

A Critique of Ernst's Critique and Request for Replication of an Arnica Study

I read with interest Dr. Edzard Ernst's latest critique of homeopathic research which focused on eleven publications from Berlin researchers.(1) For reasons you will understand below, I chose to read the Brinkhaus et al., (2) publication describing three RCTs evaluating the post-operative effects of Arnica montana and then to evaluate Dr. Ernst's critique of this research.

My general sentiment after reading the Brinkhaus et al., article is that their research design was impeccable. They described three randomized, placebo-controlled, double-blind studies. Their study was approved by an IRB, study participants signed informed consent forms, and were insured according to German law. Specific exclusion criteria were delineated for the studies. They stated clearly a null hypothesis with one primary outcome measure, and they provided details on how the outcome measure was calculated. They described the statistical approach to be taken – a sequential trial with an intention-to-treat population. They explained that with a sequential trial, one cannot specify the number of study participants a priori because the trial is stopped as early as possible. But they calculated the average number of patients based on the expected power. They specified a type I error of $\alpha=0.05$ and a power of $\beta=90\%$ “calculated with the PEST™ software package.” Overall, it is difficult for me to find fault with their design.

When I reviewed Dr. Ernst's description of this research, there was no acknowledgement that the Brinkhaus et al.

's research design was excellent. Let's evaluate each of his comments about this study:

- 1) Dr. Ernst commented, “No power calculations were provided.” Given the above description, this is clearly a misleading criticism because they explicitly stated that the power was calculated with the PEST™ software. It is unclear to me how further details would be helpful in the discussion of this research.
- 2) Dr. Ernst correctly noted that two of their three trials did not yield statistically significant differences between placebo and verum groups. It is important to understand that there is a well-known bias among researchers as well as editors of journals against the publication of research studies with negative findings. Brinkhaus et al., could have chosen not to publish the two studies with negative findings. Their publication of studies with negative as well as positive results attests to their willingness to be inclusive

of all the findings from their research, not merely the findings that are supportive of the homeopathic approach.

- 3) Dr. Ernst acknowledged that “the third RCT did demonstrate a significant reduction of 1.8 percent,” but he failed to mention the “ $p<0.02$ ” value (which is the usual manner of reporting a statistically significant finding). I can only assume that his failure to disclose the $p<0.02$ level of significance is a way of minimizing the significance of this finding.
- 4) Dr. Ernst mentioned that a post-hoc pooled analysis of all three RCTs had been done which revealed a “borderline significant effect ($p=0.04$).” It has been a generally accepted convention since the early 1900's to accept “ $p<0.05$ ” as the most common criterion for a “statistically significant” finding. To describe a p-value of 0.04 as “borderline” is again a misuse of language to minimize the finding of a statistically significant result.
- 5) Dr. Ernst noted that Brinkhaus et al., concluded that “patients receiving Arnica showed a trend toward less post-operative swelling compared to patients receiving placebo” and that the observed effects “seem to justify the use of homeopathic Arnica in cruciate ligament reconstruction.” Their data do in fact support these conclusions, and Ernst provided no reason to dispute their conclusions.
- 6) Dr. Ernst then stated, “The authors did not critically discuss the clinically irrelevant reduction in knee circumference.” This is not an accurate criticism – there is a considerable amount of discussion given to the relevance of the knee circumference as an indication of swelling as well as the advantage of using Arnica montana for treating post-operative pain and swelling. In particular, they discussed other methods for treating pain and swelling (such as oral narcotics and NSAIDs, intra-articular medications, cold therapy, and compression) along with their side-effects and expense. Dr. Ernst also failed to appreciate the researchers' efforts to use an objective measure as their outcome variable (as opposed to subjective measures of pain).
- 7) Dr. Ernst also criticized Brinkhaus et al., because their sample size was too small to find “rare adverse effects.” By definition, “rare” means that something is highly unusual or uncommon – a sample size would need to be very large to find such “rare adverse effects” and such a large sample size would be an unreasonable expectation for

this type of research. It is not uncommon for allopathic medications to be taken off the market after several years of widespread use -- if discovering all adverse side effects could be done in the initial phases of research, then it would not take years to remove all harmful drugs from the market.

- 8) Finally, Dr. Ernst commented that there was no mention of “conflict of interest” for this research study. Brinkhaus et al., referred to a “sponsor” in their publication, but the sponsor was not identified. Providing such information would in fact be advised. Dr. Ernst did not mention any conflict of interest for his own article (which represents one of many strong critiques of homeopathic research). It would be helpful to know if the work of Dr. Ernst is now, or has ever been, supported by any institution or pharmaceutical company. (For the record, the writing of this article is not being funded.)

In summary, it appears to me that Dr. Ernst was reluctant to make any positive judgments about these three RCTs which were, in fact, extremely well-designed and which yielded some statistically significant results. When a critic writes multiple articles about the poor methodology of homeopathic research but then fails to characterize a well-designed research project in an objective manner, his reliability as a critic must be questioned. It is ironic that Dr. Ernst warned of a “phenomenon that...seems to be common in this line of investigation...relatively weak data tend to be over- or misinterpreted to such an extent that the casual reader of such publications can be seriously misled.”⁽³⁾ I, too, would caution the casual reader – it seems to me that anyone who reads Dr. Ernst’s critiques should be advised to read the original research.

Dr. Len Torok’s Research

Of the eleven publications reviewed by Dr. Ernst, I focused on the Brinkhaus et al., study because of my knowledge of an unpublished study by AIH member Len Torok, MD. Dr. Torok practiced medicine for many years as an orthopedic surgeon, and after he had studied homeopathic medicine, he wanted to have the opportunity to use Arnica montana during surgery. The hospital where he was practicing required him to demonstrate that the use of Arnica was safe and that such use improved the standard of care.

Dr. Torok designed a study in which he compared two groups of patients. The control group was comprised of patients who had undergone a primary total knee replacement in the year (1997) prior to the introduction of homeopathic medicines into the hospital formulary. The experimental group was comprised of patients undergoing a primary total knee replacement with the peri-operative use of Arnica montana.

A standard dosing regimen of Arnica montana was used for the experimental group of patients: Arnica 200C was given in the preoperative holding area; a liquid dose of Arnica 200C was given every twenty minutes during the operative

procedure by the anesthesiologist; in the recovery room and on the nursing floor, the nursing staff administered Arnica 200C postoperatively at decreasing intervals of time from twenty minutes to one hour during the blood reinfusion process. The postoperative blood volume lost from the knee was collected, measured and reinfused according to the standard protocol of the blood reinfusion device.

A retrospective chart review was done to determine the blood reinfusion volumes of the control group. The blood reinfusion volumes of the control group were within the usual range of expected blood loss – an average of 650cc with a range from 300cc to 900 cc. In the experimental group, the average blood reinfusion volume was 170cc – a 74% decreased compared to the control group -- with a range from 50cc to 530cc. There were only seventeen patients in the experimental group – the hospital statistician determined that the study could be concluded because the reduction in postoperative blood loss had already reached a level of statistical significance (Dr. Torok does not recall the exact p-value). His research also indicated that the patients experienced less pain, less swelling, quicker rehabilitation, shorter hospital stays, less need for narcotics, and subsequently less nausea and vomiting and urinary retention associated with the use of narcotics. Dr. Torok treated his patients using his Arnica protocol for the following 10 years until he retired from orthopedic surgery. Dr. Torok continues to be active in homeopathic clinical medicine as well as homeopathic research in the field of dermatology.

Ever since learning about this unpublished research, it has been my hope that the study would be replicated. Thus, reading that Brinkhaus et al., had also pursued research on the use of Arnica in the orthopedic setting caught my attention. The finding of highly significant results from Dr. Torok’s research may shed light on the lack of significant findings from the knee replacement arm of the Brinkhaus et al., research. In Dr. Torok’s research, the 200c potency was used, which is known to be more potent than the 30x potency used in the Brinkhaus et al., research. Dr. Torok’s posology was also more aggressive – Arnica was administered during surgery and every twenty minutes during the reinfusion process. It is important to note that this research design was not determined in an a priori manner – Dr. Torok examined various protocols prior to selecting the design for his study.

The presence of significant findings in Dr. Torok’s study and the absence of significant findings in the Brinkhaus et al., study highlight an important fact about research. A research design tests only the null hypothesis of that particular study. Because of this, one cannot conclude from the Brinkhaus et al., study that the use of Arnica is not beneficial after knee replacement surgery; one can only conclude that there is no evidence that a 30x potency as administered in the Brinkhaus et al., research protocol is beneficial in reducing swelling. This difference is an important one to understand because it focuses attention on the research design – that is, if one’s clinical experience has suggested that a treatment is useful, one needs to experiment in order to find the research

design that may demonstrate the truth of one's experience.

In conclusion, it must be remembered that the primary purpose of publishing one's research, with positive or negative findings, is to communicate to interested persons what research design was used and what the results demonstrated. I have summarized Dr. Torok's research with the hope that the Berlin researchers (or any other researchers) will replicate his work. Please contact me at Sebastian.Irene@gmail.com if you want further information about Dr. Torok's research.

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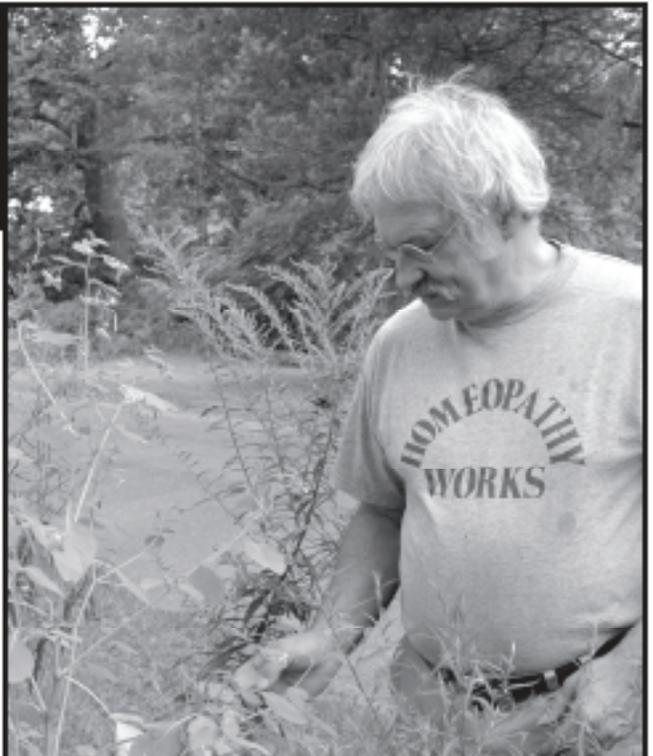
Endnotes

1. Ernst, E. Homeopathy: A Critique of Current Clinical Research. *Skeptical Inquirer* 2012; 36(6):39-42.
2. Brinkhaus B, Wilkens JM, Ludtke R, Hunger J, Witt CM, Willich SN. Homeopathic arnica therapy in patients receiving knee surgery: Results of three randomized double-blind trials. *Complementary Therapies in Medicine*. 2006;14(4):237-246.
3. Ernst, p. 42. 

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