

Original Paper

## Acupuncture Clinical Pain Trial in a Military Medical Center: Outcomes

Richard C. Niemtzow, MD,<sup>1</sup> Stephen M. Burns, MD,<sup>1</sup> Jared Cooper, MPH,<sup>2</sup> Salvatore Libretto, PhD,<sup>2</sup>  
Joan A.G. Walter, JD,<sup>2</sup> and John Baxter, MD<sup>3</sup>

### ABSTRACT

**Background:** Acupuncture may play a significant role in the management of acute and chronic pain. A United States Air Force (USAF) acupuncture clinic managed pain for active duty members, dependents, and retirees. The majority of these patients had unsuccessful control of their pain when employing conventional medications and therapies.

**Objective:** To study the benefits of acupuncture to control acute and chronic pain in active duty military members, dependents, and retirees who were not successfully palliated with conventional Western care.

**Design, Setting, and Subjects:** Measurements of pain were made on adult male (n = 58) and female (n = 60) patients ranging in age from 21 to 85 at Malcolm Grow Medical Center (MGMC), Andrews Air Force Base, Maryland, USA, from October 2003 to September 2005.

**Intervention:** Various acupuncture modalities were employed on patients with pain: acupuncture, electroacupuncture, auriculotherapy, and electroauriculotherapy. The choice of the acupuncture modality and the actual points used were based on the decision of the treating physicians, who were also trained medical acupuncturists.

**Main Outcome Measures:** We delineated anatomic areas of most frequent pain, pain scales before, during, and after therapy, pre- and post-treatment quality of life, and post-treatment patient satisfaction.

**Results:** Patients had significant improvement in pain control and a highly significant improvement in their scores on standardized Quality of Life scores at the end of the 4-week study.

**Conclusions:** Acupuncture appears to be helpful as adjunctive therapy for controlling acute and chronic pain in patients for whom standard care is not wholly effective. Possibly as a result of this intervention, patients demonstrated a highly significant improvement in both the mental ( $P < .01$ ) and physical ( $P < .001$ ) subscales of the SF-8 quality of life measure, 4 weeks following the first acupuncture treatment.

**Key Words:** Acupuncture, Electroacupuncture, Auriculotherapy, Pain, Quality of Life, Military Medical Center, Military Patients

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<sup>1</sup>Malcolm Grow Medical Center, Andrews AFB, MD.

<sup>2</sup>Samueli Institute, Alexandria, VA.

<sup>3</sup>Pentagon Flight Medicine Clinic (779th MDG), Pentagon, Washington, DC.

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## INTRODUCTION

**A**CUTE AND CHRONIC PAIN is a serious public health issue within military and civilian populations. Pain is disabling, can be a major cause of lost work productivity, and leads to increased medical costs.<sup>1</sup> Managing pain, relieving suffering, and reducing the use of treatments for pain which are potentially harmful are central to health care professionals' ethical commitment to their patients.<sup>2</sup>

The most common treatments for pain in the United States are over-the-counter (OTC) and prescription analgesic drugs. The most commonly used pain medications are non-steroidal anti-inflammatory drugs (NSAIDs) that may cause sufficient reductions in alertness and motor function and have negative impacts on mission readiness in military populations.<sup>3</sup> Other common side effects of NSAIDs include cardiovascular events and gastrointestinal bleeding.<sup>4</sup> A recent meta-analysis of all trials comparing NSAIDs found an 80% increase in the risk of myocardial infarction vs placebo.<sup>5</sup> Furthermore, NSAIDs have been shown to cause both direct and indirect irritation of the gastrointestinal tract, resulting in symptoms such as nausea, dyspepsia, gastric ulceration, and diarrhea.<sup>6</sup> Military personnel taking analgesic medication may be critically hindered by the associated cognitive and physical side effects. For military personnel, successful pain management results in an accelerated return to duty and increased mission readiness.

Acupuncture, which is almost devoid of side effects inherent to many pain medications, may be an alternative to NSAIDs and narcotic analgesics for the treatment of pain, or, when used as an adjunct to standard care, may reduce the use of such medications. For more than 5,000 years, acupuncture, a component of Traditional Chinese Medicine (TCM), has been used to improve health and treat disease in many countries. In the United States, acupuncture is a popular treatment with nearly 1,000,000 people receiving acupuncture each year, resulting in approximately 10,000,000 treatment visits annually.<sup>7</sup>

Acupuncture efficacy is based on the TCM premise that energy within the body (Qi) travels along 12 main meridians or channels. Qi movement is responsible for maintaining good health. Disease and the associated pain is said to be caused by blockages, deficiencies, or disturbances in the flow of Qi along the meridian pathways. Acupuncture employs needles to stimulate specific points on the meridians to "unblock" the energy flow. The various meridian pathways contain more than 350 acupuncture points, and stimulation of specific points is usually achieved using sterilized thin metal needles inserted through the skin on the body. Auricular acupuncture targets points on the ear and is a common form of acupuncture therapy. Acupuncture points may be stimulated by other means, including electrical, infrared, and laser modalities, or acupressure.

Clinical studies have demonstrated the effectiveness of acupuncture in the treatment of acute and chronic pain, nau-

sea, headache, heart disease, and asthma.<sup>8,9</sup> Clinical study reports show fewer side effects with acupuncture when compared to analgesic medications.<sup>10,11</sup>

The United States Armed Forces may benefit from utilizing acupuncture in the treatment of pain and thus, increase operational readiness. We sought to conduct an observational study to assess the effectiveness of the acupuncture clinic at Malcolm Grow Medical Center, Andrews Air Force Base, Maryland, in treating acute and chronic pain in active duty members and other healthcare beneficiaries. This was a pragmatic study, in which admission criteria broadly included both acute and chronic pain, and allowed the treating physician to use a combination of techniques as described below.

## METHODS

### Inclusion Criteria and Exclusion Criteria

The study was conducted at the Acupuncture Clinic at Malcolm Grow Medical Center (MGMC) at Andrews Air Force Base, Maryland, from the time period of October 2003 to September 2005, and approved by the MGMC Institutional Review Board.

Department of Defense (DoD) health care beneficiaries, consisting of active duty military and family members, and retirees were eligible for enrollment: Patients were 18 years of age or older, non-pregnant, and referred for treatment for either acute or chronic pain. Patients were excluded from participation if they: were allergic to gold (since only auricular needles made of gold were used) ( $n = 1$ ), had received acupuncture treatment within 6 months of screening ( $n = 12$ ), were currently using transcutaneous electrical nerve stimulation (TENS) therapy ( $n = 1$ ), had a cardiac pacemaker ( $n = 1$ ), or were pregnant.

### Study Design and Treatment Protocol

#### Baseline

Subjects were screened on 2 occasions before enrollment into the study. A physician conducted the first screening when the patient first checked in to receive acupuncture treatment. New patients scheduled for pain treatment were referred to the study research assistant who conducted a more rigorous screening in private. Eligible patients were requested to provide voluntary informed consent. Consented patients completed the following data questionnaires at baseline:

- A. Study Specific Demographics Questionnaire
- B. Numerical Rating Scale for Pain
- C. Study Specific Medication/Treatments Questionnaire
- D. SF-8 Quality of Life Questionnaire (*QualityMetric Inc.*)

Pain scores and medication use were also reported at each visit, and at scheduled follow-ups. At the final (4-week) follow-up, the SF-8 was readministered and the following additional questionnaire was completed:

#### E. Patient Satisfaction Questionnaire

#### A. Demographics

One-hundred eighteen patients provided demographic data. The information collected in the demographics questionnaire included age, gender, ethnicity, duty status, and location(s) of pain. One-hundred nineteen patients signed an approved institutional review board consent form and enrolled in the study.

#### B. Pain

Pain is a subjective sensation that has been defined by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."<sup>12</sup> Pain is best quantified through self-report using subjective measures. The primary question in this study was current level of pain, as measured using a 0–10 point verbal Numerical Rating Scale (NRS). The NRS is reliable and valid for pain research and is easy to administer either in person or over the telephone. The NRS had the highest reliability (0.963 in a study that evaluated the reliability of 3 pain scales [visual analog scale (VAS), NRS, and verbal rating scale (VRS)]) in a group of 91 literate and illiterate rheumatoid arthritis patients.<sup>13</sup> In this current study, pain data were collected at baseline and during each follow-up.

#### C. Medication and Previous Treatments Questionnaire

The Medication and Previous Treatments Questionnaire collected information on past and current methods of pain treatment used or received by the subject, including therapies, medications, and/or surgeries. Additionally, this questionnaire measured the subjects' expectations regarding the result of their acupuncture treatment's effectiveness.

#### D. Quality of life

The SF-8 Health Survey is a reliable and valid measure of a person's general functional health status (FHS).<sup>14</sup> The questionnaire requires only 1 or 2 minutes to complete. The SF-8 uses a single question to capture each of the 8 health domains originally validated in the widely-used functional health status measurement tool, the SF-36. The 8 domains are physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, emotional well-being, energy/fatigue, pain, gen-

eral health perception, and health change. The SF-8 served as a secondary outcome measure and was administered at baseline and at 4 weeks post treatment.

#### Post Treatment

Post treatment follow-ups were conducted at 4 time intervals; at 24 hours, 1 week, 2 weeks, and 4 weeks, using the NRS and the Medication and Previous Treatments questionnaire. At 4 weeks, 2 additional forms were administered: The SF-8 and the patient satisfaction questionnaire.

#### E. Patient Satisfaction

The term "patient satisfaction" is widely used and measured often in health care settings, and it is generally well-known that "satisfied and dissatisfied patients behave differently."<sup>15</sup> Satisfied patients demonstrate higher treatment adherence and cooperation, are more likely to continue using their medical care services, maintain a relationship with a specific provider, participate in their own treatment,<sup>15</sup> and cooperate with their healthcare providers by disclosing important medical information.<sup>16</sup>

For this study, subjects were given a questionnaire in which they were required to gauge their level of satisfaction relative to specific aspects of their overall care, the specific treatment, and results. Subjects were asked to indicate their level of satisfaction on a 5-point scale in response to the various aspects of their treatment, from "strongly disagree" to "strongly agree."

### TYPES OF ACUPUNCTURE TREATMENTS

Once enrollment into the study was complete, the treating physician took the subject's medical history, including the specific chronic pain history. The physician first treated all patients with auricular acupuncture.<sup>17</sup> Each treatment was adjusted based on whether the pain was focal, regional, or systemic. If auricular acupuncture was determined to be less than fully successful, the physician then selected another appropriate modality: dry needling, French Energetics,<sup>18</sup> microcurrent, electroacupuncture (CraigPens),<sup>19–21</sup> electro-auriculotherapy, or piezo-electric stimulation. Administration of either auricular, traditional, or electroacupuncture was adjusted based on assessment of the patient's response to treatment. The physician made adjustments until the subject experienced complete or near complete pain relief (0–1 on the NRS), at which point that treatment ended. The physician sometimes elected to use several modalities in 1 therapy session. After the initial treatment at baseline, study subjects continued to receive follow-up acupuncture treatment as needed on a "walk-in basis" without a prior appointment. Follow-up treatments were not required as a condition for participation in the study, but all

subjects were re-contacted for data collection at the specified follow-ups.

## RESULTS

The most prevalent chronic pain conditions among subjects were back and neck pain, with 63 incidents of low back pain, 40 incidents of mid/upper back, and 38 incidents of neck pain.

### Demographics

One-hundred nineteen subjects provided institutional review board informed consent and were enrolled into the study; 118 provided demographic data (Table 1).

### Pain

One-hundred eighteen subjects reported an initial mean pain score of 5.5 on the NRS 0–10 scale prior to acupuncture treatment. Mean pain scores at every follow-up after

treatment showed highly significant improvement at  $P < .001$  when compared to baseline scores (Fig. 1).

### Physical and Mental Health Quality of Life Scores

The SF-8 scale yields 2 summary scores: Physical and Mental. In addition, there are 2 general individual items that often have strong predictive value: General Health and Vitality. The scales are standardized such that the population mean equals 50 with a standard deviation of 10, with higher scores indicating better self-reported health. Quality of life (QOL) data were collected for 117 participants at baseline and 105 at 4-week follow-up.

Paired  $t$  tests showed that both Physical and Mental QOL significantly increased at 4 weeks ( $t = -7.96$ ,  $df = 104$ ,  $P < .001$ ;  $t = -3.38$ ,  $df = 104$ ,  $P < .01$ , respectively); General Health and Vitality were also both significantly higher at follow-up than at baseline ( $t = -2.65$ ,  $df = 104$ ,  $P < .01$ ;  $t = -4.00$ ,  $df = 104$ ,  $P < .001$ , respectively). Table 2 illustrates means and standard deviations for all participants providing SF-8 data at both baseline and 4-week follow-up. Figure 2 displays baseline and follow-up means.

It was of interest to explore whether SF-8 QOL scores varied as a function of reduction in pain or treatment success. It was hypothesized that patients who had greater reductions in pain (as measured by NRS scores at baseline and 4-week follow-up) would also show greater improvements in Physical and Mental QOL as measured by the SF-8 at the same time point. Although correlations between both changes in both Physical QOL and Mental QOL, and changes in NSR pain ratings from baseline to 4-week follow-up were in the hypothesized direction, they were non-significant.

### Patient Satisfaction

There were 3 significant results measured from the patient satisfaction questionnaire: overall treatment satisfac-

TABLE 1. DEMOGRAPHIC AND PAIN CHARACTERISTICS

SEX	
Female	60
Male	58
ETHNICITY	
Alaska Native/American Indian	7
Asian	4
Black	36
Hispanic	3
White	74
Other	5
MARITAL STATUS	
Divorced	12
Married	89
Separated	2
Single	11
Widowed	4
EDUCATION	
High School	9
Some College	44
Undergraduate	37
Graduate	28
MILITARY STATUS	
Active Duty	53
Dependent	33
Military Retiree	32
PAIN LOCATION	
Low Back	63 (25%)
Mid/Upper Back	40 (16%)
Neck	38 (15%)
Lower Extremity	23 (9%)
Head	14 (6%)
Upper Extremity	14 (6%)
Chest	5 (2%)
Stomach	5 (2%)
Other	50 (20%)

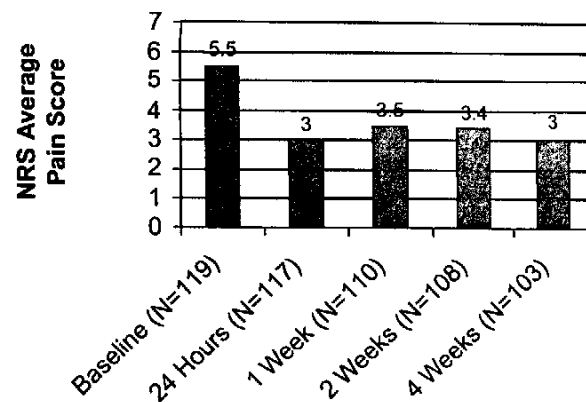


FIG. 1. Mean pain scores on the Numerical Rating Scale (NRS), scored 0–10.

TABLE 2. SF-8 MEANS AT BASELINE AND 4-WEEK FOLLOW-UP (n = 105 AT BASELINE AND FOLLOW-UP FOR ALL SCORES)

		Mean	Std. Deviation	Std. error Mean
Physical Summary Score	Baseline	34.1195	8.44359	0.82401
	Follow-up	41.0543	8.71528	0.85052
Mental Summary Score	Baseline	49.4335	10.21149	0.99654
	Follow-up	52.3719	8.62870	0.84208
General Health Scale	Baseline	43.5863	7.58312	0.74004
	Follow-up	45.5193	6.28502	0.61336
Vitality Scale	Baseline	45.0955	8.27443	0.80750
	Follow-up	48.4640	8.26249	0.80634

tion, perceived pain levels, and effectiveness of treatment. A total of 103 subjects provided patient satisfaction data; 65% of subjects reported that their pain level had improved after 4 weeks, while 75% of subjects said that the treatment was effective. When asked how satisfied they were on a 0-10 scale, a total of 66% of subjects were satisfied with their treatment ( $\geq 6/10$ ), with 50% of subjects stating they were very satisfied with their treatment ( $\geq 8/10$ ) (Fig. 3).

Subjects were asked to compare their pain level at 4 weeks to the level before receiving any acupuncture treatment. Four subjects reported that their pain was entirely gone, while 64 others reported that their pain levels were improved compared to their baseline prior to the first acupuncture treatment (Figure 4).

When asked their response to the acupuncture treatment effectiveness in treating their pain, 77% of subjects reported that the treatment was effective (Figure 5).

## DISCUSSION

Mean pain reduction was most significant at 24 hours after initial treatment when compared to other pain measure-

ments obtained at other follow-up telephone calls. This finding may be related to the fact that all follow-up treatments were left to the discretion of the subject. Hence, some subjects did not choose to have another treatment for several days or even weeks. This may indicate that the acupuncture was effective treatment, but the pain slowly returned over the ensuing days. At the initial post-treatment call at 24 hours, every subject had received his/her first treatment within the previous 24 hours. At subsequent follow-up calls, they had received a varying number of treatments based upon the number of times they chose to return for a "walk-in" follow-up treatment.

One limitation of the study was that the usage of pain medication was not controlled or effectively tracked. Subjects could start and stop taking various pain medications at their own discretion and thus, their medication use may have confounded the results. In addition, patients often did not accurately recall medication names, dosages, or usage. This limitation should be considered in the context of the fact that the acupuncture clinic only treated patients referred by their primary care physician. In most cases, these referrals were made because the standard care (often involving pain medication) was not effective. Hence, for many of these sub-

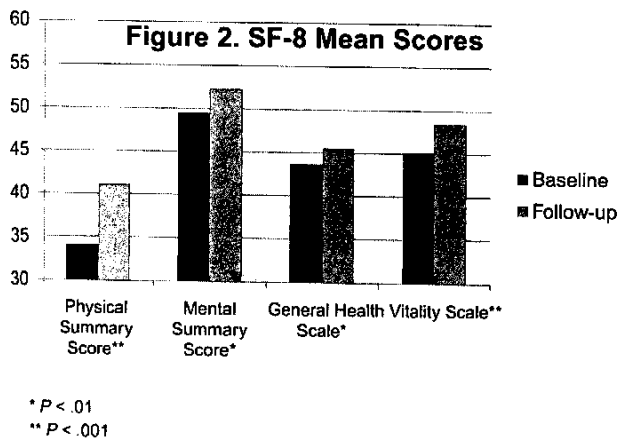


FIG. 2. SF-8 mean scores at baseline and follow-up.

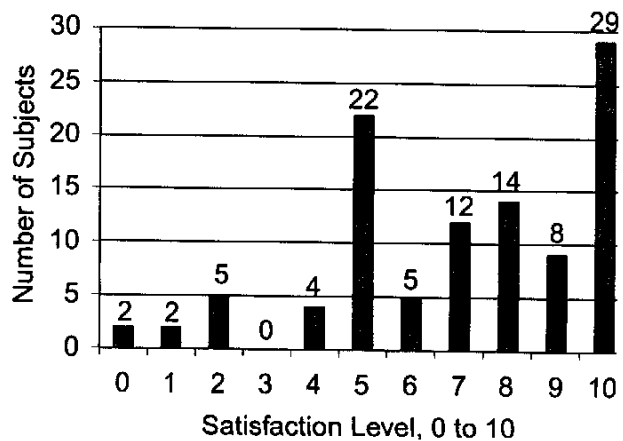


FIG. 3. Frequency of patient satisfaction scores.

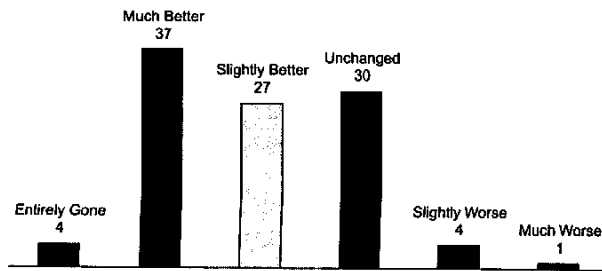


FIG. 4. Pain level at 4 weeks compared to pre-treatment.

jects, medication was ineffective or unsatisfactory. If so, the reduction in pain scores can more credibly be attributed to the acupuncture treatments, rather than to concurrent use of pain medication.

Many patients had more than 1 site of pain at initial inclusion in the study. It is possible that pain relief occurred at 1 or more pain sites during the treatment period, but that other pain persisted. Since net pain scores may not truly reflect the site-specific pain reduction, the study results might have been more meaningful if pain at each site had been recorded and tracked separately.

Quality of life scores were generally low when compared to national norms, possibly due to suffering and functional disability related to chronic pain. Although mean scores for all of the quality of life measures improved during the course of the study, improvements did not correlate with significant pain reduction.

## CONCLUSIONS

The most prevalent chronic pain conditions among subjects were back and neck pain, with 63 incidents of low back pain, 40 incidents of mid/upper back, and 38 incidents of neck pain. Subjects reported highly significant improvement in Physical Quality of Life scores ( $P < .001$ ) after 4 weeks

of acupuncture treatment. Significant mean pain reduction was sustained when measured at each follow-up.

Sixty-five percent of subjects reported an overall improvement in their pain levels 4 weeks after their first treatment; 75% of subjects regarded their acupuncture treatment as effective.

This trial evaluated the effectiveness of acupuncture as it is practiced at the Acupuncture Clinic at MGMC. Despite the diversity of acupuncture techniques and the complex pain challenges of the patients, most of whom had failed standard pain management, the data suggest that the clinic serves its intended purpose; namely, offering a beneficial adjunctive therapy for pain management. Future research could focus on various aspects of cost savings, optimal treatment techniques, elimination or more effective control of medication use during the trial, and evaluation of the course of pain abatement through site-specific pain ratings.

As a result of these encouraging results, the Air Force decided to create a project that would teach the Battlefield Acupuncture (BA) under the name "United States Air Force Auricular Stimulating Program (ASP)" to family practice physicians participating in a residency program at MGMC. BA appeared to be a very rapid and efficient auricular technique to control many categories of pain. It is well-known that primary care physicians perform a number of procedures that have traditionally been the purview of specialists (e.g., colonoscopies). ASP can easily be taught to physicians without the need for the physicians to be acupuncturists. This teaching program is currently ongoing at MGMC.

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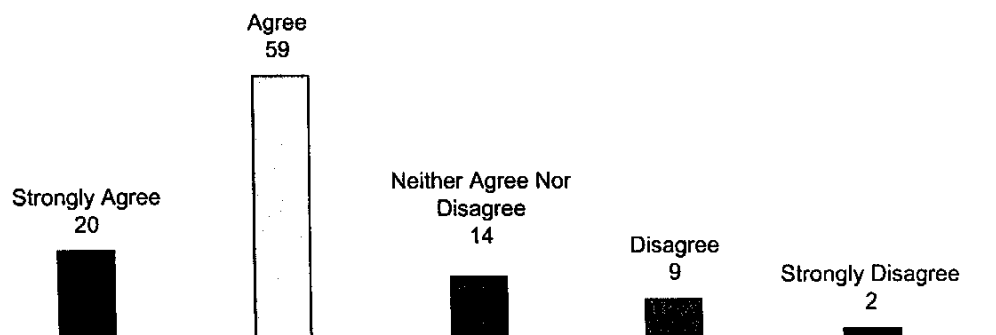


FIG. 5. Acupuncture effectiveness in treating pain.

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Address correspondence to:

Richard C. Niemtzw, MD, PhD, MPH  
Colonel, USAF, MC, FS

Major Consultant to the Air Force Surgeon General  
for Complementary and Alternative Medicine

Home address:

9800 Cherry Hill Road  
College Park, MD 20740

E-mail: n5ev@aol.com

Website: www.n5ev.com