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Efficacy of methylprednisolone in controlling complications after impacted lower third molar surgical extraction

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Abstract *Introduction:* Impacted third molar extraction causes considerable swelling in the days immediately following surgery. The aim of the present investigation was to evaluate the efficacy of methylprednisolone as a single 40-mg intramuscular dose in controlling the complications of impacted lower third molar surgical removal. *Materials and methods:* Thirty-five patients were evaluated within the framework of a consecutive sampling and double-blind study with intrasubject measurements. Extraction comprised ostectomy with tooth sectioning of both lower third molars under local anesthesia. The study group received 40 mg of methylprednisolone injected into the gluteal region, while the controls received no such medication. In each individual one molar was randomly assigned to the study group and the other to the control series – with extraction of the two teeth being spaced 1 month apart. Evaluations were made of postoperative pain, trismus and swelling, and measurements were obtained for oral aperture and various distances (tragus-lip commissure, gonion-lip commissure and gonion-external canthus of the eye) before surgery and 2–7 days after extraction. Statistical correlations were made based on the Student *t*-test for the comparison of means of related samples. *Results:* A statistically and clinically significant association was observed 2 days after surgery between methylprednisolone administration and

increased oral aperture and diminished facial swelling. Likewise, less pain was recorded in the study group 6 h after surgery. *Conclusion:* The results confirm the efficacy of methylprednisolone in providing a more comfortable postoperative course after surgical extraction of impacted lower third molars.

Keywords Corticosteroids · Oral surgery · Impacted lower third molar extraction

Introduction

In many patients, impacted third molar extraction causes considerable swelling of the facial soft tissues in the days following surgery. This has led to the use of a great variety of drugs to control this postoperative complication, among which the corticoids have become the most widely accepted options [1–4]. The use of corticoids as anti-inflammatory agents dates back to 1949, when Hench and Kendall first described the antiinflammatory effects of these substances in the treatment of rheumatoid arthritis [5].

The first publication involving the administration of corticoids in dental practice was that of Spies et al., in 1952 [6]. Since then, the use of these drugs has become widely accepted in oral surgery, and many articles have been published reporting the synthesis of new molecules, the administration of different active substances, various administration routes and doses [3, 4, 7–13]. However, this great diversity and the design defects in many studies make it very difficult to define concrete guidelines for the administration of these drugs in the surgical extraction of impacted lower third molars [14].

Considerable controversy exists in the literature on how to quantify postoperative facial swelling [15, 16] – a parameter which is essential for assessing corticoid antiinflammatory efficacy. In this context, different methods have been used to evaluate corticoid performance (Table 1), although few offer objective and reproducible assessments of swelling.

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Table 1 Methods used to measure facial swelling (Pedersen and Maerck-Moller [40])

Linear measurement method	Bidimensional measurement method	Three-dimensional measurement method
Facial arches	Frontal photography	Stereophotography
Calibrators	Modified facial arches	Facial arch with lateral plates
Imprint marks	Cephalostat	
Ultrasound	Computed tomography	

The present study examines the efficacy of methylprednisolone as a single 40-mg intramuscular dose in controlling the complications (trismus, facial soft tissue swelling and postoperative pain) of impacted lower third molar surgical removal under local anesthesia.

Materials and method

A consecutive sampling, double-blind study with intra-subject measurements was conducted in a series of 35 patients treated in the Service of Oral Surgery and Implantology (School of Dentistry of the University of Barcelona, Spain) between April 2000 and May 2001. The inclusion criteria were: healthy subjects of either sex aged 18 years or older, no contraindications for corticoid administration [14] and required extraction of both lower third molars. Extraction of these teeth was required to be of similar difficulty, with ostectomy and tooth sectioning. The difficulty was determined by means of the Pell and Gregory classification [17]. Each molar had to be located underneath the occlusal line of the second molar (class B), and the mesio-distal distance of the wisdom tooth was greater than the distance between the second molar and the ascendent mandibular ramus (class II). The molars were also required to be located symmetrically in the orthopantomograph. The same surgeon, dentist and third-year student of the Master of Oral Surgery and Implantology (School of Dentistry of the University of Barcelona) performed the two extractions (spaced 1 month apart) in each patient. Extraction was carried out under local anesthesia (4% articaine with 1:100,000 adrenalin) in which a maximum of three 1.8-ml carpules were given per patient and operation. The duration of surgery was calculated from the time of incision to placement of the last suture. The duration of the shortest intervention was required to be 75–100% that of the longest intervention.

In no case was premedication provided before extraction. The prescribed postoperative medication consisted of amoxicillin 750 mg or (for patients allergic to penicillin) erythromycin 500 mg [both via the oral route (p.o.) every 8 h for 7 days], metamizol 575 mg p.o. every 6 h for 3 days and 0.12% chlorhexidine rinses twice a day for 15 days. In each patient corticoid administration was randomly assigned to either the first or the second extraction. In the study group, and following molar extraction, methylprednisolone as a single 40-mg dose was injected into the gluteal muscle. No such medication was provided during the intervention for the patients of the control series.

The patients scored pain on a 10-cm visual analog scale (VAS) – with the extremes corresponding to “no pain” and “maximum pain imaginable” – every hour for the first 6 h after extraction, and on the following 3 days only in the morning and at night. Each patient also subjectively assessed swelling by means of a descriptive scale in which 0 = no swelling, 1 = mild, 2 = moderate or 3 = severe swelling.

A physician other than the operating surgeon in turn independently evaluated trismus and postoperative swelling by recording the unforced oral aperture with calipers and three distances (tragus-lip commissure, gonion-lip commissure and gonion-external canthus of the eye) with silk thread. To establish the reproducibility of those measures made with a silk thread, a permanent ink point was marked at the gonion. All of the measurements were made prior to the operation, at 9:00 a.m., and again 2 and 7 days after extraction. The values recorded preoperatively were taken to be the baseline reference values.

In addition to informed consent to third molar extraction, the patients gave their written consent to corticoid use.

The non-parametric test of Wilcoxon for related samples was used to compare values. Statistical significance was considered to be $p \leq 0.05$. In the case of a statistical significant parameter the Student *t*-test was carried out to quantify the difference between groups. The SPSS ver. 9.0 statistical package for Microsoft Windows (serial no. 7116391; SPSS, Chicago, Ill.) was used throughout.

Results

Of the 35 patients initially included in the study, four were excluded on the grounds that the two interventions differed in duration by more than 25%. There were no infectious complications or adverse effects attributable to corticoid use. The final 31 patients comprised 15 males and 16 females (48.4 and 51.6%, respectively), with a mean [$\pm$ standard deviation (SD)] age of 22 ± 2.8 years. There were no differences between the study group and controls in terms of preoperative oral aperture and the facial distances used to assess swelling (Table 2), or in relation to the duration of surgery. In the group administered methylprednisolone, the duration of extraction was 22 ± 6.4 min (range: 15–35), while in the control group the duration was 21.1 ± 5.4 min (range: 14–37). Significantly better performance ($p \leq 0.05$) was recorded 2 days after extraction in the methylprednisolone group versus the controls in terms of the following parameters (Table 3): oral aperture (3.7 mm), tragus-lip commissure

Table 2 Preoperative oral aperture and facial swelling (in mm)

Preoperative control (parameter)	Study group	Control group	<i>p</i>
Oral aperture	48.19±5.94	48.71±6.35	0.483
Tragus-commissure	105.26±6.69	106.13±7.19	0.066
Gonion-commissure	91.13±7.11	91.48±6.64	1.000
Gonion-external canthus of the eye	109.61±5.86	108.74±7.99	0.388

(2.1 mm), gonion-lip commissure (3.4 mm) and gonion-external canthus of the eye (1.7 mm). However, 7 days after surgery the intergroup differences in terms of oral aperture and swelling measurements were no longer significant.

The study group reported significantly less facial soft tissue swelling at all postoperative controls according to the patient-filled questionnaires (Table 4).

With respect to postoperative pain determined by the VAS, a statistically significant reduction was recorded 6 h after extraction in the study group versus the controls [18.97±18.39 mm (range: 0–73) and 29.33±21.12 mm (range: 1–76), respectively; $p=0.011$]. However, the pain reductions recorded at the subsequent controls were no longer significant between groups.

Discussion

The surgical extraction of impacted lower third molars often causes swelling of the facial soft tissues, trismus and pain [17]. It therefore constitutes a good model for evaluating the efficacy of different antiinflammatory drugs [18, 19]. On the other hand, individual variability can be obviated in such studies, since each patient can serve as his or her own control [20]. It was decided not to use placebo administration because it would require an invasive procedure. In addition the patients could be denied this procedure.

In order to reduce inflammation, corticoids must be administered at doses in excess of the physiological concentrations released under normal conditions [8]. In this sense, the body produces approximately 15–30 mg of hydrocortisone daily – a figure that can reach 300 mg under conditions of stress [21]. Different corticoids, with different efficacies, biological half-lives and mineralocorticoid actions, can be used [14]. It is therefore very important to know the relative potency of each type of

molecule. On the other hand, the ideal drug possesses only minimum mineralocorticoid action and provides therapeutic activity in the immediate postoperative period – i.e. when the inflammatory reaction is most intense [22]. Synthetic molecules undergo slower metabolism, as a result of which their plasma and tissue presence is considerably prolonged [23]. Dexamethasone and methylprednisolone have possibly been the most widely used corticoids in oral surgery, primarily due to their great antiinflammatory action and minimum mineralocorticoid effects [13]. In this context, methylprednisolone meets all of the requirements just mentioned, since it is five-fold more potent than hydrocortisone, lacks mineralocorticoid action and has a biological half-life of 18–36 h [3, 4, 14, 24–28]. Table 5 shows the main controlled trials evaluating perioperative steroid use in oral surgery.

Different corticoid administration routes have been used in oral surgery. Oral dosing is possibly the most comfortable option for the patient; it also ensures a rapid and almost complete absorption [29] although it does not seem to be as effective as parenteral administration. However, it should be noted that the studies published in the literature [9, 25] have used low doses, and the observation periods have been short in comparison with studies employing the parenteral route. On the other hand, the oral route has the inconvenience of requiring good patient compliance for a number of days after surgery in order to ensure treatment efficacy. For these latter reasons, Montgomery et al. [14] have questioned the efficacy of corticoids via the oral route following the extraction of impacted third molars.

In most cases the parenteral route must be restricted to the preoperative and immediate postoperative period [14]. The intramuscular route offers a series of advantages: in actual fact it is not dependent upon patient compliance, good plasma levels are reached and antiinflammatory action is persistent. However, the experience of the surgeon, patient discomfort and the need for specific material by which to administer the drug can limit its use. Esen et al. [20] have mentioned the possibility of suppression of the activity of the adrenal gland cortex from administration of the corticoid by the intramuscular route; however other authors [7, 8, 11–13] are of the opinion that no such risk exists. Intramuscular injection as a single dose either before or after surgery is effective against pain, swelling and trismus in the immediate postoperative period [14].

The intravenous route provides excellent plasma drug concentrations – which are reached immediately –

Table 3 Oral aperture and swelling 2 days after extraction (in mm). Comparisons were made using the Student *t*-test for related samples

Control at 2 days postsurgery (parameter)	Study group (SG)	Control group (CG)	SG – CG ^a	Standard deviation	<i>p</i>
Oral aperture	36.87	33.19	+3.68	6.54	0.005
Tragus-commissure	107.97	110.10	–2.13	4.19	0.002
Gonion-commissure	94.84	98.23	–3.39	5.39	0.003
Gonion-external canthus of the eye	111.84	113.48	–1.65	4.02	0.038

^aSG – CG, Mean of the study group minus mean of the control group

Table 4 Qualitative patient evaluation of facial swelling at the postoperative controls

Postoperative control		Mean		Difference of means (SG – CG)	SD	p
		SG ^b	CG ^b			
Day 0	6 h ^a	0.90	1.23	–0.32	0.79	0.031
Day 1	Morning	1.03	1.55	–0.52	0.96	0.006
	Night	1.19	1.81	–0.61	0.84	<0.000
Day 2	Morning	1.39	1.74	–0.35	0.75	0.014
	Night	1.29	1.61	–0.32	0.65	0.010
Day 3	Morning	0.94	1.35	–0.42	0.85	0.010
	Night	0.77	1.19	–0.42	0.67	0.002

^a6 h, Control examination at 6 h after surgery

^bSG, Study group; CG, control group

although an even greater experience with administration is required than with the intramuscular route, and the disposable injection material is more complex. Moreover, studies involving the intravenous route suggest that while a single preoperative dose offers almost immediate benefit in terms of pain, swelling and trismus, a supplementary oral or intramuscular dose is usually needed to ensure optimum clinical efficacy [14].

With respect to dosage, Huffman [10] compared the administration of 40 and 125 mg of methylprednisolone in impacted lower third molar extraction. Although the larger dose effectively reduced inflammation, the difference between the two doses was not significant – possibly because facial swelling was estimated subjectively by visual inspection and palpation. In our study 40 mg of methylprednisolone was administered to reduce swelling while avoiding the increased risk of adverse effects associated with larger drug doses.

In this contest, corticoids have been associated to multiple adverse effects – most of which are a consequence of mineralocorticoid action, or of chronic administration [30]. The associated side effects and contraindications can be minimized by using glucocorticoids with only minimum mineralocorticoid action on a point-dosing basis. As in other studies [8, 10, 13, 20, 31], we recorded no adverse reactions or complications attributable to administration of the corticoid.

In the same way as regards adverse effects, different authors have shown that hypothalamic-hypophyseal suppression only occurs in the context of prolonged corticoid treatments. As a result, such suppression should not be regarded as a contraindication for corticoid use in impacted lower third molar extraction, since administration is carried out on a point basis [4, 32–37].

There are many ways to objectively assess facial swelling, and no particular method has been shown to be

Table 5 Controlled trials evaluating perioperative steroid use in oral surgery

Reference	Number of patients	Type of surgery	Treatment groups ^a	Results
Beirne and Hollander, 1986 [3]	31	Impacted thirds	mP 125 mg intravenous(IV) just prior to surgery	Swelling: significantly less with mP Trismus: no statistical difference
Sisk and Bonnington, 1985 [4]	60	Impacted thirds	Flurbiprofen 50 mg orally or mP 125 mg IV just prior to surgery	Analgesic effect: no difference; Mouth opening: no difference; Swelling: objective mP better, subjective mP and flurbiprofen better than placebo at 72 hours postoperative
Skjelbred and Lokken, 1982 [7]	47	Bilateral thirds	B 9 mg intramuscular (IM) perioperatively	B vs. placebo: Swelling: 23 mm: 51 mm on third day; 3.5 mm: 11.3 mm on sixth day Mouth opening reduced 23% vs. 44% at third day. Reduced 7 vs. 21% at sixth day postoperative
Caci and Gluck, 1976 [9]	129	Impacted thirds	P 5 mg every 4 h on the day of surgery, then every 6 h for 3 days thereafter	P significantly reduced trismus and pain, but no effect on edema
Huffman, 1977 [10]	129	Impacted thirds	40 mg mP or 125 mg P IV immediately preoperatively	Significant reduction in edema with both groups at 24 and 48 h postoperatively; no difference between groups at any time

^aB, Betamethasone; P, prednisolone; mP, methylprednisolone

superior or more precise than the rest [31]. The fact that our study included an extensive series of patients allowed us to choose a simple and low-cost measurement technique based on 3/0 silk thread for the linear measurements. We measured the following distances: tragus-lip commissure [1, 38], gonion-lip commissure [31] and gonion-external canthus of the eye [1, 31] with a silk thread. As an indirect estimation of swelling we used oral aperture, measured with calipers. It is obvious that subjective parameters are placebo-sensitive. For this reason, objective evaluation of swelling was included in the study.

Some studies [1, 20] have shown that swelling is considerable on the second postoperative day, regardless of whether corticoids are administered or not. Esen et al. [20] reported a statistically significant 42% reduction in swelling on the second postoperative day among patients administered corticoid – based on computed tomography measurements. Schultze-Mosgau et al. [38] administered 32 mg of methylprednisolone via the oral route and 400 mg of ibuprofen and achieved a 56 and 22% reduction in facial swelling on the first and third postoperative day, respectively, in the study group. In our series, the administration of 40 mg of methylprednisolone significantly reduced facial swelling 2 days after extraction.

Esen et al. [20] also observed an important reduction in oral aperture on the second postoperative day in both the study and control groups. However, in the former group the reduction was significantly less than in the control group (10.5 and 16.7 mm vs. the preoperative aperture, respectively). This same tendency was also recorded after 7 days: the patients in the study group showed greater oral apertures than the controls, although the intergroup difference was no longer statistically significant. We obtained very similar results, with a reduction in oral aperture of 11.3 mm in the study group and 15.5 mm in the control series ($p=0.004$) 2 days after extraction. However, the intergroup differences 7 days after surgery were no longer significant.

When they investigated postoperative pain, Esen et al. [20] found analgesic consumption on the day of surgery to be 42% lower when the corticoid was administered. In another study [38] involving a 100-mm VAS for pain, a statistically significant reduction in pain was recorded on the first postoperative day, with mean scores of 43.5 mm and 11.5 mm in the study group and controls, respectively. Baxendale et al. [39] observed a statistically significant reduction in pain (VAS score) 4 h after surgery in the study group; however, the results were not significant at the subsequent controls. In our study, a comparatively greater decrease in pain score was recorded 6 h after extraction in the corticoid group (19 mm) versus the controls (29.3 mm), with no significant intergroup differences being noted at the subsequent controls.

The results of the present study show that the immediate postoperative administration of 40 mg of methylprednisolone via the intramuscular route significantly reduces swelling, trismus and pain, thereby contributing to limiting the typical discomfort experienced by patients in the period immediately following the surgical extraction of impacted

lower third molars. These findings should be taken into account by oral surgeons, since they may considerably improve the postoperative course in patients requiring dental surgery involving ostectomy and tooth sectioning.

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