Official Title: Use of Dermabond in Mitigation of Spinal Cord Stimulation Trial Lead Migration

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Use of Two Standards of Care: Dermabond versus Suture in Mitigation of Spinal Cord Stimulation Trial Lead Migration

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Background, Rationale and Context

Spinal Cord Stimulation is a FDA approved and effective treatment for chronic pain. It is indicated in patients with varying medical conditions ranging from neuropathic pain syndromes to failed back surgery syndrome.[1] A prognostic test (trial) is required prior to the permanent implantation of a Spinal Cord Stimulation (SCS) system. The Spinal Cord stimulator 'trial' (prognostic tests) requires precise placement of SCS leads in the thoracic epidural space to capture the pain areas including the low back and lower extremities.[1] Standard medical practice is to place two SCS leads per patient treated to obtain appropriate neuroanatomical coverage. Since the leads are not anchored into the deep tissue (thoracolumbar fascia), migration of the leads can occur and result in suboptimal trial resulting in a technical failure of the prognostic test increasing the possibility of false negative results. Migration of the SCS leads can result in up to 2.49 mm to 3.24 mm migration in the leads depending on trial length .[2,3] Early studies on SCS leads placed percutaneously demonstrates migrations rates occurring in 13.2 to 69.2% of cases.[4,5] During the trial the distal end of the leads are within the thoracic and lumbar epidural space, and the proximal end of the leads are externalized and can be prone to migration. The leads are typically secured in place with tape alone or tape and suture and/or dermabond.

The suture is a silk sterile surgical suture material. Dermabond is a quick drying adhesive that is currently utilized for assisting in the closure of medical incisions with minimal risk. The use of Dermabond has not been formally investigated but is in common use for securing SCS 'trial' leads. It is unknown which standard of care mechanism of securing SCS trials leads is superior in reducing lead migration. One may be more effective alternative to decrease the incidence of such lead migration, thereby allowing for improvement of outcomes during spinal cord stimulation trial lead placement (in anticipation of surgical placement of spinal cord stimulators for the treatment of chronic pain).

Objectives

Main objective

Determine if the use of Dermabond plus suture as compared to suture alone at the insertion site of a trial spinal cord stimulator lead will lead to less lead migration at the end of the trial period (typically 5-8 days).

Additional Objectives

1. Assess if lead migration changes effectiveness of 'trial'
2. Compare patient satisfaction between patients with migration and without

3. Assess trial lengths effects 5 versus 6 versus 7 versus 8 days on lead migrations rates
4. Determine if there is a change in lead position when using Dermabond plus suture vs suture alone when laying prone on the operating table and then standing and having a PA x-ray performed with radiology

Methods and Measures

Design

All patients who are being considered for a permanent spinal cord stimulator placement are required to have spinal cord stimulator 'trial' leads placed to ensure they are an appropriate candidate for treatment with this device. These trial leads are placed by pain medicine physicians in the pain centers and are secured with either tape and suture, or tape and a combination of Dermabond with suture. Security is at the discretion of the inserting physician. Currently it is not known which method is the best method of securing trial leads to prevent lead migration.

Interventions and Interactions

This study will be a controlled trial of the two standard of care methods of securing SCS leads in which the trial leads (left and right) will be secured with 1 lead being secured with a suture only while the 2nd lead will be secured after placement with both a suture in addition to Dermabond. All other factors in the SCS trial lead placement will be unaffected by this study. In this manner, the patient will serve as their own control. This will limit confounding factors between patients that may predispose them to migration based on body habitus, sheer forces of back musculature, and other physical attributes that could augment lead migration. In the standard of care SCS 'trials', one lead is typically place to the left of midline (1-2 cm from midline), and another lead to the right of midline (1-2 cm from midline). Although, the anatomy of the two placement location should be identical, we will randomize which lead (left or right) in each patient gets suture plus Dermabond versus suture only to limit any potential procedural (though unlikely) bias in which SCS lead gets secured in a certain fashion. This is within participant randomization. Demographics of the subject to be retrieved include the following: Age, BMI, height, weight, race, ethnicity, history of spine surgery, sex at birth. We will also collect the radiological information required to meet the study objective of this protocol.

As is the standard of care with this subject population, once procedure is completed on Day 0, the patient will be sent for X-ray imaging right after the trial as well as between days 5-8 post procedure. During this second X-ray, the placement of the leads will be evaluated by measuring the amount of lead migration by a physician not involved in the trial. Lead migration will be measured in millimeters from original placement on X-ray imaging. Of note, imageing is obtained during the placement of the trial leads via fluroroscopy. Depending on the location,

the post trial images may be done via x-ray imaging or via fluoroscopy. Either radiological studies are acceptable methods to be used in the analysis of lead migration for this study. The average and median mm of migration per trial will be compared between the two mechanisms of securing the lead. The rate of migration is defined as greater than 4 mm between the two groups. Patient satisfaction survey will also be reviewed upon lead removal by a member of the study team.

Setting

This will be a single center, academic setting at Atrium Wake Forest Baptist with the Pain Service Line.

Subjects selection criteria

- **Inclusion Criteria**
  Any patient presenting to the Pain Service Line for SCS 'trial' lead placement in the thoracic spine defined as terminal tip end in the thoracic spine.

- **Exclusion Criteria**
  Allergy to Dermabond and/or Suture material.
  Inability to place two leads in the patient.
  Lead placement outside of the thoracic spine

- **Sample Size**
  Assuming the mean lead migration for use of Dermabond is 2.49 mm compared to mean non-Dermabond usage of 3.24mm, with variance of 1mm, total sample size need for study with study power of 80% with 95%CI for 2-tail test is 56 for both the groups. Lead migration is estimated to occur at a rate of about 13.2% and this number would provide enough analysis to determine if there is a difference in the rates of migration between the groups. No interim analysis will be performed as there is no potential significant harm to the patient and both approaches are standard of care.

Outcome Measure(s)

- **Primary Outcome Measure**
  Migration rate of trial leads anchored with Dermabond + suture versus suture alone.

  - **Title**: Migration rate of trial leads anchored with Dermabond + suture versus suture alone

  - **Description**: Change in 'trial' lead position as measured in millimeters when comparing initial x-ray after placement versus x-ray taken at lead removal 5-8 days after placement.

  - **Time Frame**: 5-8 days after placement of trial lead

- **Secondary Outcome Measure**
    - **Title**: Number of patients who received pain relief from the SCS 'trial'
    - **Description**: Number of responders to the prognostic lead placements defined as >50% pain relief over the length of the trial.
    - **Time Frame**: 5-8 Days after placement of trial leads
- **Secondary Outcome Measure**
    - **Title**: Patient satisfaction
    - **Description**: Lower satisfaction in patients that had lead migration versus patients that did not
    - **Time Frame**: 5-8 Days after placement of trial leads
- **Secondary Outcome Measure**
    - **Title**: Effect of length of trial on migration
    - **Description**: Does a longer trial predispose to a higher rate of infection within a 5-8 day period
    - **Time Frame**: 5-8 Days after placement of trial leads
- **Secondary Outcome Measure**
    - **Title**: Prone fluoroscopy vs upright PA x-ray
    - **Description**: Difference in lead position on prone fluoroscopy versus upright PA x-ray when comparing Dermabond plus suture versus suture only at lead insertion site
    - **Time Frame**: 5-8 Days after placement of trial leads

Analytical Plan

Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Subject Recruitment Methods

All patients undergoing percutaneous SCS trial at Atrium Health - Wake Forest Baptist will be invited to participate in this study. All records will be kept in a secure locked location. Any electronic files will be maintained behind the medical center firewall with password protection. All information collected are de-identified without any patient specific information that can be identifiable to a particular patient.

If any collected patient identifying information corresponding to the unique study identifier will be utilized a linkage file will be stored separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed within 6 years.

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Informed Consent

Informed consent will be obtained from all subjects prior to their participation in this research study. This evaluation will determine if it is in the subject's best interest to utilize the Dermabond plus suture or suture alone for best evaluation of the success of the lead placement for potential spinal cord stimulator placement.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed within 6 years via existing confidential material destruction service at Atrium Wake Forest Baptist Medical Center consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

Risks

To date, no study had been conducted comparing one method versus the other of securing trial leads, even though individual pain medicine physicians have been utilizing both methods as part of their standard of care. This study will be providing this information by comparing 2 approved methods of securing spinal cord stimulator trial leads. The investigators in this trial will be utilizing the randomization to secure in the assigned method.

In addition, an allergy to Dermabond may be experienced, which would include such reactions as redness, itching, or hives at the application site.

References

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