The Effectiveness of Battlefield Acupuncture in Addition to Standard Physical Therapy Treatment after Shoulder Surgery: A Protocol for a Randomized Clinical Trial

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Study protocol

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Abstract

Introduction: There is a large incidence of shoulder instability among active young athletes and military personnel. Shoulder stabilization surgery is the commonly employed intervention for treating individuals with instability. Following surgery, a substantial proportion of individuals experience acute post-operative pain, which is usually managed with opioid pain medications. Unfortunately, the extended use of opioid medications can have adverse effects that impair function and reduce military operational readiness, but there are currently few alternatives. However, Battlefield Acupuncture (BFA) is a minimally invasive therapy demonstrating promise as a non-pharmaceutical intervention for managing acute post-operative pain.

Methods: This is a single-blind randomized clinical trial featuring a 2x5 mixed-model factorial design. The two independent variables are intervention (2 levels; standard physical therapy and standard physical therapy plus Battlefield Acupuncture) and time (5 levels; 24-hours, 48-hours, 72-hours, 1-week, and 4-weeks post shoulder stabilization surgery). The primary dependent variable is worst and average pain as measured on the Visual Analog Scale. Secondary outcomes include medication usage, Profile of Mood States, and Global Rating of Change.

Discussion: The magnitude of the effect of BFA is uncertain; current studies report confidence intervals of between group differences that include MCIDs between intervention and control groups. The results of this study may help determine if BFA is an effective adjunct to physical therapy in reducing pain and opioid usage in acute pain conditions.


Background

Shoulder and glenohumeral instability are a serious problem for athletes and military personnel[1–6]. These younger, more active populations are at high risk for glenohumeral instability with military personnel sustaining shoulder dislocations at a greater rate compared to the overall United States (U.S.) population (3.13 per 1,000 person years)[2, 7, 8]. The risk of shoulder dislocation is greater still at Military Service Academies with an incidence of 4.35 per 1,000 person years[5]. Management of these injuries generally consists of shoulder stabilization surgery, often resulting in acute post-operative pain which is treated with opioid pain medications. Extended use of opioids for pain management present potential health risks and produce a myriad of side effects that adversely affect readiness. Unfortunately, there are no widely accepted alternatives or integrative therapies to prescription opioids for acute post-surgical pain management.

Shoulder stabilization surgery is the “gold standard” for treatment of shoulder dislocation in young, active patients[4, 9–11]. This type of orthopedic surgery is associated with excellent short-term results and good long-term maintenance of shoulder function after chronic, unidirectional, and traumatic dislocation[4, 9–11]. However, as many as 80% of patients who undergo orthopedic surgery experience acute post-operative pain, which acutely impairs physical function and is a risk factor for the development of persistent pain[12]. Given the number of military personnel undergoing shoulder stabilization surgery, and the debilitating effects of post-operative pain, non-pharmaceutical strategies to decrease post-operative pain are warranted.

Opioid prescription is the widely employed method to manage post-operative pain in Military Health Systems. The Veteran’s Administration (VA) reported the average length of post-operative opioid use in post-surgical patients as 15 days[13]. Prolonged use of opioids post-surgery presents a possible health risk for dependence and side effects such as drowsiness and impaired cognition, leading to necessary duty limitations that affect operational readiness. However, there are currently few alternative pain management options. Thus, alternative and/or integrative methods of treating acute and chronic post-surgery pain without readiness reducing side-effects are needed.
Battlefield Acupuncture (BFA), an auricular acupuncture protocol developed to treat acute and chronic pain in austere environments[14], may provide an integrative pain treatment option to decrease prescription medication usage for a myriad of musculoskeletal conditions[15–18]. The Technique was taught and adopted throughout all branches of the Department of Defense (DoD) over the past two decades in an effort to provide alternatives to side effect laden prescription medications[18]. Despite wide-scale adoption by military medical providers, there is inconsistent evidence of BFA’s effectiveness in reducing pain and opioid medication use.

In a recent systematic review, pooled results of auricular acupuncture in 458 patients included significant reductions in pain compared to a sham intervention[17]. While no adverse events were reported, medication use was also not impacted[17]. In a study of 30 patients presenting to an emergency department with low back pain, the addition of BFA to standard care resulted in significantly reduced pain when compared with standard care alone[19]. Conversely, in a study of 233 patients following lower extremity surgery, BFA applied within 30 minutes of arrival to the post-anesthesia care unit did not result in significantly reduced pain, reduced opioid use, or improved quality of life when compared with standard of care or placebo treatments[20]. Most recently, in a study of 40 U.S. Military Academy Cadets who underwent shoulder surgery, those receiving BFA 24-hours after surgery demonstrated significantly reduced worst and average pain from baseline to 1-week post-surgery, with confidence intervals that suggest promising, but not conclusive results[21].

BFA is an integrative pain treatment method that may be effective in reducing pain and opioid use post-surgery. The purpose of this study is to determine differences in pain, mood, self-reported improvement, and medication use during and after a standard physical therapy rehabilitation protocol supplemented with BFA, compared to a standard physical therapy rehabilitation protocol alone, for patients following shoulder stabilization surgery. The primary objective is to assess the effect of BFA on post-surgical pain (average and worst pain at 48-hours and 72-hours post-surgery). We hypothesize standard rehabilitation supplemented with BFA will produce greater reductions in pain compared to standard rehabilitation alone at 48-hours and 72-hours post-surgery.

Additional objectives are to assess the effect of BFA on; 1) medication use, 2) mood, and 3) self-reported improvement throughout the 4-week post-operative rehabilitation period, and 4) pain at 1-week and 4-weeks post-surgery. It is hypothesized that participants receiving standard rehabilitation supplemented with BFA will have greater reductions in medication use and improvements in patient’s self-reported mood and improvement across the 4-week post-operative follow-up period. Further, that participants receiving standard rehabilitation with BFA will have lower pain levels at 1-week, but no difference at 4-weeks post-surgery compared to those receiving standard rehabilitation only.

**Methods/design**

**Trial Design**

This study is a single-blind randomized clinical trial. All participants will complete five study sessions following surgery: 24-hours, 48-hours, 72-hours, 1-week, and 4-weeks post-surgery (Fig. 1). Participants will receive an email the day prior to each study session to promote retention and compliance. Data collection began in November 2019 and will continue for four years. All components of the study will be completed at the U.S. Military Academy at West Point, New York. The current Standard Protocol Items: Recommended for Interventional Trials (SPIRIT) guidelines for creating protocols for randomized clinical trials were followed ([Supplemental Materials][22]). Results of this trial will be reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) Statement[23] and Template for Intervention Description and Replication (TIDieR) Checklist[24].

**Participants and Study Setting**
Participants will be recruited from the population of patients presenting to the Arvin Cadet Physical Therapy Clinic and the Keller Army Community Hospital (KACH) Physical Therapy and Orthopedic Clinics prior to and status-post shoulder stabilization surgery. 105 male and female Department of Defense (DoD) beneficiaries, ages 17–55 will be recruited for the study. A 15% drop-out rate is anticipated, which will result in at least 90 patients completing the study, with 45 patients per treatment group. On average KACH orthopedic surgeons perform eight shoulder stabilization surgeries monthly, suggesting the recruitment goal is feasible.

Inclusion Criteria:

1. DoD beneficiaries age 18 to 55 years old (17 if cadet)
2. Prior to or within 24 hours post shoulder stabilization surgery
3. Self-reported pain rating of at least 2 out of 10 on a numerical pain rating scale (NPRS)

Exclusion Criteria:

1. Self-reported pregnancy
2. History of blood borne pathogens, infectious disease, or active infection
3. History of metal allergy
4. History of bleeding disorders or currently taking anti-coagulant medications
5. Participants not fluent in English

Randomization/Allocation/Blinding

Participants will be screened prior to consent as part of routine clinical care by the investigative team during the first post-operative visit, 24 hours after surgery. Those meeting criteria for inclusion will be informed as to the need and purpose of the research and invited to participate. Study participants will complete informed consent followed by a baseline examination (Supplemental Materials). Consenting participants will be randomized into one of two groups via a concealed allocation process; the control group (standard physical therapy rehabilitation) or the intervention group (BFA plus a standard physical therapy rehabilitation). Following informed consent and baseline examination, a second investigator blinded to the baseline examination will open a sealed envelope containing a folded index card labelled with the participant’s group assignment. The randomization sequence will be created with a 1:1 allocation using random block sizes of five on Excel 2010 (Microsoft, Redmond, WA, USA) by an investigator not involved with participant recruitment or data collection. Group assignment will be recorded with a unique participant identifier and secured in a separate folder until completion of all data collection through the final follow-up.

Participants and the treating physical therapists will not be blinded to group assignment. Verification of the medication log by the outcome assessor may be another source of bias. Outcome assessors who record pain, self-report function, and mood surveys, perform data reduction, and perform data analysis will be blinded to the participants’ treatment group. Participants frequently require clarification of outcome measure instructions during completion of data collection forms and may require additional assistance if the surgery is performed on their dominant extremity. Participants will interact with the outcome assessor and complete data collection forms behind a closed curtain, where the outcome assessor is not able to see the patient. Such blinding should minimize either conscious or unconscious researcher recording and reporting bias during completion and verification of the data collection forms.

Interventions

Standard physical therapy rehabilitation (active control group):
Both groups will receive standard postsurgical physical therapy (Appendix 1) with therapeutic exercises that will be focused on range of motion and muscle activation.

Battlefield acupuncture (study intervention group):

Using aseptic technique (proper hand washing, personal protective equipment (PPE), and ear cleansing with an alcohol swab), auricular acupuncture using the five points within the BFR protocol will be used until the participant reports zero to one out of 10 pain on a Numerical Pain Rating Scale (NPRS). Each ear will be punctured with ASP needles at five sequential points: Cingulate Gyrus, Thalamus, Omega 2, Point Zero and Shen-Men (Fig. 2, Appendix 2). The acupuncture sequence will begin on the same side of the shoulder surgery and begin at the Cingulate Gyrus point. Following each ASP needle placement, the participant will be asked to stand and move/walk for at least 30 seconds while being monitored for any side effects, including light headedness, dizziness/loss of balance or nausea. Self-reported current pain level will be reassessed. If the participant's pain is above zero out of 10 on the NPRS, the contralateral ear will be punctured with the ASP needle in the Cingulate Gyrus. ASP needle application will continue, alternating between ipsilateral and contralateral ears in order through the remaining four points, until a desired pain level of zero to one out of 10 is achieved.

There is no standard time for the ASP needles to remain in the participant’s ears, but they may remain up to 3–5 days as they naturally work their way out of the skin. There are no documented cases of loss of treatment effect should participants remove ASP needles premature to their natural falling off. Repeat treatment may be provided during follow-up visits and is left to the discretion of the treating physical therapist and preference of the patient. If ASP needles remain in place at follow-up visits and the patient requests additional treatment, additional ASP needles will be placed adjacent to locations used previously.

All BFA treatments will be performed by investigators trained and certified investigators on the standard BFA protocol developed by Dr. Niemtzow[14]. Participants will continue to receive the standard of care in accordance with the post-operative protocol between study follow-up visits.

Outcome Measures

Demographic characteristics will be recorded and include sex, age, ethnicity, military demographics, height, weight, and surgical history. The primary outcome measure will be pain (average and worst pain over the past 24 hours, assessed on the Visual Analogue Scales [VAS]) at 48-hours, 72-hours, 1-week, and 4-weeks after surgery. Secondary outcome measures will be medication use (opioids and non-opioid medications), patient self-reported mood (Profile of Mood States [POMS]), and patient self-reported improvement (Global Rating of Change Scale [GROC]). All participants will complete all outcome measures at five post-surgical timepoints: 24-hours, 48-hours, 72-hours, 1-week, and 4-weeks (Fig. 1).

The VAS assesses the perception of pain intensity by asking the patient to mark their level of pain along a 100 mm line, where the left limit indicates no pain and the right limit indicates the worst pain imaginable[25, 26]. The VAS is a valid and reliable measure of pain intensity [25–29] with a minimal clinically important difference (MCID) of 10 mm and patient acceptable symptoms state of 30 mm in acute, post-operative pain[28].

The POMS is a 40-item questionnaire designed to measure the transient emotional states of tension-anxiety, depression-dejection, fatigue-inertia, vigor-activity, confusion-bewilderment, and anger-hostility in sports and other settings[30]. The POMS is a valid and reliable measure of mood in athletes and sports[30, 31].

The GROC is a 15-point self-report Likert scale (-7 to + 7, with −7 equaling a very great deal worse, 0 equaling no change or improvement, and + 7 equaling a very great deal better) of patient perceived status since the onset of treatment[32].
The GROC is valid and reliable with a MCID of two points[32], although numerous studies define major improvement as five or greater.

Data Analysis

An a priori power analysis was performed using G*Power, version 3.1.9.2 (Heinrich-Heine-Universitat Dusseldorf, Dusseldorf, Germany) with \( \alpha = 0.05 \), \( \beta = 0.80 \), and an effect size of 0.6 (change in VAS worst pain between 24-hours and 1-week post-surgery), resulting in a required sample of 90 participants. The effect size was determined through examination of previously collected pilot data at the same institution[21]. To account for a potential drop-out rate of 15%, a total of 105 participants will be enrolled.

Descriptive statistics, including measures of central tendency and dispersion, will be calculated for demographic data. Frequency distributions will be estimated for categorical data. The primary aim, the effect of BFA on acute post-operative pain (average and worst pain assessed by VAS), will be examined with a 2-by-2 mixed-model analysis of variance (ANOVA), with intervention group as the between-subjects factor (BFA plus standard physical therapy rehabilitation versus standard physical therapy rehabilitation alone) and time as the within-subjects factor (48-hours and 72-hours). An additional 2-by-5 mixed-model ANOVA with intervention group as the between-subjects factor and time as the within-subjects factor (24-hours, 48-hours, 72-hours, 1-week, 4-weeks) to determine the effect of BFA on medication use, self-reported improvement (GROC), and mood (POMS) over a 4-week post-operative period. The effect of BFA on acute versus subacute post-operative pain will be assessed using a 2-by-2 mixed-model ANOVA with intervention group as the between-subjects factor and time (1-weeks and 4-weeks) as the within-subjects factor. Alpha will be set at 0.05 for all omnibus comparisons. Planned pairwise comparisons will be performed to examine the differences between baseline and follow-up periods, using the Sidak’s test to control for family-wise type I error. The Cohen \( d \) coefficient will be used to assess effect size.

When post-intervention data points are missing, data will be replaced using multiple imputation for participants who received their allocated intervention[33]. All statistical analyses will be performed with the statistical package SPSS version 26 (IBM, Chicago, IL, USA).

Discussion

BFA may be an effective adjunct to physical therapy to reduce pain and opioid utilization in patients with acute pain[17, 19, 21]. However, the magnitude of the effect of BFA is uncertain. Current studies report confidence intervals that include MCIDs between intervention and control groups, but lack blinded of outcomes assessors[17, 19, 21]. The results of this study may help determine if BFA is an effective adjunct to physical therapy in reducing pain and opioid usage in acute pain conditions.

This study is not without limitations and design constraints. The primary limitation is physical therapists and patients are not blinded to treatment groups. While comparison with a sham group may elucidate potential placebo effects associated with BFA, we elected to forgo the method due to lack of feasibility in maintaining a realistic sham treatment at our institution. However, blinding of outcomes assessors to group allocation will be conducted to minimize bias.

Trial Status

This study was approved by the RHC-A IRB; protocol ID number 19KACH0003, initially approved 3 September 2019, modification approved 28 October 2019. Recruitment began 25 September 2019 and will be tentatively completed in December 2022.

Abbreviations
Declarations

Ethics Approval and Consent to Participate

An ethics review was conducted by the Keller Army Community Hospital (KACH) Human Research Protections Office and will be monitored by the Regional Health Command – Atlantic (RHC-A) Institutional Review Board (IRB) to ensure compliance with federal regulations for the protection of human medical research subjects. This study was approved by the RHC-A IRB; protocol ID number 19KACH0003. Written informed consent will be obtained from all participants. Any adverse events resulting from participation in the study, or compromise of data security will be immediately reported by the Primary Investigator to the IRB according to established policies and procedures.

Consent for Publication

Informed consent was obtained for publication of images depicted in Figure 2 and Appendix 2 of this manuscript.

Availability of Data and Materials

The coded electronic research data for this study will be stored in Research Electronic Data Capture (REDCap), an encrypted, access controlled, password protected electronic data capture and management system housed on a DoD server and maintained by the Uniformed Services University of the Health Sciences Information Technology. Data from the study are available by email request to the lead author for the purpose of systematic review and meta-analysis.
Competing Interests

The authors completed the International Committee of medical Journal Editors (ICJME) Form for Disclosure of Potential Conflicts of Interest. They reported no conflicts of interest.

Funding

This work was supported by a grant from the Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) program at the Uniformed Services University of the Health Sciences (USUHS). USUHS/MIRROR did/will not have a role in the study design; collection, analysis, interpretation of data, and writing of the report. USUHS/MIRROR provided technical assistance with regulatory approval and data management systems. USUHS/MIRROR will have approve content of the final report submission.

Author Contributions

Table 1. Author roles and responsibilities. PI, Principal Investigator; AI, Assistant Investigator; BFA, Battlefield Acupuncture.

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<td>DLG</td>
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<td>Protocol development; data analysis; manuscript preparation</td>
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Author contributions are consistent with the Contributor Roles Taxonomy (CRediT) (docs.casrai.org/CRediT) methodology for attributing contributions.

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References


14. 10.1089/acu.2007.0603


23. 10.1186/1745-6215-11-32


Figures
### Figure 1

Proposed recruitment flow for the study along with interventions performed and outcomes collected at each post-surgical timepoint. BFA, Battlefield Acupuncture; VAS, Visual Analog Scale; POMS, Profile of Mood States; GROC, Global Rating of Change Scale; PRN, Pro Re Nata (As Needed).

<table>
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<th>GROC</th>
<th>POMS</th>
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![Figure 1](image)

### Figure 2

The five auricular acupuncture points of the Battlefield Acupuncture protocol.

### Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix2BFA.pdf
- Appendix1StandardPhysicalTherapy.pdf