BATTLEFIELD ACUPUNCTURE FOR POST PARTUM PAIN: A RANDOMIZED CONTROLLED TRIAL

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Introduction

Post-partum pain can have significant ramifications for quality of life. Acupuncture is increasingly used for management of pain. However, evidenced based strategies that incorporate acupuncture for post-partum pain are lacking. We compared Battlefield Auricular Acupuncture (BFA) plus standard analgesia versus standard analgesia alone for the reduction of pain in the immediate post-partum period.

Methods

a. Design - Randomized controlled trial (RCT)
b. Setting - Mike O'Callaghan Federal Medical Center
c. Study Populations – Post-partum vaginal deliveries with initial pain score of 4 or greater on a 0-10 scale.
d. Intervention - Sedatelec® ASP Gold needles were placed bilaterally using the BFA technique.
e. Main outcome measures - Time to sustained 50% reduction from initial pain.
f. Statistical Test Used - Two sample T-Test, Kaplan Meier Time-to-Event Analysis

Results

The mean time to 50% sustained reduction of initial pain in the standard analgesia group (n=33) was 6 days compared to 5 days in the standard analgesia plus

BFA (n=37) therapy group (p=0.35). By 11 days post-partum, 87.1% in the standard group and 83.5% in the study group had achieved the primary outcome (p=0.65). The mean total morphine equivalent units (MEUs) in the standard group compared to standard plus BFA group were 88mg and 82mg respectively (p=0.45).

Conclusion

There was no statistical difference between standard analgesia and standard analgesia plus BFA therapy in achieving sustained 50% pain reduction from the initial post-partum pain score. MEUs, a surrogate pain marker, also did not achieve statistical significance. This single site RCT suggests that BFA does not provide additional benefit to standard analgesia therapy for immediate post-partum pain. To reflect real world scenarios, we recommend further study with any technique that the available acupuncturist finds the most appropriate for each patient.

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Introduction

Acupuncture is one of the oldest medical procedures still practiced regularly today. Each culture and era contributes new techniques of acupuncture. While the exact proposed mechanism of action of acupuncture on pain is not completely elucidated, it is clear that there are documented physiological effects. Specifically, stimulation with acupuncture excites nerve fibers that cause the release of endogenous opioids and oxytocin that result in functional changes in multiple organ systems. Beta-endorphin levels that have been known to regulate pain control, blood pressure, and body temperature, have been observed to increase in the brain tissues after acupuncture[1]. Functional magnetic resonance imaging studies have also demonstrated increased activation in specific regions of the brain that correlate with established acupuncture points compared against sham points[2,3]. Auricular acupuncture follows this same premise and refers to piquering various points on the ear that are believed to have functional effects to targeted areas of the body to achieve the desired result.

Acupuncture in military healthcare has been growing in the last decade. Since 2008, one organization reports training over 500 military physicians in acupuncture.[4] A study in 2018 showed that nearly 16,000 patients in the Medical Health Service (MHS) received acupuncture treatments in fiscal year 2014 alone[5]. Around the same time, a review of integrative medicine modalities in the MHS described acupuncture services offered in 83 military treatment facilities (MTF).[6] Of specific acupuncture modalities, auricular acupuncture is arguably the most portable, easiest to perform, easily taught, and has wide applications for use. In 2001, Dr Richard Niemtzow developed a specific

auricular acupuncture technique designed for rapid relief of pain, which he termed "Battlefield Acupuncture" (BFA).[7] Since its inception, BFA has achieved widespread use within the military medical system. There is also a growing body of evidence to support the use of auricular acupuncture as an effective modality in relieving acute pain. This includes pain in the intra and postoperative period,[8,9,10] low back pain and pelvic pain associated with pregnancy,[11] and migraines.[12]

Current evidence-based post-partum pain control strategies centers around pharmacotherapy as demonstrated in a 2011 Cochrane Review.[13] Furthermore, despite a diverse array of integrative medicine strategies that have been studied for labor pain management,[14,15] the same is not true for the immediate post partum period. This study attempts to explore this specific gap within the context of an evolving military health service.

Objective

The objective of this study was to determine if the addition of BFA to standard analgesia resulted in a faster sustained pain relief in the immediate post-partum period compared to standard analgesia alone for vaginal deliveries.

Methods

The study was designed as a randomized controlled trial in order to minimize the difference between the intervention and control groups. The inherent nature of the intervention precludes the ability to have a placebo or blinded group. In order to detect a difference in pain scores, a power analysis was performed, which showed at least 66

subjects would be required. Subjects who underwent a caesarean section were not included because the population was too heterogeneous (too many uncontrolled variables such as anesthesia types and dosing per different providers and different post-operative orders for analgesia).

To be recruited for the study, the woman had to have documented an initial pain score of 4 or greater (numerical pain score scale 0-10) and be at least 6 hours post-vaginal delivery. A research coordinator then performed a screening visit to obtain informed consent and HIPAA authorization as well as ensure the subject met all inclusion criteria. Once enrolled, a random number generator assigned the subject to either arm of the study. For those assigned to the BFA plus standard analgesia, a qualified provider placed semi-permanent acupuncture needles into all 5 standard BFA points (Figure 1) bilaterally for a total of 10 needles. These needles were allowed to fall out over the course of the follow up period with no repeat treatments. One hour after enrollment or provision of BFA, the mother was assessed for pain via the standard numerical pain rating scale from 0 to 10 (0 is no pain and 10 is worst pain) by the research coordinator. Research coordinators followed up with each subject for 10 additional days via telephone after the 1st follow up visit. A full overview of the study design is outlined for reference below (Addendum 1). At each follow up, the primary outcome of pain was assessed as well as secondary outcomes to include satisfaction with pain management and doses of pain medication use.

The mean time for the primary outcome was calculated using a Kaplan Meier time-to-event analysis (Addendum 2). The differences between the two groups were measured using a two sample t-test. The differences between overall satisfaction with

post-partum pain management and the total morphine equivalent units (MEUs) in the two groups were calculated using a Wilcoxon rank sum test. An unaffiliated third party performed all statistical analysis.

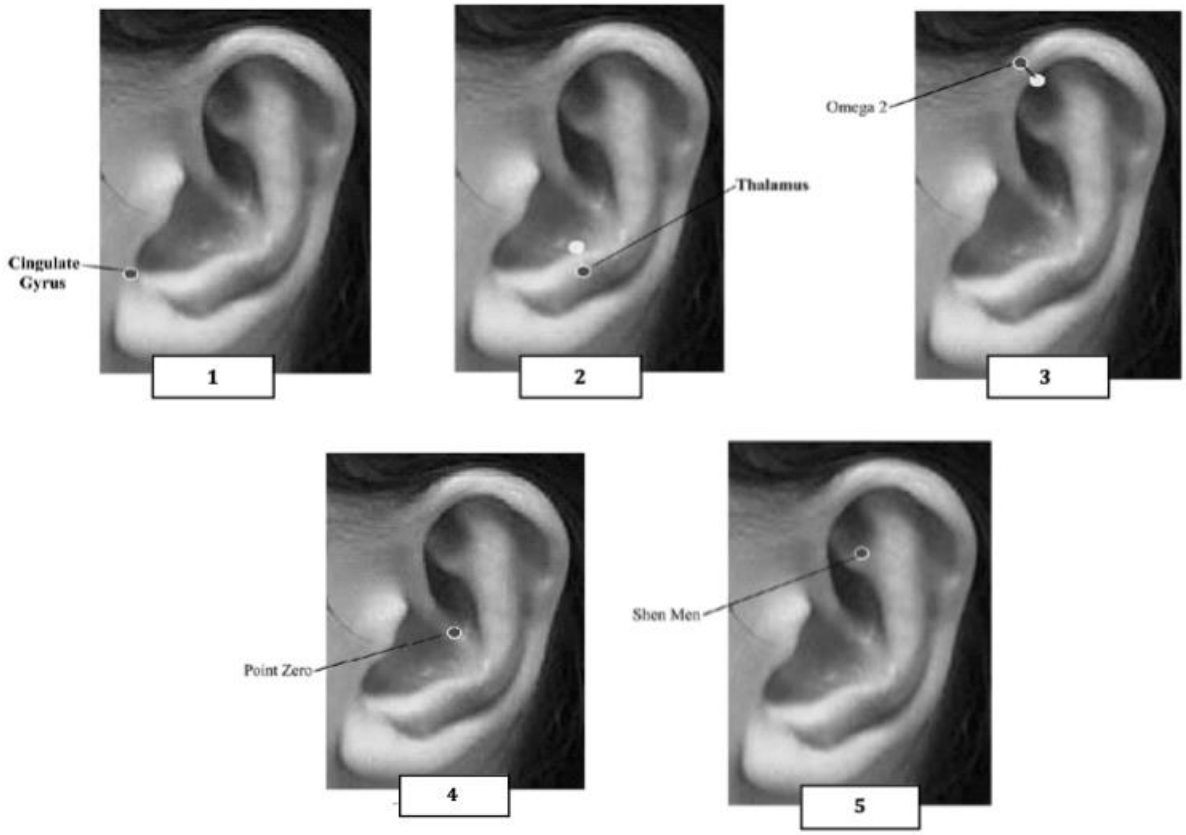


Figure 1 - Battlefield Acupuncture points shown in order of placement

Results

A total of 70 subjects that had a successful vaginal delivery were enrolled. The demographics were similar in the BFA plus standard analgesia and standard analgesia alone groups (Table 1). The mean time to 50% sustained reduction of initial pain in the standard analgesia group (n=33) was 6 days compared to 5 days in the standard analgesia plus BFA (n=37) therapy group (p=0.35) (Table 2). Of note, not all subjects in both groups had achieved the primary outcome. By 11 days post-partum, 87.1 % in the

standard group (n=28) and 83.5% in the intervention group (n=27) had achieved sustained 50% pain reduction (p=0.65).

	Standard Analgesia		Standard analgesia + BFA	
	N	mean	N	mean
Age (years)	33	28	37	27
Race/Ethnicity	**N**	**%**	**N**	**%**
Asian	0	0	5	13.5
Black	1	3	4	10.8
Hispanic, Latin or Mediterranean	6	18.2	2	5.4
Pacific Islander/American Indian/Alaskan Native	1	3	1	2.7
Other or undefined	0	0	2	5.4
White	25	75.8	23	62.2

Table 1 - vaginal delivery demographics of enrolled women

Secondary outcomes were total morphine equivalents used, satisfaction with pain management, and time in hospital postpartum ward. On an 11-point scale with 0 being dissatisfied and 10 being satisfied, the median pain management satisfaction was 10 in the standard analgesia and the standard analgesia plus BFA groups (p=1.0). The mean MEUs in the standard group compared to standard plus BFA group were 88mg and 82mg respectively (p=0.45). The different narcotic pain medications that were prescribed and used to calculate MEUs included oxycodone, oxycodone combined with acetaminophen, and morphine sulfate. One patient did receive fentanyl prior to discharge. The mean time spent in the hospital post-partum ward was 42 hours in the standard analgesia group compared to 44 hours in the standard analgesia plus BFA group (p=1.0).

	Standard Analgesia				Standard analgesia + BFA				
	N	mean	SD	median	N	mean	SD	median	p-value
Time to 50% sustained reduction of initial NPRS (days)	28	6	3	6	27	5	3	5	0.35
Morphine Equivalent Units (total mg)	33	88	58	77	37	82	113	54	0.45
Pain Management Satisfaction	31			10	28			10	1.00
Time in Hospital (hrs)	33	42	12	43	37	44	16	46	1.00

Table 2 - Primary and secondary outcomes for standard and intervention groups; NPRS - numerical pain rating scale; BFA - Battlefield Acupuncture

Discussion

In this single center randomized controlled trial, there was no statistically significant difference between the standard analgesia group and the standard analgesia plus BFA group in the mean time to sustained 50% pain reduction. The difference in the MEUs between the two groups did not reach statistical significance. The use of pain medications is an important surrogate marker for pain as the standardized pain scale is often noted to be subjective and inconsistent. By using this surrogate marker, a secondary nominal measure of pain could be accomplished. While some providers do not routinely prescribe opioids for post partum pain control, this study did enroll women who were admitted to the post partum ward under several different services. It did not exclude women with complications. In addition, the overall patient satisfaction between the two groups did not reach a statistically significant difference indicating that the patient oriented outcome of pain control was the same in both groups. Thus, despite the

discomfort associated with the placement of the acupuncture needles, this did not negatively impact a woman's experience in her pain management regimen. Furthermore, the time spent in hospital on the post-partum ward did not reach a statistical difference between the two groups. While not directly correlated, this can be used as another surrogate marker for any potential complications associated with the treatment group which may delay discharge such as inadequate pain control.

By the end of the follow up period in this study, not all women had achieved the primary outcome of sustained 50% pain reduction from the initial pain score. This suggests multiple possibilities in regards to the study design. First, that the power of the study was insufficient as the statistical analysis was not able to include all of the subjects enrolled in each group if they didn't reach the primary outcome. Second, the study did not follow the subjects for an adequate period of time to be able to detect a statistically significant difference in the primary outcome. Third, the sustained 50% reduction in pain was not an effective primary outcome to measure the effectiveness of BFA when added to standard analgesia.

A meta-analysis of post-partum analgesia due to uterine cramping demonstrated that non-steroidal anti-inflammatory drugs (NSAIDs) were better than placebo at relieving pain.[16] However, the comparison of data regarding NSAIDs and opioids were conflicting in that some showed similar effects while others were as effective as placebo. This suggests that MEUs may not be the most accurate surrogate marker of pain. In fact, by far the most commonly prescribed analgesia for the routine post-partum vaginal delivery was NSAIDs at this single center. The meta-analysis did not include any form of acupuncture so it is difficult to compare our results to existing literature.

There is more data regarding acupuncture use for pain management in labor. Based on a 2006 meta-analysis of complementary and alternative therapies for labor pain management, the authors conclude that acupuncture may be beneficial although the number of women studied have been small.[17]

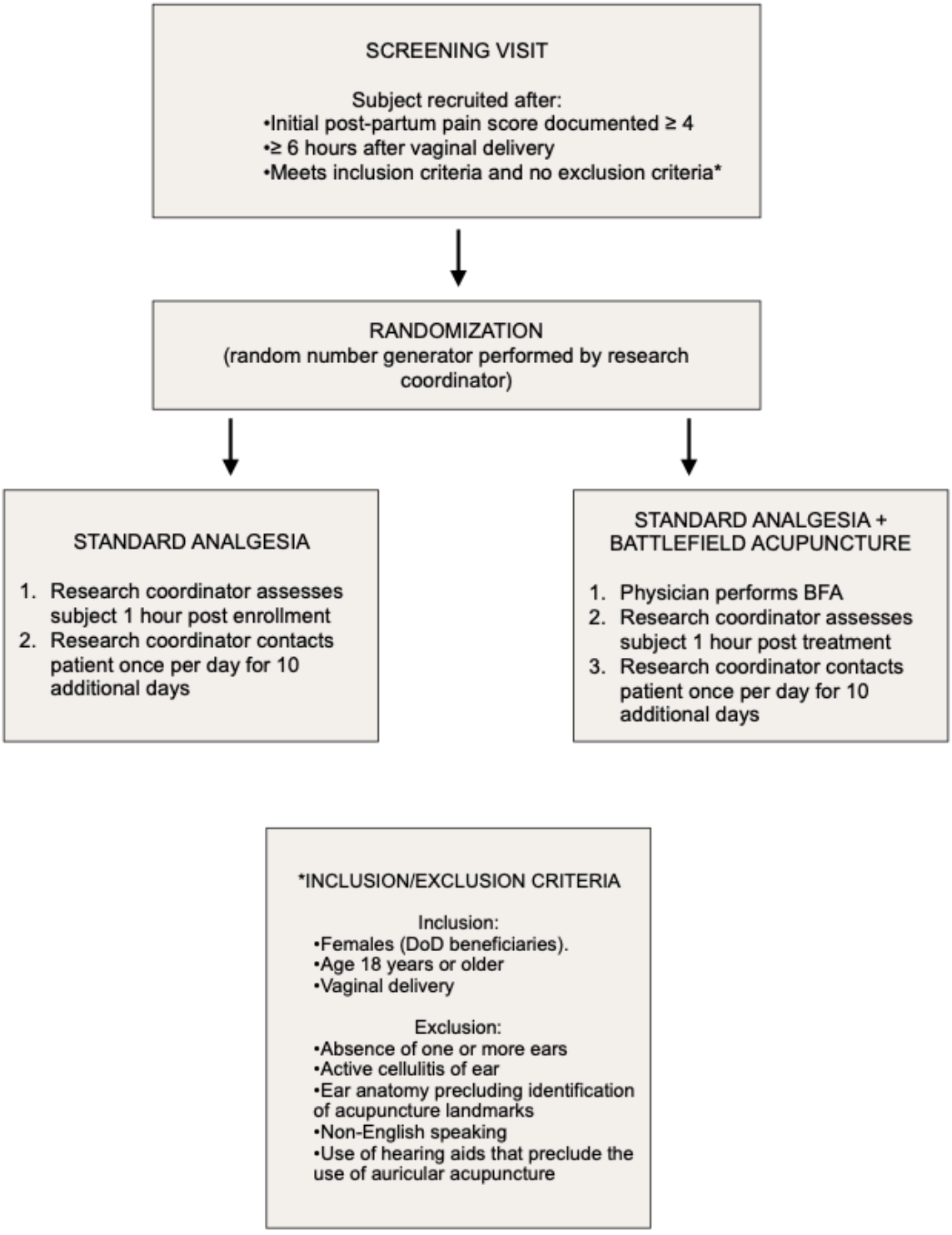
In order to provide an evidence-based answer on this intervention, the study design did not reflect the actual practice of many acupuncturists. Many providers trained in the BFA technique may have provided repeat treatments within the follow up period of this study. The technique of auricular acupuncture also would include individualized therapies, which is not limited to BFA, upon examination by an acupuncturist. Other studies on acupuncture for assessing pain control employed a strategy where the number of needles and acupuncture points were chosen at the physicians' discretion.[18] This mimics the real life scenario of a patient receiving a treatment that could change based on a clinician's level of training and their evaluation of a patients condition. Arguably, this is the more practical approach to assessing a modality of pain control that may use several techniques. For example, instead of choosing BFA as the pain control strategy for a given acupuncturist, perhaps the more clinically meaningful approach is to allow for the acupuncturist to select the most appropriate therapy for each individualized patient. This is in an inherent strength of acupuncture as a discipline.

Conclusion

This randomized controlled trial suggests that a single treatment of BFA in addition to standard analgesia compared to standard analgesia alone does not reduce the mean time to 50% reduction of pain for vaginal deliveries in the immediate post-

partum period. The use of a surrogate marker for pain, average MEUs used by each group, during the study period also supports this conclusion. Although this study did encompass a specific technique within auricular acupuncture, more studies for the immediate post-partum period pain control are needed that examines alternative treatments including the field of medical acupuncture that is not limited to auricular techniques. Based on this study's results, BFA is not an effective treatment for post-partum pain after vaginal delivery. However, patients do continue to request acupuncture. Given that there was no statistical difference in patient satisfaction of overall pain management, it is reasonable to perform this low risk procedure if a patient requests it and there are no contraindications.

Several scholarly questions are generated from this study. Can BFA be an effective pain management strategy as an adjunct to current standard of care for labor pain management? While a simple contrast to post-partum pain management, there are many layers when designing this study that takes into account the addition of a potential non-pharmacological intervention. Also, when studying acupuncture as an intervention, does allowing the acupuncturist to decide the specific technique result in a more clinically meaningful and potentially more pragmatic study design? As we are seeing more trained military physicians in medical acupuncture, a patient may likely receive more than BFA when receiving acupuncture but this would be dependent upon the clinician's training and their evaluation of an individual patient. Typically, after the interview and examination, an acupuncturist would individualize each treatment, which is not limited to auricular acupuncture alone. Thus, it seems natural that as we design studies in the future, the intervention should match the real life application.



Addendum 1 - Study design overview; BFA - Battlefield Acupuncture, DOD - Department of Defense

Treatment	N	Events	p-value				
Standard analgesia	33	28	0.646				
Standard analgesia + BFA	37	27					
Time (days)	**Number at risk**	**Cumulative events**	**Survival Probability**	**95% LCL**	**95% UCL**	**Cumulative incidence**	**Survival probability of 50% sustained reduction from initial pain**
Standard analgesic							
0	33	0	1	1	1		
1	33	2	0.939	0.861	1		
2	31	3	0.909	0.816	1		
3	30	4	0.879	0.774	0.998	0.121	12.1% achieved 50% sustained reduction from initial pain
4	29	8	0.758	0.625	0.919		
5	25	12	0.636	0.492	0.824		
6	21	16	0.515	0.37	0.717	0.485	48.5% achieved 50% sustained reduction from initial pain
7	17	17	0.485	0.341	0.689		
8	15	20	0.388	0.251	0.598		
9	12	24	0.259	0.143	0.466		
10	8	25	0.226	0.119	0.431		
11	7	28	0.129	0.052	0.321	0.871	87.1% achieved 50% sustained reduction from initial pain
Standard analgesia + BFA							
0	37	0	1	1	1		
1	36	6	0.833	0.72	0.964		
2	29	9	0.747	0.617	0.905		
3	26	11	0.69	0.553	0.86	0.31	31.0% achieved 50% sustained reduction from initial pain
4	22	12	0.658	0.518	0.836		
5	21	15	0.564	0.42	0.759		
6	18	17	0.502	0.358	0.703	0.498	49.8% achieved 50% sustained reduction from initial pain
7	16	21	0.376	0.242	0.585		
8	12	22	0.345	0.215	0.553		
9	11	26	0.219	0.115	0.421		
10	4	26	0.219	0.115	0.421		
11	4	27	0.165	0.07	0.39	0.835	83.5% achieved 50% sustained reduction from initial pain

Addendum 2 - Kaplan Meier Time-to-Event Analysis (50% Pain Reduction by Treatment Vaginal Delivery)

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