



# Comparison of Preemptive Effect of Dexamethasone and Methylprednisolone After Third Molar Surgery: A Split-Mouth Randomized Triple-Blind Clinical Trial

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## Abstract

**Aim** The study aimed to compare the efficacy of methylprednisolone and dexamethasone injected into masseter muscle preoperatively in surgical extraction of lower third molars.

**Materials and methods** This study was carried out on 20 patients who reported to the department of Oral and Maxillofacial surgery, Sri Rajiv Gandhi College of Dental Sciences and Hospital Bangalore, requiring surgical removal of bilateral mandibular third molars. The efficacy of corticosteroid was evaluated based on its ability to reduce pain, swelling and trismus following the surgical extraction of impacted lower third molars.

**Results** There was no statistical difference between the two steroids with both of them achieving equal level of pain control. There was a statistically significant difference on the second postoperative day with dexamethasone showing clinically superior result. The difference in oral aperture was found to be statistically significant with dexamethasone showing a decreased reduction in postoperative mouth opening on both second and seventh day.

**Conclusion** This study conclusively proves that patient comfort levels are far better with the use of dexamethasone.

**Keywords** Methylprednisolone · Dexamethasone · Third molar · Intramassetric · Randomized control trial · Triple-blind study

## Introduction

In today's era of ever expanding specialty of oral and maxillofacial surgery, there is a predilection to provide painless treatment and optimal quality of life. Surgical removal of lower wisdom teeth is one of the most common minor surgical procedures in oral surgery, and people may require it at some point in life [1–3]. The surgical removal of impacted lower wisdom tooth is usually associated with variable degree of tissue trauma that causes an inflammatory reaction. Pain, trismus and facial swelling are the most common complication in the postoperative period of a surgical extraction [4–6]. Laskin states that edema maximizes in 24–48 h, but Peterson says that it usually maximizes in 48–72 h and is usually resolved after the first postoperative week [7, 8].

Various corticosteroids such as betamethasone, triamcinolone, prednisolone, hydrocortisone, dexamethasone and methylprednisolone are prescribed to control pain, trismus and swelling [9, 10]. The results of randomized trials have shown low, short-dose corticosteroid regimens to be safe and effective for reducing postoperative pain. Clinical trials in oral Surgery have also supported the hypothesis that preemptive NSAIDs and corticosteroids are effective in delaying and preventing many postoperative sequelae [11].

Corticosteroids can be administered through different routes. Few reports of corticosteroids given in the region adjacent to the site of operation are available in the literature, and these gave encouraging results as compared with controls. The technique is convenient for the surgeon, as the injection is given in close proximity to the operative field, and for the patient, as the injection is given into an anaesthetized area [12].

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Our study was sought to be a split mouth, triple-blind randomized controlled trial in a bilateral third molar model with a single operator.

The aim of the present study was to perform a comparative assessment of the effect of preemptive dexamethasone and methylprednisolone at equivalent doses for the postoperative control of pain, swelling and limited mouth opening following the extraction of lower impacted third molar using intramassetric route.

## Materials and Methods

This study was carried out on 20 patients who reported to the department of oral and maxillofacial surgery, Sri Rajiv Gandhi College of Dental Sciences and Hospital Bangalore, requiring surgical removal of bilateral mandibular third molars.

### Inclusion Criteria

1. Patients who are not compromised systemically (ASA I).
2. Patients aged between 18 and 35 of either gender.
3. Patients requiring extraction of both impacted lower third molars.
4. Patients with identical level of difficulty of impacted lower third molars.

(Variation in Pedersen difficulty index of up to 2).

### Exclusion Criteria

1. Patients taking rescue drug within 6 h postoperatively.
2. Patient not willing to be part of the study.

### Sample Size Estimation

A sample size of 20 achieves 93% power to detect a mean of paired differences of 4.5 with an estimated standard deviation of differences of 3.2 and with a significance level of 0.05 using a two-sided paired *t* test. The patient, operator and assessors were blinded with regard to the side of use of methylprednisolone 40 mg and dexamethasone 8 mg thus making it a triple-blind study. One of the MDS staff in the department injected the drug. The syringe was taped with white plaster. The parameters of the study were to measure the pain, swelling and trismus after the injection of methylprednisolone or dexamethasone into the masseter muscle.

## Method of Statistical Analysis

The following methods of statistical analysis have been used in this study. Data were entered in Microsoft excel and analyzed using SPSS (Statistical Package for Social Science, Ver. 17.0).

The results were averaged (mean + standard deviation) for continuous data. Normality of data was tested using Shapiro–Wilk test.

As the data were not found to be normal, a nonparametric test (distribution free), Wilcoxon signed-rank test, was used to compare two independent groups of sampled data.

## Result

A randomized triple-blind study was conducted to assess the efficacy of methylprednisolone and dexamethasone to reduce pain, swelling and trismus after third molar surgery. A total of 20 patients in the age range of 19–34 years were included in the study as described in Table 1.

The study group includes 13 females and 7 males as mentioned in Table 2. The type of impaction included distoangular, mesioangular, vertical and horizontal as indicated in Table 3. The ramus relationship of the impacted third molars was class I and class II as mentioned in Table 4. The depth of impaction was largely position A followed by position B as mentioned in Table 5. The Pederson's difficulty index scores varied from 4 to 8 as described in Table 6. The duration of procedure varied between 20 and 60 min for dexamethasone group and 20–50 min for methylprednisolone group as mentioned in Table 7. The mouth opening varied between 18 and 32 mm at day 2 and between 28 and 40 mm at day 7 as indicated in Table 8. The tragus commissure measurement for swelling varied between 95 and 130 mm at day 2 and between 85 and 122 mm at day 7 as mentioned in Table 9. The gonion commissure measurement for swelling varied between 74 and 115 mm at day 2 and 79 mm and 104 mm at day 7 as indicated in Table 10. The gonion external canthus measurement for swelling varied between 90 and 135 mm at day 2 and between 90 and 125 mm at day 7 as mentioned

**Table 1** Age of the patients

Age (years)	Frequency	Percent
18–24	14	6.7
25–29	2	40.0
30–34	4	40.0
	15	100.00

**Table 2** Gender distribution

	Number	Percent
Male	7	35.00
Female	13	65.00
Total	20	100.00

**Table 3** Type of impactions

Type of impaction	Dexa	MP
Distoangular	8 (40%)	8 (40%)
Horizontal	4 (20%)	4 (20%)
Mesioangular	5 (25%)	5 (25%)
Vertical	3 (15%)	3 (15%)
Total	20	20

**Table 4** Pell and Gregory classification (ramus relationship)

Class	Dexa	MP
I	2 (10%)	2 (10%)
II	18 (90%)	18 (90%)
III	0 (0%)	0 (0%)
Total	20	20

**Table 5** Pell and Gregory classification (depth)

Position	Dexa	MP
A	13 (65%)	11 (55%)
B	7 (35%)	9 (45%)
C	0 (0%)	0 (0%)
Total	20	20

**Table 6** Pederson's difficulty index

Difficulty Index	Dexa	MP
4	2 (10%)	0 (0%)
5	5 (25%)	7 (35%)
6	6 (30%)	6 (30%)
7	6 (30%)	5 (25%)
8	1 (5%)	2 (10%)
Total	20	20

**Table 7** Duration of procedure (min)

Group	N	Mean	SD	Median	Min.	Max.	'P' value
Dexamethasone	20	35.5	10.98	32.5	20	60	0.379
Methylprednisolone	20	34.6	9.27	31.0	20	50	

**Table 8** Oral aperture (mm)

Time	Dexa Mean ± SD	MP Mean ± SD	Dexa versus MP P value <sup>#</sup>
Preoperatively	39.80 ± 2.82	40.10 ± 2.47	0.083
Day 2	29.20 ± 3.75	24.25 ± 3.49	< 0.001*
Day 7	36.45 ± 3.82	32.95 ± 3.33	0.001*

\*indicates significant value

in Table 11. The variation between the dexamethasone and methylprednisolone groups with regard to pain perception from 5 h after surgery to the morning of day 7 when the patient reports for suture removal is mentioned in Table 12. Table 13 reveals the pain perception for the corticoid group from 5 h after surgery to the morning of day 7 when the patient reports for suture removal. Table 14 reveals the pain perception for methylprednisolone group from 5 h after surgery to the night of day 6 when the patient reports for suture removal.

## Discussion

A 0.75 mg dose of dexamethasone is equivalent to 20 mg cortisol (hydrocortisone) and to 25 mg cortisone. The biologic half-life of dexamethasone is 36–54 h, and it is considered to be a long-acting steroid. Methylprednisolone is another commonly used corticosteroid in dentoalveolar surgery. Regarding dexamethasone, the administration of 8 mg is reported to be more effective in reducing the degree of swelling and trismus in comparison with 4 mg [13]. Thus, to make the drugs compatible, equivalent doses were adopted: 8 mg of dexamethasone and 40 mg of methylprednisolone, both corresponding to approximately 200 mg of cortisol. The inflammatory response and consequent postoperative complications associated with third molar extraction are also influenced by factors such as surgical difficulty and patient characteristics. Thus, measures were adopted in an attempt to control the variability within and between patients. Although the Pell and Gregory classification has been questioned as an appropriate method for determining the complexity of third molar extractions, one well-controlled clinical trial found that the

**Table 9** Tragus commissure

Time	Dexa Mean ± SD	MP Mean ± SD	Dexa versus MP <i>P</i> value <sup>#</sup>
At 1	102.75 ± 6.85	103.10 ± 7.11	0.180
At 2	110.90 ± 8.03	113.25 ± 9.37	0.057
At 7	103.85 ± 8.58	104.75 ± 8.61	0.071
Change from 1 to 2	8.15 ± 3.97	10.15 ± 5.91	0.095
Change from 1 to 7	1.10 ± 6.78	1.65 ± 6.82	0.108

**Table 10** Gonion commissure

Time	Dexa Mean ± SD	MP Mean ± SD	Dexa versus MP <i>P</i> value
At 1	86.25 ± 8.72	86.25 ± 8.72	1.00
At 2	92.10 ± 8.53*	95.30 ± 9.12*	< 0.001*
At 7	89.35 ± 6.47	90.00 ± 7.10	0.404
Change from 1 to 2	5.85 ± 6.89*	9.05 ± 7.44*	< 0.001**
Change from 1 to 7	3.10 ± 6.63	3.75 ± 5.42	0.404

\*indicates significant value; \*\*indicate highly significant

**Table 11** Gonion external canthus

Time	Dexa Mean ± SD	MP Mean ± SD	Dexa versus MP <i>P</i> value
At 1	102.40 ± 9.98	102.45 ± 9.95	0.317
At 2	106.70 ± 10.81*	110.05 ± 12.28*	0.001*
At 7	102.65 ± 9.43*	104.50 ± 9.90*	0.004*
Change from 1 to 2	4.30 ± 3.57*	7.60 ± 4.33*	0.001*
Change from 1 to 7	0.25 ± 3.712	2.05 ± 5.11	0.008

\*indicates significant value

**Table 12** Pain score

Time	Dexa		MP		Dexa versus MP <i>P</i> value
	Median	Mean	Median	Mean	
Day 0 (0–5) h	7.00	6.70	6.00	6.85	0.499
Day 1 morning	7.00	6.65	7.00	6.70	0.782
Day 1 night	7.00	6.80	7.00	6.60	0.157
Day 2 morning	7.00	6.50	6.00	6.35	0.485
Day 2 night	7.00	6.45	6.00	6.05	0.046
Day 3 morning	6.00	6.00	5.50	5.95	0.851
Day 3 night	6.00	5.70	6.00	5.80	0.589
Day 4 morning	5.00	5.10	5.00	5.15	0.763
Day 4 night	5.00	4.85	4.00	4.60	0.166
Day 5 morning	5.00	4.35	4.00	4.15	0.285
Day 5 night	4.00	3.75	3.00	3.60	0.405
Day 6 morning	3.00	2.80	3.00	3.05	0.096
Day 6 night	2.00	2.30	2.00	2.35	0.705

radiographic position of impacted teeth could be a good indicator of surgical difficulty and was associated with postoperative complications. In the present study, the patients were operated on by the same surgical team and had their teeth in the same radiographic position.

Furthermore, to eliminate variations in the inflammatory response resulting from individual differences, the split-mouth design was employed, in which each patient served as his/her own control.

**Table 13** Group = dexamethasone

Time	Group	Mean	SD	Median
Day 0–5 h	20	6.70	1.38	7
Day 1–morning	20	6.65	1.18	7
Day 1–night	20	6.80	1.19	7
Day 2–morning	20	6.50	1.39	7
Day 2–night	20	6.45	1.60	7
Day 3–morning	20	6.00	1.59	6
Day 3–night	20	5.70	1.56	6
Day 4–morning	20	5.10	1.65	5
Day 4–night	20	4.85	1.66	5
Day 5–morning	20	4.35	1.56	5
Day 5–night	20	3.75	1.44	4
Day 6–morning	20	2.80	1.05	3
Day 6–night	20	2.30	0.92	2

**Table 14** Group = methylprednisolone

Time	Group	Mean	SD	Median
Day 0–5 h	20	6.85	1.30	6
Day 1–morning	20	6.70	1.17	7
Day 1–night	20	6.60	1.39	7
Day 2–morning	20	6.35	1.53	6
Day 2–night	20	6.05	1.50	6
Day 3–morning	20	5.95	1.50	5.5
Day 3–night	20	5.80	1.60	6
Day 4–morning	20	5.15	1.66	5
Day 4–night	20	4.60	1.75	4
Day 5–morning	20	4.17	1.56	4
Day 5–night	20	3.60	1.66	3
Day 6–morning	20	3.05	1.14	3
Day 6–night	20	2.35	0.87	2

The time of injecting the drug can also have a profound effect on the outcome. Most of the effects of glucocorticoids are mediated through an altered protein synthesis, so onset of biologic action is generally 1–2 h, depending on the route of administration. Because activation of the early mediators of the metabolic response to surgery occurs immediately after the surgical incision, the administration of glucocorticoids after surgery might be too late to benefit fully from the anti-inflammatory effects of glucocorticoids [14]. So we chose to inject the drug before the surgical procedure. The mean operation time of 35.5 min recorded in this study is more than 21.92 min and 25.0 min reported by Raprastikul et al. [15] and Saglam et al. [16], respectively. Variability of operation time could be due to

surgeons experience, the definition of operation time and the need for extra procedure like intra massetric injection during the operation. The commonest type of impaction, distoangular ( $n = 40\%$ ), recorded in this study is different to the reports from earlier studies [14]. This could be due to the fact that patients in this study were of the age group 21–25 years, by which age the angulation generally tends to become distal. The mean age which was closely associated with impacted teeth was found to be 22.8, and in a study conducted by Bello et al, the mean age was 26.7 years. This could be attributed to the fact that most of the teeth lose their ability to erupt by this age. The intra-massetric route of administration has been preferred for this study, as described by Messer and Keller [12]. This route has a faster onset of action than the oral route and long-acting depot preparations can be injected, also the site being situated locally and performed in a previously anesthetized area, and it is beneficial for both the surgeon and the patient. The rate of absorption is highly dependent on the rate of blood flow to the site of administration. Many studies have shown it is safe to administer dexamethasone by IM injection, and Filho et al. [13] reported that the administration of 8 mg dexamethasone was more effective than 4 mg dexamethasone.

Vegas-Bustamante et al. [3] examined the efficacy of a 40-mg injection of methylprednisolone into the masseter muscle compared to a control group (no injection) on trismus, pain and edema in third molar surgery. They found pain and swelling to be more greatly reduced on day 2 and day 7 following surgery in the study group when compared to the control group. Kulkarni and Kshirsagar [17] concluded that methylprednisolone had better efficacy for the control of swelling and trismus than dexamethasone, but there was no significant difference in pain control between the two drugs.

Antunes et al. [18] evaluated the effect of two routes of administration of dexamethasone on pain, edema, and trismus in impacted lower third molar surgery and found that both oral administration and local injection of dexamethasone into the masseteric muscle achieved similar results; reduction in pain, edema and trismus was more effective in the groups of patients given dexamethasone by these administration routes compared to the control group.

Facial swelling occurs in response to the considerable trauma to the tissues in the third molar region. Onset is gradual, with peak swelling 48 h after surgery. The method employed for the measurement of edema in the present study—the demarcation of predetermined points (tragus, oral commissure, external canthus, angle) using a skin marker—was chosen by the authors, because it is a valid, easy and inexpensive method. Other methods for measuring edema have been used in different studies on third molar extractions, such as CT scan, photographs, calipers,

malleable metal rods, palpation and subjective clinical observation [19]. In our study, dexamethasone proved more effective in controlling swelling than methylprednisolone at all postoperative evaluation times. This finding may be explained by the fact that dexamethasone has a longer duration of action and greater potency in comparison with methylprednisolone. The efficacy of dexamethasone is also due to the reason that it reduces the formation of thromboxane A<sub>2</sub> which in turn reduces the amount of prostaglandin E<sub>2</sub> that is formed. This is in consensus with a study conducted by Majid and Mahmood [20] which found the swelling to be significantly reduced on second and third day postoperatively with intramassetric injection of dexamethasone. Another study by Alcantra et al also states that better control of postoperative swelling was achieved by preoperative administration of dexamethasone than methylprednisolone [21].

Trismus is also a common complication following third molar extraction and can have a negative impact on quality of life by hampering eating and speaking. Trismus has been considered as a single variable demonstrating postoperative sequelae. In our study, lesser limited mouth opening in the postoperative period was observed with the use of dexamethasone, though in the study by Alcantra et al. [21], it was found to be nonsignificant. In a study by Darawade et al. [14], dexamethasone caused less trismus out of the two drugs which was significant on the second day of evaluation. This result was also in accordance with a study done by Vegas-Bustamante et al. [3] This could be due to the long-lasting action of the drug as compared with methyl prednisolone which is intermediate acting drug and has a shorter half-life than dexamethasone. In the evaluation of postoperative pain, there were no statistically significant differences between the patients who used dexamethasone and methylprednisolone intramassetrically. The production of prostaglandins that influence the peripheral pain response is not controlled, thus emphasizing the result obtained. In study performed by Chugh et al. [22], QOL was minimally affected in patients administered dexamethasone as compared with methylprednisolone and control subjects. The preoperative submucosal use of steroids can be considered an effective, safe and simple therapeutic strategy to reduce swelling, pain and trismus after the surgical removal of impacted mandibular third molars.

Our data based on a randomized clinical trial show that the use of dexamethasone significantly reduces facial edema. This was as significant on the second postoperative day, when maximum facial swelling is expected, as after 1 week. Trismus was also reduced significantly on the second and seventh day postoperatively. There was no significant difference in the amount of pain experienced by the patients.

The study had its limitations; though self-reports are an appropriate way for assessing patient perceptions of pain following surgery, studies are needed to quantify the changes in the levels of chemical mediators of inflammation and pain after the administration of corticosteroids. Also a three-dimensional swelling was measured in a single dimension which can lead to some misrepresentations in the measurement of swelling. Another one of the limitations was although it was a bilaterally symmetrical impactions study, the Pederson index varied between 4 and 8. This can be improved further by choosing a specific type of impaction.

## Conclusion

The interventions prescribed in a typical oral and maxillofacial surgery training center are like many other specialties evidence based. Regular audit and evaluation of clinical practice is of great importance to promote better patient care; however, better evidence such as well-conducted RCTs need to be generated to further promote the field of oral and maxillofacial surgery as an evidence-based subject without compromising the value of clinical expertise and personalized patient care in creating the best outcome. This randomized control trial has helped us to conclude that intramassetric injection of 8 mg dexamethasone preoperatively definitely has a positive outcome in terms of reducing postoperative pain, swelling and trismus after lower third molar surgery without any concern about the safety of the drug. This can be recommended as a protocol for lower third molar surgery in particular.

These parameters of care are designed to provide guidance consistent with current clinical practice. While it is accepted that this does not constitute indisputable evidence the indications for care provided in this study can be implemented in today's era.

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**Compliance with ethical standards**

**Conflict of interest** Nil.

**Informed consent** Yes.

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