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[Clinical Studies]

Change in Ventricular Size and Effect of Ventricular Catheter Placement in Pediatric Patients with Shunted Hydrocephalus

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Abstract

OBJECTIVE: The multicenter, randomized pediatric cerebrospinal fluid shunt valve design trial found no difference in the rate of shunt failure between a standard valve, a siphon-reducing valve (Delta; Medtronic PS Medical, Goleta, CA), and a flow-limiting valve (Orbis Sigma; Cordis, Miami, FL); however, the valves were expected to have different effects on ultimate ventricular size. Also, the catheter position or local environment of the ventricular catheter tip might have affected shunt failure. Therefore, we performed a post hoc analysis to understand what factors, other than valve design, affected shunt failure and to identify strategies that might be developed to reduce shunt failure.

METHODS: Ventricular size was measured at as many as six different intervals, using a modified Evans' ratio (with incorporation of the frontal and occipital dimensions), in 344 patients. Ventricular catheter location was defined as being in the frontal horn, occipital horn, body of the lateral ventricle, third ventricle, embedded in brain, or unknown. The ventricular catheter tip was described as surrounded by cerebrospinal fluid, touching brain, or surrounded by brain parenchyma within the ventricle (slit ventricle). Repeated measures analysis of variance for unbalanced data was used to analyze ventricular size. A Cox model (with incorporation of time-dependent covariates) was used to evaluate the contribution of age, etiology, shunt design, ventricular size, ventricular catheter location, and environment among the cases.

RESULTS: Ventricular volume decreased in an exponential fashion, forming a plateau at 14 months, and was similar for the three valves (**P**= 0.4). Frontal and occipital ventricular catheter tip locations were associated with a reduced risk of shunt failure (hazard ratios, 0.60 [**P**= 0.02] and 0.45 [**P**= 0.001], respectively). Ventricular catheter tips surrounded by cerebrospinal fluid or touching the brain were associated with a reduced risk of failure (hazard ratios, 0.21 and 0.33, respectively; **P**= 0.0001). Patients with myelomeningocele or large ventricles had increased risk of malfunction (hazard ratios, 1.78 [**P**= 0.006] and 2.33 [**P**= 0.03], respectively).

CONCLUSION: Decline of ventricular size over time is not affected by these different shunt valve designs. This suggests that the mechanical models of hydrocephalus on which the designs were based are inadequate. Ventricular catheter tip location and ventricular catheter environment are important. Techniques to accurately place ventricular catheters and new valve designs that effectively control ventricular size might reduce shunt malfunction.

The pediatric cerebrospinal fluid (CSF) shunt design trial (SDT) was performed to compare a "standard" differential pressure valve (either slit, miter, diaphragm, or ball in cone) with a siphon-reducing valve (Delta [level 1, 1.5, or 2]; Medtronic PS Medical, Goleta, CA) and a flow-limiting valve (Orbis Sigma; Cordis, Miami, FL) (7). The overall malfunction rate was found to be 39% at 1 year and 52% at 2 years. No statistically significant difference in the overall shunt malfunction rate was observed among the three valve designs on univariate or multivariable analysis.

A prediction by the manufacturers and some retrospective information suggested that these valves might have different effects on ventricular size and that larger ventricles might reduce the risk of shunt failure (14). There was also weak evidence that certain ventricular catheter tip sites reduced the incidence of proximal shunt obstruction (1-3, 9, 13, 15). We decided to gather further information on these suppositions by performing a post hoc analysis on the prospectively gathered imaging information from the SDT.

PATIENTS AND METHODS

The methodology and the results of the SDT have been reported previously (6, 7). Between October 1, 1993, and October 31, 1995, 344 patients were randomized at 12 pediatric centers. Follow-up examinations were performed at 3 months, at 12 months, and then annually for 1 or 2 years. Primary outcome was specifically defined as shunt failure from obstruction, infection, overdrainage, and loculated ventricles. Patient eligibility and the final outcome event were blindly adjudicated.

Computed tomography, magnetic resonance imaging, or ultrasound imaging was required to be performed before trial entry and was recommended at 3 months, at 12 months, and at annual follow-up examinations as well as at any possible outcome event. All images were blinded at the data center to disguise the patient data and any features that might indicate shunt type. As many as five images for each patient were analyzed. Images from the time of shunt failure were excluded.

The blinded images were then analyzed for ventricular size, ventricular catheter tip location, and ventricular catheter tip environment. Ventricular size was measured using a modified Evans' ratio (measured as the average of the maximum lateral width of the frontal and occipital horns divided by the lateral cranial diameter) (12). Ventricular catheter location was defined as being in the frontal horn, occipital horn, body of the lateral ventricle, third ventricle, embedded in brain, or unknown. Ventricular catheter tip environment was described as surrounded by CSF, touching brain (one side of the ventricular catheter tip in apposition to the ventricular wall), or surrounded by brain (catheter tip in the ventricle, but no visible surrounding CSF).

Statistical analysis

Statistical analysis included descriptive statistics with univariate analysis of patient, shunt, and postoperative imaging information. The Kaplan-Meier method was used for estimating a shunt survivor function.

Repeated measures analysis of variance for unbalanced data was used to determine the difference of change in ventricular size over time (at as many as six different intervals) for the three categories of shunt. An unstructured covariance matrix was used, as it precluded assumptions regarding correlation between subsequent observations in the repeated series (20).

Multivariable analyses were performed using a Cox regression model to assess the significance of categorical variables (etiology of hydrocephalus, shunt design, ventricular catheter location, and ventricular catheter environment) and continuous variables (age corrected for gestation and ventricular size). This model included time-dependent covariates (ventricular catheter tip environment and ventricular size) to account for changes in the values for the covariates over time. In addition to the effect of the most recently measured ventricular size (excluding the failure cases) on risk of shunt malfunction, the effect of the baseline ventricular size was also considered as a risk factor for shunt malfunction. The proportional hazards assumption for the non-time-dependent covariates was assessed by determining the significance of a product term of time and the original covariate. Multivariable analysis with Statistical Analysis System software was performed by means of a stepwise selection algorithm to assess the significance of the regression coefficients. A two-sided P value = 0.05 was outlined to test the null hypothesis. The hazard ratio (HR) was calculated by obtaining an exponent of the regression coefficient ($e^{[beta]}$). For the significant HRs, 95% confidence intervals (CIs) were calculated. R^2 was also determined for the model and its covariates (10). R^2 represents how well the dependent variable was accounted for by its covariates.

RESULTS

Descriptive statistics on the etiology of hydrocephalus, ventricular catheter location, and ventricular catheter environment, according to cause of malfunction, are provided in Table 1. Ventricular size, estimated using the modified Evans' ratio, decreased in an exponential fashion over time for all three shunt valve designs, reaching a steady level by 14 months (Fig. 1). There was no statistically significant difference in the ventricular size among the three designs (before shunt insertion) (P= 0.25). There was also no significant difference in the decline of ventricular size over time (P= 0.43).

TABLE 1. Descriptive Statistics of Predictors, According to Causation of Malfunction[a]

Predictors	Outcome of					Total
	Censored	Obstruction	Overdrainage	Loculated Ventricle	Infection	
Hydrocephalus etiology						
Myelomeningocele	32	29	1		11	73
Tumor	22	6	1		2	31
Head injury	3	1	1			5
Postmeningitic	9	8		1		18
Aqueductal stenosis	14	8	1		1	24
IVH	48	24	3	1	7	83
Other	63	32	5		7	107
Ventricular catheter location						
Frontal horn	63	27	3		2	95
Occipital horn	56	18	2		3	79
Body of ventricle	24	15		1	4	44
Third ventricle	11	6	1		2	20
Brain	7	12	3		1	23
Unknown[b]	29	19	3	1	13	65
Ventricular catheter tip environment						
Surrounded by CSF	32	6	2			40
Touching brain	85	25	3		2	115
Surrounded by brain	24	9		1	1	35

[a] IVH, intraventricular hemorrhage; CSF, cerebrospinal fluid.
[b] Unknown refers to the inability of the assignor to specify a category; thus, a separate category of such nonrandom cases was designated.

Table 1. Descriptive Statistics of Predictors, According to Causation of Malfunction[aa] IVH, intraventricular hemorrhage; CSF, cerebrospinal fluid.[b] Unknown refers to the inability of the assignor to specify a category; thus, a separate category of such nonrandom cases was designated.

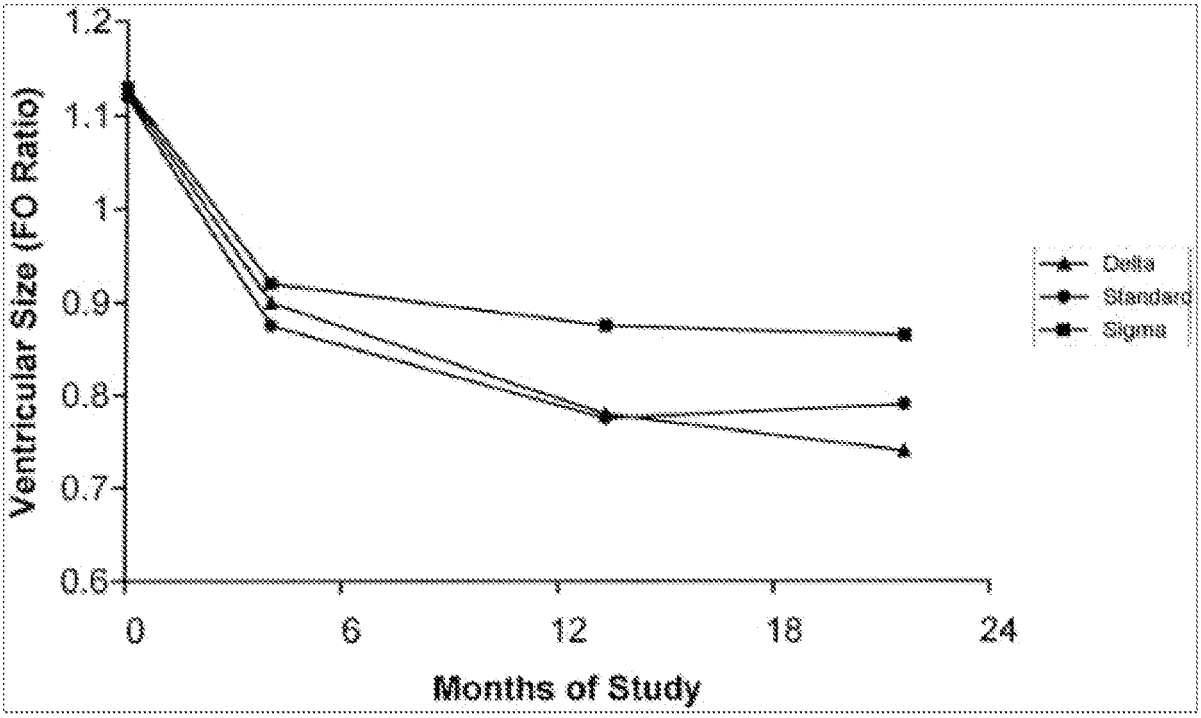

FIGURE 1. Change of ventricular size over time according to valve design. FO, frontal + occipital dimension.

Multivariable analysis using Cox regression with time-dependent covariates revealed significant effects of ventricular catheter location, ventricular catheter tip surroundings, etiology, and ventricular size (Table 2). With respect to ventricular catheter location, the occipital site had the highest shunt survival rate (HR, 0.45; 95% CI, 0.28-0.74; $P = 0.001$), and frontal catheter tip location decreased the risk of failure to approximately one-half (HR, 0.60; 95% CI, 0.39-0.91; $P = 0.02$), compared with the other locations.

TABLE 2. Results of Multivariable Analysis[a]

Predictors	HR	95% CI	*P* Value	R^2
Etiology				
Myelomeningocele	1.78	1.18–2.67	0.006	0.037
Head injury	4.56	1.07–19.39	0.04	0.018
Ventricular size	2.33[b]	1.08–5.00	0.03	0.025
Ventricular catheter location				
Occipital	0.45	0.28–0.74	0.001	0.052
Frontal	0.60	0.39–0.91	0.02	0.033
Ventricular catheter environment				
CSF	0.21	0.094–0.45	0.0001	0.13
Touching brain	0.33	0.21–0.51	0.0001	0.16

[a] HR, hazard ratio; CI, confidence interval; CSF, cerebrospinal fluid.
[b] HR of 2.33 refers to an increase in the risk of shunt malfunction for every unit increase in the ventricular size (according to the modified Evans' ratio).

Table 2. Results of Multivariable Analysis[aa] HR, hazard ratio; CI, confidence interval; CSF, cerebrospinal fluid.[b] HR of 2.33 refers to an increase in the risk of shunt malfunction for every unit increase in the ventricular size (according to the modified Evans' ratio).

Ventricular tip surrounded by CSF had the lowest HR (HR, 0.21; 95% CI, 0.094-0.45; $P = 0.0001$), followed by a catheter tip touching brain (HR, 0.33; 95% CI, 0.21-0.51; $P = 0.0001$), compared with a catheter tip surrounded by brain. Ventricular catheter tip environment proved most predictive of shunt failure as described by R^2. The summation of the R^2 for ventricular catheter tip environment categories (surrounded by CSF and touching brain) equated to 29%, accounting for three-fourths of the variability in the model. This suggests that ventricular catheter tip environment is a very strong risk factor.

Myelomeningocele was a contributing factor in shunt malfunction (HR, 1.78; 95% CI, 1.18-2.67; $P = 0.006$). Head injury was barely significant (HR, 4.56; CI, 1.07-19.39; $P = 0.04$). The large CI was reasoned to be secondary to the small number of patients (five) in this cell; thus, the contribution of this etiology was considered questionable.

For each unit increase in the most updated ventricular size (excluding the failure cases), the risk of shunt malfunction increased by more than twice (HR, 2.33; 95% CI, 1.08-5.00; $P = 0.03$). A similar general trend held for the initial ventricular size, before shunt insertion. When repeated measures analysis of variance for unbalanced data was used, no statistically significant difference in the change of ventricular size over time for the various categories of the outcome (i.e., obstruction, overdrainage, infection, and loculated ventricles) was found.

DISCUSSION

The whole tenet behind the SDT was that more physiological valves would reduce overdrainage phenomena, including slit ventricles, and result in reduced shunt failure, as had been reported particularly with the Orbis Sigma valve (Cordis) (15). Unfortunately, there was no difference in shunt failure, and the results of this study indicate that there is no difference in the decline in ventricular size between the three types of valve design. These new valves, therefore, did not perform as intended.

This finding has several implications. First, the mechanical models on which shunt design has been based are woefully inadequate (8, 11, 14). The models have typically accounted for pressure and CSF volume changes for time courses of minutes to hours. They have also relied on simplistic notions of brain biomechanics and have used mechanical properties of the brain that have rarely been tested or, in some cases, are nonsensical (17, 19). In addition, it is very likely that the mechanical properties of the brain change with hydrocephalus and are a function of age. Until more sophisticated models with better understanding of brain biomechanics are developed, it will be extremely difficult to develop better shunt valves. Therefore, making current designs adjustable, allowing for changes according to patient response, seems quite reasonable.

The other implication of change in ventricular size after CSF shunt insertion relates to the timing of postoperative imaging. The ventricles do not reach their final size until 14 months, on average. Therefore, a baseline image in a shunted patient should probably be obtained at this time, to be used as a comparison for possible future shunt problems. This time period is considerably longer than has been recommended previously (18). As shunt failure occurs in 40% of patients within the first year, several other images obtained during the course of ventricular decompression would be required to interpret scans obtained at the time of possible failure within the first year; whether this is really necessary or cost-effective is not known.

Few studies have addressed the issue of ventricular size in relation to subsequent shunt failure. Caldarelli et al. (4) categorized ventricular dilation as mild, moderate, or severe, and they reported a total complication rate (mechanical plus infective) of 49, 45.2, and 64.3%, respectively. Conversely, Sainte-Rose et al. (15) found failure rates of 44.3%, 27.1%, and 36.1% in patients with slit, normal, or large ventricles, respectively. Our study found more than double the risk of failure with each unit increase in the modified Evans' ratio for the most recent scan. This increase in risk was found in patients with functioning shunts, because all scans obtained at the time of shunt failure were excluded. The risk of such failure was independent of the type of failure (obstruction, infection, etc.). These results are difficult to reconcile, particularly when a catheter tip in a slit ventricle (as discussed below) was also a risk factor for failure. It is possible that the failure process is multifactorial; clearly, further investigation of this phenomenon is needed.

The significance of ventricular catheter location was first addressed by Becker and Nulsen (2). The frontal horn was viewed as the optimal location in this descriptive study. This concept was also held by Hoffman and Smith (9), who stated that ventricular catheters function ideally in the frontal horn, "remote from the choroid plexus" (9, p 85). Later, a large retrospective study of 1719 patients failed to support these conclusions (15). Higher risk of proximal occlusion was noted with a frontal horn location. A subsequent study by Sainte-Rose (13) (incorporating patients with the new flow-regulated Orbis Sigma valve) noted that the occipital horn was the optimal location, providing a lower risk of proximal obstruction than the frontal horn, yet it "barely reached statistical significance" (13). The results of our study, which take advantage of multivariate statistics and prospectively gathered data, indicate that placement of a catheter tip in an occipital or frontal location reduces failure rates to approximately one-half. This refutes the

notion that there "seems to be no optimum site for the ventricular catheter" (5). It is possible that placement of the ventricular catheter with an endoscope, as is currently being evaluated in a randomized trial, may reduce shunt failure.

To date, no studies based on imaging have been performed to evaluate the effect of ventricular catheter tip environment in relation to surrounding brain or CSF. It is well known that the ventricular catheters, the most common site of shunt obstruction (7), become clogged with tissue from the immediate proximity. A scanning electron microscopic study by Collins et al. (5) found ependymal tissue occluding catheter tips in one-third of 16 patients studied. Sekhar et al. (16) provided histological confirmation of obstruction of ventricular tips by glial tissue in 36 cases, ependymal tissue in 15 cases, and brain tissue in 6 cases in a series of 201 shunt revisions. In our study, a ventricular catheter tip surrounded by CSF decreased the risk of shunt failure to one-fifth, whereas a catheter tip touching brain decreased the risk to one-third, compared with a catheter tip surrounded by brain (residing in a slit ventricle). This gives credence to the notion that if the ventricular catheter can be kept in a pool of CSF, remote from brain structures, the ventricular catheter is less likely to become occluded.

Patients with myelomeningocele, as well as patients with naturally large ventricles, had a higher risk of failure. These are obviously unalterable risk factors. Nevertheless, recognition of these risk factors may help to identify patients at increased risk of failure who might benefit from interventions designed to reduce failure.

Final ventricular shape and size are obviously a complicated result of the initial ventricular size, reconfiguration of the cerebral mantle with ventricular decompression by the shunt, porencephaly or other encysted or surface collections of fluid, and, particularly with young children, brain and cranium growth. The final position and environment of the ventricular catheter tip is affected by the final ventricular shape and size, cranium growth, the catheter tip's initial position at ventricular cannulation, the devices used to guide it through the burr hole, and the intrinsic stiffness of the catheter. Given these complex effects, placing a ventricular catheter at what will ultimately be the best site is not easy. Nevertheless, the results of this study suggest that this goal is worthy of further effort. This includes the previously mentioned randomized trial of endoscopic placement of ventricular catheters, developing three-dimensional models of the hydrocephalic brain's response to shunting, and further development of CSF shunt valves designed to regulate ventricular size.

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COMMENTS

This is a retrospective analysis of the 344 children previously reported in the shunt valve design trial (1). The aim of the present study was to investigate factors, other than the valve type, as predictors of shunt failure. Myelomeningocele, large ventricles, catheter tip location in sites other than the frontal and occipital horns, and catheter tip surrounded by brain were predictors of failure.

Prognostic factors may be divided into patient variables and treatment variables; the latter may be amenable to improvement in technique, but the former are not. The surgeon is confronted with a patient, for better or worse, and must make the best of it. The etiology of the hydrocephalus is, of course, a given, as is the initial ventricular size. As the authors note, the final environment of the catheter tip is multifactorial and is often determined by ventricular compliance and the configuration of the ventricular system; thus, this may also be a patient variable not readily changed by technique. Therefore, of the prognostic factors identified in this work, only the site of the catheter tip is potentially something that the surgeon may influence. A frontal or occipital location, away from the choroid plexus, is clearly optimal, as has been noted in previous studies. The problem, then, is how to get the catheter into this location. This study did not evaluate a frontal versus occipital burr hole location. Furthermore, the use of endoscopic placement, ultrasound, or placement of the drainage holes in ventricular shunt catheters might also decrease contact of the catheter with the choroid plexus. Commercially available shunts with this design are now available.

It has been hoped that endoscopic third ventriculostomy would eliminate many of the problems associated with shunts. Unfortunately, this is not the case, and shunts remain a problem for the neurosurgeon.

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1. Drake JM, Kestle JRW, Milner R, Cinalli G, Boop F, Piatt J, Haines S, Schiff S, Cochrane D, Steinbok P, MacNeil N: Randomized trial of cerebrospinal fluid shunt valve design in pediatric hydrocephalus. Neurosurgery 43: 294-303, 1998. Ovid Full Text | Request Permissions | Bibliographic Links | [Context Link]

This report represents a further analysis of data obtained in a previous multicenter randomized investigation of the relationship between shunt design and shunt failure (1). The stated purpose of the present analysis is to identify factors, other than valve design, that might be related to shunt failure. One observation that I found of interest was the extended time required for ventricles to reach their ultimate size after initial shunt placement. The authors point out the importance of recognizing this phenomenon when interpreting the significance of “baseline ventricular size” less than 14 months after shunt insertion. It is also of interest that all of the valves behaved similarly in this regard.

Some other findings are intuitive to neurosurgeons regularly involved in the treatment of hydrocephalus. For example, it is not surprising that catheter tips located within the cerebrospinal fluid or simply touching the wall of the ventricle are less apt to become occluded than catheter tips embedded in brain, either because of slit ventricles or

misdirection of the catheter at the time of insertion. Parenthetically, no effort is made to distinguish between these two situations, although there surely must have been cases in which the catheter tip was embedded in parenchyma adjacent to the ventricle with normal size or even large ventricles. One surprising observation was the correlation between increasing baseline ventricular size and the likelihood of subsequent shunt malfunction. The authors note that this is difficult to reconcile with an intuitively higher likelihood of shunt failure in the presence of slit ventricles. If a substantial portion of these patients had catheter tips within parenchyma, rather than within slit ventricles, the discrepancy between these two observations might be explained. With regard to the apparent direct relationship between ventricular size and shunt malfunction, I find the definition of a functioning shunt a bit troubling. It is possible that larger than normal ventricles reflect suboptimal shunt function in an asymptomatic patient. If this is the case, one might logically consider such shunts at higher risk for ultimate malfunction.

A feature of this study that needs to be kept in mind is the fact that the subjects are quite young. Most were shunted as neonates or infants with a follow-up of 3 years or less. In my experience, most children with repeated shunt malfunction associated with slit ventricles are older than 3 years. It may not be valid to draw conclusions regarding the likelihood of shunt malfunction with slit ventricles in this very young cohort of patients. The authors correctly direct our attention to the need for better understanding of brain biomechanics in the presence of hydrocephalus. It is perhaps relevant that most of the patients in this study had open sutures during much of their follow-up. This might be expected to affect the biomechanical response to hydrocephalus in ways that are unique to infants (2). The reader should keep in mind that observations gleaned from this study may not be valid for older children and adults with hydrocephalus.

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This is a retrospective analysis of the shunt valve design trial study (1). In this study, the authors examined the etiology of the hydrocephalus, valve type, ventricular size, and ventricular tip location to ascertain whether there are any significant variables that either increase or decrease obstruction of the ventricular catheter, one of the most common causes of shunt malfunction.

The authors found that decrease in ventricular size was the same, irrespective of whether the valve type was a simple differential pressure valve, a differential pressure valve with an antisiphon device, or a flow-regulated valve. If the tip of the ventricular catheter was in either the frontal or occipital horn, it had a higher survival rate than if it was in the body of the lateral ventricle, the third ventricle, or embedded in the brain. If the ventricular tip was surrounded by cerebrospinal fluid or just touching brain, it had a higher chance of survival than if it was completely surrounded by brain.

The study also found a higher rate of obstruction in children whose hydrocephalus was associated with a myelomeningocele and in children with large ventricles. One wonders why those factors should affect occlusion of the ventricular catheter.

There has been an ongoing debate as to whether a frontal versus a posterior parietal entry point for the shunt catheter is associated with a decreased ventricular obstruction and/or complication rate. Even when the catheter is inserted in the posterior parietal region, often the tip of the catheter is advanced into the frontal region. By definition, in this study, the catheter tip would be in a frontal location. From the results of this study, the tip of the catheter placed in the occipital horn should have the same survival rate as a catheter tip advanced into the frontal horn. Obviously, the frontal and occipital regions are devoid of choroid plexus, and presumably, this is the reason for a lower incidence of obstruction.

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Los Angeles, California

1. Drake JM, Kestle JRW, Milner R, Cinalli G, Boop F, Piatt J, Haines S, Schiff S, Cochrane D, Steinbok P, MacNeil N: Randomized trial of cerebrospinal fluid shunt valve design in pediatric hydrocephalus. Neurosurgery 43: 294-303, 1998.

In this study, the authors have confirmed something that seems obvious to neurosurgeons actively involved in the management of hydrocephalus. We know from the shunt design trial (1) that there is no difference in malfunction among three different shunt valve designs. Now, we see that there is really no difference in the rate at which the ventricles become stabilized. This information has practical application in that the neurosurgeon desiring to have a baseline study on a patient who has been shunted with large ventricles should wait a minimum of 14 months before considering the ventricles to be stabilized.

The study also indicates that there may be a significant advantage in placing the tip of the ventricular catheter away from the choroid plexus. Placing the catheter in the occipital horn or in the frontal horn, beyond the foramen of Monro, seems to be associated with a significantly decreased rate of shunt malfunction. It is hoped that the endoscopic shunt placement trial, which will soon come to conclusion, will further confirm these data. It seems apparent that placement of the catheter in an appropriate place in the ventricle yields a better chance for long-term shunt success. It is no surprise that the authors found that myelomeningocele patients had an increased hazard ratio. Myelomeningocele patients often have deformed dysmorphic ventricles, making the desired ventricular catheter placement more difficult. Further long-term information gained from the shunt design trial should prove even more interesting in the future.

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1. Drake JM, Kestle JRW, Milner R, Cinalli G, Boop F, Piatt J, Haines S, Schiff S, Cochrane D, Steinbok P, MacNeil N: Randomized trial of cerebrospinal fluid shunt valve design in pediatric hydrocephalus. Neurosurgery 43: 294-303, 1998.
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Key words: Cerebral ventricles; Cerebrospinal fluid shunts; Diagnostic imaging; Hydrocephalus; Pediatric; Randomized clinical trials; Repeat events

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IMAGE GALLERY

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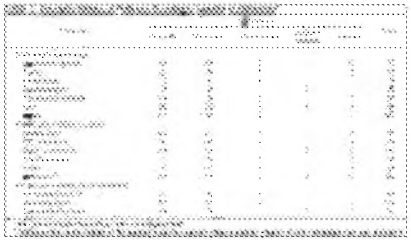

Table 1

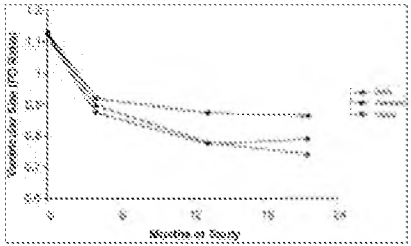

Figure 1

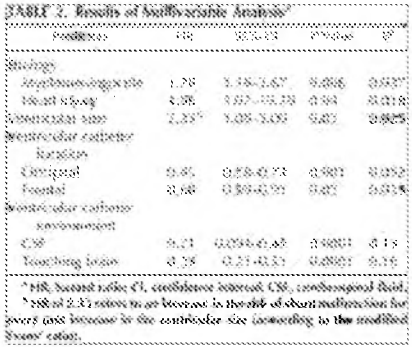

Table 2