

**A COMPARATIVE STUDY OF PAIN REDUCTION IN
UNTREATED AND TREATED ACUTE IRREVERSIBLE
PULPITIS – A CLINICAL TRIAL**

Dissertation submitted to

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment for the Degree of
MASTER OF DENTAL SURGERY



BRANCH IV

CONSERVATIVE DENTISTRY AND ENDODONTICS

MAY 2018

CERTIFICATE

**THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
CHENNAI**

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation "A COMPARATIVE STUDY OF PAIN REDUCTION IN UNTREATED AND TREATED ACUTE IRREVERSIBLE PULPITIS – A CLINICAL TRIAL" is a bonafide and genuine research work carried out by me under the guidance of Dr. C.S. KARUMARAN, M.D.S, Professor, Department of Conservative Dentistry and Endodontics, Ragas Dental College and Hospital, Chennai.


Dr. INDU C.R

Post Graduate Student

Dept. of Conservative Dentistry & Endodontics,
Ragas Dental College and Hospital, Chennai.

Date : 29/01/2018

Place: Chennai

CERTIFICATE

This is to certify that this dissertation "A COMPARATIVE STUDY OF PAIN REDUCTION IN UNTREATED AND TREATED ACUTE IRREVERSIBLE PULPITIS – A CLINICAL TRIAL" is a bonafide record work done by Dr. INDU. C .R, under our guidance during her post graduate study period between 2015-2018.

This dissertation is submitted to THE TAMILNADU Dr.M.G.R.MEDICAL UNIVERSITY, in partial fulfillment for the degree of MASTER OF DENTAL SURGERY – CONSERVATIVE DENTISTRY AND ENDODONTICS, BRANCH IV. It has not been submitted (partial or full) for the award of any other degree or diploma.

Guided By:



C.S. Karumaran

[Signature]

Dr. C.S.KARUMARAN, M.D.S.,
Professor
Department of Conservative Dentistry &
Endodontics,
Ragas Dental College & Hospital, Chennai

Dr. R. ANIL KUMAR, M.D.S.,
Professor and Head
Department of Conservative Dentistry &
Endodontics,
Ragas Dental College & Hospital, Chennai

Dr. C.S. KARUMARAN M.D.S.
DEPT. OF CONSERVATIVE DENTISTRY & ENDODONTICS
RAGAS DENTAL COLLEGE AND HOSPITAL
CHENNAI - 600 119.

[Signature]
Dr. N.S. AZHAGARASAN, M.D.S.,
Principal
Ragas Dental College & Hospital,
Chennai.

PRINCIPAL
RAGAS DENTAL COLLEGE AND HOSPITAL
UTHANDI, CHENNAI-600 119.

Dr. R. ANIL KUMAR, M.D.S.,
PROFESSOR AND HEAD,
DEPARTMENT OF CONSERVATIVE
DENTISTRY & ENDODONTICS,
RAGAS DENTAL COLLEGE & HOSPITAL,
CHENNAI.

**THE TAMIL NADU Dr. MGR MEDICAL UNIVERSITY
CHENNAI**

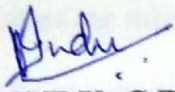
PLAGIARISM CERTIFICATE

This is to certify the dissertation titled "A COMPARATIV STUDY OF PAIN REDUCTION IN UNTREATED AND TREATED ACUTE IRREVERSIBLE PULPITIS – A CLINICAL TRIAL" of the candidate Dr. INDU C.R. for the award of MASTER OF DENTAL SURGERY in BRANCH IV - Conservative Dentistry and Endodontics.

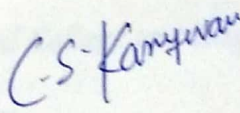
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Date: 29/01/2018

Place: Chennai


Dr. INDU .C.R
Postgraduate Student
Dept. of Conservative Dentistry
&Endodontics,
Ragas Dental College and Hospital,
Chennai.

Guide sign with seal:



Dr. C.S. KARUMARAN, M.D.S.,
Professor
Dept. of Conservative Dentistry &
Endodontics,
Ragas Dental College & Hospital,
Chennai.

Dr. C.S. KARUMARAN M.D.S.
DEPT. OF CONSERVATIVE DENTISTRY & ENDODONTICS
RAGAS DENTAL COLLEGE AND HOSPITAL
CHENNAI - 600 119.

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LIST OF ABBREVIATIONS

S.NO	ABBREVIATIONS	DESCRIPTIONS
1.	NSAID'S	NON STEROIDAL ANTI-INFLAMMATORY DRUG
2.	ZnOE	ZINC OXIDE EUGENOL CEMENT
3.	mm	MILLIMETER
4.	>	GREATER THAN
5.	<	LESSER THAN
6.	IRM	INTERMEDIATE RESTORATIVE MATERIAL

Introduction

INTRODUCTION

Irreversible pulpitis is an inflammatory condition of pulp and is characterized by acute or chronic pain that represents more than 45% of dental emergency consultation in hospitals. Acute/Symptomatic Irreversible pulpitis is associated with severe pain intermittent or spontaneous that remains even after the removal of the stimulus.⁸¹ The etiology may be due to dental caries, loss of marginal seal under the restoration, dental trauma leading to pulpal exposure or associated with dentinal cracks³³.

Recommended emergency treatment for pain associated with acute irreversible pulpitis is partial endodontic treatment (pulpotomy) or pulpectomy under local anesthesia¹⁷. The purpose of this procedure is to remove the pulp partially or completely to alleviate the pain associated with the condition.²⁹ This is possible only if local anesthesia works effectively. Achieving adequate anesthesia in such a clinical situation is a major challenge to the clinician where there is a high probability of local anesthetic failure and a need for additional anesthesia.^{34,39,49} The teeth that are most difficult to anesthetize with acute irreversible pulpitis, are the mandibular molars followed by mandibular premolars, the maxillary molars and pre-molars, and the mandibular anterior teeth.

When conventional local anesthetic techniques fails to provide adequate anesthesia, supplemental injection techniques like periodontal ligament injection, intra-ligamentary or intraosseous techniques is

advocated.⁶⁹ Intraosseous technique is a supplemental anesthetic delivery system which allows the delivery of local anesthetic solution directly into the bone distal to the tooth to be anesthetized^{17,70}, except in maxillary and mandibular second molars where the anesthetic solution is deposited mesial to the tooth to be anesthetized.¹⁹ In this technique though the rate of the onset of anesthesia is rapid, it does not alleviate the pain completely in some patients with acute irreversible pulpitis. Gallatin et al¹⁷ did a study on untreated irreversible pulpitis using an intraosseous injection of methyl prednisolone which was continued by Brami et al^{6,35} and Claffey et al³⁵. They concluded that intraosseous injection of methyl prednisolone was effective in reducing pain associated with acute irreversible pulpitis. Limitations of intraosseous techniques include active periodontal disease, limited attached gingiva and inadequate bony architecture. This technique can be widely used as a primary anesthetic technique during endodontic treatment.^{51, 17}

When complete debridement of the root canal is not possible by pulpectomy, additionally medications are prescribed to relieve the pain. Various classes of drugs have been studied for the management of pain including non-narcotic analgesics comprising NSAID's, combination of antibiotics and acetaminophen, opioids and steroids oral and supplemental administration.³⁵ Efficacy of antibiotics alone in controlling infection and thereby reducing the pain associated with inflammation is still controversial, though some studies have reported that macrolide antibiotics are effective in reducing inflammation and also the pain^{15,41}. Strong analgesics are usually

prescribed for controlling pain. But, pain associated with acute irreversible pulpitis is usually severe and cannot be relieved even with analgesics¹⁷.

Corticosteroids (Glucocorticoids) are a group of drugs that act by interrupting the synthesis and release of chemical mediators that results in reducing pain. They have widespread effects on many organ systems at supra physiological doses when given for a long-term period, usually more than 2 weeks³⁵. The use of corticosteroids in the practice of endodontic treatment is widespread. Literature reviews reveal that corticosteroids has been in use in dentistry and endodontics to relieve post operative pain, pain during endodontic therapy, pain after extraction. The use of corticosteroids is wide spread as a pulp capping agent (Ehrmann et al), intra canal medication (Rogers et al), for post operative pain control (Stewart et al, Torabinejad et al) to reduce inflammation in combination with antibiotics/anti histamines (Negm et al), and after endodontic surgery³⁵.

It has been stated that “A single dose of glucocorticoid, even if a large one, is virtually without harmful effects, and a short course of therapy up to one week is unlikely to be harmful in the absence of specific contraindications.” This has been demonstrated in an in vivo study by Czerwinski et al. who concluded that single large dose (2mg/kg) of dexamethasone was essentially without harmful side effects³⁵.

Few studies have highlighted the effectiveness of glucocorticoid orally²⁹ before and after pulpotomy/pulpectomy procedure. However pain produced by acute irreversible pulpitis originates from pulp tissue where as

post operative pain originates from periapical tissue. Here there is a situation where pain is common, but the etiology of pain is different.

The objective of this study was to evaluate and compare the pain reduction and ability to perform pulpectomy with comfort in patients who were administered intraosseous methyl prednisolone acetate (Depo-Medrol) (Group I), and compare with control group of intraosseous administration of saline (Group II), with oral prophylactic antibiotics group (Group III) and with patients where emergency pulpectomy was performed with intraosseous administration of 2% lignocaine containing 1:100000 adrenaline (group IV). Difference in pain perception and percussion pain was measured using a numeric scale between the day 0 and the seventh day in all 4 groups and recorded. The reduction in pain was measured using a numeric scale introduced by Gallatin et al ¹⁷ in all patients on day 7 and pulpectomy was performed after checking the vitality in patients of groups I, II and III. The quantum of the analgesic drug Paracetamol (Dolo 650), taken by the patient for 7 days was monitored and recorded. The reduction in pain was statistically analyzed over the 7 day period.

The null hypothesis was that there is no difference in pain reduction, among the 4 techniques tested namely intraosseous administration of methyl prednisolone acetate (Depo medrol), intraosseous saline, prophylactic oral antibiotic and emergency pulpectomy using intraosseous administration of 2% lignocaine (on day 0), in untreated and treated acute irreversible pulpitis.

Aim and Objectives

AIM AND OBJECTIVES

AIM

To evaluate the efficiency of intraosseous injection of methyl prednisolone acetate in reducing pain in untreated and treated acute irreversible pulpitis.

OBJECTIVES

1. To evaluate whether intraosseous injection of methyl prednisolone acetate is safe to administer in patients.
2. To evaluate whether intraosseous injection of methyl prednisolone acetate is effective in reducing pain in cases of acute irreversible pulpitis.
3. To evaluate whether patients who are injected intraosseous methyl prednisolone acetate required analgesics in 7 day period.
4. To find out whether it is possible to perform complete pulpectomy under local anesthesia on the 7th day in methyl prednisolone acetate group.
5. To evaluate pain and discomfort while performing complete pulpectomy on the 7th day in patients who are administered methyl prednisolone acetate.
6. To evaluate whether intraosseous injection of saline is safe to administer in patients.
7. To evaluate whether intraosseous injection of saline is effective in reducing pain in cases of acute irreversible pulpitis.

8. To evaluate whether patients who are injected intraosseous saline require analgesics in 7 day period.
9. To evaluate whether antibiotic prophylaxis was effective in reducing pain in acute irreversible pulpitis.
10. To evaluate whether patients who are administered antibiotics require analgesics to control pain due to acute irreversible pulpitis.
11. To evaluate the effectiveness of 2% lignocaine intaosseus injection in reducing pain during pulpectomy on day 0.
12. To evaluate whether complete pulpectomy was achievable on day 0 using intraosseous administration of 2 % lignocaine.
13. To evaluate effectiveness of pulpectomy done under 2% lignocaine intraosseous injection on day 0, in alleviating pain over a period of 7 days
14. To evaluate whether patients who are injected intraosseous lignocaine and pulpectomy done on day 0 required analgesics over 7 day period.
15. To evaluate and compare profound anesthesia, pain reduction and ability to perform pulpectomy with comfort in patients who were administered methyl prednisolone acetate compared to control group (saline), antibiotic group and patients where emergency pulpectomy performed with 2% lignocaine containing 1:100000 adrenaline.

Review of Literature

REVIEW OF LITERATURE

Moskow A et al (1984)⁴⁰ did study on intracanal use of a corticosteroid solution as an endodontic anodyne. The results showed a decreased subjective report of pain for the corticosteroid cases as compared to the controls through the three posttreatment time periods . A statistically significant decreased incidence of pain was reported for the corticosteroid cases as compared to the control at the 24-hour time period No clinical indication of infection was noted in either the corticosteroid or saline control cases.

Marshall JG et al (1984)³⁴ did study on the effect of intramuscular injection of steroid on posttreatment endodontic pain. Fifty patients participated in this controlled double-blind study. The results showed that, when compared with a placebo, injection of the steroid (dexamethasone, 4 mg) significantly reduced both the incidence and severity of pain at 4 h posttreatment and reduced pain at 24 h posttreatment. Other patient and treatment factors such as age, sex, tooth number, pulp and periapical status, and number of appointments had no effect on posttreatment pain. However, posttreatment pain did correlate with the presence of pretreatment pain in both incidence and severity.

Chance K et al (1987)¹⁰ did study on clinical trial of intracanal corticosteroid in root canal therapy.theintracanal medicament was applied to the instrumented canal with sterile paper points. The canal was then sealed

with Cavit. The pain experience of the patient was recorded immediately before and 24 h after endodontic treatment. The corticosteroid was effective in significantly reducing the incidence of postoperative pain in teeth where vital pulp was present. However, when the where vital pulp was present. However, when the pulp was necrotic, the corticosteroid was ineffective in reducing the incidence of postoperative pain.

Glassman G et al (1989)¹⁶ did study on a prospective randomized double-blind trial on efficacy of dexamethasone for endodontic interappointment pain in teeth with asymptomatic inflamed pulps. 40 patients with asymptomatic teeth having vital-inflamed pulps were randomly given either dexamethasone (3 tablets of 4 mg each) or a dextrose placebo identical in appearance (same dosage schedule). The outcome showed that the oral administration of dexamethasone resulted in a statistically significant reduction in endodontic interappointment pain at all three time periods evaluated, that is, at 8 hours, 24 hours, and 48 hours (p less than 0.01). It appears from the results of this study that this dosage schedule of oral dexamethasone is sufficient to significantly reduce endodontic interappointment pain for teeth with asymptomatic vital-inflamed pulps. Further studies are needed for teeth with other endodontic pulpal-periapical conditions and for symptomatic teeth.

Hinkley. A et al (1991)²¹ did study on an evaluation of 4% prilocaine with 1:200,000 epinephrine and 2% mepivacaine with 1:20,000 levonordefrin compared with 2% lidocaine with 1:100,000 epinephrine for

inferior alveolar nerve block. Although subjects felt numb subjectively, anesthetic success as defined here occurred in 46% to 57% of the molars, in 50% to 57% of the premolars, and in 21% to 36% of the lateral incisors. No statistically significant differences in onset, success, failure, or incidence were found among the solutions. We conclude that the three preparations are equivalent for inferior alveolar nerve block of 50-min duration

Walton RE et al (1993)⁷⁴ did study on prophylactic penicillin: Effect on post treatment symptoms following root canal treatment of asymptomatic periapical pathosis. Administration/non administration of penicillin prophylactically were unrelated to post treatment signs and symptoms following canal preparation. Incidence of flare-ups was very low. Occurrence of pain in the mild-moderate levels was fairly high (approximately 70% overall), but was primarily in the mild category. Overall incidence of side effects was also very low. Severe levels due to pain or swelling and flare-up incidences were low with no difference between administration or non-administration of antibiotics

Liesinger A et al (1993)³¹ in a double-blind, randomized, prospective, placebo controlled study evaluated the effect of four different doses of dexamethasone on post treatment endodontic pain. All 106 patients included in the study presented with pre-treatment pain. Endodontic instrumentation and/or obturation were performed after which patients received a randomized intra-oral intramuscular injection of placebo (1ml sterile saline), or one of four doses of dexamethasone(2mg/ml, 4mg/ml,

6mg/ml, 8mg/ml). The injection was given into either the masseter, internal pterygoid, or buccinator muscle. Patients recorded their pre-treatment pain levels on a 0–9 scale and post treatment pain levels at 4, 8, 24, 48 and 72 hours. Type and amounts of pain medication taken was also recorded. No antibiotics were given at any time during this study and both vital and necrotic teeth were included for treatment. Results showed patients receiving dexamethasone had significantly less severe pain at 4 and 8h postoperatively ($P_{0.05}$), and took significantly less pain medication ($P_{0.05}$) compared to placebo

Nobuhara W.K et al (1993)⁴⁴ did study on anti-inflammatory effects of dexamethasone on periapical tissues following endodontic over instrumentation. The number of polymorphonuclear neutrophils present in the periapical tissues was counted in a blind manner and statistical analysis of the results was performed by two-way analysis of variance. Following endodontic over instrumentation, local infiltration of dexamethasone produced a significant anti-inflammatory effect on the periapical tissues of teeth with vital or partially necrotic pulp tissue.

Kaufman E, Ilana Heling, Adam Stabholtz et al (1994)²⁶ conducted study on intra-ligamentary injection of slow-release methylprednisolone for the prevention of pain after endodontic treatment. The intra-ligamentary injection of a slow-release steroidal, the anti-inflammatory agent slow-release methylprednisolone (Depo-medrol), was compared to a placebo and to an active placebo (Mepivacaine) in preventing

postoperative pain after root canal treatment. The results clearly demonstrated that the tested drug significantly reduced the frequency and intensity of postoperative pain sequelae in the experimental set-up. A significant decrease in postoperative pain was found in the group that received methylprednisolone compared the active or passive placebo groups.

Certosimo AJ et al (1996)⁷ did study on a clinical evaluation of the electric pulp tester as an indicator of local anesthesia. The study was performed in vivo on patients requiring operative therapy. All teeth were pulp tested preoperatively for vitality using the electric pulp tester. After injection of local anesthetic, traditional parameters of dental anesthesia were verified (lip numbness, mucosal sticks). Teeth were then retested with the electric pulp tester and the results recorded. The electric pulp tester readings were compared to the patient's responses using Fisher's Exact test (two-tail). The results indicate that the electric pulp tester can be a valuable tool in predicting potential anesthetic problems in operative (restorative) dentistry

Dunbar D et al (1996)¹³ did study on anesthetic efficacy of the intraosseous injection after an inferior alveolar nerve block. An 80 reading was used as the criterion for pulpal anesthesia. One hundred percent of the subjects had lip numbness with the IAN block. For the first molar, anesthetic success, defined as achieving an 80 reading within 15 min and keeping this reading for 60 min, was 42% with the IAN and 90% with the

IAN + IO. Anesthetic failure defined as never achieving two 80 readings during the 60 min was 32% with the IAN and 0% with the IAN + IO. The onset of anesthesia was immediate with the IO injection. Eighty percent of the subjects sampled had a subjective increase in heart rate with the IO injection. The IO injection and post injection questionnaire recorded low pain ratings

Coggins Randall et al (1996)⁸ determined the efficacy of the intraosseous injection used as a primary technique in healthy human maxillary and mandibular teeth. Successful anesthesia was achieved in 75% of mandibular first molars, 93% of maxillary first molars, 78% of mandibular lateral incisors, and 90% of maxillary lateral incisors. The onset was immediate but the duration of pulpal anesthesia steadily declined over 60 minutes. There subjective increase in heart rate was 78%. Majority of the subjects had no pain or mild pain during perforation and solution deposition. Slow healing perforation sites were noticed in 3% of the subjects. He concluded that intraosseous injection provides adequate pulpal anesthesia in 75% to 93% in non-inflamed teeth when used as a primary technique.

Replogle k et al (1997)⁵⁷ did study on anesthetic efficacy of the intraosseous injection of 2% lidocaine (1:100,000 epinephrine) and 3% mepivacaine in mandibular first molars. Anesthetic success occurred in 74% of the first molars with 2% lidocaine with 1:100,000 epinephrine and in 45% with 3% mepivacaine. The difference was statistically significant

Overall, onset was rapid for the intraosseous injections, the duration of pulpal anesthesia steadily declined over the 60 minutes, the majority of the subjects had no pain or mild pain with perforation and solution deposition, and 5% of the subjects had delayed healing at the perforation sites.

Nusstein John et al (1998)⁴⁶ conducted a study to determine the anesthetic efficacy of a supplemental intraosseous injection using 2% lidocaine with 1:1,00,000 epinephrine in teeth diagnosed with irreversible pulpitis. Maxillary and mandibular vital symptomatic posterior teeth diagnosed with irreversible pulpitis were used for the study. Initially conventional infiltrations or inferior alveolar nerve blocks were given. Patients who felt pain during endodontic access received a supplemental intraosseous injection using 1.8 ml of 2% lidocaine with 1:100,000 epinephrine. 81% of the mandibular teeth and 12% of maxillary teeth required supplemental intraosseous anesthesia. He concluded that stabident intraosseous injection was found to be 88% successful in gaining total pulpal anesthesia for endodontic therapy.

Reitz J et al (1998)⁵⁸ did study on anesthetic efficacy of a repeated intraosseous injection given 30 min following an inferior alveolar nerve block/intraosseous injection. The repeated IO injection increased pulpal anesthesia for approximately 14 min in the second premolar and for 6 min in the first molar, but no statistically significant differences were shown. In conclusion, the repeated IO injection of 0.9 ml of 2% lidocaine with 1:100,000 epinephrine given 30 min following a combination IAN/IO

injection did not significantly increase pulpal anesthesia in mandibular second premolars or in first and second molars.

Parente Stephen et al (1998)⁴⁹ did study on anesthetic efficacy of the supplemental intraosseous injection for teeth with irreversible pulpitis. Patients with maxillary teeth had received infiltration anesthesia, and those with mandibular teeth had received an inferior alveolar nerve block in conjunction with long buccal infiltration. A minimum of 3.6 ml of local anesthetic was used with the conventional techniques. Modified visual analogue scales, coupled with operator evaluations, were used to measure success. The Stabident IOI was an effective supplemental anesthetic technique in 89% (+/- 5.1) or 33/37 patients evaluated. The 95% confidence interval was 74 to 97%. The IOI was successful in 91% (+/- 4.9) of the mandibular posterior teeth (31/34), 67% of the maxillary teeth (2/3) and 3% in a similar fashion to group 1. Group 3 received no PDL injection. Pre-treatment pain levels were not reported. The patients were telephoned at 24h and reported pain intensity on a 1–10 scale. The results showed a significant decrease in postoperative pain in the methylprednisolone group (P_0.05) compared to the active and passive placebo groups. In another prospective, randomized, double-blind, placebo controlled study that contained 588 consecutive patients.

Bramy et al (1999)⁶ evaluated the intraosseous administration of corticosteroid for pain reduction of symptomatic teeth necrotic teeth. Thirty-eight patients with a clinical diagnosis of pulpal necrosis with

associated periapical radiolucency participated in the study. All patients experienced moderate/severe pain at time of presentation with mild or no clinical swelling. After endodontic treatment (complete debridement), patients in a double-blind fashion randomly received an intraosseous injection of either 1ml methylprednisolone (Depo-Medrol 40mg/ml) or 1ml of sterile saline placebo. All subjects received ibuprofen and Tylenol. Their pain levels were recorded and any pain medications taken for 7days postoperatively. The results showed that the steroid group had significantly less postoperative pain and took significantly less pain medication over 7days ($P_{0.05}$). No antibiotics were taken by patients at any time during the study. In a follow-up study, Claffey et al evaluated pain reduction in symptomatic teeth with necrotic pulps using an oral dose regimen of methylprednisolone.

Gallatin et al (2000)¹⁷ evaluated pain reduction for untreated irreversible pulpitis using an intraosseous injection of methylprednisolone. Forty patients with a clinical diagnosis of irreversible pulpitis actively associated with moderate–severe pain participated in this prospective double-blind study. The involved tooth was anesthetized followed by an intraosseous injection of 1ml methylprednisolone (Depo-Medrol 40mg/ml) or 1ml of saline. The blinded solutions were administered using the Stabident system (Fairfax Dental, Inc., Miami, FL, USA). No endodontic treatment was performed. Patients were given a 7-day pain diary as well as analgesic medication. Over the 7-day observation period, subjects receiving

Depo-Medrol reported significantly less pain ($P_{0.05}$) compared to placebo while taking significantly fewer analgesic medications ($P_{0.05}$).

Douglas nagle et al (2000)¹² conducted study on effect of systematic penicillin on pain in untreated irreversible pulpitis and found that the administration of penicillin did not significantly reduce pain, percussion pain, or the number of analgesic medications taken by patients with untreated irreversible pulpitis. The majority of patients with untreated irreversible pulpitis had significant pain and required analgesics to manage this pain. Penicillin should not be prescribed for untreated irreversible pulpitis because penicillin is ineffective for pain relief.

Henry M et al (2001)⁴¹ did study on effect of penicillin on postoperative endodontic pain and swelling in symptomatic necrotic teeth. After endodontic treatment patients randomly received a 7-day oral dose (twenty-eight 500 mg capsules to be taken every 6 h) of either penicillin or a placebo control in a double-blind manner. Patients also received ibuprofen; acetaminophen with codeine (30 mg); and a 7-day diary to record pain, percussion pain, swelling, and number and type of pain medication taken. The majority of patients with symptomatic necrotic teeth had significant postoperative pain and requires analgesic medication to manage this pain. The administration of penicillin postoperatively did not significantly ($p > 0.05$) reduce pain, percussion pain, swelling, or the number of analgesic medications taken for symptomatic necrotic teeth with periapical radiolucencies.

Shepherd P.A et al (2001)⁶⁵ did study on measurement of intraosseous pressures generated by the wand, highpressure periodontal ligament syringe, and the stabident system. Intraosseous pressure generated by the use of three anesthetic systems-the Wand; a hand-operated high-pressure periodontal ligament (PDL) syringe; and the Stabident system-were studied in fresh mandibles of 14 large swine. The mandibles were drilled and tapped in one area of both the right and left posterior molar regions. Pressure gauges were attached via threaded fittings. Pressures during injection were recorded for the Wand first, then the PDL syringe, and finally Stabident. Results showed averages of 8.3 mm Hg generated by the Wand, 16.3 mm Hg with the high-pressure PDL syringe, and 43.7 mm Hg from the Stabident system

Pickenpaugh L et al (2001)⁵⁴ did study on effect of prophylactic amoxicillin on endodontic flare-up in asymptomatic necrotic teeth. The results demonstrated 10% of the 70 patients had a flare-up characterized by moderate-to-severe postoperative pain or swelling that began approximately 30 h after endodontic treatment and persisted for an average of 74 h. Of the seven patients who had flare-ups, 4 were in the amoxicillin group and 3 were not. Prophylactic amoxicillin did not significantly ($p = 0.80$) influence the endodontic flare-up.

Marshall J.G et al (2002)³⁵ did study on consideration of steroids for endodontic pain. The administration of systemic steroids is efficacious as

an adjunct to but not replacement for appropriate endodontic treatment in the attenuation of endodontic post treatment pain. Systemic steroids are also highly effective in those patients who present for treatment with moderate/severe pain and a clinical diagnosis of pulpal necrosis with associated periapical radiolucency. Glucocorticoids inhibit the production by multiple cells or factors that are important in producing the inflammatory response.

Fouad A.F(2002)¹⁵ Systemic antibiotic administration should be considered if there is a spreading infection that signals failure of local host responses in abating the advancing bacterial irritants, or if the patient's medical history includes conditions or diseases known to reduce the host defense mechanisms or expose the patient to higher systemic risks.

Meechan J.G et al (2002)³⁷ did study on Supplementary routes to local anaesthesia. Although some of these techniques can be used as the primary form of anaesthesia, these are normally employed as 'back-up'. The methods described are intraligamentary (periodontal ligament) injections, intraosseous anaesthesia and the intrapulpal approach.. The advent of new instrumentation, which permits the slow delivery of local anaesthetic solution has led to the development of novel methods of anaesthesia in dentistry.

Isett J, Reader A et al (2003)²³ conducted study on effect of an Intraosseous Injection of Depo-Medrol on Pulpal Concentrations of PGE2 and IL-8 in Untreated Irreversible Pulpitis. Pulpal concentrations of PGE2

were reduced at 1day after the intraosseous injection of 40 mg of Depo-Medrol inteeth with untreated irreversible pulpitis.

Sigurdsson Asgeir et al (2003)⁶⁶ did a review on pulpal diagnosis. It is paramount that prior to proceeding with the treatment the clinical diagnosis of the pulp and periapical tissues should be established. The diagnosis should be based on presenting symptoms, history of symptoms, diagnostic tests and clinical findings. In this review current knowledge on pulpal and periapical status as it pertains to diagnosis will be reviewed.

Gallatin J et al (2003)¹⁸ conducted a prospective, randomized, blinded study was to compare injection pain and postoperative pain of an apical primary X-Tip intraosseous technique to a coronal primary stabident intraosseous technique in mandibular first molars. The results demonstrated that the apical primary X-Tip intraosseous technique was not statistically different from the coronal primary Stabident technique regarding pain ratings of infiltration, perforation, needle insertion, solution deposition, mock or actual guide sleeve removal and postoperative pain (at the time subjective anesthesia wore off). However, on postoperative days 1 through 3, significantly more males experienced postoperative pain with the X-Tip system than with the stabident system.

Gallatin J et al (2003)¹⁹ compared the anesthetic outcomes of stabident and X-tip system in primary intraosseous injections in mandibular posterior teeth. Anesthetic success rates for the stabident technique and the X-tip technique, respectively, were 93% and 93% for the first molar, 95%

and 95% for the second molar and 81% and 83% for the second premolar, with no significant differences between the two techniques. The onset of pulpal anesthesia occurred within the first two minutes, but the duration of anesthesia declined steadily over the 60 minutes. He concluded that the two primary intraosseous injection techniques were similar regarding anesthetic success, onset and duration.

John M Nusstein et al (2003)⁴⁵ did study on comparison of preoperative pain and medication use in emergency patients presenting with irreversible pulpitis or teeth with necrotic pulps. Patients with irreversible pulpitis wait longer to seek emergency treatment. A majority (81%-83%) of emergency patients with moderate to severe pain will have taken some type of medication(s) to help control their pain, and more women than men with irreversible pulpitis will take an analgesic. By taking their preoperative medication(s), this group of patients will get relief 62% to 65% of the time; furthermore, more men than women with symptomatic teeth with necrotic pulps will experience pain relief.

Keenan JV et al (2005)²⁷ did study on antibiotic use for irreversible pulpitis. Antibiotics do not appear to significantly reduce toothache caused by irreversible pulpitis. Furthermore, there was no difference in the total number of ibuprofen or Tylenol tablets used over the study period between both groups. The administration of penicillin does not significantly reduce the pain perception, the percussion (tapping on the tooth) perception or the

quantity of pain medication required by people with irreversible pulpitis. There was no reporting on adverse events or reactions.

Whitworth JM et al (2005)⁷⁵ tested the hypothesis that the stabident intraosseous injection is a potentially high-pressure technique, which carries serious risks of anesthetic cartridge failure. A standard Astra dental syringe was modified to measure the internal pressure of local anesthetic cartridges during injection. Pressures created when injecting into air were less than those needed to inject into tissue. Fast injection produced greater intra-cartridge pressures than slow delivery. The absolute maximum intra-cartridge pressure developed during the study was 3.31 MPa which is less than that needed to fracture glass cartridges. He concluded that stabident intraosseous injection does not present a serious risk of dangerous pressure build-up in local anesthetic cartridges.

Sutherland .S et al (2005)⁶⁸ did study on antibiotics do not reduce toothache caused by irreversible pulpitis. Are systematic antibiotics effective in providing pain relief in people who have irreversible pulpitis. There was no significant difference in the mean total number of ibuprofen tablets and acetaminophen tablets taken for pain relief in either group over the study period. The administration of penicillin over placebo did not appear to significantly reduce the quantity of analgesic medication taken for irreversible

Prohic .S et al (2005)⁵⁵ did study on the efficacy of supplemental intraosseous anesthesia after insufficient mandibular block. . The results of

this study indicate that the anesthetic efficacy of the mandibular block is 74.5%, and that supplemental intraosseous anesthesia, applied after the insufficient mandibular block, provides pulpal anesthesia in 94.9% of mandibular molars. The difference between anesthetic efficacy of the classical mandibular block and anesthetic efficacy of the supplemental intraosseous anesthesia, applied after the insufficient mandibular block, is obvious.

Khan A.A et al (2007)³⁰ did study on measurement of mechanical allodynia and local anesthetic efficacy in patients with irreversible pulpitis and acute periradicular periodontitis. The administration of local anesthesia reversed the mechanical allodynia by 62%, and significant sex-specific effects were observed. In addition, the normal teeth contralateral to the symptomatic teeth had lower mechanical thresholds than those observed in healthy volunteers, suggesting that central sensitization occurs during this type of odontalgia. Thus, we show that the mechanical pain thresholds are significantly reduced in teeth with IP and APP and that the force transducer has potential application as a diagnostic aid in measuring mechanical allodynia and as an outcome measure in endodontic clinical trials.

Ianiri SR. et al (2007)⁶⁷ studied on the effect of preoperative acetaminophen or a combination of acetaminophen and Ibuprofen on the success of inferior alveolar nerve block for teeth with irreversible pulpitis. The administration of premedication with acetaminophen or a combination of acetaminophen and ibuprofen on the success of inferior alveolar nerve

block for teeth with irreversible pulpitis appears promising, although the pilot study showed no statistically significant difference versus placebo

Jensen J et al (2007)²⁵ did study on anesthetic efficacy of a repeated intraosseous injection following a primary intraosseous injection. The repeated intraosseous injection mimicked the initial intraosseous injection in terms of pulpal anesthesia and statistically provided another 15 minutes of pulpal anesthesia. In conclusion, using the methodology presented, repeating the intraosseous injection 30 minutes after an initial intraosseous injection will provide an additional 15 minutes of pulpal anesthesia.

Remmers Todd et al (2008)⁵⁹ compared anesthetic efficacy of a repeated intraosseous injection following a primary intraosseous injection. He concluded that Intra-osseous injection provided successful anesthesia in 87%. The IA block provided successful anesthesia in 60%. The results of this study indicate that the Intra Flow system can be used as the primary anesthesia method in teeth with irreversible pulpitis to achieve predictable pulpal anesthesia.

Bangerter Chad et al (2009)⁵ conducted a web based survey to investigate the use of supplemental intraosseous (IO) anesthesia among endodontists in the United States. The study also looked at the types of anesthetic solutions commonly used for IO anesthesia and in which diagnostic conditions IO anesthesia is used. It was discovered that 94.77% of the respondents used some form of IO anesthesia, with the periodontal

ligament injection (PDL) being the most commonly administered (49.78%). Symptomatic irreversible pulpitis is the pulpal diagnosis for which respondents most often use some form of IO anesthesia (61.99%), and 2% lidocaine with epinephrine 1:100,000 is the most common anesthetic solution used in IO anesthesia (37.62%). Although more than half of the respondents use some form of IO anesthesia more than twice a week, newer IO anesthesia delivery systems such as Stabident (Fairfax Dental, San Francisco, CA) and X-Tip (Dentsply International, Johnson City, TN) are used less often than the PDL injection..

Segura-Egea J. J. et al (2009)⁶³ determined the pain experienced by patients during root canal treatment and correlated with age, gender, pulpal diagnosis, previous periapical status, dental characteristics and length of treatment. 176 patients (68 men and 108 women), with ages ranged from 6 to 83 years, were randomly recruited and ranked the level of pain experienced during root canal treatment. Mandibular teeth had a significantly higher percentage incidence of pain in comparison with maxillary teeth. Pain was absent in 63% of anterior teeth compared with 44% in posterior ones. Root canal treatment was significantly more painful in teeth with irreversible pulpitis and acute apical periodontitis compared to the group with necrotic pulps and chronic apical periodontitis. He concluded that root canal treatment in teeth with irreversible pulpitis and acute apical periodontitis was more painful. Age, tooth type and length of

the treatment were factors associated with increased risk for pain experienced during the procedure.

Mohammadi .Z et al (2009)³⁸ did study on systemic and local applications of steroids in endodontics: an update review. Up to 80% of endodontic patients who report with preoperative pain continue to experience some level of pain following the endodontic procedure. Various classes of drugs have been studied for the management of post-treatment endodontic pain. Since endodontic pain is often associated with chronic inflammation, the presence of bacterial by-products, influx of primed immune cells and activation of the cytokine network and other inflammatory mediators, pain may be reduced by administration of glucocorticoid steroids

Lin Kimmy et al (2010)³³ discussed about the detection, procession and perception of pulpal pain. He also discussed about the mode of local anesthetics. He also discussed in detail about the rationale of local anesthetic failures. Psychological, gender, anatomical factors effect of inflammation on local tissues, peripheral nociceptors, and central sensitization has been discussed. Management of local anesthetic failures also been discussed in this review.

John M Nussetin (2010)⁴⁷ The dentist who treats patients diagnosed with a mandibular hot tooth (irreversible pulpitis) will often find achieving adequate pulpal anesthesia to be a challenge and the use of supplemental anesthesia techniques is usually done. Whether the clinician's

training or preference is the PDL or IO injection, these supplemental techniques have been shown to be quite effective in achieving pulpal anesthesia for teeth with irreversible pulpitis.

Vivek Aggarwal (2011)¹ The anesthetic success rates for PSA nerve blocks, buccal infiltrations, and buccal plus palatal infiltrations were 64%, 54%, and 70%, respectively, in maxillary first molars with irreversible pulpitis. None of the techniques evaluated in the present study gave 100% success rates.

Peñarrocha-Oltra David et al (2012)⁵³ analyzed the side effects and complications following intraosseous anesthesia (IA), comparing them with those of the conventional oral anesthesia techniques through a simple-blind, prospective clinical study. Both anesthetic techniques significantly increased heart rate, and Intra-osseous anesthesia caused comparatively more pain at the injection site, while limited oral aperture was more frequent with conventional anesthesia.

Puspendra Kumar Varma et al (2013)⁷² did study on anesthetic efficacy of X-tip intraosseous injection using 2% lidocaine with 1:80,000 epinephrine in patients with irreversible pulpitis after inferior alveolar nerve block: A clinical study. Ninety-three percent of X-tip injections were successful and 7% were unsuccessful. Discomfort rating for X-tip perforation: 96.66% patients reported none or mild pain, whereas 3.34% reported moderate to severe pain. For discomfort rating during solution

deposition, 74.99% patients reported none or mild pain and 24.92% reported moderate to severe pain. Supplemental X-tip intraosseous injection using 2% lignocaine with 1:80,000 epinephrine has a statistically significant influence in achieving pulpal anesthesia in patients with irreversible pulpitis.

Fedorowicz Z et al (2013)¹⁴ found that Antibiotics do not appear to significantly reduce toothache caused by irreversible pulpitis. Furthermore, there was no difference in the total number of ibuprofen or Tylenol tablets used over the study period between both groups. The administration of penicillin does not significantly reduce the pain perception, the percussion (tapping on the tooth) perception or the quantity of pain medication required by people with irreversible pulpitis. There was no reporting on adverse events or reactions.

Hamid Razavian et al (2013)²⁰ did study on X-tip intraosseous injection system as a primary anesthesia for irreversible pulpitis of posterior mandibular teeth. Intraosseous injection system resulted in successful anesthesia in 17 out of 20 patients (85%). Successful anesthesia was achieved with the IAN block in 14 out of 20 patients (70%). However, the difference (15%) was not statistically significant. Considering the relatively expensive armamentarium, probability of penetrator separation, temporary tachycardia, and possibility of damage to root during drilling, the authors do not suggest intraosseous injection as a suitable primary technique.

Thangavel Boopathi (2013)⁶⁹ Supplemental injections with different techniques and/or types of anesthesia are frequently required in patients with irreversible pulpitis, primarily because pulpal anesthesia resulting from an initial injection is often inadequate for the completion of endodontic procedure.

Bhuyan AC et al (2014)³ did study on anesthetic efficacy of the supplemental X-tip intraosseous injection using 4% articaine with 1:100,000 adrenaline in patients with irreversible pulpitis. The results of the study showed that 25 X-tip injections (83.33%) were successful and 5 X-tip injections (16.66%) were unsuccessful. When the inferior alveolar nerve block fails to provide adequate pulpal anesthesia, X-tip system using 4% articaine with 1:100,000 adrenaline was successful in achieving pulpal anesthesia in patients with irreversible pulpitis.

Mohammed Nabeel (2014)⁴² Various studies have compared the effect of different volumes of local anesthetic solution and concentration of epinephrine in the success of anesthesia. Fowler S et al and Parirokh et al found that there is no significant difference in anesthetic success between 3.6ml volume and 1.8 ml volume of 2% lidocaine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis

Cope A et al (2014)⁹ did study on the effects of antibiotics on toothache caused by inflammation or infection at the root of the tooth in adults. There were no clear differences in the pain or swelling reported by participants

who received oral antibiotics compared with a placebo when provided in conjunction with the first stage of root canal treatment and painkillers, but the studies were small and we could not exclude potentially important differences between groups.

Parirokh .M et al (2014)⁵⁰ did study on various strategies for pain-free root canal treatment. Numerous studies investigated to pain management during root canal treatment; however, there is still no single technique that will predictably provide profound pulp anesthesia. One of the most challenging issues in endodontic practice is achieving a profound anesthesia for teeth with irreversible pulpitis especially in mandibular posterior region.

Idris M et al (2014)²² did study on Intraosseous injection as an adjunct to conventional local anesthetic techniques: A clinical study. Intraosseous injection technique was successful in 21 out of 24 patients (87.5%), except three patients who had pain even after supplemental X-tip injection. Supplemental intraosseous injection using 4% articaine with 1:100,000 epinephrine has a statistically significant influence in achieving pulpal anesthesia in patients with irreversible pulpitis.

Tom.K et al (2015)⁷⁰ did study on intraosseous anesthesia as a primary technique for local anesthesia in dentistry. Computer-controlled intraosseous anesthesia is an effective primary technique for limited procedures involving one or two posterior teeth in the mandible. Compared

to traditional local anesthetic techniques, intraosseous anesthesia (1.5-1.8 mL of 4% articaine with 1:100,000 epinephrine for adults and 0.6-0.8 mL of 4% articaine with 1:200,000 epinephrine for children) offers high success rates, easy administration, fast onset times, and significant patient comfort

Bane K et al (2016)⁴ did study on Randomized Clinical Trial of Intraosseous Methylprednisolone Injection for Acute Pulpitis Pain. This study establishes that methylprednisolone injection for acute pulpitis is relieved by a minimally invasive pharmacologic approach more effectively than by the reference pulpotomy and conserves scarce dental resources (ie, endodontic equipment and supplies, dental surgeon's time).

Aminosharaie A (2016)² studied on evidence based recommendations for analgesic efficacy to treat pain of endodontic origin. NSAIDs should be considered as the drugs of choice to alleviate or minimize pain of endodontic origin if there are no contraindications for the patient to ingest an NSAID. In situations in which NSAIDs alone are not effective, the combination of an NSAID with acetaminophen or a centrally acting drug is recommended. Steroids appear effective in irreversible pulpitis.

Dan krister.R et al (2016)¹¹ did study on pain levels and typical symptoms of acute endodontic infections: a prospective, observational study. The best indicator for SAP was a reported absence of pain to cold stimuli. In teeth that did have a history of pain triggered by cold stimuli, the decision tree correctly identified SAP in 72 % of the teeth that felt too high and had hurt for less than one week.

Roya sabzin et al (2016)⁶⁰ did study on irreversible pulpitis and achieving profound anesthesia: complexities and managements.. To achieve effective pain relief conventional methods of pain control, including a pharmacological plan and the use of anesthesia techniques, must be individually tried for each patient. Considering other supplementary anesthesia techniques, intra-osseus and ligamentary, is strongly recommended for patients with inadequate pain relief.

Payman Mehrvarzafar et al (2016)⁵² did study on effect of dexamethasone intra-ligamentary injection on post-endodontic pain in patients with symptomatic irreversible pulpitis Pretreatment PDL injection of dexamethasone can significantly reduce the post-treatment endodontic pain in patients with symptomatic irreversible pulpitis.

Olivia Kerouredanetal (2017)²⁹ did study on efficacy of orally administered prednisolone versus partial endodontic treatment on pain reduction in emergency care of irreversible pulpitis of mandibular molars.

The ability of short-term corticosteroid therapy to reduce pain in irreversible pulpitis as a simple and rapid alternative to partial endodontic treatment and to enable planning of endodontic treatment in optimal analgesic conditions.

Iranmanesh F (2017)²⁴ studied on Effect of Corticosteroids on Pain Relief Following Root Canal Treatment. GCS are much more effective in the immediate post-operative period of time (up to 48 h) following root canal treatment in comparison with longer time periods. This may be due to two main reasons. Firstly, the root canal treatment itself can reduce pain by eradicating the pain stimulants such as pulp tissue remnants, bacteria and their by-products from the root canal system.

Segura-egea J J (2017)⁶³ The overuse of antibiotics and the emergence of antibiotic-resistant bacterial strains is a global concern. This concern is also of importance in terms of the oral microbiota and the use of antibiotics to deal with oral and dental infections. Antibiotics do not reduce pain or swelling arising from teeth with symptomatic apical pathosis in the absence of evidence of systemic involvement.

Materials and Methods

MATERIALS AND METHODS

Armamentarium

- Stabident system (Fairfax Dental Inc., Miami, FL, USA.).
- Injection Depo-Medrol (40 mg/ml) (Methyl prednisolone acetate , Pfizer, Belgium;
- 1.7ml cartridges of 2% Lidocaine hydrochloride with 1:1,00,000 adrenaline (Lignospan special, Septodont).
- Metal, breech type, cartridge loading, aspirating syringe (Petite blue Aspirating dental injection syringe)..
- Pulp tester (Denjoy dental pulp tester DY310).
- Endo Frost cold spray (Coltene- Roeko, Langenau, Germany).
- Contra-angle hand piece (NAC hand pieces-NSK contra angle for latch burs).
- 0.9% Saline solution [Eurolife, Tamilnadu,India]
- Amoxicillin 500 mg tablets
- Dolo 650mg (paracetamol) tablets

INCLUSION CRITERIA

- Healthy adult volunteers aged between 18 – 35 years with acute irreversible pulpitis in posterior teeth.
- Experiencing acute pain and positive response to electric pulp testing and cold testing.
- Absence of periapical radiolucency. Patients with fractured restoration and severe pain which require immediate endodontic treatment.
- Pulpitis pain in patients from severe high point restorations and crowns.
- Patients with failed composite restorations
- Ability of the patients to understand the use of pain scales.

EXCLUSION CRITERIA

- Pregnant females and lactating mothers.
- Patients with no response to Electric pulp testing and cold testing.
- Patients with contraindications to corticosteroids (systemic fungal infections, ocular herpes simplex , primary glaucoma, allergy to corticosteroids ,ulcerative colitis, severe osteoporosis, poorly controlled insulin-dependent diabetes mellitus ,compromised immune status psychosis) and contraindications to the injection techniques or solutions were excluded from this study.
- Patients with questionable periodontal health

METHODOLOGY

Eighty patients between age groups 18 to 35 with acute irreversible pulpitis pain and requiring emergency treatment participated in the study. All patients were in good health as determined by written health history and oral questioning. Patients presenting with any contraindications to corticosteroids (systemic fungal infections, ocular herpes simplex, primary glaucoma, ulcerative colitis, severe osteoporosis, poorly controlled insulin-dependent diabetes mellitus, compromised immune status, psychosis) and contraindications to the injection techniques or solutions were excluded from this study.

The primary investigator selected the patients who satisfied inclusion criteria and the clinical protocols. All the patients who consented to participate were evaluated in the General Hospital attached to the Ragas Dental College by a physician. Patients were suggested to undergo Routine blood test, blood pressure evaluation, blood sugar – random and ECG. When all the subjected parameters were satisfactory and within normal range, those patients are included in the study. Informed written consent was obtained from each subject either in English or in their regional native language in the presence of a common witness (Annexure I & II). This study approved by IRB of Ragas dental college.

The patients included in this study had a tooth with clinical diagnosis of acute irreversible pulpitis and actively had spontaneous, moderate to severe pain associated with maxillary premolars, molars, mandibular premolars or

molars. They exhibited positive response to electric pulp testing and prolonged response to cold pulp testing with Endo-Frost. The teeth had history of spontaneous pain, percussion sensitivity and radiographically widened periodontal ligament space.

Pain evaluation and percussion pain evaluation were done on a pain scale of 0 to 3, (Gallatin et al.)¹⁷

- 0 - indicated no pain.
- 1 - indicated mild pain, pain that was recognizable but not discomforting.
- 2 - indicated moderate pain, pain that was discomforting but bearable.
- 3 - indicated severe pain, pain that caused considerable discomfort and was difficult to bear.

Study is conducted in 80 patients divided into 4 groups of 20 each.

Group I-20 patients were administered intra-osseous methyl prednisolone acetate (Depo-Medrol) injection and recalled for Root Canal Treatment on the 7th day.

Group II-20 patients were administered intra-osseous saline injection and recalled on the 7th day for Root Canal Treatment (control group).

Group III-20 patients prescribed with antibiotic prophylaxis (amoxycillin 500 mg thrice daily for 3 days) were recalled on the 7th day for evaluation and Root Canal Treatment.

Group IV- 20 patients intra-osseous injection using 2% lignocaine with 1:100000 adrenaline is administered. Emergency pulpectomy performed.

Access opening followed by cleaning and shaping is done and temporary restoration given with IRM patients is recalled on the 7th days for continuing root canal treatment.

All patients from 4 groups were given 20 analgesics (Dolo 650)tablets and asked to consume whenever they experience severe pain and to not it down.

Group 1 and 2 (40 patients) were administered intra-osseous injection of either 1ml (40mg/ml) of methyl prednisolone acetate (Depo-medrol) or 1ml of 0.9% preservative free sterile saline (Sodium chloride). The Depo-Medrol solution contains 40 mg/ml of Depo-Medrol, 2.9% polyethylene glycol vehicle, 0.0195% myristyl- γ -picolinium chloride preservative, and 0.9% sodium chloride solution, according to manufacturer's manual. Depo-Medrol formulation containing benzyl alcohol is not used due to allergy concerns.

The dental cartridges are prepared by removing the rubber plunger from the standard anesthetic cartridges. The cartridges were then emptied and washed, along with the rubber plungers with soap and water rinsed in tap water using a nylon bristle brush and autoclaved. Using sterile technique, each sterilized anesthetic cartridge was filled with either 1.0 ml of Depo-Medrol or 1.0 ml of 0.9% preservative-free sterile saline solution. The cartridges were wrapped with opaque tape and a 4 digit random number was written on the tape to blind the solutions¹⁶. The envelopes will be available to primary investigator at all times, in case of necessity that were blinded to the

allocation table. 40 cartridges are prepared and kept by co-investigator containing either of the solutions and operator is unaware about the content of solutions. 20 intra-osseous 2% lignocaine cartridges are kept ready.

In Group I and II, All patients were anesthetized with 0.2ml 2% lignocaine with epinephrine at the intraosseous perforation site. Co-investigator hands over a cartridge to investigator who is blind about the content and Intra-osseous injection of 1ml solution is administered to the patient in the attached gingiva distal to the teeth piercing bone with intra-osseous anesthetic unit (Stabident system – Florida).

The area of perforation was determined by the horizontal line of the buccal gingival margins of adjacent teeth and a vertical line that passed through the distal inter dental papilla of the symptomatic tooth. The point 2 mm below the intersection of these lines was the perforation site if the site was in attached gingiva. If the site was in alveolar mucosa, the perforation site was moved just above the junction of the attached gingiva and the alveolar mucosa on the same vertical line¹⁷.

The cortical plate was perforated using the Stabident perforator (a bevel-ended solid 27-gauge wire attached to a plastic hub) in a contra-angle slow-speed hand piece. The perforator was placed through the gingiva and oriented perpendicular to the cortical plate. With the beveled end resting on the bone, the hand piece was activated in a series of short bursts, using light pressure, until a “break through” feeling was observed¹⁷. If a “break through” feeling was not felt, the hand piece was activated again until the perforator

was inserted to length. Before loading the cartridge into the syringe, the investigator vigorously shook the taped cartridge for 1 min. Because methyl prednisolone acetate separates out of solution upon standing, shaking of each cartridge ensured that, if the cartridge did contain methyl prednisolone, the drug was back in solution and ready for injection. The cartridge was placed in a standard aspirating syringe, and solution was deposited through the perforation site using a 27-gauge ultra short needle with light pressure¹⁷. The methyl prednisolone acetate (Depo-Medrol)or saline was delivered into the cancellous space over a 2-min time period. If deposition required more than light pressure, the needle was rotated 90 degrees and solution deposited.

In **Group III**, 20 patients are given antibiotic coverage penicillin (amoxicillin 500 mg) thrice daily for 3 days and recalled on 7th day for access opening and performing pulpectomy.

In **Group IV** 20 patients received intra-osseous injection using 2% lignocaine with 1:100000 adrenaline stabident system. Emergency access opening and pulpectomy attempted. Access cavity is temporized with IRM after occlusal reduction. Patients are recalled after 7 days for continuing Root canal treatment.

All 80 patients from 4 study groups received a questionnaire for survey. Twenty paracetamol tablets (Dolo 650) in a box were provided and asked to take only if severe pain persists. Patients were advised to note down the consumption of analgesics in the sheet for 7days and return the remaining tablets. Details about the dosage of medication and frequency were labelled on

the bottle. Patients were advised to take these tablets only if moderate or severe pain persists.

Each patient is asked to fill a 7-day questionnaire (survey) every day. They were instructed to record pain and percussion pain using the 4-point scale used for the initial pain recordings. Percussion pain was measured by tapping the tooth with the finger and rate the pain. Each patients recorded the number of tablets taken each day and severity of pain.

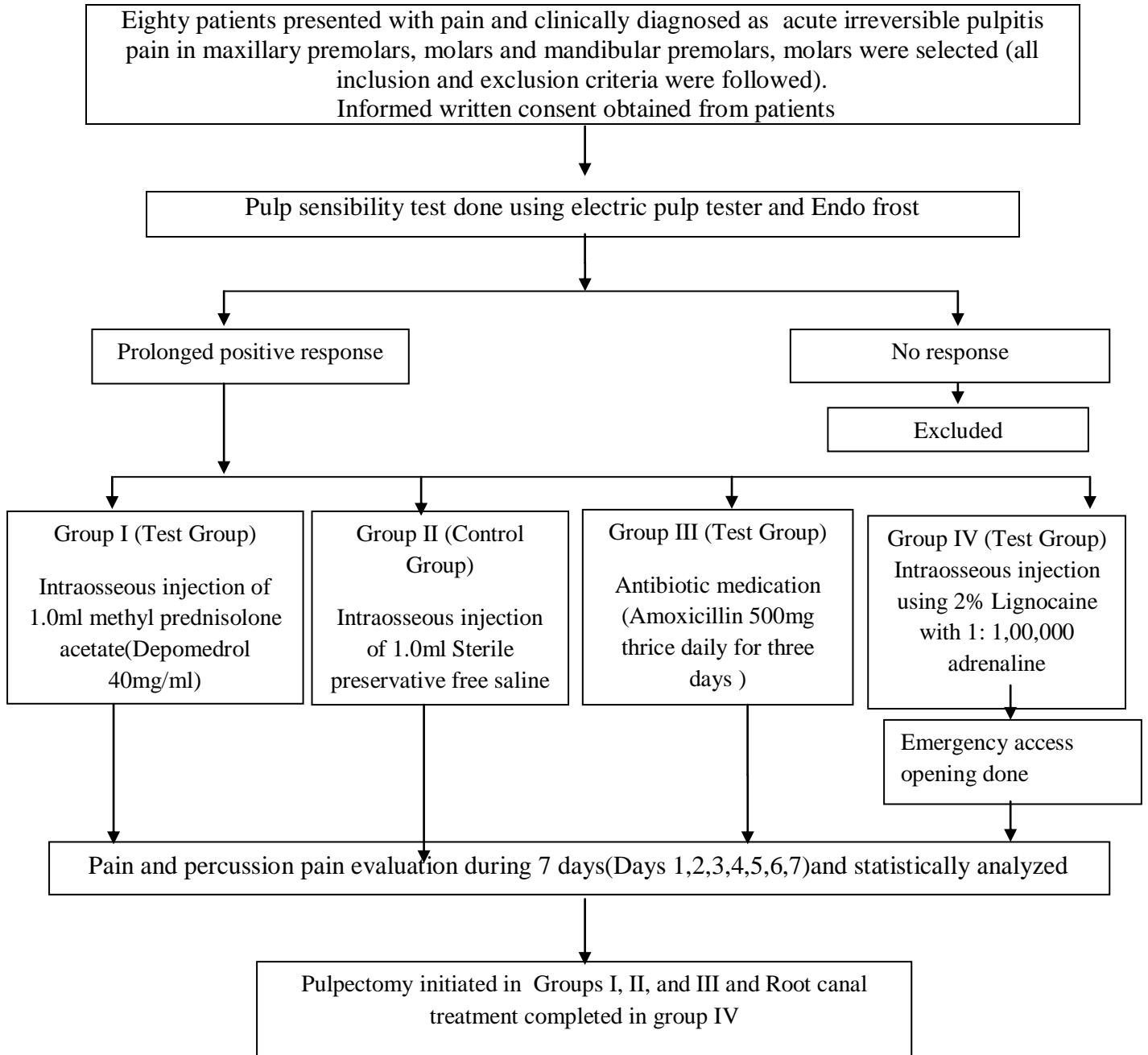
On recall appointment, pain evaluation is done in patients for the duration of seven days. Vitality was determined for each patient with electric pulp tester and Endo-frost before treatment. All patients were administered 2% lidocaine with 1:100000 adrenaline nerve block or infiltration. In groups I, II and III access opening is done and pulpectomy attempted. In group IV endodontic management is continued.

Data were collected and statistically analyzed. The preoperative parameters were statistically analyzed using the chi squared-test for nominally scaled variables (gender); the independent t test for ratio scaled variables (age); and the Pearson Chi square test for ordinally scaled variables (pain and percussion pain)is performed for all 4 study groups which participated in this study. Tooth vitality at the 7th day recall appointment was analyzed.

Ten adult patients volunteered in the pilot study who presented with moderate to severe pain .Participants in study group were divided into 2 groups of 5 each, These 10 patients were given an intra-osseous injection of either 1ml of methyl-prednisolone acetate (Depo Medrol) or 1ml

of saline (0.9% sodium chloride). Treatment procedure was explained in English and regional language and ethical clearance was obtained from the Institutional review committee of Ragas dental college and hospital, Chennai and pilot study is performed.

METHODOLOGY FLOW CHART



Figures

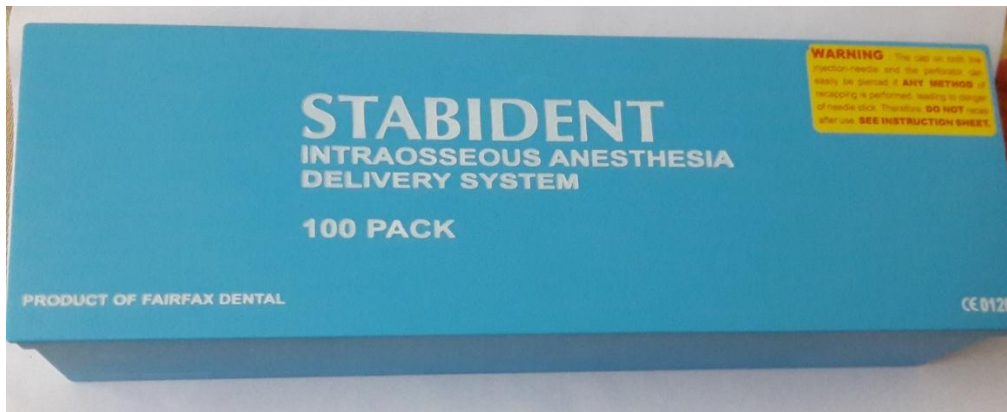


FIG.1: STABIDENT DEVICE USED FOR INTRAOSSEOUS INJECTION

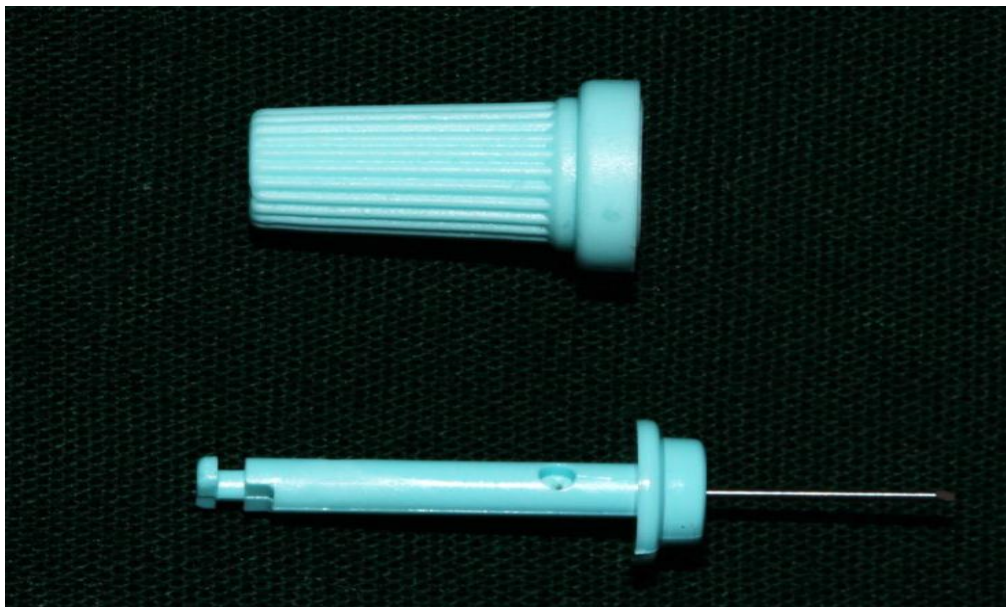


FIG.2: 27 GAUGE STABIDENT PERFORATOR

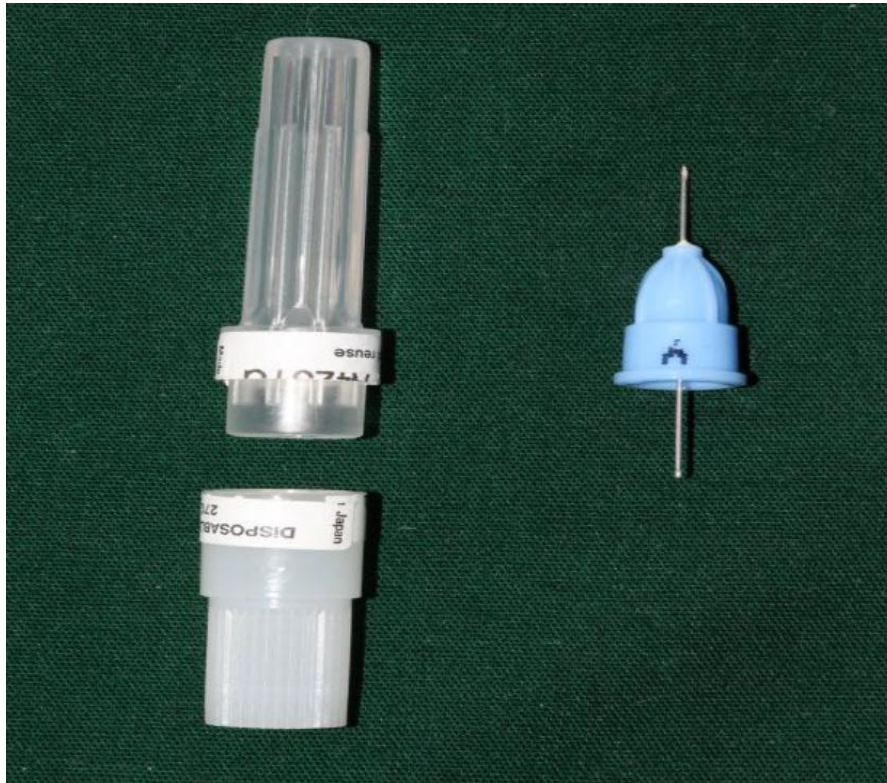


FIG.3: 27 GAUGE STABIDENT NEEDLE



FIG.4: NSK CONTRA-ANGLE HANDPIECE

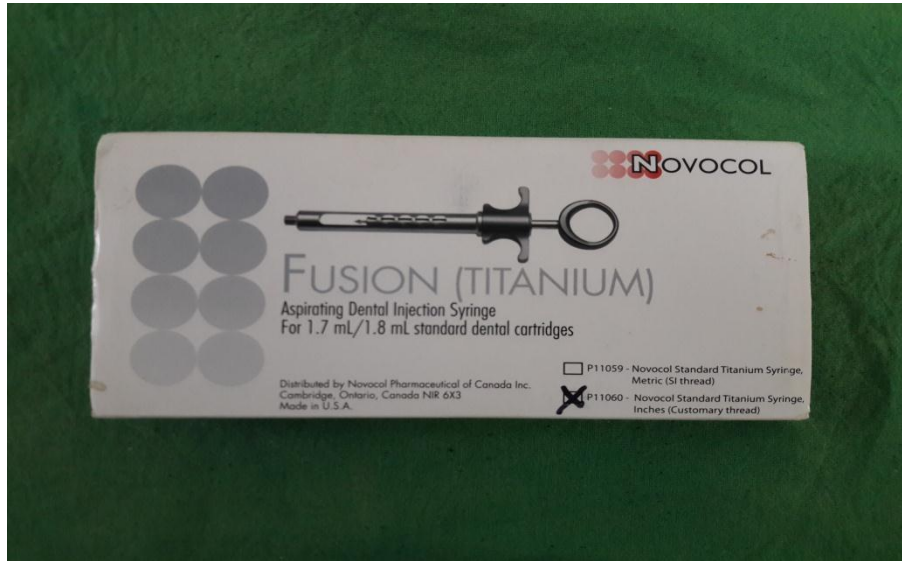


FIG.5: METAL, BREECH TYPE, CARTRIDGE LOADING ASPIRATING SYRINGE



FIG.6: 1.8 ML CARTRIDGES OF 2% LIDOCAINE WITH 1:1,00,000 ADRENALINE (LIGNOSPAN SPECIAL)



FIG.7: ARMAMENTARIUM



FIG.8: MEYHYL PREDNISOLONE ACETATE (DEPO-MEDROL)



FIG.9: PULP TESTING USING ENDO FROST



FIG.10: PULP TESTING USING ELECTRIC PULP TESTER



FIG.11: DEPO-MEDROL (METHYL PREDNISOLONE ACETATE)



FIG.12: NORMAL SALINE



FIG.13: PERFORATION USING STABIDENT PERFORATOR AT THE SELECTED SITE



FIG.14: METHYL PREDNISOLONE ACETATE (DEPO-MEDROL)/SALINE/LIGNOCAINE DEPOSITION USING 27 GAUGE ULTRA-SHORT STABIDENT NEEDLE

Results

RESULTS

Out of eighty adult volunteers who participated in the study, forty four (55%) were males and thirty six (45%) were females. They were in the age group of 18 – 35 years, with a mean age of 28 ± 4.9 years .

All the 80 patients participated in the study had acute pain and clinical diagnosis of acute irreversible pulpitis associated with the test tooth. Only permanent maxillary and mandibular posterior teeth were included in this study. **Table 1** summarizes the individual variables among the four test groups.

Group I-In 20 patients methyl prednisolone acetate (Depo-Medrol) injection and recalled for Root Canal Treatment on the 7 day.

Group II-20 patients were administered intra-osseous saline injection and recalled on the 7th day for Root Canal Treatment (control group).

Group III-20 patients prescribed with antibiotic prophylaxis (amoxicillin 500 mg thrice daily for 3 days) were recalled on 7th day for evaluation and Root Canal Treatment.

Group IV- 20 patients intra-osseous injection using 2% lignocaine with 1:100000 adrenaline is administered. Emergency pulpectomy performed. Patients are recalled on the 7th day for completion of root canal treatment.

Distribution of teeth in each study group is summarized in **table 2**.

Tables 3 and 4 shows details of age and sex distribution of patients who participated in the study. Pre-operative pain evaluation is done in 80

patients which are divided into 4 groups No difference is there between the 4 groups selected for the study regarding the preoperative parameters.

In groups I, II and IV (N-60 pts) were intra-osseous perforation with stabident system was performed .One patient out of sixty experienced pain during perforation. All sixty patients were free of pain during deposition of solution using Stabident intraosseous system.

In **table 5**, pain ratings after intra-osseous injection in all 4 groups for 7 days are summarized.

In group I, (methyl prednisolone acetate, 20 patients) all the patients were administered methyl prednisolone acetate (Depo medrol) intra-osseously with stabident system on emergency visit (day 0). On day one (next day) out of 20 patients 3 patients reported moderate pain and remaining 17 patients did not experience pain. On day two out of 20 patients 2 had moderate pain remaining 18 patients were free of pain. On day three only 1 patient reported of moderate pain and 19 patients did not experience any pain. On day four, all 20 patients were free of pain and this continued till day seven. None of the patients in this group required prescribed analgesics during this 7 day period. Pulpectomy is accomplished at the end of 7 day period under nerve block or infiltration.

In group II (control group-saline) on day one, (next day of administering saline using Stabident intraosseous system) 7 patients out of 20 had severe pain, 11 patients had moderate pain and 1 patient reported of mild pain and 1 patient did not experience any pain. 18 patients out of 20 patients

required analgesics due to pain on day one. On day two, 6 patients out of 20 had severe pain, 10 patients had moderate pain, 2 patients had mild pain and 2 patients did not experience pain. 9 patients out of 20 required analgesics on day two. On day three, 3 patients out of 20 continued to have severe pain, 6 patients had moderate pain, 5 patients had mild pain and 6 patients did not experience pain. 9 patients required analgesics. On day four, 2 patients had severe pain, 5 had moderate, 5 had mild pain and 8 patients did not experience pain. 8 patients needed analgesics. On day five, out of 20 patients 4 patients had severe pain, 4 patients had moderate pain, 4 patients had mild pain and 8 patients did not experience any pain. 8 out of 20 patients needed analgesics.

On day six, 3 patients out of 20 had severe pain, 4 had moderate pain, 5 had mild pain and 8 patients did not experience any pain. On day six, 7 patients needed intake of analgesics. On day seven, 3 patients (15%) reported with severe pain, 4 patients had moderate pain (20%) and 3 patients had mild pain (15%) where 10 patients did not experience any pain. 7 patients needed analgesics. Reduction in pain intensity in this group from day 0 over 7 day period can be attributed to the intake of analgesics. After pain evaluation and vitality testing pulpectomy was initiated in group II. 7 out of 20 patients reported pain and discomfort during access opening and pulpectomy under nerve block. Pulpectomy was achieved in remaining 13 patients without pain and discomfort.

In group III (antibiotic group), on day one (next day), 6 patients out of 20 reported to have severe pain, 7 patients had moderate pain, 3 patients

reported mild pain and 4 patients did not experience pain. 13 patients out of 20 reported intake of analgesics .On day two, 6 patients out of 20 had severe pain, 6 patients had moderate pain , 3 patients reported mild pain and 5patients did not experience pain.12 patients took analgesics. On day three, 3 patients out of 20 reported to have severe pain, 5 patients had moderate pain, 5 patients reported mild pain and 7 patients did not experience pain. On day three, 9 patients necessitated analgesics.

On day four, 3 patients had severe pain and 4 patients had moderate pain. 5 patients reported mild pain and 8 patients did not experience pain. 7 patients of this group needed analgesics. On day five, 4 patients had severe pain, 4 had moderate pain 4 patients reported mild pain and 8 patients did not experience pain, 7 patients needed analgesics. On day six, 4 patients out of 20 had severe pain, 3 had moderate pain, 4 patients reported mild pain and 9 patients did not experience pain. 7 patients needed analgesics. On recall appointment on 7th day, 3 (15%) patients reported of severe pain 4 patients had moderate pain 3 patients reported mild pain and 10 patients did not experience pain. 7 patients in this group continued to have analgesics from day one through day seven showing no significant pain relief with only antibiotics .2 Patients experienced discomfort while performing pulpectomy under nerve block on the 7th day. Remaining 18 patients pulpectomy was performed under nerve block without pain and discomfort. Complete pulpectomy was achieved in these patients.

In group IV, (2% lignocaine intra-osseous injection followed by pulpectomy is done on day 0) 6 patients reported to have pain and discomfort on day 0 while performing pulpectomy. Only partial pulpectomy was performed in 3 patients due to inability to achieve adequate anesthesia and patients experienced pain. On day one, 6 patients out of 20 had severe pain and 7 patients had moderate pain 4 patients reported mild pain and 3 patients did not experience pain. 10 Patients reported necessity for analgesics .On day two, 5 patients out of 20 patients reported of severe pain and 7 patients had moderate pain 4 patients reported mild pain and 4 patients did not experience pain 11 patients took analgesics. On day three, 4 patients out of 20 had severe pain and 5 patients had moderate pain 4 patients reported mild pain and 7 patients did not experience pain. 7 patients consumed analgesics.

On day four, 4 patients reported to have severe pain, 4 patients had moderate pain 5 patients reported mild pain and 7 patients did not experience pain. 8 patients required analgesics on these 3 days. On day five, 4 patients reported to have severe pain, 4 patients had moderate pain, 4 patients reported mild pain and 8 patients did not experience pain. 8 patients needed analgesics. On day six, 3 patients reported to have severe pain and 4 patients had moderate pain 4 patients reported mild pain and 9 patients did not experience pain.5 patients needed analgesics. On day seven, 4 patients (20%) reported severe pain, moderate pain is reported by 4 patients, 4 patients reported mild pain and 8 patients did not experience pain. 3 patients needed analgesics. 2 patients had severe pain and discomfort while performing

pulpectomy on the 7th day. Root canal treatment is completed in remaining 18 patients. In these 2 patients pulpectomy is reattempted under nerve block and patient recalled for continuing root canal treatment.

Table 6 summarizes the percussion pain in all 4 study groups.

In Group I methyl prednisolone acetate (depo-medrol group), 2 patients out of 20 had severe percussion pain on day one where as 18 patients did not experience percussion pain. On day two, 2 patients had severe percussion pain 3 patients had moderate percussion pain, 2 patients had mild percussion pain and 13 patients did not experience pain. On day three, 1 patient had severe percussion pain, 1 patient reported of moderate percussion pain, 4 patients had mild percussion pain and 14 patients did not experience percussion pain. On day four, 4 patients reported of mild percussion pain and 16 patients did not experience percussion pain. From day five to day seven none of the patients of this group reported of percussion pain.

In Group II (saline group-control) on day one, 7 patients out of 20 had severe percussion pain, 6 patients had moderate percussion pain, 6 patients reported mild percussion pain and 1 patient did not experience percussion pain. On day two, 7 patients had severe percussion pain and 9 patients had moderate percussion pain, 2 patients reported mild percussion pain and 2 patients did not experience percussion pain. On day three, 7 patients out of 20 had severe pain, 6 patients had moderate percussion pain, 4 patients reported mild percussion pain and 3 patients did not experience percussion pain. On day four, 4 patients out of 20 had severe percussion pain, 5 patients

had moderate percussion pain 8 patients reported mild percussion pain and 3 patients did not experience percussion pain. On day five, 5 patients had severe percussion pain, 4 had moderate percussion pain, 7 patients reported mild percussion pain and 4 patients did not experience percussion pain. On day six, 5 patients out of 20 had severe percussion pain, 5 had moderate percussion pain, 4 patients reported mild percussion pain and 6 patients did not experience percussion pain. They continued to take analgesics till day seven which resulted in reduction in percussion pain ratings in a small percentage. On day seven, 5 patients (25%) reported of severe percussion pain and 6 patients (30%) reported of moderate percussion pain 6 patients reported mild percussion pain and 3 patients did not experience percussion pain.

In Group III (Antibiotic Group), On day one (next day of starting antibiotic prophylaxis), 6 patients out of 20 reported of severe percussion pain, 7 reported of moderate percussion pain, 5 patients had mild percussion pain and 2 patients did not experience percussion pain .On day two, 7 patients had severe percussion pain , 8 patients had moderate percussion pain, 3 patients had mild percussion pain and 2 patients did not experience percussion pain. On day three, 6 patients out of 20 had severe percussion pain, 6 patients had moderate percussion pain, 5 patients reported mild percussion pain and 3 patients did not experience percussion pain. On day four, 4 patients out of 20 had severe percussion pain, 7 had moderate percussion pain, 6 patients reported mild percussion pain and 3 patients did not experience percussion pain. On day five, 5 patients had severe percussion pain, 5 had moderate

percussion pain, 7 had mild percussion pain and 3 patients did not experience percussion pain. Patients continued to take analgesics till day seven. On day six, 5 patients had severe percussion pain, 6 patients moderate percussion pain, 6 patients had mild percussion pain and 3 patients did not experience percussion pain. On day seven, 6 patients (30%) reported of severe percussion pain 6 patients had moderate pain, 6 patients reported mild percussion pain and 2 patients did not experience percussion pain.

In Group IV, Emergency access opening and pulpectomy is performed after administering intra-osseous 2% lignocaine with 1:100000 adrenaline on day zero. On day one (next day after lignocaine intraosseous injection and pulpectomy attempted), 3 patients reported of severe percussion pain, 4 patients of moderate percussion pain. 2 patients reported mild percussion pain and 11 patients did not experience pain. On day two, 4 patients had severe percussion pain, 5 patients had moderate percussion pain, 2 patients reported mild percussion pain and 9 patients did not experience any percussion pain. On day three, 3 patients had severe percussion pain, 2 patients had moderate percussion pain and 2 patients reported mild percussion pain .13 patients did not experience percussion pain. On day four, 2 patients had severe percussion pain, 3 patients had moderate percussion pain and 3 patients reported mild percussion pain .12 patients did not experience percussion pain. On day five, 2 patients had severe percussion pain, 2 moderate percussion pain 2 patients had mild percussion pain 14 patients did not experience any percussion pain. On day six, 3 patients out of 20 had severe percussion pain and 2 patients had

moderate percussion pain 2 patients reported mild percussion pain and 13 patients did not experience percussion pain. On day seven, 2 patients (10%) reported severe percussion pain and 3 patients had moderate percussion pain, 2 patients reported mild percussion pain and 13 patients did not experience percussion pain.

Table 7 to 14 summarizes the pain scale values of all patients from day one to day seven.

Table 15 illustrates the analgesics used by patients during this 7 day post-operative period when they had moderate to severe pain and discomfort. Statistically significant difference was there in pain and number of tablets consumed by the patients' among the 4 study groups.

Table 16 and 17 summarizes preoperative parameters (age and gender) of the study groups using t test and chi-square test. **Table 18** summarizes gender distribution using chi square evaluation in 4 methods.

Pulp sensibility testing is done with electric pulp tester and endo frost on day 0 and day 7 in group I,II and III.90% patients of methyl prednisolone acetate (Depo-medrol) group, 80% in patients of saline-control group and 85% patient in antibiotic group reported back with vital pulp on the seventh day. There was no statistically significant difference in the tooth vitality among groups I,II and III on the 7 day.

Table 19 to 22 illustrates chi square evaluation results of pain for all 4 study groups. There is significant difference in pain experienced by patients on the seventh day among 4 treatment groups Methyl prednisolone acetate

intraosseous injection was effective in reducing pain in conditions of irreversible pulpitis over 7 day period. .This is represented in **table 20**.

There is significant difference in percussion pain ratings experienced by patients in 4 groups over seven day period. This is represented in **table 22**.

Graph 1 is a bar graph showing the number of patients having pain for a duration of 7 days. **Graph 2** is a bar graph showing the number of patients having pain for a duration of 7 days.

Graph 3 and 4 compares mean pain for day 0 and day seven for methyl prednisolone acetate (depo Medrol) (group 1).

Graph 5 and 6 compares mean pain for day 0 and day seven for control group- saline (group 2).

Graph 7 and 8 compares mean pain for day 0 and day seven for antibiotic (group3) group.

Graph 9 and 10 compares mean pain for day 0 and day seven for lignocaine - emergency pulpectomy (group 4) group.

Evaluation of 4 study groups showed a significant reduction in acute irreversible pulpitis pain with intraosseous injection of methyl prednisolone acetate (Depo Medrol) when compared to control group saline, antibiotic group and emergency pulpectomy group The other 3 groups (group II,III and IV) required analgesics throughout seven day period to control pain. In Group I methyl prednisolone acetate group pulpectomy and Post endodontic restoration was performed with more ease and comfort when compared to other study groups.

Tables and Graphs

Table 1: TEST GROUPS

GROUPS	NUMBER OF PATIENTS	INJECTION TECHNIQUE	AGENTS
I	20	Intraosseous injection (Test group)	1.0ml Depomedrol (40mg/ml)
II	20	Intraosseous injection (Control group)	1.0 ml Sterile Saline
III	20	Oral medication (Test group)	Amoxicillin 500mg
IV	20	Intraosseous injection (Test group)	2% Lignocaine

Table 2: DISTRIBUTION OF TEETH CHART

MAXILLARY TEETH	NO	%	MANDIBULAR TEETH	NO	%
FIRST MOLAR			FIRST MOLAR		
Depo-Medrol	6	30	Depo-Medrol	3	15
Saline	5	25	Saline	2	10
Antibiotic prophylaxis	4	20	Antibiotic	3	15
2% Lignocaine	5	25	2% Lignocaine	1	5
SECOND MOLAR			SECOND MOLAR		
Depo-Medrol	4	20	Depo-Medrol	3	15
Saline	3	15	Saline	3	15
Antibiotic prophylaxis	4	20	Antibiotic	2	10
2% Lignocaine	3	15	2% Lignocaine	1	5
FIRST PREMOLAR			FIRST PREMOLAR		
Depo-Medrol	6	30	Depo-Medrol	2	10
Saline	5	25	Saline	2	10
Antibiotic prophylaxis	4	20	Antibiotic	1	5
2% Lignocaine	3	15	2% Lignocaine	1	5
SECOND PREMOLAR			SECOND PREMOLAR		
Depo-Medrol	3	15	Depo-Medrol	1	5
Saline	1	5	Saline	0	0
Antibiotic prophylaxis	2	10	Antibiotic	0	0
2% Lignocaine	2	10	2% Lignocaine	0	0

Table 3: AGE DISTRIBUTION

	N	Minimum	Maximum	Mean	Std. Deviation
Age (in years)	80	18	35	27.13	4.54

Table 4: SEX DISTRIBUTION

	Frequency	Percent
Male	44	55
Female	36	45
Total	80	100

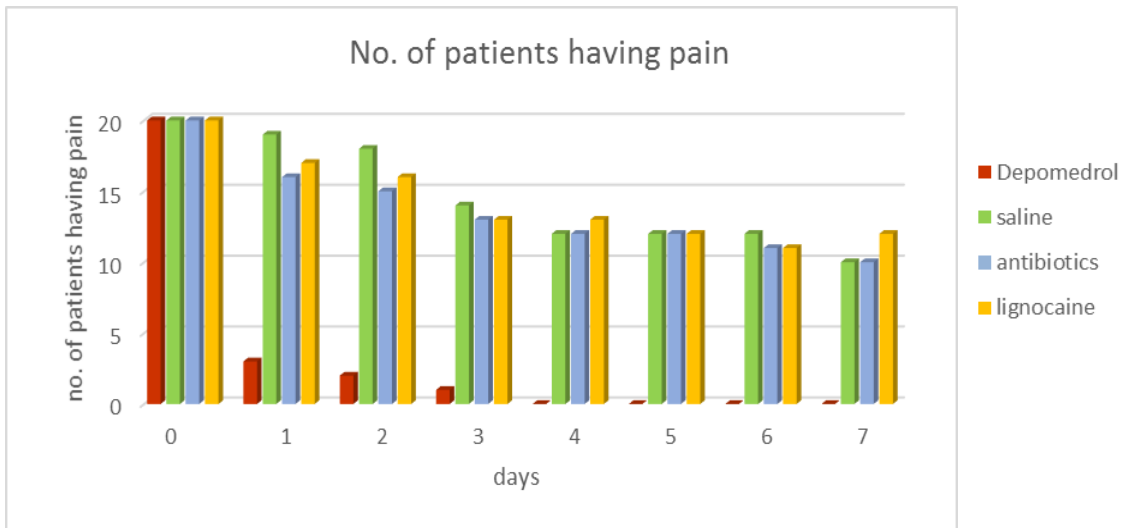
Table 5: PAIN RATINGS FOR BASELINE AND EACH POSTOPERATIVE DAY FOR 4 STUDY GROUPS

PAIN RATINGS						
Day	Method	0	1	2	3	No. of patients having pain
0	I (Depo-Medrol)	0	0	11	9	20
0	II (Saline)	0	0	13	7	20
0	III (Antibiotic)	0	0	9	11	20
0	IV (Lignocaine)	0	0	12	8	20
1	I (Depo-Medrol)	17	0	3	0	3
1	II (Saline)	1	1	11	7	19
1	III (Antibiotic)	4	3	7	6	16
1	IV (Lignocaine)	3	4	7	6	17
2	I (Depo-Medrol)	18	0	2	0	2
2	II (Saline)	2	2	10	6	18
2	III (Antibiotic)	5	3	6	6	15
2	IV (Lignocaine)	4	4	7	5	16
3	I (Depo-Medrol)	19	0	1	0	1
3	II (Saline)	6	5	6	3	14
3	III (Antibiotic)	7	5	5	3	13
3	IV (Lignocaine)	7	4	5	4	13
4	I (Depo-Medrol)	20	0	0	0	0
4	II (Saline)	8	5	5	2	12
4	III (Antibiotic)	8	5	4	3	12
4	IV (Lignocaine)	7	5	4	4	13
5	I (Depo-Medrol)	20	0	0	0	0
5	II (Saline)	8	4	4	4	12
5	III (Antibiotic)	8	4	4	4	12
5	IV (Lignocaine)	8	4	4	4	12
6	I (Depo-Medrol)	20	0	0	0	0
6	II (Saline)	8	5	4	3	12
6	III (Antibiotic)	9	4	3	4	11
6	IV (Lignocaine)	9	4	4	3	11
7	I (Depo-Medrol)	20	0	0	0	0
7	II (Saline)	10	3	4	3	10
7	III (Antibiotic)	10	3	4	3	10
7	IV (Lignocaine)	8	4	4	4	12

Table 6 : PERCUSSION PAIN RATINGS FOR BASELINE AND EACH POSTOPERATIVE DAY FOR 4 STUDY GROUPS

PAIN RATINGS						
Day	Method	0	1	2	3	No. of patients having pain
0	I (Depo-Medrol)	0	0	13	7	20
0	II (Saline)	0	1	9	10	20
0	III (Antibiotic)	0	2	8	10	20
0	IV (Lignocaine)	0	2	9	9	20
1	I (Depo-Medrol)	18	0	0	2	2
1	II (Saline)	1	6	6	7	19
1	III (Antibiotic)	2	5	7	6	18
1	IV (Lignocaine)	11	2	4	3	9
2	I (Depo-Medrol)	13	2	3	2	7
2	II (Saline)	2	2	9	7	18
2	III (Antibiotic)	2	3	8	7	18
2	IV (Lignocaine)	9	2	5	4	11
3	I (Depo-Medrol)	14	4	1	1	6
3	II (Saline)	3	4	6	7	17
3	III (Antibiotic)	3	5	6	6	17
3	IV (Lignocaine)	13	2	2	3	7
4	I (Depo-Medrol)	16	4	0	0	4
4	II (Saline)	3	8	5	4	17
4	III (Antibiotic)	3	6	7	4	17
4	IV (Lignocaine)	12	3	3	2	8
5	I (Depo-Medrol)	20	0	0	0	0
5	II (Saline)	4	7	4	5	16
5	III (Antibiotic)	3	7	5	5	17
5	IV (Lignocaine)	14	2	2	2	6
6	I (Depo-Medrol)	20	0	0	0	0
6	II (Saline)	6	4	5	5	14
6	III (Antibiotic)	3	6	6	5	17
6	IV (Lignocaine)	13	2	2	3	7
7	I (Depo-Medrol)	20	0	0	0	0
7	II (Saline)	3	6	6	5	17
7	III (Antibiotic)	2	6	6	6	18
7	IV (Lignocaine)	13	2	3	2	7

Graph 1: BAR GRAPH SHOWING THE NUMBER OF PATIENTS HAVING PAIN DURING SEVEN DAY PERIOD



Graph 2 : BAR GRAPH SHOWING THE NUMBER OF PATIENTS HAVING PERCUSSION PAIN DURING SEVEN DAY PERIOD

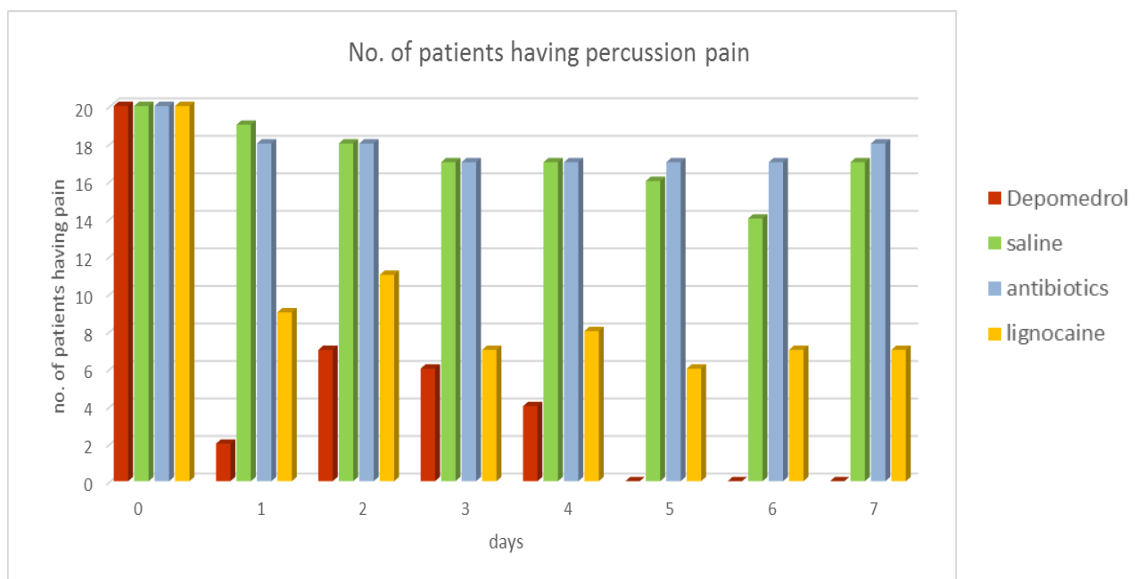


Table 7: PAIN RATINGS OF PATIENTS ON DAY 0 (BASELINE)

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	3	3	3	3
2	3	3	2	3
3	3	2	2	3
4	2	3	3	2
5	3	2	3	3
6	3	3	3	3
7	3	3	3	3
8	3	3	3	3
9	3	2	2	2
10	2	2	3	3
11	3	3	3	2
12	2	2	3	2
13	2	2	3	2
14	2	2	3	2
15	2	2	2	2
16	2	2	2	2
17	2	2	2	2
18	2	2	2	2
19	2	2	2	2
20	2	2	2	2

Table 8: PAIN RATINGS OF PATIENTS ON DAY 1

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	0	3	3	3
2	2	3	2	2
3	2	2	0	3
4	0	2	2	2
5	0	3	3	2
6	0	3	3	3
7	0	2	2	3
8	0	3	3	2
9	0	3	3	0
10	0	2	2	3
11	2	3	3	3
12	0	2	1	1
13	0	2	2	1
14	0	2	2	2
15	0	2	0	2
16	0	2	2	2
17	0	2	0	1
18	0	2	1	1
19	0	2	1	0
20	0	2	0	0

Table 9: PAIN RATINGS OF PATIENTS ON DAY 2

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	0	2	3	3
2	2	3	0	2
3	2	3	2	3
4	0	0	2	3
5	0	2	2	2
6	0	3	3	3
7	0	3	2	3
8	0	2	2	0
9	0	1	0	1
10	0	2	2	1
11	0	3	0	2
12	0	2	2	0
13	0	1	0	1
14	0	3	3	1
15	0	2	3	0
16	0	2	3	0
17	0	2	2	2
18	0	2	1	2
19	0	2	1	2
20	0	2	1	2

Table 10: PAIN RATINGS OF PATIENTS ON DAY 3

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	0	3	3	3
2	2	3	0	0
3	0	0	1	3
4	0	2	1	3
5	0	3	0	2
6	0	2	3	3
7	0	2	2	2
8	0	1	2	0
9	0	1	1	1
10	0	2	0	1
11	0	1	1	2
12	0	2	0	0
13	0	2	3	0
14	0	1	2	0
15	0	1	2	0
16	0	0	2	0
17	0	0	1	2
18	0	0	0	2
19	0	0	0	1
20	0	0	0	1

Table 11: PAIN RATINGS OF PATIENTS ON DAY 4

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	0	2	2	3
2	0	3	2	3
3	0	3	0	3
4	0	0	2	2
5	0	2	2	1
6	0	2	1	2
7	0	2	0	3
8	0	2	1	2
9	0	1	1	0
10	0	1	0	0
11	0	0	0	0
12	0	1	1	0
13	0	1	0	0
14	0	0	1	0
15	0	1	3	1
16	0	0	3	1
17	0	0	3	1
18	0	0	0	2
19	0	0	0	1
20	0	0	0	0

Table 12: PAIN RATINGS OF PATIENTS ON DAY 5

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	0	2	2	3
2	0	3	2	3
3	0	3	0	3
4	0	1	3	2
5	0	1	3	1
6	0	1	0	2
7	0	2	3	3
8	0	3	3	2
9	0	3	0	1
10	0	2	0	0
11	0	2	2	0
12	0	0	0	0
13	0	0	2	0
14	0	0	1	1
15	0	0	0	2
16	0	1	0	2
17	0	0	0	1
18	0	0	1	0
19	0	0	1	0
20	0	0	1	0

Table 13: PAIN RATINGS OF PATIENTS ON DAY 6

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	0	3	3	3
2	0	2	2	2
3	0	3	1	3
4	0	3	1	2
5	0	0	0	1
6	0	2	0	2
7	0	2	0	2
8	0	2	1	2
9	0	1	0	1
10	0	0	1	0
11	0	1	0	0
12	0	1	0	0
13	0	1	0	0
14	0	0	0	1
15	0	0	3	1
16	0	0	3	0
17	0	1	3	0
18	0	0	2	0
19	0	0	2	0
20	0	0	0	0

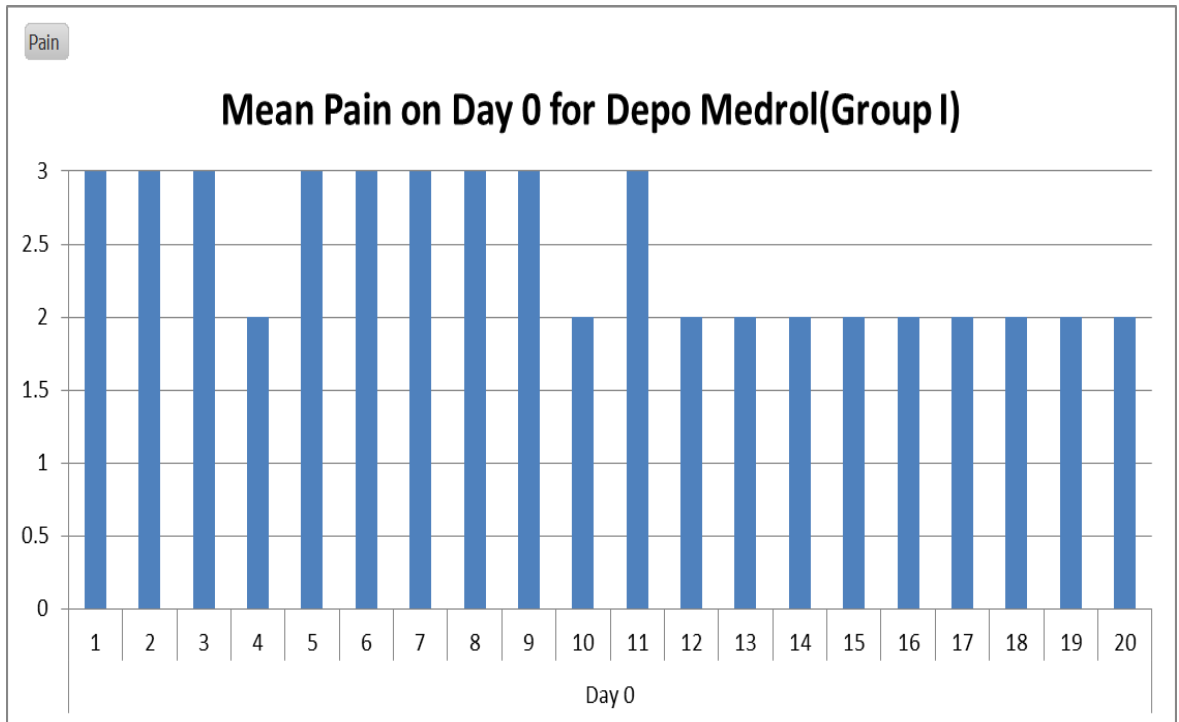
Table 14: PAIN RATINGS OF PATIENTS ON DAY 7

Patient No	Depo-medrol	Saline	Antibiotic	Lignocaine
1	0	3	3	3
2	0	3	2	2
3	0	2	1	3
4	0	3	1	2
5	0	2	1	2
6	0	2	0	2
7	0	1	0	3
8	0	0	0	2
9	0	1	0	1
10	0	1	0	1
11	0	0	0	0
12	0	0	0	1
13	0	0	3	1
14	0	0	2	0
15	0	0	3	0
16	0	0	2	0
17	0	0	2	0
18	0	0	0	0
19	0	0	0	0
20	0	0	0	0

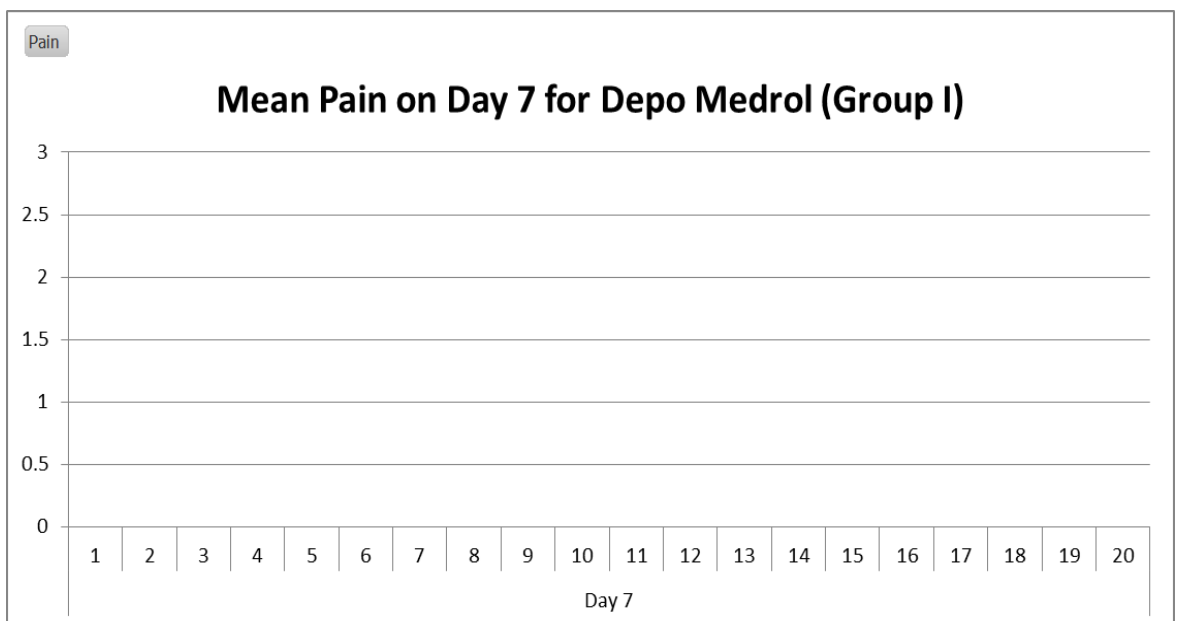
**Table 15: PAIN MEDICATION TAKEN BY PATIENTS OF 4
GROUPS DURING 7 DAY PERIOD**

Day	Method	No. of patients who took Dolo 650	No of tablets
1	I (Depo-Medrol)	0	0
1	II (Saline)	18	32
1	III (Antibiotic)	13	25
1	IV (Lignocaine)	10	24
2	I (Depo-Medrol)	0	0
2	II (Saline)	9	28
2	III (Antibiotic)	12	24
2	IV (Lignocaine)	11	20
3	I (Depo-Medrol)	0	0
3	II (Saline)	9	26
3	III (Antibiotic)	9	20
3	IV (Lignocaine)	7	20
4	I (Depo-Medrol)	0	0
4	II (Saline)	8	24
4	III (Antibiotic)	7	20
4	IV (Lignocaine)	8	18
5	I (Depo-Medrol)	0	0
5	II (Saline)	8	24
5	III (Antibiotic)	8	18
5	IV (Lignocaine)	8	15
6	I (Depo-Medrol)	0	0
6	II (Saline)	7	14
6	III (Antibiotic)	7	12
6	IV (Lignocaine)	5	9
7	I (Depo-Medrol)	0	0
7	II (Saline)	7	8
7	III (Antibiotic)	7	6
7	IV (Lignocaine)	3	4

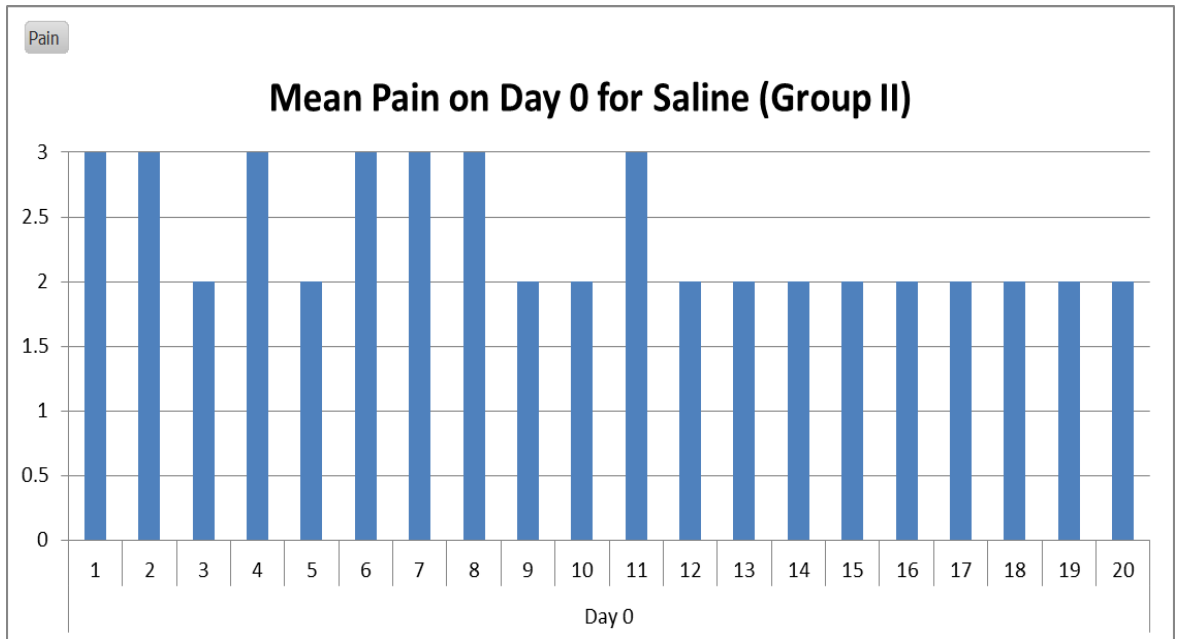
Graph 3: MEAN PAIN ON DAY 0 FOR DEPO MEDROL



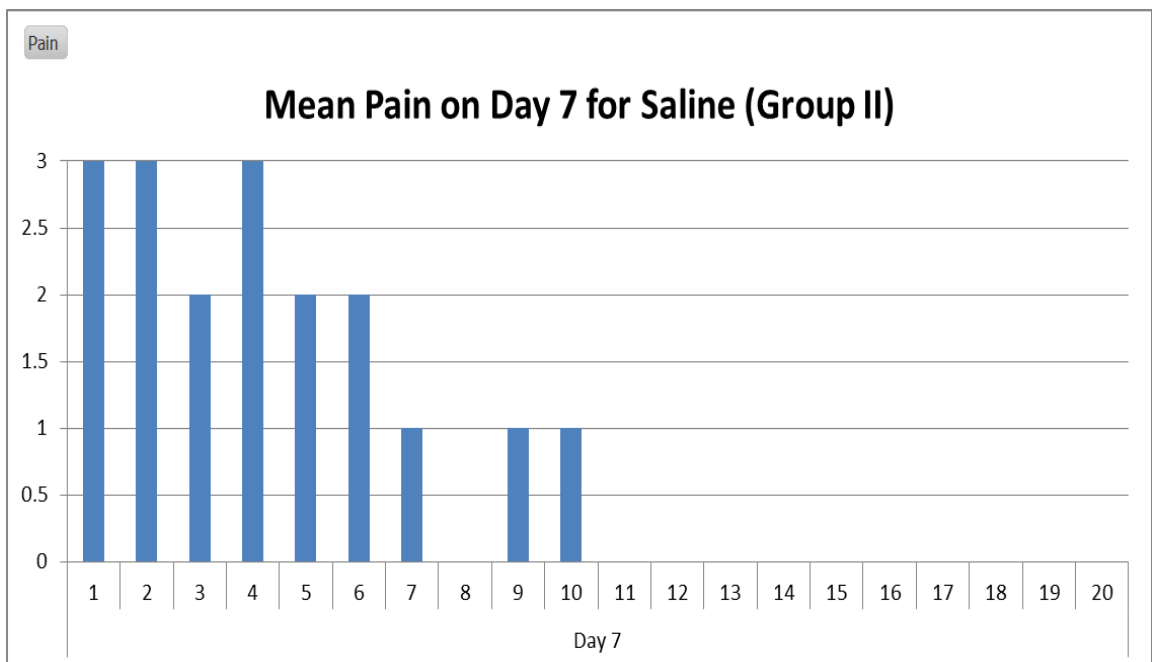
Graph 4 : MEAN PAIN ON DAY 7 FOR DEPO MEDROL



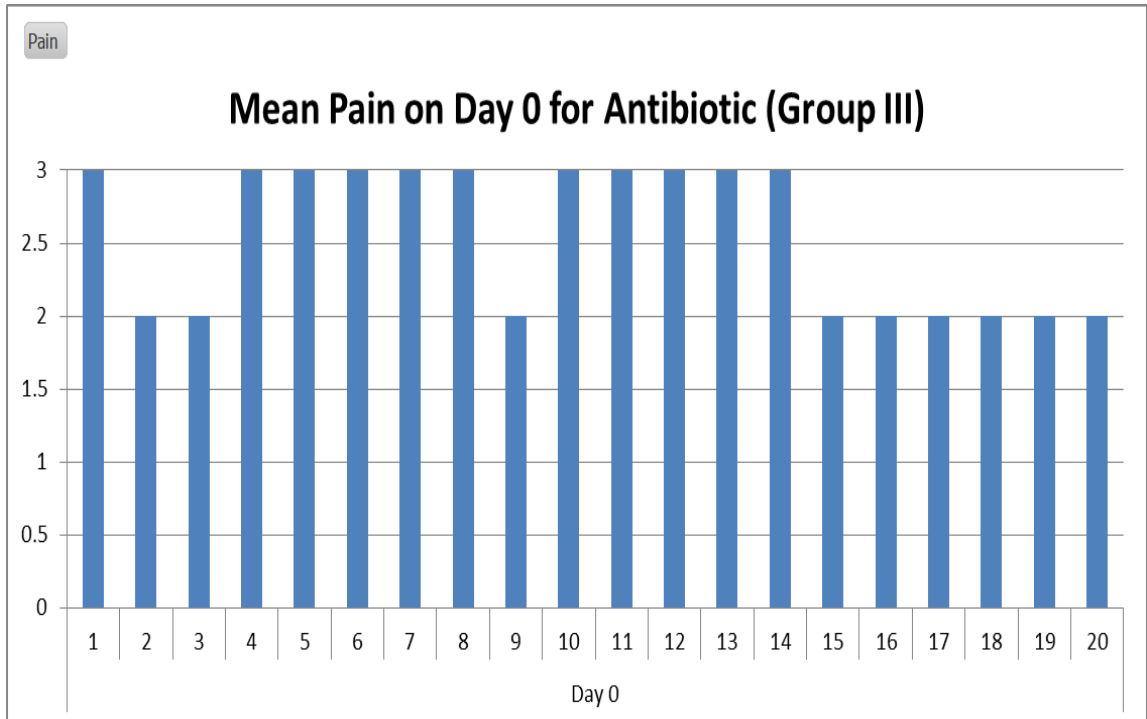
Graph 5: MEAN PAIN ON DAY 0 FOR SALINE



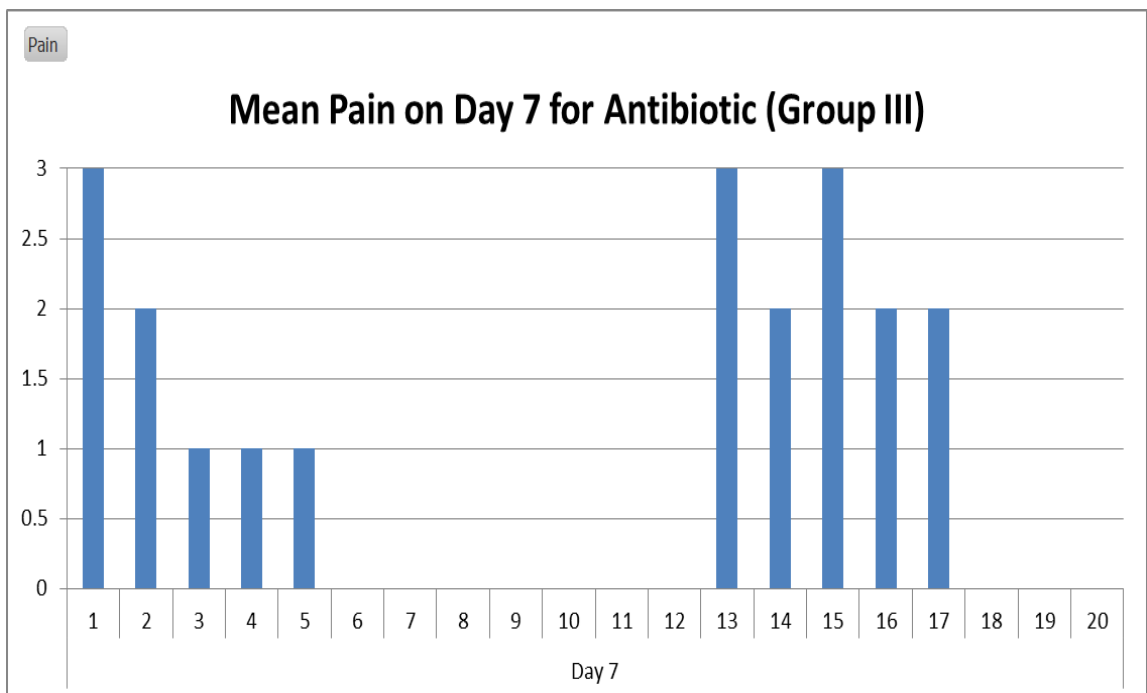
Graph 6: MEAN PAIN ON DAY 7 FOR SALINE



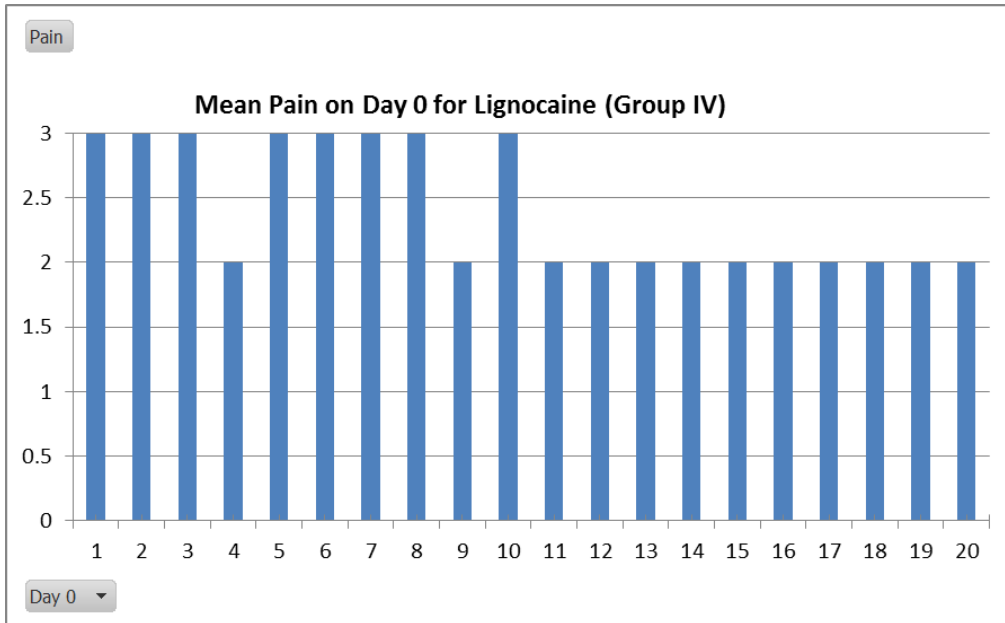
Graph 7: MEAN PAIN ON DAY 0 FOR ANTIBIOTIC



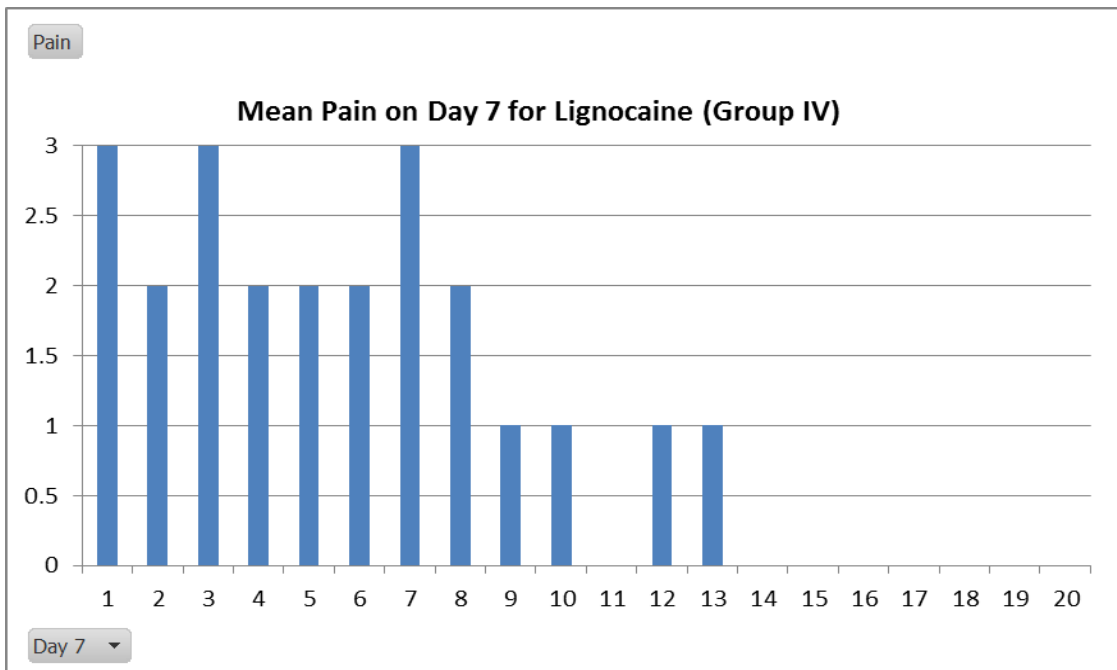
Graph 8: MEAN PAIN ON DAY 7 FOR ANTIBIOTIC



Graph 9 : MEAN PAIN ON DAY 0 FOR LIGNOCAINE



Graph 10 : MEAN PAIN ON DAY 7 FOR LIGNOCAINE



**Table 16: PRE-OPERATIVE PARAMETERS FOR GROUP I AND II
FOR RANDOMIZED DOUBLE BLIND STUDY**

Pre-operative parameters for Group I and II for randomized double blind study			
Variable	Depo Medrol	Saline	p-value
Age (mean \pm SD)	27.7 \pm 3.93	28.55 \pm 5.28	0.57

**Table 17: PRE-OPERATIVE PARAMETERS FOR GROUP I, II, III
AND IV**

Pre-operative parameters for Group I, II, III and IV					
Variable	Depo Medrol	Saline	Antibiotic	Lignocaine	p-value
Gender	12 F 8 M	10F 10 M	5F 15M	9F 11M	0.1542
Mean \pm SD	27.70 \pm 3.93	28.55 \pm 5.28	24.65 \pm 4.45	27.60 \pm 4.32	0.57

Table 18: RESULTS OF GENDER DISTRIBUTION IN VARIOUS TREATMENT GROUPS

Gender		Method I (Depo Medrol)	Method II (Saline)	Method III (Antibiotic)	Method IV (Lignocaine)	P Value
Female	Count	12	10	5	9	0.1542**
	Percentage	33.33 %	27.78 %	13.89 %	25.00 %	
Male	Count	8	10	15	11	
	Percentage	18.18 %	22.73 %	34.09 %	25.00 %	
Total	Count	20	20	20	20	
	Percentage	25.00 %	25.00 %	25.00 %	25.00 %	

**** Denotes significance at 5% confidence level**

Table 19: RESULTS OF PAIN IN VARIOUS TREATMENT GROUPS ON DAY 0

Day 0	Pain Ratings				P-Value
Method	0	1	2	3	
I (Depo-Medrol)	0	0	11	9	0.9945*
II (Saline)	0	0	13	7	
III (Antibiotic)	0	0	9	11	
IV (Lignocaine)	0	0	12	8	

**** Denotes significance at 5% confidence level**

Degrees of Freedom	9
Chi-Square	1.78
Critical Value	16.92

Since, chi-square is less than Critical Value, Null Hypothesis is accepted. There is no significant difference in pain ratings among the 4 groups with different treatment methods on day 0.

Table 20: RESULTS OF PAIN INVARIOUS TREATMENT GROUPS ON DAY7

Day 7	Pain Ratings				P-Value
Groups	0	1	2	3	
I (Depo-Medrol)	20	0	0	0	0.0295**
II (Saline)	10	3	4	3	
III (Antibiotic)	10	3	4	3	
IV (Lignocaine)	8	4	4	4	

**** Denotes significance at 5% confidence level.**

Degrees of Freedom	9
Chi-Square	18.53
Critical Value	16.92

Since, chi-square is more than Critical Value, Null Hypothesis is rejected. There is a significant difference in pain ratings among the 4 groups with different treatment methods on day 7.

Table 21: RESULTS OF PERCUSSION PAIN IN VARIOUS TREATMENT GROUPS ON DAY 0

Day 0	Pain Ratings				P-Value
Groups	0	1	2	3	
I (Depo-Medrol)	0	0	13	7	0.8847
II (Saline)	0	1	9	10	
III (Antibiotic)	0	2	8	10	
IV (Lignocaine)	0	2	9	9	

**** Denotes significance at 5% confidence level.**

Degrees of Freedom	9
Chi-Square	4.38
Critical Value	16.92

Since, chi-square value is less than Critical Value, Null Hypothesis is accepted. There is no significant difference in percussion pain ratings among the 4 groups with different treatment methods on day 0.

Table 22: RESULTS OF PERCUSSION PAIN in VARIOUS TREATMENT GROUPS ON DAY 7

Day 7	Pain Ratings				P-Value
Groups	0	1	2	3	
I (Depo-Medrol)	20	0	0	0	0.0001
II (Saline)	3	6	6	5	
III (Antibiotic)	2	6	6	6	
IV (Lignocaine)	13	2	3	2	

**** Denotes significance at 5% confidence level.**

Degrees of Freedom	9
Chi-Square	44.58
Critical Value	16.92

Since, chi-square is greater than Critical Value, Null Hypothesis is rejected. There is a significant difference in percussion pain ratings among the 4 groups with different treatment methods on day 7.

Discussion

DISCUSSION

In routine clinical practice, the most frequently encountered conundrum is treating acute irreversible pulpitis. The striking feature of symptomatic irreversible pulpitis is inflammation of pulp precipitating spontaneous to severe pain that remains even after the removal of the stimulus⁸⁰. In such cases, endodontic debridement is the most predictable method to relieve pain¹⁷. But there are many factors affecting the effective debridement of pulp during acute irreversible pulpitis. The main factor which determines effective total pulpectomy is achieving complete alleviation of pain with the help of local anesthetic agents. In most of the cases, complete local anesthesia to the pulp is unachievable and the patients' response to the local anesthesia remains unconvincing²⁹.

The success rate of local anesthesia for teeth with inflammation is reported <20% or very poor⁶⁹. Accepted hypothesis on how local anesthetic drugs prevent action potential transmission is that these drugs effectively blocks voltage dependent gates in the length of nerve fibers and prevent action potential creation. There are different types of voltage-dependent gates. One of these gates are tetrodotoxin-resistant gate. These voltage-dependent gates exists in the sensory nerve fibers which might increase in number in the inflammatory situation. This gate is hardly blocked by lidocaine, unlike other voltage- dependent gates, which might explain why teeth with acute irreversible pulpitis do not anesthetize easily.⁶⁹ When primary mode of

anesthesia is not achieved various supplemental anesthetic techniques are used to acquire adequate anesthesia like intra-ligamentary (periodontal ligament), intra-pulpal, intraosseous techniques⁶⁹. One of these methods is the administration of anesthesia by the intra-osseous approach with different anesthetic drugs⁵⁵. When patients have severe pain and needs to be controlled, anti-inflammatory agents are advised to defer the treatment. Various studies have reported regular analgesics such as benzodiazepenes (triazolam, alprazolam and diazepam) and NSAIDS in treating the pulpal pain where emergency pulpectomy is not achieved for pain reduction, in irreversible pulpitis cases. Clinicians have administrated steroids by intraosseous administration (Gallatin et al^{17,35}, Bramey et al^{6,35}) and orally (Claffy et al,³⁵ K  rour  dan et al²⁹). Steroids are useful in reducing pain associated with acute irreversible pulpitis due to their anti-inflammatory action by reducing PGE2 and IL-8 which are potent inflammatory mediators in acute irreversible pulpitis.²³ The purpose of using the Depo-medrol in the present study is to temporarily reduce the patient's symptoms until definitive endodontic treatment is performed. The painful symptoms might be reduced due to the anti-inflammatory effects of corticosteroid on the pulp. The steroid used in this study was methyl prednisolone acetate (40mg/ml).

According to manufacturers manual methyl prednisolone is a synthetic corticosteroid with anti-inflammatory and immunomodulating properties. It binds to specific nuclear receptors and activates them resulting in altered gene expression and inhibition of pro-inflammatory cytokine production. This agent

also decreases the number of circulating lymphocytes, induces cell differentiation, and stimulates apoptosis in sensitive tumor cell populations.

In this study, three experimental groups and one control group was employed, for evaluating pain reduction, in patients with acute irreversible pulpitis. In Group I, 20 patients were administered intra-osseous methyl prednisolone acetate (Depo-Medrol) injection on day 0 and recalled for evaluation and Root Canal Treatment on the 7th day.

In 1975, Lilenthal, first described the use of intraosseous injection technique. Intraosseous injection allows the deposition of solution directly into the inter-proximal bone adjacent to the tooth⁸. The two available intra-osseous systems are the Stabident® system (Fairfax Dental Inc., Miami, FL) and the X-tip system (Dentsply, York, PA). In the present study Stabident intraosseous system was used.¹⁸ The Stabident system consists of a hand piece driven perforator operated at slow speeds, a solid 27- gauge wire with a beveled end that drills a small hole through the cortical plate upon activation.¹⁹ X-Tip consists of consist of a 27-gauge perforator drill, a 25-gauge guide sleeve that fits over the drill, and a 27-gauge ultra-short needle . Once the drill leads the guide sleeve into the cancellous bone, it has to be removed and the guide sleeve left in place (through which the needle is directed into the cancellous bone.⁷⁰

The stabident intraosseous system was chosen to deliver methyl prednisolone acetate (depo- Medrol), because of its convenience and ease of delivering anesthetic solution. Oral dosing and patient compliance are

eliminated by this system and previous researches have shown that this system has rapid onset of action.^{17,46} This was proved to be more successful than periodontal ligament injection due to the increased delivery of anesthetic solution. The advantages of this method are minimal lingering numbness, more successful than IAN block for the teeth with acute irreversible pulpitis and the possibility to perform bilateral mandibular anesthesia due to the absence of anesthesia to lip and tongue in this technique, lesser volume of anesthetic solution is enough, the anesthetic solution can be added through the already produced perforation, if more amount of anesthesia needed.⁵⁵ The stabident system for intra-osseous injection are inexpensive start up, disposable costs, ease of operation and availability²⁷ and is mostly supported by peer reviewed research (Gallatin et al¹⁷, Brahmly et al⁶) as effective.

Previous researches have proved high doses of Methyl prednisolone acetate regimens when used with precautions are safe in routine treatment for a variety of disorders as routine treatment. Methyl prednisolone is a slow releasing acetate form which is usually administered for acute dermatitis and other diseases because of its prolonged anti-inflammatory effect in single high dose of 80-120mg which is repeated every 5 to 10 days if necessary¹⁷. As methyl prednisolone is in the slow releasing acetate form a 40mg dose currently prescribed in medicine was used in this study, considered very safe. The other reason for using 40mg dose in this study was because, this is the amount available in 1ml, and this will be appropriate as an intraosseous dose. Also at this dose effective anti-inflammatory effects can be achieved¹⁷.

Intraosseous injection can be used as primary anesthetic technique to achieve adequate pulpal anesthesia in both healthy and inflamed pulp⁷. Intraosseous injection when used as a primary anesthetic technique in non-inflamed teeth provides adequate pulpal anesthesia in 75% of mandibular molars and 93% of maxillary molar⁶⁹.

In a survey conducted by Bangerter et al taken among the US endodontists, the most common use of intraosseous injection was 62.19% for symptomatic irreversible pulpitis followed by 11.04% for reversible pulpitis, 7.06% for normal pulp and 4.91% for necrotic pulp. Intraosseous anesthesia was used most in posterior mandible (48.04%) followed by posterior maxilla (21.12%), anterior mandible (16.85%) and anterior maxilla(13.98%)⁸.

In group II, 20 patients were administered intra-osseous saline injection and recalled on the 7th day for pain evaluation and Root Canal Treatment (control group).

In Group III, 20 patients were prescribed oral prophylactic antibiotics (amoxicillin 500mg thrice daily for 3 days from day 0) and were recalled on 7th day for evaluation and Root Canal Treatment.

Efficiency of antibiotics alone in controlling pain and inflammation is still controversial, even though tetracyclines and macrolide antibiotics were proven to be effective in controlling inflammation in some studies⁶⁸. Investigations showed antibiotics are not useful in controlling pain in acute irreversible pulpitis, necrotic pulps and localized abscesses (Fouad et al, Nagle et al, Agnihotry et al).⁷⁹ Hence, administration of oral antibiotics were included

as an experimental group in this study to evaluate their ability in reducing pain associated with acute irreversible pulpitis.

In group IV, 20 patients, were administered with 2% lignocaine with 1:100000 adrenaline intraosseously . Emergency pulpectomy was performed on day 0, the access cavity temporized with IRM, occlusal relief provided and patients were recalled on the 7th day for evaluation of pain and continuation of the root canal treatment.

Parente et al⁴⁹ used the Stabident® intra-osseous injection in patients with irreversible pulpitis when conventional local anesthetic techniques failed.

When intraosseous injection was used as supplemental anesthesia in mandibular molars, Puspendra Kumar Verma⁷² (2013) achieved 93% success. His study showed that Supplemental X-tip intraosseous injection using 2% lignocaine with 1:80,000 epinephrine has a statistically significant influence in achieving pulpal anesthesia in patients with irreversible pulpitis. Kaitlyn Tom⁷⁰ (2015) revealed intraosseous injection as effective primary anesthetic technique in mandible using articaine⁷⁰. Ozer et al. reported 82.5 % success (47.5% higher than IANB) with IO injection using 1.5 mL of 4% articaine with 1:100,000 epinephrine.⁷⁰

Nusstein et al reported a supplemental mandibular intra-osseous injection using the Stabident® system with 1.8 ml of 2% lidocaine with 1:100,000 epinephrine was 91% successful in gaining total pulpal anesthesia for posterior teeth diagnosed with irreversible pulpitis⁴⁷.

Numerous chemical substances have been used in dentistry to make dental treatment a pain free procedure for the patients. The lidocaine, an amide local anesthetic, is widely used anesthetic solution .Various studies have compared the effect of different volumes of local anesthetic solution and concentration of epinephrine in the success of anesthesia. Fowler S et al and Parirokh et al found that there is no significant difference in anesthetic success between 3.6ml volume and 1.8 ml volume of 2% lidocaine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis.⁴² Wali et al studied by increasing the concentration of epinephrine to 1:50,000 or volume of lidocaine to 3.6 ml. His studies proved that increasing concentration of epinephrine did not result in more successful anesthesia.⁴²

The patients included in this study had a tooth with clinical diagnosis of acute irreversible pulpitis and actively had spontaneous, moderate to severe pain associated with maxillary premolars, molars, mandibular premolars or molars. They exhibited positive response to electric pulp testing and prolonged response to cold pulp testing with Endo-Frost. The teeth had history of spontaneous pain, percussion sensitivity. Pain and percussion pain was evaluated using the pain scale (0 to 3) given by Gallatin et al¹⁷. All patients were prescribed only 20 paracetamol tablets (dolo 650 tablets) and asked to consume in case of severe pain. Patients in all four groups were asked to return the remaining tablets on day 7 when they report back.

In group I, methyl prednisolone acetate (Depo-medrol)intraosseous injection was administered on emergency visit(Day 0) .While comparing the

pulpal pain, On day one, 3 out of 20 patients reported moderate pain and remaining 17 patients were free of pain. On day four, all 20 patients were free of pain and this continued till day seven. None of the patients of this group required prescribed analgesics during this 7 day period. Complete pulpectomy at the end of 7 day period following intraosseous injection of methyl prednisolone acetate was effective without any pain or discomfort to patients.

While comparing the percussion pain in Group1 [methyl prednisolone acetate], 2 patients out of 20 had severe percussion pain on day one, whereas 18 patients did not report of pain. From day four none of the patients of this group reported of percussion pain and continued till day 7. Over the seven day period there was reduction in pain probably due to the anti inflammatory effects of glucocorticoid (methyl prednisolone acetate). None of the patients in this group necessitated intake of analgesics to control pain. The results obtained in a similar study by Gallatin et al was in accordance to the study results in methyl prednisolone acetate group except that some patients in Gallatin et al study necessitated intake of analgesics to control severe pain during 7day period none of the patients in methyl prednisolone acetate (Depomedrol) group necessitated analgesics in this study.

There was a complete reduction in pulpal pain and the percussion pain after fourth day in methyl prednisolone acetate (Group I) probably due to the following reasons:

Glucocorticoids by their action on gene transcription prevents multiple cell production and factors vital for the production of inflammatory response. The action of glucocorticoids on gene transcription causes reduction in release of vasoactive and chemoactive factors and thereby reduction in secretion of lipolytic and proteolytic enzymes. This decreases the extravasation of leukocytes of tissue injury areas resulting in fibrosis. By inhibition of cytokine production, specific to interferon gamma, granulocyte/monocyte colony stimulating factor (GM-CSF), interleukins 1, 2, 3, 6 (IL-1, IL-2, IL-3, IL-6) and tumor necrosis factor alpha (TNF α) glucocorticoids opposes most of the inflammatory processes occurring during periapical inflammation³⁵.

Lipocortins represent body's natural 'NSAID-like' proteins. They reduces the synthesis of arachidonic acid by decreasing biosynthesis of cyclooxygenase and lipoxygenase products. They included substances like prostaglandins, thromboxane and leukotrienes.³⁵

Reductions in pulpal levels of both PGE₂ and IL-8 in cases of untreated irreversible pulpitis have been demonstrated after the administration of the glucocorticoid Depo-Medrol. In a double blind study of 40 patients intraosseous injection (IO) of either 40mg of methyl prednisolone acetate or sterile saline by Gallatin et al¹⁷, where no endodontic treatment was performed and the tooth was extracted at either 1 or 3 days after IO injection and pulp tissue was removed ex-vivo. Enzyme immunoassay of the pulp tissue showed a significantly lower concentration of PGE₂ at 1 day post steroid

injection. Treatment to endodontic patients with corticosteroids results in significant reductions in pulpal concentrations of PGE₂, with a trend towards a reduction in cytokine levels.²²

Glucocorticoids can induce synthesis of kinase II or angiotensin converting enzyme (ACE), which can lead to a reduction of bradykinin³⁵. Bradykinin has four main pro-inflammatory actions including vasodilation, increased vascular permeability, leukocyte chemo-attraction, and nociceptor activation. Bradykinin activates sensory nociceptors and elicits release of substance P, neurokinin A, and calcitonin gene-related peptide (CGRP) via receptors B1 and B2. Hargreaves & Costello have demonstrated reduction of bradykinin levels and postoperative pain by the administration of glucocorticoids using microdialysis probes in the oral surgery model³⁵.

Glucocorticoids if used for more than 2 weeks can cause widespread effects on many organ systems but mostly at supra physiological doses. It has been stated that ‘A single dose of glucocorticoid, even a large one, is virtually without harmful effects, and a short course of therapy up to 1 week) in the absence of specific contraindications, is unlikely to be harmful’. This was demonstrated in an *in vivo* study by Czerwinski et al.³⁵.

Bramy et al⁶ did a similar study using intra-osseous administration of corticosteroid for pain reduction of symptomatic and necrotic teeth. He did a study by administering either intra-osseous injection of 1ml methyl prednisolone (Depo-Medrol 40mg/ml) or 1ml of sterile saline placebo. A survey of pain and analgesics taken in this period was answered by all patients

in the study .The steroid group showed significantly less postoperative pain and required significantly less pain medication over 7days ($P_{0.05}$). Patients did not take any antibiotics at any time during the study^{6,35}.

In a follow-up study, Claffey et al evaluated pain reduction in symptomatic teeth with necrotic pulps using an oral dose regimen of methyl prednisolone. The materials and methods were nearly identical to Bramy et al⁶. except that no patient had clinical swelling and after the canal debridement, patients randomly received in a double-blind fashion either oral methyl prednisolone (48mg/day for 3days) or a placebo control (lactose 48mg/day for 3days). All patients received ibuprofen and Tylenol and pain recorded³⁵.The results showed that patients who received methyl prednisolone had significantly higher clinical success for the first 3days after endodontic treatment.

While comparing the pulpal pain in group II (control group-saline) on day one (next day of administering saline using Stabident intraosseous system), 7 patients out of 20 had severe pain, 11 patients had moderate pain and 2 patients reported of mild pain. Over the seven day period saline group patients continued to have pain and necessitated consumption of analgesics. On day seven, 3 patients (15%) reported with severe pain, 4 patients had moderate pain (20%)and 3 patients had mild pain (15%) whereas 10 patients did not report of any pain. After pain evaluation and vitality testing Pulpectomy was initiated in group II. 7 out of 20 patients reported pain and discomfort during access opening and pulpectomy under nerve block.

While comparing percussion pain in Group II (saline group-control) 7 patients out of 20 had severe percussion pain , 6 patients had moderate percussion pain, 6 patients reported mild percussion pain and 1 patient did not experience percussion pain on day one. This group patients experienced percussion pain throughout the 7 day period even after consuming analgesics .On day seven, 5 patients (25%) reported of severe percussion pain and 6 patients (30%) reported of moderate percussion pain 6 patients reported mild percussion pain and 3 patients did not report of percussion pain.

There is no effective reduction in pulpal pain and percussion pain in intraosseous injection of saline group because saline does not have any anti-inflammatory or analgesic effects. Saline group patients took significantly more number of analgesics during this seven day period when compared to other 3 groups and this had a significant effect on post operative pain ratings. Reduction in pain in the remaining 13 out of 20 patients could be attributed to the usage of analgesics. One patient who did not experience pain on the end of second day probably due to the pulp becoming necrotic. Post operative pain reduction in 13 patients can also be due to natural anti-inflammatory response. The increased number of pain and percussion pain in this group over seven day period demonstrates many teeth with irreversible pulpitis remain symptomatic for atleast 1 week. This was similar to the study results of Gallatin et al where saline group patients necessitated more number of analgesics than methyl prednisolone acetate (depo medrol) group¹⁷ .

In group III (antibiotic group) , on day one ,6 patients out of 20 reported to have severe pain and 7 patients had moderate pain 3 patients reported mild pain and 4 patients did not report of pain. 13 patients out of 20 necessitated intake of analgesics. Patients in this group necessitated analgesics for controlling pain over 7 day period. On recall appointment on seventh day 3(15%) patients reported of severe pain 4 patients had moderate pain 3 patients reported mild pain and 10 patients did not report of pain .2 Patients exhibited discomfort while performing pulpectomy under nerve block on the 7th day.

In Group III (Antibiotic Group), On day one,6 patients out of 20 reported of severe percussion pain and 7 reported of moderate percussion pain, 5 patients had mild percussion pain and 2 patients did not report of any percussion pain . On day seven, 6 patients (30%) reported of severe percussion pain, 6 patients had moderate percussion pain, 6 patients reported mild percussion pain and 2 patients did not report of percussion pain.

Antibiotics and analgesic were prescribed to relieve pain and inflammation. However, there is debate in the literature as to whether the prescription of antibiotics is necessary. Antibiotic effectiveness is related to both the type and concentration of the antibiotic. If antibiotics reach the target tissues in therapeutic concentrations they will be effective in managing endodontic infections and reducing endodontic symptoms, but this is a concern in pathological conditions, where the tissues may have reduced blood flow or may even become necrotic¹⁵

As early as 1962, Goldman & Pearson recognized that a number of microorganisms cultured from the necrotic pulp specimens are resistant to penicillin. If there is a spreading infection due to the failure of local host responses inhibiting the advancing bacterial irritants, exposing the patient to higher systemic risks, consider administration of systemic antibiotics¹⁵. The effectiveness of antibiotic administration in acute irreversible pulpitis conditions or the choice of antibiotic to use is not predictable, due to the polymicrobial nature of endodontic infections, and the fact that systemic antibiotics may not reach the source of bacterial proliferation, such as the necrotic pulp, in sufficient concentrations¹⁵.

There was no effect of antibiotics on reduction of pulpal pain and percussion pain as such. Hence, the reduction in the pulpal and percussion pain in Group III during these 7 days period can be attributed to the usage of analgesics.

In Group IV, Emergency access opening and pulpectomy is performed after administering 2% lignocaine with 1:100000 adrenaline intraosseously on day zero. Pulpectomy was performed in 14 patients without pain, 6 patients reported to have pain and discomfort on day 0 while performing pulpectomy. Only partial pulpectomy was performed in 3 patients due to inability to achieve adequate anesthesia and patients experienced pain. On day one, 6 patients out of 20 had severe pain and 7 patients had moderate pain 4 patients reported mild pain and 3 patients did not experience pain. 10 Patients reported the necessity for analgesics Over the 7 day period 3 patients

reported no pain because complete pulpectomy was possible in them under intraosseous 2% lignocaine. Other 17 patients experienced pain and necessitated analgesics. Out of these On day seven ,4 patients (20%) reported severe pain, moderate pain is reported by 4 patients, 4 patients reported mild pain and 8 patients did not experience pain .3 patients needed analgesics. 2 patients had severe pain and discomfort while performing pulpectomy on the 7th day

On day seven, 2 patients (10%) reported severe percussion pain and 3 patients had moderate percussion pain, 2 patients reported mild percussion pain and 13 patients did not report of any percussion pain.

The emergency pulpectomy performed using 2% lignocaine on day 0 was subjective as they vary according to each patient.6 patients had severe pain and discomfort and only partial pulpectomy was performed in 3 patients on day 0.This was probably due to inability to achieve profound anesthesia in inflammatory conditions due to the following reasons:

Wallace et al. demonstrated that the local anesthetic agents are not sufficient to prevent impulse transmission as a result of their lower excitability thresholds in cases of acute irreversible pulpitis.⁶⁹ There are few factors that led to the increased failure rate of local anesthesia in acute irreversible pulpitis.

1. The central core theory according to America Association of Endodontists states that the nerves on the outside of the nerve bundle supply molar teeth, and nerves on the inside supply incisor teeth.

2. Local acidosis (lowering of ph) due to tissue inflammation causes trapping of ions in local anesthetic molecules. As a result, the local anesthetic molecules which crosses the nerve membrane reduces. There is less of the ionized form within the nerve to achieve anesthesia.^{1,69,33}
3. Activation of nociceptors by inflammatory mediators can be another reason for the failure of anesthesia.
4. Central sensitization which is the increased excitability of central neurons and is a major central mechanism which can lead to hyperalgesia.⁶⁹

The suggested hypotheses for reduction in mechanical pain thresholds in teeth with irreversible pulpitis includes³⁰

- Sensitization of pulpal mechanoreceptors
- Sensitization of peri radicular mechanoreceptors
- Result of central sensitization

Anatomical factors, thickness and density of alveolar bone, decreased pain threshold, action of inflammatory mediators like bradykinin and prostaglandins, incomplete blockage of impulse transmission due to central sensitization are other accepted reasons for anesthetic failures³⁵.

On comparison of the 4 experimental groups, intraosseous injection of methyl prenisolone acetate produced significant reduction in pain and percussion pain ($p < 0.0001$) over 7 day observation period when compared to

control group saline, antibiotic group and emergency pulpectomy group. Pulp testing on seventh day showed that 92% of patients of group I had vital pulp. On day seven in group I when pulpectomy was performed under nerve block all the patients were pain free and comfortable and complete pulpectomy was achieved. This can be probably due to the anti-inflammatory effect of corticosteroids

On day seven , 92 percentage of patients in methyl prednisolone acetate group(depo medrol group) , 80 percentage of patients of saline group and 85 percentage in antibiotic group had vital pulp and had haemorrhagic vital tissue on coronal access. These differences were not of much statistical significance and the teeth remained vital due to the anti-inflammatory effects of methyl prednisolone acetate(Depo-medrol) in group I. 20% patients (4 patients) in the saline group(group II) tested negative response to vitality test probably, pulp had undergone necrosis .However, remaining 80 percentage of patients(16 patients)had vital pulp, the time taken for degeneration of pulp to take place and become necrotic is not clinically proved in studies. 85% of patients of antibiotic group(III) had vital pulp as antibiotics do not reduce the pain associated with symptomatic irreversible pulpitis ,in the absence of any systemic involvement¹⁵.The poly microbial nature of the infection, and the empirically prescribed antibiotic (Amoxycillin 500 mg) , a broad spectrum antibiotic not eliminating the infection could be the reasons for persistent infection⁷⁹. It is assumed that irreversibly damaged pulp will continue to

degenerate until pulp becomes necrotic if this condition is not endodontically treated¹⁷.

Number of analgesics taken by all the 4 group patients are recorded to obtain quantifiable number. Over 7 day period no patients of methyl prednisolone group took analgesics which reflected the overall pain experience of this study group reduced. On day one, 18 patients of saline group, 13 patients of antibiotic group and 10 patients of lignocaine group required analgesics for pain control. These 3 group patients continued to take analgesics over 7 day period. On day seven, 7 patients of saline group, 7 patients of antibiotic group and 3 patients of lignocaine group required analgesics. . Reduction in pain in these groups over 7 day period is attributed to the usage of analgesics.

To summarize, patients with emergency conditions like acute irreversible pulpitis, where analgesics may not alleviate pain, it can be managed temporarily by using methyl prednisolone acetate (Depo-medrol) until endodontic management is initiated. In situations, where attaining complete anesthesia is not possible due to the inflammatory condition of the pulp; due to increased number of patients in practice creating lack of time; lack of staff support where emergency patients cannot be effectively treated; coronal or root anatomy which makes pulpal debridement impossible; calcified canals or extreme painful conditions due to unknown reason where complete pulpectomy cannot be attained on emergency visit; An intraosseous injection

of methyl prednisolone acetate (Depo-medrol) can alleviate patients pain to a manageable level whence endodontic management can be performed with ease and comfort.

Further studies need to be conducted on the effect of various glucocorticoids, on their dosage, route of administration and on their ability to alleviate pain associated with acute irreversible pulpitis and periapical periodontitis.

Summary

SUMMARY

The present study was to evaluate the efficiency of intraosseous injection of methyl prednisolone acetate (Depo-medrol 40mg/1ml) in reducing pain in untreated and treated acute irreversible pulpitis.

80 patients between age groups 18 to 35 years with acute irreversible pulpitis in posterior teeth were selected in the study and informed consent was obtained. Pulp sensibility tests were done using Electric Pulp Tester and Endo Frost in all patients. They were then divided into 4 groups. **Group 1-** (20 patients) were administered intra-osseous methyl prednisolone acetate (Depo-Medrol) injection and recalled on the 7th day for pain evaluation and pulpectomy **Group 2-** (20 patients) were administered intra-osseous saline injection and recalled on the 7th day for pain evaluation and pulpectomy (control group). **Group 3-** (20 patients) prescribed with antibiotic prophylaxis (amoxycillin 500 mg thrice daily for 3 days) were recalled on the 7th day for pain evaluation and pulpectomy. **Group IV-** (20 patients) intra-osseous injection using 2% lignocaine with 1:100000 adrenaline is administered and emergency pulpectomy was performed on day 0. Access opening done and cavity was temporized with IRM cement. Patients were recalled on the 7th day for pain evaluation and continuing root canal treatment.

All 80 patients from the 4 study groups received a questionnaire (survey) for pain evaluation. Twenty paracetamol tablets (Dolo 650) were also provided and patients were asked to take only if severe pain persists. The

patients rated their pain in a numeric scale introduced by Gallatin and noted down the number of analgesics consumed for 7days and returned the remaining tablets.

On the recall appointment, the questionnaire was evaluated. Pulp sensibility test was performed for each patient with electric pulp tester and Endo frost before performing pulpectomy. All patients in groups I, II and III were administered 1ml of 2% lidocaine with 1:100000 epinephrine by nerve block or infiltration and pulpectomy was initiated. In group IV patients root canal treatment was continued. Data were collected and statistically analyzed using Chi square evaluation.

Conclusion

CONCLUSION

1. Intraosseous injection of methyl prednisolone acetate is safe to administer in patients.
2. Intraosseous injection of methyl prednisolone acetate is effective in reducing pain in cases with acute irreversible pulpitis.
3. Patients who were injected intraosseous methyl prednisolone acetate did not require prescribed analgesics for 7 day period.
4. Complete Pulpectomy at the end of 7 day period following intraosseous injection of methyl prednisolone acetate could be achieved
5. Complete pulpectomy is achieved in patients who are administered methyl prednisolone acetate without pain and discomfort.
6. Intraosseous injection of saline was safe in acute irreversible pulpitis patients.
7. Control group who were administered intraosseous saline injection had pain during seven day period and necessitated taking of analgesics.
8. Intraosseous saline injection was not effective in reducing pain in acute irreversible pulpitis.
9. No effective reduction in pain was perceived in patients of prophylactic antibiotic group
10. Patients of antibiotic group necessitated taking prescribed analgesics during 7 day period to alleviate pain.

11. In patients who were administered 2% lignocaine intraosseous injection with 1:100000 adrenaline, pain was experienced during pulpectomy.
12. Complete pulpectomy was not achieved in 2% lignocaine intraosseous group on day 0.
13. Emergency pulpectomy group needed analgesics during 7 day period to alleviate pain.
14. Profound anesthesia, pain reduction and ability to perform pulpectomy with comfort was achieved in patients who were administered methyl prednisolone acetate (Depo-medrol) compared to control group (saline), antibiotic prophylaxis group and patients where emergency pulpectomy performed with 2% lignocaine containing 1:100000 adrenaline on day 0.

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Annexures

ANNEXURE -I

CONSENT FOR ANESTHETIC TECHNIQUE

I ----- hereby acknowledge that my doctor has explained to me that i will have to undergo root canal treatment with local anesthesia in the particular region. He also explained to me about the expected treatment outcome and what could happen if my condition remains untreated.

I also understand that instead of anesthetic agent a single dose corticosteroid injection is given to me so that my doctor can perform the root canal procedure with subsided underlying pain and inflammatory changes. It has been informed that all forms of anesthesia and drugs involves certain risks, although rare, could include pain, swelling, bleeding tendency, infection, nerve damage, and some unexpected reactions.

The aim is to deposit drug in the gum region as closely as possible to the tip of the tooth root with pain and need to undergo root canal treatment and also into the adjacent bone. The drug used will be saline or depomedrol (Methylprednisolone acetate 40mg/ml single injection which is a glucocorticoid with anti-inflammatory effect. It has been explained to me that sometimes an anesthetic technique which involves the use of local anesthetic agent may not succeed completely and therefore a new technique or drug needs to be advocated to alleviate pain during the procedure technique. The expected result of this drug is subsided inflammation to ease the success of root canal treatment. The procedure involved is administering the drug near nerve end where by pain and underlying inflammation is controlled. I acknowledge that I have admitted all my medical conditions and the medicines taken by me for the same without hiding anything. I certify and acknowledge that I have read this form or had it read to me, that I understand the risks, alternatives and expected results of the technique; and that I had ample time to ask questions and to consider my decision.

Date and time

Patient's signature

Substitute's signature

Witness

Relationship to patient

If Illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

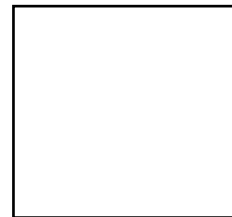
Print name of witness _____ AND

Thumb print of participant

Signature of witness _____

Date _____

Day/month/year



ANNEXURE -II

குளுக்கோர்டிகாய்ட் ஊசி (Glucocorticoid Injection)**ஏற்றிக் கொள்வதற்கான ஒப்புதல் படிவம்**

என் சம்மதத்தின் பேரிலும், மருத்துவரின் வேர் சிகிச்சைக் குறித்து தெளிவான கீழ்க்கண்ட விளக்கத்தின் பேரிலும் "வேர் சிகிச்சை" செய்துகொள்ள இதன் மூலம் ஒப்புதல் அளிக்கிறேன். மருத்துவர், நான் வேர் சிகிச்சைக்கு உட்பட வேண்டும் என்றும் அதன் பொருட்டு உள்ளூர் மயக்க மருத்தின் மூலம் வேர் சிகிச்சை செய்ய வேண்டிய பகுதி மரத்துப்போகும் நிலைக்கு உட்படுத்துதல் வேண்டும் என்றும் அதனால் ஏற்படும் விளைவுகளையும், அவ்வாறு நான் சிகிச்சைமேற்கொள்ளாவிடில் ஏற்படும் விளைவுகளைக் குறித்தும் விளக்கினார்.

குறிப்பிட்ட பகுதியில் உறுப்பிட உணர்வு நீக்க மயக்கமருத்து கொடுத்து ஒற்றை அல்லது கார்டுகொள் புராய்டு ஊசி (Corticosteroid Injection) ஏற்றிக்கொண்டால் மருத்துவர் வேர் சிகிச்சையை மேலும் எளிதாக மேற்கொள்ளும் வகையில் அறமயும். மேலும் சிகிச்சை பெறுபவர்க்கு குறைந்த வலி மற்றும் வீக்கம் குறைவாக ஏற்படும் என்று விளக்கினார். பொதுவாக மயக்கத்தினை உண்டாக்கும் பெரும்பான்மையான மருத்துகள் சில தருணங்களில் சில பக்க விளைவுகளை சதாரணமாக உண்டாக்கும். ஆனால் அவை வெகு சிலருக்கே ஏற்படுவதுண்டு, குறிப்பாக வீக்கம், ரத்தப்பீபாக்கு, நரம்பு பாதிப்பு மற்றும் எதிர்பாராத சில எதிர்விளைவுகளை ஏற்படுத்தும்.

இந்த ஊசியினை சிகிச்சை பெறப்போகிறவர்க்கு ஏற்றுவதன் நோக்கம், இந்த மருத்தினை பல்லின ஈறு பகுதியில் பல்லின் வேர் பகுதிக்கு அருகாமையிலும், அதன் அருகாமையில் உள்ள எலும்பு பகுதிக்கும் செலுத்தி எத்தவித வலியையும், சிகிச்சை மேற்கொள்பவர் உணராவண்ணம் இருக்கவே செலுத்தப்படுகிறது. இந்த ஊசி உப்புத்தன்மையுடைய அல்லது டிபோமெட்ரால் (Depomedrol) (Methyl Prednisolone acetate 40 mg/ml) ஒற்றை அல்லது ஊசி குளுக்கோர்டிகாய்ட் (Glucocorticoid) வீக்கத்தினை உண்டு பண்ணாது. சில சமயங்களில் இந்த முறையில் மரத்துப்போகும் தன்மை குறைந்தாலோ அல்லது செயல்படவில்லை என்றாலோ மாற்று முறையில் புதிய உத்தி அல்லது சில மருத்துகளை பயன்படுத்தி வலியை குறைக்கும் வழிகளை கையாண்டு "வேர் சிகிச்சை" தொடரப்படும். இந்த புதிய மற்றும் மாற்று உத்தி முறையில் நரம்பில் மருத்தினை செலுத்தி வலி மற்றும் வீக்கத்தினை குறைக்கும் முறையில் செயல்படுத்தப்படும். மேலும் நான் மருத்துவ ரீதியாக என்னுடைய உடல்நலம் குறித்தும், இந்த சிகிச்சையின் பொருட்டு நான் உட்கொண்ட மருத்துகளையும் ஒளிவுமறைவின்றி மருத்துவரிடம் கூறியுள்ளேன் என்றும் ஒப்புதல் அளிக்கிறேன்.

மற்றும் இந்த படிவத்தை மற்றவர்கள் படித்ததை கேட்டும், சுயமாக நானே படித்தும் தெளிவாக அறிந்து கொண்டவை. மயக்கமருத்தினால் ஏற்படும் அபாயங்கள், மாற்று முறைகள், புதிய உத்திகள் பயன்படுத்துவதன் மூலம் ஏற்படும் விளைவுகள் ஆகியவை ஆகும். இச்சிகிச்சையை குறித்து சந்தேகங்களை தீர்க்கும் வகையில் கேட்க வேண்டிய கேள்விகளை கேட்கவும் என்னுடைய முடிவுகளை எடுக்கவும் போதுமானளவு காலமும் அவகாசமும் எனக்கு அளிக்கப்பட்டது என்பதையும் ஒப்புதல் பெறுகிறேன்.

தேதி மற்றும் நேரம்

நோயாளியின் கையொப்பம் /
பதிலாக இருக்கும் நபரின் கையொப்பம்

சாட்சிகள்

நோயாளியின் உறவுமுறை

1.

பதில் நபரின் கையொப்பம்

சாட்சி

நோயாளிக்கு உறவுமுறை.

எழுத்தறிவு இல்லாதவரென்றால்,

எழுத்தறிவுள்ள சாட்சி ஒருவர் கண்டிப்பாக கையொப்பமிட வேண்டும் (சாத்தியமானால், பங்கேற்பாளரால் இந்த நபர் தேர்வுசெய்யப்படவேண்டும் மற்றும் ஆராய்ச்சி குழுவோடு தொடர்பில்லாதவராக அவர் இருக்க வேண்டும்). எழுத்தறிவு திறனில்லாத பங்கேற்பாளர்கள் அவர்களது பெருவிரல் ரேகையையும் பதிவுசெய்ய வேண்டும்.

ஆய்வில் பங்கேற்க சாத்தியமுள்ள நபருக்கு இந்த ஒப்புதல் படிவம் சரியாக வாசித்துக்காட்டப்பட்டதை நான் நேரடி சாட்சியாக இருந்து கவனித்திருக்கிறேன். கேள்விகள் கேட்பதற்கு அவருக்கு வாய்ப்பு வழங்கப்பட்டது என்பதையும் மற்றும் தனது ஒப்புதலை நிர்ப்பந்தமின்றி சுதந்திரமாக அவர் வழங்கியிருக்கிறார் என்றும் நான் உறுதிசெய்கிறேன்.

சாட்சியின் பெயர் (அச்சில்) _____ மற்றும்

பங்கேற்பாளரின் பெருவிரல் ரேகை

சாட்சியின் கையொப்பம் _____

தேதி _____
நாள்/மாதம்/ஆண்டு

ANNEXURE -III

PAIN EVALUATION SHEET

Name: _____ Date: _____

Age: _____ Gender: _____ OP num: _____

Chief complaint:

Past medical history:

List of medicines taken:

Group and agent administered

ANESTHETIC TECHNIQUE USED:

EPT results:

Before treatment :

After LA:

Pain before starting the procedure:

Day	Pain				No. of analgesics taken
	No Pain 0	Mild 1	Moderate 2	Severe 3	
0					
1					
2					
3					
4					
5					
6					
7					

ANNEXURE -IV



RAGAS DENTAL COLLEGE & HOSPITAL

(Unit of Ragas Educational Society)

Recognized by the Dental Council of India, New Delhi

Affiliated to The Tamilnadu Dr. M.G.R. Medical University, Chennai

2/102, East Coast Road, Uthandi, Chennai - 600 119. INDIA.

Tele : (044) 24530002, 24530003-06. Principal (Dir) 24530001 Fax : (044) 24530009


TO WHOMSOEVER IT MAY CONCERN

Date: 6.1.2018

Place: Chennai

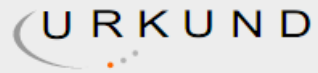
From
The Institutional Review Board,
Ragas Dental College & Hospital,
Uthandi,
Chennai – 600119.

The dissertation topic titled "A COMPARATIVE STUDY OF PAIN REDUCTION
IN UNTREATED AND TREATED ACUTE IRREVERSIBLE PULPITIS – A CLINICAL TRIAL"
submitted by **Dr. INDU .C.R** has been approved by the Institutional Review Board of
Ragas Dental College & Hospital.


Dr. N.S. AZHAGARASAN, M.D.S.,
Member Secretary,
Institutional Review Board,
Ragas Dental College & Hospital,
Uthandi,
Chennai – 600 119.



ANNEXURE -V



Urkund Analysis Result

Analysed Document: final thesis for plagiarism.pdf (D34942671)
Submitted: 1/23/2018 10:07:00 AM
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Significance: 1 %

Sources included in the report:

Dr. Vishnupriya Thesis.pdf (D34341771)
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