piroxicam cartridges (Pfizer Laboratories Div Pfizer Inc, Egypt, FELDENE®). were prepared by removing the rubber plungers from the standard anaesthetic cartridges, then washed out from it's contents, autoclaved and filled with Piroxicam from the vial to the cartridge by insulin syringe. Intra-ligamentary injection of Piroxicam for the intervention group and articaine for the control group was administered after 15 minutes of inferior alveolar nerve block injection. In Group P (Piroxicam), patients received supplemental intra-ligamentary injection of 0.4 ml of 20 mg Piroxicam.

In Group A (Articaine), patients received supplemental intra-ligamentary injection of 0.4 ml of 4% Articaine. Articaine and Piroxicam were injected using a conventional dental syringe with a 27 gauge short disposable needle. The needle was placed in the gingival sulcus at a 30- degree angle to the long axis of the tooth then apical pressure was applied until the needle wedged into the periodontal ligament between the tooth and the alveolar crest of the bone (0.2 ml on the mesial aspect of the target tooth and 0.2 ml on the distal aspect). Access cavity preparation was performed immediately after intra-ligamentary injection using a round bur size # 3 and then an Endo-Z bur (DENTSPLY, Tulsa Dental, DENTSPLY Maillefer, TN) was used for complete flaring and deroofing. Patients were asked to rate their pain level on NRS in the pain diary during access cavity preparation, where no or mild pain were considered successful anesthesia, while moderate or severe pain indicated in efficiency, in case of moderate or severe pain during access cavity preparation supplemental intra pulpal anesthesia was administrated. The tooth was then isolated with rubber dam and the patency of the canal was confirmed. During negotiation and in-

strumentation, the patient was asked to rate their pain level on NRS in the pain diary. If the pain felt was unbearable, intra-pulpal supplemental anesthesia was administered, the need for intra-pulpal supplemental injection was recorded as secondary outcome. Working length was determined using apex locator (Root ZX II, J.Morita USA, Irvine, CA), which was confirmed radiographically to 0.5 - 1 mm shorter than the radiographic apex, then root canals were mechanically prepared in crown down sequence without pressure to the full working length, using RaCe nickel titanium rotary instruments (RaCe FKG Dentaire, Switzerland) at a speed 600 rpm and torque 1.5 Ncm.

Irrigation was done using 2 ml of freshly prepared 2.5% sodium hypochlorite solution using plastic disposable syringe with needle gauge 27 between each two successive instrument. Irrigation was performed 2 mm short of the final working length, which was verified by rubber stops. Finally, 3 ml of 17% EDTA was used for 1 minute to remove the smear layer followed by 10 ml of distilled water as a final flush flush to prevent erosion of the dentinal tubules. Then canals were dried using paper points.

After completion of the instrumentation, radiograph was taken to ensure proper master cone length, then the root canals were obturated by gutta-percha points (Paper points, METABIOMED CO, Korea) by modified single cone technique using ADSEAL resin sealer (ADSEAL, META BIOMDED CO., LTD, Korea). Obturation was considered completed when the spreader no longer penetrates beyond the cervical line. All the excess sealer and gutta-percha were removed and the access cavity was sealed with Cavit (Cavit temporary filling 3M ESPE, Germany). A post operative radiograph was taken.

The details of each step were recorded in the patient's endodontic procedure form. Patient was given a NRS and will be asked to rate his pain level at 6, 12, 24 and 48- hrs after root canal treatment. Every patient was asked to mark the NRS between 0 - 10 to determine the intensity of pain if it occurred at each specified time interval. The patients were instructed to call the doctor for consultation if they felt pain and the doctor would allow the use a prescription of 200 mg Ibuprofen as one or more tablets every 8-hrs. All the data was recorded and patients not following the instructions were excluded.

Outcome assessment

Primary outcome was pain intensity intra-operatively during access cavity preparation and during instrumentation, and at 6, 12, 24, 48-hrs post-operatively by using NRS. Which is numerical 10-cm line. Pain was categorized into four categorical scores: (1) none [score 0], (2) mild [score from 1 - 3], (3) moderate [score from 4 - 6], (4) severe [score from 7 - 10]. Secondary outcome was number of patients needed supplemental intra-pulpal anesthesia and post-operative analgesic intake incidence.

Statistical analysis

Data management and statistical analysis was performed by Microsoft Office 2013 (Excel) and Statistical Package for Social Sciences (SPSS), version 21 (SPSS, Inc, IBM Corporation, NY, USA). Numerical data was described as mean and standard deviation or median and range. Categorical data will be described as numbers and percentages. Data was checked for normality using Kolmogrov-Smirnov test and Shapiro-Wilk test. Comparisons between the two groups was done using the Student's t-test for normally distributed numeric variables, while Mann-Whitney test was used to compare between two groups for non-normally distributed numeric values. Qualitative data including gender, age, arch distribution, tooth type, number of roots and number of canals were compared between the groups using the chi-square test. The significance level was set at *P*-value ≤ 0.05.

Results

From 30 enrolled patients, 20 patients were included in the study. The flow of the patients through the study followed the CONSORT flow diagram is presented in figure 1.

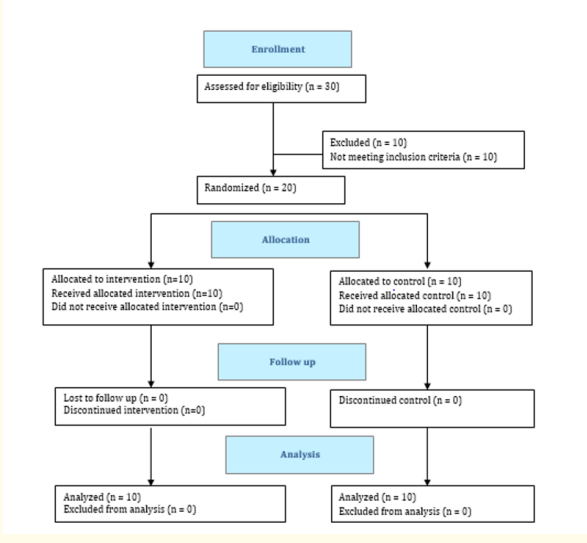

Figure 1: CONSORT 2010 flow diagram.

Demographic data

There was no statistically significant difference in baseline data of mean age values, gender distribution, tooth type distribution, or pre-operative pain intensity between the two groups ($p > 0.05$) as mentioned in table 1.

	Group P (n=10)	Group A (n=10)	p- value
Age (Years)			
Mean ± SD	30.5 ± 9.5	35 ± 9.6	0.29
Median	30.5	36.5	
Range	(18-48)	(19-51)	
Gender			
Male [n(%)]	3 (30%)	4 (40%)	0.639
Female [n(%)]	7 (70%)	6 (60%)	
Tooth type distribution			
Lower 1st molar (left) [n(%)]	3 (30%)	2 (20%)	0.831
Lower 2nd molar(left) [n(%)]	3 (30%)	2 (20%)	
Lower 1st molar (right) [n(%)]	3 (30%)	4 (40%)	
Lower 2nd molar(right) [n(%)]	1 (10%)	2 (20%)	
Pre-operative pain			
Median	7	7.5	0.57
Range	(6-8)	(6-9)	

Table 1: Median and range values, frequency (n), percentage (%) and results of students-t tests and chi square (χ^2) for the demographic data of tested groups (Group P: Piroxicam and Group A: Articaine).

Primary outcome

Comparison of pain intensity intra-operatively and post-operatively at different follow up periods between the two groups

There was significant reduction in pain in both groups, however, there was statistically significant reduction in post-operative pain intensity in the Piroxicam group during instrumentation and at 6, 12 and 24-hrs compared to the Articaine group, However there was no statistically significant difference between the two groups at 48-hrs post-operatively. Moreover, there was significant increase in pain with the Articaine group during instrumentation as summarized in table 2 and mentioned figure 2.

Time intervals	Group P			Group A			
	Median	Min.	Max.	Median	Min.	Max.	p-value
During access	1.5	0	3	2.5	0	4	0.247
During instrumentation	1.5	0	3	4.5	1	6	0.002*
After 6-hrs	0.5	0	2	3	0	4	0.043*
After 12-hrs	0	0	2	2	0	4	0.005*
After 24-hrs	0	0	1	1	0	4	0.009*
After 48-hrs	0	0	0	0	0	2	0.143

Table 2: Median and range (minimum, maximum) values of NRS scores intra-operatively and post-operatively for comparison between the two groups; (Group P: Piroxicam and Group A: Articaine) using Mann Whitney test.

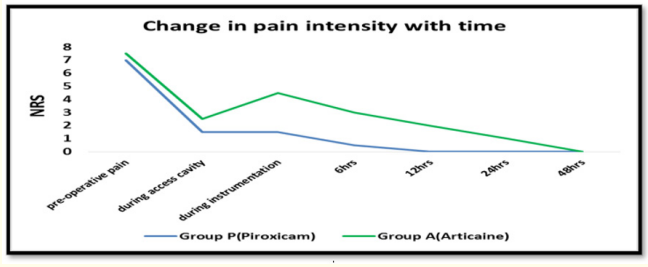

Figure 2: Line chart representing the changes in NRS values over time for the two groups; (Group P: Piroxicam and Group A: Articaine).

Pain incidence in different pain categories

There was statistically significant difference in pain incidence intra-operatively during instrumentation, and at 12, 24, 48 hrs post-operatively. However, there was no statistically significant difference in pain incidence between the two groups during access cavity preparation and at 6 hrs post-operatively as mentioned in figure 3 and summarized in table 3.

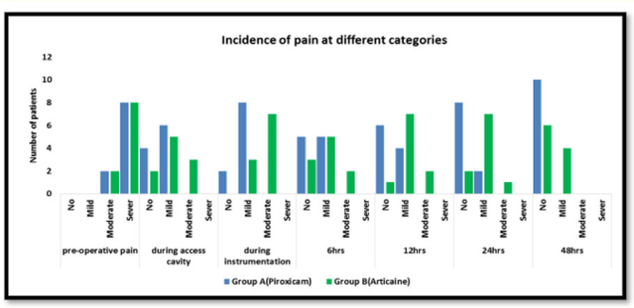

Figure 3: Bar chart representing the percentage of pain incidence at different pain categories in the two groups (Group P: Piroxicam and Group A: Articaine).

Time point	Pain category	Group P n = 10	Group A n = 10	P-value
Pre-operative	Moderate	2 (20%)	2 (20%)	
	Severe	8 (80%)	8 (80%)	0.7
During access cavity	No pain	4 (40%)	2 (20%)	
	Mild	6 (60%)	5 (50%)	0.153
	Moderate	0 (0%)	3 (30%)	
During instrumentation	No pain	2 (20%)	0 (0%)	
	Mild	8 (80%)	3 (30%)	0.004*
	Moderate	0 (0%)	7 (70%)	
At 6-hrs	No pain	5 (50%)	3 (30%)	
	Mild	5 (50%)	5 (50%)	
	Moderate	0 (0%)	2 (20%)	0.287
At 12-hrs	No pain	6 (60%)	1 (10%)	
	Mild	4 (40%)	7 (70%)	
	Moderate	0 (0%)	2 (20%)	0.041*
At 24-hrs	No pain	8 (80%)	2 (20%)	
	Mild	2 (20%)	7 (70%)	
	Moderate	0 (0%)	1 (10%)	0.025*
At 48-hrs	No pain	10 (100%)	6 (60%)	
	Mild	0 (0%)	4 (40%)	0.025*

Table 3: Frequency (n) and percentage (%) of pain incidence at different pain categories and results of Chi-square (x^2) test for comparison between the two groups; (Group P: Piroxicam and Group A: Articaine).

*Indicates significance at $p \leq 0.05$.

Secondary outcome

There was a statistically significant difference between the two groups in the incidence of the need for supplemental anesthesia and post-operative analgesic intake as mentioned in table 4 and 5.

Supplemental intra-pulpal Anesthesia	Group P		Group A		
	n	%	n	%	p-value
No	10	100%	3	30%	0.001*
Yes	0	0%	7	70%	

Table 4: Frequencies (n) and percentages (%) of patients need supplemental anesthesia in both groups (Group P: Piroxicam and Group A: Articaine).

Post-Operative Analgesic	Group P		Group A		
	n	%	n	%	p-value
No	10	100%	5	50%	0.01*
Yes	0	0%	5	50%	

Table 5: Frequencies (n) and percentages (%) of patients need post-operative analgesic in both groups (Group P:Piroxicam and Group A: Articaine).

Discussion

One of the most important aspects of endodontic practice is to control pain during and after root canal treatment [15]. Intra-operative pain control by means of local anesthetics is an integral part of the treatment. Patient's anxiety, together with the effect of pulpal symptomatic inflammation, contributes to decreasing pain threshold [16]. Not to mention the relatively low success rate of IANB, that ranged from (15% - 57%) in patients presenting with symptomatic irreversible pulpitis and even gets worse in case of mandibular molars, which is our study's concern [17].

On the basis of a recently published systematic review, the prevalence of pain after root canal treatment has been reported between 3% and 58% of the patients [18]. Endodontic studies related post-operative pain to several predictive factors such as single and multi-visit treatment, different types of intra-canal medication, different treatment procedures, analgesics, anesthetic or antibiotics,

in addition to several patient factors such as personality, behavior, physical, psychological factors, and existence of pre-treatment pain [19-21].

The purpose of this Randomized Clinical Trial was to compare between intra-ligamentary injection of 20 mg Piroxicam and 4% Articaine after inferior alveolar nerve block injection on intra-operative and post-operative pain intensity after single visit root canal treatment of mandibular molars with symptomatic irreversible pulpitis.

The present study was designed as a double-blind, parallel design, randomized clinical trial (RCT), which is a prospective, analytical, experimental study using primary data generated in the clinical environment. Individuals, similar at the beginning, are randomly allocated to two or more treatment groups and the outcomes of the groups were compared after sufficient follow-up time. This should provide an unbiased estimate of the treatment effect [22].

mandibular posterior teeth with irreversible pulpitis were selected according to Aggrawal., *et al.* Abazarpoor., *et al.* this might be related to their decreased susceptibility to pulpal anesthesia than maxillary molars and that might be due to various factors such as the different bony landmark, anatomical variation, needle deflection, accessory innervations [23,24].

Root canal treatment was completed in a single-visit. Wong., *et al*. reported that there was no significant difference in post-obturation pain incidence between single-visit or multiple-visit endodontic treatments. In addition, single-visit treatment has more advantages such as reducing the risk of flare-up induced by leakage of the temporary seal between appointments, reducing the chair time, reducing the procedural costs and decreasing the gingival trauma from rubber dam placement [25,26].

Articaine 4% with (1:100,000 Epinephrine) local anesthetic solution was used for the IANB injection, it is characterized by high protein binding and lipid solubility, so it has a rapid onset 2 - 4 minutes and long duration of action which is approximately 90 minutes [27,28]. Moreover, Fan., *et al.* reported IANB plus PDL injection using 4% Articaine could result in a high rate of anesthetic success in patients with irreversible pulpitis in the mandibular molars [29].

Piroxicam was used as it is a non-selective reversible inhibitor of cyclooxygenase enzyme (COX), it inhibits synthesis of thromboxane in platelets, thus inhibiting the secondary phase of platelet aggregation. It has a half-life of 50 hrs in the plasma [11].

Intra-ligamentary injection technique of Piroxicam (0.4 ml/20 mg) was used in this study as it enables the application of the anti-inflammatory agents in the periapical intraosseous region directly without undergoing hepatic by-pass before reaching the target site, so the bioavailability of injectable Piroxicam will be 100% [11]. It was reported that PDL injection of Piroxicam can significantly reduce post-operative pain in patients with symptomatic irreversible pulpitis [12]. Moreover, others reported the success of NSAIDS in reducing pain in similar cases [14].

The intraligamentary injection was administered using conventional dental syringe as it is equally effective with conventional or specialized syringes, as it was reported that the choice of syringe doesn't affect the efficacy [30,31].

various complications are associated with the intraligamentary injection: swelling, ischemia, extrusion of tooth, most incidents resulted from poor operator technique, this is due to rapid injection technique and injection of excessive volume of solution [32]. In our study only 0.2 ml is injected per root mesially and distally to the tooth with a slow injection rate over 10 seconds to overcome any complications [33].

In the present study the success of the inferior alveolar nerve block injection technique was checked by asking the participants about their lip numbness after 10 - 15 minutes. The pulpal anesthesia was evaluated by assessing the pain level of the symptomatic teeth at two observation points; during access cavity preparation and during instrumentation.

NRS was used for measuring intra-operative and post-operative pain intensity as it is more sensitive to small changes and easily used with limited number of choices (0 - 10), it is also characterized by its high test reliability and validity [34].

Root canals were mechanically prepared by crown down technique using RaCe nickel titanium rotary instruments. This was according to Talebzadeh., *et al*. who reported that crown-down technique decrease the extrusion of debris from the root apex and subsequently reduce the post-operative pain severity by enlarging the coronal third of the root canal and providing a path for the exit of debris from the root canals [35,36].

In this study, routine irrigation was done using 2.5% sodium hypochlorite as it is the most popular ideal irrigating solution with a potent antimicrobial effect, in addition to dissolving the pulpal remnants and collagen [37]. EDTA was used for 1 minute to remove

the smear layer through dissolving organic and inorganic materials.

Root canals were obturated using gutta-percha points by modified single cone technique. Cold lateral technique have less effect on post-operative pain compared to thermal based obturation techniques where extrusion of gutta-percha frequently occurs [38]. ADSEAL resin sealer was used as it provides good apical sealing ability, biocompatible and good adhesion [39].

Assessment of intra-operative was done during access preparation and instrumentation and post-operative pain was done after 6, 12, 24 and 48-hrs The Piroxicam group showed statistically significant decrease of intra-operative pain intensity during instrumentation compared to the Articaine group. However there was no statistically significant difference between the two groups during access cavity preparation, which was in agreement with Wali., *et al.* who reported that 20 mg of oral Piroxicam significantly increase the efficacy of IANB during root canal treatment [40].

Regarding our study, this difference in significance between the two stages of treatment might be attributed to the short duration of action of articaine as an intra-ligamentary injection which has a rapid onset within 30 seconds and lasts only for 10 - 15 minutes [41,42]. This explains the increase of pain scores during instrumentation. Low tissue PH in the area of injection affects the activity of the local anesthetic solution decreases the concentration of the unionised (lipophilic) fraction which diffuses through the nerve sheath. Moreover, areas of inflammation have an increased blood supply due to vasodilatation that might increase anesthetic wash away [43].

On the other hand Piroxicam with it's inhibitory effect on COX1 and COX2 inhibits the secondary phase of platelet aggregation and synthesis of prostaglandins, thus decreasing inflammation and sensitization of peripheral nociceptors that explains the steady pain scores of the drug during treatment [44]. This explain the need for supplemental intra-pulpal anesthesia in 70% of the patients during instrumentation in the Articaine group while no patients needed supplemental intra-pulpal anesthesia in the Piroxicam group, there was statistically significant difference between the two groups.

Results showed that there was statistically significant reduction in post-operative pain intensity in the Piroxicam group at 6, 12 and 24-hrs compared to the Articaine group, this was in agreement with Atabei., *et al.* and Joshi., *et al.* who reported that intra-ligamentary injection of Piroxicam effective in reducing post-operative pain [12,44]. This was attributed to the elimination half life of piroxicam which is 50-hrs due to a low systemic clearance rate, so it can overcome intense pain up to 48-hrs [11].

However, there was no statistically significant difference between the two groups at 48-hrs post-operatively as both groups almost showed no pain incidence at this time interval, this was in agreement with Figini., *et al.* who reported that higher incidence of pain might take place in the first 24-hrs and then declines sharply to negligible levels by time due to the resolution of inflammation and reduction of inflammatory mediators triggering pain that takes place after instrumentation [26].

Both groups showed a statistical drop at all time intervals until pain disappeared compared to pre-operative pain. The gradual decrease in intra and post-operative pain scores was obvious in group P at all time intervals but was mostly significant at 24 and 48-hrs, this was due to the normal subside of inflammation at these intervals. On the other hand group A showed a significant decrease in post-operative pain scores at all time intervals when compared to instrumentation, this was due to the significant increase of pain scores during instrumentation compared to access.

Discussing the percentage of pain incidence at 48-hrs (unlikely to the pain median at the same time interval), there was a significant difference in pain incidence between the two groups, this was due to difference in pain levels between 60% no pain in and 40% mild pain of the patients in the Articaine group compared to 100% no pain in Piroxicam group, which are both considered natural clinical decline of pain to negligible levels.

Regarding the post-operative analgesic intake, Ibuprofen was prescribed as it is the standard medication for post-operative pain relief after root canal treatment [46] and was proven to provide similar pain relief compared to other analgesics [47,48]. In the meanwhile, the low dose of 200 mg allows for a better measure of pain intensity and analgesic intake, as higher doses may obscure the outcome. Results showed that post-operative Ibuprofen was needed in 50% of the patients in the Articaine groups, while no patients needed post-operative ibuprofen in the Piroxicam group. There was statistically significant difference between the two groups, this might also be attributed short duration of action of Articaine as intra-ligamentary injection which lasted only for 10 - 15 minutes it's life span stopped in instrumentation and had completely no effect on post-operative pain.

Conclusion

Within the limitations of this study, it could be concluded that: Intraligamentary injection of Piroxicam showed a significant success in reducing intra and post-operative pain compared to Articaine. Articaine can be used as a successful supplemental technique during early stages of treatment.

Conflict of Interest

The authors deny any conflicts of interest in this study.

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