HOMEOPATHY UPDATE

Until recently, there was no evidence that homeopathic preparations had a specific therapeutic effect. We take a look at the results of new placebo-controlled clinical trials.

Since 1985 we have published several reviews on homeopathy. Following the recent publication of four comparative clinical trials in peer-reviewed scientific journals, we conducted a new literature search (a).

| a- Since 1991 we have searched all publications listed in Current Contents under the key word Homeopathy. We also crossed the key words Homeopathy and Clinical Trials in the following databases: Medline, from January 1990 to July 1995 and Emase from 1992 to January 1995. We limited our search to clinical trials published in international peer reviewed journals, thus excluding the few comparative trials published in non peer-reviewed specialised journals. |

No firm evidence that high dilutions have pharmacodynamic effects.

Proof that a homeopathic dilution has a pharmacodynamic action would not demonstrate its therapeutic activity. However, it is highly unlikely that a drug would have a specific therapeutic effect without a corresponding pharmacodynamic action.

When we last looked at this subject we found no proof of pharmacodynamic activity in the published literature.

Fundamental research: no confirmation that "water has a memory". The laboratory investigations conducted by J. Benveniste since 1985 remain highly controversial. You may recall that in June 1988 Nature published an article apparently showing a biological effect (destaining of basophilic polymorphonuclear cells) of an ultramolecular dilution of sheep
anti-IgE antiserum (the dilution greatly exceeded Avogadro's number, being of the order of $10^{-120} \text{M}$) (1,2). We have found no evidence that these findings have ever been independently confirmed.

J. Benveniste has continued his work but on different experimental models. Basically, he is now studying the possible transmission of biological effects by electromagnetic waves generated by infinitesimal concentrations.

The science writer M. Schiff was so incensed by the disbelief of the scientific community that he wrote a book reporting J. Benveniste's main findings on the electromagnetic transmission of specific biological signals, at the same time delivering a scathing critique of traditional scientific institutions (3).

Appendix 9 of his book (pages 242 to 251) contains correspondence between J. Benveniste and G. Charpak (Nobel physics prizewinner suggesting collaboration between the two. However, in a letter dated January 15, 1995, in a reply to our query, G. Charpak confirmed that J. Benveniste worked for more than a year at the French Ecole de physique et de chimie, but stated that 'Checks carried out in G. Charpak’s laboratory failed to reproduce any effects whatsoever'.

From the evidence we have analysed, we do not feel that there is anything to add to this highly publicised controversy.

**Much pharmacological research, but no independent confirmation.** We have insufficient space to give a detailed review of all pharmacological research carried out in the field of homeopathy. What can be said is that each team working on this subject seems to do so in almost total isolation (4).

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B. Bonavida (Department of Microbiology and Immunology University of California, USA) explored the biological effects of certain molecules capable of modifying the tumoral response of cancer cells.

C. Doutremepuich (Hematology Laboratory Bordeaux Faculty of Pharmacy, France) has studied the influence of dilute aspirin solutions on coagulation. M. Bastide (Immunopharmacology laboratory, Montpellier Faculty of Pharmacy, France) examined the
effects of dilute bursine solutions in chickens. J. Cambar (Renal Physiology and Pathophysiology; Bordeaux Faculty of Pharmacy France) is still studying the effects of highly dilute mercury salts in mice.

Many of these studies have been reported in peer-reviewed journals but none of the data have received independent confirmation.

A review of the literature has underlined the methodological weaknesses of most pharmacological research on homeopathy, and emphasised that most clinical trial results seem to be unreproducible (5). However, the authors concluded that certain phenomena were puzzling and fully warranted further research.


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<tr>
<th>Placebo-controlled clinical trials of homeopathy published from 1990 to early 1995</th>
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<tr>
<td>Prescrire's French edition also includes summaries and discussions of the articles listed below, which are available free on request and duty-free for subscribers.</td>
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<td>5- Gaus W and Wiesenauer M &quot;Wirksamkeitnachweis eines Homöopathikums bei chronischer polyarthritis - Stellungnahme zur kritik und ausblick&quot; Aktuel Rheumatol 1993; 18:159-162.</td>
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<td>7- Sudan BJL &quot;Abrogation of facial seborrhoeic dermatitis with homoeopathic high dilutions of tobacco: a new visible model for Benveniste's theory of &quot;memory of water&quot; Medical Hypotheses 1993; 41: 440-444.</td>
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<td>9- Werk W and Galland F &quot;Helianthus-tuberosus Therapie bei Übergewicht.</td>
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Still no proven specific therapeutic effect of homeopathy.

Clinical observations indicating that homeopathic treatments can be beneficial are regularly published in specialised journals and at conferences on homeopathy. These observations must be taken into account but in no way prove the existence of a specific therapeutic effect. Such proof can only be obtained in placebo-controlled clinical trials.

In 1991, when we last reviewed this subject, there were about a hundred published trials. Several new trials have since appeared (see inset above). Some involved common homeopathic indications such as treatment of warts, prevention of recurrent ENT infections in children, asthma, obesity, pain relief, etc. Other trials tested homeopathy in more unusual circumstances such as the rheumatoid arthritis in patients already receiving several drugs.

Few of these studies followed standard clinical trial methodology to the letter, and very few of the methodologically sound studies were based on the homeopathic principle of "fighting fire with fire".

None of the results conclusively demonstrate that a given homeopathic treatment is any more effective than a placebo administered in the same conditions. For some trials the only way of compensating for methodological weaknesses such as inadequate group sizes and imprecise end points is for other teams to repeat the studies using better designed trials.

In sum there is still no evidence from well-designed and correctly conducted comparative clinical trial that homeopathy has a specific therapeutic effect.

Not always safe.

Little progress has been made in documenting the side effects of homeopathic preparations since 1991, when we published our second update on homeopathy (6). Austrian authors reported adverse reactions in three patients (7) The first, who was recovering from a 'flu like' syndrome, took a homeopathy preparation containing, among other compounds, Quinquina...
bark ans Ipeca in 4 DH (b). After three days he developed pruritis with palmar and plantar oedema followed by erythroderma. The second patient developed a measles-like skin rash after taking a homeopathic mixture containing 15 plants (dilutions not given) in an attempt to lose weight. The third developed anaphylactic shock requiring intensive care after taking homeopathic dilutions of pollens (precise dilutions not given). Rechallenge was positive in all three cases.


b- DH stands for a 10-fold Hahnemannian dilution and CH for a 100-fold Hahnemannian dilution.

These three observations show that homeopathic preparations can induce immunoallergic reactions without having to be injected.

A World Health Organisation bulletin points out that a European directive (applied in the United Kingdom) prohibits non prescription dispensing of homeopathic preparations containing more than one part per 100,000 of mother tincture, and no more than one part per 100 of the lowest dose used in allopathic medicine (sic) in case of medical prescription (8).


We questioned all French regional pharmacovigilance centres and the pharmacovigilance unit of the French drug agency, and obtained unsatisfactory answers (c). In France, a country where homeopathy is very popular, a nationwide survey should be carried out to determine the side effects of such treatments, and the results should be made public.

c- On February 28, 1995 we wrote to all 25 French regional pharmacovigilance centres for details of any side effects notified with homeopathic drugs. 18 centres replied by April 15, 1995. 12 had received no such notifications, 3 had some information; and the remaining 3 answered that we should contact the French drug agency. Dr. Anne Castot, head of pharmacovigilance with the Agency, wrote to us on April 21, 1995, explaining that homeopathic products have only been covered by French pharmacovigilance centres since January 1, 1995.

**Our conclusion in 1996.**

Despite these new results, our conclusion is basically the same as in 1991.

No one should ignore the role of non specific factors in therapeutic efficacy, such as the natural history of a given disease and the placebo effect. Indeed, these factors can be used to therapeutic advantage.
As homeopathic treatments are generally used in conditions with variable outcome or showing spontaneous recovery (hence their placebo-responsiveness), these treatments are widely considered to have an effect in some patients.

However, despite the large number of comparative trials carried out to date there is no evidence that homeopathy is any more effective than placebo therapy given in identical conditions.

Serious adverse effects have been reported with low dilutions (<4CH) given parenterally or orally. However, high dilutions (>5 CH) administered orally or sublingually appear to be entirely safe.

We believe that homeopathic preparations should not be used to treat serious diseases when other drugs are known to be both effective and safe. In addition, regardless of the condition treated, dilution below 5CH (e.g. 3 or 4CH and especially decimal dilutions or mother tinctures) must not only be considered as having no proven efficacy but also as having potential dangers.

Pending further evidence, homeopathy remains a form of placebo therapy.

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