"A PROSPECTIVE STUDY TO COMPARE THE EFFECTS OF PREEMPTIVE PIROXICAM AND ORAL DEXAMETHASONE ON EDEMA, TRISMUS AND PAIN IN THIRD MOLAR SURGERY: A RANDOMIZED CONTROLLED TRIAL"

By

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(BRANCH III)

Under the guidance of
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BELAGAVI, KARNATAKA

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LIST OF ABBREVIATIONS USED

NSAID	-	Non steroidal anti-inflammatory drug
HPA axis	-	Hypothalamic-pituitary-adrenal axis
VAS	-	Visual Analogue Scale
IV	-	Intravenous
COX	-	Cyclooxygenase
IM	-	Intramuscular
FDDF	-	Fast dissolving dosage formulation
LPL	-	Low power laser
GI	-	gastrointestinal
CNS	-	Central nervous system

ABSTRACT

Surgical extraction of impacted third molars is an increasingly common procedure especially in the age group of 18-45 years. While standard procedures exist for sterilization, instrument use and surgical technique, the prescription following the surgery varies almost with each surgeon.

A broad overview exists on which medications are to be prescribed- antibiotics, anti-inflammatory drugs and analgesics, but there is a lack of evidence supporting any single anti-inflammatory and analgesic regimen or specific drug compounds that provide better results.

Moreover, there is large variability in terms of what the patient is to expect in terms of post-operative discomfort. Studies are needed to probe further into the postoperative prescription and search for drug compounds that can provide relief to the patient, in terms of pain, edema and trismus, in the period following surgery with minimum adverse effects.

This study aims to compare the effects of pre-emptive piroxicam and oral dexamethasone on pain, swelling and trismus following third molar surgery.

Materials and Methods:

31 patients requiring surgical extraction of mandibular third molars were included. Piroxicam Group: 20mg piroxicam tablet was given preemptively one hour before surgeryDexamethasone Group: 8mg dexamethasone tablet was given

preemptively one hour before surgeryPostoperative pain, swelling and trismus were assessed in the post-operative follow- up visits on the 2nd and 7th day post surgery.

Results:

Patients in the dexamethasone group showed significantly lesser swelling, trismus and pain on the 2nd and 7th postoperative day compared to the piroxicam group. No adverse effects were reported with either drug.

Conclusion:

From the analysis of the results of this study and within its limitations, we can conclude that use of 8mg oral dexamethasone one hour preoperatively leads to a more comfortable and pain free period for patients who undergo wisdom teeth removal.

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INTRODUCTION

Pre-emptive analgesia first gained traction after the research of CJ Woolf in 1993. The idea behind the concept is to inhibit the production of prostaglandins hence providing an early stop to the process of pain progression.[1]

Efficacy of analgesic drugs can be well evaluated after lower third molar surgery. Since extraction of an impacted third molar involves surgical trauma to the mucosa as well as the bony tissue, the post-operative period involves considerable and predictable inflammation and pain.[2]

Over the years, many compounds have been used to control the postoperative sequelae i.e. pain, facial swelling and trismus. Chief among them were opioids, corticosteroids and more recently NSAIDs. However, as knowledge regarding the adverse effects of opioids grew, including life threatening complications such as respiratory depression, and newer research revealed that peripherally acting analgesics are more effective than centrally acting agents, more and more surgeons took preference to prescribe NSAIDs and corticosteroids over opioids.[2,3]

While the duration of surgery and handling of tissues do play a role in determining the amount of inflammation that will occur, even the best executed surgical extraction of an impacted third molar does invariably lead to postoperative pain, discomfort, facial edema and trismus. Once tissue injury occurs, the extraction socket and surrounding tissues start to undergo the stages of inflammation that ultimately result in healing, starting with hemorrhage and clot formation and ultimately resulting in replacement of connective tissue with fibrillar bone and

remodelling. Hence, inflammation is both an essential step in the healing process as well as a contributor to postoperative discomfort and morbidity.[3]

It is important to take into account the psychosocial impact of postoperative inflammatory complications. Effects on speech, facial appearance and ability to perform everyday activities such as brushing and eating must be acknowledged and addressed by the operating surgeon. The choice of pharmacological management of post-operative pain, edema and trismus, therefore, forms a highly significant part of patient care. The body of research surrounding this choice is well documented and comprehensive but even so, a standardised regimen is not in place. There exists a need, consequently, to test and evaluate anti-inflammatory and analgesic efficacy of commonly prescribed medications to arrive at a decision regarding the agent best suited to manage the post-operative sequelae of this increasingly common procedure of surgical extraction of impacted third molars.[4]

Corticosteroids, while widely prescribed, have earned a cautious air due to propensity for interfering with HPA (hypothalamic-pituitary-adrenal) axis and endogenous production of glucocorticoids. They function by blocking the conversion of cell membrane phospholipids to arachidonic acid hence preventing formation of cyclooxygenase and subsequently prostaglandins, which play a key role in development of pain and inflammation. However, in more recent studies it has been proven that a single dose of corticosteroids, specifically dexamethasone, leads to minimal suppression of the HPA axis which returns to normal functioning by the seventh postoperative day.[3]

NSAIDs on the other hand, work lower down in the cascade, inhibiting conversion of the cyclooxygenase enzyme to prostaglandins ultimately achieving

reduction in pain and inflammation. Non selective NSAIDs, like piroxicam are known for risk of adverse effects such as increased bleeding tendency, gastric irritation and reduced renal function. However, these effects are dependent on the dosing and duration of therapy. Piroxicam is a superior drug in terms of its half life, which is 45 hours, once a day dosing and good analgesic and anti-inflammatory effect.[5]

Pre-emptive administration of dexamethasone and piroxicam is a novel concept that may revolutionise postoperative care by reducing not only the development of inflammatory symptoms but also the dosing and duration of pharmacological therapy, hence reducing the risk of adverse effects being experienced by the patient undergoing surgical extraction of third molars. The aim of this study is to compare the effects of pre-emptive piroxicam and oral dexamethasone on pain, swelling and trismus following third molar surgery.

AIM OF THE STUDY

To compare the effects of pre-emptive piroxicam and oral dexamethasone on pain, swelling and trismus following third molar surgery.

OBJECTIVES:

To compare the effect of of pre-emptive piroxicam and dexamethasone on postoperative sequelae following impacted third molar surgery by evaluating:

1) Pain intensity using Visual Analogue Scale at 24, 48 and 72 hours and on the 7^{th} day post operatively
2) Facial swelling preoperatively, 48 hours postoperatively, and on the seventh postoperative day.
3) Measurement of maximum mouth opening ability (trismus) preoperatively, 48 hours postoperatively, and on the seventh postoperative day

REVIEW OF LITERATURE

1. King Kim, PardeepBrar et al conducted a review on the application of corticosteroids and NSAIDs after surgical extraction of impacted third molars. This study is a review of literature to evaluate the use of NSAIDs and corticosteroids and their recommendations in dentoalveolar surgery. In the literature it is noted that combination of NSAIDs with steroids is being used to bring down pain post third molar surgery. In the case of steroids it was found that when given in adequate doses i.e. equivalent to 300 mg of cortisol, they are effective at reducing the postoperative sequelae of third molar surgery. They also noted that while IV administration has immediate effect, patient compliance is better with oral route.[3]

2. Paul A Moore, PardeepBrar et al conducted a preliminary randomized prospective clinical trial titled " Preemptive rofecoxib and dexamethasone for prevention of pain and trismus following third molar surgery". In the study, 29 subjects requiring 3rd molar surgery were divided into four groups - group 1 received placebo, group 2 received rofecoxib preoperatively and placebo intraoperatively, group 3 received placebo preoperatively and dexamethasone intraoperatively and group 4 received rofecoxib preoperatively and dexamethasone postoperatively. The group that received preoperative rofecoxib reported lower pain scores during the postoperative period, compared to those that received placebo preoperatively. They also concluded that the preoperative administration of an NSAID prior to induction of COX-2 enzymes minimizes the pain onset.[14]

3. K Boonsiriseth, Klongnoi et al conducted a study titled " Comparative study of the effect of dexamethasone injection and consumption in lower third molar surgery" wherein 20 patients underwent lower third molar removal in two appointments for each side. For both sides, 8 mg dexamethasone was given, one time orally and the second time intramuscularly. They found that 8mg of dexamethasone was more effective than 4mg at reducing the postoperative sequelae.Usually the active inflammatory phase post surgery lasts for 3 days, the duration of action with oral route almost lasted for the same time period. Whereas for IM route, the duration of actions lasted for six days. They concluded that there was no significant difference in pain, swelling or mouth opening between the two routes of administration. Hence oral route was found to be as effective as IM route of administration.[18]

4. Jose Filho, Paul Maurette et al conducted a study titled " Clinical comparative study of the effectiveness of two dosages of dexamethasone to control the postoperative swelling, trismus and pain after the surgical extraction of mandibular impacted third molars". Thirty patients were selected to undergo extraction of bilateral lower third molars scheduled in two separate appointments. For each side, either 4mg or 8mg of oral dexamethasone was given one hour before the extraction and the pain, mouth opening and facial swelling were measured. They found that facial swelling and trismus were reduced more efficiently by 8mg dosage in comparison with 4mg.[15]

5. F Graziani and L Corsi et al conducted a study titled "Clinical evaluation of piroxicam-FDDF and azithromycin in the prevention of complications associated with impacted lower third molar extraction". 30 patients requiring impacted lower third molar extraction were divided into three groups and given a three day treatment before surgery. Group 1 received fast dissolving dosage formulation (FDDF) of piroxicam 20mg/day, group 2 received oral azithromycin 500mg/day and group three received both. Following the surgery, pain, facial edema and interincisal mouth opening were measured. Consistently in this study, it was noted that when patients were administered FDDF piroxicam alone they reported lower pain scores, reduced postoperative edema and complete relief after two days, when compared to the group receiving azithromycin alone. Only two patients showed signs of infection which was not statistically significant. It was found that administration of piroxicam worked in two ways, first by delaying and blunting the onset of postoperative pain and second, by reducing the post-surgical inflammatory reaction. This property of piroxicam allows the patient to be pain free for longer and reduces the need for additional rescue medications.[9]

6. C Mcgrath, MB Comfort et al conducted a study titled " Changes in life quality following third molar surgery — the immediate postoperative period". They assessed 93 patients on the impact of oral health on the quality of life following impacted third molar extraction and found that there is a sharp deterioration in the quality of life in the immediate postoperative period which takes about a week to return to normalcy.[4]

7. Antonio Antunes, Rafael Avelar et al conducted a study titled " Effect of two routes of administration of dexamethasone on pain, edema, and trismus in impacted lower third molar surgery" wherein 67 patients requiring lower third molar extractions were divided into three groups. Group A was given intramuscular dexamethasone 8mg immediately preoperatively, group B was given oral dexamethasone 8mg one hour before the procedure and group C was designated control and given no preoperative medication. Facial edema, mouth opening and pain measurements were taken in the postoperative period. It was found that there was no statistical difference between the two routes of administration in terms of trismus and facial edema and postoperative pain was significantly reduced irrespective of the route of administration. The oral route represents a safe, convenient and inexpensive method of administration of dexamethasone in lower third molar surgery.[17]

8. O.W. Majid and W.K. Mahmood et al conducted a randomized non-blind prospective study titled " Use of dexamethasone to minimise postoperative sequelae after third molar surgery: comparison of five different routes of administration". 72 patients requiring impacted lower third molar surgery were divided into five treatment groups and one control group. The treatment groups received 4mg of dexamethasone by intramuscular, intravenous, oral, submucosal and endalveolar routes postoperatively. Facial edema, trismus and pain along with a questionnaire on quality of life were recorded. It was found that when swelling was considered, the efficacy ranged in the following order - intravenous, intramuscular, submucosal, oral and endalveolar routes in descending order. However, oral dexamethasone showed somewhat better results in reducing the degree of trismus than parenteral routes which may be

linked to a longer period of drug delivery with the oral route despite the dose being the same. In comparing pain control, the efficacy was the most with intravenous route followed by endalveolar, submucosal, oral and intramuscular route in descending order.[16]

9. Francisco H Briones, Estrella Sanchez et al conducted a systematic review titled " Update on the use of corticosteroids in third molar surgery : A systematic review of the literature". A database search across Medline, Pubmed, Cochrane and Scopus was made turning over a total of 72 articles. Out of these, 28 studies were picked based on the inclusion and exclusion criteria. They found that preoperative administration of corticosteroids has a greater efficacy in managing postoperative complications and parenteral routes have better efficacy when compared to the oral route in terms of trismus and facial edema.[21]

10. Michael G. Savage and Michael A. Henry et al conducted a study titled " Preoperative non steroidalanti inflammatory agents : Review of the literature". They searched through literature and included prospective studies where NSAIDs were used preemptively to manage post-surgical pain and inflammatory sequelae and found that preemptive administration is a valid method to achieve postoperative analgesia and reduction in edema and trismus.[5]

11. P. A. K. Trinidade, F.P.M. Giglio et al conducted a study titled "Comparison of oral versus sublingual piroxicam during postoperative pain management after lower third molar extraction". 53 patients requiring bilateral third molar surgery were given oral dose and sublingual dose of piroxicam 20mg each side following surgery and once daily for the next four days. Pain scores, facial edema and mouth opening were recorded. There were no significant differences between the two groups in terms of the pain scores, trismus or facial swelling. This was reflected in the small amount of rescue analgesics used in both groups, regardless of bone removal. While in theory, it is said that time of onset is quicker with the sublingual route, this study proved that both routes were equally effective in management of postoperative pain, swelling and pain following impacted third molar surgery.[10]

12. J.G. Meechan and R.A. Seymour conducted a review titled " The use of third molar surgery in clinical pharmacology". They took into consideration studies concerning the analgesic efficacy, anti-inflammatory activity of drugs, local anesthetics, sedation techniques and antimicrobial drugs. They noted that surgery of the impacted third molar results in pain which peaks in the early postoperative period making it useful to test the efficacy of single dose analgesics. They also found that peripherally acting analgesics with anti-inflammatory properties like NSAIDs provide better pain relief than centrally acting drugs such as opioids. While their review showed that oral route of administration of corticosteroids are not as efficacious as parenteral route, they noted this may be due to studies having a short period of postoperative observation or a low dosing regimen. This review also stated that

adrenocortical suppression is not caused by a short dosing period of corticosteroids. They concluded that there is significant clinical value in assessing drugs using the third molar surgery model.[2]

13. Mohammed Zandi undertook a study titled " Comparison of corticosteroids and rubber drain for reduction of sequelae after third molar surgery". Twenty two patients requiring surgery for bilateral impacted third molars were included in this study. For each patient, either a rubber drain was inserted post surgery or perioperative corticosteroids were given on one side while the other side was treated as control. The corticosteroid regimen included an 8mg IV injection of dexamethasone half an hour before the surgery followed by three doses of 5mg methylprednisolone in the postoperative period. Pain, edema and trismus were recorded and compared. They found that corticosteroids were more effective than drain placement in terms of reduction in facial edema and postoperative pain. They also stated that use of the rubber drain resulted in reduced pain and trismus when compared to the control side. [22]

14. Desjardins et al conducted a study titled "Analgesic efficacy of piroxicam in postoperative dental pain". They took into consideration mainly twelve randomized controlled trials evaluating the efficacy of piroxicam at various dosages after dental surgery. They found that a single dose regimen of administering piroxicam is safe with a wide range of dosing. Specifically after third molar surgery they found that while 5mg and 10mg dosages of piroxicam fail to produce sufficient analgesia, 20mg and 40mg dosages were able to produce significant analgesia comparable to aspirin 648mg. They also noted that the duration of analgesia extended close to 24 hours. [23]

15. Benetello, Sakamoto et al conducted a study titled " selective and non-selective cyclooxygenase inhibitors valdecoxib and piroxicam induce the same postoperative analgesia and control of trismus and swelling after lower third molar removal". Nineteen patients requiring bilateral third molar surgery were treated with piroxicam 20mg on one side and valdecoxib 40mg on the other postoperatively for four days. These drugs were chosen for comparison due to their similar half lives and advantage of once daily dosing. The pain scores, trismus and facial measurements were recorded. They found that there was no statistical difference between the two drugs in terms of analgesia and facial swelling. In terms of trismus the results were similar in both treatment groups. The study concluded that the nonselective COX inhibitor piroxicam was just as effective as a COX-2 selective one like valdecoxib.[20]

16. A.B. Barroso, V. Lima et al conducted a prospective randomized controlled trial titled " Efficacy and safety of combined piroxicam, dexamethasone, orphenadrine, and cyanocobalamin treatment in mandibular molar surgery". They tested the effects of a combination drug named Rheumazin® (10 mg piroxicam, 1mg dexamethasone, 35mg orphenadrine citrate and 2.5 mg cyanocobalamin) and single dose piroxicam 20mg Feldene® on eighty patients requiring lower third molar surgery. The drugs were given 30 minutes before surgery and once daily for the next 4 days. Pain scores, facial measurements and the degree of satisfaction were measured and recorded. It was found that in terms of pain, Rheumazin fared better at the 6th and 120th hours when compared to piroxicam although there was no statistical difference in the number of rescue analgesics used. Both drugs had a similar effect on

facial edema. There was no statistical difference in the degree of satisfaction reported with both groups. They concluded that the combination drug and piroxicam 20mg had an equivalent therapeutic efficacy.[24]

17. Z. O. Pektas, M. Sener et al conducted a prospective randomized study titled " A comparison of preemptive analgesic efficacy of diflunisal and lornoxicam for postoperative pain management: a prospective, randomized, single blind, crossover study". Forty patients requiring bilateral lower third molar surgery were given 1000mg diflusinal for one side and 16mg lornoxicam from the other, orally one hour before the procedure. Postoperative pain scores and amount of rescue analgesic (acetaminophen 2000mg) were evaluated and compared. There was no statistical difference in the analgesia provided or rescue analgesic consumed by the preemptive administration of both drugs. It was also found that prostaglandins reach their maximum concentration at three to four hours post surgery and the preemptive dose of both groups could manage the analgesia well. It was noted that while not statistically significant, there was more consumption of rescue analgesics in the lornoxicam group and this could be attributed to its shorter half life (3-4 h) in comparison with diflunisal (8-12 h). A significantly low incidence of adverse effects with both drugs was noted as well. They concluded that both peripheral and central sensitization to pain could be inhibited with preemptive administration of NSAIDs.[1]

18. L. Aznar-Arasa and K. Harutunian et al conducted a triple blind, randomized placebo controlled clinical trial titled " Effect of preoperative ibuprofen on pain and swelling after lower third molar removal - a randomized controlled trial". A total of 109 patients were divided into two treatment groups, 53 patients were in the preoperative group and 56 patients in the control group. In the preoperative group, patients were given 600mg of ibuprofen one hour before surgery and placebo immediately afterwards and in the control group, placebo one hour before surgery and 600mg of ibuprofen immediately after the procedure. All patients were put on a regime of amoxicillin/clindamycin (7 day course) , ibuprofen (600mg 8th hourly for 5 days), metamizol (rescue analgesic) and chlorhexidine mouthwash post surgery. Pain scores, facial swelling and maximum mouth opening were measured and recorded. It was found that there was no significant difference between the two groups in terms of pain intensity as a whole. However, just post surgery, the pain intensity was lower in the preoperative group than the control group. They also found that while rescue analgesic metamizol was used in a higher amount in the preoperative group, the result was not statistically significant. The facial edema and trismus in both groups was reported to be similar and no adverse effects were reported with both groups. The authors concluded that due to negligible difference in the analgesia provided by both dosing times of ibuprofen, there was no merit to preoperative administration of the same.[25]

19. Emanuel S Troullos, Kenneth Hargreaves et al conducted two double blind studies in their research titled "Comparison of Non steroidal Anti-Inflammatory Drugs, Ibuprofen and Florbiprofen, With Methylprednisolone

and Placebo for Acute Pain, Swelling and Trismus". In the first study, 60 subjects were divided into three groups - flurbiprofen group, steroid group and placebo group. The flurbiprofen group received 100mg of flurbiprofen orally 30 minutes before the surgery and an IV placebo immediately before the start of the surgery. In the steroid group, placebo was given orally 30 minutes before the surgery and 125 mg IV methylprednisolone just before the start of surgery. In the placebo group, both the oral and IV drugs were placebos. All four third molars were removed, with lower third molars having at least partial bony impaction. The steroid group and placebo group received 650mg of acetaminophen plus 60mg codeine whereas in the flurbiprofen group, 50mg of flurbiprofen was given. Both drugs were given fourth hourly for 72 hours. Pain, facial swelling, loss of function, local temperature and plasma cortisol levels were measured for all groups. It was found that flurbiprofen fared better compared to placebo and methylprednisolone with respect to analgesia at the 2 hour mark. In terms of facial swelling, methylprednisolone was more effective at 24, 48 and 72 hours where flurbiprofen showed a slower trend achieving edema reduction at 24 hours in comparison to placebo. Loss of function was measured by interincisal mouth opening, wherein methylprednisolone group showed a small advantage when compared to flurbiprofen at 24 and 48 hours postoperatively. The plasma cortisol levels were lower in the steroid group and no differences in local temperature were noted across all three groups. The second study was conducted on 38 patients, wherein some modifications were made to the first study protocol such as discontinuing the use of IV diazepam before surgery. The three groups were NSAID, steroid and placebo. In the NSAID group, 600 mg of ibuprofen and IV placebo were administered before

surgery and a 6th hourly regime of 600mg ibuprofen was continued in the postoperative period for 48 hours. The steroid group and placebo group were administered the same dosages as described in the first study preoperatively but postoperatively they were switched over to 10mg oxycodone 6th hourly for 48 hours. Mouth opening, pain and facial swelling were recorded. The NSAID group fared better in pain control over the first 3 hours.In terms of facial swelling, methylprednisolone was more effective compared to the other groups and at the end of 24 hours, NSAID group fared better than placebo. The authors concluded that NSAIDs manage pain better compared to steroids in the beginning hours of the postoperative period and suppress edema when compared to placebo. They also found that methylprednisolone was better at reducing edema and trismus than NSAIDs.[19]

20. A. M. Calvo, V. T. Sakai et al conducted a double blind, randomized study titled " Analgesic and anti-inflammatory dose-response relationship of 7.5 and 15 mg meloxicam after lower third molar removal: a double blind, randomized crossover study". 49 patients requiring bilateral lower third molar extraction were included in the study. The surgical extractions were done in two appointments 1-2 months apart. For one side, 7.5 mg meloxicam was prescribed once daily for four days postoperatively and for the 15mg meloxicam. Wherever bone removal was necessary, amoxicillin was prescribed as a 7 day course. The duration of surgery, pain scores, mouth opening, facial swelling and time to first rescue analgesic (paracetamol) were recorded. They found that while the efficacy of 7.5 mg meloxicam was not as effective for surgery requiring ostectomy, the 15mg meloxicam regimen was

able to provide sustained analgesia irrespective of surgical trauma. The amount of rescue analgesic consumed was also more in the 7.5mg meloxicam group requiring ostectomy. The mouth opening was similar for both groups and no significant difference was found between the groups in terms of facial swelling. They concluded that both 7.5mg and 15mg meloxicam are effective in reducing postoperative swelling, trismus and edema following surgical extraction of lower third molars, with 15mg meloxicam being a better agent for surgeries requiring bone removal.[26]

21. R Andrew Moore, Jayne Edwards et al conducted a review titled "Single dose oral piroxicam for acute postoperative pain". A systematic search was performed across MEDLINE, EMBASE, CENTRAL, Biological Abstracts and Oxford Pain Relief database. Out of 71 studies, two were identified as meeting the inclusion and exclusion criteria. One was based on surgical removal of impacted third molars and the other on gynaecological and general surgical procedures, and included two studies within the paper. They found that 20mg piroxicam was effective in providing analgesia for mild to moderately severe post surgical pain. They noted that piroxicam has a significantly lower NNT (number-needed-to-treat-to-benefit) than paracetamol 1g, dextropropoxyphene 65mg plus paracetamol 650mg and tramadol 75mg. They also reported that major side effects were not seen with a single dose regimen of piroxicam The concluded that 40mg piroxicam could be proven superior to 20mg. The authors reported that despite lack of sufficient data, the efficacy assessment done with these two studies proved robust.[27]

22. ShrutiPhulgirkar, Lingaraj J Balihallimath et al undertook a prospective study titled "Comparison of oral and sublingual piroxicam for management of postoperative pain after mandibular third molar surgery: prospective, randomized study". Thirty patients requiring bilateral third molar surgery were included in the study. For each side, a different route of administration was used, one side oral and the other side, sublingual. 20mg piroxicam was administered to the patient twice daily 12th hourly till 48 hours post surgery and a single daily dose for the next four days. Pain, facial swelling and mouth opening were measured and compared, along with the number of rescue analgesics used. The results were reported to be comparable between the two groups regarding pain, edema and trismus. The number of rescue analgesics used in the oral group was reported to be slightly higher than in the sublingual group but this result was not statistically significant. The authors concluded that 20mg of piroxicam, whether administered orally or sublingually is effective in reducing the postoperative sequelae of third molar surgery.[28]

23. F. J. Herrera-Briones, Estrella Sanchez et al conducted a systematic review titled "Update on the use of corticosteroids in third molar surgery: systematic review of the literature". A search was performed across four databases: Pubmed, Scopus, Medline and Cochrane and 72 articles were selected. Taking into account the inclusion and exclusion criteria 28 studies were finally selected(1 metaanalysis and 27 randomized controlled trials). They took into account the data regarding the drug used, route of administration and proximity to the surgical site. They found that while corticosteroids exert most of their action during the first postoperative day, their effects linger around for

three days post surgery. They noted in the study conducted by Baxendale et al oral administration of 8mg dexamethasone provided significant analgesic and anti-inflammatory effect following third molar surgery but no effect on trismus. Pederson et al found that a preoperative IM injection of 4mg dexamethasone could reduce trismus by 50 percent and pain by 30 percent. Their systematic review concluded that use of corticosteroids is helpful in reducing the trismus and inflammation post third molar surgery and preoperative administration leads to greater effect compared to postoperative. They also concluded that parenteral route of administration is better than oral and that further research and comparative studies were required.[21]

24. Giovanni Grossi, Carlo Maiorana et al conducted a study titled "Effect of Submucosal Injection of Dexamethasone on Postoperative Discomfort After Third Molar Surgery: A Prospective Study" wherein 61 patients requiring lower third molar surgery were included. They were divided into two experimental groups and one control group. In the experimental groups, once the onset of local anesthesia was ascertained, a submucosal injection of either 4mg dexamethasone or 8mg dexamethasone was administered before incision. All patients received preoperative antibiotic prophylaxis and paracetamol(500 mg) with codeine(30 mg) postoperatively as rescue analgesic. Pain scores, facial measurements, mouth opening and poSSe(postoperative symptom severity) scores were recorded. They found that in all groups, facial edema peaked at the second postoperative day and there was no statistically significant difference between all the groups on day seven. While the experimental groups fared better with facial edema compared to the control

group, no significant difference was seen between the 4mg and 8mg dexamethasone groups. In terms of trismus and pain too, the two groups did not show any statistical difference. In terms of poSSe score, the participants perceived more facial swelling with the 4mg group. The authors noted that dexamethasone and prednisolone are preferred corticosteroids due to their almost solely glucocorticoid action and no effect on leukocyte function. They noted that the data from this study could not prove that administration of dexamethasone reduced pain post third molar surgery. The authors concluded that the submucosal route achieves effective resolution of trismus and facial edema post surgical extraction of lower third molars with a lower dosage required to do so.[29]

25. Hashem M. Al-Shamiri, MahaShawky et al undertook a study titled " Comparative assessment of preoperative versus postoperative dexamethasone on postoperative complications following lower third molar extraction". A total of 24 patients were included in the study and divided equally into two groups. Group A received 8mg dexamethasone orally one hour before the surgery and Group B received the same immediately post surgery. In both groups, patients were prescribed a five day course of clindamycin 300mg and a three day course of ibuprofen 400mg thrice a day. The 400mg ibuprofen was also used as a rescue analgesic following the third post surgery day. The authors noted that dexamethasone was chosen due to its extended half life, better potency and property of low sodium retention. The rationale behind using 8mg dose was that it is roughly equivalent to the body's stress response which can go up to 300mg cortisol. In terms of facial edema, they reported

that group B showed higher increase in swelling compared to group A and have attributed the better action of preoperative administration to achieving the serum peak concentration within 1-2 hours of administration, hence effective at reducing onset and progression of facial edema. They also reported that the preoperative dose fared better than postoperative in terms of reducing trismus. Pain scores were reportedly better in the preoperative dose as well when compared to postoperative on day three post surgery. The authors concluded that the preoperative dosing of 8mg dexamethasone was more effective than postoperative in reducing facial swelling in surgical extraction of lower third molars.[13]

26. R. N. Brogden, R. C. Heel et al conducted a review titled " Piroxicam - a reappraisal of its pharmacology and therapeutic efficiency". The authors took into consideration the pharmacokinetics, pharmacodynamics, therapeutic uses and adverse effects associated with piroxicam. They noted that unlike aspirin and indomethacin, piroxicam is a selective reversible inhibitor of the COX enzyme which results in overall lower incidence of gastrointestinal complications. In the pharmacokinetic properties, the authors noted that piroxicam takes usually about 2 hours to reach peak plasma concentrations (4.5 - 7.2 mg/L), ranging between one to six hours in different patients. The elimination rate is related to liver function and to a limited extent, the renal function. The elimination half life of piroxicam is prolonged (approx 45 hours) leading to fewer fluctuations in plasma levels in between dosing. Studies in animals indicate the piroxicam has a better distribution in inflamed tissues. 20mg piroxicam has been shown to be effective at reducing moderate to

severe pain in comparison to placebo, 648mg aspirin, 10mg and 40mg piroxicam. The effect usually takes one to two hours post administration. The authors concluded by attributing the longer half life of piroxicam (30-60 hours) allowing once daily dosing for better patient compliance and reported 20mg of piroxicam is well tolerated and has a place in dental and post surgery/trauma pain and inflammation.[8]

27. J. Barden and J. E. Edwards et al conducted a review titled "Relative efficacy of oral analgesics after third molar extraction". A systematic search was made through MEDLINE, Cochrane Library, Biological Abstracts, Pubmed and the Oxford Pain Relief Database. 155 studies were chosen following inclusion and exclusion criteria, with fifteen drug and dose combinations compared to placebo used in third molar surgeries. The NNTs(number-needed-to-treat) and NNHs(number-needed-to-harm) were taken into consideration. The top NNTs were for non steroidal anti-inflammatory drugs and COX-2 inhibitors. For ibuprofen(400mg), diclofenac (50mg/100mg), rofecoxib(50mg) and valdecoxib(20mg/40mg) the NNTs were below 2.4. These values were able to justify the analgesic effect of these NSAIDs. For paracetamol (1000mg/600mg) and aspirin (600.650mg) the NNT values were 4-5. The significant NNH was for a combination of paracetamol and codeine which was between 4.3 to 7.4 indicating a larger incidence of adverse events. The authors concluded that the most effective analgesia was provided by NSAIDs and COX-2 inhibitors.[30]

28. A. Markovic, Lj. Todorovic et al conducted a clinical trial titled "Effectiveness of dexamethasone and low-power laser in minimizing oedema after third molar surgery: a clinical trial".120 patients requiring lower third molar surgery were included in this study and divided into four equal groups. In group 1, LPL (low power laser) irradiation of the surgical site was done immediately after surgery. In group 2, dexamethasone (4mg) was given IM in the internal pterygoid muscle immediately following surgery. In group 3, LPL irradiation of the surgical site and IM administration of 4mg dexamethasone was done immediately postoperatively followed by intraoral administration of 4mg dexamethasone at the 6th post surgical hour. In group 4 i.e the control group, only postoperative instructions (ice pack, soft diet) were given with no treatment. The LPL laser was used at an energy output of 4 J/cm2 with a constant power density of 50 mW and a wavelength of 637 nm. The only parameter noted was postoperative edema. They found that the edema was significantly reduced in group two compared to the other groups and in group 1 and 3 compared to the control group. They concluded that the combination therapy benefitted from the anti-edema effect of both the low power laser as well as dexamethasone.[31]

29. T. J Meredith, J. A. Vale et al conducted a study titled "Non-narcotic analgesics - Problems with overdosage". With respect to piroxicam they noted that an adult overdose may happen if quantities between 500-1800mg have been ingested, leaving a safe margin between its generally prescribed dosage of 20mg. The clinical signs and symptoms include gastrointestinal(GI) symptoms such as nausea, vomiting, diarrhea, abdominal pain and GI bleeding

along with CNS symptoms including dizziness, blurred vision, excitability, convulsions and coma. Further the liver and kidneys may be affected leading to hematuria, proteinuria, acute renal failure and hepatic dysfunction. As it is highly protein bound, forced diuresis, dialysis and hemoperfusion are not beneficial and oral doses of activated charcoal are recommended to reduce the absorption, especially if the patient has come in within 4 hours of ingestion.[33]

30. Neupert, Lee et al conducted a prospective study titled " Evaluation of dexamethasone for reduction of postsurgical sequelae of third molar removal". Sixty patients with impacted third molars present bilaterally were included in this study. The teeth were surgically extracted in two appointments 5-6 weeks apart. On each side, a preoperative dose of either 4mg dexamethasone or 1 ml sterile water was administered intravenously 5-10 minutes before surgery. Patients in both groups were given twelve tablets of an oxycodone-acetaminophen compound. Facial measurements, pain scores and mouth opening were measured daily for the first 4 days post surgery and after one week. The authors gave the rationale for choosing dexamethasone due to its increased half life, higher potency and less tendency to cause sodium retention. They chose the dose of 4mg arbitrarily citing it to be five times the endogenous cortisol levels. They found that with respect to trismus and pain, the steroid group fared better than the control whereas in terms of facial swelling there was no statistical difference between the two groups. They concluded that dexamethasone is an effective agent but further studies are required on the subject to cement its place as a postoperative drug after third molar surgery.[12]

MATERIALS AND METHODS

Subjects were dental outpatients who reported to the Department of Oral and Maxillofacial Surgery at KLE's VK Institute of Dental Sciences for lower third molar surgery. A total of 31 patients were selected after careful clinical and radiographic evaluation. They were randomly allocated to two treatment groups, oral dexamethasone (8mg) and oral piroxicam (20mg). The overall analgesic efficacy and anti-inflammatory effect of the two drugs was assessed by determination of pain intensity using the visual analogue scale, facial swelling was measured in one dimension using measuring tape and anatomic landmarks and trismus by recording the mouth opening in centimetres.

Materials Used:

- Standard third molar surgical extraction tray
- Tablet dexamethasone 8 mg
- Tablet piroxicam 20mg
- Measuring tape

Study design: Prospective randomized controlled clinical trial

Duration of study: September 2018 - September 2020

Sample size: Sample of 31 patients, who consent and fulfill the inclusion criteria

Statistical test: Statistical tests that were applied:

1. Independent t test/ Mann Whitney U test
2. Dependent t test/ Wilcoxon matched pairs test
3. Repeated measures of ANOVA

Inclusion criteria:

- Age 18-45 years
- The position of impacted tooth was assessed using 'PEDERSON'S DIFFICULTY INDEX' and teeth falling within 'slightly difficult' and 'moderately difficult' criteria were included (scores 3-4 and 5-6)
- Patients requiring bilateral impacted third molar surgeries with same degree of surgical difficulty index for the third molar or different patients with impacted third molars with same degree of surgical difficulty index

PEDERSON'S INDEX:

CLASSIFICATION VALUE

Spatial relationship

Mesioangular	1
Horizontal/Transverse	2
Vertical	3
Distoangular	4

Depth

Level A: High occlusal level	1
Level B: Medium occlusal level	2
Level C: Low occlusal level	3

Ramus Relationship/Space available

Class 1: Sufficient space	1
Class 2: reduced space	2
Class 3: no space	3

Difficulty index

Very difficult	7-10
Moderately difficult	5-6
Slightly difficult	3-4

Exclusion criteria:

Presence of systemic disease

Known hypersensitivity to drugs used in the study

Pregnancy and lactation

History of analgesic/anti-inflammatory drug intake 10 days before surgery

Subjects not willing to consent to study protocol

Methodology with flowchart:

The study included 31 randomly selected patients reporting for surgical extraction of mandibular third molars were selected after careful clinical and radiographic evaluation, irrespective of age, sex and difficulty in impaction from the outpatient department of Oral and Maxillofacial Surgery at KLE VK Institute of Dental Sciences

Patients are randomly assigned to one of the two study groups

Once the procedure and study protocol has been explained to them and informed consent signed, Group 1 patients will receive oral piroxicam 20mg and group 2 patients will receive oral dexamethasone 8mg 1 hour prior to start of the procedure

Preoperative facial measurements and mouth opening were recorded and Visual analogue scale were explained to the patient

Surgical extraction of the third molars were carried out as per standard procedure, using 2% lignocaine with 1:80,000 concentration of adrenaline

A prescription for 500mg amoxicillin thrice a day for five days and 500mg paracetamol 6th hourly for four days were provided to the patient along with a sheet with the VAS scale for them to record the pain scores on, at the end of 24, 48 and 72 hours.

Patient were called for the first follow-up visit on the 2nd postoperative day and pain, facial measurements and mouth opening were recorded

On the 7th day postoperatively, pain, facial measurements and mouth opening were recorded

Details of the procedures to be conducted during the research

- Patients reporting to Department of Oral and Maxillofacial surgery at KLE VK Institute of Dental Sciences for third molar surgery were selected after careful clinical and radiographic evaluation and randomly assigned to one of the two treatment groups
- Patients of group 1 received tablet piroxicam 20mg and those in group 2 received tablet dexamethasone 8mg 1 hour prior to start of procedure
- The facial measurements and mouth opening were measured preoperatively
- Local anesthesia was achieved by using 2% lignocaine plus adrenaline 1:80,000.
- Adequate elevation and reflection of the buccalmucoperiosteal flap was carried out, followed by buccal guttering
- Tooth sectioning, if required, was done.
- Tooth delivery was followed by meticulous irrigation of the surgical site with physiologic saline (0.9 %)
- The mucoperiosteal flap was repositioned and sutured.
- Post-extraction instructions and follow-up dates were explained to the patient.
- Both groups received amoxicillin 500mg eighth hourly for five days and paracetamol 500mg as rescue medication

Evaluation Criteria:

To evaluate:

1) Measurement of pain intensity using Visual Analogue Scale at 24, 48 and 72 hours and on the 7th day post operatively.

2) Tape measuring method for evaluation of facial swelling.

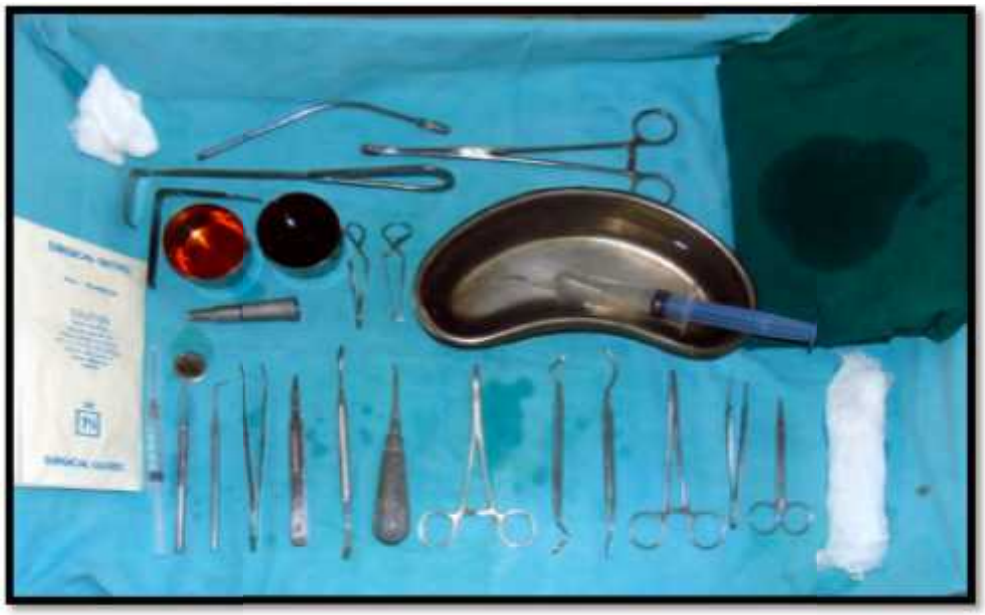
- The distance between the lateral canthus of the eye and angle of the mandible.
- The distance between tragus and corner of the mouth.
- And the distance between tragus and soft tissue pogonion were measured preoperatively, 48 hours postoperatively, and on the seventh postoperative day.

3) Measurement of maximum mouth opening ability (trismus) in millimetres between the incisal edges of the maxillary and mandibular central incisors measured preoperatively, 48 hours postoperatively, and on the seventh postoperative day.

<u>Surgical armamentarium</u>: (as shown in Figure 1)

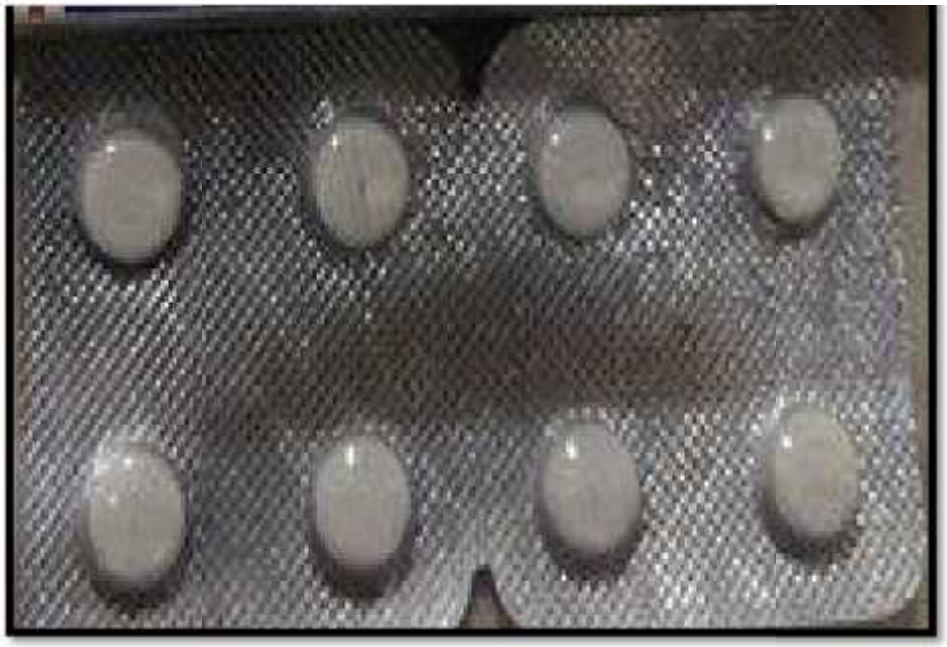
Surgical gloves	Mouth mirror
Dental explorer	Tweezer
2ml Disposable Syringe	Surgical 15 no. blade
Periosteal elevator	Straight elevator
Artery forceps	Curette
Bone file	Needle holder
Adson's tissue forceps	Scissors
Surgical handpiece and bur	Kidney tray
Irrigation syringe 20ml	Surgical drape
Towel clip	Suction tip
Langenbeck retractor	Sponge holder
Gauze piece	

Figure 1



Standard third molar surgical extraction tray

Figure 2



Picture showing 8mg dexamethasone tablet administered preemptively to patient

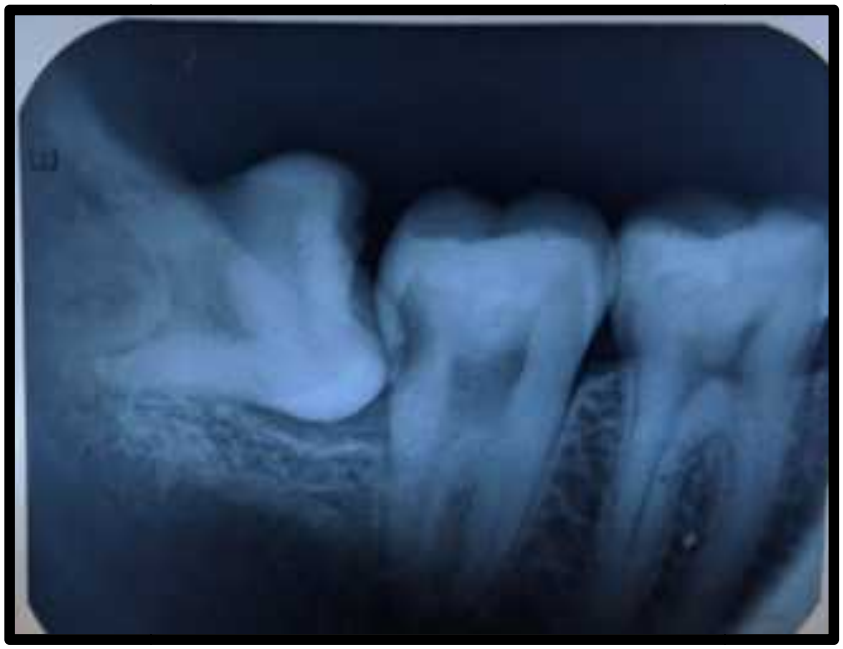
Figure 3

Picture showing 20mgpiroxicam tablet administered preemptively to patient

PATIENTS IN GROUP 1

Figure 4: Preoperative photos

Figure 4a



IOPA showing horizontally impacted mandibular third molar

Figure 4b

Preoperative facial measurement - Tragus to Corner of mouth (in cm)

Figure 4c

Preoperative facial measurement - Tragus to Pogonion (in cm)

Figure 4d

Preoperative facial measurement - Canthus to angle (in cm)

Figure 4 e

Preoperative - Mouth opening (in cm)

Figure 5: Postoperative day 2 photos

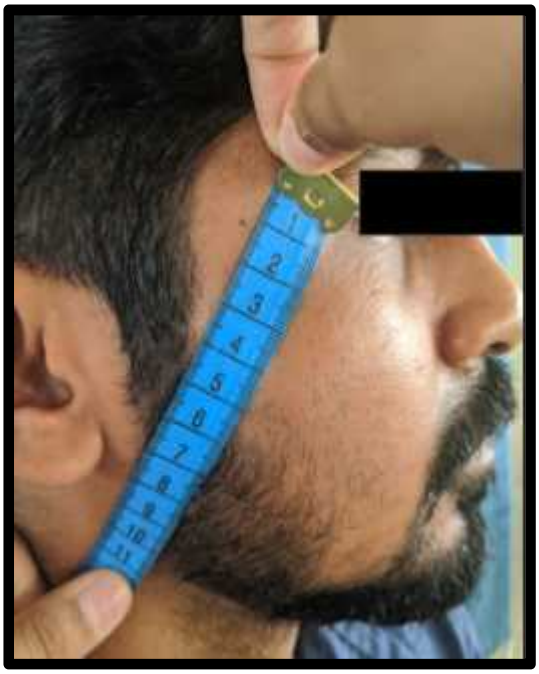
Figure 5a

2nd postoperative day facial measurement - Tragus to Corner of mouth (in cm)

Figure 5b

2nd postoperative day facial measurement - Tragus to Pogonion (in cm)

Figure 5c



2nd postoperative day facial measurement - Canthus to angle (in cm)

Figure 5d

2nd postoperative day - Mouth opening (in cm)

Figure 6: Postoperative day 7 photos

Figure 6a

7th postoperative day facial measurement - Tragus to Pogonion (in cm)

Figure 6b

7th postoperative day facial measurement - Tragus to Corner of mouth (in cm)

Figure 6c

7th postoperative day facial measurement - Canthus to angle (in cm)

Figure 6d

7th postoperative day - Mouth opening (in cm)

DISCUSSION

Surgical extraction of impacted third molar teeth is a routinely performed procedure in oral and maxillofacial surgery. This minor surgical procedure involves certain degree of trauma to both the hard and soft tissues of the oral cavity. The resulting inflammation results in considerable facial swelling, pain and trismus in the postoperative period[3]

Over the years, many studies have been conducted on pharmacological means to reduce postoperative discomfort among which NSAIDs and corticosteroids are chief choices amongst surgeons.[3]Previously, opioids were also used for this purpose but over time it has been found that peripheral sensitization also plays a major role in post-surgical pain. Thus other classes of drugs such as NSAIDs and corticosteroids which act upon the arachidonic acid cascade have been found to be more useful to control both the pain and inflammatory sequelae, especially since they don't have the undesirable adverse effects associated with opioids.[3] The efficacy of a single dose of medications can also be well evaluated in the impacted lower third molar surgery model.[2]

Preemptive administration of drugs is a newer concept taking root in the research and study of Woolf in 1993. In the pathophysiology of post-surgical pain, it was found that the injured tissue gives rise to signals that cause a state of high excitability in the CNS neurons. Therefore, if the release of COX enzyme and prostaglandins from the injured tissue could be prevented early, the activation of neurons in the CNS could be diminished thereby providing better postoperative analgesia.[6]

Piroxicam was chosen for this study due to its long half life of 45 hours and good analgesic and anti-inflammatory effect. The peak plasma concentration is seen around 2 hours after oral administration which bodes well with the preoperative dosing regimen. In this study, piroxicam 20mg was administered one hour before extraction of impacted lower third molar, allowing the drug to exert its maximal effect around the same time point at which the local anesthetic wears off. Due to its long half life, patient compliance is better with piroxicam and the risk of adverse effects is low.[6,7,8,9] The study carried out by Trinidade et al found in their study that oral administration of 20mg piroxicam in the preoperative period is able to manage post surgical inflammatory sequelae and pain.[10]

The choice of using dexamethasone in this study stemmed from its high potency, longer half life (36-72 hours)[11] and decreased tendency for sodium retention along with its widely known anti inflammatory action. 8mg of dexamethasone is almost equivalent to 300mg cortisol, released in times of stress and it was found to have better anti-inflammatory effect than lower dosages. Dexamethasone is one the only corticosteroids that provides greatest anti-inflammatory action with the least mineralocorticoid action.[12,13,14,15] The decision to use oral route of administration was taken as it is less invasive, inexpensive and has better patient compliance along with antiinflammatory efficacy comparable to parenteral and local routes.[13,16,17,18]

In this study, there were no differences between subjects allocated to both the groups in terms of gender, age of the patients or tooth number to be operated on. The surgical difficulty of the procedure was graded based on the Pederson Index. Both the groups included cases with a slight to moderate difficulty level of extraction or a Pederson score of 3 to 6.

The three parameters assessed in our study were facial swelling, trismus and pain. The facial swelling was recorded using anatomic landmarks and measuring tape. This was a reliable, convenient and affordable method.[17] The trismus was measured by recording interincisal mouth opening and pain using the VAS score.[17,18]

The facial measurements were recorded on the preoperative, second postoperative day and one week post surgery. Both groups showed a certain amount of facial swelling on the postoperative day 2 and significant resolution of the same by day 7. The dexamethasone group showed lower swelling scores on the 2nd and 7th postoperative day compared to the piroxicam group. This finding was in concurrence with the results of Emanuel Troullos et al who discovered that NSAIDs were inferior at reducing trismus and facial swelling when compared to corticosteroids.[19] Corticosteroids, along with inhibiting the arachidonic acid pathway also lead to decreased capillary dilatation thereby reducing edema more effectively.[3] Some concerns regarding hypothalamic pituitary axis (HPA) suppression are present with the use of corticosteroids in oral and maxillofacial surgery however recent studies indicate that a single preoperative dose does not cause much impairment of the same.[2,12,14]

Piroxicam did exhibit some anti-inflammatory activity showing better improvement in swelling between day 2 and day 7 than the dexamethasone group, despite higher average facial measurement scores, however it was not statistically significant.

Trismus was measured on the 2nd and 7th postoperative day. With respect to this parameter too, the dexamethasone group showed higher mouth opening values on both day 2 and day 7 post surgery. This finding was in agreement with the study

conducted by Hashem et al showing that reduction of trismus was directly correlated to the edema reduction achieved by oral dexamethasone as it aids in better muscle movement and mouth opening.[13] The reduction in trismus seen in the dexamethasone group could also be correlated to the finding uncovered by Boonsiriseth et al that after oral dosing the drug stayed in the body for 2.75 days, providing its effect in the crucial phase of acute inflammation which lasts approximately the same amount of time i.e. 3 days.[18]

Piroxicam group also showed improvement in mouth opening by the seventh day and while the trismus was greater in this group, there was higher reduction between the 2nd and 7th postoperative day compared to the dexamethasone group, however this difference was not statistically significant. In a study conducted by Graziani et al, between placebo and preemptivepiroxicam 20mg, piroxicam was found to be effective at reducing facial edema and trismuspost surgical extraction of impacted third molar teeth.[9]

The pain scores were recorded using the Visual Analogue Scale at the end of 24 hours, 48 hours and 72 hours in both the groups.[17,18] The subjects in the dexamethasone group reported lower pain scores at the end of 24 hours, 48 hours and 72 hours when compared to the piroxicam group. These findings were in correlation with the findings of Hashem et al wherein preemptive administration of dexamethasone led to early inhibition of production of prostaglandins in the injured tissues reducing edema leading to better analgesia in the postoperative period.[13] The research conducted by Antunes et al also reported reduction in post operative pain with the use of 8mg dexamethasone given one hour preoperatively.[17] In this study, between the two groups, piroxicam showed inferior analgesic activity which may be

correlated to the lower anti-edema effect compared to dexamethasone since reduction in edema has been correlated with better analgesia.[13] No adverse effects were reported with either of the drugs by subjects in both groups.

Dexamethasone, due to its negligible mineralocorticoid action and good anti-inflammatory effect is an excellent drug to manage post surgical outcomes of impacted third molar surgery. A single preoperative dose of 8mg of the drug has been found to significantly reduce the facial edema, trismus and pain, as evidenced by other studies done by Antonio Antunes et al and Jose Filho et al.[15,17] While piroxicam provides some level of anti-inflammatory and analgesic effect it is not as effective as dexamethasone. Studies such as those carried out by Benetello et al suggest that a longer course of 20mg oral piroxicam such as 4 days preoperatively as used in their study may be more effective at controlling pain and inflammation post surgical extraction of impacted third molars.[20]

CONCLUSION

The present study compared the analgesic and anti-inflammatory effects of oral 8mg dexamethasone and 20mg oral piroxicam given preemptively one hour before surgical extraction of impacted lower third molars.

In this study, subjects who were given 8 milligrams of oral dexamethasone were found to have significantly reduced facial edema, trismus and pain when compared to those who have received 20mg piroxicam. These results show that a single-dose oral administration of dexamethasone is clinically effective at managing the sequelae of impacted lower third molar surgery. Usually parenteral and postoperative administration of dexamethasone is followed more commonly within the surgical community and this study has provided evidence for the novel concept of preemptive administration as well as the benefits of the oral route. Further split mouth studies would be helpful in cementing the place of this drug as an inexpensive, non invasive and convenient option for managing the facial edema, trismus and pain following extraction of impacted third molars.

From the analysis of the results of this study and within its limitations, we can conclude that use of 8mg oral dexamethasone one hour preoperatively leads to a more comfortable and pain free period for patients who undergo wisdom teeth removal. The relative ease of administration and single dosing schedule make it an attractive candidate for pharmacological means of reducing postsurgical pain and inflammation. Its use in other minor surgeries of the oral cavity including alveoloplasty and vestibuloplasty can be studied in further research undertakings.

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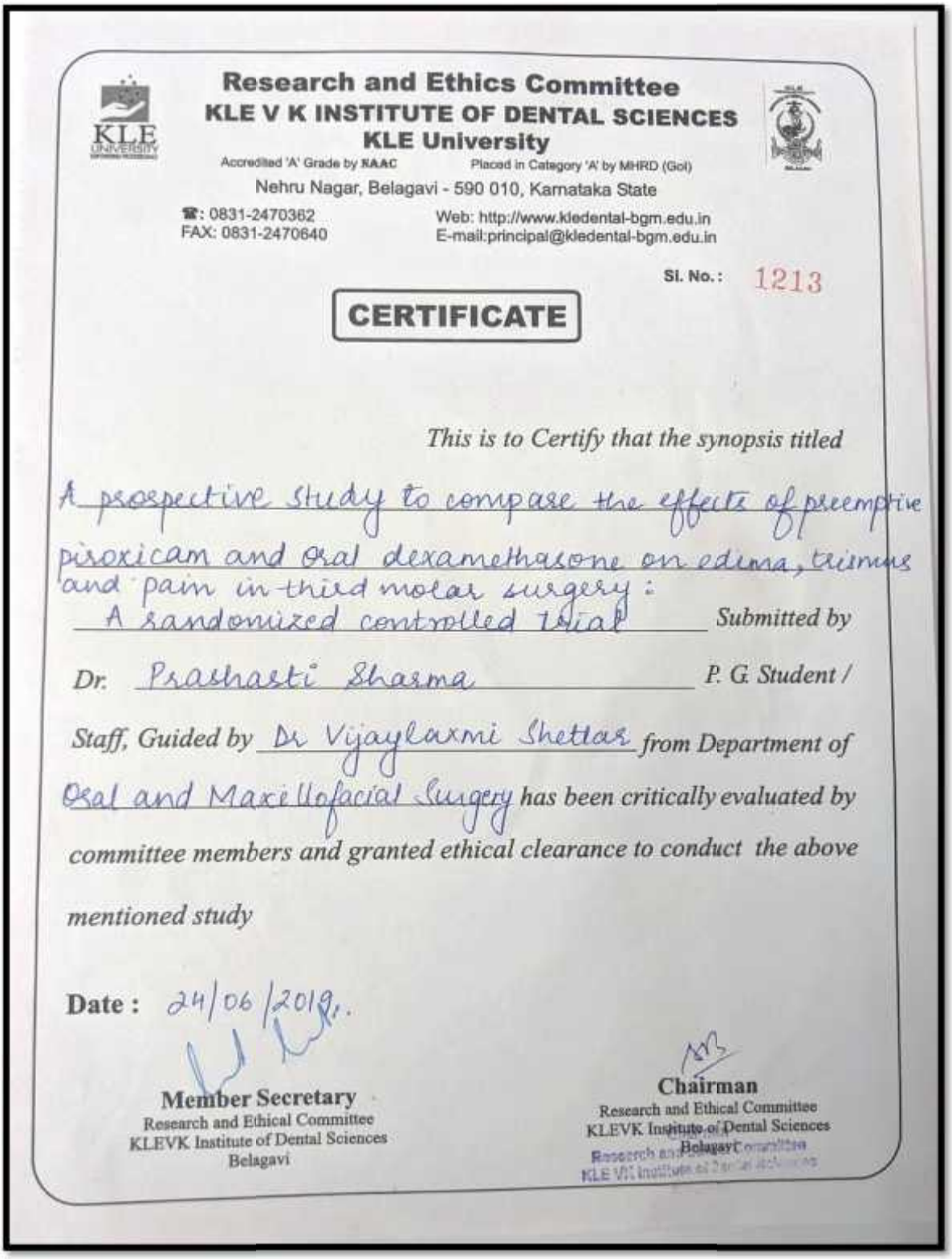
ANNEXURE – I – ETHICAL CLEARANCE LETTER



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CERTIFICATE

This is to Certify that the synopsis titled

A prospective study to compare the effects of preemptive piroxicam and oral dexamethasone on edima, trismus and pain in third molar surgery: A randomized controlled trial

Submitted by

Dr. Prashasti Sharma *P. G. Student /*

Staff, Guided by Dr Vijaylaxmi Shettar *from Department of* Oral and Maxillofacial Surgery *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 24/06/2019.

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE - II – BIOSTATISTICS CERTIFICATE

KLE V.K. Institute of Dental Sciences
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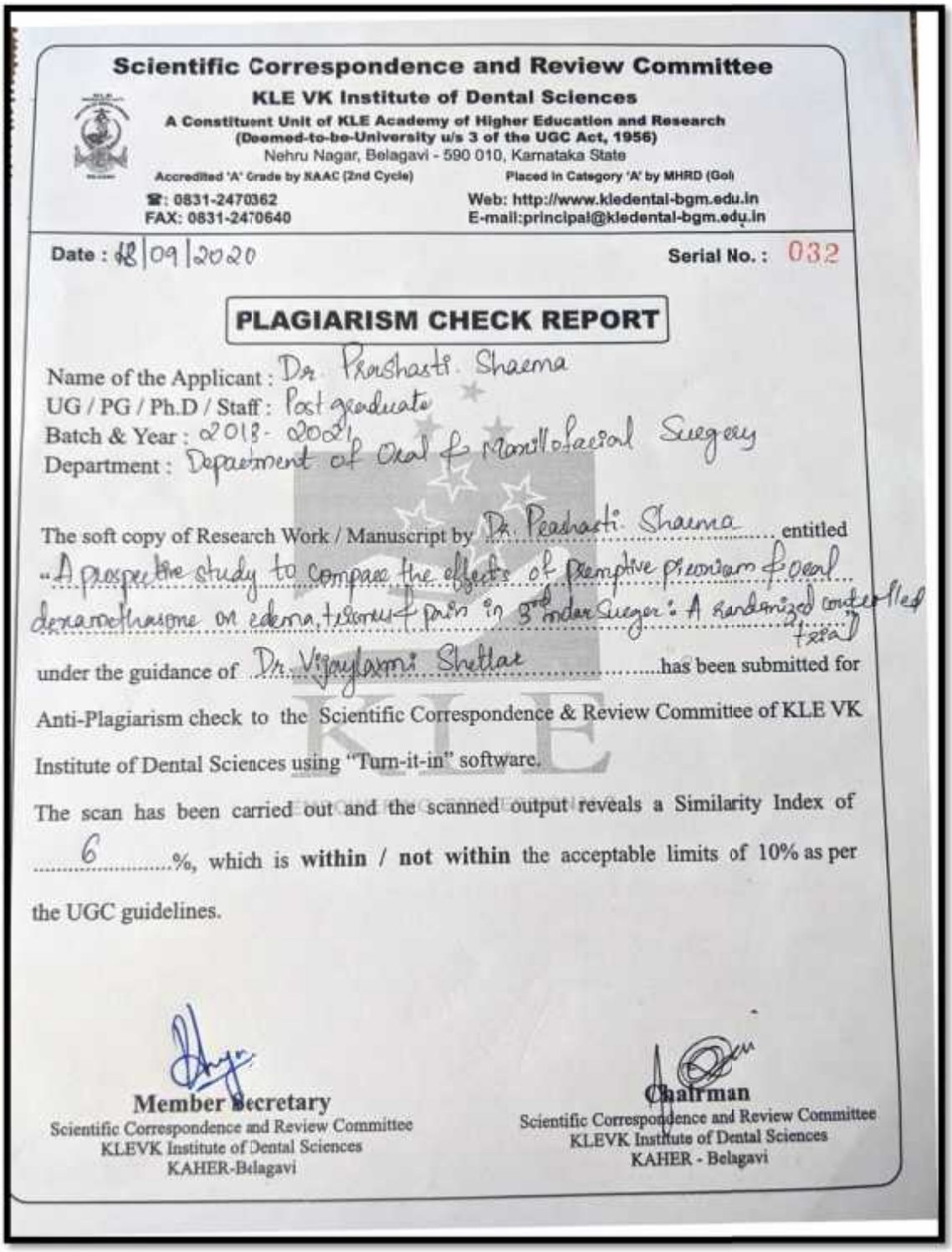
Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of **Dr. Prashasti Sharma** entitled **"COMPARATIVE EFFECT OF PRE-EMPTIVE ORAL PIROXICAM AND DEXAMETHASONE ON EDEMA, TRISMUS AND PAIN AFTER THIRD MOLAR SURGERY– A PROSPECTIVE, RANDOMIZED CONTROLLED CLINICAL TRIAL"** has been done under my guidance and considered satisfactory.

Place: Belagavi
Date: 05/09/2020

Name & Signature of Biostatistician
(Dr. S.B. Javali)

ANNEXURE - III – PLAGIARISM CHECK CERTIFICATE



Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

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PLAGIARISM CHECK REPORT

Name of the Applicant : Dr Prashasti Sharma
UG / PG / Ph.D / Staff : Post graduate
Batch & Year : 2018 - 2021
Department : Department of Oral & Maxillofacial Surgery

The soft copy of Research Work / Manuscript by Dr. Prashasti Sharma entitled "A prospective study to compare the effects of preemptive piroxicam & oral dexamethasone on edema, trismus & pain in 3rd molar Surgery: A randomized controlled trial"

under the guidance of Dr. Vijayalaxmi Shettar has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of 6%, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE – IV - INFORMED CONSENT FORM

Comparative effect of preemptive piroxicam and oral dexamethasone on edema, trismus and pain in third molar surgery: A randomized controlled trial

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

KLE'S VISHWANATH KATTI INSTITUTE OF DENTAL SCIENCES,

BELAGAVI.

I, _____ aged _____ have been informed aboutmy involvement in the study:

1) I agree to give my personal details like name, age, sex, address and the details requiredfor the study to the best of my knowledge.

2) I am informed about the study drugs, piroxicam and dexamethasone, and I will undergo the procedure regardless of the drug used. I agree and give my consent to the oral and maxillofacial surgeon to perform the procedure.

3) I have been informed about the possible complications like gastric irritation, inhibition of platelet aggregation, HPA axis suppression, immunosuppression, fluid and electrolyte imbalance and hyperglycemia

4) I permit the surgeon to utilize the information given by me and results obtained fromthis study for presentation and publication purpose.

5) I will not claim any returns for my cooperation in the study, even if it is being sponsored by any agency.

6) I will follow the instructions given by the doctor.

7) During the study, if I wish to resign from the study, I am free to do so and my treatment will still be completed in the department.

In my full consciousness and presence of mind, after understanding the procedure in myvernacular language, I am willing and give my consent to participate in this study.

Date:

Place: Belagavi

Subject's Signature Signature of witness

ತಿಳಿವಳಿಕೆಯಸಮ್ಮತಿನಮೂನೆ

ಉನ್ನತಶಿಕ್ಷಣಮತ್ತುಸಂಶೋಧನೆಯಕೆಎಲ್ಅಕೆಡೆಮಿ

(K.L.E ಯುನಿವರ್ಸಿಟಿಸ್) ಕೆಎಲ್ಇವಿಕೆಇನ್ಸ್ಟಿಟ್ಯೂಟ್ಆಫ್ಡೆಂಟಲ್ಸೈನ್ಸ್, ಬೆಳಗಾವಿ

“ ಟ್ರೈಸ್ಮಸ್, ಊತಮತ್ತುಮೂರನೇಮೋಲಾರ್ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯಲ್ಲಿನೋವುಮುಂತಾದಪೂರ್ವ-ಪೂರ್ವಪಿರೋಕ್ಸಿಯಾಮ್ಮತ್ತುಮೌಖಿಕಡೆಕ್ಸಾಮೆಥಾಸೋನ್ನಪರಿಣಾಮಗಳನ್ನುಹೋಲಿಸಲುಒಂದುನಿರೀಕ್ಷಿತಅಧ್ಯಯನ: ಏಯಾದೃಚ್ಛಿಕನಿಯಂತ್ರಿತಪ್ರಯೋಗ “

ಪ್ರಿನ್ಸಿಪಲ್ಇನ್ವೆಸ್ಟಿಗಾಟರ್: ಡಾ.ಪ್ರಶಸ್ತಿಶರ್ಮಾ

ನಾನು, ______________________________ ವಯಸ್ಸಿನ ______

ಬಗ್ಗೆತಿಳಿಸಲಾಗಿದೆ

ಅಧ್ಯಯನದಲ್ಲಿನನ್ನಪಾಲ್ಗೊಳ್ಳುವಿಕೆ

ಹೆಸರು, ವಯಸ್ಸು, ಲಿಂಗ,

ವಿಳಾಸಮತ್ತುಅಗತ್ಯವಿರುವವಿವರಗಳುಮುಂತಾದನನ್ನವೈಯಕ್ತಿಕವಿವರಗಳನ್ನುನಾನುಒಪ್ಪುತ್ತೇನೆನನ್ನಜ್ಞಾನದ

ಅತ್ಯುತ್ತಮಅಧ್ಯಯನಕ್ಕೆ

ಅಧ್ಯಯನಔಷಧಗಳು,

ಪಿರೋಕ್ಸಿಯಾಮ್ಮತ್ತುಡೆಕ್ಸಾಮೆಥಾಸೋನ್ಗಳಬಗ್ಗೆನನಗೆಮಾಹಿತಿನೀಡಲಾಗಿದೆಮತ್ತುನಾನುಬಳಸಿದಔಷಧಿಗಳ

ಹೊರತಾಗಿಯೂನಾನುಈವಿಧಾನಕ್ಕೆಒಳಗಾಗುತ್ತೇನೆ.

ವಿಧಾನವನ್ನುನಿರ್ವಹಿಸಲುಮೌಖಿಕಮತ್ತುಮ್ಯಾಕ್ಸಿಲೊಫೇಸಿಯಲ್ಶಸ್ತ್ರಚಿಕಿತ್ಸಕರಿಗೆನನ್ನಒಪ್ಪಿಗೆಯನ್ನುಒಪ್ಪುತ್ತೇನೆಮತ್ತುಒಪ್ಪುತ್ತೇನೆ.

ಗ್ಯಾಸ್ಟ್ರಿಕ್ಕಿರಿಕಿರಿ, ಪ್ಲೇಟ್ಲೆಟ್ಒಟ್ಟುಗೂಡಿಸುವಿಕೆ, ಪಿಟ್ಯುಟರಿಅಕ್ಷನಿಗ್ರಹ, ಇಮ್ಯುನೊಸಪ್ರೆಷನ್, ದ್ರವಮತ್ತುಎಲೆಕ್ಟ್ರೋಲೈಟ್ಅಸಮತೋಲನಮತ್ತುಹೈಪರ್ಗ್ಲೈಸೆಮಿಯಾಗಳಂತಹಸಂಭಾವ್ಯತೊಡಕುಗಳಬಗ್ಗೆ ನನಗೆತಿಳಿಸಲಾಗಿದೆ.

ನನ್ನಿಂದನೀಡಿದಮಾಹಿತಿಯನ್ನುಮತ್ತುಪಡೆದಫಲಿತಾಂಶಗಳನ್ನುಬಳಸಿಕೊಳ್ಳಲುನಾನುಶಸ್ತ್ರಚಿಕಿತ್ಸಕರಿಗೆಅನುಮತಿನೀಡುತ್ತೇನೆಪ್ರಸ್ತುತಿಮತ್ತುಪ್ರಕಟಣೆಯಉದ್ದೇಶಕ್ಕಾಗಿಈಅಧ್ಯಯನವು.

ಅಧ್ಯಯನದಲ್ಲಿನನ್ನಸಹಕಾರಕ್ಕಾಗಿಯಾವುದೇಲಾಭವನ್ನುನಾನುಪಡೆದುಕೊಳ್ಳುವುದಿಲ್ಲ,

ಅದುಇದ್ದರೂಸಹಯಾವುದೇಸಂಸ್ಥೆಪ್ರಾಯೋಜಿಸಿದೆ.

ವೈದ್ಯರುನೀಡಿದಸೂಚನೆಗಳನ್ನುನಾನುಅನುಸರಿಸುತ್ತೇನೆ.

ಅಧ್ಯಯನದಸಮಯದಲ್ಲಿ, ನಾನುಅಧ್ಯಯನದಿಂದರಾಜೀನಾಮೆನೀಡಲುಬಯಸಿದರೆ,

ನಾನುಹೀಗೆಮಾಡಲುಮುಕ್ತನಾಗಿರುತ್ತೇನೆಚಿಕಿತ್ಸೆಇನ್ನೂಇಲಾಖೆಯಲ್ಲಿಪೂರ್ಣಗೊಳ್ಳುತ್ತದೆ.

ನನ್ನಸಂಪೂರ್ಣಪ್ರಜ್ಞೆಮತ್ತುಮನಸ್ಸಿನಉಪಸ್ಥಿತಿಯಲ್ಲಿ,

ನನ್ನಕಾರ್ಯವಿಧಾನವನ್ನುಅರ್ಥಮಾಡಿಕೊಂಡನಂತರದೇಶೀಯಭಾಷೆ,

ನಾನುಈಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುಒಪ್ಪುತ್ತೇನೆಮತ್ತುನನ್ನಸಮ್ಮತಿಯನ್ನುನೀಡುತ್ತೇನೆ

ದಿನಾಂಕ:

ಸ್ಥಳ: ಬೆಳಗಾವಿ

ವಿಷಯದಸಂ ಸಾಕ್ಷಿಯಸಹಿ

सूचितसंमतीफॉर्म

केएलईअँकॅडमीऑफउच्चएज्युकेशनअँडरिसर्च

(केएलईयुनिव्हर्सिटीज) केएलईव्हीकेइन्स्टिटयुटऑफ़डेंटलसायन्स, बलावावी

"दोनड्रग्सच्यापिरॉक्सिकॅमआणिडिसक्सामाथासोनच्यापरिणामाचीतुलनाकरण्यासाठीसंभाव्यअ
भ्यास. तिसर्यादाहसर्जरीमध्येदुखणे, सूजआणितोंडउघडणे - एकयादृच्छिकनियंत्रितचाचर्ण"

मुख्यतपासक: डॉ. प्रशस्तीशर्मा

मी, _____ वयाच्या _____

चीमाहितीदिलीगेलीआहे

अभ्यासातमाझासहभाग

1) मीमाझेवैयक्तिकतपशीलजसेकीना , वय, लिंग, पत्ताआणिआवश्यकतपशीलांसहसहमतआहेअभ्यासासाठीमीमाझ्याज्ञानाचासर्वोत्तमआहे.

2) मलाऔषधे, पायरोक्सिकॅमआणिडेक्सॅमेथेसॉनयाविषयाबद्दलमाहितीआहेआणिकोणतीऔषधीवापरलीगेलीआहे त्याकडेदुर्लक्षकरूनमीप्रक्रियापूर्णकरू.

मीसहमतआहेआणिप्रक्रियापूर्णकरण्यासाठीतोंडीआणिमॅक्सिलोफेशियलसर्जनलामाझीसंमतीदेतो.

3) मलागॅस्ट्रिकजळजळ, प्लेटलेटएकत्रीकरण, एचपीएएॅक्सिससप्रेशन, इम्यूनोस्प्रेशन, द्रवआणिइलेक्ट्रोलाइटअसंतुलनआणिहायपरग्लासेमियायांसारख्यासंभाव्यगुंतागुंतांबाबतमाहितीमि ळालीआहे.

4) मीसर्जननेदिलेल्यामाहितीचावापरआणिप्राप्तझालेल्यापरिणामांचावापरकरण्याचीपरवानगीदेतोप्रेझें टेशनआणिप्रकाशनउद्देशासाठीहाअभ्यास.

5) अभ्यासातमाझ्यासहकार्यासाठीमीकाहीरिटर्नचादावाकरणारनाही, जरीतोअसेलकोणत्याहीएजन्सीद्वारेप्रायोजित.

6) मीडॉक्टरांनीदिलेल्यानिर्देशांचेपालनकरू.

7) अभ्यासादरम्यान, जरमीअभ्यासातूनराजीनामादेण्यासइच्छुकअसेलतरमीआणिमाझीमुक्तताकरण्यासमुक्तआहे विभागअजूनहीउपचारपूर्णहोईल.

माझ्यापूर्णप्रक्रियेतआणिमनाचीउपस्थिती, माझ्यातीलप्रक्रियासमजूनघेतल्यानंतरस्थानिकभाषा, मीयाअभ्यासातभागघेण्यासाठीमाझीतयारीदेतआहे.

तारीख:

ठिकाण:बेलगावी विषयस्वाक्षरीसाक्षीदारांचीस्वाक्षरी

ANNEXURE – V - CASE HISTORY PROFORMA

NAME: **AGE/ SEX:**

OCCUPATION: **O.P.NO.:**

ADDRESS: **DATE:**

CHIEF COMPLAINT:

HISTORY OF PRESENTING ILLNESS:

PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

DRUG ALLERGY:

PERSONAL HISTORY:

Smoking/ Alcohol/ Tobacco chewing

GENERAL PHYSICAL EXAMINATION:

EXTRA-ORAL EXAMINATION:

Facial Symmetry:

TMJ:

Lymph Node:

Mouth Opening:

INTRA-ORAL EXAMINATION:

- Soft Tissue Surrounding The Impacted Tooth: Normal/ Inflamed
- Swelling:
- Discharge:
- Pain/ Difficulty In Chewing:

PROVISIONAL DIAGNOSIS:

INVESTIGATIONS:

IOPA:

Routine Blood Investigation**:**

RADIOGRAPH AND CLINICAL CORRELATION:

DIAGNOSIS:

TREATMENT PLANNING:

DETAILS OF SURGERY:

DATE:

SURGICAL PROCEDURE:

Local Anesthesia:

Incision:

Flap:

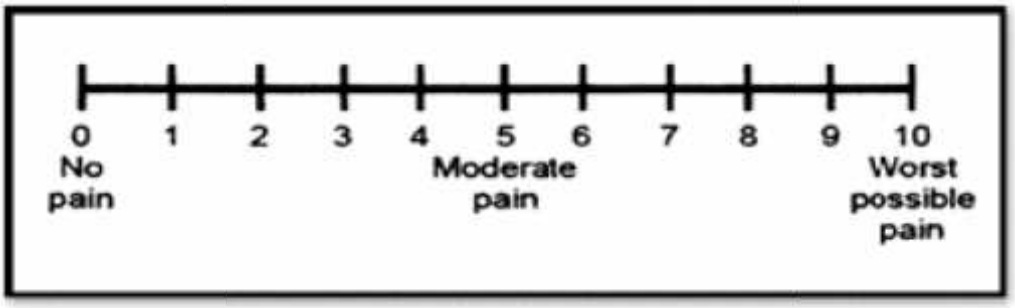
Method Of Extraction:

Closure of Site:

MEDICATION:

FOLLOW-UP:

PAIN - Visual Analog Scale (VAS)



24 hours	48 hours	72 hours

SWELLING

MEASUREMENT (in cm)	Preoperative	Post-operative day 2	Post-operative day 7
Tragus – Corner of mouth			
Lateral Canthus – Angle			
Tragus - Pogonion			

TRISMUS

	Preoperative	Post-operative day 2	Post-operative day 7
Mouth Opening (in cm)			

ANNEXURE – VI - MASTER CHARTS

PIROXICAM GROUP													
Patient Name	Sex	Age	Pederson Index	Pain (Vas Score)				Swelling (In Centimetres)			Inter Incisal Distance (In Centimetres)		
				Post Operative Day 1	Post Operative Day 2	Postoperative Day 3	Post Operative Day 7	Pre Operative	Post Operative Day 2	Post Operative Day 7	Pre Operative	Post Operative Day 2	Post Operative Day 7
Case 1	F	24	6	8	6	7	2	10.83	11.56	10.96	4	2.6	3.8
Case 2	M	20	5	7	7	5	3	11.7	12.3	11.9	4.5	3	4.5
Case 3	M	30	6	8	6	5	3	11.33	12.26	11.6	4.5	3.5	4.3
Case 4	F	32	5	9	7	5	3	10.83	11.6	11.1	4.2	2.9	4.1
Case 5	F	27	4	8	7	5	3	10.4	11.33	10.56	4	3.2	3.7
Case 6	F	38	5	7	7	5	2	11.26	11.9	11.4	4	2.8	3.6
Case 7	M	29	4	7	6	4	3	11.33	12.23	11.73	4.5	3	4.5
Case 8	M	21	5	6	5	3	2	11.5	12.06	11.56	4	2.8	3.8
Case 9	F	26	6	7	7	5	3	10.73	11.33	10.9	3.8	2.5	3.6
Case 10	F	22	6	8	6	5	2	10.83	11.06	10.86	4	2.5	3.6
Case 11	F	35	5	7	6	5	2	11.33	11.8	11.46	4.2	3	4
Case 12	F	31	6	7	6	6	3	10.33	10.96	10.43	3.5	2.5	3.3
Case 13	F	24	5	8	7	5	4	10.16	11.06	10.43	3.5	2.2	3.2
Case 14	M	33	4	8	6	3	2	11.5	12.26	11.63	4.5	3.8	4.5
Case 15	M	36	6	7	7	6	3	11.5	12.06	11	4.4	3.5	4.3
Case 16	M	38	6	6	7	5	2	11.83	12.36	11.5	4.2	3.5	4.2

Dexamethasone group													
Patient name	Sex	Age	Pederson index	Pain (vas score)				Swelling (in centiimeter)			Inter incisal distance (in centiimeter)		
				Post Operative Day 1	Post Operative Day 2	Post Operative Day 3	Post Operative Day 7	Pre Operative	Post Operative Day 2	Post Operative Day 7	Pre Operative	Post Operative Day 2	Post Operative Day 7
CASE 1	F	24	6	7	5	4	2	10.73	11.16	10.8	3.9	2.5	3.8
CASE 2	M	20	5	6	5	3	1	11.5	11.86	11.5	4.2	3.5	4.2
CASE 3	M	30	4	6	5	3	1	11.6	11.93	11.66	4.5	3	4
CASE 4	M	32	6	7	6	3	1	11.4	11.76	11.4	4.2	3.8	4.2
CASE 5	F	27	5	6	5	3	1	10.5	10.83	10.63	3.9	3	3.9
CASE 6	M	38	5	6	5	2	2	11.5	11.96	11.56	4.8	3.5	4.8
CASE 7	M	29	6	5	5	4	3	11.6	11.93	11.66	4.2	3.5	4.2
CASE 8	F	21	6	5	4	2	1	10.3	10.86	10.4	4	3.5	4
CASE 9	M	26	4	6	4	3	2	11.83	12.16	11.83	4.5	3.5	4.5
CASE 10	F	22	6	5	4	2	1	11.5	11.93	11.5	4.3	3.2	4.2
CASE 11	F	35	6	5	5	4	1	11.23	10.7	10.3	3.8	3	3.8
CASE 12	F	31	4	5	4	4	2	10.4	10.93	10.43	4	3.2	4
CASE 13	M	24	6	7	6	3	2	11.5	11.83	11.5	4.2	3.5	4.2
CASE 14	M	33	5	6	6	4	2	11.6	11.96	11.6	4	3.7	4
CASE 15	F	36	5	5	5	3	1	10.33	10.8	10.4	4	3.2	3.9