

# LIPOPHIL-MEDIATED REDUCTION OF TOXICANTS IN HUMANS: AN EVALUATION OF AN AYURVEDIC DETOXIFICATION PROCEDURE

Robert E. Herron, PhD, and John B. Fagan, PhD

**Robert E. Herron** is the director of research at the Institute of Science, Technology and Public Policy at Maharishi University of Management in Fairfield, Iowa. **John B. Fagan** is a professor of physiology and biochemistry in the Department of Physiological and Biological Sciences at Maharishi University of Management.

**Context** • Lipophilic toxicants have been associated with hormone disruption, immune system suppression, reproductive disorders, several types of cancer, and other diseases. Due to environmental persistence and bioaccumulation, body burdens of certain toxicants, such as dichlorodiphenyldichloroethylene (DDE) and polychlorinated biphenyls (PCBs), appear to be a health risk despite the toxicants' having been banned for decades.

**Objective** • To determine whether a safe, standardized, Ayurvedic detoxification procedure can mobilize lipid-soluble toxicants and stimulate their excretion.

**Design** • Cross-sectional and longitudinal evaluations.

**Setting** • Southeastern Iowa.

**Participants** • In the cross-sectional study, 48 participants who had undertaken lipophil-mediated detoxification were compared with 40 control subjects. In the prospective, longitudinal evaluation, serum levels were measured in 15 subjects before and after they underwent the detoxification procedure. These 15 subjects served as their own controls.

**Intervention(s)** • Ayurvedic lipophil-mediated detoxification procedure.

**Main Outcome Measure** • Gas chromatographic analysis of 17 serum toxicant levels (9 PCB congeners and 8 pesticides or metabolites) on a lipid-adjusted and wet-weight basis (ng/g) as parts per billion.

**Results** • In the cross-sectional study, gas chromatographic analysis of 9 PCB congeners and 8 pesticides revealed that serum PCB levels were significantly lower in the detoxification subjects than in controls. *Trans-nonachlor* (TNC), *p,p'*-dichlorodiphenyldichloroethylene (*p,p'*-DDE), *oxychlorane*, and *hexachlorobenzene* (HCB) levels were also markedly lower in the detoxification group. All subjects had undetectable levels of *p,p'*-DDT, *lindane*, and  *$\alpha$ -hexachlorocyclohexane* ( $\alpha$ -HCH). *Beta-hexachlorocyclohexane* ( $\beta$ -HCH) levels were significantly higher in detoxification subjects than in controls. In the

longitudinal evaluation, after treatment, mean levels of PCBs (46%) and  $\beta$ -HCH (58%) declined significantly in the subjects.

**Conclusions** • The higher  $\beta$ -HCH levels in the subjects in the longitudinal study appear to be an anomaly related to diet. The results of the 2 studies generally suggest that lipophil-mediated detoxification may be effective in reducing body burdens of fat-soluble toxicants. As numerous people worldwide are at risk from high body burdens of such lipid-soluble agents, further studies to evaluate this procedure appear warranted. (*Altern Ther Health Med*. 2002;8(5):40-51)

Complementary and alternative medicine (CAM) features numerous "detoxification" methods presented in books, such as *Contemporary Ayurveda*, *7-Day Detox Miracle*, *Purify Your Body*, *Hormone Deception*, and *Detoxification and Healing*.<sup>1-5</sup> However, there is little scientific research documenting the efficacy of these CAM procedures. To address this deficiency, we conducted research that evaluated an Ayurvedic detoxification procedure.

As a class, lipophilic toxicants are among the most problematic environmental contaminants known today. Toxicants are poisons produced by humans directly or as a result of human intervention, unlike toxins, which are produced by natural means. Lipophilic toxicants include polychlorinated biphenyls (PCBs), dichlorodiphenyldichloroethylene (DDE), dichlorodiphenyltrichloroethane (DDT), and a range of other lipophilic chemicals and pesticides. Due to the fat-soluble nature of these lipophilic toxicants and to their long half-lives, they tend to accumulate in plants and animals and to biomagnify up the food chain, reaching high levels in wild animals, such as raptors, seagulls, whales, seals, and polar bears. These toxicants also can rise to high levels in human food sources.<sup>6,7</sup> For instance, eating fresh-water fish is known to put the consumer at great risk for PCB exposure.<sup>8</sup> Lipophilic toxicants also have been detected in other components of the human food supply, including fast foods, meat, dairy products, and even vegetables.<sup>9-18</sup> As a consequence of chronic exposure and accumulation, many individuals carry heavy body burdens of lipophilic toxicants, and these burdens increase significantly with age in the general population.<sup>19,20</sup>

Another concern is that single chemicals with relatively low toxicity may combine and act synergistically in the human body.<sup>21,22</sup> Elderly or chronically ill persons, diabetics, alcoholics,

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AIDS patients, fetuses, and children are very likely to be hypersusceptible to adverse health effects arising from these lipophilic agents.<sup>24-30</sup>

High body burdens of these compounds can result in an elevated incidence of several types of morbidity and mortality. Adverse outcomes associated with the toxicants include several forms of endocrine disruption, developmental disorders, reproductive dysfunction, suppression of immune function, neurological problems, liver damage, dermatological disorders, cancer, and other undesirable health outcomes.<sup>21,30-67</sup>

Most policy makers have assumed that because certain toxic chemicals were banned from use decades ago in the United States, these compounds are no longer a public health threat. Emerging evidence suggests that this assumption may need to be reevaluated.<sup>68</sup> At present, the only approach for protecting the population from the health risks associated with these toxicants has been to reduce primary exposure by restricting or prohibiting manufacture and use. Control or prohibition of the release of lipophilic toxicants into the environment is obviously an essential measure necessary to protect the health of the population. However, regulation alone has not been shown to be sufficient to ensure public health, particularly for classes of toxicants with a long history of use or with environmental persistence. Such compounds remain widespread in the environment long after release has been prohibited. An additional contributor to this persistence is that many of these compounds continue to be used heavily in other nations. Despite large molecular weight and relative insolubility in water, these compounds may move via air and water. Thus, regional release translates into global exposure.<sup>69,72</sup> Methods for reducing body burdens of these toxicants would constitute a potentially powerful complementary approach to reducing toxicant-related health risks.

### EARLIER DETOXIFICATION STUDIES

Several studies have indicated that ingesting lipophilic materials in substantial amounts can stimulate intestinal excretion of lipophilic environmental contaminants deposited in adipose tissue.<sup>73,74</sup> Among these are animal studies showing that lipophilic substances may be effective in reducing body burdens of PCBs, hexachlorobenzene (HCB), hexachlorobiphenyl, and other compounds.<sup>75-85</sup> For instance, in a randomized experiment, equal amounts of a toxic, lipophilic pesticide, chlordane (Kepone), were fed to control and experimental animals. The experimental animals were given a regimen of dietary restrictions and cholestyramine, while controls were given a placebo. The animals were killed and their organs were measured for chlordane content. The organs of the group given the combined cholestyramine and food-restriction regimen had chlordane concentrations 30% to 52% lower than the organs of the control animals.<sup>74</sup>

A study on humans examined fecal excretion rates of polychlorinated dibenzo-p-dioxins, dibenzofurans (PCDD/Fs), PCBs, and HCB in 3 subjects before and after they were fed olestra (sucrose polyester), a nonabsorbable dietary fat substitute.

While on the olestra diet, the subjects substantially increased their excretion of toxicants. As the researchers noted, "Using 2,3,7,8-Cl<sub>4</sub>DD as an example, it was estimated that ingestion of 25 g/d of olestra would more than double the overall rate of elimination of that compound."<sup>86</sup> An evaluation of 2 patients with chloracne and concentrations of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) of 144,000 and 26,000 pg/g blood lipids found that olestra consumption accelerated the patients' excretion of TCDD by 8- to 10-fold. This increased TCDD excretion rate was sufficient to reduce the half-life of TCDD in the human body from 7 years to 1 to 2 years.<sup>87</sup>

Although olestra consumption appears to have no major toxic, carcinogenic, genotoxic, or teratogenic side effects, there are some mild adverse effects that must be considered in using olestra for detoxification. First, olestra consumption appears to decrease the absorption of other lipophilic substances in the gastrointestinal tract, including fat-soluble vitamins A, D, E, and K. Those who consume olestra regularly need to take extra vitamin supplements.<sup>88,89</sup> Second, subjects who consume moderate to large amounts of olestra may report increased gastrointestinal complaints, such as loose stools, cramps, diarrhea, flatulence, or nausea.<sup>88,91</sup> We have investigated a detoxification procedure that may operate on the same principle as the olestra studies, yet avoids the side effects related to the use of bioincompatible materials. The lipophil-mediated detoxification procedure evaluated in our study makes use of materials known to be compatible with biological systems, and the materials have been demonstrated to be safe in a long history of use in humans (albeit for other purposes than detoxification).

### THE LIPOPHIL-MEDIATED DETOXIFICATION PROCEDURE

The lipophil-mediated detoxification procedure used in the present study was derived from the Ayurvedic medical system of India, which has been recognized by the World Health Organization as a complete system of natural medicine.<sup>92</sup> Ayurveda has been continuously practiced in India for thousands of years. However, India had been invaded several times during the last 2,000 years. Each new group of conquerors, including the Persians, Turks, Moguls, Muslims, and British, sought to impose their laws, cultures, customs, and medical systems on the people of India. Thus Ayurveda, through its own development and through its contact with other cultures, has evolved and been modified over time. Since 1984, Maharishi Mahesh Yogi, a Vedic scholar, has worked to realign Ayurveda with its classic texts. The Maharishi's system, known as the Maharishi Vedic Approach to Health, has been investigated in more than 600 studies, including research funded by the National Heart, Lung and Blood Institute, the National Institute of Aging, and the Office of Alternative Medicine (now the National Center for Complementary and Alternative Medicine) at the National Institutes of Health. Articles reporting on various aspects of this approach have been published in independent, peer-reviewed journals.<sup>1,93-96</sup>

Several earlier studies reported beneficial psychophysiological outcomes from use of the detoxification procedure that are consistent with possible reduction of toxicant levels.<sup>97-101</sup> However, none of these studies has attempted to measure the direct effect of this procedure on serum or tissue toxicant levels.

The range of benefits observed through the application of this detoxification program includes the following: reductions in total cholesterol and urea<sup>97</sup>; improvements in mental and physical health, including increased physical well-being, energy, strength, and appetite<sup>98</sup>; reductions in cardiovascular risk factors, including sharp reductions in total cholesterol and lipid peroxide levels; reduced pulse and diastolic blood pressure; and reduced state anxiety, a measure of chronic stress.<sup>99</sup> Earlier studies also indicated that this detoxification procedure enhances cognitive function. Improvements in intelligence, memory, alertness, and psychomotor speed were observed,<sup>100</sup> as well as increased brain wave coherence.<sup>101</sup> These results may all be relevant, as neurological function can be a sensitive indicator of toxicant load.<sup>37,56,57</sup>

## METHODS

### Cross-sectional Study Group

Eighty-eight subjects were recruited through various types of publicity in southeastern Iowa. No financial incentives were given for participation in the study. The primary incentive was the opportunity for subjects to learn what their toxicant levels might be; none of the subjects had previously undergone measurement of toxicant levels.

Of the subjects, 48 (18 women, 30 men; mean age, 48.21 years) had undergone the detoxification procedure an average of 18 times; 40 had not (22 women, 18 men; mean age, 53.25 years). The mean age difference of 5.04 years between the 2 groups was statistically significant at the  $P=.012$  level. However, this difference may not be clinically or epidemiologically significant because both groups' mean ages were over 45 years, which is the category that is known to have, generally, the highest levels of environmental toxicants.<sup>19,20</sup> Nevertheless, we felt it was important to control statistically for age because it is related to accumulated toxicant body burden.<sup>19,20</sup>

All subjects signed a consent form and provided their demographic and dietary information. Subjects who indicated that they had a potentially life-threatening illness, such as heart disease or cancer, were excluded. Although we attempted to recruit subjects from all races and ethnic groups, the only volunteers were white. The percentage of nonwhites in rural southeastern Iowa is very low, less than 1% of the population. The sampling of the present study therefore reflects the racial composition of the locale in which it was conducted.

From each subject, one 10 mL blood sample was drawn, of which at least 3 mL of serum was prepared and sent to the Analytical Laboratory in the Department of Environmental Health at Colorado State University, Fort Collins, which was blind to the subjects' treatment status.<sup>102</sup> Furthermore, Colorado State University's Analytical Laboratory is the coordinating site

for analysis of human serum in the National Cancer Institute's Northeast Atlantic Breast Cancer Initiative's Quality Control Program.<sup>102</sup>

This laboratory determined the subjects' serum levels of 9 PCB congeners (Ballschmitter and Zell [BZ] numbers 74, 118, 138, 153, 156, 170, 180, 183, 187) and 8 pesticides (a-hexachlorocyclohexane [HCH], HCB,  $\beta$ -HCH, lindane, *p,p'*-DDT, *p,p'*-DDE, trans-nonachlor [TNC], and oxychlordane). Extraction with 1:1 ether:hexane and clean-up with a magnesium-silica gel (Florisil® clean-up) was followed by dual-column gas chromatographic separation and electron capture detection.<sup>102</sup> The listed PCB congeners were assayed because they are of high concern as contaminants, considering their potential toxicity, frequency of occurrence in the body, and abundance in the environment.<sup>101</sup> The listed pesticides were assayed because they are linked to major health problems.<sup>104</sup>

In this report, all toxicant data were statistically analyzed and reported on both a lipid-adjusted and a wet-weight basis (ng/g), as parts per billion (ppb). Extractable lipid was determined gravimetrically by subtracting the weight of the preweighted sample tube from the weight of the tube plus the dried extract. This result was divided by the sample weight and multiplied by 100 to yield lipid percentage. Wet weight measurements of toxicants were divided by the percentage lipid and multiplied by 100 to yield residue values on a lipid-adjusted weight basis.

We used analysis of covariance with age as the covariate to compare the detoxification and control groups for possible differences in PCB and pesticide levels. For this analysis, the PCB congeners were summed to yield a total PCB value while the 8 pesticides were analyzed separately. Since the sizes of the groups were too small to yield statistically significant results for most pesticides, simple Monte Carlo simulations were done to estimate how many subjects who exhibited the same results would be needed to allow a significant outcome. Confidence intervals were calculated for the cross-sectional results at the 95% confidence level.

Because the subjects lived in the same geographical area and were exposed to approximately the same types and amounts of environmental toxicants, the null hypothesis for the cross-sectional phase of the study was that there would be no significant difference between these groups' toxicant levels, and therefore the detoxification procedure would have no effect. The alternative hypothesis was that the detoxification procedure had some effect in reducing environmental toxicants, and this should be evidenced by significant differences ( $P<.05$ ) between the 2 groups' PCB levels and possibly other toxicant levels.

### Prospective, Longitudinal Study Group

We compared the pre- and postdetoxification treatment lipid-adjusted and wet-weight serum levels of toxicants for 15 subjects. The recruitment, sampling, and analytic methods were the same as described for the cross-sectional study. The posttest blood drawing was performed 6 to 8 weeks after administration of the detoxification procedure to allow the blood-adipose equilibrium

to be reestablished. Typically, toxin levels do not have a normal distribution in the general population,<sup>19,20</sup> which violates an essential assumption underlying parametric tests.<sup>105</sup> Although some parametric tests are relatively robust for larger samples, such a violation is likely to affect the results of a small group of subjects (N=15). We found that in the posttest for  $\beta$ -HCH levels, the kurtosis was 4.98, and for PCBs, the kurtosis was 4.92. Thus we felt the nonparametric Wilcoxon signed-ranks test was the most appropriate test for comparison.<sup>105</sup> Confidence intervals were calculated for the longitudinal results at the 95% confidence level. The dependent or paired *t*-test was used to compare the wet-weight data because they were normally distributed.

The pretest measures, the detoxification treatments, and the posttest measures were administered between August 1997 and April 1998. The toxicants studied in this research have long half-lives in the human physiology and are very difficult to metabolize.<sup>103,106</sup> These compounds generally accumulate to high levels in adipose tissues with advancing age.<sup>19,20</sup> Furthermore, there is no known method of reducing the levels of these lipid-soluble toxicants. Therefore, for the longitudinal phase of the study, our null hypothesis stated that there would be no significant difference between pretest and posttest toxicant levels or that the toxicant levels would actually go up in the posttest. If a significant reduction in levels was obtained, this would suggest some effectiveness of the detoxification procedure in decreasing toxicant levels. Description of the treatment procedure follows.

### The Detoxification Procedure

The detoxification procedure used in this study was a multimodality program performed over a 2-week period (Figure 1). Its modalities are designed to function synergistically to maximize removal of toxicants while keeping patients in a safe, comfortable, homeostatic physiological state. These modalities include oleation (ingestion of nontoxic, lipophilic foods), purgation, herbal steam baths, several types of herbal oil massage, herbal enemas, herbal dietary supplements, and a set of temporary dietary restrictions.<sup>1</sup>

The traditional understanding of this detoxification procedure is that it prevents disease and improves health by removing

toxicants that have accumulated through diet, harmful behavioral patterns, and environmental exposure.

The detoxification intervention used for both the cross-sectional and longitudinal study groups consisted of the 3 phases described below.

**Phase 1.** Over a period of 4 to 7 days, the subjects ingested increasing doses of warm, liquid, clarified butter early in the morning before eating. The doses and number of days of ingestion were determined according to Ayurvedic body type, season, age, and physiological condition. Participants also adopted a lighter diet (no fats, oils, meat, or cheese). The final step in phase 1 occurred on the morning following the last day of ingestion of warm, clarified butter. Purgation was achieved using castor oil and/or herbal preparations (Triphala, an Ayurvedic preparation composed of amalaki fruit [*Embolia officinalis*], bibhitaki fruit [*Terminalia bellerica*], and haritaki fruit [*Terminalia chebula*]). The doses of castor oil and/or herbal preparation also were prescribed according to body type, season, age, and physiological state. At home, the subjects carried out phase 1 under a physician's supervision. As shown in Figure 1, there is a rest period of approximately 1 week after the purgation at the end of phase 1 and before the beginning of phase 2.

**Phase 2.** On each of 5 consecutive days, trained personnel administered to the subjects a 2.5- to 3-hour detoxification routine at an appropriately equipped facility under the supervision of medical doctors trained in both Ayurveda and Western medicine. The detoxification routine included a body massage with herbal oils (45 to 60 min), and treatment with a stream of herbal oil poured over the forehead, or an herbal steam bath, or nasal administration of herbal oils, or other possible treatments depending on body type, season, age, and physiological condition. All treatment sessions ended with an herbal oil enema. The 2.5- to 3-hour detoxification session is very relaxing and includes a rest period after each component.

Sesame oil, which was used in the body massage and many other Ayurvedic treatments, has been shown to possess clinically useful properties, including suppression of cancer-cell growth.<sup>107,109</sup>

**Phase 3.** We recommended that the subjects continue whole-body massage at home for 10-15 minutes with warm

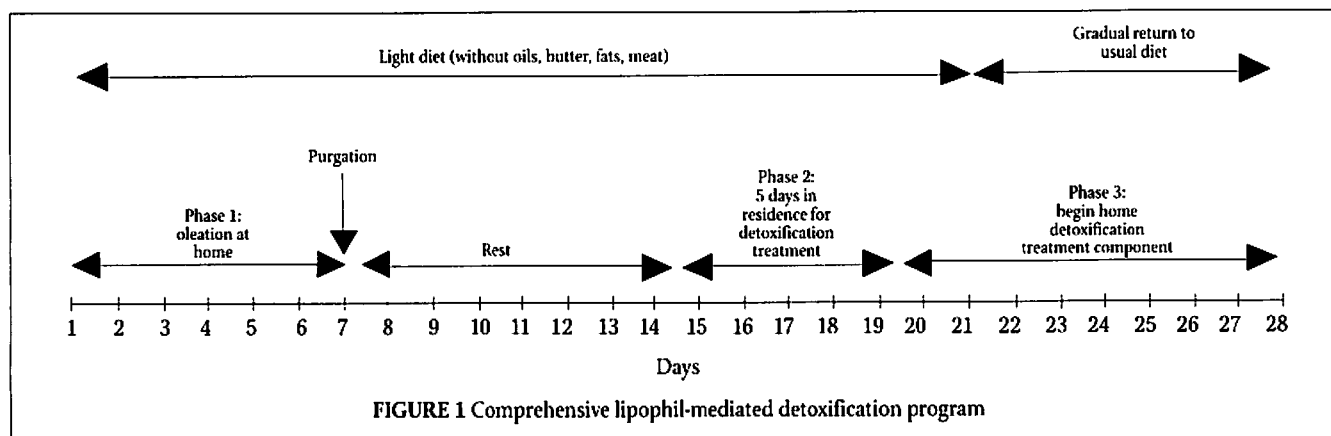


FIGURE 1 Comprehensive lipophil-mediated detoxification program

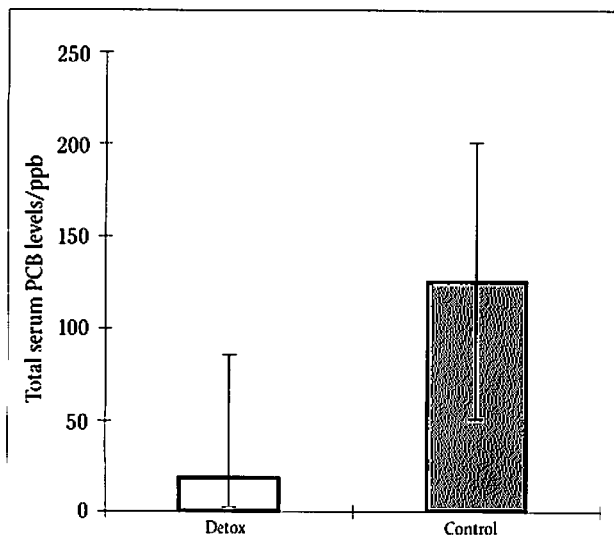


sesame oil in the morning before bathing, at least until the end of the longitudinal study (6 to 8 weeks after the end of phase 2). However, we did not monitor compliance. Ideally, subjects would continue their daily whole-body oil massage until they started phase 2 of their next detoxification treatment. The detoxification treatment is recommended at least twice a year, but can be done every 2 or 3 months.

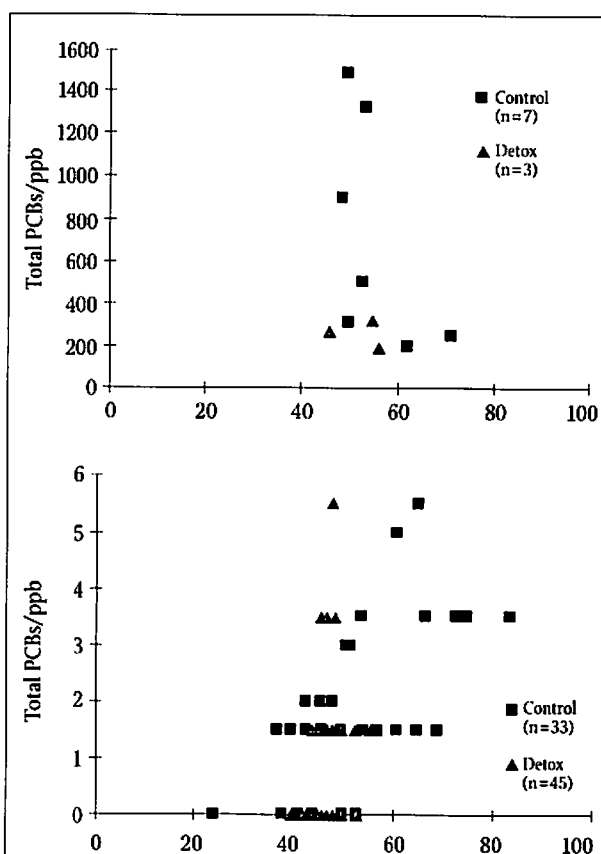
## RESULTS

### Cross-sectional Study Group

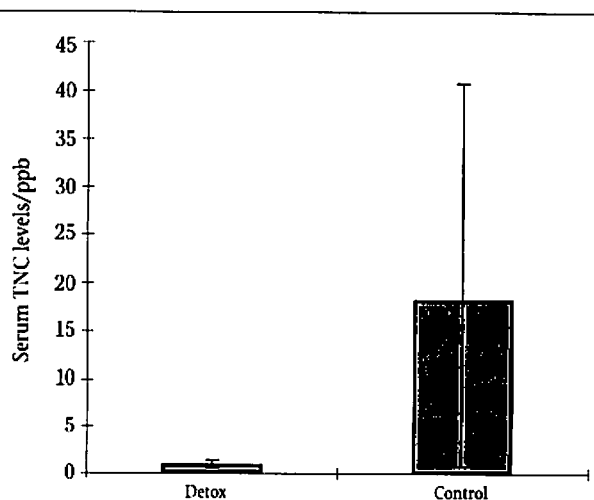
Results of the cross-sectional comparison of the levels of 17 toxicants in sera drawn from the detoxification and control groups are shown in Figures 2 to 5. As displayed in Figure 2, the adjusted mean of the lipid-adjusted, total PCB levels for the detoxification subjects was significantly lower ( $P=.045$ ) than that for control subjects (17.57 ppb, SD=242.09 ppb versus 125.43 ppb, SD=243.06 ppb). PCB body burdens were bimodally distributed (Figure 3). Body burdens for most subjects (78 of 88) were clustered tightly between 0 and 6 ppb, while body burdens of the remaining subjects ranged from 180 to 1,600 ppb. In both clusters, detoxification subjects had lower levels of PCBs. TNC, *p,p'*-DDE, oxychlorane, and HCB were markedly lower in the detoxification group than in the control group, as shown in Figures 4 through 7. Lindane, *p,p'*-DDT, and  $\alpha$ -HCH were undetectable in all subjects. These differences were not statistically significant ( $P>.05$ ) due to the small sample sizes. However, simple Monte Carlo simulations showed that these outcomes would have been significant with 180 or more subjects in each group that exhibited the same results as these subjects. Mean serum lipid levels of the control and detoxification groups were not significantly different ( $P>.05$ ).



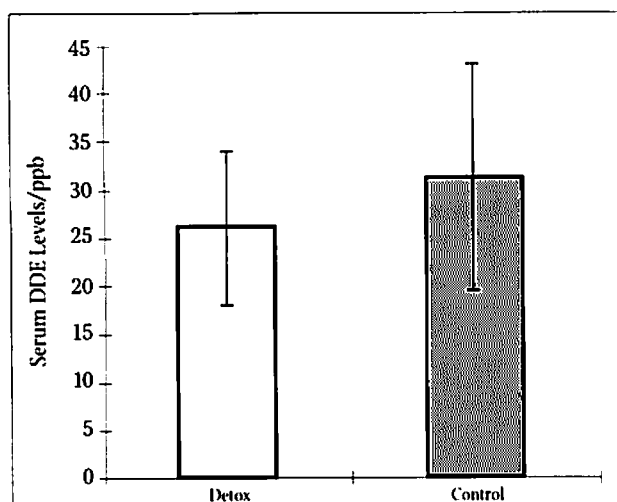
**FIGURE 2** Adjust means of total polychlorinated biphenyl (PCB) serum levels in detoxification ( $n=48$ ) and control ( $n=40$ ) groups ( $P=.045$ ). Mean PCB levels for control and detoxification groups were calculated and adjusted for serum lipid content according to the procedure described in the Methods section. Error bars indicate confidence intervals at the 95% confidence level.



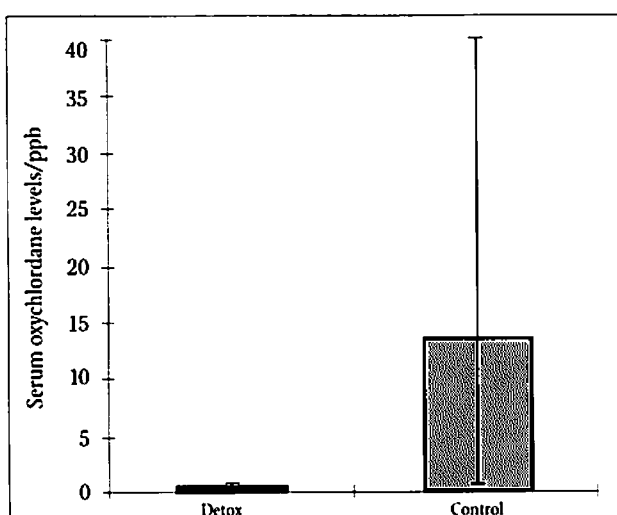
**FIGURE 3** Total lipid-adjusted serum polychlorinated biphenyl (PCB) levels for individuals in detoxification and control groups. PCB levels for individuals in control and detoxification groups were determined and adjusted for serum lipid content, as described in the Methods section.



**FIGURE 4** Mean lipid-adjusted serum trans-nonachlor (TNC) levels in the detoxification and control groups. Mean TNC levels for control and detoxification groups were calculated and adjusted for serum lipid content according to the procedure described in the Methods section. Error bars indicate confidence intervals at the 95% confidence level.



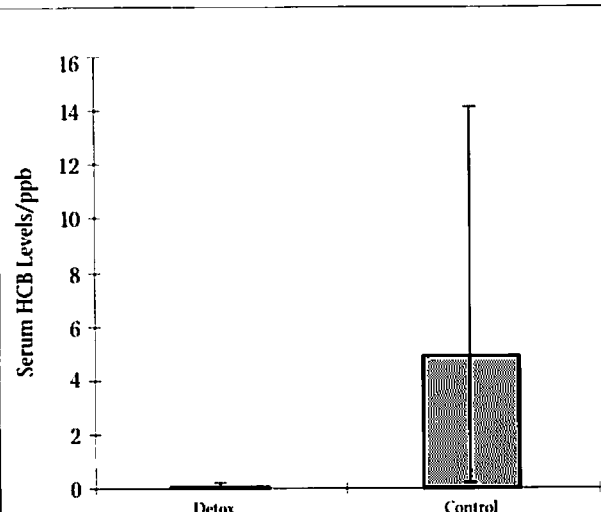
**FIGURE 5** Mean lipid-adjusted serum *p,p'*-DDE levels in the detoxification and control groups. Mean DDE levels for control and detoxification groups were calculated and adjusted for serum lipid content according to the procedure described in the Methods section. Error bars indicate confidence intervals at the 95% confidence level.



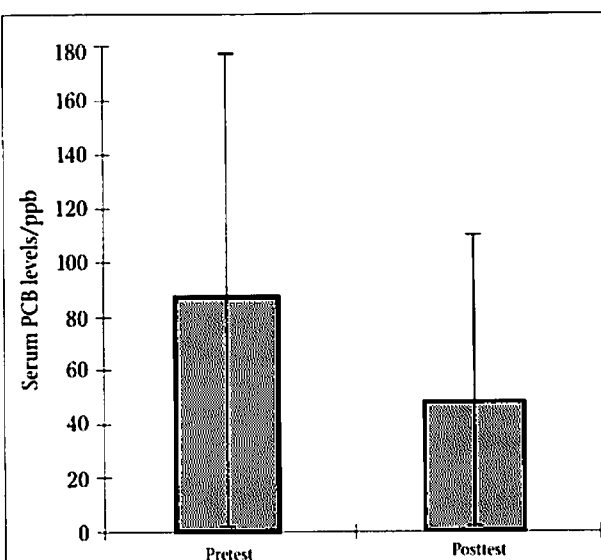
**FIGURE 6** Mean lipid-adjusted serum oxychlordane levels in detoxification and control groups. Mean oxychlordane levels for control and detoxification groups were calculated and adjusted for serum lipid content according to the procedure described in the Methods section. Error bars indicate confidence intervals at the 95% confidence level.

### Prospective, Longitudinal Study

The prospective, longitudinal study demonstrated that use of the lipophil-mediated detoxification procedure resulted in significant reductions in serum levels of PCBs and  $\beta$ -HCH. These declines were significant whether the results were analyzed on a lipid-adjusted or a wet-weight basis. As shown in Figure 8, mean lipid-adjusted PCB levels decreased 45.75% ( $P=.007$ ) from 86.99 ppb (SD=178.03 ppb) to 47.19 ppb (SD=123.62 ppb) following application of the lipophil-mediated detoxification procedure.

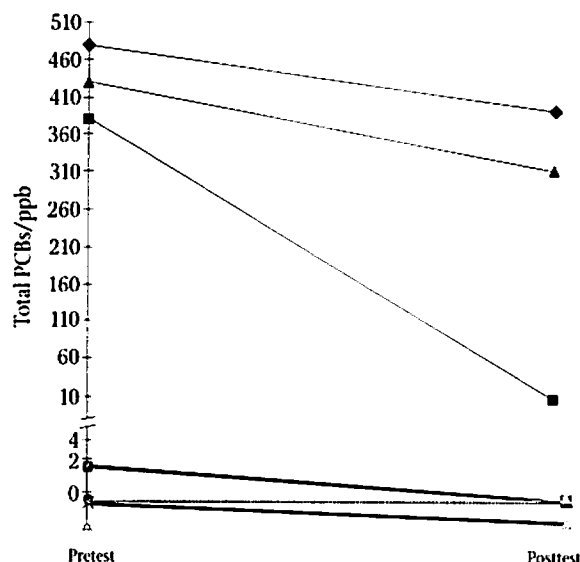


**FIGURE 7** Mean lipid-adjusted serum hexachlorobenzene (HCB) levels in detoxification and control groups. Mean HCB levels for control and detoxification groups were calculated and adjusted for serum lipid content according to the procedure described in the Methods section. Error bars indicate confidence intervals at the 95% confidence level.

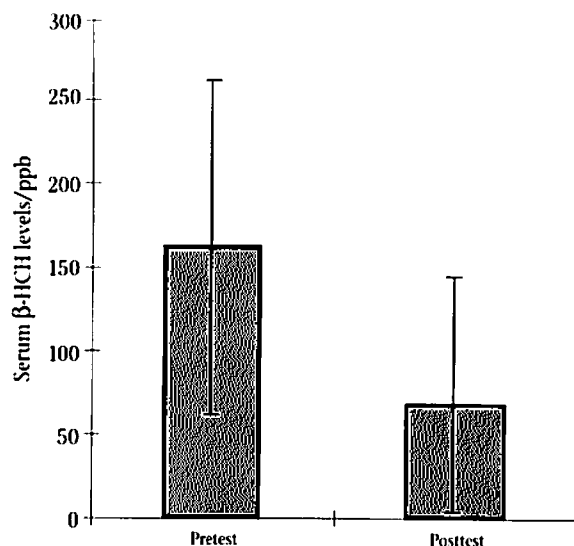


**FIGURE 8** Decline (45.75%;  $P=.007$ ) in mean lipid-adjusted serum polychlorinated biphenyl (PCB) levels after treatment using the lipophil-mediated detoxification procedure. Mean PCB levels for pre- and postdetoxification periods were calculated and adjusted for serum lipid content according to the procedure described in the Methods section. Error bars indicate confidence intervals at the 95% confidence level.

Calculated on a wet-weight basis, mean PCB levels decreased 35% ( $P=.016$ ) from 1.34 ppb (SD=0.76 ppb) to .873 (SD=.866 ppb). Individual lipid-adjusted PCB data for all 15 subjects are presented in Figure 9, showing that changes in PCB body burdens of individual subjects mirrored the changes seen in means for the group. As shown in Figure 10, mean lipid-adjusted  $\beta$ -HCH levels decreased



**FIGURE 9** Decline in lipid-adjusted serum polychlorinated biphenyl PCB levels after treatment using the lipophil-mediated detoxification procedure. Individual PCB levels for pre- and post-detoxification periods were calculated and adjusted for serum lipid content according to the procedure described in the Methods section.



**FIGURE 10** Decline (57.94%;  $P < .003$ ) in mean lipid-adjusted serum beta-hexachlorocyclohexane ( $\beta$ -HCH) levels after treatment using the lipophil-mediated detoxification procedure. Mean  $\beta$ -HCH levels for pre- and postdetoxification periods were calculated and adjusted for serum lipid content according to the procedure described in the Methods section. Error bars indicate confidence intervals at the 95% confidence level.

from 161.9 ppb (SD=197.3 ppb) in the pretest to 68.1 ppb (SD=153.7 ppb) in the posttest period, a mean decline of 93.77, or 57.94% ( $P < .003$ ). Mean wet-weight  $\beta$ -HCH levels decreased from 1.25 ppb (SD=.82 ppb) to .67 (SD=.865 ppb). This decrease of 46% was significant ( $P < .005$ ). Individual lipid-adjusted  $\beta$ -HCH data for all 15 subjects are presented in Figure 11. As with PCBs, results for individuals consistently mirrored changes in means for the group. Mean serum lipid levels were not significantly different in pretest and posttest periods ( $P > .05$ ).

#### COMMENT

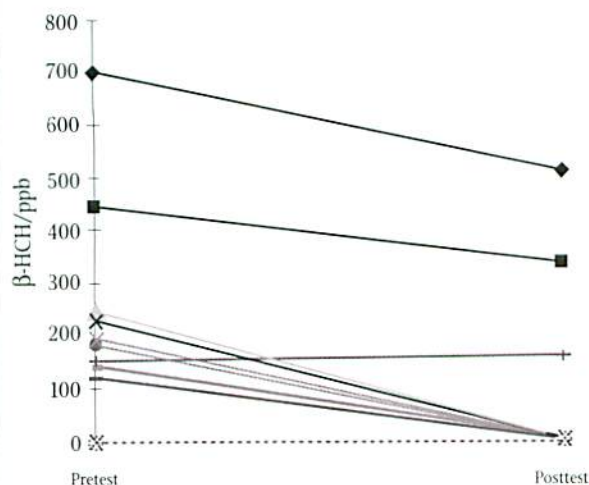
Two interesting observations emerged from the work presented here. First, both the cross-sectional and longitudinal study groups provide clear evidence that the lipophil-mediated detoxification procedure can significantly reduce body burdens of lipid-soluble toxicants. Because the half-lives of the toxicants that we studied are all several years in duration, the observed reductions in PCB and  $\beta$ -HCH levels are striking. Without this intervention, the expected drop in PCBs and  $\beta$ -HCH during the 2-month course of the study would be only a fraction of 1%. Yet application of the lipophil-mediated detoxification procedure resulted in reductions of 46% and 58%, respectively, for PCBs and  $\beta$ -HCH. The results of the cross-sectional study are consistent with those obtained in the longitudinal study, revealing lower levels of both PCBs and  $\beta$ -HCH in the experimental group compared to controls. From these results, we conclude that the lipophil-mediated detoxification procedure is effective in reducing PCB and  $\beta$ -HCH levels and is likely to reduce the levels of

other fat-soluble toxicants as well, including TNC,  $p,p'$ -DDE, HCB, and oxychlordane.

The second interesting outcome of this study is that it confirms work by others, showing that, contrary to common understanding, body burdens of banned lipophilic toxicants and their metabolites, such as PCBs, DDE, and  $\beta$ -HCH, are not decreasing in the US population but remain high and may actually be increasing. Many researchers have assumed that, because the use of certain toxicants has been prohibited, body burdens of these chemicals would continue declining to negligible levels. In contrast, the subjects in the present study were found to carry higher levels of certain toxicants than were reported to be prevalent in the general population in studies conducted before the mid-1980s.

This finding is consistent with a large body of other research. Since the mid-1980s, body burdens of DDE, PCBs, and other fat-soluble toxicants appear to have been increasing in the US population. This rise may be due to increased importation of fresh fruits and vegetables from Latin America in recent decades. In particular, imports from Mexico have increased substantially following passage of the North American Free Trade Agreement. Many toxicants that have been banned for decades in the US, such as DDT and PCBs, are still widely used in Mexico. In the report *Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves*, the US General Accounting Office stated, "7.3% of the imported foods tested contained illegal pesticide residues," including squash with DDT residues.<sup>10</sup> Due to lack of funding, legal impediments, and fragmented administration, the





**FIGURE 11** Decline in lipid-adjusted serum beta-hexachlorocyclohexane ( $\beta$ -HCH) levels in each of 15 individual subjects after treatment using the lipophil-mediated detoxification procedure. Individual  $\beta$ -HCH levels for pre- and postdetoxification periods were calculated and adjusted for serum lipid content according to the procedure described in the Methods section.

Food and Drug Administration and other government agencies are ineffective in monitoring pesticide residues in imported foods and often fail to prevent contaminated foods from entering into US commerce.<sup>110,111</sup>

### Study Limitations

Although some potential confounding variables remain in the exploratory studies presented here, the longitudinal data reduce greatly the likelihood that differences observed in the cross-sectional study were due to systematic differences in the compositions of the experimental and control populations. In addition, the compositions of the groups in the cross-sectional study were structured to minimize known variables, such as environmental and occupational exposure, age, diet, and self-selection. The subjects lived in the same geographical area and thus had similar environmental exposures to most of the chemicals studied. Age was dealt with by enrolling subjects who were approximately the same age and by statistical methods that allowed us to control for the small differences in the actual mean age of the experimental and control groups (see the Methods section).

Diet is a factor in exposure to environmental toxicants. In general, consumption of animal products is the primary contributor to nonoccupational PCB accumulations, because PCBs bio-concentrate up the food chain.<sup>7</sup> Although the detoxification group was predominantly lacto-vegetarian, while the controls were not, total consumption of animal products by the 2 groups was similar. The detoxification subjects consumed large amounts of animal products in the form of milk, cheese, butter, and other dairy products, which are known to contain PCBs and

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other toxicants.<sup>12,14</sup> For instance, a study in the United Kingdom reported that 24% of the total PCB intake (.53 mg/person/day) was due to milk and dairy consumption and another 24% was due to vegetable consumption.<sup>14</sup> Thus, dietary differences are unlikely to be responsible for the differences in the PCB levels between the 2 groups in the cross-sectional comparison and in the longitudinal phase of the study.

However, dietary differences may have contributed to differences in levels of  $\beta$ -HCH in the cross-sectional study.  $\beta$ -HCH is a metabolite of lindane, which has been banned for many years in the United States. The animal products consumed by both groups should be free of this pesticide because livestock feed (ie, corn, soy) is primarily grown in the United States. However, the non-animal-derived portion of the diets of the 2 groups may have differed sufficiently to account for the observed differences in  $\beta$ -HCH levels. In particular, as is typical of vegetarians, the detoxification group likely consumed large amounts of fruits and vegetables. Because lindane is still used heavily in Central and South America, where many of our fruits and vegetables are produced, the experimental group may have experienced greater exposure due to the tainting of these dietary components.

In the cross-sectional study, self-selection may have influenced the results, because the subjects volunteered to enter the study and were not randomized into groups. However, this appears to be an unlikely explanation for the results because none of the subjects had previously undergone measurement of their toxicant levels, and thus they had no data on body burdens on which to base their decisions to enter the study.

In the longitudinal study, self-selection also seems to be an unlikely factor to account for the results because no evidence exists indicating that levels of these intractable chemicals in the body can be reduced through expectation or suggestibility. There is no known way to reduce levels of these toxicants, and they almost inevitably accumulate with age.<sup>19,20</sup> Although using each subject as his or her own control may not be ideal, it does provide useful knowledge for guiding future randomized studies.

In this study we measured serum toxicant levels, based on the assumption that changes in serum levels reflect changes in the levels of toxicant deposition in adipose tissue. This assumption has been supported by a number of studies.<sup>102,112</sup> However, the question remains that the novel treatment studied here might influence the partitioning of toxicants between the serum and adipose reservoirs. Two facts reduce the likelihood that this might be the case. First, serum lipid levels, which are a major determinant of serum levels of fat-soluble toxicants, were not significantly different in the control and experimental groups of the cross-sectional study, nor were they different before and after treatment in the longitudinal study. Second, we intentionally waited 6 to 8 weeks after the lipophil-mediated detoxification procedure concluded before samples were taken (in both longitudinal and cross-sectional studies). This allowed

time for stabilization of any transient fluctuations in serum toxicant levels that might have been triggered by the treatment. However, because serum-adipose ratios were not measured directly, this factor can be explored in future research.

Finally, future studies should gather subjects of all racial, ethnic, and other demographic groups to reflect the diversity of the general US population. This all-inclusive sampling is important in the United States because racial groups appear to show differences in toxicant exposures.

### **Mechanism Underlying the Detoxification Procedure**

Substantial evidence, which was obtained from human and animal studies, has been published indicating that ingestion of lipophilic materials in substantial amounts can be effective in stimulating intestinal excretion of lipophilic environmental contaminants deposited in adipose tissue. For example, Guzelian and others succeeded in increasing the fecal excretion of chlordecone in humans and accelerating the rate of its disappearance from the body by administering cholestyramine orally.<sup>73,74</sup> This treatment was first attempted because it was known that this nonabsorbable, lipophilic resin binds strongly to the fat-soluble compound chlordecone in vitro.<sup>73,74</sup> These authors suggest that this strategy also may offer a practical method for treating chronic poisoning with other lipophilic toxicants. Similarly, in studies of monkeys, goats, rats, chickens, and other animals, lipophilic substances have been shown to be useful in reducing body burdens of PCBs, polybrominated biphenyls (PBBs), HCB, hexachlorobiphenyl, and other compounds.<sup>75-85</sup>

Smith and Salerno first proposed that the detoxification procedure used in the present study may be useful in reducing body burdens of environmental and occupational toxicants.<sup>111</sup> They proposed a mechanism of action for removing lipid-soluble toxicants that is consistent with the mechanism proposed by Guzelian and others. They hypothesized that doses of nontoxic lipophilic material, such as clarified butter, administered orally during the oleation phase of the detoxification procedure may serve to partition lipid-soluble toxicants from their sites of deposition, such as adipose tissue and lipid-rich membranes, move them into circulation, and, finally, into the digestive tract. They further propose that the purgation component of the detoxification procedure removes these toxicants from the digestive tract.

We propose that this same mechanism may operate through the other procedures that are part of the detoxification regimen used in this study. Each procedure involves the use of other nontoxic lipophilic materials that could serve to partition lipid-soluble toxicants from their sites of deposition and move them into the bloodstream, stimulating their excretion. Oil massage and enema treatments both employ oils that may partition toxicants from their sites of deposition. The herbs used in these treatments stimulate physiological and possibly cellular processes that may facilitate the transport of toxicants into the gut and accelerate their removal.

The steam bath treatment uses both herbs and steam to stimulate excretion of toxicants through the sweat glands. These mechanisms are all compatible with Sharma's finding that the detoxification procedure tested here reduces lipid peroxide levels and (presumably) the burden of molecules responsible for their production.<sup>59</sup>

### Multiple Modalities

The detoxification method used in this study employs multiple modalities. Previous animal studies also suggest that the use of multiple modalities may enhance the efficacy of detoxification procedures similar to the regimen used in this study. Mutter et al reported that the combination of dietary restriction along with oral administration of the lipophile olestra was reasonably effective in accelerating clearance of DDE from gerbils carrying a preestablished radio-labeled body burden of this compound. In contrast, dietary restriction and olestra treatment alone were far less effective, resulting in clearance rates that were only 5% to 10% of those achieved with the combination.<sup>60</sup> Similar results have been found in experiments designed to evaluate methods for reducing PCB levels in rats, chickens, and other animals.<sup>12-65</sup>

### Avoiding Adverse Effects of Nonbiocompatible Methods

Many of the animal studies cited above suggest that dietary administration of lipophiles can reduce toxicant burdens. However, these animal studies also reported substantial deleterious

side effects. Researchers have proposed a number of explanations for these side effects, the most likely of which is that lipophilic substances such as petroleum-based oils and synthetic resins are incompatible with biological systems. In essence, they are, themselves, toxic. In contrast, extensive evidence indicates that the materials employed in the detoxification procedure used in this study are nontoxic and that the procedure may actually enhance health.

Facilitating the mobilization and excretion of lipids may be an extremely important mechanism by which the detoxification procedure may reduce body burdens of PCBs, dioxins, DDT, and other important lipid-soluble toxicants from the system. However, there may be additional mechanisms by which the detoxification procedure removes toxicants from the system, because it also appears to attenuate levels of water-soluble toxicants.<sup>11</sup>

### CONCLUSION

This detoxification study in humans is the logical extension of past research on animals. When considering the current and future risks of environmental illness worldwide, it would be a major contribution to toxicology and public health to document a methodology that reduces human body burdens of toxicants and thereby lowers the risk of chemically induced disease. The results of this study are encouraging and should be followed up with large, randomized clinical trials.

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# THE EFFECTS OF HARP MUSIC IN VASCULAR AND THORACIC SURGICAL PATIENTS

Daleen Aragon, PhD, RN, Carla Farris MSN, RN, ARNP, and Jacqueline F. Byers, PhD, RN

**Daleen Aragon** is a clinical nurse research scientist in the department of Vascular and Thoracic Surgery and Critical Care, Orlando Regional Healthcare System, and an adjunct faculty member of the School of Nursing, College of Health and Public Affairs, University of Central Florida–Orlando. **Carla Farris** is a former graduate student, and **Jacqueline F. Byers** is an associate professor of the School of Nursing, College of Health and Public Affairs, University of Central Florida College of Health and Public Affairs, Orlando, Fla.

**Context** • Music has been used in the acute clinical care setting as an adjunct to current treatment modalities. Previous studies have indicated that some types of music may benefit patients by reducing pain and anxiety, and may have an effect on physiological measures.

**Objective** • To evaluate the scientific foundation for the implementation of a complementary therapy, harp playing. The research questions for this pilot study were: Does live harp playing have an effect on patient perception of anxiety, pain, and satisfaction? Does live harp playing produce statistically and clinically significant differences in physiological measures of heart rate, systolic and diastolic blood pressure, respiratory rate, and oxygen saturation?

**Design** • A prospective, quasiexperimental, repeated measures design was used with a convenience sampling.

**Setting** • Orlando Regional Medical Center, Orlando Fla.

**Patients** • Subjects were eligible for the study if they were postoperative and admitted to a hard-wired-bedside-monitored room of the Vascular Thoracic Unit within the 3 days of the study period.

**Intervention** • A single 20-minute live harp playing session.

**Main Outcome Measures** • Visual analog scales (VAS) were used to measure patient anxiety and pain. Patient satisfaction was measured with a 4-item questionnaire. Physiological measures (heart rate, systolic and diastolic blood pressure, respiratory rate, and oxygen saturation) were recorded from the bedside monitor.

**Methods** • Visual analog scales (VAS) were completed just before harp playing, 20 minutes after harp playing was started, and 10 minutes after completion. Patient satisfaction with the experience was measured with a 4-item questionnaire. Physiological measures (heart rate, systolic and diastolic blood pressure, respiratory rate, and oxygen saturation) were recorded from the bedside monitor at baseline (5 minutes before study setup), at zero, 5, 10, 15, and 20 minutes after

harp playing began, and at 5 and 10 minutes after harp playing stopped.

**Results** • Seventeen patients were used in this study, with a retrospective power of .91. Results indicate that listening to live harp music has a positive effect on patient perception of anxiety ( $P=.000$ ), pain ( $P=.000$ ) and satisfaction. Live harp playing also produced statistically significant differences in physiological measures of systolic blood pressure ( $P=.046$ ), and oxygen saturation ( $P=.011$ ). Although all values over time trended downward, the changes of other variables were not adequate to achieve statistical or clinical significance.

**Conclusion** • Subjects in this study experienced decreased pain and anxiety with the harp intervention, and slight reductions in physiologic variable values. It is not possible in this study to determine if the results were due to the harp music, the presence of the harpist and data collector, or both. Future research is recommended using a control group and comparison of live versus recorded harp music with a wider variety of diagnoses and procedures. (*Altern Ther Health Med.* 2002;8(5):52-60)

Music has been used as a therapeutic agent for thousands of years and has engaged many forms.<sup>1-5</sup> Music therapy is defined by the National Association for Music Therapy as the "use of music in the accomplishment of therapeutic aims: the restoration, maintenance, and improvement of mental and physical health."<sup>6</sup> Music therapy involves a prescriptive, systematic, and purposeful approach in which a therapist establishes specific objectives for treatment. In this process, the therapist assesses, plans, intervenes, and evaluates responses to therapy. In music therapy, the relationship of the client to the therapist is central to the use of music in the therapy.<sup>6</sup>

In contrast, music in medicine is more often used to "influence the patient's physical, mental, or emotional states before, during, or after medical treatment."<sup>6</sup> The aim of music in medicine is to provide an adjunct to patient care, which may or may not have specific treatment goals. When music is used in medicine, the relationship of the client to the music is key, rather than with a therapist. In a hospital or similar clinical setting, the goal of using music is to improve how the patient feels during procedures or other clinical situations. Most research related to music in the clinical setting is focused on evaluating the effects of music on physiological and psychological status.

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