

Homoeopathy is not Placebo

The analysis of placebo controlled trials of Homoeopathy and Conventional medicine carried out by Prof. Matthias Egger et al. and published in Lancet 2005: 366:726-752 does not appear to be a valid comparison. The latest technique of meta-analysis has been inappropriately applied to defame Homoeopathy. It has overturned the previous meta-analyses^{1,2} published in the same journal in the years 1994 and 1997 wherein Homoeopathy was proved to be more effective clinically than the placebo. It seems that the authors have begun their work with a bias; while they admit specific effects of Homoeopathic treatment, they found ways to disregard those. Out of numerous homoeopathic trials (110 trials), their primary outcome was based on the comparison of very small samples i.e. 8 trials of Homoeopathy (only acute respiratory infections) versus 6 trials of Conventional medicine randomly picked up for comparison. Rather, the comparison should have been made between the results of homoeopathic and conventional trials conducted simultaneously under identical settings/parameters.

ii. Besides, it is important to note that Randomised Control Trials (RCTs) in Homoeopathic research are not applicable to all chronic diseases in the light of the principles of Homoeopathy wherein selection of 'medicine', 'potency' and 'repetition' are all *individual based than disease specific*³. Since only RCTs have been compared in this study, the observation that "The clinical effects of Homoeopathy are unspecific placebo or context effects" has arisen and is irrelevant.

iii. Moreover, the study has been done on treatment outcome of four entirely diverse methods, viz. Clinical

Homoeopathy (single drug specific to a particular trial) -44%, Complex Homoeopathy (combination of drugs in different potencies) -32%, Classical Homoeopathy (holistic treatment involving physical, mental and other relevant aspects for the selection of remedy) -16% and Isopathy (using an agent which is the cause of disease) -7%. As such, there are only 16 % classical Homoeopathic trials considered in this study as against the 84% non-classical (un-homoeopathic) methods which are contrary to homoeopathic doctrines. To add more to this, there is no satisfactory statistical method available at present to evaluate trials conducted on Classical Homoeopathic principles.

iv. Further, the study is focused upon the assessment of specific effects of homoeopathic remedies. Now it is difficult to comment, without knowing which trials have been taken into consideration and whether specific effects are achievable in the time frame specified in the study.

v. Authors have also addressed the issue of 'publication bias and concluded that results cannot be trusted'. But concluding in such a way shows their bias against Homoeopathy. It is pertinent to mention here that instead of doing meta-analysis/retrospective literature studies of the trials conducted in Homoeopathy and Conventional medicine, a prospective study with the objective of testing the efficacy of Homoeopathic medicine vis-à-vis placebo effect should have been undertaken.

vi. Methodological flaws do exist in many studies and further researches are therefore needed to be carried out after removing those lacunae. Authors themselves have suggested that research is needed to identify dimensions of methodological quality that are important in different clinical contexts, different outcomes and different types of trials. While the authors have acknowledged the methodological weaknesses of

Prof. CHATURBHUJA NAYAK, Director
 Central Council for Research in Homoeopathy,
 61-65, Institutional Area, D Block Janak Puri
 New Delhi- 110018, India
 Email : ccrh@del3.vsnl.net.in
 Phone : 91-11-28525523. Fax : 91-11-28521060

the trials, their opinion that Homoeopathy is like a placebo is unfounded.

2. It is also relevant to mention that several studies/trials⁴⁻²⁶ have been carried out world over, on the efficacy of Homoeopathic treatment and the results thereof have been published in internationally reputed scientific journals including Homoeopathy, in which scientists of other disciplines were also involved who have tested the Homoeopathic medicines on scientific lines to conclude that these are effective. Some of these journals are Nature, British Medical Journal, Complementary Therapies in Medicine, European Journal of Pharmacology, Journal of Nuclear Medicine, & Biophysics, British Journal of Clinical Pharmacology, Journal of Clinical Epidemiology, International Veterinary Research in Homoeopathy, Journal of Clinical Pharmacology & Therapeutics, Dermatology, Paediatrics, British Journal of Homoeopathy, American Journal of Homoeopathy, Berlin Journal of Research in Homoeopathy, Homint etc. Then, could the results of such systematic studies be relegated to the domain of placebo effect?

3. In India too some of the Internationally reputed institutes like Central Drug Research Institute; National Potato Research Institute; University of Kalyani and Viswa Bharati University; All India Institute of Medical Sciences etc. have also carried out a number of in-vitro studies²⁷⁻²⁹, plant^{30,31,32} and animal experiments^{33,34} etc. which exhibited positive effects of homoeopathic medicines which were found absent with control (placebo) groups.

4. The Central Council for Research in Homoeopathy (CCRH), an autonomous organization under the Ministry of Health & Family Welfare, Govt. of India has undertaken a number of clinical studies as well as proving of drugs, both involving human subjects.

i. Many of the Clinical studies (more of long term observational studies) have concluded with a positive response of marked to moderate improvement in different clinical conditions. While many of these studies are continuing, a Randomized

Double Blind Placebo Controlled Trial of Homoeopathy Medicine in HIV infection³⁵ conducted by the Council showed statistically significant increase in CD4 T cell count in medicine group in comparison to the placebo group. The research findings were published in the British Homoeopathic Journal (1999) Vol.88, 49-57.

ii. 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 reproving³⁶ of some of these drugs.

To summarise, the meta-analysis published in the Lancet is not valid for the reasons given below:

1. Meta-analysis is wrongly conducted on such trials which are not of classical Homoeopathy .
2. Improper justification for comparing Homoeopathy trials with Conventional medicine trials to prove that Homoeopathic medicine has Placebo-effect,
3. Absence of Homoeopathy experts in the study team and the Editorial Board of the Journal, Lancet,
4. Justification of short listing of high quality trials from 21 to 8 does not exist in the study,
5. Isopathy, Clinical and Complex Homoeopathy trials are not actually Homoeopathic, therefore wrongly compared in the study,
6. Failure to detect presence of material in homoeopathic potency does not make it Placebo as evident from in-vitro, animal and plant studies.
7. It is wrong to assume that any effects of Homoeopathy must be non-specific placebo effects.

Will now the authors of the article published in Lancet concede to the truth that Homoeopathy is not a Placebo effect?

References:

1. David Reilly et al. "Is Evidence of Homoeopathy reproducible" 1994 - Lancet Vol.344 No.8937, 1601-1606.
2. Klaus Linde et al. "Are the clinical effects of Homoeopathy placebo effects? A meta analysis of placebo control trials" 1997 - Lancet Vol.350 834-843.
3. Donna F. Stroup et al., "Meta-analysis of Observational studies in Epidemiology- A proposal for Reporting" JAMA, April 19, 2000- Vol. 283, No. 15
4. Klienjen et al. . " Clinical trials of Homoeopathy", British Medical Journal, Vol. 302, Feb. 1991, 316-323
5. Abbot NC. Evidence of effect of homoeopathic potencies on leucocyte migration in vitro. FACT, 1996, Dec; 1(1): 12-13.
6. G. Gibson et. Al. "Homoeopathic therapy in Rheumatoid Arthritis- Evaluation of Double Blind Clinical Therapeutic Trial" - British Journal of Clinical Pharmacology 1980 Vol.9.
7. Jennifer Jacobs " Treatment of Acute Childhood diarrhoea with Homoeopathic Medicine - A randomized clinical trial in Nicaragua- Paediatrics Vol. 93 No.5 May 1994 719-725. (Statistically significant decrease in the duration of diarrhoea in the treatment group).
8. Anderson D Edwards AJ Fisher P Lovell DP. Statistical analysis of adaptive response in sister chromatoid exchanges in human lymphocytes after treatment with very low and extremely low doses of N-methyl-N-nitro-Nitrosoguanidine using a study design to control variability. Br. Homoeopath J, 1999, Jan;88(1): 7-16.
9. Badulici S Chirulescu Z Chirila M Rosca A. Treatment with Zincum metallicum CH5 in patients with liver cirrhosis. Biomedical Therapy, 1999, 17(1): 7-20.
10. Baker RD Smith CW. Comment on the paper, 'Growth of yeast cultures as in vitro model for investigating homoeopathic remedies' British Homoeopathic Journal, 1985, Apr;74(2):93-6.
11. Bascands JL Cabos-Boutot C Manual Y Girolami JP. Pretreatment with low doses of Cadmium (Cd) protects rat renal mesangial cells against the direct toxic effects of Cadmium. Journal of OMH, 1990, Dec;3(3):9-13.
12. Baumans v Oude Luttikhuis WMT Bol C Visser JJ Beynen AC. Cholesterol metabolism in cholesterol-fed rabbits treated with Chelidonium3x(=D3) International Journal of Veterinary Homoeopathy, 1987, Apr;2(1):8-12.
13. Begum R Koshy R Sengupta A. Effect of homoeopathic drugs plumbum and opium on experimentally induced lead toxicity in rats. Indian Journal Experimental Biology 1994, Mar;32(3):192-195.
14. Belon P Cumps J Ennis M Mannaioni PF Sainte-Laudy J Roberfroid M Wiegant FAC. Inhibition of human basophil degranulation by successive histamine dilutions: results of a European multi-centre trial. Inflammation Research, 1999, 48(1) s17-s18.
15. Davenas E Poitevin B Benveniste, J. Effect on Mouse peritoneal macrophages of orally administered very high dilutions of Silica, European Journal of Pharmacology, 1987, March 31; 135(3): 313-319
16. Belougne-Malfatti E Ag7uejouf O Doutremepuich F Belon P Doutremepuich C. Combination of two doses of acetyl acid: experimental study of arterial thrombosis. Thrombosis Research, 1998,
17. Brown V Ennis M. Flow-cytometric analysis of basophil activation; inhibition by histamine at conventional and homeopathic concentrations. Inflammation Research , 2001, Apr;50 Suppl 2:S47-8.
18. Calabrese EJ McCarthy ME Kenyon E. The occurrence of chemically induced hormesis. Health Physics, 1987, May(5):531-541.
19. Cazin JC Cazin M Gaborit JL Boiron J Belon P Cherruault Y Papapanayotour C. A study of the effect of decimal and centesimal dilutions of arsenic on the retention and mobilization of arsenic in the rat. Human Toxicology, 1987, Jul;6(4):315-320,
20. Dutta S Mallick P Khuda Bukhsh AR. Efficacy of a potentized homoeopathic drug (Arsenicum Album-30) in reducing genotoxic effects produced by arsenic trioxide in mice II. Comparative efficacy of an antibiotic, actinomycin D alone and in combination with either of two microdoses. Complementary Therapies in Medicine, 1999, Sep;7(3):156-63
21. Daurat V Dorfman P Bastide M. Immunomodulatory activity of low doses of interferon "a,b" in mice. Biomedical Pharmacotherapy, 1988.; 42:197-206.
22. Fisher P House I Belon P Turner P. The influence of Homeopathic Remedy plumbum metallicum on the excretion kinetics of lead in rats., Human Toxicology, 1987, Jul; 6(4) : 321-324
23. Hadji L Arnoux, B Benvinist J Effect of dilute histamine on coronary flow of isolated guinea-pig heart. Inhibition by magnetic field. FASEB J, 1991 ; 5(1) : A1583
24. Jacobson JS Workman SB Kronenberg F. Research on complementary/alternative medicine for patients with breast cancer: a review of the biomedical literature. Journal of Clinical Oncology, 2000.; 18(3):668-683.
25. Jerman I Berden M Skaja M. Instrumental measurements of different homeopathic dilutions of potassium iodide in water. Acupuncture Electrotherapy Research, 1999.;24:29-44.
26. Khanna KK , Chandra S. Control of tomato fruit rot caused by fusarium rooseum with homoeopathic drugs. Indian Phytopathology, 1976.;29:269-272,
27. Hari Singh et al. "Effect of Homoeopathic Drugs in Controlling of Multiplication of Hepatitis -B Virus" Central Council Research in Homoeopathy. Quarterly Bulletin Vol. 11(1&2) 1989.
28. G. Gupta , B.P. Singh, "Homoeopathy Drugs as Inhibitors of Tobacco Mosaic Virus" - Indian Journal of Homoeopathy 1980 Oct.
29. B. Chandra, Girish Gupta "In-vitro inhibitory effects of Homoeopathic drugs against candida albicans" Biological Memoirs Vol.29, Dec. 2003.
30. Khurana SMP, Effects of Homoeopathic drugs on plant viruses. Planta Medicine ,20,pp.142-146,
31. Khanna KK & S Chandra, "Effects of some Homoeopathic drugs on the spore germination of four isolates of Alternaria Alternata" Indian Phytopathology, 29,pp.195-197.
32. M. Pandey, A Saxena and R.C. Gupta " Anti-fungal Effects of Homoeopathic Medicines, Madras Agricultural Journal, Vol.74 No.3.
33. E.N. Sundaram et all. - "Screening of homoeopathic drugs for hypoglycaemic activity - an experimental approach" CCRH Quarterly Bulletin Vol.20(1&2) 1998.
34. G. Gupta, L.M. Singh, "Anti-viral efficacy of Homoeopathic Drugs against Animal viruses" - British Homoeopathic Journal. Vol.74, July 1985.
35. D.P. Rastogi et al. "Homoeopathy in HIV Infection: a trial report of double-blind placebo controlled study" British Homoeopathic Journal, April,1999 Vol.88.
36. V.M. Nagpaul et al. - " Tarentula hispanica - a reprovig" British Homoeopathic Journal, April, 1987, Vol.76.

