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Original Article

Influence of stereotactic imaging on operative time in deep brain stimulation

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ABSTRACT

Background: Various techniques are used across institutions for implantation of deep brain stimulation (DBS) leads. The most used techniques for each step include preoperative MRI fused to in-frame CT, intraoperative fluoroscopy, and postoperative CT, but postimplantation MRI also is used, as it was at our center. We present the quality assurance study performed at our institution after a change from postimplantation MRI performed across the hospital to postimplantation in room CT.

Methods: Retrospective chart review of 123 patients who underwent bilateral DBS leads placement without same-day generator placement that was performed. The patients were divided by the type of postoperative imaging that was obtained. Patients were excluded if a unilateral lead placement was performed, if the case was a revision of an existing lead or deviated from the normal protocol. Operative room times and procedure times for each group were analyzed with Wilcoxon rank sums test (WRST) to determine any significant differences between groups.

Results: Postoperative MRI was performed for 82 patients, while postoperative CT was performed for 41 patients. A WRST showed a significant reduction in both operative room time (209 min to 170 min, $P < 0.0001$) and procedure time (140 min to 126 min, $P = 0.0019$).

Conclusion: In-room CT allowed for a significant reduction in operative room time. Lower operative room time has been associated with increased patient comfort, and decreased cost. CT did not alter the revision rate for procedures. The significant reduction in procedure time may be attributed to increased team familiarity with procedure over time.

Keywords: Deep brain stimulation, Operative time, Stereotactic imaging

INTRODUCTION

Deep brain stimulation (DBS), a common neurosurgical procedure that has been in practice since the 1980s, is commonly used to treat diseases such as Parkinson's disease (PD), essential tremor (ET), and dystonia. Innovations in surgical technology, including improvements in neuroimaging and stereotactic navigation, have led to a diversity of methodology for implantation. Surgeons vary in their preferred technique for implantation of DBS systems. An international survey in 2013 indicated that a stereotactic approach using preoperative MRI fused with CT in-frame, intraoperative fluoroscopy, and postoperative CT was the most

frequently used technique.[1] Image-verification of lead placement before conclusion of surgery is preferred at some centers.[1,3] In other theatres, postimplantation imaging is obtained in the postoperative period.[1,5,8] Each of these options offer advantages as well as disadvantages. For example, postoperative CT can be obtained more quickly than an MRI, but may display image artifacts resulting in less informative imaging. Postoperative MRI may provide a more detailed image at the cost of time. Intraoperative CT or MRI may prolong operative time, but allow for immediate revision if required. Delayed CT or MRI may reduce the shift due to edema, pneumocephalus, and loss of CSF at the time of surgery and more precisely provide the location of the lead long term. In some cases, MRI may not be possible due to imaging-related device safety concerns.[7,9] When the clinical outcomes are relatively comparable, the imaging modality itself may be less important. Therefore, developing a surgical strategy that reduces operative times may be of utmost importance, since it has been linked to decreased infection rates, lower patient costs, and increased patient comfort.[4,6]

In 2017, in efforts to increase patient comfort and workflow efficiency, a change was made to the standard DBS operation at our institution. As with all changes, quality assurance studies should be performed along the way to verify the technique provides the desired effects without causing unexpected complications.

MATERIALS AND METHODS

Patients at the University of Arkansas for Medical Sciences implanted with DBS with neurosurgeon EP underwent a two-stage procedure with awake, frame-based intracranial lead placement in stage 1 and implanted pulse generator placement in the second stage generally 7 days later. Procedures were similar for all indications and targets. The faculty surgeon was assisted by rotating resident surgeons during all cases. For intracranial lead placement, the patient arrived in the preoperative suite early on the morning of their operation. While in the preoperative suite, a Leksell (Elekta, Stockholm, Sweden) stereotactic frame was applied under local anesthetic. The patient was transported to the MRI suite for stereotactic image acquisition. The patient returned to the preoperative suite, while the neurosurgeon performed stereotactic planning. Once frame-based coordinates were obtained, the patient was brought into the operating room and positioned supine on the operative table. The frame was set to the first side coordinates. The patient was prepped and draped in sterile fashion and local anesthetic infiltrated at the incision sites. The incision was made, burr hole drilled, and outer ring of the burr hole fixation device placed in usual fashion. An impedance electrode was passed to target checking impedances along the planned trajectory. The lead was advanced to target. Fibrin sealant was inserted into the burr hole and the center locking mechanism of burr hole fixation device used to secure the lead. The lead was connected to a macrostimulation platform. The neurosurgeon then proceeded to the side of the patient to perform intraoperative testing. The lead was tested with a 0–3+, 60 mcs, 130 Hz configuration. The patient was tested just after implantation, and at increments of 0.5 V or smaller until clinical side effect was appreciated or until 5 V was reached. If testing reached clinical side effect at too low an amplitude, the lead was repositioned to a more appropriate target and macrostimulation repeated. Once the lead was in desired position, a fluoroscopic image was taken, the stage disassembled and another fluoroscopic image obtained to ensure the lead did not migrate. The frame was then positioned to the coordinates for the contralateral side, where the process was repeated. Once both leads were in place, proximal lead boots were placed and the two proximal leads tunneled under the galea to the parietal region of the desired side. The incisions were irrigated well and closed. The frame was released from the bed and the patient transferred to a stretcher. In the surgical protocol for cases before 2017, the patient was transferred across the hospital to the MRI scanner, where a stereotactic image was obtained. Once the leads were verified to be in desirable location, the operative room was called and the staff allowed to break down the field. In the event, the lead was not in a good position, the patient was transported back across the hospital to the operating room and the lead revised.

In 2017, the postimplantation imaging protocol changed with the acquisition of an intraoperative CT scanner. Instead of transporting the patient across the hospital for a stereotactic MRI, the patient's head contained in the Leksell frame was detached from the bed, the regular head extension of the operative table was attached to support the patient and the Mayfield frame removed from the bed. The intraoperative mobile CT scanner was positioned over the patient. The CT localizer box was attached to the frame and a stereotactic CT obtained. Lead position was checked against the planned trajectories, and if the leads were in a desirable place the frame removed and the patient transported to the recovery room. In the event, the leads were not in a desirable place, the head extension of the bed was removed, Mayfield frame reattached, and the lead revised.

In December 2018, we performed a quality assurance study to ensure that the new technique was providing the desired benefit of efficiency without any unwanted complications and used SQUIRE guidelines to report our findings.[8] The Hospital's Institutional Review Board (IRB) approved a prospective database for research purposes in 2011 and waived the need for informed consent for this specific retrospective analysis within the database. The IRB approved access of the database to identify patients treated

between May 2014 and November 2018. An anonymized and retrospective chart review was performed for 141 patients. Data were extracted and pooled into our institution's electronic data capture software (Research Electronic Data Capture, Vanderbilt University). This information included demographics (surgery date, age, and gender), DBS planning and confirmation imaging modalities (either MRI or CT), patient diagnosis (PD/ET/dystonia), as well as DBS target (STN/GPi/VIM). Patient charts were also reviewed for any indications over the 4.5-year study period of complications such as postoperative infection, skin erosion, or need for lead revision. The patient consent was waived because it did not impact the course of patient treatment.

Patients were divided into two main groups based on pre- and postoperative imaging modalities: MRI-verified and CT-verified. A total of 123 patient cases were reviewed after exclusion of unilateral cases, cases where generator and extension placement were completed during the same procedure, lead revisions, and a case where revision was required after MRI showed a misplaced lead, due to the expected significant variance in operative times in these instances. For purposes of this study, the operative room time was recorded in minutes from the time the patient entered the room until the operative room staff was released to start cleaning the room. The procedure time was recorded in minutes from the time of incision to the time of closure. Wilcoxon rank sum tests were used to compare the imaging modality groups with respect to operative room time and procedure time. Due to the similarity in procedure between targets and diseases and to maintain adequate statistical power, no sub-analysis was done based on target or disease.

RESULTS

Of the 123 patients meeting inclusion criteria in the 54-month study period, postoperative MRI was obtained for 82 patients and postoperative CT for 41 patients. There were no statistical differences in sex or age between the groups [Table 1]. The distribution of diagnosis and targets between groups is shown in [Table 1]. In the MRI group, median operative room time was 209 min, with a procedure time of 140 min. The CT group had significantly shorter operative room times and procedure times [Table 1]. Operative room time was 170 min ($P < 0.0001$) and procedure time 126 min ($P = 0.0019$) [Figure 1]. The 30-day, 3-month, and lifetime complication rates were not statistically different between groups [Table 1]. In the MRI group, there were three infections at 30 days, three new infections at 3 months, and one new infection at 10 months. In the CT group, there were three infections by 3 months and no delayed infections. There were no early erosions in the MRI group, compared with two in the CT group. Three erosions developed at 3 months, another developed at 8 months, and the most delayed erosion developed at 3 years postimplant in the MRI group. Two erosions developed within the 1st 30 days in the CT group, two further erosions within the 1st 3 months and 1 additional erosion at 4 months. In the MRI group, two lead revisions were performed at 3 years for fracture and loss of effect, respectively. No lead revisions were performed in the CT group. No hemorrhages occurred in the MRI group. In the CT group, there was one symptomatic tract hemorrhage at the time of surgery.

DISCUSSION

Operative technique for placement of DBS systems varies greatly between institutions. Many of these techniques will result in similar procedure accuracy, safety, and clinical outcomes. Nuances of procedures have been debated at length.[12] Ultimately institutional factors around technique feasibility will influence the surgical strategy. In 2017, our institution adopted a technique for postimplant lead verification using the mobile CT scanner. We found that the postimplant CT images would allow verification of lead accuracy without transporting patients across the hospital to the MRI suite. We acknowledged a tradeoff: the intraoperative CT images do not yield image quality to detect small tract hemorrhages or direct visualization of the target nuclei that MRI would. The first few patients were imaged with both CT and MRI to assure that the verification with the CT was accurate using local imaging protocols. This CT imaging technique avoids events that extend operative case time related to MRI, as illustrated in the case of one patient excluded from our analysis who required lead revision after the MRI detected a Z-axis lead migration that occurred after the concluded intraoperative fluoroscopy and closure of skin. This patient required two transports across the hospital to MRI and resulted in an operative room time of 331 min. With the new CT verification strategy, the patient's lead migration would be detected faster with the patient still on the operative table.

Our data reveal that the change in lead verification procedure has meaningfully shortened operative room time and procedure time. There was a significant reduction in operative room time (209 min to 170 min, $P < 0.0001$). The procedure time reduction (140 min to 126 min, $P = 0.0019$) is likely a result of improved efficiency as operative room staff gained familiarity with the procedure over time, since there was not a change to the overall surgical technique. There remains a 25 min difference between reduction in procedure time and operative room time that we believe is a direct result of the change in lead verification procedure related to transport and imaging time. No direct comparison of patient comfort can be made based on the retrospective data set; however, one can surmise that shorter operative room time in an awake patient without transport across the hospital would be more

Table 1: Summary of demographics, medical characteristics, and procedure times.

Variable	Confirmation modality		*P*-value
	MRI (*n*=82)	CT (*n*=41)	
Demographics			
Age†	66.0 (59.0, 71.0)	65.0 (59.0, 73.0)	0.8614
Female‡	43.9% (36)	34.1% (14)	0.3349
Diagnosis			
Tremor‡	39.0% (32)	34.1% (14)	0.6939
Parkinson‡	62.2% (51)	65.9% (27)	0.8428
Target			
GPI‡	19.1% (16)	36.6 (15)	0.0488
STN‡	41.5% (34)	26.8% (l1)	0.1641
VIM‡	39.0% (32)	36.6% (15)	0.8458
Procedure time			
Room†	209.0 (192.8, 226.0)	170.0 (1620, 180.0)	<0.0001
Operation†	1400 (123.0, 166.8)	126.0 (120.0, 135.0)	0.0019
Complications			
1 month‡	3.7% (3)	73% (3)	0.3992
3 month‡	11.0% (9)	17.1% (7)	0.3978
Lifetime‡	17.1% (14)	19.5% (8)	0.3045

†Median and interquadtile range. *P*-value from Wilcoxon rank sum test. ‡Percent and count. *P*-value from Fisher's exact test

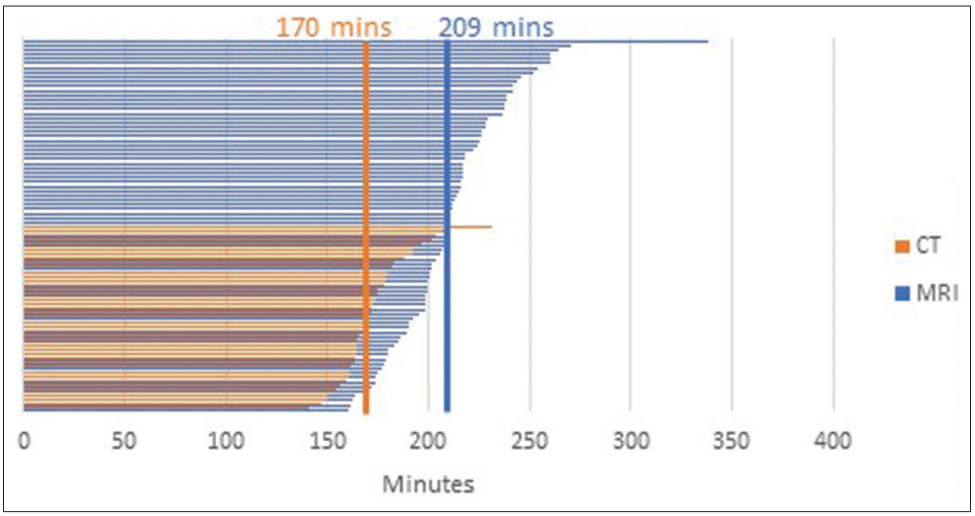

Figure 1: Individual case times for MRI (blue) versus CT (orange) operative room times. Average operative room time for CT-verified cases was 170 min, while for MRI, it was 209 min.

comfortable. Operative room and anesthesia staff members have often expressed to the neurosurgeon their preference for the in-room CT over transportation to MRI.

In adopting any new technique, careful evaluation of changes in patient quality and outcomes should be assessed. The current quality assurance study was performed to assess the benefit in efficiency from our postimplantation imaging change as well as relieve concerns over the change in imaging modality and information yield. We were reassured that lead visualization and intracranial hemorrhage concerns were not impacted with the use of CT. Lead accuracy was not different in the two populations. We had expected that the reduction in transport across the hospital with fresh incisions and shorter operative time might decrease the long-term complication rate, but this did not significantly change (17.1% vs. 19.5%, $P = 0.8045$). The smaller size of the CT-imaged population did not statistically impact this analysis. The natural history and lifetime failure rate for DBS, including infection and mechanical complications in our series, are slightly higher than for other series.[11] Factors such as surgical candidate selection, postoperative wound care, patient activity, and progression of symptoms

contribute to the long-term complication rate.[2,10,11] The rate of intraoperative hemorrhage and pneumocephalus is notably low, mitigating the argument for use of higher-resolution imaging as verification. There is a low risk of lead-related hemorrhage, and the option for further imaging after departure from the operating room remains when there is clinical concern. The cause for early erosions in the CT group is unknown, but could be related to thin skin with poor tissue planes for closure, tension on the wound due to the bulk of the burr hole cap under the scalp, or poor closure technique by closing surgeon. Each erosion case was treated with irrigation and debridement and surgical revision of the scalp with retention of the implants.

Reduction in operative times may translate into improved operative room efficiency and utilization. In some institutional settings, this may realize financial savings related to lower case time costs. More likely, the shorter DBS operative time could contribute a revenue benefit to the institution through the opportunity to increase operative case volume. The improvement of comfort of the experience to patients and the diminished challenges to the operating room staff and clinician team through eliminated transport across the hospital complex cannot be quantified using the current retrospective analysis, but these elements are important quality improvements. Our analysis confirmed that the reduction in operative room time is worth the change in technique, enabling improved utilization of the operative room, and staff resources. This is a quality assurance study evaluating the effects of a change in operative procedure at a single institution. There is no blinding and potentially a Hawthorne effect might bias the data; although our retrospective study was conceived after CT had been in use for over a year, the surgical team might have altered behavior in some of the latter cases in the series based on awareness of the study. We recognize that it is difficult to generalize the findings of our study to other institutions. We encourage other institutions who may be contemplating similar changes to conduct a quality assurance study that will like ours validate their efforts.

CONCLUSION

In-room CT has proven to be a useful tool in reducing operative room time for placement of bilateral DBS leads. Although the image information obtained is less detailed than with MRI, the verification of lead placement is accurate. The change in imaging technique does not appear to affect the overall complication rate. Reductions in operative times associated with the optimal lead-verification imaging techniques may help neurosurgical teams develop a more efficient operative plan for patients who undergo DBS, resulting in financial benefit to the institution, improved patient comfort, and clinician satisfaction.

Declaration of patient consent

Patient's consent not required as patients identity is not disclosed or compromised.

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Nil.

Conflicts of interest

Erika Petersen receives consulting and speaking fees from Medtronic, Neuros Medical, Nevro, and Abbott. She also receives research funding from Medtronic, Neuros Medical, ReNeuron, and Nevro. She has stock options in SynerFuse. None of these had any bearing on this manuscript.

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