A Prospective, Randomised Control Trial of Acupuncture for Select Common Conditions within the Emergency Department

Abstract

A trial was conducted among patients admitted to the Emergency Department of The Northern Hospital, Epping, Melbourne, Australia to assess the potential of acupuncture to reduce waiting times, reduce pain and satisfy the desire of patients to see complementary medicine within mainstream healthcare. 45 patients were randomly assigned to an acupuncture group (32) and a conventional treatment group (13). Comparison of the physiological parameters following treatment revealed no significant differences between the two groups (Table 3). These results demonstrate that acupuncture and conventional treatment are equally effective to reduce pain, however the acupuncture group received a significantly higher rate of patient satisfaction with the treatment.

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Introduction and literature review

Acupuncture has been used to reduce pain in China for thousands of years. In more recent times there has been research in the West on the effectiveness of acupuncture for the treatment of pain. The quality and quantity of this evidence however, is insufficient to prove the efficacy of acupuncture. There is currently no literature on acupuncture within an emergency department situation.

In regard to scientific trials, there is the obvious difficulty of finding an appropriate placebo. To address this, some trials have used a sham needle[1]. This is where a superficial needling technique is used at non-acupuncture points. The problem with this is that these non-acupuncture points may still lie on a channel and of course the sun luo and fen luo, the little capillary network of vessels of the jingluo, connect the surface to the interior jingluo/channels and this may indeed induce a response. Other researchers have used a sham needle that does not penetrate the skin at all, and although it is apparently realistic (for the patient), since some acupuncture techniques only lightly stimulate the point, even this might be enough to exert an effect.

Much experimental research has explored the mechanism behind acupuncture analgesia. Research indicates that acupuncture induces the formation of opioid-like peptides. An animal study found that electroacupuncture inhibits the release of stress-induced substance P through the activation of descending serotonergic pathways meeting up with opioidergic systems.[2] Some results, however, have been contradictory. For example, one study looking at acupuncture treatment for chronic pain syndrome found that the degree of symptom relief achieved with acupuncture correlated with an increase in plasma met-enkephalin and that plasma beta-endorphin concentrations were unchanged.[3] However, another study in patients with recurrent pain who received electroacupuncture found increased endogenous opioid beta-endorphin in lumbar cerebrospinal fluid CSF levels and no change in met-enkephalin levels.[4] Another trial investigating the effects of acupuncture for chronic headache found that acupuncture results in a decrease of inflammatory cytokines interleukin-1, interleukin-6 and tumour necrosis factor alpha, TNF-alpha.[5]

One study investigating the immune effects of acupuncture in a group of 90 patients suffering from various painful disorders found a considerable increase in beta-endorphin levels of patients receiving acupuncture and that these remained high even 24 hours after acupuncture treatment.[6] Other studies using electroacupuncture have indicated that a combination of two frequencies produces a release of all four opioid peptides. Enkephalin, beta-endorphin and endomorphin are released at a frequency of 2 Hz and dynorphin is released at 100Hz, therefore a combination of frequencies results in a maximum therapeutic effect.[7,8]

Despite troubles with acupuncture research, acupuncture has become widely accepted in Western medical circles for the treatment of a number of conditions. Some of the strongest clinical evidence is for the treatment of dental and temporomandibular dysfunction pain, and research findings are promising for idiopathic headaches, fibromyalgia and osteoarthritis.[9,10] With regard to pain from osteoarthritis, a trial to test the efficacy of acupuncture compared with minimal acupuncture and with no acupuncture in patients with osteoarthritis of the knee found that after eight weeks of treatment, pain and joint function were improved more with acupuncture than with minimal acupuncture or no acupuncture.[11]

Acupuncture is also well proven to treat painful conditions associated with pregnancy. A randomised controlled study found that acupuncture relieves pelvic and low-back pain in late pregnancy.[12] Another randomised single blind controlled trial involving 386 pregnant women with pelvic girdle pain concluded that acupuncture complements standard treatment for the management of pelvic girdle pain during pregnancy and that acupuncture was superior to stabilising exercises.[13] There are also studies that demonstrate acupuncture to be an effective alternative to pharmacological analgesia during labour.[14]

Recent studies indicate that 50% of Australians are using some form of alternative or complementary therapy every year.[15,16,17] Patients are becoming increasingly suspicious of pharmacotherapy and more interested in "natural" remedies, feeling they receive more care from alternative health practitioners who take a more holistic approach to their patient's health.[18]

In response to the increasing use of alternative therapies by the general public, the Australian Medical Association AMA issued a position statement on Complementary Therapies. In issuing this statement, Kerryn Phelps stated in the preamble:

"As evidence emerges that some complementary therapies are effective, it becomes ethically impossible for the medical profession to ignore them".

Acupuncture has been practised for thousands of years and as such is arguably the most established alternative therapy. It has been embraced by the medical profession, with an estimated 20% of general practitioners utilising it.[19] The Northern Hospital in Melbourne, Australia, has two acupuncture clinics in Ambulatory Care; these clinics take referrals from other subspecialties (e.g. general surgery) as well as from the community. Although these clinics are run by medical acupuncturists, this trial will be conducted by a traditional TCM practitioner.

It is recognised that acupuncture offers a safe and effective alternative to pharmacotherapy. Acupuncture has long been listed on the Medicare Benefits scheme as a rebatable item, and as quality research accrues, its efficacy is becoming more established.

Methods

Study design

Prospective, randomised controlled trial.

Objectives

Primary outcomes

It is anticipated that following treatment the acupuncture group, as compared with the control group, will have a greater improvement in all of the parameters mentioned below:

- improved pain scores as measured by Visual Analogue scale, VAS
- a lowering of heart rate (HR), blood pressure (BP), respiratory rate (RR)
- satisfaction with the treatment

Subjects

Recruitment

Patients presenting to the Emergency Department with conditions fulfilling the inclusion criteria (see below) will be offered the chance to participate in a trial of acupuncture versus conventional medical treatment. The selection of appropriate patients will be by the Emergency Physician on R.A.T. (Rapid Assessment Team) duty, as the current practice in the ED is for an Emergency Physician to perform the initial assessment of all patients presenting to the ED. Written informed consent will be obtained and then the patient will be randomised to receive either acupuncture or conventional medical treatment. An initial set of routine physiological observations (HR, BP, RR) and a pain score as indicated by a Visual Analogue Scale (VAS) of symptom severity will then be performed on all patients.

Acupuncture group

Patients randomised to receive acupuncture will be seen by the Acupuncturist in the General Practice After Hours Clinic (GPAHC) area for a consultation lasting 30-40 minutes. Following the treatment, at the point of discharge from the acupuncturist's care, patients in this group will be briefly assessed by the doctor rostered to the Fast Track clinic, which runs concurrently in the GPAHC. This doctor will ensure that the patient is able to be discharged from the care of the Emergency Department, and be provided with any correspondence/referrals/prescriptions as necessary. This doctor will also collect the second set of physiological observations (HR, BP, RR) and VAS needed as data for the trial, and administer a brief patient satisfaction survey.

Conventional treatment (control) group

Patients randomised to the control group will be seen by an Emergency Department doctor and receive the conventional medical treatment for their condition, at the discretion of the treating doctor. Discharge from the Emergency Department will also be by this doctor, after they have taken the second set of data (as above) for the trial.

Triage category	Description
1	People who need to have treatment immediately or within two minutes are categorised as having an immediately life-threatening condition. People in this group are critically ill and require immediate attention. Most would have arrived in Emergency Department by Ambulance. They would probably be suffering from a critical injury or cardiac arrest.
2	People who need to have treatment within 10 minutes are categorised as having an imminently life-threatening condition. People in this group suffer from a critical illness or are in very severe pain. People with serious chest pains, difficulty in breathing and severe fractures are included in this group.
3	People who need to have treatment within 30 minutes are categorised as having a potentially life-threatening condition. People in this group suffer from severe illness, bleed heavily from cuts, have major fractures, or are dehydrated.
4	People who need to have treatment within one hour are categorised as having a potentially serious condition. People in this group have less severe symptoms or injuries, such as a foreign body in the eye, sprained ankle, migraine or earache.
5	People who need to have treatment within two hours are categorised as having a less urgent condition. People in this group have minor illnesses or symptoms that may have been present for more than a week, such as rashes or minor aches and pains.

Above:
The five triage categories

Inclusion criteria
Patients within triage categories 3,4 or 5, who present with the following acute conditions:
- Migraine headache
- Tension headache
- Torticollis
- Muscular back pain
- Acute musculoskeletal pain (excluding likely fracture)
- Hyperemesis gravidarum
- Chemotherapy-induced nausea and vomiting
- Anxiety/panic attack
- Viral upper respiratory tract infection
- Dysmenorrhoea

Exclusion criteria
- Triage categories 1 and 2
- Haemodynamic instability or suspected critical illness
- Acute, severe pain requiring parenteral narcotic analgesia
- Undifferentiated conditions where further investigations are needed

Withdrawal criteria
Anyone who develops needle phobia.

Variables
Independent variables
Patients will be individually assessed and prescribed appropriate acupuncture according to TCM theories.

Dependant variables
These will include physiological observations (HR, BP, RR) and VAS as assessed by a triage nurse or doctor.

Extraneous variables
These will be limited, as the trial will be conducted in a short period of time within the patients' emergency department stay. Any medication that may be prescribed in addition to the acupuncture will only be prescribed after the final assessment for the acupuncture trial is concluded.

Materials
Acupuncture needles
0.25 x 30mm, 0.25 x 40mm, 0.32 x 75mm, 0.30 x 30mm, 0.30 x 40mm, 0.30 x 75mm, 0.18 x 13mm, 0.18 x 25mm.

Heat lamp
TDP CQ 26/7.

Electroacupuncture machine
Hwato SDZ 2.

Acupuncture procedures
Differentiation of patterns
Pain in Chinese medicine may be due to excess or deficiency, exterior attack, interior disharmony, traumatic injury, heat or cold etc. The main patterns of disharmony and the guideline treatments are given in Table 1 below.

Acupuncture technique and needle depth
The treatment principle is to move qi and blood to alleviate pain. Patients will be differentiated according to TCM theory using tongue and pulse diagnosis and zangfu and channel pathology. Local and distal points will be chosen accordingly.

For patients experiencing acute anxiety or who are new to acupuncture, treatment will begin using ear acupuncture. The points to be used are according to

Category	Pain symptom	Tongue	Pulse	Points (all reduced)
Wind	Sudden onset, migratory pain, upper body, wind-cold, wind-heat or wind-damp.	May be unchanged	Floating	Fengchi GB-20, Wangu GB-12, Dazhui DU-14, Fengmen BL-12, Lieque LU-7, Waiguan SJ-5
Cold	Severe, fixed, deep, stiffness better with warmth worse with cold	White coat	Deep and slow	Qihai REN-6, Mingmen DU-4. Heat lamps were used instead of moxa.
Heat	Local redness, swelling and heat worse with heat better with cold (this is theoretical and not necessarily practical as most pain is better with heat)	Yellow coat, red body	Floating and rapid	Quchi L.I.-11, Dazhui DU-14, Erjian M-HN-10, Waiguan SJ-5, Erjian L.I.-2, Neiting ST-44, Chize LU–5, Zulinqi GB-41.
Damp	Dull ache, numbness, fixed, heavy, swelling, distension	Thick greasy coat, Flabby, teeth marks	Slippery	Fenglong ST-40, Jianshi P-5, Lieque LU-7
Qi stagnation	Distension, migratory pain	Slightly purple	Wiry	Taichong LIV-3, Hegu L.I.-4, Ganshu BL-18, Qimen LIV-14, Zulinqi GB-41
Blood Stasis	Severe, sharp and fixed pain	Dark purple	Full and choppy	Xuehai SP-10, Geshu BL-17, Dazhu BL-11

Table 1: **TCM patterns and treatments**

the National Acupuncture Detoxification Association (NADA). The object is to increase endorphin levels quickly to relax the patient.

In all cases I will open the four gates (Hegu L.I.-4 and Taichong LIV-3). In China there is a saying "xuan mai, kai si guan", "if the pulse is wiry, open the four gates". In reality however, the four gates are regularly used for the treatment of all pain regardless of the pulse, even in deficient cases. From my experience a wiry pulse is always present in severe, debilitating pain.

Appropriate supplementary points will then be chosen accordingly, i.e. a mixture of local and distal points according to point category and according to the patterns seen in Table 1. Needles will be inserted to the depth required to obtain a strong qi sensation (deqi). Strong reduction techniques will be used locally and distal points will be tonified or reduced as required. Bleeding techniques at the jing-well points provide fast relief in excess conditions affecting the channels and will also be applied. Other points considered for acute pain include the xi-cleft points.

An electroacupuncture device will be attached to the needles and the points stimulated for approximately 20 minutes. Studies using electroacupuncture have indicated that a combination of two frequencies produces a release of all four opioid peptides, enkephalin, beta-endorphin, endomorphin and dynorphin, resulting in a maximum therapeutic effect. Considering the main aim is to reduce pain and waiting times, electroacupuncture will be set on dense and disperse to increase the anodyne effect.

A TDP heat lamp will be used over the affected area at an acceptable distance to further improve the effect

	Conventional group	Acupuncture group	t	P
Pain score (M ± SD)	54.71 ± 17.98%	64.39 ± 24.07%	-1.460	0.151
Respiratory rate (M ± SD)	18.75 ± 2.51 / min	17.88 ± 1.521 / min	0.926	0.359
Heart rate (M ± SD)	87.41 ± 19.49 / min	77.22 ± 16.32 / min	1.964	0.056
Systolic blood pressure (M ± SD)	140.12 ± 29.16 mmHg	129.16 ± 14.06 mmHg	1.586	0.120
Diastolic blood pressure (M ± SD)	136.06 ± 28.94 mmHg	129.41 ± 26.74 mmHg	0.791	0.433

Table 2: Pre-treatment physiological parameters

of treatment, as is regular practice in China, even in conditions of excess heat.

If applicable, I will also use what I call active puncture methods to conclude the treatment. These will mainly be used to treat back, neck and shoulder pain in particular. Examples are needling Houxi SI-3 or Luozhen M-UE-24, while getting the patient to perform gentle head rotations for wry neck. Another example for acute lower back pain is Yaotongxue N-UE-19 and Zanzhu BL-2 while the patient rotates and bends forwards, backwards and to the side. A further example using six channel theory is needling Waiguan SJ-5 of hand shaoyang to treat disorder affecting the upper portion of foot shaoyang, while the patient gently stretches. Table 1 shows examples of common TCM patterns and treatment for acute pain.

Data management and statistical analysis.

Data analysis

SPSS 12.0 for Windows (November 2003) will be used for data management and analysis. Descriptive statistics (frequency, mean and standard deviation) will be used to examine participants' demographic data, physiological parameters, effect of treatment and ED length of stay. The physiological parameters examined by the study will be pain score, heart rate, systolic and diastolic blood pressure and respiratory rate. The participant characteristics of the two groups (conventional treatment and acupuncture) will be compared to establish equivalence of the groups. Non-parametric data will also be compared using Chi square test for independence and t-tests will be used to compare parametric data. [20,21,22]

T-tests will be used to compare test physiological parameters between and within the two groups of participants. Independent samples t-test will be used to compare the mean physiological parameters of both groups to establish equivalence of pre-treatment parameters and examine the effect of treatment on post-test parameters.[22,23,24] Paired samples t-test will be used to compare the pre-treatment and post-treatment physiological parameters within each group.[22,23,24] Significance will be indicated by a probability value of 0.05 or less.

Ethical considerations

A proposal will be submitted to the Ethics Committee of the Northern Hospital for approval.

Timetable

The trial will run for a period of four months from June 2003 – October 2003.

Results

Group comparisons

There were a total of 45 participants in the study. Of these, 32 were in the acupuncture group and 13 were in the conventional treatment group. The characteristics of the two groups were examined to determine if there were any statistically significant differences in age, gender or pre-treatment physiological parameters.

There were no significant differences in the age or gender of both groups. The age of participants was 45.46 ± 16.18 years for the conventional group and 40.25 ± 14.68 for the acupuncture group, t (43) = -1.048, p = 0.300. Males accounted for 53.3% of the conventional group and 39.4% of the acupuncture group, ($c2 = 0.814$, df = 1, p = 0.367). There were no significant differences in the pre-treatment physiological parameters of both groups (Table 2). These results demonstrate that there were no significant differences between groups, indicating equivalence of the two groups.

Effect of treatment

The effect of treatment was examined using the following outcome measures: physiological parameters pain score as measured by VAS, respiratory rate, heart

	Conventional group	Acupuncture group	t	P
Pain score (M ± SD)	32.81 ± 21.68%	38.48 ± 23.55%	-5.672	0.422
Respiratory rate (M ± SD)	17.80 ± 1.52 / min	18.03 ± 4.00 / min	-0.215	0.830
Heart rate (M ± SD)	76.50 ± 12.95 / min	74.56 ± 15.50 / min	0.429	0.670
Systolic blood pressure (M ± SD)	80.65 ± 16.29 mmHg	78.42± 14.06 mmHg	0.496	0.622
Diastolic blood pressure (M ± SD)	76.25 ± 12.72 mmHg	76.03 ± 13.37 mmHg	0.054	0.957

Table 3: **Post-treatment physiological parameters**

rate, systolic and diastolic blood pressure), degree of effect reported by the patient, presence of side effects and ED length of stay.

Conventional group

Following treatment there were decreases in all physiological parameters examined in the conventional treatment group. There was 22.18 ± 24.08% decrease in the pain score, t (15) = 3.685, p = 0.002. There were significant reductions in heart rate (7.81 ± 11.86, t (15) = 3.685, p = 0.002), systolic blood pressure (59.47 ± 16.89, t (15) = 14.521, p < 0.001) and diastolic blood pressure (59.81 ± 22.88, t (15) = 10.46, p < 0.001). There was also a non-significant reduction in respiratory rate (1.13 ± 2.23, t (15) = 2.369, p = 0.069).

Acupuncture group

The findings for the acupuncture group were similar to those of the conventional treatment group. Again, there were decreases in all physiological parameters examined following treatment except respiratory rate. There was 25.90 ± 17.64% decrease in the pain score, t (32) = 8.433, p < 0.001. There were significant reductions in systolic blood pressure (50.74 ± 12.20, t (32) = 23.150, p < 0.001) and diastolic blood pressure (53.37 ± 22.10, t (32) = 13.66, p < 0.001). There was a non-significant increase in respiratory rate (0.35 ± 2.71, t (32) =-0.728, p = 0.472) and non-significant reduction in heart rate (1.70 ± 9.16, t (32) = 1.039, p = 0.307).

Group comparisons

Comparison of the physiological parameters following treatment revealed no significant differences between the two groups (Table 3). These results demonstrate that acupuncture and conventional treatment are equally effective.

Comparison of ED length of stay showed no significant differences between the two groups. The ED length of stay was 238.93 ± 82.48 minutes for the conventional treatment group and 255.94 ± 132.03 minutes for the acupuncture group.

The self reported data collected from patients showed no significant differences in the perceived effectiveness of the two treatments, the reported incidence of side effects or the willingness to have that treatment again. Positive effects of treatment were reported from 75.0% (n = 12) of the participants who were managed with conventional treatment and 84.4% (n = 27) of participants who underwent acupuncture (c2 = 0.615, df = 1, p = 0.433). Side effects were reported by 5.9% (n = 1) of the participants who were managed with conventional treatment and 18.2% (n = 6) of participants who underwent acupuncture (c2 = 1.410, df = 1, p = 0.235). The acupuncture side effects were minimal and related to pain reported at the needle site and insertion. Willingness to undergo the same treatment in the future was reported by 58.8% (n = 10) of the participants who were managed with conventional treatment and 81.8% (n = 27) of participants who underwent acupuncture (c2 = 3.083, df = 1, p = 0.0.79).

Future research potential

- This trial could be continued in the Northern Hospital ED.
- A trial designed to determine if acupuncture, as compared to a control group, is also able to reduce rates of representation with the same condition.
- This type of trial could be applied to other departments within the public hospital system such as the orthopaedic, neurological and maternity wards.
- Given that the results have proven positive for the treatment of acute pain, this style of trial could be applied in frontline emergency relief situations with practitioners working alongside Westerns doctors with triage nurses.
- There is potential to experiment with other styles

of acupuncture treatment such as Dr. Zhu's head acupuncture and hand / foot / nose acupuncture, as these are powerful techniques used in China in emergency situations when other methods fail.

Discussion

Certain characteristics of Chinese medicine make it hard to fit into experimental studies. In addition to placebo difficulties it is sometimes difficult to equate diagnostic terminology. For example where the Western aetiology of torticollis is a detracted state of the cervical muscles resulting in torsion of the neck, TCM is likely to ascribe it to wind invasion resulting in stagnation of qi and blood in the affected channels.

TCM may be in direct conflict with modern scientific method in that its theory and practice involve integrating variables while current scientific research involves controlling and eliminating variables. Most doctors of Chinese medicine understand that TCM is more than science; it is a combination of art and science. There will always be difficulty in conducting scientific trials in acupuncture that will satisfy both the medical fraternity and TCM doctors.

This trial, however, is a good template for sound acupuncture research. The acupuncture was performed according to TCM theory and practice and points were varied according to presenting patterns of disharmony. The scientific data was collected in a controlled environment.

Conclusion

It was originally anticipated that the acupuncture group would have a greater reduction in pain scores, heart rate, blood pressure and respiratory rate than the control group and also find a greater satisfaction rate with the treatment. On analysing the relationship between projected outcomes and actual outcomes, in hindsight, the projected outcomes were too optimistic. Most of the objectives in fact, were not met.

The results do however demonstrate that acupuncture and conventional treatment are equally effective to reduce pain in the emergency department. The patient satisfaction rate or willingness to undergo the same treatment in the future for the acupuncture group was 81.8% compared with only 58.8% reported by the participants were managed with conventional treatment. This is an important factor as the results of this trial paved the way for Royal Melbourne Institute of Technology (RMIT) acupuncture students to provide treatment for pain relief in the emergency department of the Northern Hospital.

The results show that trials of this nature need prioritisation within the public healthcare system to reduce the strain presently experienced as a result of an increasing and increasingly unwell population. ■

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Footnotes

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