Battlefield acupuncture to treat low back pain in the emergency department

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A B S T R A C T

Introduction: Battlefield acupuncture (BFA) is an ear acupuncture protocol used by the military for immediate pain relief. This is a pilot feasibility study of BFA as a treatment for acute low back pain (LBP) in the emergency department (ED).

Methods: Thirty acute LBP patients that presented to ED were randomized to standard care plus BFA or standard care alone. In the BFA group, outcomes were assessed at the time of randomization, 5 min after intervention, and again within 1 h after intervention. In the standard care group outcomes were assessed at the time of randomization and again an hour later. Primary outcomes included post-intervention LBP on a 10-point numeric pain rating scale (NRS) and the timed get-up-and-go test (GUGT). F-test and chi square tests were used to compare differences between groups demographics to evaluate randomization, and Analysis of Covariance (ANCOVA) was used to assess differences in primary/secondary outcomes.

Results: We randomized 15 patients to BFA plus standard care, and 15 patients to standard care alone. Demographics were similar between groups. Post-intervention LBP NRS was significantly lower in the BFA group compared with the standard care group (5.2 vs. 6.9, ANCOVA p = 0.04). GUGT was similar between groups (21.3 s vs. 19.0 s, ANCOVA p = 0.327). No adverse events from acupuncture were reported.

Discussion: This pilot study demonstrates that BFA is feasible as a therapy for LBP in the ED. Furthermore, our data suggest that BFA may be efficacious to improve LBP symptoms, and thus further efficacy studies are warranted.

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1. Introduction

1.1. Background

There are more than 2.5 million emergency department (ED) visits for low back pain each year, and opioid pain relievers are prescribed at more than 60% of those visits [1]. Opioid prescribing for acute low back pain is associated with a dose-dependent increased risk for surgery and longer duration of disability, [2] as well as the development of chronic opioid use [3]. Chronic prescription opioid use exposes patients to risk of addiction, overdose, and death.

Acupuncture has been used to treat pain for thousands of years. Research on ear acupuncture has demonstrated positive results for acutely painful conditions in a variety of settings [4] including the ED [5, 6]. Unlike opioids, acupuncture has an excellent safety profile [7].

In an effort to decrease problematic opioid use among wounded soldiers and veterans, the United States military has implemented an ear acupuncture protocol called Battlefield Acupuncture (BFA) [8]. BFA has been taught to military physicians as well as medical professionals with no prior training in acupuncture, and has been widely implemented at US Department of Defense and Veterans Affairs hospitals [8]. BFA involves the placement of small, semi-permanent acupuncture needles at 5 pre-specified points in the ear [9]. The needles resemble studs, are placed with an easy-to-operate individual use applicator, and can be left in place for several days. Patients can engage in their regular daily activities while the needles are in place. The needles can be removed at any time by grasping the end of the needle and gently pulling.

1.2. Importance

The United States is in the midst of an opioid epidemic [10]. By prescribing opioids for low back pain, emergency providers expose patients to increased risk of disability and death, [2, 3] with little evidence of long-term benefit [10]. Safer options for acute pain relief are needed. BFA is used in the US military to treat acute painful conditions with

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the intention of reducing opioid use, and may be a useful tool for pain relief in the civilian setting as well. However, more research is needed to on the use of this military protocol for pain relief in the civilian acute care setting.

1.3. Goals of this investigation

This pilot study seeks to examine the feasibility and efficacy of BFA to treat low back pain in the ED. The study hypothesis is that ear acupuncture will improve pain and mobility of patients that present with low back pain to the ED, and that the modality would be feasible for providers to administer in the ED.

2. Methods

2.1. Study design

This was an IRB-approved, randomized controlled trial of ear acupuncture plus standard care compared with standard care alone to treat low back pain in patients that presented to an ED. The trial was registered at Clinicaltrials.gov with registration number NCT02399969.

2.2. Study setting and population

This study was conducted in the ED of an urban academic medical center. Research assistants identified participants with chief complaint of “low back pain” and assessed them for eligibility for participation. Individuals over the age of 18 that presented to the ED with the chief complaint of low back pain were eligible. This population included subjects with both acute and acute-on-chronic low back pain. The exclusion criteria were as follows: significant trauma with concern for possible spinal cord injury, new weakness or neurologic deficit, new loss bowel/bladder control, back pain above T12, history of active cancer, currently taking anticoagulant medications, temperature > 38 °C, probable urinary tract disease, pregnancy.

2.3. Study protocol

Subjects were randomized to standard care alone or standard care plus BFA. Simple randomization occurred by placing group allocation into opaque, unmarked envelops which concealed group assignment; these envelops were then shuffled to generate a random sequence. Standard care was provided at the discretion of the treating physician. The patients randomized to receive BFA received the treatment according to the protocol described in the US Air Force Acupuncture Center’s Battlefield Acupuncture Protocol Book [9]. The procedure involves placement of ASP indwelling semi-permanent needles in up to 5 pre-specified points on the ear, corresponding with established auricular acupuncture points. The needles were placed in the following order: 1. cingulate gyrus, 2. thalamus, 3. omega 2, 4. point zero, and 5. shen men. Treatments were provided by physicians trained in administering the procedure under the supervision of a certified physician-acupuncturist. An example of the needles used in this study and an illustration of the 5 pre-specified ear acupuncture points can be seen in Figs. 1 and 2.

2.4. Measures

In both groups, baseline measurements were taken at the time of randomization. In the standard care alone control group, measurements were repeated an hour later. In the BFA group, measurements were repeated 5 min after treatment with BFA, and again an hour after receiving the BFA treatment. Data was collected by research assistants that were not blinded to group assignment.

Primary outcomes were:
1. Timed get up and go test (GUGT): Time (seconds) that a person takes to rise from a chair, walk three meters, turn around, walk back to the chair, and sit down. If a person could not get up in 30 s to ambulate, the test was stopped.
2. Numeric rating scale (NRS) for back pain: Patients were asked “On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your back pain right now?”

Secondary outcomes were:
1. NRS for pain radiating to leg
2. Range of motion (ROM) of the lumbar spine: Active ROM (Flexion and Extension) was measured using a goniometer
3. Length of stay (LOS): research assistants extracted LOS data after discharge.
4. Medications before and during the visit: research assistants surveyed patients regarding medications taken prior to the ED visit, and extracted from the medical record the medication administered during the ED visit.
5. Safety Outcomes: Patients were asked to report any adverse events noted during or after the procedure. If the placement of the acupuncture needles was too painful for a patient to tolerate then the needle was removed and this was noted.

Fig. 1. Gold ASP needle.
2.5. Data analysis

We evaluated whether BFA or standard therapy was best at improving timed up and go (GUGT, seconds), low back pain (LBP, 0–10), leg pain (Leg, 0–10), lumbar flexion (Flex, degrees) and lumbar extension (Ex, degrees) using Analysis of Covariance (ANCOVA). ANCOVA was set up as follows:

(a) post-intervention value as the dependent variable;
(b) the standard control and BFA as levels of the independent variable, group; and
(c) the pre-intervention values as the covariate.

Patients that were not able to tolerate the placement of all the needles or had needles removed prematurely were included in the intention-to-treat analysis.

3. Results

3.1. Characteristics of study subjects

Screening, inclusion, and exclusion of subjects is summarized in the CONSORT diagram (see Fig. 3). We randomized 30 patients to standard therapy alone or BFA plus standard therapy, with 15 patients per group. 4 standard therapy patients and 1 BFA patient dropped out prior to post-intervention data collection. Baseline characteristics of subjects are outlined in Table 1. There were no significant differences between groups in terms of demographics and ED length of stay. 20% of patients reported taking opioid analgesics prior to arrival to the ED (2/15 in BFA group and 4/15 in standard care group). 7/15 patients in the BFA group and 7/15 patients in the standard care group received opioid medications during their ED visit.

3.2. Study outcomes

Primary and secondary outcomes are summarized in Table 2. Post-intervention LBP was significantly lower in the BFA group compared with the standard care group (5.2 vs. 6.9, ANCOVA p = 0.04). GUGT
was similar between groups (21.3 s vs. 19.0 s, ANCOVA \( p = 0.327 \)). Flexion (49.8 vs. 48.2, Extension (22.8 vs. 18.1), and Leg pain (1.4 vs. 2.2) were all better in the BFA group, but these did not achieve statistical significance.

Two BFA patients complained of discomfort at needle insertion site, but there were no serious adverse events from acupuncture.

4. Discussion

4.1. Significance

This was a pilot study to test the feasibility of the military’s BFA protocol in a civilian ED setting. BFA was feasible for use in the ED setting as an adjunct to standard care for low back pain. The BFA procedure was well-tolerated by patients and did not interfere with standard ED care.

This study was conceived in response to the growing opioid crisis in the United States. Consistent with previous research, subjects in this study were frequently administered opioid medications both during their ED visit. Because the opioid crisis continues to worsen, the CDC recently recommended limiting opioid prescribing and using non-opioid and non-pharmacologic treatments as first line therapies for chronic painful conditions [10]. Emergency physicians rarely use non-pharmacologic treatments in the management of acute pain. This study explores the possibility of using a non-pharmacologic modality to treat pain in the acute care setting, in order to provide alternatives to opioid pain relievers.

4.2. Limitations

This study had a small sample size and was not powered to definitively detect clinical outcomes. Neither the patients nor the assessors were blinded, introducing bias. We were not able to perform an intention-to-treat analysis on patients that left prior to the final assessment. Acupuncture was available during limited hours, which slowed enrollment. Some patients had already seen a physician or received some form of treatment prior to inclusion in the study. Enrollment later in the encounter, as well as discomfort related to performing GUGT and ROM measurements may have contributed to the loss-to-follow-up in this study.

4.3. Conclusions

This pilot study demonstrates that BFA is feasible as a non-pharmacologic complement to standard care for LBP in the ED. BFA may be efficacious to improve LBP and lumbar range of motion. The BFA protocol warrants further study with larger, blinded, randomized controlled trials in order better elucidate the efficacy of this treatment modality in civilian acute care settings.

Prior presentations

Randomized Trial of Acupuncture vs. Standard Therapy to Treat Low Back Pain in The Emergency Department, American College of Emergency Physicians Scientific Assembly Las Vegas, NV, October 17, 2016.

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None.

Conflict of interest

The authors have no conflicts of interest to report.

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