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Effect of electromagnetic-navigated shunt placement on failure rates: a prospective multicenter study

Clinical article

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Object. As many as 40% of shunts fail in the first year, mainly due to proximal obstruction. The role of catheter position on failure rates has not been clearly demonstrated. The authors conducted a prospective cohort study of navigated shunt placement compared with standard blind shunt placement at 3 European centers to assess the effect on shunt failure rates.

Methods. All adult and pediatric patients undergoing de novo ventriculoperitoneal shunt placement were included (patients with slit ventricles were excluded). The first cohort underwent standard shunt placement using anatomical landmarks. All centers subsequently adopted electromagnetic (EM) navigation for routine shunt placements, forming the second cohort. Catheter position was graded on postoperative CT in both groups using a 3-point scale developed for this study: (1) optimal position free-floating in CSF; (2) touching choroid or ventricular wall; or (3) intraparenchymal. Episodes and type of shunt revision were recorded. Early shunt failure was defined as that occurring within 30 days of surgery. Patients with shunts were followed-up for 12 months in the standard group, for a median of 6 months in the EM-navigated group, or until shunt failure.

Results. A total of 75 patients were included in the study, 41 with standard shunts and 34 with EM-navigated shunts. Seventy-four percent of navigated shunts were Grade 1 compared with 37% of the standard shunts (p = 0.001, chi-square test). There were no Grade 3 placements in the navigated group, but 8 in the standard group, and 75% of these failed. Early shunt failure occurred in 9 patients in the standard group and in 2 in the navigated group, reducing the early revision rate from 22 to 5.9% (p = 0.048, Fisher exact test). Early shunt failures were due to proximal obstruction in 78% of standard shunts (7 of 9) and in 50% of EM-navigated shunts (1 of 2).

Conclusions. Noninvasive EM image guidance in shunt surgery reduces poor shunt placement, resulting in a significant decrease in the early shunt revision rate. (DOI: 10.3171/2010.3.JNS091237)

Key Words • hydrocephalus • ventriculoperitoneal shunt • electromagnetic neuronavigation

OVER 3000 shunt procedures are performed each year in the United Kingdom and over 18,000 in the US.2 As many as 40% of shunts fail in the first year,4,8 most commonly due to proximal obstruction with ingrowth of choroid plexus or gliosis around the ventricular catheter.7,13 Each episode of shunt malfunction carries the risk of additional morbidity or death to the patient and adds to health service costs.

To what extent ventricular catheter placement determines future shunt failure has not yet been determined, with the exception that a catheter that misses the ventricle entirely will fail immediately. Drake and Sainte-Rose5 reported that approximately 4% of ventricular catheters are misplaced, failing to cannulate the ventricle completely. Despite published case series indicating lower rates of shunt failure using endoscopically guided ventricular catheter insertion,11,15 the endoscopic shunt insertion trial reported that shunt failure rates were not significantly different between the endoscopic and control groups at 1 year.9 Placement of the tip of the ventricular catheter away from the choroid plexus did not differ significantly between groups, despite placement under direct vision in...
the endoscopic group. In that study the position of the bur hole and catheter trajectory were not navigated and continued to be based on anatomical landmarks, which may have adversely affected final ventricular catheter position.

The development of neuronavigation in the field of neurosurgery is changing, with a move toward improved accuracy in all fields. Most optical tracking systems are not easily adaptable to CSF diversion procedures, mainly due to the need for rigid head fixation. The use of noninvasive magnetic tracking eliminates this drawback, providing rapid navigation at depth, without line-of-sight issues. We conducted a prospective cohort study of de novo shunt placement, comparing standard placement using anatomical landmarks with EM image-guided placement, to determine optimal ventricular catheter placement and whether catheter position affects shunt failure rates.

**Methods**

**Patient Population and Study Design**

The study was conducted at 3 European neurosurgical centers in the United Kingdom and The Netherlands, including both adult and pediatric patients. Between September 2007 and May 2008, a consecutive cohort of patients undergoing de novo standard shunt placement was included. Subsequently, all centers changed to EM-guided shunt placement, and a cohort of patients who received navigated shunts between May 2008 and May 2009 were added to the study. Patients with hydrocephalus of any origin and normal size or enlarged ventricles undergoing de novo shunt placement were included. Patients with slit ventricles, and those with abnormal ventricular anatomy in which image guidance is used in routine clinical practice, were excluded. Patients undergoing shunt revision were also excluded.

The study protocol aimed to prospectively follow all patients with shunts until shunt failure or 1 year, whichever occurred sooner. The primary outcome measure was grade of shunt placement. The secondary outcome measure was shunt failure, as defined by any subsequent shunt procedure and categorized into proximal obstruction, valve obstruction, distal catheter obstruction, overdrainage, and infection. Early shunt failure was defined as failure occurring within 30 days of insertion. Statistical analysis was performed using SPSS Version 16 (SPSS, Inc.).

**Surgical Technique**

Shunt procedures were performed by surgeons of varying training levels and seniority. The type of valve and catheter used was based on surgeon preference. In the standard placement cohort, bur hole placement was determined by ventricular anatomy and based on anatomical landmarks. Ventricular catheter length was based on surgeon judgement. In the EM-navigated shunt cohort, the StealthStation Axiem navigation system (Medtronic, Inc.) was used. This system utilizes a transmitter coil array to encompass the head within a cubital low-energy magnetic field, to provide a frame of reference to determine the location of a pointer in space. A DRF applied to the scalp identifies the location of anatomy within the frame of reference (Fig. 1a). The head does not require rigid fixation and can be moved at any time during a procedure. The reference frame used at our institution (a stick-on design) does not require additional skin incisions, allowing entirely noninvasive navigation. The bur hole and catheter trajectory were planned preoperatively in 3 planes to achieve a catheter tip position that was free-floating in CSF, equidistant from the ventricular walls and away from the choroid plexus (Fig. 1c). Either CT scanning or MR imaging was used for volume imaging. The EM styllet was used as the trocar to insert the ventricular catheter to the preplanned length (Fig. 1b). The rest of the shunt procedure was the same in both groups.

**Grading of Shunt Placement**

All patients in both study groups underwent postoperative imaging (either CT or MR imaging) within 72 hours of shunt placement. All shunts were graded by the 2 senior authors (T.B. and C.L.M.), blinded to patient name and outcome, according to the following protocol developed for this study (examples in Fig. 2): (1) Grade 1, catheter tip floating in CSF equidistant from ventricular walls, away from choroid and a straight trajectory from the bur hole; (2) Grade 2, catheter tip touching ventricle wall or choroid; and (3) Grade 3, part of catheter tip within parenchyma or failure to cannulate ventricle completely.

**Results**

The baseline characteristics of the study patients are shown in Table 1. There were 41 standard shunts inserted and 34 navigated shunts inserted. In all cases, distal drainage was to the peritoneum. Forty-nine percent of the patients were children or neonates in the standard shunt placement group, as were 44% in the EM-navigated group. All patients with standard shunt placement were followed-up for 12 months or until shunt failure. Patients in the EM-navigated shunt group had a median follow-up of 6 months. Early shunt failure data are available for both cohorts.

**Grade of Shunt Placement**

Table 1 demonstrates the grade of shunt placement achieved in each group. Twenty-five (74%) EM-navigated shunts were free floating in CSF (Grade 1) compared with 15 standard shunts (37%; p = 0.001, chi-square test). Eighteen shunts were classified as Grade 2 (touching the ventricular wall) in the standard group compared with 9 in the EM-navigated group (p = 0.11, chi-square test). There were no Grade 3 placements in the navigated group. Eight shunts (19.5%) were determined to be Grade 3 in the standard group (p = 0.005, Fisher exact test).

**Early Shunt Failure**

Nine of the 14 shunt failures in the standard group occurred within 30 days of surgery (Table 2). Only 2 shunt failures occurred within 30 days in the EM-navigated group, reducing the 30-day revision rate from 22 to 5.9%.
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The shunt failures within 30 days were due to proximal obstruction in 78% of standard shunts (7 of 9 failures) and 50% of navigated shunts (1 of 2 failures; Table 2).

**Overall Shunt Failure**

Overall there were 14 shunt failures in the standard group (34%) compared with 6 in the EM-navigated group (17.6%; *p* = 0.107, chi-square test). In Fig. 3 left, the Kaplan-Meier survival curves for both standard and EM-navigated shunt placement are shown. There was no significant difference in shunt survival (*p* = 0.165; log rank 1.925). There were 3 infections in the standard group (7.3%), compared with 1 (2.9%) in the navigated group.

**Failure Related to Shunt Placement**

Table 2 lists each shunt failure in both study groups. Figure 3 right demonstrates the Kaplan-Meier survival curves for the standard shunts according to grade of placement. Eight (19.5%) of the standard shunts were Grade 3 and 75% of these (6 shunts) failed. There was a statistically significant difference in shunt survival between Grade 1 and Grade 3 shunts (*p* = 0.003, log rank 8.629) and between Grade 2 and 3 shunts (*p* = 0.004, log rank 8.500). The difference in shunt survival between Grade 1 and 2 placements was not significant (*p* = 0.871, log rank 0.026).

Eliminating Grade 3 shunts reduces the overall failure rate of standard shunts from 34 to 24%. In the EM-navigated group most shunt failures were Grade 1 shunts and related to valve dysfunction or infection. Shunt failure due to proximal obstruction occurred in 7 patients in the standard group compared with 2 proximal catheter obstructions in the EM-navigated group. The single proximal obstruction within 30 days in the EM-navigated group was secondary to a hematoma along the shunt track. The rate of proximal obstruction alone falls from 17 to 6% using EM-navigated placement (*p* = 0.129, Fisher exact test).

**Pediatric Shunt Failure**

In the standard group there were 20 patients < 18 years of age. Six shunts (30%) in this group failed; 4 of these were early failure due to proximal obstruction. In the EM-navigated group there were 15 children, and 3 shunts (20%) failed in this group. These 3 failures occurred because of infection in 1 patient and valve blockage in 2 patients. There was no significant difference in overall shunt failure in the pediatric cohort using EM-navigated shunt placement (*p* = 0.39, Fisher exact test).

**Discussion**

This study has shown that the number of shunts placed into an optimal position within the ventricle can be improved significantly using image guidance. The in-
The incidence of poor placement is reduced using this method and consequently the incidence of early shunt revision is reduced significantly, from 22 to 5.9%. Misplacement of the ventricular catheter outside the ventricle can be eliminated using EM navigation. Although the median follow-up period in the EM-navigated group was only 6 months, we opted to report our results given that no standard shunts failed between 6 months and 1 year and because of the significance of the reduction in the early revision rate.

Published single-institution case series from our group and others have demonstrated the utility of noninvasive EM navigation in accurately placing ventricular catheters. Azeem and Origitano reported on a retrospective series of 34 ventricular catheters placed using EM guidance, of which 24 were routine ventriculoperitoneal shunt procedures with enlarged ventricles. These authors reported no episodes of proximal failure in this group, but the length of follow-up was not specified. They compared these results with those from a cohort of freehand-placed shunts and found an 18% proximal obstruction rate with freehand placement, which is comparable to our 22% early failure rate in the standard shunt group.

Although the overall reduction in shunt failure from 34 to 17.6% does not reach statistical significance, there was a large reduction in proximal shunt obstruction from 17 to 6%. Valve dysfunction and infection contribute significantly to shunt failure and remain a problem in both study groups. Eliminating proximal obstruction due to poor placement appears to expose other mechanical elements of the system to failure, as our overall shunt survival is surprisingly not significantly different between the study groups.

A proportion of all shunts are poorly placed when inserted using the freehand technique, requiring immediate revision and exposing patients to additional risk and morbidity. In the modern era of noninvasive neuronavigation, we believe this is unacceptable. Our study demonstrates that with the use of image guidance, the incidence of a Grade 3 shunt placement (part of catheter tip within parenchyma or failure to cannulate ventricle completely) can be eliminated, significantly reducing the immediate revision rate due to poor placement. Although the use of image guidance for shunt placement adds cost to the procedure, the cost in our countries of a shunt revision is 10 times greater than the cost of a navigation stylet.

Interestingly, 2 of the 8 Grade 3 catheter placements have survived, suggesting that even with a limited portion of the ventricular catheter within a CSF-containing space, this placement provides adequate drainage for a minority of patients.

There have been several criticisms of the use of image guidance in routine shunt surgery, in addition to cost implications. Potential issues include time added to procedure and the need for head fixation, with the risk of pin-related complications in children and restriction of movement during shunt tunnelling. The use of EM technology, using a stick-on DRF, avoids the problem of additional incisions and does not require rigid head fixation. Using skin tracer technology for registration eliminates the need for the application of fiducials prior to volume
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scan acquisition, so diagnostic multislice imaging can be used for navigation, avoiding the need for additional volume imaging. Where additional imaging is required, volume CT necessitates additional radiation dosage. At our institution, the Siemens protocol for a volume scan only increases the radiation exposure from 1000 mSv to 1080 mSv. The use of MR volume imaging also avoids this issue. We have not found that the use of navigation adds significant additional operative time to the procedure. Approximately 5 to 10 minutes additional time is required for the setup and registration.

A randomized controlled trial of navigated shunt placement would provide the gold-standard evidence to support or refute the use of image guidance in routine shunt placement. If the magnitude of the reduction in 30-day failure rate is correct, for an adequately powered study to detect reduction from 22 to 6% (power 80%, \( \alpha = 0.05 \)) would require a total of 150 shunts. However, given the results from the current study, it is uncertain whether a randomized trial is required or would receive ethical approval given the clear advantage in preventing poor shunt placement. Yet only such a multicenter study with a longer duration of follow-up would be able to determine the true impact of EM navigation and initial optimal shunt placement on shunt survival in the long term.

There are several limitations to this pilot study. First, in the pediatric cohort, particularly the neonates, the large ventricular size and propensity of the ventricles to collapse after shunt insertion means a Grade 2 placement was almost inevitable. Although the study cohorts are well balanced in terms of age, because this is a consecutive cohort, no attempts have been made to balance the groups in terms of ventricular size. In addition, whereas grading of shunt placement was blinded to patient details and outcome, some (but not all) of the study population was treated by the grading clinicians, therefore blinding to study cohort may not have been achieved. However, it was our intention that the grading system be so objective that bias could not have significantly affected the outcome.

Published research and audit (review of practice and outcomes) relating to shunt surgery strives to reduce the frequent complications of mechanical obstruction and infection. One obvious, but rarely studied, target is eliminating catheter misplacement and early shunt revision. Not only is an early shunt revision due to improper catheter placement avoidable, it also exposes the patient to other problems, such as infection with all its potential adverse complications.

Over the past few decades, using navigation for craniotomies has become almost routine practice in most developed countries. With the availability of a noninvasive reproducible form of navigation for shunt placement, which can prevent catheter misplacement and eliminate one cause of shunt revision, it is difficult to argue against implementing its usage for all shunt placements in addition to small and slit ventricles.

Conclusions

The use of noninvasive image guidance in routine shunt surgery can eliminate poor shunt placement, resulting in a dramatic reduction in immediate and early shunt revisions rates, which are almost always secondary to proximal obstruction in this group. This study highlights the application of noninvasive electromagnetic neuronavigation in all routine procedures to eliminate avoidable complications.

Disclaimer

The authors report no conflict of interests concerning the materials or methods used in this study.

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