Acupuncture for the Treatment of Chronic Pain in the Military Population

Factors Associated With Treatment Outcomes

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Objectives: Acupuncture is characterized as an alternative or complementary medicine with a low complication rate and minimal side effects. There is a lack of robust evidence that shows acupuncture is an effective treatment for chronic pain. The purpose of this study was to determine which (if any) characteristics can predict successful response to acupuncture in chronic pain patients treated at military treatment facilities.

Methods: Data from 222 patients who received treatment for a chronic pain condition were collected from 2 medical centers. The patients underwent at least 4 acupuncture treatments and had an average pain score of 4 or higher on a 0- to 10-point numerical rating scale or visual analog scale in the week before treatment initiation. A successful outcome was defined to be a 2-point or greater reduction on the numerical rating scale or visual analog scale 12 weeks postinitial treatment.

Results: The overall treatment success rate was 42.3%. Multivariate logistic regression found a higher baseline pain rating and the use of stimulation needles to be associated with a positive outcome (odds ratio [OR] = 1.26; 95% confidence interval [CI], 1.03-1.55; P = 0.02 and OR = 2.73; 95% CI, 1.39-5.32; P = 0.03, respectively). Only the presence of one or more psychological comorbidities was found to be associated with treatment failure (OR = 0.67; 95% CI, 0.49-0.92; P = 0.01).

Discussion: The use of electrical stimulation and higher baseline pain score were associated with a positive treatment outcome, while the presence of a psychological comorbidity diminished the likelihood of treatment success. Practitioners should consider using electrical stimulation more frequently, and addressing psychopathology before or concurrent to treatment, when initiating acupuncture.

Key Words: acupuncture, complementary and alternative medicine, military medicine

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A cupuncture is characterized as an alternative or complementary medicine with a low complication rate and little to no side effects. Acupuncture has been practiced in China for more than 2500 years and has become popular in many European and western countries. In 1997 and 2002, the National Institutes of Health Consensus Development Panel reviewed data on acupuncture and found strong evidence for efficacy in emesis control and dental pain; however, they determined there was a lack of significant evidence for chronic pain. 1,3

The epidemiology and treatment of pain are constantly being evaluated to determine which therapeutic modalities have the best success rate. Complementary and Alternative medicine (CAM) research has been slowly increasing in the past decade; however, due to regulatory issues, funding and support, much is still unknown about many CAM treatments.⁴ Acupuncture is one of the most commonly used CAM treatments for pain. More than 10 million acupuncture procedures are performed yearly in the United States.⁵

In 2010, the Pain Management Task Force was created to provide recommendations and guidelines for military pain treatment and research. One of the main aims was to increase research in CAM treatments, with a strong focus on acupuncture. Since then, studies have been increasing in size and complexity to satisfy the need for acupuncture and alternative medicine research. Many studies have been conducted that attempt to identify factors that determine acupuncture success.

Three previous studies have examined whether patient beliefs about the helpfulness of acupuncture affected treatment outcomes in patients with chronic back pain; however, the results were inconsistent.⁷⁻⁹ In 2010, a study of 422 patients examined the pretreatment preferences and expectations of patients and patient outcomes. The results showed that patients with higher pretreatment expectations for the success of acupuncture expressed a preference for acupuncture over other back pain treatments and had a positive impression of acupuncture. However, none of the variables predicted short to long-term improvement of back-related symptoms.¹⁰

Prady and colleagues conducted a systematic review of 31 acupuncture trials, including randomized controlled trials and quasi-randomized controlled trials. This study found little evidence that preferences in treatment or randomization affected outcomes. Furthermore, their analysis of demographic factors was inconsistent and provided no statistical evidence for variations in outcomes. Limitations included no representation of non-English trials and low quality reporting of outcome measures in individual trials. ¹¹

We conducted a multi-site, retrospective, electronic medical record review to determine which (if any) characteristics can predict successful response to acupuncture. We hypothesized that certain demographic and clinical factors (eg, diagnosis, lesser disease burden, lack of coexisting psychopathology) would be associated with successful treatment, and that these factors could be used to guide treatment and future study. To our knowledge this is the first study of its kind to be conducted at military treatment facilities.

METHODS

Data Collection

Data collection for this multi-site retrospective electronic medical record review was performed at Womack Army Medical Center (WAMC) and Walter Reed National Military Medical Center (WRNMMC). The study was approved by the WAMC IRB, which served as the IRB of record for both institutions. Patients were selected using a preexisting list of patients provided by the Defense Health Agency National Regional Medical Directorate who received acupuncture treatment for pain at WAMC or WRNMMC. Data were mined from the military electronic medical record system (Armed Forces Health Longitudinal Technology Application, a.k.a. AHLTA) by a member of the research team.

Selection Criteria

To be eligible for inclusion in the study, patients must have been at least 18 years old at the time of first acupuncture treatment, enrolled in the Defense Enrollment Eligibility Reporting System (DEERS), received treatment for a chronic pain condition, reported a duration of pain ≥ 3 months, and had an average pain score of 4 or higher on a 0- to 10-point numerical rating scale (NRS) or visual analog scale (VAS) in the week before treatment initiation. Exclusion criteria included <3 treatments, treatments performed by individuals not certified to perform acupuncture (eg, untrained physical therapists), and lack of pain data.

Variables collected for analysis of their association with treatment outcome included age, sex, race/ethnicity, education, military status (eg, active duty officer, active duty enlisted, retiree, civilian), pain duration, pain location, pain type (neuropathic, nociceptive, or mixed), smoking status, obesity (body mass index > 30), inciting event (traumatic or nontraumatic), number of acupuncture sessions, length of acupuncture sessions, frequency of acupuncture sessions, use of electrical stimulation needles, presence of psychological comorbidities (eg, mood disorder, anxiety, post traumatic stress disorder, substance abuse, depression), and pain level at baseline. Treatment success was defined as 2-point or greater reduction in average pain score on a 0 to 10 NRS or VAS pain scale 12 weeks after initial treatment (window, 10 to 14 wk).

Neuropathic pain was defined as pain arising from a disease or lesion affecting the somatosensory system, and nociceptive pain was considered as pain arising from the activation of peripheral nerve endings resulting from tissue injury.¹² The classification of pain as neuropathic, nociceptive, or mixed was based on clinical evaluation, which is considered to be the current "gold standard." ^{13,14}

Statistical Analysis

Patients were categorized by outcome (treatment success/failure) based on their NRS or VAS pain rating score at 12 weeks after the initial treatment. A successful outcome was predefined as a 2-point or greater reduction in pain score on the NRS or VAS. A χ^2 test was performed to assess differences between patient outcomes based on medical center. The race/ethnicity variable was recoded to consolidate underrepresented groups. Patients who identified as Hispanic (n = 3) and Asian (n = 9) were recoded as "Other."

Continuous data were assessed for normality and the presence of outliers via the Shapiro-Wilk test and Mahalanobis' Distance, respectively. Mann-Whitney tests were performed to assess differences between outcome groups based on baseline and posttreatment pain scores. Wilcoxon signed rank tests were used to compare pretreatment and posttreatment pain for both treatment groups. Kruskal-Wallis tests examined whether the treatment groups differed on the remaining baseline characteristics. Correlation of baseline characteristics and clinical variables with treatment outcome was accomplished with Pearson and Spearman correlations.

Binary logistic regression was used to assess the relationship between a successful outcome and a patient's clinical and demographic characteristics. These predictor variables were selected for stepwise inclusion on the basis of likelihood ratio. A preliminary multiple linear regression was conducted to evaluate potential multicollinearity among the continuous predictors.

Data were analyzed with the IBM SPSS version 20 (IBM Corporation, Armonk NY). Statistical significance was based on a significance level of P < 0.05. The Bonferroni adjustment was used to mitigate type I error inflation in cases of multiple comparisons. Associated 95% confidence intervals (CIs) are provided as appropriate.

RESULTS

A total of 1619 patients were screened for inclusion criteria. From this sample, 250 individuals were selected for inclusion in the study. Eighteen individuals were excluded for lack of baseline pain scores or follow-up pain scores, and 10 individuals were excluded as outliers on the basis of Mahalanobis distance. Thus, 222 patients were included in the analyses and comprised the study population, 94 (42.3%) who experienced a successful treatment outcome and 128 (57.7%) with an unsuccessful treatment result. Baseline demographic and clinical characteristics of patients are shown in Table 1. Prevalence and types of pain locations and psychological comorbidities are shown in Tables 2 and 3, respectively. No significant difference was found in the proportion of successful treatment outcomes between WAMC (n = 53, 41.1%) and WRNMMC (n = 41, 44.1%) (P = 0.66).

Tests showed no evidence for significant differences between outcome groups based on their underlying demographics (age, sex, race/ethnicity, education, military status, smoking status, and obesity) (Table 4). Most individuals (n = 183, 82.4%) did not have data on educational status and so whereas no statistically significant difference was found between the groups, the data are not presented in Table 4.

As expected, the outcome variable (treatment success) was strongly correlated with posttreatment pain score

Characteristics	Total (n [%])
Study site	
Walter Reed	129 (58.1)
Womack	93 (41.9)
Age (mean [SD]) (y)*	46.82 (15.92)
Sex	
Males	138 (62.2)
Females	84 (37.8)
Race/ethnicity	•
White	126 (56.8)
Black	49 (22.1)
Other	35 (15.8)
Unknown	12 (5.4)
Military status	
Active duty officer	40 (18.0)
Active duty enlisted	86 (38.7)
Retiree	73 (32.9)
Civilian	23 (10.4)
Smoking	
Yes	49 (22.1)
No	173 (77.9)
Obese	
Yes	70 (31.5)
No	152 (68.5)
Opioid use	
None	134 (60.4)
0.20	40 (01 ()

*Age data only available from Walter Reed (n = 129).

0-30 mg ME

Traumatic injury

Pain classification

Nociceptive Neuropathic

Yes No

Both

 $> 30 \,\mathrm{mg} \,\mathrm{ME}$

(r=-0.68, P<0.001). Treatment success was also significantly correlated with the use of stimulation needles $(\rho=0.14, P=0.03)$ but no other variables (age, race/ethnicity, education, pain duration, pain location, pain type, injury status, number of acupuncture sessions, length of acupuncture sessions, frequency of acupuncture sessions, use of stimulation needles, opioid use, smoking status, obesity, presence of psychological comorbidities, or pain level at baseline) predicted treatment outcome.

In univariate analysis, baseline pain scores were not significantly different between the successful treatment group (M = 6.03; 95% CI, 5.73-6.33) and the unsuccessful treatment group (M = 5.67; 95% CI, 5.43-5.91) (P = 0.06). In contrast, posttreatment pain scores were significantly lower for the successful treatment group (M = 2.73; 95% CI, 2.36-3.11) than for the unsuccessful treatment group

Table 2. Baseline Pain Location

Location	Total (n [%])
Headache	19 (8.6)
Neck	50 (22.5)
Extremity	78 (35.1)
Lower back	113 (50.9)
Other back	19 (8.6)
Other	22 (9.9)

Table 3. Psychological Comorbidities

Location	Total (n [%])
Mood disorder	7 (3.2)
Anxiety disorder	71 (32.0)
Post traumatic stress disorder	39 (17.6)
Substance abuse	5 (2.3)
Depression	65 (29.3)
None	48 (21.6)

(M=5.81; 95% CI, 5.55-6.07) (P<0.001). The successful treatment group experienced a significant mean decline in pain score of 3.30 (95% CI, 3.01-3.58; P<0.001), whereas the unsuccessful treatment group remained relatively constant with a mean change in pain score of 0.14 (95% CI, -0.05 to 0.33; P=0.17).

The analyses indicated no significant difference between groups based on duration of pain (P=0.21), the number of treatment sessions (P=0.89), or the number of psychological comorbidities (P=0.28). The successful treatment group had a range of 0 to 3 psychological comorbidities and a mean of 0.7 (95% CI, 0.6-0.9). The nonsuccessful treatment group had a range of 0 to 4 psychological comorbidities and mean of 0.9 (95% CI, 0.7-1.1).

 TABLE 4. Patient Characteristics by Outcome

	Success Failure			
Variables	(n [%])	(n [%])	(P)	
Total	94 (42.3)	128 (57.7)	0.02	
Study site	,	, ,		
Walter Reed	53 (41.1)	76 (58.9)	0.66	
Womack	41 (44.1)	52 (55.9)		
Age (mean [SD])* Sex	53 (15.9)	76 (16.0)	0.64	
Males	38 (40.4)	46 (35.9)	0.50	
Females	56 (59.6)	82 (64.1)	****	
Race/ethnicity	50 (53.0)	02 (0)		
White	55 (64.0)	76 (56.7)	0.40	
Black	19 (22.1)	32 (23.9)	****	
Other	12 (14.0)	26 (19.4)		
Military status	()	== (-,)		
Active duty officer	20 (21.3)	20 (15.6)	0.53	
Active duty enlisted	34 (36.2)	52 (40.6)		
Retiree	31 (33.0)	42 (32.8)		
Civilian	9 (9.6)	14 (10.9)		
Smoker	, ,	, ,		
Yes	19 (20.2)	30 (23.4)	0.57	
No	75 (79.8)	98 (76.6)		
Obese				
Yes	24 (25.5)	46 (35.9)	0.10	
No	70 (74.5)	82 (64.1)		
Opioid use				
None	61 (45.5)	73 (54.5)	0.16	
0-30 mg ME	21 (43.8)	27 (56.2)		
> 30 mg ME	11 (29.7)	26 (70.3)		
Traumatic injury				
Yes	34 (43.6)	44 (56.4)	0.82	
No	60 (42.0)	83 (58.0)		
Pain classification				
Nociceptive	33 (41.2)	47 (58.8)	0.99	
Neuropathic	11 (37.9)	18 (62.1)		
Both	50 (44.2)	63 (55.8)		

*Age data only available from Walter Reed (n = 129).

48 (21.6)

37 (16.7)

78 (35.1)

143 (64.4)

80 (36.0)

29 (13.1)

113 (50.9)

TABLE 5. Regression Coefficients					
Variables	В	Wald	df	P	Odds Ratio (95% CI)
Baseline pain	0.23	5.07	1	0.02	1.26 (1.03-1.55)
Psychological comorbidity	-0.40	6.15	1	0.01	0.67 (0.49-0.92)
Use of stimulation needles	1.00	8.56	1	0.03	2.72 (1.39-5.32)
Constant	-0.78	1.54	1	0.21	` <u> </u>

Results of the binary logistic regression are presented in Table 5. The regression was conducted to determine which independent variables (sex, race, military status, pain duration, pain location, pain type, type of pain, presence of psychological comorbidities, total number of psychological comorbidities, opioid use, number of acupuncture sessions, length of acupuncture sessions, frequency of acupuncture sessions, use of stimulation needles, smoking status, obesity, presence of a traumatic injury, or pain level at baseline) were predictors of outcome (treatment success or unsuccessful treatment). Age was not considered in the regression analysis as data were only available from 1 of the 2 data collection sites. Regression results indicate the overall model was statistically reliable in distinguishing between treatment success; $\chi^2(4, n = 218) = 16.81, P < 0.01$. The model correctly classified 60.6% of the cases overall (75.2% of unsuccessful treatments and 40.9% of successful treatments). Table 5 shows regression coefficients, Wald test values, and odds ratios (ORs) for significant predictors. Wald statistics indicated that only baseline pain score (OR = 1.26; 95% CI, 1.03-1.55; P = 0.02), presence of a psychological comorbidity (OR = 0.67; 95% CI, 0.49-0.92; P = 0.67), and use of stimulation needles (OR = 2.72; 95% CI, 1.39-5.32; P = 0.03) significantly predicted treatment success.

DISCUSSION

Our primary objective for this multi-center, retrospective study was treatment success. Of the patients analyzed, 94 (42.3%) had successful treatment outcomes and 128 (57.7%) had nonsuccessful treatment outcomes. Our study showed that while treatment groups did not differ on baseline pain scores, posttreatment pain scores were significantly lower for the successful treatment group (P < 0.001). The successful treatment group experienced a mean decline in pain score of 3.30 (95% CI, 3.01-3.58), whereas the unsuccessful treatment group remained relatively constant with a mean change in pain score of 0.14 (95% CI, -0.05 to 0.33). Regression results indicate the overall model was statistically reliable in distinguishing between treatment success and failure (P < 0.01). The model correctly classified 60.6% of the cases overall (75.2% of unsuccessful treatments and 40.9% of successful treatments). We found that those patients with the absence of a psychological comorbidity and the use of electrical stimulation acupuncture treatment significantly predicted success.

Compared with Witt et al, 15 we found no correlation to treatment success and sex. In 2006, Witt and colleagues examined 11,630 patients in a randomized pragmatic trial. The study included 3 arms: randomized acupun cture, randomized control (delayed acupuncture), and nonrandomized acupuncture. After 3 months, back function, back pain, and quality of life improvement was more significant in the acupuncture group compared with the

control (P < 0.001, respectively, for all variables). Back function, back pain, and quality of life improvement after 3 months was more pronounced in the nonrandomized acupuncture group compared with the randomized acupuncture group (P = 0.044, 0.023, 0.004, respectively). Similar to our findings, the acupuncture effects were significantly more pronounced in patients with worse initial back function (P < 0.001), as well as in younger patients (P < 0.001) and patients with > 10 years of schooling $(P = 0.01)^{16}$ The findings that higher baseline pain scores, a measure of disease burden, were associated with better outcomes, is in contrast to similar studies performed in other cohorts. 17,18 There are few potential reasons for this finding. First, since our primary outcome was a 2-point drop in VAS score, it is potentially easier for a patient to report a higher drop in pain score when the baseline is higher, for example from 8/10 to 6/10 than from 4/10 to 2/10. Second, the significance of baseline pain may be noise due to the sample size.

In 2013, MacPherson and colleagues performed a meta-analysis of 17,922 patients with chronic pain. This study found no evidence for most treatment-related characteristics affecting pain outcomes. The characteristics studied included style of acupuncture, use of electrical stimulation, addition of moxibustion, experience of the acupuncturist, and frequency and duration of sessions. In comparing acupuncture to nonacupuncture controls, the authors did find a positive relationship between an increased number of needles used and an increased treatment effect (P = 0.01). In contrast to our finding that electrical stimulation improved treatment results, MacPherson and colleagues concluded that there is little evidence suggesting treatment-related characteristics effect the pain outcome of acupuncture patients.¹⁹

Witt and colleagues reanalyzed data from 4 pragmatic, randomized controlled trials that evaluated the effectiveness of acupuncture treatment. A total of 9900 patients were included in the study. They identified that women responded more positively to acupuncture treatment compared with men (P = 0.028). People living in a multi-person household had a more positive effect than those patients who lived in a single household (P = 0.002). Patients who had a previous positive acupuncture experience were more likely to have a positive outcome than those who had not experienced acupuncture or those who had a previous negative experience (P = 0.005). Patients who had failed other treatments had a worse outcome than those who had not failed treatments; however, they still experienced some improvement of pain. ¹⁵

The use of acupuncture in the military is gaining in popularity and acceptance. This is partly the result of increasing opioid use and the subsequent abuse and addiction potential that has gained National attention. Military Medicine has been working to change its culture since 2010, when the Pain Management Task Force issued

recommendations to explore alternative treatments such as acupuncture, meditation, and biofeedback. In particular, the military has embraced a particular form of acupuncture entitled "Battlefield Acupuncture" whereby 5 specific acupoints are placed in the ear. 22,23 Our population is also unique in that it represents a young, very active, generally healthy group who often face physical and psychosocial stressors that may be different, and perhaps more pronounced, than a civilian cohort. In addition, medications typically used to treat chronic pain such as adjuvants and particularly opioids, are often discouraged in this population due to their potential for cognitive effects and, for opioids, physical dependence, and addiction. Therefore, there has been a strong emphasis on the use of complementary and alternative treatments in the military health care system.

One important limitation in the study is the small sample size. It was estimated that 3000 patients would be included in this analysis. Many of the patients were excluded for <4 treatments and for being seen by a different CAM provider such as chiropractors or massage therapists. Sample size and generalization are also limited by number of participating sites. The retrospective design of the study has its inherent limitations, and the lack of consistent data reporting in the electronic medical record limited both the quality of the data and the number of patients included in the analysis. Had our sample size been larger, more robust associations may have been found. Furthermore, we decided to use only acupuncture applied by physicians trained in medical acupuncture. Although there are many different types of acupuncture and nonphysician providers who provide services to our patient population, most physicians in the military receive the same type of acupuncture training, which adds consistency to treatment and hence analysis.

Overall no single outcome variable could predict a successful treatment outcome. However, the combination of baseline pain, number of psychological comorbidities, and use of stimulation needles correctly classified 60.6% of cases. These factors should be considered when determining which patients to initiate treatment for, and in the design of future randomized trials. More studies with larger sample sizes are needed to determine best clinical predictors of treatment outcome after acupuncture.

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