Study Narrative

Title: Audio Distraction for Traction Pin Placement: A Randomized Controlled Trial

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Participant Contact Project Narrative

1. *Summary*
    a. Traction pin placement is a common way to temporarily manage femur fractures and unstable acetabular fractures while awaiting surgery. Skeletal traction is thought to reduce patient discomfort by improving fracture alignment as well as relaxing muscle spasm pain felt from the broken bone by stretching out the leg. Skeletal traction may also help prevent articular surface damage in the hip by decreasing joint pressure. Despite the benefits of skeletal traction, insertion of the traction pin can be a painful and unpleasant experience for the patient. Our study hopes to see if listening to music with headphones during insertion of the traction pin decrease patient pain and anxiety.

2. *Study aims:*
    a. Primary:
        i. To determine if audio distraction will improve subject's overall experience during skeletal traction pin placement compared to those without audio distraction.
        ii. To determine if subject anxiety decreases with the use of audio distraction compared to those without audio distraction during skeletal traction pin placement
        iii. To determine if subject pain decreases with the use of audio distraction compared to those without audio distraction during skeletal traction pin placement

    b. Secondary:
        i. To determine if audio distraction changes provider perception of procedure difficulty
        ii. To determine if audio distraction changes overall skeletal traction pin placement procedure time
        iii. To determine if pain medicine use is different in patients who have audio distraction compared to those without audio distraction during skeletal traction pin placement.

3. *Background, Rationale, Significance*
    a. Lower extremity injuries, including acetabular and mid shaft femur fractures, are common injuries seen at trauma centers (Liao, HHS 2015). The incidence of acetabular fractures has remained stable at 3/100,000 per year (Laird, JBJ 2005) and diaphyseal femur fractures occur at a rate of 1/10,000 per year (Weiss, JBJS 2010). Femur and acetabular fractures may disrupt the mechanical axis of the lower extremity, therefore causing joint dysfunction if not properly repaired (Probe, AAOS 2003). Due to these possible complications, lower extremity fractures are acute issues which are immediately addressed in an emergent setting. There has been effort to improve outcomes by earlier intervention and surgery (Plaisier, Injury 2000). If these fractures are unable to be repaired acutely, the current standard of care in orthopedics is to place a skeletal traction pin.

Supracondylar femoral skeletal traction pin placement continues to be the popular choice for preoperative stabilization of lower extremity fractures, including acetabular and femoral fractures (Resell, 2009). The traction pin theoretically improves pain and provides axial reduction of pelvic and lower extremity fractures. This, in theory, prevents significant skeletal muscle contraction and improves the ease of fracture reduction in the operating room. Traction has also been hypothesized to decrease damage to articular cartilage from impingement on bone (Browner, ES 2015). This has been the standard of care for decades in orthopedics and therefore has not been adequately studied or demonstrated in the literature.

Skeletal traction is useful in immobilization and stabilization of fractures, and can be applied quickly and safely with minimal contraindications (Defroda, EJTES 2016). There is also data to support less discomfort with traction pin placement compared to casting for lower extremity fractures (Resell 2009). However, the procedure is relatively invasive and can cause significant discomfort and anxiety in the patient. The supplies needed such as needles for anesthesia, scalpel, traction pin set, drill, and traction frame can be intimidating for a patient already experiencing discomfort from a lower extremity fracture.

Given that skeletal traction is the current standard of care at our institution; our study will focus on the use of audio distraction during placement of skeletal traction and the effect on patient discomfort. There have been multiple studies examining the use of various distraction techniques for pain and anxiety, mainly with patients undergoing GI procedures, such as colonoscopy (Bampton 1997, Bechtold 2006, Palankis 1994, Silva 2016, Smolen 2002). The goal of our study is to investigate the use audio distraction with subject preferred music from an mp3 player, and the effect on patient anxiety and pain during the placement of a skeletal traction pin. Then also retrospectively observe if audio distraction alters secondary outcome measures.

b. A pilot study has not been performed, as such there is no preliminary data. However, results of studies addressing audio distraction and patient discomfort in Colonoscopy procedures identify significant decreases in subject pain [$p<0.0001$], discomfort [$p=0.037$], and providers' perception of procedure difficulty [$p<0.02$] (Bechtold 2006 & Costa 2010). These studies also identify significant increases to overall patient satisfaction [$p<0.0001$].

c. This research will be important to the scientific and orthopedic community as it will potentially establish a method of improving patient care during a frequently used and uncomfortable orthopedic procedure.

4. *Approach*
    a. Study design

i. This will be a prospective randomized controlled trial at Regions Hospital in Saint Paul, MN and Hennepin County Medical Center in Minneapolis, MN to compare primary outcomes of subjects between audio distraction groups during traction pin placement. This study will also include a cross-sectional descriptive element by examining above listed secondary outcome measures. It will explore if either of these outcomes are different between the two subject groups in an exploratory fashion.

Group selection was randomized through Microsoft Excel 2010, of which subjects are split into blocks of 10, with each block held at a fix ratio of 0.5 for audio distraction and without audio distraction.

i. Inclusion
    1. >18 years old
    2. Conscious, oriented, able to give informed consent
    3. Medical need for distal femoral or proximal tibial skeletal traction pin placement

ii. Exclusion
    1. Medical contraindication to skeletal traction
    2. Endotracheal intubation
    3. Unable to participate in verbal communication throughout the procedure and in the recovery phase
    4. Sensory impairment to pain
    5. Inability to make accurate mark on VAS 2/2 cognitive, motor or visual deficiencies.

b. Data collection process
    i. Identify patients at Regions Hospital who meet inclusion criteria who are determined to need skeletal traction pin placement
        1. Patients meeting inclusion criteria will be identified by the on call junior residents at Regions Hospital and Hennepin County Medical Center
    ii. Recruitment of patients for inclusion in this study will be complete by the orthopedic resident placing the skeletal traction pin. Patients will be recruited for inclusion in this study after determining the medical need for placement of a skeletal traction pin.
    iii. Consent
        1. Written informed consent will be obtained by the orthopedic resident performing traction pin placement prior to initiating steps for traction pin placement
        2. Patients will acknowledge that the study has been explained adequately and that they are free to withdraw from study at any time without effect on their treatment and management
        3. Patients will provide consent for participation in this study at the time of consenting for placement of the skeletal traction pin. Minors do not meet inclusion criteria for this study.

iv. Data sources needed for this study
    1. Chart review for current injury, date and time of injury, and medications given during hospital visit.
    2. Chart Review for patient age, gender, height and weight
    3. Survey for patient
        a. Visual analog scale (VAS) to rate pain
        b. Visual analog scale (VAS) to rate anxiety
        c. Visual analog scale (VAS) to rate overall patient experience
    4. Survey for resident
        a. Cooperation of patient on 1-10 scale; fully cooperative to combative
        b. Ease of procedure on 1-10 scale; easy to most difficult
    5. Overall time required for placement of skeletal traction pin
v. Process steps for data acquisition
    1. Demographic data (age, sex, injury, date/time of injury)- completed by patient; obtained by resident, and/or retrospective chart review by the research assistant.
    2. Time of procedure from injection of lidocaine to completion (disconnecting drill); obtained by resident
        a. Start time just prior to lidocaine injection
        b. Stop time after drill disconnected from pin
    3. Medications given during procedure; obtained via retrospective chart review by research assistant
    4. Post-procedure VAS pain, anxiety, and experience surveys completed by patient, obtained by resident immediately after hanging of traction weight.
    5. Post-procedure patient compliance and ease of procedure surveys completed by the resident after completion of procedure

c. Intervention, treatments
    i. Standard of care will be provided by the orthopedic resident for skeletal traction pin placement. Those included in this study and randomized into the treatment arm will be given an mp3 device to listen to genera of music of their choosing in addition to be treated to the current standard of care. Those randomized into the control arm will be treated to the current standard of care
    ii. Patients will be randomized by the orthopedic resident into 2 groups; Audio distraction with music versus control group with no music. This will be done by sealed envelopes drawn after consent for the procedure.

d. Outcomes/endpoint and other variable definitions, and instruments used
    i. A 10-point visual analog scale for patient experience (1 worst possible experience, 10 best possible experience)
        1. Singer 1998; Results suggested that the satisfaction VAS is both reliable and valid.

ii. A 10-point visual analog scale for pain (1 no pain, 10 worst pain)
    1. Bijur 2001; Results demonstrated that the VAS is sufficiently reliable to be used to assess acute pain
    2. Todd 1996; demonstrated the validity of the VAS for acute pain measurement among ED patients to measure acute pain

iii. A 10-point visual analog scale for anxiety (1 no anxiety, 10 worst anxiety)
    1. Hornblow 1976; Results suggest that VAS is sufficiently reliable to be used to assess acute pain.

iv. Pain medication used pre/post traction pin placement

v. Overall time required for placement of skeletal traction pin

vi. Resident perception of procedural difficulty

vii. Intermediary Newman-Keuls (SNK) analysis techniques will be utilized to regularly perform preliminary *post-hoc* tests. This will aid towards

e. Statistical analysis plan

i. T-Test of Sampling Demographic Data

ii. T-test of Primary Outcome Measures between subject groups
    1. Pain Survey Scores
    2. Anxiety Survey Scores
    3. Experience Survey Scores

iii. Linear & Logistic Regression Analysis of Primary Outcomes
    1. Addition of Demographic Covariates
    2. Observing both Linear & Non-Linear identities of the relationship.

iv. T-Test of Secondary Outcome Measures between subject groups
    1. Perception of Difficulty
    2. Procedural Time
    3. Pain Medication

v. Linear & Logistic Regression Analysis of Secondary Outcomes
    1. Addition of Demographic Covariates
    2. Observing both Linear & Non-Linear identities of the relationship

vi. Power analysis or statement of precision

A power analysis was performed to estimate the minimum sample size needed to adequately detect a clinically significant change in anxiety and pain scores between the audio distraction groups. At a Type I error rate of 0.05 (α=0.05) and 80% power (β=0.80), the power analysis identifies a minimum sample size of 42 total participants, 21 for each group. The estimated effect size is 2.0 on the utilized 10-point scale with a two-sided standard deviation of two. These measures for effect size are adopted from a previously performed colonoscopy audio distraction study which identified clinically significant results (Costa 2010). A power analysis for secondary outcome measures was not performed due to their non-inferential nature.

vii. Strengths

1. Regions Hospital and Hennepin County Medical Center provides sufficient access to the study population and the facility is adequate to conduct the study. Both Level I Trauma centers.
2. Adequate qualified staff members to conduct the study
3. Staff will be adequately trained on the protocol and their specific research related duties.
4. Exhaustive primary & secondary outcome assessment.
5. Use of verified survey techniques.
6. Conservative effect size estimate compared to previous research.

viii. *Limitations*

1. Traction pin placement is typically done in an acute situation, which may limit how much information we will be able to get from the patient survey
2. Subject recall bias with pain measurement
3. Different techniques for traction pin placement
    a. Attempt to have a standardized procedure for the residents to follow
4. Pain tolerance of patients
    a. This will be controlled by appropriate randomization
5. Recall bias with procedural difficulty assessment in participating resident providers. Comparing procedural difficulty to previous experience, not novel.

5. State that a score of five dictates a normal procedural difficulty then rate procedural difficulty based on that score. Median value selected on 10-point scale.
   Setting/Environment/Organizational feasibility
    a. This study will be conducted at Regions Hospital in Saint Paul, MN and Hennepin County Medical Center (HCMC) in Minneapolis, MN
    b. This HealthPartners setting is a level 1 trauma center with the patient population appropriate to carry out the proposed study. HCMC is a level 1 trauma center with a similarly appropriate patient population.
    c. The orthopedic department leadership has been engaged in development and approval of this study

6. Risks and Benefits
    a. Potential risk factors with audio distraction group
        i. Patient may not hear resident when attempting to communicate
            1. Resident will be able to communicate with an assistant in the room to get the attention of the patient, if needed.
        ii. Patient may receive less pain management with the assumption they will have higher pain tolerance from the audio distraction
            1. Resident will continue to follow standard of care for traction pin placement
        iii. Benefit for patient in audio distraction group to experience less discomfort during traction pin placement

iv. Benefit to society, as this study may provide an opportunity for providers to decrease the level of discomfort in patients who need traction pin placement.

7. Data Confidentiality and Privacy
    a. In order to secure patient confidentiality and data security, all data will be de-identified. All patients will be assigned a research identification number (not their MRN) that cannot be associated with their name, birthdate, or other identifying information.
    b. Patient information will only be accessed via secure servers for Regions Hospital and on encrypted password-protected computers. If it is necessary to transmit patient data, it will be transmitted in the de-identified format, using only patient research identification numbers.
        i. De-identified data will be shared with collaborating sites (HCMC)
    c. At the end of the study, the electronic files will be permanently deleted and patient identifiers will be removed. All hard copies will be shredded.

8. Timeline
    a. August 2017: IRB submission
    b. September 2017: IRB approval
    c. October 2017: Protocol implementation
    d. October 2017: Patient enrollment
    e. October 2018: Patient enrollment closes
    f. November 2018: Data analysis
    g. December 2018: Manuscript preparation
    h. February 2019: Manuscript submission

9. Dissemination/Sharing Results/Integration and Impact
    a. We do plan on publishing to peer reviewed orthopedic journals such as;
        i. The Journal of Bone and Joint Surgery
        ii. Clinical Orthopedics and Related Research
        iii. Journal of Orthopedic Trauma
    b. We plan to disseminate the information on a local and regional level by presenting at;
        i. University of Minnesota Grand Round
        ii. Regions Department of Orthopedic Surgery Grand Rounds
        iii. Minnesota Orthopedic Society poster presentation
        iv. Mid-America Orthopedic Society poster presentation
    c. Results will be shared with HealthPartners
        i. The results of this project could possibly change the stand of care for placing skeletal traction pins at Regions Hospital

10. References

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