

# Neuropathy Patients Try Alternative Therapies

BY CHRISTINE KILGORE

Contributing Writer

BETHESDA, MD. — Despite little evidence backing their efficacy, complementary and alternative medicine therapies are used regularly by more than 40% of patients with painful diabetic neuropathy, Dr. Martin Stevens said at a meeting sponsored by the National Institute of Health's Pain Consortium.

Well-designed, prospective, randomized trials of complementary and alternative medicine (CAM) therapies have been relatively few and far between. Many of the CAM approaches—which range from  $\alpha$ -lipoic acid and benfotiamine to biofield therapies, near-infrared phototherapy, and static- and pulsed-magnetic field therapies—pose “significant challenges” for adequate blinding and determination of a placebo response, said Dr. Stevens, professor of medicine at the University of Birmingham (England).

Overall, the literature shows that about 25% of patients taking CAM therapies for painful diabetic neuropathy report a response, “which is very close to what we'd consider a placebo response,” he said. Yet surveys suggest that only about one-third of patients with painful diabetic neuropathy respond to conventional pharmacologic therapies, such as nonsteroidal drugs, antidepressants, and non-addicting analgesics, which explains the growing popularity of CAM approaches, Dr. Stevens said.

A recently published study of Reiki, a hands-on therapy based on the theoretical existence of a bioenergy field intrinsic to the human body, suggests how powerful the placebo response and the therapeutic effects of ongoing involvement with a health care provider can be, Dr. Stevens noted.

Just over 200 patients with type 2 diabetes and painful diabetic neuropathy were randomized to receive Reiki, mimic Reiki, or usual care. Patients in the Reiki and mimic-Reiki groups underwent two treatments in the first week, followed by weekly treatments, for a total of 12 weeks. Patients in the usual-care group were assessed at the start and end of the 12-week period, said Dr. Stevens, one of the study investigators.

Global pain scores and walking distance improved from baseline in both the Reiki and mimic-Reiki groups, but not in the usual-care group.

There were no significant differences between the two groups at the final visit, indicating that the reduction in pain is consistent with the notion that “a sustained partnership between the health care provider and the patient can have direct therapeutic benefits,” Dr. Stevens and his coinvestigators wrote (*Diabetes Care* 2007;30:999-1001).

“Seeing the patient on a regular basis clearly does help their perception and their pain ... whatever else you chose to do to them,” he said at the NIH meeting.

The etiology of pain complicating diabetes is still

poorly understood, he noted. It may result from the dysfunction of pain-signaling pathways at multiple levels, such as cutaneous nociceptors, afferent neurons, and the spinal and supraspinal pathways, he said.

A survey of 180 consecutive outpatients with diabetic neuropathy and other peripheral neuropathies found that the most frequently used CAM therapies were megavitamins (35%), magnetics (30%), acupuncture (30%), herbal remedies (22%), and chiropractic manipulation (21%).

Almost 50% had tried more than one form of alternative treatment, and almost half did not consult a physician before starting CAM. Patients with diabetic neuropathy used CAM more frequently than patients with other neuropathies, the survey showed (*J. Neurol. Sci.* 2004;218:59-66).

Dr. Stevens and other investigators at the University of Birmingham are recruiting patients for a 12-week, randomized, double-blind, controlled study of taurine, a ubiquitous  $\beta$ -amino acid found in high concentrations in the central and peripheral nervous systems. The amino acid—probably one of the better-studied CAM therapies for painful diabetic neuropathy—functions as an antioxidant, calcium modulator, analgesic, and neuromodulator, Dr. Stevens said.

He hopes to recruit 180 patients to participate in the investigation and expects it to take at least another year to complete. ■

## Disparities in Diabetes Treatment Remain After Britain Introduces P4P

BY JONATHAN GARDNER

London Bureau

Pay for performance significantly increased the percentage of patients achieving some diabetes treatment goals in one London primary care trust, but did not improve disparities between white British and ethnic minority patients, according to an observational study.

Researchers from Imperial College London, the University of Leicester, and Wandsworth Primary Care Research Center, London, reviewed electronic general practice records for 4,284 adult type 1 and 2 diabetes patients enrolled in 32 practices in Wandsworth Primary Care Trust before and after the National Health Service implemented a pay-for-performance contract with general practitioners in 2004 (*PLoS Med.* 2007 June 12 [Epub doi:10.1371/journal.pmed.0040191]). National treatment targets for diabetes patients included HbA<sub>1c</sub> less than or equal to 7.0%, blood pressure less than 140/80 mm Hg, and total cholesterol less than or equal to 193 mg/dL.

In terms of cholesterol control, significantly more patients met the treatment target for total cholesterol in 2005, compared with 2003 (70.4% vs. 57.5%, respectively). Improvements were uniform across all ethnic groups except for the Bangladeshi group, which had significantly greater improvement in cholesterol control relative to the white British group after adjusting for age, gender, deprivation, and practice-level clustering. Similarly, there were also large improvements in hypertension control across all ethnic groups except for black Caribbean patients, who had significantly less improvement in blood pressure control, compared with white British patients after adjusting for age, gender, deprivation, and practice-level clustering, the researchers wrote.

The also found no significant difference in the percentage increase of white British or minority patients prescribed angiotensin-converting enzyme inhibitors and lipid-lowering drugs, although black Africans remained significantly behind white British patients in terms of the percentage prescribed the lipid-lowering drugs in 2005 (63.9% vs. 48.8%).

Researchers also found that significantly more patients reached recommended levels of HbA<sub>1c</sub> in 2005, compared with 2003 (37.4% vs. 35.1%) except for black Caribbean patients, who had significantly less improvement, compared with the white British group. They also found, compared with white British patients in 2005, that black Caribbean, black African, Indian, and Pakistani patients had significantly greater percentages prescribed oral hyperglycemic agents. And, while significantly more patients overall were treated with insulin in 2005, compared with 2003, the increases in insulin prescribing were significantly lower in the black African and south Asian groups, compared with the white British group.

“Although diabetes management improved in all ethnic groups after the introduction of pay-for-performance incentives in UK primary care, disparities in prescribing and intermediate clinical outcomes persisted,” wrote the researchers, led by Christopher Millett, of the Imperial College London's department of primary care and social medicine. “Hence, the main lesson from this study for health-care systems in other countries is that pay-for-performance by itself may not be sufficient to address ethnic disparities in the quality of care.”

The authors acknowledged that they were unable to definitively link changes in diabetes management to the pay-for-performance program, in part because their study design was unable to allow for a control group. ■

## Olive Oil May Decrease Cardiac Risk in Diabetes

BY HANNAH BROWN

Contributing Writer

BARCELONA — Additional supplementation of olive oil in the diets of patients with type 2 diabetes may reduce their risk of cardiac problems, according to research presented at an international congress on prediabetes and metabolic syndrome.

In a preliminary study to identify a potential mechanism through which the Mediterranean diet protects against cardiovascular disease, Dr. Mohammed Hammami, head of the biochemistry laboratory, Université du Centre, Monastir, Tunisia, and colleagues analyzed the relationship between homocysteine and other modifiable cardiovascular risk factors, including diet, in type 2 diabetes patients.

Previous work has linked high levels of homocysteine to a high prevalence of macroangiopathy, coronary heart disease, and renal insufficiency in patients with type 2 diabetes. In addition, clinical trials testing vitamin supplementation in these patients have resulted in decreased homocysteine levels in patients with diabetic dyslipidemia, suggesting that lowering homocysteine levels could reverse the lipid problems.

The researchers recruited 70 patients with type 2 diabetes and evaluated their nutritional habits based on a validated food frequency questionnaire. On average, those with diabetes consumed foods high in fat. Dr. Hammami and his colleagues

measured mean homocysteine levels, which were 13.6 plus or minus 6.06 micromol/L for the group; 27.5% of participants had levels of plasma homocysteine assessed as high (greater than 15 micromol/L). Further studies showed an inverse correlation between homocysteine levels and dietary saturated fatty acids or daily cholesterol intake.

According to Dr. Hammami, plasma homocysteine levels were lower in patients with diabetes who consumed extra virgin olive oil than in those who consumed little or none (10 micromol/L vs. 14 micromol/L, respectively). “Our study supports other studies showing the beneficial effects of the Mediterranean diet on the cardiovascular risk factors, essentially on homocysteine levels,” he said.

“We have revealed a potential mechanism by which a Mediterranean type of diet may affect coronary risk,” Dr. Hammami continued. “The consumption of olive oil, the major fat in this diet type, may lead to decreased levels of homocysteine.”

He suggested that his study “should be followed up by investigations on the effects of the different components of olive oil”—not only oleic acid but also minor components such as vitamins and polyphenols—“on the reduction of homocysteine levels.” Dr. Hammami said he plans to do more extensive patient recruitment and supplementary analysis on such things as thiolactonase activity measurement. ■