

NARRATIVE REVIEW

HOMEOPATHY IN CANCER CARE

Moshe Frenkel, MD

Homeopathy is a controversial system of care that is practiced extensively in Europe, Asia, and South America primarily for functional and minor ailments. In this review, published studies on homeopathic remedies and cancer were examined. Data were obtained from multiple research disciplines, ranging from basic science to scientifically valid animal and clinical studies. The data from a few laboratory experiments in cancer models show some beneficial effect of homeopathic remedies on selected cancer cell lines. However, in the clinical arena, this effect is

not clear. Several published outcome studies and some randomized controlled trials have shown that there may be a role for homeopathy in symptom relief and improving quality of life in patients touched by cancer. Such effects have not been demonstrated unequivocally, and specific antitumor effects have not been shown in any controlled clinical research to date, which raises the need for further clinical trials to investigate the use of homeopathy in cancer care. (*Altern Ther Health Med*. 2010;16(3):12-16.)

Moshe Frenkel, MD, is an associate professor at the University of Texas, Houston, and former medical director of the Integrative Medicine Program, The University of Texas MD Anderson Cancer Center, Houston.

*Corresponding author: Moshe Frenkel, MD
E-mail: frenkelm@netvision.net.il*

Homeopathy is a form of health care that is widely practiced worldwide and is one of the main complementary and alternative medicine (CAM) treatments commonly used by patients in Europe, India, Israel, and Latin America.¹⁻⁵

Even though sales of homeopathic medicines in the United States grew at an annual rate of 20% to 25% during the 1990s,³ this complementary method of care did not gain the same popularity as it did in Europe, Asia, and South America, and currently only 1.8 % of CAM users in the United States utilize it.⁶ Despite homeopathy's low popularity, homeopathic medicines in the United States are regulated by the US Food and Drug Administration following the Homeopathic Pharmacopoeia of the United States (HPUS) that was established in 1897 and is still updated regularly. According to the HPUS, consumers can buy homeopathic substances without a prescription for self-limiting diseases that are amenable to self-diagnosis as long as the medicines do not contain toxic substances.⁷ Most authorities assume that homeopathic drugs are safe as long as conventional medical care is not delayed.^{3,7}

HOMEOPATHY AT THE CENTER OF CONTROVERSY

Homeopathy is a controversial method based on the "principle of similars," whereby highly diluted preparations of substances that can cause disease-like symptoms in healthy volunteers are used to stimulate healing in patients who have similar symptoms when ill.^{8,9} Many scientists think that the principles underlying homeopathy violate natural law. They do not accept that it has any

biological effects and consign any positive response to the placebo effect. The dispute centers mainly on the issue of whether high-potency remedies (preparations diluted beyond Avogadro's number) can be effective. The skepticism comes from the understanding that potencies (dilutions) of substances beyond 7C (7 dilutions, each 1:100) do not contain a sufficient number of molecules of the original material to be pharmacologically active.^{10,11}

Some reports suggest that even with high dilutions, there is clinical response that cannot be ignored. The evidence supporting homeopathy has grown in recent years and is supported by some scientific findings in an array of fields.^{6-8,12-15} Authors of a metaanalysis of 89 randomized, placebo-controlled trials of homeopathy concluded that their results were not compatible with a hypothesis that the clinical effects of homeopathy are completely due to placebo.¹⁶

A large prospective multicenter cohort study was recently published, involving 103 homeopathic primary care practices in Germany and Switzerland and 3709 patients. The patients had various conditions, such as allergic rhinitis, headache, atopic dermatitis and multiple recurrent infections in children. The study revealed that disease severity decreased significantly ($P < .001$) between baseline and 2 and 8 years of follow-up. The authors suggested that patients who seek homeopathic treatment are likely to improve considerably. This effect was maintained for as long as 8 years. Because the study was not intended to prove cause and effect, the authors were unable to conclude if this effect was related to the homeopathic remedies themselves or to the physicians' attitudes and approaches to the patient.¹⁷

HOMEOPATHY AND CANCER

People use homeopathy for a range of health concerns, from wellness and prevention to the treatment of diseases and conditions such as diarrhea,¹² attention deficit disorder,¹³ allergies,¹⁴ depression,¹⁵ and others.¹⁸ But the question that comes to mind is whether this treatment has any place in more serious situations and life-threatening disorders, such as cancer. It is well known that

over the past 2 decades, the use of CAM has been on the rise worldwide, and patients with cancer are increasingly opting to be treated with various CAM therapeutic regimens and at higher rates than the general population.²⁰⁻²⁴

In Europe, homeopathy is popular for common ailments, as well as for cancer care. In fact, a questionnaire-based study showed that homeopathy was one of the eight most popular complementary therapies used by cancer patients in the United Kingdom.²⁵ In France, a recent study in an oncology department revealed that 34% of patients were using complementary medicine and that, among those patients, homeopathy was the most frequently used (42%).⁴ A recent survey at two oncology day hospitals in Italy found that 17% of patients used CAM, with herbal medicine and homeopathy the most commonly used forms.⁵

A large descriptive survey of 956 cancer patients in 14 European countries revealed that 35.9% of cancer patients were using some form of CAM (range among countries, 14.8% to 73.1%). Homeopathy was the most commonly used CAM therapy in Belgium and in the top five in six other countries (Turkey, Czech Republic, Sweden, Italy, Spain, and Greece). In the remaining seven countries, it was still highly used but followed the use of herbal remedies.²⁶

Even with the popular use of these remedies in cancer care in Europe, it is still unclear whether homeopathy has any clinical effect, and until recently, homeopathy has not received attention as a possible option of care. A 2008 clinical report from India on 14 patients treated apparently effectively with homeopathic remedies as part of a unique National Cancer Institute (NCI) program drew the conclusion that homeopathy might have effects on cancer care.²⁷ Those were preliminary findings that drew attention to the issue of homeopathy in cancer care, but it still remains to be proven in properly designed clinical trials. This unique NCI program is better known as “The Best Case Series” (BCS).

NCI Best Case Series

The safety and efficacy of many CAM approaches have not been well studied, especially in the field of cancer care. Because of this scarcity of knowledge, the NCI has developed a program that allows CAM practitioners to present their data for evaluation and further research toward rigorous scientific validation. In the past 10 years, the NCI's BCS program has invited CAM practitioners from all over the world to submit retrospective data on patients that document significant tumor reduction in response to alternative modalities of cancer treatment. Each case has been reviewed against the same rigorous standards of evidence that are acceptable for novel conventional cancer therapies. The NCI-BCS program offers practitioners treating cancer patients expert assistance in identifying and compiling persuasive case studies, as well as the opportunity to have their data evaluated at the National Institutes of Health.²⁸

In 1999, the NCI-BCS program evaluated the cancer treatment protocol developed at the P. Banerji Homeopathic Research Foundation (PBHRF) in Kolkata, India. The “Banerji Protocol” constitutes a new method of using ultradiluted natural substances

classically used in homeopathic medicines through prescribing specific remedies for specific diseases. As documented by this clinic, a group of 21888 patients with malignant tumors were monitored at PBHRF between 1990 and 2005. This group of patients used the Banerji Protocol without being subjected to any additional method of conventional care. Of these, 941 patients had breast cancer. The clinic's physicians reported that in 19% of the cases, the malignant tumors completely regressed, and in another 21% of cases, the tumors were static or improved after treatment. For patients with static tumors, the follow-up continued for at least 2 years, and for some, follow-up has continued for 10 years. (Personal communication: conversation with Prasanta Banerji at the PBHRF in Kolkata, 2008.)

Ten cases from the PBHRF were presented to the NCI for review by the BCS program. Four cases of lung and esophageal cancer were found to have confirmed pathological diagnoses of cancer and adequate pretreatment and posttreatment medical imaging studies indicating tumor response. The patients treated with the Banerji Protocol approach received only the remedies prescribed at the PBHRF clinic and did not receive any additional conventional treatment such as surgery, radiation, or chemotherapy. The remedies prescribed have been classically used as homeopathic medicines. After rigorous evaluation of the findings, the NCI concluded that there was sufficient evidence of possible efficacy to warrant further research. The Office of Cancer Complementary and Alternative Medicine of the NCI currently is working with researchers at the All India Institute of Medical Sciences to obtain approval for a prospective outcomes monitoring and evaluation study at the PBHRF clinic.

Laboratory Research and Homeopathy

In the field of cancer research, a very limited number of reports have systematically investigated the effects of homeopathic remedies in clinical trials or in experimental model systems. Interestingly, however, the limited existing reports on laboratory research with homeopathic remedies in cancer are quite promising. MacLaughlin and his group evaluated the effect of homeopathic preparations on human prostate cancer growth in an animal model.²⁹ They found that, in vivo, prostate tumor xenograft size was significantly reduced in *Sabal serrulata*-treated mice compared to untreated controls ($P = .012$). Their study revealed a significantly stronger biologic response to homeopathic treatment, as manifested by cell proliferation and tumor growth, than to control treatments. The response in the human prostate cancer was specifically induced by *S serrulata*; other homeopathic remedies had no effect. The researchers concluded that *S serrulata* thus should be further investigated as a specific homeopathic remedy for prostate pathology. A complex homeopathic remedy frequently prescribed by Brazilian physicians for immunodeficiency disorders was tested on sarcoma 180-bearing mice, and significant tumor regression was noted in the treatment group.³⁰ In another study, researchers reported that the homeopathic remedy *Chelidonium* caused amelioration of p-dimethylaminoazobenzene-induced hepatocarcinogenesis in mice.³¹

A few studies from India indicate that homeopathic remedies at ultralow doses may be able to decrease tumor progression. Kumar et al evaluated the inhibitory effects of potentized homeopathic preparations against N-nitrosodiethylamine (NDEA)-induced hepatocellular carcinoma in rats as well as 3-methylcholanthrene-induced sarcomas in mice.³² Administration of the remedies retarded the tumor growth and significantly reduced the elevated marker enzyme levels as revealed by morphological, biochemical, and histopathological evaluation. The specific remedies *Ruta 200C* and phosphorus 1M (1000C) were found to reduce the incidence of 3-methylcholanthrene-induced sarcomas and also increase the lifespan of mice harboring the tumors. Sunila and Kuttan evaluated the effect of *Thuja occidentalis* extract on the inhibition of lung metastasis induced by melanoma cells in C57BL/6 mice.³³ A remarkable reduction in tumor-nodule formation was shown, regardless of whether the drug was given simultaneous with (74.4%) or before (71.5%) tumor cell administration. The level of collagen hydroxyproline (21.13 µg/mg protein) was higher in the lungs of control animals with lung metastases than in the lungs of normal animals (0.98 µg/mg protein); however, the level was significantly reduced in animals treated with the homeopathic remedy *Thuja occidentalis*. The lifespan of the *Thuja*-treated animals also was reported to be significantly increased.

In 2004, Pathak et al from The University of Texas MD Anderson Cancer Center reported that an ultradiluted dose of the homeopathic remedy called *Ruta graveolens*, commonly prescribed as the standard Banerji Protocol therapeutic regimen for brain cancer, selectively induced cell death in glioblastoma multiforme cells, while promoting proliferation in normal peripheral blood lymphocytes.³⁴

In another interesting study that was recently published and conducted at The University of Texas MD Anderson Cancer Center, four ultradiluted remedies (Carcinosin, Phytolacca, Conium, and Thuja) exerted preferential cytotoxic effects against two breast cancer cell lines, causing cell cycle delay/arrest and apoptosis without affecting the normal mammary epithelial cells. These effects were accompanied by altered expression of the cell cycle regulatory proteins, including downregulation of phosphorylated Rb and upregulation of the CDK inhibitor p27, which were likely responsible for the cell cycle delay/arrest as well as induction of the apoptotic cascade that manifested in the activation of caspase 7 and cleavage of PARP in the treated cells. Interestingly, the cytotoxic effect of two of the remedies investigated in this study, Carcinosin and Phytolacca, appeared similar to the activity of paclitaxel, the most commonly used chemotherapeutic drug for breast cancer.³⁵

Not all laboratory studies revealed favorable results. Thangapazham et al investigated the effect of the homeopathic medicines *Conium maculatum*, *S serrulata*, *Thuja occidentalis*, *Asterias*, *Phytolacca*, and *Carcinosin* on prostate and breast cancer cells. They found that none of the homeopathic remedies tested in different potencies produced significant inhibitory or growth-promoting activity in either prostate or breast cancer cells.³⁶

Interestingly, the same authors conducted another study in which they evaluated the effects of commonly used homeopathic

remedies in cell and animal models of prostate cancer. The researchers found no effects on cell viability or gene expression in three prostate cell lines with any remedies at any exposure time, but there was a 23% reduction in tumor incidence ($P < .0001$), and for animals with tumors, there was a 38% reduction in tumor volume in homeopathy-treated animals vs controls ($P < .02$). At time of sacrificing, experimental animals with tumors had a 13% lower average tumor weight ($P < .05$). Tumors in these treated animals showed a 19% increase in apoptotic cell death ($P < .05$) and reduced PCNA-positive cells. The authors concluded that the findings indicate that selected homeopathic remedies have no direct cellular anticancer effects but appear to significantly slow the progression of cancer and reduce cancer incidence and mortality in Copenhagen rats injected with MAT-LyLu prostate cancer cells.³⁷

An intriguing recent report by Amri et al tried to explain the molecular mechanisms of the observed reduced tumor volume in mice that were inoculated with human prostate cancer cells and treated with ultralow concentrations of *S serrulata*. The examination of the ultrastructural cytomorphology revealed cellular disintegration incompatible with the well-defined apoptosis or necrosis cell death. The analysis indicated a novel caspase-independent cell death, which might explain the significant tumor size reduction in the treated animals. The authors concluded that their data suggested that these ultralow concentrations triggered a pathway not yet characterized as cell death and not related to classical apoptosis or necrosis.³⁸

Clinical Research

Only a few clinical research studies have tried to investigate homeopathy with high-quality research designs, despite homeopathy's widespread use. Searches of five major scientific literature databases were conducted in June 2005 by Ernst at the University of Exeter (UK) in collaboration with an investigator at MD Anderson Cancer Center.³⁹ Fifty-four potentially relevant studies of homeopathy and cancer were identified: 12 animal or in vitro studies and 42 human studies. Only the six human studies with a control group were selected for independent review. The quality of each study was assessed using Jadad Criteria. The researchers summarized that five of the six trials indicated that homeopathic remedies might be effective in cancer care. However, the authors concluded that the evidence that emerged from their review was not convincing due to the very limited number of studies and limited quality of the data that were available for them to evaluate.

A more recent review of clinical trials in homeopathy and cancer was performed by The Cochrane Collaboration.⁴⁰ This review concentrated on the effectiveness and safety of homeopathic medicines that were used to prevent or treat adverse effects of cancer treatments. The reviewers found eight controlled trials with a total of 664 participants. Three were studies of adverse effects of radiotherapy, three were studies of the effect on side effects of chemotherapy, and two were studies of the effects on menopausal symptoms associated with breast cancer treatments. The review found preliminary data that suggest beneficial effect of homeopathy in dermatitis during radiotherapy- and chemotherapy-induced

stomatitis. There was no convincing evidence for the efficacy of homeopathic remedies for other adverse effects of cancer treatments. On the other hand, as far as the safety issue is concerned, no serious adverse effects were related to the homeopathic remedies that were used.

One of the controlled studies mentioned in both reviews was a triple-blinded study (Jadad score 5) of single and combination homeopathic remedies for women with a history of breast cancer who were experiencing hot flashes.¹⁹ Even though the results were not positive for the primary outcome (hot flashes), one cannot ignore details that might point to some benefit. In this study, Jacobs et al evaluated 83 breast cancer survivors. Patients who suffered from an average of three hot flashes daily for a month before the trial were randomized into three groups: a placebo combination and a verum single remedy, a verum combination medicine and a verum single remedy, and two placebo combinations. The single individually selected remedies consisted of 35 homeopathic medications, mainly *Sepia*, *Calcarea carbonica*, *Sulfur*, *Lachesis*, and *Kali carbonicum* (mostly high potencies). The combination remedy was Hyland's Menopause (Hyland's Inc, Los Angeles, California), which contains *Amyl nitrate*, *Sanguinaria canadensis*, and *Lachesis*. A significant improvement in general health score was observed in both homeopathy groups as compared with the placebo group. However, those taking the combination remedy had an increase in hot flashes and headaches. This may have been related to the participants' taking the combination daily for a year, in contrast to the over-the-counter instructions that specified taking only until symptoms decreased or for 7 days if they did not decrease.

Kulkarni conducted a randomized clinical trial to test the effectiveness of homeopathy on the severity of radiotherapy-related side effects.⁴¹ Patients with different types of cancer (N=82) were randomized into three parallel arms receiving either placebo, *Cobaltum 30C*, or *Causticum 30C*. Patients were evaluated weekly using an 18-point radiation reaction profile, and the average severity score was calculated at the end of the study. The reaction profile scores in both experimental groups were lower than that in the placebo group. Oberbaum tested the effectiveness of a homeopathic remedy called *Traumeel S* for chemotherapy-induced stomatitis after allogeneic or autologous stem cell transplantation.⁴² Patients (N=30) were randomized to two groups: the *Traumeel S* oral rinse or a placebo rinse. *Traumeel S* contains *Arnica 2X* ("X" means decimal potency), *Calendula 2X*, *Millefolium 3X*, *Chamomilla 3X*, *Symphytum 6X*, *Belladonna 2X*, *Aconitum 2X*, *Bellis perennis 2X*, *Hypericum 2X*, *Echinacea angustifolia 2X*, *Echinacea purpurea 2X*, *Hamamelis 1X*, *Mercurius sol*, and *Hepar sulfuris 6X*. Significant differences favoring the *Traumeel S* group were observed in terms of reduction in the severity or duration (or both) of stomatitis and in time to worsening of symptoms. Patients in that group showed a reduction in oral pain and discomfort, dryness of mouth and tongue, difficulty swallowing, and dysphagia.

Balzarini tested the effectiveness of homeopathic treatment for skin reactions during radiotherapy for breast cancer.⁴³ Patients (N=61) were randomized into groups receiving three granules of *Belladonna 7C* twice daily and the homeopathic remedy X Ray 15 C

once daily or placebo. Patients treated with homeopathy noted a decrease in skin temperature and hyperpigmentation, but these differences were no longer significant by the end of the 10-week follow-up. Total severity scores favored homeopathy, but statistical significance for the difference was noticed only during recovery.

Pathak and Banerji did not conduct a randomized clinical trial, but their work is worth mentioning, as they described 15 patients diagnosed with documented intracranial tumors who were treated exclusively with the homeopathic remedies *Ruta 6c* and *Calcarea phosphorica 3X* without additional chemotherapy or radiation.³⁴ Of these 15 patients, six of the seven who had glioma showed complete regression of the tumors. Thompson and Reilly described a study population of 100 consecutive patients with cancer who had been referred to an National Health Service homeopathic hospital for complementary therapies.⁴⁴ The study evaluated the homeopathic approach in relation to symptom control and its impact on mood disturbance and quality of life. Fifty-two patients completed the study; in those patients, satisfaction was high, and 75% (n = 38) rated the approach as helpful or very helpful for their symptoms. Symptom scores for fatigue and hot flashes improved significantly over the study period, but scores for pain did not.

Not all clinical trials yielded findings favorable to homeopathy. Thompson et al compared homeopathy with placebo in 53 breast cancer survivors with estrogen-withdrawal symptoms.⁴⁵ Patients randomized to homeopathy were prescribed 71 individually selected remedies, most commonly *Sulfur*, *Sepia*, *Carcinosin*, *Natrum muriaticum*, *Belladonna*, and *Arnica* (mostly high potencies). No significant differences in symptom relief were noted between the experimental and placebo groups. Ernst et al in two commentaries on this issue stated that they felt that currently available randomized clinical trials are so few in number and are so burdened with significant limitations that there is no reason to believe that homeopathic medicines have anything to offer to patients suffering from cancer.^{11,39} They also concluded that there is no evidence at all that homeopathic remedies can change the natural history of any cancer. However, Ernst et al reviewed only clinical studies that describe improvement in symptoms related to cancer therapies^{11,39} and did not actually address the issue of the effect on disease progression, an issue that Banerji raised in this NCI BCS publication. Banerji's work, while intriguing and interesting, has been purely observational and with a small number of patients. This type of observation needs to be followed by a high-quality clinical trial in order to confirm the effect on disease progression.

One also cannot ignore the findings that are available from preclinical data and animal studies, as mentioned above. As we can see, much headway has been made in homeopathic cancer research in recent years. Much of this effort resides in the realm of basic science; however, anecdotal evidence and the few clinical trials that do exist raise the issue that homeopathy may be of value in cancer care, mainly in reduction of conventional treatment side effects and supportive care.⁴⁶ In his review of the role of homeopathy in cancer care, Paterson mentions that whether conventional practitioners like it or not, many cancer patients will continue to

turn to alternatives, including homeopathy, in increasing numbers.⁴⁷ As a result, oncologists who are sufficiently open-minded to acknowledging the role of homeopathy in cancer care have a challenge to collaborate in performing the high-quality studies that are needed to determine whether homeopathy has any benefit in treating patients with cancer.

In summary, data from multiple research disciplines, ranging from studies that evaluate the effect of homeopathic remedies on cancer cell lines to scientifically valid animal and clinical studies, raise some clues that necessitate further studies. Several published outcome studies and the randomized clinical trials mentioned in this article suggest two main results. First, the homeopathic remedies used in the clinical trials that were mentioned appear to be safe and without adverse effects. Second, there may be a role for homeopathy in improving quality of life in some cancer patients. Such effects have not been demonstrated unequivocally, and specific antitumor effects have not been shown in any controlled clinical research to date. However, the positive reports from the few laboratory experiments in cancer models that are mentioned in this review are indeed noteworthy. Appropriate clinical trials are still needed to investigate the use of homeopathy in cancer care.

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