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A CADAVER MODEL DESCRIBING A NOVEL RETROGRADE APPROACH FOR PERCUTANEOUS PLACEMENT OF AN IMPLANTABLE TIBIAL NERVE STIMULATION LEAD

<u>Hypothesis / aims of study</u>

To aid and clarify the approach for percutaneous lead placement for permanent implantation of tibial nerve stimulation lead electrode. We hypothesized that 1) ultrasound identification of the tibial artery, and 2) fluoroscopic imaging, would be independent tools that will augment bony landmarks and 3) retrograde percutaneous approach may offer clinical advantage over the antegrade approach.

<u>Study design, materials and methods</u>

A cadaver model was developed to guide delivery of permanently implanted tibial nerve leads. Quadrapolar electrode leads were placed percutaneously with the guidance of 1) bony landmarks 2) ultrasound and 3) fluoroscopic imaging in 4 below the knee cadaver legs. The tibial artery was identified proximally and a guide wire placed to help both ultrasound and fluoroscopic identification and serve as a point of reference in identifying the tibial nerve for lead placement. The tibial nerve leads were placed percutaneously with a standard lead introducer. Both antegrade (proximal to distal) and retrograde approaches (distal to proximal) were explored. Both approaches were evaluated real time with ultrasound (transverse and longitudinal) and fluoroscopy (lateral and anterior-posterior). Then the cadaver leg was dissected and the lead placement was evaluated with respect to depth and orientation to the nerve, whether it was crossing the nerve or lying more parallel to the nerve. Data from each leg dissection was used to guide the next lead placement to improve the accuracy of each subsequent percutaneous lead delivery.

<u>Results</u>

Ultrasound easily identified the wire in the artery in both transverse and longitudinal planes, and the nerve posterior to that in all specimens. Flouroscopy, lateral and anterior-posterior, was effective in identifing the vector of lead placement, whether crossing the tibial nerve vs. placement more parallel to the nerve. The antegrade approach was modified by migrating more proximally from 5-7 cm above to the medial malleous to 9-10 cm above to try and get a more superficial, parallel vector for a more parallel lead placement. However, antegrade approaches were always crossing the tibial nerve and went deep to the nerve, with only 1-2 electrodes in close proximity to the nerve, Figure 1. The retrograde approach, starting at the level of the medial malleolus, about 1 finger breadth behind (in general about 1/3 the distance from the medial malleolus to Achilles tendon), Figure 2, was easy and effective in placing the lead parallel to the nerve with 3-4 electrodes in close proximity to the nerve, Figure 3.

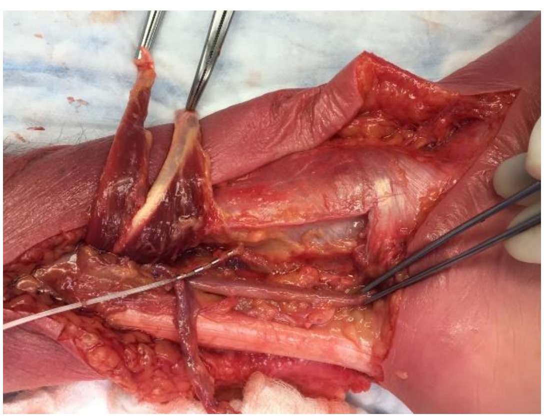

Figure 1

Figure 2


Figure 3

Interpretation of results

This cadaver model, below the knee leg using a wire in the tibial artery, was an excellent tool for assessing percutaneous tibial nerve lead placement. The sequence of ultrasound and fluoroscopic guidance, then dissection of the lead with reference to the tibal nerve, provided appreciation of the trajectory and depth of the lead and improved subsequent lead placement. Antegrade approach, even with a more proximal start to achieve a more parallel trajectory, always resulted in more of a crossing lead with fewer electrodes in proximity to the nerve. The retrograde approach was 1) more reliably predicted using bony landmarks and 2) was easily observed with safety enhanced by using ultrasound and 3) resulted in consistently more parallel lead placement.

Concluding message

We report a novel, safe retrograde method of percutaneous lead placement parallel to the tibial nerve, avoiding key vascular structures. The retrograde approach, starting posterior to the medial malleolus, was easier and reproducibly placed a more parallel lead that may optimize tibial nerve stimulation. Ultrasound, a common tool in many clinicians office, was effective in localizing the tibial artery to aid orientation and depth of placement of the stimulation lead and maximize safety. We are optimistic that this minimally invasive retrograde percutaneous approach can be done in the physicians office under local anesthesia.

Disclosures

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