Acupuncture Shows Clinical, Cost Effectiveness

BY JONATHAN GARDNER
London Bureau

A short course of traditional acupuncture can relieve nonspecific lower-back pain better than usual care at a small increased cost to payers, a new study has found.

The study (BMJ 2006 [Epub doi: 10.1136/bmj.38878.907361.7C]) randomized 160 adults from York, England, into acupuncture and 81 into usual care of physical therapy, manipulation, pain relief drugs, and exercise, following up at 12 and 24 months to test back pain. Researchers selected a larger group for acupuncture to test differences in pain relief among patients treated by different acupuncturists.

Patients who underwent up to 10 acupuncture treatments over 3 months saw their mean score on the 100-point SF-36 bodily pain index—in which 100 equals no pain—increase from 30.8 at baseline to 64 at 12 months and 67.8 at 24 months. By comparison, those in the usual-care group rose from 30.4 at baseline to 58.3 at 12 months and 59.5 at 24 months. The difference at 12 months did not achieve statistical significance, but the difference at 24 months did, researchers said. Their conclusion: "Weak evidence was found of an effect of acupuncture care on nonspecific low back pain at 12 months, but stronger evidence of a small benefit at 24 months."

Although the researchers said they had chosen a sample size to determine at least a 10-point difference in pain relief, they wrote: "A difference of at least 5 points in the mean score of the SF-36 bodily pain dimension is, however, considered to represent a clinically worthwhile benefit and a difference of between 5 and 9 points can be viewed as a moderate effect."

An accompanying economic analysis (BMJ 2006 [Epub doi: 10.1136/bmj.38932.806134.7C]) found that acupuncture cost the National Health Service £459.70 per patient, £114.50 more than usual care.

Acupuncture resulted in a gain of 1.453 quality-adjusted life years—a measurement of a patient's quality of life year in which 1 year in perfect health equals 1.0—while usual care resulted in a gain of 1.426 quality-adjusted life years.

The researchers said the incremental cost of per quality-adjusted life year of acupuncture over usual care was £4,241 at 24 months, below the £20,000 cost-effectiveness standard set by the National Institute for Health and Clinical Effectiveness. ■

Approval of Triptan for Kids Still Pending

LOS ANGELES — A relatively low dose of oral almotriptan significantly relieved migraine pain, photophobia, and phonophobia in a large, randomized, placebo-controlled, parallel group study of adolescent patients, Dr. Steven L. Linder reported at the annual meeting of the American Headache Society.

However, because of a stringent definition of success set by the Food and Drug Administration, the study was still considered a negative trial, failing once again to pave the way to approval of a triptan in the treatment of acute migraine in adolescents or children.

Instead, results of the multicenter study will be considered "exploratory data" by the FDA, said Dr. Linder, a pediatric neurologist in private practice in Dallas.

The study randomized 714 preteens and adolescents aged 12-17 years with a history of severe migraines to receive placebo or 6.25 mg, 12.5 mg, or 25 mg of almotriptan, a 5-$HT_{1B/1D}$ agonist, for the treatment of one migraine attack of moderate to severe intensity. The FDA required study results to be gauged on a four-pronged primary end point at 2 hours that included pain relief as well as the absence of photophobia, phonophobia, and nausea.

All four end points had to show superiority over placebo at a significance of 0.05 for the results to be considered positive.

All three dosages outperformed placebo in reducing pain, meeting this criterion in 71.8%, 72.9%, and 66.7% of patients assigned to the groups taking 6.25 mg, 12.5 mg, and 25 mg of the drug, compared with 55.3% of patients who received placebo.

An audience member, Dr. Marcelo E. Bigal, commended the study despite its negative primary end point.

—Betsy Bates

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