Int. J. Oral Maxillofac. Surg. 2019; 48: 274–281
https://doi.org/10.1016/j.ijom.2018.07.016, available online at https://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Randomised Controlled Trial
Oral Surgery

Acupuncture on anxiety and inflammatory events following surgery of mandibular third molars: a split-mouth, randomized, triple-blind clinical trial

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A. C. V. Armond, J. C. R. Glória, C. R. R. dos Santos, R. Galo, S. G. M. Falci: Acupuncture on anxiety and inflammatory events following surgery of mandibular third molars: a split-mouth, randomized, triple-blind clinical trial. Int. J. Oral Maxillofac. Surg. 2019; 48: 274–281.

Abstract. The aim of this study was to compare the effects of acupuncture and placebo acupuncture on the control of pain, oedema, and trismus following the extraction of third molars and on the control of preoperative anxiety. Sixteen patients (mean age 22.5 ± 3.45 years) each underwent four acupuncture sessions, one prior to each surgery and the others at 24, 48, and 72 hours after each surgery (left and right tooth). Oedema was determined using measurements of the face and trismus was determined by maximum mouth opening at baseline and at 24, 48, 72 hours and 7 days following surgery. Postoperative pain was evaluated by the patients using a visual analogue scale (VAS) at 24, 48, and 72 hours following surgery. Anxiety was evaluated using the State–Trait Anxiety Inventory and a VAS at baseline and before and after acupuncture prior to surgery. The statistical analysis was performed using the paired *t*-test and Wilcoxon test. Acupuncture showed a better performance in the control of oedema at 48 hours ($P = 0.026$), 72 hours ($P = 0.046$), and 7 days ($P = 0.040$) when compared to placebo. There was no statistically significant difference between the acupuncture and placebo groups in the control of pain, trismus, or anxiety.

Key words: acupuncture; third molar; oral surgery.

Accepted for publication
Available online 20 August 2018

The surgical removal of mandibular third molars is one of the most frequently performed procedures in oral surgery. The most common indications for this procedure include caries, pericoronitis, cyst formation, and periodontal problems, as well as removal for orthodontic indications[1–3]. Although very common, this procedure is often associated with postoperative complications resulting from the inflammatory response, such as pain, oedema, and trismus[4,5]. Some studies have suggested that the patient's social and professional life, as well as their quality of life, is directly affected by the removal of a third molar[6,7]. In a study performed in Norway, about 30% of people who underwent third molar extraction failed to attend work or school after the surgical procedure, reporting pain (23%) and oedema (9.5%) as the reasons for their absence[7].

In addition to postoperative problems, anxiety is an emotional state often associated with impacted third molar surgery[8]. This may occur before and during the procedure, affecting the patient psychologically and psychosomatically. This state may be associated with an increase in postoperative complications[8,9]. Dental anxiety can vary from fear of pain to phobia. Patients may also experience tremors, arrhythmias, and vasovagal reactions, and in some cases it is difficult or impossible to perform the treatment[10].

Several drugs are used to reduce and control postoperative complications, including non-steroidal anti-inflammatory drugs, corticosteroids, and analgesics[11–13] taken as preventive and postoperative medication, as well as benzodiazepine anxiolytics, opioids, and barbiturates for the control of anxiety before the dental treatment[14]. However, several side effects are associated with these medications[13]. Acupuncture has been used as an alternative therapy in dentistry to minimize side effects and avoid the overuse of medicines; this has proven to be a safe and effective practice[15].

The aim of this split-mouth, triple-blind randomized clinical trial was to compare the efficacy of acupuncture and placebo acupuncture for the control of pain, oedema, trismus, and preoperative anxiety in patients undergoing the extraction of third molars.

Materials and methods

Study design

A triple-blind randomized clinical trial with a split-mouth design was conducted. This study was approved by the Research Ethics Committee and was conducted in accordance with the recommendations of the CONSORT (Consolidated Standards of Reporting Trials) guidelines[16] and the STRICTA extension (Standards for Reporting Interventions in Clinical Trials of Acupuncture)[17]. The trial has been registered at clinicaltrials.gov (ID number NCT03545022). All patients involved signed an informed consent agreement describing the procedures and the objectives of the study prior to their inclusion in the research.

Sample selection and eligibility criteria

The sample size was obtained by calculating each dependent variable (pain, oedema, trismus, and anxiety) in a pilot study involving four patients, considering a 5% significance level and 80% test power. The largest sample among the variables, pain, was used in the study. A difference of 10.5 found between the groups and a standard deviation of 10.25 were used to calculate the sample size. A minimum sample size of 15 patients was determined; 20% was then added to compensate for possible losses, resulting in a total required population of 18 patients (36 teeth).

Eighteen subjects aged between 17 and 30 years, who were healthy according to their medical history and a physical examination, were recruited. The inclusion criterion was an indication for bilateral extraction of asymptomatic mandibular third molars of class IIB according to the classification of Pell and Gregory (1933)[18]. The following were considered exclusion criteria: patients who had used any type of medication in the 15 days prior to the study; hypersensitivity to drugs, substances, or any materials used in the trial; pregnancy or lactation; previous case of pericoronitis; patients who had previously undergone any kind of acupuncture treatment. This study was performed at the Surgery Clinic of the Federal University of the Jequitinhonha and Mucuri Valleys, Diamantina, Brazil, from August 2016 to March 2017.

Randomization and masking

Patients who met the study criteria were randomized to the type of acupuncture (active acupuncture or placebo acupuncture) and to the side of the first surgery (right or left). The randomization was performed by lottery, by a researcher not involved in the study. Four papers in two opaque envelopes were used, one noting the side of the tooth and the other with the protocol of acupuncture treatment to be received, protocol 1 or 2.

The patients, the surgeon, the acupuncturist, and the investigator were unaware of which acupuncture treatment was used at each surgery (active or placebo). In order to conceal the randomization, the needles for the active and placebo protocol were identical and were delivered to the acupuncturist in two boxes labelled protocol 1 and protocol 2, and the codes were revealed only after completion of the study.

Active and placebo needle

For both types of treatment, 0.25 × 30 mm stainless steel needles were used (Dux, Brazil). The protocols differed in the actual needle size delivered, and the placebo needle was not inserted into the patient's skin but was identical in appearance to the active needle[19]. Needles measuring 0.25 × 30 mm were used as active needles; for the placebo needles, the needles were cut short by 5 mm, to measure 0.25 × 25 mm. The needles were partially inserted into opaque guide tubes filled with condensation silicone. This process was used to simulate the needle insertion for the patient and the acupuncturist and for needle support, as shown in Fig. 1. The active needles and the placebo needles were attached to the skin with an adhesive pedestal which held the needles in place, even without them being inserted into the skin.

Acupuncture

The points chosen for acupuncture were based on Traditional Chinese Medicine (TCM)[20–22]. Acupuncture was applied in four sessions, the first 30 minutes prior to surgery and the others at 24, 48, and 72 hours following surgery, before measurement of the study variables. The points were manually stimulated and the needles were inserted up to 4 mm. Needles were applied at 11 different points – nine bilateral points and two single points. They were applied at the two single points for anxiety control preoperative: GV20 (Baihui – located on the highest place of the head) and Yintang (midway between the two eyebrows). The bilateral points used to reduce pain, oedema, and trismus were LI4 (Hegu – on the dorsum of the hand, between the first and second metacarpal bones), LIV3 (Taichong – on the dorsum of the foot), ST44 (Neiting – proximal to the web margin between the second and third toes), SJ21 (Ermen – in the depression anterior to the supratragic notch and slightly superior to

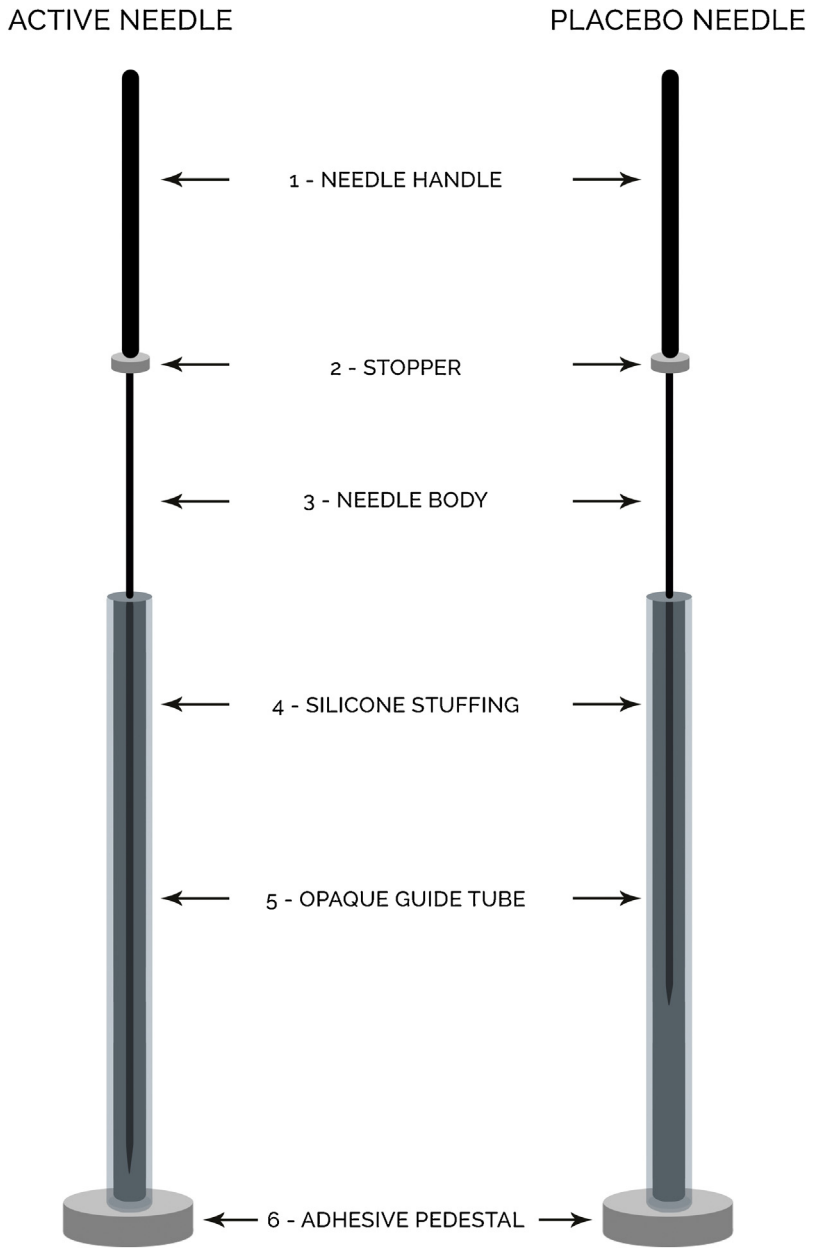

Fig. 1. Schematic illustration of the active and placebo needles.

the condylar process of the mandible), SI19 (Ting-Kong – anterior to the tragus and posterior to the condylar process of the mandible, in the depression formed when the mouth is open), ST6 (Jiagle – one finger-breadth anterior and superior to the lower angle of the mandible where the masseter muscle attaches at the prominence of the muscle when the teeth are clenched), ST7 (Towei – on the face, anterior to the ear, in the depression between the zygomatic arch and the condylar process of the mandible), UB60 (Kunlum – in the depression between the external malleolus and tendo calcaneus), and GB34 (Yanglingquan – in the depression anterior and inferior to the head of the fibula). All patients received the same treatment at all sessions.

The acupuncture treatment was performed by a specialist, a member of the Brazilian Dental Society of Acupuncture (SOBA) with 13 years of experience. The patients were informed that the treatment would be randomized to the acupuncture protocols (active and placebo) and were advised to lie down comfortably in the dental chair. After the needle devices were inserted, the needles were re-stimulated manually once after 10 minutes and removed after a further 10 minutes.

Surgery

Every participant received a single dose of oral dexamethasone 8 mg 1 hour prior to each surgical procedure. Each patient underwent two surgical extractions separated by a minimum interval of 45 days. The intervention was performed by the same surgeon specialist in this type of procedure.

Intraoral oral antisepsis was performed by mouth-washing with an aqueous solution of 0.2% chlorhexidine digluconate for 1 minute and extraoral oral antisepsis with 10% polyvinylpyrrolidone iodinated alcoholic solution (PVP-I) prior to surgery. The technique of regional blockade of the inferior and lingual alveolar nerves, with supplementary buccal nerve anaesthesia, was used to provide local anaesthesia. A careful and slow injection of the solution was conducted, after negative aspiration, with a maximum volume of 5.4 ml of local anaesthetic with 2% lidocaine and 1:100,000 epinephrine.

For the surgical procedure, a horizontal incision was made on the alveolar ridge distolingual to the second molar and an intrasulcular incision was made encircling the second molar to the region of the interdental papilla, between the second and first molar. The mucoperiosteal flap was raised followed by ostectomy and sectioning of the tooth under constant irrigation with 0.9% sodium chloride solution. The extraction was then performed using straight Seldin-type elevators, with careful curettage, bone regularization, and cleaning of the surgical cavity by means of abundant irrigation with saline solution. The flap was sutured with isolated stitches using 4–0 silk thread.

Postoperative care

Patients received instructions on haemostatic care, feeding, hygiene of the operated region, restriction of physical effort, and other routine recommendations indicated for this type of intervention after all surgeries. The patients were instructed to apply 0.12% chlorhexidine digluconate aqueous solution to control dental plaque from the second day, every 12 hours for 7 days. The patients were also instructed to take one tablet of paracetamol 750 mg as the analgesic medication, every 6 hours, only in the case of pain. The suture was removed on day 7 after the extraction.

Variables

The evaluation of the study variables was done by the same blinded evaluator who

was calibrated for the evaluations. The calibration was performed using measurements of eight volunteers at two different sessions with an interval of 3 weeks between them. The intra-class correlation coefficient was 0.98 for the evaluation of oedema and 0.89 for the evaluation of trismus.

For the evaluation of the presence and intensity of postoperative pain, a coded record (protocol 1 or 2) was used, identifying the patient, the operated side, and the chronology of the intervention (first or second surgery). Each record contained three visual analogue scales (VAS) in the form of a 10-cm line, without demarcations, with the number 0 (no pain) on the left edge and the number 10 (extreme pain) on the right edge. The volunteers were instructed to mark, with a vertical trace, the point of the scale that best defined their degree of pain sensation after the surgical procedure, which was later measured with a ruler. The marking was performed at three time points: 24, 48, and 72 hours postoperative.

Facial swelling (oedema) was determined by measurement with a tape measure according to the method described by Gabka and Matsumura (1971)[23] (Fig. 2). Three measurements were performed between the five reference points: tragus, pogonion (soft tissue), lateral corner of the eye, angle of the mandible, external corner of the mouth. The measurements were obtained preoperatively (baseline) and at 24, 48, and 72 hours and 7 days following the surgery. The sum of the preoperative measurements was the standard of normality for each side. The evaluation of swelling was done by subtracting the sum of the preoperative measurements (at baseline) from the sum of the postoperative measurements.

Maximum mouth opening was used to assess the level of trismus. The distance between the left upper and lower incisor was measured with a digital caliper and transcribed, in millimetres, for data recording. The measurement was determined in the preoperative period (baseline) and at 24, 48, and 72 hours and 7 days following the surgery. After verification of the measurements in the postoperative period, the difference in the measurements before and after the surgical procedure was obtained, determining the level of trismus.

Anxiety was evaluated with the Spielberger State Trait Anxiety Inventory (STAI) questionnaire, translated into Portuguese and validated by Biaggio et al. (1977)[24], and also with a VAS for anxiety. The STAI is a validated questionnaire consisting of two parts, each with 20 questions. One part, STAI-S, evaluates the state of anxiety, which is defined as anxiety in response to a situation. The other part, STAI-T, evaluates the anxiety trait, defined by the level of anxiety normally felt by the subject. The two parts are scored from 20 to 80, with the highest values indicating the highest levels of anxiety. Values $\geq$40 indicate a high level of anxiety and $\geq$50 a very high level. The VAS consisted of a 10-cm line without divisions. The patients were instructed to mark their level of anxiety at that moment, with '0′ indicating no anxiety and '10′ indicating a high level of anxiety; this was later measured with a ruler[9,25]. The STAI-S and STAI-T questionnaires and the VAS were completed at the time of the first evaluation of the patient. The STAI-S questionnaire and VAS were also applied before the preoperative acupuncture and after acupuncture, immediately before the surgery. After applying the questionnaire and the VAS at the time after acupuncture, the difference between the scores was obtained, determining the difference in anxiety.

The duration of surgery was recorded with a stopwatch in seconds, from the time of the initial incision to the time of the final suture. The number of paracetamol tablets taken after surgery was recorded by the patient by the seventh postoperative day.

Data processing and statistical analysis

The statistical analysis of the data was performed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA). The process included descriptive statistics and combination tests for comparison of the acupuncture and placebo protocols. The Shapiro–Wilk normality test was used to verify the data distribution, and parametric or non-parametric tests were later performed. The Wilcoxon test for paired samples was used when the distribution of the data was non-normal and the paired *t*-test was used for the data with a normal distribution.

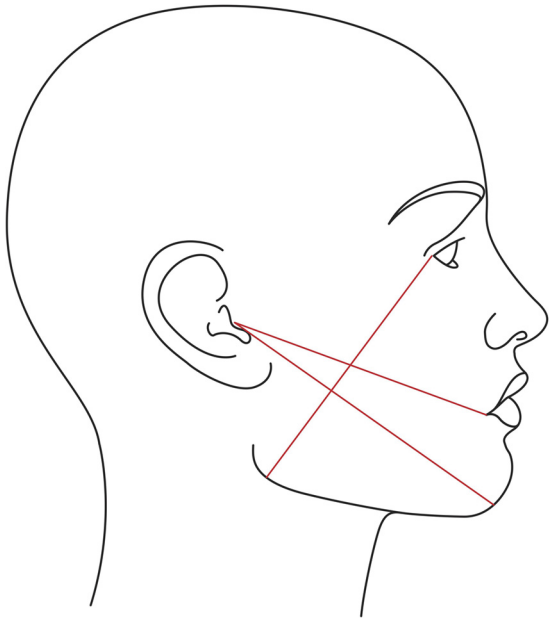

Fig. 2. Facial measurements for the evaluation of oedema.

Results

A flow diagram of the recruitment and selection of patients is given in Fig. 3. Eighteen patients were initially selected; however, one patient chose not to participate in the second surgery and was excluded from the sample. Thus, 17 patients participated in all stages of the study, three male and 14 female patients with a mean age of 22.5 $\pm$ 3.45 years. There was no case of adverse reaction to the acupuncture protocols or medications used, and one case of paresthesia was recorded.

No statistically significant difference in the duration of surgery or consumption of analgesics was found between the groups (Table 1).

There were no statistically significant differences in postoperative pain scores at time points 24, 48, and 72 hours between the acupuncture and placebo groups. However, at 48 and 72 hours, the mean pain intensity was lower in the acupuncture

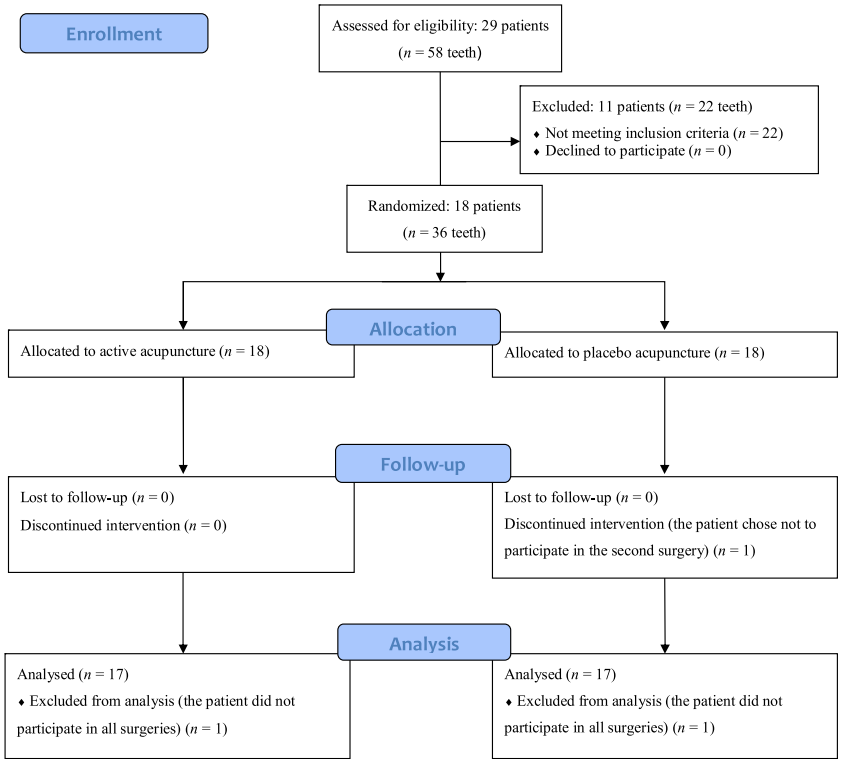

Fig. 3. Study flow diagram.

Table 1. Comparison of the duration of surgery and consumption of analgesics between protocols; mean values.

	Acupuncture	Placebo	*P*-value
Analgesic consumption (*n*)	12.0	9.9	0.255[a]
Duration of surgery (s)	783	738	0.309[b]

[a] Paired *t*-test.
[b] Wilcoxon test.

Table 2. Comparison of the pain intensity scores (VAS in millimetres) between the acupuncture and placebo protocols at the different postoperative evaluation time points; mean ± standard deviation values.

Postoperative evaluation time point	Acupuncture	Placebo	*P*-value
24 hours	23.35 ± 17.65	18.76 ± 21.15	0.393[a]
48 hours	20.05 ± 18.53	27.65 ± 28.74	0.636[a]
72 hours	9.23 ± 13.65	19.94 ± 28.50	0.245[a]

VAS, visual analogue scale.
[a] Wilcoxon test.

group than in the placebo group (Table 2) (Fig. 4).

In the evaluation of trismus, a reduction in mouth opening was found at all evaluation time points, with the peak of reduced opening occurring at 48 hours following the surgery for both protocols. There was no significant difference between the acupuncture and placebo groups (Table 3).

In the evaluation of facial oedema, facial measures increased at 24, 48, and 72 hours after surgery for both protocols, and the peak of oedema occurred at 48 hours postoperative (Fig. 5). The difference between the protocols was statistically significant at 48 hours, 72 hours, and 7 days following the surgery. The difference between the means at the 48-hour time point was 2.94 ($P = 0.026$), at the 72-hour time-point was 3.23 ($P = 0.046$), and at the 7-day time-point was 2.99 ($P = 0.040$) (Table 4).

In the evaluation of preoperative anxiety using both the STAI-S questionnaire and the VAS for anxiety, the reduction in anxiety did not differ significantly between the two protocols . However, the mean reduction in anxiety in the acupuncture protocol was greater than in the placebo protocol for both the questionnaire and VAS (Table 5).

Discussion

Studies using acupuncture have shown promising results in the control of pain[20], oedema[26], trismus[21], and anxiety[9,25]. The use of this technique is interesting considering the negative effects of the excessive use of medicines and the side effects of the medications most commonly used for the control of these complications.

Although TCM therapies are being evaluated in clinical trials more frequently, the literature on this subject is still limited. Few clinical trials have evaluated the effect of acupuncture on postoperative complications[15,19,20,26–28]. It appears that no clinical trial using the placebo needle methodology has yet been done to evaluate the effect of acupuncture on pain, oedema, and trismus following third molar extraction. Therefore, a comparison of the results found in this study with those of other studies available in the literature is limited.

In this study, confounding factors such as the duration of surgery, surgical difficulty, and patient characteristics were minimized by using the same surgeon for all surgeries, including teeth for removal that were all in the same radiographic position, and having the patient serve as her/his own control through the use of a split-mouth design. In addition, there was no difference in surgery time or number of analgesics consumed between the groups.

The pain level expected after third molar surgery depends on the degree of surgical trauma, on the need to remove bone tissue, and the extent of the periosteal displacement[29]. In this study, the mean VAS pain scores were lower in the acupuncture group than in the placebo group at 48 hours and 72 hours postoperative, and the reduction in pain was progressive. However, there was no statistically significant difference between the groups. Although there are methodological differences, this study found similar results to some previous studies, in which no statistically significant difference between the protocols was found but the patients experienced lower pain with the active protocol than with the placebo protocol[19,28,30]. Several studies have attributed these results to the placebo effect of acupuncture; however, in order to evaluate the placebo effect, a group without treatment would be needed[19,20,31,32]. Some studies have found statistical differences

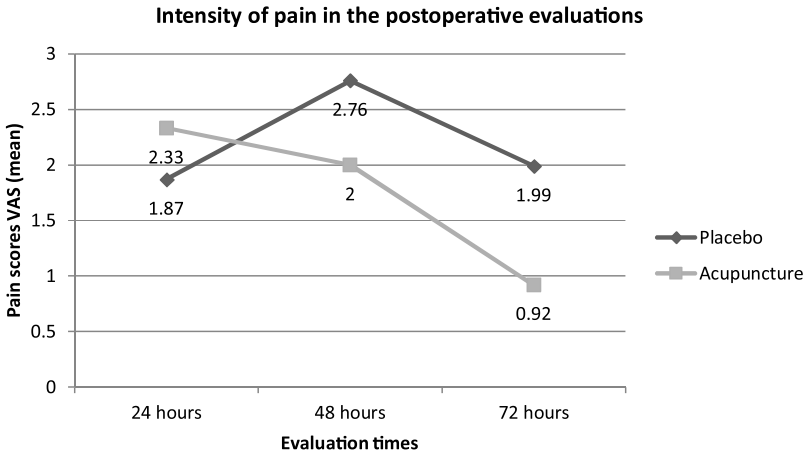

Fig. 4. Comparison of pain intensity between the protocols at the different evaluation time points.

Table 3. Comparison of mouth opening reduction (in millimetres) between the acupuncture and placebo protocols at the different postoperative evaluation time points; mean ± standard deviation values.

Postoperative evaluation time point	Acupuncture	Placebo	*P*-value
24 hours	−16.97 ± 13.30	−17.03 ± 11.34	0.987[a]
48 hours	−18.76 ± 10.18	−19.75 ± 13.63	0.775[a]
72 hours	−14.10 ± 9.72	−14.65 ± 11.28	0.860[a]
7 days	−4.21 ± 7.83	−4.71 ± 7.86	0.868[b]

[a] Paired *t*-test.
[b] Wilcoxon test.

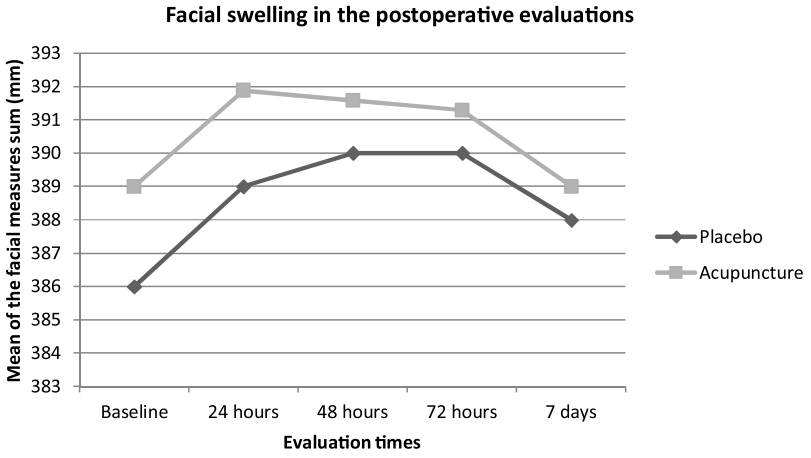

Fig. 5. Comparison of facial oedema between the protocols at the different evaluation time points.

Table 4. Comparison of facial swelling (in millimetres) between the acupuncture and placebo protocols at the different postoperative evaluation time points; mean ± standard deviation values ().

Postoperative evaluation time point	Acupuncture	Placebo	*P*-value
24 hours	2.00 ± 2.15	3.05 ± 2.92	0.255[a]
48 hours	1.70 ± 2.31	4.64 ± 4.07	0.026[a]
72 hours	1.41 ± 2.39	4.64 ± 5.02	0.046[a]
7 days	−0.52 ± 2.57	2.47 ± 3.98	0.040[a]

This table shows the difference from baseline to the evaluation time-point (baseline sum value subtracted from the postoperative sum value).
[a] Paired *t*-test.

only when compared to a group without any treatment and some studies have found statistically significant results when the patient believed that they were receiving acupuncture[26,30,32,33]. A meta-analysis that assessed the effect of acupuncture on pain in different studies showed that acupuncture has a small effect when compared to placebo acupuncture, but the placebo effect is still unclear[34].

Post-surgical facial oedema occurs in response to the tissue manipulation and trauma at the time of surgery. The onset is gradual and it reaches a maximum at 48 hours after the procedure, with expected regression starting on day 4 and total regression after 7 days[29]. The maximum peak occurred at 48 hours after surgery in the placebo group and at 24 hours after surgery in the acupuncture group. The difference in oedema between the placebo and acupuncture groups was statistically significant at 48 hours, 72 hours, and 7 days postoperative. This difference can be attributed to changes in cortisol levels. Some studies have shown that acupuncture increases the level of cortisol in the blood, and cortisol is responsible for decreasing levels of oedema after third molar extraction[15,35].

Trismus reaches its maximum peak on the second postoperative day and regresses up to the seventh day[29]. The maximum peak found was at 48 hours after the procedure. There was no statistically significant difference between the protocols for the control of trismus, although the mean values of reduction in the acupuncture group were slightly lower than those in the placebo protocol group. The literature shows a strong relationship between pain and trismus, indicating that pain may be one of the main reasons for limited mouth opening after third molar extraction[36]. This evidence may explain the absence of a statistically significant difference despite reports of improvements in trismus with acupuncture reported in the literature[21].

State anxiety is felt as a transient emotional condition of the human body, characterized by subjective and consciously perceived symptoms of apprehension and by hyperactivity of the autonomic nervous system. State anxiety also includes dental anxiety[8]. There was no statistically significant difference between the treatment protocols with regard to anxiety, although the reduction in anxiety shown by STAI-S and VAS was higher in the acupuncture group than in the placebo group. This finding differs from those reported in some previous studies, although the methodologies

Table 5. Comparison of the reduction in anxiety score between the acupuncture and placebo protocols for the STAI-S questionnaire and VAS; mean ± standard deviation values.

	Acupuncture	Placebo	*P*-value
Anxiety reduction STAI-S	1.94 ± 7.42	1.52 ± 5.30	0.859[a]
Anxiety reduction VAS	7.94 ± 20.27	3.35 ± 10.54	0.365[b]

STAI-S, State–Trait Anxiety Inventory, state anxiety; VAS, visual analogue scale.
[a] Paired *t*-test.
[b] Wilcoxon test.

used were different[9,22]. A systematic review that evaluated the effect of acupuncture on anxiety control revealed that evidence of acupuncture in anxiety control is still limited and that a large proportion of the studies evaluated found no statistically significant differences[37].

A study that analyzed the results of different articles on acupuncture emphasized that although widely used, there is no relevant scientific evidence for acupuncture as compared to placebo[33,38]. The scientific evidence for the clinically relevant specific effects of acupuncture remains controversial because, when compared to an untreated group, it is effective, but when compared to placebo, there is a large reduction in the treatment effect[9]. Many studies have suggested hypotheses for the placebo effect of acupuncture[32,38]. However, the use of the term 'placebo effect' in acupuncture is also controversial[31]. The benefit of placebo treatment may be due to incidental (and unknown) elements of the intervention and these factors are called 'non-specific' effects. The mechanism is unknown but can be mediated by factors such as patient–practitioner communication, therapeutic ritual, and patient expectations about treatment[31,33]. The non-specific effects of acupuncture and their implications have been evaluated and the expectation is one of the major factors of the placebo mechanism[30,32,33]; this helps to explain why acupuncture is more accepted in China than in the West. The efficacy of acupuncture is concealed by the placebo effect in clinical trials. If only the placebo effect is considered to assess the efficacy of acupuncture, efficacy is definitely obscured by the placebo effect[31,39]. In addition to the placebo effect, Koog et al.[39] have reported the nocebo effect of acupuncture. Despite being little studied, this is clinically significant in the treatment of acupuncture. Although the placebo methods used in clinical trials on acupuncture have already been questioned, the placebo needle method used in the present study has been shown in previous studies to be effective in blinding the participants[19,40]. Considering these effects, a hypothesis for the results found in this study is due to the placebo effect and non-specific effects of acupuncture.

The main limitation of this study is related to the division of treatment groups, in which there was no untreated group or group in which the usual treatment was practiced to evaluate the real effect of acupuncture and its application in clinical practice[31,39]. However, with a split-mouth study design this is not possible, since the patient has only two lower third molars. Thus, for comparison with an untreated group, the patient could not be his/her own control, which could also be considered a limitation. It is suggested that further studies be performed using the placebo acupuncture methodology, blinding the participants involved and considering the non-specific effects, in order to strengthen the scientific evidence regarding the use of acupuncture.

Despite the limitations of this study, the results indicate that acupuncture achieves better results in the control of postoperative oedema when compared to treatment with placebo acupuncture, and there was no difference between the protocols in the control of pain, trismus, and anxiety.

Funding

No funding was provided for the elaboration of this study.

Competing interests

There was no conflict of interest during the elaboration of this study.

Ethical approval

This study was approved by the Human Research Ethics Committee of the Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Brazil. The protocol number is 1.688.806.

Patient consent

Not required.

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