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Experiences with a gravity-assisted valve in hydrocephalic children

Clinical article

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Object. Over the past decade, a gravity-assisted valve (GAV) has become a standard device in many European pediatric hydrocephalus centers. Because past comparative clinical outcome studies on valve design have not included any GAV, the authors in this trial evaluated the early results of GAV applications in a pediatric population.

Methods. For a minimum of 2 years the authors monitored 169 of 182 hydrocephalic children who received a pediatric GAV at their first CSF shunt insertion (61.5%) or as a substitute for any differential pressure valve (38.5%) at 1 of 7 European pediatric hydrocephalus centers. Outcomes were categorized as valve survival (primary outcome) or shunt survival (secondary outcome). The end point was defined as valve explanation.

Results. Within a follow-up period of 2 years, the valve remained functional in 130 (76.9%) of 169 patients. One hundred eight of these patients (63.9%) had an uncomplicated clinical course without any subsequent surgery, and 22 (13%) were submitted to a valve-preserving catheter revision without any further complications during the follow-up period. Thirty-nine patients (23.1%) reached an end point of valve explantation: 13 valve failures from infection (7.7%), 8 (4.7%) from overdrainage, and 18 (10.6%) from underdrainage.

Conclusions. Compared with nongravitational shunt designs, a GAV does not substantially affect the early complication rate. Valve-preserving shunt revisions do not increase the risk of subsequent valve failure and therefore should not be defined as an end point in studies on valve design. A significant impact of any well-established valve design on the early complication rate in shunt surgery is not supported by any current data; therefore, this correlation should be dismissed. As overdrainage-related complications have been shown to occur late, the presumed advantages of a pediatric GAV remain to be shown in a long-term study. (*DOI: 10.3171/2009.4.PEDS08204*)

KEY WORDS • hydrocephalus • children • shunt • complication • cerebrospinal fluid • gravity-assisted valve

THE majority of the 150 currently available hydrocephalus valves, as well as the much smaller selection of the frequently used versions, are based on differential pressure technology. In vitro these valves share a predisposition to overdrainage in the vertical position¹²

despite improvements such as adjustability and so-called flow control. The clinical relevance of this predisposition remains a controversial subject because all hypotheses seem to be compromised by a general lack of clearly defined clinical data pertaining to overdrainage and its sequelae.^{7,17,18} Laboratory tests of shunt systems conducted in Germany by Aschoff and others^{2,6} along with accumulated

J Neurosurg: Pediatrics / Volume 4 / September 2009

Abbreviation used in this paper: GAV = gravity-assisted valve.

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clinical experience with overdrainage-induced problems have directed increased attention to the early signs and previously underestimated late adverse effects of chronic overdrainage. This shift in expert awareness has advanced the development of a contemporary version of the GAV for pediatric patients. To date, only single-center results have been published.^{39,10,14} Because major comparative studies on valve design⁸ have not been focused on any GAV, we conducted a complementary trial on a pediatric GAV.

Methods

Study Eligibility

Patients up to the age of 16 years who were scheduled to receive a pediatric GAV (paediGAV, B Braun/Aesculap) for the first time were eligible to participate in this prospective study. Indications for a GAV were 1) newly diagnosed hydrocephalus with documented cerebral ventriculomegaly requiring CSF shunt insertion, or 2) documented shunt malfunction due to obstruction or overdrainage or following shunt infection in patients with a standard differential pressure valve. This approach is the standard therapeutic procedure at the 7 European centers participating in the study, and written parental consent was obtained in every case. In discussions, the local ethics committees confirmed that their approval was not necessary for the study to proceed.

Patients were excluded if they exhibited an active CSF infection, any systemic disorder precluding CSF diversion, or septated ventricular loculations requiring > 1 ventricular catheter. Patients who did not attend follow-up examinations or who died < 3 months after shunt placement for reasons unrelated to hydrocephalus or to the shunt were also excluded. Patients who did not attend the final follow-up examination or who died of non-shunt-related causes > 3 months after shunt placement were classified as dropouts. Since these patients did not demonstrate any demographic or etiological differences from the study group, they were entered into the database and included in the statistical analysis.

Patient Population

One hundred eighty-two patients were enrolled between January 2003 and January 2005. They received a pediatric GAV for the first time during an initial shunt procedure (61.5%) or as a substitute for any standard differential pressure valve (38.5%). Initial shunt procedures were performed in 83 (96.5%) of 86 children < 1 year of age and in 21 (25%) of 83 children \ge 1 year of age. Thirteen of 182 initially enrolled patients were excluded from the study because they were continuously inaccessible for follow-up (8 patients) or because they died < 3 months after shunt placement for reasons unrelated to hydrocephalus or the shunt (5 patients). The baseline characteristics of the remaining 169 patients are shown in Tables 1 and 2. There were 71 female (42%) and 98 male (58%) patients with an age range from newborn to 16 years. The mean age was 4.3 years, with a median of 0.93 year.

Treatment Protocol

Each patient received a GAV (Fig. 1) combining 1 of 2 levels of the opening pressure of the differential pres-

Age (yrs)	No. of Patients	No. Preterm (%)
0 to <1	86	42
1 to <2	8	2
2 to <4	13	3
4 to <6	10	2
6 to <8	6	1
8 to <10	9	3
10 to <12	10	3
12 to <14	18	4
14 to 16	9	1
total	169	61 (36.1)

sure components (4 or 9 cm H₂O) with 1 of 4 levels of the opening pressure of the gravitational component (14, 19, 24, or 29 cm H₂O). Available fixed settings were (in cm H₂O) 4/14, 4/19, 4/24, 9/19, 9/24, or 9/29. The manufacturer's recommendations for the optimal valve settings are 4/24 (\leq 6 months of age), 9/24 (6 months to 5 years of age), and 9/29 cm H₂O (> 5 years of age). The indication for surgery, extent of hair removal, site of shunt insertion, valve setting, surgical technique, perioperative medication, and subsequent treatment of shunt malfunction were left to the regulations of each participating center, because we wanted the results to reflect everyday hospital situations.

Follow-Up Monitoring

Patients were to complete a perioperative assessment and a follow-up at 3, 6, 12, and 24 months after surgery. In

TABLE 2: Cause of hydrocephalus in 169 patients

Disorder	No. of Cases (%)
hemorrhage	51 (30.2)
dysraphic malformation	40 (23.7)
Chiari malformation	15
Dandy-Walker malformation	5
no specification	20
nondysraphic malformation	14 (8.3)
arachnoid cyst	5
connatal aqueductal stenosis	3
angioma	1
schizencephaly	3
Walker-Warburg syndrome	1
no specification	1
idiopathic	18 (10.7)
infection	16 (9.5)
neoplasm	14 (8.3)
other	13 (7.7)
neurofibromatosis	1
hydranencephaly	1
hypoxia	1
no specification	10
head injury	3 (1.8)

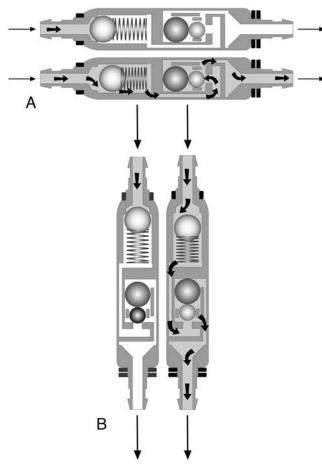


Fig. 1. A: Schematic showing the paediGAV construction in the horizontal position. The ball in the closed conus compartment (normal ICP) and the gravitational compartment contributing no additional resistance *(upper)*. Ball in the open conus compartment (ICP < 9 cm H₂O), with the gravitational compartment open and contributing no additional resistance *(lower)*: ICP > (9 + 0 =) 9 cm H₂O. B: Schematic showing the paediGAV construction in the vertical position. The ball is in the closed conus compartment (ICP < 9 cm H₂O), and the gravitational compartment is closed, contributing full gravitational resistance of 20 cm H₂O), *(left)*. The ball is in the open conus compartment (ICP > 9 cm H₂O), with the gravitational compartment contributing full gravitational resistance (here: 20 cm H₂O) and open *(right)*: ICP > (9 + 20 =) 29 cm H₂O.

cases of subsequent valve-preserving procedures within the follow-up period, another perioperative assessment was added for each intervention. If the end point of valve explantation was reached, the type and site of shunt malfunction were recorded. A record of each assessment was sent to the study office and checked for completeness by the study nurse. A copy was sent to the study headquarters and reviewed by an independent physician not belonging to the paediGAV study group.

Primary and Secondary Outcomes

The end point in this study was valve explanation due to overdrainage, underdrainage, or infection. The primary outcome category was valve survival even if it involved any type of shunt malfunction treated with a valve-preserving procedure, the loss of a patient from the study because of a non-shunt related death after at least 1 completed followup assessment, and surgical complications preserving all parts of the shunt. The secondary outcome category was shunt survival without any surgery after implantation.

Statistical Analysis

Follow-up was submitted to consistent criteria. Patient age was not corrected for the separate variable of prematurity. Patient-related variables assessed for their effect on valve and shunt survival included disease origin, gestation age, age at the time of shunting, and first shunt implantation versus valve exchange. The only surgeon-controlled variable was the valve setting. Fragmentary informationattributable to the participating centers' different diagnostic approaches to head circumference, radiological examinations, and frontal/occipital horn ratio-was entered into the database but was not submitted to statistical analysis. For categorical data, absolute and proportional frequencies were given. Metrical variables were described as the means ± SDs, medians, and ranges (minimum and maximum). In the case of categorical data, group comparisons were made using the chi-square and Fisher exact test when appropriate. Since normality for all metrical variables cannot be assumed, the Mann-Whitney U-test was used for comparison of the 2 groups, and the Wilcoxon test was used for paired samples. Age and pressure were respectively dichotomized as < versus ≥ 1 year of age and as $\le 4/24$ versus $\ge 9/19$ cm H₂O. Survival analyses with respect to age, and de novo implantation versus revision were conducted using Kaplan-Meier curves. For the respective confirmative analyses, the log-rank test and Cox regression models were used. The level of significance was $\alpha = 0.05$ (2-tailed). No adjustment of the α level was made for multiple testing (Bonferroni correction) because of the exploratory nature of the study.

Results

None of the etiological factors (Table 2) were associated with the frequency of underdrainage, overdrainage, infection, or any other outcome event (p > 0.005, chisquare test). The median follow-up among 169 patients, including those who reached the end point of valve explantation, was 21.8 months. Thirty-two patients (18.9%) with a median follow-up of 12 months were classified as dropouts; 6 of them (3.5%) died > 3 months after shunt placement for non-shunt-related reasons, and 26 (15.4%) did not attend the final follow-up examination. The dropout group showed no demographic or etiological differences from the study group (Wilcoxon test).

Valve Setting

The pattern of the choice of opening pressure (P_0) settings differed largely across the participating centers. The overall distribution of valve settings is shown in Fig. 2. With regard to the opening pressure of the ball in the conus component ($P_0 = 4$ or 9 cm H₂O), the higher P_0 was chosen in 76% of cases. Low-opening-pressure valves were predominantly used in the younger age group (Fig. 3). Valve setting was not associated with the frequency of infection, overdrainage, or underdrainage (p > 0.005, chi-square test). Provided the described choice pattern, the different valve settings did not correlate with shunt or valve survival.

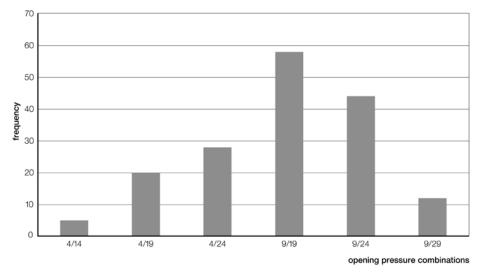


Fig. 2. Bar graph demonstrating the frequency with which a valve was chosen. Frequency refers to the number of cases. Data in 2 patients could not be verified; therefore, the graph represents data in 167 patients.

Early Complications

The most frequent reason for a surgical revision during the follow-up period was underdrainage in 28 children (16.5%)—due to proximal catheter obstruction in 17 (10.0%), valve obstruction in 8 (4.7%), and distal catheter obstruction in 3 (1.8%)—followed by infection in 11 (6.5%) and overdrainage in 8 (4.7%; Table 3).

Shunt and Valve Survival

The rate of overall shunt survival was 72.6 and 62.0% at 1 and 2 years after shunt insertion, respectively (Fig. 4). The rate of overall valve survival was 79.2 and 75.6% at 1 and 2 years, respectively (Fig. 5). Age at surgery showed an insignificant trend toward better results in children older than 1 year in terms of both shunt survival (80.0 vs 65.6% at 1 year and 66.9 vs 57.4% at 2 years after shunt insertion) and valve survival (86.2 vs 72.4% at 1 year and 80.3 vs 71.1% at 2 years after shunt insertion). Compared with a primary shunt insertion, a valve exchange showed an insignificant trend toward better results in terms of shunt

survival (75.2% for valve exchange vs 71.2% for primary insertion after 12 months and 64.9 vs 60.3%, respectively, after 24 months) as well as valve survival (82.9 vs 77.0% at 1 year and 79.6 vs 73.0% at 2 years, respectively). These variables were not independent given that a younger age correlated with primary shunt insertion, and an older age with valve exchange.

Repeated Operations

The average interval between shunt surgery and reoperation was 0.8 months for infection, 2.8 months for obstruction, and 10.9 months for overdrainage. Seventysix percent of all reoperations and 89% of all valve explantations were performed within 12 months after the initial surgery. The risk of surgery declined by 50% every 6 months for the first 2 years after surgery. Valve-preserving operations carried a small risk of subsequent valve explantation only if they were performed earlier than 3 months after the initial shunt placement. After this interval they had no impact whatsoever on valve survival. The

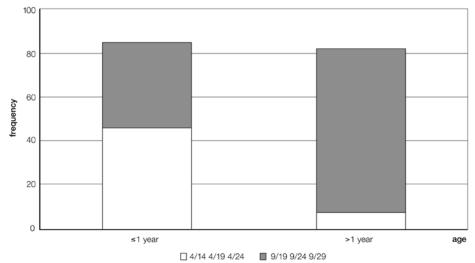


Fig. 3. Bar graph revealing the age-dependent choice of valve pressure setting.

TABLE 3: Reasons for revision among 169 patients

	Cases (%)		
Reason for Op	1st Op Per Patient	Total No. Ops	
underdrainage			
proximal catheter obstruction	17 (10.0)	20 (11.8)	
valve obstruction	8 (4.7)	8 (4.7)	
distal catheter obstruction	3 (1.8)	8 (4.7)	
infection	11 (6.5)	13 (7.7)	
overdrainage	8 (4.7)	8 (4.7)	
unknown	8 (4.7)	8 (4.7)	
catheter obstruction	6 (3.6)	9 (5.3)	
total	61	74	

overall risk of valve explantation after a valve preserving operation was not increased in comparison with the risk in patients who did not undergo any repeat operative procedures (77.2 vs 75.3%).

Discussion

In 1998 Drake et al.8 did not find significant differences in shunt survival among 3 common valve designs: a standard differential pressure valve, an adjustable differential pressure valve, and a so-called flow-controlled valve. Using comparable criteria, our results with the GAV did not differ significantly in terms of overall shunt survival. Taking into account some methodological differences, the similarity of the results in both studies-independent of both the substantially different design of all the analyzed valves and the circumstances of investigation-remains striking and provides reasonable doubt as to whether valve features can be assessed based on the early results of shunt procedures. Shunt and valve survival in the first 2 years after insertion seems to be determined predominantly by the constantly high rate of early complications, which may be a function of how and in whom surgery is performed rather than of a particular valve design. Regarding the most common early

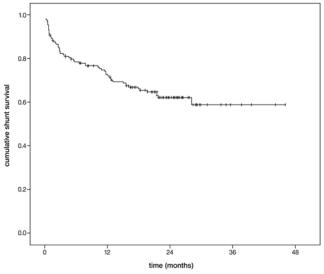


Fig. 4. Kaplan-Meier curve depicting long-term shunt survival.

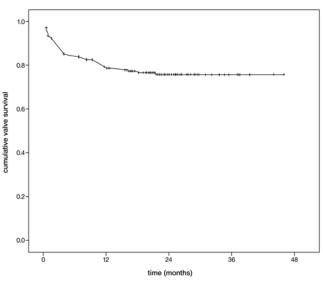


Fig. 5. Kaplan-Meier curve indicating long-term valve survival.

complications, it has already been shown that shunt infections are related to a number of defined surgical and logistic criteria.^{4,5} The high rate of mechanical complications may very well be associated with a high rate of ventricular catheter misplacement related to unguided insertion. Furthermore, the dynamic change in proportions between brain volume, head size, and ventricular volume in the first 12–24 months in children younger than 1 year of age at the time of shunt insertion does make the proximal catheter the most vulnerable part of the shunt system, and thus the resulting migration and occlusion become the most common reasons—13.6% in our series—for early shunt failure. These factors are independent of shunt design. We found a small but persistent proportion of collapsed ventricles after shunt surgery despite the use of gravitational valves. Apart from the critical consideration of the correct surgical placement of the GAV-oblique positioning at surgery can permanently increase CSF drainage¹⁶-the available fixed pressure settings of the valve may not correspond adequately to the hydrostatic needs of a child. Whether factors other than hydrostatic pressure (for example, the time course of elevated intracranial and intraabdominal pressure during crying or coughing) can contribute to overdrainage remains unknown. In contrast to other trial designs, we continued our follow-up after valve-preserving operations. The low impact of the replacement of ventricular or abdominal catheters on the risk of subsequent valve explantation supports the assumption that the majority of early shunt problems seem to be independent of valve features. Exceptions may be the proven associations between catheter blockage and high-resistance valves¹¹ and the significant overdrainage related to the choice of inadequate shunt systems or incorrectly positioned valves.⁶ Nonphysiological CSF diversion associated with chronic overdrainage and leading to a nonphysiological, low intracranial pressure may be compensated for by the child for a long time while creating irreversible morphological and hemodynamic consequences during this clinically "silent" period. Again, the findings of Drake and coworkers,8 as well as our study data revealing no differences in early results despite

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the use of substantially different valve designs, support the assumption that a poor valve design can remain undetected during this early, clinically silent period. Returning years later for chronic headaches, a significant number of these initially symptom-free children frequently exhibit an irreversible slit ventricle syndrome.¹⁹ We believe that regarding the clinical impact of a valve design, attention must be focused on the long-term effects. Avoiding irreversible long-term sequelae would also enable the justification of current considerable cost differences among the large variety of valve designs and additional components.

The true hope behind advancing valve designs is to improve the psychosocial development and quality of life in hydrocephalic children. As most of the relevant criteria can be assessed only at the ages of 5-6 years,¹³ there are no current data confirming the effects of any given valve design. At the same time and for the same reasons, the relevance of shunt-related morphological changes, which can be assessed much earlier, remains unknown for the destiny of patients. We therefore conclude that probably the only effective way to determine the impact of valve properties on the developing nervous system in hydrocephalic children will be to establish long-term protocols initially monitoring morphological data, such as ventricular dimensions and skull properties, progressively extending to an assessment of intracranial brain and CSF volumes and late complication rates, and, once the child reaches the age of 5-6 years, considering aspects pertaining to quality of life and psychosocial development.

Conclusions

Compared with other shunt designs, the use of a pediatric GAV does not significantly affect the early complication rate in children. Valve-preserving shunt revisions do not increase the risk of subsequent valve failure. A significant impact of valve design on the early complication rate in shunt surgery is not supported by current data; therefore, we suggest using long-term protocols that focus on quality-of-life aspects and late complication rates and monitoring morphological data such as intracranial brain and CSF volumes and skull properties to describe the impact of valve features on the developing nervous system in hydrocephalic children. The expected superior clinical performance of paediGAV, which to date has only been revealed in laboratory tests,^{1,15} remains to be demonstrated in just such a long-term study.

Disclosure

For every patient enrolled in the study, the referring department was refunded by Aesculap/Tuttlingen for administrative costs. This study was supported in part by Aesculap Braun/Miethke (M.M.J., R.E., and M.K.). Drs. Fritsch, Rohde, and Haberl are consultants for Aesculap.

Acknowledgments

The authors thank the following contributing members of the paediGAV study group: Dr. P. Hanlo (Utrecht), Dr. A. Joedicke (Berlin), Dr. G. Kammler (Hamburg), Dr. J. Krauss (Würzburg), and Dr. M. Rittierodt (Hattingen). Thanks are extended as well to Dipl. Ing.Ch. Miethke (Fa. Miethke), Dipl.Ing.R. Schulz (Fa. Miethke), P. Ecker (Fa. Aesculap), and C. Trittel (Fa. Aesculap) for logistic support and A. Backes (München) for translation.

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Manuscript submitted July 22, 2008. Accepted April 16, 2009.

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