J Neurosurg 98:284–290, 2003

Lack of benefit of endoscopic ventriculoperitoneal shunt insertion: a multicenter randomized trial

JOHN R. W. KESTLE, M.D., JAMES M. DRAKE, M.D., D. DOUGLAS COCHRANE, M.D., Ruth Milner, M.Sc., Marion L. Walker, M.D., Rick Abbott III, M.D., and Frederick A. Boop, M.D. for the Endoscopic Shunt Insertion Trial participants

University of Utah, Primary Children's Medical Center, Salt Lake City, Utah; University of Toronto, The Hospital for Sick Children, Toronto, Ontario; University of British Columbia, British Columbia's Children's Hospital, Vancouver, British Columbia, Canada; Beth Israel Medical Center, New York, New York; and University of Tennessee, Memphis, Tennessee

Object. Endoscopically assisted ventricular catheter placement has been reported to reduce shunt failure in uncontrolled series. The authors investigated the efficacy of this procedure in a prospective multicenter randomized trial.

Methods. Children younger than 18 years old who were scheduled for their first ventriculoperitoneal (VP) shunt placement were randomized to undergo endoscopic or nonendoscopic insertion of a ventricular catheter. Eligibility and primary outcome (shunt failure) were decided in a blinded fashion. An intention-to-treat analysis was performed. The sample size offered 80% power to detect a 10 to 15% absolute reduction in the 1-year shunt failure rate.

The authors studied 393 patients from 16 pediatric neurosurgery centers between May 1996 and November 1999. Median patient age at shunt insertion was 89 days. The baseline characteristics of patients within each group were similar: 54% of patients treated with endoscopy were male and 55% of patients treated without endoscopy were male; 30% of patients treated with and 26% of those without endoscopy had myelomeningocele; a differential pressure valve was used in 51% of patients with and 49% of those treated without endoscopy; a Delta valve was inserted in 38% of patients in each group; and a Sigma valve was placed in 9% of patients treated with and 12% of those treated without endoscopy. Median surgical time lasted 40 minutes in the group treated with and 35 minutes in the group treated without endoscopy. Ventricular catheters, which during surgery were thought to be situated away from the choroid plexus, were demonstrated to be in it on postoperative imaging in 67% of patients who had undergone endoscopic insertion and 61% of those who had undergone nonendoscopic shunt placements. The incidence of shunt failure at 1 year was 42% in the endoscopic insertion group and 34% in the nonendoscopic group. The time to first shunt failure was not different between the two groups (log rank = 2.92, p = 0.09).

Conclusions. Endoscopic insertion of the initial VP shunt in children suffering from hydrocephalus did not reduce the incidence of shunt failure.

KEY WORDS • hydrocephalus • ventriculoperitoneal shunt • endoscopy • randomized trial

H YDROCEPHALUS is a common pediatric disorder⁶ that is usually managed by VP shunt insertion. The failure rate of VP shunts in children is approximately 40% at 1 year after insertion.^{5,9} The most common cause of shunt failure is ventricular catheter obstruction¹⁴ by the choroid plexus.² To minimize this problem, surgeons attempt to place the ventricular catheter away from the choroid plexus (in the frontal horn, above the foramen of Monro, or in the occipital horn),¹⁴ a task most often achieved using anatomical landmarks.

In the early 1990s, fiberoptic endoscopes became available for use in shunt placement surgery. They fit in the ventricular catheter lumen and protrude through a slit in the tip of the catheter. This allows visualization inside the ventricle so that the catheter can be placed away from the choroid plexus.¹⁹ Evidence from uncontrolled series indicates that endoscopic insertion of the ventricular catheter reduces the incidence of VP shunt failure. Crone³ reported a 3% annual shunt failure rate following endoscopic catheter placement, and subsequently, Taha and Crone¹⁵ described their experience with 100 patients. In 68 of these 100 patients, a large (4-mm) endoscope in a peel-away sheath was used to identify the choroid plexus. The scope was removed and the ventricular catheter was threaded down the sheath. In the remaining 32 patients, a tiny endoscope was passed through the lumen of the ventricular catheter for shunt placement. Postoperative imaging demonstrated proper catheter placement in 98% of patients. The mean follow up was 2.5 years and 13 patients (13%) experienced shunt failure.

Manwaring¹¹ reported his experience with more than 200 endoscopically guided procedures. The ventricular catheter placement method was similar to that used by Taha and Crone.¹⁵ The tip of the ventricular catheter was positioned in the frontal horn, at the foramen of Monro, or through the

Abbreviations used in this paper: CSF = cerebrospinal fluid; CT = computerized tomography; MR = magnetic resonance; VP = ventriculoperitoneal.

Endoscopic ventriculoperitoneal shunt insertions

foramen into the third ventricle. Postoperative neuroimaging visualized tip positioning at the selected site in 90% of cases. Forty-nine percent of endoscopic shunt insertions and 67% of nonendoscopic ones required revision in the 1st year.

Å series of 37 patients who had undergone shunt placement surgery with endoscopy were compared with 40 randomly selected patients who had undergone surgery without endoscopy.¹⁷ Frameless stereotaxy was used in 12 of the endoscopically assisted cases and in none of the standard shunt placement cases. The first postoperative image was assessed by two independent, nonblinded examiners. The position of the catheter tip was optimal in 34 of 42 endoscopic procedures compared with 17 of 40 standard insertion procedures. Long-term shunt patency was not reported in this study.

There are potential risks associated with endoscopic shunt placement. Taha and Crone¹⁵ found that the operative time was slightly longer when using the endoscope. Manwaring¹¹ attributed a shunt infection to the use of the endoscope. Bleeding, injury to the ventricular wall, hypothalamic dysfunction, eye movement abnormalities, seizures, fluid leak, and cardiac arrest have all been reported as complications of endoscopic neurosurgery at an overall rate of 7 to 8%.^{7,16} Many of these factors are also potential complications of endoscopic shunt placement. In addition, the endoscopic equipment is expensive and disposable.

Based on the suggestive evidence from uncontrolled series, we conducted a randomized clinical trial. Our specific objective was to measure the time to first shunt failure after its placement with the aid of an endoscope and to compare it with the time to first shunt failure after its insertion without an endoscope, in children with hydrocephalus.

Clinical Material and Methods

Patient Characteristics

The study population consisted of 55% male patients with a median age of 89 days. The most common causes of hydrocephalus were myelomeningocele (108 [27%] of 393) and intraventricular hemorrhage (82 [21%] of 393). Thirteen patients had persistent hydrocephalus after undergoing a third ventriculostomy. Baseline characteristics of patients in the study groups were similar (Table 1).

Study Entry and Exclusion Criteria

Patients eligible to enter the study were younger than 18 years of age, had clinically suspected hydrocephalus, were scheduled to undergo a VP shunt insertion procedure, and had ventriculomegaly based on neuroimaging (ultrasonography, CT scanning, or MR imaging studies). Those at risk of an immediate complication or those slated to undergo shunt placement for a condition other than hydrocephalus were excluded. The specific exclusion criteria were: 1) the presence of a previously inserted indwelling shunt; 2) an active shunt, CSF, or abdominal infection; 3) spread of tumor into the subarachnoid space documented on enhanced CT or MR imaging of the head or spine; 4) loculation(s) within the ventricular system; 5) either a Dandy–Walker malformation or an arachnoid cyst as the cause of hydrocephalus; 6) hydranencephaly; 7) severe prematurity with

TABLE 1 Baseline characteristics of 393 patients who underwent placement of a VP shunt

Characteristic	Endoscope (194 patients)	No Endoscope (199 patients)
median age (days)	84	110
sex (% male)	54	55
gestational age (wks)	38	38
birth weight (g)	2920	2960
cause of hydrocephalus		
myelomeningocele	57	51
intraventricular hemorrhage	46	36
aqueductal stenosis	10	19
tumor	9	10
CSF infection	8	8
head injury	5	8
two or more causes	9	8
other	11	16
unknown	39	43
median head circumference (cm)	40	40
previous third ventriculostomy	6	8
previous subcutaneous reservoir	8	11
previous external ventricular drain	20	15
previous subgaleal shunt	7	2
baseline imaging results		
transependymal edema	21	22
intraventricular blood	19	21

thin fragile skin through which a shunt might erode; 8) other systemic disorders that would preclude the insertion of a VP shunt; or 9) other difficulties that would preclude a 1-year follow up. Pediatric neurosurgeons who had performed five or more endoscopic ventricular catheter insertions were eligible for participation in the study.

Treatment Protocol

The shunt insertion procedure was not dictated by our protocol except for the following items: 1) the shunt was in an adequate position when CSF was flowing from the distal end; 2) Orbis Sigma valves were inserted through a hole in the skull and dura mater, which was just large enough to permit the passage of the ventricular catheter; and 3) if using Delta valves, a subgaleal pocket was created in order to avoid compression by the scalp. Surgeons were allowed to choose the specific features of the shunt, but antisiphon devices and other flow-control devices were not allowed.

The endoscope was passed down the lumen of the ventricular catheter. Use of an endoscope outside the ventricular catheter or through a separate entry site was not permitted. The goal of endoscopic insertion was the placement of the ventricular catheter tip away from the choroid plexus.

Perioperative care of the patients was conducted according to each surgeon's usual practice. Patients were required to undergo surgery within 1 month of being found eligible for the procedure.

Patient Outcome

The primary outcome in this study was shunt failure as previously defined in the Shunt Design Trial.⁴ There were four categories of shunt failure (obstruction, overdrainage, loculation, and infection), and the occurrence of any of them was accepted as the primary end point.



FIG. 1. Schematic outline of study design.

Shunt Obstruction. There were four different definitions of shunt obstruction. If a patient demonstrated the requisite features of any of these four definitions, shunt obstruction was said to have occurred. First, shunt obstruction occurred if a patient had at least one of the following symptoms or signs and at least one positive result on an ancillary test. Symptoms included headache, nausea, vomiting, decreased level of consciousness, irritability, decreased school performance, or the loss of developmental milestones. Signs included papilledema, bulging fontanelle, nuchal rigidity, sixth cranial nerve paresis, loss of upward gaze, new seizures (or increased seizure frequency), increasing head circumference, fluid tracking along the shunt tubing, umbilication of the shunt reservoir, or inability to depress the shunt reservoir. Note that fluid accumulation around the burr hole site in the early weeks following surgery was not considered to be indicative of shunt failure unless it was extreme and progressive or resulted in the leakage of CSF through the wound. Small fluid collections are common and normally resolve spontaneously.

A positive result on an ancillary test was described as follows: 1) results of CT scanning, ultrasonography, or MR imaging studies demonstrating enlarged ventricles compared with their appearance on 3-month studies or ventricles that failed to decrease in size compared with their appearance on preoperative studies (normalization of ventricle size is not a mandatory criterion for shunt function); 2) disruption or migration of the shunt system exhibited on plain radiographs; 3) radionucleotide or iodinated contrast study displaying shunt obstruction; 4) intracranial pressure monitoring indicating persistent elevation of pressure with or without plateau waves; or 5) shunt tap in which fluid cannot be aspirated or high pressure is recorded or symptoms and/or signs of shunt obstruction are relieved.

Second, shunt obstruction occurred if there were no symptoms or signs of obstruction but the ventricles were increased in size and there was no clinical or radiographic evidence that atrophy was the cause of the ventricular enlargement. Third, a CSF leak that did not resolve and required a shunt revision was considered to be a shunt obstruction. Last, in the rare event of an emergency shunt revision with no ancillary tests or a revision prior to the 3-month follow-up scan, obstruction was judged to be present or absent by using clinical information, results of imaging studies (if available), and the operative findings.

Shunt Overdrainage. Shunt overdrainage occurred in the presence of either large subdural fluid collections associated with brain compression or symptoms and signs otherwise indicative of shunt obstruction, or slit ventricle syndrome. The latter was characterized by smaller than normal ventricles associated with postural headache, chronic headache, intermittent headache of an incapacitating nature, and documentation of one of the following factors: transient enlargement of the ventricles as demonstrated on imaging, extreme negative pressure (on intracranial pressure monitoring or a shunt tap) with associated headache while the patient was in an upright position, or sustained elevations of pressure higher than normal and associated with headache.

Loculated Compartments. The presence of a loculated portion of a ventricular system, which is enlarged more than normal, compressing surrounding brain, and which requires repeated operation, was considered to be evidence of shunt malfunction and accepted as an end point of the study.

Shunt Infection. Shunt infection was indicated by the presence of purulent discharge through the wound or erosion of the shunt material through the skin. Further, it was characterized by the presence of one of the following symptoms or signs plus positive results of at least one of the following ancillary tests. Symptoms and signs consisted of those indicative of shunt obstruction, fever, meningismus, wound erythema, abdominal pain and/or distention, abdominal mass, or peritonitis. Ancillary tests performed included the culture or identification of organisms on Gram staining of CSF obtained from shunt lumen or abdominal fluid collection, if present, which was withdrawn under sterile conditions or from purulent material around the shunt. The growth of organisms from the entire shunt material in broth culture in the absence of other positive culture results was not considered to be indicative of an infection.

The secondary outcomes considered were subtype of shunt failure, surgical complications, patient survival, cause of death, and ventricular catheter position. Follow up was scheduled to be performed 4 to 12 weeks after shunt surgery and annually thereafter.

Sample Size

The overall 1-year shunt failure rate in the control group from the literature was 30 to 40%.^{1,4,5,13,14} The clinically important difference was chosen as a decrease in the 1-year shunt failure rate to 20%. Using Cochrane and colleagues'¹ cost analysis model of shunt failure, we calculated that such a reduction in shunt failure would result in a savings of more than \$1.5 million over 3 years at the study centers. The alpha value was chosen to be 0.05 (two-tailed test), and the power was 80%. A 2-year accrual period with a minimum 1-year follow up was planned. Based on these parameters, a sample size of 350 patients¹⁰ would have an 80% power to detect a reduction in the incidence of shunt failure at 1 year from 0.5 to 0.35, from 0.4 to 0.25, from 0.3 to 0.2, or from 0.2 to 0.1.

Endoscopic ventriculoperitoneal shunt insertions

Survival Analysis

The primary analysis included all patients in their originally assigned randomization groups (that is, an intentionto-treat analysis).¹² Patients who were subsequently judged to be ineligible were left in the primary analysis. Data in patients who did not meet the end point were censored at the last follow up. Data in patients who underwent other intracranial surgery, which, on blinded review, was thought potentially to affect shunt function, were excluded at the time of that surgery. In addition, data in patients were censored at the time of death if the cause of death was not shunt related. Deaths due to shunt failure were considered as an end point in the appropriate category. Time to shunt failure or data censoring was used to generate Kaplan-Meier curves for patients in the endoscopically treated group and those who underwent standard insertion procedures. These results were compared using a log-rank test. Statistical significance occurred at probability values less than 0.05.

Patient Group Assignment

Patients were individually randomized to treatment groups. Randomization was stratified by surgeon and shunt valve (Fig. 1). A permuted block randomization scheme was generated from a random number generator. An Access software program was designed to store the randomization scheme and to display sequentially the treatment assignments after patient demographic data were entered. The program was tested and installed on a computer in the operating room at each center. Patient consent was obtained prior to surgery and randomization was performed in the operating room by participating surgeons.

Blinding Method

Blinding of surgeons to the treatment assignment was not possible. An adjudication process for eligibility and primary outcome similar to that used in the Shunt Design Trial⁸ was followed. All case report forms, clinical notes, and imaging studies were sent to the data coordinating center, masked, and reviewed. The blinded review process was used to determine whether a patient met the entry and outcome criteria for the study. The results of the blinded review process were used as the primary outcome for the trial.

Results

Patient accrual began in May 1996 and closed in November 1999. Minimum follow up took place 1 year postsurgery. Three hundred ninety-three patients were randomized: 194 to endoscopic shunt insertion and 199 to standard shunt insertion. Seventeen of the 393 patients were subsequently ruled to be ineligible for the study during the blinded adjudication process. Nine of the 17 patients had been randomized to endoscopic insertion, eight to standard insertion. The reasons for ineligibility were no hydrocephalus (four patients), ventricular catheter placement in an old external ventricular drain track (four patients), shunt insertion into an empty hemicranium after hemispherectomy (three patients), spread of tumor into the subarachnoid space (two patients), arachnoid cyst (one patient), loculated ventricles (one patient), Dandy-Walker malformation (one patient), and previously inserted shunt (one patient).



FIG. 2. Kaplan–Meier curves showing the shunt failure rate in patients in the group treated with endoscopy (*solid line*) and those treated without endoscopy (*dotted line*). Log-rank test = 2.92, p = 0.09.

Surgical Procedure

Surgeons usually chose to use differential pressure (standard) valves (195 [50%] of 393) or Delta valves (150 [38%] of 393). The administration of perioperative antibiotics (339 [86%] of 393) and the removal of hair (268 [68%] of 393) were common practices. The median time for surgery was 35 minutes.

Bleeding was observed during the endoscopic procedure in 18 patients. The source of bleeding reportedly originated from an unknown site (six patients), the ventricle wall or ependyma (five patients), the choroid plexus (three patients), an old blood clot (three patients), or the occipital horn (one patient). In three of these 18 cases, bleeding interfered with adequate visualization through the endoscope and the shunt was placed without endoscopic assistance. In one of 18 patients, the fluid was very dark from a previous hemorrhage. The surgeon was concerned that the shunt would become blocked because of the consistency of the fluid, and thus no shunt was inserted. Visualization was poor in one other patient, who had hydrocephalus caused by meningitis; the murky yellow fluid interfered with visualization and the shunt was placed without endoscopic assistance.

Shunt Failure

The overall incidence of shunt failure was 0.38 at 1 year postsurgery and 0.47 at 2 years postsurgery. There was no significant difference in the time to shunt failure in comparing patients in the endoscopic and nonendoscopic groups (log rank = 2.92, p = 0.09; Fig. 2). The incidence of shunt failure at 1 year was 0.42 in patients in the endoscopic group and 0.34 in those in the nonendoscopic group (Table 2). Time to shunt failure (Kaplan–Meier curves) was not appreciably different when the 17 ineligible patients were excluded from analysis, when all deaths were counted as primary end point events, or when shunt revision was used as the end point (rather than the blindly judged end point).

 TABLE 2

 Surgery details in 393 patients who underwent placement of a VP shunt

Surgical Detail	Endoscope (194 patients)	No Endoscope (199 patients)
type of shunt inserted		
standard	98	97
Delta	74	76
Orbis Sigma	21	26
prophylactic antibiotics	166	173
hair removal method		
shaved	78	80
clipped	51	59
neither	56	54
cranial entry site		
coronal	78	92
occipital	108	103
procedures used to assist ventricular		
catheter placement		
ultrasonography	16	32
x-ray film	0	2
stereotaxis	0	0
ventricular catheter placed on first	159	166
attempt		
abdominal entry technique		
direct observation	107	113
trocar	66	79
additional procedures	28	23
median surgical time (mins)	40	35

Obstruction was the most common type of shunt failure, occurring in 106 (27%) of 393 patients (Fig. 3), that is, in 66 (34%) of 194 cases treated with endoscopy and in 40 (20%) of 199 cases treated without endoscopy (Table 3). The most common location for obstruction was the ventricular catheter in both groups. The incidence of infection was 44 (11%) of 393.

Patient Complications

There were 29 complications prior to discharge; 18 oc-



FIG. 3. Schematic diagram demonstrating outcomes in 393 randomized patients.

TABLE 3Shunt failure data

Shunt Failure	Endoscope (194 patients)	No Endoscope (199 patients)
overall incidence (95% con	fidence interval)	
1 yr	0.42 (0.35-0.49)	0.34 (0.27-0.41)
2 yrs	0.51 (0.43-0.59)	0.42 (0.34-0.50)
3 yrs	0.65 (0.55-0.75)	0.55 (0.40-0.70)
type (no. of patients [%])		
obstruction*	66 (34)	40 (20)
overdrainage	7 (4)	7 (4)
loculation	3 (2)	6 (3)
infection	20 (10)	24 (12)
obstruction of		. ,
ventricular catheter*	33 (17)	22 (11)

* "Obstruction" refers to shunt failure due to obstruction as defined in the text. "Obstruction of ventricular catheter" refers only to obstruction due to ventricular catheter occlusion.

curred in patients in the endoscopically treated group and 11 in those in the standard insertion group (Table 4). Two patients in the group treated with endoscopy experienced intracranial hemorrhage. In one of these patients, there was no associated clinical manifestation at the time of discharge; in the other child, seizures and bilateral posterior temporal hemorrhages occurred at regions remote from the surgical site, but their causes remained unclear. An infant in the endoscopically treated group, who had had massive hydrocephalus and cardiac anomalies, died immediately after shunt insertion and myelomeningocele closure. At the time of death the case was reviewed by a blinded adjudicator, who thought that the death was not due to the treatment group assignment.

Catheter Position

When the surgeon placed the ventricular catheter, he or she recorded the location of the catheter tip. This position was compared with that demonstrated on the first postoperative brain image obtained in 137 patients treated with endoscopy and 149 patients treated without endoscopy. If the first postoperative image was an MR image or an ultrasonography scan, the position of the catheter tip could not always be determined. Among 130 of 137 patients in the endoscopically treated group, the surgeon thought that the ventricular catheter tip was situated away from the choroid plexus (in the frontal horn, above the foramen of Monro, or in the occipital horn) at the time of surgery. On the first postoperative image, it was away from the choroid plexus in 87 (67%) of 130 patients. Among 140 of 149 patients treated without endoscopy, the surgeon thought that the catheter tip was located away from the choroid plexus at the time of surgery. On the first postoperative image, it was away from the choroid plexus in 86(61%) of 140 patients.

The time to shunt failure based on catheter position as demonstrated on the first postoperative scan is depicted in Fig. 4.

Discussion

Ventricular catheter placement by using endoscopic procedures appeared very promising based on results of uncontrolled series in the literature and prompted our undertak-

Endoscopic ventriculoperitoneal shunt insertions

Complications noted prior to hospital discharge in 29 patients	TABLE 4
	Complications noted prior to hospital discharge in 29 patients

Complication	Endoscope	No Endoscope
intracranial hemorrhage	2	0
new or worsened neurological deficit	0	0
wound dehiscence	1	3
postop subcutaneous fluid	7	1
transient CSF leak	2	0
seizures	3	2
non-shunt infection	0	2
persistent emesis	1	1
pneumocele	1	0
bruising along shunt	0	2
death	1	0
total	18	11

ing of this randomized trial. Data from our study, however, showed no advantage to endoscopic shunt insertion. Shunt failure rates were not significantly different; the incidence of shunt failure at 1 year was 0.42 in patients in the group treated with endoscopy and 0.34 in those treated without endoscopy. The theoretical basis for a reduced shunt failure rate in devices placed with the aid of an endoscope was decreased obstruction of the ventricular catheter; however, this was not observed. Early complications were not reduced in patients in the endoscopic insertion group and the median duration of surgery was slightly longer with the endoscope.

There are a number of differences between this trial and the studies previously reported in the literature. Our method of shunt insertion was restricted to the use of small endoscopes that fit in the lumen of the ventricular catheter. These scopes were chosen because they were in common use and were thought to be an improvement over the larger ones. They did not create a large track in the brain, which might leak CSF, and the catheter tip could be placed in the same position as the tip of the endoscope.

In the studies by Crone³ and Manwaring,¹¹ the majority of endoscopic insertions were performed using a larger endoscope and a peel-away sheath to guide ventricular catheter placement. In the study by Theodosopoulos and colleagues,¹⁷ endoscopy was supplemented with stereotactic guidance, shunt revisions were included, and most of their patients were adults. In our trial we assessed first shunt insertions in children only.

The current study is more rigorous than those published in the past in terms of specific entry and outcome criteria, randomization, adequate power, and blind adjudication of outcome. In all previous studies, there was potential observer bias because outcome was assessed by the treating surgeon. The only study with a control group¹⁷ did not include clinical follow up and its researchers focused specifically on the position of the catheter.

Data from previous research has supported the idea that ventricular catheter position affects the incidence of shunt failure.¹⁸ The results of a secondary analysis of catheter position in our trial indicate that shunt failure is less common if the ventricular catheter is situated away from the choroid plexus, as demonstrated on postoperative imaging. The goal of placing catheters away from the choroid plexus may still be reasonable, but the problem is how to accomplish this goal. Despite the surgeons' belief that a catheter



FIG. 4. Graph demonstrating the position of the ventricular catheter tip away from *(dotted line)* the choroid plexus or in proximity to it *(solid line)* at follow up.

had been placed away from the choroid plexus at the time of its insertion (in both groups), it was found to be in this position only approximately two thirds of the time on the postoperative image, and the endoscope did not appear to help (67% of endoscopic insertions and 61% of standard insertions were located away from the choroid plexus on the postoperative scan).

There are a number of potential reasons for this discrepancy. It is possible that the surgeons mistook the location of the catheter tip. Visualization was suboptimal when there was blood or other debris in the ventricle. In addition, with large ventricles, the small endoscopes may not have provided enough light for the surgeons to see well.

Alternatively, the ventricular catheter tip may have moved after its placement for a number of reasons. The endoscope acts as a stylette during placement. If the original trajectory of catheter insertion extends toward the choroid plexus, the surgeon may redirect the catheter anteriorly, toward the frontal horn. It is possible that this could result in distortion of the cerebral mantle, and when the scope is removed the brain would return to its normal position, perhaps pulling the catheter back into the choroid plexus. In addition, when the ventricle becomes smaller, the position of the catheter relative to the choroid plexus may change. Many ventricular catheters are designed as straight tubes. When inserted they are bent at the insertion site at a 90° angle. The elasticity in the tubing tends to straighten the tube after placement, resulting in movement of the tip in the ventricle. Finally, the entire shunt system occasionally migrates in a caudal direction after its insertion. Any of these circumstances may result in catheter tip movement and obstruction despite initial placement in an optimal position. Future researchers should address optimal catheter positioning procedures, changes in ventricle size and shape after shunt placement, and changes in catheter position over time.

Conclusions

Data from the previous literature generated interest in endoscopic ventricular catheter placement, but results of this trial demonstrated no benefit in the endoscopic insertion group and the procedure cannot be recommended.

Acknowledgments

Dr. Kestle acknowledges the support of his colleagues in Vancouver, BC, Canada, and Salt Lake City, Utah, who provided clinical coverage while he conducted this work: Drs. P. Steinbok, D. Cochrane, M. Walker, D. Brockmeyer, and L. Carey. The clinical research coordinating skills of Nancy MacNeil and Patty Mavor were key to the successful completion of this trial.

Appendix

- Principal Investigators: John R. W. Kestle, M.D., and James M. Drake, M.D.
- Executive Committee: John R. W. Kestle, M.D., James M. Drake, M.D., D. Douglas Cochrane, M.D., Ruth Milner, Marion L. Walker, M.D., and Rick Abbott III, M.D.
- Steering Committee: John R. W. Kestle, M.D., Ruth Milner, M.Sc., Nancy MacNeil, and Patty Mavor
- Adjudicators: John R. W. Kestle, M.D., James M. Drake, M.D., and D. Douglas Cochrane, M.D.
- The following persons and institutions participated in the Endoscopic Shunt Insertion Trial. Note that the participating centers are listed in order of the number of eligible patients entered in the trial.
- Children's Hospital of Alabama, Birmingham, Alabama
- Paul A. Grabb, M.D., W. Jerry Oakes, M.D., and Timothy B. Mapstone, M.D.

Arkansas Children's Hospital, Little Rock, Arkansas

- Frederick Boop, M.D., Charles Teo, M.D., and Bruce Cherny, M.D. Primary Children's Medical Center, Salt Lake City, Utah
- Marion Walker, M.D., Lyn Carey, M.D., Douglas Brockmeyer, M.D.,
- and John R. W. Kestle, M.D. British Columbia's Children's Hospital, Vancouver, British Columbia, Canada
- John R. W. Kestle, M.D., D. Douglas Cochrane, M.D., and Paul Steinbok, M.D.

Oregon Health Sciences Center, Portland, Oregon

Joseph Piatt, M.D.

Children's Hospital of Pittsburgh, Pennsylvania

- David Adelson, M.D., Ian Pollack, M.D., and Leland Albright, M.D.
- Children's Hospital of Michigan, Detroit, Michigan
- Alexa Canady, M.D., Sandeep Sood, M.D., and Steven Ham, M.D. The Hospital for Sick Children, Toronto, Ontario, Canada
- James M. Drake, M.D., and James T. Rutka, M.D.
- New York University Medical Center, New York, New York
- Howard Weiner, M.D., and Jeffrey Wisoff, M.D.
- Barrow Neurological Institute, Phoenix, Arizona
- Harold Rekate, M.D., and Bruce Cherny, M.D.

Birmingham Children's Hospital, Birmingham, United Kingdom Spiros Sgouros, M.D.

- University of Wisconsin Hospital and Clinics, Madison, Wisconsin Bermans Iskander, M.D.
- New York Hospital, New York, New York
- Mark Souweidane, M.D.
- Beth Israel Hospital, New York, New York

Rick Abbott III, M.D., and Cheryl Muszynski, M.D.

- University of Mississippi Medical Center, Jackson, Mississippi
- Andrew Parent, M.D.
- Academisch Ziekenhuis Vrije Universiteit, Amsterdam, The Netherlands

Peter Vandertop

References

1. Cochrane D, Kestle J, Steinbok P, et al: Model for the cost anal-

ysis of shunted hydrocephalic children. Pediatr Neurosurg 23: 14-19, 1995

- 2. Collins P, Hockley AD, Woollam DH: Surface ultrastructure of tissues occluding ventricular catheters. J Neurosurg 48:609-613. 1978
- 3. Crone KR: Current applications of endoscopy to ventricular shunts, in Pediatric Section American Association of Neurological Surgeons: 21st Winter Meeting Program. Vancouver. BC: AANS, 1992, p 71 (Abstract)
- 4. Drake J, Kestle J: Rationale and methodology of the multicenter pediatric cerebrospinal fluid shunt design trial. Pediatric Hydrocephalus Treatment Evaluation Group. Childs Nerv Syst 12: 434-447.1996
- 5. Drake JM, Kestle JR, Milner R, et al: Randomized trial of cerebrospinal fluid shunt valve design in pediatric hydrocephalus. Neurosurgery 43:294-305, 1998
- 6. Fernell E, Hagberg G, Hagberg B: Infantile hydrocephalus-the impact of enhanced preterm survival. Acta Paediatr Scand 79: 1080-1086, 1990
- 7. Jones RFC, Teo C, Stening WA, et al: Neuroendoscopic third ventriculostomy, in Manwaring KH, Crone KR (eds): Neuroendoscopy. New York: Mary Ann Liebert, 1992, Vol 1, pp 63-77
- 8. Kestle J, Drake J: The pediatric shunt design trial: lack of evidence for observer bias. Neurosurgery 41:736, 1997 (Abstract)
- 9. Kestle J, Drake J, Milner R, et al: Long-term follow-up data from the Shunt Design Trial. Pediatr Neurosurg 33:230-236, 2000
- 10. Machin D, Campbell MJ: Statistical Tables for the Design of Clinical Trials. Oxford: Blackwell Scientific, 1987
- 11. Manwaring KH: Endoscopic-guided placement of the ventriculoperitoneal shunt, in Manwaring KH, Crone KR (eds): Neuroendoscopy. New York: Mary Ann Liebert, 1992, Vol 1, pp 29-40
- Montori VM, Guyatt GH: Intention-to-treat principle. CMAJ 165: 12. 1339-1341, 2001
- 13. Piatt JH Jr, Carlson CV: A search for determinants of cerebrospinal fluid shunt survival: retrospective analysis of a 14-year institutional experience. Pediatr Neurosurg 19:233-242, 1993
- 14. Sainte-Rose Ĉ, Piatt JH, Renier D, et al: Mechanical complications in shunts. Pediatr Neurosurg 17:2-9, 1991/1992
- 15. Taha JM, Crone KR: Endoscopically guided shunt placement. Techn Neurosurg 1:159–167, 1996
- 16. Teo C, Rahman S, Boop FA, et al: Complications of endoscopic neurosurgery. Childs Nerv Syst 12:248-253, 1996
- Theodosopoulos P, Abosch A, McDermott MW: Intraoperative fi-17. ber-optic endoscopy for ventricular catheter insertion. Can J Neurol Sci 28:56-60. 2001
- 18. Tuli S, O'Hayon B, Drake J, et al: Change in ventricular size and effect of ventricular catheter placement in pediatric patients with shunted hydrocephalus. **Neurosurgery 45:**1329–1335, 1999 19. Walker ML, MacDonald J, Wright LC: The history of ventric-
- uloscopy: where do we go from here? Pediatr Neurosurg 18: 218-223, 1992

Manuscript received June 27, 2002.

Accepted in final form September 30, 2002.

This trial was supported by the Medical Research Council of Canada, Ottawa, Ontario, Canada (Grant No. 9609CT-34488-CT-CAAA-34012); the Hospital for Sick Children Foundation, Toronto, Ontario, Canada (Grant No. XG 96-0888); the Spina Bifida Association of America; and the Primary Children's Medical Center Foundation, Salt Lake City, Utah (Grant No. 258), all of which were awarded to John R. W. Kestle, M.D.

Address reprint requests to: John R. W. Kestle, M.D., Division of Pediatric Neurosurgery, University of Utah, Primary Children's Medical Center, 100 North Medical Drive, Suite 2400, Salt Lake City, Utah 84113. email: john.kestle@hsc.utah.edu.