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- The technology is widely accepted and / or has become standard of care.
- New literature on the topic exists in the past five years but does not substantially change the conclusions.

This report is for reference purposes and should be viewed cautiously in current medical practice.



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Technology Assessment Report

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- federal, state and local government health care policy makers and specialists; and
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**Acupuncture for Chronic Osteoarthritis Pain,
Headache, and Low Back Pain**

Prepared under the direction of the
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Description of Treatment/Procedure

Acupuncture treatment consists of inserting needles into specific sites at which stimulation of the tissue is reported to exert a maximum therapeutic effect. These sites may be the classically defined acupuncture points or points defined by other criteria. The stimulation may be manual manipulation of the needles or may involve heat or electricity. The exact mechanism for pain relief has not been established.

Potential Uses

Acupuncture is indicated as a non-pharmacological alternative to conventional therapy for patients a) with adverse consequences of pharmacological approaches, b) whose preference is to not take pharmacological agents, or c) whose comorbidities prevent them from taking certain drug therapies.

Contraindications

Acupuncture is contraindicated when there is a strong need to treat the patient's medical condition with conventional medicine and when patients are severely debilitated or terminally ill. In both instances, however, acupuncture could be used as an adjunct therapy.

Efficacy of Treatment/Procedure

Evidence pertaining to the use of acupuncture for osteoarthritis, headache, and low back pain is detailed in the update report and summarized below. The studies include randomized trials and systematic reviews.

Updated Committee Summary

Based on a review of evidence available to date, the ICSI Technology Assessment Committee finds the following:

1. The quality of the literature continues to be a concern. As noted in the original report, there are difficulties defining the appropriate experimental model for pain, small sample sizes, difficulties selecting an appropriate control group, and inadequate follow-up. Researchers are being encouraged to compare acupuncture with a standard of care rather than a placebo. The NIH Consensus Panel concluded that further studies of the physiology and clinical value of acupuncture were warranted based on the evidence available. Increased funding by the NIH should foster higher quality research.
2. The following conclusions from the original report continue to be valid:
 - a. The benefits of acupuncture are not experienced by every patient. To date, there is no way to identify who is most likely to benefit from the procedure. Acupuncture may be helpful for patients who have unsuccessfully exhausted the conventional treatment modalities, who experience adverse consequences with conventional approaches, who prefer to not take pharmacological agents for their condition, or whose comorbidities prevent them from taking certain drug therapies. There is an ongoing need for monitoring of acupuncture trials and for outcome assessment.
 - b. If acupuncture is being considered, it must be part of a comprehensive pain treatment program that may include behavioral, pharmacological, and/or physical therapies. The role of acupuncture in a comprehensive treatment program is still being defined. Patients should receive a limited number of treatment sessions with an opportunity to re-evaluate their treatment options after completion of those sessions.
 - c. Acupuncture is a safe procedure when performed by properly trained individuals in a clinical environment using sterile, disposable needles.
3. For osteoarthritis, acupuncture and sham acupuncture produce similar results. Acupuncture is at least as efficacious as standard oral medications (including diazepam). (Conclusion Grade II)
4. For headache pain, acupuncture has been shown to be superior or equal to sham acupuncture in both children and adults and comparable to physiotherapy or beta-blockers in adults. (Conclusion Grade III)
5. For low back pain, acupuncture has been found to be more beneficial than no treatment or placebo and comparable to active control treatments (including TENS). The incidence of adverse effects is substantially lower than for many other accepted interventions. In low back pain of nociceptive origin, greater and longer duration improvement was noted following low frequency stimulation. (Conclusion Grade III)

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Technology Assessment Update

Acupuncture for Chronic Osteoarthritis Pain, Headache, and Low Back Pain

Prepared under the direction of the
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Reason for Update

Since the original report was approved in 1997, there have been several newly published controlled trials, systematic reviews, and meta-analyses. A National Institutes of Health (NIH) Consensus Conference on Acupuncture was held in November, 1997. The new findings are summarized in this update. In addition, information about specific clinics is changing. There are new acupuncture clinics at other medical centers and clinics in the Twin Cities area. Acupuncture continues to be indicated as a non-pharmacological alternative to conventional therapy for patients with adverse consequences of pharmacological approaches, for patients whose preference is to not take pharmacological agents for their condition, or for patients whose comorbidities prevent them from taking certain drug therapies.

Previous Conclusion

There have been controlled (Grade A) studies of the effectiveness of acupuncture for the treatment of pain associated with osteoarthritis, migraine and/or tension headache, and low back pain. Many of the studies are flawed, however, due to difficulties with defining the appropriate experimental model for pain, small sample sizes, difficulties in selecting an appropriate control group, and inadequate follow-up.

Recognizing that the literature is flawed, the ICSI Technology Assessment Committee concludes the following:

1. The benefits of acupuncture are not experienced by every patient. To date, there is no way to identify who is most likely to benefit from the procedure. Acupuncture may be helpful for patients who have unsuccessfully exhausted the conventional treatment modalities. There is an ongoing need for monitoring of acupuncture trials and for outcome assessment.
2. If acupuncture is being considered, it must be part of a comprehensive pain treatment program that may include behavioral, pharmacological, and/or physical therapies. The role of acupuncture in a comprehensive treatment program is still being defined. Patients should receive a limited number of treatment sessions with an opportunity to re-evaluate their treatment options after completion of those sessions.
3. Acupuncture is a safe procedure when performed by properly trained individuals in a clinical environment using sterile, disposable needles.
4. For pain associated with osteoarthritis, there is evidence of efficacy equivalent to treatment with diazepam. No difference was reported between true and sham acupuncture.
5. For headache pain, acupuncture has been shown to be superior or equal to sham acupuncture and comparable to physiotherapy or beta-blockers.
6. Studies of acupuncture for low back pain have found acupuncture to be more beneficial than no treatment or placebo in the form of inert surface electrodes and comparable to superficial insertion of needles following an intradermal shot of lidocaine or TENS. In low back pain of nociceptive origin, manual stimulation, low frequency stimulation, and high frequency stimulation each resulted in improvement with greater and longer duration improvement noted following low frequency stimulation.

Recent Evidence

In 1996, the FDA removed needles from the experimental medical devices category. The needles are now regulated as is any medical device with requirements for good manufacturing practices and single-use standards of sterility.

An NIH Consensus Conference on Acupuncture was held in November, 1997 (NIH Consensus Development Panel, 1998). The majority of the evidence cited at the conference was obtained from studies involving penetration of the skin by thin, solid, metallic needles which are manipulated manually or by electrical stimulation. This summary will focus only on those conclusions that pertain to the pain conditions addressed by this report.

The Consensus Panel addressed a number of questions. For the question of efficacy of acupuncture compared to placebo or sham acupuncture, the Panel concluded that there are reasonable studies

showing relief of pain with acupuncture for diverse pain conditions. However, there are also studies that do not find acupuncture to be efficacious for pain. There is controversy regarding the use of sham acupuncture (commonly used in the control group) since placement of a needle in any position produces a biological response. In describing the place of acupuncture in the treatment of pain, the Panel concluded that acupuncture may be a reasonable option for low back pain. The evidence was considered to be less convincing (although there are some positive clinical trials) for osteoarthritis and headache. The Panel found that there was considerable evidence that opioid peptides are released during acupuncture and that the analgesic effects are at least partly explained by their actions. The hypothalamus and pituitary gland may also be activated by acupuncture stimulation. However, the definition and characterization of the acupuncture point remains controversial as does the scientific basis of key traditional oriental medicine concepts. Training and credentialing of acupuncture practitioners was viewed by the Panel as an important element in the integration of acupuncture into the health care system. There is also a need for understanding and communication among practitioners of oriental and Western medicine. Although adverse events are rare, patients need to be fully informed of their treatment options, expected outcomes, potential risks, and safety practices in place to minimize those risks. It was concluded that, for osteoarthritis, headache, and low back pain (among other conditions), “acupuncture may be useful as an adjunct treatment or an acceptable alternative or may be included in a comprehensive management program.” Furthermore, “there is sufficient evidence of acupuncture’s value to expand its use into conventional medicine and to encourage further studies of its physiology and clinical value.”

Osteoarthritis

Ernst (1997) completed a systematic review of controlled clinical trials of acupuncture for treatment of osteoarthritis. Thirteen studies were identified. Due to differences between the studies in diagnostic criteria, site of osteoarthritis, acupuncture site(s), and outcome measures, a meta-analysis was not possible. Of the 13 studies, 7 reported acupuncture was more effective in reducing pain, 5 reported no difference between study groups, and 1 reported significant greater reduction in pain with physiotherapy. However, of the 7 studies showing benefit from acupuncture, 4 failed to control for placebo effects, 2 were not randomized trials, and 2 lacked formal statistical analyses. Of the 5 randomized trials comparing acupuncture to sham acupuncture, 4 had equivocal results. In the 5 studies with 40 or more patients, 1 reported a benefit from acupuncture. In the studies with fewer than 40 patients, 6 reported a benefit from acupuncture. The author concluded, based on the most rigorous trials, that acupuncture and sham acupuncture alleviated symptoms to approximately the same degree. Based on the data available, it was not possible to determine whether this observation was due to similar specific effects of acupuncture and sham acupuncture or due to non-specific effects associated with both procedures.

Patients with symptomatic osteoarthritis of the knee were eligible for inclusion in a randomized trial comparing acupuncture as an adjunct to standard oral medication with standard oral medication alone (Berman et al., 1999). The patients experienced at least moderate pain for most days in the last month, were age 50 years or above (the mean age was 65 years), were taking analgesic or anti-inflammatory agents for at least 1 month, and had documented radiographic changes of osteoarthritis. The study excluded patients who received corticosteroid injection into the knee within 4 weeks prior to entry into the study, had severe chronic or uncontrolled concomitant illness, or who had a history or clinical indications of bleeding diathesis. Of 73 randomized (37 to the acupuncture group and 36 to the control group), 58 completed the 12 week study (29 in each group). Patients in the control group were offered acupuncture after completion of the study. The acupuncture protocol consisted of needles inserted at 9 sites with electrical stimulation of 2 of the sites. The treatment continued for 8 weeks with 4 weeks follow-up after the last treatment. The analysis focused on two outcome measures: the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score (with pain and disability subscales) and the Lequesne Algodysfunctional Index (an assessment of pain and physical dysfunction). Assessments for both treatment groups were completed at baseline, 4 weeks, 8 weeks, and 12 weeks. In comparing the two treatment groups, an intention-to-treat analysis was done with the last score carried forward for those who did not complete the protocol. Those who dropped from the study were younger, had experienced osteoarthritis for a longer period of time, and had a higher mean total WOMAC score. The acupuncture group had a significant decrease from baseline in mean WOMAC scores (total, disability, and pain) at 4, 8, and 12 weeks (all $p < 0.001$) although the 12 week scores (4 weeks after the end of treatment) were higher than the 8 week scores. The control group scores did not differ from

baseline and the scores from the acupuncture group were significantly different from the control group at all time points ($p<0.001$). A similar pattern was observed for the Lequesne scores with significant differences from baseline for the acupuncture group and significant differences from the control group at all assessments ($p<0.001$ except $p<0.008$ at 4 weeks). No adverse effects of acupuncture were reported. The authors concluded that acupuncture was an effective and safe adjunctive therapy to conventional care.

Headache

Twenty-two children (ages 7 to 15 years) with migraine were included in the study presented by Pintov, Lahat, Alstein, Vogel, and Barg (1997). They excluded children with chronic illness, allergies, or who required daily medications. None of the children received antimigraine treatment or opiate-containing preparations. The children were 'alternatingly randomized' to true acupuncture (TA, $n=12$) or placebo acupuncture (PA, $n=10$) groups. In the PA group, the acupuncture needles were inserted into the stratum corneum while in the TA group, the needles were inserted subdermally. The children completed 10 weekly sessions. Migraine diaries were completed at baseline for the 10 weeks before the study, for 10 weeks during the study, and for 10 weeks after the treatment ended (all of the children completed the study). Plasma panopiod activity was assessed at baseline and after 5 and 10 weeks of treatment. Panopiod activity was also assessed in a group of 10 children without migraine. TA led to a significant decrease in the frequency and intensity of migraine headaches. The frequency decreased from a mean of 9.3 per month to a mean of 1.4 per month. The intensity (rated on a scale of 0 to 10) decreased from 8.7 to 3.3 (p -values were not reported). For the PA group, frequency decreased from 9.4 to 9.3 per month and intensity decreased from 7.8 to 6.2. Both of the migraine groups had lower panopiod activity levels at baseline (relative to the children without migraine). After treatment, the panopiod activity of the PA group was unchanged while the activity of the TA group increased significantly ($p<0.01$ at 10 weeks compared to baseline and to the PA group). The authors concluded that acupuncture may be an effective treatment in children with migraine headaches.

Hu (1998) treated 89 cases of migraine in patients ranging in age from 7 to 90 years. The patients received a mean of 14 treatments with the selection of stimulation points based in characteristics of the individual patient's migraines. The treatment was considered markedly effective (defined as quick cure with relief of headache and disappearance of accompanying symptoms) in 55 cases (61.8%), effective (defined as alleviation of the headache, decrease of seizures, and withdrawal of medication) in 16 cases (18%), and ineffective (defined as no obvious improvement of the headache) in 3 cases (3.4%). Treatment was discontinued in 15 cases (16.9%); the reasons were not specified.

A systematic review of randomized or quasi-randomized (e.g., alternation) trials of acupuncture for recurrent headaches was presented by Melchart et al. (1999). All of the included trials involved patients with recurrent headaches (all types) and compared acupuncture with a control condition. Since the trials were heterogeneous (with respect to the interventions and the outcome measurement methods) and the reporting was often insufficient, a quantitative meta-analysis was not done. A response rate ratio was calculated based on trials that either reported global response (improvement) data or provided data from which response could be determined. The rate ratio was defined as the proportion of responders in the true acupuncture group divided by the proportion of responders in the sham acupuncture group. In all, 22 trials with 1042 patients were included (15 with migraine headache patients, 6 with tension-type headache patients, and 1 with patients of mixed headache types). There were 14 trials comparing true acupuncture with sham, 5 comparing acupuncture with drug treatment, 2 comparing acupuncture with physiotherapy, and 1 comparing acupuncture with either no treatment or a biobehavioral treatment. Of the 14 sham-controlled trials, 2 found no benefit of true acupuncture over sham acupuncture, 3 found trends favoring true acupuncture, and 6 found true acupuncture to have significant benefits over sham acupuncture. The remaining 3 trials were judged to be uninterpretable. The response rate ratio (based on data from 10 sham-controlled trials) was 1.53 (95% CI: 1.11-2.11). In the 7 trials comparing acupuncture with other treatments, the results were highly contradictory ranging from control significantly better to acupuncture significantly better. Methodological and/or reporting shortcomings were noted for many of the trials.

Low Back Pain

Van Tulder, Koes, and Bouter (1997) completed a systematic review of conservative treatments for acute and chronic low back pain. Acupuncture was evaluated as a treatment for chronic low back

pain. The review included only randomized, controlled trials. The 6 trials that used acupuncture were considered to be of low quality. Four of the trials found positive results (acupuncture was more effective than the reference treatment) and two found negative results. The authors concluded that there was no evidence that acupuncture is an effective treatment for chronic low back pain.

A review of the effectiveness of acupuncture in the management of acute, subacute, or chronic nonspecific low back pain was reported in 1999 (van Tulder, Cherkin, Berman, Lao, & Koes). The review identified 11 randomized, controlled trials (including the 6 trials cited above) of needle acupuncture using traditional or contemporary acupuncture points either with or without electrical stimulation. Pooling of the data was not done because the outcomes were poorly presented in 6 of the 11 studies. In addition, the studies were viewed as clinically heterogeneous with respect to the type and duration of the disorder, the types of acupuncture used, and the outcome measures. Three of the studies compared acupuncture with no treatment. The reviewers found the results to be contradictory and concluded that there was no evidence to show that acupuncture was more effective than no treatment. Two studies compared acupuncture with conventional treatment (trigger point injection or transcutaneous electrical nerve stimulation [TENS]). The reviewers considered both studies to be neutral and concluded that there was moderate evidence that acupuncture was not more effective than conventional treatment. There were 8 studies comparing acupuncture with placebo or sham acupuncture. Two were of higher quality; their results were viewed as contradictory. Of the 6 lower quality studies, 5 were viewed as neutral and the outcome of 1 study was considered unclear. It was concluded that there was limited evidence that acupuncture was not more effective than placebo or sham acupuncture. Of 8 studies in which the authors of the study concluded that acupuncture was effective, the reviewers considered the results to be positive in just 2. In the absence of high quality randomized, controlled trials, acupuncture was not recommended as a regular treatment for patients with low back pain. It was noted that the incidence of adverse effects was substantially lower than that of many other accepted interventions.

A meta-analysis of randomized, controlled trials of acupuncture for back pain was performed by Ernst and White (1998). Of 30 references identified, 9 presented data suitable for inclusion in a meta-analysis. A total of 377 patients were represented. The combined odds ratio was 2.30 (95%CI 1.28-4.13) favoring treatment. No significant heterogeneity was detected. When a separate meta-analysis was done including only the four sham-controlled, evaluator-blinded trials, the odds ratio was 1.37 (95%CI 0.84-2.25). There were too few studies to determine whether publication bias may have influenced the results. Acupuncture appeared to be superior to various control interventions for the treatment of back pain but there was insufficient evidence to assess whether acupuncture was superior to placebo. Despite the lack of statistical heterogeneity, the existing trials do involve different study populations, different types of acupuncture, different outcome measures, and different lengths of follow-up which makes it difficult to reach a firm conclusion.

Grant, Bishop-Miller, Winchester, Anderson, and Faulkner (1999) reported the results of a randomized trial comparing acupuncture with TENS in patients age 60 years and older with back pain for more than 6 months. They excluded patients being treated with anticoagulants or systemic corticosteroids, patients with dementia, patients previously treated with acupuncture or TENS, patients with cardiac pacemakers, patients with severe concomitant disease, and those unable to apply the TENS machine. The treatment period was 4 weeks. Patients in the acupuncture group were treated at points on the back (selected for the individual patient) two times per week for 20 minutes. Patients in the TENS group were given TENS units to use at home as required for up to 30 minutes per session with a maximum of 6 hours per day. Those in the TENS group also met with the physiotherapist two times per week for 20 minutes. All treatments were administered by the same physiotherapist and patients were advised to not add any new analgesics or treatments during the course of the trial. Four outcomes were assessed: a visual analog scale (VAS) describing pain level over the previous week, the pain subscale of the Nottingham Health Profile Part 1 (NHP), the number of analgesic tablets consumed in the previous week, and spinal flexion measured from C7 to S1. The outcome measures were assessed at baseline, 4 days after the final treatment session, and 3 months after the conclusion of treatment. The two groups were similar at baseline in age, the ratio of males to females, and the site of treatment (out-patient vs. home). Although not statistically significant, the two groups were considered to be different at baseline on the four outcome measures. For the VAS, the scores were 140 for the acupuncture group and 101 for the TENS group ($p=0.06$). For the pain subscale, the scores were 76.7 for the acupuncture group and 50.1 for the TENS group ($p=0.09$). The number of tablets consumed in the previous week was 28 for the

acupuncture group and 42 for the TENS group ($p=0.10$). Spinal flexion was 4.93 cm for the acupuncture group and 5.68 cm for the TENS group ($p=0.16$). As a result of these differences, intergroup comparisons after treatment and at follow-up were not performed. The acupuncture group experienced decreases in the VAS score of 49% after treatment ($p<0.001$ with respect to baseline) and 57% at the 3 month follow-up ($p<0.0001$). The TENS group had a decrease in VAS score of 53% after treatment ($p<0.001$) and 37% at 3 months ($p<0.01$). For the pain subscale, the acupuncture group had decreases of 30% after treatment ($p<0.001$) and 51% at 3 months ($p<0.0001$). The corresponding values for the TENS group were 68% ($p<0.0001$) and 65% ($p<0.01$). The number of tablets taken decreased by 46% after treatment ($p<0.05$) and 50% at 3 months ($p<0.01$) for the acupuncture group with decreases of 33% ($p<0.05$) and 43% ($p<0.01$) for the TENS group. Spinal flexion was increased by 10% after treatment ($p<0.05$) in the acupuncture group but by only 7% (NS) at 3 months. The increases in flexion in the TENS group (5% after treatment and 7% at 3 months) were not significant. The authors noted that at least 5 patients in the TENS group purchased their own systems and continued treatment after the 4 week study treatment period. Both acupuncture and TENS were considered to be effective for the treatment of chronic back pain in the elderly.

A pilot study that involved random assignment to either spinal manipulation, acupuncture, or nonsteroidal anti-inflammatory medication (tenoxicam with ranitidine) was reported by Giles and Müller (1999). The patients were at least 18 years of age and had experienced spinal pain for at least 13 weeks. They excluded patients with disorders other than mild to moderate osteoarthritis, previous spinal surgery, spinal anomalies, or leg length inequality with postural scoliosis. The spinal manipulation group ($n=36$) was treated with high-velocity, low-amplitude spinal manipulation. The goal was 6 treatments in a 3 to 4 week period. The acupuncture group ($n=20$) was treated at 8 to 10 points (chosen for the individual). Electrical stimulation was added when the patient was able to tolerate the needles for 20 minutes. The goal, again, was 6 treatments in a 3 to 4 week period. The medication group received medication for 3 to 4 weeks. They also were seen by a clinician for 15 to 20 minute appointments to equate the clinician exposure time. Outcomes were assessed using the Oswestry Questionnaire (low back and thoracic spine pain); the Neck Disability Index (neck pain); VAS tests for the low back, upper back, and neck; and a pain frequency measure. It was also noted whether a patient crossed over to another treatment following the study period. There were problems completing the protocol as planned resulting in longer periods of time between the before and after questionnaires and longer treatment periods. There were also missed follow-up questionnaires. Of 77 randomized, Oswestry Index data were available for 69, Neck Disability Index data were available for 39, and the VAS data were available for 69 (lower back), 40 (upper back), and 50 (neck) patients. Significant improvements in these scores were observed for the whole group and the manipulation group. The improvements ranged from 13.5% to 25% for the whole group ($p\leq 0.03$) and from 30.4% to 50% for the manipulation group ($p\leq 0.002$). Pain frequency decreased only in the manipulation group ($p=0.007$). After the study period, 43% changed their treatment because of inefficacy or side effects. No side effects were reported in either the manipulation or the acupuncture groups. Spinal manipulation, if not contraindicated, was thought to result in greater improvement than acupuncture or medication for patients with chronic spinal pain syndromes.

McPherson, Gould, and Fitter (1999) also reported the results of a pilot study. The goal of the study was to evaluate whether the procedures used in the pilot study were suitable for a randomized controlled trial. The authors also planned to use the pilot study results to assist in determining an appropriate sample size for a randomized trial. Eligible patients (ages 18 to 65 years) were referred by a general practitioner after experiencing low back pain for at least the previous month. The study excluded patients with major structural abnormalities, carcinoma, past operations on the back, pregnancy, bleeding disorders, ankylosing spondylitis, or pending litigation. Twenty patients were enrolled; two dropped out too early to contribute to the analysis. Ten acupuncture sessions, 1 or 2 per week, were planned. Each session lasted 20 to 30 minutes. Needle locations were individualized and were changed during the course of treatment, if needed. The treatment may also have included the use of moxibustion, heat lamps, and local massage as well as advice on rest and exercise. The patients were assessed at baseline, after 4 treatment sessions, at the end of treatment, and after 6 months follow-up. The outcome measures included the Oswestry low back pain disability questionnaire, a present pain intensity scale (from the McGill Pain Questionnaire), a scale assessing the effect on daily living, and the SF-36 general health questionnaire. Fifteen patients completed 10 sessions, and 1 each completed 8, 7, and 4 sessions. Fourteen patients completed the end of treatment assessment and 14 completed the 6 month follow-up assessment (not the same 14,

however). As a result, the comparisons of baseline and end of treatment and baseline and end of follow-up were done using slightly different sets of patients. For the Oswestry questionnaire, the mean score improved from 38 at baseline to 27 at the end of treatment ($p=0.017$) and from 40 at baseline to 23 at the end of follow-up ($p=0.002$). For the present pain scale, the mean score decreased from 2.8 at baseline to 1.9 at the end of treatment (NS) and from 2.7 at baseline to 1.6 at the end of follow-up ($p=0.012$). The effect on daily living measure improved from 2.3 to 1.4 at the end of treatment ($p=0.004$) and from 2.2 to 1.1 at the end of follow-up ($p=0.001$). At the end of treatment, significant improvements (all $p<0.05$) were noted in the physical functioning, social functioning, bodily pain, vitality, and mental health subscales of the SF-36. At the end of follow-up, significant improvements (all $p<0.05$) were observed in the physical functioning, social functioning, bodily pain, and vitality subscales. The authors concluded that a randomized trial was justified and that more careful patient monitoring could reduce the drop-out rate.

Risks and Limitations

Yamashita, Tsukayama, Tanno, and Nishijo (1998) reported the occurrence of adverse effects related to 55,291 acupuncture treatments administered by 76 trained acupuncturists over a 5 year period. The reasons for receiving acupuncture treatment were not provided. There were a total of 64 adverse events. Failure to remove the needles after treatment occurred in 16 (0.03%) of the treatments. Dizziness, discomfort, or perspiration due to transient hypotension occurred in 13 (0.02%) cases. A burn injury caused by thermotherapy occurred in 7 (0.01%) cases. Ecchymosis with pain occurred in 6 cases (0.01%) and ecchymosis without pain occurred in 5 cases (0.009%). Malaise was reported in 5 cases (0.009%). Other reported events (less than 5 per event) included minor hemorrhage, aggravation of complaint, itching and/or redness, pain in the puncture region, and a fall from the treatment bed. The authors believed that all major events were reported but acknowledged that some less severe events may not have been if the acupuncturist or patients did not regard the event as a problem. No cases of pneumothorax, spinal lesion, or infection were reported. Adequate training was viewed as a way to greatly reduce the number of severe adverse effects.

The publications cited in this report represent predominantly English language journals (the exceptions being the systematic reviews of Ernst and White (1998) and van Tulder et al. (1999)). This limitation excludes a considerable amount of data from countries where acupuncture is more widely used (e.g., France, Japan, and China). Thus, it must be recognized that the information presented in this report captures only a narrow view of how acupuncture is used in practice worldwide.

In addition, there has been a lack of financial support in the past for studies of acupuncture. With studies now being funded by the NIH, the publication of an increasing number of higher quality studies can be expected.

Updated Conclusion

Based on a review of evidence available to date, the ICSI Technology Assessment Committee finds the following:

1. The quality of the literature continues to be a concern. As noted in the original report, there are difficulties defining the appropriate experimental model for pain, small sample sizes, difficulties selecting an appropriate control group, and inadequate follow-up. Researchers are being encouraged to compare acupuncture with a standard of care rather than a placebo. The NIH Consensus Panel concluded that further studies of the physiology and clinical value of acupuncture were warranted based on the evidence available. Increased funding by the NIH should foster higher quality research.
2. The following conclusions from the original report continue to be valid:
 - a. The benefits of acupuncture are not experienced by every patient. To date, there is no way to identify who is most likely to benefit from the procedure. Acupuncture may be helpful for patients who have unsuccessfully exhausted the conventional treatment modalities, who experience adverse consequences with conventional approaches, who prefer to not take pharmacological agents for their condition, or whose comorbidities prevent them from taking certain drug therapies. There is an ongoing need for monitoring of acupuncture trials and for outcome assessment.
 - b. If acupuncture is being considered, it must be part of a comprehensive pain treatment program that may include behavioral, pharmacological, and/or physical therapies. The role of acupuncture

in a comprehensive treatment program is still being defined. Patients should receive a limited number of treatment sessions with an opportunity to re-evaluate their treatment options after completion of those sessions.

c. Acupuncture is a safe procedure when performed by properly trained individuals in a clinical environment using sterile, disposable needles.

3. For osteoarthritis, acupuncture and sham acupuncture produce similar results. Acupuncture is at least as efficacious as standard oral medications (including diazepam). (Conclusion Grade II, see Appendix A)

4. For headache pain, acupuncture has been shown to be superior or equal to sham acupuncture in both children and adults and comparable to physiotherapy or beta-blockers in adults. (Conclusion Grade III, see Appendix B)

5. For low back pain, acupuncture has been found to be more beneficial than no treatment or placebo and comparable to active control treatments (including TENS). The incidence of adverse effects is substantially lower than for many other accepted interventions. In low back pain of nociceptive origin, greater and longer duration improvement was noted following low frequency stimulation. (Conclusion Grade III, see Appendix C)

References

Evidence is classed as described below.

I. CLASSES OF RESEARCH REPORTS

Primary Reports of New Data Collection:

- Class A: Randomized, controlled trial
- Class B: Cohort study
- Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study
- Class D: Cross-sectional study
Case series
Case report

Reports that Synthesize or Reflect upon Collections of Primary Reports:

- Class M: Meta-analysis
Decision analysis
Cost-benefit analysis
Cost-effectiveness study
- Class R: Review article
Consensus statement
Consensus report
- Class X: Medical opinion

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in Section I, above, and are assigned a designator of +, -, or \emptyset to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from a limited number of studies of weak design for answering the question addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because the studies that have been done are inconclusive due to lack of generalizability, bias, design flaws, or inadequate sample sizes.

Grade IV: The support for the conclusion consists solely of the statements of informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

The symbols +, -, ø, and N/A found on the conclusion grading worksheets are used to designate the quality of the primary research reports:

+ indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

- indicates that these issues have not been adequately addressed;

ø indicates that the report is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference and therefore the quality has not been assessed.

Berman BM, Singh BB, Lao L, et al. A randomized trial of acupuncture as an adjunctive therapy in osteoarthritis of the knee. *Rheumatology (Oxford)* 1999;38:346-54. (Class A)

Ernst E. Acupuncture as a symptomatic treatment of osteoarthritis: a systematic review. *Scand J Rheumatology* 1997;26:444-447. (Class R)

Ernst E, White AR. Acupuncture for back pain: a meta-analysis of randomized controlled trials. *Arch Intern Med* 1998;158:2235-2241. (Class M)

Giles LG, Müller R. Chronic spinal pain syndromes: a clinical pilot trial comparing acupuncture, a nonsteroidal anti-inflammatory drug, and spinal manipulation. *J Manipulative Physiol Ther* 1999;22:376-81. (Class A)

Grant DJ, Bishop-Miller J, Winchester DM, Anderson M, Faulkner S. A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly. *Pain* 1999;82:9-13. (Class A)

Hu J. Acupuncture treatment of migraine in Germany. *J Tradit Chin Med* 1998;18:99-101. (Class D)

MacPherson H, Gould AJ, Fitter M. Acupuncture for low back pain: results of a pilot study for a randomized controlled trial. *Complement Ther Med* 1999;7:83-90. (Class D)

Melchart D, Linde K, Fischer P, et al. Acupuncture for recurrent headaches: a systematic review of randomized controlled trials. *Cephalalgia* 1999;19:779-786. (Class R)

NIH Consensus Development Panel on Acupuncture. Acupuncture. *JAMA* 1998;280:1518-1524. (Class R)

Pintov S, Lahat E, Alstein M, Vogel Z, Barg J. Acupuncture and the opioid system: implications in management of migraine. *Pediatr Neurol* 1997;17:129-33. (Class C)

van Tulder MW, Cherkin DC, et al. The effectiveness of acupuncture in the management of acute and chronic low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 1999;24:1113-1123. (Class R)

van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain: a systematic review of randomized controlled trials of the most common interventions. *Spine* 1997;22:2128-2156. (Class R)

Yamashita H, Tsukayama H, Tanno Y, Nishijo K. Adverse events related to acupuncture. *JAMA* 1998;280:1563-1564. (Class D)

Appendices – See next pages

Appendix A: Conclusion Grading Worksheet

Work Group's Conclusion: For osteoarthritis, acupuncture and sham acupuncture produce similar results. Acupuncture is at least as efficacious as standard oral medications (including diazepam).

Conclusion Grade: II

Author/Year	Design Type	Class	Quality +, -, Ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ <i>Work Group's Comments (italicized)</i>
Eriksson, Lundeberg, & Lundeberg (1991)	Case Series	D	Ø	-32 patients ages 51-73 years; osteoarthritis of cervical spine (pain for ≥ 6 months); previously responded to acupuncture and opioids with good results -Treatment: 40 min of acupuncture at 7 points with manual and electrical stimulation with or without either diazepam (5 mg, given 1 hour before acupuncture) or naloxone (0.8 mg given just before acupuncture)	-Level of pain intensity and unpleasantness rated before, during, and after treatment (every 10 minutes for 140 minutes) -After electroacupuncture both pain intensity (p<0.05) and pain unpleasantness (p<0.01) decreased -After diazepam and electroacupuncture pain unpleasantness decreased (p<0.05) but pain intensity was unchanged -After naloxone and electroacupuncture, neither pain scale was reduced	-Acupuncture induced analgesia may partly be mediated through endogenous opioids which are affected by pretreatment with diazepam or naloxone. NOTES: risk for type II error is high due to limited number of patients (minimum of 70 would be needed to detect differences in all scores with 80% power) <i>Work Group's Notes: unclear whether subjects also participated in Thomas et al. study</i>
Thomas, Eriksson, & Lundeberg (1991)	RCT	A	-	-44 patients ages 42-77 years; osteoarthritis of the cervical spine (pain for ≥6 months) -Treatments: a. diazepam (5 mg) b. placebo-diazepam (5 mg) c. acupuncture (40 min, 7 points, manual stimulation) d. sham acupuncture (superficial insertion of needles)	-Level of pain intensity and unpleasantness rated before and 2 hours after treatment -After diazepam pain intensity (p<0.05) and unpleasantness (p<0.01) decreased; after placebo diazepam pain unpleasantness decreased (p<0.05) -After acupuncture, pain intensity (p<0.005) and unpleasantness (p<0.001) decreased; after sham acupuncture, pain intensity (p<0.05) and unpleasantness (p<0.05) also decreased -Reduction in intensity and unpleasantness in acupuncture group was not different from that in diazepam or sham acupuncture groups but did differ from that in placebo diazepam group (p<0.05)	-Benzodiazepines may be replaced by acupuncture in the treatment of pain and other conditions associated with unpleasantness. NOTES: risk for type II error is high; minimum of 70 patients needed to detect significant difference with 80% power <i>Work Group's Comments: cross-over study with order of treatments randomized and 3-5 days between treatments; unclear whether subjects also participated in Eriksson et al. study</i>

Appendix A: Conclusion Grading Worksheet (cont)

Takeda & Wessel (1994)	RCT	A	∅	<p>-40 volunteers (20 M, 20 F) with grade I-IV osteoarthritis of the knee</p> <p>-Randomized to acupuncture (with manual stimulation at 5 points) or sham acupuncture (superficial insertion approx. 1 inch from acupuncture points); both were 3 times per wk for 3 wks; 30 min per session</p> <p>-Patients assessed before treatment, after 3 wks of treatment, and 4 wks later</p>	<p>-Pain Rating Index scores (based on McGill Pain Questionnaire) decreased significantly (p<0.05) after treatment and 4 wks later for both groups</p> <p>-Pain, stiffness, and function indices (from Western Ontario and McMaster Universities OA Index [WOMAC]) also decreased significantly after treatment for both groups</p> <p>-Pain threshold scores increased from baseline (more force tolerated) (p<0.05) for both groups and at all 4 sites; thresholds differed for different sites (p<0.05)</p> <p>-Gender was added as a factor in the analysis – significant gender effect observed for WOMAC indices and pain threshold scores</p>	<p>-Both true and sham acupuncture decreased pain, stiffness, and physical difficulty in persons with osteoarthritis of the knee with no significant difference between the 2 treatments. Men responded better to acupuncture as did those who experienced Te chi.</p> <p>NOTES: did sample size analysis (19 per group required for power of 0.80 to detect groupXtime interaction); one person from each group dropped out of the study (unrelated to arthritis/treatment) – they were replaced by new subjects</p>
Ernst (1997)	Review	R	N/A	<p>-13 controlled, clinical trials of acupuncture for symptomatic osteoarthritis</p> <p>-Meta-analysis was not possible because various measures of pain were used</p>	<p>-7 studies report an apparent positive result (greater pain reduction in acupuncture recipients than controls); 4 of these failed to control for placebo effects; 2 were not randomized; 3 had inadequate sample size; 2 lacked formal statistical analysis</p> <p>-Of 10 RCTs, 5 had positive results; of 5 RCTs comparing acupuncture with sham acupuncture, 4 were negative</p> <p>-Older studies, studies published in journals dedicated to acupuncture, and studies with sample size of <40 tended to come to a positive conclusion</p> <p>-2 double-blind RCTs concluded that acupuncture was not superior to sham needling.</p>	<p>-For pain associated with osteoarthritis, both acupuncture and sham acupuncture have similarly positive effects.</p> <p>NOTES: did not include trials in which one form of acupuncture was tested against another (non-sham) acupuncture</p>
Berman, et al. (1999)	RCT	A	+	<p>-73 patients over age 50 with symptomatic knee osteoarthritis</p> <p>-Randomized to acupuncture or control groups</p> <p>-Acupuncture group received acupuncture biweekly for 8 wks at 9 points, 2 of which received electrical stimulation</p> <p>-Control group maintained current level of oral therapy for 12 wks</p> <p>-Pain assessed at baseline, 4 wks, 8 wks (end of treatment), and 12 wks</p>	<p>-58 remained in study through follow-up at 12 wks after baseline (7 from acupuncture and 8 from control group dropped out); those who dropped out had higher total WOMAC score, longer duration of osteoarthritis, and were younger (all p≤0.05)</p> <p>-Intention-to-treat analysis (36 in acupuncture group, 37 in control group): baseline pain scores did not differ; acupuncture group had decreased WOMAC total, disability, and pain scores relative to baseline (p<0.001); Lequesne score also decreased relative to baseline (p<0.008) in the acupuncture group; control group had no significant changes from baseline; groups were significantly different at all points except baseline (p<0.001)</p> <p>-For 62 patients who received acupuncture all WOMAC scores (total, disability, pain) and the Lequesne score decreased from baseline at 4 and 8 wks (all p<0.001); WOMAC scores were less than baseline at 12 wks (p<0.004)</p> <p>-No side effects were reported</p>	<p>-These data suggest that acupuncture is an effective and safe adjunctive therapy to conventional care for patients with osteoarthritis of the knee.</p> <p>NOTES: did sample size analysis (35 patients per group needed for 80% power to demonstrate significant improvement in WOMAC score); control group was offered acupuncture after completion of control assessments (data included in acupuncture group for within-group analyses)</p>

Appendix B: Conclusion Grading Worksheet

Work Group's Conclusion: For headache pain, acupuncture has been shown to be superior or equal to sham acupuncture in both children and adults and comparable to physiotherapy or beta-blockers in adults.

Conclusion Grade: III

Author/Year	Design Type	Class	Quality +,-,Ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ <i>Work Group's Comments (italicized)</i>																																																				
Vincent (1989)	RCT	A	Ø	-32 patients with classical or common migraine (independent diagnosis of migraine by neurologist, at least 2 of 3 migrainous symptoms, at least 2 full days of headaches per month) -Randomized to acupuncture (8 classical points, manual stimulation) or minimal sham acupuncture (light surface needling at nonclassical points) -4 wk baseline, 6 weekly treatments, 6 wk follow-up plus follow-up at 4 mo and 1 yr	<p>Results for pain score (weekly, based on intensity), medication (#tablets), and scaled medication (#tablets and potency) for true and sham groups:</p> <table border="1"> <thead> <tr> <th>Measure</th> <th>Baseline</th> <th>Treatment</th> <th>Follow-up*</th> </tr> </thead> <tbody> <tr> <td></td> <td>6 wk</td> <td>4 mo</td> <td>1 yr</td> </tr> <tr> <td>Pain Score#</td> <td></td> <td></td> <td></td> </tr> <tr> <td>True</td> <td>27.8</td> <td>18.8</td> <td>15.7</td> </tr> <tr> <td>Sham</td> <td>27.2</td> <td>27.9</td> <td>11.6</td> </tr> <tr> <td>Medication</td> <td></td> <td></td> <td>8.0^</td> </tr> <tr> <td>True</td> <td>10.2</td> <td>6.5</td> <td>6.3</td> </tr> <tr> <td>Sham</td> <td>9.2</td> <td>7.5</td> <td>6.6</td> </tr> <tr> <td>Scaled Medication</td> <td></td> <td></td> <td>7.1</td> </tr> <tr> <td>True</td> <td>9.8</td> <td>6.7</td> <td>5.1</td> </tr> <tr> <td>Sham</td> <td>11.2</td> <td>9.1</td> <td>7.6</td> </tr> <tr> <td></td> <td></td> <td></td> <td>9.6</td> </tr> <tr> <td></td> <td></td> <td></td> <td>8.1</td> </tr> </tbody> </table> <p>*data at 4 mo and 1 yr available from 12-14 patients #p<0.03 (difference between groups across time) ^p<0.05 (true vs. sham at 1 year)</p>	Measure	Baseline	Treatment	Follow-up*		6 wk	4 mo	1 yr	Pain Score#				True	27.8	18.8	15.7	Sham	27.2	27.9	11.6	Medication			8.0^	True	10.2	6.5	6.3	Sham	9.2	7.5	6.6	Scaled Medication			7.1	True	9.8	6.7	5.1	Sham	11.2	9.1	7.6				9.6				8.1	<p>-Weekly pain scores were reduced by 43% in the true group and by 14% in the sham group between baseline and initial follow-up. The corresponding changes in medication intake were 38% and 28%. The reductions in pain scores were maintained at 4 months and 1 year.</p> <p>NOTES: analysis is based on 30 patients (1 from each group did not complete study); both groups perceived their respective treatments as equally credible</p>
Measure	Baseline	Treatment	Follow-up*																																																							
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			8.1																																																							
Carlsson, Fahlcrantz, Augustinsson (1990)	RCT	A	-	-62 female patients with pre-dominance of chronic tension headache -Randomized to acupuncture therapy done over 2-3 months with 1-2 sessions (30-45 min) per week; acupuncture done at classical points (with electrical stimulation) 4 to 5 times (≥ 20 minutes each) over 2-4 weeks (with additional 4-5 sessions if patients noted clear pain relief) -Evaluated 3-8 wks before treatment and 4-9 wks after	<p>Groups were comparable at baseline in intensity of headache, muscle tenderness, and neck mobility</p> <p>-Intensity of headache was decreased after treatment for both groups:</p> <table border="1"> <thead> <tr> <th></th> <th>Baseline</th> <th>After Treatment</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>Physiotherapy</td> <td>3.72</td> <td>2.52</td> <td><0.001</td> </tr> <tr> <td>Acupuncture</td> <td>3.78</td> <td>3.24</td> <td><0.05</td> </tr> </tbody> </table> <p>-Muscle tenderness decreased significantly (p<0.01) after treatment for all 6 muscles tested in the physiotherapy group and significantly (p<0.05) for 3 of 6 muscles tested in the acupuncture group -Neither treatment affected neck rotation -Intake of analgesics was reduced only in the physiotherapy group</p>		Baseline	After Treatment	p	Physiotherapy	3.72	2.52	<0.001	Acupuncture	3.78	3.24	<0.05	<p>-Patients with tension headache treated with acupuncture or physiotherapy obtained a reduction of headache intensity and a decrease in tender points but no effect on the limited neck mobility. The improvement was most pronounced in the physiotherapy group.</p> <p>NOTES: 2 patients in acupuncture group did not come to treatment and 1 was ineligible; another 5 in acupuncture group and 2 in physiotherapy group dropped out (analysis is based on 23 in acupuncture group and 29 in physiotherapy group)</p>																																								
	Baseline	After Treatment	p																																																							
Physiotherapy	3.72	2.52	<0.001																																																							
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Appendix B: Conclusion Grading Worksheet (cont)

Tavola, Gala, Conte, & Invernizzi (1992)	RCT	A	∅	<p>-30 patients (26 women, 4 men) with tension-type headache</p> <p>-Randomized (15 per group) to acupuncture (6-10 needles, no stimulation, points were individualized) or sham acupuncture (shallow needle insertion in same regions but in areas without acupuncture points); both groups had 8 weekly sessions of 20 minutes</p> <p>-1 month baseline, 2 months of treatment, 12 months follow-up</p>	<p>-Groups similar at baseline in age, male/female ratio, education, duration and age of onset of headache; also similar frequency, duration, and intensity of headache episodes, headache index, and analgesic consumption during baseline period</p> <p>-Frequency of episodes decreased significantly over time (baseline to 1 month after treatment) (p<0.001); mean decrease was 44% for acupuncture group and 21% for placebo group (interaction of time and treatment was non-significant)</p> <p>-Headache index and analgesic consumption decreased significantly over time (both p<0.0001) with non-significant treatment/time interaction (although decreases were greater in acupuncture group)</p> <p>-12 months after treatment, 53% of acupuncture group and 47% of placebo group maintained an improvement of at least 33%.</p>	<p>-Traditional Chinese acupuncture is not differently effective than placebo in the treatment of muscle-tensive headache.</p> <p>NOTES: all participants completed the follow-up</p>
Hesse, Møgelvang, & Simonsen (1994)	RCT	A	∅	<p>-85 patients with history of migraine with or without aura (at least 2 years)</p> <p>-Randomized (after 1 month run-in period) to acupuncture (dry needling of trigger points with choice of points, number of treatments, and time between treatments determined individually) plus placebo tablets or beta-blocker (metoprolol, 100 mg daily) plus placebo stimulation (superficial touching with blunt end of needle)</p> <p>-Study period was 17 wks; typically acupuncture/placebo stimulation was done 1-3 weeks apart with 6-8 treatments in 17 wks</p>	<p>-Both groups had reduced attack frequency (p<0.01) with no difference between treatments</p> <p>-Global rating of attacks differed between groups (p<0.05) with higher rating (more severe) for acupuncture group</p> <p>-Duration of migraine attacks did not differ significantly</p> <p>-Side effects were reported by 3 patients (3 side effects) in the acupuncture group and 14 patients (18 side effects) in the metoprolol group</p> <p>-Based on pill counts all but 1 patient in the acupuncture plus placebo group and all but 2 in the metoprolol group took at least 75% of prescribed tablets</p>	<p>-Trigger point inactivation by dry needling is a valuable supplement to the list of migraine prophylactic tools, being equipotent to metoprolol in the influence on frequency and duration (but not severity) of attacks, and superior in terms of negative side-effects.</p> <p>NOTES: 8 patients withdrew from the study after randomization; attempted to blind patients and investigators</p> <p><i>Work Group's Comments: analysis was not intention-to-treat</i></p>

Appendix B: Conclusion Grading Worksheet (cont)

Pintov, Lahat, Alstein, Vogel, & Barg (1997)	Non-Random	C	∅	<p>-22 children (ages 7-15 yrs) with migraine with or without aura</p> <p>-<i>Alternately</i> randomized to either true acupuncture (n=12; needles inserted subdermally) or placebo acupuncture (n=10; needles inserted in stratum corneum); both groups had 3 needles inserted in the upper and lower extremities for 15 minutes at 10 weekly sessions</p> <p>-10 children without migraine served as controls for the panoploid study</p>	<p>-No differences in migraine frequency or intensity between groups before treatment</p> <p>-Results (p-values not reported):</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td colspan="2" style="text-align: center;">True Acupuncture</td> <td colspan="2" style="text-align: center;">Placebo</td> </tr> <tr> <td style="text-align: center;">Before Tx</td> <td style="text-align: center;">After Tx</td> <td style="text-align: center;">Before Tx</td> <td style="text-align: center;">After Tx</td> </tr> <tr> <td style="text-align: center;">9.3</td> <td style="text-align: center;">1.4</td> <td style="text-align: center;">9.4</td> <td style="text-align: center;">9.3</td> </tr> </table> <p>Frequency (# per month)</p> <p>Intensity (0-10 scale)</p> <p>-Both treatment groups had panoploid activity levels below controls before treatment; after treatment the placebo group was unchanged; the true acupuncture group had increased panoploid activity (p<0.01)</p>	True Acupuncture		Placebo		Before Tx	After Tx	Before Tx	After Tx	9.3	1.4	9.4	9.3	<p>-Acupuncture may be an efficient alternative treatment for children with migraine headaches. The treatment is safe and cost-effective with no side effects and can be repeated according to clinical need. Acupuncture leads to an increase in activity of opioidergic system.</p> <p>NOTES: all children completed 10 weeks of treatment and 10 weeks of follow-up</p>
True Acupuncture		Placebo																
Before Tx	After Tx	Before Tx	After Tx															
9.3	1.4	9.4	9.3															
Melchart et al. (1999)	Review	R	N/A	<p>-22 trials (1042 patients) (randomized or quasi-randomized); patients with recurrent headache; compared acupuncture with control; at least one clinical outcome related to headache</p> <p>-Included non-English language studies</p> <p>-Quality of trials assessed</p> <p>-For sham-controlled trials, extracted data on global "response" (improvement after treatment) to calculated rate ratio (responders in acupuncture group /responders in sham group)</p>	<p>-15 trials with migraine headache, 6 with tension-type headache, 1 with various headaches</p> <p>-14 trials compared true acupuncture with sham, 5 with medication, 2 with physiotherapy; 1 compared acupuncture with no treatment and biobehavioral treatment</p> <p>-Of 14 trials of acupuncture vs. sham 2 found no benefit over sham, 3 showed trends in favor of acupuncture, 6 found acupuncture significantly better (3 trials were uninterpretable)</p> <p>-Based on 10 trials providing data on responders 117 of 182 (64%) of acupuncture patients were responders vs. 71 of 169 (42%) of sham acupuncture patients; pooled responder rate ratio of 1.53 (95% CI: 1.11-2.11)</p> <p>-7 trials comparing acupuncture with other treatments had highly contradictory results</p>	<p>-Overall, the existing evidence suggests that acupuncture has a role in the treatment of recurrent headaches. The majority of trials comparing true and sham acupuncture show at least a trend in favor of true acupuncture. There is no evidence to assess how acupuncture compared to no treatment and insufficient evidence whether it is as effective as other headache treatments.</p> <p>NOTES: Meta-analysis on frequency or intensity of headache or medications was not possible due to heterogeneity of trials and insufficient reporting; acupuncture interventions varied considerably; majority of trials had methodological and/or reporting shortcomings; 11 trials had follow-up of at least 6 months after therapy</p>												

Appendix C: Conclusion Grading Worksheet

Work Group's Conclusion: For low back pain, acupuncture has been found to be more beneficial than no treatment or placebo and comparable to active control treatments (including TENS).

Conclusion Grade: III

Author/Year	Design Type	Class	Quality +, -, \emptyset	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ <i>Work Group's Comments (italicized)</i>																												
Mendelson, Selwood, Kranz, Loh, Kidson, & Scott (1983)	RCT	A	\emptyset	<p>-95 volunteers with chronic low back pain</p> <p>-Assessed psychological state, suggestibility, spinal mobility, and pain at baseline</p> <p>-After 2 wk baseline observation period, randomly assigned to receive acupuncture (group I) or placebo (group II) first (4 wks) followed by 4 wk rest period, 4 wks of alternate treatment, and 4 wks follow-up</p> <p>-Acupuncture treatment at 4-8 points; manual stimulation</p> <p>-Placebo treatment was injection of 2% lidocaine at non-acupuncture/non-tender sites plus superficial needles</p> <p>-Both treatments were 2x/wk</p>	<p>-77 patients completed trial</p> <p>-Groups did not differ at baseline but had elevated depression, neuroticism, and hypochondriasis compared to normal subjects</p> <p>-1st treatment phase: both groups had significant reduction in Visual Analogue Scale of Pain score (p<0.001) with difference between groups not significant; McGill pain scores decreased similarly in 2 groups with percentage of patients with a decrease being similar; analgesic intake decreased in both group (p<0.01) with no difference between groups</p> <p>-2nd treatment phase: VAS Pain score decreased significantly for group I (p<0.001) and for group II (p<0.03) with significant difference favoring group I (p<0.05); no difference between groups in number of patients achieving significant pain relief; McGill pain scores decreased similarly in the two groups with similar percentages of patients reporting decreased pain; analgesic intake did not change significantly</p>	<p>-No overall difference in the effectiveness of acupuncture and placebo was demonstrated. However, group I had a somewhat better response than group II suggesting a difference based on treatment order. The results of this study suggest that, in this patient group, the placebo-component of acupuncture treatment is more important clinically than the physiological.</p> <p>NOTES: designed study so that a 60% response rate to acupuncture and a 35% response rate to placebo would be recognized as a significant difference; 5 failed to complete first phase, 4 in acupuncture 1st group reported to be pain free and did not begin second phase, 9 failed to complete second phase</p>																												
MacDonald, Macrae, Master, & Rubin (1983)	RCT	A	-	<p>-17 consecutive patients with chronic low back pain who had failed to derive sufficient relief from appropriate conventional treatments</p> <p>-Randomized to superficial (4 mm depth) acupuncture (n=8; with or without electrical stimulation) or placebo (n=9; surface electrodes carrying no current) at "trigger points"; maximum of 10 weekly sessions (up to 20 min each)</p>	<p>-Groups were comparable at baseline</p> <p>-Mean percentage reductions:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Acupuncture</th> <th>Placebo</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>Pain relief after tx</td> <td>77.4</td> <td>30.1</td> <td><0.01</td> </tr> <tr> <td>Pain score reduction</td> <td>57.2</td> <td>22.7</td> <td>NS</td> </tr> <tr> <td>Activity pain score reduction</td> <td>52.0</td> <td>5.8</td> <td><0.05</td> </tr> <tr> <td>Physical signs reduction</td> <td>96.8</td> <td>29.2</td> <td><0.01</td> </tr> <tr> <td>Severity and pain area reduction</td> <td>73.8</td> <td>18.9</td> <td><0.01</td> </tr> <tr> <td>Combined average reduction</td> <td>71.4</td> <td>21.4</td> <td><0.01</td> </tr> </tbody> </table>		Acupuncture	Placebo	p	Pain relief after tx	77.4	30.1	<0.01	Pain score reduction	57.2	22.7	NS	Activity pain score reduction	52.0	5.8	<0.05	Physical signs reduction	96.8	29.2	<0.01	Severity and pain area reduction	73.8	18.9	<0.01	Combined average reduction	71.4	21.4	<0.01	<p>-This study shows unequivocal strong support for a beneficial effect of superficial acupuncture in reducing four of five measures of efficacy and an overall mean of those measures of chronic back pain severity.</p> <p><i>Work Group's Comments: the number and duration of the treatment sessions was not reported</i></p>
	Acupuncture	Placebo	p																															
Pain relief after tx	77.4	30.1	<0.01																															
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Activity pain score reduction	52.0	5.8	<0.05																															
Physical signs reduction	96.8	29.2	<0.01																															
Severity and pain area reduction	73.8	18.9	<0.01																															
Combined average reduction	71.4	21.4	<0.01																															

Appendix C: Conclusion Grading Worksheet (cont)

Lehmann et al. (1986)	RCT	A	<p>-</p> <p>-53 patients admitted to rehabilitation program for chronic disabling low back pain</p> <p>-Randomized to TENS (n=18), mock TENS (n=18) (fully discharged battery), or electroacupuncture (n=17)</p> <p>-TENS treatments were offered daily except weekends for 3 wks; stimulation over center of pain</p> <p>-Electroacupuncture was offered 2x/wk; points chosen for patient</p>	<p>-4 in acupuncture group dropped out after 1 tx; 4 in TENS group and 3 in mock TENS group dropped out after 3 treatments (all are included in analysis); at 6 months follow-up there were 12 patients from acupuncture group, 14 from TENS group, and 18 from mock TENS group</p> <p>-Rate of return to gainful activity did not vary across treatment groups</p> <p>-All groups improved on ratings of back pain and functional ability from admission to discharge (p=0.01-0.0001) with a non-significant regression from discharge to follow-up</p> <p>-Acupuncture mean scores were highest on 10 of 11 outcome measures at discharge and 6 of 11 measures at follow-up</p>	<p>-Neither electroacupuncture or subthreshold transcutaneous electrical stimulation was shown to affect the patients' rehabilitation in a multidisciplinary inpatient treatment program.</p> <p>NOTES: some patients had prior lumbar surgery (randomization was stratified); one patient dropped out after randomization; program included educational and exercise training sessions; at discharge and at follow-up each treatment group considered education to have contributed more to the overall benefit than electrotherapy (p<0.05)</p>
Thomas & Lundberg (1994)	Non Random	C	<p>-43 patients with chronic low back pain (primarily nociceptive)</p> <p>-33 were randomized to an initial "trial" with either manual stimulation of needles (MS), electrical low frequency stimulation of needles (LF), or electrical high frequency stimulation (HF); the assigned treatment was the initial "trial" treatment; each patient received 1 "trial" treatment with each mode of stimulation and then chose which they preferred to continue treatment</p> <p>2x/wk; 9-10 points; 30 min session; 6 wks</p> <p>-10 were on a waiting list for later treatment (controls)</p>	<p>-3 did not complete all three "trial" sessions and were not included in analyses; 3 others excluded from comparison between treatment modes but included in assessment of response to acupuncture</p> <p>-Groups (including controls) did not differ at baseline</p> <p>-Treated group (all modes) improved (after tx and/or after 6 months follow-up) on mobility (except left leg raise), pain descriptor words, and subjective assessment of condition (all p<0.05); activities of daily life related to pain were not improved</p> <p>-Of 27 with definite preference for a treatment mode 7 chose MS, 9 chose LF, and 11 chose HF</p> <p>-MS group had significant improvement in subjective assessment of pain after treatment (p<0.01)</p> <p>-LF group had significant improvements in activities and right lateral flexion at follow-up (both p<0.05), pain descriptor words used after treatment (p<0.05) and at follow-up (p<0.01), and subjective assessment of pain after treatment and at follow-up (both p<0.001)</p> <p>-HF group had significant improvements in left straight leg raise at follow-up (p<0.05) and subjective assessment of pain after treatment (p<0.001)</p>	<p>-A better long term outcome can be expected when using acupuncture selectively for nociceptive pain and when the mode is low-frequency (2Hz) electroacupuncture.</p> <p>NOTES: of 3 excluded from comparison analysis - 2 received more than 1 treatment and 1 received no treatment beyond "trial" sessions</p> <p><i>Work Group's Comments: randomization was used to determine initial treatment mode for 3 "trial" treatments but patients selected the treatment mode for remainder of study</i></p>

Appendix C: Conclusion Grading Worksheet (cont)

Ernst & White (1998)	Meta-analysis	M	N/A	<p>-12 randomized, controlled trials of acupuncture for the treatment of any type of back pain (including studies cited above); 9 chosen for meta-analysis</p> <p>-Included English, French, German, Spanish, Italian, & Polish language studies</p> <p>-Quality of studies assessed</p>	<p>-Overall meta-analysis included data from 377 patients in 9 studies; Odds Ratio=2.30 (95%CI: 1.28-4.13) favoring acupuncture treatment; no significant heterogeneity between studies</p> <p>-Meta-analysis of 4 studies sham-controlled, evaluator-blinded studies resulted in OR=1.37 (95%CI: 0.84-2.25)</p> <p>-Too few studies to conclude whether publication bias influenced the results of the meta-analysis</p>	<p>-Collectively, these data suggest that acupuncture is an effective treatment for back pain. However, the combined results of 4 sham-controlled, evaluator-blinded studies did not show acupuncture to be superior to placebo and further studies are required to conclude with certainty whether acupuncture has specific effects in addition to its nonspecific effects.</p>
van Tulder, Cherkman, Lao, & Koes (1999)	Review	R	N/A	<p>-11 randomized, controlled trials involving subjects with nonspecific low back pain (either subacute [≤ 12 wks] or chronic [> 12 wks]); included at least 1 of 4 primary outcome measures (pain intensity, global measure, functional status, and return to work)</p> <p>-Methodological quality of studies assessed</p> <p>-Included English, French, German, & Polish language studies</p> <p>-Assigned levels of evidence (1=strong to 4=no or conflicting) to effectiveness of acupuncture</p>	<p>-Studies were found to be clinically heterogeneous with respect to type and duration of disorder, interventions, and outcomes; pooling was not possible</p> <p>-3 studies compared acupuncture to no treatment; all were of lower quality; conclusions of reviewers were contradictory: <i>conflicting evidence</i></p> <p>-2 studies compared acupuncture with conventional treatment; 1 of higher quality, 1 of lower quality; conclusion of reviewers was neutral; <i>moderate evidence</i></p> <p>-8 studies compared acupuncture to placebo or sham acupuncture; 2 of higher quality (conclusions of reviewers were positive and neutral for those studies); for 5 of 6 lower quality studies conclusions of reviewers were neutral; <i>conflicting evidence (based on higher quality studies)</i></p>	<p>-There is no convincing scientific evidence to show that acupuncture is effective in the management of acute and chronic low back pain. However, because the studies in this review were of poor quality, the effectiveness of acupuncture for low back pain remains unclear.</p>
Grant, Bishop-Miller, Winchester, Anderson, & Faulkner (1999)	RCT	A	∅	<p>-60 patients over age 60 with complaint of back pain</p> <p>-Randomized to 4 wks acupuncture (n=32) or TENS (n=28)</p> <p>-Acupuncture: 2x/wk for 4 wks; 2-8 needles; 20 min session</p> <p>-TENS: at home; up to 30 min per session to max of 6 h/day; 20 min visit 2x/wk with therapist</p> <p>-Evaluated (blinded) at baseline, 4 days after final treatment, 3 months after treatment</p>	<p>-30 in acupuncture group and 27 in TENS group completed the study</p> <p>-Groups were borderline significantly different (p=0.06-0.16) at baseline with higher pain scores and reduced spinal flexion and tablet consumption in the acupuncture group</p> <p>-Both groups had significant reductions in pain scores at end of treatment and maintained at follow-up (p<0.01)</p> <p>-Tablet consumption reduced in both groups (p<0.05) at end of treatment and maintained at follow-up (p<0.01)</p> <p>-Spinal flexion improved in acupuncture group after treatment (p<0.05) but was not maintained</p>	<p>-A 4-week course of either acupuncture or TENS had demonstrable benefits on subjective measures of pain and allowed them to reduce their consumption of analgesic tablets. The benefits of both treatments remained significant 3 months after completion.</p> <p>NOTES: did sample size estimation based on 75% response to acupuncture and 40% to TENS (30 per group)</p>

Technology Assessment Report

Acupuncture for Chronic Osteoarthritis Pain, Headache, and Low Back Pain

Prepared under the direction of the
Technology Assessment Committee
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TA #36

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Description of Technology/Procedure

Acupuncture is a form of oriental medicine. In oriental medicine, the goal is to correct a disturbed energy balance; it is based on a philosophical rather than biological approach (Andersson & Lundeberg, 1995). Energy is believed to flow within the body along lines known as channels or meridians. There are 14 main channels. Needles are inserted into the classical acupuncture points located on those channels (or other points, see below) and are then manipulated in an attempt to restore the energy flow to a state of balance thereby restoring the patient to a state of health (Vincent & Richardson, 1986).

In the broadest sense, acupuncture has been used to describe the stimulation of tissue at a set of specific sites at which the stimulation is reported to exert a maximal therapeutic effect. In the "modern" definition, these points include trigger points, tender areas, and points in the same dermatome as the "pain" (Vincent & Richardson, 1986; Belgrade, 1994). In more classical or traditional approaches, those points may be either the "classically" defined points or points selected based on traditional principles of pulse and tongue diagnosis, opposing forces of Ying and Yang, concepts of tonification and sedation as well as other principles from oriental medicine (Belgrade, 1994). Electroacupuncture (EA) is a hybrid derived from traditional acupuncture but modified to use electrical methods of diagnosis and treatment (Vincent & Richardson, 1986).

The depth of the needle insertion varies depending on the thickness of the underlying soft tissues. In muscle tissue, needling depth is often to the center of the muscle belly (Belgrade, 1994). Stimulation is used to achieve a deep sensation ("De qi" or "Teh-Chi") described as a special feeling of soreness, numbness, heaviness, distention around the region of needle penetration, or radiating paraesthesia (Xu, Shibasaki, & Shindo, 1993; Andersson & Lundeberg, 1995). The needle stimulation may be manual (up and down thrusting or back and forth rotation) or may involve heat or electricity (Belgrade, 1994). The duration of the treatment session is typically 20 to 45 minutes and the frequency varies from once per day to once every 1 to 2 weeks. The typical course is 10 to 20 treatments but there are few absolute guidelines (Belgrade, 1994).

Although there is little doubt that acupuncture has a strong placebo effect, its benefits exceed what would be expected with a placebo effect, alone. Lewith and Machin (1983) reported that mock transcutaneous nerve stimulation (TNS or TENS) was effective for 30% to 35% of chronic pain patients. Sham acupuncture, inserting needles into points supposedly ineffective for the condition being treated, was effective for 50% of patients. True acupuncture was effective for 60% to 75% of patients.

Proposed Mechanism of Action of Acupuncture Analgesia

Recently, considerable attention has been focused on identifying a physiological mechanism to explain the effects of acupuncture. It has been proposed that the analgesia associated with acupuncture is endorphin-mediated. Endorphins are opioid peptides. Administration of an opiate antagonist (naloxone) has been shown to reverse acupuncture analgesia in most, but not all, cases. In addition, cerebrospinal fluid levels of beta-endorphin were elevated following acupuncture in patients with recurrent pain (Clement-Jones, Tomlin, Rees, McLoughlin, Besser, & Wen, 1980; Han & Terenius, 1982; Andersson & Lundeberg, 1995). Although the role of endorphins is generally acknowledged, the exact mechanism for pain relief has not been established (Murray, 1995).

Much of the work on endorphins has been performed on lower species, in whom analgesia may be induced as a response to stress thereby mediating the acupuncture response (Han & Terenius, 1982). Other substances that may be involved in the acupuncture response include norepinephrine, acetylcholine, dopamine, glutamate, gamma-aminobutyric acid, cAMP, serotonin, biogenic amines, and substance P and other peptides (Han & Terenius, 1982; Terenius, 1984; Xu et al., 1993; Belgrade, 1994; Murray, 1995). Andersson and Lundeberg

(1995) noted similarities between acupuncture and muscle exercise. In both cases, afferent nerve fibers are activated and neurotransmitters and hormones are released. Other constructs for the physiological basis of acupuncture include a neural reflex mechanism that uses a cutaneous stimulus to achieve a visceral response and a change (increase) in blood flow as a result of peripheral stimulation. Thomas and Lundeberg (1996) suggested that different acupuncture modes and parameters activate different inhibitory mechanisms at various sites. Vincent and Lewith (1994) noted that the release of peptides would have only a short-term effect thus some other explanation was needed for long-term effects of acupuncture.

Indications

It is not possible to identify who is most likely to benefit from acupuncture. Acupuncture is indicated as an alternative to conventional therapies, especially when those therapies have failed. This report focuses on acupuncture for osteoarthritis, migraine and tension headache, and low back pain.

Contraindications

Acupuncture is contraindicated when there is a strong need to treat the patient's medical condition with conventional medicine (e.g., neoplasm or infection). It is also contraindicated for patients who are severely debilitated or terminally ill. In both instances, however, acupuncture could be used as an adjunct therapy.

Efficacy of Treatment or Procedure

Attempts to evaluate the efficacy of acupuncture using standard research methodologies have proven difficult. Problems include the appropriateness of the experimental model for pain, methods of assaying the neurochemicals, small sample sizes, and potential overlap of acupuncture and stress-induced analgesia. There are also a number of variables, many of which are difficult to control. These include: the definition of acupuncture, the choice of points, the type of stimulation, the frequency and duration of treatments, and finding a placebo similar to acupuncture but not expected to have a significant effect (Belgrade, 1994; Thomas & Lundeberg, 1996). It can be argued that functional measures (e.g., return to work, level of physical activity, level of medication intake) are more appropriate for describing the outcomes of an acupuncture program. Comparisons between studies are complicated by the differences in methodologies used.

Vincent and Richardson (1986) discussed the choice of a control group. A control group that underwent no treatment allows for statements regarding the changes in patients that could be expected given no treatment. However, this type of control group provides little information about the role of the treatment being studied. If the control group is given a pre-existing treatment, it is possible to establish whether a new treatment has any advantage in terms of efficacy, side effects, or use of clinical resources but does not allow for determination of the importance of specific ingredients within the treatment under study. A placebo group has become the standard in research. A placebo group addresses questions about what proportion of improvement is achieved through treatment factors. Placebo treatments may be either acupuncture or non-acupuncture. A non-acupuncture treatment (e.g., mock TNS) must be viewed by the patient as a credible treatment alternative. Acupuncture placebo treatments usually involve either rubbing the skin with the acupuncture needles (but not inserting the needles) or superficially inserting the needles at theoretically irrelevant sites. This form of placebo is most effective for patients with no prior experience with acupuncture. It is possible that any needling may have therapeutic effects that would make it difficult for acupuncture to show a superiority. Han (1994) noted that an acupuncture point is actually an area and it is unknown how far away the irrelevant sites would have to be. Vincent and Richardson

(1986) also noted that for research, a standard treatment protocol is necessary yet this is contrary to the individualized nature of acupuncture treatment. Double-blind trials would be nearly impossible to execute (requiring a naive and inexperienced practitioner) necessitating single-blind trials with independent outcome assessment and monitoring of patients' perceptions of the true and placebo treatments and the therapists' behavior while administering the two treatments.

Although cross-over studies have been suggested as an alternative for the evaluation of acupuncture efficacy, Lewith and Machin (1983) noted that patients may be reluctant to change to the alternative treatment if they are having success. In addition, there may be insufficient time to assess the long-term benefits and the benefits may overlap if there is insufficient time between treatments. Different conditions may need longer follow up times (Vincent & Richardson, 1986).

Osteoarthritis

Thirty two patients with osteoarthritis of the cervical spine were studied by Eriksson, Lundeberg, and Lundeberg (1991). This group of patients had previously responded well to acupuncture and opioids. It was determined that their pain was nociceptive in origin. The patients had experienced pain for 6 months or more and complained of aching at rest. Each patient underwent acupuncture for 40 minutes including both manual and electrical stimulation of the needles. Pain was rated by the patients before, during, and after treatment using visual analog scales for pain sensation intensity (a sensory component) and unpleasantness (an affective component). EA induced a significant alleviation of chronic nociceptive pain from cervical osteoarthritis, especially the affective component of the score ($p < 0.05$ for the sensory component; $p < 0.01$ for the affective component). When acupuncture was preceded by diazepam (1 hour before) or naloxone (immediately before), the pain alleviating effect of acupuncture was reduced (the only significant reduction [$p < 0.05$] in pain was in the affective component following diazepam).

A similar group of 44 cervical spine osteoarthritis patients (Thomas, Eriksson, & Lundeberg, 1991) was treated with diazepam, placebo diazepam, acupuncture, or sham acupuncture (intradermal insertion with no stimulation). The order of treatments for an individual patient was randomized with 3 to 5 days between trials. The sensory and afferent scales were used with pain assessed before and 2 hours after the treatment. Diazepam was found to reduce the affective ($p < 0.01$) and sensory ($p < 0.05$) components of pain while placebo diazepam alleviated the affective ($p < 0.05$) but not the sensory component. Acupuncture reduced the affective and sensory ($p < 0.01$) components as did sham acupuncture ($p < 0.05$). There was no significantly different reduction in pain between treatment with acupuncture, diazepam, or sham-acupuncture. There was significantly less reduction in pain ($p < 0.05$) with the placebo diazepam. The authors concluded that benzodiazepines may be replaced by acupuncture for treatment of pain and other conditions associated with unpleasantness.

Takeda and Wessel (1994) compared acupuncture with sham acupuncture. The 40 subjects all had grade I - IV osteoarthritis of the affected knee. Inclusion criteria included pain in one or both knees, radiological evidence of osteoarthritis, no change in medications for arthritis and other conditions in the last 3 weeks, and no previous experience with acupuncture of the knee. Subjects were randomized to either the acupuncture or sham acupuncture groups. Pain, stiffness, and function were determined by a blinded assessor before treatment, after 3 weeks of treatment, and at 4 weeks after completion of treatment. The treatment consisted of 3 sessions per week for 3 weeks. For the acupuncture treatment the needles were inserted, rotated, and inserted deeper until the subject experienced Teh-chi or until the full depth of the needle was reached. The needles were left in place for 30 minutes and each was manually rotated back and forth for 5 minutes. The sham acupuncture treatment consisted of superficial insertion of the needles (just enough to puncture the skin) approximately 1 inch from the acupuncture points. The needles were

touched periodically to give the impression that movement of the needles was taking place. Over the course of the treatment and follow-up, both the sham and true acupuncture were found to decrease ($p<0.05$) pain, stiffness, and physical difficulty in persons with osteoarthritis of the knee. There were no differences in response between the treatment groups. Male patients tended to respond better (regardless of the treatment) as did those who experienced Teh-Chi during the treatment.

Headache

Hansen and Hansen (1984) reported data on 18 patients with chronic (average duration of disease was 15 years) tension headache. Using a cross-over design, they evaluated traditional Chinese acupuncture and a placebo (not specified). Each treatment was administered 6 times during a 3 week period with a 3 week interval between treatments. Significantly greater relief ($p<0.05$) was reported with the acupuncture treatment (31% reduction in pain compared to 21% for the placebo group).

Thirty-two classical or common migraine headache patients were randomly assigned to either acupuncture or sham acupuncture groups by Vincent (1989). Patients who had an independent diagnosis of migraine from a neurologist, suffered from at least 2 or 3 migraine symptoms, and had at least 2 full days of headaches per month were included in the study. The acupuncture group was treated at 8 classical acupuncture points (4 bilaterally). Needles were inserted to depths of 1 to 2 cm and left in place for 15 minutes. There were 10 seconds of manual stimulation every 5 minutes. The sham group received surface needling with very light stimulation 2 to 3 cm from the classical acupuncture points. A 4 week baseline period was followed by 6 weekly treatments and a 6 week follow-up period. The credibility of both treatments was assessed along with headache intensity (via diary entries 4 times per day), medications used, and psychological variables. One patient from each group discontinued the treatments before completing the series leaving data from 30 subjects for the analysis. Both groups achieved reductions in both pain and medication scores after the treatment but the changes were significantly greater ($p<0.03$) for the acupuncture group. The 2 subject groups each perceived their treatment as credible. Gains were maintained at 4 months and at 1 year with further improvement noted in the acupuncture group. At 1 year, there was a significant difference ($p<0.05$) in the pain scores of the true acupuncture and sham acupuncture groups. Five of the patients had continued acupuncture treatments.

Carlsson, Fahlcrantz, and Augustinsson (1990) compared acupuncture to physiotherapy for treatment of chronic tension headache in 62 patients (33 with mixed tension and migraine headache with a predominance of tension headache) invited to participate in the study. The patients were randomized to one of the two treatment options. A visual analog scale was used to assess the severity of the headache. Muscle tenderness (via palpation of 6 pericranial muscles) and neck mobility were also determined. Both groups were similar at baseline. The physiotherapy sessions were individualized for each patient and included components to teach the patient to handle situations with as little tension as possible. There were a total of 10 to 12 sessions over a 2 to 3 month period. Acupuncture (including EA in the second and subsequent sessions) at 6 classical Chinese acupuncture points was completed over a period of 2 to 4 weeks with 4 to 5 sessions (an additional 4 to 5 sessions were completed if the patient reported relief). Both groups reported significant reductions in headache intensity ($p<0.001$ for the therapy group and $p<0.05$ for the acupuncture group) with significantly lower (less pain) scores for the physiotherapy group. Muscle tenderness was significantly reduced ($p<0.01$) for all 6 muscles in the therapy group but only for 3 muscles in the acupuncture group. Neck rotation was not affected by either treatment. Only the physiotherapy group markedly decreased their intake of analgesics.

Tension headache patients were randomly assigned to either an active treatment group or a placebo group (Tavola, Gala, Conte, & Invernizzi, 1992). The acupuncture group was treated at 6 to 10 points. The needles were inserted to a depth of 10 to 20 mm until the

patient showed pain, torpor, or swelling around the point. The choice of points was made on an individual basis and was allowed to change from session to session. The placebo treatment consisted of insertion of the same number of needles in the same general areas (but not at acupuncture points) to a depth of 2 to 4 mm. Sessions were 20 minutes in length and were held once a week for 8 weeks. Headache intensity, duration, and frequency were monitored along with a headache index, the consumption of analgesics, and a headache improvement index. There was a decrease in frequency of episodes, a decrease in the headache index, and a decrease in the use of analgesics, with greater (although not significant) decreases in the acupuncture group. At one month after treatment, 87% of the acupuncture group and 60% of the placebo group showed at least a 33% improvement. By one year, 53% of the acupuncture group and 47% of the placebo group were still considered responders (>33% improvement). It was concluded that traditional Chinese acupuncture was not differently effective from the placebo.

Hesse, Mogelvang, and Simonsen (1994) studied migraine patients. All of the patients (n=85 initially with n=77 in the final analysis) had a history of migraine for at least 2 years with 2 to 6 anamnestic attacks monthly. None had prior experience with acupuncture. The patients were randomly assigned to receive either acupuncture with placebo tablets or 100 mg per day of metoprolol (a selective beta blocker) with placebo stimulation. The acupuncture treatment consisted of trigger point inactivation by dry needling the point for a few seconds with the sharp end of the needle. The placebo stimulation consisted of superficial touching with the blunt end of the needle. Both activities took place at the most tender trigger points in the muscles of interest. The number of trigger points needled per treatment, the interval between treatments, and the total number of treatments were determined individually for patients in the acupuncture group; for the others, the variables were chosen at random from the range of values achieved by the treatment group. Patients kept a diary of the frequency, severity, and duration of migraine attacks, did a global rating of the migraine attack, and noted the frequency of tension type headaches and the consumption of analgesics. Patients in both groups experienced a significant ($p < 0.01$) decrease in the frequency of attacks with no difference between groups. The global rating of the migraine attack was significantly ($p < 0.05$) higher (more severe) for the acupuncture group. There was no difference between groups with regard to the duration of the attacks. Side effects were more notable in the metoprolol group (18 events vs. 3 in the acupuncture group). Compliance with the drugs was good (only 1 in the metoprolol group and 2 in the placebo tablet group took fewer than 75% of the pills prescribed, based on pill count data). The authors considered the acupuncture treatment to be a valuable supplement to the list of treatment options when beta-blockers are contraindicated or when the side effects are unbearable.

Low Back Pain

Coan et al. (1980) randomly assigned 50 chronic low back pain patients (pain for 6 months) to either an immediate treatment group or a delayed treatment group (control). The treatment consisted of at least 10 sessions of acupuncture performed according to the classical meridian theory. The delayed group began treatment 8 weeks or more after their initial evaluation. There was no placebo acupuncture condition; the acupuncturists considered that unethical. Information was gathered on the patients' history of back surgery, medication use, and physical ability (e.g., straight leg raise, range of motion of the back). In the group receiving immediate treatment, at a mean of 10.3 weeks after the start of treatment, 83% reported improvement, 17% reported no change, and none were worse. In the delayed treatment group, at the end of the no treatment period (a mean of 15 weeks), 31% reported improvement, 44% reported no change, and 25% reported they were worse. Following acupuncture, at a mean of 25 weeks into the study, 75% reported improvement with 25% reporting no change. When the 2 groups were combined 31 of 39 patients who received adequate treatment reported improvement. The remaining 11 patients were considered to have received inadequate treatment (7 took no treatment at all

and 4 stopped treatment after 6 or fewer sessions). At 40 weeks, 58% of those who received adequate treatment were improved compared to 11% of those who received inadequate treatment. The authors noted that some patients did not show a response until they had completed 8 to 10 treatments.

In a cross-over study by Mendelson, Selwood, Kranz, Loh, Kisdon, and Scott (1983), 95 chronic low back pain patients were randomly assigned to receive either acupuncture or a placebo treatment for the first phase of the study. The acupuncture (with an average of 8 needles at classic acupuncture points) consisted of manual stimulation of the needles until "Teh-Chi" was achieved. The needles were then left in place for 30 minutes. The placebo group received an intradermal shot of lidocaine (at non-acupuncture, non-tender sites) followed by superficial insertion of the needles. The needles were left in place for 30 minutes with no stimulation. Each treatment phase was 4 weeks with a 4 week rest period between treatments. Patients were evaluated at baseline, during the rest period, and during the follow-up period. Variables monitored included psychometric scale scores, suggestibility, expectation of pain relief, spinal mobility, and pain (using a visual analog scale and questionnaires). Of the initial group of 95, 77 completed all phases of the study. In the first treatment phase, both groups experienced a significant ($p < 0.001$) decrease in pain score (40% for the acupuncture group and 26% for the placebo group; $p > 0.6$). During the second treatment phase, the decrease in pain continued. For the group now receiving placebo treatments, the decrease was 40% ($p < 0.001$) while the group now receiving acupuncture decreased by 19% ($p < 0.03$). The difference between groups was significant ($p < 0.05$). There was a trend toward a difference based on treatment order with those treated with acupuncture initially having a better response when subsequently treated with the placebo. Overall, the pain reduction was 26% with acupuncture and 22% with placebo ($p > 0.6$).

Macdonald, Macrae, Master, and Rubin (1983) chose inert surface electrodes for their placebo condition. The acupuncture treatment group experienced only subcutaneous insertion of the needles with care taken to avoid penetrating the muscles or their fascia. Time of insertion was increased if a treatment failed to produce beneficial results. If necessary, electrical stimulation was added to the treatment protocol. The maximum number of treatments administered was 10 (with fewer treatments given if further improvement did not occur or if the patient's pain progressed). The 17 patients (all with chronic low back pain that had failed to respond to appropriate conventional methods of treatment) were randomly assigned to either the acupuncture or placebo treatment. The acupuncture group responded significantly better than the placebo group for the following variables: pain relief after each treatment ($p < 0.01$), activity pain score reduction ($p < 0.05$), physical signs reduction ($p < 0.01$), severity and pain area reduction ($p < 0.01$), and combined average reduction ($p < 0.01$). Only the pain score reduction was not significantly different between the two groups (values of 57.2% for the acupuncture group and 22.7% for the placebo group were reported).

A comparison of TENS, mock TENS (with a fully discharged battery), and acupuncture (EA) was reported by Lehmann et al. (1986). The 54 patients were randomly assigned to one of the treatment groups while controlling for whether they had prior lumbar surgery. The TENS treatments were administered 5 days/week for 3 weeks while the EA treatments were twice a week. The choice of acupuncture points was determined based on the individual patient's pattern of pain (with other aches and pains often treated concomitantly). The programs were evaluated using physical measures (including trunk strength and spine range of motion) and pain ratings (including peak pain, average pain, and degree of disability). For each treatment, there were significant improvements from the initial evaluation to completion of the treatment program ($p < 0.002$) and a non-significant regression from discharge to follow-up (6 months). No significant differences were observed between treatment groups with respect to overall rehabilitation although the acupuncture group had slightly better results.

Thomas and Lundeberg (1994) studied patients with chronic low back pain (6 months or longer) of nociceptive origin. Of an initial group of 43 patients, 33 were randomized to one of three treatments (manual stimulation of the needles, low frequency electrical stimulation of the needles, and high frequency electrical stimulation of the needles) and 10 were put on waiting list and served as untreated controls. The treatment the patient was randomized to became their initial "trial" treatment. Each patient was allowed to try each of the treatments and to then continue (for up to 10 sessions) with the protocol of their choice. The acupuncture needles were inserted at 9 to 10 points. Manual stimulation (rapid backwards and forwards rotation) was done to produce Teh Chi. For the manual stimulation group, this procedure was repeated on every needle at 5 minute intervals. For the electrical stimulation, 2 pairs of needles were connected to the electrical stimulation unit (with no further stimulation of the remaining needles). Low frequency stimulation was at 2 Hz while high frequency stimulation was at 80 Hz. Each session lasted for 30 minutes. Patients were evaluated at 6 weeks and 6 months. The parameters studied included activities of daily life related to pain, pain descriptors, and a clinical assessment of mobility. At 6 weeks, the patients receiving treatment (of any type) had improved on mobility (all aspects except straight leg raise), words (pain descriptors), and subjective assessment (by the patient). Activity (number of activities showing <50% pain) was not significantly improved. When patients were divided by type of stimulation used, data from 27 patients was available (7 with manual stimulation, 9 with low-frequency stimulation, and 11 with high-frequency stimulation). Following treatment, the low frequency stimulation group showed significantly greater improvements (compared to the other stimulation methods) for words (number of words describing the intensity or unpleasantness of the pain) ($p<0.05$) and the subjective assessment of pain ($p<0.001$). Both the manual stimulation ($p<0.01$) and the high-frequency stimulation ($p<0.001$) groups improved on the subjective assessment of pain. At 6 months, patients in the low frequency stimulation group continued to improve on mobility of right lateral flexion ($p<0.05$), number of activities showing <50% pain ($p<0.05$), words chosen from the word chart ($p<0.01$), and the subjective assessment ($p<0.001$). For the high frequency group, straight leg raise was significantly improved at the follow-up ($p<0.05$).

Related Studies of General Chronic Pain

A number of studies have looked at the effects of acupuncture on patients with a wide range of chronic pain conditions. Lee, Anderson, Modell, and Saga (1975) studied patients who had already attempted pharmacological therapy and/or surgery. The group included patients with osteoarthritis, rheumatoid arthritis, low-back pain, and headache. One group of patients ($n=128$) had treatments on 4 successive days alternating between proper (meridian) and arbitrary points. A second group of patients ($n=133$) had all treatments in the proper locations. Electroacupuncture was used. There was a trend toward increased pain relief with successive treatments but there was no difference between treatment sites. The majority (54%) of patients reported an excellent degree (75%) of pain relief immediately after the fourth and final treatment. At 4 weeks after treatment, excellent results were reported by 18% of the patients. Given that the 18% had unsuccessfully attempted to use conventional therapies, the authors concluded that acupuncture may have a role for those whose pain relief is resistant to other methods.

ter Riet, Kleijnen, and Knipschild (1990) completed a meta-analysis of studies that used needle acupuncture (including EA) to treat patients with chronic pain of at least 6 months duration. The methodology of each study was scored on a 100 point basis taking into account factors like number of patients, length of follow-up, blinding, and description of procedures used. The highest score (among 51 publications) was 62 out of 100. The authors noted that no studies of high quality seemed to exist. Results from studies that scored 50% or greater of the maximum score were often contradictory. Notable deficiencies included heterogeneous study groups, inadequate numbers of patients, loss to follow-up, and

inadequate periods of follow-up. They found it impossible to reach a definitive conclusion about the efficacy of acupuncture for the treatment of chronic pain.

Patients with idiopathic pain disorder were studied by Thomas, Arner, and Lundeberg (1992). The 12 patients were preoccupied with pain (not solely due to headache) for at least 6 months. The pattern of pain was either not related to or inconsistent with any pathology that was present. The pain was also not due to any affective disorder. Pain intensity, on a scale of 0 (no pain) to 100 (worst pain ever), was recorded daily every 2 hours for 2 weeks prior to treatment and throughout the treatment phase. Treatments were administered at 2 to 3 week intervals (or more frequently). The goal was 10 sessions but, on average, 7 sessions were completed. Ten of the 12 patients reported little or no benefit of acupuncture while 2 reported longer lasting benefits. It was concluded that other treatments might offer more benefits in cases of idiopathic pain disorder.

Carlsson and Sjolund (1994) completed a follow-up of 211 patients with chronic non-malignant pain who were treated with needle acupuncture 3 to 5 years previously. Pain was classified as nociceptive (e.g., migraine, localized tissue destruction), neurogenic (e.g., nerve, nerve root, or CNS injury), or psychogenic (conditions not fitting either of the above categories). All patients who had reported pain relief immediately following their last treatment session (n=85) were sent, and responded to, a questionnaire. Thirty percent of those with post-treatment pain relief experienced relief of <1 month, 30% had relief for 1-6 months, and 40% had relief for >6 months (many for >1 year). Immediately after treatment, 50% of those with nociceptive pain reported relief compared to just 32% of those with neurogenic pain and 15% of those with psychogenic pain. The long-term outcome was also better for the nociceptive pain group. Only those patients with pain relief of >6 months had a noticeable increase in activity at home or at work. Included in the patient population were 48 with predominantly migraine headache and 31 with predominantly tension headache. Patients with migraine responded better to acupuncture both initially and in follow-up evaluations. Relief of greater than 6 months duration was noted for 36% of the migraine patients and 10% of the tension headache patients ($p<0.005$).

Risks and Limitations

Common side effects include fainting (about 1% of patients), bruising (about 1% of needle sticks), and persistent soreness that outlasts the treatment by hours to days. Rare, but reported, conditions include cellulitis and contact dermatitis (due to the nickel content of most stainless steel needles), abortion (due to stimulation of uterine contractions and cervical dilatation), pneumothorax, hepatitis B (when clean needle techniques have not been used), other infections such as endocarditis, staphylococcal sepsis, and osteomyelitis, and spinal cord and peripheral nerve injuries (due to migration of a broken needle fragment) (Belgrade, 1994).

Acupuncture is not intended to replace pharmacologic or other conventional treatment but rather, to be an alternative or adjunctive therapy (Owens & Ehrenreich, 1991). The use of acupuncture may reduce the dosage and frequency of pharmacologic intervention.

Alternative Forms of Treatment

Conventional approaches to treatment of chronic pain include the use of medications (e.g., NSAIDs, antidepressants, opioids), neural blocks, physical therapy, and biofeedback and meditation techniques.

Several forms of therapeutic touch can be considered as alternatives or adjuncts to these conventional treatments (Owens & Ehrenreich, 1991). These methods may or may not result in complete elimination of pain, improved quality of life, and reduced use of pharmacologic agents. Some examples are:

- ¥ Healing Touch - massaging of points along one or more of the 12 meridians to achieve a rebalance or repatterning of the energy flow (life force);
- ¥ Meridian Tracing - massaging of points along the meridian that traverses the area of discomfort;
- ¥ Reflexology - massaging of the hands or feet (key areas on the hands and feet correspond to specific regions of the body).

Alternatively, acupuncture points may be stimulated using the fingers or knuckles (acupressure), laser technology, or TENS units.

Epidemiology and Costs

At Abbott-Northwestern Hospital's Pain Clinic, it is estimated that there are 10 to 20 patient treatments per week. At an acupuncture facility, it is likely that there are more than 50 patient treatments per week.

The charge for each treatment session can vary from \$40.00 to \$100.00. A typical program may include 10 sessions.

Summary

This report focused on the use of acupuncture specifically for treatment of pain associated with osteoarthritis, migraine and/or tension headache, and low back pain. There have been controlled (Grade A) studies of the effectiveness of acupuncture in those areas. Many of the studies are flawed, however, due to difficulties with defining the appropriate experimental model for pain, small sample sizes, difficulties in selecting an appropriate control group, and inadequate follow-up.

Recognizing that the literature is flawed, the ICSI Technology Assessment Committee concludes the following:

1. The benefits of acupuncture are not experienced by every patient. To date, there is no way to identify who is most likely to benefit from the procedure. Acupuncture may be helpful for patients who have unsuccessfully exhausted the conventional treatment modalities. There is an ongoing need for monitoring of acupuncture trials and for outcome assessment.
2. If acupuncture is being considered, it must be part of a comprehensive pain treatment program that may include behavioral, pharmacological, and/or physical therapies. The role of acupuncture in a comprehensive treatment program is still being defined. Patients should receive a limited number of treatment sessions with an opportunity to re-evaluate their treatment options after completion of those sessions.
3. Acupuncture is a safe procedure when performed by properly trained individuals in a clinical environment using sterile, disposable needles.
4. For pain associated with osteoarthritis, there is evidence of efficacy equivalent to treatment with diazepam (Thomas et al., 1991). No difference was reported between true and sham acupuncture (Takeda & Wessel, 1994).
5. For headache pain, acupuncture has been shown to be superior (Hansen & Hansen, 1984; Vincent, 1989) or equal to (Tavola et al., 1992) sham acupuncture and comparable to physiotherapy (Carlsson et al., 1990) or beta-blockers (Hesse et al., 1994).
6. Studies of acupuncture for low back pain have found acupuncture to be more beneficial than no treatment (Coan et al., 1980) or placebo in the form of inert surface electrodes (Macdonald et al., 1983) and comparable to superficial insertion of needles following an intradermal shot of lidocaine (Mendelson et al., 1983) or TENS (Lehmann et al., 1986). In low back pain of nociceptive origin, manual stimulation, low frequency stimulation, and

high frequency stimulation each resulted in improvement with greater and longer duration improvement noted following low frequency stimulation (Thomas & Lundeberg, 1994).

References

Evidence is graded according to the following system:

Grade A: Conclusion based on a randomized, controlled trial that has been published in a peer reviewed journal.

Grade B: Conclusion based on a well-designed study published in a peer-reviewed journal (but not on a randomized, controlled trial) such

as:

¥ a trial using historical or other non-randomized controls;

¥ a prospective cohort study;

¥ a case-control study; or

¥ a meta-analytic study.

Grade C: Conclusion based on one of the following (but not on any studies of the types mentioned above):

¥ an uncontrolled case series; or

¥ expert opinion.

Position statements, panel consensus statements from the NIH or elsewhere, review articles, and textbook chapters that cite primary evidence are not assigned a grade because they are not primary evidence. The individual studies cited in such secondary sources can be graded according to the categories presented above.

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