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for Medical Research**

Acupuncture: Evidence from Systematic Reviews and Meta-analyses

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This Health Technology Report has been prepared on the basis of available information of which the Foundation is aware from public literature and expert opinion and attempts to be current to the date of publication. It has been externally reviewed. Additional information and comments relative to the report are welcome and should be sent to:

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SUMMARY

- This report's objective is to provide an overview of evidence from systematic reviews and meta-analyses on the effectiveness of acupuncture for any condition that has been assessed in this manner.
- Two-thirds of Canadians used some form of alternative or complementary medicine in 2000, and 1-2% reported seeing an acupuncture practitioner in 1998/99.
- Acupuncture, in the strictest sense refers to "insertion of dry needles, at specially chosen sites, for the treatment or prevention of symptoms and conditions." It is a relatively safe procedure, but it can lead to both minor (fainting, exacerbation of symptoms) and serious (hepatitis, traumatic injury of body tissue) adverse events.
- Twenty-three reviews were included: two on dental and temporomandibular dysfunction (TMD) pain; one on headaches; one on tinnitus; three on asthma; one on stroke rehabilitation; two on antiemesis; five on neck/back pain; two on chronic pain; one on fibromyalgia; one on induction of labour; one on addictions; two on smoking cessation; and one on weight reduction. Unanimously these reviews call for higher quality research with greater sample size.
- Among the studies included in the review there are wide variation of treatments such as manual or electrical stimulation, number of needles per treatment, technique of needle insertion, and frequency of treatment. All of these factors may influence the outcome.
- Acupuncture was found to be effective for the treatment of dental and TMD pain and antiemesis (nausea/vomiting) in comparison to other chosen interventions. The results for idiopathic headaches and fibromyalgia were reported as encouraging. The evidence was inclusive for the treatment of back pain, chronic pain, smoking cessation, and asthma. Effectiveness was not supported by the evidence for tinnitus, stroke rehabilitation, neck pain, addictions, and weight reduction.
- Dental and TMD pain and antiemesis appear to be two areas in which acupuncture is reproducibly effective. For all other indications the methodology design and quality is either too weak to draw conclusions, the studies have not been done, or, in studies of better quality, acupuncture does not appear to be more effective than standard of care or control chosen.
- Clearly, more research of higher methodological quality is called for. Issues of blinding, the use of a credible control, varying diagnosis amongst differing philosophical approaches, and the diversity of treatment points chosen and techniques used challenge this particular area of complementary medicine.

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INTRODUCTION

Two-thirds of Canadians used some form of complementary or alternative medicine in 2000, mostly vitamins ¹. Sixteen percent of Canadians saw an alternative health care provider in 1998/99, and of those people, 16% (or 1-2% of the total population) saw an acupuncturist. In Canada, the incorporation of complementary or alternative medicine into one's health care regime is more common in the western provinces, in women aged between 25 and 44 years, and in those living with chronic conditions ². Medical schools are incorporating complementary and alternative medicine training in their curricula, with ten out of sixteen Canadian medical schools providing some exposure to acupuncture ³.

A large body of research exists in acupuncture, covering virtually every symptom ⁴. In the 1950's the Central Committee in China was interested in this question and thousands of studies were performed. The results led the Committee to bestow equal recognition to Traditional Chinese Medicine (TCM) and Western Medicine ⁵.

This project is Part II of a request from several Regional Health Authorities and Alberta Health and Wellness, regarding two key objectives: to present information on the regulation of acupuncture in Alberta, including the scope of practice and coverage of services; and to conduct a systematic review of current scientific evidence to determine the effectiveness of acupuncture, and the conditions for which it has been found to be effective. Objective two is addressed in this report.

Part I, titled "*Overview of the Regulation of Acupuncture in Alberta*", addressed the first objective and was completed in May 2001 ⁶. In Part I, three categories of certification or governance were found to be in place: those who are members of a professional college or association (eg. physical therapists) prior to their study of acupuncture; those who have completed training in an acupuncture program and have passed a provincial exam; and those who have knowledge of acupuncture (eg. from another country), but are practicing without a governing body. Acupuncture is usually performed in a clinical setting, and is not covered by the Alberta Health Care Insurance Plan. As the insertion of needles will be considered a 'restricted activity' under the new Health Professionals Act, these activities will only be allowed to be practiced by those governed by a regulating body.

Growing demands on the health care system for provision of complementary medicine, the evolution of legislation regarding the regulation of health professionals, in conjunction with requests from the community for funding coverage for acupuncture treatment illustrate the importance and timeliness of this review.

SCOPE OF THE REPORT

Due to the breadth of this topic and the challenge of reviewing the extensive body of research on acupuncture, the approach of systematically assessing the available reviews was chosen to evaluate the current evidence for the efficacy of acupuncture. In choosing this approach, it is acknowledged that there are areas in which acupuncture is used that have not been assessed and reported as a systematic review.

Though the scope for this report did not limit the search of scientific evidence to specific medical conditions, systematic reviews meeting methodological inclusion criteria are reviewed on the following topics: dentistry, headaches, tinnitus, asthma, stroke rehabilitation, nausea/vomiting, neck/back pain, chronic pain, fibromyalgia, labour induction, addiction, smoking cessation, and weight/appetite reduction.

This assessment will not be comprehensive including all of the primary acupuncture research, and all the conditions currently treated by acupuncture, but for the systematic reviews and meta-analyses published in English between 1990 and 2001 that met the inclusion criteria (see Appendix A). Primary studies published since the reviews have not been included; the results from these primary studies may change some of the conclusions derived at in this systematic review.

The findings from this review are summarized by medical condition and the overall results compared with those from the United States' National Institute of Health Consensus statements and other systematic reviews of reviews.

There are many issues in acupuncture research that need to be explored and addressed in future studies which are pointed out briefly in this report. These issues range from the quality and assessment of methodology to the appropriate acupuncture treatment regimen.

DEFINITION

Acupuncture, in the strictest sense, refers to “insertion of dry needles, at specially chosen sites for the treatment or prevention of symptoms and conditions”⁷. The Chinese term “zhenjiu” references both acupuncture and moxibustion. The latter is the use of a herb *Artemisia vulgaris* (mugwort) which is burned over the acupuncture site for purposes of warming⁷⁻⁹.

Acupuncture is performed with solid needles ranging in length from 1 cm to 10 cm¹⁰. They are made of gold, silver, copper, stainless steel, or a combination of metals¹⁰ and may be inserted under the skin no more than 8 cm deep. As technology evolved it was applied to traditional forms of healing. Electroacupuncture refers to the technique of introducing an electrical current to the inserted needles at various frequencies. A laser beam, directed at the acupuncture site and stimulated, has developed into a technique

called laser acupuncture. Techniques of fire needles involve inserting red-hot needles at an acupuncture point.

Staple puncture is the application of a metal staple to an acupuncture point where it remains for a prolonged period of time. Cupping is a technique by which a vacuum force is applied to acupuncture sites. Bloodletting refers to the pricking of the skin for the purpose of releasing blood. This may be aided with the application of a cup over the site. A less invasive procedure is acupressure which refers to the stimulation of a point manually with pressure with the intention of stimulating Qi flow. Intramuscular stimulation is a technique of applying needles to areas of tenderness. There is debate in the acupuncture community over which of these techniques fall under the classification of acupuncture.

'De qi' is the sensation of numbness, tingling, electrical sensation, fullness, distension, soreness, warmth, and itching which may be felt subjectively around the acupuncture point⁸. The practitioner may have a sensation of tenseness or dragging to the needle¹¹. This sensation may be sought by some practitioners through twirling, plucking, or thrusting of the needles. In Western terms these are signs that A-delta fibers are activated¹⁰. In TCM this indicates that the Qi has arrived. There is controversy amongst practitioners of acupuncture as to whether it is necessary to elicit this sensation to render the treatment effective⁸.

COMPLICATIONS OF ACUPUNCTURE

Acupuncture is a relatively safe procedure, but it can also lead to both minor and serious adverse events. There is an increasing amount of literature on adverse effects of acupuncture; however, there is still a concern about under reporting in the studies of the more minor adverse effects of acupuncture.

Norheim's study of the literature from 1981 to 1994 examined 78 case reports (N= 193 treatments) of adverse effects with needle acupuncture¹². He classified the complications as mechanical organ injuries such as pneumothorax (n=23) and medulla spinalis injury (n=13); infections such as hepatitis (n=100) and auricular chondritis (n=16); and other effects such as argyria (n=5) and problems with implanted needles (n=5). Many of the effects seem to be linked to practitioner competence, or patients' ongoing health conditions.

White et al. and MacPherson et al. both examined the adverse events occurring with acupuncturists in the U.K., in over 32,000 and 34,000 consultations respectively^{13,14}. In MacPherson et al. no serious adverse effects were reported, as defined as requiring hospitalization, or leading to permanent disability or death, and there was a rate of 1.3/1000 consultation of minor adverse events such as severe nausea and fainting. White et al. also found no serious adverse events in their study. Significant minor events such as fainting, lost needles, and exacerbation of symptoms were reported at a rate of 14/10,000 consultations. In addition, both studies reported on 'minor events' or

'mild transient reactions' occurring in a much larger percentage of the treatments, though these were not considered significant.

Using combined data from published literature, Ernst ¹⁵ found that the most commonly reported adverse events were drowsiness and fainting, increased pain, nausea/vomiting, and infections. Infections, including Hepatitis C, were usually due to using/reusing unsterile needles, or practitioner error. In a 2001 systematic review by Ernst and White on the safety of acupuncture they reviewed nine studies, which included almost 250,000 treatments ¹⁶. Thirty-eight percent of all patients experienced bleeding and 45% experienced an aggravation of pain symptoms. Overall 28% of patients experienced some adverse effect, serious effects were rare, as supported by their systematic review of life threatening adverse effects in 1997 ¹⁷.

Across the studies common mild or 'non-significant' adverse effects included pain at the needling site, nausea, bleeding, aggravation of some symptoms and faintness or fatigue ^{13-15, 17, 18}. Infections, such as hepatitis, were often due to poor hygiene technique such as reusing unsterilized needles. Some cases of traumatic injury of body tissue including pneumothorax, cardiac tamponade, spinal trauma, and hematoma ¹⁹ have also occurred usually due to practitioner error.

Some key challenges identified in consistent reporting of adverse effects are summarized by Ernst and White ¹⁶. The method of defining adverse events and of collecting/reporting of these events differs across the studies. As well, the style of acupuncture differs across cultures and practitioner groups, which have differing risk levels for adverse events. Finally, the rate of adverse events may vary according to the condition being treated, and the body part being stimulated during that treatment. Yamashita et al. suggest that a distinction should be made between the reporting of results due to negligence and those due to adverse events of the acupuncture technique itself ¹⁸.

The studies' conclusions are consistent in that they found that the rate or incidence of serious adverse events due to acupuncture treatment is low but that they do occur ^{12,13,15-18}. Acupuncture is not free of risk, it is important to track and report minor side effects as they may progress into a more serious event. If there is not a consistent and thorough process for reporting these events, the evidence on adverse effects remains limited and incomplete. MacPherson and colleagues ¹⁴ stated that the adverse event rate, when compared with primary care drugs, suggests that acupuncture is a relatively safe treatment, and many researchers concur that it is a relatively safe technique ^{12, 15, 16}.

FINDINGS

Of the thirty-three studies selected, twenty-three systematic reviews met the inclusion criteria, including five Cochrane Reviews (see Appendix A). A table of data extraction and quality assessment of included systematic reviews can be found in Appendix B. Though there is growing debate as to whether the Cochrane Reviews should continue

to be a 'gold standard' for systematic review methodology, they currently have the most rigorous methodology, and therefore, a quality assessment of these reviews was not undertaken²⁰. The other reviews were assessed using criteria based on those set out in Greenhalgh²¹ (see Appendix D). Though this quality assessment may not be as rigorous as initially intended by its authors, it has been consistent across the reviews. Once agreed upon criteria have been developed for the assessment of the methodological quality of primary studies in acupuncture, the same approach should be taken for the assessment of systematic reviews.

The methodology of a review was considered to be satisfactory if it contained a concise research question(s) and inclusion criteria, an adequate search strategy, and included a quality assessment evaluation²²⁻²⁸. If a review also attempted to integrate and/or statistically analyze the data, it was considered to be of good quality²⁹⁻³⁶. The rest of the reviews were considered to be of poor methodological quality³⁷⁻³⁹.

Dental and temporomandibular pain

Two reviews focused on dental pain, temporomandibular dysfunction (TMD) and facial pain. Eight of the 16 studies reviewed by Ernst and Pittler²⁴ regarding dental pain were also included in Rosted's review²². In Ernst and Pittler, eleven studies examined pain due to dental surgery and five studies evaluated pain induced in an experiment. Methodological quality was assessed using the Jadad Scale⁴⁰ (Appendix C). Though the authors state that the heterogeneity of treatments and low quality of many of the studies reviewed limit the conclusions that can be drawn, the data suggest that acupuncture can be effective in the treatment of dental pain. The method and regimen of acupuncture that most effectively relieves dental pain, however, remains unclear.

Rosted's review²² examined seven studies on pain associated with tooth extraction and eight studies on TMD/facial pain. Overall the review's methodology was fairly rigorous. Descriptions of the treatment and practitioner's qualifications were assessed as part of the quality assessment, but these details were not presented.

Eleven studies indicated that acupuncture was effective and seven of these studies were rated at a high level due to their methodological quality. Rosted concluded that most of the studies suggest that acupuncture is effective in controlling dental and TMD/facial pain. He stated concerns, however, about the clinical relevancy of this treatment as a surgical analgesic, as the time needed for acupuncture to take effect was much longer than other analgesics.

Headache

Only one review met the inclusion criteria⁴¹. This Cochrane Review addressed the question whether acupuncture was more effective than no treatment, sham or other treatments used for headache of three types: migraine, tension, and mixed. The Jadad Scale⁴⁰ was used to assess study quality (Appendix C) of the 26 RCTs (16 RCTs for migraine headaches, six RCTs for tension-type headaches, and four RCTs for various

headache types). Evaluation of the appropriateness of acupuncture point selection was undertaken by someone trained in both Western and TCM acupuncture.

Sham-controlled studies for migraine and tension-type headaches, reported favourable results for acupuncture, though the methodological quality of many of the studies was rated as weak. There were a small number of studies for all types of headaches indicating mixed results for acupuncture compared with each of physiotherapy, drugs, and massage/relaxation.

Four out of 16 studies evaluating the effectiveness of acupuncture for the treatment of migraines were rated at a high level in relation to their methodological quality. Of these four studies, two studies showed a benefit from acupuncture, one study showed no difference in comparison to sham acupuncture, and one study noted that acupuncture was less effective when compared to standard care.

For tension-type headaches, two out of the six RCTs were rated as high for methodological quality. These two studies indicated that acupuncture was effective for the treatment of tension type headaches.

The authors stated that acupuncture appears relatively safe when administered by qualified providers. Although the type of acupuncture used and whether it should be widely recommended could not be answered by the evaluators, and patients wishing to try it should not be discouraged.

Tinnitus

One systematic review focused on acupuncture as a treatment for tinnitus. Park et al.²³ identified six RCTs which compared electro or manual acupuncture in the treatment of tinnitus to sham, physiotherapy, biofeedback, or medication. Park and colleagues evaluated methodological quality using the Jadad Scale⁴⁰ (Appendix C). The type of acupuncture stimulation and number of sessions were described but not the appropriateness of the acupuncture treatment. Four studies found no effect of acupuncture on tinnitus; three of these studies achieved passable methodological quality scoring by the Jadad criteria. Due to the low methodological quality overall, the heterogeneity of the samples, and the findings of 'no effect', the conclusion of the reviewers was that evidence did not support the use of acupuncture for the treatment of tinnitus.

Asthma

Two systematic reviews assessed the effectiveness of acupuncture in the treatment of asthma, in addition to a Cochrane Review. Kleijnen and colleagues²⁸ reviewed 13 RCTs that were based on needle acupuncture. They reported on the style of acupuncture (all but one were based on formula acupuncture) but did not evaluate the appropriateness of points chosen. The methodological quality of the 13 studies was rated on the Kleijnen scoring system (see Appendix C). No studies of high enough quality were found to conclude if acupuncture was effective in the treatment of asthma.

In 1996 Linde and his colleagues published a review²⁹ of 15 trials including all but two of the studies included in the Kleijnen et al. review. These excluded studies were not randomized trials. They were concerned that there had been no evaluation as to the appropriateness of point selection; therefore four physicians who also taught and practiced acupuncture evaluated the appropriateness of the acupuncture points chosen. There was variability in the assessment of adequacy of treatment choice, but none of the studies were evaluated as being totally inadequate. Jadad's Scale⁴⁰ was used as well as Linde's own scale to assess methodological quality ratings and were compared to the ratings obtained in the Kleijnen scoring system (Appendix C). More similarity was found between the Linde and Kleijnen ratings than those of Jadad. They concluded that there was insufficient research of high enough quality to recommend to acupuncturists to stop treating asthma patients, nor to recommend to non-acupuncturists to start its use.

A Cochrane Review by Linde, Jobst and Patton⁴² using similar inclusion criteria was published in 2000. Seven studies matched the criteria and were evaluated using the Jadad Scale. One of the authors was experienced in acupuncture and evaluated the adequacy of the sham-acupuncture, but not the appropriateness of the acupuncture treatment. Objective measurements for lung function were included as well as drug use. Subjective results were also accounted for in these studies. They concluded that the efficacy of acupuncture for asthma can not yet be determined.

Although there were a variety of criteria used to evaluate the methodological quality of the studies, the results obtained were consistent in stating that the evidence did not support or refute the use of acupuncture in the treatment of asthma.

Stroke rehabilitation

A review by Park and colleagues²⁵ included nine RCTs comparing needle acupuncture to standard medical and rehabilitative treatments or sham electro-acupuncture. The search included more than one complementary database, and study quality was assessed using Jadad's Scale⁴⁰ (Appendix C). They identified variability in treatment schedules, types of stimulation, time of initiation of acupuncture, acupuncture sites, and use of quality of life measures. Numerous different stroke assessment scales were used in the primary studies to measure the outcome, challenging the ability to make comparisons between the studies. No mention was made of the evaluation of the appropriateness of treatment, although the duration of treatment and whether it was manual or electroacupuncture was documented. The authors found the quality of studies to be poor (only two studies obtained a Jadad score of 3 or more) and stated that the evidence does not support the use of acupuncture for stroke rehabilitation, though the findings show some promise.

Nausea and emesis

Pericardium 6 (P6) is used in the treatment of post-operative nausea and vomiting (PONV). Two systematic reviews evaluated the effectiveness of P6. The Lee and Done

meta-analysis³⁰ included 19 studies that evaluated post-operative nausea and vomiting by comparing acupuncture and/or TENS to a control group receiving either sham acupuncture or treatment or a pharmacological intervention. No specific complementary database was searched to locate primary studies nor was there a stated search of the grey literature. Eleven of the 19 studies scored three or better on Jadad's Scale⁴⁰ (Appendix C), though there were many issues noted that hindered comparison, including diversity of techniques used for stimulation of the point. Acupuncture was not deemed effective in the control of nausea and vomiting in the pediatric population. P6 stimulations for early or late PONV compared to pharmaceutical treatments was reported to have an equal effect, and when compared to sham or no treatment was superior in 20% to 25% of adults within 6 hours of laparoscopic and gynecological procedures. There was inadequate data to determine effects of treatment versus sham for late PONV.

Vickers' review³¹, which included a complementary database in the search strategy, identified 33 studies and evaluated the methodological quality using the Vickers Scale⁴⁰ (Appendix C). They divided the studies into nausea and vomiting post-operatively, following cancer chemotherapy, and morning sickness. A diversity of treatments were assessed in the primary studies such as acupuncture, electroacupuncture, needle acupuncture, TENS, and acupoint injections. Using acupuncture while under anaesthesia was found to be ineffective at controlling emesis, in four studies. All but two of the remaining 29 studies reported a positive effect for acupuncture in P6 anti-emesis. The author concluded that P6 stimulation seems to be effective except when it was administered under anaesthesia.

Back and neck pain

Five systematic reviews, including a Cochrane Review, examined the efficacy of acupuncture for the treatment of neck or back pain. White and Ernst³³ reviewed the methodological quality of 14 RCTs on the treatment of acupuncture in neck pain using a modified Jadad Scale. The initial diagnosis varied, including ankylosing spondylitis, myofascial pain, osteoarthritis, and pain of undefined etiology. The method of acupuncture treatment varied, although most studies used formula acupuncture. The control groups varied, including sham needling, TENS or laser, physiotherapy, waiting lists, and medication. These reviewers were of the opinion that there was no evidence from sound clinical trials to support the use of acupuncture for neck pain.

The Smith et al. review³² examined the use of acupuncture on traditional and non-traditional points for chronic neck and back pain in 13 RCTs. Eleven RCTs evaluated the effectiveness of acupuncture in chronic neck or back pain and two studies assessed acupuncture for acute low back pain. They used the Jadad Scale⁴⁰ to assess methodological quality and also tested their own tool, the Oxford Pain Validity Scale (OPVS) in the review (see Appendix C). There was no assessment as to appropriateness of acupuncture site selection. Nine out of 11 studies used multiple treatments for chronic neck and back pain. Acupuncture, electro acupuncture or laser acupuncture

was compared to sham, needling, laser, or TENS, waiting lists, or standard clinical therapy. Most of the studies on chronic neck and back pain found either no difference between acupuncture and control treatments, or found an initial positive effect for acupuncture, but often after 24 hours there was no significant difference between the treatments. The two studies examining acute low back pain after a single treatment were evaluated to have no benefit over sham or acupuncture with anaesthetic spray. The conclusion of the reviewers was that there was no evidence to support the treatment of back or neck pain by acupuncture.

Using methodological criteria adapted from Koes (see Appendix C), Strauss²⁶ reviewed results from four controlled clinical trials for chronic low back pain (LBP). There was no evaluation of the appropriateness of the acupuncture treatment, although the discussion did address many of the problems associated with the assessment of acupuncture including the skill of the acupuncture provider. Three of the studies reported positive results for acupuncture, however these were of poor methodological quality. The heterogeneity of patients and treatment methods, and practitioner qualifications, made drawing any conclusion regarding the effectiveness of acupuncture in chronic LBP difficult. Though the author believed that acupuncture was a safe and popular treatment for LBP, he recommended that rigorous research was needed to determine the most appropriate treatment methods for specific conditions of LBP.

Ernst and White³⁶ included 12 RCTs (9 into the meta-analysis) on back pain. Methodologically this review was rigorous, with good data integration and assessment of treatment adequacy. Acupuncture was shown to be superior to waiting list and physiotherapy but was not found to be superior to placebo except in one study on severe pain. Odds ratios for unblinded studies suggested a strong placebo effect. They recommended that further studies explore the specific and non-specific effects of acupuncture, as well as the adverse effects and cost-effectiveness of the various treatments for back pain, to assist in determining the usefulness of these therapies.

The Cochrane Review by van Tulder⁸ examined 11 RCTs on the effect of acupuncture in chronic and acute lower back pain. This review followed the Cochrane Back Review Group's rules for assessing methodological quality (see Appendix C). No assessment as to appropriateness of treatment was made. There was conflicting evidence from low quality trials comparing acupuncture to no treatment, moderate evidence that acupuncture was not more effective than TENS or trigger point injections, and limited evidence that acupuncture was not more effective than sham for the treatment of chronic LBP. Overall this review reports that the effectiveness of acupuncture in the treatment of LBP was unclear and, since there are effective alternatives, the authors do not recommend acupuncture as a regular treatment for LBP.

Chronic pain

Two reviews focused on the effectiveness of acupuncture for the treatment of chronic pain. The appropriateness of treatment was not evaluated in either review.

The review by Ezzo et al.³⁴ used the Jadad Scale (see Appendix C) to evaluate 51 RCTs in which patients with pain longer than 3 months were treated with needle acupuncture. The review assessed the number of treatments, number of points needled, eliciting of 'de qi', and type of acupuncture (whether formula or individualized). Only 'number of treatments' seemed to be correlated with a positive outcome. The authors found that the control group participants in studies using sham acupuncture (needles were inserted) as the control had a proportionally higher improvement rate compared to the control group participants in studies using inert controls such as, TENS, sugar pills, and mock acupuncture (in which needles were not inserted). This led the authors to propose, amongst other possibilities, that sham acupuncture was not physiologically inert. They stated that they found limited evidence that acupuncture was more effective than waiting lists and the evidence was inconclusive on whether acupuncture was more effective than physiologically inert controls, sham acupuncture, or standard care.

The ter Riet, Kleijnen and Knipschild's meta-analysis³⁹ also evaluated 51 studies using needle acupuncture (excluded surface electrodes or laser acupuncture), but these studies included patients with chronic pain of at least 6 months duration. They assessed methodological quality based on criteria developed by ter Riet and colleagues (see Appendix C) and found that further research needed to be conducted with more homogeneous study groups, and better methodological design. The reviewers stated that there are no published studies of high enough quality and that the efficacy of acupuncture for this condition remains inconclusive.

Fibromyalgia

One review addressed the use of acupuncture for the treatment of fibromyalgia²⁷. The reviewers used the Jadad Scale to rate the methodological quality of the studies (see Appendix C). They did not, however, identify the style (eg. classical TCM or formula acupuncture), appropriateness of treatment, or the qualifications of the acupuncture practitioner. The authors based their conclusions on one high quality RCT, which found significant improvement in both subjective and objective pain measures compared to sham acupuncture but the duration of benefit was unknown. A few patients had worsening of symptoms during the treatment with acupuncture. They state that their review may provide some practical information for practitioners on possible benefits and risks of acupuncture. Based on limited evidence, acupuncture is more effective than sham acupuncture for improving symptoms (pain relief, reducing morning stiffness, increasing pain threshold, and improving global ratings) in patients with fibromyalgia syndrome.

Obstetrics

A Cochrane Review was conducted by Smith and Crowther⁴³ to determine the effects of acupuncture for the induction of labour. The authors noted that there were limited observation studies published that suggested acupuncture appeared safe and effective.

None of the published trials, however, met the inclusion criteria and the authors suggest the need for a well-designed RCT.

Addictions

Ter Riet and colleagues³⁸ conducted a meta-analysis that included 22 studies. Quality of studies was assessed using criteria developed by the authors (see Appendix C). The outcomes assessed, however, were not clearly defined in terms of addiction treatments, as they were only stated as the cessation of smoking, use of heroin, or use of alcohol. In addition, no biochemical verification of cessation/abstinence was included.

Fifteen of the 22 studies examined the use of acupuncture (excluded surface electrodes or laser acupuncture) in smoking cessation and reported acupuncture as not effective in comparison to placebo; however placebo treatment was not identified. Five studies reviewed the use of acupuncture in heroin addiction. The methodological quality of all five studies was rated as low and therefore it was difficult to draw any conclusions. Two studies using acupuncture for the treatment of alcohol addiction reported a positive effect for acupuncture treatment but these studies suffered from high drop-out rates. No mention was made of the appropriateness of the acupuncture points used in any of these studies, though the practitioner and treatment description were assessed as part of the quality assessment. The conclusion from this review was that the evidence does not support the use of acupuncture in the treatment of addictions.

Smoking cessation

Two reviews examined acupuncture in the treatment of smoking addiction; the Cochrane Review by White and colleagues⁴⁴ and a meta analyses by White et al.³⁵. The Cochrane Review included 18 RCTs in which smoking cessation was the outcome. Acupuncture was compared to sham acupuncture or an alternative form of cessation intervention or to no intervention. There was no assessment of appropriateness of acupuncture sites chosen, but the treatment regimen was described in the primary studies. Only four studies reported any form of biochemical validation of smoking cessation. Three studies indicated strong positive results for acupuncture in the treatment of smoking addiction. In two of these studies prolonged auricular acupuncture was applied. The authors proposed that perhaps more rigorous study into the effects of intensive and continuous treatment was warranted. As well, they suggested the importance of studying acupuncture effects during acute nicotine withdrawal. The review concludes that acupuncture was not superior to sham acupuncture. Compared with other anti-smoking interventions there was no difference but early results indicated it was superior to no intervention.

The meta analysis³⁵ of 14 RCTs (12 RCTs sham-controlled) was thorough and methods, as well as limitations, were clearly stated. The authors came to the same conclusions as the Cochrane Review that there was no evidence that acupuncture was more or less effective than sham acupuncture or other smoking cessation interventions.

Weight loss

One systematic review on the effectiveness of acupuncture and acupressure in weight loss and hunger suppression was identified³⁷. Four sham-controlled clinical trials were assessed by an “accepted instrument” used by Kleijnen, Knipschild, ter Riet (see Appendix C). One study used an acupressure device, while all other studies used varying auricular points. The conclusion of the reviewers was that further, well-designed research needs to be conducted to provide sufficient evidence regarding the effectiveness of acupuncture in appetite or weight reduction, but that there currently was no convincing evidence to support the effectiveness of acupuncture for weight loss or hunger suppression.

Summary

For the various conditions listed in Table 1, the respective reviews found that the evidence supports acupuncture as an effective treatment for dental pain, and nausea/vomiting. Though the evidence for the other conditions such as idiopathic headaches, back pain, chronic pain, and fibromyalgia was often inconclusive due to methodological weaknesses, and/or conflicting results reported by the primary studies included in the reviews, the results look promising. These reviews, the majority with a good quality rating, found acupuncture to be as effective in the short term as the conventional interventions or no treatment for these conditions. Many of the authors noted that better quality studies provided negative results while poorer quality studies tended to report positive results. Furthermore, they agreed that there appeared to be insufficient evidence and that better quality research was needed.

Table 1: Conclusions and quality rating of the systematic reviews

Condition	Review	Conclusions	Quality Rating
Dental and TMD	Ernst E, Pittler MH ²⁴ 1998	Acupuncture can be effective in alleviating dental pain	Satisfactory
	Rostad P ²² 1998	Acupuncture was more effective than sham and had a similar effect as conventional treatment	Satisfactory
Headache	Linde K, et al. ⁴¹ 2001	Evidence supported the value of acupuncture for the treatment of idiopathic headaches but the quality and amount of evidence is not convincing	Cochrane Review
Tinnitus	Park J, et al. ²³ 2000	Evidence of efficacy does not support acupuncture for the treatment of chronic tinnitus	Satisfactory
Asthma	Kleijnen J, et al. ²⁸ 1991	Efficacy not supported by the results of well performed clinical studies	Satisfactory
	Linde K, et al. ²⁹ 1996	Insufficient evidence to draw reliable conclusions	Good
	Linde K, et al. ⁴² 2000	Not enough evidence to make recommendations about the value of acupuncture	Cochrane Review
Stroke	Park J, et al. ²⁵ 2001	Evidence does not support acupuncture in stroke rehabilitation	Satisfactory
Nausea and Emesis	Lee A, Done ML ³⁰ 1999	Evidence indicates significant reduction in adults versus no treatment; comparable results versus antiemetic drugs	Good
	Vickers AJ ³¹ 1996	Acupuncture seems to be effective except when it is administered under anesthesia	Good
Back and Neck Pain	White AR, Ernst E ³³ 1999	Evidence from clinical trials does not support the treatment of neck pain	Good
	Ernst E, White AR ³⁶ 1998	Combined results indicated that acupuncture for back pain was superior to control interventions but not to sham	Good
	Smith LA, et al. ³² 2000	Evidence from valid trials indicates no analgesic efficacy for neck and back pain	Good
	Strauss AJ ²⁶ 1999	Efficacy for chronic low back pain has not been demonstrated by good clinical studies	Satisfactory
	Van Tulder MW, et al. ⁸ 2001	Evidence indicates that acupuncture is not proven effective for the treatment of low back pain	Cochrane Review

Table 1: Conclusions and quality rating of the systematic reviews (cont'd)

Condition	Review	Conclusions	Quality Rating
Chronic Pain	Ezzo J, et al. ³⁴ 2000	Limited evidence indicates that acupuncture is more effective than no treatment; inconclusive that it is more effective than sham, standard care or inert controls	Good
	ter Riet G, et al. ³⁹ 1990	Efficacy of acupuncture in chronic pain (at least 6 months) remains doubtful	Poor
Fibromyalgia	Berman BM, et al. ²⁷ 1999	Based on one good quality trial the evidence indicated significant symptom improvement compared to sham but duration of benefit was unknown	Satisfactory
Obstetrics	Smith CA, Crowther CA ⁴³ 2001	Observational studies provided promising findings but no randomized controlled studies were located	Cochrane Review
Addictions	ter Riet G, et al. ³⁸ 1990	Efficacy for smoking, heroin and alcohol addictions are not supported by evidence from good clinical studies	Poor
	White AR, et al. ⁴⁴ 2000	Evidence indicates that acupuncture does not appear to be effective for smoking cessation	Cochrane Review
	White AR, et al. ³⁵ 1999	Evidence indicates that acupuncture appears to be better in treating smoking addictions compared to those on waiting lists	Good
Weight Reduction	Ernst E ³⁷ 1997	Based on two rigorous studies there was no effect on body weight	Poor

OTHER REVIEWS

Systematic reviews are a synthesis and critical appraisal of primary studies and therefore play an important role in evidence-based decision making. Many of the primary studies included in a systematic review may not be easily accessible to a number of practitioners or busy practitioners may not have time to read all the published research, hence the value of systematic reviews. A main limitation of this systematic review of systematic reviews is that it did not take into account the evidence from new research that may add to or change the conclusions. For example, since the publication of the systematic review by Park and colleagues²⁵ on the effectiveness of acupuncture for stroke, a sham controlled study considered of good quality, indicated negative results. The addition of this study to the systematic review would strengthen the evidence to recommend against the use of acupuncture for this indication.

In 1997 the National Institute of Health held a 2 and 1/2 day conference on acupuncture specifically to evaluate the scientific data on the conditions, risks, and benefits. They stated that there seemed to be potential usefulness based on the studies but, due to flaws in design, sample size, and other factors, the results of the research were often equivocal. The role of acupuncture in nausea and vomiting resulting from chemotherapy as well as post-operative surgical and dental pain appeared to have some of the best evidence. They also acknowledged that there are many other conditions for which acupuncture may be useful as an alternative or adjunct treatment. Their concluding comments focused on the issues of training and licensure, summarizing that there was sufficient evidence to support further research and integration into conventional medicine⁴⁵. Based on these results Medicare does not cover acupuncture services. The coverage and analysis group, however, are open to receiving further evidence on the efficacy of acupuncture (informed placement of needles with or without twirling, but not with electrical stimulation or moxibustion) for post-operative chemotherapy pain and nausea in adults and post-operative dental pain for dental conditions covered by Medicare⁴⁶.

Ernst and White⁴ reviewed seven systematic reviews on the effectiveness of acupuncture for dental pain, low back pain, neck pain, osteoarthritis, stroke, smoking cessation and weight loss. They concluded that there was strong evidence on the efficacy of acupuncture for dental pain, low back pain, and nausea/vomiting. In addition, they stated the need for rigorous research by experts in the field, and funding support to allow for the expansion of acupuncture research.

Linde et al.⁴⁷ published a bibliography of systematic reviews in acupuncture. The reviews they included were on the following topics: chronic pain, headaches, dental/TMD pain, rheumatic diseases, addiction, nausea, asthma, tinnitus, weight/appetite reduction, and stroke rehabilitation. They only found convincing evidence in support of acupuncture for postoperative nausea and against acupuncture for smoking cessation. They also concluded that there were key issues around

methodological problems, lack of research infrastructure and funding for research and pointed to the complexities of acupuncture as a group of treatments for many and various medical conditions.

A final review by Vickers ⁴⁸ published in the fall of 2001 looked at effectiveness in the treatment of acute pain, chronic pain, addiction, asthma, nausea/vomiting, obesity, stroke rehabilitation, tinnitus, and various other conditions. They found acupuncture to be effective for postoperative and chemotherapy nausea/vomiting, and postoperative dental pain. They also found that the evidence for acupuncture in obesity, smoking cessation and tinnitus suggested it is 'unlikely to be of benefit'. For the other conditions, the evidence was insufficient to support any conclusions.

Comparison of these reviews with this report finds consistent support for the effectiveness of acupuncture in the treatment of postoperative nausea/vomiting, and dental pain.

ISSUES IN ACUPUNCTURE TREATMENT AND RESEARCH

Many issues have arisen with regards to developing a study model for acupuncture research. Three key areas will be discussed:

- selection of control groups;
- complexities of acupuncture; and
- study design and assessment of methodological quality.

Selection of control groups

The use of a control group is a key part of clinical trials. It is the comparator group for the experimental group receiving the treatment being investigated. The selection of 'credible' controls ^{4, 26, 49, 50} poses a challenge for acupuncture research as controls can range from placebo or 'sham' controls, to standard care, to no treatment at all. The use of standard care or no treatment versus placebo or sham, and the effects of some 'sham' techniques on outcomes, are issues of debate in the literature ^{51, 52}.

Vickers and de Craen reviewed methodological literature and provided a summary of arguments for and against the use of placebo controls in acupuncture ⁵². Placebo use enables blinding and potentially decreases drop-out rates of participants in 'known control groups'. Non-placebo control groups can have a higher drop-out rate, because participants know they are not receiving treatment. Vincent and Lewith suggest routine assessment of control group members' perceptions of their treatments through a 'credibility scale' ⁵³. The aim is to reflect patient perceptions of efficacy of their treatment, and therefore the credibility of the placebo control.

Streitberger and Kleinhenz have developed a 'placebo needle', which mimics the visual and tactile sensations of acupuncture with a needle that does not break the skin, but disappears into the handle ⁵⁴. Irnich et al. used 'sham' laser acupuncture with visual

and acoustic signals similar to those found during active laser acupuncture⁵⁵. These placebo or sham controls increase the patient's perception of actually receiving acupuncture treatment, and also enables double-blinding.

Placebo or 'sham' were defined in the studies included in the systematic reviews as using non-traditional acupuncture points, superficial puncturing of the skin without stimulation, introduction of a sensation without puncturing (eg. acupressure), or, in the case of electroacupuncture, the use of electro stimulators without connecting the cables⁹. 'Sham' acupuncture, the most commonly used control in acupuncture studies, is where needling is done at theoretically irrelevant sites^{53,56}. It was initially believed that acupuncture at these sites would have no effect, but many people now believe that inserting a needle anywhere in the body or applying pressure to any site evokes a response^{52,53,57}. This evocation of response can also be found with other placebo controls mentioned. Others believe that there is a strict process to ensuring that 'sham' is truly placebo, based on where the needling is done in relation to the treatment acupuncture⁵⁶.

The specific and nonspecific effects of sham techniques are unclear. For example, if the sham control group also shows benefits, the acupuncture treatment may be deemed ineffective in comparison to the 'control' group; however, this may be misleading if the 'sham' treatment was actually evoking a physiological response similar to the acupuncture treatment group. Though this does not clarify the issue around placebo controls, it does illustrate the complexity, and the impact of individual treatment styles. Though the effects, both specific and non-specific, of acupuncture at various sites need to be determined, the value of sham acupuncture as a control is clear: the patients can then be blinded to treatment, 'improving' the quality of the research study⁵⁸. The choice of control group in acupuncture research, like in conventional medicine research, needs to be guided by the research question, and the objectives of the research⁵².

Complexities of acupuncture

Acupuncture is a complex 'umbrella' of treatment approaches. Acupuncture includes such a diverse constellation of philosophies and treatment styles. This means the most accurate determination of effectiveness of acupuncture should include the evaluation of each single, well-defined approach, versus evaluating the 'umbrella' of treatments as a single approach⁵⁸. However, the many types and methods of acupuncture are often combined and compared in the systematic reviews. For example, manual stimulation and electrostimulation have seldom been compared to each other as to their effectiveness, but are considered the same in many systematic reviews.

As well, many microsystems are used in treating varying conditions. Ear acupuncture is perhaps the most widely used, although other systems such as scalp, hand, foot, nose, and abdominal acupuncture are also considered specialties. Formula and TCM acupuncture are two different styles, which are also often grouped together in reviews. TCM focuses on a balanced system. It uses point selection based on symptoms, pulse, and tongue diagnoses, and the choice of points used may vary from day to day as the

balance shifts. The “formula” or standardized approach in which the same prescription of points are used for each patient repeatedly is better suited for research, but perhaps not reflective of actual experience ^{5,7}.

The individualization of diagnosis and treatment may be more similar to psychotherapy or physiotherapy where the skill of the therapist and the bond with the patient are as important in producing an effect as the treatment strategies ^{7, 49}. Therapy is adjusted according to the subtle shifts as they occur rather than continuing with a standard pattern. There have not been studies to elucidate the effectiveness of any one of these acupuncture approaches over the other or whether they are equal in their effect, yet they are compared against placebo or sham in studies.

There is also variability in the technique of needle insertion and manipulation that may influence the efficacy but are often not reported in studies. Electrical or manual stimulation may alter the outcome. Diameter, length, depth of insertion, duration of retention, the number of needles per treatment, temperature of the needles, the number of treatments, and materials of the needles may all be factors which influence the outcome ^{7, 49}.

Linde et al. ²⁹ included four expert opinions in acupuncture to evaluate the adequacy of the acupuncture treatments from a clinician’s perspective. They were given a questionnaire to evaluate the choice of acupuncture points used in the studies. Linde et al. found a low level of agreement between the four experts and posed questions of clinical relevance.

Few researchers have investigated what adequate acupuncture treatment is, due to the complexity described above, and little agreement has been reached for the various conditions treated with acupuncture. Birch broke this challenge down into the administration of adequate treatments, and the adequacy of the reporting of the treatments ⁵¹. The difficulties in determining adequate treatment can be captured by the following: Which sources/evidence does one use? Can the treatments from a study be standardized to a broader population, or is it specific to those individuals? How many treatment points and sessions are the correct number for certain conditions? Is the condition used alone or in conjunction with any other modes of treatment? ⁵¹. The issue of inadequate reporting makes assessment of the research difficult and makes the generalizability impossible. The inclusion of key information is necessary to be able to determine the adequacy of the treatment used.

Study design and assessment of quality

The issue of study design is a challenge for acupuncture research. Some of the systematic reviews, and the primary studies reviewed within, either lacked a strong research design, and/or an adequate description of the design on which a reader could base an opinion ⁵⁹. For example, Linde points to the problem of small sample size in many studies, leading to underpowering of the results ⁴⁷. In addition, some of the reviews found a positive correlation between low methodological study quality and

positive outcomes^{28, 32-34, 37, 38}. This makes the determination of efficacy very difficult, as it is hard to differentiate between true positive effects, and false positive effects due to poor study quality, leading to inconclusive results.

There is also the issue of assessing methodological quality of studies, not only for acupuncture specifically, but for complementary medicine overall. Acupuncture is based on differing philosophical models^{4, 49} than Western Medicine. Using methodological criteria validated in conventional clinical trials, to evaluate acupuncture trials may not be appropriate⁴⁹. As in the determination of adequate treatment, one needs to attempt to separate the quality of the research from the quality of the reporting⁶⁰.

Many systematic reviews examined in this report used the Jadad Scale^{40, 61} as their quality assessment tool, as it is 'the' validated tool among the assessment scales available⁶¹. This scale includes five criteria (see Appendix C), four of which look at randomization and blinding. Therefore, if a study does not describe the randomization process or blinding methodology, the quality is deemed to be poor, without considering other criteria⁵⁹. It also does not evaluate specifics important in acupuncture efficacy research, such as the appropriateness of treatment, the skill of the therapist, and the type and duration of treatment. Difficulties in blinding both practitioner and patient^{4, 49} are intrinsic to acupuncture, and some criticism of the Jadad Scale has been based on this⁵⁹. Double blinding can, however, also be of the patient and the assessor of the results, which means that acupuncture research could meet this criterion after all^{61, 62}. This latter inclusion for double blinding is not known or understood by some researchers, so studies may meet that criterion and be underscored in the quality assessment.

Any quality scale should explore the clinical relevance of the question, the internal and external validity, the appropriateness of the methodologies, and the ethical implications. There are many scales presently being used, though the key criteria to be assessed have not been agreed upon. Experts debate whether five criteria, such as the Jadad Scale, are enough to effectively determine quality of any research⁵⁹ and, on the other hand, whether longer lists of criteria may be too unwieldy. There is also some discussion whether scoring studies using set criteria is a useful tool for determining the quality of the research^{60, 61}. The criteria are often used solely to present the study data (10 trials were randomized, 12 were not) in a standard format, rather than to use it as a tool to analyze the study. These issues also extend to the systematic reviews, as the quality of reviews varied from poor to good, and the review details provided were minimal in some cases^{28, 37, 39}. Associated with this is the lack of agreement on an appropriate tool to assess the quality of studies in complementary medicine.

The continuing goal is the development of standardized and accepted criteria that are effective in evaluating the quality of studies in complementary and alternative medicine^{26, 39, 59}.

DISCUSSION

This project was undertaken to provide a critical appraisal of the scientific literature and determine the status of acupuncture as a treatment option for various conditions, to assist health care decision-makers in Alberta, both regionally and provincially regarding acupuncture services. Acupuncture has become increasingly popular, especially for conditions of a chronic or recurring nature. Though the determination of effectiveness of treatment for each condition is the primary objective of the report, much of the discussion has focused on the quality of the evidence and the issues in acupuncture treatment and research.

Just as there are methodological limitations of the primary research studies, there are methodological limitations of systematic reviews. The quality of the systematic review is impacted by the quality of the reporting of the studies included in the review. This is even more of an issue when critically appraising systematic reviews, which is further removed from the primary research.

Overall, the systematic reviews examined (10 out of 18, excluding Cochrane Reviews, had ratings of poor to satisfactory) were of low quality methodologically, and reported mixed findings with inconclusive results. Dental pain, and nausea/vomiting are the two conditions for which evidence supported the efficacy of acupuncture as a treatment.

For **dental and TMD pain**, two reviews both found that acupuncture can be effective as a treatment, though there was no discussion as to the specific type and method of acupuncture that would be the most appropriate ^{22, 24}. Rosted, finding most studies in favour of acupuncture, had concerns with the clinical relevancy of such findings, as there are other analgesics available, with simpler procedures ²².

A Cochrane Review on **headaches** found that though the procedures seemed safe, there were mixed results, and therefore the authors made no statements regarding the efficacy of acupuncture for migraine or tension headaches ⁴¹.

The one review on **tinnitus** found that there was no difference between acupuncture and sham, and that the evidence did not support the use of acupuncture ²³.

Three reviews including a Cochrane Review on **asthma** reported inconclusive results, and that claims of efficacy were not supported. One difference with the study by Kleijnen et al. ²⁸, however, is that they used only relative effectiveness as their outcomes, meaning that acupuncture would have to be more, not equally effective to the controls, to show results. Though the evidence was not strong enough to support claims of efficacy, Linde et al. ²⁹ concluded that the evidence was also not strong enough to recommend to those using it, to discontinue. Overall, however, the use of acupuncture was not supported for the treatment of asthma.

The one review on **stroke rehabilitation** found that though the evidence did not support acupuncture effectiveness, the findings were promising enough to warrant

further and better research to determine the actual effectiveness of acupuncture as a treatment option²⁵. However, two recently published blinded, placebo controlled trials showed no effect of acupuncture (personal communication, Vickers, White).

In the two reviews on **nausea and vomiting**^{30, 31}, acupuncture was found to be effective, except for children and when acupuncture was administered under anaesthesia. The positive effects were better than sham acupuncture or no treatment, and equivalent to antiemetics.

Four of the five reviews focused on **back or neck pain**, found that the effectiveness of acupuncture for these types of conditions was not supported by strong evidence^{8, 26, 32, 33}. A rigorous meta-analysis³⁶ by Ernst and White found that acupuncture was an effective treatment relative to other types of treatment, and that their relative usefulness needs to be investigated. Though Strauss²⁶ believes that acupuncture is safe and should be evaluated in more rigorous studies, the Cochrane Review Group concluded that since there were effective alternatives, that acupuncture not be recommended as a regular treatment⁸. These conflicting conclusions add to the uncertainty in the interpretation of the research to date.

The two reviews on **chronic pain**^{34, 39} found that the evidence was inconclusive overall. Ezzo et al.³⁴ also concluded that acupuncture for patients with chronic pain was more effective than the waiting list control group. Ezzo and colleagues also questioned whether sham acupuncture is inert, and what impact that may have.

The review on **fibromyalgia** discussed adverse reactions to the acupuncture treatment, and even questioned whether this was an appropriate treatment for fibromyalgia²⁷. Though their findings were based on one quality RCT with positive results, they still felt that their review provided information on the benefits and risks, and raised questions on efficacy that required further research.

Two reviews on **addictions** to alcohol or heroin; **smoking addiction**; and **weight/appetite reduction**^{38, 37} indicated that the evidence was of poor quality and found little support for the effectiveness of acupuncture. Acupuncture appeared to be better than doing nothing for smoking addiction according to the results of the Cochrane Review⁴⁴ and another systematic review³⁵ with a good quality rating. The review on weight and appetite reduction provided little information on which to evaluate the quality, and the treatments being reviewed together were very heterogeneous, both of which made the evaluation extremely difficult³⁷. Currently the evidence does not support the use of acupuncture in addiction treatment or weight/appetite reduction.

CONCLUSIONS

Growing demands on the health care system for public funding of complementary health services, the changes in legislation regarding the regulation of health care professionals, in conjunction with demand from the community for funding coverage for acupuncture treatment underline the importance and timeliness of this review.

A large body of primary research exists in acupuncture, covering virtually every symptom. Due to the breadth of this topic and the challenge of reviewing the extensive body of research on acupuncture, the approach of systematically assessing the available reviews was chosen to evaluate the current evidence for the efficacy of acupuncture. In choosing this approach, it is acknowledged that there are limitations.

There are many issues in acupuncture research which are highlighted briefly in this report that need to be explored and addressed in future studies. These issues range from the assessment of study methodology to the appropriateness of an acupuncture treatment regimen. The studies included in the reviews had many limitations and variations. Variability among the studies included the technique of needle insertion and manipulation, grouping of range of acupuncture techniques, the number of needles per treatment, temperature of the needles, material composition of the needles, and selection of control comparators. All of these factors may influence the study's outcomes and the overall conclusions of the systematic reviews.

Many researchers concur that acupuncture is a relatively safe procedure however, it is not without risk. Acupuncture can lead to both minor (drowsiness, nausea and fainting) and serious (traumatic injury of body tissue) adverse events. There is an increasing amount of literature published on adverse effects of acupuncture, but there is still a concern about under reporting.

Twenty-three systematic reviews on conditions such as dental pain/TMD, headaches, tinnitus, asthma, stroke, nausea/vomiting, neck/back pain, chronic pain, fibromyalgia, labour, addictions, and obesity, were included in this appraisal of systematic reviews. This systematic review confirms the findings from other reviews which indicate consistent support for the effectiveness of acupuncture in the treatment of postoperative nausea/vomiting, and dental pain. For other indicators the robustness of the effect of acupuncture is debatable and its clinical value questionable for conditions such as idiopathic headaches, chronic pain, smoking and fibromyalgia, however some reviews indicated promising results. The results from these reviews^{27, 34-36, 41}, the majority of which had a good quality rating, found acupuncture to be as effective as the alternative interventions or no treatment in the short term.

Overall, in terms of the volume of research that has been created in studying acupuncture there is a paucity of good quality research with large sample sizes, randomization, and control for placebo effects. There was a lack of study detail provided in the reviews in regards to descriptions of the practitioners involved. Hence it was not possible to relate treatment effect or no effect to service provider.

APPENDIX A: METHODOLOGY

Two searches were performed - in January and July 2001. The following outlines the search strategy and the databases used. Effort was made to find criteria accepted by the acupuncture community as well as the scientific community for use in the critical appraisal of the quality of systematic reviews for acupuncture. No quality assessment tool specific to acupuncture was found.

Two of the co-authors (LB and CH) selected the articles based on the inclusion and exclusion criteria while two co-authors (LB and PLT) extracted data from the reviews and evaluated their methodological quality using criteria by Greenhalgh²¹ as outlined in Appendix B. The authors of the reviews were not contacted for missing information.

Search Strategy

Databases Searched	Subject headings (Bolded) and Textwords combinations
MEDLINE (Ovid) 1990-May2001 and PreMEDLINE to July 21, 2001	Acupuncture (exploded) OR acupuncture acupressure OR Electroacupuncture OR electro-acupuncture OR staple acupuncture OR staple-acupuncture OR stapleacupuncture OR staple puncture OR staple-puncture OR staplepuncture OR moxibustion
HealthSTAR (Ovid) 1991- Jan 2000 – database discontinued	
Best evidence (Ovid) Jan/Feb 2001	
CINAHL (Ovid) 1990-March 2001	
EMBASE (Ovid) 1990-April 2001	
AMED (Ovid) May 2001	
Cochrane Database of Systematic Reviews 1st Quarter 2001	Acupunctur* OR acupressure OR electroacupuncture OR electro-acupuncture OR staple acupuncture OR staple-acupuncture OR stapleacupuncture OR staple puncture OR staple-puncture OR staplepuncture OR moxibustion
CMA practice guidelines- CPG infobase June 22, 2001	acupuncture OR moxibustion
National guideline clearinghouse June 22, 2001	acupuncture OR moxibustion
DARE, HTA, EED June, 2001	Acup OR moxibustion

Databases Searched	Subject headings (Bolded) and Textwords combinations
WWW: ECRI, Bandolier, and other HTA agencies websites	acupuncture OR acupressure OR electroacupuncture OR electro-acupuncture OR staple acupuncture OR staple-acupuncture OR stapleacupuncture OR staple puncture OR staple-puncture OR staplepuncture OR moxibustion

Two other databases, ISTAHC, PsycInfo (February 2001), were searched but there were no relevant studies found. Articles were submitted by various people interested in acupuncture, and access was granted to a private collection of journals of acupuncture. This 'grey literature' was hand searched for articles that complied with the inclusion criteria. Reference lists of retrieved reviews were search for systematic reviews and meta analyses.

Publication type limits (where available): meta-analysis, systematic review

“A systematic review is an overview of primary studies that use explicit and reproducible methods” ²¹.

“A meta-analysis is a mathematical synthesis of the results of two or more primary studies that addressed the same hypothesis in the same way” ²¹.

These publication types were searched as textwords and where publication type limiting was not available by using this search string: (Subject headings OR Textwords) AND (systematic review OR meta analysis OR critical appraisal OR metaanaly\$ OR meta-analy\$ OR metanaly\$ OR critical\$ apprais\$ OR systematic\$ review\$)

Inclusion criteria: Articles were selected if they were systematic reviews, which includes but is not limited to meta-analyses. The study must have human participants, but with no restriction of age group or nationality. Reviews were required to have an intervention of acupuncture as being the primary treatment intervention in the study. Studies addressing any medical indication were included if they were published within the past 11 years (1990 – 2001). Only reviews available in English were evaluated.

Exclusion criteria: Reviews were excluded if the use of a tool to evaluate the methodological quality of the primary studies was not apparent. If reviews used the same methodological criteria and had the majority of primary studies in common, the older publications were excluded.

Included studies:

- Ernst E, Pittler MH. *The effectiveness of acupuncture in treating acute dental pain: a systematic review* ²⁴
- Rosted P. *The use of acupuncture in dentistry: a review of the scientific validity of published papers* ²²
- Park J, White AR, Ernst E. *Efficacy of acupuncture as a treatment for Tinnitus* ²³

- Kleijnen J, ter Riet G, Knipschild P. *Acupuncture and asthma: a review of controlled trials*²⁸
- Linde K, Worku F, Stor W, Wiesner-Zechmeister M, Pothmann R, Weinschutz T, et al. *Randomized clinical trials of acupuncture for asthma – a systematic review*²⁹
- Park J, Hopwood V, White AR, Ernst E. *Effectiveness of acupuncture for stroke: a systematic review*²⁵
- Lee A, Done ML. *The use of nonpharmacologic techniques to prevent postoperative nausea and vomiting: a meta-analysis*³⁰
- Vickers A. *Can acupuncture have specific effects on health? A systematic review of acupuncture antiemesis trials*³¹
- White AR, Ernst E. *A systematic review of randomized controlled trials of acupuncture for neck pain*³³
- Smith LA, Oldman AD, McQuay HJ, Moore RA. *Teasing apart quality and validity in systematic reviews: an example from acupuncture trials in chronic neck and back pain*³²
- Strauss AJ. *Acupuncture and the treatment of chronic low-back pain: a review of the literature*²⁶
- Berman BM, Ezzo J, Hadhazy V, Swyers JP. *Is acupuncture effective in the treatment of fibromyalgia?*²⁷
- Ezzo J, Berman B, Hadhazy VA, Jadad AR, Lao L, Singh BB. *Is acupuncture effective for the treatment of chronic pain? A systematic review*³⁴
- ter Riet G, Kleijnen J, Knipschild P. *Acupuncture and chronic pain: a criteria-based meta-analysis*³⁹
- White AR, Resch KL, Ernst E. *A meta-analysis of acupuncture techniques for smoking cessation*³⁵
- ter Riet G, Kleijnen J, Knipschild P. *A meta-analysis of studies into the effect of acupuncture on addiction*³⁸
- Ernst E. *Acupuncture/acupressure for weight reduction? A systematic review*³⁷
- Linde K, Melchart D, Fischer P, Berman B, White A, Vickers A, et al. *Acupuncture for idiopathic headache (Cochrane review)*⁴¹
- Linde K, Jobst K, Panton J. *Acupuncture for chronic asthma*⁴²
- van Tulder MW, Cherkin DC, Berman B, Lao L, Koes BW. *Acupuncture for low back pain*⁸
- White AR, Rampes H, Ernst E. *Acupuncture for smoking cessation*⁴⁴
- Smith CA, Crowther CA. *Acupuncture for induction of labour*⁴³

- Ernst E, White AR. *Acupuncture for back pain: a meta-analysis of randomized controlled trials*³⁶

Excluded Studies:

- Ernst E, White AR. *Acupuncture as a treatment for temporomandibular joint dysfunction: a systematic review of randomized trials*⁶³ - methodological quality was not discussed
- Ernst E. *Acupuncture as a symptomatic treatment of osteoarthritis. A systematic review*⁵⁰ - did not use a 'tool' to evaluate methodological quality
- Ernst E. *Acupuncture as an adjuvant therapy in stroke rehabilitation?*⁶⁴ - does not discuss methodological quality
- Hopwood V. *Acupuncture in stroke recovery: a literature review*⁶⁵ - methodological quality was not discussed
- Rosted P. *Survey of recent clinical studies on the treatment of skin diseases with acupuncture*⁶⁶
- Melenger A, Borg-Stein J. *Acupuncture and sports medicine. A review of published studies*⁶⁷
- South NA. *Acupuncture for the treatment of withdrawal symptoms in detoxification processes*⁶⁸ - did not review methodological quality of the studies.
- Ashenden R, Silagy CA, Lodge M, Fowler G. *A meta-analysis of the effectiveness of acupuncture in smoking cessation*⁶⁹ - included in the review by White and Rampes
- Green CJ; Kazanjian A; Rothon DA. *Acupuncture in the management of alcohol and drug dependence*⁷⁰ – report in draft stage
- Baillie AJ, Mattick RP, Hall W, Webster P. *Meta-analytic review of the efficacy of smoking cessation interventions*⁷¹ - no clear systematic review of the literature is outlined. Databases used are not identified.
- Melchart D, Linde K, Fischer P, White A, Allais G, Vickers A, Berman B. *Acupuncture for recurrent headaches: a systematic review of randomized controlled trials*⁷² – included in Cochrane reviews

Three 'reviews' were identified by the search that are currently in the form of protocols, not reviews, with the Cochrane group. They are as follows:

- He L, Zhou D, Wu B, Li N. *Acupuncture for Bell's palsy (Protocol)*¹¹
- Green S, Buchbinder R, Hall S, Barnsley L, Forbes A, Smidt N, et al. *Acupuncture for lateral elbow pain in adults (Protocol for a Cochrane Review)*⁷³
- Richardson MA, Allen C, Exxo J, Lao L, Ramirez G, Ramirez T, et al. *Acupuncture for chemotherapy-induced nausea or vomiting among cancer patients (Protocol for Cochrane Review)*⁷⁴

APPENDIX B: DATA EXTRACTION AND QUALITY ASSESSMENT OF INCLUDED STUDIES

Table 2: Data extraction and quality assessment of included studies

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Dental and TMD Pain								
<p>The effectiveness of acupuncture in treating dental pain: a systematic review</p> <p>Ernst E, Pittler MH 1998²⁴</p> <p>[Satisfactory]</p>	<p>To assess the effectiveness of acupuncture in dental pain.</p>	<p>Systematic review</p> <p>N= 16</p> <p>- 11 studies were RCTs and the other 5 were CCTs.</p> <p><i>Search:</i> Medline, Cochrane Library, EMBASE, CISCOM, their own files, reference lists of retrieved articles, and experts in the field were asked for published and unpublished work</p>	<p><i>Inclusion:</i> controlled trials, conducted in humans, any language, tested acupuncture as a treatment of dental pain</p> <p><i>Exclusion:</i> case reports, uncontrolled studies, trials comparing one form of acupuncture to another</p> <p><i>Intervention:</i> any manual or electro acupuncture</p>	<p>Used Jadad criteria to assess quality</p> <p>Both authors evaluated studies independently using pre-defined, standardized criteria, and discrepancies were decided through discussion.</p>	<p>Endpoint: pain – intensity, relief, and/or threshold</p> <p>No confidence intervals and few p-values reported.</p>	<p>No data integration occurred.</p> <p>5 trials used acupuncture in an experimental setting and 11 in a clinical setting.</p> <p>No mention about assessment of the treatment method or practitioner, other than the recommendation to address optimal acupuncture techniques.</p>	<p>Data reviewed suggest acupuncture can be effective in alleviating dental pain.</p> <p>The conclusions that can be drawn are limited, due to the low methodological quality of most studies, the heterogeneity of the methods of the study trials and of the acupuncture techniques.</p> <p>Sham acupuncture had positive effects as well.</p> <p>No conclusive evidence about the type of acupuncture that is best for dental analgesia, and therefore limits the clinical relevance.</p>	<p>Clear question, search adequate. Data extraction was detailed, and quality assessment was adequate.</p> <p>Results interpreted in a simplistic way. Comparisons of studies using various techniques and duration, and for different conditions. Difficult to glean the practical implications.</p> <p>Inadequate description and assessment of acupuncture treatment and practitioner.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
The use of acupuncture in dentistry: a review of the scientific validity of published papers Rosted P 1998 ²² [Satisfactory]	To review and discuss the scientific validity of published papers on the efficacy of acupuncture in dentistry based on predefined methodological criteria.	Systematic review N= 15 - all RCTs <i>Search:</i> Medline, Biological Abstracts, Excerpta Medica, Science Citation Index, Embase and CISCOS	<i>Inclusion:</i> randomized, blinded studies; acupuncture needles were used, electro-acupuncture if needles used; a reference group existed, either sham or standard treatment modality; Languages - English, German, Danish, Swedish, Norwegian <i>Exclusion:</i> studies using TENS or laser acupuncture, studies written in Italian, French, or Russian <i>Intervention:</i> needles were used, including electro-acupuncture	Quality was assessed by a list of 24 predefined criteria with a maximum total of 92 points, based on Linde's criteria Each criterion rated on a scale of 1-4, from excellent to bad, methodologically. The critical point to be considered as meeting criteria was 60%.	Outcomes of the studies were only listed as positive or negative in relation to pain and analgesia during dental procedures. The main endpoints of this review were for quality assessment. A % score of methodological criteria met, was the endpoint. There were no statistics provided, with p-values or confidence intervals.	Data integration was minimal, but the data from all studies were charted together for comparison and then grouped according to the score from excellent to bad, and compared that to the positive and negative outcomes of the studies. Seven studies dealt with molar extraction, which allowed for comparison among them. Three of the criteria used to assess the studies were: detailed description of treatment, detailed description of placebo, and description of therapist qualifications	Of the seven molar extraction studies, three of four had positive results. This finding must be interpreted with caution, as more rigorous studies are needed. Practical value is questionable, as the time needed for acupuncture before a procedure is much longer than other methods of anesthetic. For facial pain and TMD, four studies meeting criteria had positive results, and could be said to be a valid alternative. Eleven of 15 RCTs were in favour of acupuncture and shown it to be better than sham, or similar to conventional treatments. Studies scoring the highest methodologically were in favour of acupuncture.	Objective is clear, search strategy was adequate and inclusion/exclusion criteria clear. Outcomes described in a simplistic way of positive or negative. Makes it difficult to determine the validity of the results related to the efficacy of acupuncture. Description and assessment of method quality was more than adequate, and appropriate comparisons and conclusions drawn on this area. This is not a treatment effectiveness study, as much as a methodology effectiveness study. Data was grouped to illustrate if there were patterns between the methodological score and the study outcomes.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Headache								
Acupuncture for idiopathic headache Linde K, et al. Cochrane review 2001 ⁴¹	To assess whether there is evidence that acupuncture is (i) more effective than no treatment (ii) more effective than “sham” acupuncture (iii) as effective as other interventions.	Systematic review N = 26 <i>Search:</i> MEDLINE, Embase, Cochrane Field for Complementary Medicine, Cochrane Controlled Trials Register, personal communications and bibliographies of obtained articles	<i>Inclusion</i> - Randomized or quasi-randomized; recurrent headaches; compare acupuncture to any type of non-acupuncture control; report one clinical outcome related to headache. <i>Exclusion</i> – trials with a focus on facial pain, only comparing different forms of acupuncture, reporting physiological or laboratory parameters only, duration of study less than 4 weeks <i>Intervention</i> - any type of acupuncture	Jadad and Internal Validity Scale developed by Linde Quality of acupuncture assessed by a specialist in acupuncture and in headache.	Two authors independently reviewed and used the two scales	Evaluated acupuncture treatment categorized by types of headaches - migraine and migrainous (15) - tension-type (6) - mixed (1) and by type of control group - sham (14) - other treatment (7) - no treatment (1)	Supports the role of acupuncture in the treatment of recurrent headaches, but most trials were small and were methodologically weak.	

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Tinnitus								
Efficacy of acupuncture as a treatment for Tinnitus Park J, et al. 2000 ²³ [Satisfactory]	To summarize and critically review all randomized controlled trials on the efficacy of acupuncture as treatment for tinnitus	Systematic review N= 6 - all RCTs <i>Search:</i> Medline, Cochrane Controlled Trials Register, Embase, CISCOM (including AMED and British Library Alternative Medicine database), content pages of all Korean journals were hand-searched, a Japanese researcher was contacted for Japanese studies, and reference lists of obtained studies.	<i>Inclusion:</i> studies in any language, must be an RCT, any form of acupuncture compared to any form of control intervention, adults with chronic tinnitus <i>Exclusion:</i> duplicate publications, non-clinical trials, non-randomized CCTs <i>Interventions:</i> any form of acupuncture	Study quality was assessed using the Jadad method, and data extracted on a predefined form. Study selection and data extraction was done independently by two authors; disagreement settled by discussion between all 3 authors.	The main endpoint was subjective benefit or mean improvement: Annoyance, loudness, and awareness were the outcome measures % improvement measures Confidence intervals and p-values for outcomes not provided. The original plan was for a meta-analysis, but data were too heterogeneous.	Each study's data were fairly well described, but not well integrated. The acupuncture and control treatments were well described, but there was no mention of the practitioner.	Two studies found a positive effect and four studies that were sham controlled found no difference between the two interventions, suggesting non-specific effects of acupuncture. Methodological quality was poor, with only three studies reaching the minimum quality standard. Authors questioned whether crossover designed trials were appropriate, as acupuncture may have lasting effects. Difficult to interpret result as the groups were very heterogeneous. Effectiveness of acupuncture is not supported by evidence.	The objective was clear, and the search strategy adequate. The inclusion criteria were clear. Quality assessment was adequate according to the Jadad scoring, though the sample was quite small. Data extraction was adequate, except for the area of practitioner experience and qualifications was missing. Studies reviewed provide little information, as the outcome measures varied across studies, and there was no integration of data to provide an overall result that would be useful as a practical application.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Asthma								
Acupuncture and asthma: a review of controlled trials Kleijnen J, et al. 1991 ²⁸ [Satisfactory]	Whether there is compelling evidence from clinical research that acupuncture is efficacious in asthma.	Systematic review N = 13 RCTs <i>Search:</i> Medline, Medline CD-ROMs, Excerpta Medica, and correspondence/visits with colleagues. Journals of alternative medicine were screened using a title services bulletin, and the Journal of Traditional Chinese Medicine was screened for English studies.	<i>Inclusion:</i> needles were used, including electroacupuncture; a reference group was used <i>Exclusion:</i> surface electrodes or laser acupuncture, double publications, Russian publications unless "random allocation" or "double blind" were mentioned in English abstract <i>Interventions:</i> any acupuncture treatment using needles	Quality assessed using 18 predefined, well established methodological criteria, with a maximum score of 100. Two authors scored the studies independently.	Positive/negative outcome, regarding acupuncture producing better results than the sham treatment. No p values or confidence intervals were noted.	Data integration: Data was summarized and the outcome of the trial was listed at the bottom of the quality assessment. Both the description of the procedure and the assessment of quality of practitioner were part of the quality assessment criteria.	Continuing debate around whether sham acupuncture is an active placebo or not, and the differences between traditional and Western methods. Concerns with the use of meta-analysis and the statistical pooling of results. No studies of high quality seem to have been published. Though eight of the 13 studies had positive results, only three had quality scores above 50 and the five negative result studies had scores over 50. Claims of the efficacy of acupuncture in the treatment of asthma are not supported by well performed clinical trials.	The objective is fairly clear, but the search was not comprehensive. The inclusion/exclusion criteria were clear. Quality was assessed using standard criteria and scoring. Study outcomes were only listed as positive or negative without any statistical values attached. The lack of data presentation in the initial studies lead to poor presentation in this review.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
<p>Randomized clinical trials of acupuncture for asthma – a systematic review</p> <p>Linde K, et al. 1996²⁹</p> <p>[Good]</p>	<p>To provide a transparent overview of characteristics, methodological quality, adequacy of acupuncture and the results of the existing controlled trials.</p> <p>To provide suggestions for future research.</p>	<p>Systematic review</p> <p>N = 15 RCTs</p> <p><i>Search:</i> Medline, Embase, Scisearch, Medline CD-ROMs (1983-94), various databases for complementary medicine (IDAG, AMED, CISCOM), Kleijnen's review (1991), references in obtained articles, contacts with researchers in the field</p>	<p><i>Inclusion:</i> randomized or possibly randomized (as defined by Cochrane); human patients with asthma/asthma-like symptoms, needles inserted into acupuncture points or other points, or that acupuncture points are stimulated by other means (pressure, laser); there was a therapeutic effect; and all languages that at least one reviewer can read (English, French, German, Russian, Italian, Spanish, Dutch)</p> <p><i>Exclusion:</i> non-randomized studies</p> <p><i>Intervention:</i> needles inserted into acupuncture points or other points, or that acupuncture points are stimulated by other means (pressure, laser)</p>	<p>Quality was assessed using two scales: Jadad and one developed by Linde. The studies were assessed by two independent reviewers.</p> <p>Agreement was then quantified by performing an intraclass coefficient. The results of both scales were turned into %s scales and then other coefficients were done.</p>	<p>The main outcomes were FEV (forced expiratory volume) or PEFR (peak expiratory flow rate) changes. The results were reported in quantitative means with p-values and confidence intervals.</p> <p>Studies were then assessed as positive or negative, and these results compared with the results in the original studies.</p>	<p>Data was integrated comprehensively across the trials on key variables and results.</p> <p>There was an assessment tool piloted for acupuncture quality used in the studies, by four physicians blinded to the studies.</p>	<p>From a clinical standpoint comparability of the trials is very limited and interpretation and clinical application is very difficult.</p> <p>Difficult to interpret the low rater-agreement findings of the piloted tool assessing acupuncture quality. May be due to a lack of agreement of what good quality acupuncture is, a poorly designed tool, or an inability to interpret for clinical applications, the experimental research.</p> <p>Assume that the differences in the conclusions depends mostly on the beliefs and attitudes of the reviewers.</p> <p>Due to the heterogeneity of the trials and insufficient data, the highly contradictory results are difficult to interpret.</p> <p>Can neither recommend to acupuncturists to cease treating asthma patients nor recommend to start its use.</p>	<p>The objective is clear. The search strategy and inclusion criteria are comprehensive.</p> <p>Quality assessment was completed in a very comprehensive manner using two scales separately and integrated.</p> <p>Quantitative measures of the studies' results were included for readers to see and all studies were compared on key variables.</p> <p>Their conclusions were detailed and supported by the review of the trials in their study.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Acupuncture for chronic asthma Linde K, et al. Cochrane Review 2000 ⁴²	"...to assess the effects of acupuncture for the treatment of asthma or asthma-like symptoms."	Systematic review N = 7 RCTs <i>Search:</i> Cochrane Airways Group trials register, the Cochrane Complementary Medicine Field trials register and reference lists of articles Authors of the studies were contacted for missing information.	<i>Inclusion</i> – RCTs and possible RCTs using acupuncture with a minimum of 1 week observation period, patients with asthma or asthma-like symptoms, all interventions adjunctive to conventional asthma treatment in which needles were inserted or acupuncture points were stimulated in another way <i>Exclusion:</i> <i>Intervention</i> - Any form of stimulation of acupuncture points	Quality was assessed using the Jadad Scale	At least two researchers independently reviewed articles. A reviewer experienced in acupuncture assessed the adequacy of "sham" acupuncture.	Subjective and objective outcome measures, quality of life, medication used, global assessment were used. Only one study used tailored acupuncture rather than repetitive points. Three studies compared lung function and found insignificant changes. All studies with small sample size	Did not find acupuncture superior to sham. Further research is needed. Points of some of the sham treatments would be considered for treatment of asthma by TCM standards.	

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Stroke Rehabilitation								
Effectiveness of acupuncture for stroke: a systematic review Park J, et al. 2001 ²⁵ [Satisfactory]	To summarize and critically review all randomized controlled trials of the effectiveness of acupuncture as a treatment for stroke.	Systematic review N= 9 RCTs <i>Search:</i> Medline, Cochrane Controlled Trials Register, Embase, CISCOM (including AMED), other complementary publications, personal files of reviewers, Chinese database accessed through the China Academy of Traditional Chinese Medicine, Japanese studies found in the library of Toyama Medical Centre, and two leading Korean acupuncture journals were searched. Reference lists of all obtained studies were also searched.	<i>Inclusion criteria:</i> prospective RCTs, any form of needle acupuncture compared to any non-acupuncture control treatment <i>Exclusion:</i> use of historical controls, disorders other than stroke, not a controlled trial, reporting a case series Decisions on inclusion and exclusion were made by two authors and disagreements resolved between all four authors <i>Interventions:</i> any form of acupuncture using needles	Data extracted using predefined criteria, and quality was assessed using the Jadad scale with a maximum score of 5. Data extraction by two authors independently, except for two studies written in Chinese, which were assessed and data extracted by one author.	Variety of outcome measures across studies: Scandinavian Stroke Scale, Chinese Stroke Scale, Barthel Activities of Daily Living index, Nottingham Health Profile, motor function, balance, number of days in hospital. P-values were indicated for the study outcomes. Western scales of improvement vs. eastern scales led to heterogeneity of outcome measures.	Data was difficult to integrate due to the variety of outcome measures. The treatment was described, but there was no assessment of its appropriateness or the practitioner.	Lack of homogeneity of interventions and outcome measures makes a systematic review very difficult. There was a trend of improvement when using Chinese scales, and no significant improvement when using a Western scale. The findings are sufficiently promising to warrant further, high quality studies. Overall evidence does not support the effectiveness of acupuncture for stroke rehabilitation	The objective of the study was clear. Search strategy was sufficient and inclusion criteria were clear. Quality assessment was done using a validated tool, and data extraction was comprehensive and methodical. There was no data integration, so the overall findings, though robust, were based on summary not integration. The authors state that the poor methodological quality impacts on the certainty of the interpretations of the results. This indicates the need for further study.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Nausea and Emesis								
<p>The use of nonpharmacologic techniques to prevent postoperative nausea and vomiting: a meta-analysis.</p> <p>Lee A, Done ML 1999³⁰</p> <p>[Good]</p>	<p>To quantify the efficacy of non-pharmacologic techniques compared with antiemetics in preventing PONV</p> <p>To quantify the efficacy of nonpharmacologic techniques compared with placebo in preventing PONV</p>	<p>Meta-analysis N= 19 RCTs</p> <p><i>Search:</i> Medline, Embase, reference lists of obtained studies, review articles, and Cochrane register of controlled trials. The retrieved studies were then compared with National Library of Medicine database</p> <p>Intervention: any acupuncture technique stimulating P6.</p>	<p><i>Inclusion:</i> any language, published, RCTs, evaluate nonpharmacologic techniques with control, either placebo (sham or no treatment) or antiemetic drugs</p> <p><i>Excluded:</i> cost-effectiveness studies, use of nonpharmacologic techniques in the treatment of established PONV, inadequate randomization</p>	<p>Jadad 5 point scale was used to assess quality</p> <p>Data abstracted independently by 2 authors using a standardized form. An intraclass correlation coefficient was calculated - reliability .79 between authors.</p> <p>The raters agreed on consensus scores and study inclusion for meta-analysis, and discussed discrepancies.</p>	<p>Outcome measures were early or late nausea and/or vomiting - PONV: early (0-6 hours) and late (0-48 hours)</p> <p>Relative Risks and confidence intervals were calculated for early nausea, early vomiting and late vomiting, by study, overall, trial size, and study quality</p>	<p>Data integration was done through a meta-analysis of most of the studies' data, using relative risks.</p> <p>There was no mention of any description or evaluation of the practitioner.</p> <p>All techniques stimulated the P6 acupuncture point.</p>	<p>Well-designed pediatric studies failed to show a significant benefit using nonpharmacologic techniques.</p> <p>There was a significant reduction in early onset PONV in adults versus placebo or drugs, and in late onset PONV versus drugs. Limitation in combining different nonpharmacologic techniques, and the variation in the length of treatment from 5 minutes to 7 days.</p> <p>Late outcomes results were based on studies with small samples, so interpretation must be done with caution.</p> <p>Insufficient data to determine the role of acupressure in late PONV.</p> <p>Findings are useful to those who have adverse reactions to antiemetic drugs or wish to reduce their drug intake.</p>	<p>The objectives and inclusion criteria were clear. The search strategy did not explore any complementary databases.</p> <p>The quality assessment method was strong, supported by reliability coefficient.</p> <p>Clear outcome measures and strong quantitative analysis.</p> <p>Data was integrated well, but there was no description or assessment of the practitioner.</p> <p>Findings are robust and should be generalizable to the larger population due to the strength of methods and findings.</p> <p>The authors recognized and stated limitations and the potential impact on the conclusions.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Can acupuncture have specific effects on health? A systematic review of acupuncture antiemesis trials Vickers AJ 1996 ³¹ [Good]	To examine whether Pe6 acupuncture point stimulation has specific effects in the control of nausea and vomiting associated with surgery, cancer chemotherapy, and morning sickness.	Systematic review N = 33 CCTs, 28 of these RCTs <i>Search:</i> CISCOP, Medline, Embase, citation tracking, and leading authorities were contacted to see if the list of references was comprehensive	<i>Inclusion:</i> stimulation of Pe6 by needling, manual pressure or electricity; condition of nausea/vomiting resulting from surgery, cancer chemotherapy, or pregnancy; clinical outcome of patients receiving Pe6 stimulation compared with patients receiving no intervention, placebo, or non-acupuncture treatment <i>Exclusion:</i> duplicate studies, and components of pooled studies which were included <i>Intervention:</i> acupressure, needling (including electro-acupuncture), TENS, acupoint injection	Study quality was assessed using a checklist containing common criteria, with each being scored as good, fair, or poor, with no weighting differences between criteria, and no overall scoring.	Outcome measures were various measures related to presence and degree of nausea/vomiting, or measures of the differences between groups, including p-values. These were then presented as positive or negative in an overall table.	Minimal integration of the data, except for the sub-analysis which included only randomized placebo controlled trials in which Pe6 acupuncture was not administered under anaesthetic. There was no mention of assessment of the acupuncture treatment or qualifications of acupuncturist, though the acupuncture intervention was adequately described.	Pe6 stimulation is an effective antiemetic technique, though not under anaesthetic. Those studies using electrical stimulation found little difference between groups, which may be due to an inherent effect of the electrical stimulation itself, in treatment and control groups. The author left the conclusions up to the readers. 27 of 29 studies that did not use anaesthesia showed acupuncture as statistically superior.	Objective was clear, as were the inclusion criteria. Search was inadequate, as there was little opportunity to find grey literature. Assessment of study quality was adequate, but the scoring was quite subjective, and there was not standard weighting of each criteria. Outcome measures were reported with statistical data, though there was little integration of the data, and no mention of the practitioner qualifications or experience. Summary of the quality and the results, minimal data integration of the results. Based on the number of positive versus negative findings, the author's interpretation seems feasible; however, with caution.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Back and Neck Pain								
<p>A systematic review of randomized controlled trials of acupuncture for neck pain</p> <p>White AR, Ernst E 1999³³</p> <p>[Good]</p>	<p>To establish whether there is evidence for or against the efficacy of acupuncture in the treatment of neck pain.</p>	<p>Systematic review</p> <p>N = 14 RCTs</p> <p><i>Search:</i> Medline, Embase, Cochrane Library, CISCOP, their own files, all reviews were included, and reference lists scanned for further articles</p>	<p><i>Inclusion:</i> RCTs, control group used, needle acupuncture, electroacupuncture and laser acupuncture all included, no language restrictions</p> <p><i>Exclusion:</i> non RCTs, studies using two different forms of acupuncture, listing no statistical data, or if subjects had headaches, or pain in multiple sites</p> <p><i>Intervention:</i> all types of acupuncture – needle and laser acupuncture used</p>	<p>Quality was assessed using the Jadad Scale with a maximum score of 5.</p> <p>Data was extracted by both authors independently on a prepared form.</p>	<p>The outcome measure was pain in all studies and Range of Motion (ROM) in a couple of studies.</p> <p>Results were recorded as one treatment being more effective than the other, using a p-value to show validity.</p>	<p>Data integration occurred in the results and discussion text, though the table provided a summary only.</p> <p>The adequacy of the acupuncture treatment was not assessed, but the authors felt that it appeared to be satisfactory in most cases.</p>	<p>Studies were balanced between positive and negative. Pattern between a better quality study and negative outcomes.</p> <p>Adequacy of acupuncture used in clinical trials needs to be addressed more effectively in future studies.</p> <p>Some studies suggest that precise techniques may produce similar results to random needling.</p> <p>.There is sufficient equipoise in the results of the review to justify further studies, assuming acupuncture is shown to be safe.</p> <p>The efficacy of acupuncture in the treatment of neck pain is not supported by current evidence.</p>	<p>Search adequate, the objectives and the inclusion and exclusion criteria were clear.</p> <p>Quality was assessed using a standard tool.</p> <p>The endpoints were well described with p-values included, but little data integration occurred.</p> <p>Though the adequacy of the acupuncturist or treatment was not assessed, the review's authors recognized this limitation and the need in future studies for this variable to be included.</p> <p>Their conclusions and recommendations make sense and are supported by the findings in their study.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Acupuncture for back pain: a meta-analysis of randomized controlled trials. Ernst and White 1998 ³⁶ [Good]	To perform a meta-analysis of trials of acupuncture for the treatment of back pain.	Meta-analysis N = 12 RCTs <i>Search:</i> Medline, Cochrane Controlled Trials Register, CISCOM, gray literature, authors' files of published literature, bibliographies of retrieved articles, abstracts	<i>Inclusion:</i> any human back pain, RCTs, dry needles inserted into skin, published in English, French, German, Spanish, Italian or Polish <i>Exclusion:</i> trials where one form of acupuncture is compared with another, 2 nd publication on a trial	Jadad Scale modified by authors Data was extracted and quality assessed by both authors independently and differences were settled by discussion.	Pain, global assessment, patient and physician improvement rating Odds ratios were used to analyze data, with confidence intervals	Data was well integrated using the meta-analysis technique with studies grouped according to quality and design. Adequacy of treatment was assessed by 6 experienced acupuncturists and rated on a Visual Analog Scale.	The high odds ratio of unblinded studies may suggest an association between acupuncture and a placebo effect. Acupuncture has been shown to be superior to various control interventions, but it was not shown to be superior to placebo in sham-controlled studies. Further studies required to determine specific effects as well as non-specific effects.	Objective is clear, search strategy was adequate, and inclusion/exclusion criteria were clear. Quality assessment used a validated tool. Endpoints were stated, though there were multiple endpoint measures. Data was analyzed well, and integrated thoroughly. The assessment of treatment adequacy was rigorous, though only 9 of the 12 included studies were incorporated into the meta-analysis. The limitations of the study were clearly described, and next steps for research suggested. The findings were clear and supported.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Teasing apart quality and validity in systematic reviews: an example from acupuncture trials in chronic neck and back pain. Smith LA, et al. 2000 ³² [Good]	To assess the analgesic efficacy and the adverse effects of acupuncture compared with placebo for back and neck pain; To develop a new tool, the OPVS, to measure validity of findings from RCTs and enable ranking of trial findings according to validity within qualitative reviews	Systematic review N= 13 RCTs (11 in chronic neck/back pain and 2 in acute back pain) <i>Search:</i> Medline, Embase, Cinahl, Psychlit, PubMed, Cochrane Library, Oxford Pain Relief Database, reference lists of retrieved studies and reports Authors were not contacted for more data.	<i>Inclusion:</i> RCTs, comparison of acupuncture (with/out electric stimulation) or laser acupuncture, with an inactive control group, group size ≥10, has pain outcomes <i>Exclusion:</i> unpublished reports, abstracts, active treatment control groups, <10 patients per group, insufficient data <i>Intervention:</i> acupuncture, acupuncture with electric stimulation, or laser acupuncture	Authors created the Oxford Pain Validity Scale to measure the quality of studies and used it to assess the included studies. Quality was assessed by two authors independently.	Pain intensity, pain relief, global measures of efficacy measured as early (within 24 hours) or late (1 week to 6 months) Where appropriate used p-values and confidence intervals or non-parametric tests – Mann-Whitney U Test	Findings were categorized as acute or chronic, and then by single versus multiple acupuncture points. Data was integrated to look at the relationship between validity (OPVS score) and trial outcomes (positive/negative). The Mann-Whitney U test with CIs and p-values was used to analyze and illustrate these relationships. The acupuncture interventions were well described, but there was no mention of the experience or qualifications of the practitioner.	Though the trial conclusions lead to no relationship between study validity and trial findings, this review's authors found that there was an inverse relationship – higher validity scores and negative findings. There was insufficient data to answer many questions. OPVS may be a useful tool to score trials according to validity in qualitative reviews. One benefit of this method may be that broader inclusion criteria can be used methodologically, without decreasing the overall validity. No convincing evidence for analgesic effectiveness of acupuncture in treating back or neck pain.	Objectives and inclusions criteria were clear, and the search was fairly thorough, no search on a complementary medicine database. Data extracted was in good detail. Large discrepancy in methods of treatment which reduced the degree of analysis that could be performed. Quality/validity assessment tool was comprehensive and added a further degree of strength to their findings than just a count of positive/negative outcomes. Data was integrated in the analysis of validity and study outcomes, but was minimal regarding the actual outcomes and effectiveness of treatment. Their overall conclusions were robust, and wouldn't be significantly altered if inclusion criteria were adjusted to include or exclude certain studies.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Acupuncture and the treatment of chronic low back pain: a review of the literature Strauss AJ 1999 ²⁶ [Satisfactory]	To determine strength of the evidence Evaluate the standard of the research Propose a research design to evaluate acupuncture treatment	Systematic review (though states only a literature review) N = 4 CCTs <i>Search:</i> MEDLINE, CINAHL, MANTIS, AMED, AMI, and the Internet; reference lists	<i>Inclusion:</i> experimental treatment regimen included acupuncture, subjects suffered with chronic low back pain, clinical trial, published in English <i>Exclusion:</i> abstracts and unpublished studies <i>Intervention:</i> any method of acupuncture	Scored according to set of criteria (adapted from Koes), where each criterion had a weighting, maximum score =100 No information was provided on who extracted the data, and how many individuals were involved.	Main endpoints were pain intensity or the number of patients reporting improvement or recovery Studies were listed only as 'positive' or 'negative' in terms of effectiveness, and no specific outcome measures or statistics were provided.	There was minimal integration of data. Assessed whether the studies mentioned the qualifications of the acupuncturist, and the details of the intervention.	Three studies showed favourable results. This review shows some important methodological shortcomings in acupuncture studies evaluating clinical efficacy. Proposed future research design. Important that single-blind sham controlled RCTs are completed to show the validity of this therapy. One cannot make conclusions regarding the effectiveness of acupuncture, from these poorly designed trials.	Search strategy was not comprehensive, with minimal searching in complementary medicine databases, or grey literature. The objectives and inclusion criteria were clear. Authors used a set of criteria that assessed the necessary items to be able to determine a study's quality and a treatment's efficacy. No mention of who did the reviewing. Little data integration occurred. Description of the acupuncture treatment and the practitioner were both assessed. Very few details, outside of the table of quality assessment, on the studies. Difficult to check or duplicate the review's methods and findings.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Acupuncture for low back pain van Tulder MW, et al. Cochrane Review 2001 ⁸	To assess the effects of acupuncture for the treatment of non-specific low back pain.	Systematic review N = 11 RCTs <i>Search:</i> Cochrane Complementary Medicine Field trials register, Cochrane Controlled Trials Register, Medline, Embase, Science Citation Index and reference lists of articles	<i>Inclusion</i> - RCTs the use of needle acupuncture with non-specific low back pain Acute pain – 12 weeks or less or chronic pain – more than 12 weeks <i>Exclusion</i> – non-RCT and controlled before and after studies, etiologies of infection, metastatic disease, neoplasm, osteoporosis, rheumatoid arthritis, or fractures, Acupressure or laser treatments <i>Intervention</i> – needling with hand or electrical stimulation	Quality was assessed using the Cochrane Back Review Group criteria	Two researchers independently assessed trial quality and extracted data. Blinded with respect to authors, institution and journal. Disagreements were discussed, if no consensus a third party made the final decision.	Used one of four primary outcome measures VAS, pain intensity, a global measure (overall improvement, proportion of patients recovered, subjective improvement of symptoms), functional status (Roland Disability Scale, Oswestry Scale) and return to work.	Acupuncture is not proven effective for the treatment of back pain according to the studies identified in this review.	

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Chronic Pain								
<p>Is acupuncture effective for the treatment of chronic pain? A systematic review</p> <p>Ezzo J, et al. 2000³⁴</p> <p>[Good]</p>	<p>To summarize the evidence of the effectiveness of acupuncture for chronic pain according to the type of control group.</p> <p>To perform a sensitivity analysis to examine whether low quality acupuncture trials are associated with positive outcomes.</p> <p>To identify key feature of acupuncture associated with + results.</p> <p>To identify future research areas</p>	<p>Systematic review</p> <p>N = 51 RCTs</p> <p><i>Search:</i> Medline, Cochrane Complementary Medicine Field Trials Registry, CAMPAIN, (included in above EMBASE, Psycinfo, Acubase, AMED, Dissertation Abstracts), Conference proceedings, and abstracts were hand searched, reference lists of obtained studies.</p>	<p><i>Inclusion:</i> randomized design, had a comparison group and between group analysis was done, pain duration >3 months, used needles, English language, pain relief measurement included (letters to authors of trials for further information to determine inclusion)</p> <p><i>Exclusion:</i> multiple studies of same data</p> <p><i>Intervention:</i> any form of acupuncture</p>	<p>Used Jadad 5 point scale</p> <p>Two independent reviewers; interrater disagreements resolved through discussion.</p>	<p>Used a +/-/neutral scale for comparative effectiveness. Positive (+) meant acupuncture was significantly more effective than the reference, neutral (0) meant that acupuncture was not significantly different than the reference group, and negative (-) meant that acupuncture was significantly less effective than the reference group</p> <p>The authors mention the use of p-values</p>	<p>Data was extracted on 4 key aspects of acupuncture, to test 4 hypotheses: total number of treatments, number of acupuncture points needed per session, 'de qi' elicited, and formula vs. individualized treatments given</p> <p>Studies were also divided by control group types (4): waiting lists, physiologically inert controls, sham, standard care</p> <p>SPSS, chi-square, logistic regression, and non-parametric statistical analysis performed</p> <p>Best evidence synthesis was used to indicate the strong evidence to inconclusive evidence</p> <p>Acupuncture treatment was analyzed, but neither appropriateness nor the practitioner's experience or qualifications were mentioned.</p>	<p>Sensitivity analysis showed a significant association between lower quality studies and positive outcomes, as well as on individual quality items.</p> <p>Sham acupuncture studies were the best quality, but further research needs to determine whether it is a placebo or has non-specific effects.</p> <p>Of the four key aspects of acupuncture treatment examined, the number of treatments was the only one significantly associated with positive outcomes.</p> <p>Acupuncture is more effective than waiting lists, but authors were unable to determine relative effectiveness versus placebo, sham acupuncture, or standard care for chronic pain.</p>	<p>Objectives and inclusion criteria were clear, and search comprehensive.</p> <p>Dividing the studies by control group type makes the results more comparable to other studies.</p> <p>P-values were used for outcomes assessment to define significance, but were not presented in the review.</p> <p>Data was well integrated across studies, and the use of statistical methodologies makes the findings more reproducible.</p> <p>Authors reported the results in the context of the unknowns (eg. Possible confounders) and the limitations of the study.</p> <p>Review findings are robust, and the removal of one or two studies would not change the findings.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Acupuncture and chronic pain: a criteria-based meta-analysis ter Riet G, et al. 1990 ³⁹ [Poor]	Whether compelling evidence from clinical research exists that acupuncture treatment is efficacious in chronic pain.	Criteria-based meta-analysis N=51 <i>Search:</i> Medline, Medline CD-ROMS, Excerpta Medica, colleague's correspondence, grey literature, recent Chinese literature available in English was screened	<i>Inclusion:</i> needles used, "chronic" was mentioned in title or abstract or pain had lasted > 6 months; reference group was used; Russian articles if the words "randomized" or "blind" were mentioned in the English abstract <i>Exclusion:</i> surface electrodes; laser acupuncture; did not address chronic pain; duplicate studies on same data, studies not addressing chronic pain, if study was uninterpretable <i>Intervention:</i> acupuncture using needles	Quality was assessed using 18 pre-defined methodological criteria with a total score = 100 Two authors scored the studies independently and discussed discrepancies	Outcome was the effect of acupuncture in alleviating pain, measured as positive (+) or negative (-). A + result meant that acupuncture produced better results than the control group (if an existing treatment). No p-values or confidence intervals were noted	Data was integrated according to methodological scores and +/- outcomes. Relationship to all study outcomes, relationship to study outcomes for studies using a sham reference group, and relationship to study outcomes according to chronic pain site The quality criteria included whether the study mentioned the qualifications of acupuncturist and provided an adequate description of acupuncture	No definitive conclusions on the efficacy can be drawn due to poor methodological quality of studies. Some reviewer bias may be involved as they were not blinded to the study outcomes. More research needs to be conducted with more homogeneous study groups and stronger methodological quality overall. Results are contradictory as they were split between positive and negative for all of the chronic pain conditions in the review.	Search was not comprehensive, but their objectives and inclusion criteria were clear. Used a verified tool to assess study quality. Data was integrated well according to methodological scores. Study outcomes were only listed as positive or negative without any statistical data presented. The authors examined the relationships between study quality and 3 variables well, but the actual results of the included studies are not presented for examination.

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Fibromyalgia								
<p>Is acupuncture effective in the treatment of fibromyalgia?</p> <p>Berman BM, et al. 1999²⁷</p> <p>[Satisfactory]</p>	<p>To assess the effectiveness of acupuncture in the treatment of fibromyalgia syndrome (FMS).</p> <p>To report any adverse effects.</p> <p>To generate hypotheses for future investigation.</p>	<p>Systematic review</p> <p>N= 7 – 3 RCTs, 4 cohort studies</p> <p><i>Search:</i> Embase, MANTIS, Medline, Cochrane</p> <p>Complementary Medicine Field Trials Registry, CAMPAIN, CISCOM, NIH-OAM, reference lists from obtained articles, and grey literature was hand searched</p> <p>Databases not searched because they were included in the above searches: Acupuncture Database, Acupuncture Literature Analysis and Retrieval System, Current Awareness Topics/Alternative and Allied Medicine Database, and Dissertation Abstracts</p>	<p><i>Inclusion criteria:</i> human, all languages, patients of FMS treated with acupuncture, RCT, quasi-randomized, or cohort study design</p> <p>FMS diagnosis according to the ACR for 3 of the studies</p> <p><i>Exclusion:</i> letters, surveys, historical essays, manuscripts that did not present the results of a population of patients with FMS; complete data not yet available</p> <p><i>Intervention:</i> any form of acupuncture</p>	<p>RCTs were assessed according the Jadad scale, and cohort studies using Cochrane Collaboration guidelines for assessing non-experimental designs, though scores were not indicated</p> <p>The number of reviewers and method of settling discrepancies was not stated.</p>	<p>Outcomes were pain, pain relief measured on a variety of scores and reported in different ways.</p> <p>P-values were included for individual study results.</p>	<p>Data from studies was not integrated, just summarized.</p> <p>There is no information as to whether the review assessed the type of intervention or the qualifications of the practitioner performing the acupuncture</p>	<p>Two studies showed adverse effects to the acupuncture, which may be related to the etiology of the disease. Physicians should be aware that a small number of FMS patients may feel worse with acupuncture.</p> <p>High quality RCTs are needed.</p> <p>This review may provide practitioners some practical information on the benefits and risks of acupuncture, and should be seen as raising questions for future research, not addressing them.</p> <p>One high quality RCT showed that patients receiving real vs. sham acupuncture experienced significant improvements in subjective and objective pain measures. More evidence is needed to support this.</p>	<p>Objectives and inclusion criteria were clear, and the search strategy was comprehensive.</p> <p>Only three studies had any follow up periods, and few used any endpoint measures that weren't self-reported.</p> <p>Quality assessment uses two validated tools, but the authors don't report the quality scores, just a summary of data extraction (even though a study's "high score" is mentioned in the results.</p> <p>Evidence is based on only 1 study, and therefore would be considered sensitive.</p> <p>Their conclusion that this review can be used for some practical purposes and raising research questions, not addressing them is accurate.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Induction of Labour								
Acupuncture for induction of labour Smith CA, Crowther CA Cochrane Review 2001 ⁴³	To determine the effects of acupuncture for third trimester cervical ripening or induction of labour	Systematic review N = 0 RCTs <i>Search:</i> The Cochrane Pregnancy and Childbirth Group trials register, the Cochrane Controlled Trials Register and bibliographies of relevant papers	<i>Inclusion:</i> critical trials comparing acupuncture used for third trimester cervical ripening or labour induction with placebo, no treatment or other methods listed above it on a predefined list of labour induction methods <i>Exclusion:</i> duplication of studies	No trials met the inclusion criteria.			Need for a well designed RCT to evaluate the role of acupuncture.	

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Addictions								
<p>A meta-analysis of studies into the effect of acupuncture on addiction</p> <p>ter Riet G, et al. 1990³⁸</p> <p>[Poor]</p>	<p>To examine whether compelling evidence from clinical research exists that acupuncture is efficacious in cigarette smoking, heroin, or alcohol addiction</p>	<p>Meta-analysis</p> <p>N = 22 CCTs – 14 of these appear to be RCTs</p> <p><i>Search:</i> Medline, Medline CD-ROM, Excerpta Medica, grey literature through a titles bulletin of the National Centre for Information and Documentation on Alternative Medicine, recent Chinese literature available in English was screened</p>	<p><i>Inclusion criteria:</i> humans addicted to smoking, heroin, or alcohol; reference group was used; needles, press needles, or staples were used; Russian articles if “randomized” or “blind” were mentioned in the English abstract</p> <p><i>Excluded:</i> studies using surface electrodes or laser acupuncture, duplicate studies</p> <p><i>Intervention:</i> acupuncture involving needles</p>	<p>A list of 18 predefined criteria with a total score of 100. Points were weighted according to importance.</p> <p>Two authors scored the studies independently and then discussed and resolved differences.</p>	<p>Endpoints: cessation of smoking, using heroin, or using alcohol</p> <p>No p-values or confidence intervals listed for any studies.</p> <p>The outcomes of the studies – positive, negative, or uncertain – were determined by the reviewers by screening for statements such as “x is more efficacious than y” or “x is not significantly more effective”</p> <p>The cumulative distribution of quality scores by addiction, was presented.</p>	<p>Little integration of data; a summary table of outcomes and quality assessment scores was provided. Used criterion-based meta-analysis vs. pooling results, and displayed according to quality score.</p> <p>The qualifications of the acupuncturist and description of the treatment modality is assessed as part of the quality assessment.</p>	<p>Trend between quality of studies and result, in that higher quality studies had more negative results.</p> <p>There is no evidence that acupuncture is efficacious in the treatment of addiction to smoking.</p> <p>The utility of acupuncture in heroin addiction remains unproven.</p> <p>Future research in alcohol addiction needs to address the high drop-out rates seen in this review.</p> <p>Criteria-based meta-analysis works well when the studies are of varying quality and method.</p> <p>Acupuncture has not proven to be efficacious as a treatment for these addictions.</p>	<p>Objective was quite broad; it could be more specifically stated. Their literature search was adequate and their inclusion criteria were clear.</p> <p>No results other than +/- were included in the study.</p> <p>Findings seem to be robust in that they saw a common pattern across studies, which wouldn't have changed drastically if a study was removed.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Smoking Cessation								
Acupuncture for smoking cessation White AR, et al. Cochrane Review 2000 ⁴⁴	To determine the effectiveness of acupuncture in smoking cessation in comparison with sham, other interventions, no intervention.	Systematic review N = 18 RCTs <i>Search:</i> Cochrane Tobacco Addiction Group trials register, PsycLit, Dissertation Abstracts, Medline, Embase, Health Planning and Administration, Social SciSearch, Smoking & Health, Biological Abstracts, and DRUG. Relevant articles identified from published reviews, clinical trials and conference abstracts, as well as smoking and health bulletins and bibliographies.	<i>Inclusion</i> – Randomized trials comparing a form of acupuncture to sham-controlled, other or no treatment for smoking cessation, smokers over 18 years <i>Exclusion</i> – <i>Intervention</i> - any needle procedure in to acupuncture points (including ear, face, and body) included electroacupuncture	Quality was assessed using the Cochrane Review Group criteria. Two reviewers independently extracted data, they were not blinded, disagreements were resolved by discussion.	Patients lost in follow-up were considered to continue to smoke. Complete abstinence was considered. Follow-up first recorded after first treatment (less than 6 weeks), 6 and 12 months. If more than one control group, then comparisons of the most and least favourable were used.	Did not extract data on withdrawal symptoms. Did not identify practitioners level of skill.	Majority of studies did not report on the randomization process nor confirmed the smoking cessation biochemically. No evidence that acupuncture increases the number who successfully quit smoking compared to sham, but appeared to be better than doing nothing. Methodological weakness in the primary research	

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
<p>A meta-analysis of acupuncture techniques for smoking cessation</p> <p>White AR, et al. 1999³⁵</p> <p>[Good]</p>	<p>To determine the effectiveness of acupuncture in smoking cessation</p> <p>To compare the effectiveness of different techniques</p>	<p>Meta-analysis</p> <p>N = 14 studies</p> <p><i>Search:</i> Medline, EMBASE, British Library, CISCOM, Science Citation Index, reference lists of previous reviews of acupuncture and addiction, the results of a previous study's contacted experts in the field and a search of grey literature were included</p> <p>Further data or clarification from authors when required</p>	<p><i>Inclusion criteria:</i> randomization, treatment or control groups, English, French or German no restrictions on technique or length of follow-up.</p> <p>Only subject blind studies using a sham control were included in primary analysis</p> <p>All studies included in comparison of treatments</p>	<p>Assessed randomization, concealment of randomization, minimization of practitioner interaction, and sample size calculation</p> <p>Used Riel et al. 18 predefined criteria – score up to 100</p> <p>Found overall quality poor with major items being lack of biochemical confirmation and randomization details, influence of acupuncturist, and length of follow-up</p>	<p>Outcome measure was complete cessation of smoking at 3 time points: right after intervention, 6 months, 12 months</p> <p>Participant reports vs. biochemical confirmation, and sustained vs. point prevalence of abstinence used when possible</p> <p>Odds ratios and confidence intervals were described (success:failure ratio of treatment group/s:ratio of control group)</p> <p>Low quality scores indicate poor methodological rigour.</p>	<p>Subgroups allocated according to acupuncture technique, number of attendances, country of origin, journal status, and control procedure</p> <p>Data was integrated on the variables mentioned above</p> <p>They don't mention their assessment of the acupuncture technique, but they do state that a specialist should be the one evaluating the actual technique</p>	<p>Acupuncture did seem to be more effective than waiting list controls, illustrating a placebo effect, though short-term</p> <p>Acupuncturist should be used to measure the quality of the technique</p> <p>This review reflects that lack of clear hypotheses re: role of acupuncture in smoking cessation both mechanically or behaviorally</p> <p>Future research needs to be: higher quality regarding major methodological aspects, biochemical validation of cessation, longer follow up.</p> <p>No evidence that acupuncture is more effective than sham, or that one acupuncture technique is more effective than another</p>	<p>Though it was stated that they contacted original authors for additional study details, they then stated that lack of detail in the study re: randomization and blinding was a key deficiency across studies.</p> <p>This meta-analysis was thorough. It clearly stated its methods, limitations of method and of the findings.</p> <p>Fairly robust – removing one study's results wouldn't drastically change the results</p> <p>They state different scenarios if a study was removed, or some studies were grouped together and analyzed, results remained the same.</p>

Table 2: Data extraction and quality assessment of included studies (cont'd)

Study (Quality Rating)	Question/objective	Design type Sample size Search strategy	Inclusion/exclusion criteria interventions	Assessment Tool	Endpoint measurement	Data integration	Interpretation and conclusion	Reviewers assessment
Weight Loss								
Acupuncture/acupressure for weight reduction? A systematic review Ernst E 1997 ³⁷ [Poor]	To decide whether acupuncture/acupressure have specific effects on body weight reduction or appetite.	Systematic review N = 4 RCTs <i>Search:</i> Medline, CISCOP, reference lists of obtained studies	<i>Inclusion:</i> placebo or sham controlled studies, on body weight loss or appetite, human participants <i>Exclusion:</i> studies comparing one form of acupuncture to another <i>Intervention:</i> permanent press needles with ear acupuncture, one study also using acupressure	Quality was assessed using an accepted tool (Kleijnen et al.), with a maximum score = 100	The outcomes hunger and body weight were endpoints for two studies. No p-values or confidence intervals were reported	Little data integration; a summary table of extracted data was presented. No description of the practitioner experience or qualifications, but an adequate description of the interventions.	Trends were not possible due to heterogeneity of treatment modality, treatment period, study sample, and study design. The two lower methodological quality studies had positive results, while the 2 more rigorous studies did not. Future studies should be well-designed and rigorous. There is no convincing evidence that acupuncture/acupressure have effects in reducing body weight or appetite.	Objectives and inclusion criteria are not specific, and the search strategy was not adequate. Quality assessment was completed with a standard tool. Due to the heterogeneity of the study methods, and findings, in conjunction with the small sample of studies, the review's findings of no evidence are sound. However, the review's methods, including search strategy, statement of objectives, and clarity of inclusion criteria, are weak. These weaknesses likely played a role in the inconclusive findings.

APPENDIX C: QUALITY ASSESSMENT TOOLS

Jadad Scale for Evaluating Randomized Controlled Trials ^{23-25,27,29,30,32-34,41,42}

Add a point for a “yes” and give no points for a “no”

1. Was the study described as randomized (this includes the use of words such as random, randomly and randomization)?
2. Was the study described as double-blind?
3. Was there a description of withdrawals and dropouts?
4. Was the method to generate the sequence of randomization described and was it appropriate (table of random numbers, computer-generated etc.)
5. Was the method of double-blinding described and was it appropriate (identical placebo, active placebo, dummy, etc?)

Deduct one point if:

6. The method to generate the sequence of randomization was described and it was inappropriate (table of random numbers, computer-generated etc)?
7. The method of double-blinding described and was it appropriate (identical placebo, active, dummy, etc)?

Vickers Scale for Evaluating Randomized Controlled Trials ^{31,57,75}

1. Adequate description of the population from which the participants are drawn.
2. Sample size adequate.
3. Random allocation to the treatment arms.
4. Prognostic variables adequately assessed.
5. Full description of test intervention.
6. Where possible a credible, inactive placebo should be used. If no placebo is available, standard care may be used (but should have been compared previously to placebo).
7. The use of appropriate outcome measures for the condition and the therapy.
8. Patients blind to treatment allocation and researchers blinded when assessing outcome.
9. Withdrawal and no-respondents less than 20% of initial sample.
10. Appropriate use of inference statistics.

A ranking of very good receives 4 points, good – 3, fair – 2 , not satisfactory – 1 and poor - 0.

Very good reflects a study which has adequately met the criteria and the results may be considered valid.

Good reflects that the major criteria were met and the results have not been affected

Fair reflects the criteria have not been met fully and that the results have probably not been affected

Poor reflects that the criteria have not been met adequately and that the outcome of the study has probably been influenced by this.

List of Methodological criteria: ter Riet G, Kleijnen J, Knipschild ^{28,37-39}

Criteria	Weight
<i>Comparability of prognosis</i>	
A. Homogeneity (1)	3
B. Prestratification (2)	3
C. Randomization	12
D. Comparability of relevant baseline characteristics shown	2
E. ≥ 50 patients per group	10
F. $\leq 20\%$ loss to follow-up (3)	5
<i>Adequate intervention</i>	
G. Avoidance of DNIC (4)	2
H. Adequate description of acupuncture procedure (5)	10
I. Mentioning good quality of the acupuncturist	15
J. Existing treatment modality in reference group	3
<i>Adequate Effect Measurement</i>	
K. Patients blinded	10
L. Evaluator blinded	5
M. Follow-up after treatment ≥ 3 months (6)	5
N. Pain (7)	3
O. Use of medication	2
P. Activities of daily living	3
Q. Remark of side-effects	2
<i>Data presentation</i>	
R. Reader is given opportunity to do inferential statistics	5

Methodological criteria: Linde ^{29,41}

1. Method of allocation to groups
2. Concealment of allocation
3. Baseline comparability
4. Blinding of patients
5. Blinding of evaluators
6. Likelihood of selection bias after allocation to groups by drop-outs

Each item is scored as follows

0=criterion not met or insufficient information

1=criterion met

Maximum score is 6

An adaptation of this scale is used in ²⁹, where the 6th and 7th criteria include the handling of withdrawals, and the handling of inferential statistics.

Maximum score is 7

Methodological Criteria: Cochrane Collaboration Back Review Group ⁸

Patient selection

- a. were the eligibility criteria specified
- b. treatment allocation
 - i. was the method of randomization described and adequate
 - ii. was the treatment allocation concealed
- c. were the groups similar at baseline regarding the most important prognostic indicators

Intervention

- a. were therapeutic and control interventions operationalized
- b. was the care provider blinded
- c. was controlled for co-interventions which could explain the results
- d. was the compliance rate (in each group) unlikely to cause bias
- e. was the patient blinded

Outcome measurement

- a. was the outcome assessor blinded
- b. was at least one of the primary outcome measures applied
- c. was there a description of adverse effects
- d. was the withdrawal/drop-out rate unlikely to cause bias
- e. timing of follow-up measurement performed
 - i. was a short-term follow-up measurement performed
 - ii. was a long-term follow-up measurement performed
- f. was the timing of the outcome assessment in both groups comparable

Statistics

- a. was the sample size for each group described
- b. did the analysis include an intention-to-treat analysis
- c. were the point estimates and measures of variability presented for the primary outcome measures

Methodological criteria: Strauss adapted from Koes ²⁶

Study Population

- a. Description of inclusion and exclusion criteria (1 point)
- b. Similarity of relevant baseline characteristics: the duration of complaints, value of outcome measures, age, recurrence status, radiating complaints (1 point)
Adequate validity, accuracy, and reliability of diagnosis (1 point)
- c. Randomisation procedure adequate: randomisation procedure described (2 points).
Randomisation procedure which excludes bias (2 points)
- d. Dropouts described for each study group separately: information from which group and with reason for withdrawal (3 points)
- e. Loss to follow-up: <20% loss to follow-up (2 points), <10% loss to follow-up (2 points)
- f. Smallest group immediately after randomisation: >50 subjects in the smallest group (6 points), > 100 subjects in the smallest group (6 point).

Interventions

- g. Interventions included in protocol and described adequately: acupuncture treatment described (5 points)
- h. Pragmatic study: comparison with an existing treatment modality (5 points)
- i. Co-interventions avoided: other physical therapy modalities or medical interventions are avoided in the design of the study except analgesics (5 points)
- j. Placebo (or sham) controlled: comparison with a placebo or sham therapy (3 points).
Adequate description and use of an appropriate placebo or sham (2 points).
- k. Good qualification of acupuncturist: mentioning of qualified education and work experience of the acupuncturist (5 points).

Measurement of Effect

- l. Patients blinded: placebo controlled: Attempts for blinding (3 points), blinding evaluated and fully successful (2 points).

- m. Outcome measures relevant: use (measured and reported) of: pain, global measure of improvement, functional status (activities of daily living), spinal mobility, medicine consumption (1 point each). Validity and reliability of instruments (1 point).
- n. Blinded outcome assessments: each blinded measurement mentioned under point M. Earns 2 points. Control of observer and subject bias (1 point).
- o. Follow-up period adequate: moment of measurement during or just after treatment (2 points). Moment of measurement 3 months or longer (2 points)

Data Presentation and Analysis

- p. Intention to treat analysis: when loss to follow-up is less than 10%: all randomised patients for most important outcome measures and on the most important moments of effect measurement minus missing values, irrespective of non-compliance and co-interventions. When loss to follow-up is greater than 10%: intention to treat as well as an alternative analysis which accounts for missing values (5 points).
- q. Frequencies of most important outcomes presented for each treatment group. For most important outcome measures, and on the most important moments of effect measurement. In the case of (semi-) continuous variables: presentation of the mean or median with standard error or percentiles (5 points). Use of descriptive as well as inferential statistics. Literature review (1 point), good use of references (1 point)

Methodological Criteria: Oxford Pain Validity Scale ³²

This Scale is to be used with trials that are randomized and have an $N \geq 10$. There are five main categories with a possible score being between 0 and 16.

1. Blinding maximum 6 points)
2. Size of trial groups (maximum 3 points)
3. Outcomes (maximum 2 points)
4. Baseline pain and internal sensitivity (maximum 1 point)
5. Data Analysis (maximum 4 points)
 - Definition of outcomes
 - Data presentation: location and dispersion
 - Statistical testing
 - Handling of dropouts

APPENDIX D: CRITERIA FOR EVALUATING SYSTEMATIC REVIEWS

Papers that summarise other papers (systematic reviews and meta-analyses) by Trisha Greenhalgh ²¹:

1. Can you find an important clinical question which the review addressed?
2. Was a thorough search done of the appropriate databases and were other potentially important sources explored?
3. Was methodological quality assessed and the trials weighted accordingly?
4. How sensitive are the results to the way the review has been done?
5. Have the numerical results been interpreted with common sense and due regard to the broader aspects of the problem?

APPENDIX E: CHECKLIST OF DATA REQUIRED IN A COMPLETE REPORT OF ACUPUNCTURE TREATMENT ⁷⁶

1. Patient's posture
2. Number of needles*
3. Needle size, manufacturer
4. Rationale and justification for point selection (traditional, tenderness, formulae)
5. Points used (international nomenclature), nonstandard points carefully described
6. Laterality
7. Depth*
8. Stimulation (eg manipulation, electrical, moxabustion) strength and duration
9. Needle sensation induced
10. Duration of needling*
11. Frequency and number of repetitions**
12. Other simultaneous interventions
13. Subsequent changes to treatment

* where values vary, the median and range should be quoted

** where electrical stimulation is used, details of device, pulse width, waveform, frequency, and strength of stimulation (eg. presence of muscle contractions) should be included.

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