Official title: Battlefield Acupuncture and Its Use In Multimodal Perioperative Anesthesia Care

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Title: Battlefield Acupuncture and Its Use In Multimodal Perioperative Anesthesia Care

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Investigators Affiliations: John D. Dingell VA Medical Center, Detroit Medical Center (DMC),

INTRODUCTION:

Battlefield acupuncture is an auricular therapy (Ear acupuncture) which has been in existence for centuries, with roots tied to Eastern Asian medicine. Ease of application, low cost, and minimal side effects make battlefield acupuncture a perioperative modality that has been linked to decreased morbidity and mortality in patients undergoing surgical procedures and anesthesia (1). In the United States, there is pressure by government and the medical community to decrease opioid use, especially in the perioperative time period. Opiate use due to postoperative pain, postoperative nausea and vomiting (PONV), perioperative anxiety have all been linked to increased hospital stays, increased morbidity and mortality, and ultimately higher healthcare costs (2). Anesthesia providers can be trained in application of acupuncture in the perioperative time period. Through analysis of rates of postoperative opioid use, postoperative nausea and vomiting and perioperative anxiety, the efficacy and utility of battlefield acupuncture will be realized as an effective adjunct to multimodal anesthesia care.

HYPOTHESIS AND OUTCOMES:

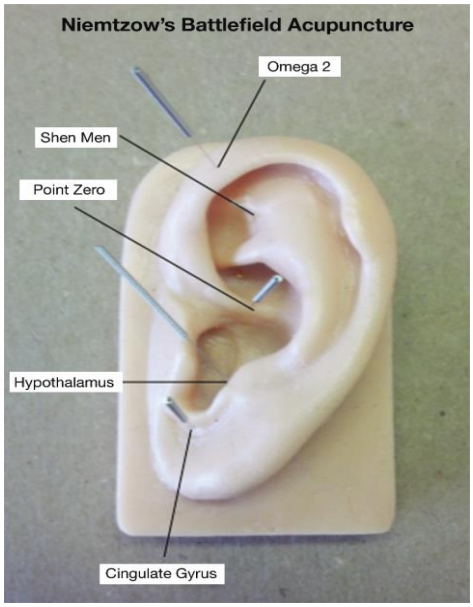
The study hypothesis is that perioperative battlefield acupuncture for general surgery and urology cases undergoing general anesthesia will decrease opioid requirements, postoperative pain, the incidence of PONV, and the incidence of perioperative anxiety in comparison to simulated (placebo) perioperative battlefield acupuncture.

STUDY DESIGN AND METHODS

This will be a prospective randomized study to compare auricular battlefield acupuncture to sham auricular battlefield acupuncture in patients undergoing general surgery and urology cases with general anesthesia. Participants in the study will be randomly assigned to either receive auricular battlefield acupuncture (treatment group) or simulated (placebo; control group) auricular battlefield acupuncture. Battlefield acupuncture needles will be utilized in the test arm and blunt needle pressing and covering with acupuncture stickers will be utilized in the control arm as a sham treatment. Location of needles and stickers will be placed according to 5 VA approved BFA auricular acupuncture points associated with PONV, pain, and anxiety respectively (Figure 1; 3). In both arms, the treatment ear will be covered after treatment so as to blind the patient. Both battlefield acupuncture and control groups will receive small band aids on the battlefield acupuncture needle sites. Both the evaluators for post procedure assessment along with the patient will be blinded in regards to what group they are in.

Figure 1. Battlefield acupuncture points.

Source: Teresa M. Kerge et al 2013.US Service Members With Polytrauma. Practical Pain Management- http://www.practicalpainmanagement.com/pain/spine/trauma/us-service-members-polytrauma



Inclusion Criteria:

1- Patients with an American Society of Anesthesiologists (ASA) Physical Status classification of 1 to 4

2 - Patients aged between 18 and 100 scheduled to undergo scheduled suitable inpatient/outpatient cases under anesthesia.

3 - Patients must be willing and fit to give written informed consent

4 - Inpatient stay required

Exclusion Criteria:

1 - Coagulopathies

2 - Patients with continuous epidural

3 - Uncooperative patient

4 - Psychiatric disorders and language deficiencies that may interfere with the assessment of pain

5 - Insufficient understanding of the pain scoring system.

6 - Outpatient stay

This study will be performed at the John D. Dingell VA Medical Center. Only a trained MD anesthesiologist will recruit patient in the preoperative period, where informed consent will be obtained. Computerized randomization will take place at the time the patient presents for surgery. Consent will be taken preoperatively.

Anesthetic Plan:

The anesthetic management will be general anesthesia with the provision of intravenous opioids intraoperatively and during recovery. Fentanyl will be the sole intra operative opioid. No other alterations of anesthetic management will take place pre or intra operatively. The battlefield acupuncture or sham battlefield acupuncture will be placed in the postoperative care unit (PACU).

Acupuncture Plan

Typically acupuncture needles which are semi-permanent needles have the characteristics of remaining in the ear acupoints for up to 3-4 days before being pushed out toward to the surface by the previous flattened epidermis. The test arm (treatment group) will received actual acupuncture needles, while the control arm will received sham or placebo acupuncture via pressing of a blunt needle on the specified BFA locations and then application of adhesive stickers. In the control group simulating acupuncture, the needles will never enter the patients' skin and will give the impression to the patient that the procedure has taken place. The ear

treated will be covered with a bandage via non-skin sensitive tape so as to blind the patient to which treatment group they are in.

Techniques:

The treatment group (Group 1) will receive postoperative auricular battlefield acupuncture. The control group (Group 2) will receive sham (placebo) postoperative auricular battlefield acupuncture as described above.

Data:

Data gathering will be performed by Dr. Padmavathi Patel, MD and/or a CRNA. Data collection will occur in the PACU (Post-Anesthesia Care Unit) before the PACU nurses evaluate the patient for discharge. Assessment will occur at 1 hour and 24 hour post procedure. The assessment will occur on the next day by either a medical student and/or CRNA at the patients' bed side.

Assessment of the battlefield acupuncture efficacy will be performed by testing the incidence of PONV, incidence of postoperative anxiety, and pain. Pain will be assessed via the visual analog scale (VAS) scoring system.

A study investigator will record the following:

1. At times 1 hour and 24 hours the following will be assessed:
2. Incidence of PONV
3. Incidence of postoperative anxiety
4. Pain score on an 11-point (0 to 10) Visual Analog Scale (VAS) at rest and with activity
5. Postoperative opioid consumption via morphine equivalents used
6. Patient satisfaction with analgesia score (0 to 100%)
7. Any occurrence of acupuncture site infection, acupuncture site bleeding, allergic reaction to acupuncture needles, or scar tissue formation at site of acupuncture needle.

<u>Statistical Analysis:</u>

An unpaired students-t-test procedure (two-sample assuming equal variances, two-tail significance $p<0.05$, 95% confidence interval) was performed to examine mean differences between the two

study groups on all continuously scaled variables. A Repeated measures ANOVA will be used to measured differences between time for continuous variables at the 2 measured time points (1 hour and 24 hours). Assumptions of normality and/or homogeneity of variance will be checked and verified. Comparisons between study groups on proportional differences will be examined using a non-parametric Fisher's Exact Chi-square test, when applied to 2x2 tables. Statistical significance will be set at a p-value ≤ 0.05. All continuous data will be expressed as the mean with 95% upper and lower confidence intervals or Mean ± Standard deviation.

A binary outcome, superiority power analysis based on a rate of 33% reduction of opioid consumption in the auricular battlefield acupuncture group compared to controls (sham auricular battlefield acupuncture) concluded 72 participants (36 patients per group) would be necessary to achieve 80% power with a $p<0.05$.

Human Subjects (Risks & Benefits)

There may be a risk of disclosure of sensitive information. Any information containing protected health information (PHI) such as master list documents containing patient names and medical record numbers will be stored securely in a locked office inside a locked filing cabinet at the VA site. All other data will use a subject number assigned and remove all 18 types of PHI information De-identified and be hard copies (paper records) will also be stored securely in a locked office inside a locked filing cabinet. Digital data will be stored on VA servers behind the VA firewall (H: Drive vhadetpatelp1$ (\\Vhadetfpc8.v11.med.va.gov) and secured in the investigator's lab (C4683 John Dingell VA Medical Center). Study data will only be accessible to investigators involved in the study. Statistical analysis will be performed on de-identified encrypted digital data at a non-VA site (Department of Anesthesiology, DMC). No financial incentives will be offered and no penalty will be applied for not participating in this study.

Risks and Side Effects-Acupuncture

The auricular battlefield acupuncture technique is considered to be safe and simple to perform. The site of needle insertion is unlikely to pose harm to any vital structures and visual identification of the auricular structures is not difficult. There are potential risks of acupuncture site infection, acupuncture site bleeding, ineffectiveness of acupuncture, worsening of localized pain symptoms

following acupuncture (although unlikely), allergic reaction to acupuncture needles, and scar tissue formation at site of acupuncture needle.

Benefits:

A direct benefit to patients may be a decrease in post-operative opioid requirements, decreased postoperative pain decreased incidence of PONV and decreased perioperative anxiety.

The societal benefits to participating in this study may be improved knowledge of anesthesia practice methods in improving post-operative pain control and reducing side effects for patients in the future. There is no financial benefit to participating in this study.

Use of Information/Investigators

This study will be conducted under the supervision of: Dr. Padmavathi Patel, MD.
Other key personnel include Aashish J. Kumar, MD, Baher Boctor MD, Michael C. Weber, DO And George McKelvey, PhD,

Retention of Records/Ethical Issues

Each patient will be assigned a unique three-digit number that will be linked to a separate list located in the regulatory binder. None of the sensitive material including but not limited to the patient's name, identification number, date of birth, etc., will be accessible to any individual except to those involved in the study. Removal of access to research study data will occur for study personnel when they are no longer part of the research team. All patient data will be kept in a locked cabinet in a locked room in the P.I's secure office. All VA research data will be stored and disposed of according to the current VA Record Retention Policy. In accordance with VA policy, procedures will be put in place for reporting incidents, i.e. theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls. None of the investigators, co-investigators, or other key personnel will receive any financial benefits from the research study. The study will be conducted at the John Dingell Veteran Affairs Medical Center (VA) by the Department of Anesthesiology at Wayne State University, pending approval by the CIC VA and the Human Investigation Committee at Wayne State University.

IRB Review

Investigators will prepare and submit all required documentation and obtain John D. Dingell VA Medical Center Internal Review Board (IRB) approval to implement the study prior to conducting the research. Notification to the John D. Dingell VA Medical Center IRB office regarding any changes to the protocol will be filed as amendments and not initiated until approval is obtained. Final closure of the study will be filed with the John D. Dingell VA Medical Center IRB office. All investigators have completed the mandatory Human Research Participant On-line Training (CITI Program).

Outside Consultants/Collaborators

Non

Contractual Agreements

N/A

Costs To Subjects:

There will be no additional costs to subjects as a result of taking part in this study. The anesthetic care of the patient, including the medications that are used as part of the patient's management and recovery, are subject to billing by the medical personnel at John D. Dingell VA Medical Center.

Conflicts Of Interest:

N/A

Confidentiality:

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Each patient will be assigned a unique three-digit number that will be linked to a separate list located in the regulatory binder. None of the sensitive material including but not limited to the patients' name, identification number, date of birth, etc., will be accessible to any individual except to those involved in the study. All patient data will be kept in a locked cabinet in a locked room in the anesthesia research office. Patient research data will be kept for three years following the study closure. Paper records will be shredded after a period of three years. The study will be conducted by the Department of Anesthesiology at John D Dingell VA Medical Center, pending approval by the WSU IRB and the CIC at the John D Dingell VA Medical Center.

Subject Compensation: No financial incentives will be offered to subjects.

Facilities and Equipment The study will be conducted in the inpatient setting at John D Dingell VA Medical Center.

References & Literature Cited

1) Lu, Z., H. Dong, Q. Wang, and L. Xiong. "Perioperative acupuncture modulation: more than anaesthesia." *British Journal of Anaesthesia Br. J. Anaesth.* 115.2 (2015): 183-93.

2) Fleckenstein, Johannes, Petra I. Baeumler, Caroline Gurschler, Tobias Weissenbacher, Michael Simang, Thorsten Annecke, Thomas Geisenberger, and Dominik Irnich. "Acupuncture for post anaesthetic recovery and postoperative pain: study protocol for a randomised controlled trial." *Trials* 15.1 (2014): 292.

Teresa M. Kerge et al 2013.US Service Members With Polytrauma. Practical Pain Management-http://www.practicalpainmanagement.com/pain/spine/trauma/us-service-members-polytrauma

Department of Veterans Affairs	**VA Research Consent Form**	
Title of Study	Battlefield Acupuncture and its use in multimodal perioperative anesthesia care	
Participant's Name		
Participant ID Number		**Date:**
Principal Investigator	*Padmavathi Patel, MD*	**VAMC:** John D. Dingell VA Medical Center

You are being asked to volunteer to take part in a research study at the John D Dingell VA Medical Center. Participation in this research study is voluntary. This consent form gives you information about the study. It is important that you read and understand the information on this form.

A total of 72 patients will take part in this study at the John D Dingell VA Medical Center. The John D. Dingell VA Medical Center is the only location where this study is being carried out.

This study is being sponsored by the John D Dingell VA Medical Center. There is no external funding source or sponsor for this study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Please read this form and ask any questions you may have before agreeing to be in the study.

PURPOSE OF RESEARCH STUDY:

You are being asked to volunteer to be in a research study to test a treatment called acupuncture. Acupuncture is a painless medical technique that involves the insertion of extremely thin needles on your skin at specific points on your body. The aim of the study is to observe if acupuncture improves your post-operative experience as a patient. In this study a technique call Battlefield acupuncture will be used where acupuncture needles will be placed on five specific points on your ear. Acupuncture may decrease the amount of post-surgery pain and post-surgery worry (anxiety) you may feel, it may also reduce the amount of post-surgery pain medications (opioid medications) you may require and prevent post-surgery nausea and vomiting (PONV). In addition to observing if acupuncture improves the patient experience this study will also observe if acupuncture decreases patient length of stay at the hospital and if acupuncture decreases the occurrence of any well-known surgical side effects such as pain, nausea, vomiting or anxiety.

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Because you may be like other individuals who have developed postoperative pain and nausea/vomiting after their surgery, we would like to invite you to volunteer to participate in this study. Currently, there is no sole, unimodal approved treatment for PONV, perioperative anxiety and postoperative pain.

The only aspect of this research study that is experimental is the use of acupuncture to treat PONV, perioperative anxiety and postoperative pain. Although acupuncture has been used to treat many ailments over the past many centuries safely for many years, acupuncture is not without risks.

STUDY PROCEDURES:

This study is comparing Battlefield acupuncture (acupuncture needles placed on the ear) to normal conventional treatment in patients undergoing general surgery and urology cases under general anesthesia. If you agree to take part in this research study, you will be randomly assigned into one of two patient study groups Treatment (Battlefield acupuncture) or Controls (simulated acupuncture). If you are assigned into the treatment group following your surgery you will receive traditional acupuncture treatment where 4 small needles will be painlessly placed into your skin upon ear regions believed to relieve pain, post-operative nausea and anxiety. Once placed on you, the acupuncture needles will be covered by an adhesive sticker to make sure of the stability of needle placements. If you are assigned to the Control (simulated acupuncture) group you will receive simulated acupuncture in which the anesthesiologist lightly presses acupuncture needles onto the same 4 acupuncture points without the needles entering your skin with an adhesive sticker placed over the area so that you will not know if you have acupuncture needles on you. In both study groups, the area in which you receive acupuncture or simulated acupuncture will be covered after treatment so you will not know which of the 2 study groups you are in. Following your surgery at 1 hour and 24 hours post-surgery we will ask you if you are experiencing vomiting or any feelings of nausea, if you are feeling any anxiety, your pain score on a scale from 0 (no pain) to 10 (unbearable pain) and record how much pain medication you have given following surgery and your satisfaction with analgesia score (0 to 100%). Acupuncture needles and adhesive stickers will be removed approximately 24-28 hours following your surgery. The timeframe of your participation in this study will be the period of 24-28 hours following your surgery.

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RISKS:
By taking part in this study, you may experience the following risks:

-acupuncture site infection, acupuncture site bleeding, ineffectiveness of acupuncture
-worsening of localized pain symptoms following acupuncture, although unlikely
-allergic reaction to acupuncture needles, scar tissue formation at site of acupuncture needles

To minimize potential risks all physicians performing acupuncture in this study will be experienced practioners in acupuncture techniques. Use of clean-needle techniques and sterile single-use needles will minimize any risk of infection. There will be regular patient monitoring for rapid treatment if any of these adverse do occur.

BENEFITS:
As a participant in this research study, there may be no direct benefit for you; however, information from this study may benefit other people with perioperative pain now or in the future.

STUDY COSTS:
Medical care that is part of this research project will be provided at no cost to you.

ALTERNATE COURSES OF ACTION:
You may choose to not participate in this study.

STATEMENT OF RESEARCH RESULTS:
When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

COMPENSATION:
You will not be paid for taking part in this study.

CONFIDENTIALITY:

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All the information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. Federal agencies including, but not limited to, the FDA, OHRP, ORO, and the VA Office of the Inspector General (OIG) may have access to the records. Paper copies of research records (your answers to questions) will be kept in a locked cabinet within a locked research office. Data will also be coded and stored on a password-protected computer that is also kept in a locked research office. The FDA may also choose to inspect research records that included your individual medical records. Research records will be kept in accordance with the VA record retention policy. Until that time your research records will be kept in a secure location.

RESEARCH PARTICIPANT'S RIGHTS:

You have read each page of this consent form or each page has been read to you. A member of the research team has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been told that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

If you have any questions, concerns or complaints about this study now or in the future, you may Contact Dr. Padmavathi Patel, MD and/or one of her research team members at the following phone number: 248-390-4609. If you have questions or concerns about your rights as a research participant or the validity of this study, the Chair of the Investigational Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other the research team, you may call the Research Compliance Office at (313) 576-4467 to ask questions or voice concerns or complaints, or you may call the Patient Advocate at (313) 576-1000, ext. 65158

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The results of this study may be published, but your records will not be revealed unless required by law. In case there are medical problems or questions, you have been told you can call Dr. Padmavathi Patel, MD during the day and the nurses and physicians who will be available to you 24 hours a day.

The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation. No reimbursement, compensation or free medical care is offered by Wayne State University. You may be among the veterans required to pay co-payments for medical care and services provided by the VA. These co-payments requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

Your signature on this form indicates that you have had this research explained to you and your questions about it answered, and you voluntarily consent to participate in this study. You will receive a signed copy of this consent form.

x_____	x_____	x_____
Research Participant's Signature	Date	Time

x_____	x_____	x_____
Signature of person obtaining consent (Study personnel must be approved by IRB.)	(Print Name)	Date

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Research Participant's Initials: _____