

# Randomized Controlled Trial to Evaluate the Efficacy of Oral Dexamethasone and Intramuscular Dexamethasone in Mandibular Third Molar Surgeries

SAMRAT SABHLOK<sup>1</sup>, PRACHI KENJALE<sup>2</sup>, DEEPTHI MONY<sup>3</sup>, ISHA KHATRI<sup>4</sup>, PRATIKA KUMAR<sup>5</sup>

## ABSTRACT

**Introduction:** Surgical removal of impacted third molar is the most commonly performed dento-alveolar procedure and is associated with post-operative pain, swelling and trismus.

**Aim:** The aim of the study was to compare the efficacy of dexamethasone administered orally with that of dexamethasone administered as an intra-masseteric injection in surgical removal of mandibular third molars.

**Materials and Methods:** Sixty patients with impacted mandibular third molars were selected to undergo surgical removal of mandibular third molars. They were divided into three groups of twenty each, viz., Control Group, Group taking Oral dexamethasone and Group taking Intra-masseteric dexamethasone. Evaluation was done over a

period of seven days postoperatively to study the effects of the drug in terms of swelling, trismus and pain.

**Results:** ANOVA test was done and comparisons were made. It was found that there was a statistically significant difference with respect to the group taking oral dexamethasone in terms of resolution of trismus. It was also found that there was no statistical significance with respect to reduction in swelling in either of the groups.

**Conclusion:** Thus, it can be concluded that the oral route is superior compared to the intramuscular route when administering dexamethasone in surgical removal of mandibular third molars, with respect to drug dosage, bio-availability and resolution of trismus.

**Keywords:** Corticosteroids, Intra-masseteric injection, Trismus

## INTRODUCTION

Among dento-alveolar interventions surgical removal of third molar is one of the most commonly performed procedures. Like any surgical intervention these are also associated with postoperative sequelae, such as pain, swelling and trismus. The extent of the postoperative complications depends on various factors such as individually varying physiological inflammatory response, the degree of tissue trauma and the extent of bone manipulation [1].

When body tissues are injured the normal physiologic response is inflammation and pain to varying degree. Inflammation occurs after every surgical intervention and should be expected [2]. The most important component of inflammation is vasodilatation, which allows cells and mediators entry to the affected area, these are responsible for neutralizing and removing the antigens and the remains of damaged tissue [3]. This manifests as swelling, pain and difficulty in opening the mouth after surgical removal of third molars this can affect the quality of life of the patient hence at such times, steroids with their anti-inflammatory action can be quite useful in preventing the discomfort associated with such procedures [4].

The pharmacologic management of inflammation mainly includes blocking the formation or inhibiting the action of mediators of inflammation [5]. Steroids, non-steroidal anti-inflammatory agents, enzymes, antihistamines are some of them.

The initial phase of the inflammatory process is marked by the production of vasoactive substances, such as prostaglandins and leukotrienes, corticosteroids act by suppressing their production, thereby reducing fluid transudation and consequent oedema [6].

Dexamethasone given as an intra-masseteric injection is seen to reduce the complications following third molar surgeries [7]. This assumption forms the basis of the present study which aims at evaluating the efficacy of oral dexamethasone given postoperatively

as against intramuscular dexamethasone given postoperatively in mandibular third molar surgeries. Dexamethasone was selected because it is a long acting corticosteroid and has minimal mineralocorticosteroid activity and maintains a therapeutic plasma level throughout immediate postoperative period [8].

## MATERIALS AND METHODS

A randomized control trial was designed in the Department of Oral and Maxillofacial Surgery, Dr DY Patil Dental College and Hospital, Pimpri, Pune, India, from May 2014 to April 2015. A total of 60 patients were randomly selected as sample for the study. All patients who had unilateral mesioangular Class II, Position B impacted mandibular third molars and those who were willing to participate in the study were included. Patients who were receiving anti inflammatory therapy and those with systemic diseases were excluded from the study. Those who reported any habits such as smoking or alcohol intake were not included in the study.

All the 60 patients were randomly and equally allocated by lottery system to the three study groups namely Group A, the control group not receiving dexamethasone, Group B, receiving oral dexamethasone postoperatively and Group C, receiving intramuscular dexamethasone postoperatively in the form of intra-masseteric injection. Each of the three groups consisted of 20 patients. Single blind technique was used. The patients went through history taking, clinical examination and preoperative procedure of taking measurements.

During the extraoral examination the preoperative measurements were calculated by marking the points A- lateral corner of the eye, B- angle of the mandible, C-tragus, D-lateral corner of the mouth, E-soft tissue pogonion and distance AB, CD, CE (in cm) were measured using a measuring tape, the measuring facial width was done with the method used by Gabka and Matsumara

[9]. This acted as control for follow up measurements. Intraoral examination included measuring the mouth opening by measuring the inter-incisal distance (in cm) using divider and ruler. After which the patients underwent surgical removal of the impacted mandibular third molar. All surgical procedures were performed by a single surgeon. Postoperative instructions and antibiotics were provided. The patients in Group B received tablet dexamethasone 4mg/day for 5 days, and the patient in Group C were given a single dose of 4mg intramuscular dexamethasone in the form of intra-masseteric injection immediately postoperatively. They were followed up on the 2<sup>nd</sup>, 3<sup>rd</sup> and 7<sup>th</sup> postoperative day. The facial swelling was assessed by measuring distance AB, CD, CE and comparing to the preoperative control measurements. Trismus was also evaluated by measuring the interincisal distance and comparing with pre-determined control measurements. Pain was evaluated using a visual analogous scale, pain was rated by the patient on the basis of a visual analogous scale with 0 (No Pain), 1-3 (Mild Pain), 4-6 (Moderate Pain), 7-10 (Severe Pain). The proforma containing all this data was duly filled by the investigator. The data was thus collected from all the 60 patients.

## STATISTICAL ANALYSIS

Statistical analysis was carried out for each group using the ANOVA test with regards to postoperative pain, facial swelling and trismus. Statistically significant readings were obtained while comparing the interincisal distance between the three groups. When inter-group comparison was done, postoperatively, the ANOVA (f) value was 5.59 and p-value was 0.04. Thus, the results in this case are statistically significant. This was true with respect to the control group and the group taking oral dexamethasone. Results with respect to the group taking intra-masseteric dexamethasone were statistically insignificant.

On the 3<sup>rd</sup> postoperative day, the ANOVA (f) value was 4.57 and p-value was 0.01. This was true with respect to the control group and the group taking oral dexamethasone. Thus, the results in this case are statistically significant. Results with respect to the group taking intra-masseteric dexamethasone were statistically insignificant.

On the 7<sup>th</sup> postoperative day, the ANOVA (f) value was 5.58 and p-value was 0.009. This was true with respect to the control group and the group taking oral dexamethasone. Thus, the results in this case are statistically significant. Results with respect to the group taking intra-masseteric dexamethasone were statistically insignificant.

## RESULTS

From the above statistical analysis the following conclusions were drawn.

S.No	Authors	Study Design	Inference		
			Pain	Swelling (In Cm)	Trismus
1.	Dionne RA et al., [15]	dexamethasone 4 mg or placebo 12 hours and 1 hour before surgery	Significant reduction in pain postoperatively	Significantly suppressed inflammation postoperatively	Significant reduction in trismus postoperatively
2.	Moore PA et al., [16]	10 mg dexamethasone was administered preoperatively intravenously	There was significant reduction in pain postoperatively	Significant reduction in swelling postoperatively	Significant reduction in trismus postoperatively
3.	Graziani F et al., [17]	dexamethasone 4 mg or 10mg as endo-alveolar powder or 10mg as submucosal injection was administered	No statistically significant difference between all groups when postoperative pain was evaluated	No statistically significant difference between all groups when postoperative swelling was evaluated	No statistically significant difference between all groups when postoperative trismus was evaluated
4.	Grossi GB et al., [18]	4 mg and 8 mg of dexamethasone was administered preoperatively as submucosal injection	No statistically significant difference between all groups when postoperative pain was evaluated	No statistically significant difference between all groups when postoperative swelling was evaluated	No statistically significant difference between all groups when postoperative trismus was evaluated
5.	MR Markiewicz et al., [19]	dexamethasone was administered preoperatively intravenously	There were no statistically significant differences in mean pain scores	Treatment with corticosteroids was associated with significantly less oedema during both early and late assessment	Treatment with corticosteroids was associated with significantly less trismus during both early assessment

## Facial Swelling

The results were statistically insignificant when comparisons were made to evaluate facial swelling.

## Trismus

When comparison was done amongst the groups with respect to post-operative trismus, the results were found to be statistically significant. This was true with respect to the control group and the group taking oral dexamethasone. Results with respect to the group taking intra-masseteric dexamethasone were statistically insignificant. On the 2<sup>nd</sup> postoperative day, the results were statistically insignificant. On the 3<sup>rd</sup> postoperative day, with respect to the control group and the group taking oral dexamethasone, the results were statistically significant. Results with respect to the group taking intra-masseteric dexamethasone were statistically insignificant. On the 7<sup>th</sup> postoperative day, with respect to the control group and the group taking oral dexamethasone, the results were statistically significant. Results with respect to the group taking intra-masseteric dexamethasone were statistically insignificant.

Hence, it was found that oral dexamethasone was more effective in controlling postoperative sequelae after surgical third molar surgeries.

## DISCUSSION

Oral invasive procedures like the most commonly performed surgical removal of the impacted third molars can give significant post-operative sequelae to the patient since the procedure may involve severe laceration and tissue trauma to soft and hard tissues surrounding it [10]. This can cause pain, swelling and limited mouth opening to the patients [11,12]. The swelling after third molar surgeries is not immediate but appears gradually around 2 days after the procedure. Although some amount of inflammatory response is good for healing but an increased response can be detrimental to the quality of life for the patient. To overcome these complications, clinicians mostly prescribe corticosteroids [13,14].

Corticosteroid therapy is one of the means employed to reduce the postoperative sequelae of pain, swelling and trismus. The administration of corticosteroids in different dosage and through various routes has proven to be effective to control pain, inflammation, and trismus. Corticosteroids act by inhibiting inflammatory mediators that trigger vascular exudation and oedema. They also have some analgesic effects derived from their anti-inflammatory action and prostaglandin-inhibiting capacity. Although corticosteroids are most effective during the first 24 hours postsurgery, their effect can also be observed up to three days [3].

6.	Laureano Filho JR et al., [20]	4 mg and 8 mg of dexamethasone 1 hour preoperatively	No effect on pain control	8mg of dexamethasone was more effective in reduction of swelling	8mg of dexamethasone was more effective in reduction of trismus
7.	Omer Waleed Majid et al., [21]	dexamethasone 4 mg submucosally or intramuscularly	dexamethasone groups showed significant reductions in pain at all intervals	dexamethasone groups showed significant reductions in swelling at all intervals	Submucosal dexamethasone resulted in significantly less trismus than controls on day 1 postoperatively
8.	Rakesh B Nair et al., [22]	4mg dexamethasone was administered submucosally	no statistical significant difference was found in postoperative pain	Postoperative swelling seemed to be less on 2 <sup>nd</sup> day	no statistical significant difference was found in postoperative pain
9.	Vyas N et al., [23]	single dose 40-mg (1cc) of methylprednisolone acetate, injected into the masseter muscle, preoperatively one hour before the surgery or postoperatively	A single dose of 40 mg (1cc) methylprednisolone acetate injected into the masseter muscle preoperatively is more effective in reducing pain	A single dose of 40 mg (1cc) methylprednisolone acetate injected into the masseter muscle preoperatively is more effective in reducing swelling,	A single dose of 40 mg (1cc) methylprednisolone acetate injected into the masseter muscle preoperatively is more effective in reducing trismus
10.	Dattatraya A Darawade et al., [14]	Oral 8 mg dexamethasone and 40 mg methyl prednisolone were prescribed randomly 1 hour prior to the surgery.	No statistical significant difference was found in postoperative pain	Reduction in swelling was found to be significantly more with dexamethasone than methyl prednisolone	Reduction in trismus was found to be significantly more with dexamethasone than methyl prednisolone
11.	Marsal Moretto Noboa et al., [24]	submucosal local injection dexamethasone (4mg/1mL) after local anesthesia, and oral dexamethasone tablet (4mg) one hour before procedure	No statistical significant difference was found in postoperative pain	Swelling values were not statistically different between observed groups	Trismus values were not statistically different between observed groups
12.	Samrat Sabhlok et al., Present study	Intramuscular dexamethasone inj (4mg/ml) immediately postoperatively and Oral dexamethasone tablet (4mg) one tablet for 5 days	No statistical significant difference was found between the two groups in postoperative pain	No statistical significant difference was found between the two groups in postoperative swelling	Reduction in trismus was found to be significantly more with Oral dexamethasone tablet (4mg) one tablet for 5 days.

**[Table/Fig-1]:** PubMed Search of Similar studies since the year 2000

A Pubmed search was done for similar studies which have been conducted in the past 15 years. The results of the same are listed in [Table/Fig-1] [14-24]. Most of these studies have administered corticosteroids preoperatively whereas in our study we administered it postoperatively.

The present study attempted to evaluate the efficacy of oral dexamethasone as against intramuscular dexamethasone in mandibular third molar surgeries. We chose to use a dose of 4mg for intraoral injections as a study by Grossi GB et al., [18] said there was no significant difference between 4mg and 8mg dose of parenterally administered dexamethasone. Filho et al., found the administration of 8 mg dexamethasone was more effective than 4 mg dexamethasone to reduce the degree of trismus [20]. Messer and Keller reported a significant decrease in clinical facial swelling, pain and trismus in 500 patients using 4 mg of IM dexamethasone immediately after surgery [5].

To be effective, a drug should be administered at a dose greater than or equal to the amount of cortisol released physiologically by the body. The literature diverges in its opinion on the ideal dosage of steroid administration. While some authors recommend the administration of 125 mg [25], other studies recommend a dose no greater than 40 mg to avoid possible adverse effects. Hence the other group in our study received a total of 20 mg as oral dose of dexamethasone [4].

In our study, the group receiving oral dexamethasone showed statistically significant difference in mouth opening. This is not consistent with the finding of Boonsiriseth et al., in their study there is no statistically significant difference between the groups [26].

An interesting fact that was noted on personal communication with the patients in group B and group C was that they all experienced pain in the form of Mild Pain i.e. 1-3 on the visual analogous scale or Moderate Pain i.e. 4-6 on the visual analogous scale.

## CONCLUSION

The use of corticosteroids had a positive effect on the patients after the surgical removal of third molars in terms of reduction of pain. The patients taking oral dexamethasone had shown significant difference in the mouth opening. This could be attributed to the dose of the oral dexamethasone administered. Further studies need

to be done to establish the ideal dose of dexamethasone required after dentoalveolar surgeries to prevent or curtail postoperative complications.

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**PARTICULARS OF CONTRIBUTORS:**

1. Reader, Department of Oral and Maxillofacial Surgery, Dr D.Y. Patil Dental College and Hospital, Pune, Maharashtra, India.
2. Dental Surgeon, Mumbai, Maharashtra, India.
3. Consultant, Oral and Maxillofacial Surgery, Navi Mumbai, Maharashtra, India.
4. Consultant, Department of Oral and Maxillofacial Radiology, Dashabhujia CBCT Centre, Pune, Maharashtra, India.
5. Assistant Professor, Department of Oral Pathology, Government Dental College, Indore, Madhya Pradesh, India.

**NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:**

Dr. Samrat Sabhlok,  
Reader, Department of Oral and Maxillofacial Surgery, Dr D.Y Patil Dental College and Hospital,  
Pimpri, Pune-411018, Maharashtra, India.  
E-mail: samratsabhlok@yahoo.com

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