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Submucosal injection of dexamethasone and methylprednisolone for the control of postoperative sequelae after third molar surgery: randomized controlled trial

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Abstract. Pain, swelling, and trismus are known sequelae of third molar surgery that can significantly affect the individual's quality of life (QOL). These should be minimized to improve QOL. The purpose of this study was to compare the effects of the preoperative submucosal administration of equivalent doses of two commonly used steroids on these postoperative sequelae. A randomized controlled clinical trial was conducted involving 60 subjects requiring the removal of impacted mandibular third molars. Extraction cases with a similar difficulty index were included. The participants were allocated randomly to three groups: the placebo group received normal saline injection (control), while the 8 mg dexamethasone group and 40 mg methylprednisolone group received submucosal injections of these steroids preoperatively. Each participant was assessed for postoperative pain, swelling, and trismus, along with a subjective assessment of QOL through a structured questionnaire. The participants administered dexamethasone showed significant reductions in pain and trismus compared to the control group ($P < 0.05$). Submucosal injection of dexamethasone was found to be superior to methylprednisolone only in terms of the reduction in swelling. QOL was minimally affected in patients administered dexamethasone as compared to 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.

Key words: impacted third molar; corticosteroids; dexamethasone; methylprednisolone.

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The surgical removal of third molars is the most common oral surgical procedure performed worldwide. Due to the presence of loose connective tissue and high vascularity, even a meticulous surgical technique can result in considerable pain, swelling, and trismus. These postoperative sequelae can cause great distress, and anything that compromises quality of life (QOL) even for a short period of a few days is unacceptable to the highly cognizant and extremely busy generation of today. Thus we, as medical professionals, are obligated to render better control of this postoperative discomfort for patients undergoing third molar surgery.

Corticosteroids have been used to control postoperative inflammation and the associated symptoms of third molar surgery for several decades. Their anti-inflammatory effect has been utilized to advantage to reduce the oedema induced by the surgery; however, their direct effects on pain control and trismus are controversial[1].

Methylprednisolone and dexamethasone are the most commonly advocated steroids in dentoalveolar surgery because of their dominant glucocorticoid effect and minimal sodium retention activity. Despite their beneficial role as demonstrated by numerous studies[2–4], there is a lack of consensus regarding the optimal dose, route of administration, timing, and duration of treatment. This is primarily because of the use of non-standardized parameters and a paucity of good controlled clinical trials. There are studies both promoting and recommending avoiding the use of 8 mg as the dose of dexamethasone. Similarly, methylprednisolone has been used at doses of 20 mg, 40 mg, 80 mg, and 125 mg in different studies. The superiority of or preference for one drug over the other has not been stated conclusively. Hence a study comparing these two steroids in equivalent doses might provide insights into these controversies.

The purpose of this study was to compare the effects of the preoperative submucosal administration of methylprednisolone 40 mg and dexamethasone 8 mg in terms of postoperative sequelae after mandibular third molar surgery.

Materials and methods

Clinical trial design

The study was approved by the Ethics Committee of the All India Institute of Medical Sciences, Jodhpur. This clinical trial was a single-centre, parallel-group, prospective, randomized, open-label controlled trial with blinded end-point assessment of methylprednisolone 40 mg, dexamethasone 8 mg, and placebo in patients undergoing third molar surgery who satisfied the eligibility criteria. The study was conducted in accordance with the International Conference on Harmonisation Good Clinical Practice (ICH-GCP) and other regulatory guidelines.

Inclusion criteria were healthy patients (American Society of Anesthesiologists category 1 or 2) requiring the removal of an impacted mandibular third molar, with no periodontal disease or associated localized infection. Single impacted teeth with a similar surgical difficulty, as assessed by the surgeon, were included in the study. Exclusion criteria were medically compromised patients, pregnant or breast-feeding women, and patients with a known history of allergy or adverse effects associated with the antibiotics and analgesics to be used in the study.

Patients with third molar extractions of similar surgical difficulty were selected by the operating surgeon using a combined assessment based on the Pederson difficulty index and other features such as root pattern, cheek flexibility, bone density, and patient age.

The subjects were randomized in an open-label manner to either placebo (normal saline injection), dexamethasone 8 mg, or methylprednisolone 40 mg single injection at the time of surgery, after obtaining written informed consent. The randomization codes were computer-generated and were concealed in opaque, sealed envelopes.

Evaluation of efficacy

The clinical examination of each patient on the day of surgery included preoperative mouth opening and facial measurements. Mouth opening was measured with a ruler as the maximum distance between the incisal edges of the upper and lower central incisors. Facial swelling was measured with silk thread using four reference points: tragus, pogonion (inferior most point on the midline of the chin), gonion (angle of the mandible), and the corner of the mouth. It was calculated as the sum of the two diagonals made between these reference points.

After local anaesthesia, the interventional drug was infiltrated into the submucosal tissues of the buccal vestibule in the region of the third molar in all three treatment groups. The surgical procedure was performed by the same surgeon in all cases, using the standard technique of removing bone and sectioning the tooth using a bur and air-driven hand-piece. Primary closure of the surgical wound was done using a 3–0 silk suture. After the surgical procedure, routine postoperative instructions were given and regular antibiotics, along with 0.012% chlorhexidine rinses, were prescribed. In the case of pain, the patient was advised to take a tablet of aceclofenac 100 mg.

Trismus and facial swelling were recorded on days 2 and 7 postoperative using the same method as described above. All preoperative and postoperative measurements were recorded by a single non-operating investigator who was blinded to the intervention used.

Pain was recorded objectively on a 10-cm visual analogue scale (VAS); extreme scores were 'no pain' (0) and 'worst pain imaginable' (10). The patient was asked to mark the intensity of pain on a VAS each day for 7 days. The time at which each analgesic was taken was recorded by the patient from the first postoperative day to the seventh postoperative day. The total number of rescue tablets (aceclofenac 100 mg) taken in the 7 days and the VAS score were calculated to evaluate pain.

For the assessment of QOL, each patient was asked to file a response to a structured questionnaire. The patient's perception of adverse effects was recorded on six subscales: eating, speech, sensation, appearance, sickness, and interference with daily activities were assessed. Each question was scored as not affected (score 0) or affected (score 1).

Statistical analysis

Data were expressed as the mean ± standard deviation (95% confidence interval), or as the number and percentage. The data analysis was done using IBM SPSS Statistics version 21.0 (IBM Corp., Armonk, NY, USA). Results were analysed as an intention-to-treat analysis with the last observation carried forward (LOCF). A two-sided *P*-value of less than 0.05 was considered statistically significant.

Results

A total of 69 patients fulfilled the inclusion criteria. Of these 69 patients, nine were excluded. Sixty patients requiring the removal of an impacted mandibular third molar were included in the study; 38 were male and 22 were female, and their mean age was 29.7 years.

The patients were randomized to the placebo group ($n = 17$), dexamethasone