



Clinical Study

Electromagnetic stereotactic navigation for external ventricular drain placement in the intensive care unit



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ABSTRACT

Placement of external ventricular drains subjects patients to risks of injury, intracerebral hematoma, and failure from improper placement. Traditional free-hand placement has been associated with a relatively frequent occurrence of these complications. We sought to assess the accuracy of ventriculostomy when performed using image-navigation technology in the intensive care unit (ICU). Thirty-five patients were consecutively enrolled in a single-arm trial evaluating the accuracy and complications from ventriculostomies performed at the ICU bedside using electromagnetic image guidance technology. The duration of any additional imaging and the length of the total procedure were also quantified. There were no unacceptably placed ventriculostomy catheters; only two catheters were not perfectly placed in the ipsilateral frontal horn. There was only one patient with tract hemorrhage. The use of image guidance technology added approximately 36 minutes to the time from when the need was identified to when successful drainage was achieved ($p = 0.002$), but added only 4 minutes of operative time ($p = 0.12$). Accuracy of placement demonstrated a statistically significant improvement in the accuracy of ventriculostomy over historical data. There were two registration failures which were converted to the traditional technique; there were no other complications arising from the use of image-guided technology. Electromagnetic image guidance is feasible and accurate. Image guidance technology eliminated unacceptably placed catheters and may reduce the risk of catheter-associated intracerebral hemorrhages.

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1. Introduction

Placement of an external ventricular drain (EVD) is essentially a blind procedure based on landmarks, where there are small but real risks of neurologic injury. Rates of inappropriately located ventricular catheters range from 6% to 20%,^{1–5} with a frequency of approximately one in eight patients (11–13%) in larger series that specifically addressed location of catheters.^{6–8} The large number of EVDs placed annually for a variety of indications will inevitably also produce a substantial number of unintended injuries, repeated procedures, and delays in life-saving therapy. In 2006, according to procedural data published by the American Association of Neurological Surgeons, 42,446 intracranial pressure (ICP) monitoring procedures were performed, which, even at the most conservative estimates, equates to thousands of inappropriately placed catheters. Despite adequate training and significant experience, problems with placement do occur.

There are many factors that can make the accuracy of traditional free-hand passage of a semi-rigid EVD problematic. First,

there is the challenge of aberrant anatomy, as the brain may be shifted from trauma or be abnormal due to the underlying pathology. Second, there may be altered resistance or elastance of the ependyma from congenital scarring or increased turgidity of the brain due to elevated intracerebral pressures. This may eliminate tactile confirmation of successful placement. Third, ventricular volume may be reduced as a consequence of displacement by clotted intraventricular blood, small ventricles in pediatric patients, or in those with swollen parenchyma.

Use of computer-assisted stereotactic navigation can help overcome these problems, but typically requires the use of an operating room. We assessed the feasibility and efficacy of EVD placement with stereotactic navigation using a portable, next-generation electromagnetic (EM) system deployed in our intensive care units (ICU). This system is more compact than an optical system and does not require head fixation to an external frame. Our primary question was not whether placement could be more accurate, but rather if error could be eliminated and how much additional time was required. The study was designed to look at benchmarks of performance in placement of EVDs both immediately prior to the introduction of stereotactic navigation technology and then during a trial consisting of 50 consecutively enrolled patients for whom consent could be obtained to place EVDs utilizing stereotactic navigation technology.

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2. Materials and methods

2.1. Study design and patient demographics

Approval was obtained from the St. Joseph's Medical Center Institution Review Board to conduct this study. As part of the consent process, we required that either the patient was of cognitive ability to consent or that the patient's power of attorney or lawful decision maker was physically present in the hospital for obtaining research consent.

Study inclusion criteria included any patient requiring ventricular drainage or ICP monitoring for any condition. Exclusion criteria focused on basic safety and were not designed to exclude any patient based on possible poor outcome of the primary condition. The decision regarding whether an individual patient was medically safe enough to receive an EVD at all, for example, as a consequence of warfarin-related coagulopathy or thrombocytopenia, was left to the discretion of the practicing neurosurgeon. Patients initially deemed to be acceptable candidates for EVD placement were excluded if they were medically or neurologically judged to be too high a risk to allow for the additional time necessary to place the EVD using stereotactic navigation and/or for the delay involved in obtaining a stereotactic imaging study. Patients were also excluded if informed consent could not be granted within an acceptable timeframe. As a consequence of the urgency of EVD placement in most patients, less than 10% of eligible patients could be enrolled in the trial. A consecutive trial was felt to not be in the best interest of patients and to not reflect the likely use of the technology in the real world. No pediatric patients were enrolled.

Twenty patients were prospectively tracked to establish procedure time benchmark measurements, referred to as the "pre-trial period". This number of patients was not designed to be powered as a case-control to assess outcomes nor complications. Over the following 8 months, 35 patients consented and were consecutively enrolled in this prospective, single institution trial. The trial was stopped in advance of reaching the goal of 50 patients due to difficulties in obtaining consent in the majority of eligible patients. The most common indication for EVD placement was aneurysmal subarachnoid hemorrhage, followed by spontaneous intraparenchymal hemorrhage and hydrocephalus. Other indications included subarachnoid hemorrhage of unknown origin, tumor, dural arteriovenous fistula, hydrocephalus, and stroke.

2.2. Study procedure

Work-up with standard ocular-sparing gantry angled 5-mm slice thickness CT imaging was used to evaluate the indication for EVD placement, such as hydrocephalus or trauma requiring ICP monitoring. Frameless stereotactic guidance requires a higher resolution CT scan that includes facial structures to allow for surface registration. Thus, all patients had an additional 0.6-mm slice thickness CT scan performed, frequently with intravenous contrast to assess for vascular pathology when indicated. This high-resolution CT scan was then transferred across to the Digital Imaging and Communications in Medicine network to be reformatted for use in frameless stereotactic navigation.

We utilized the Medtronic S7 platform (Medtronic Sofamor Danek, Inc., Memphis, TN, USA) for frameless stereotactic navigation in conjunction with an EM reference system. The EM system utilizes a dynamic reference frame that is affixed to the patient's forehead with an adhesive backing as opposed to an optical reference system which requires rigid fixation to the skull. The EM system consists of the dynamic reference frame, registration probe, ventricular catheter EM stylet, and an EM antenna. A unique property

of the EM system is that the tip of the stylet is tracked, rather than the handle as is the case for most optical reference systems.

Prior to sterile field preparation, the contours of the patient's face and scalp were surface registered to the patient's high-resolution CT scan using the S7 registration software by a registered nurse (RN) or patient care technologist (PCT). These individuals had previously undergone hands-on training in separate sessions with a Medtronic representative. Neurosurgical residents also underwent formal hands-on training with the S7 platform for familiarity and advanced-level troubleshooting advice. Surface registration was verified by external anatomical landmarks by the RN or PCT as well as the neurosurgical resident performing the procedure.

Patients were sterilely prepped as per our ICU protocol described in previous studies.^{9,10} The placing surgeon established an entry point either by manual measurement of Kocher's point^{11,12} or by use of the navigation stylet. A small stab incision was made, followed by a 6-mm twist drill craniotomy. A sharp dural opening was made. A clindamycin and rifampin-impregnated catheter (Bactiseal catheter; Codman & Shurtleff, Inc. Raynham, MA, USA) was then advanced using the EM stylet in the trajectory of the foramen of Monro using the navigation screen as well as the traditionally utilized landmarks of the tragus and ipsilateral medial canthus. Acceptable placement was determined either by sufficient and sustained egress of cerebrospinal fluid (CSF) or acceptable placement based on navigation images. The distal end of the catheter was tunneled subcutaneously 3 to 4 cm to a separate exit site and secured with ligatures. The distal end of the catheter was then connected to a closed drainage system. Patients received a single dose of antibiotics (cefuroxime sodium 1.5 g or cephazolin 1 g) intravenously within 1 hour of initiation of the procedure as per institutional procedure. Patients then received a confirmation CT scan using standard 5-mm thick slices for assessment of the ventricular tip placement, as well as assessment of any potential hemorrhage associated with the passage of the catheter.

All time points of the procedure, starting from the hospital note determining the need for ventricular drainage to the end of the procedure, were recorded by the observing RN or PCT. We measured procedure duration from two different sources: that written by the surgeon in the hospital record and one provided by the assisting RN or PCT. The following durations were calculated as follows: the surgeon's procedure time was the difference between the time noted on the procedure note and the time noted on the initial evaluation note; the RN/PCT procedure time was the difference between when the EVD procedure was requested by the surgeon and when the final suture had been tied; the navigation imaging time was the difference between the time noted when the patient left the ICU to have the high-resolution CT scan and when they returned to the ICU; the prep time was the difference between the time of the start and end of scalp sterile preparation; the procedure time was the difference between when the skin incision was made and when the last suture was tied. The number of passes and complications were also noted by either the surgeon performing the procedure or an RN. Radiographic data, including width of the frontal horns at the level of the foramen of Monro, presence or absence of midline shift, post-procedure hemorrhages, and the Kakarla grade⁷ were recorded separately by the lead author (M.M.), independent of the procedure.

2.3. Statistical analysis

Primary outcomes were compared between the two groups by use of the Fisher exact test for categorical data with two nominal variables, and Student's unpaired two-tailed *t*-test for continuous outcome measures. The number need to treat was calculated as per Sackett and Haynes.¹³

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