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Scientific proving of ultra high dilutions on humans

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Background: **Homeopathic drug provings or pathogenetic trials (HPTs) are the pillar of homeopathy. This review summarizes the authors' findings and interpretations derived from a series of homeopathic drug proving between 1994 and 2015. It gives an overview over a series of attempts to use modern scientific experimental methodology to answer the question, whether such HPTs produce symptoms in healthy volunteers that can be distinguished from placebo symptoms.**
Methods: **Various experimental models were used: repeated crossover trials with categorical data collection, and a single-case, randomised study. Final models use diligent qualitative data-collection in experienced volunteers. In those, raters decide whether symptoms are typical for a remedy delivered or not. The design is triple-blind and placebo-controlled.**
Result: **While previous attempts were inconclusive, this new model allowed to separate placebo symptoms from verum symptoms repeatedly in a series of two definitive studies following promising pilot studies. Results were statistically significant. Also, some signs of the purported non-local signature of homeopathic effects were visible, and the consequences for future methodology is discussed.**
Conclusion: **Provided some cautionary notes are taken into account, HPTs can be used to separate out true specific symptoms from placebo symptoms. By the same token this is a road to experimental proof that homeopathic remedies are not just placebos. However, this needs to be taken forward by independent groups.** *Homeopathy* (2015) **104**, 322–327.

Keywords: Remedy provings; Pathogenetic trials; High dilutions; Homeopathy; Double blind experimental studies

Introduction

This review summarizes the authors' findings and interpretations derived from a series of homeopathic drug proving between 1994 and 2015.

In UHD 1994, H Walach reported that, in spite of the existence of clinical trials in homeopathy, no single study had hitherto been reported which experimentally put to trial the very foundation of homeopathic reasoning: the 'Remedy-Proving' of a homeopathic substance in agitated high dilution with healthy volunteers.[1] It was with this method that Hahnemann began his work on homeopathy: he administered all then known pharmaceutical substances to healthy volunteers, initially in crude doses, later in what he called 'potentized' form – stepwise highly diluted. He then recorded the symptoms carefully and used the data in turn for therapy, applying the principle 'like cures like': treating patients who showed symptoms with agents which were able to produce similar symptoms in healthy subjects. He later tried to overcome toxicological effects by stepwise diluting and succussing the drugs. This dilution process gradually reached a point at which no molecules of the original solute is likely to be left in the solution. Thus, given Avogadro's number (6.023×10^{23} molecules per mole of a substance), a one-molar solution stepwise diluted 12 times by a factor of 100 is highly unlikely to contain any one molecule of solute in a litre of solution. This corresponds to a homeopathic preparation of C12. Hahnemann did not know about these facts. Yet he held that by the dilution process of stepwise succussing, 'the dynamic power' of the remedy could be brought to the fore. These vitalistic

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conceptions, reminiscent of Paracelsus' notion of 'arcana', can be understood in both systems-theoretic and semiotic ways. The question was addressed, whether so-called high dilutions or potencies, beyond Avogadro's number, can produce effects in healthy volunteers more and/or other than placebo, and if so, whether it is possible to investigate this phenomenon in a scientifically acceptable way.

The claim that an ultra-high dilution of a homeopathic remedy, Atropa belladonna C30 (100^{-30}), could produce effects different from placebo, was investigated in a pilot study.[2] In a double-blind crossover trial, four weeks of Belladonna C30 were compared to four weeks of placebo in 47 healthy volunteers. Data were collected daily. The number and types of changes were recorded into a predefined category system. Single-case evaluation showed differences between the two experimental phases for 21 subjects. Group evaluation showed only the tendency toward a difference between placebo and Belladonna C30. In UHD 1994, the author suggested that the claim that homeopathic high dilutions can produce symptoms other than placebo in healthy subjects should be put to further investigation. This suggestion had various reasons:

For one, such homeopathic pathogenetic trials (HPTs) are the pillar of homeopathy, after all.[3] Hahnemann introduced them, many people still conduct them, new remedies are tested using that model in a somewhat refined mode.[4,5] So the question is not only useful but necessary, whether these HPTs produce anything else than placebo noise.

Secondly, the throng to do clinical studies of homeopathy 'to prove that it works', strong as it was in the 90ies, had lessened, probably due to the insight that they are not only too costly, but also too tricky to conduct, fraught with a lot of error variance on top of the organisational hazards.

Thirdly, HPTs have such seemingly clear predictions that can be tested. Other than animal or plant research, which is surely experimentally 'cleaner', HPTs in humans are closer to the clinical core of homeopathy. Thus, this area is promising still.

Methods and results

The first pilot study suggested that there were some indications of differential effects between placebo and Belladonna stemming from the cross-over-design, but these were not clear enough. There were clear effects on an individual level of analysis – more symptoms under Belladonna than under placebo in some cases, in other cases the opposite. This yielded statistically significant differences on the individual level which also could be aggregated to an overall significant result, but when all data were lumped together, these differential effects cancelled each other out.

So it was a clear next step to test, whether in a randomised single-case design such findings could be replicated more clearly. We conducted such a series of single-case studies and were – again – puzzled, to put it mildly.[6] We saw clear indications for effects under Belladonna, statistically significant, but so did we see – statistically significantly so – more symptoms typical for Belladonna than for placebo with placebo! This was the first indication that the simple, causal-local model, which was then used as a working hypothesis by our group and all other researchers implicitly, might be wrong. This model, probably still held by the majority of researchers in the field, posits that somehow the succussion and dilution process preserves some specific information about the substance that makes up the remedy without any molecular or material traces of the substance itself. For, after all, dilutions beyond Avogadro's number, i.e. homeopathic potencies beyond 23X or CH12 are, statistically considered, void of molecules of the original substance. This is of course a purely statistical consideration, as a few molecules due to adhesion or other forces, might actually make it into the final remedy, as suggested by findings and theories, that high potentized homeopathic drugs may act as 'nanomedicine'.[7]

But it would be very hard to argue that molecules of the original substance are systematically responsible for clinical effects of high homeopathic potencies of CH30 or beyond. Apart from that, due to the succussion process in silica-glass phials other molecules in the nano range, mainly silica, but also traces of other substances are present in homeopathic dilutions. So how could one argue, on molecular grounds, that the *molecules* of the original substance themselves are responsible for homeopathic therapeutic effects?

Thus, various models of how *information* about these molecules might be 'preserved' have been proposed, mostly using ordering forces in water to suggest the formation of 'informed' water or 'changed structures' in the dipoles or clusters water consists of. All of them are local-causal models that suppose 'something active' is present in remedies that is not present in placebos. Had that been the case we should not have seen effects typical for a remedy, symptoms of Belladonna, with placebo in that study. But we did. This started a thinking process about other models, and, together with findings from other writers and our own clinical study on homeopathy in headaches,[8] convinced us that only a non-local model of homeopathy would fit the picture.[9,10]

In between we tried to replicate our original 1993 finding with Belladonna in healthy volunteers with a larger sample. We did that, but the findings were disappointing.[11] We replicated the effect that, overall, symptoms with placebo and symptoms with Belladonna canceled each other out in an improved crossover-design that took care of potential carry-over effects, and no real difference emerged.

Negative findings are always more challenging than positive ones. There might be a systematic error in the data, or the effect might simply not be there. Fervent homeopaths did not believe our data. They were very little discussed. Most people simply thought there must be something wrong. The only challenge came from Heribert Möllinger, Jeremy Sherr and people affiliated with that movement who thought that the flaw was with the comparatively coarse grained assessment of symptoms and with using naïve volunteers as opposed to experienced practitioners who have intimate knowledge of their body and its

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