

# Acupuncture Nearly Halves Headache Days

BY NANCY WALSH  
New York Bureau

EXETER, ENGLAND — Data emerging from a large German research initiative sponsored by that country's insurance companies continue to support the use of acupuncture in the treatment of chronic pain conditions.

Two reports from the Acupuncture in Routine Care (ARC) study, presented at a symposium on alternative and complementary therapies sponsored by the universities of Exeter and Plymouth, demonstrated statistically significant and clinically relevant benefits for acupuncture when used in addition to routine care for headache and neck pain.

A total of 15,056 patients with migraine or tension-type headache were enrolled in the ARC headache study and randomly allocated to receive up to 15 acupuncture treatments during a 3-month period along with conventional treatment with analgesics, or to a control group receiving conventional treatment but no acupuncture. Patients who did not agree to randomization received acupuncture and were monitored as a third group, said Susanne Jena,

M.D., of the Institute for Social Medicine, Charité Medical Center, Berlin.

Three-quarters of the patients were female, and their mean age was 44 years. Of the 3,182 who agreed to randomization, 1,613 were in the acupuncture group and 1,569 were in the control group.

After 3 months of treatment, the frequency of headache days per month decreased from 8.4 days to 4.7 days in the two acupuncture groups, a significantly greater reduction than in the control group (8.1 days per month before treatment and 7.5 days per month post treatment).

The data also were analyzed according to headache type. Patients with migraine had an average of 7 days per month with headache before treatment and 4 days per



Data from European research suggest that acupuncture reduced headache days and analgesia use, as well as significantly cutting neck pain scores.

month with headache after treatment including acupuncture; those with tension type headache decreased from an average of 10 days per month with headache to 5 days per month, she said.

The improvements persisted for the subsequent 3 months, she said.

Among the control group, 70% of patients required concomitant treatment

with analgesics, compared with 50% of patients in the acupuncture groups.

The second report, from the ARC neck pain study, found similar results among 13,846 patients with chronic neck pain. In this cohort, 68% of whom were women with a mean age of 53 years, 1,753 were randomized to receive acupuncture, 1,698 served as controls, and 10,395 who had declined randomization also received acupuncture.

After 3 months of treatment, improvements on the neck pain disability score were more pronounced in the acupuncture groups than in the control group, said Claudia Becker-Witt, M.D., also with Charité. Scores fell from 56.4 to 39.6 in the acupuncture groups and from 54.5 to 51.2 in the control group, a statistically significant difference.

In both studies, the acupuncture groups also experienced significantly greater improvements in quality of life.

About 8% -9% of patients in both studies experienced side effects from acupuncture; they were not life threatening.

Analyses of cost-effectiveness and overall health benefits are being done, Dr. Becker-Witt said. ■

## Pediatric Migraine Guidelines Decry Lack of Data on Kids

BY DIANA MAHONEY  
New England Bureau

When it comes to drug therapy for migraines, don't treat children like little adults.

There are currently no agents approved by the FDA for the acute treatment of migraine in children or adolescents. New practice guidelines developed by the American Academy of Neurology (AAN) support the use of conventional analgesic medications, such as ibuprofen and acetaminophen, for acute migraine pain in children aged 6 years and older but do not recommend most of the newer drugs being used to prevent and treat adult migraine pain.

One exception is sumatriptan nasal spray (Imitrex), which the guidelines recommend for treating migraine pain in children older than 12 years.

"It is not that the newer medications are ineffective in children and adolescents," said lead author Donald W. Lewis, M.D. "Rather, they have been insufficiently studied in the pediatric population." In fact, the most definitive conclusion the guideline authors reached was that there is a "clear and urgent need for methodologically sound randomized controlled trials for the use of prophylactic drugs in pediatric migraine," Dr. Lewis said in an interview with CLINICAL NEUROLOGY NEWS.

Dr. Lewis, a pediatric neurologist at Children's Hospital of the King's Daughters in Norfolk, Va., and his coauthors reviewed the results of 166 placebo-controlled trials of migraine therapy conducted in children between the ages of 3 and 18 years during the last 2 decades. The evaluation included 5 agents for acute migraine treatment and 12 for migraine

prevention. The authors used a four-tiered classification system to assess the quality of the available evidence, to determine whether the evidence supported specific recommendations, and, if it did, to gauge the strength of the recommendations (Neurology 2004;63:2215-24).

The treatment agents included in the evaluation were ibuprofen, acetaminophen, sumatriptan nasal spray, rizatriptan (Maxalt), and zolmitriptan (Zomig). The preventive agents were flunarizine (Sibelium), cyproheptadine (Periactin), amitriptyline (Elavil), divalproex sodium (Depakote), topiramate (Topamax), lev- etiracetam (Keppra), propranolol (Inderal), trazodone (Desyrel), pizotifen (Sandomin), nimodipine (Nimotop), and clonidine (Catapres).

Of drugs to treat acute migraine, both ibuprofen and sumatriptan nasal spray were classified as effective, although the data for nasal sumatriptan only support a recommendation for use in adolescents. Acetaminophen was judged probably effective and also recommended for use. Both the oral triptan preparations as well as subcutaneous sumatriptan were not recommended because there were no data to support or discourage their use.

Only one of the preventive drugs—flunarizine—has been studied in rigorous controlled trials in children and was deemed by the guideline authors as "probably effective" in children. However, the calcium channel blocker is not available in the United States.

**Physicians still need standardized criteria with which to diagnose migraine headaches and for classifying response to treatment in children.**

Of the remaining prophylactic agents, there is insufficient evidence to recommend cyproheptadine, amitriptyline, divalproex sodium, topiramate, or lev- etiracetam, according to the guidelines. Propranolol and trazodone are not recommended because of conflicting evidence, and pizotifen, nimodipine, and clonidine are not recommended because the data did not show them to be effective.

Given the prevalence of migraine headaches in children—up to 23% in 11-

to 15-year-olds—"there is a disappointing lack of evidence to support pharmacologic interventions," said Dr. Lewis. Although the failure of the various therapeutic and prophylactic drugs to demonstrate statistically significant efficacy does not preclude their use in the pediatric population, "good clinical judgment has to be used, particularly with respect to dosing and age ranges," he said.

Fortunately, some proven adult interventions are effective, and the guidelines recommend their use in children as well.

"Not all children require drug treatment for migraines, and in fact it is often not the first line of attack and should never be the sole approach," said Dr. Lewis. Lifestyle changes are often in order and can be very effective, he said. "In teens especially, poor diet, lack of sleep, too much caffeine, and school and social stress is a big problem. The first step is to modify these factors."

Lifestyle information, including nutritional education, a prescription for daily

exercise, and, when indicated, behavioral therapy, should be part of every migraine treatment protocol, as should a migraine calendar to record the frequency and intensity of migraine.

These steps help to ensure that each child gets the treatment that meets his or her individual needs.

"There is no one 'right' way to treat migraine in children," Dr. Lewis said. "Interventions need to be tailored to the individual."

One often overlooked key to the development of successful interventions, Dr. Lewis contended, is the fact that parents, teachers, caregivers, and physicians often don't recognize migraines in children—either because of a misperception that children don't experience migraines or because the children are not able to fully articulate the nature of the pain.

"The problem needs to be fully recognized, and potential interventions need to be more rigorously pursued" before more definitive treatment recommendations can be made, he said.

In addition to their call for well designed, multicenter clinical trials of migraine interventions in children and adolescents, the guideline authors also highlight the need for standardized criteria for diagnosing migraine headaches and for classifying treatment response in this population.

Further, future research trials should result in increased understanding of observed variations in effects of treatments by age and sex, according to Dr. Lewis.

Both the American Academy of Pediatrics and the American Headache Society have endorsed the new guidelines, according to a press release issued by the American Academy of Neurology. ■