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Effect of preoperative ibuprofen on pain and swelling after lower third molar removal: a randomized controlled trial

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Abstract. The aim of this study was to compare the analgesic and anti-inflammatory effects of preoperative and postoperative administration of ibuprofen after the surgical removal of impacted lower third molars. A triple-blind, randomized, placebo-controlled clinical trial of 120 patients requiring the surgical removal of lower third molars was performed. The subjects were randomized into the experimental group (patients were administered 600 mg of ibuprofen (p.o.) 1 h before the surgical procedure, followed by placebo just after the end of the operation) or into the control group (subjects received the same medication but the administration sequence was reversed). Pain was assessed using visual analogue scales, and consumption of rescue analgesic. The facial swelling and trismus were evaluated by measuring facial reference distances and maximum mouth opening. There were no significant differences between the two study groups regarding postoperative pain, rescue analgesics consumption, facial swelling and trismus. There was a slightly higher need for rescue analgesics in the experimental group. The preoperative intake of ibuprofen does not seem to reduce pain, facial swelling and trismus after impacted lower third molar removal when compared to the postoperative administration of the same drug.

Key words: third molar; pre-emptive analgesia; nsaids; ibuprofen; postoperative pain.

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The extraction of impacted lower third molars is the most common surgical procedure in dentistry. The postoperative course is characterized by pain, swelling and trismus in varying degrees affecting the patient's quality of life.[1] Postoperative pain is related to alterations in the central and peripheral nervous systems induced by surgical trauma.[2] This tissue injury causes the release of cyclooxygenase-2 (COX-2) which induces the activity of prostaglandins that sensitize peripheral nociceptors and induce inflammation symptoms.[3] Woolf[4] first introduced the concept of pre-emptive analgesia to reduce the severity and duration of postoperative pain. Pre-emptive analgesia is defined as an antinociceptive treatment that is started preoperatively and is active during surgery, reducing the physiological consequences of induced nociceptive transmission.[2]

Traditionally, it has been suggested that the administration of non-steroidal antiinflammatory drugs (NSAIDs) prior to surgery may be more effective when compared with postoperative intake, causing an early inhibition in the production of prostaglandins and activation of peripheral and central sensitisation. There are

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numerous publications on this subject but the results are contradictory.[5–9] These studies usually only assess pain and do not evaluate the anti-inflammatory effects of NSAIDs comparing different times of administration. The purpose of this randomized clinical trial is to compare the analgesic and anti-inflammatory effects of preoperative (1 h before surgery) and postoperative (immediately after completing the surgical procedure) administration of 600 mg of ibuprofen p.o. in the surgical removal of impacted lower third molars.

Materials and methods

A randomized, triple-blind, placebo-controlled clinical trial was performed in 120 patients. All participants underwent the surgical removal of an impacted lower third molar between February 2008 and October 2010. This trial was design complying with the CONSORT guidelines for clinical trials.[10]

The study was approved by the Research Ethics Committee (CEIC) of the Dental Clinic of the University of Barcelona. Before enrolment, the objectives, implications and possible complications of this clinical trial were explained to all the patients and they agreed to participate by signing an informed consent form. The main inclusion criterion was the presence of an impacted lower third molar that required surgical removal. Exclusion criteria were patients aged below 18 years or over 45 years, patients with significant systemic diseases (ASA III or ASA IV), pregnancy, history of allergy to ibuprofen or other NSAIDs, lactose intolerance, gastrointestinal pathology, presence of symptoms associated with the third molar the week prior to extraction, and history of analgesic and/or anti-inflammatory drug intake 10 days before surgery. Antibiotic prophylaxis was not given. Sequentially numbered envelopes were used to conceal the allocation of patients to the two groups. The group assignment for each patient was predetermined by a sequence of random numbers in blocks (generated in www.randomization.com). Identical capsules containing 600 mg of ibuprofen or 600 mg of placebo were manufactured (Farmacia Coliseum, Barcelona, Spain).

All surgeries were performed by second-year residents of the Master degree programme of Oral Surgery and Implantology (University of Barcelona) using a similar surgical technique. The patients did not receive any financial compensation for participating in the study. The incorporation of each subject in the study was decided before knowing the assigned group. The extraction of impacted lower third molars was performed under local anaesthesia with articaine 4% and epinephrine 1:100,000 (Artinibsa; Inibsa, Lliça de Vall, Spain). The surgical field and all the surgical material were sterile. The surgeon raised a full-thickness flap, which was protected by the Minnesota retractor. A lingual flap retraction using a Freer periosteal elevator was only performed when the surgeon consider it to be necessary. Sterile low-speed (20,000 rpm) handpieces and sterile saline solution were used for bone removal and tooth sectioning when necessary. To close the wound, 3-0 silk sutures (Silkam, Braun; Tuttlingen, Germany) were used. The surgical technique was similar to that described by Leonard.[11] The following medication was prescribed: an antibiotic (amoxicillin 750 mg p.o. every 8 h for 7 days; patients with previous history of allergy to penicillin were prescribed clindamycin 300 mg p.o. every 6 h for 7 days (Dalacin 300; Pfizer, Madrid, Spain)), a NSAID (ibuprofen 600 mg p.o. every 8 h for 5 days starting 8 h after extraction), an analgesic (metamizol 575 mg p.o. as rescue medication), and a mouthrinse (0.12% chlorhexidine mouthwash two times a day for 15 days). In the preoperative group, patients were administered 600 mg of ibuprofen (p.o.) 1 h before the surgical procedure, followed by placebo just after the end of the operation. In the control group, the administration sequence was reversed (placebo was given 1 h before the extraction, and 600 mg of ibuprofen were administered when surgery had been completed).

All subjects were instructed to measure the intensity of the postoperative pain in different visual analogue scales (VAS) of 100 mm. Pain was assessed every 2 or 4 h within the first 14 h, and then the patient measured pain intensity every 8 h between 24 and 64 h postsurgery. They also had to record the number of rescue medication capsules needed during the first 72 h of the postoperative period. Facial swelling and trismus were registered at 48 h and 7 days after the extraction by a blinded surgeon who was not involved in the operation. Trismus was assessed by measuring maximum mouth opening with callipers, and facial swelling was determined by the following facial distances: gonion–lip commissure, gonion–external canthus of the eye, tragus–lip commissure.[12] The following variables were also gathered: age, gender, smoking habit, operated side, position of the third molar (Pell and Gregory and Winter classifications), bone retention, duration of the surgical procedure, bone removal and tooth sectioning.

All patients, the statistician and the surgeons who performed the extraction and follow-up examinations were unaware of the medication given to each participant. The sample size was calculated using the statistical programme G × Power 3.0. (Heinrich-Heine-Universität, Düsseldorf, Germany).[13] with an alpha value of 0.05, a statistical power of 90%, and in order to detect differences of 10 mm in the variable VAS (mm) postoperative pain, assuming a loss at follow-up of 20%.

Statistical analysis was performed using SPSS Software for Windows 15.0 (SPSS v15.0, SPSS Inc., Chicago, USA, licensed from the University of Barcelona). Demographic data were analysed using χ^2 tests and ANOVA. To compare the two groups regarding pain intensity, facial swelling and trismus, repeated measures ANOVA tests were used and Student's t tests for independent samples. The rescue medication intake variable was analysed using t tests. The level of significance was set at $p < 0.05$.

Results

120 patients were enrolled, although 11 (7 in the preoperative group and 4 in control group) were lost because they did not attend follow-up visits. Figure 1 shows the CONSORT flow chart of the recruitment of participants.[10] The results were based on the analysis of 109 participants; 53 in the preoperative group and 56 in the control group. The study groups were similar regarding gender, age, smoking habit, bone retention of the third molar and duration of surgery (Table 1).

The peak pain occurred at 6 h, with a higher value for the control group ($p > 0.05$). There were no significant differences between the two groups regarding pain intensity (ANOVA, $F = 0.66$; df = 5.17; $p = 0.66$). When the analysis was made for each individual pain assessment time, a significant difference was found just after the end of the surgical procedure, when the experimental group showed less pain intensity than the control group (Student's $t = -2.0$; df = 67.8; $p = 0.04$). Table 2 shows the results for pain intensity, rescue medication intake, facial swelling and mouth opening variables in the two study groups.

The rescue medication intake showed no statistical differences between groups during the first 3 postoperative days (ANOVA, $F = 2.19$; df = 1; $p = 0.14$) although the patients in the preoperative group needed a higher dose of metamizol,

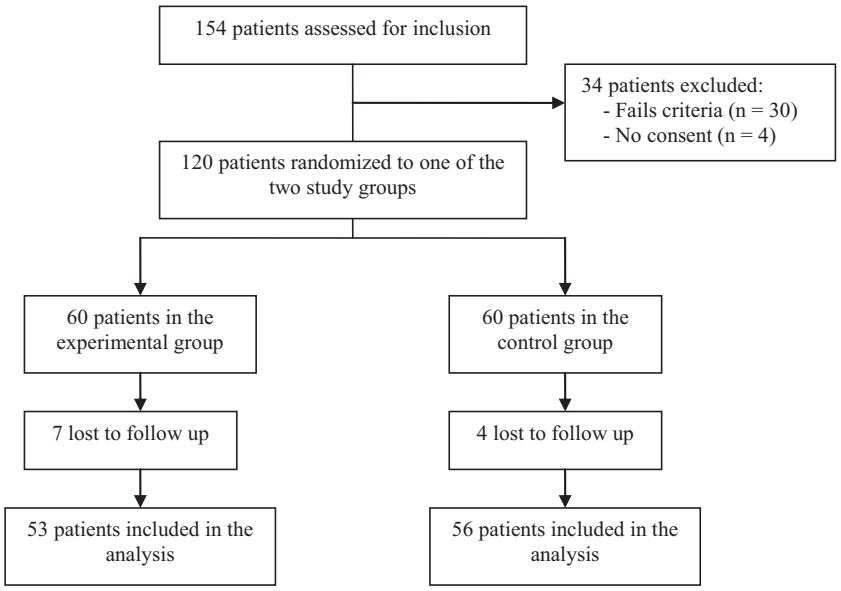

Fig. 1. CONSORT flow chart of the participants in the trial.

especially on the second postoperative day (Student's $t = 2.0$; df = 99.3; $p = 0.04$) (Table 2).

The variables gonion–lip commissure, gonion–external canthus of the eye, tragus–lip commissure, and mouth opening were similar in both groups. No adverse effects related to ibuprofen or metamizol were registered.

Discussion

Management of pain after third molar extractions is important, particularly as most patients are treated in outpatient clinics. Postoperative symptoms after surgical removal of a third molar can be adequately controlled with the use of NSAIDs.[14,15] It has been argued that these agents are more effective when administered before surgery.[16]

Some studies evaluating the preoperative administration of NSAIDs and pain in oral surgery have been published. The beneficial effects of the preoperative administration of piroxicam[17] ketorolac,[18] meloxicam,[19] parecoxib[20] and dexamethasone with rofecoxib[21] have been documented. Some authors found a lower consumption of rescue analgesics[17] and a delay in the onset of pain[6] when the NSAIDs were administered before the surgical procedure. Other publications state otherwise, and do not seem to support preemptive analgesia with NSAIDs. Many papers failed to show a positive effect of the preoperative medication, and some recent papers suggest that the postoperative administration groups might have lower pain intensity rates.[5,7,9,22–24] In the present sample, the differences in pain intensity were negligible (<5 mm VAS pain) and do not seem to validate the use of ibuprofen prior to surgery.

In a meta-analysis that evaluated the preoperative administration of NSAIDs in several fields of surgery, the authors state that the pre-emptive intake of NSAIDs should not be applied systematically. They base their recommendations on the lack of enhanced analgesic effects and on the potential adverse effects such as increased intraoperative bleeding.[25] This last statement seems to be controversial since another review concluded that the evidence that NSAIDs increase the incidence of bleeding after surgery is ambiguous.[26] In the present clinical trial, the frequency of intra and postoperative complications such as bleeding were not assessed.

A more recent meta-analysis claimed that the effects of preemptive NSAIDs administration on postoperative pain intensity did not reach levels of statistical significance sufficient to draw a positive conclusion. Nevertheless, a trend towards lower postoperative pain scores and reduced need of supplemental analgesic consumption was noted.[27]

In order to avoid the transmission of noxious afferent information from the periphery to the spinal cord and brain, analgesics must provide a sufficiently dense and long duration of blockade. It has been suggested that prevention of pain hypersensitivity could be even more pronounced if pre-emptive analgesia extends its duration into the postoperative period. Therefore, for the correct management of acute postoperative pain, inflammatory mediators and nociceptive inputs should be inhibited well into the postoperative period.[27]

The lack of differences between the two groups in the present trial can be justified by the fast absorption of the drug. A study by Jones et al.[28] showed that the maximum plasma peak after the administration of 400 mg of ibuprofen p.o. occurred after 32 min. It is also known that the maximum concentrations of prostaglandins around damaged tissues are obtained approximately 1 h after injury.[29] Another important aspect that has to be taken into account is the use of local anaesthetics. Jung et al.[22] suggested that these agents have an analgesic effect, reducing the flow of sensory input from the periphery to the central nervous system. This is an important consideration and seems to support the use of long-lasting anaesthetics to increase the residual analgesic effect. In the present study, a 4% articaine solution was used in all patients. Another important issue that could be related to the similarity between the two groups is that all patients received 600 mg of ibuprofen, 8 h after the surgical procedure. If no NSAIDs had been prescribed, and the patients had been advised only to take the rescue medication when needed, the differences would

Table 1. Main clinical features of the patients.

	Experimental group	Control group	*p* value
Gender (male/female)	(24/29)	(27/29)	0.76
Age (years)	26.4 ± 6.2	25.9 ± 5.5	0.66
Operated side (right/left)	(26/27)	(29/27)	0.77
Smoking habit (cig/day)	7.7 ± 7.6	7.3 ± 8.3	0.78
Surgery duration (min)	28.0 ± 10.4	26.5 ± 9.2	0.43
Bone retention (complete/partial)	(44/9)	(45/11)	0.72
Pell&Gregory position (A/B/C)	(7/43/3)	(15/39/2)	0.20
Pell&Gregory position (I/II/III)	(3/47/3)	(5/48/3)	0.80
Winter position (1/2/3/4)[a]	(13/27/9/4)	(9/25/15/7)	0.38
Bone removal (Yes/No)	(50/3)	(47/9)	0.08
Tooth sectioning (Yes/No)	(41/12)	(37/19)	0.19

The level of significance was determined with χ^2 and *t* tests.

[a] 1, horizontal; 2, mesioangular; 3, vertical; 4, distoangular.

Table 2. Values of postoperative pain, rescue medication intake, mouth opening and facial swelling.

	Mean ± standard deviation		*t*-Student (p)
	Preoperative group	Control group	
VAS pain intensity (mm)			
End of surgery	1.4 ± 4.7	5.5 ± 14.2	0.04*
2 h	11.3 ± 15.6	11.9 ± 15.2	0.82
6 h	25.9 ± 15.6	29.4 ± 22.3	0.45
10 h	24.2 ± 20.4	24.7 ± 22.8	0.92
14 h	25.8 ± 24.9	24.2 ± 20.9	0.71
24 h	20.6 ± 23.4	20.7 ± 19.9	0.97
32 h	22.3 ± 21.2	20.5 ± 18.9	0.63
40 h	26.0 ± 24.6	23.7 ± 23.6	0.61
48 h	19.7 ± 24.1	17.8 ± 20.5	0.65
56 h	19.2 ± 18.6	18.3 ± 20.3	0.81
64 h	21.9 ± 25.8	19.0 ± 23.4	0.55
Rescue medication intake (capsules)			
1st day	1.2 ± 1.0	1.2 ± 1.1	0.82
2nd day	1.2 ± 1.5	0.7 ± 1.2	0.04*
3rd day	1.1 ± 1.7	0.7 ± 1.2	0.15
Gonion-lip commissure (mm)			
Preoperative	91.6 ± 7.1	94.3 ± 7.6	0.06
48 h	98.4 ± 8.1	102.5 ± 9.6	0.02*
7 days	94.2 ± 7.8	97.7 ± 8.4	0.03*
Tragus-lip commissure (mm)			
Preoperative	114.9 ± 6.5	117.3 ± 6.8	0.06
48 h	118.4 ± 6.5	120.8 ± 6.3	0.05*
7 days	115.4 ± 6.5	118.4 ± 7.2	0.02*
Gonion-external canthus of the eye (mm)			
Preoperative	105.9 ± 7.4	107.8 ± 6.8	0.16
48 h	110.2 ± 8.1	110.9 ± 6.9	0.61
7 days	107.4 ± 7.7	108.7 ± 6.8	0.38
Mouth opening			
Preoperative	51.8 ± 5.4	53.0 ± 5.7	0.26
48 h	35.3 ± 9.9	34.9 ± 8.9	0.83
7 days	45.2 ± 9.1	46.2 ± 8.8	0.56

* Statistical significant difference.

probably have been more obvious, since the pain intensity measurements would be higher. Nevertheless, instructing the subjects not to take ibuprofen would reduce the external validity of this study, as most patients undergoing third molar removal in a standard clinical environment are prescribed NSAIDs.

To the authors' knowledge, very few reports have studied the effect of the time of administration of ibuprofen and postoperative swelling after third molar extractions. Previous studies.[21,30] showed a significant reduction of trismus and facial oedema when corticosteroids were used alone or in combination with NSAIDs. Only a slight reduction was observed when NSAIDs were used. These authors.[21,30] speculated that preoperative administration might have a beneficial effect on postoperative swelling. The results found in the present sample showed that oedema and trismus were not reduced when ibuprofen was administered prior to the extraction.

The lack of differences between the two groups of this study could be related to several factors, such as the use of articaine (which allowed the postoperatively administered patients to have an adequate plasma level of ibuprofen before pain onset), the average duration of the surgical procedure (27 min) which allowed only a small interval between the administration of the drug in the experimental and control groups, and also that the mean pain intensity levels were generally low (less than 30 mm) showing that both treatment options were effective for the majority of cases.

In conclusion, the preoperative intake of ibuprofen does not seem to reduce pain, facial swelling and trismus after impacted lower third molar removal when compared to its postoperative administration.

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Competing interests

None declared.

Ethical approval

The study was approved by the Research Ethics Committee (CEIC) of the Dental Clinic of the University of Barcelona.

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