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#### REVIEW

# Practical Applications and Safety of Battlefield Acupuncture for Pain Management: A Systematic Literature Review

Nan Dai<sup>[]</sup>, Xiaohui Liu<sup>1,2</sup>, Hejia Wan<sup>[]</sup>

School of Nursing (Nursing School of Smart Healthcare Industry), Henan University of Chinese Medicine, Zhengzhou, People's Republic of China; <sup>2</sup>Henan Provincial Hospital of Traditional Chinese Medicine (The Second Affiliated Hospital of Henan University of Traditional Chinese Medicine), Zhengzhou, People's Republic of China

Correspondence: Xiaohui Liu, Email 1173652033@qq.com

Background: Pain is complex and subjective, causing physical and psychological damage. Western medical treatments are prone to dependence, gastrointestinal problems, and organ damage. Battlefield acupuncture (BFA) integrates traditional Chinese medicine with contemporary military medicine, achieving a rapid analgesic effect. In the domain of pain management, it is effective. Despite controversy, it is recommended as an analgesic for pain populations.

**Purpose:** The present study evaluated the clinical efficacy and safety of BFA, with a view to informing pain management strategies and validating its credibility.

Methods: Databases including PubMed, Cochrane Library, Web of Science, and Embase were searched from 2015–2025. Randomized controlled studies(RCTs) on BFA for pain were included. Outcome measurements were pain scores and adverse event rates. Two authors independently assessed studies using the Cochrane risk of bias tool for randomized trials(RoB-1). Heterogeneity was addressed via narrative synthesis.

Results: Of 800 articles screened, 11 RCTs (n=1,232; BFA: 530 patients) matched criteria. BFA was compared with opioids, non-opioids, exercise or physical therapies for various types of pain. Four studies reported lower BFA pain scores, and four found no difference. No severe adverse event rates were noted, but mild reactions were recorded. RoB grades: two A, eight B, one C.

Conclusion: Evidence supports the efficacy and safety of BFA for acute pain. The utilisation of BFA in the context of alleviating mild to moderate pain is recommended, particularly in conjunction with electroacupuncture therapies. However, limitations include small sample sizes, blinding issues, and inconsistent protocols. Research into specific pain types and long-term efficacy should be focused on.

Registration: PROSPERO CRD420251011281.

Keywords: pain management, acupuncture therapy, analgesics

# Introduction

Pain as the fifth vital signs, not only is the body damage or disease signals, or many disease patients with low quality of life and recovery confidence is one of the important reasons, has become the third largest health problems following cardiovascular and cerebrovascular diseases, tumors under and after.<sup>1</sup> Analgesic methods for managing pain encompass a variety of pharmacological and non-pharmacological approaches designed to alleviate discomfort associated with various medical conditions.Pharmacologic analgesia consists of three main categories: nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and adjuvant analgesics.NSAIDs including ibuprofen and para-aminophenol (paracetamol), are among the most commonly used analgesics. For instance, they have the capacity to mitigate intraoperative pain during pulpotomies in milk teeth.<sup>2</sup> In addition, their efficacy extends to the management of chronic pain, encompassing both orthopedic and postpartum contexts.<sup>3</sup> Morphine has demonstrated efficacy in the management of severe pain, particularly

in cases of sickle cell disease pain crises.<sup>4</sup> However, its utilization is frequently accompanied by significant adverse effects and the potential for dependency. This has prompted the investigation of multimodal strategies that integrate non-opioid and non-opioid analgesics to mitigate the risks associated with narcotic pain relief.<sup>5</sup> Adjunctive analgesics medications such as local anesthetics like bapentin, mesobamol, and lidocaine patches may be useful in neurological conditions or local pain control. Evidence suggests that these medications may be used in combination with NSAIDs to improve overall pain management.<sup>6</sup> Although Western medicine can achieve short-term analgesic purpose, in the long run, the toxic side effects and addiction dependence of drugs are unavoidable, which makes more and more people in need of pain management start to pay attention to the greener and safer non-pharmacological therapies.Non-pharmacological analgesic methods, such as manual therapy, acupuncture, and massage can effectively manage pain.<sup>7</sup>

Auricular Acupuncture(BFA) is one of the non-pharmacological therapies, and many studies have shown that it has significant efficacy in pain management.<sup>8</sup> In 2001, Prof. Niemtzow of the United States based on Chinese auricular acupuncture therapy developed a combination of traditional Chinese medicine theory and modern military medicine needs, through the stimulation of specific acupuncture points to achieve rapid analgesic effect of the treatment method and named it "battlefield acupuncture (BFA)", a type of auricular acupuncture that is often used in specialized scenarios.<sup>9</sup> Because of its unique advantages in analgesia, it is now widely used abroad.<sup>10</sup> As of 2019, more than 100 people have achieved BFA Instructor status and more than 4600 clinical practitioners have earned Veterans Health Administration specialty certifications, including clinicians, registered nurses, nurse practitioners, and many other healthcare-related practitioners.<sup>11</sup> The scope of BFA is also gradually expanding, which involves primary care settings, physical therapy settings, pain clinics, emergency departments, inpatient units, integrative health clinics, and acupuncture clinics.

Current research suggests that the analgesic mechanism of BFA involves multidimensional biological effects. The core mechanism can be summarized as follows: by stimulating specific acupoints in the ear (such as the cingulate gyrus, thalamus, and Shenmen acupoint), BFA activates central nervous system structures related to pain regulation. This hypothesis is further substantiated by the findings of functional magnetic resonance imaging (fMRI) studies, which have demonstrated that stimulation of these specific ear acupoints can modulate neural activity in the thalamus, cingulate gyrus, and sensory cortex. In addition, these studies have shown that BFA can inhibit the transmission of nociceptive signals to the cerebral cortex, thereby leading to a swift alleviation of pain.<sup>12,13</sup> Concurrently, BFA may engender an immediate effect by promoting the transient release of neurotransmitters such as beta-endorphin and serotonin, and by reducing the inflammatory response by regulating the secretion of anti-inflammatory cytokines such as IL-10.14,15 Furthermore, the anatomical correlation between ear acupoints (such as the zero point and shenmen) and the vagus nerve suggests that BFA may modulate the balance of the autonomic nervous system through afferent fibers of the vagus nerve, reduce sympathetic nerve excitability, and alleviate pain-related stress responses.<sup>9,12</sup> It is noteworthy that BFA has the potential to reduce peripheral and central inflammation and enhance the neuronal regeneration process in neuropathic pain by inhibiting pro-inflammatory factors (such as  $TNF-\alpha$  and IL-6) and promoting the expression of brain-derived neurotrophic factor (BDNF).<sup>15,16</sup> While the aforementioned mechanism provides a theoretical foundation for the use of BFA, its clinical efficacy remains a subject of debate. A number of studies have indicated that the analgesic effect of BFA may be influenced by the placebo effect, and its efficacy in postoperative pain management has not been demonstrated to be significant.<sup>9</sup> Furthermore, the precise mechanism of action of this agent remains to be fully elucidated. To further refine our understanding of its biological targets and to identify personalized efficacy differences, there is a need for additional high-quality randomized controlled trials that integrate neuroimaging and molecular biotechnology.<sup>9,14</sup>

## **Methods**

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was used for this systematic review and has been registered in the PROSPERO database (CRD420251011281).

#### Study Design

The study design used in this research is a systematic review.

# Search Strategy

A computerized search was conducted of PubMed, Cochrane Library, Web of Science, and Embase for randomized controlled trials published on the use of battlefield acupuncture for pain relief. The time frame encompassed from January 2015 to January 2025. Search expressions were meticulously constructed using a combination of subject headings and free words. Boolean logical operators ("AND" and "OR") were applied to each database. The following search terms were utilized:"acupuncture""battlefield acupuncture""combat acupuncture""military acupuncture""war zone acupuncture""discomfort""ache""suffering""analgesia""pain relief""pain management""pain control""Randomized controlled trial".

# Inclusion and Exclusion Criteria

#### Inclusion Criteria

- Research type: the types of included literature studies are randomized controlled trials(RCTs) and are limited to English.
- Population: clear criteria for pain diagnosis, battlefield acupuncture or combined battlefield acupuncture, no restrictions on race, gender, or age.
- Intervention measures: the intervention group was treated with simple BFA or combined with BFA on the basis of the control group.
- Comparison: the control group used basic treatment, such as opioid drugs or non-steroidal antiinflammatory drugs.
- Outcome:Level of pain assessment and other secondary outcome indicators.

#### Exclusion Criteria

- Repeated publication of literature.
- Summary of the meeting or Meta analysis.
- The full text is still not available by contacting the author.

# Study Selection and Data Extraction

The included literature was independently screened by two researchers (Dai and Wan) according to the established criteria. Duplicate literature was removed after checking for duplicates using EndNote. A preliminary screening was then performed by reading the titles and abstracts, and the full text was further screened to finally include literature that met the established criteria. In instances of disagreement, a discussion was initiated and a consensus was reached with the third reviewer (Liu). A comprehensive data extraction process was conducted using Microsoft Office Excel (Microsoft Office 2016) to obtain general information from the included literature. This included the first author, publication date, research design, research purpose, sample information, intervention measures, intervention frequency, course of treatment, outcome indicators, main conclusions, limitations, and future prospects. Due to the substantial variations in intervention frequency, data collection time, and pain assessment tools across the included literature, a descriptive method was employed to provide a comprehensive account.

# Quality Evaluation of Literature

The Cochrane risk of bias tool for randomized trials (RoB-1) was utilized to assess the risk of bias of the included RCTs. The evaluation encompassed several domains, including random sequence generation, allocation concealment, blinding of implementation, integrity of research data, selective reporting of results, and other measurement biases. The evaluation yielded a categorization of "low risk of bias", "unclear risk of bias", and "high risk of bias" for each item. A score of A is assigned for  $\geq$ 5 low-risk items, B for 3 to 4 low-risk items, and C for  $\leq$ 2 low-risk items.<sup>17</sup> The risk of bias assessment chart was plotted using Review Manager 5 (RevMan 2014). The quality assessment was independently cross-checked by two researchers (Dai and Wan), and disagreements were resolved by consulting a third author (Liu).

# Results

# Characteristics of Studies

We searched a total of 800 articles, including 127 articles in PubMed, 22 articles in The Cochrane Library, 133 articles in Web of Science, and 518 articles in Embase. Following deduplication, a thorough examination of the titles and abstracts, and a subsequent screening based on a thorough review of the full texts, 11 documents were ultimately selected for inclusion, as illustrated in Figure 1. It was observed that all 11 documents included in the final analysis were randomized controlled trials. Of the 11 documents, three incorporated a three-arm design, while the remaining eight employed a twoarm design. The interventions administered to the experimental group included BFA, as well as BFA in combination with conventional analgesic treatment. The control group interventions encompassed a variety of modalities, including opioid and non-opioid drugs, therapeutic exercise, cold compresses, and electrical stimulation. The total sample size was 1,232 cases, with patients ranging in age from 18 to 60 years. Of these, 530 patients were administered BFA treatment. The types of pain involved included four articles on acute pain, five articles on postoperative pain, one article on cancer pain, and one article on postpartum pain. In terms of intervention effects, six studies reported that BFA had lower pain scores than the control group at 5 min,<sup>18</sup> 30 min,<sup>19,20</sup> the day after surgery,<sup>21</sup> day 1,<sup>22</sup> and day 7,<sup>23</sup> while the other five studies reported that there was no statistically significant difference in pain scores between the BFA group and the control group.<sup>16,24-27</sup> Eleven studies examined the efficacy of BFA in reducing analgesic drugs. In these 11 studies, neither the intervention group nor the control group reported serious adverse events (eg, bleeding, bruising, dizziness, etc). However, a few studies qualitatively described the adverse reactions as minor and transient. The majority of the studies (10 out of

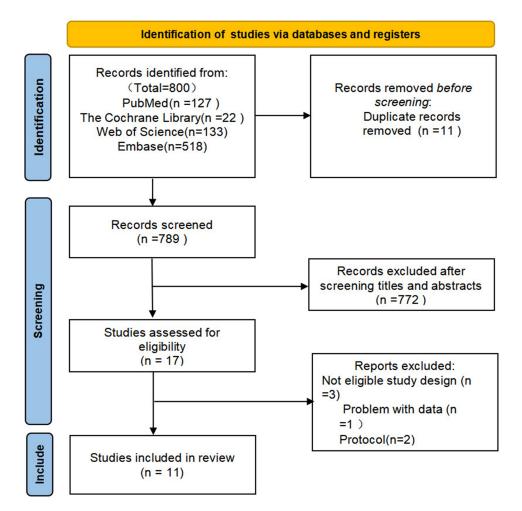


Figure I PRISMA diagram article selection process. Adapted from Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n72. Creative Commons.<sup>28</sup>

11) utilized ASP (Aiguille D'Acupuncture Semi-Permanente: French) gold needles for BFA, while one study employed a push needle.

## Results of the Literature Quality Assessment

All 11 RCT studies specifically described the method of generating random sequences, which is considered a low risk for bias. 9 studies used opaque envelopes for allocation concealment, and the remaining 2 did not specify the method of allocation concealment.Nine studies that did not blind acupuncture operators or patients were high risk of bias, and the remaining 2 were low risk of bias. There were 5 studies that did not implement blinding of outcome assessors as a high risk offset, 4 studies that implemented blinding of outcome assessors as a low risk, and the other 2 were not sure so they were unclear offsets.The majority of subjects in 8 studies completed follow-up, and methods such as intentional analysis of missing data were used to reduce this offset, so it is a low risk of offset. 1 study had only 53.7% of patients returning a pain diary for 10 d and did not use any other method of remedial measures, so it is a high risk of offset. 2 studies had a low rate of loss of precaution but did not state the reason for the shedding, which is potentially at risk of offset, and therefore an indeterminate risk of offset.All 10 studies reported all outcome indicator results in full according to the program report, which is a low risk bias. However, 1 study did not indicate the presence of unreported prespecified indicators due to lack of reference to registry information, an indeterminate risk offset. 6 studies were funded by the nonprofit research institutions fund, <sup>16,19–21,24,27</sup> and 5 studies did not mention funding.All studies were unclear about the presence of other biases. 2 RCTs had a B rating, and 1 had a C rating.The results of the quality assessment are shown in Table 1, and the risk of bias for the included studies is shown in Figures 2 and 3.

## BFA in Pain Management

#### Acute Pain

Acute pain is a major symptom that often accompanies patients presenting to the emergency department, and pharmacologic analgesia is currently the treatment of choice. Fox et al<sup>18</sup> randomly divided 30 patients with acute low back pain into a routine care group (n=15) and a routine care group combined with BFA (n=15). The BFA placed ASPs at 5 acupoints in the cingulate gyrus, thalamus, Omega2, Zero point and Shenmen of both ears of the patients, and left the needles in place for 7–8 min. The results showed that the pain scores of the BFA combined with routine care group were significantly lower than those of the control group at 5 min after the intervention (5.2 vs 6.9, P = 0.04) and no adverse reactions were reported. Johnston et al<sup>19</sup> randomized 52 patients suffering from acute or subacute low back pain into a BFA group and a standard care control group of 26 each. The BFA group received the BFA intervention using an ASP to puncture five acupoints, namely cingulate gyrus, thalamus, omega 2, shenmen, and zero point, sequentially in each of the patient's ears. Before intervention, the visual analog scale (VAS) of pain was 76.7 mm (SD 15.5 mm) in the BFA group and 68.4 mm (SD 18.5 mm) in the control group. After 30-40 min of intervention, the VAS score was 33.4 mm (SD 26.4 mm) in the BFA group and 21.5 mm (SD 14.4 mm) in the control group, and the difference between the effects of the two groups was 12 mm (95% CI 0.1-23.8 mm). Jan et al<sup>26</sup> divided 90 patients with acute abdominal pain, limb trauma, and low back pain in the emergency department into a BFA group, a sham control group, and a standard analgesic group, and the BFA protocol used was modified from the original one by omitting the pause interval between stabs at two acupoints, instructing the patient to move around (eg, walk) after a single needle was inserted, and the step of pain assessment. After 2 h of intervention, the mean pain scores of the three groups did not show statistically significant differences, and the findings were inconsistent with those of Johnston et al. The reasons for this inconsistency may be related to the interference of opioids in the trial or the modification of the BFA protocol, and the future needs to be further investigated under more stringent experimental criteria to determine the analgesic efficacy of BFA alone in different pain categories. The analgesic efficacy of BFA alone in different pain categories should be further investigated under more stringent criteria. Eucker et al<sup>20</sup> randomized 236 patients with acute musculoskeletal pain into 68 cases in the usual care (UC) group, 84 cases in the BFA group + UC group, and 84 cases in the peripheral acupuncture(PA) groups+ UC group. The results showed that the pain scores in the BFA group and PA groups were significantly reduced by 1.6 points (95% CI 0.7-2.6) and 1.2 points (95% CI 0.3-2.1), respectively, compared with usual care at 1 h, which exceeded the predefined threshold of clinical significance (1.3 points), and the safety of both groups was good, with no serious

Quality

First Author, Year	Study Aim Design	Sample Characteristic	Intervention	Frequ
Plunkett 2018 <sup>24</sup>	 RCT To evaluate the effectiveness of BFA in reducing post- tonsillectomy pain and opioid consumption.	Ninety-five adult tonsillectomy patients aged 18–60 years were randomized into 45 cases in the intervention group and 50 cases in the control group	Intervention group: under the patient's anesthesia, a unilateral dominant ear (determined by writing habits) was selected and 5 ASP Control group: postoperative analgesic drugs and cold compresses as needed	Single treatm

Year	Design	0.00	Characteristic	intervention	Trequency	Treatment	Indicators	Fiam Conclusions	Linitation	i uture i rospects	Evaluation
Plunkett	RCT	To evaluate the	Ninety-five adult	Intervention group:	Single	20min	1 Defense &	The present study was	<ul> <li>Low follow-up rate</li> </ul>	<ul> <li>In order to verify the</li> </ul>	В
2018 <sup>24</sup>		effectiveness of BFA	tonsillectomy patients	under the patient's	treatment		Veterans Pain Rating	unable to confirm the	<ul> <li>Low compliance</li> </ul>	long-term effects of battle-	
		in reducing post-	aged 18-60 years	anesthesia, a			Scale (DVPRS)	hypothesis that	<ul> <li>Short BFA reten-</li> </ul>	field acupuncture or its	
		tonsillectomy pain	were randomized into	unilateral dominant			<li>② Morphine</li>	battlefield acupuncture	tion time	synergistic effects with	
		and opioid	45 cases in the	ear (determined by			milligram	can effectively reduce		other analgesic regimens,	
		consumption.	intervention group	writing habits) was			equivalents (MME)	the degree of pain or		future larger-scale, rigor-	
			and 50 cases in the	selected and 5 ASP			③ Postoperative	opioid use in adults		ously designed trials are	
			control group	Control group:			incidence of nausea	after tonsillectomy. No		needed.	
				postoperative			and vomiting	statistically significant		<ul> <li>Standardized training for</li> </ul>	
				analgesic drugs and			4 Time to resume	difference in pain scores		BFA should be developed	
				cold compresses as			eating	was observed between		to improve consistency of	
				needed			$\bigcirc$ Adverse events	the two groups during		practice.	
							(eg, bleeding,	hospitalization (at			
							infection, etc).	discharge) and 10 days			
								after discharge			
								(P>0.05). Additionally, a			
								lack of statistically			
								significant variation in			
								morphine equivalents			
								was observed between			
								the two groups during			
								surgery, in the post-			
								operative recovery			
								room, and 10 days after			
								discharge (P=0.096). It			
								is noteworthy that no			
								severe adverse			
								reactions were			
								reported in either			
								group.			

Course of

Key Outcome

Main Conclusions

Limitation

Future Prospects

Shah.2019 <sup>21</sup>	RCT	The objective of this	The sample	Intervention group:	Single	3–7d	1 visual analog	Short-term efficacy:	<ul> <li>Small sample size</li> </ul>	• Expand the sample size.	В
011111,2017		study is to evaluate	population of this	Under general	treatment		scale (VAS)	Auricular acuPuncture	<ul> <li>Unified postopera-</li> </ul>	<ul> <li>Explore the long-term</li> </ul>	5
		the effects of BFA on	study comprised 99	anesthesia, five ASP			<li>2 percentage of</li>	significantly reduced	tive analgesia plan	efficacy and safety of BFA.	
		pain, opioids, nausea,	cases of adult patients	needles were			normal diet and	rest Pain (VAS 2.9 vs	<ul> <li>Unclear short-</li> </ul>	<ul> <li>Use imaging techniques</li> </ul>	
		diet resumption, and	aged $\geq 18$ , which were	implanted in the			activity	4.3, P=0.01) and activity	term analgesic	and other methods to	
		mobility after adult	divided into two	bilateral auricles at			③ number of pain	Pain (VAS 5.2 vs 6.5,	mechanism of bat-	explore the mechanism of	
		tonsillectomy	groups: an	the following			medications taken	P=0.01) on the day of	tlefield acupuncture	BFA's analgesic effect.	
		compared to the	intervention group of	acupoints: cingulate			Complications:	surgery, and imProved			
		control group.	50 cases and a control	gyrus, thalamus,			nausea, vomiting,	activity ability (35.1% vs			
		control & oup.	group of 49 cases.	Omega 2, zero			secondary bleeding,	20.8% normal activity,			
			8 F	point, and shenmen.			dehydration, etc.	P=0.01) on the same			
				Control group:			⑤ Incidence of	day.			
				Only blank			adverse reactions	Long-term effect: From			
				bandages were			(eg, infection, local	the first PostoPerative			
				affixed to the same			irritation)	day, there was no			
				acupoints				significant difference			
				ucuponito				between the two			
								grouPs in terms of Pain,			
								oPioid use, nausea and			
								vomiting			
								Safety: There was no			
								statistically significant			
								difference in the			
								PostoPerative bleeding			
								rate between the two			
								grouPs (10% in the ear			
								acuPuncture group vs			
								20% in the control			
								group, P=0.13)			
	1							group, r=0.13)			

(Continued)

#### Table I (Continued).

First Author, Year	Study Design	Aim	Sample Characteristic	Intervention	Frequency	Course of Treatment	Key Outcome Indicators	Main Conclusions	Limitation	Future Prospects	Quality Evaluation
Johnston 2019 <sup>19</sup>	RCT	Compare the analgesic effect, functional recovery and safety of BFA with standard drug therapy in patients with acute and subacute low back pain in the emergency department.	Fifty-two adult patients aged 18–55 were divided into a battlefield acupuncture group (26 cases) and a control group (26 cases).	Intervention group: Five ASPs were implanted in both ears, based on the cingulate gyrus, thalamus, Omega2, zero point, and Control group: Patients received standardized drug treatment selected by the attending physician based on clinical judgment	Single treatment	2h-7d	<ol> <li>VAS.</li> <li>brief psychiatric rating scale (BPRS)</li> <li>Patient satisfaction</li> <li>Use of additional pain medication</li> <li>48–72h after discharge</li> </ol>	Short-term efficacy: The BFA group had a more significant reduction in VAS pain scores compared to the control group after 30 minutes (33.4 mm vs 21.5 mm, effect size difference 12.0 mm, 95% CI 0.1–23.8 mm). Long-term effect: No statistically significant difference in functional score improvement between 48 and 72 hours (median 12.0 in the BFA group vs 8.0 in the control group, effect size difference 4, 95% CI –9.0 to 16.0). Safety: No adverse events occurred in either group, and BFA was well tolerated.	<ul> <li>Single-blind design: neither patients nor assessors were blinded</li> <li>Sample limitations: mainly young and healthy patients (mean age &lt;40 years), patients with pathological low back pain were excluded</li> <li>Heterogeneity of the control group: the standard treat- ment group had a variety of drugs (eg, NSAIDs, muscle relaxants, opioids)</li> <li>Short-term follow- up: the primary endpoint was only assessed for 30 minutes, and there was insufficient data on long-term efficacy.</li> </ul>	<ul> <li>In the future, multi-center, large sample RCTs can be conducted to add sham acupuncture control groups to verify specific effects.</li> <li>Investigate the analgesic mechanism of BFA in com- bination with imaging or biomarkers.</li> <li>Further verify the efficacy in specific low back pain subgroups.</li> <li>Explore a standardized application path for BFA in emergency pain manage- ment to reduce opioid dependence.</li> </ul>	В

Eucker 2024 <sup>20</sup>	RCT	The purpose of this study was to determine the feasibility, acceptability, and effectiveness of adding ED acupuncture to treat acute episodes of musculoskeletal pain in the neck, back, and extremities.	Usual care group (UC):68 BFA+UC:84 Peripheral acupuncture(PA) +UC:84	UC: NSAIDS, opioids (if necessary), ice or heat AA+UC: select bilateral ears and place acupuncture needles at five specific points PA+UC: acupuncture at easily accessible points on the head, neck, and limbs (eg, Hegu, Zusanli)	Single treatment	20–30min	<ol> <li>Numeric rating scale(NRS)</li> <li>Patient satisfaction</li> <li>Opioid/non- opioid drug use</li> <li>Incidence of adverse events (bleeding, bruising, dizziness)</li> </ol>	Battlefield acupuncture combined with peripheral acupuncture can significantly reduce the pain score of patients with acute musculoskeletal pain, and the effect is better than that of routine care. Both acupuncture methods showed high feasibility (recruiting more than one patient per day on average) and high satisfaction. No adverse events occurred.	<ul> <li>Unicentric design: Only conducted in urban emergency departments in the southeastern United States, and the results may not be applicable to rural or other areas</li> <li>Limited population representation: Only English speak- ers were included</li> <li>Missing data pro- cessing: Multiple interpolations were used to fill in miss- ing values, which may cause potential bias</li> <li>Short-term follow- up: Only assessed changes in pain within I hour, and did not track long- term effects</li> </ul>	<ul> <li>Future multicenter studies in different regions and populations.</li> <li>Tracking the potential impact of BFA on long-term pain management.</li> <li>Exploring the synergistic effect of BFA with other non-drug interventions such as medication and physical therapy.</li> <li>In-depth study of the physiological mechanism of BFA in pain relief.</li> </ul>	Β
Crowell,2025 <sup>16</sup>	RCT	To evaluate the effectiveness of BFA combined with physiotherapy compared to physiotherapy alone in terms of pain management, emotional state, self- reported improvement and medication use in patients after shoulder surgery.	88 patients undergoing shoulder joint surgery were randomly divided into an intervention group of 43 patients with an average age of 21.1 ±1.8 and a control group of 45 patients with an average age of 21.8±2.3.	Intervention group: Based on the control group, ASP was implanted at five specific acupoints in the patient's both ears. The five acupoints are: cingulate gyrus, thalamus, Omega2, zero point, and Shenmen Control group: therapeutic exercise, cold compress, electrical stimulation, patient health education	Each treatment lasts 30 minutes, and the retention time is 3–5 days.	A total of four treatments after surgery: baseline (ie, 24–48h after surgery), 72h, I week, 4 weeks	<ol> <li>VAS</li> <li>profile of mood states (POMS, Total Score Range: 0-600)</li> <li>global rating of change (GROC, -7 to 7 points)</li> <li>Opicid and non- opicid medication use within 4 weeks after surgery</li> </ol>	The BFA joint standard physical therapy was not significantly better than physical therapy alone in terms of pain, mood, self-reported improvement, or medication use. Both groups experienced significant reductions in postoperative pain over time (main effect significant, interaction not significant). No serious adverse events were reported in the intervention group.	<ul> <li>Single-blind design, only the evaluator was blinded</li> <li>No placebo con- trol group was set</li> <li>Sample size was small</li> <li>7 patients could not be contacted, and patient compli- ance was reduced</li> <li>The analgesic mechanism of BFA was not explored</li> </ul>	<ul> <li>In the future, multi-center, large-sample, three-arm trials can be conducted.</li> <li>Long-term follow-up time can be increased.</li> <li>The optimal acupoint combination for BFA can be explored.</li> <li>The analgesic mechanism of BFA can be explored in combination with imaging</li> <li>The value of BFA in pain management can be veri- fied in other pain populations.</li> <li>A standardized training system can be developed to improve operational consistency.</li> </ul>	В

(Continued)

Dai et al

#### Table I (Continued).

First Author, Year	Study Design	Aim	Sample Characteristic	Intervention	Frequency	Course of Treatment	Key Outcome Indicators	Main Conclusions	Limitation	Future Prospects	Quality Evaluation
Collinsworth 2019 <sup>23</sup>	RCT	Evaluate the effectiveness of BFA combined with physiotherapy compared to physiotherapy alone in reducing postoperative shoulder pain and the amount of analgesic drugs used.	40 patients were randomly divided into an intervention group with 21 cases and an average age of 20.3, and a control group with 19 cases and an average age of 20.5.	Intervention group: Five acupuncture points (cingulate gyrus, thalamus, Omega 2, zero point, and Shenmen) were implanted in the patient's bilateral ears. Control group: Therapeutic exercise, cold compress, electrical stimulation, and patient health education.	Each treatment lasts 30 minutes and is left in place for 3–5 days.	The first treatment is 24 hours after the operation, and subsequent treatments are repeated at 72 hours, I week, etc.	VAS     Opioid/non- opioid drug use     (3) global rating of change (GROC)     (4) Patient-Specific Functional Scale (PSFS)	The mean and worst pain VAS scores in the intervention group were significantly lower than those in the control group within 7 days after surgery, but no significant differences were found at later times. There was no significant difference in the use of opioid analgesics between the two groups. No serious adverse events occurred in the BFA intervention group.	<ul> <li>Single-blind design</li> <li>No placebo control group</li> <li>Small sample size</li> <li>Does not explore the neurophysiological mechanism of BFA</li> </ul>	<ul> <li>In the future, multi-center, large-sample, three-arm trials can be conducted.</li> <li>Long-term follow-up time can be increased to evalu- ate the long-term efficacy of BFA.</li> <li>The optimal acupoint combination for BFA can be explored.</li> <li>The analgesic mechanism of BFA can be studied by combining imaging and other methods.</li> <li>A standardized training system can be developed to improve operational consistency.</li> </ul>	В
Kim,2019 <sup>25</sup>	RCT	To evaluate whether the BFA combined drug analgesia method can provide faster relief of immediate postpartum pain (within 24 hours after vaginal delivery) and improve patient satisfaction compared with analgesia using individual drugs.	70 cases of vaginal delivery were randomly divided into an international group (37 cases) and a control group (33 cases). The average age of the control group was 28 years. The average age of the control group was 28 years.	Internation Group: Based on the control group, the following five acupuncture points are implanted in the patient's ears: cingulate gyrus, thalamus, Omega2, zero point, and Shenmen Control Group: Conventional analgesics such as opioids and non- steroidal anti- inflammatory drugs.	One treatment within 6–10 hours after birth	Leave the needle in for 3–7 days.	<ol> <li>Numerical pain rating scale (NPRS)</li> <li>morphine equivalent units (MEUs)</li> <li>Patient satisfaction</li> <li>Length of stay</li> <li>Incidence of adverse reactions</li> </ol>	The analgesic effect of a single BFA combined with a drug for the relief of immediate postpartum pain is comparable to that of a drug alone, but BFA tends to relieve pain more quickly.	<ul> <li>Small sample size</li> <li>BFA only a single treatment</li> <li>Some patients did not complete the 11-day follow-up, and the long-term efficacy of BFA was not obvious</li> <li>Only patients with an NPRS ≥ 4 were included, and most patients had mild pain, which may reduce the significance of the treatment effect</li> <li>No blinding was performed</li> </ul>	<ul> <li>Optimize the BFA intervention treatment plan, explore the efficacy of repeated BFA treatment.</li> <li>Carry out multi-center and expanded sample size.</li> <li>Explore the analgesic mechanism of BFA through basic research.</li> </ul>	В

Baldawi 2022 <sup>22</sup>	RCT	To explore the analgesic effect of BFA as an adjuvant therapy for American veterans undergoing major surgery under general anesthesia.	72 patients were randomly divided into an intervention group of 36 with an average age of 64 and a control group of 36 with an average age of 64.2.	Internation Group: Five acupuncture points (Omega2, Shenmen, Zero Point, Thalamus, and Cingulate) were inserted on the patient's ear on the same side as the operation. Control Group: A blunt needle was used to make shallow punctures in the skin of the ear, which were then removed immediately, and covered with adhesive tape.	Single treatment	Leave the needle in for 3–4 days.	<ol> <li>VAS</li> <li>MME</li> <li>Incidence of nausea and vomiting</li> <li>Length of hospital stay</li> <li>Postoperative anxiety score</li> <li>Incidence of adverse reactions</li> </ol>	The intervention group had a lower consumption of analgesic drugs 24 hours after surgery than the control group (18.3 MME vs 38.6 MME, P<0.001). The pain intensity of the intervention group was significantly lower at 6, 12, 18 and 24 hours after surgery, and the intervention group had a lower incidence of nausea and vomiting than the control group (2.8% vs 66.7%, P<0.001). No adverse events were reported in either group.	<ul> <li>High heterogeneity in the types of sur- gery performed on patients</li> <li>Small sample size</li> </ul>	<ul> <li>In the future, the analgesic efficacy of BFA for specific types of surgery can be further analyzed</li> <li>The analgesic mechanism of BFA can be explored in combination with neuroimaging techniques</li> <li>Long-term follow-up can be increased to evaluate the long-term analgesic efficacy of BFA</li> </ul>	A
Jan 2020 <sup>26</sup>	RCT	To evaluate the analgesic effect of modified BFA as an adjuvant to standard analgesia in patients with acute abdominal pain, low back pain or traumatic pain in the extremities in the emergency department.	90 patients were randomly divided into a BFA group (30 cases, average age 47), a sham acupuncture group (30 cases, average age 48), and a routine care group (30 cases, average age 49).	BFA group: ASP was inserted at five acupoints on the bilateral occipital girdle, thalamus, Omega 2, Shenmen and zero points. Sham acupuncture group: a piezoelectric sham acupuncture device was used to simulate the BFA procedure without skin contact. Routine care group: only received routine drug analgesia.	Single treatment	Leave the needle in for < 10 min	<ol> <li>NPRS</li> <li>Proportion of patients with adequate analgesia or pain relief ≥30%</li> <li>MME</li> <li>Medical cost</li> <li>Adverse reaction rate</li> <li>Patient satisfaction</li> </ol>	There was no significant difference in the change of pain scores at 0, 1, and 2 hours between the battlefield acupuncture group and the sham acupuncture group and the conventional care group, and there was no statistical difference in the adequate analgesia rate, the proportion of pain relief $\geq$ 30%, the amount of opioids used, and the cost comparison among the three groups. No serious adverse events were rethe thported in any of ree groups.	<ul> <li>Small sample size</li> <li>Mixed analysis of pain types</li> <li>The analgesic effect of BFA was not verified for a single pain type</li> <li>A modified version of BFA technology was used</li> </ul>	<ul> <li>Optimize BFA intervention treatment plans</li> <li>Conduct large-scale RCTs on the analgesic effect of BFA on single pain types</li> <li>Explore the synergistic analgesic effect of BFA with other non-drug therapies</li> <li>Increase long-term follow-up time</li> <li>Evaluate the long-term analgesic efficacy of BFA</li> </ul>	A

(Continued)

Dai et al

#### Table I (Continued).

First Author, Year	Study Design	Aim	Sample Characteristic	Intervention	Frequency	Course of Treatment	Key Outcome Indicators	Main Conclusions	Limitation	Future Prospects	Quality Evaluation
Fox 2018 <sup>18</sup>	RCT	To assess the feasibility, safety and efficacy of BFA as an adjunct to usual care for patients with acute low back pain in the emergency department.	30 patients were randomly divided into an intervention group of 15 with an average age of 43 years and a control group of 15 with an average age of 38 years.	Intervention group: Five acupoints, namely, the cingulate gyrus, thalamus, Omega2, zero point, and Shenmen, were implanted in the patient's bilateral ears. Control group: Routine care, including the use of analgesic drugs such as piroxicam, NSAIDs, and opioids.	Single treatment	Leave in place for 7–8 minutes.	<ol> <li>NRS</li> <li>Timed Up and Go Test.(TUGT)</li> <li>Lumbar spine mobility</li> <li>Analgesic drug consumption</li> <li>Lower extremity radiological score</li> <li>Lumbar spine mobility</li> <li>Length of hospital stay</li> </ol>	The intervention group had a significantly lower pain score than the control group after 5 minutes of BFA intervention (5.2 vs 6.9, P=0.04). There was no statistically significant difference between the two groups for other outcome measures (GUGT, radiation pain in the lower extremities, lumbar spine mobility); no adverse events were reported in either group.	<ul> <li>Small sample size</li> <li>No blinding of patients and assessors</li> <li>Not fully compliant with the original BFA protocol</li> <li>Intention-to-treat analysis not performed</li> <li>Only effects within I hour after BFA intervention assessed</li> <li>Long-term analgesic efficacy of BFA not tracked</li> </ul>	<ul> <li>In the future, multi-center, large-sample RCTs on BFA can be conducted</li> <li>Explore the combination of BFA with other non- drug analgesic therapies</li> <li>Explore the analgesic mechanism of BFA in com- bination with imaging technology</li> </ul>	с

Mao 2021 <sup>27</sup>	RCT	To evaluate the	360 patients were	Electroacupuncture	Once a	10 weeks	① brief pain	In week 12, the pain	• Lack of sham acu-	<ul> <li>In the future, imaging</li> </ul>	В
'lao 2021	RCI					10 weeks	inventory(BPI)				в
		efficacy of	randomly divided into	group: Select 4 main	week		<ol> <li>patient-reported</li> </ol>	scores of the	puncture control	technology or biomarker detection can be combined	
		electroacupuncture combined with BFA	an electroacupuncture group (145 cases,	points + other supplementary			outcomes	electroacupuncture group decreased by 1.9	group Sample mostly	to reveal the analgesic	
			• • •	,			measurement	• • •		Ŭ,	
		compared to routine	mean age 61.9 years),	points near and			information system	points and those of the	comprised of early	<ul> <li>mechanism of BFA</li> <li>Conduct sham acupunc-</li> </ul>	
		care for chronic	a battlefield	distal to the painful			(PROMIS)	BFA group decreased	cancer survivors		
		musculoskeletal pain	acupuncture group	area, and stimulate			<ol> <li>Weekly analgesic</li> </ol>	by 1.6 points, both of	<ul> <li>Limited sample</li> </ul>	ture control groups	
		in cancer survivors.	(143 cases, mean age	with an			, ,	which were significantly	representativeness		
			62.6 years), and a	electroacupuncture			drug use	better than the	Insufficient long-		
			conventional care	instrument.				decrease of 0.5 points	term follow-up		
			group (72 cases, mean	BFA group:				in the conventional care	• Only assessed for		
			age 61.4 years) in a	According to the				group. The non-	24 weeks		
			2:2:1 ratio.	original BFA				inferiority of BFA was	Mechanism of BFA		
				protocol				not reached (difference	analgesia not		
				Routine care group:				0.36 points, upper limit	explored		
				drug analgesia, such				of unilateral CI 0.664>			
				as non-steroidal				non-inferiority			
				anti-inflammatory				threshold 0.657,			
				drugs, opioids, and				<i>P</i> =0.055). Both			
				physical therapy.				electroacupuncture and			
								BFA significantly			
								reduced the			
								interference of pain in			
								daily life, and the			
								improvement in PROMI			
								scores was more			
								obvious, and both			
								groups reduced opioid			
								use, but the BFA group			
								had a smaller reduction.			
								Only one case in the			
								electroacupuncture			
								group was discontinued			
								due to ecchymosis,			
								accounting for 0.7%,			
								and 15 patients in the			
								BFA group were			
								discontinued due to			
								pain, accounting for			
								10.5%.			

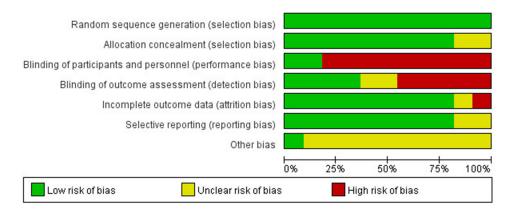


Figure 2 Risk of bias assessment in included studies on BFA for pain management.

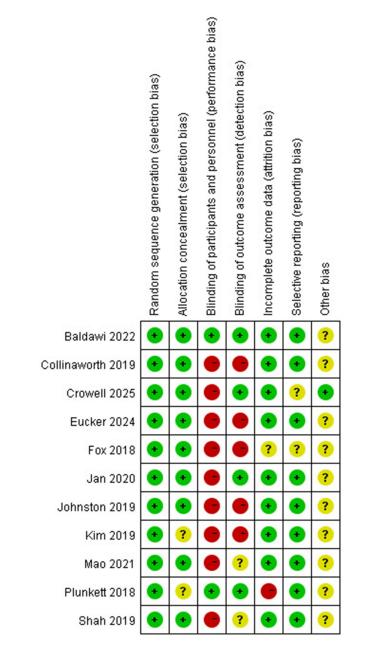


Figure 3 Methodological quality evaluation included studies on BFA for pain management.

adverse events.Evidence from the above studies suggests that BFA is effective in immediate pain relief as one of the analgesic tools, but there is a lack of studies related to the long-term efficacy of BFA.<sup>29</sup> The therapeutic effect of BFA depends more on the patient and the type of pain<sup>30</sup> and the current studies on BFA have problems such as small sample sizes, irrational control group settings, and incomplete implementation of blinding, etc. In the future, more randomized controlled trials comparing the difference in efficacy between BFA and standard pain management are needed to explore the potential long-term benefits of BFA.

#### Postoperative Pain

Postoperative pain, in addition to affecting the patient's normal activities, can cause psychological and physiological changes in the patient. The higher the patient's pain level, the greater the likelihood of anxiety and the consequent decrease in adherence to rehabilitation.<sup>31,32</sup> Baldawi et al<sup>22</sup> randomly divided 72 patients undergoing general anesthesia into 36 cases each in the BFA group and the control group, and the corresponding interventions were implemented in both groups after entering the anesthesia room: in the BFA group, a 2-mm stainless steel needle was inserted into the patient's ear with a syringe, and five auricular acupoints, namely, Omega 2, shenmen, point zero, thalamus, and the cingulate gyrus were taken from the same side of the ear as that of the surgery, and the right ear was taken if the site of the surgery was in the midline region. The BFA needle will fall off automatically after 3 to 4 days. The control group used a blunt needle to make a shallow puncture in the patient's ear and then removed it immediately. The acupoints were the same as those in the BFA group. The incidence of postoperative VAS score, Morphine Milligram Equivalent (MME), total days of hospitalization, nausea, vomiting and other adverse reactions were compared between the two groups. The results showed that the BFA group had lower VAS scores than the control group at 6, 12, 18, and 24 h postoperatively (P <0.001), and the mean MME at 24 h was lower than that of the control group (18.3 vs 38.6, P < 0.001). The incidence of nausea and vomiting was lower in BFA patients than in the control group (2.8% vs 36.1%, 0 vs 30.6%). The difference in the total number of days of hospitalization between the two groups was not statistically significant. The presence of a small number of patients who underwent surgery contributed to the lack of homogeneous comparison between the two groups. The analgesic efficacy of BFA treatment is usually better on the first postoperative day, when patients can feel pain relief within a few minutes, and the duration of pain relief depends on the nature of the pain. However, this analgesic effect diminishes with time after 24h of treatment. The results of the study should be interpreted with caution due to sample size limitations and the uneven distribution of procedure types across the groups. Anil et al<sup>33</sup> randomly divided 134 patients scheduled to undergo tonsillectomy into two groups: a test group and a control group. Both groups underwent the same interventions after receiving general anesthesia. In the test group, five acupoints were punctured sequentially in the auricle according to the acupoints in the test group, and a bandage was placed in the same five acupoints in the control group. Postoperative pain scores, opioid dosage, incidence of nausea and vomiting, and recovery from eating and activity were compared between the two groups. The findings indicated that pain scores at rest and severe pain scores on the day after tonsillectomy were lower in the test group than in the control group (2.94 vs 4.26, P = 0.01, 5. 16 vs 6.51, P = 0.01), and the percentage of activity was higher in the test group than in the control group (35.1 vs 20.8, P = 0.01). However, on the first postoperative day and the following 14 days, no statistically significant differences were observed when comparing the two groups in terms of pain scores, opioid dosage, incidence of nausea and vomiting, and diet and activity recovery. Another randomized controlled study also focused on the analgesic efficacy of BFA in patients after tonsillectomy.<sup>24</sup> 95 adult patients after tonsillectomy were divided into two groups in a 1:1 ratio. In the intervention group, five ASPs (cingulate gyrus, thalamus, Omega 2, zero point, and shenmen) were implanted in the patient's dominant ear after general anesthesia was induced. The control group used conventional postoperative analgesic drugs. The results showed that there was no statistically significant difference in pain scores between the two groups during hospitalization (at discharge) and 10 days after discharge (P>0.05). There was also no statistically significant difference in morphine equivalent between the two groups during surgery, in the recovery room after surgery, and 10 days after discharge (P=0.096). No adverse events were reported in either group. Combining the two articles, BFA can significantly reduce the pain score on the first day after tonsillectomy in adults, but the analgesic effect is short-lived, and there is no difference from the control group after 24 hours, which may be related to the short retention time of the needle or the natural tendency of tonsil pain to relieve. In the future, it is necessary to optimize the intervention plan of BFA and

pay attention to the long-term analgesic needs. Collinsworth et al<sup>23</sup> randomly divided 40 postoperative shoulder patients into a standard physical therapy group (n=19) and a BFA combined physical therapy group (n=21). The combined group implanted ASP in the cingulate gyrus, thalamus, Omega2, zero point, and Shenmen. The results showed that the mean pain VAS score of the intervention group was reduced by 11.86 points (95% CI -22.25 to -1.46) and the most painful VAS score was reduced by 14.71 points (95% CI -28.81 to -0.61) at 7 days after surgery. However, there was no statistically significant difference in opioid use between the two groups (P > 0.05). Crowell et al<sup>16</sup> used a single-blind randomized controlled design and included 95 patients who underwent surgery for shoulder instability (88 cases completed the follow-up). The results showed that there was no significant difference between the two groups in terms of VAS scores, Profile of Mood States (POMS) total scores, Global Rating of Change (GROC) scores and opioid consumption within 4 weeks  $(5.1\pm7.2 \text{ vs } 4.4\pm5.7 \text{ tablets})$  showed no significant differences (P>0.05). Combining the conclusions of the two papers, the efficacy of BFA for postoperative analgesia in the shoulder is controversial and the evidence is limited. The contradictory conclusions of the two studies due to differences in sample size, blinding, and timing of intervention suggest that the analgesic efficacy of BFA may be affected by factors such as operational specifications and population characteristics. Further high-quality, multi-center RCTs are needed in the future to verify its long-term efficacy and safety. Further research is needed in future studies to explore how to prolong the postoperative analgesic effect of BFA and when BFA treatment is most effective for postoperative pain.

#### Cancer Pain

The incidence of cancer pain reaches 50% in patients undergoing active cancer treatment and 90% in patients with advanced cancer.<sup>34</sup> Most cancer pain grades range from moderate to severe, and opioid analgesics are often used clinically for pain management, but the resulting adverse drug reactions are difficult to avoid.<sup>35</sup> In 2021, Mao et al<sup>12</sup> randomized breast cancer survivors with chronic musculoskeletal pain into three groups: an electroacupuncture group (n = 145), a BFA group (n = 143), and a usual care group (n = 72). This study was conducted using a randomized controlled trial, in which patients with breast cancer and chronic musculoskeletal pain were randomly assigned to one of the three groups. The BFA group (n = 143), and the usual care group (n = 72). The electroacupuncture group and the BFA group received either electroacupuncture or BFA treatment 10 times per week for a total of 12 weeks. The usual care group received only usual care and no acupuncture treatment. Following a 12-week intervention period, the Brief Pain Inventory (BPI) scores demonstrated a reduction of 1.9 and 1.6 points in the electroacupuncture and BFA groups, respectively, in comparison to the control group receiving standard care. These findings indicate that electroacupuncture and BFA may offer superior pain management outcomes in patients with breast cancer when compared to conventional care methods. The noninferiority outcomes also imply that BFA is potentially comparable in efficacy to electroacupuncture in alleviating pain. To further explore the comparative efficacy of electroacupuncture and BFA in breast cancer survivors, the team conducted a subgroup analysis of breast cancer survivors participating in the pre-existing trial.<sup>33</sup> They constrained the 165 breast cancer survivors to a common pre-randomization baseline mean and compared the modelbased mean estimates at weeks 12 and 24 via constrained mixed models. The results showed that the analgesic effect of the electroacupuncture group was significantly better than that of the BFA group at week 12 (-0.90 [-1.45, -0.36], P=0.001) and week 24 (-0.82 [-1.38, -0.27], P=0.004). However, no significant differences were observed between the two groups in terms of physical health and mental health scores, as measured by the Patient-Reported Outcome Measurement Information System. With respect to the occurrence of adverse events, the BFA group exhibited a higher incidence in comparison with the electroacupuncture group, with adverse events primarily comprising pain at the needle site. In comparison with the usual care group, both the electroacupuncture group and the BFA group exhibited significant enhancements in physical health and mental health scores in the Patient-Reported Outcome Measurement Information System at week 12. The findings of these studies suggest that BFA can serve as an auxiliary analgesic agent in the management of cancer pain, and the combination of electroacupuncture can significantly enhance the quality of life of cancer patients. It should be noted that the majority of these studies are based on clinical trials, and there is a need for further theoretical discussion and mechanistic research to fully elucidate the underlying mechanisms.

#### Postpartum Pain

A randomized controlled trial was conducted by Kim et al<sup>25</sup> to compare the analgesic effects of BFA combined with routine pain care and routine pain care, respectively, in women who had a singleton vaginal delivery within 6–10 hours. Seventy subjects who met the criteria for natality were randomly divided into three groups: 37 in the trial group and 33 in the control group. Both groups received routine pain care, with the experimental group receiving BFA, in which ASP was placed into both ears in the order of cingulate gyrus, omega 2, shenmen, and zero point by a professional acupuncturist. The needles were dislodged by themselves during the follow-up period, and the treatment was performed only once. The mean time required for 50% pain reduction in patients after the initial treatment was 6 days in the experimental group (n = 33) and 5 days in the conventional care group (n = 37). After 11 days postpartum, the pain relief rates were 83.5% and 87.1% in the experimental group (n = 27) and the conventional pain care group (n = 28), respectively, with no statistically significant difference (P = 0.65). Considering that the reasons for the lack of statistical significance in the comparison between the groups were that BFA was only used for a single treatment, the sample size was small, the follow-up period was insufficient, only patients with numerical pain rating scale(NPRS) score 4 were included, and most patients had mild pain, which significantly reduced the efficacy of the treatment, more research is needed in the future to demonstrate the efficacy of BFA in the actual application of postpartum analgesia in different childbirth methods.

# Discussion

The results of this study indicate that the types of pain amenable to BFA-based pain management include acute pain, postoperative pain, cancer pain, and postpartum pain. With respect to the evaluation of the analgesic efficacy of BFA, a total of six out of eleven studies reported that the BFA group exhibited lower pain scores in comparison to the control group. Conversely, five out of eleven studies reported that there was no statistically significant difference in pain scores between the BFA group and the control group. This outcome does not provide sufficient evidence to definitively affirm the efficacy of BFA in pain management. However, it is crucial to acknowledge the encouraging trend exhibited by BFA in terms of immediate analgesia. In conjunction with the results of the Cochrane risk bias assessment (2/11 grade A, 8/11 grade B, 1/11 grade C), the reason for this result may be related to the fact that the majority of the studies had methodological flaws.For instance, the sample size is often inadequate, with 3/11 studies having a sample size of <30 per group, <sup>19,23,26</sup> and a minimum sample size of only 15 per group. Secondly, the implementation of the blind method was also inadequate. Due to the particular nature of BFA operation, it is not feasible to fully blind the patient and the acupuncture operator. This limitation has been previously documented in the extant literature. In addition to the inadequate implementation of the blind method, the use of painkillers and the high heterogeneity of pain types will also affect the analgesic efficacy of BFA to a certain extent. The analgesic efficacy of BFA is closely related to the BFA operation process and the operator's technique. According to the BFA Protocol, the BFA operation process is as follows:<sup>36</sup> A total of 10 specific acupoints on the left and right ears of the patient are inserted alternately in sequence. The specific acupoints and their designated order are delineated as follows: cingulate gyrus (1, 2), thalamus (3, 4), Omega2 (5, 6), zero point (7, 8), shenmen (9, 10), as show in Figure 4. In the interval between each insertion, the patient is to be asked to rate the pain and perform activities such as walking, raising their arms, or taking a deep breath to determine whether adverse reactions, including pain, nausea, or dizziness, are induced. The application is to be halted once the pain subsides or when the patient makes a request to do so.Six studies in this review adhered to the BFA protocol, while two studies followed the US Air Force Acupuncture and Integrative Medicine Center Protocol.In terms of acupoint selection, all studies selected the five acupoints of the cingulate gyrus, thalamus, Omega 2, zero point, and shenmen, but there were minor differences in the order of insertion and the number of acupoints. Although some studies reported following the BFA protocol, in practice they did not fully adhere to it. Some authors have employed a modified version of BFA manipulation,<sup>26</sup> which involves the elimination of several steps. These steps include the insertion of two needles into the gap, the request that the patient walk, and the assessment of the patient's pain. The findings of these studies indicate that there is no substantial difference in analgesic efficacy between the BFA group and the sham acupuncture group or the conventional care group. The efficacy of BFA may be related to the original technique, in contrast to the positive results shown in other BFA analgesia studies that were based solely on the BFA protocol.<sup>21,23</sup>

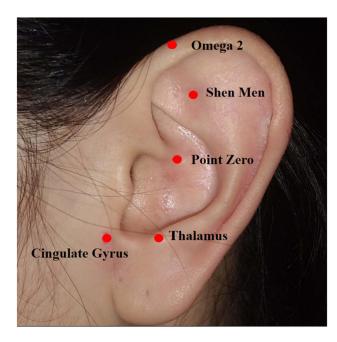


Figure 4 The five auricular acupuncture points of the battlefield acupuncture.

Furthermore, the level of experience of the acupuncture practitioner is a contributing factor. This operational skill can be mastered through brief training sessions.<sup>37</sup> However, given the absence of uniform training standards, the efficacy of BFA may be contingent upon the operator's varying degrees of experience and the techniques employed.

The evaluation of BFA's therapeutic efficacy has predominantly relied on patient-reported pain intensity, with the employment of various quantifiable pain scoring instruments. Five studies in this study used VAS as the outcome measure for pain, four studies used NRS(NPRS), and one study each used defense and veterans pain rating scale (DVPRS) and brief pain inventory (BPI) as outcome measures. Currently there is a lack of objective quantitative indicators on BFA analgesia, such as laboratory test indicators, through objective indicators can help us better understand the mechanism of BFA analgesia, to provide scientific evidence to support the development of the clinical application of BFA.

A paucity of studies has been conducted on the subject of serious infections caused by BFA treatment.<sup>38</sup> A few studies have shown that some patients may experience mild side effects during BFA placement, such as localized ear pain, bleeding, and dizziness, which resolve on their own after a few minutes.<sup>39</sup> Although many studies have included the occurrence of adverse events in BFA as one of the observational indicators, few studies have described in detail how to deal with ah after the occurrence of an adverse event and how to avoid the occurrence of adverse events. These issues can be addressed through standardized training and the development of detailed strategies for dealing with adverse events, thereby improving the clinical safety of BFA and patient compliance.

Combining the current research status, BFA has the following merits and demerits.

## Merits

- Instant pain relief: BFA can significantly relieve pain within a few minutes by stimulating five specific points on the ear, and is especially effective for acute pain.<sup>18</sup> Castañeda et al<sup>40</sup> conducted a questionnaire survey of 66 BFA operators. According to the operators' reports, approximately 70.7% of patients experienced pain relief following BFA treatment, and 66% of patients felt that the duration of BFA's pain relief was 2 weeks or less.
- The procedure is characterized by its high safety profile and minimal adverse effects. BFA utilizes diminutive semipermanent gold needles, which, when inserted with the requisite expertise, are nearly non-invasive, thereby circumventing the potential risks of hemorrhaging associated with traditional acupuncture.

- This approach has been demonstrated to reduce patients' drug dependency. In light of the ongoing opioid epidemic, there is an imperative for non-pharmacological modalities to alleviate pain. BFA provides a non-pharmacological analgesic alternative that assists patients in reducing their reliance on opioids and other analgesics.<sup>22</sup>
- The cost and ease of use of BFA are notable advantages. In comparison to invasive treatments or long-term drug management, BFA is both economical and less intensive to train. This characteristic facilitates its adoption and integration into treatment regimens by healthcare providers.For example,<sup>41</sup> if the cost of a box of 200 ASPs is \$81.00, it has been determined that a single box of ASPs can alleviate the pain of 20 veterans for a period of one week (based on the insertion of a maximum of five acupoints in each ear). This calculation indicates that each veteran would incur a cost of \$4.05 per week, resulting in a total expenditure of \$210.60 for the treatment of each veteran over the course of one year.According to 2016 statistics from the US Department of Defense,<sup>42</sup> patients treated with certified opioid medications spend approximately \$115.00 to \$294.13 per week. The US Veterans Affairs conducts BFA training, and basic teaching can be completed through an intensive 4-hour course. Participants are authorized to perform clinical BFA operations after passing the assessment.<sup>37</sup>

# Demerits

- The extant research evidence on BFA is controversial. Preliminary studies have verified the benefits of BFA in analgesia; however, current research has shown inconsistent or even invalid results due to heterogeneity in research methodology and research design. Such heterogeneity includes pain type, control design, and operator experience. Methodological limitations, such as small sample size and insufficient blinding, have also been observed.<sup>10</sup>
- The absence of standardized guidelines is a salient issue. There is a paucity of uniform standards for the indications, frequency of intervention, and course of treatment of BFA. The scope of BFA analgesia encompasses diverse forms of pain, including acute pain, postoperative pain, and cancer pain. The frequency of intervention varies, ranging from a single treatment to once a week, with the duration of intervention spanning from a few minutes to several weeks.<sup>19,21,27</sup>
- The precise mechanism of action remains to be elucidated. The extant literature predominantly focuses on clinical efficacy observations, and the proposed mechanisms of action exhibit significant variability (eg,  $\beta$ -endorphin release, nerve regeneration, immune regulation). A unifying conclusion on the analgesic mechanism of BFA remains elusive, potentially leading to a misinterpretation of its underlying mechanisms.<sup>12</sup>

This review offers an evidence-based foundation for clinical decision-making, the optimization of BFA intervention programs, and patient pain management through systematic review methods.For clinicians, the systematic review of the effectiveness and safety of BFA in pain management provides a reference for clinical multimodal analgesic strategies. The review suggests that, while current clinical evidence partially verifies the effectiveness of BFA in immediate pain relief, high-quality RCTs are still needed to clarify its analgesic mechanism of action and the precise population for which it is suitable, and to explore its synergistic analgesic effect with other therapies. The implementation of novel pain management techniques has the potential to mitigate drug-related risks and the associated medical and economic burden for patients.

# Limitation

This study exclusively encompasses English literature, while excluding studies published in other languages. Due to the substantial disparities in the frequency of interventions, the time of data collection, the utilized pain assessment tools, and other factors, the included literature is merely described in a descriptive manner. This approach precludes the presentation of objective quantitative results to support the evidence.

# Conclusion

This study shows that BFA involves the field of pain management, including but not limited to the following types of pain: acute pain, postoperative pain, cancer pain, and postpartum pain. Its analgesic efficacy is mixed. This conclusion is consistent with the views of other scholars.<sup>43</sup> However, it is noteworthy that the majority of the included studies

corroborated the efficacy and safety of BFA in prompting pain relief. Consequently, it is recommended that BFA be utilized as an adjuvant analgesic for patients experiencing mild to moderate pain, in conjunction with other therapeutic modalities such as electroacupuncture and analgesics, to achieve a multimodal analgesic effect. With regard to the safety evaluation, no studies have reported cases of serious infections caused by BFA. A limited number of patients have reported transient ear pain, bleeding, or dizziness, which have been observed to self-resolve within minutes. Future research should prioritize the investigation of BFA in relation to specific pain types, the long-term analgesic efficacy of BFA, and the mechanisms by which BFA provides analgesia. To overcome the current limitations of research in this field, large-scale, multicenter, and multilevel high-quality studies are necessary. These studies can serve as a reference for multimodal analgesic strategies.

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# Disclosure

The authors report no conflicts of interest in this work.

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