Efficacy of Homeopathic Arnica
A Systematic Review of Placebo-Controlled Clinical Trials

E. Ernst, MD, PhD, FRCP(Edin); M. H. Pittler, MD

Background: The efficacy of homeopathic remedies has remained controversial. The homeopathic remedy most frequently studied in placebo-controlled clinical trials is Arnica montana.

Objective: To systematically review the clinical efficacy of homeopathic arnica.

Materials and Methods: Computerized literature searches were performed to retrieve all placebo-controlled studies on the subject. The following databases were searched: MEDLINE, EMBASE, CISCOM, and the Cochrane Library. Data were extracted in a predefined, standardized fashion independently by both authors. There were no restrictions on the language of publications.

Results: Eight trials fulfilled all inclusion criteria. Most related to conditions associated with tissue trauma. Most of these studies were burdened with severe methodological flaws. On balance, they do not suggest that homeopathic arnica is more efficacious than placebo.

Conclusion: The claim that homeopathic arnica is efficacious beyond a placebo effect is not supported by rigorous clinical trials.

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HOMEOPATHY IS a system of medicine that was developed about 200 years ago and has remained highly controversial ever since.1 Essentially it is based on the “law of similars” and on the assumption that even non-material dilutions (“potentiations”) can be clinically effective.2 The law of similars claims that if a given remedy causes a certain symptom in a healthy person, the remedy should then be useful for treating that symptom in a patient who suffers from it. Homeopathic potentiations are prepared by serial dilutions and “succussions” (vigorous shaking) and often are so dilute that the likelihood of them containing a single molecule from the mother tincture is nil. Homeopaths believe that “potentizing” in this way will not reduce but rather increase the activity of the resulting remedy. It is in particular the use of highly diluted material that overtly flies in the face of science and has caused homeopathy to be regarded as placebo therapy at best and quackery at worst.

Thus, the efficacy of homeopathic remedies has always been a matter of bitter controversy.3 Recently the issue has been addressed in various ways. A recent systematic review found most homeopathic trials to come to positive conclusions.4 The authors, however, abstain from making a definitive conclusion as to the efficacy of homeopathic remedies. In their view, methodological problems with most clinical trials of homeopathy preclude a definitive judgement as to its efficacy.

Another approach to evaluate homeopathy is to perform a meta-analysis across all trials.5 Even though such a meta-analysis yielded a significantly positive result, with a combined odds ratio of 2.45 favoring homeopathic remedies over placebo, the conclusions that can be drawn from such a meta-analysis are limited and several caveats have been identified. There could be indefinable bias6 and the pooling of trials of vastly different remedies for vastly different conditions is of debatable legitimacy.7

A further approach is to systematically review homeopathic trials pertaining to a single disease or condition. We have chosen this method to assess homeopathy for postoperative ileus8 and delayed-onset muscle soreness,9 the 2 conditions most frequently submitted to controlled trials. In one case this resulted in a positive result9 and in the other in a
negative overall result\(^9\) for homeopathy; eg, homeopathic remedies used to treat delayed-onset muscle soreness were not significantly better than placebo in alleviating symptoms. Yet again, several caveats preclude a firm conclusion.

Another approach could be to analyze homeopathic trial data by the type of remedy used; this was chosen for the present article. Its aim is to systematically review the homeopathic remedy most frequently submitted to controlled trials.

**RESULTS**

Eight studies fulfilled all of the aforementioned inclusion criteria and were admitted to this review.\(^13-21\) Methodological details and outcomes of these trials are summarized.

### Table 1. Key Data From Placebo-Controlled Clinical Trials of Homeopathic Arnica

<table>
<thead>
<tr>
<th>First Author</th>
<th>Condition Treated</th>
<th>Trial Design</th>
<th>Sample Size</th>
<th>Experimental Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hildebrandt(^15)</td>
<td>Delayed-onset muscle soreness</td>
<td>Double-blind</td>
<td>42 Healthy women</td>
<td>Arnica D2 (n = 6) D3 (n = 6) D4 (n = 6) D5 (n = 6) D6 (n = 6) D8 (n = 6); 3 × 16 drops daily for 6 d after exercise</td>
</tr>
<tr>
<td>Kaziro(^16)</td>
<td>Prevention of postsurgical complications</td>
<td>Randomized, double-blind</td>
<td>118 Patients after extraction of wisdom teeth</td>
<td>Arnica 200C twice daily for 3 days postoperatively (n = 39)</td>
</tr>
<tr>
<td>Pinsent(^17)</td>
<td>Prevention of postsurgical complications</td>
<td>Randomized, double-blind</td>
<td>59 Patients after tooth extraction</td>
<td>Arnica 30C 1 dose 30 min preoperatively; 3 doses each 15 min postoperatively; 1 dose every 2 h for 6 doses (n = 23)</td>
</tr>
<tr>
<td>Tveiten(^18)</td>
<td>Delayed-onset muscle soreness</td>
<td>Randomized, double-blind</td>
<td>36 Participants in the Oslo Marathon (Norway)</td>
<td>Arnica montana D30 5 pills twice daily for 5 d starting 1 d prior to race (n = 20)</td>
</tr>
<tr>
<td>Gibson(^19)</td>
<td>Acute trauma</td>
<td>Double-blind</td>
<td>20 Orthopedic patients</td>
<td>Arnica 30 (n = 11)</td>
</tr>
<tr>
<td>Campbell(^20)</td>
<td>Experimentally inflicted mechanical bruising</td>
<td>Single-blind crossover trial</td>
<td>13 Healthy volunteers</td>
<td>Arnica 10M†</td>
</tr>
<tr>
<td>Savage(^21)</td>
<td>Experimentally inflicted mechanical bruising</td>
<td>Double-blind crossover trial</td>
<td>10 Healthy volunteers</td>
<td>Arnica 30C†</td>
</tr>
<tr>
<td>Livingston(^22)</td>
<td>Stroke</td>
<td>Randomized double-blind</td>
<td>40 Patients admitted to hospital up to 7 d after acute event</td>
<td>Arnica “in M potency” (n = 20)</td>
</tr>
</tbody>
</table>

\(^*\) Lower creatinine kinase concentration on day 6 in group C vs placebo.

\(^†\) One tablet before being bruised and 2 after, on the same day, and 2 more tablets on the next day.
arnica in Table 1. Two studies\textsuperscript{15,17} yielded a statistically significant positive result (ie, arnica superior to placebo), 2 studies\textsuperscript{20} had a numerically positive result (ie, no formal test statistics were applied but an advantage of the arnica groups was apparent) and 4 studies\textsuperscript{16,18,19,21} showed a significantly negative result (ie, arnica not superior to placebo). Most trials included in this review are methodologically weak. Generally speaking, the more rigorous studies\textsuperscript{18,22} tended to be the ones that yielded negative findings. There is no obvious common denominator to differentiate between positive and negative studies, neither in terms of potency applied nor in terms of indication. For example, one trial on delayed-onset muscle soreness had positive results\textsuperscript{15} while another (methodologically superior) one had negative results.\textsuperscript{18} Similarly, one study of postsurgical complications had positive results\textsuperscript{17} and another had negative results.\textsuperscript{16} In addition, there are no data to suggest that one potency of arnica is superior to another.

Arnica is the classic homeopathic remedy for trauma of various kinds. “The word injury is constantly associated with the usefulness of arnica in trauma . . . this is especially true for soft tissue damage causing bruising, bleeding, and dislocation.”\textsuperscript{22} The 	extit{Homoeopathic Pharmacy} lists as its first indication “trauma” and even recommends it as a first-aid treatment.\textsuperscript{23} The results of this systematic review unfortunately fail to lend support to this. On balance, the trial data do not support the notion that arnica is efficacious.

There are several ways of explaining this. The evidence could be scarce and a type II error could have produced a false-negative overall picture. This is not borne out by the data presented earlier. No other homeopathic remedy has been subject to more controlled clinical trials.

<table>
<thead>
<tr>
<th>Control Treatment</th>
<th>Main Outcome Measures</th>
<th>Main Results</th>
<th>Comments</th>
<th>Jadad Score\textsuperscript{14}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo drops as per verum schedule (n = 6)</td>
<td>Soreness intensity (rating scale) and duration, maximal isometric muscle strength, serum creatine kinase concentrations</td>
<td>Less decrease in muscle strength in group B vs placebo (both arms); no differences in terms of soreness intensity; shorter duration of soreness in group B (both arms) and C (left arm only) vs placebo\textsuperscript{13}</td>
<td>No randomization; no numerical results provided (figures only); no allowance for multiple comparisons</td>
<td>1</td>
</tr>
<tr>
<td>Metronidazole 400 mg twice daily (n = 41)</td>
<td>Pain (visual analog scale), trismus, edema, wound healing</td>
<td>No difference between arnica and placebo in any outcome measure</td>
<td>Metronidazole was shown to be superior to placebo or arnica</td>
<td>2</td>
</tr>
<tr>
<td>Placebo twice daily for 3 d postoperatively (n = 38)</td>
<td>Pain, bleeding</td>
<td>Less pain with arnica, no significant difference for bleeding</td>
<td>41 dropouts</td>
<td>4</td>
</tr>
<tr>
<td>Placebo pills as per verum schedule (n = 16)</td>
<td>Blood tests, including serum creatine kinase concentrations; soreness intensity (visual analog scale) and duration</td>
<td>No significant intergroup differences, but a trend for soreness and serum creatine kinase concentrations to be lower with arnica than placebo</td>
<td>No allowance for multiple comparisons</td>
<td>4</td>
</tr>
<tr>
<td>Placebo (n = 9)</td>
<td>Pulse rate, blood pressure, respiratory rate, subjective symptoms</td>
<td>No significant intergroup differences</td>
<td>No mention of randomization, frequency and dose of medication not stated</td>
<td>2</td>
</tr>
<tr>
<td>Placebo</td>
<td>Extent of bruising, subjective symptoms</td>
<td>Results numerically favored arnica</td>
<td>Small sample size, no statistics</td>
<td>1</td>
</tr>
<tr>
<td>Placebo</td>
<td>Extent of bruising, subjective symptoms</td>
<td>Results numerically favored arnica</td>
<td>Small sample size, no statistics</td>
<td>2</td>
</tr>
<tr>
<td>Placebo (n = 20)</td>
<td>3-mo mortality</td>
<td>No significant intergroup difference</td>
<td>Small baseline differences in disfavor of arnica-treated group</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 2. Scoring System to Measure the Likelihood of Bias\textsuperscript{a}

\textbf{Yes = 1 point; no = 0 points}

\begin{itemize}
  \item A. Study described as randomized (this includes the use of words such as random, randomly, and randomization)?
  \item B. Study described as double-blind?
  \item C. Was there a description of withdrawals and dropouts?
  \item D. Method to generate the sequence of randomization described and appropriate (table of random numbers, computer-generated, and so forth)?
  \item E. Method of double-blinding described and appropriate (identical placebo, active placebo, or dummy)?
\end{itemize}

**Deduct 1 point if:**

\begin{itemize}
  \item F. Method of double-blinding described and inappropriate (comparison of tablet vs injection with no double dummy).
\end{itemize}

\textsuperscript{a}Method developed by Jadad et al.\textsuperscript{14}
The existing studies could be severely flawed and therefore produce a misleading result. The trials certainly are burdened with a multitude of methodological limitations. Small sample size and lack of test statistics are frequent and obvious ones. However, such drawbacks would be likely to create a false-positive rather than a false-negative result.

Arnica could have been applied wrongly. Homeopaths do not treat a specific condition but rather the whole human being. Thus, it is not strictly according to the teaching of Hahnemann (the “inventor” of homeopathy) to use arnica for trauma much like an allopathic drug. There are, however, exceptions to this rule, and arnica is certainly one of them. The above quotations demonstrate that arnica is used for the conditions for which it was tested in the trials reviewed here.

Therefore, the hypothesis that homeopathic arnica is, in fact, not effective beyond a placebo effect must be considered. It is not possible to “prove a negative” with these data. It is, however, possible to comment on the most likely explanation of the overall result of this systematic review.

It is concluded that the hypothesis claiming that homeopathic arnica is clinically effective beyond a placebo effect is not based on methodologically sound placebo-controlled trials.

Reprints: E. Ernst, MD, PhD (e-mail: E.Ernst@exeter.ac.uk).

REFERENCES


ARCHIVES OF INTERNAL MEDICINE


Marc D. Silverstein, MD; John A. Heit, MD; David N. Mohr, MD; Tanya M. Petterson, MS; W. Michael O’Fallon, PhD; L. Joseph Melton III, MD

Background: The incidence of venous thromboembolism has not been well described, and there are no studies of long-term trends in the incidence of venous thromboembolism.

Objectives: To estimate the incidence of deep vein thrombosis and pulmonary embolism and to describe trends in incidence.

Methods: We performed a retrospective review of the complete medical records from a population-based inception cohort of 2238 patients who resided within Olmsted County, Minnesota, and had an incident deep vein thrombosis or pulmonary embolism during the 25-year period from 1966 through 1990.

Results: The overall average age- and sex-adjusted annual incidence of venous thromboembolism was 117 per 100,000 (deep vein thrombosis, 48 per 100,000; pulmonary embolism, 69 per 100,000), with higher age-adjusted rates among males than females (130 vs 110 per 100,000, respectively). The incidence of venous thromboembolism rose markedly with increasing age for both sexes, with pulmonary embolism accounting for most of the increase. The incidence of pulmonary embolism was approximately 45% lower during the last 15 years of the study for both sexes and all age strata, while the incidence of deep vein thrombosis remained constant for males across all age strata, decreased for females younger than 55 years, and increased for women older than 60 years.

Conclusions: Venous thromboembolism is a major national health problem, especially among the elderly. While the incidence of pulmonary embolism has decreased over time, the incidence of deep vein thrombosis remains unchanged for men and is increasing for older women. These findings emphasize the need for more accurate identification of patients at risk for venous thromboembolism, as well as a safe and effective prophylaxis. (1998;158:585-593)

Reprints: John A. Heit, MD, Hematology Research, Plummer 549, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (e-mail: heitj@rcf.mayo.edu).