Efficacy of Auricular Acupuncture in Reducing Pain after Third-Molar Extractions

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Efficacy of Auricular Acupuncture in Reducing Pain after Third-Molar Extractions

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Objective: The purpose of this randomized, double-blind, prospective clinical study was to determine if therapeutic auricular acupuncture based on the Battlefield Acupuncture protocol would reduce postoperative pain and use of pain medications following third-molar extractions compared to placebo auricular acupuncture. **Methods:** Twenty active-duty military members or DoD beneficiaries that required extraction of three or more third molars under IV sedation participated in the study. Following the extractions, the subjects were randomized to receive either placebo auricular acupuncture (n=12) with two gold-plated auricular semi-permanent needles in therapeutically neutral points (bilaterally) or therapeutic auricular acupuncture (n=8) using five gold-plated auricular semi-permanent needles (bilaterally) in the therapeutic points established by the Battlefield Acupuncture protocol. All needle placement was completed by an acupuncture-credentialed dentist. The subjects recorded VAS pain scores and the amount and type of pain medication used daily in a journal over a two-week period. Data were analyzed with a two-way repeated-measures ANOVA (α=0.05). **Results:** VAS scores were not significantly different (p=0.11) between the placebo and the therapeutic auricular acupuncture treatment group at any point during the two-week post-surgical period. There was no significant difference in the consumption of Ibuprofen (p=0.10) between the two groups, however, there was a significant interaction (p=0.03). Ibuprofen use was greater for the therapeutic auricular acupuncture treatment group from day 5 to day 8. There was no significant difference in the consumption of Percocet (p=0.58) between the two groups over the two-week period. There was no significant difference in the difficulty of the extractions or length of the procedure between the two groups (p>0.05). **Conclusions:** Compared to the placebo, therapeutic auricular acupuncture using the five Battlefield Acupuncture points did not reduce post-surgical pain or the use of pain medication over time. However, the relatively small sample size (n=20) may have limited the statistical power of this pilot study.

INTRODUCTION

Acupuncture is based on ancient Chinese philosophy dating back nearly 4000 years to the Haung Di Nei Jing text in which it is believed that energy flows through the body along meridians or channels (Oleson, 2014). It is according to this ancient philosophy that medical symptoms such as pain and disease occur when the flow of energy “qi” (pronounced “chee”) is disturbed and that by inserting fine needles into specific acupuncture points it is thought to restore 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 commonplace in recent years. Acupuncture is traditionally done with conventional manual stimulation using fine acupuncture needles but other methods of may include stimulation using electrical impulses, lasers,

ultrasound, light, magnets, pressure (Naik, 2014) or moxibustion (acupuncture treatment that involves burning of *Artemis vulgaris* leaves on the needle or insertion point) (Goertz et al., 2006).

Microsystem acupuncture is a focused form of acupuncture completed on the ears, face, hands or 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 fetal 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. Different auricular acupuncture treatment protocols not only aid in pain relief but it also can be used to treat addiction, xerostomia, neurologic disorders and other syndromes (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 has been shown to be reversed with the administration of naloxone (Simmons and Oleson, 1993).

Battlefield Acupuncture (BFA) is a form of auricular 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.

Evidence from several clinical trials supports the use of acupuncture for the management of various pain conditions to include acute and 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 the treatment of dental pain, anxiety, gagging, temporomandibular joint (TMJ) pain and disorder (TMD), orofacial pain, headaches, and xerostomia (Naik, 2014). BFA has been helpful for the treatment of acute pain in patients presenting with combat related injuries and effectively reduced pain perception as 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 placebo group when measured 24 hours later (Goertz et al., 2006).

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 observed that postoperative pain was significantly decreased and postoperative analgesic intake was lower in the study group when compared to the placebo 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.

Third molar extraction is a common outpatient dental procedure that predictably results in temporary post-operative pain. This pain is frequently managed with oral non-steroidal anti-inflammatory medications and with combination narcotics. The postoperative pain experience following dental extractions is influenced by several factors such as: the duration and difficulty of the surgery, the inflammatory response to surgical trauma, the presence and severity of pre-operative pain, the patient anxiety and threshold for pain. Because the removal of third molars is 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 before gradually decreasing. As a result, many of these patients can have postoperative pain lasting up to seven days barring post-operative complications.

This study aims to determine whether auricular acupuncture completed at the time of 3rd molar extraction will reduce postoperative pain and analgesic usage during a two week post-operative recovery period. The null hypotheses tested were that there would be no significant differences in 1) pain, 2) Ibuprofen use or 3) Percocet use between the auricular acupuncture (therapeutic) group and the placebo group over time.

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 two principle investigators (PI) and seven associate investigators (AI) (four Oral Surgeons, two Oral Facial Pain Specialists and one Patient Coordinator).

Forty subjects were recruited from the active duty military population and Department of Defense beneficiaries who presented to Wilford Hall Ambulatory Surgical Center (WHASC) for third molar extraction evaluation. Patients requiring extraction of a least three third molars were eligible to be included in the study. The AI Oral Surgeons screened patients presenting for third molar extraction. Inclusion criteria included: 1) ASA Class I or II, 2) a diagnosis and treatment plan requiring at least three third molars to be extracted, 3) 18-25 years old, and 4) subjects must be Active Duty military 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 therapeutic acupuncture group or a placebo acupuncture group.

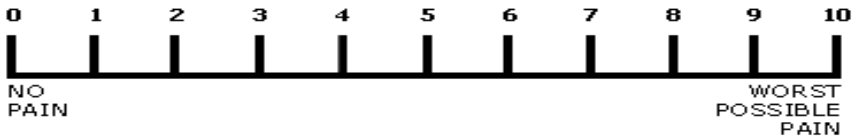
Subjects presented to WHASC Oral Surgery Clinic for treatment by an Oral Maxillofacial Surgery (OMS) first or second year resident. The patient assessed their pain level using a visual analog scale prior to surgery. The OMS resident completed the Intravenous (IV) conscious sedation, local anesthetic and third molar extractions. 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.

Immediately following the surgery, an AI trained to administer auricular acupuncture completed the acupuncture. Based on computer generated randomization model, the patients were placed into the therapeutic or placebo group. The patients were blinded to the group to which they were assigned. Both ears were disinfected using a 70% isopropyl alcohol prep and sterile gold Acupuncture Semi-Permanent

(ASP) needles (Sedatelec, Lyon, France) were placed. Ten ASP needles in total were placed in the order of Cingulate Gyrus, Thalamus point, Omega 2, Point Zero, and Shen Men in the acupuncture treatment group. Four ASP needles total were placed on the placebo group at placebo sites Helix 1 and Helix 6 as used in the study by Simmons and Oleson in 1993. 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 return to have them removed by one of the investigators. If at any time the subject decided to withdraw from the study they had the option to have the acupuncture needles removed.

The patient was prescribed three post-operative prescriptions; 1) 0.12% Chlorhexidine gluconate mouth rinse (rinse twice daily with 15mL for thirty seconds and expectorate), 2) 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 3) Percocet (oxycodone 5mg/acetaminophen 325mg) combination analgesic (take one tablet every 4-6 hours as needed for moderate to severe pain). Patients also received a two-week journal in which they reported pain 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 (see example below). Pain assessments were completed by the patient approximately every eight hours (upon waking, mid-day and at bedtime) by marking an X corresponding to their pain level on the VAS.



The journal also included areas to indicate the location and the quality of the pain (dull, sharp, throbbing, constant) and when and the amount of medication they took (ibuprofen or Percocet).

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 a principle investigator. The VAS pain score was calculated in millimeters (0-100). With a higher score indicating a greater pain experience. The data from the journals was input using Excel and analyzed to determine pain scores and medication use over the two week post-op period. Additionally, the average extraction difficulty of the two groups was calculated. The data from the two groups were compared to determine if any statistically significance difference was present. 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 procedure length, and the non-normally distributed variable of procedure difficulty 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 and Percocet consumption between treatment groups. P-values were two-tailed with statistical significance set at $p < 0.05$.

RESULTS

The study enrolled 40 patients who were randomly assigned to either the therapeutic group that received auricular acupuncture in the battlefield acupuncture points or the placebo group. No patients returned to have acupuncture needles removed. Twenty patients returned the two-week journal with a 50.0% journal return rate. Of those that returned the journals eight participants had been assigned to the therapeutic group and twelve had been assigned to the placebo group. Participant age ranged from 18-23 years with a mean age of 21.0 years. The age difference between the groups was not statistically significant (p=0.47). Of the twenty patients, fifteen (75.0%) were ASA I and five (25.0%) ASA II. The median length of procedure was 35.2 minutes. Figure 1 and Table 1 summarizes the mean of outcomes (i.e., VAS pain score, Ibuprofen use and Percocet use). Table 2 summarizes the number of extractions per difficulty and extraction difficulty per group. Table 3 summarizes descriptive statistics for the two groups.

Table 1 – Mean and standard deviation of VAS pain scores and ibuprofen and Percocet use per day.

	VAS Pain Score		Ibuprofen Use		Percocet Use	
	Therapeutic	Placebo	Therapeutic	Placebo	Therapeutic	Placebo
Pre-op	0.04 (0.11)	0.17 (0.58)	NA	NA	NA	NA
Day 1	3.83 (1.74)	3.45 (1.81)	1.38 (0.74)	1.67 (0.89)	1.50 (0.76)	0.75 (1.06)
Day 2	4.09 (2.04)	3.58 (1.90)	2.00 (1.07)	1.83 (0.72)	1.25 (1.16)	1.00(0.95)
Day 3	4.32 (2.31)	3.42 (1.73)	1.50 (0.93)	1.58 (0.90)	1.00 (1.20)	0.75 (0.87)
Day 4	4.37 (3.11)	3.10 (1.45)	1.75 (1.04)	1.67 (0.78)	0.75 (1.16)	0.58 (0.79)
Day 5	2.84 (1.80)	2.24 (1.42)	1.38 (0.92)	1.08 (1.00)	0.38 (0.74)	0.25 (0.45)
Day 6	3.71 (2.20)	1.96 1.65)	1.50 (1.07)	0.83 (1.11)	0.50 (1.07)	0.25 (0.45)
Day 7	2.75 (1.90)	1.69 (2.46)	1.50 (1.20)	0.50 (0.52)	0.38 (0.52)	0.42 (0.90)
Day 8	2.26 (1.60)	1.13 (2.16)	1.50 (1.07)	0.25 (0.45)	0.13 (0.35)	0.42 (1.16)
Day 9	1.41 (1.19)	0.66 (1.61)	0.88 (0.83)	0.33 (0.89)	0.00 (0.00)	0.25 (0.62)
Day 10	1.33 (1.29)	0.32 (0.78)	0.63 (0.92)	0.08 (0.29)	0.13 (0.35)	0.00 (0.00)
Day 11	0.54 (0.91)	0.00 (0.00)	0.38 (0.52)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Day 12	0.39 (0.57)	0.00 (0.00)	0.13 (0.35)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)

Day 13	0.15 (0.28)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Day 14	0.14 (0.26)	0.00 (0.00)	0.00(0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)

Table 2 – Number of extractions per difficulty and extraction difficulty per group

	Simple		Moderate		Difficult	
	Therapeutic	Placebo	Therapeutic	Placebo	Therapeutic	Placebo
Total Extractions	14	35	16	12	2	1
Percent	43.75 %	72.92%	50.00%	25.00%	6.25%	2.08%

Extraction Difficulty, median (IQR)	Therapeutic (n = 8)	Placebo (n = 12)	P value
Simple	1.5 (0.00)	3.0 (2.00)	0.13
Moderate	2.0 (0.75)	1.0 (0.75)	0.16
Difficult	0.0 (0.00)	0.0 (0.00)	0.77

Table 3. Descriptive Statistics of Characteristics in Participants.

Characteristics	Therapeutic (n = 8)	Placebo (n = 12)	P value
Age (years), mean (SD)	21.8 (0.9)	20.5 (1.6)	0.06
Length (Minutes)	38.4 (15.3)	33.1 (17.1)	0.49
ASA I, n (%)	5 (62.5)	11 (91.7)	0.11

The repeated measures ANOVA results indicated no significant difference in the VAS pain score between the two groups ($p=0.11$). However, there was a significant time effect ($F= 27.70$, $p<0.0001$), which means over time there was a significant decrease in pain. The interaction between time and treatment group was not significant ($p=0.61$). See Figure 1a.

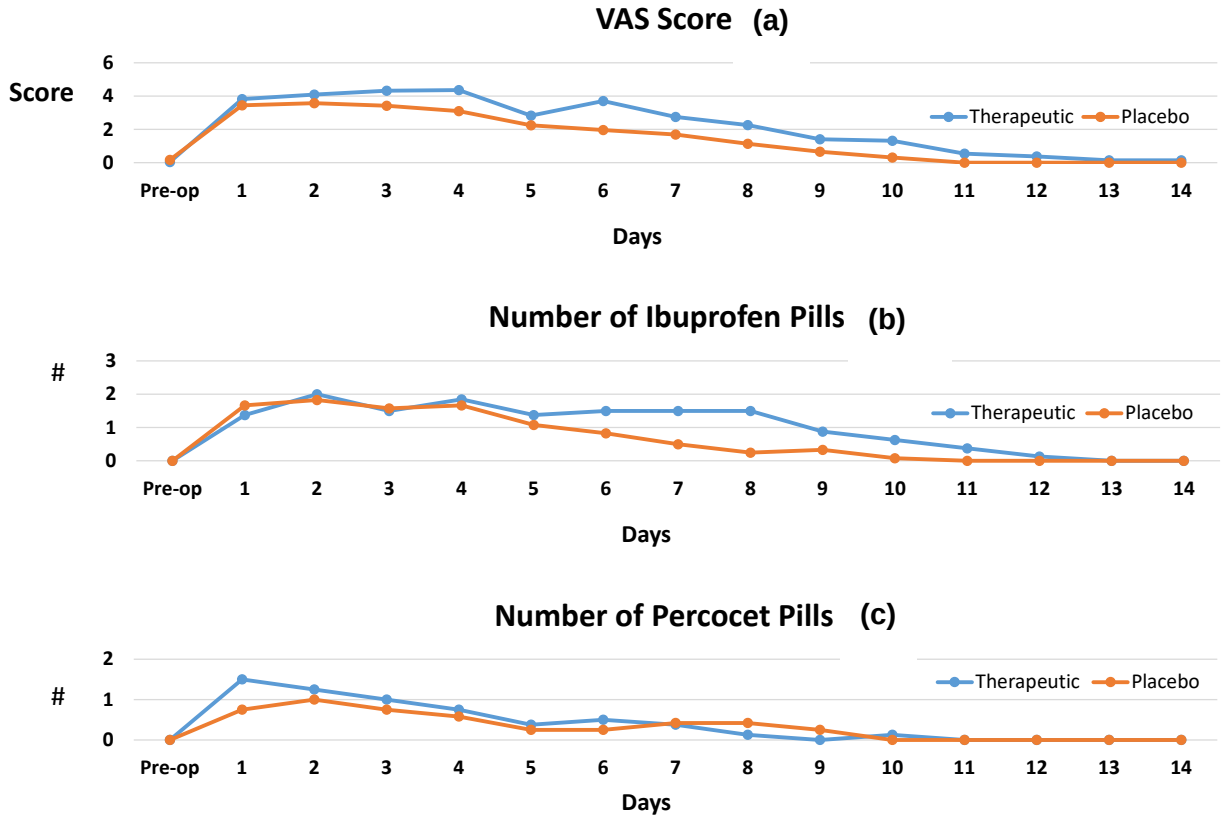
The repeated measures ANOVA results indicated no significant difference in Ibuprofen use between the two groups ($p=0.010$). However, there was a significant time effect ($F=21.4$, $p<0.0001$), which means over time there was a significant decrease in Ibuprofen use. The interaction between time and treatment group was significant ($F=2.19$, $P=0.032$), which means during days 5 through 8 there was an increase in the consumption of ibuprofen for the therapeutic acupuncture group with a decrease in consumption for the placebo group. See Figure 1b.

The repeated measures ANOVA results indicated no significant difference in Percocet use between the two groups ($p=0.58$). However, there was a significant time effect ($F=9.04$, $p<0.0001$), which means over time there was a significant decrease in Percocet use. The interaction between time and treatment group was not significant ($p=0.52$). See Figure 1c.

Based on the results of the Wilcoxon Rank Sum Test there was no significant difference in extraction difficulty between the two treatment groups ($p>0.13$). Also, there was no significant difference in

ASA classification (p=0.11) between the two groups based on the results of the Pearson Chi-Square test. An unpaired t-test found no significant difference between the two groups based on the length of the procedure (p=0.49) or age of the subjects (p=0.06).

Figure 1 (a-c) – Mean VAS scores and mean number of Ibuprofen and Percocet pills taken over two weeks



Discussion

It is well understood that patients will experience a predicted increase in pain as soon as the anesthesia wears off following surgery since tissue has been damaged. This increase in pain was supported by the data analysis. Patients typically continue to experience pain and edema with a peak usually occurring 3 to 5 days following surgery and then there is a steady decrease in the following days and our data showed a similar result with pain peaking on days 1 through 4 before steadily decreasing. The inflammatory stage of healing typically develops approximately three to five days following tissue injury and is usually associated with pain reaching its zenith. This peaking of pain is accompanied by the principal signs of inflammation: redness, swelling, warmth and pain. The pain that a patient experiences is related

to the release inflammatory mediators such as histamine, kinins and prostaglandins which can result in localized edema produced by fluid transudate. (Hupp et al., 2008).

Early results of the study indicated a statistically significant difference in pain scores between the auricular acupuncture therapeutic and the placebo groups but as additional subjects returned pain journals and the data was calculated that difference was lost. In the end there was not a statistically significant difference between the pain scales of patients who were in the auricular acupuncture therapeutic group and the placebo group. Therefore, the null hypothesis tested that there would be no significant difference in pain over time between the auricular acupuncture therapeutic group and the placebo group was not rejected. Previous studies have shown that acupuncture produces an endogenous release of endorphins that can be reversed with Naloxone (Simmons and Oleson, 1993), thus reducing the perceived pain of patients. Recent studies have shown that sham acupuncture has been as efficacious at treating disease as true acupuncture (Lowe et al., 2017). In an attempt to limit bias and placebo effect between acupuncture groups both groups received some form of acupuncture and though the Battlefield Acupuncture points have been studied to reduce pain, the unintentional effect of using sham acupuncture points may have also resulted in less pain overall as well.

Though the journals did not have an area for subject feedback, one subject noted on the bottom of several of the journal pages that they had difficulty sleeping while having the acupuncture needles in place and that it made them irritable during the day. This subject had a much higher than average daily pain score and medication use score. One disadvantage of using auricular acupuncture is the possibility of sleep disturbances if you roll in your sleep or if you are normally a side sleeper as you may unintentionally manipulate the needles. This can result in episodes of wakefulness and a poor nights rest. Sleep deprivation has been shown to promote a generalized hyperalgesia which can increase pain scores (Larson and Carter, 2016).

The null hypotheses tested that there would be no significant difference in the consumption of ibuprofen or Percocet between the auricular acupuncture (therapeutic) group and the placebo group was not rejected. However, the therapeutic group consumed a statistically significant greater amount of ibuprofen than the placebo group from days 6 through 8. However, it was noted that patients were not consuming medications as directed. The patients were advised to take Percocet during times of breakthrough pain and not as the primary source of pain control. It was noted that some were using only the narcotic for pain control or would take the pain medication when they only had slight pain. It is not clear why this behavior occurred. It may have been due to a fear of developing more severe pain or the patient may have experienced the euphoria that can be associated with narcotic medications wished to continue that high. This finding was prevalent in both groups and is consistent with the opioid epidemic in America. During this study the DoD changed its recommendations and recommended that providers manage patients pain following most procedures with non-narcotic medications to avoid the potential for addiction (VA/DOD CPG).

The limited statistical power due to the small sample size (n = 20) 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 the repeated-measures ANOVA with 2 groups and 15 repeated measures at the alpha level of 0.05 (NCSS PASS 2011 v.11.0.8). Only half of the journals (i.e., 50% from the 40 subjects enrolled) were returned and many participants either did not respond to attempts to collect outstanding journals or would state that they would bring them by and then wouldn't. Initially, the patients were scheduled a two week post-operative appointment so that they could return the journal but many of the patients cancelled that appointment or simply didn't show. This may have been related to the distance the patients had to travel to the surgical center. Many of which had to drive in excess of 30 minutes. In an attempt to increase the journal return rate, the additional measure of providing self-addressed stamped envelopes to the subjects was used so that they would not have to travel to return the journals. Unfortunately, this technique found little increased success. In hindsight, asking our young population to faithfully fill out a journal three times a day for two weeks may have been a limiting factor. The use of data collection applications might have improved our collection percentages especially with their popularity amongst the 18-25 age group. However, the use of applications in human studies requires a lengthy and often unsuccessful approval process through the 59th Medical Wing, thus preventing this study from incorporating an application. Use of such an application would allow for immediate transfer of data. Hopefully, future studies will be able to incorporate such technology with better compliance.

One of the biggest obstacles that was faced was the geographic separation of the providers. The oral surgery staff and residents covered multiple hospitals and the consenting providers were not always available to consent qualifying and willing patients due to their work requirements placing them elsewhere. There were times when there were no 1st or 2nd year OMS residents available to complete the surgical procedure for patients who consented to participate in the study. Perhaps expanding the protocol to include all OMS residents would be one option to increase surgical availability. In addition two of the three qualified acupuncturists were located in a geographically separated building resulting in a disruption in patient care for those doctors in order for them to travel to the WHASC to provide the acupuncture. With these limitations patients were not always willing to adjust their schedules to be seen on a day that was inconvenient for them when another surgery slot was available on a better day. If all the providers were collocated fewer interrupts to care would have occurred and patients would have had greater freedom for appointments.

Future studies should consider a single workplace for all investigators, avoid/limit rotations of staff and residents away from the surgery center, expand surgery residents completing procedures to include 1st through 4th year OMS residents, and the use of an app for secure data collection, reminder notifications, surveys and messaging. Improving each of these may increase the rate of enrollment as well as improve data collection.

CONCLUSIONS

Compared to the placebo, therapeutic auricular acupuncture using the five Battlefield acupuncture points did not reduce post-surgical pain or the use of pain medication over time. However, the relatively small sample size (n=20) may have limited the statistical power of this pilot study.

Disclaimer: 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. The views expressed are those of the authors and do not reflect the official views or policy of the Uniformed Services University, Department of Defense, or its Components. The authors do not have any financial interest in the companies whose materials are discussed in this manuscript.

REFERENCES

Asher GN et al. Auriculotherapy for pain management: a systematic review and meta-analysis of randomized controlled trials. The Journal of Alternative and Complementary Medicine. 2010 Oct 1;16(10):1097-108.

Burns C, Ferris G, Feng C, Cooper J, Brown M. Decreasing the pain of local anesthesia: A prospective double-blind comparison of buffered, premixed 1% lidocaine with epinephrine versus 1% lidocaine freshly mixed with epinephrine. J Am Acad Dermatol 2006;54:128-31.

Burns S, York A, Niemtzow RC, Garner BK, Steele N, Walter JAG. Moving acupuncture to the frontline of military medical care: a feasibility study. Medical Acupuncture. 2013; 25(1): 48-54.

Department of Veterans Affairs and Defense Department. VA/DoD clinical practice guideline for opioid therapy for chronic pain. February 2017.

Filshie J, White A, Cummings M. Medical Acupuncture: A Western Scientific Approach. 2nd ed. China: Elsevier 2016:5, 152-153.

Goertz MH, Niemtzow R, Burns SM, Fritts MJ, Crawford CC, Jonas WB. Auricular acupuncture in the treamtment of acute pain syndromes: a pilot study. Mil Med 2006 Oct; 171(10):1010-1014.

Hupp, JR, Ellis E III, Tucker MR. Contemporary oral and maxillofacial surgery. 5th ed. St. Louis: Mosby; 2008: 48.

Juodzbalys G, Daugela P. Mandibular third molar impaction: review of literature and a proposal of a classification. J Oral Maxillofac Res. 2014 Jul 1;5(2):e1. doi: 10.5037/jomr.2014.5201. eCollection 2014 Apr.

Larson RA, Carter JR. Total Sleep Deprivation and Pain Perception during Cold Noxious Stimuli in Humans. Scand J Pain. 2016 Oct:13:12-16 Epub 2016 Jun 16.

Lowe C, Aiken A, Day AG, Depew W, Vanner SJ. Sham acupuncture is as efficacious as true acupuncture for the treatment of IBS: A randomized placebo controlled trial. Neurogastroentrerol Motil 2017 Jul:29(7). doi: 10.1111/nmo.13040. Epub 2017 Mar 2.

Mayer DJ, Price DD, Rafii A. Antagonism of acupuncture analgesia in man by the narcotic-antagonist naloxone. Brain Res 1977;121:368-372.

Naik PN, Kiran RA, Yalamanchal S, Kumar VA, Goli S, Vashist N. Acupuncture: alternative therapy in dentistry and its possible applications. Medical Acupuncture. 2014; 26(6):308-314.

Oleson T. Auriculotherapy manual: Chinese and western systems of ear acupuncture. 4th ed. China: Elsevier 2014:2,14,26,46, 64.

Simmons MS, Oleson TD. Auricular electrical stimulation and dental pain threshold. Anesth Prog 1993 May; 40:14-19.

Tavares MG, Machado AP, Motta BG, Borsatto MC, Rosa AL, Xavier SP. Electro-acupuncture efficacy on pain control after mandibular third molar surgery. Braz Dent J. 2007; 18(2):158-162.

Usichenko TI, Dinse M, Hermsen M, Witstruck T, Pavlovic D, Lehmann C. Auricular acupuncture for pain relief after total hip arthroplasty–a randomized controlled study. Pain. 2005 Apr 30;114(3):320-7.

Vachiramon A, Wang WC, Vachiramon T. The use of acupuncture in implant dentistry. Implant Dent. 2004;13(1):58-64.