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Battlefield Acupuncture for Adult Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract. Pain is a major public health problem, causing heavy social and economic burdens to patients and society while consuming tremendous medical resources at the same time. Thus, there is a critical need to find low-cost, efficacious, and therapeutic approaches to help manage pain. While acupuncture is increasingly recognized as a promising pain-relieving method, less is known about a specific form of auricular acupuncture known as Battlefield Acupuncture (BFA). The BFA technique involves the sequential placement of semi-permanent, single-use, French ASP® golden needles to five specific acupoints in one or both ears, where they are left in place for 3–4 days or longer [Niemtzow, R.C., Battlefield acupuncture. *Med. Acupunct.* 19: 225–228, 2007]. The BFA needles (more accurately described as tiny conical darts) pierce the ear in designated locations in a particular order [Levy, C.E., N. Casler and D.B. FitzGerald. Battlefield acupuncture: an emerging method for easing pain. *Am. J. Phys. Med. Rehabil.* 97: e18–e19, 2018.]. (Figs. 4 and 5) It was developed

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by Dr. Richard C. Niemtzow in 2001, as a subgroup form of an auricular acupuncture technique based on the somatotopic arrangement of an inverted fetus pattern on the external ear [Romoli, M. Ear acupuncture: historical abstract–differences of ear cartography between the east and the west. *Dtsch. Z. Akupunkt.* 53: 24–33, 2010.]. Currently, BFA is widely used in the US military, but to our knowledge, there is no review which comprehensively synthesizes the current publications surrounding pain management. This review aims to investigate the effects and safety of BFA in adults with pain. Electronic databases were searched for randomized controlled trials (RCTs) published in English evaluating efficacy and safety of BFA in adults with pain, from database inception to September 6, 2019. The primary outcome was pain intensity change, and the secondary outcome was safety. Nine RCTs were included in this review, and five trials involving 344 participants were analyzed quantitatively. Compared with no intervention, usual care, sham BFA, and delayed BFA interventions, BFA had no significant improvement in the pain intensity felt by adults suffering from pain. Few adverse effects (AEs) were reported with BFA therapy, but they were mild and transitory. BFA is a safe, rapid, and easily learned acupuncture technique, mainly used in acute pain management, but no significant efficacy was found in adult individuals with pain, compared with the control groups. Given the poor methodological quality of the included studies, high-quality RCTs with rigorous evaluation methods are needed in the future.

Keywords: Battlefield Acupuncture; Auricular Acupuncture; Adult; Pain; Review.

Introduction

Pain has been regarded as a significant public health concern with profound physical, emotional, social, and economic burdens (Pizzo *et al.*, 2011). It is the most common complaint in medical practice (Fishman, 2007). Despite significant scientific research, the clinical practice of pain management still struggles to deliver adequate and timely pain relief to patients. Inadequate pain management affects patients' psychological and physiological health outcomes, is associated with more complications from primary diseases, prolongs the recovery period, and increases healthcare expenditures (Patrick *et al.*, 2015). According to data from the Centers for Disease Control and Prevention (CDC) 2016 National Survey, in the United States alone, about 50.0 million (20.4%) adults experienced chronic pain and 19.6 million (8.0%) adults had high-impact chronic pain (Dahlhamer *et al.*, 2018). The cost of chronic pain is approximately $560–$635 billion annually, including medical costs, reduced productivity, and disability programs (Dahlhamer *et al*., 2018). Currently, pharmaceuticals, including opioids, are the most common treatment for pain. The current unprecedented opioid crisis in the United States of America has resulted in over 70,000 drug-related overdose deaths in 2017, of which almost 70% were due to opioids (Hedegaard *et al*., 2018). Given the opioid crisis, pain management stakeholders have faced significant challenges in the provision of relief for both acute and chronic pain (National Academies of Sciences *et al*., 2017). It is thus of paramount importance to promote efforts that can both reduce pain while decreasing opioid utilization. Therefore, multi-modal pain management strategies involving nonpharmacological modalities, such as acupuncture treatment, are recommended (Mohiuddin, 2019).

Acupuncture has shown promising efficacy for pain with a variety of causes, including low back pain (Wee *et al*., 2019; Xiang *et al*., 2019), visceral pain (Lee *et al*., 2019),

postoperative pain (Fuentealba Cargill and Biagini Alarcon, 2016; Pouy *et al*., 2019), osteoarthritis (Zhang *et al*., 2017), and dysmenorrhea (Xiang *et al*., 2017). Auricular acupuncture has been recognized as a micro-acupuncture system regulating body function in a wide range of health problems (WHO, 1991). As a promising nonpharmacological treatment, auricular acupuncture deserves increased attention and research efforts as a viable pain management tool (Asher *et al*., 2010).

Pain management is a persistent issue facing the US military health care system, and currently, the most widely used auricular acupuncture method used in the army is Battlefield Acupuncture (BFA) (Niemtzow *et al*., 2015). BFA is quickly and easily learned and has been recognized as a pain relieving nonpharmacologic intervention. Previous publication reported that BFA provides clinically significant pain management (Holt, 2017; Federman *et al*., 2018). BFA has been shown to be effective for treating a variety of pain conditions, including lower back pain (Fox *et al*., 2018; Wee *et al*., 2019), surgical pain (Abdelfatah *et al*., 2018), postsurgical pain (Collinsworth and Goss, 2019), and neuropathic pain (Estores *et al*., 2017). In the US, BFA is the subject of significant research interest as the opioid epidemic evolves (Fox *et al*., 2018). BFA has been recommended for both individual or group settings in order to deliver the service efficiently to veterans that suffer from pain (Federman *et al*., 2018). However, despite the growing popularity of BFA, many BFA studies suffer from small sample sizes or other methodologic concerns. Thus, the efficacy of this therapy for acute and/or chronic pain remains to be determined. To our knowledge, no systematic review of the efficacy and safety of BFA in pain management exists. This review aims to synthesize the data with regards to the safety and efficacy of BFA procedures, thereby providing guidance to inform current practice and research.

Materials and Methods

Search Strategy

The comprehensive search strategy was designed and conducted by an experienced librarian from Mayo Clinic, Rochester Campus with input from the study's principal investigators. An electronic literature search was conducted from the following multiple databases: Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, Ovid MEDLINE (R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, and Daily, Ovid Cochrane Database of Systematic Reviews, and Scopus, from each database's inception to September 6, 2019, publications in the English language only. Relevant controlled vocabulary supplemented with keywords was used to search for clinical trials of BFA for pain in adults. The actual strategy listing all search terms used and how they are combined is available in the appendix.

Study Eligibility

Eligible publications had to meet the following criteria: RCTs using BFA as the treatment intervention, published in English language from the above databases. Only studies using

placebo, sham acupuncture, no treatment, or conventional care as control interventions were included. Non-RCTs such as case reports, case-control trials, and cohort studies were excluded.

Participants aged 18 years or above suffering from pain were included. There was no restriction on sex, ethnicity, type of pain, pain generator, pain severity, frequency, or pain duration. Any trial evaluating the efficacy and safety of BFA on pain management was included in this review, regardless of treatment frequency and duration. Any study evaluating pain intensity change and safety outcomes of BFA in pain management was included if they compared BFA to no treatment, placebo, sham acupuncture, or conventional treatment.

The primary aim was to investigate the impact of BFA therapy on pain relief in adults. Test variables such as the Visual Analogue Scale (VAS), Numeric Pain Rating Scale (NPRS), Numeric Rating Scale (NRS), and Brief Pain Inventory (BPI) were included. If possible, a secondary examination of safety outcomes such as adverse events (AE), complications, and side effects of BFA were also assessed.

Quality Assessment and Publication Bias

The potential bias of each trial was assessed with Cochrane Risk of Bias Tool for Randomized Controlled Trials (Higgins *et al*., 2011) by two independent reviewers in the following seven domains: selection bias, detection bias, performance bias, reporting bias, attrition bias, and other sources of bias. Each domain was evaluated as either "low", "unclear", or "high" in bias. The two reviewers made judgments independently, and any discrepancy was resolved by consensus or by contacting the original author.

Data Extraction

Important data were extracted by two reviewers independently from the searched publications. This data for each article included first author, publication year, setting, condition, population, sample size, intervention, control, effect, provider, selected points, treatment frequency, follow up and outcome. Any discrepancy was resolved by discussion or consensus with a third reviewer, or by contacting the original authors if necessary.

Data Synthesis and Analysis

We used the software Review Manager version 5.3.5 (Cochrane, London, United Kingdom) to conduct the statistical analysis. Descriptive variables including details of participants, setting, interventions, comparators, outcomes, and safety were collected from each trial. For trials using the same or similar outcome measures, a meta-analysis was performed. The pooled data was described as a mean difference (MD), which was calculated for continuous outcomes, and a risk ratio (RR) was summarized as the effect size for dichotomous outcomes with 95% confidence intervals (CIs). $P < 0.05$ was indicative of significant difference between the experiment and control groups. The Chi-squared test and Higgins I^2 test

were used to assess heterogeneity between studies, with $I^2 > 50\%$ and >75% indicative of substantial and considerable heterogeneity, respectively. The fixed-effect model was used if the heterogeneity was not significant ($I^2 < 50\%$); otherwise, a random-effect model was used when the included studies had significant heterogeneity ($I^2 > 50\%$). The fixed-effect model was also used if the study number in the meta-analysis was very small (Borenstein *et al*., 2010). If possible, subgroup meta-analysis was conducted on different study outcomes in order to maximize the similarities among studies that would be combined.

Publication Bias

Due to the limited number of articles, publication bias evaluation was not conducted by the funnel plot.

Results

Study Selection

Using our search strategy, 208 potential publications were identified from the above databases, and 27 additional records were identified through other sources. After excluding 3 duplicates, 232 records remained. Another 220 studies were excluded by screening the titles and abstracts, and 12 articles with full-text were obtained. Ultimately, only nine studies (Goertz *et al*., 2006; Moss *et al*., 2015; Estores *et al*., 2017; Fox *et al*., 2018; Garner *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019) were included in this review, and among them, five RCTs (Goertz *et al*., 2006; Estores *et al*., 2017; Garner *et al*., 2018; Crawford *et al*., 2019; Kim *et al*., 2019) were included in the quantitative analysis. A PRISMA flow diagram of this review is shown in Fig. 1.

Characteristics of the Included Studies

The characteristics of the included RCTs are presented in Table 1. In total, nine RCTs with 692 subjects were included in this systematic review, with the sample size ranging from 24 to 233. Seven of the nine studies were conducted in military settings (Goertz *et al*., 2006; Moss and Crawford, 2015; Garner *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019), one in both military and civilian settings (Estores *et al*., 2017), and one in an urban academic medical center (Fox *et al*., 2018). Seven studied acute pain, including post-surgery-pain (Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019), acute sore throat (Moss *et al*., 2015), and acute pain syndromes (Goertz *et al*., 2006), while the other two studied chronic pain, one investigating chronic pain and insomnia (Garner *et al*., 2018) and the other evaluating spinal cord injury related neuropathic pain (Estores *et al*., 2017). Eight were two-arm parallel studies (Goertz *et al*., 2006; Moss *et al*., 2015; Estores *et al*., 2017; Fox *et al*., 2018; Garner *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Kim *et al*., 2019),

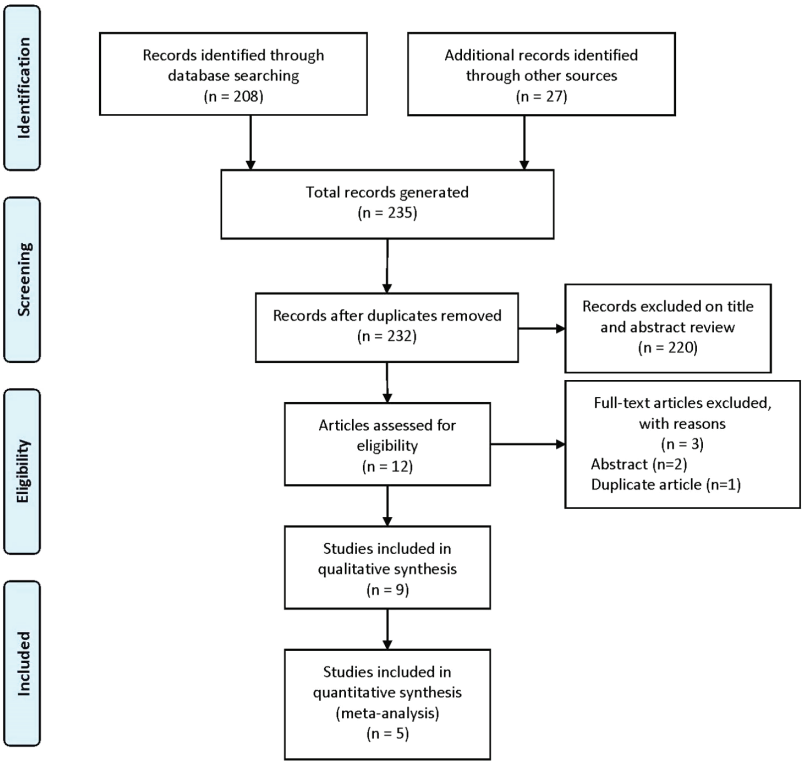

Figure 1. PRISMA flow chart.

and one was a three-arm parallel study (Crawford *et al*., 2019). Three studies evaluated the change of pain intensity with the NRS (Goertz *et al*., 2006; Estores *et al*., 2017; Fox *et al*., 2018), two with the Numerical Pain Rating Scale (NPRS) (Crawford *et al*., 2019; Kim *et al*., 2019), two with the VAS (Moss *et al*., 2015; Collinsworth *et al*., 2019), one with the Defense & Veterans Pain Rating Scale (DVPRS) (Plunkett *et al*., 2018), and one with the BPI (Garner *et al*., 2018). All the above RCTs were single-center except one trial (Estores *et al*., 2017).

In the included studies, BFA was used as the experimental treatment. In six studies, experimental groups consisted of BFA plus standard care (Goertz *et al*., 2006; Moss *et al*., 2015; Fox *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019), in the other three studies (Estores *et al*., 2017; Garner *et al*., 2018; Plunkett *et al*., 2018), BFA alone was regarded as experimental intervention. For control interventions, six studies used standard care (Goertz *et al*., 2006; Moss *et al*., 2015; Fox *et al*., 2018; Garner *et al*., 2018; Collinsworth *et al*., 2019; Kim *et al*., 2019), one study used sham BFA plus standard care and standard care (Crawford *et al*., 2019), one used no control intervention (Plunkett *et al*., 2018) and one used a delayed BFA group (Estores *et al*., 2017).

BFA therapy providers varied in these trials. Three trials (Moss *et al*., 2015; Fox *et al*., 2018; Kim *et al*., 2019) were conducted by trained physicians, two by acupuncturists (Goertz

Table 1. Main Characteristics of the Included Studies in the Systematic Review and Meta-Analysis

Author	Year	Setting	N	Arm	Condition	Interventions	Control	Effect
Kim (Kim *et al.*, 2019)	2019	Wilford Hall Ambulatory Surgical Center	70	2	Post-Partum Pain	BFA + Standard analgesia	Standard analgesia	Negative
Crawford (Crawford *et al.*, 2019)	2019	United States Air Force hospitals	233	3	Post lower extremity surgery	mBFA+ standard care	Sham BFA+ standard care /standard care	Negative
Collinsworth (Collinsworth *et al.*, 2019)	2019	Keller Army Community Hospital	41	2	Postsurgical shoulder pain	BFA + standard care	Standard care	Negative
Fox (Fox *et al.*, 2018)	2018	Icahn School of Medicine at Mount Sinai	30	2	Acute Lower back pain	BFA + standard care	Standard care	Positive
Garner (Garner *et al.*, 2018)	2018	US military regional medical treatment facility located in Germany	45	2	Chronic Pain and Insomnia	BFA	Standard care	Positive
Plunkett (Plunkett *et al.*, 2018)	2018	Womack Army Medical Center	95	2	Post-tonsillectomy pain	BFA	No intervention	Negative
Estores (Estores *et al.*, 2017)	2017	University of Maryland Rehabilitation and Orthopedic Institute and the VA Maryland Healthcare System	24	2	SCI related neuropathic pain	BFA	Delayed group	Positive
Moss (Moss *et al.*, 2015)	2015	Air Force family medicine clinic	54	2	Acute sore throat	BFA plus standard treatment	Standard treatment	Positive
Goertz (Goertz *et al.*, 2006)	2006	Malcolm Grow Medical Center, Andrews Air Force Base	100	2	Acute pain syndromes	BFA + standard emergency medical care	Standard emergency medical care	Negative

(*Continued*)

Notes: Battlefield acupuncture (BFA); Modified Battlefield acupuncture (mBFA).

Table 1. (*Continued*)

Author	Provider	BFA Points	Treatment	Follow up	Follow up Techniques	Pain Intensity	Safety
Kim (Kim *et al.*, 2019)	A trained physician	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Bilateral)	Once	10 days	Via phone	NPRS	No complication
Crawford (Crawford *et al.*, 2019)	Physicians guided by an acupuncturist	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Bilateral)	Once	24 hours, 48 hours, 1 week, and 1 month post intervention	In-person, via phone, email, or text message	NPRS	—
Collinsworth (Collinsworth *et al.*, 2019)	Trained physical therapists	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Bilateral)	Once	24 hours,72 hours, 7 days, 14 days, and 6 weeks after surgery	Daily diary	VAS	No AE
Fox (Fox *et al.*, 2018)	Trained physicians	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Mono-lateral)	Once	5 min, 1 hour after intervention	In person	NRS	Discomfort at needle insertion
Garner (Garner *et al.*, 2018)	Trained advanced practice nurses	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Bilateral)	Once	4 days	Daily diary	BPI	Pain, irritation, or redness at the insertion, light headed
Plunkett (Plunkett *et al.*, 2018)	Trained Providers	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Mono-lateral)	Once	10 days	Daily diary	DVPRS	Safe
Estores (Estores *et al.*, 2017)	Acupuncturists	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Bilateral)	Weekly sessions for eight weeks	4 weeks	Weekly diary	NRS	Safe
Moss (Moss *et al.*, 2015)	Trained physicians	Cingulate Gyrus; Thalamus; Omega 2; Point Zero; and Shen Men (Bilateral)	Once	6, 24, and 48 hours	Via phone, E-mail, or text message	VAS	—
Goertz (Goertz *et al.*, 2006)	Acupuncturists	Cingulate gyrus and thalamic nuclei (Bilateral)	Once	24 hours	Via phone	NRS	—

Notes: Numerical pain rating scale (NPRS); Numeric rating scale (NRS); Brief Pain Inventory (BPI); Visual Analogue Scale (VAS); Defense &Veterans Pain Rating Scale (DVPRS); Adverse event (AE).

et al., 2006; Estores *et al*., 2017), one by physicians guided by an acupuncturist (Crawford *et al*., 2019), one by trained providers (Plunkett *et al*., 2018), one by trained physical therapists (Collinsworth *et al*., 2019), and one by trained nurses (Garner *et al*., 2018).

Patients in most trials had one BFA treatment, except one trial wherein subjects received one session of BFA weekly for eight weeks (Estores *et al*., 2017). All participants in the included trials were followed between 5 minutes to 6 weeks post treatment, via diary (Estores *et al*., 2017; Garner *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019), phone (Goertz *et al*., 2006; Moss *et al*., 2015; Crawford *et al*., 2019; Kim *et al*., 2019), in-person interview (Fox *et al*., 2018; Crawford *et al*., 2019), email (Moss *et al*., 2015; Crawford *et al*., 2019), or by text message (Moss *et al*., 2015; Crawford *et al*., 2019).

Four trials (Moss *et al*., 2015; Estores *et al*., 2017; Fox *et al*., 2018; Garner *et al*., 2018) reported beneficial effects of BFA or BFA plus standard treatment on pain intensity, while the other five did not (Goertz *et al*., 2006; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019).

Risk of Bias Assessment

Regarding random sequence generation and allocation concealment, eight studies (Goertz *et al*., 2006; Moss *et al*., 2015; Fox *et al*., 2018; Garner *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019) used appropriate random sequences generation and allocation concealment and were classified as "low risk"; one study (Estores *et al*., 2017) did not provide sufficient information and was rated as "unknown risk". Except for one study (Garner *et al*., 2018) that performed intervention blinding of participants and personnel, all the other studies were rated as "high risk" with respect to performance bias due to the inherent difficult nature of blinding for the BFA intervention. Blinding of outcome assessment was conducted in one study (Goertz *et al*., 2006) which was classified as "low risk" with respect to detection bias, while the other eight trials were classified as "high risk". Three studies (Moss *et al*., 2015; Garner *et al*., 2018; Crawford *et al*., 2019) described the completeness of outcome data for each main outcome, while the other six (Goertz *et al*., 2006; Estores *et al*., 2017; Fox *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Kim *et al*., 2019) reported incomplete outcome data and were evaluated as "high risk". All studies performed per-protocol analysis and were classified as "low risk" with respect to reporting bias. All the included trials were classified as "low risk" with respect to other biases. In summary, most of the trials (Goertz *et al*., 2006; Moss *et al*., 2015; Estores *et al*., 2017; Fox *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019) were evaluated as poor quality due to two or more high or unclear risk bias, except one trial with fair quality with one criterion not met (Garner *et al*., 2018). Results of risk-of-bias assessments of the nine RCTs are presented in Fig. 2.

Outcomes

Of nine RCTs included in this study, four studies (Moss *et al*., 2015; Estores *et al*., 2017; Fox *et al*., 2018; Garner *et al*., 2018) reported significant reduction in pain intensity, while

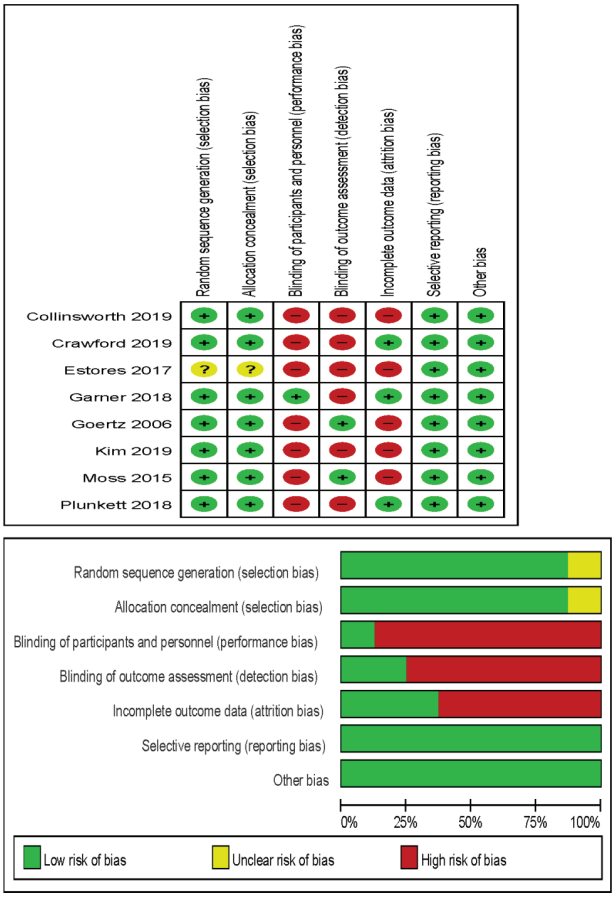

Figure 2. Risk of bias summary.

the other five (Goertz *et al*., 2006; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Crawford *et al*., 2019; Kim *et al*., 2019) did not. Finally, five trials (Goertz *et al*., 2006; Estores *et al*., 2017; Garner *et al*., 2018; Crawford *et al*., 2019; Kim *et al*., 2019) involving 344 participants with similar pain intensity outcomes were analyzed quantitatively. The final meta-analysis of the overall studies reported non-significant pain relief of BFA or BFA plus standard care therapy compared to the control groups (MD=–0.17, 95% CI [–0.61, 0.28], $p = 0.62$) (Fig. 3). The other four trials (Moss *et al*., 2015; Fox *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019) relevant to the effect of BFA on acute pain management were excluded due to lack of raw data, i.e., mean and standard deviation.

Among all the included RCTs, six studies (Estores *et al*., 2017; Fox *et al*., 2018; Garner *et al*., 2018; Plunkett *et al*., 2018; Collinsworth *et al*., 2019; Kim *et al*., 2019) reported safety issues of BFA, while there was no relevant information provided in the other studies (Goertz *et al*., 2006; Moss *et al*., 2015; Crawford *et al*., 2019). Besides four trials (Moss *et al*., 2015;

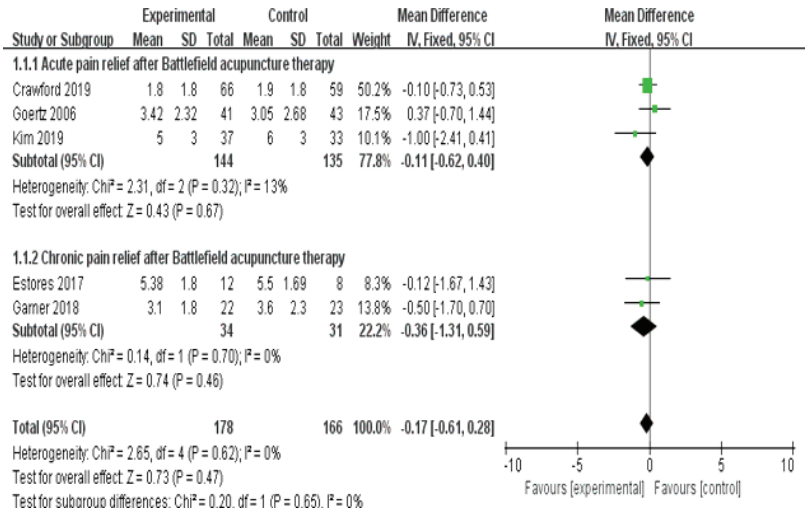

Figure 3. Battlefield acupuncture therapy for pain management.

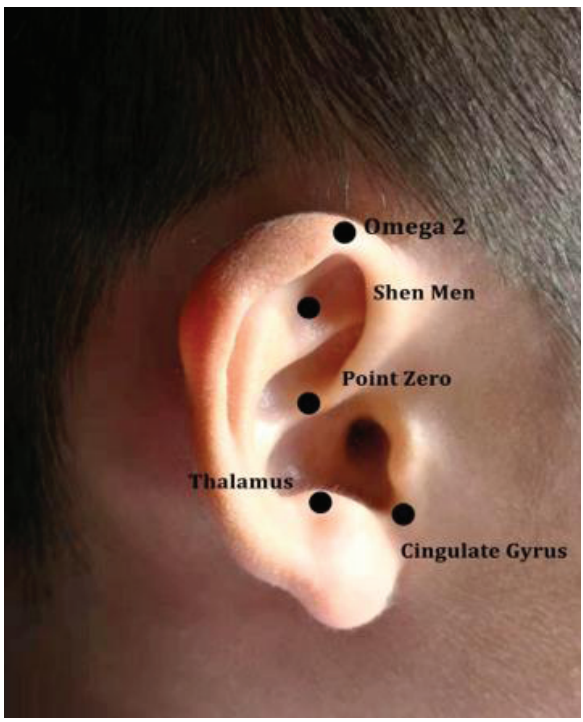

Figure 4. Battlefield Acupuncture points in ear: Cingulate Gyrus, Thalamus, Omega 2, Point Zero, and Shen Men.

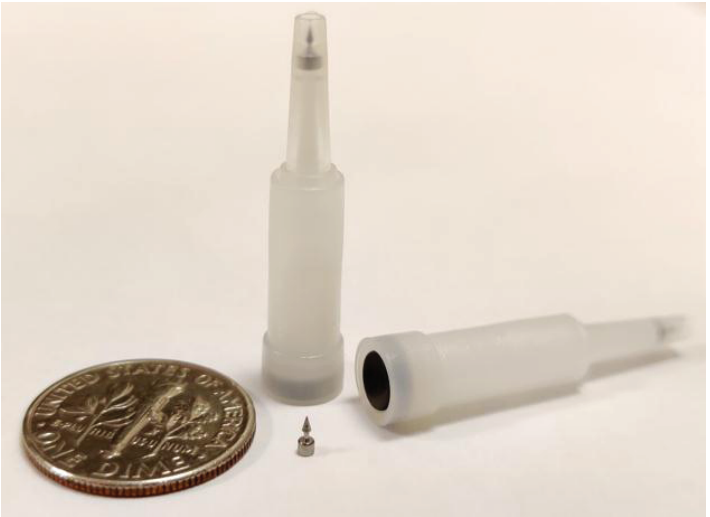

Figure 5. ASP semi-permanent ear needles.

Estores *et al*., 2017; Collinsworth *et al*., 2019; Kim *et al*., 2019) that briefly mentioned BFA was safe, adverse events for BFA were recorded in two studies (Fox *et al*., 2018; Garner *et al*., 2018). A total of 30 participants with acute low back pain in the emergency department were randomized to BFA plus standard care or standard care alone. Among all the participants, two reported discomfort at the needle insertion site when they received BFA treatment, but no serious AEs were reported. Pain, irritation, or redness at the insertion site and lightheadedness were reported (Fox *et al*., 2018). To assess the feasibility and efficacy of BFA therapy in improving chronic pain and insomnia over an eight-day period, 45 military beneficiaries suffering from chronic pain and insomnia were randomized into either a BFA group or a usual care group. The former received the BFA intervention for up to 4 days, while the latter received usual care. Patients in both arms completed the pain and sleep daily diaries until day 8 (Garner *et al*., 2018). Nine AEs were reported: seven participants reported pain, irritation, or redness at the needle insertion site, and two participants reported lightheadedness immediately after the needle insertion. All the above AEs were minor, transitory, and tolerable in nature without need for further medical attention.

Discussion

The existing literature on BFA is focused mainly on the relief of acute pain (7/9 RCTs), but the data do not demonstrate significant pain reduction with BFA. Based on the results of this exploratory review, BFA is a safe, quick, and easily learned acupuncture technique for pain management. However, there was no statistically significant difference in reduction of pain intensity between BFA and control groups. This lack of difference may be due to a number of factors.

Firstly, the overall methodologic quality assessment of most RTCs was ranked as poor. Three areas of methodologic weakness were mainly identified among the included studies.

First, participants and BFA intervention providers were not adequately blinded as to the characteristics of treatment interventions; second, study assessors were not adequately blinded to the reported outcome; and lastly, an intentional analysis for missing data was only conducted in three studies. Due to the manual manipulation characteristics of BFA, it is difficult to accomplish a BFA protocol with adequate blinding, and this source of bias may be unavoidable.

Secondly, a lack of significant effect could be due to varying levels of practitioner proficiency and/or experience between the various trials. The BFA protocol is relatively simple, is easy to administer, and does not require specific positioning of the patient during treatment, which translates to ease of use for both patients and providers. It can also be learned easily by non-acupuncturist providers and is capable of being delivered by medical clinicians of various disciplines, e.g., physicians, nurses, and physical therapists. Required training includes 4 hours of the BFA theoretical course and clinical practice, as well as a short examination (King *et al*., 2013; Niemtzow *et al*., 2018). However, the study efficacy and safety outcomes may still depend on the provider experience and technique. This should be considered for future studies.

Thirdly, concomitant pain medication usage may affect the level of pain intensity change. Opioid analgesics are commonly used post-surgery and could obscure the pain relief of BFA. BFA associated effects should be evaluated independently of analgesic medication use (Jan *et al*., 2017), which was difficult to apply in our review due to the variety of medications prescribed for acute and chronic pain management. To fully explore the beneficial effects of BFA, future trials would need to control the use of potentially confounding analgesic medications more closely.

Furthermore, most of the included trials were in military settings, and seven of nine trials were for acute pain compared to two for chronic pain, with most of the acute pain cases for post-operative pain (Taylor *et al*., 2018). Previous publications have concluded that the current quantity and quality of BFA research is not sufficiently robust to justify its adoption as an evidence-based practice (Federman and Gunderson, 2017). Could BFA have more universal applicability in non-military healthcare settings? To this point, civilian use of BFA for pain has only been sporadically reported, highlighting the need for further research in civilian populations (Tsai *et al*., 2016; Fox *et al*., 2018).

Strengths and limitations: BFA has been added to the pain management toolkit of the US Army as part of its response to the opioid epidemic. To our knowledge, this is the first review to synthesize the currently available research on the effects and safety of BFA for pain relief. We identified several limitations in this review. Only RCTs published in the English language were included in our review, which likely excluded relevant studies published in other languages. Additionally, the methodology of most of the included trials in this review was poor and not powered to definitively detect clinical outcomes.

Conclusion

While BFA remains a safe, fast, and easily learned acupuncture method for pain management, its efficacy remains uncertain due to the poor methodological quality of the included studies. Further rigorous well-designed RCTs are needed for future evaluation of this promising pain management modality.

Acknowledgment

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