

Auricular Acupuncture in the Treatment of Acute Pain Syndromes: A Pilot Study

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This pilot study used a randomized controlled clinical trial design to compare the effects of standard emergency medical care to auricular acupuncture plus standard emergency medical care in patients with acute pain syndromes. Eighty-seven active duty military personnel and their dependents with a diagnosis of acute pain completed the study, which was conducted in the emergency room (ER) at Malcolm Grow Medical Center, Andrews Air Force Base, Maryland. The primary outcome measure was change in pain level from baseline, as measured by the Numerical Rating Scale. Participants in the acupuncture group experienced a 23% reduction in pain before leaving the ER, while average pain levels in participants in the standard medical care group remained basically unchanged. ($p < 0.0005$). However, both groups experienced a similar reduction in pain 24 hours following treatment in the ER. More research is needed to elucidate treatment effects and to determine mechanisms.

Introduction

Pain is a serious public health problem among both military and civilian populations and a major cause of medical expenses, absenteeism, and disability.¹ In a given 2-week period, approximately 13% of the U.S. workforce loses productive time due to a common pain condition such as headache or backache, and this lost productive time costs an estimated \$61.2 billion per year.² Acute pain in the military leads to lost duty time and reduced productivity; acute pain in the battlefield, whether induced by the enemy or by other means, is detrimental to mission readiness.

Standard interventions for acute pain in the military can cause unfavorable side effects and logistical difficulties. Narcotic analgesics adversely affect physical and mental performance. For example, a specialized flight crew member placed on a narcotic may have to be withdrawn from aeronautical duties, and other military missions involve reliance on alertness and fine motor skills. Often the standard of care is not easily portable; for example, intravenous morphine is routinely recommended for analgesia following combat casualties, but insertion of the intravenous catheter is often prohibited by harsh conditions or tactical requirements.³ Furthermore, the safety and side effects of non-narcotic analgesics have recently come under scrutiny. In April 2005, the U.S. Food and Drug Administration asked manufacturers of nonprescription nonsteroidal anti-inflammatory drugs such as ibuprofen to revise their labeling to

provide more specific information about potential cardiovascular and gastrointestinal risks of their products.⁴

The Agency for Health Care Policy and Research's Clinical Practice Guideline on Acute Pain Management states that managing pain and relieving suffering is an ethical obligation that lies at the core of a health care professional's commitment and that any potentially harmful treatments should be minimized.⁵ Beyond these ethical issues, alleviating pain allows military personnel to return to duty more quickly and facilitates movement in the field, thus allowing critical missions to proceed.⁶

To preserve military battlefield readiness, there is a need for conservative, portable, and easily administered treatments. Acupuncture has been demonstrated to reduce pain and may provide an option for acute pain treatment, but this has not been studied. The research described in this study provides clinical data for this modality, and it is an incremental yet important step toward providing clinical applications of acupuncture relevant to military personnel.

Acupuncture

Acupuncture has been used to improve health and treat disease for >2500 years, as one component of the broad-based traditional Chinese health care system. It has become an increasingly popular form of complementary and alternative medicine (CAM) therapy in the United States; it is estimated that more than one million persons in the United States each year receive acupuncture, resulting in approximately 10 million treatment visits.⁷ A variety of providers, from conventionally trained medical doctors to practitioners of traditional Chinese medicine, use acupuncture to treat a broad range of health conditions, including acute pain syndromes.

Acupuncture theory is based on the premise that energy, called Qi, travels along 12 prescribed pathways or meridians within the body and is responsible for maintaining good health. Blockages, deficiencies, or disturbances in the flow of Qi result in disease. Acupuncture employs needles to stimulate specified points on the body for the purpose of regulating this energy flow. There are more than 350 acupuncture points located on meridian pathways. Although stimulation of acupuncture points is most often achieved by using very thin metal needles to pierce the skin, other techniques including moxibustion (acupuncture treatment involving burning of *Artemis vulgaris* leaves on the needle or on the insertion point), electrical stimulation, ultrasound, and lasers can also be used.

Clinical studies have demonstrated the effectiveness of acupuncture in the treatment of chronic and acute pain, nausea, headache, heart disease, and asthma. A 1997 National Institutes of Health consensus statement found "promising" results for the efficacy of acupuncture in treating adult postoperative

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and chemotherapy nausea and vomiting, as well as acute post-operative dental pain.⁸ The National Institutes of Health also stated that acupuncture may be useful in stroke rehabilitation and in treating addiction, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, and carpal tunnel syndrome. Since 1997, further studies have demonstrated the effectiveness of acupuncture in treating pain syndromes, including low back pain;⁹ facial, head, and neck pain;¹⁰ and postsurgical pain.¹¹

Studies have addressed potential biological explanations for the effects of acupuncture. It has been established that acupuncture stimulates the release of endogenous opioids in the body and that acupuncture's analgesic effects are blocked in a dose-response manner by naloxone, an opioid antagonist.¹² A rapidly developing area of study is the use of functional magnetic resonance imaging technology, which demonstrates that stimulation of acupuncture points alters signals in both cortical and subcortical structures and the limbic system.¹³ Cho et al.¹⁴ have demonstrated in human subjects that the cingulate gyrus and the thalamic areas, specifically activated in the presence of applied pain stimulation, show brain activity that correlates with decreased pain sensation during and after acupuncture. These effects are apparently distinct from belief in and expectation of relief from acupuncture.¹⁵ Another potential explanation for the treatment effects of acupuncture is the gate theory, first proposed in 1965 by Melzack and Wall.¹⁶ Smaller diameter nociceptive fibers can be blocked by tactile stimulation that activates larger diameter fibers. According to the gate theory, acupuncture may act in a similar way by inhibiting nociceptor function through gentle stimulation of the mechanoreceptors at the needle insertion point, thus producing an analgesic effect.

Auricular Acupuncture

Auricular acupuncture refers to stimulation of points on the external ear. Identified as a form of treatment in ancient Chinese documents dating back to 500 B.C., its current use was codified by the French physician, Dr. Paul Nogier, in the 1950s. Dr. Nogier originally proposed this therapy as a treatment for low back pain when he observed that stimulation of a particular point on the ear was effective in eliminating sciatic pain. Through clinical empirical observation, he came to believe that direct stimulation of other points on the ear affected organ systems throughout the body. As with acupuncture in general, auricular acupuncture is used clinically for a myriad of conditions. However, the majority of research has focused on the area of pain control.¹⁷

Objectives

In this study, we aimed to (1) gather preliminary outcomes data on the effectiveness of auricular acupuncture in treating acute pain in military personnel who present to the emergency room at Andrews Air Force Base in Maryland; (2) determine the feasibility of conducting a randomized clinical trial of auricular acupuncture in the treatment of military personnel with acute pain; and (3) gather data on the effect size of auricular acupuncture in treating acute pain conditions.

Methods

Screening

We screened active duty male and female military personnel and their dependents between the ages of 18 and 50 with acute pain syndromes for possible inclusion in the study. When patients presented to the emergency room (ER) at Malcolm Grow Medical Center, they met with a triage nurse who took a brief history of the subjective complaint. The triage nurse flagged patients as potential study participants by including a study inclusion/exclusion form with the patient's ER chart. Patients then underwent the standard ER evaluation and management protocol with the ER physician. This included a history of chief complaint, physical examination procedures, laboratory tests if indicated, diagnosis, and a treatment plan. The ER physician identified participants potentially eligible for and interested in the study by conducting initial patient evaluations and referring patients to an on-site study coordinator who explained the study protocol, confirmed eligibility, and obtained informed consent.

We invited patients to participate if they had acute pain syndromes that did not require medical intervention beyond pain management strategies, as diagnosed by the attending ER physician. We excluded persons if they were unwilling or unable to participate in study treatment and follow-up, admitted to the hospital for care, pregnant, or nursing, unable to give informed consent, allergic to adhesive tape, gold, or other needle components, or if they required medical intervention other than pain management. Approximately 40% of eligible patients screened agreed to participate.

Randomization

We used a computerized random number generator to develop a simple block randomization schedule and prepared a set of sealed, numbered opaque envelopes containing the randomization sheets. We determined treatment group assignment by selecting the next envelope in sequence. We put both the numbered envelopes and the numbered randomization sheets in the patient chart and later compared them to the original randomization schedule as a quality assurance measure. We randomized 50 participants into each group over a period of 3 months.

Treatment Protocol

All participants in the study had access to emergency medical care, including prescription medications and other appropriate treatments. We asked patients to complete the study forms in the ER, receive a follow-up telephone interview, and record medication use for 24 hours in a medication diary. After obtaining informed consent to enter the study, we collected basic demographic data, including date of birth, race, ethnicity, gender, and marital status.

Standard Medical Care Group

Participants randomized into the standard medical care group had a visit from the acupuncturist who asked how they were feeling and encouraged them to get up and walk around their hospital room as a distraction from the pain. The acupuncturist then placed a small adhesive bandage on the lower lobe of each ear in an attempt to blind other ER personnel regarding study group assignment.

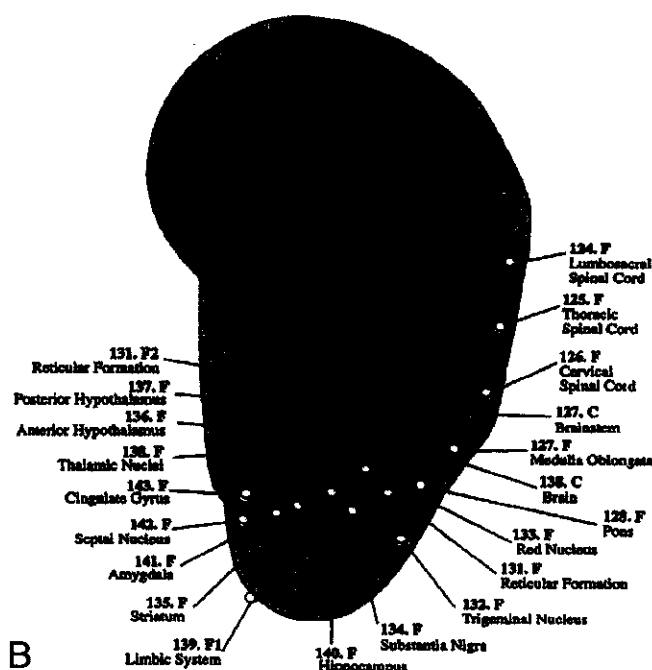


Fig. 1. (A) SEDATELEC ASP auricular acupuncture needles. (B) Auricular acupuncture points. *, Points used in this study: cingulate gyrus (143 F) and thalamic nuclei (138 F). **, Black denotes points on the posterior aspect of the ear.

Acupuncture Care Group

Patients in the acupuncture group received auricular acupuncture by medical acupuncturists using sterile Aiguille Semi-Permanent (ASP) needles (SEDATELEC; Lyon, France; Fig. 1A) bilaterally at two acupuncture points, the cingulate gyrus and thalamic nuclei (Fig. 1B). Point selection was based on functional magnetic resonance imaging studies showing that the cingulate gyrus and thalamus are areas of the brain that appear to mediate acupuncture analgesia.¹⁴ In addition, R. Niemtow (personal communication) has found pain attenuation in the treatment of several hundred patients using auricular acupuncture in the cingulate gyrus and thalamic regions of the ear.

The ASP is a small needle housed within a small plastic injector that allows the acupuncturist to insert a needle in a rapid manner to decrease discomfort. ASP needles are intended for single use and manufactured in a sterile environment. After needle placement, we covered the ASP needle with a small adhesive patch to keep the needle securely in place and to prevent contamination. The needles remained in the ear for approximately 4 to 6 days before they fell out on their own. We gave patients the option of returning to the Malcolm Grow Acupuncture Clinic to have the needles removed, but no patients chose this option.

Blinding

It was not possible to blind patients or the treating acupuncturist. We placed a small, adhesive patch in the same anatomical location of the ear lobe for those patients receiving medical treatment to blind the research coordinator, outcome assessors, and other ER staff. Assessors who were blinded to treatment group conducted 24-hour telephone follow-up. We asked participants not to disclose whether or not they received acupuncture to either ER staff or during the follow-up.

Outcome Measures

The primary endpoint for the study was current level of pain, as measured using a 0- to 10-point verbal Numerical Rating Scale (NRS), before leaving the ER and again at the time of the follow-up telephone call. We chose the NRS because it has been shown to be reliable and valid in previous pain research in the ER setting, and it is easy to administer both in person and over the telephone.¹⁸

Follow-Up Measurements

We gave participants NRS forms in an opaque envelope with their study identification number and the date written on the outside and asked them to complete the form, put it in the envelope, seal it, and drop it off at the front desk before they left the ER. We also collected data on ER administration of medications and prescription information from the patient chart. A research assistant blinded to treatment assignment collected 24-hour follow-up data on pain via the NRS and use of medications after leaving the ER, per the participant's medication diary.

Statistical Analysis

We compared baseline characteristics between the two treatment groups using χ^2 tests for categorical variables and independent *t* test analyses for continuous variables. We performed a series of these tests to look for differences between groups on a number of relevant baseline variables, including demographic information and intensity of pain. Since the distribution of the three individual pain scores was fairly normal, we assessed changes in pain levels between baseline and follow-ups using independent *t* tests. We ran nonparametric Kruskal-Wallis tests as well to see whether consistent results would be reached as with the independent, parametric *t* test. Since the same conclu-

TABLE I
BASELINE CHARACTERISTICS

	Acupuncture Group (n = 50)	Standard Medical Care Group (n = 50)	p
Age	30.40 (9.67)	32.76 (7.45)	0.18
Gender (%)			
Female	42 (n = 21)	64 (n = 32)	0.03
Ethnicity (%)			
Non-Hispanic	96 (n = 48)	93 (n = 47)	0.61
Education level (% higher than high school)	72 (n = 36)	92 (n = 46)	0.10
Marital status (% married)	50 (n = 25)	68 (34)	0.27
Pain for <24 hours	40 (n = 20)	48 (N = 24)	0.76
Baseline pain level	6.98 (1.68)	7.78 (1.84)	0.03

Data are expressed as frequencies or means (SD).

sions were reached with both tests, we assessed all outcome measures of pain administered at baseline, immediately after treatment, and at 24-hour follow-up assessment using the independent *t* test analysis and the intention-to-treat principle. We calculated effect sizes by taking the difference between the mean changes in pain in the intervention group and those in the standard care group and dividing it by the SD of the change score in the total population.

Results

Baseline characteristics across the two groups were similar (Table I). The only exceptions were the distribution of females across groups and baseline pain levels. There was no difference between how males and females reported their pain and pain differences; therefore, gender was not a confounding factor. SF-8 survey responses showed that the acupuncture group reported better health at baseline compared to 1 year ago than the standard care group, but this difference did not confound the pain variable ($p = 0.50$). Regression analysis showed that only 7% of the variation in changes in pain from baseline to follow-up was explained by differences in baseline characteristics, with each individual variable nonsignificant. Therefore, baseline data that was different across groups did not significantly affect the outcome.

We found a statistically significant difference ($t = 7.40$, mean difference = 2.18, 98 df, $p < 0.0005$) between groups regarding change in pain levels while in the ER. Participants in the acupuncture group experienced a 23% reduction in pain, compared to those in the standard medical care group, whose pain levels remained basically unchanged (Table II). Both groups experienced a reduction in pain 24 hours following treatment in the ER. Participants in the acupuncture group showed a 3.4 point

decrease on the NRS, while participants in the standard care group showed a decrease of 3 points. This difference was not significant ($t = 0.67$, mean difference = 0.368, 82 df, $p = 0.50$). The most common acute pain complaints were pain in the lower back (27%), lower extremities (13%), head (9%), and neck (8%).

The effect size for the difference between pre- and post-ER visit between groups was $d = 1.50$, while the effect size for the difference between pre-ER visit and 24-hour follow-up between groups was $d = 0.15$.¹⁹

We lost 13% of the 100 participants who entered the study to follow-up at 24 hours. Of the patients that we were able to reach at 24-hour follow-up, 19% reported that they did not get a prescription at the hospital. Eight percent of the patients reported that they had not gotten their prescription filled if one was prescribed. There was no difference between the two groups on frequency of taking the medication ($p = 0.783$) or whether medication was prescribed ($p = 0.712$). The standard care group reported having more pain at all three administrations of the NRS: preintervention ($t = -2.28$, mean difference = 0.80, 98 df, $p = 0.03$), postintervention ($t = -6.99$, mean difference = 2.980, 98 df, $p < 0.0005$), and at 24-hour follow-up ($t = -2.02$, mean difference = 1.20, 82 df, $p = 0.05$). Some of the descriptive data showed that this group seemed to be more bothered by emotional problems and their general health was worse now compared to a year ago than the acupuncture group.

It appeared that participants with graduate-level education were more likely to report no improvement; in fact, the only two patients who reported getting worse after treatment were in this category. Participants at the high school graduate level were more likely to report some improvement. By increasing the sample size in subsequent studies, we suspect the effects from differences in education level will be muted.

TABLE II
RESULTS

	Intervention Group	n	Mean	SD	Mean Difference between Groups	p
Difference in pain between pre- and post-ER	Acupuncture group	50	2.330	1.999	2.18	0.000
	Standard care group	50	0.150	0.591		
Difference in pain between pre- and 24-hour follow-up	Acupuncture group	41	3.415	2.32	0.368	0.503
	Standard care group	43	3.047	2.68		

Discussion and Conclusions

Our experience in this pilot study showed that placing small needles in two easily administered ear acupuncture points appeared acceptable to patients and seemed to decrease pain levels during their ER stay. Thus, this minimally invasive therapy may be an effective adjunct to standard emergency care for acute pain syndromes. The simple use of small needles placed in the cingulate gyrus and thalamic areas of the ear are a novel therapeutic means that may prove useful as an immediate pain treatment or a narcotic substitute. At \$1.52 per patient, this is certainly an affordable therapy to practice and research.

This treatment approach may also be acceptable in a battlefield setting, as many combat environments permit needle insertion into the ear. Although auricular acupuncture can be easily administered by a trained practitioner, further research should investigate whether it could be self-administered and/or whether accurate needle placement could be achieved via the buddy system on the battlefield. Future research is needed to explore determinants of auricular acupuncture's utility as an adjuvant pain therapy in battlefield medicine.

Since this was a pilot study, a full-scale randomized trial using sham acupuncture is an important next step. Future studies must evaluate long-term pain control, investigate relapse rate, and explore whether acupuncture can be used as a substitute for prescription pain medications. Another area that merits further research is investigating the underlying neurophysiological mechanisms by which the cingulate gyrus and the thalamic areas of the ear could be pathways to pain attenuation.¹⁴

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