

Efficacy of single dose intramuscular methylprednisolone injection into the masseter muscle following the surgical extraction of impacted lower third molars.

Abstract:

Aim and Objectives: The clinical study was conducted to evaluate the effect of a single 40 mg dose of methylprednisolone into the masseter muscle via the intrabuccal approach following the surgical extraction of impacted lower third molars under local anesthesia.

Materials and Methods: In this single center, prospective, randomized controlled, double blind study 100 participants were divided into 2 groups. The study group received a single dose of Inj Methylprednisolone 40mg into the masseter muscle via the intrabuccal approach postoperatively, while the control received an I.M placebo drug. The efficacy of this procedure in controlling typical post-operative complications (pain, swelling, and mouth opening) was evaluated.

Results: The patients administered methylprednisolone showed superior results after 2 and 5 days in terms of facial swelling ($p < 0.05$) and on 5th day after intervention with a p-value of 0.008 in terms of pain.

Conclusion: Results obtained showed that 40 mg of Methylprednisolone can effectively reduce the patient discomfort post operatively after surgical removal of impacted teeth.

Keywords: Corticosteroids, Impacted third molars, Methylprednisolone, Masseter muscle

Introduction:

The extraction of impacted lower third molars is the most common procedure in oral surgery, and usually produces pain, trismus and facial swelling in the postoperative period.[1] Single dose of glucocorticoids have shown to inhibit the synthesis and/or release of pro-inflammatory and inflammatory mediators in a variety of surgical procedures, with a reduction of fluid transudation and therefore edema.[2] The mandibular third molar is the most common tooth to become impacted and several studies have been carried out to develop protocols to reduce post-operative complications associated with its removal.

The surgical removal of impacted third molars involves, trauma to soft and hard tissue and can result in considerable pain, swelling and trismus.[3] This postoperative sequel can cause distress to the patient and affect the patient's quality of life after surgery. Many clinicians have emphasized the necessity for better discomfort control in patient undergoing third molar surgery, and several types of medications have been proposed. [4,5]

Hench and Kendall were the first to demonstrate the use of corticosteroids as anti-inflammatory agents in the treatment of rheumatoid arthritis.[6] Their use in dental practice began in the early 1950s, when Spics et al. and Horton administered hydrocortisone to prevent inflammation in oral surgery. [7]

Using steroids for longer periods have certain complications, but in dental surgeries the dosages are less and for short duration, hence the chance of adverse effect is very less. The

¹D. SATHIYANATHAN, ²VIVEK SUNIL NAIR,

³K. SANKAR, ⁴N. J. ESWARI, ⁵ANUSUYA M,

¹Department of Oral and Maxillofacial Surgery, Madha Dental College and Hospital, Chennai

²Department of Oral and Maxillofacial Surgery, Bharathi Vidyapeeth Deemed University Dental College, Pune.

³⁻⁵Department of Oral and Maxillofacial Surgery

⁴Mahatma Gandhi Postgraduate Institute of Dental Sciences, Pondicherry.

Address for Correspondence: Dr. Vivek Sunil Nair
Department of Oral and Maxillofacial Surgery,
Bharati Vidyapeeth Deemed University Dental College,
Katraj, Pune.
Email : vivek.nair@bharatividyapeeth.edu

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glucocorticoids commonly used in oral surgery are dexamethasone (p.o.), dexamethasone acetate (i.m.), methylprednisolone (p.o.), and methylprednisolone acetate and methylprednisolone sodium succinate (i.v. and i.m.). [8]

The present clinical study was conducted to evaluate the effect of a single 40 mg dose of methylprednisolone into the masseter muscle via the intrabuccal approach following the surgical extraction of impacted lower third molars under local anesthesia. The efficacy of this procedure in controlling typical post-operative complications (pain, swelling, and mouth opening) was evaluated.

Material and Methods:

The study was conducted in the Department of Oral and Maxillofacial Surgery between May 2017 and October 2018. 100 patients were selected from the outpatient department of the institute. Subjects undergoing surgical removal of impacted third molar teeth and who was willing to give informed consent were included in the study and were randomly assigned either to receive (group 1) or not (group 2) methylprednisolone 40mg I.M postoperatively. Inclusion criteria included patients having mandibular third molar with Pell and Gregory's class II position B impaction and age between 18 and 35 years. Patients with contraindication to the use of corticosteroids, patients taking antibiotics or anti-inflammatory drugs within 2 weeks of the study and patients having pericoronitis or infections at the time of operation were excluded from the study. Approval of Research and Ethics committee of the institution was obtained to conduct this study.

In this single center, prospective, randomized controlled, double blind study, one hour before the surgery, patient was randomized to either one of the group. The study group received a single dose of methylprednisolone 40mg I.M postoperatively, while the control received an oral placebo drug. Both the patients and the surgeon were blinded to the drug. A third person, staff nurse of the department, who was not involved in the study, was made in charge of dispensing the drugs randomly and maintaining the record of drug dispensed to each patient. This record was not revealed to the investigator till the completion of study and obtaining results. Pain, facial contour and mouth opening were measured at the baseline and post surgically on day 2, 5, after two weeks and after one month.

The surgical procedure was performed under local anaesthesia using 2% Lignocaine hydrochloride containing 1:80,000 adrenaline. Standard inferior alveolar nerve block and long buccal nerve block of surgical site was given. Using standard ward's mucoperiosteal flap, bone guttering was done with low speed straight hand piece and no. 703 bur. The wound closure was done using 3-0 black braided silk sutures. Standard post-operative instructions were given to the patients. The study group received a single dose of Inj Methylprednisolone 40mg into the masseter muscle via the intrabuccal approach postoperatively, while the control received an I.M placebo drug.

Severity of pain perception was assessed using a 10 cm Visual Analogue Scale. Accordingly, '0' was recorded as no pain and '10' as worst pain.

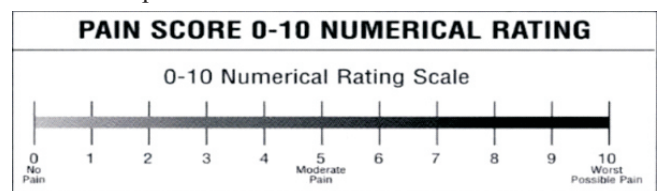


Figure 1: Scale used for assesment of Pain

Swelling was assessed clinically by making the patient sit upright and measuring the distance between 5 fixed points on surgical side of the face using tape and finding the average. The measurements were made in closed mouth position. The fixed points were, A: the most posterior point at the midline on the tragus, B: lateral canthus of the eye, C: the most lateral point on the corner of the mouth, D: soft tissue pogonion which is the most prominent point at the midline on the chin and E: most inferior point on angle of the mandible. The 3 lines were AD (Figure 2a), AC (Figure 2 b) and BE (Figure 2c).



Figure 2a: Line AD (A: the most posterior point at the midline on the tragus, B: lateral canthus of the eye and D: soft tissue pogonion which is the most prominent point at the midline)

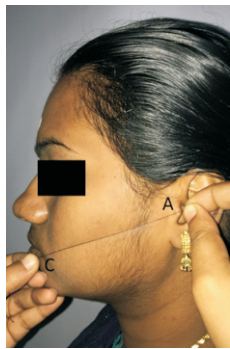


Figure 2b: Line AC (A: the most posterior point at the midline on the tragus, B: lateral canthus of the eye and C: the most lateral point on the corner of the mouth)

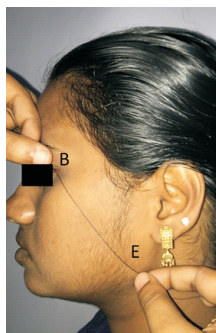


Figure 2c: Line BE (B: lateral canthus of the eye and E: most inferior point on angle of the mandible)

Trismus was assessed by measuring the mouth opening. It was evaluated by measuring the inter-incisal distance at maximum mouth opening using a Vernier calliper (Figure 3).

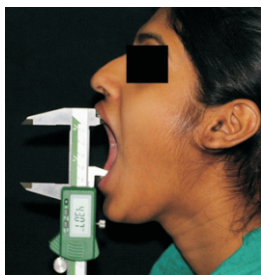


Figure 3: Mouth opening measured using a digital vernier calliper

Results:

A total of 100 patients were enrolled in the study. There were no complications in the form of infection, and no adverse events attributable to corticosteroid use. The preoperative data relating to pain, mouth opening and facial swelling showed no differences between the two groups in terms of the different preoperative measurements made, or in the duration

of surgery. The patients administered methylprednisolone showed superior results after 2 and 5 days in terms of facial swelling ($p < 0.05$). (Table 1) As regards postoperative pain, it was found there was a significant difference between the groups only at 5th day after intervention with a p-value of 0.008. (Table 2) Methylprednisolone did not show any improvement in trismus as the results are statistically insignificant. (Table 3)

Time point	Groups	Median (IQR)	Test statistics	P-value
Pre-intervention	Group 1	11.7 (11.0-12.0)	-1.68	0.092
	Group 2	11.8 (11.3-12.3)		
2 nd day	Group 1	12.0 (11.4-12.3)	-2.12	0.033
	Group 2	12.2 (11.6-12.8)		
5 th day	Group 1	11.7 (11.3-12.0)	-1.99	0.046
	Group 2	11.8 (11.4-12.3)		
14 th day	Group 1	11.6 (11.0-12.0)	-1.68	0.092
	Group 2	11.7 (11.3-12.2)		
30 th day	Group 1	11.6 (11.0-12.0)	-1.74	0.081
	Group 2	11.7 (11.3-12.2)		

*Significant difference ($p < 0.05$)

Table 1: Comparison of Swelling in the two study groups at different time periods

Time point	Groups	Median (IQR)	Test statistics	P-value
Pre-intervention	Group 1	2 (2-2)	1	0.317
	Group 2	2 (2-2)		
2 nd day	Group 1	2 (2-2)	0	1.000
	Group 2	2 (2-2)		
5 th day	Group 1	0 (0-0)	-2.6	0.008*
	Group 2	0 (0-0)		

Table 2: Comparison of Pain in the two study groups at different time periods

Time point	Groups	Median (IQR)	Test statistics	P-value
Pre-intervention	Group 1	40 (38-42)	-0.44	0.656
	Group 2	40 (40-42)		
2 nd day	Group 1	34 (30-38)	0.99	0.320
	Group 2	32 (28-38)		
5 th day	Group 1	39 (37-40)	-0.85	0.395
	Group 2	40 (38-40)		
14 th day	Group 1	40 (38-42)	-0.93	0.353
	Group 2	40 (40-42)		
30 th day	Group 1	40 (40-42)	-0.60	0.547
	Group 2	40 (40-42)		

Table 3: Comparison of mouth opening in the two study groups at different time periods

Discussion:

Surgery for impacted third molars is one of the most frequent procedures in Oral and Maxillofacial Surgery and can lead to immediate postoperative pain, swelling and trismus. The postoperative discomfort is due to inflammation, which is

body's nature defense mechanism to cell injury or death. This response is manifested by redness, warmth pain, and swelling of the affected area.

Lisa Gersema et al[9] have mentioned that when tissue damage occurs, large quantities of histamine, bradykinin, serotonin, and other substances are released into the surrounding area. These substances, especially histamine cause local vasodilation to occur, thereby increasing blood flow to the damaged area. The permeability of the venous capillaries and venules is also increased. Leukocytes infiltrate into the damaged area and phagocytes invading organisms and debris. The inflammatory process is necessary if healing is to occur, but often excessive inflammation causes the patient unnecessary pain, edema and trismus.

There are several methods to reduce postoperative discomfort in third molar surgery. Some of the methods are cryotherapy, Ultrasound Bone Surgery, use of drain, electro-acupuncture, Primary and secondary closure of surgical wound, and using corticosteroids drugs.[10-13] The use of corticosteroids (e.g. dexamethasone, methylprednisolone) is another preventive strategy for limiting postoperative edema and trismus following third molar impaction procedures. There are different types or forms of corticosteroids available in the pharmacy, and there are different routes of administration. Roger E. Alexander et al[14] had described about the most commonly used forms of corticosteroids i.e. dexamethasone sodium phosphate, methylprednisolone acetate methylprednisolone sodium succinate.

In our study we have used methylprednisolone acetate (I.M) which has anti-inflammatory properties, probably related to their actions on the microvasculature as well as to cellular effects. They also impede endothelial sticking of leucocytes and diapedesis through capillary wall. Reduced cellular adherence to the vascular endothelium is probably secondary to the actions of the migration inhibiting factor by glucocorticoids. The plasma half-life of methylprednisolone is 2.1 to 3.5 hours. The biological half-life (e.g. in terms of anti-inflammatory effect) outlasts the plasma half-life, lasting from 18 to 36 hours. Total elimination of methylprednisolone requires 4 biological half-lives, that is 144 hours. It means that the maximum time that prednisolone can persist in the organism is six days. Methylprednisolone has no mineralocorticoid activity, the half-life is approximately 18-36 hours, and the drug is 5- fold more potent than hydrocortisone.

The steroid should be administered as soon as the need is realized during surgery. There is a chance for some benefit, and there is no significant risk unless the patient has one of the specified contraindications. The benefits of using an intramuscular form during surgery are less likely to occur because of the delay in tissue uptake.

A onetime intramuscular form, such as 40 mg methylprednisolone acetate is advantageous as recommended by various authors.[15,16] The drug can be injected before the surgery into the deltoid, gluteus, masseter, or medial pterygoid muscle on one or both the side, immediately, after administration of sedation or local anesthesia. The intramuscular route affords good plasma drug concentration and prolonged anti-inflammatory action with a single pre or post-operative dose.

Adverse effects that are seen with corticosteroids correlate with the dose and duration of the therapy. Dexamethasone and methylprednisolone reportedly have the least adverse effects on leukocyte chemotaxis. The longer-acting forms will generally have a more depressing effect on the adrenal glands. Dosages of methylprednisolone of < 40mg will reportedly not produce any adverse systemic effects.[14]

Postsurgical facial edema is hard to quantify accurately, because it involves 3 dimensions of measurement with an irregular, convex surface and can manifest itself internally as well as externally. Over the years, numerous researchers tried various measurement techniques in an effort to objectively measure edema and make comparisons between patient populations. Most of the measurements are directly made onto the skin surface. In order to use a more sensitive method to measure swelling, in this study, facial edema was evaluated by measuring the distance of the tragus to outer corner of the mouth and tragus-pogonion, thus, modifying the tape measuring method described by Schultze-Mosgau et al.[17]

In our study we had two groups of patients having 50 in each group, who were injected with 40mg of methylprednisolone via the intra buccal approach immediately after the surgery and the other group received a placebo. On comparing both the groups, we found the edema significantly reduces from the 2nd day and continues to reduce even on 5th day post-operatively in both the groups, but, more reduction was noted in the group 1 (inj. methylprednisolone). The median (IQR) of swelling during pre-intervention was 11.7 (11.0-12.0) and 11.8 (11.3-12.3) in group 1 and group 2 respectively. Using Mann-Whitney U test, it was found there was no significant

difference between the groups before intervention with a p-value of 0.092. However, there was a significant difference between the groups at day 2 and 5 where group 1 had a better score in comparison with group 2 and the P-value was determined to be 0.033 and 0.046 respectively. This denoted that facial edema gets reduced better in the group 1 which is more consistent compared to the other studies.

Corticosteroids are primarily used after surgical procedures, for suppressing tissue mediators of inflammation, thereby reducing transudation of fluids and lessening edema. Although some reduction of post-operative pain generally accompanies a reduction of edema, steroids alone do not have a clinically significant analgesic effect. In our study using Mann-Whitney U test, it was found there was a significant difference between the groups only at 5th day after intervention with a p-value of 0.008 which could be attributed to the reduction in swelling and the patient feeling more comfortable in Group 1.

Babatunde Olamide Bamgbose et al (18) stated from his study that Independent T-test did not show any significant difference in reduction of mouth opening (trismus) between the study groups ($P > 0.05$). Consistent with this study, the present study shows that, though the median (IQR) of trismus was varying at day 2 and 5, the difference between the groups was not found to be significant on running the Mann-Whitney U test.

Conclusion:

Administration of methylprednisolone 40mg into the masseter muscle via intra buccal route, postoperatively offers a good anti-inflammatory and reduces the facial edema considerably and pain to some extent. There was no difference in the mouth opening between both the groups. So Inj. Methylprednisolone 40mg has good anti-inflammatory action and can be safely administered in patients with no absolute contraindications to steroids. The postoperative discomfort can be reduced considerably if maxillofacial surgeons use the drug during routine surgical removal of third molars.

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