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Acupuncture intervention for acute pain in the Emergency Department trial: a consensus process

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Abstract

Purpose: This document describes the consensus process and intervention for a National Institutes of Health (NIH)-funded multi-site feasibility study utilizing acupuncture for **ACU**te pa**I**n in **T**he Emergenc**Y** Department (ACUITY). The acupuncture intervention is designed to be flexible and responsive to the most common Emergency Department (ED) scenarios, including trauma, acute pain of the low back, abdomen and/or musculoskeletal system, renal colic and headache.

Background: Opioids remain a primary treatment for acute ED pain with attendant risk of adverse effects, addiction liability, diversion and death. Effective/safer options for acute pain are needed. Although acupuncture therapy has shown promise for acute pain in the ED alone or in

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Supplemental material

Supplemental material for this article is available online.

conjunction with usual care, pragmatic trials are needed to obtain definitive and generalizable evidence.

Methods: An Acupuncture Advisory Panel was convened that included nine acupuncture experts with 5–44 years of experience in practice and 2–16 years of experience in the acute pain care setting. A modified Delphi process was used with provision of a literature review, surveys of our panel members, three online discussions and email discussion as needed. The STandards for Reporting Interventions in Controlled Trials (STRICTA) checklist was used as a guide.

Results: A responsive acupuncture intervention was agreed on for ACUITY. Session forms were fashioned in REDCap (Research Electronic Data Capture program to capture essential treatment data, assess fidelity and inform our design for a future pragmatic multi-site randomized controlled trial (RCT) of acupuncture in the ED, and for use by other future researchers.

Conclusion: Development of a responsive manualization intervention provides the appropriate framework for conducting a future, pragmatic, multi-site, definitive RCT of acupuncture in the ED.

Trial registration number: NCT04880733 (ClinicalTrials.gov).

Keywords

acupuncture therapy; acute pain; consensus intervention; Emergency Department; modified Delphi process

Background

"Pain is a public health problem, … a major driver of health care utilization and medication use, a major cause of disability, and a key factor in quality of life and productivity."[1] Pain accounts for up to 78% of Emergency Department (ED) visits,[2,3] where acute pain continues to be undermanaged and/or improperly managed.[2,4]

As of 2012, providers in the United States prescribed 50 times more opioids than the rest of the world combined,[5] reflecting a persistent national epidemic. While recent programs focused on the ED have resulted in a decrease in ED opioid prescriptions nationally,[6] opioids remain a primary method of pain treatment for acute pain in the ED.[7,8] The probability of long-term opioid use increases after as few as 5 days of prescribed opioids after the initial treatment of pain.[9] In a 2015 study, 14% of opioid-naïve patients who were prescribed an opioid in the ED were still using opioids roughly 12 months after the ED visit.[10] In addition to their addictive liability, the immediate adverse effect profile of opioids can be underappreciated given their common use. Specifically, both major adverse effects (respiratory distress) and minor adverse effects (constipation, nausea/vomiting, dizziness, sedation, pruritus and urinary retention) are burdensome for patients and negatively impact health, well-being and (potentially) health care costs.[11] Nonpharmacologic options that demonstrate feasibility, efficacy and effectiveness are needed to treat pain and mitigate reliance on opioids.

Acupuncture therapy in the treatment of acute pain

In numerous systematic reviews with meta-analyses, acupuncture has been shown to reduce post-surgical pain compared to sham acupuncture, controls and usual care with a reduction in opioid use and lowered incidence of opioid-related side effects, such as nausea, dizziness, sedation, pruritus and urinary retention.[12–15] While the Joint Commission has urged caution regarding opioid use in hospitals,[16] effective 1 January 2018, they also revised their pain management standard, requiring their accredited hospitals and facilities to provide nonpharmacologic therapy options for pain, with acupuncture as one option.[17]

Poorly managed or acute exacerbation of chronic pain is not uncommon in the ED.[18] In a large individual patient data meta-analysis (n = 39 trials, n = 20,837 participants), acupuncture was found to be superior to placebo/sham controls and usual care in the treatment of chronic pain, where 85% of benefit persisted at 1 year following care[19] and where baseline pain severity was a positive predictor of response.[20]

Acupuncture in the ED

Systematic reviews have found that acupuncture provided in the ED improves levels of pain and patient satisfaction with respect to pain relief, with a lower adverse effect profile.[15,21,22] A 2018 systematic review of various acute pain conditions found that acupuncture was more efficacious than intravenous (IV) morphine, comparable to conventional ED treatment and superior to standard ED care alone when used on an adjuvant basis.[23] Another systematic review found immediate pain relief from ear acupuncture extending to the first 48 h to be equivalent to analgesics with fewer side effects.[24]

Acupuncture in the ED continues to be promising in randomized clinical trials (RCTs). In an RCT enrolling 300 ED patients presenting with acute pain, acupuncture was superior to parenteral morphine for pain relief with a faster onset of action and fewer adverse effects.[25] A multicenter randomized non-inferiority RCT (n = 528) found the benefits of acupuncture to be comparable to pharmacotherapy for ED patients presenting with acute low back pain (aLBP), migraine and ankle sprains.[26] In ED patients with acute renal colic, acupuncture was associated with a much faster and deeper analgesic effect with a better tolerance profile compared to titrated IV morphine.[27] The link between pain and anxiety in the ED was explored in a retrospective study of ED patients with acute pain (n = 182) wherein acupuncture decreased pain intensity comparably to analgesics, with the additional benefit that patients reported reduced anxiety, with a high degree of acceptability among both medical providers and patients.[28]

Anxiety is often comorbid with acute pain presentations in the ED. While there are various types and levels of anxiety, catastrophizing and anxiety have been shown to increase patient self-reported pain levels in the ED.[29] Moreover, anxiety plays a role in post-operative and post-procedural complications.[30] The effect of acupuncture on pain interacts with effects on anxiety, depression, nausea and vomiting, and sleep quality, and increases a patient's sense of well-being.[31] In systematic reviews and meta-analyses, acupuncture has demonstrated efficacy in anxiety disorders[32] and in pre-operative anxiety,[33–35] with fewer side effects

than conventional treatments. Acupuncture at *Yintang* reduced pre-operative anxiety in neurosurgical patients.[36] Auricular acupressure has been shown to reduce anxiety when applied during hospital transport.[37,38] An overview of systematic reviews on anxiety found acupuncture to be more effective than controls while acknowledging a need for improved study methodology.[39] Any additional benefit of anxiety reduction in the ED cannot be overlooked.

Safety

Acupuncture has a low risk of adverse events. The National Institutes of Health (NIH) consensus statement on acupuncture, published in 1998, stated that "the incidence of adverse effects is substantially lower than that of many drugs or other accepted procedures for the same conditions."[40] Systematic reviews and surveys have clarified that acupuncture is safe when performed by appropriately trained practitioners[41–48] with infrequent minor side effects such as feeling relaxed, elated or tired, or experiencing sensation or itching at the needle insertion site.[45] Rare serious complications such as infection or pneumothorax are directly related to insufficient training.[46,47,49]

Here, we describe the process of creating a consensus acupuncture intervention for acute pain in the ED as part of a multi-site, feasibility study titled ACUITY (**ACU**te pa**I**n in **T**he Emergenc**Y** Department), which is registered at www.clinicaltrials.gov (NCT04880733). Institutions participating in this project (all based in the United States) include Albert Einstein School of Medicine (Bronx, NY); Case Western Reserve University/University Hospitals (UH), Cleveland Medical Center (Cleveland, OH); Vanderbilt University Medical Center (VUMC; Nashville, TN); and University of California San Diego (UCSD; La Jolla, CA). Trial sites include UH, VUMC and UCSD. The consensus acupuncture intervention achieves one milestone of our NIH-funded study that provides a framework for our RO1 multi-center feasibility pilot and future pragmatic, multi-site definitive RCT (NIH UG3/UH3) of acupuncture in BraveNet Practice-Based Research Network (PBRN) clinic-affiliated EDs.[50,51]

Methods: intervention protocol consensus process

Subject matter experts were identified by their published work and knowledge of practice, and were contacted by email and telephone. The resulting Acupuncture Advisory Panel (AAP) included nine acupuncture experts with 5–44 years of experience in acupuncture practice and 2–16 years of experience providing acupuncture in the acute pain care setting. Three members are the lead acupuncturists at our trial sites. A modified Delphi process was used to develop the acupuncture intervention protocol. Dr Nielsen and Dr Dusek prepared the literature review details and survey questions (Supplemental file 1). Dr Nielsen collated the survey responses, led the consensus discussions and finalized consensus topics for panel approval.

Modified Delphi process

Researchers have adapted the Medical Research Council's guidance of 2000[52] and 2008[53] in developing and evaluating complex interventions that have interacting components.[54] The process of forming a consensus-based intervention protocol, sometimes called manualization,[54–56] describes one such adaptation that seeks to strike a balance between standardization and flexibility in acupuncture research[55] for trials on depression,[57] stroke[58,59] and chronic pain.[54,56,60,61] The Delphi process, developed by the RAND Corporation, is widely used for convergence of expert opinion within certain topic areas.[62] It is part of the development of research protocols and manuals[63] and typically involves a formal process of using questionnaires to gather information from experts, summarizing areas of consensus and reviewing with experts one or more times until consensus is obtained. Consensus is defined as general agreement from group discussion resulting in clear support for each included item.

Preliminary information from trials of acupuncture for acute pain in the ED and AAP survey

To contextualize our intervention in the existing trial literature, and to prepare the AAP members for discussion, we created a table of a literature review of studies including RCTs and observational research on acupuncture for acute pain in the ED, specifically detailing acupuncture intervention parameters such as condition treated, study design, time to administer acupuncture, number of needling sites, needle details (length, gauge), needle retention time, points required (if any), local and distal point options, optional points, if obtaining *de qi* was included, and costs if calibrated. This was sent to AAP by email on 17 December 2020.

AAP members then responded to a list of questions (Supplemental file 1) on intervention parameters and details that reflected their approach to the treatment of acute pain in the ED, specifically, aLBP, musculoskeletal pain, headache, abdominal pain and renal colic. The survey responses were collated and distributed to panel members prior to the first conference call. Zoom conference calls with the AAP members were convened on 18 January, 1 February and 8 February 2021, with email discussion between meetings. The AAP worked to obtain item consensus at each meeting and confirmed final consensus again before tackling additional items. The STandards for Reporting Interventions in Controlled Trials (STRICTA) checklist was used as a guide (see Supplemental file 3 for a glossary of terms).

Results and conclusion

A consensus acupuncture intervention was agreed upon for acupuncture in the treatment of acute pain in the ED, detailed in Table 1. Steps in care (Table 1) and traditional acupuncture point options (Supplemental file 2) were intended to provide a balance between standardization and flexibility in allowing acupuncturists to customize an acupuncture session to a participant's specific presentation of acute pain. Session forms were then fashioned in REDCap (Research Electronic Data Capture program) to capture essential

treatment data and to track fidelity to the intervention. The development of a consensus acupuncture intervention achieves one milestone of our NIH-funded study (R01AT010598) and provides a framework for the future pragmatic, multi-site definitive RCT (NIH UG3/UH3) of acupuncture in BraveNet PBRN clinic-affiliated EDs (ACUITY).[64]

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1:

Consensus Responsive Acupuncture Intervention for acute pain in the ED

Element of intervention	Rationale	Notes
Single acupuncture session based on expert consensus protocol	Based on data from literature, acupuncture can reduce acute pain and anxiety and potentially reduce narcotic exposure in the ED.	Study design for a single acupuncture treatment combines opportunity and need in ED setting coordinated with usual care and usual care staff.
Steps or staging of care would include 'asking' * interview and can include range of motion (ROM) observation, palpation of region, channels and Hara (abdomen); should include point selection and needling (de qi at practitioner discretion); needle retention; removal of needles and resting or changing position to treat another 'part of the body', palpation and point selection and needling (de qi at practitioner discretion); needle retention, removal of needles and resting. End of session check in, assessment of pain and ROM, patient's response and readiness to move, self-care recommendations.	Common steps in an acupuncture intervention adapted to ED setting. Electro-acupuncture, moxibustion, Gua sha and Ba guan, cupping, are not part of the current study though may be appropriate and effective for acute pain.	Intervention parameters, range of time for session length, needle retention and number and location of needle sites detailed below.
Positioning and comfort of patient Acupuncture intervention includes optimal patient comfort to enhance treatment benefits. These include optimal patient positioning, attention to room temperature and lighting, attention to level of noise/disturbance.	Consensus recommending support of patient comfort to include attention to positioning, temperature, lighting and noise when able in the fast-paced ED.	Options to record in session form when acupuncturist is not able to control comfort or access factors in a way that might have affected treatment.
TCM pattern diagnosis	TCM 'diagnosis' is inconsistently used in studies including acute pain care studies. Acupuncturists may incorporate TCM 'diagnosis' as part of their evaluation but it will not be tracked in this study.	Will not capture.
Panel of points Point options will include local, proximal and acute pain area (if feasible), regional to acute pain area (if feasible) and/or distal points as well as ear point options.	General consensus (See acupuncture point options document Supplement 1).	For charting purposes, session forms organize points on relevant channels, distinguishing local, distal, and regional/ torso or auricular.
Auricular treatment	Auricular therapy, needling and extended acupressure therapy with seeds, can be effective for acute pain. Ear treatment, including extended treatment with ear seeds, is part of current study design as participants will be encouraged to stimulate ear seeds for up to one week after the acupuncture intervention. Retained ear needles and ear magnets will not be used in this study.	Consensus supports inclusion of auricular acupuncture during the ED visits and applying auricular acupressure seeds to extend the treatment benefit after ED care.
Distal and local points are expected to be treated in each session	Local and distal point treatment is fundamental to acupuncture practice based in traditional East Asian Medicine.	While distal and local points will be the commonly used, exceptions are appropriate when a patient is treated in a chair or point selection is restricted for another reason. The intention is to capture all acupoints used in a session.
Ah shi points	Study design includes option of treating Ah shi points.	Ah shi points will be described relative to nearby acup points and/or anatomical sites. Ah shi points will be captured.
Treatment of anxiety/stress	Anxiety is often comorbid with acute pain. Treatment of anxiety is part of study design. Point options specific for anxiety, stress, relaxation are included.	Consensus supports use of points for anxiety. Points for anxiety/stress will be captured.
Microsystems (Richard Tan, Korean hand) or trademarked treatments	No study data exists to support exclusive use of these specific microsystems. Trademarked and microsystems are excluded.	Exclusive use of any microsystems or trademarked treatment besides auricular is proscribed. A point or two from

Element of intervention	Rationale	Notes
(Master Dong, Master Tung) and superficial needling	Restricting needing to shallow insertion also excluded as this has been used in trials as sham controls and less effective.	trademarked systems as part of a larger treatment is permitted with rationale.
Number of insertion sites: expected range of 1–18 needle sites generally; 6–16 expected/likely. Fewer points if participant is needle phobic.	Mean number of needles used: almost 70% of acupuncture trials for chronic pain used 5–14 needles. (Vickers et al, 2018). Acute pain acupuncture trials have reported pain relief with use of even fewer.	Sessions for an acupuncture naïve or trepidatious patient might include fewer acupuncture points. It would be unusual to use more than 20 points. The number of needles used per session, or if only ear seeds used, will be reliably captured on the session forms.
Acupuncture session time range including intake and treatment aims for 30–60 minutes, with average 45 minutes per study design.	Mean session times for prior studies of acupuncture in the ED range from 10 to 30 minutes.	Session time and needle retention time will be recorded and captured.
Range of needle retention time expected to be 15–30 minutes.	Resting with needle retention is part of acupuncture therapy. Limited needle retention times can mitigate the effect of acupuncture needling on pain. Practitioners will gauge needle retention time per patient and presentation need.	The duration of the acupuncture needle retention will be at the discretion of the practitioner with the expectation of relaxation with retained needles and or resting after withdrawal. Care taken to assess a patient's response to treatment. Session time and needle retention time will be recorded and captured.
Treatments will vary based on patient's unique presentation	Effective acupuncture is responsive to unique needs of each patient's presentation and clinical condition. The responsive approach will be used in the study with recommendation of a panel of points as opposed to repeating a set point prescription.	A responsive manual allows an acupuncturist discretion in treatment choices within a range of identified points options with ability to select additional points with rationale. Points will be captured.
Obtaining de qi	De qi felt by the patient and the practitioner is a unique part of acupuncture needling. Research demonstrates a role for obtaining de qi in the treatment of pain.	Obtaining de qi is recommended as part of care but is at the discretion of the practitioner on any given day for any given patient or point of insertion. Treatment notes will capture whether intention of acupuncturist was to obtain de qi.
Frequency of needle stimulation	It is expected that needles will be inserted and manipulated as point stimulation. Frequency of needle stimulation within the study's single acupuncture session is left to the discretion of the acupuncturist.	Frequency of manipulation of retained needles at the discretion of the acupuncturist and will not be tracked in session form.
Patient movement with retained needles	Some pain protocols engage patient movement or walking while needles are retained. Although not a recommended aspect of the current consensus intervention, movement with retained acupuncture needles may be done on occasion with at the discretion of the acupuncturist. If movement is used during a session the acupuncturist will remain present, and gentle movement will be engaged while the participant is on the ED bed or sitting in a chair. Movement would be conducted away from the site of needle insertion (i.e. - moving the shoulder with needle inserted in the lower extremity). Ambulation with retained acupuncture needles is not included.	Care must be taken in terms of loss of needles during patient movement during needle retention, an approach that may be used with rationale, on occasion by acupuncturist.
Information and recommendation on use of non-coated vs coated needles	Research shows non-coated or 'course' needles may enhance analgesic effect compared to silicone coated needles. The study design only allows for use of non-coated needles.	Study will recommend needle types, gauge and length to be consistent at each site, and include only non-coated needles.
Needle gauge and length	Needle length not to exceed 75% of safe depth for specific body area where there is risk of organ puncture or damage to other tissue. Needle size in gauges expected to be those commonly used and to prevent bending of needle if patient moves: 30 (0.30 mm) and 32 (.25 mm) gauge; 34 (0.22 mm) for ear points in session.	Various needle lengths need to be available to respond to patient size/ thickness from robust to frail. Safety regarding needle size and safe depths to be reviewed in safety lecture.

Element of intervention	Rationale	Notes
Depth of needle insertion will be based on anatomy and effective depths per point location, with information provided on safe depths and adverse event risks reported in the literature.	Recommendations are based on using needles that are 75% of safe depth for a particular point (details in Safety Review).	Practice of only very shallow needling not recommended as has been shown as a less effective sham in trials.
Bloodletting needling	While some texts recommend to intentionally microbleed certain points in the treatment of acute low back pain, bloodletting is not part of study design.	While not part of study design, expert panel supports occasional use of micro-bloodletting at the discretion of the acupuncturist.
Scalp needling	During the Delphi process one panel expert noted his use of scalp needling for inpatient care. While not part of study design, expert panel supports occasional use of scalp needling at the discretion of the acupuncturist.	No single treatment would use scalp needling alone.
Self-care recommendations Study design intends basic recommendations relative to traditional East Asian Medicine and acute pain, keeping in mind patients may also be given usual care instructions.	General/basic recommendations that extend and support the benefit of an acupuncture treatment from a traditional East Asian Medicine perspective. General recommendations relevant to the acute pain presentation, (general food/diet/water; general movement/activity/exercise; general breathing awareness) are appropriate.	Self-care recommendations will be captured from a general list.
Other Trial Requirements Acupuncturists may not refer to other practitioners except by referring back to the patients/participants' referring provider in ED. Acupuncturist may not see the patient privately (outside of the trial session) during the duration of the trial	Part of study protocol.	
Practitioner Qualifications Acupuncturists will be state-licensed, and malpractice insured with no malpractice claims. Acupuncturists should have a minimum of 5 years post-licensing practice (at least 50% of the time in patient care) with experience in acute pain care. There may be exceptions for 3 years' experience per individual applicant, for example with other health care licensure relevant to acute pain care.		
Study Intervention Training Acupuncturists will participate in training for the protection of Human Subjects for Research, as well as the study protocol, special Safety Review for the study, and the logistics of delivering and recording study treatments. They will be certified for participation in the study.		

* 'Asking' in traditional East Asian medicine is shorthand for patient interview and history taking that typically includes questions about appetite, diet, digestion, stool, sleep, urination, sweating, menstrual cycle, senses, emotional state as well as description of presenting problem(s), including location and nature of pain.