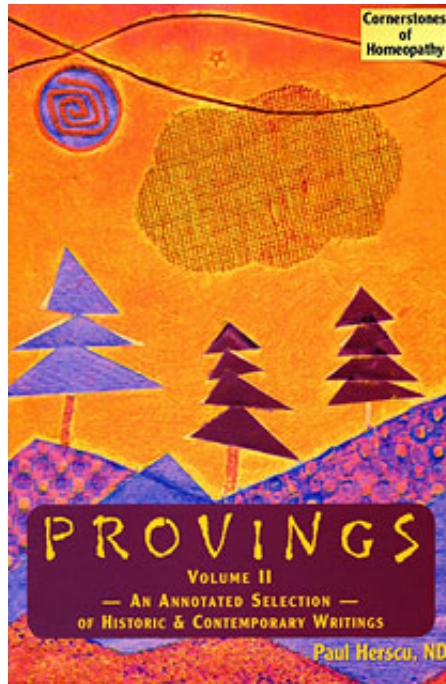


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The Pillar of Homeopathy

Homeopathic Drug Provings in a Scientific Framework

Harald Walach, PHD—*British Homeopathic Journal*,
October 1997, Volume 86, pp. 219-224

(This article is one of those that tested Belladonna versus placebo. What it showed in several of the experiments was that Belladonna could not be differentiated from the placebo. In fact at times, the placebo had a greater effect. I placed these findings in bold type. This again affirms the fact that in a full proving of a new substance, it is conceivable and even probable that if the study was not conducted well, symptoms would be included that do not belong to the materia medica of the substance being proven. This explains why we find a multitude of symptoms in many new provings.

The rest of the article proposes a study design. The lack of a cohesive model does not allow the experimenter to have a clear image of what to pay attention to in the proving. As a result, the two most crucial points of the test—which symptoms to use, and the time frame of the study—are either left out, ambiguous or incorrect. I believe the author is clearly thinking in the right direction. The only reason his studies failed reflect back to the lack of a cohesive model. - PH)

Abstract

The few controlled trials conducted so far have not shown that the symptoms observed by volunteers in a proving are different from placebo. This finding is discussed from a methodological point of view. Provings conducted so far have not convincingly put the method to experimental trial. Provings designed to improve practical prescribing in homeopathy, using qualitative methodology, should be distinguished from trials to show that substances in homeopathic dilutions produce symptoms different from placebo. Both methodologies can be combined and a protocol is suggested.

Keywords: Homeopathic provings; Methodology; Clinical trials; Protocols.

Introduction

In a homeopathic proving, a substance is given to healthy volunteers and their symptoms are noted for therapeutic purposes. This idea is the pillar on which homeopathy rests. Homeopathic drug proving has been the most important part of homeopathic theory and the foundation of its practical application every since Hahnemann discovered that *China* was able to produce malaria-like symptoms in 1790.¹ In a proving, healthy volunteers take substances and note their symptoms. In the early provings Hahnemann and his disciples used medicines in the substantial dosages which were then in use. These did, of course, produce many toxic symptoms. Hahnemann therefore decided to dilute these substances stepwise, incidentally discovering the principle of potentization. In the last edition of his *Organon*, he established the 30c potency as a common potency for drug provings and healing purposes alike." A large part of the homeopathic *materia medica* is based on drug provings. Rarely has the challenge been met to determine whether these symptoms are really different from the placebo symptoms provers experience when taking a placebo substance. This topic was raised by Martini,^{iiivvvi} who stated that the symptoms produced by homeopathic substances were not different from placebo. I have argued that these conclusions were not adequate to homeopathic practice and theory." I set out to study the principle of homeopathic drug provings, using controlled experimental methodology.

Controlled Experiments: Summary

All our studies used *Belladonna 12* or 30cH and pilules (size 3, all materials obtained from DHU/Homlnt, Karlsruhe) impregnated with the same amount and concentration of alcohol as a control. All studies were blind and intra-individually controlled by some form of cross-over design.

Pilot Study

The first study compared *Belladonna 30cH* with placebo for 4 weeks. Intake of medication was 3 times a week, 2 pilules. There was a one-week run-in period and one week of post-observation, with no washout phaseTM Data were collected using a diary with preformulated categories. The results were ambiguous. On a single case basis nearly half the provers, 21 subjects out of 45, clearly experienced different symptoms in each of the experimental phases. However, 8 of them exhibited a pattern contrary to expectation, with significantly more symptoms on placebo than on *Belladonna*. Data analyzed for the whole group therefore showed no clear-cut differences. Significant

differences were few, and approximately the same number of symptoms were in favor of *Belladonna* as in favor of placebo. Thus no final conclusion could be reached.

The study had shortcomings. It did not allow distinction between possible pathogenetic symptoms and therapeutic effects; no stable baseline without intake of test substance was established so that it was not clear whether placebo symptoms were different from baseline symptoms. The lack of washout might also have posed problems, although *Belladonna*, being short-acting, is not likely to produce long-lasting symptoms.

Another pilot trial was done to test the hypothesis of individual reactivity, using a single-case randomization experiment as described by Edgington.^{ixx}

Single Case Randomization Experiment

In such an experiment, the sequence of administration of placebo and test substance is randomized per subject. Each person received placebo and *Belladonna* in a unique random order. This allows statistical evaluation of each single case, thus establishing a probability of whether the observed pattern could have been produced by chance. 4 phases with *Belladonna* and 4 phases with placebo, each lasting a week, were randomized per subject. The test substance was *Belladonna*, to be taken once a week. 14 volunteers took *Belladonna* 12cH, 11 *Belladonna* 30cH. Data collection was with a prestructured diary with 16 *Belladonna* and 15 *non-Belladonna* symptoms—changes, modalities and localizations—taken from the literature and from the previous study. The baseline probability of *Belladonna* or *non-Belladonna* symptoms was therefore evenly distributed. The *Belladonna* symptoms were clear-cut (e.g. sudden change v. slow change, during the night v. during the day, redness, swelling, heat v. paleness, coldness and weakness). *Belladonna* symptoms were summed to yield one score, which was used to calculate the statistics. Visual analysis was employed to supplement statistical analysis.

2 of the 25 single experiments approached significance. In one case, clearly more *Belladonna* symptoms were observed with *Belladonna* 30cH ($p = 0.071$). In another case, more *Belladonna* symptoms were observed with placebo ($p = 0.14$). Other experiments showed on visual inspection that more *Belladonna* symptoms were reported with *Belladonna*, but also with placebo. We also found indications of a carry-over effect. This latter result shows that intra-individually controlled experiments in pathogenesis

trials might be flawed. The experiments reporting more *Belladonna* symptoms with placebo did not give conclusive evidence that the lack of *Belladonna* symptoms with *Belladonna* was due to a therapeutic effect.

This multiple single-case experiment thus does not permit the conclusion that *Belladonna* produces more *Belladonna* symptoms than placebo. It is conceivable that our data collection of *Belladonna* symptoms was too coarse. Paradoxical effects may also be observed which cannot be attributed to therapeutic effects of *Belladonna*, with some subjects reporting more *Belladonna* symptoms when taking placebo. This confirmed the finding from the first pilot trial, with the additional problem that hidden therapeutic effects can't be used to explain this effect. We concluded that this methodology was not a viable alternative for putting a pathogenetic trial to experimental test.

Replication Study of the First Pilot Trial

We conducted a larger study with improved but similar design and 2 populations*—homeopathic physicians and students, and volunteers with no homeopathic training, all in good general health as defined by a standardized list of symptoms. 2 weeks of baseline observation were compared to 2 weeks of placebo and 2 weeks of *Belladonna* 30cH in random sequence.

The results were disappointing. 87 volunteers gave valid data. The general data produced a contradictory picture. Physical well-being was worse with placebo ($p = 0.058$), compared to baseline and *Belladonna*, emotional well-being did not change at all, intake of test substances was lowest with placebo ($p = 0.044$), the number of symptoms greatest with *Belladonna* ($p = 0.04$), but life-events were reported most frequently during the observation and *Belladonna* phase. Thus again, we have no clear-cut pattern, but contradictory findings. Mean number, intensity, and duration of symptoms reported did not show a significant difference between placebo and *Belladonna*. 9 symptom patterns based on our previous findings and on the literature were formulated as *a priori* hypotheses and tested. None of these showed more symptoms with *Belladonna*, but some showed superiority of placebo in producing these symptoms. The claim that *Belladonna* produces more and different symptom patterns in healthy volunteers was thus not confirmed overall.

It is difficult to discuss these results. One could argue that the fixed intake regimen could have missed the optimal dose for producing

symptoms. This might be true, but it is difficult to see why some significant changes against baseline should have occurred with placebo but not with *Belladonna*. Also, having nearly twice as many volunteers as in the pilot, even minor effects should have been noticeable. What is bewildering is not the fact that *Belladonna* was no different from placebo and baseline, but that placebo caused more of the effects expected with *Belladonna*. The method of data collection was the same as in the first pilot trial. It might be that this method is still too coarse, although a fair amount of sophistication is possible using the categorization scheme. Possibly a more complex method of numerical pattern detection, such as Group of Membership Analysis^{xixxiiv} would be better.

One consistent and disturbing result remains. Placebo powerfully produces effects which would have been attributed to the homeopathic medicine if placebo control had not been employed. The main thrust of these experiments is thus the challenge to prove that homeopathic medicines really are different from placebo.

Proposed Design for Experimental Pathogenesis Trials

A placebo-controlled double-blind study will be required to answer the question as to whether homeopathic substances produce different symptoms from placebo. As carry-over effects may confuse the issue, I propose a parallel group design. Half the provers receive placebo, the other half the homeopathic test substance. Allocation will be random. The test substance would be a well-known homeopathic medicine chosen at random from a predefined set of possible substances at the beginning of the proving. The set is to be agreed by the proving director and the study coordinators. It should include a range of well-known and frequently used substances, preferably ones with acute effects.

Data Collection

Data collection will be done using a non-structured diary. The proving director will see every prover personally before study entry. He or she will ascertain that the prover is in adequate health compared to his individual standard. Provers will then be trained.^{xvi} They will observe and note whatever symptoms they experience. The diary records symptoms on a 4-point scale of intensity. The proving director will interview each volunteer weekly. Whenever necessary, the written account will be altered according to what the proving director agrees with the prover. There will be daily telephone contact. Before any further information on the test substance is

given, the proving records will be verified and mutual agreement reached between prover and director as to which symptoms are thought to be genuine proving symptoms.

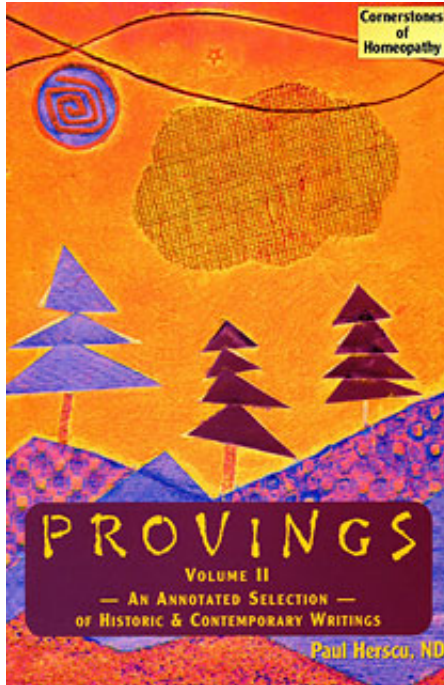
Data Transformation and Study Target

The verified proving record will be handed over to homeopaths familiar with *materia medica* and computerized repertorization who have been selected in advance. The name of the substance proven will be made known to these experts, but not the group code. The experts then examine the diary entries and define the symptoms and signs which are part of the drug picture. Every proving symptom is thus given a score. If it is a symptom of the substance proven, a score will be given and multiplied by grading the intensity of the symptom from 1 to 4. This will create one single variable, the number of graded symptoms of the particular drug studied per period. If no grading is given by the subject, the grading will automatically be 1, mild. This variable of graded scores will be the study target. A secondary variable might be the number of symptoms not found in the traditional *materia medica*, which would be evaluated the same way.

Test Substances

The medicine used has to meet the following criteria. It should be acute, well-known and widely used, so as to maximize the probability of a prover reacting. The definite choice of substances will be made according to a vote of experienced proving directors. A set of possible substances will be defined before the beginning of the study. After that, 2 strategies can be employed:

- 1) The full set of substances will be employed in the study. For each prover a single substance will be selected at random. A particular prover will receive either the substance or the respective placebo. The choice of substance may depend on the findings of the case-taking interview.
- 2) Before the trial a random choice will be made among the medicines selected, and the same medicine will be used for all provers, without the proving director knowing which medicine. This procedure is meant to prevent bias in the proving director when clarifying the symptoms given by the provers. A batch of the medicines used will be retained by the manufacturer.



Paul Herscu

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