

Effect of *Arnica montana* 6 cH on edema, mouth opening and pain in patients submitted to extraction of impacted third molars

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Zusammenfassung

Diese Studie hatte das Ziel, die homöopathische Wirkung von *Arnica montana* C6 und der eines Placebos auf Ödeme, Kieferklemme (Trismus) und Schmerzen bei Patienten zu untersuchen, die sich einer Extraktion des beidseitig befallenen dritten unteren Molaren unterzogen. Das Experiment wurde als Crossover- und Doppelblind-Studie angelegt. Die Daten zeigten, dass das Ödem durch die Behandlung mit *Arnica montana* C6 signifikant reduziert wurde ($p < 0,05$). Auf den Trismus und die Schmerzen zeigten sich keine signifikanten Effekte im Vergleich zur Kontrollgruppe.

Schlüsselwörter: *Arnica montana* C6; antiinflammatorisch; klinische Evaluation

Summary

This study had the objective to evaluate the homeopathic action of *Arnica montana* 6 cH and placebo on edema, mouth opening (trismus) and pain in patients submitted to extraction of bilaterally impacted lower third molars. The experiment was carried out as a crossover and double-blind study. The data showed that edema was significantly reduced by the treatment with *Arnica montana* 6 cH ($p < 0.05$) and did not demonstrate significant effect on trismus and pain as compared to control group.

Keywords: *Arnica montana* 6 cH; antiinflammatory; clinical evaluation

Resumen

Este estudio avalió la acción homeopática del la *Arnica montana* 6 cH y placebo en lo edema, abertura de la boca (trismus) y dolor en pacientes sometidos bilateralmente la extracción de bajo impacto de los terceros molares. El experimento se realizó del forma crossover y doble-cegó. Los datos mostraron reducción significativamente del edema por el tratamiento con *Arnica montana* 6 cH ($p < 0.05$) y no demostró efecto significativo en lo trismus y dolor cuando comparó con el grupo controle.

Palabras clave: *Arnica montana* 6 cH; antiinflamatório; Avaliação Clínica

Introduction

Homeopathy is a word derived from the greek, *homoios*, meaning like or similar, and *pathos*, meaning disease. It comprises a form of therapeutics based on the principle *Similia similibus curentur* in which the administration of minute doses of a remedy would in healthy persons produce symptoms similar to those of the disease. Most homeopathic medications have a wide spectrum of action. However, some homeopathic remedies have very specific symptomatic indications including *Arnica montana*.

WAGNER et al. [1] and WAGNER and JURCIC [2] evaluated the immunological activity in vitro/in vivo of many plant extracts. These authors observed increased phagocytosis by granulocytes and macrophages and also an increased effectiveness in the carbon clearance test after using *Arnica montana* extracts. PUHLMANN et al. [3] also evaluated the immunological activity of two *Arnica montana* polysaccharides in cultured cells demonstrating a pronounced increase

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in phagocytosis. Two compounds of *Arnica montana*, helenaline and 11 α , 13 dihydrohelenaline, inhibited platelet aggregation induced by collagen, the formation of thromboxane, and the secretion of serotonin [4]. These authors concluded that helenaline and 11 α , 13 dihydrohelenaline inhibited platelet aggregation through the interaction with platelets sulfhydryl groups. These events are probably associated with the reduction of phospholipase A₂ activity.

The plant *Arnica montana*, when ingested, can induce vascular dilation, blood stasis and increased capillary permeability. Hemorrhagic and purpuric lesions can occur as a consequence of these effects. This plant, when applied locally, induces severe inflammation, and produces vesicular eruptions and red pustules. It can also cause venous hemorrhage [5, 6]. The affinity of this plant for muscle tissue may cause contraction and hypertrophy leading to muscle pain and contusion sensation [7]. This toxic plant to muscle can induce pain and rigidity similar to the accumulation and crystallization of lactic acid after excessive physical exercise. Similarly, *Arnica montana* can affect the central nervous system and sympathetic system causing paralysis [8].

McIVOR [9] related the absence of edema in 90 % of patients, submitted to surgical removal of third molars, treated with *Arnica montana* for 3 days after surgery. KAZIRO [10] demonstrated that metronidazole was more effective in controlling pain, cicatrization and edema following lower third molar extractions than *Arnica montana* 200 cH and placebo.

The association of *Arnica montana* 7 cH with *Hypericum* 15 cH was effective in 76,7 % of patients for treating chronic dental pain [11]. DULCETTI Jr. [12] used *Arnica montana* 6 cH or *Hypericum* 6 cH following surgeries including simple and multiple extractions, extraction of impacted or partially impacted molars, tumors removal and gingivectomy. The author

related the absence of pain in the majority of cases. LÖKKEN et al. [13] evaluated the action of six homeopathic medications: *Arnica*, *Hypericum*, *Staphisagria*, *Ledum*, *Phosphorus* and *Plantago*. These medications were tested in regard to pain control, edema and trismus following extractions of impacted lower third molars. There was no difference found among the groups in regard to pain and edema. However, most of these homeopathic extracts were effective in controlling trismus three days post-operatively.

The control of pain, edema and limited mouth opening after surgical removal of impacted lower third molars is widely documented in scientific literature. Many authors adopted the utilization of this experimental model due to the many advantages including reliability and applicability [14-18].

Based on the observations mentioned above, the effect of *Arnica montana* 6 cH on edema, mouth opening and pain was evaluated in patients submitted to extraction of impacted lower third molars.

Material and Methods

Preparation of the *Arnica montana* 6 cH and Placebo

The medication was obtained from a tincture of *Arnica montana*. One ml of the tincture was first diluted in 99 ml of hydroalcoholic solution (30 %), and it was then manually dynamized (100 suction), obtaining the potency of 1 cH. The dynamizations were repeated six times as described above, obtaining the final 6 cH form [19].

The *Arnica montana* 6 cH was stored in 40 containers for posterior use. The control sample (placebo) was prepared the same way as described above without the *Arnica montana* active compounds, and placed in other 40 containers. The 80 containers were labeled and divided in 4 groups of twenty each, paired and coded: X, Y;

A, B; α , β ; 1, 2. The codes referred to the medication and control were only revealed to the patients at the end of the clinical assays.

Patients

Thirty-two patients were selected, 24 female, 8 male with ages varying from 17 to 25 years old. All patients had bilateral and symmetrical impacted lower third molars with bone retention. The patients were healthy and did not present any allergic reactions to substances used pre- and post-operatively such as chlorexidine, acetaminophen, poly-vinyl-pyrrolidone-iodine (PVPI) and local anesthetics. Patients currently using analgesics, antiinflammatories, sedatives, or any other drugs that could interfere with the parameters evaluated were not included in this study. Also, pregnant and lactating women, and patients presenting clinical signs of pericoronitis were all not included in the study. The patients, after receiving verbal and written explanation about the objective of the study, signed a consent form and the project was approved for the Ethical Commission in Research at the University of Alfenas, Minas Gerais, Brazil.

Clinical Evaluation

Therapeutic Procedures

The patients received a container labeled as described above and were instructed to use, 3 days prior to surgery, five drops of either homeopathic and placebo sublingually 3 times a day (morning, afternoon and evening) and 5 drops immediately before surgery, making a total of 10 administrations pre-operatively of each substance.

After each surgery, five drops of either placebo and *Arnica montana* were administered, 2 times a day at the day of surgery, and 5 drops 3 times a day at the first day after surgery.

Surgical Procedures

All the surgeries were performed in the morning, always by the same surgeon with minimal intervals of fourteen days between the first and second surgery. The pre-operative evaluations and surgical procedures were standard for all patients.

All the patients were submitted to intra-oral and extra-oral antiseptics with clorexidine at 0.12 % and topic PVPI at 10 %, respectively. The inferior alveolar, lingual and buccal nerves were blocked using the application of 4.5 ml of Citocaine, (prilocaine at 3 % and felypressin at 0.03 ui/ml, Cristalia – Chemical Pharmaceuticals Products Limited).

Linear and angled incision, followed by mucoperiosteal flap elevation, osteotomy and segmentalization of tooth was performed with high speed carbide spherical bur, under abundant irrigation with saline solution at 0.9 %.

Following tooth removal scraping and guttering of socket was performed. After the alveolus was filled with blood clot, suture was performed.

The duration of the surgery was determined between the incision and the suture closure. The data concerning the surgery were recorded in individual forms. After the end of the surgery, the patient received a form containing the scales for the assessment of pain intensity.

Following surgery, twelve pills of Tylenol®, 750 mg, were given to the patients. They should be taken in case of moderate or intense pain. All the frequency of escape medication administration and total pill consumption were all recorded in the same form.

Evaluation of the edema

The facial contour of the patient was evaluated in the pre-operative assessment through the use of a modified face bow [20, 21], in the area of the third molar to be extracted. This device consisted of an face arch bow adapted through the insertion of a

acrylic plate parallel to the face of the patient. The plate was transfixed with nine millimetered screws which were inserted until touching the skin of the patient. The distance of the acrylic plate until the edge of the screws were evaluated in millimeters. The measurements were recorded in individual forms, as well as the measurements from the nine screws. The differences between the pre- and postoperative values, in millimeters, were considered as facial edema.

Evaluation of mouth opening

To evaluate mouth opening, the maximum opening was preoperatively measured in millimeters through the distance between the superior and inferior central incisors. This procedure was taken at 24, 48, 72 and 168 hours postoperatively. The difference between the preoperative and postoperative values was assessed as the total measurement of mouth opening in millimeters.

Evaluation of pain

Three parameters were used for the evaluation of pain:

- 1) Pain intensity evaluated through the use of a visual scale at the day of surgery and also at the first day postoperatively.
- 2) Consumption of analgesics, at the day of the surgery and also at the first postoperatively day.
- 3) Total duration of postoperative analgesic procedure taken from the end of the surgery until the moment the patient took the escape medication (Tylenol, 750 mg).

Statistical Analysis

The Student "t" test was used for the statistical analysis of the results obtained during the various phases of the experiment. The significance level considered in this test was $p < 0.05$.

Results and Discussion

The decision to choose the homeopathic medicament *Arnica montana* for controlling edema, limitation of mouth opening and pain was made based on several evidences by many authors [22-26], and after clinical evaluations [9, 12, 28, 29].

In this work, the edema reduction observed in all postoperative periods indicated the anti-inflammatory activity of *Arnica montana* 6 cH, when used for three days before surgery (Figure 1). These results are compatible with the ones observed by MCIIVOR [9], who also related an anti-inflammatory action of *Arnica montana* when used for three days prior to surgery. However, the author did not specify the form of preparation and dosage of the medication as well as the method to evaluate edema. The author did not indicate if analgesic medication was used or if the study was double blind and controlled with placebo.

FERNANDES [30] did not demonstrate differences in edema in patients submitted to extraction of impacted lower third molars treated with *Arnica montana* 6 cH or placebo 6 cH thirty minutes prior to surgery.

The results of the present work are in disagreement with the data of LÖKKEN et al. [13], who determined that *Arnica montana* was inefficient in controlling edema induced by the extraction of impacted third molars, when used three hours after surgery.

Because homeopathic medication act by stimuli, the organism needs time to respond to it. This fact associated with the information related by MCIIVOR [9], DRAIMAN [22] and DULCETTI Jr. [12], who suggest the need to use homeopathic medication for a period of three to seven days, led us to use *Arnica montana* 6 cH for three days prior to surgery. Most of the studies which used *Arnica montana* in short preoperative instances or only postoperatively obtained less significant and negative results [10, 13, 30].

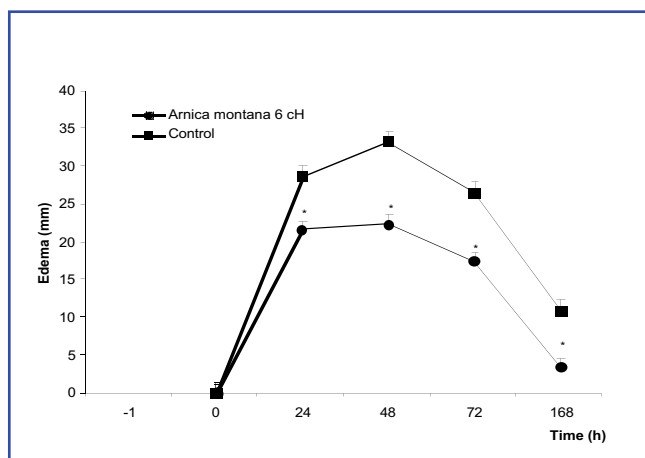


Figure 1: Effect of Arnica montana 6 cH and control medication on edema.

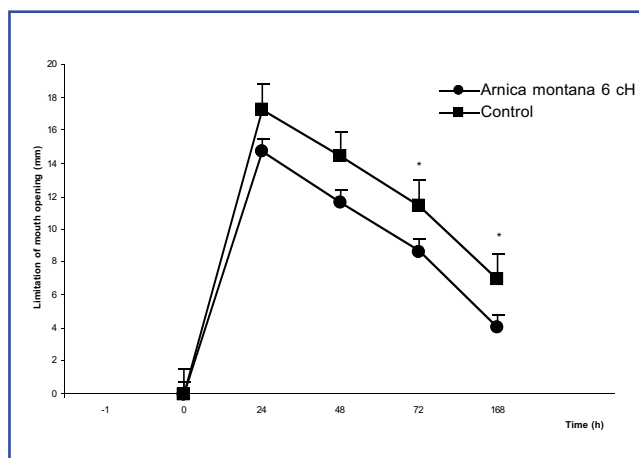


Figure 2: Effect of Arnica montana 6 cH and control medication on limitation of mouth opening.

The disagreement between the results obtained in this work and by FERNANDES [30] and LÖKKEN et al. [13] suggested the administration of homeopathic medication three days before surgical intervention.

The homeopathic therapeutics is based on the body response stimulated by the medicament which presents pathogenesis similar to the clinical picture of the patient [31-33]. The greater the similarity between the elected medicament and the clinical picture, the more specific the response will be [34].

The homeopathic medication can act by primary or secondary action [31, 33, 34]. Primary action is referred to biochemical properties of the drugs. On the other hand, secondary action refers to the organic response induced by the medicament.

The possible biological mechanisms involved in the reduction of edema have to consider the primary and secondary effects of the homeopathic medication *Arnica montana*. It is possible to encounter the active principles of the original substance in the *Arnica montana* 6 cH. The active principles began to be absent only in the 12 cH form onwards [32, 34, 35].

McIVOR [9], studying at a homeopathic level, and TESKE and TRENTINI [36] in a phytotherapeutic level verified

the anti-inflammatory activity of *Arnica montana* as being caused by decreased vascular permeability.

In vitro and in vivo evaluations have demonstrated an increase in phagocytosis by granulocytes and macrophages. These studies also showed an increased effectiveness of carbon clearance test in isolated cells and in animals submitted to the action of the extract of *Arnica montana* [1-3]. The phagocytosis have the function to remove inflammatory stimuli of injured cells, chemical substances released and possibly microorganisms present in the area of inflammation [39-41]. The increased phagocytary action of these cells induce by the homeopathic medicament *Arnica montana* 6 cH could remove more rapidly the inflammatory stimuli, decreasing the inflammatory edema caused by the surgical aggression.

Some articles suggest that the primary and secondary actions of the active principles of *Arnica montana* may function in a similar way as the corticoids. The stress represents a state of tension in which the organism has mobilized forces to deal with dangerous situations. KOSSACK-ROMANACH [34] has stated that stress factor activate the hypothalamus-hypophysis-adrenal system. In animals, this phase is characterized by hypertrophy

of the adrenal cortex. The author defines the mechanism as General Adaptation Syndrome.

TAYABAS [37] suggests that *Arnica montana* in small doses induces a stress condition. The organism reacts through the General Adaptation Syndrome characterized by increased corticoids secretion which represents non specific form of treatment.

The organism under physical or mental stress increases the production of cortisol by the adrenal cortex. The cortisol acts by increasing gluconeogenesis in the liver, augmenting the blood levels of aminoacids and promoting increasing mobilization of fatty acids which allows prompt reaction of the organism to any non specific stimuli [38]. This author also relates the anti-inflammatory action of cortisol: stabilization of lysosomal membranes, decrease in capillary permeability and diminished migration towards the injured area.

PUHLMANN et al. [3] have described an increase in tumor necrosis factor (TNF α) secretion by the macrophages, under the action of the acid protein arabine 3, 6 galactane extracted from *Arnica montana*. The TNF α acts stimulating neutrophilia, increasing leucocyte adherence and inducing corticosteroids secretion.

The helenaline and 11 α , 13 dihy-

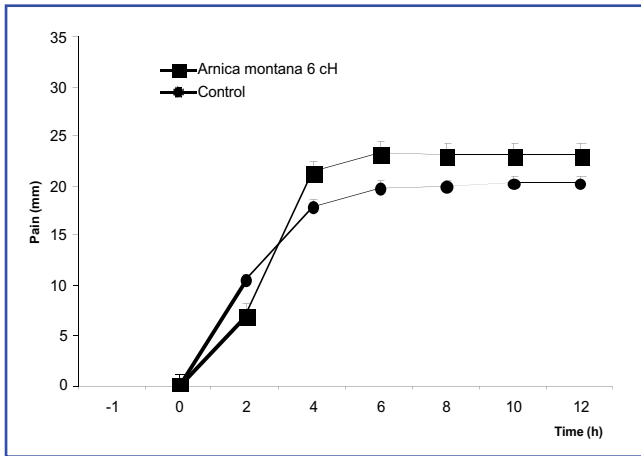


Figure 3: Effect of *Arnica montana* 6 cH and control medication on pain.

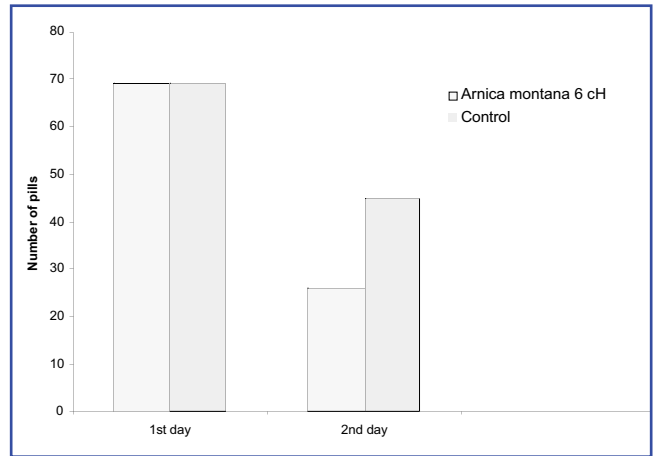


Figure 4: Consumption of escape medication (Tylenol® 750 mg) postoperatively.

drohelenaline extracted from *Arnica montana* inhibited the platelet aggregation, the formation of thromboxane and secretion of serotonin by acting in the reduction of phospholipase activity [4]. The phospholipase is the enzyme responsible for the metabolism and conversion of cellular membrane phospholipids into arachidonic acid. The arachidonic acid will then be converted by cyclooxygenase and lipoxygenase into prostaglandin, prostacyclin and leukotrienes, all chemical mediators of the inflammation. The similarity between the helenaline-derived compounds and corticoids is the phospholipase blockage action. The clinical results of the *Arnica montana* on edema and pain are similar to the results gathered by most authors in regard to the action of glucocorticoids after postoperative surgical events [42-48]. *Arnica montana* and glicocorticoids are potent anti-inflammatories but weak analgesics.

The results of this work demonstrate that the homeopathic *Arnica montana* 6 cH was not efficient in controlling the increasing mouth opening in comparison to control group at 24 and 48 hours. There was slight improvement after 72 and 168 hours (figure 2).

If only the initial periods are

considered, these results are in agreement with the results from FERNANDES [30]. In regard to final periods, 72 and 168 hours, our results are similar to those of LÖKKEN et al. [13].

In the present study, considering significant differences $p < 0.05$, we can suggest that the limitation of mouth opening at 24 and 48 hours postoperatively is mostly related to pain. However, a direct correlation can not be considered, because the edema was always present in postoperative periods which could influence the limitation of mouth opening (figure 2).

The analogous visual scale is a form very common to evaluate postoperative pain [18, 42, 44, 45, 49, 50, 51].

The pain evaluated in this work

Table 1: Duration (minutes) until the necessity of analgesic taken by the patient who received *Arnica montana* 6 cH and Control.

Arnica	Control
225.70 ± 14.77	195.28 ± 14.01

Mean ± standard deviation. Two patients of Group *Arnica montana* and 3 patients of Control Group did not use escape medication (Tylenol 750 mg). The differences were not statistically significant.

was affected similarly in the *Arnica montana* 6 cH as well as the control groups (figure 3). These data are similar to the ones of LÖKKEN et al. [13] and FERNANDES [30], but different from the ones obtained by DULCETTI Jr. [12].

The consumption of analgesics in the postoperative period have been frequently used for the evaluation of the postoperative pain [43, 52, 53, 46].

The consumption of Tylenol in the first days was similar for the two groups, with mean of 2.16 pills per patient. In the second day, there was decreased consumption of analgesics in the *Arnica montana* group as compared to the control group ($p < 0.10$) with the mean of 0.81 and 1.41 pills, respectively (figure 4).

The postoperative period required

Table 2: Duration of surgery in minutes in patients who received *Arnica montana* 6 CH and Control.

Arnica	Control
25.03 ± 2.05	23.66 ± 1.85

Mean ± standard deviation. The differences were not statistically significant.

for a escape medication was, in general, thirty minutes longer for the *Arnica montana* group as compared to the control group (table 1 and 2). These results did not present statistical difference and confirmed the analgesic similarity between the two substances evaluated. These results are compatible with those ones obtained by FERNANDES [30] who also used this methodology to evaluate analgesic effectiveness of *Arnica montana* 6 cH.

Due to the fact that the post-operative pain reaches a peak within the 12 first hours and then declines rapidly [54, 55], it can be speculated that the analgesic is useful only within this period to be clinically efficient. In function of the increased anti-inflammatory activity and decreased analgesic action presented by *Arnica montana* 6 cH, given for three days before surgery, it is suggested the administration of *Arnica montana* must be associated with efficient analgesics.

The association of efficient anti-inflammatories with analgesics was recommended by SISK & BONNINGTON [42], GALLARDO et al. [56], TROULLOS et al. [44], DIONNE [15], URQUHART [17], SCHULTZE-MOSGAU et al. [50] and SEYMOUR et al. [54].

Another clinically interesting association would be *Arnica montana* with local anesthetics of long duration. When these anesthetics are used, the patient passes the peak of pain under anesthesia, requiring decreased amounts of analgesics [57,58].

Conclusion

From all the results, it can be concluded that:

Facial edema was significantly reduced by the action of *Arnica montana* 6 cH; the limitation in mouth opening was decreased in all periods for *Arnica montana* 6 cH group, and *Arnica montana* 6 cH did not have an effect on post-operative pain.

The plant *Arnica montana* acts in

the vessel wall damaging the endothelial membrane and disrupting its surface continuity. This allows the passage of cellular elements from blood and plasma to tissue. These two effects, anti-coagulant and damage to vascular endothelium, explain the hemorrhages caused by *Arnica*.

These results were explained by the activity of *Arnica montana*, reducing the capillary permeability and, consequently causing reduced edema and less bleeding during surgery.

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