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Acupuncture for acute management and rehabilitation of traumatic brain injury (Protocol)

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[Intervention Protocol]

Acupuncture for acute management and rehabilitation of traumatic brain injury

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the efficacy and safety of acupuncture in the acute management or rehabilitation (or both) of patients with a traumatic brain injury (TBI). This includes cognitive, neurological, motor, emotional, or behavioral complications, or a combination of such complications.

We will investigate the following hypotheses.

1. Acupuncture is efficacious in the treatment of acute TBI.
2. Acupuncture can enhance the speed and extent of rehabilitation of TBI complications.
3. Acupuncture can reduce the occurrence and recurrence of TBI complications.
4. Acupuncture can improve the quality of life of TBI patients.
5. Acupuncture is safe.

BACKGROUND

Traumatic brain injury (TBI) is defined as a blow to the head, or a penetrating head injury, that disrupts the function of the brain. Not all blows to the head result in a TBI. The severity of a TBI may range from mild (a brief change in mental status or consciousness) to severe (an extended period of unconsciousness or amnesia after the injury) (CDC 2008).

Signs of and symptoms resulting from a TBI depend upon the severity of the injury, the location of the injury and the type of TBI (diffuse or focal). A person with a mild TBI may remain conscious or may experience a loss of consciousness for a few seconds or minutes. Other symptoms of mild TBI include headache, confusion, lightheadedness, dizziness, blurred vision or tired eyes, ringing in the ears, bad taste in the mouth, fatigue or lethargy, a change in sleep patterns, behavioral or mood changes, or trouble with memory, concentration, attention, or thinking. A person with a moderate or severe TBI may show these same symptoms, but may also have a headache that gets worse or does not go away, repeated vomiting or nausea, convulsions or seizures, an inability to awaken from sleep, dilation of one or both pupils of the eyes, slurred speech, weakness or numbness in the extremities, loss of coordination, and increased confusion, restlessness, or agitation (CDC 2008).

Management of TBI can be classified as acute management and rehabilitation. Acute management consists of maintenance of adequate pulmonary gas exchange and brain perfusion to avoid secondary brain damage. This is supplemented by early management of hypoxia, hypercapnia, hypotension, and increased intracranial pressure. Bleeding from injuries is controlled as required and intravascular volume is promptly replaced with crystalloid or blood transfusion to maintain cerebral perfusion. Other complications to monitor for and prevent include hyperthermia, hyponatraemia, hyperglycaemia, and fluid imbalance (Parikh 2007).

Subsequent to acute TBI, patients may develop complications manifesting in different forms of disability. These include cognitive, neurological, motor, emotional, or behavioral problems. Rehabilitation is, therefore, essential, and aims to reduce disabilities and enable the patient to achieve the maximum degree of pre-injury function, within the limits imposed by their residual cognitive, neurological, and motor functions (Chua 2007). TBI rehabilitation may consist of two phases. The inpatient phase may span one to three months, and include the acute neurosurgical and early rehabilitation phase prior to transfer to some form of specialized Traumatic Brain Injury unit. The outpatient or community phase may continue for one to two years or even longer depending on the age of the patient, severity of injury and residual disability (Khan 2003).

Description of the condition

Traumatic brain injuries (TBIs) represent a serious public health problem world wide. According to the National Center for Injury Prevention and Control, which is a part of the US Centers for Disease Control and Prevention, TBI accounts for 50,000 deaths, 235,000 hospitalizations, and 1.1 million emergency department visits annually (Langlois 2006). It has been estimated that in the European Union, TBI accounts for one million hospital admissions per year (Hyder 2007). Recent estimates suggest that there are about 25,000 people with TBI admitted to Australian hospitals annually (Rosso 2007). These figures probably underestimate the true incidence of TBI because of classification and diagnostic errors, as well as under-reporting of mild injury. Males are around twice as likely as females to experience TBI (Langlois 2006). Combining deaths, hospitalizations, and emergency department visits, children aged 0 to 4 years and adolescents aged 15 to 19 years are more likely to sustain TBI than individuals in other age group. For hospitalization alone, adults aged over 75 years have a higher incidence of TBI (Langlois 2006). The etiology of TBI is very diverse and includes falls (28%), motor vehicle traffic accidents (20%), being struck by/against something (19%), assault (11%), unknown (9%), other (7%), bicycle (3%), other transport (2%), and suicide attempts (1%) (Langlois 2006). Apart from injuries of domestic origin, blasts are a major contributor to TBI among active duty military personnel in war zones (Scott 2005). After acute treatment, rehabilitation can be required for a number of years. Therefore, TBI represents a public health concern in terms of loss of, or reduction in, workforce economic productivity (or both) and an increase in utilization of healthcare resources in the treatment and rehabilitation of those who survive the injuries.

Description of the intervention

Acupuncture is one of the best known complementary and alternative medicines (CAM). Its use can be traced back more than 2000 years in China (Wu 1996). Acupuncture is commonly used as a routine treatment in China, Japan, Korea, and Taiwan, and has been gaining popularity in the United States and other parts of the western world (Ernst 2001). Acupuncture involves the stimulation of specific points on the skin, the acupoints or meridian points, by the insertion of fine needles. Similar to other forms of Traditional Chinese Medicine (TCM) treatment modalities, the application of acupuncture is based on the principles of TCM in terms of a vital force or energy named 'Qi' which circulates between organs along channels called meridians. 'Qi' energy must flow at the appropriate strength and quality through each of these meridians and organs for health to be maintained. The meridian points are located along these meridians and act as a means of altering the flow of 'Qi' (Kaptchuk 2002).

However, the mechanisms underlying the effects of acupuncture remain poorly defined. Extensive research has shown that acupuncture analgesia may be initiated by stimulation, in the muscles, of high-threshold small-diameter nerves. These nerves are able to

send messages to the spinal cord and then activate the spinal cord, brain stem (periaqueductal grey area), and hypothalamic (arcuate) neurons, which in turn trigger endogenous opioid mechanisms. The responses include changes in levels of endogenous opioids (e.g. endorphins and enkephalins) or stress-related hormones (e.g. adrenocorticotrophic hormone) in the plasma or corticospinal fluid (Pomeranz 1989).

Studies in animals and humans have demonstrated that acupuncture can cause multiple biological responses, including circulatory and biochemical effects. These responses can occur locally or close to the site of application, or at a distance. They are mediated mainly by sensory neurons to many structures within the central nervous system. This can lead to activation of pathways affecting various physiological systems in the brain as well as in the periphery (Jansen 1989; Johansson 1993; Magnusson 1994; Sun 2001). Based on our preliminary search on the use of Traditional Chinese Medicine in TBI, we found that there are more than 30 studies in Chinese databases of the clinical efficacy of acupuncture in the acute management or rehabilitation (or both) of TBI. In order to provide the best available evidence to guide good clinical practice and planning of acute management and rehabilitation for TBI, a systematic analysis of all randomised controlled trials of acupuncture for TBI is needed.

How the intervention might work

The application of acupuncture in neurological conditions has been reviewed in a number of Cochrane systematic reviews, although these reviews reported that trials of acupuncture efficacy are equivocal or contradictory. These include idiopathic headache (Melchart 2008), insomnia (Cheuk 2007), Bell's palsy (He 2008), epilepsy (Cheuk 2006), stroke rehabilitation (Wu 2008), and acute stroke (Zhang 2008). Given that TBI also shares a neurological pathophysiology, acupuncture may have a role in TBI treatment or rehabilitation (or both) and is therefore worthy of a systematic review in its own right.

Why it is important to do this review

Acupuncture is commonly and widely used in China and is increasingly used by people in other countries. The report from the Consensus Development Conference on Acupuncture held at the National Institutes of Health (NIH) in 1997 stated that acupuncture is being "widely" practised "by thousands of physicians, dentists, acupuncturists, and other practitioners" for the relief or prevention of pain, and for various other health conditions. According to the 2002 National Health Interview Survey, which is the largest and most comprehensive survey of complementary and alternative medicines used by American adults to date, an estimated 8.2 million American adults had used acupuncture, and an estimated 2.1 million American adults had used acupuncture in the

previous year (NIHCP 1997). A telephone interview-based study (UMHS 2003) conducted by the University of Michigan Medical School revealed that 80% of TBI patients believed that complementary and alternative medicines, ranging from massage to herbal medicine, were effective. As such, many patients suffering from TBI approached complementary and alternative medicine themselves, in addition to conventional medical treatment or a rehabilitation program.

There is increasing interest in the use of acupuncture as a treatment modality for different neurological disorders (Ernst 2001). A number of Chinese studies have suggested good therapeutic effects of acupuncture on TBI (Ding 2007; Li 2003). Therefore, we have formulated the following research question for which we would like to perform a systematic review to rigorously assess whether acupuncture is efficacious and safe in the acute treatment or rehabilitation (or both) of patients suffering from TBI.

OBJECTIVES

To determine the efficacy and safety of acupuncture in the acute management or rehabilitation (or both) of patients with a traumatic brain injury (TBI). This includes cognitive, neurological, motor, emotional, or behavioral complications, or a combination of such complications.

We will investigate the following hypotheses.

1. Acupuncture is efficacious in the treatment of acute TBI.
2. Acupuncture can enhance the speed and extent of rehabilitation of TBI complications.
3. Acupuncture can reduce the occurrence and recurrence of TBI complications.
4. Acupuncture can improve the quality of life of TBI patients.
5. Acupuncture is safe.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials.

Types of participants

Individuals suffering from traumatic brain injury (TBI) ranging from mild to severe (Kay 1993; Rosenthal 1990) who are of any age and of either gender.

Types of interventions

We will include trials evaluating all forms of acupuncture therapy, which involves the penetration of the skin with needles, including scalp acupuncture, body acupuncture, auricular acupuncture, tongue acupuncture, injection acupuncture or electro-acupuncture, or any combination of the above, regardless of frequency of treatment, duration of treatment period and location(s) of stimulation (e.g. scalp, body, tongue, or ear). We will exclude other forms of acupuncture therapy which do not involve penetration of the skin with a needle, such as acupuncture, laser acupuncture, and percutaneous neuromodulation.

Acupuncture can be given alone or in combination with conventional medical treatment for TBI. The control intervention may be no treatment, placebo acupuncture, sham acupuncture, or conventional medical treatment (which may be baseline treatment) for TBI. We will analyse these separately. Placebo acupuncture refers to a needle attached to the skin surface (not penetrating the skin but at the same acupoints) (White 2001). Sham acupuncture refers to a needle placed in an area close to, but not in, acupuncture points (Lund 2006; Streitberger 1998; White 2001) or subliminal skin electro-stimulation via electrodes attached to the skin (SCSSS 1999).

Acute management involves the stabilization of the patient immediately after the injury; the time phase may be from onset to one month. Rehabilitation involves the treatment of long-term impairments and the return of the patient to the community; the time phase may be from one month to two years after onset. The treatment comparisons to be investigated in this review are listed below.

1. Acupuncture alone versus no treatment.
2. Acupuncture alone versus placebo or sham treatment.

We will exclude studies comparing different forms of acupuncture only (different manipulation methods or different acupoints), since these studies cannot yield the net effect of acupuncture and hence are unable to demonstrate the efficacy of acupuncture *per se*.

Types of outcome measures

Primary outcomes

- Functional outcome assessed by objective, validated, reliable scales, e.g. Barthel Index (BI), Functional Independence Measurement (FIM) or Fugl-Meyer assessment (FMA).
- Glasgow Outcome Score (GOS).

- Morbidity.
- Mortality for acute TBI.

Secondary outcomes

- Validated quality of life (QOL) measures, e.g. SF-36 questionnaire.
- Frequency and severity of adverse effects.

Search methods for identification of studies

We aim to identify all relevant trials regardless of date, language, or publication status.

Electronic searches

We will search the following electronic databases:

- the Cochrane Injuries Group's Specialised Trials Register;
- the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, latest issue);
- MEDLINE on OVID (1950 to date);
- EMBASE (1980 to date);
- CINAHL (1982 to date);
- AMED (the Allied and Complementary Medicine Database, 1985 to date);
- PsycINFO (1960 to date);
- Chinese Acupuncture Trials Register;
- the Trials Register of the Cochrane Complementary Medicine Field;
- NCCAM (National Center for Complementary and Alternative Medicine);
- NIH (National Institute of Health Clinical Trials Database);
- TCMLARS (Traditional Chinese Medical Literature Analysis and Retrieval System, 1984 to date);
- China Biological Medicine Database (to date);
- Chinese Medical Current Contents (to date);
- CNKI (China National Knowledge Infrastructure, 1979 to date);
- VIP (Wei Pu Information, 1989 to date);
- Wang Fang Data (1980 to date).

The following search strategy was formulated in MEDLINE using a combination of MESH headings and text words. This strategy will be modified, where appropriate, for use in other electronic databases:

MEDLINE (Ovid SP)

1. exp acupuncture analgesia/
2. exp acupuncture, ear/
3. exp electroacupuncture/

4. exp meridians/
5. exp acupuncture points/
6. Acupuncture Therapy/
7. (meridian point* or meridian* or (ching adj2 lo) or (jing adj2 lu) or jingluo or acu point* or acu-point* or acupoint*).ab,ti.
8. (acupuncture or electroacupuncture or electro-acupuncture or electro acupuncture or Zhenjiu or Zhenci or Cizhen or Dianzhen).ab,ti.
9. 6 or 3 or 7 or 2 or 8 or 1 or 4 or 5
10. exp Craniocerebral Trauma/
11. exp Brain Edema/
12. exp Glasgow Coma Scale/
13. exp Glasgow Outcome Scale/
14. exp Unconsciousness/
15. exp Cerebrovascular Trauma/
16. ((head or crani* or cerebr* or capitis or brain* or forebrain* or skull* or hemispher* or intra-cran* or inter-cran*) adj3 (injur* or trauma* or damag* or wound* or fracture* or contusion*)).ab,ti.
17. ((head or crani* or cerebr* or brain* or intra-cran* or inter-cran*) adj3 (haematoma* or hematoma* or haemorrhag* or hemorrhag* or bleed* or pressure)).ti,ab.
18. (Glasgow adj3 (coma or outcome) adj3 (scale* or score*)).ab,ti.
19. "rancho los amigos scale".ti,ab.
20. ("diffuse axonal injury" or "diffuse axonal injuries").ti,ab.
21. ((brain or cerebral or intracranial) adj3 (oedema or edema or swell*)).ab,ti.
22. ((unconscious* or coma* or concuss* or 'persistent vegetative state') adj3 (injur* or trauma* or damag* or wound* or fracture*)).ti,ab.
23. or/10-22
24. 9 and 23
25. randomi?ed.ab,ti.
26. randomized controlled trial.pt.
27. controlled clinical trial.pt.
28. placebo.ab.
29. clinical trials as topic.sh.
30. randomly.ab.
31. trial.ti.
32. or/25-31
33. humans.sh.
34. 32 and 33
35. 34 and 24

We will also search the Chinese academic literature databases using keywords in simplified Chinese, and using synonyms of acupuncture ('Zhenjiu', 'Zhenci', 'Cizhen') and synonyms of traumatic brain injury ("Nao Wai Shang").

Searching other resources

We will search the reference lists of all relevant papers for further studies.

Data collection and analysis

Selection of studies

We will perform double data extraction. Two review authors (Lee S, Chu V) will independently examine titles and abstracts retrieved from the search and select all potentially relevant studies. We will retrieve the full text of the article, and the same review authors will evaluate these independently against the inclusion criteria. Review authors will not be blinded to the names of the authors, institutions, or journal of publication of potentially relevant trials. The review authors will then extract data from included trials. We will resolve all disagreements by discussion to reach consensus. Where disagreement occurs, the third review author (Wong V) will consider the article and contribute to the discussion.

Data extraction and management

The following information will be extracted.

Study methods:

- design (for example, randomized controlled trial);
- randomization method (including sequence generation);
- method of allocation concealment;
- blinding method;
- type of informed consent;
- stratification factors.

Participants:

- inclusion and exclusion criteria;
- number (total and per group);
- age and sex distribution;
- types of traumatic brain injury (TBI);
- GSC for TBI severity;
- post-TBI complications.

Intervention and control:

- type of acupuncture;
- details of treatment modalities and strategies including duration of treatment;
- type of control(s);
- details of control treatment (e.g. in line with Standards for Reporting Trials of Acupuncture (STRICTA) reporting system for acupuncture studies).

Follow-up data:

- duration of follow up;
- numbers of treatment withdrawal and reasons for treatment withdrawal;
- recurrence of TBI complications after treatment.

Outcome data:

- as described in the 'Types of outcome measures' section.

Analysis data:

- methods of analysis (intention-to-treat or per protocol analysis, or both);
- comparability of groups at baseline (yes/no);
- statistical methods used.

One author will enter the information into Review Manager 5.0 (RevMan 2008) and the other authors will check.

Assessment of risk of bias in included studies

Two authors (Lee S, Chu V) will independently assess the methodological quality of each eligible trial using the Cochrane Collaboration's tool for assessing risk of bias (Higgins 2008). A third author (Wong V) will resolve any discrepancies regarding the methodological quality.

We will examine the risk of bias derived from the methods used to generate the allocation sequence, the concealment of allocation, blinding, incomplete outcome data, selective outcome reporting and other sources of bias. We will come to a judgement relating to the risk of bias for each domain as follows: 'Yes' indicates low risk of bias, 'No' indicates high risk of bias, and 'Unclear' indicates unclear or unknown risk of bias (Higgins 2008).

Measures of treatment effect

We will use odds ratio (OR) with 95% confidence intervals (CI) for binary outcomes. We will use weighted mean difference (WMD) with 95% CI for continuous outcomes.

Unit of analysis issues

We will subject different units for analysing odds ratios (OR) to a sensitivity analysis.

Dealing with missing data

We will contact the authors of included studies to supply missing data. We will assess missing data and drop-outs/attrition for each included study, and will discuss and assess the extent to which the results and conclusions of the review could be altered by the missing data. If, for a particular outcome, fewer than 70% of patients allocated to the treatment are reported on at the end of the trial, we will not use that outcome due to potential bias.

Assessment of heterogeneity

We will assess clinical heterogeneity by comparing the distribution of important participant factors between trials (age, gender, specific types of TBI), and trial factors (sequence generation, allocation concealment, blinding, losses to follow up, treatment type, co-interventions). We will assess statistical heterogeneity by examining the I^2 statistic (Higgins 2008), a quantity which describes approximately the proportion of variation in point estimates that is due to heterogeneity rather than sampling error. If significant heterogeneity is present (i.e. $I^2 \geq 50\%$ (Higgins 2008)), we will investigate trials for possible explanations.

Assessment of reporting biases

We will draw funnel plots (estimated differences in treatment effects against their standard error) if sufficient studies are found. Asymmetry could be due to publication bias, but could also be due to a relationship between trial size and effect size. In the event that a relationship is found, we will examine the clinical diversity of the studies (Egger 1997).

Data synthesis

Where the interventions are the same or similar enough, we will synthesize results in a meta-analysis if there is no important clinical heterogeneity. If no significant statistical heterogeneity is present, we will synthesize the data using a fixed-effect model, otherwise we will use a random-effects model in the meta-analysis.

Subgroup analysis and investigation of heterogeneity

If data permit, we will conduct subgroup analyses for the different interventions' objectives (acupuncture for acute management, acupuncture for rehabilitation), different types of TBI (mild, moderate, severe), and different age groups, to assess whether the treatment effects vary between subgroups.

Sensitivity analysis

We will perform sensitivity analyses to assess the impact of study quality. These will include:

- all studies;
- only those with low risk of bias.

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* Indicates the major publication for the study

HISTORY

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CONTRIBUTIONS OF AUTHORS

All authors contributed to drafting and editing this protocol.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Hospital Authority, Hong Kong.
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External sources

- No sources of support supplied