

Ibuprofen arginine for pain control during scaling and root planing: a randomized, triple-blind trial

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Abstract:

Objectives: The aim of this controlled clinical trial was to investigate the analgesic efficacy and tolerability of ibuprofen arginine in patients with mild-to-moderate periodontitis during and after non-surgical periodontal treatment.

Methods: This randomized, triple-blind, placebo-controlled, parallel-group trial assessed the analgesic efficacy of ibuprofen arginine (Spedifen[®]) in patients undergoing routine periodontal scaling and root planing. 64 patients with chronic periodontitis received either 800 mg ibuprofen arginine or placebo 30 min. before treatment. Numeric pain and electronic visual analogue scales ranging from 0 to 100 were used.

Results: The average pain levels during treatment were lower following ibuprofen arginine (quartiles: 0.5, 4.5, 11) compared with placebo (4, 16, 26), corresponding to a percentage reduction in median pain of 72% ($p = 0.023$). The median maximum pain was 28 (inter-quartile range 10–50) following placebo and 10 (4–31) following ibuprofen arginine ($p = 0.065$).

Conclusions: In patients with mild-to-moderate chronic periodontitis, ibuprofen arginine was safe and superior to placebo for alleviating pain during non-surgical periodontal treatment. Its painless administration and rapid onset of action make it well suitable for pain management in a general dental office.

Key words: analgesics; dental prophylaxis; dental scaling; ibuprofen; non-narcotic; periodontics

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Chronic periodontitis is a common inflammatory disease of the gums and related bones (AAP 2000a). It appears to be an independent risk factor for pre-term birth (Jarjoura et al. 2005), and emerging evidence points to an increased risk for cardiovascular disease (DeStefano et al. 1993, Khader et al. 2004, Desvarieux et al. 2005). Periodontal health, on the other hand, correlates with improved quality of life (Needleman et al. 2004). Periodic professional mechanical plaque removal is a standard procedure listed under internationally recognized “parameters of care” to control chronic periodontitis and to maintain periodontal health, although its efficacy on the prevention of periodontal diseases is currently

being debated (AAP 2000b, Needleman et al. 2005).

Pain or discomfort is often associated with non-surgical plaque removal (Pihlstrom et al. 1999, van Steenberghe et al. 2004, Hoffman et al. 2005, Kocher et al. 2005). Common procedures for pain management are infiltration anaesthesia or topical anaesthetics (Svensson et al. 1994, Jeffcoat et al. 2001, Perry et al. 2005). However, many patients fear injections. Undesirable side-effects of topicals include their distasteful flavour, the anaesthetic effect on the entire gingival mucosa or possible adherence problems when using patches (Stecker et al. 2002). The ideal anaesthetic agent is characterized by convenient and painless administration, fast onset, adequate

duration, and minimal adverse effects. Non-steroidal anti-inflammatory drugs (NSAIDs) meet most of these criteria and their efficacy for dental surgery pain is well established. In fact, half of the double-blind, placebo-controlled studies submitted to the American Food and Drug Administration seeking approval for acute pain management during the past decade were conducted in patients experiencing pain after extraction of third molars (Ridgway 2004). Controlled clinical trials on drug efficacy for pain control during non-surgical periodontal treatment, however, are lacking.

There is no evidence that any one non-selective NSAID is more effective than the other for non-specific pain

management, but ibuprofen is nowadays considered the safest inexpensive choice (Sachs 2005). The addition of arginine to ibuprofen enhances the rate and extent of absorption of ibuprofen so that ibuprofen arginine becomes bio-available about three times more rapidly than generic ibuprofen (Fornasini et al. 1997).

We hypothesized that ibuprofen arginine*, because of its rapid onset of action and long duration, its favourable safety profile and the possibility of easy oral administration shortly before a dental procedure, is a promising agent to achieve pain control during and after periodontal scaling and root planing (SRP) (Fornasini et al. 1997, Black et al. 2002). Therefore, we conducted a randomized, controlled clinical trial aiming to investigate the analgesic efficacy and tolerability of ibuprofen arginine during and after SRP in patients with chronic mild to moderate adult periodontitis. We opted for a single dose of 800 mg ibuprofen arginine (one-third of the maximum daily dosage) because clinical trials comparing pain intensity ratings with ibuprofen serum levels suggest that increased single doses lead to better analgesia. (Laska et al. 1986, Towheed et al. 2000).

Materials and Methods

Participants

Patients had to be between 30 and 75 years of age and present with mild-to-moderate chronic periodontitis, defined as having at least one tooth with a pocket depth ≥ 6 mm and two more teeth having a pocket depth ≥ 4 mm on each side of the upper or lower jaw (AAP 2000a). Exclusion criteria included the following: contraindications for ibuprofen arginine, intake of analgesics within 2 days before the investigation, serious medical conditions, dentine hypersensitivity, abscesses and gross caries, professional hygiene within the last 2 months, oral pain before treatment and a positive pregnancy test.

Study protocol

We performed a randomized, triple-blind, placebo-controlled, parallel-group trial in a single general dental

office in Frauenfeld, Switzerland. A dentist screened all his patient charts and invited potentially eligible patients to participate in the study between 14 June 2003 and 30 April 2004. All participants had experienced SRP previously and were accustomed to the level of discomfort secondary to these procedures. Participants were not surveyed with regard to previous discomfort from scaling procedures.

Following recruitment and obtaining informed consent, participants were randomly assigned to receive either 2×400 mg film-coated tablets containing the active ingredient ibuprofen arginine or 2×400 mg placebo tablets containing cellactose. To ensure concealment of random allocation, the dentist advised a member of the office staff not otherwise involved in the study to open the next sealed blister pack containing the study medication according to the randomization list. We decided to ask a member of the dental practice not otherwise involved in the study to dispense the study medication because the manufacturer of the study medication could not provide placebo tablets exactly matching the active drug size. Packaging and colour of all tablets were identical. The patients and the drug-dispensing person were kept unaware of the existence of a size difference. Thereby, we could maintain blinding of the dentist and patients for group allocation.

An independent statistician generated a randomization list with blocks of eight, stratified for gender and age (\leq or > 55 years). Investigators involved in data analysis and manuscript writing were kept blinded with respect to the identity of the two treatment groups until the first draft version of the study report had been written. The randomization code was broken only after all investigators agreed on the interpretation of the analyses.

We conducted the study in full accordance with the Declaration of Helsinki (<http://www.wma.net/e/policy/b3.htm>). The regional ethics committee as well as the Swiss health authorities approved the study protocol. Biomet Inc. (Basel, Switzerland), a clinical research organization, managed the organizational parts of the study and ensured adherence to standards of the International Conference on Harmonization/WHO Good Clinical Practice <http://www.who.int/medicines/library/par/ggcp/GGCP.shtml>. It was contractually agreed that the

financial sponsor did not have any influence on the analysis and the decision to publish the results.

Treatment protocol

Participants scheduled to undergo SRP either of the maxilla or the mandible arrived fasting for a morning appointment and received a standard meal (one slice of bread and one beverage) in the dental office 1 h before the beginning of treatment. A board-certified periodontist then performed SRP using manual and ultrasonic instrumentation. The informed consent stated that participants may request an anesthetic injection ('rescue procedure') at any time in case they felt that the pain was intolerable. As the subjects were of various ages, educational backgrounds and none of them had previously participated in a study, one jaw quadrant† was treated without administration of any study medication. (This 'rehearsal' allowed participants to acquaint themselves with the pain-recording procedures after scaling, particularly the exact timing, and served as an opportunity to solve any uncertainties regarding the usage of the different pain scales used.) Immediately after treatment of the first quadrant, patients swallowed the study medication according to group allocation, either verum or placebo. Thirty minutes thereafter, the other jaw quadrant – always the left one – was treated, and then pain levels were recorded as follows.

Pain recordings

Patients had to record their subjective pain levels at pre-defined time points according to the following schedule: immediately (i.e. at 0 min.) after SRP, including recordings of the maximum and the average pain experienced during the procedure, and then pain levels at 15 and 30 min. after treatment while participants were resting in the office, and after discharge at 1, 2, 4, 6, 8, 10, and 24 h after treatment. An electronic visual analog scale (electroVAS) was used to acquire and store values in the range 0–100 using a 100 mm linear scale, where the extreme on the left side indicates no pain and the extreme on the right side reflects the strongest pain imaginable. This electroVAS,

*Ibuprofen arginine is marketed in Switzerland and in other countries under the brand name Spedifen®.

†According to international terminology, a jaw quadrant is half of the maxilla or the mandible.

developed at the University of Zurich, is able to store a series of measurements and an entry becomes invisible after the subject has confirmed the data value. Patients were prompted by an auditory signal to enter their pain level at the pre-determined time points. For all scheduled measurements, three electro-VAS recordings were obtained, each separated by a 1 min. interval. In addition to these triplicate electro-VAS pain recordings, participants were asked to indicate their pain on a computer-assisted numeric rating scale for the time they were in the dental office (i.e. up to 30 min. after ending treatment). For this purpose, participants were shown a horizontal, continuous numeric range, with a value of 0 indicating no pain on the left side to a value of 100 indicating the strongest pain imaginable on the right side of the range.

Primary outcome measures

The primary outcome measure was pain during and after treatment of the study quadrant with a focus on the period until discharge from the dental office, i.e. 30 min. after intervention.

Secondary outcome measures

Secondary efficacy outcome measures were the pain levels over the entire study period, i.e. extending over 24 h. Safety was assessed by the incidence of adverse events during and after treatment.

Statistical analysis

We performed the primary analyses on the population including all treated patients, with supportive evaluations on a per-protocol set. The per-protocol analysis excluded six protocol violators: four cases because of daily intake of acetylsalicylic acid, 100 mg, and two cases because of steroid intake. We calculated means (standard deviations (SD)) and quartiles [25th, 50th (median), 75th] for continuous data and proportions for binary data.

A planned analysis of the pain levels using repeated measures analysis of variance techniques was not possible because of violations of model assumptions (e.g. non-normal distributions). We therefore compared maximum and average pain during treatment and pain levels at each time point after treatment between groups using the Wilcoxon

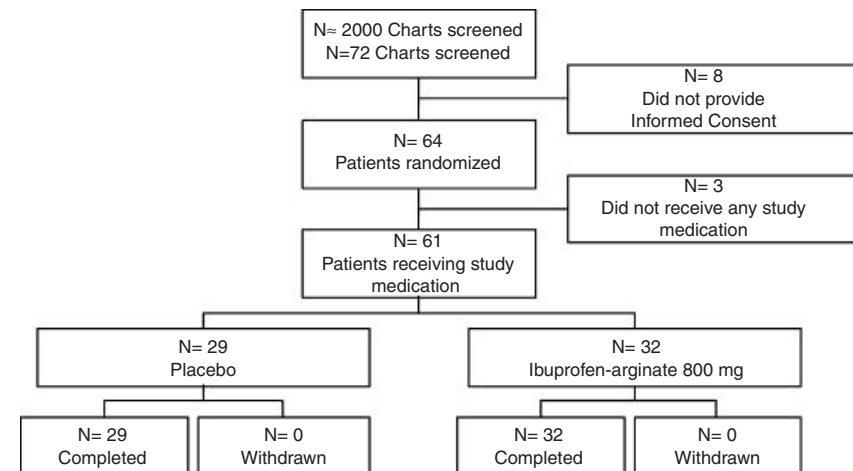


Fig. 1. Recruitment and study design.

rank-sum tests. In addition, we a priori defined a compound measure that was termed “average in office pain”. This compound pain score was calculated as the mean of the following four pain assessments: average pain during treatment, pain immediately after treatment, and pain at 15 and 30 min. after treatment (i.e. before discharge from the dental office). We again used the Wilcoxon rank-sum test to compare this compound measure between groups.

All statistical comparisons were conducted two-sided. Statistical significance was assumed for $p < 0.05$. We performed the analyses using SAS 8.2 (SAS Institute Inc., Cary, NC, USA).

Results

We screened approximately 2000 patient charts from the general dental practice and invited 72 patients, of whom 64 fulfilled the inclusion criteria and were included in the study (Fig. 1). After randomization, two of these were found to violate an inclusion criteria (age and informed consent), and one withdrew consent to participate. As neither of these three participants received study medication, and in line with GCP guidelines, we excluded these subjects from the primary evaluations because this was not suspected to introduce any bias.

Table 1 shows the baseline characteristics. No mucosal lesions were present in this study population. All participants had bleeding on probing and the two groups were well balanced with respect to age and gender (stratification parameters) as well as furcation involvement

and depth of probing. The treatment distribution between upper and lower jaws was 37 maxillary (58%) versus 27 mandibular (42%) quadrants.

No relevant differences were detected between values recorded with the two different pain scales or between the two analysed patient populations, i.e. all treated patients and per-protocol (data not shown). Figure 2 summarizes the results related to the primary outcome parameters. The median maximum pain during treatment was 28 (inter-quartile range: 10–50) for the placebo group and 10 (inter-quartile range: 4–31) for the ibuprofen arginine group ($p = 0.065$). The median average pain during treatment reached 16 (4–26) in the placebo group and 4.5 (0.5–11) in the group treated with ibuprofen arginine, corresponding to a significant pain reduction of 72% ($p = 0.023$). The median pain levels immediately after as well as 15 and 30 min. after treatment were zero in both groups, with a slightly higher inter-quartile range observed in the placebo group (0–5; 0–2 and 0–2) as compared with the ibuprofen arginine group (0–1, 0–0, 0–0). With a value of 4 (1.75–12.5), the calculated compound score “average in office pain” was low in the placebo group, but still significantly higher than the value of 1.38 (0.13–5.13) in the ibuprofen arginine group ($p = 0.0296$). After discharge from the dental office, pain levels throughout the patient population remained low but were systematically lower in the ibuprofen arginine group, although statistical significance was not reached at individual time points (Fig. 3). Finally, no adverse events were reported during this study.

Table 1. Baseline characteristics of treated patients

	Ibuprofen arginine (n = 32)	Placebo (n = 29)
Age (mean \pm SD)	56.0 (12.9)	53.6 (11.1)
Female/male (n, %)	16 (50)/16 (50)	16 (55)/13 (45)
Bleeding on probing (%)	100	100
Furcation involvement (n, %)	25 (78)	22 (76)
Depth of probing in mm (mean \pm SD)	3.32 \pm 0.43	3.44 \pm 0.43

Results are numbers and percentages. The two groups were well balanced with respect to age and gender, as well as furcation involvement and probing depth. All participants had bleeding on probing.

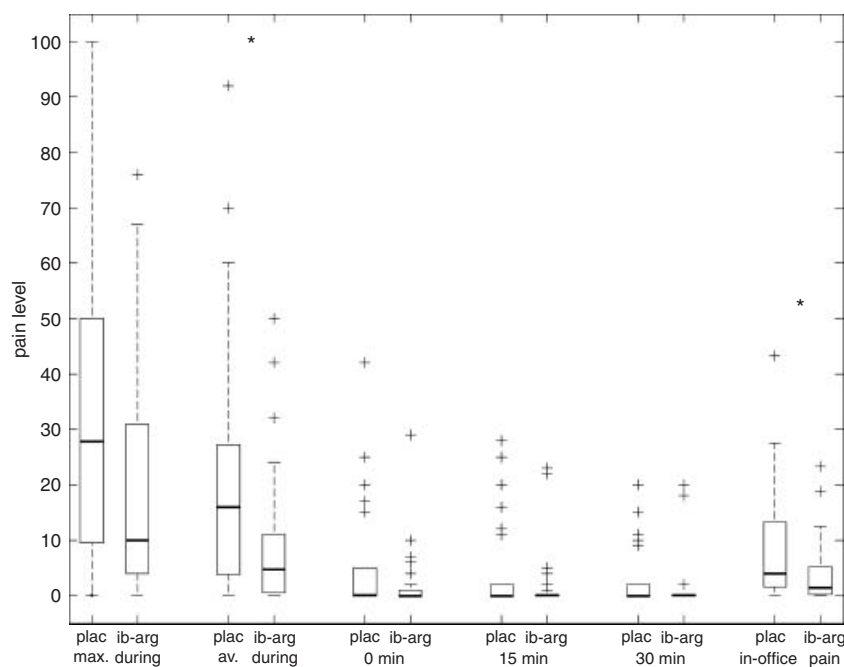


Fig. 2. Box-plots showing distribution of pain levels related to primary outcome parameters in the placebo (plac) and the ibuprofen arginine (ibu-arg) group. Bold lines represent median pain scores, upper and lower bounds of the box 25th and 75th percentiles, respectively, and whiskers extend to the most extreme data value within 1.5 times the interquartile range of the box, A + indicates a value outside these ranges. Significant differences ($p < 0.05$, indicated by an asterisk*) were observed for the average pain level during treatment (av. during) and for the calculated compound score “in office pain”. The median maximum pain during treatment (max. during) was 28 in the placebo group and 10 in the ibuprofen arginine group. The median pain levels immediately after (0 min) as well as 15 and 30 minutes after treatment were zero in both groups, with a slightly higher interquartile range observed in the placebo group.

Discussion

There are three main findings from this investigation. First, an oral dose of 800 mg ibuprofen arginine given pre-emptively reduced average and maximum pain levels during SRP compared with placebo. Second, pain levels after treatment were generally low and did not differ significantly between the two groups. Third, we did not observe any adverse events during this trial.

The strengths of this clinical trial include the control of confounding factors by enrolling a clearly defined

patient group from a general dental practice and by using a stratified randomization, which led to well-balanced groups at baseline. We blinded patients, treatment providers and all other investigators for study medication (Gotzsche 1996). Furthermore, blinding during analysis and report writing limited potential bias in the interpretation of data. Standardization of patient treatment included morning appointments, meals and treatment by a single dentist. Concealment of random allocation was ensured by keeping the recruiting and treating dentists unaware of the random-

ization list and by delegating drug administration to office staff otherwise uninvolved in the treatment. Finally, dual pain assessment including a numeric pain scale and an electronic VAS with the described methodology (timer-triggered triplicate data entry) can be considered state of the art (Rosier et al. 2002).

A limitation is the slight size difference between the placebo and the ibuprofen arginine tablets. However, patients and the dispensing office staff were kept unaware of this difference and the tablets were matched for packaging and colour. We included only patients who were enrolled in a regular recall system for periodontal treatment; hence, patients presenting for initial SRP were excluded. Previous pain experience was not addressed. Finally, we did not randomize for the treated jaw quadrants.

Neglecting dental care may cause oral and possibly systemic morbidity (DeStefano et al. 1993, Khader et al. 2004, Desvarieux et al. 2005, Jarjoura et al. 2005). Many patients avoid professional oral hygiene because of pain during treatment and fear of anaesthetic injection (Milgrom et al. 1997, Kaakko et al. 1998, Matthews et al. 2001). In a recent multicentre study, 64% of recall patients were willing to accept mild to moderate pain during non-surgical periodontal treatment to avoid infiltration anaesthesia (van Steenberghe et al. 2004). The pain experienced by our patients was also in the mild-to-moderate range. We showed in this clinical trial that pain can be diminished by the pre-emptive administration of a single dose of 800 mg ibuprofen arginine. The median maximum pain differed by 18 points (28 versus 10) and the median average pain differed by 11.5 points (16 versus 4.5) between the placebo and treatment group. These values compare with the generally accepted minimal clinically important difference of around 15 on a 100-point scale in acute pain situations (Wells et al. 1993, Todd & Funk 1996, Kelly 1998, Stahmer et al. 1998). In terms of the clinical meaning of percent pain reduction for patients with moderate pain, a diminution greater than 45% has been reported as “very much” improvement and was defined as clinically meaningful (Cepeda et al. 2003). As few alternatives to local anaesthetic injections are available, one could argue that even if the threshold of a “minimal clinically important difference” had not been achieved, maximizing patient com-

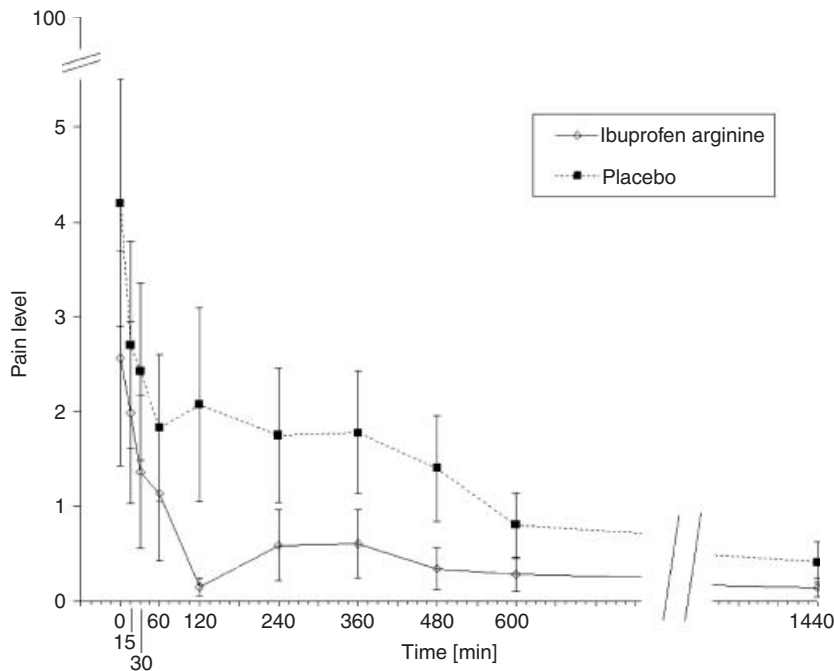


Fig. 3. Pain levels (mean \pm SE) after periodontal scaling and root planing up to 24 hours post-treatment.

fort is a meaningful goal, as long as the method used is safe and available at a low cost.

Different options are available for intra-oral pain control in clinical practice, and combinations may be feasible. Anaesthetic gels are available, but they have a distasteful flavour, which tends to spread in the oral cavity. This problem is reduced by embedding the anaesthetic agent in mucoadhesive patches (Perry et al. 2005). A recent single-blind study reported adequate pain relief during SRP with transmucosal patches containing lidocaine. One of these patches covers a gingival span of three to four teeth. Therefore, application of these patches to the buccal gingiva (i.e. excluding lingual/palatal surfaces) in a full dentition requires at least eight patches at a net cost of approximately \$ 2 each, summing up to \$16 for a full-mouth treatment.[‡] Also, concerns regarding the patch adhesiveness and safety in young individuals have been raised, whereas their effectiveness and safety in elderly patients (older than 65 years) has not been evaluated (Leopold et al. 2002, Stecker et al. 2002).

[‡]<http://www.net32.com/ec/dentipatch-46-1mg-lidocaine-local-anaesthetic-bioadhesive-d-33713?vendorId=63>, or <http://www.darbydental.com/scripts/prodpage.aspx?CAT=8&SUB=2862&GRP=9503690>, both accessed November 29, 2005.

In our study, pain after treatment was generally low in both groups without significant differences. Thirty of 32 (94%) patients, having received ibuprofen arginine, and 23 of 29 (83%) patients, having received placebo, had pain levels below 10 immediately after treatment. A previous study has reported higher pain ratings after non-surgical periodontal treatment, which may be the result of the different study population, as they primarily recruited previously untreated patients (Pihlstrom et al. 1999).

Given the known safety profile of ibuprofen arginine, it is not surprising that no adverse events were observed during this clinical trial.

In conclusion, this randomized, triple-blind, placebo-controlled trial showed the superiority of ibuprofen arginine over placebo for pain control during routine SRP. For patients with mild to moderate chronic adult periodontitis treated in a general dental practice, a single dose of 800 mg ibuprofen arginine taken 30 min. before treatment proved to be an effective and safe medication for maximizing comfort during treatment.

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Clinical Relevance

Scientific rationale for study: Fear of pain often keeps patients from complying with a periodontal maintenance program. Non-steroidal anti-inflammatory agents have proven effective in alleviating post-surgical dental pain, but randomized-con-

trolled clinical trials testing their analgesic efficacy during professional mechanical plaque removal are lacking.

Principal findings: In patients with mild-to-moderate periodontitis, 800 mg ibuprofen arginine taken 30 min. before SRP was superior to

placebo for pain control during and after the procedure.

Practical implications: We call the clinician's attention upon this easily applicable and effective pain management modality for maximizing patient comfort during professional oral hygiene.

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