The Comparison of the effect of two different doses of methylprednisolone on pain, swelling and trismus after 3rd molar surgery.

Abstract:

Objective : The aim of this study was to compare the effects of intravenous administration of 1.5mg/kg and 3mg/kg of methylprednisolone sodium succinate on pain, swelling and trismus after third molar surgery.

Study Design: Twenty five healthy patients with bilaterally symmetrical impacted mandibular third molars were included in this study. Either 1.5mg/kg or 3mg/kg of methylprednisolone was administered by intravenous route 1 hour before the operation. At the second operation the other dose was applied. Facial swelling was evaluated by using cotton sutures. Trismus was determined by measuring maximum interincisal opening. Pain was determined by using visual analogue scale.

Results : There was no statistically significant difference in pain swelling and trismus between the two groups.

Conclusion : No significant benefit of higher dose of methylprednisolone administered.

Key Words: Methylprednisolone, third molar, Surgery.

Introduction:

Surgical extraction of third molars may be considered as one of the routine aspects of Oral & Maxillofacial surgery. Patients complain of pain, swelling and limitation in mouth opening, which are associated with the inflammatory response following third molar surgical extractions and are the factors which affect their daily life.[1]

A single dose of glucocorticoid inhibits the synthesis and/or release of proinflammatory mediators and facilitates the synthesis and/or release of anti-inflammatory mediators in a variety of major surgical procedures. This property of corticosteroids is well known and they are widely used to decrease the oedema related to third molar surgery. The potential complications of peri-operative corticosteroid use are adrenal suppression and delayed wound healing. A single large dose of I.V glucocorticoid injection is reported not to delay wound healing or produce infectious complications in oral surgery or major abdominal, thoracic and orthopedic surgery while providing sufficient anti-inflammatory effect.[1]

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Patients undergoing the surgical removal of impacted third molar teeth usually experience significant post-operative pain and swelling. These patients therefore present an ideal clinical experimental model to study these sequelae and the potential therapeutic effects of anti-inflammatory drugs.[2]

Patient variation concerning the individual tendency for developing oedema postoperatively is considerable and no single drug prevents oedema in all patients. Because of these

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factors, it is very difficult to assess the exact value of these drugs. In order to study this, one needs a very accurate human model and should include a sufficiently large series of similar procedures. The procedure should often cause postoperative oedema. Also because of the huge variations among patients with respect to the development of oedema, two similar operations on the same patient are of much value, every patient being his or her own control.[3]

Patients and Methods:

This study was conducted in the Department of Oral and Maxillofacial Surgery & Oral Implantology, I.T.S Centre for Dental Studies and Research, Muradnagar, Ghaziabad. Twenty five OPD patients (19 males and 6 females) who visited the Department of Oral & Maxillofacial Surgery, I.T.S Centre for Dental Studies and Research Muradnagar, Ghaziabad for elective removal of impacted mandibular third molars were included in this prospective, crossover, doubleblind randomized study. The inclusion criteria included the age group between 18-40 years and patients with bilateral symmetrically impacted mandibular third molars were selected. Patients with history of pericoronal infection & allergy to the drug used were excluded from the study. There was no control group in the study. Orthopantomographic radiograms/ IOPA were obtained to ensure the similarity of the type of impaction.

Each patient had 2 operations separated by 3 weeks. Either 1.5mg/kg

(Group A) or 3mg/kg (Group B) of methylprednisolone was administered by intravenous route prior to the first operation. At the second operation, the other dose was applied. The methylprednisolone dose was prepared, administered 1 hour before the surgery. All the operations were performed by the same experienced oral & maxillofacial surgeon. The surgical procedure was done with Ward's incision & Moore Gillbe collar technique (involves buccal and distal bone guttering around the impacted third molar with a straight fissure bone cutting bur) for bone removal and was followed by suturing with 3-0 black braided silk. Preoperative as well as postoperative recordings were done for all patients on both the sides.

The facial swelling was measured by means of cotton sutures. The markings were made with indelible ink. Three measurements were made between 5 fixed reference points: tragus, soft tissue pogonion, outer corner of mouth, lateral canthus of the eye and angle of the mandible preoperatively, on the second and seventh postoperative days. The preoperative sum of the 3 measurements was considered as the baseline for that side. The difference between each postoperative measurement and the baseline indicated the facial swelling for that day and it was done on 2nd and 7th postoperative days. Trismus was evaluated by measuring the distance between the mesio-incisal corners of the upper and lower right central incisors at maximum opening of the jaws preoperatively and on the second and seventh postoperative days in both the groups. The difference between each postoperative measurement and the preoperative measurement indicated the trismus for that day.

Following each operation a questionnaire consisting of visual analogue scale (VAS) of 10 units concerning postoperative pain and the number of consumed analgesic tablets was given to the patients. The patients were given non steroidal antiinflammatory drugs (NSAIDS) after the surgery for the control of pain. The patients were asked to answer the questionnaire preoperatively and on second and seventh postoperative days and were recalled on the second (48 hours after surgery) and seventh postoperative days.

The data obtained from the measurements of facial swelling, trismus and visual analogue scale scores were statistically evaluated by nonparametric 2-paired samples test.

Results:

Two patients were excluded from the study because they did not turn up for follow-up. All the patients tolerated the medication well with no serious complications or side effects. Pain

The mean pain scores in this study was 4.4 and 4 (on VAS scale from 0-10) for Group A (1.5mg/kg body weight methylprednisolone) and Group B (3mg/kg body weight methylprednisolone) respectively on the 2nd post-operative day and 1.08 and 1 (on VAS scale from 0-10) for Group A and Group B respectively on the 7th postoperative day. But the difference in the pain scores between the two groups was not statistically significant (p<0.05) on the 2nd as well as on the 7th postoperative day. The number of analgesic doses taken in Group A (4.0±4.8) was not significantly different from Group B (3.9±4.7) (P=0.972)

Facial swelling:

The facial swelling was due to surgical edema. The patients were asked to apply ice packs immediately after the surgery to reduce edema. On the second postoperative day, the facial swelling was increased in both groups. The mean swelling in this study was 11.70 mm and 11.49 mm for Group A and Group B respectively on the 2nd postoperative day and 0.2 mm and 0.12 mm for Group A and Group B on the 7th postoperative day, but the difference in swelling between the two groups was not statistically significant (p<0.05) on the 2nd well as on the 7th postoperative day.

Trismus:

The mean trismus (reduction in mouth opening in millimeters (mm) as compared to preoperative values) in this study was 10.65mm and 9.72mm for Group A and Group B respectively on the 2nd postoperative day and 1.68mm and 1.67mm for Group A and Group B on the 7th postoperative day, but the difference in trismus between the two groups was not statistically significant on the second as well as on the 7th postoperative day. Nearly all of the patients regained their preoperative day after both operations.



Fig 1: Measurement of Facial Swelling- Distance from tragus to the soft tissue pogonion



Fig 2: Measurement of facial Swelling- Distance from tragus to the corner of mouth



Fig 3: Measurement of facial Swelling: Distance from lateral canthus of eye to the angle of mandible

Table-1: VAS scores \pm SD of pain scores between the 2 groups VAS scores \pm SD 2ndVAS scores \pm SD 7th

The total no. of

postoperative day postoperative day

analgesic doses

 $mean \pm SD$

VAS scores ±SD 2 nd VAS scores ±SD 7 th postoperative day postoperative day mean ± SD		The total no. of analgesic doses	
Group A (!.5mg/kg MP)	4.4±0.82	$1.08 \pm 0.574.0 \pm 4.8$	
Group B (3.0mg/kg MP)	4±0.82	1.0±0.57	3.9 ±4.7

The difference in the VAS scores and the total number of analgesic doses (P=0.972) was not

statistically significant on the second and seventh postoperative days

MP= methylprednisolone sodium succinate

Table II: Comparison of the facial swelling between the 2 groups

2 nd mean± SD	¹ postoperative day (mm)	7 th postoperative day (mm) mean± SD
Group A (!.5mg/kg MP)	11.70 ± 2.485	0.2 ± 0.374
Group B (3.0mg/kg MP)	11.49 ±2.548	0.12 ±1.306

The differences in the facial swelling were not statistically significant on the second and seventh postoperative days.

MP=methylprednisolone sodium succinate

Table III. Comparison of the limitation in mouth opening (trismus) between the 2 groups

Trismus 2 nd Trisn postoperati Mean ±SD	nus 7 th ve day(mm)	postoperative day(mm) Mean ±SD
Group A (!.5mg/kg MP)	10.65± 1.469	1.68±1.108
Group B (3.0mg/kg MP)	9.72 ±2.851	1.67±1.381

The difference in the limitation of mouth opening was not statistically significant on the second and seventh postoperative days.

MP = methylprednisolone sodium succinate

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Discussion:

Patients usually suffer from trismus, pain and facial swelling in the postoperative period following third molar surgery. The inflammatory response following third molar surgery can be reduced by glucocorticoids. All steroids must be administered before the infliction of tissue damage and not during or after surgery. Methylprednisolone is widely used in surgical procedures for its anti-inflammatory action and a constant dose of methylprednisolone has been used in most of the previous studies. From the pharmacological aspect, optimal therapeutic doses are generally identified in terms of the amount of drug per kilogram of body weight of the patient ... Effects of the different doses of methylprednisolone on trismus and pain relief have not been evaluated on a crossover basis in previously reported studies except for the one study done by Ustin Yakup et al (2003).[1] This study was designed to compare the efficacy of 1.5mg/kg and 3mg/kg intravenous methylprednisolone given one hour preoperatively before surgical extraction of mandibular third molars.

Minimal mineral corticoid activity and extended biologic activity are the desirable characteristics in selection of the appropriate corticosteroid. Methylprednisolone sodium succinate meets these requirements because it is five times as potent as hydrocortisone; it has no mineralocorticoid activity and it biologic half life is about 18 to 36 hours so the drug was injected 1 hour before surgery.

Effectiveness of the oral route of administration is dependent on patient compliance and repeated dosing is required to maintain adequate blood levels during the postoperative period. The intramuscular route provides a prolonged antiinflammatory effect; however, this may cause a higher risk for adrenal suppression, we preferred preoperative administration via the I.V route because this offers instantaneous blood levels just before the surgical trauma.1 Bahn (1982) advocated the use of oral glucocorticoids for chronic supplementation and intravenous route for immediate response.[11] Gersema & Baker and Beirne & Hollander recommend the administration of 125mg methylprednisolone parenterally, mentioning that this dose will reduce the inflammatory sequelae with no significant side effects.

For investigating the therapeutic efficacy of an antiinflammatory drug, every effort should be made to standardize the procedure. Application of a constant dose of methylprednisolone will result in different plasma concentration of the drug related to individual variations in the body mass. From a pharmacological point of view, it would be reasonable to standardize the dose, taking the body weight into consideration. A crossover study design is also important to eliminate the variations in inflammatory response resulting from individual differences. The surgical technique and team should be same in all the procedures and the patients should be meticulously selected to ensure the similarity of the inflammation caused by surgical trauma.

Skjelbred and Lokken administered 40 mg of intravenous methylprednisolone two hours after surgery. They reported a 46% reduction in swelling compared with placebo on day 3 and a 60% reduction on day 6.

Perhaps the greatest danger of the administration of exogenous steroids is the potential suppression of the hypothalamic-pituitary adrenal axis, resulting in adrenal atrophy. The determining factor in this phenomenon is the plasma level of the exogenous steroid as reflected by the type of drug, dosage and the duration of therapy. Dosages above the physiologic levels of approximately 20mg hydroxycortisone for five days or longer may cause adrenal suppression for days or months (up to two years) which may prevent the glucocorticoid surge necessary for dealing with acute stress, but even huge doses given in the morning for four days or less are relatively innocuous in effecting persistent suppression. It should be emphasized that persistent adrenal suppression generally occurs only when glucocorticoid supplementation exceeds physiologic levels for a period of five days or longer. Short-term high dose glucocorticoid therapy however does not cause significant adrenal suppression. Although animal experimentation indicates a tendency toward delayed healing and decreased resistance to infection with steroid supplementation above physiologic levels, it is not clear if these effects are always clinically significant.[15]

Dosages should be carefully titrated for each patient; however it is permissible to err on the side of overmedication because brief excess is innocuous and provides greater security. Keeping dosages below physiologic levels or reducing dosages to these levels allows the hypothalamic–pituitary adrenal axis mechanism to function and to stimulate recovery of even an atrophic adrenal gland.[15]

The prescription of systemic steroids is absolutely contraindicated for patients who have active, incompletely healed or healed tuberculosis, ocular herpes simplex, primary glaucoma and acute psychosis are also usually considered

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absolute contraindications. Relative contraindications include diverticulitis, active or latent peptic ulcer, Cushing's syndrome, renal insufficiency, hypertension, thrombophlebitis, osteoporosis, diabetes mellitus, myasthenia gravis, acute or chronic infections as well as pregnancy- especially in the first trimester. Naturally, all harmful side effects and potential dangers of corticosteroid treatment should be taken into consideration. However, in this series of third molar surgeries, no infection has been seen that could be attributed to the use of corticosteroids nor any problems with wound healing had been experienced such as wound failure as a result of too low tensile strength of the wound due to possible inhibition of fibroblast activity.[15]

The results of this study indicate that there is no significant benefit of a single I.V dose of 3mg/kg methylprednisolone over the lower dose of 1.5mg/kg in preventing pain, swelling and trismus after third molar surgery. Considering the potential side effects associated with the application of corticosteroids, it may be concluded that higher dose of methylprednisolone is not required for reducing the postoperative sequelae after third molar surgery.

Limitations of This Study:

There was no control group in this study.

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