ORIGINAL RESEARCH

Auricular Acupuncture Using Battlefield Acupuncture Protocol Following Total Knee Arthroplasty

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Introduction

Total knee arthroplasty (TKA) is a common musculoskeletal surgical procedure, usually performed for osteoarthritis which causes knee pain and reduced function and quality of life. Over 700,000 TKA surgeries are performed annually in the US.[1] A 2017 study projected the total annual incidence of primary TKA surgeries to grow 143% from the year 2012 to the year 2050.[2]

Pain regimens after TKA usually incorporate opiate- and non-opiate analgesics, because opiate pain medications have side effects of respiratory depression, constipation, and nausea.[3] There have been increasing numbers of deaths from opiate pain medication overdose, with opioids being involved in 49,860 drug overdose deaths in 2019.[4] There has been an effort to reduce the amount of opioid medications used and to use multimodal methods of pain control.[3]

Acupuncture has been a part of Traditional Chinese Medicine for several thousand years. Its theory is based on regulating the flow of Qi along the body's 12 meridians to keep the body in balance and harmony.[5] In the last half century acupuncture has become popular in the West, proving beneficial for different conditions such as nausea and pain.[6] Many studies have looked at the mechanism of acupuncture. It is proposed to affect ascending and descending inhibition of pain signals (the gate theory of pain), release neuropeptides including endogenous opioids, and promote neuroplasticity in brain centers responsible for pain.[5,7,8]

Many different acupuncture protocols and techniques are practiced. One technique is Battlefield Acupuncture (BFA). BFA is an auricular acupuncture protocol developed by Dr. Richard Niemtzow for treatment for acute and chronic pain in the combat theater setting.[9] In BFA, tiny needles are placed in five specific acupuncture points on one or both ears. Practitioners can be trained in BFA in as little as 3-4 hours, and it can be applied quickly in a clinical setting.[10] Since its creation in 2001 BFA has been studied for many indications to reduce pain.

The results are mixed but show potential. In a study of 284 veterans receiving BFA in individual and group sessions, 82% of subjects had reported improvement in immediate pain scores.[11] Estores et al showed efficacy of BFA with the treatment of neuropathic pain in patients with spinal cord injury.[12] A recent review of BFA studies reported that most studies published show a reduction in acute pain scores across a variety of healthcare settings, including the Emergency Department (ED) and immediate postoperative period, but cautions that the quality of studies available are lacking.[10]

Some placebo-controlled studies with sham-BFA have demonstrated less favorable results. One military study comparing BFA to both sham-BFA and usual care did not demonstrate improved pain scores or quality of life in postoperative patients following lower extremity surgery.[13] A meta-analysis of placebo controlled BFA Randomized Control Trials (RCTs) of both acute and chronic adult pain did not demonstrate significant differences in pain scores.[14] Evidence-based conclusions continue to be limited by the limited number of RCTs available, and it remains unclear which pain conditions and healthcare settings may most benefit from BFA.

The aim of our study was to compare BFA to sham BFA in relief of pain, reduction in opiate medication use, and improvement in functional measures in subjects after total knee arthroplasty.

Methods

This was an IRB-approved prospective, single-blinded, randomized controlled trial comparing modified BFA plus standard of care versus sham BFA plus standard of care conducted in the Acute Rehabilitation Unit (ARU) at the Veteran Affairs Greater Los Angeles Healthcare System. IRB #1615792-3.

Modified Battlefield Acupuncture Protocol

Subjects' ears were cleaned with an alcohol prep pad. Acupuncture needles on adhesive backing were placed at 5 acupuncture points on the ears in the specific order: cingulate gyrus, thalamus, omega 2, shen-men, and point zero. Needle placement started on the ear ipsilateral to the surgical knee, and alternated between ears, with ranging of the surgical knee five times between each needle placement. The BFA protocol technique for this study differed from traditional BFA in that it did not have subjects walk between needle placement, but instead had subjects flex and extend their surgical knee five times. The subjects reported their pain in the post-surgical knee after each placement. If the subject continued to experience pain, the next placement proceeded, continuing until all five points on each ear were placed or the subject reported complete pain relief. The needles were left in for five days or until discharge from the ARU, whichever came first.

Sham acupuncture was performed with sham needles. They had similar packaging and adhesive backing but had a plastic nib in place of the needle in the center of the adhesive. They were placed over the same acupuncture points with the same ranging of the knee between placements.

Recruitment

Men and women between the ages of 18-85 receiving first-time single-limb total knee arthroplasty who were admitted to the ARU were included in the study. Study exclusion criteria consisted of: patients using more than 120mg/24 hours of oral morphine equivalents (mEQ) at the time of enrollment, those with untreated mental health issues, those with current illicit substance abuse, pregnant patients, patients with active malignancy or active signs of sepsis, those with ear wounds, or those with deformities or missing portions of the ear.

Information regarding the study was provided to patients in the pre-operative orthopedic clinic before the patient's scheduled surgery. No compensation was provided to participants.

Randomization

Participants were randomly assigned into the treatment group or the sham group by a random number generator (www.randomization.com). Subjects were blind to their randomization, but the study team was not blind to treatment being given.

Intervention

After admission to the ARU, subjects were approached about participating in the study. Subjects willing to participate signed an informed consent per IRB protocol and completed initial surveys. They were then randomized and received either treatment or sham BFA. The medical providers managing the patients in the ARU were not restricted in their prescription patterns, provided standard care to both groups, and were not aware of their randomization.

Data Collection

Chart review in the electronic medical record was performed to collect demographic data and outcome data. The two primary outcomes measured were visual analog scale (VAS) pain scores recorded by nurses during their ARU admission and oral mEQ use during admission.

Our study used two surveys that were administered at four time points: after admission to the ARU, prior to discharge from the ARU, and 4- and 8-weeks after ARU discharge. Study team members called patients by telephone to administer the surveys at the 4- and 8-week time points. The first survey used was the Pain Outcomes Questionnaire-Short Form (POQ-SF) which is a 20-item inventory that uses a Likert-type scale (0-10) to quantify pain's impact on their ability to perform tasks and on their mental state. A lower score shows improved function. This form has been validated previously in VA populations and works as a multi-dimensional measure of pain and recognizes the biopsychosocial model of pain[15]. The Knee Outcome Scale - Activities of Daily Living (KOS-ADL) was also used. The Knee Outcome Scale – Sports, which is commonly part of the full survey, was excluded due to its lack of relevance to our study population. This is a self-report measure that rates perceived disability with 5 being "no difficulty" and 0 being "unable to perform." A higher score shows improved function. This survey has previously shown to have test-retest reliability coefficient of 0.97, suggesting it is a reliable and valid tool for assessment of functional limitations that result from impairments of the knee, including post arthroplasty.[16]

Data Analysis

Welch Two Sample t-tests were used to conduct comparisons between treatment and sham groups to assess for changes between pain scores and mEQ. The P-value for significance was set at $p = <0.05$. A mixed ANOVA (analysis of variance) was used to determine any significant differences in POQ-SF or KOS-ADL scale at enrollment, 4-weeks and 8-weeks, and Tukey HSD test was used for post-hoc analysis. All analysis was performed using the statistical software R by a resident physician researcher.

Results

Patient Demographics

A total of 43 patients were enrolled and met all inclusion criteria. All subjects were males. Nine subjects were not included in the final analysis because not all data measurements were able to be obtained or they were lost to follow-up. The final analysis included 34 subjects: 19 in the BFA treatment arm and 15 in the sham arm.

	Sham	Treatment
N	15	19
Age (years)	66.7	69.1
BMI	29.4	29.7

Table 1. Patient Demographics

Comparison of Treatment and Sham

No significant difference was found in average daily pain scores between BFA and sham groups (5.57 vs 4.95, 95% CI [-0.47-1.69], p=0.25). There was also no significant difference in day 1 initial pain scores between BFA and sham groups (4.90 vs 5.44, 95% CI [-0.80-1.89], p=0.41). There was no significant difference between BFA and sham groups in average mEQ (57.36 vs 51.59, 95% CI [-28.10-16.57], p=0.60) or mEQ day 1 post-procedure (65.13 vs 48.75, 95% CI [-42.07-9.32], p=0.20).

Using mixed ANOVA testing no significant difference was found between treatment and sham groups at admission, 4-week, or 8-week intervals in POQ-SF score ($F_{(2,96)}=0.39$, p=0.68) or in KOS-ADL score ($F_{(2,96)}=0.15$, p=0.87). Within both BFA and sham groups, there was a statistically significant interaction between time points (admission vs. 4 weeks after discharge, and 8 weeks after discharge) on POQ-SF ($F_{(2,96)}=36.56$, p=<0.001) and KOS-ADL ($F_{(2,96)}=18.23$, p=<0.001). Both POQ-SF and KOS-ADLS showed improvement in function over time with majority of improvement by 4 weeks after discharge. Improvement was defined by lower POQ-SF scores and higher KOS-ADL scores.

	Admit	Week 4	Week 8
POQ-SF BFA - Sham	-6.01	-10.28	-17.02
KOS-ADL BFA - Sham	-3.41	-0.49	0.44

*Table 2. The difference in mean POQ-SF and KOS-ADL scores between BFA and sham groups at different time points. P >0.05 unless otherwise noted. * = p<0.05; ** = p<0.01; *** = p<0.001*

	Admit – Week 4	Admit – Week 8	Week 4 – Week 8
POQ-SF BFA	48.39***	50.73***	2.34
POQ-SF Sham	44.13***	39.73***	-4.40
KOS-ADL BFA	-19.68**	-21.84***	-2.16
KOS-ADL Sham	-16.77*	-18.00*	-1.23

*Table 3. The difference in mean POQ-SF and KOS-ADL scores within BFA and sham groups at different time points. P >0.05 unless otherwise noted. * = p<0.05; ** = p<0.01; *** = p<0.001*

No definitive conclusions can be made from the data collected during this study as not enough subjects were enrolled to properly power the study. A prior power analysis was conducted which determined that the minimum sample size required is N=100 to find significance using paired t-tests and ANOVA, but only 34 subjects were included in the final analysis.

Discussion

Our preliminary results find no significant difference in pain scores, opioid use post-operatively, or functional outcomes between the treatment and sham groups. Both treatment and placebo groups improved in function as measured by POQ-SF and KOS-ADL over time, but there was no between-group difference at any time point. The study ended with fewer than anticipated subjects enrolled and is underpowered to draw firm conclusions. Our study has also seen intermittent slowdowns in enrollment due to operating room closure for cleaning and remodeling, as well as closures due to the COVID19 pandemic.

It is possible that the effect size of BFA intervention was too small to be measured in the setting of TKA, a major lower extremity surgery that can be very painful.

Our results should not dissuade others from offering BFA treatment for pain as it is a safe and inexpensive form of analgesia. Future studies looking at different indications for use of BFA are warranted.

Limitations

Our study subjects were restricted to those admitted to the ARU per IRB recommendations. This limited the ability of capturing pain reduction in the immediate post-operative period as subjects are typically admitted to the ARU on postoperative day one, two or three. The restriction to ARU population also had the implication that the patient population had lower levels of function and mobility in comparison to the higher functioning subjects that are discharged home directly post-operatively with home skilled therapies. The lack of financial incentive or any tangible incentives also dissuaded a significant number of possible participants during recruitment. As our study is unfunded, we were unable to provide any compensation to participants for their time in completing outcome surveys which some patients stated was a barrier to their participation. In addition, upon interviewing possible participants it was frequently noted the some had hesitations using complementary or alternative forms of medical treatment such as acupuncture. Study recruitment was also limited by operating room renovations resulting in potential study participants having procedures at outside hospitals. The COVID pandemic also reduced elective surgical total knee arthroplasty procedure. Post-operative physical therapy on the surgical floor also diverted potential study participants to complete rehabilitation at home and not in the Acute Rehabilitation Unit.

Abbreviations

ADL- activity of daily living
BFA- battlefield acupuncture
KOS-ADL- Knee Outcome Survey-ADLs
mEQ- oral morphine equivalents
POQ-SF- Pain Outcome Questionnaire-Short form
TKA- total knee arthroplasty

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