Accuracy and Outcome Assessment for MR Guided Deep Brain Stimulator Implantation

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Introduction

Deep brain stimulators (DBS) are surgically implanted devices that are increasingly being used to treat the symptoms of movement disorders in patients that do not respond adequately to pharmacologic therapy. DBS electrodes must be precisely positioned within specific brain structures to be effective. Conventional DBS electrode insertion is performed stereotactically and is supplemented by intraoperative physiologic mapping to help refine electrode position. The latter requires an awake, cooperative patient and the insertion of microelectrodes into the brain to perform physiologic mapping.

We have developed a direct image guided approach that permits DBS implantation in anesthetized patients without need of intraoperative physiologic mapping. The purpose of this study was to determine the efficacy and accuracy of this image guided approach and to compare clinical outcomes with that achieved with standard methodologies.

Methods

All surgical procedures were performed in a 1.5T scanner (Intera, Philips Medical Systems) that was equipped with an in-room monitor. The study was approved by the university's committee on human research and all patients provided informed consent. General anesthesia was established and patients were secured to the MR table top with a Malcom-Rand carbon-fiber fixation device. A preliminary volumetric MR acquisition was performed to determine appropriate burrhole location(s). A sterile field was then established with a custom drape that permitted movement between magnet isocenter and rear bore opening.

Burrhole access was created with an MR compatible drill and a trajectory guide (Nexframe, Medtronic) was attached to the skull. An external MR-visible stem was inserted into this guide to indicate orientation. MR imaging was then performed to identify the target, desired path and pivot point of the trajectory guide. Trajectory guide alignment was achieved with a fluoroscopic MR sequence and manual adjustments. Two orthogonal confirmation scans, whose line of intersection corresponded to the desired trajectory, were then acquired to check appropriate alignment and adjustments were made if needed. The external stem was then removed and a rigid ceramic stylet and peel away sheath were inserted through the trajectory guide to the required depth. Imaging was performed after the stylet was inserted 1/3, 2/3 and fully to target depth to confirm trajectory and to screen for hemorrhage. Stylet position was determined by repeating the anatomical scan used to visualize the selected target and the error between the intended and actual position of the stylet in the target plane was determined (radial error). Once appropriately positioned, the ceramic stylet was removed, leaving the sheath in place, and the flexible DBS electrode (Medtronic model 3389, 28cm length) was introduced through this channel.

Clinical outcomes were assessed using the Unified Parkinson's Disease Rating Scale (UPDRS) part III, preoperatively and 6 months after DBS. The effect of DBS was determined by the percent improvement of the UPDRS-III score, both on medication and off.

Results

A total of 41 DBS electrodes have been implanted in 24 patients in 28 operative procedures (15 unilateral procedures, 13 bilateral procedures). Patients suffering from Parkinson's disease (n=22, mean age = 58) and dystonia (n=2, mean age = 40) were treated. Stimulation electrodes were placed in the dorsolateral subthalamic nucleus (STN) for Parkinson's patients and posterior globus pallidus internis (GPi) for dystonia patients. All procedures were considered to be technically successful; however, one procedure was halted after insertion of the first electrode due to the presence of a small hemorrhage that was later found to be asymptomatic. Procedures times, measured from skin incision to closure, averaged 216±22 minutes for bilateral and 182±47 minutes for unilateral procedures over the last 14 surgeries.

Mean radial error (Figure 1) on initial stylet insertion was 1.2 ±0.6 mm, (range: 0.1 - 2.8 mm). Adjustments to the initial alignment, performed prior to stylet insertion, were made in 39% of cases based on the confirmation scans. Accuracy in these cases was 1.1 ±0.7 mm, which was not significantly different from studies where no alignment adjustments were necessary. A single brain penetration was made in 37/41 electrode insertions and two penetrations were required in the remaining four (average number of brain penetrations = 1.1). In the four cases where two brain penetrations were necessary, stylet insertion was aborted after partial insertion in three cases and full insertion in the other. Accuracy when more than one brain penetration was necessary tended to be inferior (1.8+/-0.9 mm).

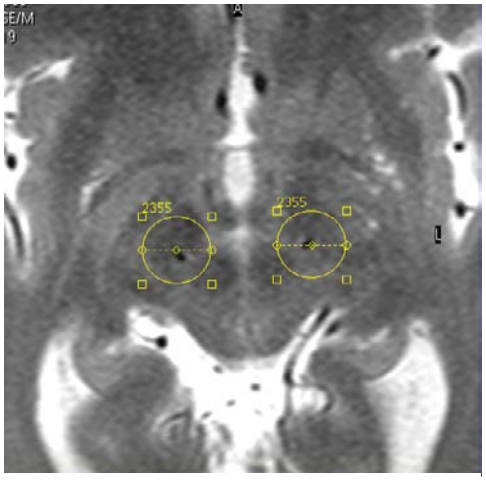

Figure 1 – Targets specified within the STN are shown (ROI centers) superimposed on post-implantation images. The small black signal voids near the ROI centers are the actual stylet positions after MR guided implantation. Radial error is the distance between the prescribed target and actual stylet position in this scan plane.

At six months, the improvements in the UPDRS-III score has averaged 67±19% on medication and 76±13% off medication. These values compare favorably with outcomes based on conventional delivery of DBS electrodes. Two early procedures produced scalp wound infections requiring lead removal and led to adjustments in sterile practice.

Conclusions

The placement of DBS electrodes using direct MR image guidance, and without physiologic assessments, appears to be both accurate and clinically efficacious. The average initial placement error was 1.2±0.6 mm, resulting in a single brain penetration in 90% of the cases. Favorable clinical outcomes have been demonstrated in Parkinsonian patient's 6-months post-implantation.