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Commentary

OXFORD

The Implementation and Effectiveness of Battlefield Auricular Acupuncture for Pain

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The provision of nonpharmacological pain management options is gaining increased attention that is due in part to the high prevalence of pain and the serious problems associated with using opioids to manage that pain. One such evidence-based [1] option, acupuncture, is included

in the American College of Physicians clinical guidelines for low back pain [2] and in the pain management strategy recommended by the U.S. Department of Health and Human Services [3]. Although providers may refer patients to many evidence-based nonpharmacological

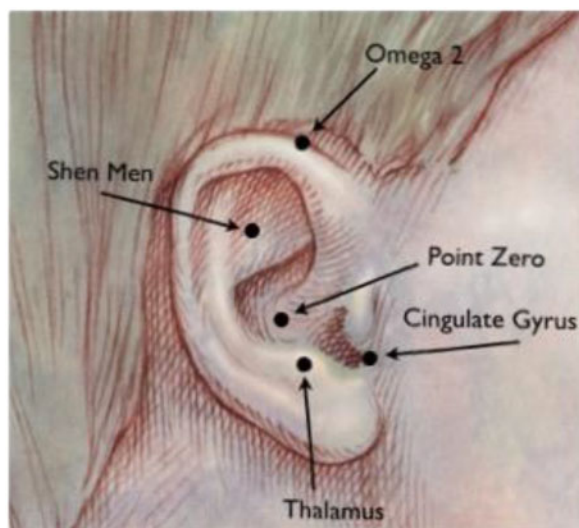


Figure 1. The five points in the battlefield acupuncture protocol. Reproduced with permission from Niemtow et al. [5].

pain management approaches, providers have relatively limited pain management options outside of opioids or analgesics for patients presenting with pain *during* the clinic visit.

Given the prevalence of pain among the military and veteran populations, the U.S. Department of Defense (DoD) and Veterans Health Administration (VA) have committed to offering safe and practical nonpharmacological options for pain management. One emerging, potentially effective therapy offered in the DoD and VA settings for immediate, short-term pain relief is battlefield acupuncture (BFA). BFA is a form of auricular acupuncture developed by Colonel (Retired) Richard C. Niemtow, MD, PhD, a radiation oncologist, for use among military personnel as an adjunct therapy to manage pain [4, 5]. It is notable for its ease of administration and for the fact that it can be learned and administered by a wide variety of non-acupuncturist clinicians [6–9]. The BFA protocol involves inserting semipermanent needles at each of five points in succession into each ear (see Figure 1) until pain relief is elicited or until all needles are inserted. Between needle insertions, the patient, if ambulatory, walks around for a few minutes to assess pain relief. The needles then remain in the ear for several days.

Auricular acupuncture has been performed for thousands of years in several countries and is based on theories of the traditional Chinese acupuncture meridian system. As detailed in Drs. Niemtow and Nogier's article [5], French physician Dr. Paul Nogier popularized auricular acupuncture in the 1950s, using <2-mm gold-plated acupuncture semipermanent (ASP) needles, and was the first to produce a visual map of the auricular acupuncture points. Dr. Niemtow then adapted that to develop BFA, which uses the four specific points that Dr. Nogier used plus the Shen Men point: 1) cingulate gyrus,

2) thalamus, 3) omega 2, 4) Shen Men, and 5) Point Zero. Dr. Niemtow's technique was readily used in the battlefield to reduce pain because the sterilized ASP needles can be easily carried, inserted in the ear in <5 minutes, used anywhere, and delivered by non-acupuncturists. Review articles provide additional detail on BFA and its history [4, 5, 7].

Several have posited various mechanisms for BFA's effectiveness. One review of auricular acupuncture studies by Hou et al. posits that BFA affects not only the autonomic nervous system, but also the neuroendocrine system, neuroimmunologic factors, neuroinflammation, and neural reflex, as well as antioxidation [9]. A second review by He et al. notes, "... auricular acupuncture plays a role in vagal activity of autonomic functions of cardiovascular, respiratory, and gastrointestinal systems. Mechanism studies suggested that afferent projections from especially the auricular branch of the vagus nerve to the nucleus of the solitary tract form the anatomical basis for the vagal regulation of auricular acupuncture" [10].

The present commentary summarizes the work our research teams have conducted to examine BFA's implementation and effectiveness within the DoD and VA health care systems.

The Introduction of BFA into the VA and DoD Systems

With a Joint Incentive Fund grant, the VA and DoD collaboratively developed a system-wide approach to disseminating acupuncture training, including BFA, with the goal of facilitating its delivery in any setting where patients needed pain relief [7, 8]. The two agencies began training clinicians in the BFA protocol in 2014, using a "train-the-trainer" model, in which a group of clinicians were trained, who then became instructors and trained additional providers in their geographic areas. By 2016, more than 2,000 clinicians had been trained, with slightly more than half of those being DoD clinicians. To date, the VA recognizes about 100 certified BFA instructors and more than 4,600 VA clinicians across a range of disciplines who have been trained to deliver BFA in accordance with their state licensures, including medical doctors, registered nurses, nurse practitioners, chiropractors, licensed acupuncturists, occupational therapists, doctors of osteopathic medicine, physician assistants, and physical therapists. BFA has been integrated into many VA medical departments and clinics, including primary care, pain clinics, physical therapy, emergency departments, inpatient settings, integrative health clinics or Whole Health programs, and chiropractic and acupuncture clinics [11]. With regard to the DoD, they are developing a Defense Health Agency Procedural Instruction (DHAPI) for acupuncture. It will be the first guidance for the DoD on acupuncture practice within military treatment facilities and will outline BFA as a

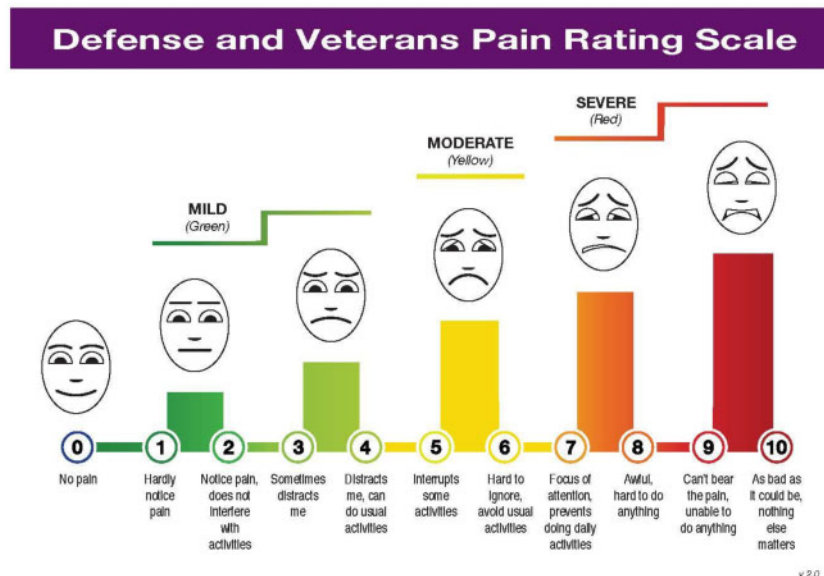


Figure 2. Defense and Veterans Pain Rating Scale. Reproduced with permission from Buckenmaier et al. [21].

Tier 1 acupuncture protocol that can be performed with a prescription.

Clinicians outside the VA or DoD can now be trained in BFA via private sector classes if BFA is in their scope of practice [12]. Also, the VA is collaborating with the Indian Health Service to help them start a BFA training program.

Effectiveness

Given that BFA is an emerging therapy, to our knowledge, only four small studies have examined its effectiveness to date, with all finding short-term improvements in pain. Three were small randomized trials: 1) one among military medical center emergency department patients with acute pain [6], 2) another among patients of an Air Force family medicine clinic with pain from acute sore throat [13], and 3) one among emergency department patients with low back pain [14]. A feasibility study was conducted among patients using a military aeromedical evacuation system [15]. Two 2017 meta-analyses or reviews examined the broader array of auricular techniques (with BFA included), with both concluding that auricular acupuncture in general, either as a standalone or as an adjunct technique, appears to reduce pain for most people [16, 17].

Our team very recently conducted two examinations of BFA for pain in a national sample of 11,406 patients receiving 28,438 procedures from 808 providers [18, 19] and one additional study in a sample from one large BFA clinic [20]. All of the BFA clinics were within the VA and used the Defense and Veterans Pain Rating Scale (DVPRS) [21] (see Figure 2) immediately before and after BFA delivery. We used the DVPRS because it had been included in a standardized note template that was disseminated to all

VA medical facilities (this template did not include pain functionality; no other patient-reported health outcomes are routinely available in the VA's electronic health records). Only *immediate* posttreatment pain relief outcomes were available, so our data do not provide information about the effectiveness of BFA for reducing the long-term burden of pain.

In our study of a high-volume VA BFA clinic ($n = 751$ patients) [20], we examined BFA's effectiveness for self-reported pain when delivered in group vs. individual settings and when delivered repeatedly over time. Overall, we found a decrease in pain for 82% of patients. These decreases were common in both the group (80%) and individual settings (87%). BFA's effectiveness persisted with repeated use; that is, each treatment appeared to have the same type of effect whether it was given once or on multiple occasions.

In our first examination of the national sample of BFA users in the VA, we similarly found BFA to be beneficial to a high proportion of patients [18]. Specifically, more than three quarters of patients reported an immediate decrease in pain intensity after receipt of BFA, with nearly 60% reporting a 2-point (minimal clinically important) decrease. On average, the decrease in pain intensity was -2.2 points (standard deviation = 2.8) at initial BFA treatments and -2.1 points (standard deviation = 2.4) at subsequent BFA treatments. We also found that BFA was effective across a wide range of veterans, with many having preexisting chronic pain or physical or psychological comorbid conditions. Those with histories of opioid use experienced less improvement in pain intensity than others.

In a second study of this national VA sample [19], we examined the degree to which BFA acts as a "gateway" to subsequent use of acupuncture. We conducted this

examination because several BFA providers reported in our BFA implementation study (Giannitrapani et al. [22]) that patients who originally were reluctant to try complementary and integrative health therapies before using BFA became open to trying other complementary and integrative health therapies for pain when they felt their pain improve with BFA. Using a propensity score analysis, we found that patients who used BFA had more than ten times greater odds of subsequently using traditional acupuncture within 3 months after their BFA visit, after adjustment for several health conditions, demographic characteristics, and pain level.

BFA Implementation in the VA

In addition to examining the effectiveness of BFA, we also examined how well it is being implemented in the VA. Our first study [11] identified the challenges that BFA providers experience in implementing BFA and any successful strategies used to overcome these challenges. We conducted semistructured telephone interviews with 23 BFA providers across the nation from June 2017 through January 2018. We asked about several implementation issues and identified eight main implementation issues that VA BFA providers faced: 1) Providers were organizing the delivery of BFA in a variety of ways; 2) some had insufficient time to provide BFA to meet patient demand; 3) some were facing some negative beliefs and lack of knowledge about BFA from medical facility leadership, other health care providers, and patients; 4) there was a lack of BFA indication guidelines or effectiveness data; 5) some experienced a time delay between training and practice due to administrative bureaucracy; 6) some experienced a loss in self-efficacy when they did not deliver BFA frequently; 7) some did not have sufficient room or needles to provide as many treatments as they would have liked; and 8) facility leadership and administrative buy-in is critical.

Our second study on BFA implementation examined VA BFA providers' perspectives on the advantages and disadvantages of BFA [22]. We used content from the above 23 interviews and conducted an additional 20 interviews with providers from high-performing sites across the nation. We found that BFA providers perceived BFA's advantages to be: 1) It can simultaneously effectively control pain while reducing opioid use; 2) BFA may alleviate pain that has been unsuccessfully treated by conventional methods; 3) BFA gives providers a treatment option to offer patients with substance use disorder; 4) BFA can help build a trusting patient-provider relationship; 5) BFA can facilitate open communication; and 6) BFA can create the opportunity for hope. BFA providers also reported their perceptions of BFA's disadvantages: 1) There are insufficient clinical guidelines on when to administer BFA; 2) BFA provides only short-term pain relief; 3) BFA can be uncomfortable for some; 4) BFA may not be an effective treatment option unless it

can be provided "on demand"; and 5) BFA can promote euphoria, which can have deleterious consequences for patient self-care. In sum, BFA providers perceived BFA to have many benefits, both clinical and relational, including potential utility in helping address the current opioid crisis. They also reported that BFA is easy to deliver and low risk and has clinical and relational utility. We also asked the high-performing sites how they overcame what we found to be the largest implementation hurdle—the minimal amount of clinical evidence. We found that some sites encouraged facility leadership and patients to observe and/or experience BFA. Clinical facility leaders were invited to attend BFA trainings, where they learned to administer BFA and received BFA from other attendees. Patients learned about BFA delivery and effectiveness by observing other patients receive BFA in a group format (with patient permission).

The results of these two studies point to several facilitators and barriers to the implementation of a novel, seemingly effective, nonpharmacological pain management option. One prominent barrier to BFA's implementation was the lack of a stronger evidence base. This barrier is typical for novel treatments, especially treatments that are considered complementary and integrative health. However, the evidence for other complementary and integrative health pain management options has grown significantly over recent years, which has the potential to open clinicians' and patients' minds to BFA as another pain management option. Also, that a lack of stronger evidence was an implementation barrier also points to the need for improved dissemination of the research findings that *do* exist. Another barrier to implementing novel therapies is having sufficient clinicians trained to deliver it. This training barrier is beginning to be eroded, now that BFA training is available outside the VA and DoD settings, as noted above.

Being able to meet patient demands for effective nonpharmacological treatments is just part of the VA's current (e.g., Whole Health transformation) [23] and long history of innovation, and with innovation comes expected implementation issues. Nevertheless, these implementation difficulties are counterbalanced by the positive aspects of the VA and DoD's implementation of BFA. One such aspect is that millions of veterans and active military personnel now have another nonpharmacological pain management option available to them that, for many, has worked. Another positive result is that some health care systems or providers look to the VA's health care system as ammunition for their own implementation of an emerging therapy (e.g., "if the government can make BFA available, why can't we?").

Future Research Needed

As with most emerging therapies, additional research on BFA is needed on several fronts. For example, only three small trials have been conducted, and, given their size,

they most likely lacked the power to accurately assess the effectiveness of BFA. As such, larger randomized controlled trials of BFA are warranted, with medium- and long-term follow-up. Additional research should be conducted to determine for what conditions BFA does and does not work well. Our [18] national examination began to address this question, as did some of the smaller randomized controlled trials, but clearly more work needs to be done. Also, studies should include measures of pain functionality or impairment, which many consider as important as or more important to assess than pain severity. Studies should incorporate measures such as quality of life and general well-being, which could reflect an improved overall health status due to BFA, in spite of pain continuing to be present. Also, to date, BFA has been examined only among military and veteran populations because it is not as frequently available in civilian settings. However, given the likelihood that it will be spreading to the population served by the Indian Health Service and the general population in the near future, more research is needed to examine BFA effectiveness among nonmilitary populations. Ultimately, clinical practice guidelines on dosage, frequency, and clinical indications will need to be developed from the evidence that emerges from this next wave of effectiveness research.

Conclusion

On the basis of work conducted to date, there is some evidence that BFA is a potentially effective, immediate, but short-term nonpharmacological pain management tool that can be used in adjunct with other pain therapies. In our effectiveness studies, we observed that BFA produced a minimal clinically important improvement in pain for at least half of those who received the treatment, in every patient population examined, including patients who had recently filled an opioid prescription and patients with significant psychological and physical comorbidities. We also observed that both individual and group BFA sessions were effective, with the former being only marginally more effective than the latter.

In implementing BFA, VA providers are delivering BFA by means of a variety of models. Although they continue to experience challenges in implementing BFA in their facilities (most notably, the perceived lack of evidence that accompanies most new treatments), new strategies to address these challenges are continually being developed. Given its effectiveness in providing immediate, short-term pain relief, from the perspective of both providers and patients, BFA is one potentially important tool in the toolkit to address patients' pain. Finally, the immediate, short-term relief that BFA can provide may provide a "window" to allow some patients to engage in other, more long-term approaches, such as yoga and tai chi, ultimately moving toward more of a self-management model to address their chronic pain.

Authors' Contributions

All authors made a significant contribution to the study concept and design, acquisition of data, or analysis and interpretation of data; drafting/revising the manuscript for important intellectual content; and approval of the final version to be published. The authors contributed to the paper as follows: SLT wrote this article, obtained funding for this article, and led (and obtained funding for) four studies summarized in the article; KFG edited this article and led one of the studies summarized in the article; PEA edited this article and participated in two studies summarized in the article; ERT edited this article and participated in two studies summarized in the article; DGF edited this article and led one study summarized in the article; JRH edited this article and participated in two studies summarized in the article; JO edited this article and participated in two studies summarized in the article; BK edited this article and participated in three studies summarized in the article; and SBZ edited this article and participated in two studies summarized in the article.

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Conflicts of interest: All authors declare no conflict of interest.

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