An Adaptive Pragmatic Randomized Controlled Trial of Emergency Department Acupuncture for Acute Musculoskeletal Pain Management

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Study objective: Acute musculoskeletal pain in emergency department (ED) patients is frequently severe and challenging to treat with medications alone. 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.

Methods: In this pragmatic 2-stage adaptive open-label randomized clinical trial, Stage 1 identified whether auricular acupuncture (AA; based on the battlefield acupuncture protocol) or peripheral acupuncture (PA; needles in head, neck, and extremities only), when added to usual care was more feasible, acceptable, and efficacious in the ED. Stage 2 assessed effectiveness of the selected acupuncture intervention(s) on pain reduction compared to usual care only (UC). Licensed acupuncturists delivered AA and PA. They saw and evaluated but did not deliver acupuncture to the UC group as an attention control. All participants received UC from blinded ED providers. Primary outcome was 1-hour change in 11-point pain numeric rating scale.

Results: Stage 1 interim analysis found both acupuncture styles similar, so Stage 2 continued all 3 treatment arms. Among 236 participants randomized, demographics and baseline pain were comparable across groups. When compared to UC alone, reduction in pain was 1.6 (95% confidence interval [CI]: 0.7 to 2.6) points greater for AA+UC and 1.2 (95% CI: 0.3 to 2.1) points greater for PA+UC patients. Participants in both treatment arms reported high satisfaction with acupuncture.

Conclusion: ED acupuncture is feasible and acceptable and can reduce acute musculoskeletal pain better than UC alone. [Ann Emerg Med. 2024;84:337-350.]

Please see page 338 for the Editor's Capsule Summary of this article.

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INTRODUCTION

Background

Musculoskeletal disorders are the leading cause of pain and disability, affecting over 1.7 billion people worldwide.[1] Chronic musculoskeletal pain impairs health, function, and well-being and is associated with chronic opioid use.[1,2] As chronic pain begins as acute pain and is characterized by acute pain exacerbations, effective acute pain management is essential in mitigating the transition to and worsening of chronic pain. Treatment is particularly challenging in emergency department (ED) settings, where acute pain is typically severe, associated with emotional and psychological stressors, and compounded by diagnostic uncertainty.[3,4] Medications alone provide only a limited degree of pain relief, have potential side effects, and are limited in reducing chronic pain.[5-8] Moreover, significant disparities exist in the ED treatment of pain, resulting in worse pain outcomes for historically minoritized and medically underserved populations.[9] Thus, innovative multimodal approaches to improve equitable acute musculoskeletal pain management are needed in the ED.

Importance

International organizations are increasingly calling for nonpharmacologic strategies, including acupuncture, to treat pain.[10,11] Acupuncture is safe and effective for chronic

Editor's Capsule Summary

What is already known on this topic

Acupuncture is uncommon in the emergency department (ED).

What question this study addressed

For ED patients with acute musculoskeletal pain, does the addition of acupuncture to usual care improve pain management?

What this study adds to our knowledge

In this 3-arm randomized, controlled trial of 236 subjects, the treatment arms with 2 different styles of acupuncture were associated with decreased pain scores compared to usual care alone; however, the magnitude of the differences were small and near the threshold of clinical importance.

How this is relevant to clinical practice

In this trial of ED patients with acute musculoskeletal pain, acupuncture was associated with modest reductions in pain.

pain conditions, such as cancer pain, neck and low back pain, knee osteoarthritis, and headache.[12,13] Its analgesic effects are postulated to be mediated through inflammatory and endogenous opioid pathways.[14] Side effects are typically mild and transient, such as needle site pain or bruising, and serious events are extremely rare.[15,16] Although traditional private, hour-long acupuncture sessions are less feasible in space- and time-limited ED environments, more efficient treatment styles have been developed for community clinic and military settings. These include battlefield acupuncture, where ear needles are placed in up to 5 specific bilateral auricular acupoints to treat pain,[17,18] and peripheral acupuncture where needles are placed in acupoints that are easily accessible when fully clothed (eg, head, neck and extremity acupoints).[15,19] Recent meta-analyses have shown that collectively the different styles of acupuncture are superior to sham needling controls (eg, placing acupuncture needles in nonacupoints, nonpenetrating needles, or shallow needles) in the ED and other settings.[20-22] These studies have also demonstrated physiologic effects with needles beyond placebo, prompting experts to recommend the use of nonsham controls in larger pragmatic trials to assess treatment effectiveness of acupuncture.[23]

Currently, there is limited data on the efficacy of ED acupuncture for acute pain, and the acupuncture style best-suited to the ED environment remains unclear.[22] Previous work has been mostly limited to observational or small pilot randomized studies in the United States and a few larger trials in other countries.[21,24-26] Moreover, no study has compared different acupuncture protocols (eg, battlefield/auricular acupuncture [AA] and peripheral acupuncture [PA]) to determine which is more feasible, acceptable, or effective in the ED.

Goals of This Investigation

Therefore, we conducted a pragmatic adaptive randomized control trial of ED acupuncture for acute musculoskeletal pain. A major goal of this study was to expand the indications for acupuncture from prior research to be more generalizable to an ED population experiencing mixed pain conditions (eg, new acute pain and acute exacerbations of chronic pain). Moreover, we adapted features from 2 styles of acupuncture to determine which may be more suitable and efficacious in an ED setting: AA based on the battlefield acupuncture protocol, and PA based on community acupuncture but restricting needle sites to accessible head, neck and extremity acupoints to treat pain. Thus, the objectives of this study were the following: (1) to identify which style of acupuncture is feasible, acceptable, and more efficacious for treating acute episodes of musculoskeletal pain in the ED, and (2) to determine the effectiveness of that acupuncture style compared to control (no acupuncture) on pain reduction in the ED.

METHODS

Study Design and Setting

This pragmatic, 2-stage adaptive open-label randomized clinical trial was approved by the Institutional Review Board (Protocol # Pro00104140), registered on February 7, 2020, with clinicaltrials.gov (registration number NCT04290741) and released to the public on February 28, 2020. The detailed study methods were previously published.[27] In brief, the first stage objective was to identify which style of ED-based acupuncture, AA or PA, is more feasible, acceptable, and potentially more efficacious in ED patients with acute musculoskeletal pain. The second stage objective was to determine the effectiveness of the selected acupuncture style compared to attention control receiving usual care only (UC) on pain reduction. The adaptive approach required a planned interim analysis at the end of Stage 1 to determine whether to make adaptations, such as dropping one of the acupuncture treatment arms for Stage 2, based on the United States Food and Drug Administration-recommended criterion of probability of being the best treatment.[28,29] This study took place in a US academic tertiary care ED with 80,000 visits per year staffed by attending physicians, resident physicians, and

physician assistants. We used the Consolidated Standards of Reporting Trails (CONSORT) checklist to report our findings.[30] The Duke University Health System Institutional Review Board has reviewed and approved this study on January 29, 2020 (Protocol No: Pro00104140).

Selection of Participants

Trained clinical research coordinators performed all patient screening, recruitment, informed e-consent, and enrollment procedures. Licensed acupuncturists trained in traditional Chinese medicine explained and delivered acupuncture treatments.[27] A convenience sample of patients was enrolled during 8-hour periods, typically occurring sometime between 8 AM and 8 PM Monday–Friday. English-speaking adult ED patients with acute (≤7 days) new onset or exacerbations of chronic pain in the neck, back, arms, or legs, deemed musculoskeletal by ED clinicians, were included.[31] Exclusion criteria included: (1) no pain at triage; (2) contraindication to needles at acupuncture sites (eg, skin infection); (3) unable to attend clinic; or (4) serious medical condition (eg, active coronavirus disease 2019 [COVID-19] infection).

Interventions

Two different acupuncture interventions (AA and PA) were performed by licensed acupuncturists while in the ED and are described in detail elsewhere.[27] In brief, (1) for AA, the acupuncturist placed press needles in up to 5 bilateral ear sites corresponding to the battlefield acupuncture protocol.[17,18] (2) For PA, the acupuncturist placed needles in select head, neck, and extremity sites based on the acupuncturist's clinical discretion.[15,19] (3) As an attention control to account for placebo effects from seeing an additional health care provider, the UC participants received the same initial evaluation and pretreatment interaction with study acupuncturists prior to randomization as the 2 acupuncture groups, but did not receive acupuncture treatment. All participants in all 3 study arms received UC at the discretion of their blinded ED clinical team, which in the ED setting typically consists of nonopioid and occasionally opioid medications, less frequently ice or heat packs. These treatments are initially ordered and administered in triage while the patients are in the waiting room after a triage physician assessment, with additional treatments determined by the primary ED team once they were assigned to an ED room.

Participants were randomized 1:1:1 in Stage 1 and 2:2:1 in Stage 2 to AA+UC, PA+UC, or UC, respectively, using a computer-generated unstratified block randomization sequence stored in a secure electronic file, with sequence electronically hidden and visible only at randomization to the acupuncturists. Although participants and acupuncturists were not blinded, reasonable attempts were made to blind all other research and clinical personnel, described in detail elsewhere.[27]

Measurements

Data were collected at study baseline (enrollment) and 1 hour posttreatment in a secure REDCap database through iPad in the ED.[32] Acupuncture treatment details based on Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) recommendations, ED medications, and adverse events were recorded by study personnel in REDCap.[33]

Outcomes

The primary endpoints for Stage 1 were feasibility, acceptability, and safety. Feasibility was assessed by patient recruitment and retention rates, with a goal average of ≥ 1 patient enrolled and completed 1-hour follow-up per study day. Acceptability was assessed by patient-reported satisfaction with acupuncture treatment, with a goal average of ≥ 4 on a 5-point Likert scale (from 5=very much to 1=not at all). Safety was evaluated by adverse events, most commonly nonserious bleeding, bruising, or pain at needle sites, which has been reported in the literature at a rate of roughly 7%.[15,34] Potentially serious adverse events, such as pneumothorax, are exceedingly rare (<0.01%).[15,34] The primary endpoint for Stage 2 was change in current pain score (0 to 10 numeric rating scale) from study baseline to 1 hour posttreatment. We used a minimally clinically significant difference in pain score of 1.3 previously validated in ED patients.[35]

Secondary measures included satisfaction with treatment (1 to 5 Likert scale) and medication use, including opioid and nonopioid medications, assessed by patient report and electronic medical record data. Additional patient self-reported data included demographics; pain characteristics; nonmedical opioid use using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST); the simplified graded chronic pain scale; as well as pain interference, sleep disturbance, and physical function using the validated Patient-Reported Outcomes Measurement Information System (PROMIS)-29 instruments.[36-39] The question timeframe was modified from "over the past 7 days" to "over the past 24 hours (1 day)" for study baseline assessments due to the acute duration (≤7 days) of pain.

Analysis

A sample size of 220 total subjects for Phase 1 was calculated using a minimally clinically significant difference

in pain score of 1.3, 90% power, and $\alpha = 5\%$ based on a 2-stage adaptive design with 90 subjects allocated 1:1:1 to 3 arms (AA+UC, PA+UC, UC) in Stage 1 and the remaining 130 subjects to 2 arms assuming 1:2 control:treatment allocation for Stage 2, adjusted for one planned interim analysis using O'Brien-Fleming type of alpha spending function and a 10% dropout rate.[27-29,40,41]

Primary analysis for the primary endpoint was based on intention-to-treat including all randomized subjects combined from both stages with at least one follow-up evaluation. For all outcomes, complete case analysis was conducted by excluding subjects missing the 1-hour outcome.

Because UC for pain in this ED site starts immediately after triage, an exploratory analysis to assess within-group differences in response to usual care versus acupuncture examined differences in pain scores over time from triage to study baseline to 1 hour posttreatment across treatment groups using ANOVA, with the outcome being the difference-of-differences ([one-hour – baseline] – [baseline – triage]).

To determine whether the subgroup of patients with pre-existing chronic pain had a different response to acupuncture than those without chronic pain, we fit an ANOVA model with chronic pain (defined as Grade 2 or 3 on the Graded Chronic Pain Scale) and the interaction of chronic pain and study arm.

All analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC). Unless otherwise noted, tests of hypotheses were 2-sided with a 5% level of significance.

Handling of Missing Data. For the primary intention-to-treat analysis, 10 patients were missing change in 1-hour pain score data (1 missing baseline and 9 missing 1-hour pain scores). An additional 2 patients recorded 0 pain at baseline (time of enrollment); as all subjects reported pain as their reason for ED visit, these were deemed to be likely data-entry errors and were treated as missing. As numeric rating scale pain score was also recorded during the pretreatment period just prior to randomization, the 3 missing baseline pain scores were imputed using the last observation carried backward method with the pain score just prior to randomization as the baseline pain value. Based on the Shapiro–Wilk test, pain scores were normally distributed with mild deviation.[42,43] Hence, multiple imputation methodology was used to impute missing values of the primary outcome of 1-hour pain score, wherein the imputation regression model included baseline pain, age, sex, race, and ethnicity as predictors, along with all the first-order interactions of those terms. Change scores were then calculated as estimated reductions from the recorded baseline and imputed 1-hour values. Five imputed datasets were generated, and the results of analysis on each of these combined for a final 1-hour change in pain score using standard methodology. For secondary outcomes, missing values were not imputed.

Analyses. As baseline characteristics were similar between groups, the primary outcome was compared using unadjusted ANOVA. Secondary outcomes were compared using separate unadjusted ANOVAs for continuous variables, Kruskal-Wallis for ranked (Likert scale) variables, and chi-squared for categoric variables. Adverse events were tabulated; ordered by frequency; and summarized by seriousness, severity, and possible association with acupuncture. Incidence rates of adverse events were compared by Fisher's exact test.

Interim Analysis. One interim analysis was planned at the end of Stage 1 to assess feasibility based on patient recruitment and retention rates, safety based on adverse events, and probability of being the more efficacious treatment arm analyzed from the 1-hour change in pain scores.[29] An independent data safety monitoring committee, including a biostatistician, emergency physician-researcher and medical acupuncturist, monitored trial safety and performance and recommended adaptations based on interim analysis.

RESULTS

At interim analysis, 1 acupuncture arm was not clearly superior to the other, and both trended toward superior compared to control. Therefore, all 3 study arms were continued in Stage 2 with a new allocation ratio of 2:2:1 AA+UC:PA+UC:UC.

Characteristics of Study Subjects

From February 10, 2020, to May 3, 2021, 911 patients were screened, and 236 patients were randomized to 1 of 3 arms (68 UC, 84 AA+UC, 84 PA+UC, Figure 1). We attained our feasibility goal with on average more than 1 subject enrolled per day and >95% of subjects in the intention-to-treat population completing the 1-hour primary outcome. The study population consisted of broad demographic characteristics representative of the typical ED population seeking care for musculoskeletal pain[3] and were similar across the AA+UC, PA+UC and UC arms (Table 1). Enrolled subjects had a mean age of 46.1 years (16.5 standard deviation [SD], range: 19 to 85). The most common self-identified race was Black (53.6%), and 7.2% identified as Hispanic. In addition, 56.6% of subjects were employed either full-time or part-time,

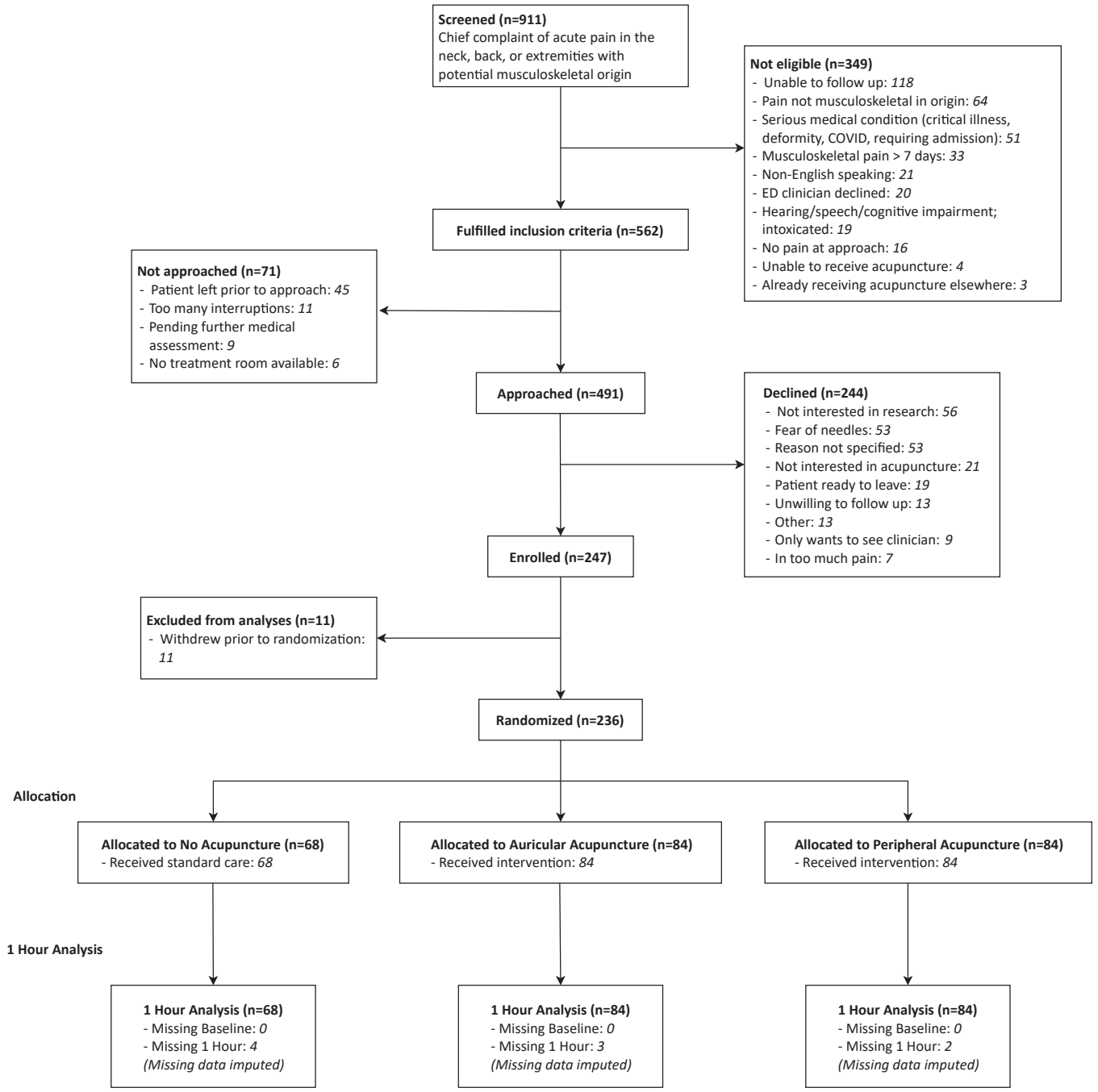

Figure 1. CONSORT flow diagram.

whereas 21.7% reported being unemployed or unable to work.

Baseline pain and clinical characteristics for the AA+UC, PA+UC, and UC groups are shown in Table 2. Overall, the most common primary pain locations were lower back (36.9%), legs (26.7%), and neck (14.4%). Most subjects (66.9%) reported having pain in more than one location, and 56.0% reported that their current painful condition was due to trauma or injury. The majority of subjects reported having at least some pain in the past 3 months (79.3%) and that pain had limited their life or work activities (66.5%). All 3 arms had similar study baseline pain scores (mean [SD]: AA+UC 7.0 [2.3], PA+UC 7.2 [2.2], UC 7.0 [2.1]). Only 18% of study participants had ever tried acupuncture before. There were no differences in prestudy baseline ED administration of opioid and nonopioid analgesics between the groups (Table 2).

Table 1. Patient Characteristics.

Characteristic	Control (N=68)	Auricular (N=84)	Peripheral (N=84)	Total (N=236)
Age (y)				
Mean (SD)	46.5 (16.5)	47.4 (16.0)	44.6 (17.0)	46.1 (16.5)
Range	(19.0-83.0)	(19.0- 80.0)	(19.0- 85.0)	(19.0-85.0)
Age 65 years or older	11 (16.4%)	14 (16.7%)	13 (15.5%)	38 (16.2%)
Missing	1 (1.5%)	0	0	1 (0.4%)
Sex (male or female)				
Female	36 (53.7%)	52 (61.9%)	44 (52.4%)	132 (56.2%)
Male	31 (46.3%)	31 (36.9%)	40 (47.6%)	102 (43.4%)
Missing or prefer not to answer	1 (1.5%)	1 (1.2%)	0	2 (0.8%)
Race				
Black or African American	39 (58.2%)	46 (54.8%)	41 (48.8%)	126 (53.6%)
White or Caucasian	17 (25.4%)	30 (35.7%)	33 (39.3%)	80 (34.0%)
Asian	3 (4.5%)	0 (0.0%)	2 (2.4%)	5 (2.1%)
Native American or Alaska Native	0 (0.0%)	1 (1.2%)	1 (1.2%)	2 (0.9%)
More than one race	2 (3.0%)	2 (2.4%)	2 (2.4%)	6 (2.6%)
Other	3 (4.5%)	2 (2.4%)	4 (4.8%)	9 (3.8%)
Missing or prefer not to answer	4 (5.9%)	3 (3.6%)	1 (1.2%)	8 (3.4%)
Ethnicity				
Hispanic or Latino	5 (7.5%)	3 (3.6%)	9 (10.7%)	17 (7.2%)
Not Hispanic or Latino	59 (88.1%)	76 (90.5%)	72 (85.7%)	207 (88.1%)
Missing or prefer not to answer	4 (5.9%)	5 (6.0%)	3 (3.6%)	12 (5.1%)
Marital status				
Never married	29 (43.3%)	31 (36.9%)	36 (42.9%)	96 (40.9%)
Living together	6 (9.0%)	2 (2.4%)	4 (4.8%)	12 (5.1%)
Married	19 (28.4%)	21 (25.0%)	24 (28.6%)	64 (27.2%)
Separated or divorced	11 (16.4%)	22 (26.2%)	15 (17.9%)	48 (20.4%)
Widowed/widower	1 (1.5%)	5 (6.0%)	4 (4.8%)	10 (4.3%)
Missing or prefer not to answer	2 (2.9%)	3 (3.6%)	1 (1.2%)	6 (2.5%)
Level of education completed				
Less than high school	5 (7.5%)	6 (7.1%)	5 (6.0%)	16 (6.8%)
Graduated high school or GED	24 (35.8%)	19 (22.6%)	22 (26.2%)	65 (27.7%)
Some college	19 (28.4%)	27 (32.1%)	26 (31.0%)	72 (30.6%)
Graduated college	7 (10.4%)	20 (23.8%)	17 (20.2%)	44 (18.7%)
Some postgraduate coursework	6 (9.0%)	1 (1.2%)	6 (7.1%)	13 (5.5%)
Completed postgraduate degree	6 (9.0%)	10 (11.9%)	7 (8.3%)	23 (9.8%)
Missing or prefer not to answer	1 (1.5%)	1 (1.2%)	1 (1.2%)	3 (1.3%)
Current employment status				
Employed full-time	34 (50.7%)	41 (48.8%)	34 (40.5%)	109 (46.4%)
Employed part-time	8 (11.9%)	9 (10.7%)	7 (8.3%)	24 (10.2%)
Retired	11 (16.4%)	8 (9.5%)	12 (14.3%)	31 (13.2%)
Homemaker	0 (0.0%)	1 (1.2%)	2 (2.4%)	3 (1.3%)
Student	3 (4.5%)	2 (2.4%)	3 (3.6%)	8 (3.4%)
Volunteer	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (0.4%)
Unemployed or laid off	5 (7.5%)	8 (9.5%)	11 (13.1%)	24 (10.2%)
Unable to work	4 (6.0%)	10 (11.9%)	13 (15.5%)	27 (11.5%)
Missing or prefer not to answer	2 (2.9%)	5 (6.0%)	2 (2.4%)	9 (3.8%)

Table 1. Continued.

Characteristic	Control (N=68)	Auricular (N=84)	Peripheral (N=84)	Total (N=236)
Approximate annual household income				
Less than $10,000	7 (10.4%)	12 (14.3%)	12 (14.3%)	31 (13.2%)
$10,000-$20,000	12 (17.9%)	12 (14.3%)	11 (13.1%)	35 (14.9%)
$20,000-$50,000	21 (31.3%)	19 (22.6%)	31 (36.9%)	71 (30.2%)
$50,000-$90, 000	9 (13.4%)	14 (16.7%)	11 (13.1%)	34 (14.5%)
More than $90,000	8 (11.9%)	8 (9.5%)	4 (4.8%)	20 (8.5%)
Missing or prefer not to answer	11 (16.2%)	19 (22.6%)	15 (17.9%)	45 (19.1%)
Insurance status*				
Medicare	11 (16.2%)	17 (20.2%)	17 (20.2%)	45 (19.1%)
Medicaid	9 (13.2%)	14 (16.7%)	19 (22.6%)	42 (17.8%)
Private insurance	30 (44.1%)	36 (42.9%)	32 (38.1%)	98 (41.5%)
Worker's compensation	2 (2.9%)	0 (0.0%)	1 (1.2%)	3 (1.3%)
Disability	1 (1.5%)	1 (1.2%)	3 (3.6%)	5 (2.1%)
No health insurance or missing	19 (27.9%)	20 (23.8%)	20 (23.8%)	59 (25.0%)
Prefer not to answer	2 (2.9%)	4 (4.8%)	7 (8.3%)	13 (5.5%)

*Subjects were able to report more than one insurance type.

Main Results

Table 3a shows the mean pain score at triage, study baseline, and change from triage to study baseline along with prebaseline administration of ED medications. Changes in pain score from ED arrival at triage to study baseline were similar across the groups, with an overall participant mean change in pain score of −0.8 (SD 1.9). Moreover, similar numbers of pain medications were given during this time interval among the 3 groups, indicating a similar effect of UC ED medications at baseline.

Table 3b shows the mean pain score at 1 hour posttreatment and the estimated reductions in pain at 1 hour posttreatment based on the multiple imputation model. Greater pain reductions at 1 hour were observed for AA+UC (2.1; 95% confidence interval [CI]: 1.6 to 2.6) and PA+UC (1.6; 95% CI: 1.1 to 2.1) compared with UC (0.5; 95% CI: −0.1 to 1.0), but only AA+UC had a clinically significant greater pain reduction than UC of >1.3 on the 11-point pain numeric rating scale. Figure 2 shows the box-whisker plots and distributions of paired pre- and posttreatment pain scores for individuals in each group. Opioids ordered in the ED posttreatment or prescribed on ED discharge did not differ among the groups (Table 3b). Participants in both the AA+UC and PA+UC groups reported comparably high satisfaction with their overall acupuncture experience at 1-hour, with a mean satisfaction score of 4.4 (SD 0.9) on a 5-point Likert scale (Table 3b), demonstrating acceptability of the interventions.

The results of the exploratory analyses are shown in Table 3b. There was no impact of pre-existing chronic pain on pain response for any treatment arm nor as a main effect in the exploratory models. The results of the complete case analyses were similar to those of the intention-to-treat analyses (Table E1, available at http://www.annemergmed.com).

Overall, there were few adverse events and no serious adverse events reported (Table E2, available at http://www.annemergmed.com). The most common adverse events were transient pain, bleeding or bruising at needle sites, self-limited headache, or brief episodes of anxiety.

LIMITATIONS

Limitations of this study include a single urban ED in southeastern United States, which may limit generalizability to other environments, such as rural EDs and other geographic locations. However, studies from other countries have shown similar efficacy of ED acupuncture for treating pain, and ours adds to this body of literature as one of the largest United States-based studies. Enrollment was limited to English-speaking patients due to a lack of validated non-English versions for most of the questionnaires used, which may limit applicability to non-English-speaking populations. However, only 2.3% of screen fails were attributed to not speaking English, and the final study population reflects the demographics of the population seen in our ED. Treatment delivery by licensed acupuncturists may limit comparison to other ED-based trial protocols that trained other clinicians, like physicians, or environments with no available acupuncturists. Although every attempt was made to blind ED clinicians

Table 2. Baseline Clinical Characteristics.

Characteristic	Control (N=68)	Auricular (N=84)	Peripheral (N=84)	Total (N=236)
PRIMARY current pain location				
Neck	9 (13.2%)	13 (15.5%)	12 (14.3%)	34 (14.4%)
Upper back	6 (8.8%)	7 (8.3%)	5 (6.0%)	18 (7.6%)
Lower back	25 (36.8%)	32 (38.1%)	30 (35.7%)	87 (36.9%)
Left arm	7 (10.3%)	7 (8.3%)	6 (7.1%)	20 (8.5%)
Right arm	4 (5.9%)	5 (6.0%)	5 (6.0%)	14 (5.9%)
Left leg	6 (8.8%)	7 (8.3%)	14 (16.7%)	27 (11.4%)
Right leg	11 (16.2%)	13 (15.5%)	12 (14.3%)	36 (15.3%)
Pain in more than one location				
Yes	46 (67.6%)	60 (71.4%)	52 (61.9%)	158 (66.9%)
Onset of current pain				
Gradual	15 (22.4%)	21 (25.0%)	20 (24.1%)	56 (23.9%)
Sudden	12 (17.9%)	15 (17.9%)	20 (24.1%)	47 (20.1%)
Due to trauma or injury	40 (59.7%)	48 (57.1%)	43 (51.8%)	131 (56.0%)
Previous episodes of pain in the past year				
Yes	24 (36.4%)	32 (38.6%)	31 (40.3%)	87 (38.5%)
Chronic Pain grade				
Grade 0: chronic pain absent	47 (69.1%)	51 (60.7%)	56 (66.7%)	154 (65.3%)
Grade 1: mild chronic pain	0 (0.0%)	1 (1.2%)	2 (2.4%)	3 (1.3%)
Grade 2: bothersome chronic pain	4 (5.9%)	12 (14.3%)	3 (3.6%)	19 (8.1%)
Grade 3: high impact chronic pain	17 (25.0%)	20 (23.8%)	23 (27.4%)	60 (25.4%)
Baseline 24-hour PROMIS physical function				
Median (IQR)	12 (7-16)	11 (6-16)	10 (6-16)	11 (6-16)
Range	4-20	4- 20	4-20	4-20
Missing	0	1	1	2
Baseline 24-hour PROMIS pain interference				
Median (IQR)	15.5 (7-18)	15 (8- 20)	16 (10- 20)	16 (8-20)
Range	4-20	4-20	4-20	4-20
Missing	0	1	1	2
Baseline 24-hour PROMIS sleep				
Median (IQR)	13 (12- 14)	12 (12- 14)	12.5 (12-15)	13 (12- 14)
Range	8-20	7-20	10-20	7-20
Missing	1	2	2	5
Self-reported opioid use in past week				
Yes	18 (26.5%)	23 (27.4%)	16 (19.0%)	57 (24.2%)
No	50 (73.5%)	61 (72.6%)	68 (81.0%)	179 (75.8%)
Self-reported nonopioid medication use in past week				
Yes	52 (76.5%)	71 (84.5%)	66 (78.6%)	189 (80.1%)
No	16 (23.5%)	13 (15.5%)	18 (21.4%)	47 (19.9%)
Baseline ASSIST-Opioid score*				
Yes opioid use	6	12	10	28
No opioid use	62	71	74	207
Missing	0	1	0	1
Median (IQR)*	0 (0- 0)	6 (0- 12.3)	1.5 (0- 6)	1 (0- 6)
Range*	0- 20	0-33	0-31	0-33

Table 2. Continued.

Characteristic	Control (N=68)	Auricular (N=84)	Peripheral (N=84)	Total (N=236)
Ever received acupuncture before				
Yes	8 (13.1%)	15 (21.7%)	12 (18.5%)	35 (17.9%)
No	53 (86.9%)	54 (78.3%)	53 (81.5%)	160 (82.1%)
Missing	7	15	19	41

ASSIST, Alcohol, Smoking and Substance Involvement Screening Test; *IQR*, interquartile range; *PROMIS*, Patient-Reported Outcomes Measurement Information System.
*ASSIST scores are only reported among those answering yes to nonmedical opioid use in the ASSIST questionnaire.

and outcomes assessors, patients could not be blinded to treatment assignment. However, we accounted for potential placebo effects of extra clinician time and attention by having study acupuncturists evaluate and interact with all control participants. Lastly, we used multiple imputation for missing pain scores which may have introduced bias. However, the missingness was very small, and we minimized any effect by adjusting for variables, such as age, sex, race, and ethnicity, in the multiple imputation. Moreover, the complete case analyses showed similar results. Future research should include multisite randomized controlled trials with varied ED settings to further evaluate acupuncture's efficacy across different patient groups and practice environments.

DISCUSSION

Improved Acute Musculoskeletal Pain Management

Effective management of acute pain is critically important to mitigate associated morbidity and disability; however, the current reliance on opioid medications presents substantial risks.[8,44] Previous studies of acupuncture in the ED have shown greater improvements than sham acupuncture and similar benefits as medications for treating acute pain, but have been limited by small sample sizes.[13,22,26,45] Our study builds on prior work by demonstrating efficacy for a broader range of pain indications in a large representative population of ED patients in a pragmatic randomized controlled trial design. Although modest improvements in pain scores 1 hour after acupuncture were demonstrated across each group, when combined with the modest improvements with medications, the overall pain reduction becomes much more clinically significant. These are similar to the modest reductions found for most common pain medications.[5,6] Moreover, pain is a heterogeneous and individualized experience. Although the group effect of PA did not reach clinical significance, many individuals within each acupuncture group did achieve clinically significant pain reductions (Figure 2). Lastly, the 2 different acupuncture

Table 3a. Baseline Pain and ED Analgesia.

Outcome	Control (N=68)	Auricular (N=84)	Peripheral (N=84)	Total (N=236)
Current pain NRS at time of triage				
Mean (SD)	7.8 (2.0)	7.7 (2.2)	8.0 (2.1)	7.8 (2.1)
Range	3-10	2-10	2-10	2-10
Missing	2	0	1	3
Current pain NRS at study baseline (enrollment)				
Mean (SD)	7.0 (2.1)	7.0 (2.3)	7.2 (2.2)	7.0 (2.2)
Range	(2-10)	(2-10)	(1-10)	(1-10)
Missing	0	0	0	0
Change in pain: triage to study baseline (enrollment)				
Mean (SD)	−0.8 (1.7)	−0.8 (1.8)	−0.7 (2.1)	−0.8 (1.9)
Range	(−8.0 to 2.0)	(−8.0 to 4.0)	(−9.0 to 7.0)	(−9.0 to 7.0)
95% CI for mean	(−1.2 to −0.4)	(−1.2 to −0.3)	(−1.2 to −0.3)	(−1.0 to −0.5)
ED analgesia received prebaseline	37 (54.4%)	54 (64.3%)	46 (54.8%)	137 (58.1%)
Opioid medication	17 (25.0%)	22 (26.2%)	17 (20.2%)	56 (23.7%)
Nonopioid pain medication	31 (45.6%)	49 (58.3%)	40 (47.6%)	120 (50.8%)

Table 3b. Outcomes at 1 Hour.

Outcome	Control (N=68)	Auricular (N=84)	Peripheral (N=84)	Total (N=236)	*P* Value
Current pain NRS at 1 hour					
Mean (SD)	6.6 (1.9)	4.9 (2.9)	5.6 (2.6)	5.6 (2.6)	
Range	2-10	0-10	0-10	0-10	
Missing	4	3	2	9	
Change in pain from triage to 1 hour					
Mean (SD)	−1.2 (2.1)	−2.9 (2.8)	−2.4 (2.7)	−2.2 (2.7)	
Range	(−7.0 to 5.0)	(−9.0 to 7.0)	(−10.0 to 3.0)	(−10.0 to 7.0)	
Missing	6	3	2	11	
Change in pain from study baseline to 1 hour*					<.001†
Mean (SD)	−0.5 (2.0)	−2.1 (2.9)	−1.6 (1.9)	−1.5 (2.4)	
Range	−6 to 5	−9 to 7	−7 to 5	−9 to 7	
95% CI for mean§	(−1.0 to 0.1)	(−2.6 to −1.6)	(−2.1 to −1.1)	(−1.8 to −1.1)	
Control–auricular: mean (95% CI)‖		1.6 (0.7-2.6)			
Control–peripheral: mean (95% CI)‖			1.2 (0.3-2.1)		
Percent change in pain from study baseline to 1 hour*					.002‡
Mean (SD)	1.5 (50.7)	−23.8 (59.1)	−23.8 (33.7)	−16.9 (49.7)	
Range	−95.3 to 250.0	−100.0 to 350.0	−100.0 to 125.0	−100.0 to 350.0	
95% CI for mean§	(−10.4 to 13.5)	(−35.1 to −12.6)	(−34.4 to −13.2)	(−23.4 to −9.7)	
Control–auricular: mean (95% CI)‖		25.4 (5.9- 44.9)			
Control–peripheral: mean (95% CI)‖			25.4 (6.0- 44.7)		
Difference in changes: (baseline to one-hour) - (triage to baseline)					
Mean (SD)	0.4 (3.1)	−1.4 (4.0)	−0.9 (2.9)	−0.7 (3.5)	
Range	(−4.0 to 13.0)	(−11.0 to 8.0)	(−12.0 to 8.0)	(−12.0 to 13.0)	
95% CI for mean	(−0.4 to 1.2)	(−2.3 to −0.5)	(−1.6 to −0.3)	(−1.2 to −0.3)	
Missing	6	3	2	11	
ED analgesia postbaseline to 1 hour	24 (35.3%)	22 (26.2%)	17 (20.2%)	63 (26.7%)	
Opioid medication	9 (13.2%)	6 (7.1%)	5 (6.0%)	20 (8.5%)	
Nonopioid pain medication	21 (30.9%)	17 (20.2%)	13 (15.5%)	51 (21.6%)	
Discharge opioid prescription ordered	10 (14.7%)	8 (9.5%)	6 (7.1%)	24 (10.2%)	
Overall satisfaction with acupuncture at 1 hour					
Mean (SD)	NA	4.3 (1.0)	4.4 (0.9)	4.4 (0.9)	
Range		(1.0-5.0)	(1.0- 5.0)	(1.0-5.0)	
95% CI for mean		(4.1-4.5)	(4.2-4.6)	(4.2-4.5)	
Missing		7	9	16	

NA, Not applicable.
*Missing values were imputed for 1-hour change score calculations.
†*P* value from overall ANOVA test. *P* values for pairwise comparisons, adjusting for multiple comparisons using Bonferroni's method are noted as follows:
Control vs auricular: <.001.
Control vs peripheral: .002.
Auricular vs peripheral: .21.
‡*P* value from overall ANOVA test. *P* values for pairwise comparisons, adjusting for multiple comparisons using Bonferroni's method are noted as follows:
Control vs auricular: .002.
Control vs peripheral: .002.
Auricular vs peripheral: 1.00.
§Without adjusting for multiple comparison.
‖Simultaneous confidence intervals, adjusting for multiple comparisons, for pairwise differences in means using Bonferroni's method.

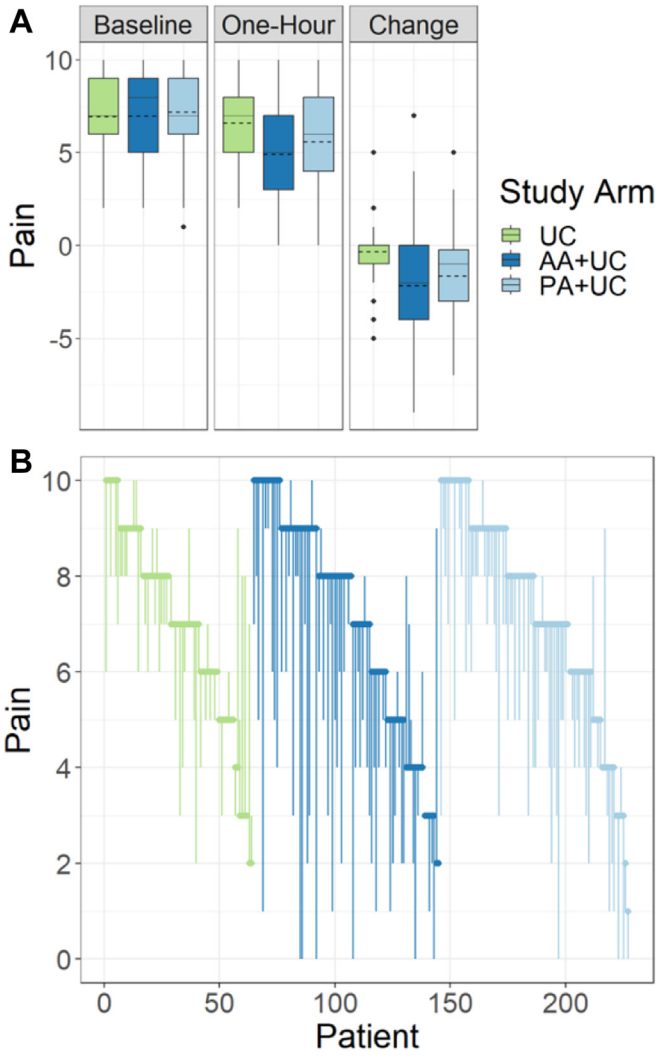

Figure 2. Distributions of pain scores across treatment arms. *A,* Box-whisker plots showing median (–), mean (–), and upper and lower quartiles (box) across patients in usual care only (UC), auricular acupuncture + UC (AA+UC) and peripheral acupuncture + UC (PA+UC) study arms at baseline (pretreatment), 1 hour posttreatment, and change in pain from baseline to 1 hour. *B,* Paired pre- and 1-hour posttreatment pain scores by participant in each study arm, with pretreatment pain score indicated by the circles and posttreatment pain score indicated by the vertical line from the circle. Most participants in UC had little change in pain, whereas most participants in AA+UC and PA+UC had large decreases in pain scores at 1 hour. *AA*, auricular acupuncture; *PA*, peripheral acupuncture; *UC*, usual care only.

interventions were similarly effective, allowing for increased flexibility in terms of both patient preference and clinical implementation.

Although we did not identify a significant difference in ED opioid administrations and discharge prescriptions after acupuncture, many pain experts agree that any prevention of new opioid use is clinically meaningful as it prevents the negative sequelae of opioid side effects and misuse.[46] Moreover, pain improvements were better with acupuncture, addressing the concern that reduction in opioids in some people may have led to undertreatment of pain. Previous work in ED and cancer patients has shown that acupuncture can outperform opioids in treating pain and may reduce opioid prescriptions.[21,47,48] One study, comparing acupuncture and intravenous morphine for acute pain in an ED setting, found that acupuncture was more likely to cause significant reduction in pain (≥50%) and was faster than morphine alone.[21] Another study comparing acupuncture patients with those using nonsteroidal anti-inflammatory drugs and physical therapy found that acupuncture patients were prescribed fewer opioids and had fewer ED visits.[48] Thus, acupuncture may be an important treatment option for reducing opioid prescribing and subsequent use.

Delivery of Acupuncture to an ED Population

Ours is one of the first pragmatic randomized controlled trials of acupuncture to intentionally and successfully enroll a large number of people from medically underserved and minoritized groups in the United States.[16,49,50] Few prior studies of acupuncture have reported the race of participants. By minimizing the number of exclusion criteria that have historically excluded these populations and systematically approaching all potentially qualifying patients for the study, our study population is reflective of our general ED population.[51,52] More than 50% of participants self-identified as Black, and 7% self-identified as Latino. More than half reported low income <$50,000, and over half had public or no health insurance. These rates are higher than US national averages reporting 36.1% with income under $50,000 and 8.3% with no health insurance.[53,54]

Furthermore, we successfully adapted acupuncture to a fast-paced, relatively chaotic ED environment by keeping treatments between 20 to 30 minutes and focusing on pain relief and needling of sites easily accessible while seated in a chair or laying in a stretcher fully clothed.[55,56] Our ability to recruit and perform acupuncture on 236 ED patients during a 1-year period demonstrates feasibility. Participants in both acupuncture intervention arms reported high patient satisfaction and minimal side effects, demonstrating acceptability in this ED population. Our findings underscore those from recent work developing community acupuncture clinics for medically underserved populations reporting high participant interest in and satisfaction with acupuncture treatments, supporting implementation of acupuncture more broadly.[18,49,57,58]

In conclusion, these results indicate that both auricular and PA are feasible, acceptable, and effective in the ED for acute musculoskeletal pain and should be further explored for more widespread implementation.

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