

GENERAL ARTICLE

Homoeopathy will not end by pseudo-analysis

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The meta-analysis of placebo-controlled trials of Homoeopathy and Conventional Medicine¹ done by Aijing Shang et al. and published in Lancet (2005, Aug.27) is a well-designed endeavour to malign Homoeopathy, particularly at a time when there is a paradigm shift from the conventional therapy to Homoeopathy, owing to its low-cost, harmless and effective medicines. But, this article is published and being given worldwide coverage to belittle Homoeopathy and compel its users to look at it with derision and suspicion. The researchers have cleverly designed their study to hit two birds with one stone, i.e. firstly, to prove that the homoeopathic treatment is a placebo response and secondly, to prove the superiority of conventional medicine over homoeopathy. It is quite natural that the homoeopaths all over the world have raised questions on various facets of this meta-analysis. Hence, various methods used by the authors to designate Homoeopathy as a Placebo effect and uphold the conventional therapy, need to be addressed thoroughly to dispel the confusion.

1. The unmatched numbers

The authors although have analyzed 110 homoeopathy trials and 110 matched conventional medicine trials, yet in reality, they have framed their opinion by analyzing the outcomes of 08 Homoeopathy trials and 06 conventional medicine trials, on the plea of considering large trials of higher quality. Table 2 of the article shows that they have screened 21 (19%) homoeopathy trials and 9 (8%) Allopathy trials as the high quality trials (double blind, with adequate generation of allocation sequence and adequate concealment of allocation). Instead of identifying 12 more allopathy trials of high quality to match 21 homoeopathy trials, it is not known, why they have come down to unmatching ratio of 8:6. Did the authors fail to procure the additional required high quality trials to match the homoeopathic numbers? They have admitted that, smaller trials of lower quality have exhibited more beneficial effect, in both the groups, but they have discarded the

majority of trials on the ground of low quality methodology and have been tempted to reach at a conclusion by comparing the outcomes of 08 Homoeopathy and 06 Allopathy trials. Will the results of these 8 trials hold good when more than one thousand trials have been carried out and published in reputed journals which vindicate the efficacy of Homoeopathy?

2. Randomised Control Trials: Are these applicable to Homoeopathy?

The research workers claim to have studied the Placebo controlled trials of higher methodological quality only, from both the systems. But, now the basic question arises, whether the Randomized Controlled Trials are fitting research tools to study the effects of homoeopathic medicines, and are they tailored to the doctrines of Homoeopathy? Definitely NOT. We know, Homoeopathy is tuned to the problems of the PATIENT, not of the DISEASE per se. Contrary to the approach of Disease Diagnosis in the parlance of Conventional Medicine, Homoeopathy advocates Person Diagnosis. Considering that the whole individual is a patient, not merely his organs or systems, a homoeopathic physician treats the patient as a whole. Individualisation being the hallmark of homoeopathy, a particular medicine may be needed to treat a number of disease conditions whereas a number of patients suffering from the same disease may require different medicines in view of their varying physical/mental characteristics and response to environmental stimuli. The selection of medicine, its potency, dosage and repetition etc. are tailored to each individual patient. Hence, it is natural that, during a trial, there will be a number of variables. Thus randomization of patients, placebo-controlled trials and administering pre-determined medicines or selecting one or a very few medicines to different patients, randomly, do not fit to the tenets of Homoeopathy.

On the contrary, a single drug is usually tested, during research, in Conventional Medicine, against a

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particular disease condition. As such, Randomised Control Trials are the most suitable modalities for research in Allopathy. The definition of trials of higher methodological quality may be valid for the researchers in Conventional Medicine but has least relevance in the realm of research in Homoeopathy. It proves that the researchers have adopted an inappropriate tool to judge the efficacy of Homoeopathy vis-à-vis Allopathy.

3. Why to compare the Incomparables?

Allopathy and Homoeopathy are two distinct therapies which conspicuously differ in many areas – their origin, concept, philosophy, patient approach and treatment modalities and so also in the research settings. The research in Conventional Medicine does not take notice of the most of the cardinal features of Homoeopathy; the most important being the process of individualizing the patient, matching his characteristic features with those of the medicines and choosing the most similar medicine (similimum) for the patient. Thus, all the patients enrolled in a trial, in particular disease condition, may need different medicines/potencies/dosage, in their first and subsequent prescriptions. Thus, variables are many in homoeopathic research and this poses difficulty to randomize and select the suitable controls. Furthermore, the most problematic area in Homoeopathy is double blind study. Since the physician himself has to interrogate the patient, elicit his symptomatology, analyse and evaluate them to select the most appropriate homoeopathic remedy for him, how can the double blind method be applicable in such trials? Of course, the double blind placebo controlled techniques can be adopted in in-vitro trials, intended to study the effects of a single drug. But, trying a single drug in a particular disease is not strictly homoeopathic. On the other hand, since a single medicine is usually tried against a specific disease, in conventional studies, double blind placebo control and randomizations are easy to follow. With such conflicting and divergent concepts and approaches existing between these two therapies, what led the researchers to compare those, using the same parameters and tools is not known.

The authors have included in their analysis, the results of the study carried out by R.G. Gibson et al.² in rheumatoid arthritis wherein, although both the groups were allowed to continue the conventional therapies; the first group was administered placebo, while the second group, homoeopathic medicines. The results of the second group were more encouraging in the sense that the complaints (pain, stiffness, etc.) of the patients were reduced, dropouts were less and adverse effects of medicines were

less too. It is not known whether the researchers have included this study in their final list of 08 homoeopathic trials of the so called 'high quality'; probably NOT.

4. Results of the first comparative prospective study favouring Homoeopathy ignored:

It is unfortunate that the researchers have not considered the first prospective study³ carried out by Claudia Witt et al, where the objective was to evaluate the effectiveness of homoeopathy versus conventional treatment in routine care. The following excerpts from the observations and conclusions drawn by the authors, speak in favour of Homoeopathy:

- "... the assessments by both adult and child patients (evaluated separately) were more favourable 6 or 12 months after diagnosis and initiation of homoeopathic treatment than for conventional treatment. A similar apparent superiority of homoeopathic treatment was also seen in the physicians' assessments for the children, although not for the adults."
- "The quality of life analysis of the component scales revealed statistically significant differences, again in favour of homoeopathic approach".
- "The prospective observational studies on homoeopathy have shown improvements in quality of life."
- "From a community perspective, the differences observed in the present study appear to support the use of homoeopathic treatment."
- "Patients seeking homoeopathic treatment had better outcome over all compared with the patients on conventional treatment, whereas total costs in both groups were similar."

5. Were the trials done under similar circumstances?

NO. It is gathered that 08 Homoeopathy and 06 Allopathy trials considered by the research workers trials of higher quality are related to Respiratory Tract Infections. But, it is not known whether the diagnoses of Respiratory tract infections, in both the trials, were same or not. Moreover, these studies must have been done, in the past, by different teams of experts, with different objectives under different circumstances, such as: settings laboratories, techniques/methodology, variables, parameters, outcome assessments, methods of selecting medicines and dosage and investigations carried out.

Thus, with such magnitude of variations between Homoeopathy & Allopathy trials, is it rational to compare their efficacy and come to a wrong conclusion?

6. Were the Homoeopathic trials classical?

NOT ALL; a few only. Homoeopathic interventions were classified as:

- Classical Homoeopathy i.e., comprehensive homoeopathic history taking followed by the prescription of a single individualized remedy, possibly with subsequent change of remedy in response to changing symptoms.
- Clinical Homoeopathy, where all patients received a single, identical remedy and no comprehensive homoeopathic history was taken.
- Complex Homoeopathy, when the prescription included a mixture of several different medicines.
- Isopathy, if the agent that was judged to be the cause of the disorder was used in different form (e.g., pollen in pollinosis).

The number of trials, included by the authors, in different homoeopathic interventions are as under:-

• Classical Homoeopathy	: 18 (16%)
• Clinical Homoeopathy	: 48 (44%)
• Complex Homoeopathy	: 35 (32%)
• Isopathy	: 08 (7%)

Out of the above four homoeopathic interventions, Classical Homoeopathy alone is true homoeopathy whereas the other three do not come under its realm. A single medicine administered to all patients suffering from the same disease (Clinical Homoeopathy) is just like Allopathy. A combination of medicines (Complex Homoeopathy), unless proved as such, given at a time, loses its homoeopathicity. Similarly, the patients suffering from pollinosis, although caused from same pollen, may exhibit different symptoms in different patients and may not be cured by using the potentised pollen (Isopathy). These three interventions might have been adopted by some research scholars to demonstrate and prove that homoeopathic medicines are not placebos; that they have actions both in-vitro and in-vivo. Thus, should the results of these studies which are based on non-homoeopathic interventions, be analysed to prove that the homoeopathic treatment is a failure?

Secondly, they have taken only 18 (16%) trials where interventions were employed following Classical Homoeopathy as against 92 (84%) trials involving

non-homoeopathic interventions. And, it is not known out of the eight Homoeopathy trials, they have considered in the final stage, how many belong to Classical Homoeopathy. Are they justified to form an adverse opinion on Homoeopathy on the basis of the result of a meager percentage of trials (16%)?

7. Homoeopathy is not Placebo effect

While comparing the efficacy of homoeopathy vis-a-vis Allopathy trials, in an erroneous way, by adopting wrong interventions, the research scholars out of their own wisdom have injudiciously come to a highly malicious conclusion that their finding is compatible with the notion that the clinical effects of homoeopathy are placebo effects. A number of research studies have been undertaken by the scientists of modern medicine, pharmacology, epidemiology, social & preventive medicine, statistics and Homoeopathy and the positive results in favour of Homoeopathic medicines have been published in internationally reputed journals like British Medical Journal^{4,50,73}, European Journal of Pharmacology^{5,40}, Paediatrics⁶, Complementary Therapies in Medicine^{7,38,63,72,75}, International Journal of Veterinary Homoeopathy^{8,42,71}, Inflammation Research^{9,10}, Human Toxicology^{11,12,34}, British Homoeopathic Journal (now Homeopathy)^{13,14,15,21,23,24,30,31,32,35,44,51,52,53,55,68,77}, Indian Journal of Homoeopathic Medicine¹⁶, Journal of American Institute of Homoeopathy^{17,18,57,60,67}, Journal of Alternative and Complementary Medicine¹⁹, Nature²⁰, Berlin Journal of Research in Homoeopathy^{22,70}, Bio-medical Therapy^{25,37,47,56}, Perspectives in cytology and genetics^{26,39,64,65,66}, Homoeopathy^{27,28,29}, Comm. Br. Homoeopath Research Group³³, New Scientists³⁶, Alternative Therapeutic Health Medicine⁴¹, Hahnemann Gleanings⁴³, Vet Hum Toxicol^{45,46}, British Journal of Clinical Pharmacology^{48,2,74}, Immunopharmacol Immunotoxicol⁴⁹, Complementary Health Practitioners Review⁵⁴, Indian Phytopathology⁶², Homoeopathic update⁶⁹, Homoeopathic International⁷⁶ etc.

The medical journal Lancet which has published the latest controversial article on Homoeopathy, had earlier published three articles^{78,79,80} (including two meta-analyses) which provide inputs in favour of Homoeopathy. But what is most unfortunate, is the role played by the Editorial Board of the famous Journal. In earlier occasions, when the published articles were in favour of Homoeopathy, they preferred to remain quiet. But, while publishing the meta-analysis of A. Shang et al which advocates the superiority of allopathy over homoeopathy, the Editorial Board was enthusiastic to further defame homoeopathy through their scathing attack, under

the caption 'The end of homoeopathy'. Furthermore, to make the malicious propaganda more vivacious, they have published an excerpt from the editorial comment, on the cover page of the journal as "Now doctors need to be bold and honest with their patients about homoeopathic lack of benefit".

It is needless to harp on the issue that effects of homoeopathic medicines are not placebo response. These medicines act and act favourably, as evident from some of the following research reports of the highest scientific standards published in the medical journals of international repute, during the last two decades.

1. Three Orthodox Scientists J.Klijnen et al. published their review of homoeopathic clinical research with the conclusion, "The amount of positive evidence even among the best studies came as a surprise to us. Based on this evidence, we would readily accept that homoeopathy can be efficacious, if only the mechanism of action were more plausible"⁸¹
2. Two more statistical meta-analyses by Boissel et al.⁸² and Linde et al.⁷⁹ concluded that the clinical effects of homoeopathy cannot be ascribed to placebo effects alone. Using a rather unusual technique of combining p-values of the selected trials to answer the question: "Does homoeopathy have an effect?", Boissel concluded that it does, with a probability below 0.001. Adopting a more common meta-analytical technique of determining the odds-ratio for each trial and then combining these, Linde et al. observed that the combined odds-ratio for studies was 2.45 in favour of Homoeopathy, which means that homoeopathic medicines had a 2.45 times greater effect than placebo.
3. The final report "COST Action B4-Unconventional Medicine' (1999) and its supplement submitted to the European Commission concerning use and development of Complementary and Alternative Medicine, states that the available clinical trial evidence suggests that homoeopathy has an effect greater than placebo⁸³.
4. M.Taylor et al. at the University of Glasgow while performing a meta-analysis of all the data from four studies on allergic conditions, found the results so significant ($P=0.0004$) that they concluded: either homoeopathic medicines work or controlled clinical trials do not. Since modern science is based on controlled clinical trials, it is more likely a conclusion that the homoeopathic medicines are effective⁸⁴.
5. D.Reiley et al. have published an outcomes study with the observation that homoeopathy was as at least as effective and safe as conventional medical care for the treatment of respiratory tract infections including allergies and ear pain; adverse effects were significantly lower in the group treated with homoeopathy and patient satisfaction was high in both groups but significantly higher in the group treated with homoeopathy⁸⁵.
6. M.Anelli et al. published another outcomes study in Homoeopathy, which was a pilot survey of 1025 patients receiving homoeopathic treatment in six European Countries which stated that patient satisfaction was high, the changes of quality of life were positive and satisfaction with consultation was high⁸⁶.
7. As a part of fundamental research on homoeopathy to validate the similia principle and to study the effects of ultra high dilutions in various biological systems, efforts have been made to obtain evidence in animals, or in isolated organ systems or cells in vitro. The most significant study was conducted by R.Van Wijk et al. which showed that self recovery on the cellular level is stimulated by small doses of threatening conditions applied according to the similia principle⁸⁷.
8. About 90 researchers from the field of physics, biology and immunology from different Universities and Institutes in Europe have formed an International Group of Researchers studying the effects of Homoeopathic Ultra High dilutions and have studied the effects in the areas like – protective effects of serially agitated high dilutions of heavy metals (Mercury, Cadmium, Cisplatinium) on the mortality of poisoned mice; effects of serially agitated high dilutions of acetylsalicylic acid on bleeding time, platelet aggregation and co-agulation; of thyroxine on activity of frogs; of bursin/interleukin3/thymulin on hormonal and cellular immune responses etc.
9. A multi-centric trial in four independent laboratories in four different European countries in 1999 showed that higher dilutions of histamine (150 – 190) inhibit anti-Ig E induced basophil degranulation. In 3 labs., a statistically significant inhibition was found whereas in the fourth lab., the results approached significance⁸⁸.

This study was repeated by V.Brown et al. with an automated counting protocol (to avoid human bias), which confirmed the earlier findings that histamine solutions, both at pharmacological concentrations

and higher dilutions led to statistically inhibition of basophil activation by anti-Ig E⁸⁹.

8. Indian studies counter Placebo hypothesis:

The Central Council for Research in Homoeopathy (CCRH), an autonomous organization of Department of AYUSH, under the Ministry of Health & Family Welfare, Govt. of India has undertaken a number of studies (more of long-term observational studies) which have concluded with a positive response of marked to moderate improvement in different clinical conditions. While many of these trials are continuing, a Randomized Double Blind Placebo Controlled Trial of Homoeopathy Medicine in HIV infection conducted by the Council showed statistically significant increase in CD4 T cell count in medicine group in comparison to the placebo group⁹⁰.

Proving of Drugs on apparently healthy human volunteers, through double blind placebo controlled technique, have also been carried out by the Council to ascertain the drug effects. The drugs proved in 30CH and 200CH potencies (which do not contain any material residue of the mother substance) have shown their effects distinct from the placebos and reproduced on re-proving of some of these drugs⁹¹.

Not only the clinical researches conducted by CCRH and other reputed institutions of India like University of Kalyani, Viswa Bharati University, All India Institute of Medical Sciences, Central Drug Research Institute, Gauranga Clinic & Centre for Homoeopathic Research (Lucknow), involving the scientists of homoeopathic and allied sciences, vociferously speak in favour of homoeopathy, but also the placebo controlled studies done on animal/plant models and in vitro trials on viruses & fungi further reiterate its scientific background^{92,93,94}.

9. Clinical Effects of Homoeopathy not Unspecific Placebo or Context Effects

The researchers have gone to the extent of giving opinion that the hypothesis that the clinical effects of homoeopathy are unspecific placebo or context effects., "We emphasize that our study, and the trials we examined, exclusively addressed the narrow question of whether homoeopathic remedies have specific effects. Context effects can influence the effects of interventions, and the relationship between patient and carer might be an important pathway mediating such effects. Practitioners of homoeopathy can form powerful alliance with their patients, because patients and carers commonly share strong beliefs about the treatment's effectiveness, and other cultural beliefs, which might be both empowering

and restorative." On the basis of their remarks, the reports have been published in the Newspapers all over the world that homoeopathy has an effect only in the mind and has no curative powers. Had the homoeopathic medicines been placebo, how could these cure the animal diseases, inhibit the growth of viruses and fungi in laboratory set ups, alter the physiological activities in animal models where mind has no role to play? Besides, successful treatment of tumours, warts, cysts, stones and other organic lesions under homoeopathic care, rule out the role of 'placebo' or 'mind' or 'context effects'.

The researchers have admitted the effects of homoeopathic medicines when they say, "Indeed we found that trials of homoeo-pathy tended to be of higher methodological quality than conventional-medicine trials, although most trials of either type of medicine were of low or uncertain quality. In both groups, smaller trials and those of lower quality showed more beneficial treatment effects than larger trials and those of higher quality." But, they discard these results under the pretext of smaller trials of lower quality. Moreover, while determining the standards of high quality trials, the researchers should have taken the views of classical homoeopathic experts.

The authors have admitted that "further research is needed to identify the dimensions of methodological quality that are important in different clinical context, different outcomes, and different types of trials". Then, why have they suggested, "... rather than doing further placebo-controlled trials of homoeopathy, future research efforts should focus on the nature of context effects and on the place of homoeopathy in health-care systems." Are they not diverting the attention of the public from the real truth?

10. Why meta-analysis/retrospective study?

The research workers have done the meta-analysis of the research trials, done by others in the past, in the fields of Homoeopathy and Conventional Medicine and come to a very harsh and damaging conclusion, which is aimed at jeopardizing the fabric of homoeopathy. If they were at all interested to verify the efficacy of homoeopathy in an unprejudiced way, instead of resorting to such retrospective studies, they could have gone for prospective studies, involving homoeopathic experts who believe in and treat as per Classical Homoeopathy, formulating the protocols/study designs/methodology, in conformity with the doctrines of homoeopathy, particularly for the in-vivo studies and undertaking in vitro studies involving experts of the concerned areas, by adopting double blind placebo controlled techniques.

Conclusion

Both the Conventional Medicine and Homoeopathy have significant contributions to the health care delivery system. The merits of one system should not be cited to nullify the benefits of the other.

The highly qualified experts in their respective disciplines, using so called modern research techniques and statistical jargons, have gone beyond the jurisdiction of their expertise to assail Homoeopathy about which they know little. Will now they come forward to undo the damage they have done to Homoeopathy which has always thrived on people's experience, not on the mercy of its critics.

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