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Investigation of the Efficacy of Auricular Acupuncture Adjunctive Therapy in the Reduction of Post-operative Pain in a Third Molar Extraction Model
A Pilot Study

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Investigation of the Efficacy of Auricular Acupuncture Adjunctive Therapy in the Reduction of Post-operative Pain in a Third Molar Extraction Model: A Prospective, Blind, Randomized Clinical Trial

A THESIS

Presented to the Faculty of

The Air Force Postgraduate School of Dentistry

Of the Uniformed Services University

Of the Health Sciences

In Partial Fulfillment

Of the Requirements

For the Degree of

MASTER OF SCIENCE

In Oral Biology

By

Heather Marie Brooks, BS, DDS

Dunn Dental Clinic
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19 May 2017

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Dean, Air Force Postgraduate Dental School

DEDICATION

I dedicate this thesis to my husband Daryl and our daughter Arianna. It is only with your love and support that I was able to accomplish this endeavor with the best of my ability. I love you and am so blessed to have you in my life.

To my parents who instilled a strong work ethic in me and encouraged me throughout this process.

To God, whom all my strength, perseverance, and abilities are produced. I am grateful for the many blessings and grace you have extended me throughout this process.

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I have had many individuals assist me in this endeavor and acknowledge the efforts and guidance of many who aided me in the process of research and thesis writing. The completion of this research project would not have been possible without the initial approval of Col (Ret) K. Vandewalle and Col D. Fallis to pursue this study. My thesis was improved greatly by the time and effort of my Associate Investigators and research committee members: Lt Col S. McMahon, Col R. Townsend, and Maj B. DeLong. I would also like to thank my Associate Investigators Maj J. Krutoy and Lt Col C. Labella for your time and commitment to recruiting patients for this study. I would like to thank Dr. J. Park for an outstanding job completing multiple statistical analyses for this study and to Dr. A. Bush for her projected power analysis. Also, the completion of this research would not have been possible without the work and assistance by the AEGD-2 and OMS Residents who aided in screening for potential patients and to the OMS Residents completing the surgical procedures. Lastly, thank you to the OMS staff and Wilford Hall Ambulatory Surgical Center for allowing this study to be completed.

ABSTRACT

Objective: The purpose of this randomized, double-blind, prospective clinical study was to evaluate whether addition of auricular acupuncture would reduce postoperative pain and analgesic use in patients undergoing third molar extraction with deep sedation. Auricular acupuncture has been suggested as a means to stimulate an endogenous opioid system and has been used to manage chronic pain maladies including TMD and migraines. Recent research indicated that it may also be effective for acute pain management. There are several proposed mechanisms of this pain reduction, two of which are: 1) the gate control theory in which activation of non-noxious Aβ fibers inhibits pain input to the brain, and 2) a placebo effect. This study used the Battlefield Acupuncture protocol developed by Dr. Richard C. Niemtzow. **Materials/Methods:** Gold Acupuncture Semi-Permanent (ASP) needles were placed in five predetermined points placed in each ear in the experiment group by a dentist credentialed in Battlefield Acupuncture protocol in addition to normal acute pain management procedures. Patients in the acupuncture placebo group had auricular acupuncture placed in two predetermined neutral points in each ear. Patients were given a two week journal to fill out following surgery that indicated their pain three times per day, the location and quality of their pain, and the times which they consumed either Ibuprofen or Percocet prescriptions. A two-way repeated measures analysis of variance (ANOVA) was used to test if there was a significant difference in the change in the VAS pain scores, ibuprofen use, and Percocet use, respectively

between treatment groups. **Results/Conclusion:** Pain was significantly reduced in the auricular acupuncture experiment group from day 1 to 5 compared to the placebo group. There was no statistical difference between groups regarding Percocet nor Ibuprofen consumption. The limited statistical power due to the small sample size (n = 13) may have contributed to limiting the significance of some of the statistical comparisons conducted. Further studies should be completed with greater power to better determine the effectiveness of Battlefield Acupuncture to reduce post-op pain and narcotic/analgesic medication consumption.

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I. BACKGROUND AND LITERATURE REVIEW

Acupuncture is rooted in ancient Chinese philosophy based on energy flow along 12 primary and 8 additional meridians or pathways similar to global longitudinal lines (Oleson, 2014) that run in the body. Acupuncture has been practiced for over 3000 years. According to acupuncture philosophy, medical symptoms occur when the flow of energy, Qi, is obstructed; placing fine acupuncture needles into specific parts of the body restores the flow of energy (Vachiramon et al., 2004). While it is still considered an alternative medicine technique in the United States, acupuncture use has become more widespread and popular in recent years. Acupuncture is traditionally completed with conventional manual stimulation using fine acupuncture needles. Acupuncture does not necessarily always involve needles and may also include stimulation with the use of electrical impulses, lasers, ultrasound, moxibustion (acupuncture treatment that involves burning of Artemis vulgaris leaves on the needle or insertion point) (Goertz et al., 2006), light (photo acupuncture), magnets, or acupressure (application of pressure at selected body sites) (Naik, 2014). Microsystem acupuncture is a focused form of acupuncture completed on the ear, face, hand, and scalp. These microsystems are postulated to contain a "distribution of acupoints that replicate the anatomy of the whole organism," (Oleson, 2014) and activation points on the auricle have been determined based upon an inverted somatotopic infant body superimposed on the auricle, where the fetal head is represented by the inferior aspect of the ear and the feet are represented by the more superior aspect of the ear. Auricular acupuncture not only aids in pain relief, but it may also facilitate healing via improvement in blood circulation (Oleson, 2014).

The generally accepted theory behind acupuncture's mechanism of action is that fine needles, once inserted, stimulate small myelinated nerve fibers, which then send afferent signals to the central nervous system and activate three centers: the spinal cord, the midbrain, and the pituitary hypothalamus (Vachiramon et al., 2004). Oleson asserted that it is the lower limbic brain, the hypothalamus, and the brainstem that play a more active role in acupuncture analgesia (Oleson, 2014). Simmons and Oleson determined that auricular electric stimulation increased pain firing threshold by 23% compared to a placebo group when completed in conjunction with electric pulp testing. They additionally suggested that acupuncture elicits an endogenous opioid system response via release of endorphins (Mayer et al., 1977; Oleson, 2014) that can be reversed by the administration of naloxone (Simmons and Oleson, 1993).

Battlefield Acupuncture (BFA) is a form of auricular or ear acupuncture that was created by Dr. Richard C. Niemtzow in 2001. The protocol for BFA involves stimulation of five ear acupuncture points - the Cingulate Gyrus, Thalamus point, Omega 2, Point Zero, and Shen Men in each ear. The technique involves placement of up to ten gold Acupuncture Semi-Permanent (ASP) needles (Sedatelec, Lyon, France) (Burns et al., 2013) into five acupuncture points in each ear. The BFA technique was easily understood and implemented by nurses who had no previous acupuncture skill or knowledge (Burns et al., 2013) and adds little additional time to treatment of patients - thirty minutes or less.

Evidence from clinical trials supports the use of acupuncture for the management of various pain conditions to include acute or post-operative pain. Usichenko et al. (2005) demonstrated that on-demand opioid use was reduced by 36% using auricular acupuncture in 29 patients who received total hip arthroplasty. Asher et al. (2010) calculated in their systematic review that auricular acupuncture reduced opioid requirement by 40%, which was larger than the opioid sparing effects of commonly used analgesics acetaminophen and ibuprofen (Filshie et al., 2016).

Acupuncture has shown efficacy in dentistry for treatment of dental pain, dental anxiety, gag reflex, temporomandibular joint (TMJ) pain or temporomandibular disorder (TMD), orofacial pain, headache, and xerostomia (Naik, 2014). BFA has been helpful for treatment of acute pain in patients presenting with combat related injuries and effectively reduced pain perception determined by visual analog scale during medical evacuation (Burns et al., 2013). An auricular acupuncture protocol involving two of the five points of the BFA technique, the Cingulate Gyrus and the Thalamus point reduced patient pain by 23% in patients visiting the emergency room. However, the pain reduction was similar to the control group when measured 24 hours later (Goertz et al., 2006). To date, BFA has not been studied as an adjunct for reduction of postoperative pain after third molar extractions.

Tavares and colleagues (2007) studied postoperative pain following third molar extractions in 24 patients. They used electrical acupuncture on two bilateral (four total) auricular points and 6 bilateral systemic points (12 total) outside the head and neck region and they only studied postoperative pain over the first 72 hours. They determined that postoperative pain was significantly decreased and postoperative analgesic intake was lower in the study group when compared to the control group. Auricular acupuncture involves structures studied during dental training that are easily accessed during dental treatment, and would be far more familiar to dentists than systemic acupuncture points. Thus, auricular acupuncture would be a better treatment adjunct for control of postoperative pain associated with dental procedures.

Extraction of third molars is a common outpatient dental procedure for patients ages 18-25 that predictably results in temporary post-operative pain, which is frequently managed with oral non-steroidal anti-inflammatory medications and combination narcotics. The postoperative pain experience following dental extractions is influenced by several factors: the duration of the procedure, the difficulty of the surgery, the inflammatory response to surgical trauma, the presence and severity of pre-operative pain, the presence of pre-procedural anxiety, and the patient's individual threshold for pain. Due to the fact that removal of third molars are frequently elective, the third molar extraction model has repeatedly shown efficacy as an effective clinical procedure to study analgesic effects. Patients undergoing these types of procedures are typically healthy, ambulatory, and have few comorbid diseases (Tavares et al.,

2007). Additionally, third molar extraction models are befitting protocols for acute pain research because they produce consistent postoperative pain that begins within a few hours following surgery, dependent on the types of local anesthetics and/or sedatives used as well as the metabolic characteristics of adjunctive medications that were administered.

Pain during the first few hours post-surgery, following third molar extractions is negligible due to the use of local anesthetics. Additionally, use of long lasting local anesthetics such as bupivacaine may result in delay of returned sensation to the surgical area for up to 8 hours. It is not uncommon for these types of surgeries to require gingival flap reflection, which results in additional pain and edema that peaks at or around day three and subsequently decreases. As a result, many of these patients can have postoperative pain lasting up to seven days (barring other post-operative complications arise such as infection or acute alveolar osteitis).

II. OBJECTIVE

The purpose of this randomized, double-blind, prospective clinical study is to determine whether addition of auricular acupuncture will reduce postoperative pain and analgesic use in patients undergoing third molar extraction with deep sedation.

III. HYPOTHESES

Null hypothesis 1: There will be no difference in postoperative pain perception when auricular acupuncture is placed at the time of third molar extractions. Research Question: Does auricular acupuncture reduce pain following third molar removal?

Null hypothesis 2: There will be no difference in postoperative combination analgesic consumption when auricular acupuncture is placed at the time of third molar extractions. Research Question: Does auricular acupuncture reduce pain enough that it reduces consumption of analgesic medications following third molar removal?

IV. MATERIALS AND METHODS

This research study was approved by the Wilford Hall Ambulatory Surgical Center (WHASC) Institutional Review Board (IRB), Federal Wide Assurance (FWA) #20160041H, 59th Medical Wing Clinical Research Division Protocol Office, JBSA-Lackland, TX as a minimal risk study. This study was a randomized, double-blind, placebo-controlled prospective clinical trial that evaluated the effect of auricular acupuncture on postoperative pain following third molar extraction. The study was accomplished by six investigators: the principle investigator (#1), and five associate investigators (#2,3,4,5 and #6). Twenty-seven subjects were recruited from active duty military members and Department of Defense beneficiaries who presented to Wilford Hall Ambulatory Surgical Center (WHASC) for evaluation of third molars for extraction. Congenitally missing third molars are common, so patients presenting with three or more third molars were eligible to be included in the study. Patients that presented with supernumerary teeth were also included. Associate investigators #3, #4, or #6 screened patients presenting for third molar extraction(s). Inclusion criteria included: 1) healthy patients that had an ASA Class I or ASA Class II status, 2) a diagnosis and treatment plan requiring at least three third molars to be extracted (note: patients may have another tooth concurrently extracted such as a non-restorable second molar or supernumerary tooth), 3) age: 18-25 years old, and 4) subjects must be Active Duty or Department of Defense beneficiaries. Patients were excluded from the study for the following reasons: 1) basic military trainees, 2) poorly controlled system disease (ASA Class III or ASA IV), 3) allergy to gold, 4) currently pregnant or

breastfeeding, 5) absence of ear, 6) active cellulitis of ear, 7) ear anatomy that precludes identification of acupuncture landmarks, 8) use of hearing aids that precludes the insertion of acupuncture needles, 9) non- English speaking ability, 10) consumption of narcotics/opioids in the last 6 months, 11) history of narcotic/opioid abuse, 12) chronic pain comorbidity, 13) history of acupuncture exposure, 14) post-operative complications requiring treatment additional to routine care such as antibiotic therapy, incision and drainage, local anesthesia, or alveolar dressing, and 15) bleeding disorder or ongoing blood thinner therapy. Prior to any research-related procedures being performed, each subject signed an informed consent and a HIPAA Authorization Document. Subjects were randomly assigned using a computer-generated model to either the experiment acupuncture group or a placebo acupuncture group (control).

Subjects then presented to WHASC Oral Surgery Clinic for their extraction appointment at the time recommended by the operating surgeon, an Oral Maxillofacial Surgery (OMS) resident in their first or second year of training. The patient assessed and assigned their pain level using a visual analog scale just before the surgical procedure began. As part of standard care, Intravenous (IV) sedation was completed by the surgical team, with placement of the IV catheter completed by an OMS resident or qualified dental assistant. Deep sedation and local anesthetic were administered and monitored by OMS resident. Third molar extractions were completed by the same resident completing conscious sedation. Upon completion of the extractions,

the provider indicated the length of the procedure, amount of anesthetic used, sedation medications and amount used, and assessed the difficulty (simple, moderate, or difficult) of each extracted tooth based upon the third molar impaction classification suggested by Juodzbalys and Daugela (2014) on the same surgical information sheet that included the preoperative pain assessment.

During the recovery period, upon commencement of extractions and placement of sutures as needed, investigators #2, #5, or #6 entered the room to perform the auricular acupuncture or placebo acupuncture. Investigator #2, #5, and #6 are credentialed to perform auricular acupuncture (training received at Battlefield Acupuncture Course, Naval Dental School, Bethesda, MD, 2013, Battlefield Acupuncture Course, WHASC, San Antonio, TX, 2016, and Battlefield Acupuncture Course, Joint Base Andrews, MD, 2014 respectively). Both ears were disinfected using a 70% isopropyl alcohol prep and the proposed acupuncture site scrubbed to reduce the chance of infection. After the alcohol dried, approximately 20-30 seconds later, gold Acupuncture Semi-Permanent (ASP) needles (Sedatelec, Lyon, France) were placed based on group allocation. Ten ASP needles in total were placed in the BFA points for the experiment group and four ASP needles total on the control group at placebo sites Helix 1 and Helix 6 used in the study by Simmons and Oleson in 1993.

Based on the computer-generated model, the patients were randomized into an experimental or placebo group. The experimental group received a modified form of the Battlefield Acupuncture protocol created by Dr. Niemtzow. The traditional BFA protocol requires the patient to ambulate after each acupuncture needle is placed. The ASP needles are placed in the order of Cingulate Gyrus, Thalamus point, Omega 2, Point Zero, and Shen Men are completed in each ear and the treatment stopped once the patient reports 0-1/10 pain. Because the patients in this protocol were anesthetized and sedated, the patient should have no pain during placement of the ASP needles and thus no indicator of how many needles are necessary in that specific patient. Therefore, all ten prescribed sites in the BFA protocol were placed in the experiment group and the patient was not ambulated after needle placement for patient safety reasons. ASP needles were placed in the helix of each ear for the placebo acupuncture group at the sites Helix 1 and Helix 6 used in the Simmons and Oleson study in 1993. The patients in both groups were blinded to the group to which they were assigned. The acupuncture sites were covered with an adhesive plaque provided with the ASP needles by Sedatelec and medical tape to prevent premature loss of the needle. The patient and their escort were reminded of the acupuncture needles that are still in place beneath the bandage and to expect that they will spontaneously fall out within 2 to 4 days.

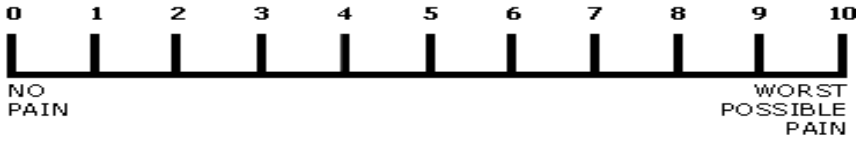
Risks discussed with the study participants included discomfort at acupuncture site, possible discomfort while sleeping or when objects contact the ear, possible bleeding

or bruising, broken needles, feeling dizzy or nauseated, fainting, feeling light-headed or euphoric, and drowsiness. In the event the acupuncture needles did not fall out within six days, patients were instructed to come in and have them removed by one of the investigators. The acupuncture needles were sterile, gold-plated semi-permanent ear acupuncture needles for single use. If at any time during the study, the subject decided to withdraw from the study, they had the option to either have the acupuncture needles removed by one of the investigators or allow them to fall out on their own.

Upon discharge, the patient was given three post-operative prescriptions that are part of standard care: 0.12% Chlorhexidine gluconate mouth rinse (rinse twice daily with 15mL for thirty seconds and expectorate), Ibuprofen 800mg (take one tablet with food every eight hours for the first 72 hours and then take as needed for mild to moderate pain), and Percocet (oxycodone 5mg/acetaminophen 325mg) combination analgesic (take one tablet every 4-6 hours as needed for moderate to severe pain). Patients received a two-week journal upon discharge. The journal did not include any patient identifiers and only included the assigned number of the patient that was randomly assigned by the computer-generated model. Patients self-reported pain in the journal using a 100 mm Visual Analogue Scale (VAS) with descriptors “no pain” at the left end and “worst possible pain” at the right and opposite end. VAS are often used to measure pain intensity (Burns et al., 2006). Pain assessments were completed by

the patient every eight hours by marking an X on the same 100mm visual analog scale for pain that was used preoperatively.

Figure 1: 100mm Visual Analog Scale



The journal also included an area for patients to indicate where their pain was located as well as the quality of the pain: dull, sharp, throbbing or constant. Patients also indicated each time they took either ibuprofen or oxycodone/acetaminophen, the amount taken, and hour it was taken.

After the two-week period was complete, the research subjects were asked to return their journals to the oral surgery clinic where they were collected by the principle investigator. The VAS pain score was calculated by measuring the millimeter distance from the left end of the scale using a standard ruler. A high score translated to a higher pain intensity experienced by the patient. The data from the journals was input using Excel and analyzed to determine whether the experiment group had a lower pain perception and consumed fewer postoperative medications for

breakthrough pain, most specifically narcotics, as compared to the placebo acupuncture group.

V. STATISTICAL ANALYSIS

Statistical data analysis was performed in SAS Version 9.3 for Windows (SAS Institute, Cary, North Carolina). Normally distributed variables were summarized by mean and standard deviations and non-normal by the median and inter-quartile range (IQR). T-tests were conducted on the continuous and normally distributed variable of age, and the non-normally distributed variable of procedure length was analyzed using non-parametric Wilcoxon rank sum tests. The Binary variable of ASA Classification (ASA Class I or II) was summarized by frequencies and percent and were analyzed using Pearson chi-square tests. A two-way repeated measures analysis of variance (ANOVA) was used to test if there was a significant difference in the change in the VAS pain scores, ibuprofen consumption, and Percocet consumption, respectively between treatment groups. P-values are two-tailed with statistical significance set at $p < 0.05$.

VI. RESULTS

A. Descriptive Statistics

The study enrolled 27 patients who were randomly assigned to either the experiment group that received acupuncture in the battlefield acupuncture points with known pain-blocking potential or the placebo group. No patients returned to have acupuncture needles removed. Thirteen patients returned the two-week journal with a 48.1% journal return rate. Five participants were assigned to the experiment group and eight were assigned to the placebo group. Participant age ranged from 18-23 years with a mean age of 20.8 years (SD = 1.6). The age difference between participants in the experimental and placebo groups was statistically significant (p = 0.03). Of thirteen patients, nine (69.2%) had medical history of ASA I. The median length of procedure (minutes) was 35 minutes (IQR = 20 - 40). No significant statistical group differences were found for the length of procedure and the number of ASA I. Table 2 summarized the mean and standard deviation of outcomes (i.e., VAS pain score, ibuprofen use, Percocet use).

Table 1. Descriptive Statistics of Characteristics in Participants

Characteristics	Experimental (n = 5)	Placebo (n = 8)	P
Age (years), mean (SD)	22.0 (1.2)	20.1 (1.4)	0.03
Length (Minutes), median (IQR)	30 (20 - 35)	40 (20 - 42.5)	0.65
ASA I, n (%)	3 (60.0)	6 (75.0)	0.61

Table 2. Descriptive Statistics of Outcomes: Mean and Standard Deviation (SD)

	VAS Pain Score		Ibuprofen Use		Percocet Use	
	Experimental	Placebo	Experimental	Placebo	Experimental	Placebo
Pre-op	0.00 (0.00)	0.29 (0.70)	NA	NA	NA	NA
Day 1	2.33 (1.86)	4.46 (1.01)	1.60 (0.55)	1.25 (0.71)	1.20 (0.84)	1.13 (1.25)
Day 2	2.70 (0.79)	4.54 (1.50)	2.60 (0.55)	1.38 (0.52)	0.60 (1.34)	1.38 (0.92)
Day 3	2.72 (1.09)	4.55 (2.00)	2.00 (0.71)	1.38 (0.74)	0.80 (1.30)	0.88 (0.99)
Day 4	2.43 (1.81)	3.78 (1.88)	2.20 (0.84)	1.38 (0.52)	0.80 (1.30)	0.63 (0.92)
Day 5	2.05 (1.96)	2.76 (2.00)	1.20 (0.84)	1.00 (0.93)	0.40 (0.89)	0.25 (0.46)
Day 6	2.92 (2.03)	2.04 (2.13)	1.40 (1.34)	0.88 (1.13)	0.60 (1.34)	0.13 (0.35)
Day 7	2.88 (2.28)	1.91 (3.05)	1.40 (1.14)	0.50 (0.76)	0.40 (0.55)	0.38 (1.06)
Day 8	1.70 (1.67)	1.49 (2.65)	1.60 (1.14)	0.38 (0.74)	0.20 (0.45)	0.50 (1.41)
Day 9	1.23 (1.68)	0.95 (1.96)	0.60 (0.89)	0.50(1.07)	0.00 (0.00)	0.25 (0.71)
Day 10	0.95 (1.55)	0.52 (0.93)	0.80 (1.10)	0.13 (0.35)	0.00 (0.00)	0.00 (0.00)
Day 11	0.69 (1.12)	0.11 (0.31)	0.40 (0.55)	0.13 (0.35)	0.00 (0.00)	0.00 (0.00)
Day 12	0.49 (0.68)	0.08 (0.22)	0.20 (0.45)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Day 13	0.11 (0.25)	0.08 (0.22)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Day 14	0.11 (0.24)	0.08 (0.21)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)

NA: Not applicable

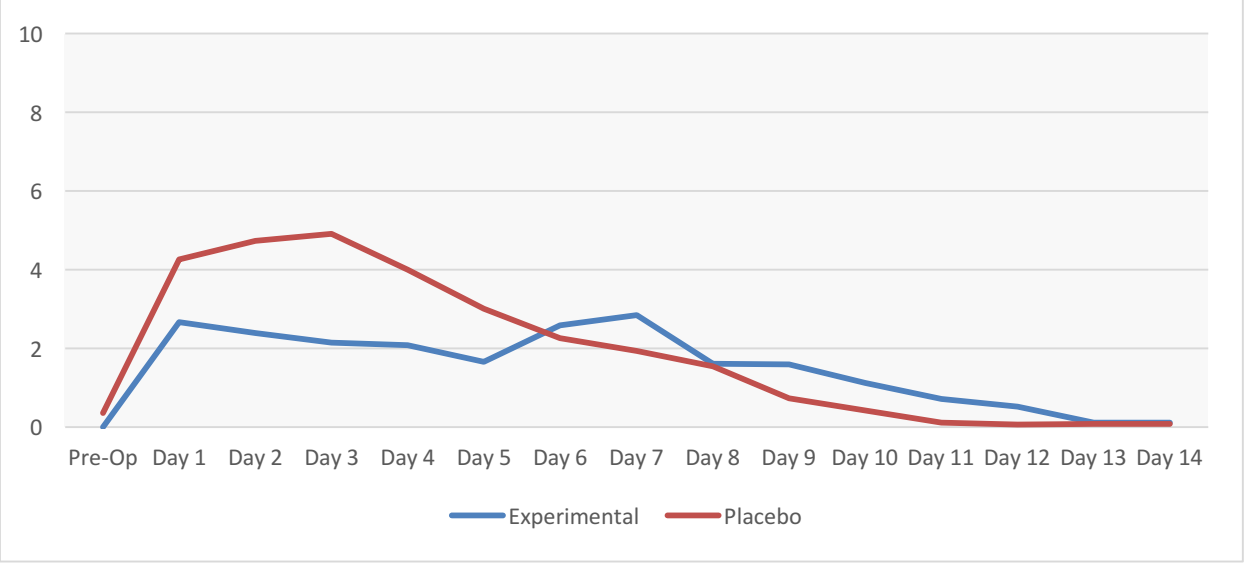
B. Repeated Measures ANOVA Results

A two-way repeated measures ANOVA was conducted to compare the effect of battlefield acupuncture (BFA) treatment on reduction in pain, ibuprofen use, and Percocet use over the two weeks following surgery. The length of procedure and age were included in the model as control variables. Sphericity was tested for each effect, and there was no violation of the sphericity assumption.

C. VAS Pain Score Over Time

The repeated measures ANOVA results indicate no significant change in the VAS pain score over time (Figure 2, time effect: p=0.98) and no difference in the VAS pain scores between treatment groups (p = 0.61). The interaction between time and treatment group was significant ($F = 1.78_{df = 14}$, p = 0.049). When the repeated measures ANOVA was run with the first five days after surgery, a marginally significant difference in the VAS pain scores was identified between treatment groups ($F = 5.09_{df = 1}$, p = 0.05).

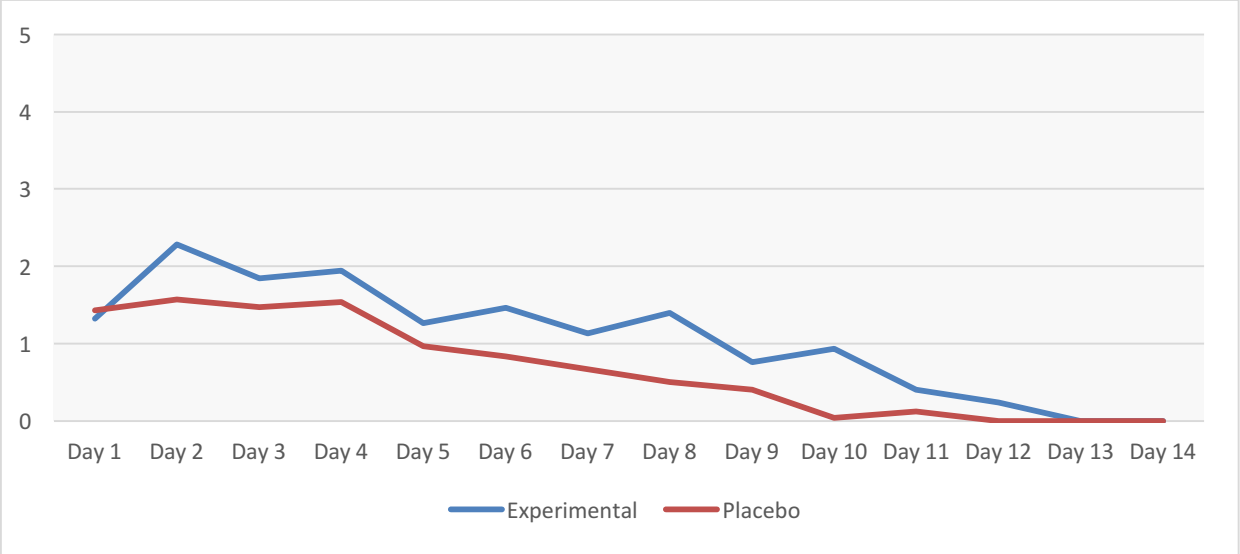
Figure 2: Least Squares Means of VAS Pain over Time



D. Ibuprofen Use over Time

The repeated measures ANOVA results show no significant change in ibuprofen use over time for both groups (Figure 3, time effect: p=0.80). There was no difference in ibuprofen use between treatment groups (p = 0.22). The time and treatment group interaction was not significant (p = 0.95).

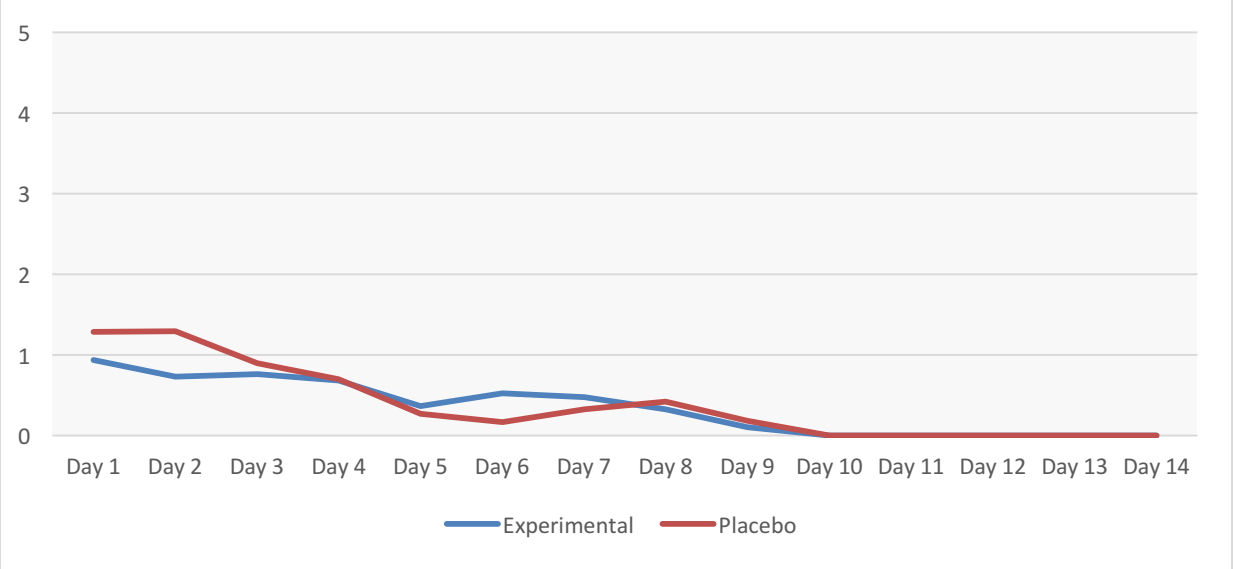
Figure 3: Least Squares Means of Ibuprofen Use over Time



E. Percocet Use over Time

The repeated measures ANOVA results show no significant change in Percocet use over time for both groups (Figure 4, time effect: p=0.94). There was no difference in Percocet use between treatment groups (p = 0.89). The time and treatment group interaction was not significant (p = 0.99).

Figure 4: Least Squares Means of Percocet Use over Time



VII. DISCUSSION

It is well understood that patients will experience a predicted increase in pain on day 1, as soon as the anesthesia wears off following surgery since a tissue injury has occurred. This known increase in pain was supported by the data analysis. While third molars may be extracted using local anesthesia only, patients are often referred to Oral Surgeons for extractions to be completed with sedation, which infers the increased difficulty of the surgical extraction case or the challenge of patient management. Patients typically experience their largest increase in pain and edema 3 to 5 days following surgery. This peak in pain is consistent with the inflammatory stage of healing which develops three to five days following tissue injury and is accompanied by the cardinal signs of inflammation: redness, swelling, warmth, and pain. The pain that patients experience is directly related to inflammatory mediators histamine, kinins, and prostaglandins released by leukocytes in addition to edema produced by fluid transudate (Hupp et al., 2008).

The significant interaction identified between time and treatment group suggests that there was a difference in pain intensity levels between groups over the first five days post-surgery. After day 6, both groups demonstrated levels of decreasing pain that were statistically similar.

Two potential explanations may explain this difference. While there was not a statistically significant difference between the pain scales of patients who were in the BFA experiment group versus the placebo group beyond day 6, there was a significant difference between pain and time for days 1 through 5. This difference may suggest that the battlefield acupuncture produced an endogenous opiate response, thus reducing the perceived pain of patients in the experiment group. Additionally, the BFA experiment group discontinued Percocet 1 day earlier than the placebo group and in general the average Percocet consumption was lower, but this was not found to be statistically significant. Should this study increase in power with a larger number of participants, there is potential for a greater difference to be identified.

Second, the lack of statistically meaningful pain relief after day 5 in the experimental group may be explained by decreased release of endogenous opioids after the loss of ASP needles. ASP needles are typically retained in the ear only 2-4 days, and the similar VAS scores after day 5 may reflect the loss of effective needling. Unfortunately, documentation of needle loss was not addressed in the journal instructions. The statistically significant difference between the experiment and placebo groups does appear to suggest that the positive effect of battlefield acupuncture cannot be easily explained as placebo.

The experiment group consumed more ibuprofen than the placebo group (an average of 1.92 doses per day versus the placebo group's 1.28 doses per day). The question that ensues is whether the pain reduction experienced by the experiment group from day 1 to 5 was due to the auricular acupuncture or the ibuprofen consumption. To adequately answer this question would require a greater number of participants; therefore, additional evaluation should be completed.

It was identified through the post-op journal analysis that patients were not consuming medications as directed. Percocet, a narcotic which should be used for break-through pain or severe pain management was often taken when the patient's VAS pain level was in a mild to moderate range. This was not expected as it went against verbal and written instructions to only use Percocet for moderate to severe pain. It is not clear if this behavior was due to a fear of developing more severe pain if they didn't take it or if the narcotic provided a perceived benefit beyond pain relief. If the pain is only a two out of ten, then ibuprofen should be sufficient to manage the pain. This finding is consistent with the opioid abuse potential and overuse that has become an epidemic in America and illustrates an area in which dental providers have the opportunity to better educate patients regarding the use of non-steroidal anti-inflammatory medications by the clock and the safe and proper consumption of narcotic-analgesics when indicated.

The limited statistical power due to the small sample size (n = 13) in the present study may have played a role in limiting the significance of some of the statistical comparisons conducted. A sample size of 40 (20 per group) would have provided 80% power to detect an effect size of 0.46 or approximately 0.9 standard deviation difference between groups, and an effect size of 0.69 or approximately 1.4 standard deviation difference among means for pain scores over time (the repeated measure) and for the interaction term, when testing with RM ANOVA with 2 groups and 15 repeated measures at the alpha level of 0.05 (NCSS PASS 2011 v.11.0.8). A post hoc power analysis revealed that the present study only had 20% power.

There were several unforeseen obstacles and lessons learned throughout this study. Only 48.1% of the journals were returned and many participants did not respond to attempts to collect outstanding journals. The age of the population, level of maturity and responsibility amongst this age-group, as well as their level of investment in the study may have played a role in the data collection process. Many forgot to complete the data or return their journal. Since most of the participants were under the age of 25, perhaps if surveys should had been designed to be collected electronically on a smart device, more journals may have been returned. Additionally, many participants did not mark their pain on the VAS line with an X as instructed and instead circled the number of their pain. In these situations, the pain measurement was made to the center of the circle. Recapturing the journals was amplified by the fact that many patients cancelled or did not show for their follow-up appointment and were unable to

be contacted. The collection rate may have been worsened by the geographically disbursed patient population, many of whom travel more than 30 minutes to the clinic. This may have had an effect on the number of patients who traveled back to the clinic for the follow-up appointment or to simply drop off their journal. One possible solution to this geographic challenge may be to coordinate to have patients scan and e-mail or fax the journal. In the future, it may be beneficial to employ a secure system which prompts patients to complete their post-operative survey, such as the smartphone application mCare which is currently being evaluated by Chester C. Buckenmaier, III in his study entitled "Defense and veterans pain rating scale (DVPRS) and post-operative survey through a bi-directional secure mobile messaging system" to determine the efficacy of this technology to complete his post-operative survey. Use of such an application would allow for immediate transfer of data and eliminate a follow-up appointment which was research driven in order to acquire the 2 week post-op journal data (2016).

Additionally, the spatial complexity of the patient referrals and the health system increased the logistical difficulty of the study. The primary duty location of two out of three certified acupuncturists in the study was located in a separate facility than the oral surgery department, which required increased time that these AIs had to block their patient schedules and be available to complete the procedures. Patient scheduling may have been more flexible if all investigators were located in the same building. Additionally, the oral surgery residents and oral surgery staff rotate duty

locations. There were times when there was only 1 resident or no 1st or 2nd year OMS residents available to complete the surgical procedure for patients who consented to participate in the study or no associate investigators were available to consent patients for the study, yet there may have been multiple 3rd year OMS residents available to complete the study. Perhaps expanding the protocol to include all OMS residents would be one improvement to this challenge.

One additional logistical limitation that is perhaps unique to the military system is that some patients may have their evaluation and surgery on the same day when they are referred from another military facility. Some patients travel up to 4 or 5 hours from their home to have their third molars extracted. IRB requirements do not allow for enrollment of participants for same day procedures because of the limited time that they have to contemplate the risks and benefits of their participation in the study. Due to this, there may have been some lost opportunities for enrollment.

Future studies should consider: 1) single workplace for all investigators, 2) avoid/limit rotations of staff and residents away from the surgery center, 3) expand surgery residents completing procedures to 1st through 4th year OMS residents, and 4) prompted secure survey/messaging. Improving each of these may increase the rate of enrollment as well as improve data collection.

VIII. CONCLUSION

Post-operative pain after third molar extraction was not significantly reduced in patients receiving Battlefield Acupuncture compared to the placebo acupuncture after two weeks. The Battlefield Acupuncture group had statistically significant reduction in pain scores from day 1 to 5 compared to the placebo acupuncture group. Patients receiving Battlefield Acupuncture did not have significantly different consumption of Percocet nor Ibuprofen compared with the placebo acupuncture group over the two-week period. However, the BFA experiment group had increased ibuprofen consumption (although not statistically significant) compared to the placebo group over the first 5 days following surgery suggesting little to no role with the noted difference in post-operative pain intensities between the study groups. Further randomized controlled studies should be completed to rule out the effect of inflammatory reduction due to ibuprofen to truly determine the ability of Battlefield Acupuncture to reduce post-op pain following third molar extractions as well as increase the power of the study and improve the ability to note a difference between experiment groups.

Disclaimer

The views expressed in this study are those of the authors and do not reflect the official policy of the United States Air Force, the Department of Defense, the Uniformed Services University of the Health Sciences or the United States Government. The authors do not have any financial interest in the companies whose materials are

discussed in this article. “The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402.”

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