

ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

Science-based Information for Clinicians

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Acupressure for Nausea and Vomiting of Pregnancy

By Adriane Fugh-Berman, MD

ALTHOUGH ACUPUNCTURE IS MORE WIDELY ACCEPTED FOR PAIN treatment, the evidence for its effectiveness in treating nausea and vomiting of various etiologies is much stronger than for pain. Stimulation of acupuncture points does not have to be done by needles; finger pressure, electrical stimulation, and heat stimulation (usually by smoldering moxa, a cone or a stick of the compressed herb mugwort) have all been used instead of needles.

There are at least 33 controlled trials of acupuncture point stimulation in the treatment or prevention of nausea and vomiting.¹ This plethora of trials is partially due to the extreme ease of performing these trials. Most acupuncture treatments are tailored to individual patients and are highly dependent on practitioner preference points. So, not only would a single practitioner treat different patients with the same disease differently, but different practitioners may choose different points to treat on the same patient.

However, for nausea and vomiting, most practitioners use the same single point, called Neiguan or P6, located two cun below the distal wrist crease, between the palmaris longus and the flexor carpi radialis tendons. A "cun" is a Chinese measurement equaling the width of the interphalangeal joint of the patient's thumb; two cun equals approximately three finger-breadths. Although other antiemesis points exist, P6 is the most popular. (See *Figures 1 and 2.*)

The invention of acupressure bracelets by a Chinese sailing enthusiast who suffered from seasickness has made the use of this technique even easier, for both clinical practice and clinical trials. Worn on the wrists, acupressure bracelets are elastic strips that contain a button that presses on the P6 point. Adjusting the bracelets so that the button stimulates the correct point for half the patients and the incorrect point for the control group is an easy way to control trials of nausea and vomiting.

So what is the supporting evidence in using acupoint stimulation for nausea and vomiting of pregnancy? Seven controlled treatment trials and one prevention trial of P6 stimulation for morning sickness

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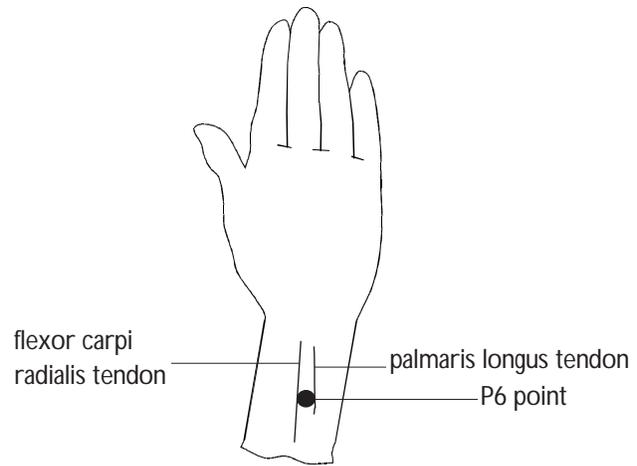
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have been conducted. All but one showed significant improvement for nausea in the treated group. It is not clear, however, that vomiting is improved by this technique.

Clinical Trials

Sea Bands™ (a brand of P6 acupressure bands) have been tested in a number of trials with quite varied methodologies. The most recent (and only negative) trial was a relatively large community-based trial in which 161 symptomatic volunteers were assigned to bands correctly placed, bands incorrectly placed, or no treatment.² Bands were used for three days and symptoms recorded for two days before and after the intervention. All groups reported decreased nausea and vomiting but there were no significant differences between the groups. Two factors that appear to be different in this trial are the fact that all participants were given information on “non-pharmaceutical interventions” (these are not further described) on the first day of the study; so what was really being tested was whether the use of acupressure bracelets had any additive effect to non-pharmaceutical interventions. Additionally, all participants were allowed to use antiemetics. Although the effect of medication was separately analyzed, the fact remains that subjects were receiving multiple interventions that may well have obscured any benefit of acupressure.

Figure 1. P6 or Neiguan Acupressure Point



In a small, randomized, crossover trial, eight women with morning sickness used Sea Bands™ for five days, followed by five days without therapy.³ This group was compared to eight women who had no therapy for five days, followed by five days of acupressure bands. Extent of nausea and vomiting was assessed by patient self-report at baseline, day five, and day 10; acupressure bands significantly reduced morning sickness compared to no intervention. This is not an ideal trial because patients were aware of which days they were being treated.

Two other trials of symptomatic women compared correctly placed with incorrectly placed Sea Bands™. Both trials, one with 16 women⁴ and one with 42 women,⁵ showed significant reductions in nausea scores.

In a double-blind, controlled trial of 60 women at 7-12 weeks of pregnancy, women were treated in three-day cycles for 12 days.⁶ Half the time they were treated with active Sea Bands™ and half the time with a placebo band (which had a blunted button that would not cause adequate pressure on the P6 point). Symptoms were reported according to the Dundee scale. Slight = occasional nausea without vomiting; moderate = daily nausea, no vomiting; troublesome = periodic vomiting with or without nausea; severe = daily nausea and vomiting. More than 60% responded to a Sea Band™ that pressed on an acupressure point, while 30% responded to the placebo band. This trial also compared bilateral vs. unilateral stimulation and found no difference between the two.

In another trial, self-administered acupressure was tested. Sixty women with morning sickness were assigned to two groups: one group was taught how to apply acupressure at the P6 point; the other group was taught how to apply acupressure at a placebo point on the palm.⁷ Nausea was measured by symptom score and improved more in the experimental group than in the

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controls; however, there was no difference in the frequency or severity of emesis.

Electrical stimulation has also been tested. One crossover trial of 23 women in the first 14 weeks of pregnancy with nausea and/or vomiting used special wristwatch-sized TENS units that delivered a continuous current to P6.⁸ Each woman used an active device for 48 hours and a deactivated device for 48 hours. The order of use was randomly assigned. This study found improvement in 87% of women receiving active treatment and 43% receiving placebo treatment; the difference was significant. Nausea scores were also significantly better in the treatment group; however, maximum nausea scores did not differ between the two groups. Vomiting was not separately analyzed.

The fascinating part of this study, published in *J Repro Med*, was the authors' scrupulous avoidance of any acknowledgment that this was an acupuncture point stimulation study. The term "sensory afferent stimulation" is used in the title and throughout. The words "acupuncture," "acupressure," "P6," or "Neiguan" appear nowhere in the paper; placement of the unit is described as "the volar side of the wrist." Even the references avoid all mention of acupuncture point stimulation studies. One can only surmise that the authors feared any affiliation with alternative medicine enough that they masked what they were actually testing.

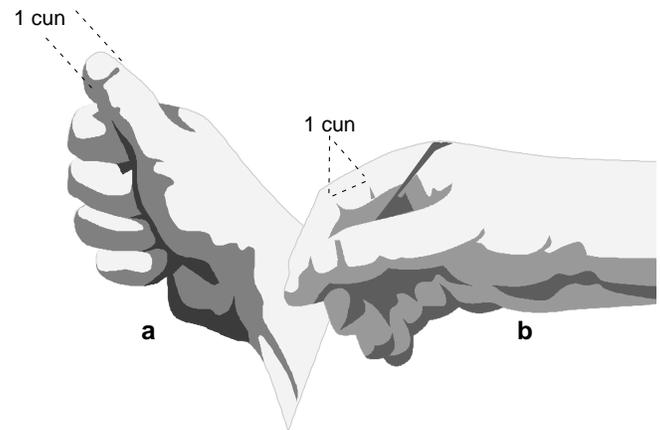
Only one prevention study was identified. Three hundred fifty women attending a prenatal clinic were allocated into three groups: One group received no treatment, one group was taught the location of the P6 point and was asked to apply finger pressure for five minutes every four hours on four successive mornings, and one group was told to stimulate a dummy point near the right elbow.⁹ Each group was asked to record frequency and severity of morning sickness and record the symptoms. Sickness was significantly less in women stimulating the P6 point than in the placebo point or untreated groups. Although reporting rates were equivalent in all three groups, the number of completed forms (the only ones analyzed) differed, with the control group having a higher rate of completed forms.

No trials were identified that tested acupuncture point stimulation for hyperemesis gravidarum. It would be very interesting to see whether the addition of acupoint stimulation to standard treatment makes a difference in hyperemesis gravidarum.

Conclusion

While most of the available evidence supports the use of acupuncture point stimulation to reduce nausea symptoms for patients with morning sickness, there is little

Figure 2. Cun



evidence that the technique reduces vomiting. For patients with mild-to-moderate morning sickness (especially those for whom nausea predominates over vomiting), this technique is worth a try. Patients can easily learn the location of this point in order to apply finger pressure; another option is acupressure bracelets, which are inexpensive and an easy way to achieve constant stimulation of the point. ♦

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Soybeans and Breast Cancer

PART II OF A SERIES
ON PHYTOESTROGENS

By *Adriane Fugh-Berman, MD*

SOYBEANS AND OTHER PHYTOESTROGENS ARE BEING touted as breast cancer preventatives, but the real picture is not that clear. Although there is a rationale for a reduction in breast cancer risk in premenopausal women who consume a diet high in soy products, there is little evidence that soy benefits postmenopausal women and no evidence that it benefits women with breast cancer. And the phytoestrogen supplements proliferating on drugstore shelves may have very different effects than adding tofu to a stir-fry.

Soybeans, mainly in the form of fresh, dried, pressed, or fermented tofu, are a common food in China, Japan, Korea, and other Asian countries. Although several epidemiological studies show a protective effect of soy consumption on breast cancer risk, results are not entirely consistent.

Epidemiological Studies

A case-control study that compared food choices of 200 Chinese women with breast cancer in Singapore with 420 matched controls found that soy product intake had a protective effect in premenopausal women, but no effect on postmenopausal women.¹ Another case-control study of premenopausal and postmenopausal women in China did not find a protective effect in either group.²

A recent case-control study of 288 premenopausal and postmenopausal women found that those with breast cancer excreted much lower amounts of phytoestrogens in their urine than women without breast cancer.³ In postmenopausal women, phytoestrogen supplementation markedly increased sex hormone binding globulin (SHBG);⁴ high levels of SHBG are associated with lower breast cancer risk.

A peculiar epidemiological study found a protective effect of miso (fermented soy paste) on breast cancer in a Japanese population living in Hawaii.⁵ The major problem with this study is that it used the dietary intake of husbands as a surrogate for their spouses. While couples eating together may have similar diets, in a number of these cases, the spouse was already dead and thus unavailable as a dinner companion. While it is possible that a widower's diet reflects his dead wife's diet, it may just as well reflect his mother's or girlfriend's, his own cooking, or the menu at the closest greasy spoon.

In Vitro and In Vivo Data

There are experimental data supporting the view that phytoestrogens may have a protective effect against breast cancer. Phytoestrogens are natural selective estrogen receptor modulators (SERMS) that have demonstrable hormonal effects on women. Genistein (an isoflavone that is the predominant phytoestrogen in soybeans) suppresses the growth of many cancer cells in vitro.⁶ In addition, genistein inhibits protein kinase, DNA topoisomerase, and several other enzymes involved in signal transduction. Results of studies in animal models of mammary carcinogenesis have been mixed.¹

Reproductive Hormones

Phytoestrogen intake clearly has a strong effect on hormone levels in premenopausal women. Soybean intake substitutes weak estrogens for strong ones. Although phytoestrogens are less than 1% as potent as endogenous estrogens in binding assays, they can elicit equivalent biological responses.⁷ Because dietary phytoestrogens occupy estrogen receptors and fulfill the roles of endogenous estrogens, they down-regulate production of endogenous estrogens. Several studies have shown that serum estrogens are lower in Asian women than white Western women.⁸

This effect has also been demonstrated experimentally. A study of six premenopausal women found that daily consumption of 36 ounces of soy milk (containing about 200 mg isoflavones daily) for one month decreased serum 17-beta-estradiol levels by 81% at mid-cycle and 49% in the luteal phase.⁹ This decrease persisted for two to three cycles. Progesterone levels and DHEAS levels were also decreased. Menstrual cycle lengths increased by an average of 3.5 days, but because of the small sample size this difference was not statistically significant.

Another study of six women with regular menstrual cycles who consumed 60 g of soy protein (containing 45 mg isoflavones) daily for one month found that the heavy soy intake increased follicular phase length and/or delayed menstruation.¹⁰ Midcycle surges of luteinizing hormone and follicle-stimulating hormone were significantly suppressed as well.

Breast Secretory Activity

A study that examined the effects on nipple secretions in 24 premenopausal and postmenopausal women ingesting 38 g genistein-enriched soy protein isolate (containing 38 mg genistein) for five months found erratic elevations in estradiol concentrations, increased volume of breast secretions by nipple aspirate, and

increased epithelial hyperplasia after supplementation.¹¹ This was not a predicted finding. This study, however, is problematic and difficult to interpret, given a high dropout rate; possible stimulation of prolactin levels by breast pumping to obtain nipple aspirate; five women taking HRT or OC during the study; and the inexplicable inclusion of one subject despite the fact that she had a pituitary adenoma and was being treated with bromocriptine. Additionally, the product used was unusual, i.e., soy protein fortified with genistein.

Guide to Soy Products

- **Tofu:** bean curd (made by adding a coagulant to the liquid squeezed from cooked soybeans). This is a bland and versatile Asian food that comes in many forms. Usually sold in blocks, often labeled as to texture, ranging from “silken” (very soft, used in shakes and puddings), to soft, firm, and extra firm. Softer types are usually used in soups and the firmer type in stir-fry, casseroles. There are many varieties of pressed, dried, and fermented tofu.
- **Tempeh:** a fermented, firm tofu product that is usually packaged in blocks.
- **Miso:** fermented bean paste, used as a base for Japanese soups and sauces.
- **Soy grits, soy flour, soy powder:** different particle sizes of soybeans (usually made from defatted soybean flakes).
- **Green soybeans:** fresh soybeans, usually boiled.
- **Textured soy protein:** may be made from isolates, concentrates, soy grits, or soy flour. Often processed to resemble different sorts of meat.
- **Soymilk:** a milk substitute made from cooked soybeans. American varieties may have various flavorings added.
- **Soy protein isolate:** a 90% protein product prepared from defatted soybeans. Used in infant formulas as well as many commercially prepared soy products.
- **Soy protein concentrate:** usually contains 65% protein. Prepared from defatted soybeans and used in many commercially prepared soy products. ❖

Adapted from Messina MJ, et al. Soy intake and cancer risk: A review of the in vitro and in vivo data. *Nutr Cancer* 1994;21: 113-131.

Postmenopausal Women

Phytoestrogens may have different, and possibly opposite, effects in premenopausal and postmenopausal women. In premenopausal women, the effect of a diet high in phytoestrogens is anti-estrogenic, although in postmenopausal women phytoestrogens have estrogenic effects. The reason for this may be that because background estrogen levels are already low in postmenopausal women, adding dietary phytoestrogens increases estrogen effects, which is why phytoestrogen supplementation helps hot flashes. (See Premiere Issue of *Alternative Therapies in Women's Health*).

Some argue that phytoestrogens must be beneficial at all ages because breast cancer rates are lower in Asian women throughout the life span at all ages than in Western women. However, lower postmenopausal breast cancer rates may have nothing to do with postmenopausal soybean intake. It may be that premenopausal soybean intake reduces lifetime risk of developing breast cancer. Additionally, other dietary and environmental differences may factor into this reduced risk. For example, Chinese and Japanese consuming a traditional diet consume more fiber, less fat, less meat, almost no dairy products, and more fruits, vegetables, and grains than do Westerners. Any of these factors (or a combination) could contribute to lower breast cancer rates.

Women with Breast Cancer

There are no clinical studies of the effect of phytoestrogen intake in women with breast cancer. It may be theorized that in premenopausal women with breast cancer, the reduction in endogenous estrogens by soy food supplementation would be beneficial. In postmenopausal women with breast cancer, there is little reason to think that soy food supplementation would be beneficial. It is unclear what the combined effects of tamoxifen treatment and soy supplementation would be.

Phytoestrogens can cause cancer cells to grow. In an immunocompromised mouse model, phytoestrogen implants caused estrogen receptor positive (but not estrogen receptor negative) breast cancer implants to grow.¹² A recent in vitro study found that four types of phytoestrogens (genistein, daidzein, formononetin, and equol) stimulated estrogen-dependent gene expression in MCF-7 breast cancer cells.¹³ Combinations were even more stimulatory than individual compounds.

Soy and Endometrial Cancer

Unlike conjugated estrogens or the SERM tamoxifen, soy foods do not increase endometrial cancer rates and

in fact may decrease it. A case-control study of 332 endometrial cancer cases and 511 controls among a multi-ethnic population in Hawaii found that high soy intake appears to protect against endometrial cancer in both premenopausal and postmenopausal women.¹⁴

Recommendations

In premenopausal women, soy food supplementation lowers endogenous estrogen levels and may help reduce the rate of breast cancer occurrence or recurrence. There is no convincing evidence that soy food supplementation prevents breast cancer occurrence or recurrence in postmenopausal women, nor is there convincing evidence that soy supplementation is harmful. There is a dearth of information on combining soy food supplementation with tamoxifen.

Soy foods have been a staple in Asian cuisine for thousands of years and can be presumed safe. However, the recent availability of purified isoflavone or mixed-phytoestrogen pills is worrisome. There are no long-term safety data available for these food-free phytoestrogens, and their use should be discouraged. ❖

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CME Questions

1. In premenopausal women, soybean intake:
 - a. raises estradiol levels.
 - b. lowers estradiol levels.
 - c. does not affect estradiol levels.
2. In binding assays, phytoestrogens in soybeans are:
 - a. equal in potency to endogenous estrogens.
 - b. 100 times more potent than endogenous estrogens.
 - c. 100 times less potent than endogenous estrogens.
 - d. None of the above.
3. In pregnant women, controlled trials show that acupressure at the P6 point is effective for:
 - a. nausea.
 - b. vomiting.
 - c. hyperemesis gravidarum.
 - d. All of the above.
4. The P6 acupressure point for treating nausea and vomiting is located near the:
 - a. wrist.
 - b. elbow.
 - c. knee.
 - d. shoulder.
5. Which of the following herbs contain caffeine?
 - a. Stevia (*Stevia rebaudiana*)
 - b. Guarana (*Paullinia cupana*)
 - c. Siberian ginseng (*Eleutherococcus senticosus*)

Label Review

FAT BURNER™

Label Information

“Zero calories”

“Whether you’re on a diet or simply need a refreshing beverage, FAT BURNER™ may be perfect for you.”

“FAT BURNER™ contains hard-working diet and energy ingredients such as Chromium Picolinate and Ginseng.”

Suggested Use

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“With zero calories and no carbonation, FAT BURNER™ is the perfect refresher anytime.”

“FAT BURNER™ beverages are available in a variety of great-tasting fruit flavors.”

Ingredients

Water, natural and artificial flavors (glycerol ester of wood rosin, gum arabic), citric acid, FD&C Red #40, potassium sorbate, potassium benzoate, aspartame, stevia, ascorbic acid, Siberian ginseng, inositol, L-carnitine, guarana, vitamin A palmitate, chromium picolinate, vanadyl sulfate.

Supplement Facts

Amount per serving		% daily value
Calories		0
Total fat		0
Total carbohydrate		0
Vit A	100 IU	2%
Vit C	0 mg	2%
Chromium	50 mcg	40%
Potassium	40 mg	1%
Inositol	14 mg	
L-carnitine	10 mg	
Vanadium	7 mcg	
Herbal energy blend	67 mg	

Siberian ginseng (*Eleutherococcus senticosus*) (root)

Guarana (*Paullinia cupana*) (seed)

Stevia (*Stevia rebaudiana*) (leaf)

(FAT BURNER™ is a trademark of Great American Nutrition™.)

Price: 1 bottle, 16.9 oz, \$0.95

Analysis of Ingredients

Vitamin A, vitamin C, and potassium: these amounts are inconsequential. It’s hard to fathom how 0 mg of vitamin C can be 2% of the RDA.

Chromium: an essential nutrient that potentiates insulin action. Can improve glucose tolerance in some mild diabetics at doses of 150-200 mcg/d. Many diets supply less than 50 mcg/d. In adults, doses up to 200 mcg/d are safe. This is a safe and adequate dose of chromium, but there is no evidence that it facilitates weight loss.

Inositol: an essential growth factor at the cellular level. Average dietary intake is 1 g daily from fish, meat, and dairy (it is also synthesized by intestinal bacteria.) In rodents, deficiency can cause accumulation of hepatic or intestinal triglycerides. In female gerbils, prolonged deficiency of inositol leads to progressive weight loss. The amount of inositol in this supplement is inconsequentially small, and there is no evidence that inositol supplementation facilitates weight loss (in gerbils, the opposite is true).

Carnitine: a conditionally essential nutrient involved in lipid metabolism. Average intake in non-vegetarians is 100-300 mg day. The amount of carnitine in this supplement is inconsequential.

Vanadium: arguably an essential trace metal. Vanadium can affect iodine metabolism and thyroid function in animals. Average dietary intake is 15-30 mcg. It is toxic large doses, but safe up to 100 mcg. The amount of vanadium in this supplement is safe, but there is no evidence it facilitates weight loss. (Theoretically, it is possible it could help with weight control in someone with subclinical hypothyroidism).

Herbal Energy Blend

Siberian ginseng: a tonic herb, often used to treat conditions with fatigue as a component

Guarana: a caffeine-containing herb

Stevia: an herbal sweetener

If the total amount of these herbs is only 67 mg, little effect should be expected. Larger amounts of guarana can certainly cause caffeine effects, and even small amounts can affect those who are sensitive to caffeine. ❖

If you would like to see a particular product reviewed, please send the label, package insert, and any promotional materials to Adriane Fugh-Berman, MD, *Alternative Therapies in Women's Health*, P.O. Box 740056, Atlanta, GA 30374.

With Comments from Adriane Fugh-Berman, MD

Hot Flashes: Dong Quai Unsuccessful

Source: Hirata JD, et al. Does dong quai have estrogenic effects in postmenopausal women? A double-blind, placebo-controlled trial. *Fertil Steril* 1997;68:981-986.

Design and Setting: Randomized, double-blind, placebo-controlled study conducted at a large health maintenance organization in northern California.

Subjects: 71 symptomatic postmenopausal women with FSH levels in the postmenopausal range.

Treatment: Dong quai (*Angelica sinensis*)

Dose/Route/Duration: 4.5 g po qd x six months.

Outcome Measures: Number of hot flashes, estrogenization of vaginal epithelial cells, or endometrial thickness measured by sonogram.

Results: There was no significant effect on any of the outcome measures.

Funding: Northern California Kaiser Foundation Hospitals, Inc. Community Service Program

Comments: This was a well-designed study with appropriate outcome measures for an estrogenic herb. According to the *Chinese Herbal Medicines Materia Medica* and other sources, dong quai is not considered estrogenic. It is unclear why investigators chose a non-estrogenic herb and measured estrogenic outcomes. Dong quai is a Chinese herb commonly prescribed to women for various conditions. Chinese herbs are seldom used alone but are used in individually tailored mixtures. In North America, dong quai is often used alone

by consumers who consider it a panacea for "women's problems." At least for hot flashes, the herb used on its own is clearly ineffective. ❖

Harvard Survey of Alternative Medicine Use Updated

Source: Eisenberg DM, et al. Trends in alternative medicine use in the United States, 1990-1997: Results of a follow-up national survey. *JAMA* 1998; 280:1569-1575.

Objective: To document trends in alternative medicine use between 1990 and 1997.

Setting/Methods/Subjects: National random-digit dialing telephone survey of 2055 English-speaking adults over the age of 18.

Results: Between 1990-1997, women have become more common users of alternative therapies (48.9%) than men (37.8%). Patterns of use that were similar in 1990 and 1997 included: more common use in the West; in those 35-49 years old; in those with some college education; and in those with annual incomes over \$50,000. In both surveys, use was less among African-Americans than other groups.

Use of at least one alternative therapy has increased from 33.8% in 1990 to 42.1% in 1997. The probability of seeing an alternative practitioner increased from 36.3% to 42.1%. The largest increases in use of specific therapies were seen in herbal medicine, massage, megavitamins, self-help groups, folk remedies, energy healing, and homeopathy. The most common conditions treated were back problems, allergies,

fatigue, arthritis, headaches, and neck problems. Of those taking prescription drugs, 19.4% reported concurrent use of high-dose vitamins, herbs, or both. Using conservative estimates, Americans spent an estimated \$14.6 billion on visits to practitioners in 1990 and \$21.2 billion in 1997. Most of this expenditure was out-of-pocket. The percentage of those using alternative therapies who discussed this use with their medical doctor did not change significantly between 1990 (38.5%) and 1997 (39.8%). A large proportion of alternative therapies for principal medical conditions is done without input from either physicians or alternative therapy practitioners.

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Comments: Extrapolating results to the general population is difficult because both surveys excluded non-English-speaking people and those without telephones. In addition, response rate was low in both surveys (60% in 1997, 67% in 1990). Despite these limitations, these survey results are important and show the growing use of alternative therapies among the American mainstream. Particularly interesting is that the number of patients who told their physicians about alternative medicine use has not changed in seven years. With almost one in five of patients on prescription medications also using herbs and/or vitamins, it is imperative that physicians ask about and document such use in order to track therapeutic effects, adverse effects, and interactions with conventional treatments. ❖

In Future Issues:

Black Cohosh for Menopausal Symptoms

Biofeedback for Migraine