TITLE: Shen Men acupuncture for anxiety preceding lumbar epidural steroid injections in acupuncture-naïve patients: a randomized controlled trial

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Title: Shen Men acupuncture for anxiety preceding lumbar epidural injections in acupuncture-naïve patients: a randomized controlled trial

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Condition or Intervention to be studied: The condition being studied is the change in anxiety in patients prior to a fluoroscopic-guided epidural injection of the lumbar spine. The internvetion to be studied is the use of Shen Men acupuncture and its effect on anxiety on this population.

Research questions/specific aims: To compare change in anxiety pre- to post-intervention prior to a fluoroscopic-guided epidural injection of the lumbar spine between patients receiving Shen Men acupuncture vs. sham acupuncture vs. simulated acupuncture.

Hypothesis: Patients receiving Shen Men acupuncture will report a greater mean decrease in anxiety than patients in the sham and/or simulated groups.

Primary outcome: Change in anxiety (State/State Trait Inventory).

Secondary outcomes:

1. Blinding assessment
2. Belief surrounding acupuncture as treatment for anxiety
3. Use of sedatives or anxiety medications after intervention and prior to injection

Background: Interventional spine techniques are commonly utilized for the treatment of spinal pain (1). The reporting of anxiety in patients undergoing interventional spine techniques is common (2). Up to 82% of interventional pain physicians use a sedative agent during a spine procedure to reduce anxiety (3). The use of sedative agents during a spine procedure has been shown to increase the risk for neurologic injury (4). Auricular acupuncture is a minimally invasive method and has been shown to be effective in reducing pre-operative (5,6) and pre-dental procedure anxiety (7).

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3. Kohan L, et al. A review and survey of policies utilized for interventional pain procedures: a need for consensus. J Pain Res. 2017;10:625-34.
4. Apfelbaum JL, et al. Practice guidelines for postanesthetic care: an updated report by the American Society of Anesthesiologists Task Force on Postanesthetic Care. Anesthesiology. 2013;118(2):291-307.
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6. Wang SM, et al. The use of auricular acupuncture to reduce preoperative anxiety. Anesth Analg. 2001 Nov;93(5):1178-80.
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Study design: Randomized controlled clinical trial

Enrollment target: 99

Inclusion criteria:
1. Age 18+
2. Spine pathology that meets criteria for lumbar epidural injection

Exclusion criteria:
1. Contraindications to acupuncture
2. Previous experience of acupuncture
3. Pregnant women
4. Non-English speaking

Study procedures:
1. Patients will be screened prior to the day of their procedure. If eligible, patients will be approached for study participation upon admission to the holding area of the procedure unit.
2. Once consent is obtained, patients will be randomized into one of three groups: intervention, sham, and simulated acupuncture groups.
3. Patients will complete the State Anxiety Inventory subscale.
4. Patients will then undergo the intervention for 20 min.
5. Following the intervention, patients will complete the State Anxiety Inventory subscale again.

Sample size analysis and statistical analysis plan:
1. Test: ANCOVA
2. Alpha level: 0.05/3 comparisons = 0.0167
3. Beta or power level: 0.8
4. Primary outcome variable estimate: Within-group standard deviation of change in State Anxiety Inventory subscale score = 7.1 points
5. Number of groups being compared: 3
6. Effect size or change expected between groups: 6 points
7. Resulting number per group: 33
8. Total sample size required: 99

The primary outcome will be compared between groups using ANCOVA, with the first State Anxiety Inventory subscale score as a covariate and the second State Anxiety Inventory subscale score as the outcome. If any baseline imbalances in patient characteristics or procedure are noted, the model will also be adjusted for these covariates.
The success of blinding will be assessed using the Bang Blinding Index.
Balance on baseline characteristics and procedure will be assessed by calculating standardized differences (difference in means or proportions divided by the pooled standard deviation) between groups. Balance will be assessed using two thresholds: (1) $1.96 \times (2/40)^{1/}2 = 0.438$ and (2) 0.2.

1. Michalek-Sauberer A, et al. Auricular acupuncture effectively reduces state anxiety before dental treatment – a randomized controlled trial. Clin Oral Investig. 2012 Dec;16(6):1517-22.
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