Acupuncture, a component of traditional Chinese medicine, has been used in China for over 3,000 years. More recently, there has been a revived interest in the West with hundreds of clinical trials conducted since the early 1970s. These trials investigated the safety and efficacy of acupuncture for a wide range of health problems, and, as a result, a plethora of systematic reviews and meta-analyses have been published in an attempt to summarize available data. In fact, in 1996 a complementary medicine field was established within the Cochrane Collaboration to review trials of complementary medicine, including acupuncture. Several national reviews also evaluated the evidence regarding the use of acupuncture, such as the National Institute of Health (NIH) consensus conference.1

However, a number of methodological issues in many of the published acupuncture articles resulted in a slow pace of acupuncture’s acceptance by the biomedical community. To the entrenched scientist, accepting theories of energy channels and qi has proven difficult in some circles. The conclusion of many published meta-analyses assessing the efficacy of acupuncture was that the evidence was inconclusive, because the quality of the included studies was not sufficiently high and that studies with more robust methodology were needed to reach a definite conclusion. At the same time, numerous articles were published highlighting shortcomings in acupuncture research and making recommendations for the design and execution of future acupuncture trials.2,3

Making Progress
Standards for reporting interventions in controlled trials of acupuncture have also been developed and adopted by several journals.4 This helped to improve the quality of some of the more recently published acupuncture trials, which also tend to include larger sample sizes than older studies. The number of individuals with both methodological skills and practical expertise in complementary medicine has also been increasing. A number of meta-analyses of acupuncture have been updated to incorporate more recent evidence from better-performing clinical trials as a result.

For instance, the management of headache has been the subject of a number of meta-analyses over the years; some of them have been recently updated. A Cochrane review in 2001 included 26 mostly small randomized or quasi-randomized trials in 1,151 patients with several types of headache. The majority of the included trials were of questionable quality and had significant methodological and/or reporting shortcomings. So while this review suggested that acupuncture might have a place in the treatment of idiopathic headaches, the quality and amount of evidence was not convincing.5 The same group had similar conclusions in an earlier meta-analysis including 22 studies with a total 1,042 patients and indicated the need for well designed large studies to assess the efficacy of acupuncture in treatment of headache.6

Recent Findings
Sun and Gan7 recently performed a meta-analysis of 31 trials that included a total of 3,916 patients who received traditional needling acupuncture treatment. Of the 31 trials, 17 investigated migraine, 10 tension-type headaches, and four included mixed chronic headaches. Most of the trials (16) compared true acupuncture versus sham acupuncture; whereas eight studies compared acupuncture with pharmacologic therapy. Of note, 12 trials included in the previous reviews were excluded for this meta-analysis due to inadequate quality of data. At the same time, 17 new trials published since the last review were included. These were generally superior in quality and had larger sample size. Four main end points were included in this meta-analysis: headache intensity, headache frequency, response
rate, and headache related quality of life (QoL) as assessed by the physical and mental health measures from Short Form (SF-36) Health Survey. The response rate was defined as at least 33 percent improvement in headache index, headache frequency, or overall evaluation. Two follow-up times were included: an early follow-up defined as the measurement closest to eight weeks but no later than three months after randomization, and a late follow-up, defined as the measurement closest to six months but later than three months after randomization. Early response rate was significantly higher with true versus sham acupuncture (53 vs. 45 percent, p=0.0003) when all the studies were combined.

A subgroup analysis found a similar significant reduction for tension type headache but not for migraine. Combined late response rate, reported in only two studies, was also significantly higher with true acupuncture (65 vs. 53 percent, p=0.01). Headache intensity at the early follow up was not reduced with true versus sham acupuncture when all studies were combined, nor was it improved in the subgroup analysis including migraine headache. However, there was a significant though small, reduction in headache intensity during the late follow-up period with true acupuncture with a mean reduction of -2.62mm (95 percent CI -5.07, -0.17). For tension type headache, intensity was reduced at both the early (p=0.02) and late (p=0.01) follow-up periods. Headache frequency and health related QoL were not improved with true vs. sham acupuncture.

When compared with pharmacological treatments, acupuncture was significantly more effective in reducing headache intensity at the early follow up, headache frequency, and response rate (62 vs. 45 percent, p=0.0009). Health related QoL also showed significantly better physical function with acupuncture at early follow-up. Notably, acupuncture was also associated with fewer side effects compared with pharmacologic treatments.

Findings of Sun and Gan were similar to two recent Cochrane reviews that updated the original review. The first review focused on use of acupuncture for migraine prophylaxis. This meta-analysis included 4,419 participants from 22 randomized trials with a post-randomization observation period of at least eight weeks. The authors concluded that there is consistent evidence that acupuncture provided additional benefit to treatment of acute migraine attacks. While they found no evidence for an effect of true intervention over sham interventions, the included studies suggested that acupuncture is at least as effective as, or possibly more effective than prophylactic drug therapy and has fewer adverse effects. The authors suggested that this apparent contradiction of finding a benefit over drug treatment but not over sham interventions might be due to several issues, including: a placebo effect of acupuncture, direct physiological effects of sham acupuncture relevant to pain processing, or lack of blinding and possible bias in comparisons with routine care and prophylactic drug care.

The second recent Cochrane review by the same group included 11 trials with 2,317 participants with tension-type headache. All included trials had a post-randomization observation period of at least eight weeks. There was a small but statistically significant benefit of acupuncture over sham for several outcomes including response, headache

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days within four weeks of the observation period and headache intensity.

Another recent meta-analysis on acupuncture for tension-type headache (TTH) included cross-over trials with observation periods shorter than eight weeks. While this latter review reported a larger difference between the groups in the number of headache days per month (2.93 versus 1.56 in the Cochrane review), the difference was not statistically significant. The difference in inclusion criteria between the two systematic reviews resulted in inclusion of different studies, more statistical heterogeneity, and a negative conclusion regarding headache frequency.

Other non-pharmacological treatment options for headache have been investigated, and published studies have compared some of these modalities with acupuncture. For instance, Soderberg et al. compared treatment with acupuncture, physical training, and relaxation training in patients with chronic TTH. Relaxation training and physical training resulted in a long-lasting reduction in headache intensity, more headache-free days, and more headache-free periods. Patients in the relaxation group had significantly more headache-free periods and more headache-free days directly after the last treatment compared with the acupuncture group.

Other trials compared acupuncture with physiotherapy, relaxation, and massage and suggested that the other modalities were superior to acupuncture. However, these studies had methodological shortcomings, and therefore their results should be interpreted with caution.

### Showing Promise

The use of acupuncture has also been investigated for a number of other pain related conditions including postoperative pain, low back pain, osteoarthritis, and dysmenorrhea. While the evidence from a number of meta-analyses suggests that acupuncture has a role in the management of painful conditions, some have included studies of poor methodology. Publication bias is always a concern; negative research being less likely to be published compared with positive studies. It was also suggested that the inclusion of acupuncture studies with small sample size was a factor that might cause overestimation of the effectiveness of the intervention in systematic reviews. Therefore caution is needed when interpreting the results of these meta-analyses.

Recent reviews have adopted more rigid inclusion criteria, only including studies with higher quality and larger sample sizes. The results of these reviews suggest that there is a role for acupuncture in the management of headache. There is also no doubt that the lack of significant side effects associated with acupuncture and other non-pharmacological treatments is appealing, as they can be as or more bothersome than the chronic conditions themselves.

The bottom line is that more research is needed. Studies need to incorporate acupuncture as part of a multimodal regimen for management of headache. Studies also need to establish the optimal timing of administration of acupuncture, acupoints to be used, and optimal frequency of acupuncture treatment. Above all, fundamental research into the mechanism of action of acupuncture is of paramount importance.

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** ISSUES IN FOCUS **

Research into the mechanism of action of acupuncture is of paramount importance.

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Ashraf S. Habib, MBChB, MSc, FRCA is Associate Professor in the Department of Anesthesiology at Duke University Medical Center in Durham, NC.

Tong J. Gan, MB, MHS, FRCA, MD is Professor and Vice-Chair in the Department of Anesthesiology at Duke University Medical Center in Durham, NC.