A Prospective Randomised Double Blind Study Evaluating the Efficacy of Intra Venous Methylprednisolone in Third Molar Surgery

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Abstract

Purpose: To evaluate the efficacy of 40 mg pre-operative and 80 mg post-operative doses of intravenous methylprednisolone (Solumedrol) in the reduction of post-operative complication after surgical removal of impacted mandibular third molars.

Materials And Methods: A prospective randomised double blind study was carried out in The Department of Oral and Maxillofacial surgery, GITAM Dental College and Hospital, Visakhapatnam On fifty patients with impacted mandibular third molars randomly divided into two groups of twenty five patients each after obtaining the ethical committee approval. Parameters taken for consideration are swelling, pain and trismus preoperatively, immediate post operative, 2nd and 7th post operative days. WBC count on pre operative and 7th post op day. The study solution was administered intravenously just before administration of local anesthesia. Post operative dose of the drug was given 6 hours after the pre operative dose.

Results: Significant difference was observed between placebo and steroid groups with respect to pain, swelling and mouth opening from pre-operative to 2^{nd} day. Non-significant difference was observed between placebo and steroid groups with respect to WBC counts (cells/mm3) at pre-operative, 7^{th} day and difference of pre-operative to 7^{th} day at 5% level of significance (p>0.05).

Conclusion: Patients in steroid group have reported less discomfort and quicker return to work when compared to those patients in control group supporting the administration of intravenous methylprednisolone.

Key words: Impacted mandibular third molars, Intravenous Methylprednisolone, Pain, Swelling, Trismus.

Introduction: Extraction of mandibular third molars accounts for a large volume of cases in contemporary oral surgical practice and requires much planning and surgical skill, during both pre-operative diagnosis and post-operative management. The incidence of impacted third molars has been reported to be 68.6% in Indian population¹.

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I. Introduction

Third molar surgeries are associated with post-operative complications like pain, swelling and trismus which are distressing to the patient and pose a great burden to the economy due to time off from work. It has been reported that a total work off of 10 days is being taken post-operatively by patients due to these complications². Studies have revealed that the average expenditure due to absence from work and post-operative medication was much higher than the actual cost of surgery. A threefold decrease in the quality of life has been reported in patients who experience the adverse effects of third molar surgery like pain, swelling and trismus alone or in combination, when compared to those who were asymptomatic.³ Many clinicians have thus emphasized the necessity for better control of pain, swelling and trismus post-operatively. The acute post-operative squeals of surgical procedures are manifestations of inflammation due to tissue injury. The inflammatory process is necessary for healing to occur, but often excessive inflammation results in pain, edema and trismus. Strategies for managing these clinical symptoms are aimed at interfering with the inflammatory process, to limit the intensity and shorten the duration of clinical signs of inflammation. Several methods of controlling these immediate inflammatory responses include the use of drugs such as analgesics and

corticosteroids, different surgical closure techniques with or without drains etc. Among many drugs used before or just after lower third molar surgery, corticosteroids have become a widely accepted option.

The use of corticosteroids in dental practice by Spies in 1952 for the treatment of temporomandibular joint arthritis⁴ triggered the use of anti-inflammatory properties of corticosteroids in third molar surgeries. Since then the use of these drugs has become widely accepted in third molar surgery and many articles have been published reporting the synthesis of new molecules, various administration routes and doses. Dexamethasone and Methylprednisolone are the two commonly used corticosteroids in third molar surgery. Various doses of these drugs have been administered through oral, parenteral or local routes by several investigators. But because of the great diversity in the study designs, it has been difficult to define definite guidelines for administration of these drugs emphasizing the need for further research. In an attempt to find an answer to this ambiguity, this study was designed to evaluate the efficacy of intravenous methylprednisolone sodium succinate in controlling the post-operative swelling, pain and trismus in third molar surgery.

II. Materials And Methods

This prospective randomized double blind study was carried out in The Department of Oral and Maxillofacial surgery, GITAM Dental College and Hospital, Visakhapatnam to evaluate the efficacy of 40 mg pre-operative and 80 mg post- operative doses of intravenous methylprednisolone (Solumedrol), in the reduction of post-operative complication after surgical removal of impacted mandibular third molars. The study was carried out in fifty patients with impacted mandibular third molars randomly divided into two groups of twenty five patients each after obtaining the ethical committee approval. The inclusion criteria for this study were healthy patients below 30 years of age with impacted mandibular third molars partially or completely covered with bone, requiring bone removal for their extraction. Pregnant and lactating mothers, patients with pericoronitis and those on steroid therapy were excluded from the study. In this double blind study, the solutions were randomly coded by an authority involved neither in the administration of the drug nor in the operative procedure and study, from a random number table. Each subject was randomly assigned either to the steroid group or to the placebo group. The solutions were blinded by masking the appropriate syringes with white tape, which were labeled in coded alphabets (fig 5). Parameters taken for consideration are swelling, pain and trismus recorded pre- operatively, immediately after the surgery, on second and seventh post-operative days among patients of both the groups. WBC count was also noted pre-operatively and on 7th postoperative day. Facial swelling was measured by a modification of tape measuring method described by Gabka and Matsumara. (Fig 6, 7 and 8) Three measurements were made between 5 reference points: tragus, soft tissue pogonion, lateral corner of the eye, angle of the mandible and outer corner of the mouth. The pre-operative sum of all the three measurements was considered as the base line and the difference between each post-operative and the baseline measurements would give the changes in the facial swelling.

Trismus was evaluated by measuring the distance between the mesial incisal corners of the upper and lower central incisors at maximum mouth opening (Fig 9). Pain was evaluated subjectively by Faces pain rating scale. This scale combines pictures and numbers to allow pain to be rated by the patient. The faces range from smiling face to sad and crying face. A numerical rating has been assigned to these faces, ranging from 0 to 10 in ascending order, proportionate to increase of pain (Fig 10). The patient is asked to rate his or her pain using appropriate picture. After a thorough clinical examination, a detailed case history was recorded. Informed consent has been obtained regarding the surgical procedure and administration of study drug. Pre-operatively IOPA (Intra Oral Peri Apical radiographs (Fig 11) were obtained for all cases. Difficulty of impaction was assessed by PEDERSON index. Pain, swelling and maximum mouth opening were recorded pre-operatively. Pre-operative blood sample was collected for WBC count. The study solution was administered intravenously just before administration of local anaesthesia. The patients were given classical inferior alveolar nerve bock supplemented by long buccal nerve block using 2% lignocaine hydrochloride with vasoconstrictor (1:80,000). The three limbs of the Wards incision - anterior releasing incision, distal and crevicular incisions are planned according to the position of the impacted tooth. A full thickness mucoperiosteal flap was raised. After the need for and extent of bone removal has been determined, a hand piece with adequate speed and torque is used to remove bone from the occlusal aspect of the tooth if necessary. Buccal and distal bone is removed down to the cervical line of the impacted tooth. Tooth sectioning was dependent upon the position of the impacted tooth. Following the removal of tooth, bony socket was irrigated with sterile saline solution. A tension free flap closure was obtained with simple interrupted sutures in 3-0 black silk suture material. Immediately after completion of the surgical procedure, swelling, pain and maximum mouth opening were recorded. The patient was given post-operative instructions and all patients were prescribed 50 mg diclofenac sodium 12 hourly and 500 mg amoxicillin 8 hourly orally for 5 days post-operatively.

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Post-operative dose of the study drug was given 6 hours after the pre-operative dose. Patients were recalled on second and seventh days to record the intensity of swelling, pain and trismus. Suture removal was done on the seventh day and blood sample was collected on same day for post-operative WBC count.



Fig-2 ARMAMENTARIUM



Fig-3 METHYLPREDNISOLONE SODIUM SUCCINATE (STUDY DRUG)

28



Fig 4: NORMAL SALINE (PLACEBO)



Fig 5: CODED SYRINGES

20

MEASUREMENT OF FACIAL SWELLING



Fig 6: TRAGUS TO CORNER OF MOUTH MEASUREMENT



Fig 7: TRAGUS TO POGONION MEASUREMENT



Fig 8: LATERAL CORNER OF EYE TO ANGLE OF MANDIBLE MEASUREMENT

30

EVALUTION OF TRISMUS



Fig 9: MEASUREMENT OF INTERINCISAL DISTANCE

EVALUTION OF PAIN

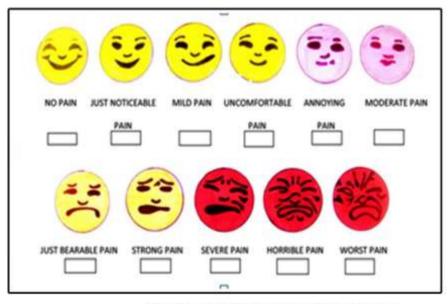


Fig 10: FACES PAIN RATING SCALE



Fig 11: INTRA ORAL PERI APICAL RADIOGRAPH



Fig 12: PRE OPERATIVE



Fig 13: INCISION



Fig 14: EXTRACTED MANDIBULAR THIRD MOLAR



Fig 15:WOUND CLOSURE

III. Results

Method of Statistical Analysis:

The data were collected on forms and entered into a Microsoft Excel Worksheet and analyzed using SPSS (Statistical Package for Social Sciences, Version 7.5) statistical package. Proportions were compared using Chi-square ($\chi 2$) test of significance. Proportion of cases belonging to specific group of parameter or having a particular problem was expressed in absolute number and percentage.

Table 2:Chi-square (χ 2) test for (2 x 2 tables)

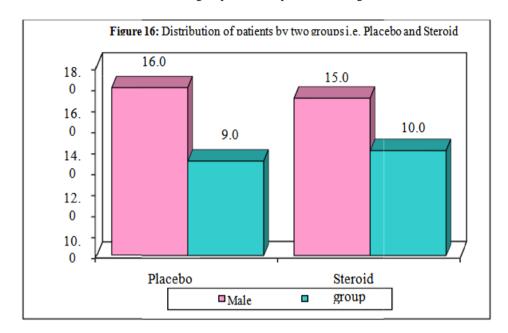
Group	Attribute characteristic finding		Total
Group 1	a	b	a+b
Group 2	c	d	c+d
Total	a+c	b+d	N

a,b,c,d are the observed numbers.

N is the Grand Total

$$\chi 2 = \frac{N (ad-bc)^2}{(a+b) (c+d) (a+c) (b+d)}$$

The results were averaged (mean + standard deviation) for each parameter between the groups. Paired't' test and unpaired 't' test was used to find a significant difference between the two means. In all the tests "p" value of less than 0.05 was accepted as indicating statistical significance.

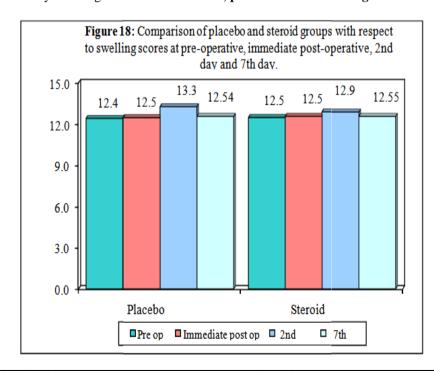


The distribution of male and females in two groups are also presented in figure 16.

The mean age of males and females in placebo and steroid groups is presented in the following figure 17. it can be seen that, the mean age of total patients in placebo group is (24.56 ± 3.58) , in which the mean age of males is (25.44 ± 3.54) which is slightly greater than females (23.00 ± 3.28) . Similarly, the mean age of total patients in steroid group is (23.16 ± 4.29) , in which the mean age of males is (23.00 ± 4.02) which is slightly smaller than females (23.40 ± 4.88) .

Mean scores of placebo and steroid groups with respect to swelling at pre-operative, immediate post-operative, 2^{nd} day and 7^{th} day are depicted in figure 18.

- 1) Significant difference was observed between placebo and steroid groups with respect to swelling scores at 2nd day with **t=2.2825**, **p<0.05** at 5% level of significance. It means that, the 2nd day swelling scores are significantly higher in placebo group as compared to steroid group.
- 2) Significant difference was observed between placebo and steroid groups with respect to difference of preoperative to 2nd day swelling scores with **t=4.6689**, **p<0.05** at 5% level of significance.



DOI: 10.9790/0853-161108 www.iosrjournals.org 17 | Page

Mean swelling scores of pre-operative, immediate post-operative, 2^{nd} day and 7^{th} day in placebo and steroid groups with respect to swelling scores by paired 't' test are depicted in figure 19. Significant difference was observed between pre-operative to 2^{nd} day, pre- operative to 7^{th} day, immediate post operative to 2^{nd} day, immediate post operative to 7^{th} day and 2^{nd} day to 7^{th} day with respect to swelling scores. A 5% level of significance (p<0.05) is obtained in placebo group. It means that, the reduction or increase in swelling scores from pre-operative to 2^{nd} day and 7^{th} day are found to be significant and different in placebo and steroid group.

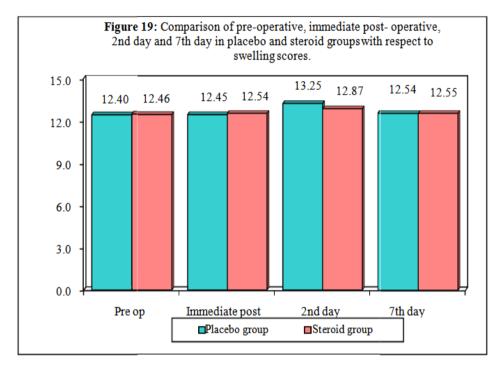
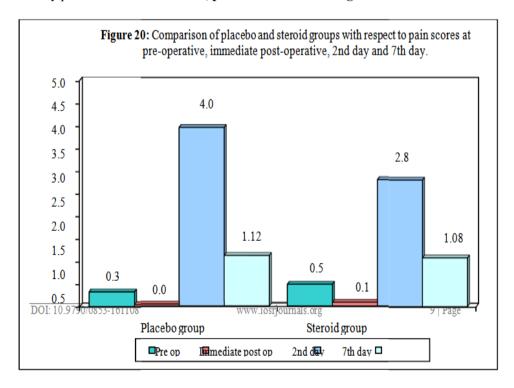


Figure 20 shows comparison of placebo and steroid groups with respect to pain scores at preoperative, immediate post-operative, 2^{nd} day and 7^{th} day and their differences by Mann-Whitney 'U' test. Significant difference was observed between placebo and steroid groups with respect to difference of preoperative to 2^{nd} day pain scores with t=-2.1149, p<0.05 at 5% level of significance.



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Figure 21 shows comparison of pre-operative, immediate post-operative, 2^{nd} day and 7^{th} day in placebo and steroid groups with respect to pain scores by Wilcoxon matched pairs test. Significant difference was observed between pre-operative to 2^{nd} day, pre- operative to 7^{th} day, immediate post operative to 2^{nd} day and 2^{nd} day to 7^{th} day with respect to pain scores in placebo group (p<0.05). Significant difference was observed between pre-operative to 2^{nd} day, immediate post operative to 2^{nd} day, and 2^{nd} day to 7^{th} day with respect to pain scores in steroid group

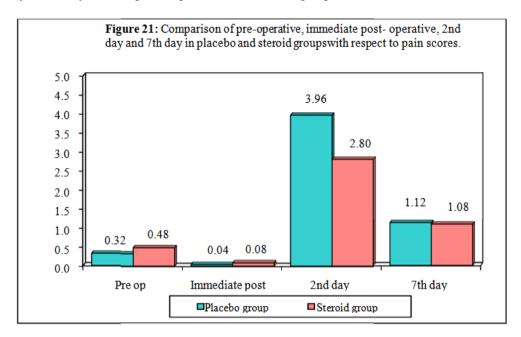


Figure 22 shows comparison of placebo and steroid groups with respect to mouth opening scores at pre-operative, immediate post-operative, 2^{nd} day and 7^{th} day and their differences by unpaired 't' test. Significant difference was observed between placebo and steroid groups with respect to mouth opening scores at 2^{nd} day with t=-2.3735, p<0.05.

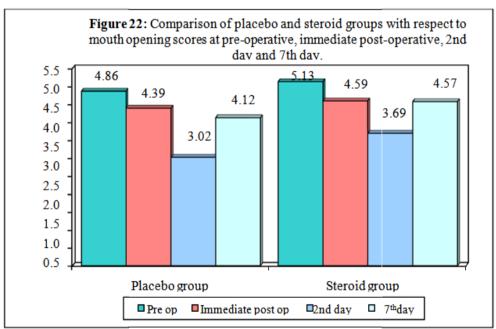


Figure 23 shows comparison of pre-operative, immediate post-operative, 2nd day and 7th day in placebo and steroid groups with respect to mouth opening scores by paired't' test.

Significant difference was observed between pre-operative to 2^{nd} day, pre- operative to 7^{th} day, immediate post operative to 2^{nd} day and 2^{nd} day to 7^{th} day except immediate post operative to 7^{th} day with respect to reduction in mouth opening scores at 5% level of significance (p<0.05) in placebo group and in steroid group.

DOI: 10.9790/0853-161108 www.iosrjournals.org 19 | Page

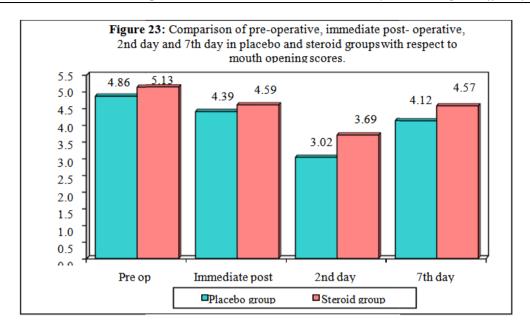


Figure 24 shows comparison of placebo and steroid groups with respect to WBC counts (cells/mm3) at pre-operative and 7^{th} day and their differences by unpaired the test. Non-significant difference was observed between placebo and steroid groups with respect to WBC counts (cells/mm3) at pre-operative, 7^{th} day and difference of pre-operative to 7^{th} day (p>0.05).

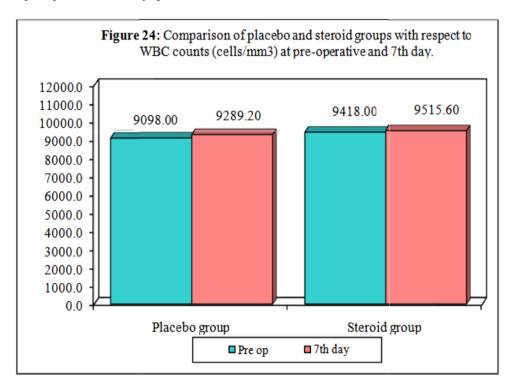
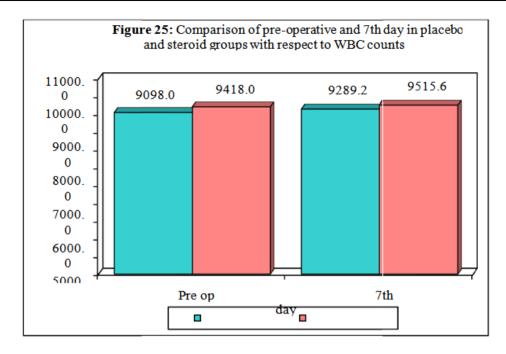


Figure 25 shows comparison of pre-operative and 7^{th} day in placebo and steroid groups with respect to WBC counts by paired 't' test.

Non-significant difference was observed between pre-operative to 7^{th} day with respect to reduction in WBC counts (cells/mm3) with (p>0.05) in placebo and in steroid group.

DOI: 10.9790/0853-161108 www.iosrjournals.org 20 | Page



IV. Discussion

Surgical removal of impacted mandibular third molars is the most frequent surgical procedure in oral surgery. The most common reasons for their removal include recurrent pericoronitis, periodontal problems, unrestorable carious lesions on second or third mandibular molars, presence of cysts and tumors or to prevent future complications. The surgical extraction of impacted mandibular third molars often causes swelling of facial soft tissues, trismus and pain. ¹⁷ These post-operative sequelae are quite annoying to the patient and would affect their quality of life by delaying the period of recovery. These complications are attributed to the inflammation produced as a result of surgical trauma. Oral surgeons have been using corticosteroids to minimize these sequelae and have obtained satisfactory results.³⁰ In 1949, Hench and Kendal used corticosteroids as anti inflammatory agents for the treatment of rheumatoid arthritis. Their use in dental practice began in the early 1950's when Spies et al, Strean and Horton administered hydrocortisone to prevent inflammation in oral surgery²³. Since then different corticosteroids with different efficacies, various routes of administration and doses have been used in oral surgery.⁴ Steroids are known to exhibit their anti inflammatory activity by preventing the release of fatty acids from membrane phospholipids, thereby reducing formation of cyclooxygenase and lipooxygenase products which are important inducers of post- operative inflammatory process leading to edema and pain.²⁴ The analgesic activity of glucocorticoids has been related to their antiinflammatory action by inhibiting phospholipase A2 and thus inhibiting the formation of arachidonic acid. ²⁴ In order to reduce inflammation, corticosteroids must be administered at doses in excess of the physiological concentrations released under normal conditions. In this sense, the body produces approximately 15-30 mg of hydrocortisone daily, a figure that can reach 330 mg under conditions of stress.²¹

In choosing an agent best suited for short term, high dose therapy, one would desire a steroid with minimal mineralocorticoid activity that maintains a therapeutic plasma levels throughout immediate post-operative period (when acute inflammatory reaction is most intense). Various synthetic formulations of steroids have been manufactured to meet these ideal requirements and are being made available commercially.¹¹

The most widely used corticosteroids in oral surgery are betamethasone, dexamethasone and methylprednisolone administered via intravenous, oral or intramuscular route. Among them methylprednisolone which is fivefold more potent than hydrocortisone with relatively less mineralocorticoid activity and longer biological half life of 18-36 hours has been chosen for this study. Methylprednisolone has been widely used in oral surgical procedures for its anti inflammatory actions in doses of 10 mg, 40 mg, 80 mg and 125 mg. Studies of Ustun of Ustun have tall holder than the post-operative sequelae. We administered 120 mg of methylprednisolone was efficient in controlling the post-operative sequelae. We administered 120 mg of methylprednisolone in divided doses of 80 mg IV pre-operatively and 40 mg IV post-operatively to maintain the plasma levels of the drug during the post-operative period. Various routes of administration (PO,IV,IM and submucosal) of steroids have been advocated E. E.Vegas et al has Jasmine Kaur et al has the complex to the intramuscular route of steroid application has been shown to decrease complications in the immediate post interventional period. But there are several stringent reasons, such as a

slow onset of action highly dependent on the rate of blood flow at the site of administration, an increased risk of adrenal suppression and local complications like necrosis, hematoma and abscess formation which discourage the intramuscular route of drug administration. ¹⁸

Carmen et al²², Ibrahim Gatta et al²⁴, found that oral administration of methylprednisolone significantly reduced swelling and pain after third molar surgery. Though oral dosing is possibly the most comfortable option for the patient, it does not seem to be as effective as parenteral administration.¹⁵ The attainment of the immediate high plasma drug concentrations, have encouraged the intravenous administration to be considered frequently as the effective route of administration.¹⁵ Sayed et al¹⁶ investigated the pharmacokinetics of intravenous methylprednisolone sodium succinate and oral methylprednisolone and reported that the bioavailability of drug is incomplete following oral administration. Studies have shown that parenteral administration of the steroid pre-operatively and immediately after surgery obtained good results.¹¹ We administered intravenous methylprednisolone pre-operatively to provide high instant plasma levels of the drug to significantly reduce the production of inflammatory mediators and a second intravenous dose 6 hours post-operatively to ensure that adequate concentration of the plasma levels of the drug is maintained during the post-operative period. A few investigators have put forward that MP in combination with NSAIDS provided greater relief from pain, swelling and trismus. Cemil et al ³¹, Olsted et al ²⁶, Emmanuel et al ²⁷, Graziani et al ³⁰, Selvimovic et al ²⁹ and Marc Leon et al ²⁸ administered methylprednisolone in combination with diclofenac potassium, paracetamol, flurbiprofen, ibuprofen, meloxicam respectively and found that a combination of methylprednisolone and NSAIDS worked better. We administered 50 mg diclofenac sodium in both the groups for a period of 5 days post-operatively.

Intensity of pain was evaluated either by Visual Analogue Scale or by counting the number of analgesics taken by the patients, in most of the studies. Milles et al 17 and Stefen et al 18 found that less number of analgesic tablets were taken by patients in steroid group when compared to placebo. Few other investigators using visual analogue scale, found that the pain scores were significantly higher in placebo on 2^{nd} post-operative day and the scores returned to the pre-operative scores by 7^{th} post-operative day in both the groups. $^{24, 20, 21, 18}$ We recorded pain scores by using visual analogue scale and analysed the severity of pain statistically by Mann Whitney U test and Wilcoxon matched paired test. The results showed a statistically significant (p< 0.05) reduction of pain on second post-operative day in steroid group when compared to placebo but the difference was insignificant (p >0.05) by 7^{th} post-operative day. However, two female patients in steroid group reported a higher pain scores on the seventh post-operative day also, which can be attributed to their apprehension towards the surgical procedure.

Various methods have been used to measure facial swelling and edema. In our study, facial swelling was determined by a modification of tape measuring method of Gabka and Matsumara²³. Obviously, this method is not as accurate as computed tomography(CT) or magnetic resonance imaging (MRI) for making precise measurement of facial soft tissue volume. However, it is a non invasive, simple, cost effective and time saving method which provides numeric data for determination of tissue contour changes. Milles et al ¹⁷ reported that swelling may increase on the third day after surgery. So we recalled the patient on the second post-operative day to record the intensity of swelling, pain and trismus. According to our results, paired't' test analysis and unpaired't' test analysis showed a significant (p< 0.05) reduction of swelling in steroid group when compared to placebo on 2^{nd} post-operative day, while the difference between pre-operative and 7^{th} post-operative day measurement was insignificant (p > 0.05) in both the groups i.e. by the 7^{th} post-operative day the facial measurements have returned to the pre-operative measurements in both the groups. This suggests that post-operative dose of the steroid was effective in limiting the rebound swelling that would occur within the first 48-72 hours. This was in accordance with the studies of Lorens et al ²¹, Ibrahim et al ²⁴, Ustun et al ²⁰, Stephan Acham et al ¹⁸ and C.Holland. ¹⁹

Trismus in both the groups was high on second post-operative day but the steroid group showed a significantly (p< 0.05) greater amount of mouth opening when compared to placebo group according to the paired 't' test and unpaired 't' test analysis. Mouth opening has returned to the pre-operative measurements by 7^{th} post- operative day in both the groups. Similar observations were also recorded by Ibrahim et al²⁴, Ustun et al²⁰, Stephen et al ¹⁸, Carmen et al²²Milles et al¹⁷. The paired 't' test evaluation showed that the steroid group did not show any significant (p > 0.05) alteration in WBC count post-operatively, indicating that short term steroid dose as administered in our study would not influence the WBC count significantly. Thus according to our results the pre and post-operative administration of intravenous methylprednisolone obtained a significant 5% reduction (p < 0.05) of post-operative complications after mandibular third molar surgery on 2^{nd} post-operative day, suggesting that an intravenous post-operative dose six hours after the pre-operative dose would provide a significant reduction of rebound swelling when compared to placebo, thus minimising its co morbidities like pain, and trismus.

V. Conclusion

In order to improve the quality of life of patients after third molar surgery, several studies have been carried out evaluating the efficacy of various drugs for reducing the sequelae of inflammation. The purpose of our study was to compare the efficacy of intravenous methylprednisolone with the control group in the reduction of pain swelling and trismus after mandibular third molar surgery. We administered pre-operative and post-operative intravenous doses of 80 mg and 40 mg methylprednisolone sodium succinate respectively and found a 5% reduction of swelling, pain and trismus when compared to placebo which was statistically significant. Though 5% reduction of complications appears to be a marginal improvement, we have noticed that patients in steroid group have reported less discomfort and quicker return to work when compared to those patients in control group supporting the administration of intravenous methylprednisolone. However, there is a need for further studies to be carried out with larger sample size and with different dosage schedule.

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23 | Page

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Op No: Date: Name: Case No: Age/Sex:

Occupation: Address: Chief Complaint:

Annexure -I

Case Paper

History Of Presenting Illness:

Past Medical History: Past Dental History: Personal History:

Diet: Habit:

Oral Hygiene: General Physical Examination:

Vitals

Blood Pressure: Respiratory Rate: Pulse: Temperature:

Extraoral Examination-Facial Symmetry: Lips:

Cheeks:

Mouth Opening:

Lymph nodes: Intraoral Examination: Hard tissue examination: No of teeth:

Impacted teeth:

Examination of lower third molar: Soft tissue coverage:

Cusps: Caries:

Pus discharge: Tenderness: Difficulty of Impaction index:

Soft tissue examination: Buccal mucosa: Tongue:

Palate:

Floor of mouth: Investigations:

1.Wbc Count. (Pre Op): 2.Iopa.:

Final Diagnosis-Treatment Plan-Treatment Done-

Treatment Done-

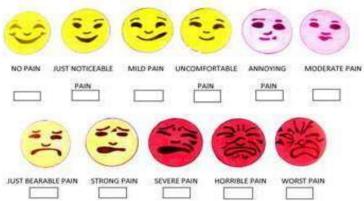
Evaluation of parameters:

Pre-operative:

Measurement of swelling:

1. Distance from lateral corner of eye to the angle of mandible – Distance from tragus to outer corner of mouth - Distance from tragus to pogonion – **Measurement of maximum mouth opening**: Inter incisal distance –

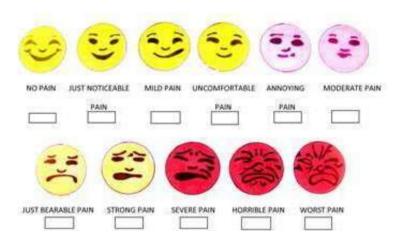
Evaluation of pain:



Immediate post-operative measurement:

Measurement of swelling:

Distance from lateral corner of eye to the angle of mandible – Distance from tragus to outer corner of mouth - Distance from tragus to pogonion- *Measurement of maximum mouth opening:* Inter incisal distance – *Evaluation of pain:*

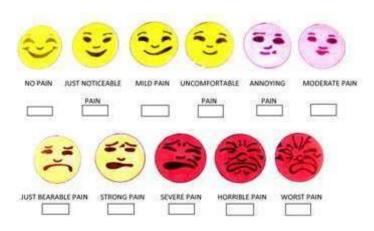


2nd Post-Operative Day:

Measurement of swelling:

Distance from lateral corner of eye to the angle of mandible – Distance from tragus to outer corner of mouth - Distance from tragus to pogonion –

Measurement of maximum mouth opening: Inter incisal distance – **Evaluation of pain:**



7th POST-OPERATIVE DAY:

Measurement Of Swelling:

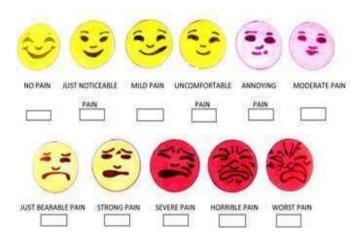
Distance From Lateral Corner Of Eye To The Angle Of Mandible – Distance From Tragus To Outer Corner Of Mouth -

Distance From Tragus To Pogonion -

Measurement Of Maximum Mouth Opening:

Inter Incisal Distance -

Evaluation of pain:



7th POST-OP WBC COUNT: