Out-of-hospital Auricular Acupressure in Elder Patients with Hip Fracture: A Randomized Double-Blinded Trial

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Abstract

Objectives: Auricular acupressure is known to decrease the level of anxiety in patients during ambulance transport. The purpose of this randomized, double-blind, sham control study was to determine whether auricular acupressure can decrease not only the level of anxiety but also the level of pain in a group of elder patients with acute hip fracture.

Methods: With the assistance of the Vienna Red Cross, 38 patients with acute hip fracture were enrolled into this study. Patients were randomized into two study groups: the true intervention group and the sham control group. Subjects in the true intervention group (n = 18) received bilateral auricular acupressure at three auricular acupressure points for hip pain. Patients in the sham group (n = 20) received bilateral auricular acupressure at sham points. Baseline demographic information, anxiety level, pain level, blood pressure, and heart rate were obtained before the administration of the appropriate acupressure intervention. The level of anxiety, level of pain, hemodynamic profiles, and level of satisfaction were reassessed once the patients arrived at the hospital.

Results: Patients in the true intervention groups had less pain (F = 28, p = 0.0001) and anxiety (F = 4.3, p = 0.018) and lower heart rate (F = 18, p = 0.0001) on arrival at the hospital than did patients in the sham control group. As a result, the patients in the true intervention group reported higher satisfaction in the care they received during the ride to the hospital.

Conclusions: The authors encourage physicians, health care providers, and emergency rescuers to learn this easy, noninvasive, and inexpensive technique for its effects in decreasing anxiety and pain during emergency transportation.

ACADEMIC EMERGENCY MEDICINE 2006; 13:19–23 © 2006 by the Society for Academic Emergency Medicine

Keywords: ear acupressure, anxiolysis and analgesia, hip fracture

Hip fractures in elders are associated with significant morbidity and mortality. A study from the United States indicates that hip fractures reduced the average life expectancy by six years as compared with an age- and gender-matched general population.[1] In fact, the estimated lifetime cost for all hip fractures in the United States has been reported to exceed $20 billion. About 72% of patients with hip fracture reported moderate to serve pain, but only 56% received analgesics.[2] Therefore, it is important not only to prevent the occurrence of hip fractures but also to appropriately manage fractures that have occurred.

In central Europe, ambulances are dispatched with paramedic personnel but without physicians for all patients who have hip fractures with reported pain of <9 on a visual analog scale (VAS) with a range of 0–10. The paramedic personnel are not allowed to administer any pharmacologic interventions or perform any invasive procedures without the presence of a physician.[3] As a result of this policy, many elder patients with hip fractures experience significant pain and anxiety during the ambulance transport to the hospital.[4] It is well documented that

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Received February 6, 2005; revision received June 26, 2005; accepted July 5, 2005.

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doi: 10.1197/j.aem.2005.07.014
ISSN 1069-6563
PII ISSN 1069-6563583

these pain and anxiety symptoms provoke a sympathetic response that leads to tachycardia, hypertension, arteriolar vasoconstriction, reduced wound perfusion, and decreased tissue partial pressure.[5] This sympathetic response is particularly harmful in elders, where it may lead to cardiovascular instability and contribute to major morbidity and mortality. Thus, there is an urgent need for the introduction of nonpharmacologic interventions that can be applied by paramedic personnel to elder patients during transport to the hospital.

Previously, nonpharmacologic interventions such as local warming were found to be effective treatments for nausea, vomiting, and pain during ambulance transport.[6,7] Our research team also demonstrated that auricular acupressure, performed in an out-of-hospital setting, is effective for the management of anxiety in patients with minor injury and medical illnesses.[8,9] In this follow-up investigation, we explored the role of auricular acupressure as an out-of-hospital treatment for elder patients with hip fractures. Because various auricular points represent various parts of the human body, the selection of specific auricular acupressure points is needed as a treatment for various organs involved by the disease. We therefore designed a prospective, randomized, sham control trial to determine whether ear acupressure at three specific preselected auricular acupressure points can decrease pain and anxiety for elder patients with hip fractures.

METHODS

Study Design

This randomized controlled study was conducted on consecutive elder patients who had sustained hip fractures and were transported to the hospital by ambulance. The institutional review board approved the study protocol, and informed consent was obtained from all subjects.

Study Setting and Population

Included patients were aged 80–95 years, American Society of Anesthesiologists physical status II–III, who sustained an isolated hip fracture without any additional trauma. A minimum age limit of 80 years was set because the rate of hip fractures in patients older than 80 years was 25% greater than that in younger populations.[2] Patients were transported to local hospitals by ambulances staffed by paramedics. The primary outcomes of the study were anxiety and pain level, as determined by psychological and physiologic measures. Subjects were randomly assigned to receive either true auricular acupressure (true intervention group) or sham auricular acupressure (sham control group). A repeated-measures design was used, in which each subject's pain and anxiety were evaluated before and after the auricular acupressure intervention. We excluded all patients who were not fluent in German, patients with ear deformity, patients with severe neurologic or psychiatric disorders, and patients who take sedatives or analgesics on a long-term basis.

Measures

VAS. This is a self-reported scale commonly used to assess different levels of various conditions that a person experiences. The scale consists of a 100-mm line that represents the extremes of symptoms at either end of the continuum, ranging from 0 to 100. In this study, we used this scale to assess the level of pain, anxiety, and satisfaction with treatment. These were rated as follows: a VAS-Pain with 0 represents "no pain" and 100 represents "extreme pain," a VAS-Anxiety with 0 represents "not anxious" and 100 represents "extremely anxious," and a VAS-Satisfaction with 0 represents "not satisfied" and 100 represents "extremely satisfied."

Blood Pressure and Heart Rate. The cardiovascular system is highly responsive to a variety of psychological and behavioral states. Both heart rate and blood pressure have been widely used as dependent variables in behavioral studies designed to alter levels of anxiety and are frequently cited as physiologic indices of stress in psychology, aviation medicine, and anesthesia.

Study Protocol

Once a potential study subject was identified by a telephone triage system, two paramedics, paramedic T (treatment) and paramedic D (data collection), were dispatched to care for the patient. All patients were treated according to the guidelines of the Austrian Red Cross Ambulance Service. These guidelines are accepted as the basis of paramedical education in Austria. Once the paramedics arrived at the site of the accident and provided "standard of care" management, patients were invited to participate in the study. After obtaining written informed consent, paramedic T (treatment) left the immediate site of the accident and paramedic D (data collection) obtained baseline data on demographic characteristics and hemodynamic parameters (blood pressure and heart rate). The patient also completed the pain and anxiety VAS before the acupressure intervention. During evaluation, patients lay on a stretcher and completed the VAS on a piece of paper.

After paramedic D performed the baseline assessments, paramedic T opened a sealed envelope to determine the patient's group assignment and performed the assigned intervention accordingly. With paramedic D not present in the immediate area, paramedic T performed the auricular acupressure based on group assignment.

True Intervention Group. Subjects in this group received bilateral auricular acupressure at three auricular acupressure points for hip pain (Figure 1). All acupressure was performed with 1-mm acupressure plastic beads covered with an opaque ear patch to secure the locations of the beads. All acupressure beads were secured during the ambulance ride to the hospital.

Sham Control Group. Subjects in this group received bilateral auricular acupressure at a sham point. A sham point is defined as an acupuncture point that is not documented to have any pain-reducing or anxiolytic effect. The sham acupuncture point of this study is located at the tip of the concha and is reported to achieve homeostasis of the stomach (Figure 1).

To minimize bias, paramedic T was not told that he was performing a true or a sham intervention. Instead, he was instructed that the aim of this study was to compare

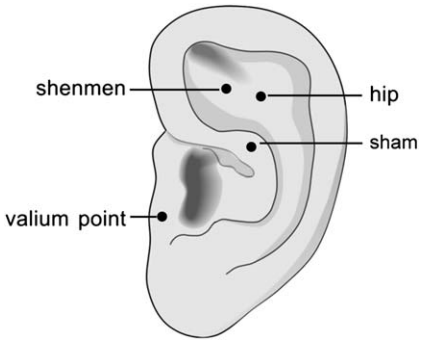

Figure 1. Acupressure points used in the study.

acupressure intervention using two groups of ear points. None of the paramedics involved in the study had knowledge about or were experienced with acupressure or similar treatments. To ensure the accuracy of treatment performance, paramedic T was intensively trained by a physician with experience in acupressure and acupuncture at the University Hospital of Vienna. Paramedic T was trained to identify the four ear points used in this study and to ensure the standardization of applying the pressure beads. He was not instructed which point had any specific effect.

Following the administration of the intervention, paramedic T covered the ears of all subjects with ear patches. This was done to assure blinding of paramedic D, who was involved in the outcome assessment. The patient was next moved to the ambulance. To maintain blinding, paramedic D sat in the front of the ambulance, while paramedic T stayed with the patient in the back (sections of the ambulance are separated by a rigid wall). On arrival at the hospital, paramedic D reassessed pain, anxiety, and satisfaction outcomes without the presence of paramedic T. Finally, the completed datasheets were put into opaque envelopes and sealed by paramedic D to ensure complete blinding.

It is important to note that great care was spent on ensuring that either treatment or data collection was performed in absence of the other paramedic. The design of the ambulance provides no possibility for paramedic D to be aware of the auricular acupressure intervention during transport. To ensure that the blinding system was maintained and that the treatment was performed accurately, a physician otherwise not involved in data collection or treatment performed ten on-site audits of the methodology and data collection.

Data Analysis

Based on previous investigations,[8] a sample size of 18 subjects in each group was required to detect a decrease of 25% in anxiety and pain equal to the difference of one standard deviation (effect size = 1) with a power of 80% and an α of 0.05. Normally distributed data are presented as mean (±SD). Baseline characteristics of the two groups were analyzed using Student's t-test for continuous data and chi-square test for categorical analysis. Two-way repeated-measures analysis of variance was used to analyze the changes in anxiety, pain, and physiologic parameters (heart rate, systolic blood pressure, diastolic blood pressure) at two different times (baseline and on arrival at the hospital). Comparisons were considered significant if $p < 0.05$. Analysis was conducted using SPSS (version 10.0; SPSS Inc., Chicago, IL).

RESULTS

A total of 38 patients with a hip fracture, transported to the hospital by ambulance with paramedics only, participated in this study (Figure 2). The mean (±SD) age of participants was 86.2 (±4.2) years (range, 80–94 years). The participants were randomly placed into two groups (true intervention and sham control groups). There were 18 patients in the true intervention group and 20 patients in the sham control group. There were no differences in the demographic data and baseline pain, anxiety, and hemodynamic parameters (Tables 1 and 2). The out-of-hospital time of transportation was also comparable in both groups: 29 ± 12 minutes (true intervention) versus 32 ± 15 minutes (sham control).

A two-way repeated-measures analysis of variance performed for anxiety demonstrated a significant time effect ($p = 0.001$) and a group × time interaction ($F = 4.3$, $p = 0.018$), showing a change in anxiety scores based on time and group assignment. Subjects who received acupressure as the true intervention group had significantly lower anxiety scores on arrival at the hospital as compared with individuals who received the sham control intervention (Figure 3). Similarly, a two-way repeated-measures analysis of variance that examined the levels

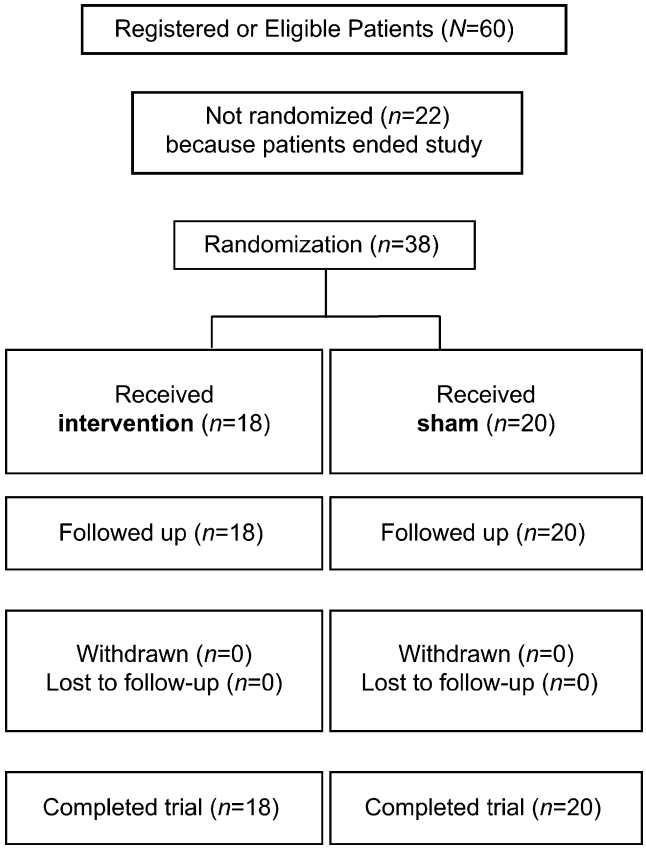

Figure 2. Consolidated standard for reporting clinical trials: CONSORT flow diagram.

Table 1
Baseline Demographic Data

	True Intervention	Sham Intervention
Age, mean ± SD (yr)	86.5 ± 4.0	86.0 ± 4.8
Body weight, mean ± SD (kg)	69.9 ± 17.3	67.0 ± 15.3
Gender		
Male	3	2
Female	15	18
Side of fracture		
Right	10	11
Left	8	9
Type of fracture		
Femoral neck	9	11
Intertrochanteric	9	9

of pain found a time effect ($p = 0.0001$) and a group × time intervention ($F = 28$, $p = 0.0001$). That is, subjects in the true intervention group experienced significantly less pain on arrival at the hospital (Figure 4).

Similar to pain and anxiety scores, subjects in the true intervention group were found to have lower heart rate on arrival at the hospital ($F = 18$, $p = 0.0001$). Interestingly, there were no differences in systolic blood pressure (repeated measure, $F = 3.1$, $p = 0.093$) and diastolic blood pressure ($F = 0.9$, $p = 0.34$) between the true intervention and sham control groups.

DISCUSSION

Under the conditions of this study, we found that auricular acupuncture applied at three specific points is effective in reducing pain and anxiety in elder patients who have sustained a hip fracture. These findings are significant in Austria because elder patients are typically transported to the hospital in an ambulance without a physician, and thus no pharmacologic intervention can be used.

In Europe, millions of patients are transported to hospitals every year by ambulances that may be staffed either by paramedics alone or by paramedics and a physician. Because paramedics are not allowed to administer medications during ambulance transport, many of these patients experience significant anxiety and pain during this period. Over the past few years, our collaborative research team has focused on identifying various interventions that are not only nonpharmacologic and easy to apply, but also effective in reducing anxiety and pain.[6–9] Our results indicate that ear acupressure performed by paramedics reduces pain and anxiety in a group of elder patients with hip fracture. Interestingly, the average heart rate of patients in the true intervention group was significantly lower than the average heart rate of those in the sham control group. This is of importance because increased heart rate leads to increased myocardial oxygen demands. In an elder patient population that may have an underlying coronary disease, this sudden increase in myocardial oxygen demand may lead to detrimental effects.

Table 2
Hemodynamic Data

	True Intervention	Sham Intervention
Systolic BP (mmHg, mean ± SD)		
Before	124.9 ± 12.2	124.7 ± 7.4
After	119.7 ± 18.8	126.4 ± 19.5
Diastolic BP (mmHg, mean ± SD)		
Before	74.3 ± 9.4	78 ± 7.7
After	72.5 ± 12.9	80.7 ± 13.3
Heart rate (bpm, mean ± SD)		
Before	95.4 ± 8.3*	92.3 ± 11.7
After	72.5 ± 9.4	90 ± 8

* $p = 0.0001$.

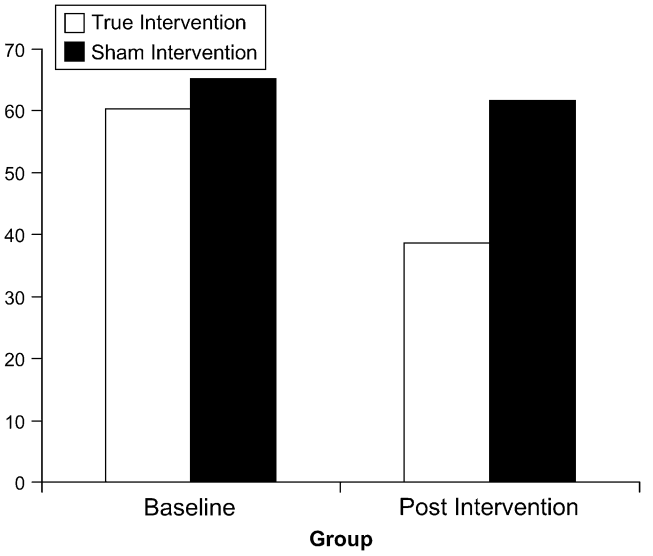

Figure 3. Visual analog scale values for anxiety. True intervention differs from sham intervention significantly ($p < 0.001$).

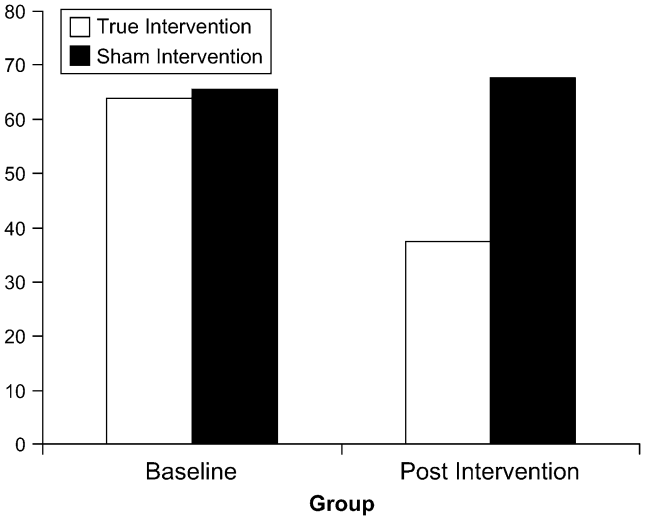

Figure 4. Visual analog scale values for pain. True intervention differs from sham intervention significantly ($p < 0.001$).

The potential mechanism for the effectiveness of auricular acupressure may be similar to that which has been documented in the acupuncture literature. Stimulating a particular point with either a needle or pressure can activate small myelinated nerve fibers that send impulses into the spinal cord, midbrain, pituitary, and hypothalamus[10] and cause a measurable release of endorphins into blood.[11] Besides this, various neurotransmitters such as serotonin, norepinephrine, and possibly γ-aminobutyric acid are known to interrupt incoming stress signals in the central nervous system.

Patients in the true intervention group reported being more satisfied with the care they received during the ride to the hospital. One interesting observation noted in our study is that patients in the sham control group also reported being relatively satisfied with the care they received during transportation. With the addition of this simple, inexpensive technique, the quality of care given to this patient population in the out-of-hospital setting has significantly improved. The cost of ear acupressure is minimal (3 cents per patient), but the benefit may be enormous (lower heart rate, less pain, and less anxiety). Currently, there is an increased emphasis on patients' satisfaction as an important component within the general medical literature and the health care industry.

Finally, over the recent years, more and more data have indicated that the use of a nonpharmacologic, noninvasive intervention is beneficial for out-of-hospital relaxation and analgesia in patients with illnesses or trauma.[6–9] However, not every nonpharmacologic, noninvasive intervention is suitable for every condition encountered during ambulance transport. For example, traditional body acupressure technique requires undressing the patients, which may not be feasible for those patients who have sustained hip fractures.

LIMITATIONS

Our trial could not compare the effect of analgesic drugs (e.g., nonsteroidal anti-inflammatory drugs or opioids) with acupressure due to the legal limitations on out-of-hospital emergency care in central Europe. Further research is needed to analyze if drug-based analgesia or acupressure is more effective in acute out-of-hospital trauma care.

It would have been interesting to see the potential effects of acupressure in the early hospital phase (e.g., during primary radiograph investigation). Our trial design could not assess these effects due to the lack of human resources for an intrahospital follow-up. In the future, research projects dealing with out-of-hospital analgesia should focus on the early "posttransport phase" of trauma care.

CONCLUSIONS

We found that auricular acupuncture applied at three specific points is effective in reducing pain and anxiety in elder patients who have sustained a hip fracture. We encourage clinicians and ambulance personnel to learn this simple technique and implement this technique in their routine clinical care. Future studies should also focus on the effect of this intervention on the overall outcome of the patients and the basic mechanism of ear acupressure in decreasing pain and anxiety.

The authors thank the emergency dispatchers of the Vienna Red Cross who strongly supported this study.

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