Neuromonitoring with pulse-train stimulation for implantation of thoracic pedicle screws

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Researchers from Syracuse, New York, report a new, highly accurate, neuromonitoring method that can be used during thoracic spine surgery to prevent malpositioning of pedicle screws such that they enter the spinal canal and possibly cause postoperative neurological impairment. Findings of this prospective, blinded, and randomized study are reported and discussed in two companion papers published today online, ahead of print, in the *Journal of Neurosurgery: Spine*, specifically "Neuromonitoring with pulse-train stimulation for implantation of thoracic pedicle screws: a blinded and randomized clinical study. Part 1: Methods and alarm criteria. Clinical article" and "Neuromonitoring with pulse-train stimulation for implantation of thoracic pedicle screws: a blinded and randomized clinical study. Part 2: The role of feedback. Clinical article" by Blair Calancie, Ph.D., and colleagues.

Background

Disorders of the back and spine are extremely common, particularly in older adults. Nerve roots or the spinal cord itself can become compressed, leading to neurological symptoms of pain, numbness, and weakness. Sometimes, spine surgery is required to treat these types of problems.

The thoracic spine has 12 vertebrae, stacked on top of one another like building blocks. Each vertebra has a pair of "pedicles"—short, thick

pieces of bone that connect the back part of a vertebra (the vertebral arch) with the front part (the vertebral body). Collectively, these structures enclose the spinal canal, through which the spinal cord passes from the base of the brain down to the upper lumbar vertebrae.

Certain types of spine surgery require that neighboring vertebrae be fused together to prevent movement. This is frequently accomplished by placing bone fragments on selected vertebrae and mechanically stabilizing the vertebrae by implanting multiple bone screws, which are used to anchor a pair of rods placed along either side of the spine. The bone fragments grow into the patient's vertebrae and form a strong bone fusion.

Modern spine fusion surgery is generally considered safe, but occasionally things can go wrong. When performed in the thoracic spine, bone screws are inserted into the pedicles with the screw tips ending in the vertebral body. If a screw is angled too far medially (inwardly into the spinal canal), it can compress and damage the spinal cord. This in turn can cause new neurological symptoms in the lower body and, in the worst case, permanent paralysis.

To avoid this possibility, researchers from Syracuse developed and tested a new intraoperative neuromonitoring method that they hoped could decrease the risk that a malpositioned pedicle screw might breach the spinal canal. The researchers separate their detailed findings into two companion articles in the Journal of Neurosurgery: Spine, the first describing the method itself and the second demonstrating how information gained from the neuromonitoring procedure can affect the surgical protocol.

New Intraoperative Neuromonitoring Method

Intraoperative neuromonitoring is fairly new. Although it has been in use

at major university/academic centers for roughly the past 20 years, it is only now starting to be used in smaller community hospitals. The general idea is to perform intraoperative neuromonitoring testing intermittently during surgeries that directly place the brain and/or spinal cord at risk and watch for any changes in test results that might reflect a loss or worsening of nerve function due to technical issues such as placing a bone graft against the spinal cord or overstraightening the spine in a patient with scoliosis. Early detection of such a change can give the surgeon time to "undo" whatever action led to the change in test results, thereby avoiding new problems or symptoms.

There are currently two intraoperative neuromonitoring tests of brain and spinal cord function that are used widely in thoracic spine surgery: somatosensory evoked potential testing, which focuses on function of the spinal cord's sensory pathways, and motor evoked potential testing, which focuses on function of the spinal cord's motor pathways. Although both tests provide valuable information to the surgeon, neither one can detect bone screws that are placed too close to the spinal cord, except for the rare instance in which a screw actually penetrates the cord—at which point permanent damage may already have been done.

The new intraoperative neuromonitoring procedure described in the companion papers involves two steps: 1) initiation of electrical stimulation (4-pulse trains) passing within the trajectory track planned for the pedicle screw; and 2) measurement of electromyographic (EMG) responses to the stimulation from the patient's leg muscles.

The neuromonitoring results are based on tests conducted during thoracic spine surgeries performed in 71 patients at Upstate University Hospital and Crouse Hospital in Syracuse, NY. During these operations, 802 screws were placed in vertebrae to anchor spinal rods. The authors describe how during this type of operation, the surgeon creates a pathway, or track, in the center of the pedicle by using a pedicle finder

(similar to an awl). The surgeon then inserts a probe into the pedicle track to "feel" for any defect that might indicate a present or potential breach in the side of the pedicle nearest the spinal canal (the medial wall). These steps are integral parts of the operation: if no defect is found, the surgeon normally inserts the screw, whereas if a defect is found, the surgeon can revise the track if it seems necessary. For the purposes of the present study, before placing the pedicle screw in the track, the surgeon inserted a second ball-tip probe capable of delivering electrical stimulation to navigate the pedicle track, paying attention specifically to the medial wall of the track.

Brief, low-intensity pulses of electricity (repetitive stimulus trains at intensities up to 20 mA) were delivered through the ball-tip while the surgeon moved the probe along the pedicle's walls. If the dense bone of the pedicle wall was intact, it provided insulation from the electrical current, rendering the stimulation inert. Conversely, if there was a defect in the wall facing the spinal cord, motor nerve fibers in the spinal cord were activated. This activation was confirmed by measuring electromyographic (EMG) activity from leg muscles whose nerves were acted upon by these spinal cord motor nerve fibers.

The researchers sought a particular stimulation threshold—the minimum stimulus intensity needed to cause an EMG response from the leg during electrical stimulation of the pedicle track. In theory, the lower the stimulus intensity, the higher the probability that a pedicle wall breach has occurred near the spinal cord; identification of a low stimulus threshold thus serves as a caution against placing a screw along that pedicle track.

Testing the New Method

To provide a comparison, the researchers stimulated the pedicle screw itself, once inserted, and assessed EMG responses to this stimulation

from leg muscles as well as from intercostal and abdominal muscles. Postoperative computed tomography (CT) scans were later examined and compared with intraoperative EMG recordings by multiple reviewers who were blinded to (kept unaware of) patient identities and intraoperative test results. This was done to determine how well intraoperative neuromonitoring of pedicle track thresholds could predict which screws once inserted would veer too far medially and thereby encroach upon the spinal cord.

The researchers report that postoperatively 32 pedicle screws were found to have breached the spinal canal to an extent (2 or more millimeters) that is clinically relevant and should be avoided. This medial malpositioning of all 32 pedicle screws had been predicted intraoperatively, prior to screw insertion, by EMG responses of leg muscles to the 4-pulse train stimulation delivered within the pedicle tracks.

In contrast, electrical stimulation of the screw after placement did not always elicit a response from the targeted muscles, even when the spinal canal had been breached. As expected, neither somatosensory nor motor evoked potential testing was effective in detecting signs of screw malpositioning, confirming that these "standard-of-care" tests were ineffective for detecting and/or preventing this type of surgical risk.

By applying a receiver operating characteristic analysis, the researchers found that their new method of pedicle-track 4-pulse stimulation and leg muscle responses proved most effective when a combination of 10-mA (lower threshold cutoff) and 15-mA (upper threshold cutoff) stimulation intensities was used. In this study, a 10-mA threshold had an 88% chance of detecting a clinically relevant medial breach (2 or more millimeters) by an implanted screw and a 15-mA threshold increased that chance to 100% accuracy.

Providing Feedback to the Surgeon

The second paper on the new neuromonitoring method covers the role of feedback during surgery. Although the study was prospective, blinded, and randomized, under specific conditions some blinding was discarded.

During Phase 1, which covered the first 65 cases, as a rule no neuromonitoring feedback was given to the surgeon during the operation. Exceptions to this rule, however, were made in cases in which muscle responses to pedicle-track stimulation indicated a breach of the medial pedicle wall that would result in direct physical contact between screw and spinal cord. This was indicated by leg muscle responses to a stimulation intensity of 4 mA or less. When this occurred, "break-the-blind" feedback was relayed to the surgeon. During Phase 2, "planned feedback" was provided to the surgeon in 50% of the remaining pedicle tracks. Here too, break-the-blind feedback was relayed to the surgeon in cases randomized to no planned feedback if the leg muscle response was highly predictive of a breach that could lead to endangerment of the spinal cord.

The researchers broke the blind for 29 pedicle tracks. Based on this information, the surgeon revised the pedicle track before the screw was ever placed. The researchers say it's conceivable that any one of these 29 screws could have caused permanent neural injury had its malpositioning not been prevented by this new form of intraoperative testing.

Feedback to the surgeon and consequent revision of pedicle tracks "led to a significant reduction in the numbers of screws with clinically relevant medial malpositioning." Among the pedicle tracks for which feedback to the surgeon was provided and surgical revision of the track was performed, there was no instance of clinically relevant medial encroachment on the spinal canal.

Summary Findings

For the researchers, the success of the new neuromonitoring method was verified by the high chances of detecting a clinically relevant medial breach (2 mm or more) before screw placement: 88% using a 10-mA stimulation threshold and 100% using a 15-mA threshold. The rates of false positives associated with this neuromonitoring method were 10% when the alarm threshold selected was 10 mA and 26% when it was 15 mA. These values demonstrate that this new neuromonitoring method represents a considerable improvement over other methods of detecting medial screw malpositioning used today, such as screw stimulation and monitoring of somatosensory and motor evoked potentials.

With this NIH-funded prospective, randomized, and blinded clinical study—a first in the field of neuromonitoring—these researchers have proved that use of their novel real-time intraoperative test can significantly reduce the incidence of pedicle screws placed too close to the spinal cord during thoracic spine surgery, thereby making the surgical procedure safer for patients undergoing this surgery.

More information: Calancie B, Donohue ML, Harris CB, Canute GW, Singla A, Wilcoxen KG, Moquin RR: Neuromonitoring with pulse-train stimulation for implantation of thoracic pedicle screws: a blinded and randomized clinical study. Part 1: Methods and alarm criteria. Clinical article. J Neurosurg Spine, published ahead of print April 1, 2014. DOI: 10.3171/2014.2.SPINE13648

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