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Pre-emptive effect of dexamethasone and methylprednisolone on pain, swelling, and trismus after third molar surgery: a split-mouth randomized triple-blind clinical trial

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Abstract. The aim of this study was to compare the effect of dexamethasone 8 mg and methylprednisolone 40 mg for the control of pain, swelling, and trismus following the extraction of impacted third molars. Sixteen healthy patients with a mean age of 20.3 (standard deviation 1.25) years received a single oral dose of either drug 1 h prior to each surgical procedure (left and right teeth). At 24, 48, and 72 h and 7 days following surgery, swelling was determined using linear measurements on the face and trismus was determined by maximal mouth opening. Postoperative pain was self-recorded by the patients using a visual analogue scale at 8-h intervals for a period of 72 h. Data analysis involved descriptive statistics and the Wilcoxon, and paired *t* tests ($P < 0.05$). Dexamethasone controlled swelling better than methylprednisolone at all postoperative evaluations ($P < 0.02$) and led to greater mouth opening 48 h after surgery ($P = 0.029$). No statistically significant difference was found between drugs with regard to pain. In conclusion, pre-emptive dexamethasone 8 mg demonstrated better control of swelling and limited mouth opening in comparison to methylprednisolone 40 mg, with no differences between drugs regarding pain control.

Keywords: third molar surgery; corticosteroids; swelling; pain; trismus.

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Introduction

The surgical removal of impacted third molars is an invasive procedure that involves extensive tissue trauma and a considerable postoperative inflammatory response. Although the inflammatory process is necessary for healing, when exacerbated it may cause pain, swelling, and limited mouth opening.[1–3] Corticosteroids are among the most widely employed preoperative medications administered for the control of such complications.[4–9]

Corticosteroids act in the initial phase of the inflammatory process by suppressing the production of vasoactive substances, such as prostaglandins and leukotrienes, thereby reducing fluid transudation and consequent oedema.[2] Although these drugs may help control pain, they should be used in combination with an analgesic with a clinically significant effect.[1] The adverse effects of steroids depend on the dose and duration of administration. Prolonged use can delay healing and increase one's susceptibility to infection, whereas side effects are rare in therapies that employ a single dose or brief duration, such as those often used in oral surgery.[2,6]

The effectiveness of corticosteroids following oral surgery has been determined by comparing the use of a single dose and placebo, or the comparison of different concentrations of a single drug or different routes of administration.[10–14] To date, however, there is no consensus on the type, dosage, time, and mode of administration of these drugs. Furthermore, the effect of different types of corticosteroid in the surgical extraction of impacted third molars remains under-investigated.

The aim of the present study was to perform a comparative assessment of the effect of pre-emptive dexamethasone and methylprednisolone at equivalent doses for the postoperative control of pain, swelling, and limited mouth opening following the extraction of impacted third molars.

Materials and methods

Study design

A randomized, triple-blind, clinical trial was carried out with a split-mouth design. This study received human research ethics committee approval and was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.[15] Each patient signed a statement of informed consent prior to inclusion in the study. The trial is registered at clinicaltrials.gov, number NCT01603498.

Sample size calculation and pilot study

Considering a 95% confidence level, the sample size was calculated based on each dependent variable analyzed (pain, swelling, and trismus). The parameters used to perform the sample size calculation were obtained from a pilot study involving four patients. The estimate for the comparison of repeated quantitative measurements was used for pain, trismus, and swelling.[16] The largest sample size among the variables (pain) was used in the study. The difference found between groups (2,3 points on the pain scale) and the standard deviation from the pilot study (3,2 points) were used to calculate the sample size for pain. A minimum of 16 patients was determined, to which 10% was added to compensate for possible losses, resulting in a total of 18 participants. The patients who participated in the pilot study were not included in the main study.

Sample selection, masking, and randomization

Eighteen healthy subjects aged 18–25 years were selected to participate in the study, which was carried out at the university oral surgery clinic. The inclusion criteria were an orthodontic indication for bilateral extraction of impacted mandibular third molars and similar surgical difficulty between sides (Class II position B) based on the Pell and Gregory classification,[17] assessed by clinical and radiographic examinations. The following were exclusion criteria: use of an anti-inflammatory agent or analgesic other than those being tested during the study or within 15 days prior to the beginning of the study; hypersensitivity to the drugs or other substances employed in the study; pregnancy or lactation.

To ensure that the patient, principal investigator, surgeon, and statistician were unaware of which medication was administered at each surgery, the corticosteroid capsules were of the same colour and size, were stored in similar bottles, and were coded as drug 1 or drug 2 by a specialized compounding pharmacy (Pharmacy Manipulation Amphora). The drugs used in the different surgeries were only revealed after the acquisition and analysis of all data.

The randomization procedure was performed by a researcher not directly involved in the evaluation of the patients and surgeries, using sequentially numbered sealed envelopes. Each envelope had the combination (obtained by means of a draw) of the drug to be administered (drug 1 or drug 2) and the side of the surgery (right or left). For each patient enrolled, the researcher opened the envelope, informed the principal investigator and surgeon of the side to be operated on and gave the drug to the patient 1 h prior to surgery. The second surgical procedure was performed on the contralateral side, with the administration of the second drug 1 h prior to surgery. Thus, the patient, surgeon, and principal investigator responsible for the assessments of swelling and trismus were masked to the type of medication used during each surgical procedure.

Surgical procedures and medications

One hour prior to each procedure, the patients received a single oral dose of either dexamethasone 8 mg or methylprednisolone 40 mg. Each patient underwent two surgical extractions (performed in the morning) separated by a period of 3–4 weeks and conducted by the same experienced surgeon. Prior to surgery, the patients were submitted to extraoral antisepsis with an alcohol solution of 10% povidone–iodine (PVP-I). Local anaesthesia was performed with lidocaine 2% and epinephrine 1:100,000, employing a maximum volume of 5.4 ml. A standardized technique was used for all surgeries. First, an incision was made on the alveolar ridge from distal to mesial on the mandibular branch to reach the distolingual region of the second molar, followed by an intrasulcular incision encircling the second molar to the region of the interdental papilla between the second and first molar. The mucoperiosteal flap was raised and an ostectomy was performed. The tooth was sectioned and removed with the aid of straight Seldin elevators, followed by careful curettage, bone regularization, and cleaning of the surgical cavity with copious irrigation using saline solution. The flap was sutured with four interrupted stitches using silk thread 4.0. The duration of surgery was recorded in minutes, from the time of the initial incision to the time of the final suture.

Postoperative management

After all surgeries, patients received instructions regarding local haemostatic measures, feeding, cleaning of the operated region, and the restriction of physical exertion, and other routine postoperative recommendations. The patients were given instructions to take one tablet of paracetamol (acetaminophen) 750 mg immediately following surgery and every