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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) ■, 1–6.

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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reactions, and can therefore distinguish better between transient accidental changes and systematic ones due to the ingestion of a remedy. So a very constructive discourse with these homeopaths ensued. Heribert Möllinger was charged to use the 'diligent method' of data collection, and marry it with a rigorous design method of completely blinding everyone. The 'diligent method' means that the data-collection is supervised by someone who is in daily personal or phone contact with volunteers who are trained and know about HPTs. The daily contact is meant to weed out symptoms from accidental changes and also to not overlook tiny changes that might go unnoticed otherwise.

It is a very thorough qualitative method of data-collection that is close to Hahnemann's original method, with the exception that it is conducted within the framework of a blinded design: Neither the director of the proving, nor the volunteers know about the remedy tested, and, to keep all parties alert, some volunteers receive placebo. Interestingly enough, all people who conduct such provings, using placebo, always talk about the experience that placebo volunteers – or dogs, or wives or other persons in the household, for that matter – tend to also produce proving symptoms, although they do not ingest the remedy. Routinely these symptoms are discarded or ignored, sometimes they are even used. But no one seems to be bothered by the fact that, by theory, they should not have been there. How should, in a local-causal model, where the cause of the symptoms is supposed to be the remedy and its ingestion, someone who in fact did not ingest it, experience remedy-typical symptoms, and why?

Heribert Möllinger adopted the idea and conducted a thoroughly blinded HPT with his volunteer group in Freiburg, Germany, homeopathic physicians and well experienced all of them. He tested a new substance, cod liver, in CH30. He saw beautiful symptoms, clear, decisive, strong. Funny enough, they happened all in the placebo group, and to the best of our knowledge the data never saw the light of day.

The observation that specific homeopathic proving symptoms are also observed under placebo has been discussed by G Bayr already in 1986 in *The British Homeopathic Journal*: 'The type of change observed during homeopathic drug trials can also be noted following exhibition of placebo. This makes it more difficult to evaluate the results of homeopathic drug tests'[12] Bayr proposed to weight symptoms for the statistical analysis according to their homeopathic symptom characteristics. To the best of our knowledge, he actually never followed this plan. In a homeopathic drug proving of Galphimia glauca we did not see significant numerical differences between Galphimia glauca C12 and placebo, but it appeared that there were more individualizing and characteristic symptoms under Galphimia.[13]

However, in a recent randomized placebo-controlled rigorously blinded homeopathic drug proving of Okoubaka aubrevillei C12 we used qualitative research methods based on the homeopathic classification of specific highly individualizing 'characteristic' symptoms to eliminate noncharacteristic symptoms for the primary statistical analysis.[14] Characteristic symptoms were categorised using content analysis. Secondary outcome parameters were the qualitative differences in profiles of characteristic and proving symptoms and the total number of all proving symptoms. The number of symptoms was quantitatively analysed on an intention-to-treat basis using analyses of covariance with the subject's expectation and baseline values as covariates.

No significant differences in number of characteristic symptoms in both groups were observed between Okoubaka (mean $\pm$ standard deviation 5.4 $\pm$ 6.0) and placebo (4.9 $\pm$ 5.6), the qualitative comparison of the symptom profiles showed a high overlap of symptoms between both verum and placebo in concordance with the clinical experience regarding Okoubaka aubrevillei. This result can be interpreted that a strong nocebo response occurred in both groups. Alternatively it may be possible that there was a specific reaction in both groups. But this would mean, that the specific ('Okoubaka') effect was not related to the Okoubaka carrier substance sucrose globules.

To research whether there is a specific element of action we decided to develop a new design that might allow us to not only use HPTs as a research model but also decide between competing theories. The design is only applicable for substances that are already well known and have a good basis in the materia medica. Thus, it is only a research tool, and not a development tool.

The basic idea is as follows: data is collected by the 'diligent method': with daily contact to determine the validity of a change as a real 'symptom' produced by ingesting a potential UHD. Triple blinding of treatment allocation is used: Blind not only the volunteers but all involved in a study against the type of remedy tested, by having a third party choose from a long list of potential remedies. Use placebo as well, and use well known remedies. Have the study in three arms, not in two, and use two groups with two different true remedies and one group with placebo. When the data are all collected, hand them over to another person, the materia-medica expert. This person only receives the list of symptoms and does not know about who received what remedy. And this person, and only this person, is then informed about the remedies that were tested in this study by the independent party.

This materia-medica expert decides, for each symptom: Was it a symptom typical for remedy X, typical for remedy Y, for both, or for neither? As the homeopathic materia medica is not always clear cut, and depending on the types of remedies that are chosen randomly, there might be some overlap sometimes.

This procedure yields a simple quantitative score: The number of symptoms typical for remedy X in group A. The number of symptoms typical for remedy Y in group A. The number of symptoms typical for both or for neither in group A. And the same for the other groups. Using this method, we can convert qualitative information – the remedy picture, the symptoms typical for a remedy – into quantitative information – number of symptoms typical for a remedy in a given group. And these numbers can be tested against each other very easily, using simple statistical tests.

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We conducted two pilot studies, one with one remedy only tested against placebo,[15] and one study with two remedies tested against placebo.[16] In both studies we saw tendencies, some of them significant, of more symptoms typical for the remedy studied in the actual group that received it. But we also saw strange crossings: symptoms typical for a remedy in the group that received the other remedy. Or symptoms typical for the remedy in the group that later received it.

This was similar to a kind of 'presentiment' effect which George Lewith and his group have reported: symptoms typical for the remedy were seen significantly more frequently even before the remedy was ingested, but only in the group that would later receive it.[17,18] We refined the protocol, decided for the three-armed approach and conducted two studies which we combined into one dataset. The two studies had one remedy in common and a second remedy that was different in each study in addition to a placebo group. We collapsed the data of the common remedy symptoms and discarded the symptoms of the third group. This was decided in advance in a protocol deposited beforehand and due to theoretical considerations based on our theory of generalised entanglement.[19]

This approach proved effective: We saw clearly more remedy-typical symptoms in the groups that had ingested the remedy than in the placebo group (but also traces of the symptoms typical for the other remedies that were tested, but not used in the evaluation).[20] This was, in our view, both a clear indication, if not proof, that homeopathic UHDs produce more symptoms that are typical for the substance than placebo, and also a clear indication that a local-causal model is likely not adequate to describe homeopathic effects. It is, by the way, important to note that not the absolute number of symptoms was different between placebo and homeopathy groups, but the qualitative pattern, although sometimes also less symptoms could be seen under placebo.

Heribert Möllinger subsequently used our model to provide the yet clearest result with very well known substances, arsenicum and natrum muriaticum.[21] This result was so clear, with no crossings-over of symptoms, that various journal editors who we submitted it to insinuated in their rejection letters that the results could have only be the outcome of fraud, flaw or fiction. Other approaches that were implicitly built on a local model of homeopathy were abandoned, as far as we can see, as they never produced clear cut results between homeopathy and placebo or control.[22,23]

A summary of our findings is presented in Table 1. We conclude that homeopathic UHDs apparently produce some specific symptoms in healthy volunteers that can be – by and large – distinguished from the symptoms of other remedies and from the noise produced by placebo.

Is this scientifically accepted and acceptable? Yes and no. The results follow from very stringent, rigorously blinded and controlled trials and thus are valid. However, to transfer a finding and an experimental result into a scientific fact requires several further steps Replications by independent groups have to follow. This has not happened yet. The empirical findings have to be explained within the framework of a theory that is accepted if not by the majority then at least by a recognizable group of scientists. And

Table 1 Summary of the authors' homeopathic pathogenetic trials

Study (Reference)	*Design, substance*	*Data-collection*	*Outcome*
Walach 1993[1,2]	Crossover, double-blind, Belladonna 30C and placebo	Categorical diary of symptoms	Significant differences on individual level, no differences at group level
Walach, Hieber, Ernst-Hieber 1994[6]	Single-case randomisation design, Belladonna 12C, 30C and placebo in random order of weeks	Diary of 10 symptoms typical for Belladonna and 10 distractor symptoms	2 cases with statistically significantly more Belladonna symptoms, one with Belladonna, one with placebo; 3 cases visually suggestive of effect
Walach et al 2001[11]	Improved crossover, double-blind, Belladonna 30C and placebo; replication of (1)	Categorical diary of symptoms	No group difference of symptoms
Walach et al 2004[15]	Parallel group, Cantharis 30C and placebo; pilot	Diligent and qualitative collection of symptoms; transformation into numerical score	Medium sized effect for typical symptoms of cantharis and large effects for a-typical symptoms in the proving group compared with placebo
Möllinger et al 2004[16]	Parallel group, Calendula, Ferr. Mur 30C and placebo; pilot	Diligent and qualitative collection of symptoms; transformation into numerical score	Significantly more calendula symptoms in the calendula and ferr-mur-group compared to placebo
Walach et al 2008[20]	Parallel group, two verum arms C30, one placebo arm; two separate studies with one remedy similar the second different; triple-blind; remedy chosen by third party from list of 60 remedies; definitive study	Diligent and qualitative collection of symptoms; transformation into numerical score; combination of the symptoms of groups with the same remedy vs. placebo; discarding the third remedy	Significantly more remedy-typical symptoms in the homeopathy groups compared with placebo
Möllinger et al 2009[21]	Parallel group, two verum arms (Nat mur, ars alb C30) vs. Placebo	Diligent and qualitative collection of symptoms; transformation into numerical score	Significantly more remedy-typical symptoms in both groups compared with placebo
Teut et al. 2008[13]	Parallel group, verum and placebo arm, (Galphimia glauca vs Placebo)	Diligent and qualitative collection of symptoms; transformation into numerical scores	No group significant differences compared to placebo
Teut et al. 2013[14]	Parallel group, verum and placebo arm, (Okoubaka aubrevillei vs Placebo)	Qualitative content analysis to categorize characteristic symptoms	No significant group difference of characteristic symptoms

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the findings have to published in respected scientific journals major journals. While step one − strong experimental findings − has been achieved, steps two to four are still largely future ambitions. Recently the homeopathic community has harmonized national homeopathic drug proving guidelines and developed an international standard.[24] Inclusion of our innovative qualitative methods could help to identify specific responses.

We tried to get funding for follow-up studies following this concept, but did not succeed. We believe that ours is probably the most promising approach in the human research field of homeopathy. It has been developed thoroughly, proven that it can be used, has replicable results and a sound theoretical underpinning.

There were many public debates, with journalists, with critics of homeopathy, who all claim there is no evidence that homeopathy is different from placebo. We routinely send them our HPT studies described above asking for a solid rebuttal or critique. Mostly the journalists publish their articles without even mentioning the findings, still claiming homeopathy is proven a placebo, period. And critics never come back with any real criticism. The best we have heard was: the design was too complicated to be sensible.

Conclusion

Meanwhile authors quote our systematic review of HPTs[25] which revealed many methodological flaws in HPT reports published between 1945 and 1995. But that review was predicated on a simple causal model of homeopathy, assuming that, if the HPT were well blinded and placebo-controlled, we could see the difference between homeopathy and placebo clearly. Our work has shown that this is likely wrong. We have paved the way over the last 20 years to a sustainable model of HPT research in the face of scientific critique that was never harsher than now. It is difficult to understand why it is not picked up by eager young minds. True, one has to make a leap and leave aside the causal-local thinking that underpins most of current research. But then, perhaps this is the leap we all have to make, even in other areas of life and of science. Perhaps it would be a promising leap?

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