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### ***Clinical Research in Homeopathy***

Homeopathy has been a difficult modality to study using conventional Western methods. The fact that many preparations used theoretically contain no remaining molecules of the original substance has hindered efforts to elucidate a mechanism of action as an active principal cannot be isolated. (You may remember from the May issue that homeopathic remedies are made by serial dilution of substances in solution, using succussion – rapid and forceful shaking of the solution – between each dilution step; if the total dilution factor is greater than Avogadro's number,  $6.022 \times 10^{23}$ , it is considered devoid of any molecules of the original substance. So a 12c potency which means a 1:100 dilution done 12 times, with a total dilution factor of  $10^{24}$ , is affecting the patient by non-molecular means.\* Succussion is considered the key to this action.) And the fact that proper remedy selection must be tailored to the individual patient rather than to the named disease has made the typical double-blind controlled study a difficult prospect. Despite presenting some unique demands, homeopathic research can and has been done with positive results when study design accommodates homeopathic methodology.

In 1991, a Dutch group (Kleijnen et al.) performed a meta-analysis of clinical studies spanning 25 years and covering 107 controlled human medical trials (not comprehensive of all studies conducted in that time). Every trial was given a score based on rigid assessment criteria (quality of the description of patient characteristics, number of patients in the study, type of randomization implemented, clarity of method description, extent of double-blindness, and quality of the description of results). Of the 22 publications judged to be of good quality (scores  $>55/100$ ), 15 showed positive results with significant differences between treated and untreated (or placebo) patients. These studies included treatment of respiratory and other infections, diseases of the digestive system, hay fever, rheumatologic disease, mental/psychological problems, and other ailments including post-op recovery after abdominal surgery. Of the 105 total studies that could be interpreted, 77% showed positive results.

When looking at individual trials, it becomes obvious that study design greatly affects outcome; studies that permit individual prescribing using proper homeopathic method (remedy selection based on the unique characteristics of each patient's symptom portrait, personality, body type, etc.) rather than using one remedy for all patients based on the named disease, show decidedly better results. In 1983 a study was conducted on patients with osteoarthritis (Shiple et al., score 50/100); patients were divided into three groups, one of which received homeopathic *Rhus tox* 6x (1:10 dilution done 6 times), another fenoprofen, and the third placebo. Only the group on fenoprofen showed significant reduction in symptoms. By contrast, a 1989 study on primary fibromyalgia (Fisher et al., score 45/100) used *Rhus tox* 6c (1:100 dilution done 6 times) but only patients for whom proper homeopathic prescribing suggested its use were included in the study, which was conducted double-blind versus placebo with a cross-over design; after entry into the trial there was no contact between homeopath and patient. The results were positive in favor of *Rhus tox* with significantly reduced pain. Another option in study design is to allow patients of all homeopathic types to enter the study (each of course having the same Western diagnosis), and to give each one his or her own individualized remedy. A study in patients suffering from migraine headaches (Brigo, 1987; Brigo and Serpelloni, 1991; score 68/100) included just over 100 participants. Each patient received a classical homeopathic interview and individualized remedy selection; 60 patients were then chosen whose remedy match

appeared to be the most accurate. Then based on randomized double-blind technique, 30 were given their respective remedy (30c potency) and 30 placebo. Patients periodically filled in a questionnaire on the frequency, intensity and characteristics of their pain symptoms. Treatment lasted for a few months, and results showed significant improvement in the group receiving their individualized remedies.

Acute ailments tend to fare better in same-remedy studies as homeopathic selection is less dependent on individual patient characteristics in such cases; remedies chosen based simply on the typical symptoms of the acute presentation can be successful. A 1987 double-blind study using homeopathy in preparation for childbirth (Dorfman et al., score 80/100) with a combination of five remedies (*Caulophyllum*, *Arnica*, *Actea racemosa*, *Pulsatilla*, and *Gelsemium* at the 5c potency) given twice daily throughout the ninth month of pregnancy showed a significantly reduced duration of labor (5.1 hours versus 8.5 hours,  $p < 0.001$ ) and reduced percentage of dystocia (11.3% versus 40%,  $p < 0.01$ ). This study also demonstrated the ability to use homeopathic remedies prophylactically. Another study (Amodeo et al., 1988) used *Arnica* 5c for patients subjected to prolonged venous perfusion in order to prevent/treat phlebitis. The double-blind, placebo-controlled trial showed that *Arnica* reduced pain and inflammation, and the formation of hematomas; Doppler flowmetry also showed an improvement in blood flow for the patients receiving *Arnica*. In practice though, if a patient's acute condition leads to long-term symptoms, or if the acute presentation is part of a chronic disease process, then individual prescribing is usually required.

Studies in isolated organs and in vitro cells are still quite preliminary (the majority being conducted in Europe), testing the effects of various simple dilutions and homeopathic succussed preparations in an effort to elucidate possible mechanisms of action, or at least patterns of behavior. As far as efficacy is concerned in the laboratory setting, a 1994 review of 106 laboratory studies (Linde et al.) – 82 in animal models, 14 in plants, 6 in isolated organs, and 5 in cell cultures – revealed primarily positive results (including the 30% that obtained scores better than 50/100). The authors note that few of the research protocols have been repeated by independent teams. Methodology and reproducibility have been the major stumbling blocks, primarily due to the lack of any real idea of how homeopathic remedies work (especially those which theoretically contain no molecules of the parent substance – necessitating a non-molecular explanation and therefore non-molecular testing paradigms). So far, studies suggest that the reaction of tissues and cells to low dilutions is often the opposite of their reaction to homeopathic high dilutions (i.e. the former producing toxic effects and the latter protective effects), supporting the homeopathic principle of similars – the idea that a homeopathic remedy will tend to heal a constellation of symptoms in the ill patient that is similar to those produced by the parent substance when taken by healthy test subjects. This effect is more pronounced in the laboratory setting when the homeopathic high dilution is used on tissues and cells that have been sensitized by disease. For example, the plant *Phytolacca* contains a mitogenic glycoprotein which can induce the lymphoblastic transformation of B lymphocytes in culture; when tested in homeopathic form (5c, 7c, and 15c potencies) it had no effect on resting lymphocytes, but did inhibit mitosis of lymphocytes stimulated with phytohemagglutinin (28-73% inhibition) with maximum effect by the 15c potency in one study, and by the 7c potency in another.

There is certainly ample precedent for using medications whose mechanism of action is unclear, but for homeopathy this handicap has been compounded by the lack of a familiar molecular paradigm. This should not, however, preclude its appropriate use since it has shown benefit for human and animal patients with a high margin of safety. For more information on homeopathic research please see *The Emerging Science of Homeopathy; Complexity, Biodynamics, and Nanopharmacology (revised edition)* by Paolo Bellavite MD and Andrea Signorini MD (North Atlantic Books, 2002).

\*Quantum physics is beyond the scope of this article (and its author) but for those interested please see the double

entanglement theory of homeopathic action as one possible explanation for its effects: *Entanglement Model of Homeopathy as an Example of Generalized Entanglement Predicted by Weak Quantum Theory*, by H. Walach, Samueli Institute; *Forsch Komplementärmed Klass Naturheilkd* 2003; 10:192-200. Quantum mechanics, and specifically weak quantum theory, predicts entanglement/correlatedness within quantum systems. Homeopathy uses two instances of entanglement: one between the remedy and its original substance, and one between the similar symptom portraits of the original substance and the patient.