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The efficacy of homeopathic *Arnica montana* 200 CH on dental surgical treatments: a double-blind, placebo-controlled study

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ABSTRACT

Objectives: The aim of this placebo-controlled study was to assess the efficacy of single dose homeopathic *Arnica montana* 200 CH in dental surgeries.

Methods: The study included 79 patients undergoing wisdom teeth extractions, implant placements, cystectomies, augmentation procedures, alveoloplasties, lefort-1 osteotomies at Istanbul Medipol University's Department of Oral and Maxillofacial Surgery. The patients were randomly divided into two groups using a computer program. Three globulesof *Arnica montana* 200 CH were administered in the sublingual area in the patients group 1, and glucose globules were administered in the sublingual area in the patients into group 2. After each patient's surgical operation, the surgeoncompleted a survey about operation time and scope. In addition,a self-assessment survey was completed by the patients the day after their operationsto evaluate their post-operational swelling and pain.

Results: *Arnica montana* did not appear to significantly prevent post-operative swelling and pain when compared to the placebo ($p < 0.05$).

Conclusions: This study showed that the use of *Arnica montana* before a physically traumatic procedure is not more effective than the use of a placebo. However, the results should be evaluated in other studies, including the administration of *Arnica montana* after a physically traumatic procedure to clearly demonstrate its homeopathic efficiency.

Keywords: Homeopathy, *Arnica montana*, placebo effect, dental surgery

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Homeopathy is an alternative source of medicine that was created by Samuel Hahnemann in 1796. "*Simila Similibus Curentur*" (like cures like) was the main part of Hahnemann's theory. He believed that a substance that causes the symptoms of a disease in healthy people could heal similar symptoms in sick people [1-3]. Homeopathic drugs or remedies are produced by systematic repetitive dilution in alcohol or distilled water [4]. These dilutions, called potencies,continue until none of the original substance's molecules are left the liquid. However, the solution remembers information from the original substance but it is controversial [5]. Homeopaths evaluate their patients' medical situations and life histories and choose appropriate remedies from a reference book. The remedies are often prepared from plants,

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minerals, or animals in the form of sugar pellets [6].

Homeopathy is an adjuvant therapy used in medicine. *Arnica montana*, commonly referred to as leopard's bane, is a homeopathic remedy used for preventing traumatic pain and edema. *Arnica montana*'s roots have many anti-inflammatory substances as well as thymol, which is fungicide. It has been used in alternative medicine for centuries and is very popular with patients undergoing surgery [6]. The globules *Arnica montana* globules are absorbed in once and allowed to slowly dissolve under the tongue. It is advised not to touch pellets or homeopathic globules with your fingers.

Homeopathy (HP) is used for a number issues in dentistry, including teething, dental abscesses, toothaches, surgical traumas, and nervousness or anxiety [7]. Homeopathic remedies are used by dentists as adjunct to other in daily practice, and many dentists are also homeopathstoo[4, 8]. Pinsent *et al*. [9] reported a reduction in pain when homeopathic *Arnica montana* was used in dental extractions. However, many clinicians have reported that no significant difference was found inplacebo-controlled studies that use homeopathic remedies [6].

This study investigated the efficacy of single-dose homeopathic *Arnica montana* 200 CH on dental surgical treatments. The placebo effects are also summarized.

METHODS

The patients, whosought wisdom teeth extractions, implant placements, cystectomies, augmentation procedures, alveoloplasties, and lefort-1 osteotomies at Istanbul Medipol University's Department of Oral and Maxillofacial Surgery and were ages 18 to 75 with no systemic diseases of both genders were chosen for the study. The exclusion criteria were: patients had used antibiotics and non-steroidal anti-inflammatory within the last 6 months. All the patients completed an informed consent. This study was approved by the Istanbul Medipol University Animal Care and Ethics Committee (Document number 350 from the Ministry of Health, Republic of Turkey).

First, the patients were divided into two groups using a computer program. The *Arnica montana* globules were prepared and classified into X and Y groups by a homeopath. The placebo and *Arnica montana* globules were given to the patients by a surgeon who did not know which participants were in groups X and Y. *Arnica montana* 200 CH globules were administered in the sublingual area in the patients in group 1. Glucose globules that seemed to be the same as *Arnica montana*, which was diluted with alcohol and distilled water, were given administered in the sublingual area in the patients in group 2. Three globules were placed in the patients' sublingual areasusing a plastic spoon15 minutes before their operations. Non-steroidal anti-inflammatory drugs (NSAID, flurbiprofen, 300 mg) and antibiotics (amoxicillin, 1g) were also prescribed to all the patients after their surgeries. Both groups took the same dose of NSAIDs and antibiotics. The patients completed a surveythe day after their surgical procedures (Table 1), and the results were evaluated using a four point scale. All surgical operations were achieved by two surgeons. The surgeon's observations about the scope and times of the operation werealso evaluated on a four point scale (Table 2). The operation type (conventional or piezo surgery) was also recorded.

A self-assessment questionnaire was given to the patients after their surgical procedures. The questionnaire asked the patients about the presence of pain, postoperative edema, sleep disorders, dysphagia, dysphonia, and daily activity disorders. These parameters were evaluated on afour-point scale ranging from 0 to 3, where'' 0'' was: not affected, ''1'' was mildly affected, ''2'' was moderately affected, and ''3'' was severely affected.

Table 1. Patients' self-assessment questionnaire for the day after the surgical operation

	Day after the surgical operation
Presence of pain	
Edema	
Sleeping disorders	
Dysphagia	
Dysphonia	
Daily activity disorders	
0: NOT AFFECTED	
1: MILDLY AFFECTED	
2: MODERATELY AFFECTED	
3: SEVERELY AFFECTED	

Table 2. Questionnaire for the surgeons' opinions about the operation.

Patient Group				
Name-Surname				
Age				
Gender				
Operation Option	**Conventional** **Yes**	**Piezo-Surgery** **No**		
Post-Op Emergency				
Observations from Operation	**Same**	**Better**	**Worse**	**No Idea**
Scope of the Operation				
Operation Time				
0 – Any Sight				
1 – Poor View				
2 – Good View				
3 – Excellent View				

Statistical Analysis

The study adopted a double-blinded design. A Mann Whitney U test was used for statistical analysis. The qualitative variants were evaluated using Pearson Ki-square and Fisher Ki- square tests. Statistical significance was $p < 0.05$.

RESULTS

A total of 100 patients were included the study but 6 patients were eliminated because theydid not meet the age criteria. In total, 94 patients were randomized. In the study, 5 patients in the *Arnica montana* group

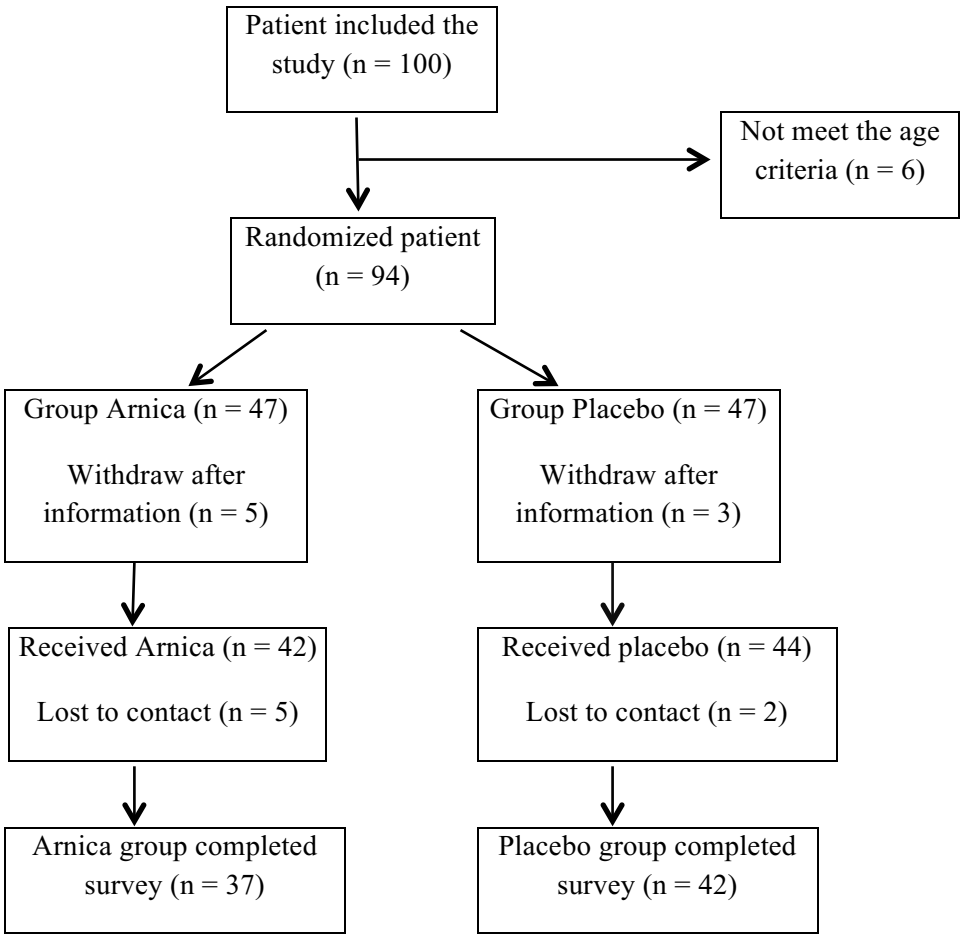

Figure 1. CONSORT flow chart of the study

Table 3. Gender distributions of the patients

			Gender		*p* value
			Female	Male	
Group	Arnica	n (%)	19 (51.4)	18 (48.6)	0.473
	Placebo	n (%)	26 (61.9)	16 (38.1)	
Total		n (%)	45 (57.0)	34 (43.0)	

Table 4. Age distributions of the patients

	Group	N	Median	Minimum	Maximum	*p* value
Age	Arnica	37	38.00	20	73	0.217
	Placebo	42	34.00	18	75	

and 3 patients in the placebo group were withdrawn after information about the present study. In addition 5 patients in *Arnica montana* group and 2 patients in the placebo group did not return for their self-assessment surveys. Therefore, the *Arnica montana* group (Group 1) included 37 patients and the placebo group (group 2) included 42 patients (Figure 1). In the study, 45 patients were female and 34 patients were male (Table 3).

The average age was 34 years in plasebo group and 38 years in Arnica group. There is no statistically significant difference in demographic distributions (Table 4).

Wisdom teeth extraction of 38 patients, implant placement of 28 patients, sinus lifting of 6 patients, oral cystectomy of 4 patients, alveoloplasty 1 patient and bone augmentation of 2 patients were performed in this study. No significant difference was found between patient groups (Table 5).

Surgeon experiences foroperation time and purview of the operation area during surgery were recorded after surgery. No significant difference was found between two groups (Table 6).

Patients who applied emergency service with unexpected reason were recorded. One patient in Arnica group (group 1) was applied emergency service with unexpected vomiting and nausea. The reason of this situation was not identified. No statistical significant difference was found between two groups.

There was no any significant difference in pain intensity between the groups on 24 hours. In addition there were not any significant differences between the groups swelling, regarding sleeping, eating, phonetics, and daily routine and missed work at above mentioned time intervals (Table 7).

Table 5. Performed different surgery operations*

Group	Surgery Options					
	Wisdom Teeth Extraction	Implant Placement	Sinus Lifting	Oral Cystectomy	Alveoloplasty	Bone Augmentation
Arnica, n (%)	17 (45.9)	13 (35.1)	3 (8.1)	3 (8.1)	0	1 (2.7)
Placebo, n (%)	21 (50.0)	15 (35.7)	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)
Tota, n (%)	38 (48.1)	28 (35.4)	6 (7.6)	4 (5.1)	1 (1.3)	2 (2.5)

*$p = 0.897$

Table 6. Surgeon experience*

			Surgeon experience for operation time and purview of the operation area during surgery			
			Same	Better	Worse	No Idea
Group	Arnica	n (%)	31 (83.8)	4 (10.8)	2 (5.4)	0
	Placebo	n (%)	30 (71.4)	6 (14.3)	5 (11.9)	1 (2.4)

*$p = 0.586$

Table 7. Evaluation of patients' self-assessments survey of next day after surgery

	Groups		Never	Mild	Moderate	Severe	*p* value
Pain	Arnica	n (%)	14 (37.8)	18 (48.6)	3 (8.1)	2 (5.4)	1.000
	Placebo	n (%)	15 (35.7)	21 (50.0)	4 (9.5)	2 (4.8)	
Post-operative swelling	Arnica	n (%)	13 (35.1)	17 (45.9)	5 (13.5)	2 (5.4)	0.962
	Placebo	n (%)	16 (38.1)	19 (45.2)	6 (14.3)	1 (2.4)	
Sleeping	Arnica	n (%)	32 (86.5)	3 (8.1)	1 (2.7)	1 (2.7)	0.742
	Placebo	n (%)	35 (83.3)	4 (9.5)	3 (7.1)	0	
Eating	Arnica	n (%)	17 (45.9)	16 (43.2)	2 (5.4)	2 (5.4)	0.799
	Placebo	n (%)	17 (40.5)	20 (47.6)	4 (9.5)	1 (2.4)	
Phonetics	Arnica	n (%)	28 (75.7)	7 (18.9)	1 (2.7)	1 (2.7)	0.274
	Placebo	n (%)	29 (69.0)	13 (31.0)	0	0	
Daily routine and missed work	Arnica	n (%)	32 (86.5)	2 (5.4)	1 (2.7)	2 (5.4)	0.137
	Placebo	n (%)	33(78.6)	8 (19.0)	1 (2.4)	0	

DISCUSSION

Because HP is an individual treatment,it is very difficult to achieve an evidence-based study. HP treats the person, not the disease. In allopathic medicine given drugs related with the disease is contrary to the doctrine of Hahnemann. However in emergency cases HP drugs can also be used to relieve the symptomatic ailments [10]. *Arnica montana*, in allopathic medicine, is commonly used after acute trauma or operation to soothe pain, bleeding and swelling. *Arnica montana* is the most known remedy in homeopathy which is used at edema and trauma cases and it also can be easily found in the market.Usage of Arnica globules is only oral way for sublingual area. The dose was chosen on the recommendation of the homeopath. It's a common using of *Arnica montana* for dentistry. The hypothesis of our study is that use of *Arnica montana* could be helpful for reduction of post-operative pain and edema at dental surgical operation and could provide better operation conditions such as less bleeding for surgeon. However our findings indicated that single dose of *Arnica montana* 200 CH do not bring any change in post-operative conditions for surgeon and patients. In our study *Arnica montana* 200 CH was applied 15 minutes before the operation. No evidence was found relating with its decreasing or increasing the bleeding during the operation. It was found out that when compared with placebo, *Arnica montana* decreased pain and swelling to some extend but not a degree of statistical significance. Unfortunately *Arnica montana* could be more effective when gives post operation. In addition more than one dose is more potent from single dose. This is the biggest shortcoming of our study. We believe that lack of methodology of the study make the *Arnica montana* inactive. However using of NSAID and antibiotics may affect edema and pain naturally so the results can be easily affected at both of two groups.

In a randomly double blind study carried out by Caziro [6] in order to decrease the post-op complications of metronidazole, *Arnica montana* 200 CH and placebo were given to 118 patients who had their tooth extracted. In the decrease of pain and edema, there was no statistical difference between placebo and arnica but metronidazole was more effective. The reason for this is that metronidazole provides a better infection control. In our study no significant difference was found between the two groups. In their study, Pinsent *et al*. [9] showed a decrease in the bleeding and pain after the tooth extraction of 59 patients, using *Arnica montana* made no difference in terms of bleeding but was more effective in terms of pain.

Mazzocchi and Montanaro [11] observed a decrease in pain and swelling on 200 patients who were given another HP remedy of *Sympthytum* 5CH when they received dental implants. However study design was not a controlled prospective, it was retrospective. In a random study investigating the effect of using different dosage of *Arnica montana* on pain and swelling control after hand surgery, Stevinson *et al*. [12] found out that when compared with placebo no statistical difference was found in decreasing pain

and swelling. However the number of patients wasn't statistically enough for the study. In their random controlled study with 111 patients who had tonsillectomy surgery, Robertsson *et al*. [13] gave *Arnica montana* 30CH to patients and compared the results with the placebo group. As a result, *Arnica montana* showed a little difference in decreasing the pain but no statistical difference was found.

In a study carried out on 343 patients who had orthopedic arthroscopy, knee prosthesis and cruciate ligament reconstruction, *Arnica montana* was given for pain control and the results were compared with the group placebo applied. As a result in the group who were given *Arnica montana*, a significant difference was observed in decreasing swelling. In addition to this, a statistical difference was observed in decreasing pain in the group who had cruciate ligament reconstruction [3]. In another controlled study the effectiveness of *Arnica montana* was assessed on acute inflammation in the rats [2]. Less edema was observed on the group who took *Arnica montana* before the process then the group who took *Arnica montana* after the process. Also in a study investigating the effect of *Arnica montana* to the chronic inflammation in animals, a statistically significant decrease was observed in inflammation in the group which took arnica before the process [13].

Piezoelectric surgery techniques areminimally invasive techniques that reduce the risk of damage to soft tissues and important structures, such as nerves, blood vessels, and mucosa, so piezoelectric surgery help better healing. This surgery also reduces damage to osteocytes during the operations[14]. Even though it has been suggested that the use of a piezoelectric device provides distinct advantages in the surgical operations, it should not be forgotten that long operation time and heat generation during bone cutting decrease healing procedures [15]. In our study, we have no data on the postoperative effect of both surgical methods. We think that it does not directly affect the surgical outcomes because of advantages and disadvantages of both methods.

There is limited data on homeopathy in medicine and dentistry. Since the studies carried on were in inadequate in terms of the number of the subjects and because of the methodological errands homeopathy did not give enough scientific evidence [16]. The fact that we used different types of anti-inflammatory, antibiotics and anesthetic substances on patient in pre and post operation periods might affect the results. In addition, the patients weren't classified into age and other ailment and symptom groups. Applying for an operational procedure, every patient aged 18-75 and not having any serious systemic disease was included into the study. *Arnica montana* was given just before the operation and one day later the patients were assessed with 4 point assessment scale. However, homeopathic remedies recovering are observed as the person's subjective well-being. Testing subjective well-being could have made the study more meaningful.

Human being is positively or negatively affected with many audio stimulants. Although the studies performed on the patients are double blind designed, the patients always think that they are taking something which will make them well [17]. This is named as the placebo effect which is identified as a substance which increases the healing of the illness despite of having no healing effect [18]. Since Beecher stated that the effect of placebo on healing was 30%, academic circles have accepted this as such but it is known that the placebo affect can change between 0% and 100%. Even the posture and voice tone of the clinician can change the expectation of the patient and these types of differences affect the homeopathic treatment to a great extent [19].

Limitations

Our study is a placebo controlled one but how much the placebo affects our study is obscure. However, it is clearly observed that pain, swelling and discomfort are less than expected in both groups. The number of those who were affected from pain and swelling in high quantity ranged between 2.4% and 5.4%. Some researchers especially against the homeopathy believe that homeopathic remedies only make placebo effect.We believe that results cannot be evaluated a scientific failure because planning of methodology is not enough to understand homeopathic effect. In addition new study models can be created especially included pre and post-operative homeopathic medication for explain the all properties of *Arnica montana* clearly in later studies. Moreover, it is necessary to investigate the potency, time and the way of giving homeopathic remedies.

CONCLUSION

When compared with placebo group, no statistical difference was found in the group who took a single dose of Arnica montana before 15 minutes from the operation especially using NSAID and antibiotics. What's more, our study has proved that when compared with placebo, the usage of *Arnica montana* is neither superior nor shows a negative effect. However, the results must be evaluated by taking into consideration that they are just one in the few studies done in this field.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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REFERENCES

[1] Baker DG, Myers SP, Howden I, Brooks L. The effects of homeopathic *Argentum nitricum* on test anxiety. Complement Ther Med 2003;11:65-71.
[2] Conforti A, Bellavite P, Bertani S, Chiarotti F, Menniti-Ippolito F, Raschetti R. Rat models of acute inflammation: a randomized controlled study on the effects of homeopathic remedies. BMC Complement Altern Med 2007;7:1.
[3] Brikhaus B, Wilkens JM, Lüdke R, Hunger J, Witt CM, Willich SN. Homeopathic Arnica therapy in patients receiving knee surgery: result of three randomized double-blind trials. Complement Ther Med 2006;14:237-46.
[4] Eames S, Darby P. Homeopathy and its ethical use in dentistry. Br Dent J 2011;210:299-301.
[5] Linde K, Clausius N, Ramirez G, Melchart D, Eitel F, Hedges LV, et al. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. Lancet 1997;350:834-43.
[6] Kaziro GS. Metronidazole (Flagyl) and *Arnica montana* in the prevention of post-surgical complications, a comparative placebo controlled clinical trial. Br J Oral Maxillofac Surg 1984;22:42-9.
[7] Mathie RT, Farrer S. Outcomes from homeopathic prescribing in dental practice: a prospective, research-targeted pilot study. Homeopathy 2007;96:74-81.
[8] Varley P. What do homeopathic dentists do? Homeopathy 2007;96:72-3.
[9] Pinsent RJFH, Baker GPI, Ives G, Davey RW, Jonas S. Does Arnica reduces pain and bleeding after dental extraction? MHRG Newsl 1984;11:71-2.
[10] Ernst E, Pittler MH. Efficacy of homeopathic Arnica: a systemic review of placebo-controlled clinical trials. JAMA 1998;133:11.
[11] Mazzocchi A, Montanaro F. Observational study of the use of symhytum 5CH in the management of pain and swelling after dental implant surgery. Homeopathy 2012;101:211-6.
[12] Stevinson C, Devaraj VS, Fountain-Barber A, Hawkins S, Ernst E. Homeopathic Arnica for prevention of pain and bruising: randomized placebo-controlled trial in hand surgery. J R Soc Med 2003;96:60-5.
[13] Robertson A, Suryanarayanan R, Banerjee A. Homeopathic *Arnica montana* for post-tonsillectomy analgesia: a randomised placebo control trial. Homeopathy 2007;96:17-21.
[14] Vercellotti T. Technological characteristics and clinical indications of piezoelectric bone surgery. Minerva Stomatol 2004;53:207-14.
[15] Stelzle F, Frenkel C. The effect of load on heat production, thermal effects and expenditure of time during implant site preparation - an experimental ex vivo comparison between piezosurgery and conventional drilling. Clin Oral Implants Res 2014;2:140-8.
[16] Macêdo SB, Ferreira LR, Perazzo FF, Carvalho JC. Anti-inflammatory activity of *Arnica montana* 6cH: preclinical study in animals. Homeopathy 2004;93:84-7.
[17] Kleijnen J, Knipschild P. Clinical trials of homeopath. BMJ 1991;302:316-23.
[18] Jütte R. The early history of the placebo. Complement Ther Med 2013;21:94-7.
[19] Kirsch I. The placebo effect revisited: lessons learned to date. Complement Ther Med 2013;21:102-4.