PEDIATRIC GRAVITATIONAL SHUNTS: INITIAL RESULTS FROM A PROSPECTIVE STUDY

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Object. The authors’ goal in this paper was to evaluate prospectively the efficacy and safety of a new pediatric gravitational shunt to determine whether it warrants inclusion in a randomized, controlled trial with other shunts.

Methods. A total of 55 children between the ages of 0 and 6 years (median age 0.5 years, average age 4 ± 6 years) underwent primary shunt implantation; all received the Miethke Paedi-GAV. The follow-up period ranged between 12 and 77 months (mean 47 ± 21 months). The primary end point of the study was the first shunt failure necessitating revision.

The 1- and 2-year shunt survival rates were 75 and 68%, respectively. The average failure-free shunt survival duration was 1423 ± 641 days. Based on imaging findings, no slitlike ventricles occurred. The complication rate was 33%, and the median time to shunt failure was 45 days. Underdrainage occurred in one child (1.8%) and overdrainage in two children (3.6%).

Conclusions. These preliminary results prove the Miethke Paedi-GAV to be a safe and effective pediatric shunt worthy of inclusion in a randomized comparison with other shunts in the pediatric population.

Key Words • hydrocephalus • overdrainage • gravitational shunt • pediatric neurosurgery
cluded from the analysis. The remaining 55 children (27 boys and 28 girls) fulfilled the inclusion criteria: age at the time of shunt insertion younger than 16 years, minimal follow-up period of at least 12 months, yearly clinical and imaging follow-up examinations, and no prior definitive hydrocephalus treatment (such as shunt placement or endoscopic third ventriculostomy).

No shunts were placed in children weighing less than 1500 g. However, patients were included if they had received a reservoir when they weighed less than 1500 g and later underwent shunt placement when their body weight exceeded 1500 g. During the follow-up period two children died 2.5 and 4.5 years after shunt insertion. In both cases death was due to the rapid progress of brain tumors and therefore was unrelated to shunt failure.

Because the aim of the study was to evaluate the safety and efficacy of the shunt, no origin of hydrocephalus was excluded (Table 1). The patients' ages at the time of the shunt implantation procedure ranged from 2 days to 10 years (mean age 15 ± 27 months, median age 2 months; Table 1). At the time of shunt insertion 42% were younger than 1 month old and only 24% were older than 1 year. The average follow-up period was 47 ± 21 months (range 12–77 months). Informed consent was obtained for each child from his or her parents. A local institutional ethics committee approved the study.

**Valve Technology and Valve Opening Pressure**

The small outer dimensions of the Paedi-GAV (outer diameter 4 mm, length 15 mm) work well in small children, and the valve’s comparatively large CSF pathways provide a specific constructive element to prevent valve occlusion.

The device itself consists of two valves in one housing (Fig. 1). The first is a conventional ball-in-cone valve similar to many other differential pressure valves. Typically, the opening pressure of this valve remains the same independent of body posture. In contrast, the second valve is a gravitational subunit; its opening pressure changes based on its position. The valve is deactivated when the patient is supine, providing no resistance to flow, but as the patient moves into an upright position the opening pressure continuously increases. The hydrostatic pressure, which some may call the siphoning effect, is counteracted by an analog increase in the opening pressure of the gravitational subunit. The mechanism behind this is a counterbalancing principle in which the weight of a heavy metal ball counteracts the weight of the “hanging CSF column.”

An opening pressure of 9 cm H2O (~7–mm Hg) for the differential pressure portion of the Paedi-GAV was chosen for all 55 children. The opening pressure of the gravitational subunit ranged between 10 and 20 cm H2O (Fig. 2) depending on the child’s height.21,22 Thus the opening pressure of all Paedi-GAV units was 9 cm H2O in the supine position and ranged from 19 to 29 cm H2O—depending on the chosen gravitational subunit—in the upright position.

**Outcome Evaluation**

Each child underwent an examination before shunt insertion; at intervals of 1.5, 6, and 12 months postoperatively; and yearly thereafter. Magnetic resonance imaging was the preferred imaging modality, but if it was unavailable computed tomography was used to visualize the intracranial morphology. The ventricle size was assessed using the FOHR;23 the head circumference was also recorded at each examination. According to the study protocol, children and their parents were questioned as to the patient’s history with a focus on specific problems and complaints regarding the shunt. A portion of the questions highlighted the general physical and mental development of the children. The assessment was completed based on a predefined, structured clinical examination.
Complication and Shunt Survival

Once a shunt had to be revised, it was defined to have reached its survival end point. If shunt failure was suspected then a complete history was taken and a physical examination along with magnetic resonance or computed tomography imaging was performed.

If we suspected overdrainage, underdrainage, or mechanical shunt failure, a complete shunt system examination was conducted using an x-ray fluorospot. In addition, the CSF pressure was measured by reservoir puncture.

For children with suspected shunt infections, CSF samples were taken via the shunt system’s reservoir and general infection markers (C-reactive protein and white blood cell counts) were assessed. A potential shunt infection was determined based on an increase in infection markers together with increased CSF cell counts. Skin macerations over the shunt’s path—also without signs of general infection or increased CSF cell counts—were also treated as a potential shunt infection. Cases of confirmed organism colonization around the shunt were treated as a proven shunt infection.

All suspected or proven infections or shunt failures resulted in surgical revision, and by definition the shunt had reached its survival end point. Reimplantation of the shunt was undertaken only if the infection resolved.

Statistical Analysis

We used nonparametric statistical analysis tools only: the Mann–Whitney U-test, Wilcoxon test, Kruskal–Wallis test, and analysis of variance were calculated using SPSS version 8 software (SPSS Inc.). Significance was assumed for probability values less than 0.05.

Results

Shunt Survival

The shunt survival rates 12 and 24 months after implantation were 75% and 68%, respectively. After a maximum of 77 months, 68% of the primarily implanted shunts were not revised (Fig. 3), and the mean failure-free shunt survival was 1423 ± 641 days. The median time until shunt failure requiring revision was 45 days (mean 218 ± 468 days).

Ventricle Size and Head Circumference

The ventricles were clearly dilated preoperatively (FOHR index 0.67 ± 0.12) and were significantly reduced in size postoperatively (FOHR index 0.50 ± 0.12) (p < 0.0000; Fig. 4). During the entire follow-up period we did not observe any very small or slitlike ventricles.

Approximately 50% of the children had macrocephaly before shunt insertion, and their head circumferences were greater than the 97th percentile (Fig. 5). After the shunt operation, two time periods may be discriminated. Within the 1st year after shunt insertion the patients’ head growth ceased. Accordingly the number of children with normalized head circumferences (between the 3rd and 97th percentile) increased, whereas the percentage of children with macrocephaly decreased from 47 to 13% (Fig. 5).

A surprising but clear trend could be seen pertaining to head growth after the 1st postoperative year. Following this time point until a certain percentile level was reached, the children’s head growth followed closely the same percentile level at which it had previously stabilized (Fig. 5). However, the head circumference evolution after treatment of these children with and without posthemorrhagic hydrocephalus was significantly different (Fig. 5).
Although initially at similar percentile levels ($p = 0.739$), children with posthemorrhagic hydrocephalus had clearly smaller heads ($p = 0.001$) 1 year after shunt placement. In this study, the head circumferences in children with posthemorrhagic hydrocephalus evolved to a level between the 10th and 25th percentile 1 year after shunt placement in most instances. On the contrary, the head circumference of children with non–posthemorrhagic hydrocephalus typically reached a level between the 50th and the 75th percentile (Fig. 5). This discrepancy remained stable over the course of the follow-up examinations.

A few children with posthemorrhagic hydrocephalus developed head circumferences less than the 3rd percentile, but even these children had normal-sized and not slitlike ventricles. Accordingly, the microcephalic state cannot be due to overdrainage.

**Shunt Complications**

No shunt-related death occurred. The overall complication rate during the entire observation period was 33%. Overdrainage occurred in two children (3.6%) and underdrainage in one (1.8%). Tube disconnection and displacement forced a revision in three children (5%). In another child the ventricular catheter was blocked by ingrowths of tumor tissue from a huge malignant ventricular tumor. We observed five early (within 6 weeks after the shunt operation) shunt infections. With a frequency of 12 and 7%, respectively, the infection rate in children younger than 1 year was significantly higher than that in older children ($p = 0.0026$).

Five premature children with very thin skin presented with a local skin maceration within the first 2 weeks following shunt placement. The likely cause was the superficial skin closure technique that was initially undertaken. We believe that the suture filaments acted as a wick provoking CSF flow through the skin, which macerated it. Because the skin erosions were far away from the valve itself, it is highly unlikely the valve’s size was at fault. The valve’s small dimensions did not overstress the premature children’s skin, which could be a cause for skin maceration with larger shunt designs. Although not indicated strictly, we treated these as shunt infections as well. However, we have since modified our technique to glue the superficial skin with histoacrylate and limit stitching to subcutaneous tissue. Since this change in surgical technique, we have not seen a similar type of complication.

**Discussion**

**Rationale for Another Shunt Design and Further Shunt Studies**

Many shunt designs have been aimed at physiological CSF drainage. In clinical practice, however, newer shunt designs have often reduced the incidence of one type of hydraulic mismanagement at the expense of increasing other shunt-related complications. For instance, the reduction in overdrainage rates resulted in elevated underdrainage rates in some designs. Accordingly it is not surprising that clinical trials in which different shunt designs have been compared did not reveal any relevant difference between the devices. Because we are faced with 1- and 2-year shunt survival rates of 50 to 70% and 47 to 53%, respectively, we cannot end our search for better shunts.

One major issue responsible for shunt failure is the systematic hydraulic mismanagement in the majority of shunt designs. For instance, the consequences of a variant hydrostatic pressure on the shunt performance are not addressed with many constructs.

Whether the promising results attained using gravitation-
Gravitational shunts in children

al valves in adults21,22,26 may be reproduced in children has not yet been answered. One report on children in which gravitational valves were studied lacked a sufficient number of patients as well as a sufficiently long follow-up period.4 The results of another study are inconclusive because the authors inserted the Paedi-GAV in cases of shunt revisions only,27 which is known to increase the risk for repeated shunt failure.37 Our aim in this study was to gather sufficient data concerning the efficacy and safety of the Paedi-GAV and to determine whether the shunt qualified for a prospective randomized trial in children who were not previously treated with shunts.

Effectiveness and Safety of the Paedi-GAV

Because of the limitations of a nonrandomized study, statistically significant comparisons with historical data cannot be made. However, our first impressions of the performance of this new valve design are positive. Our 1- and 2-year shunt survival rates of 75 and 68%, respectively, are at least comparable with other recently published studies concerning shunts in children.9,11,12,20,24,29,30,36,40,43,44 Because of the restrictions of our study’s design the data must be interpreted carefully, but the statement that the Paedi-GAV is not clearly worse than other shunt designs seems justified.

The main rationale for developing gravitational shunts was to enable physiological CSF drainage regardless of the patient’s posture. Overdrainage incidences range widely in the literature between 0 and 40%. This rate may be understood better if we consider the different definitions of overdrainage and underdrainage along with the specific anatomical information (if taken into account at all) that affects hydrostatic pressures, such as patient height, that differ among studies.9,11,12,20,32,35 Against this background, our data again need careful interpretation. The overdrainage rate in this study (3.6%) falls easily within the range of recently published overdrainage rates for different modern shunt designs.9,11,12,20,32 The same holds true for our underdrainage rate of less than 2%. Overall these figures allow the assumption that the hydraulic performance of the Paedi-GAV is at least not clearly worse than that of other pediatric shunts.

Our intention in this pilot study was not to draw any conclusions concerning the potency of the Paedi-GAV to reduce the incidence of SVS, because it normally takes at least one decade from the time of the first shunt insertion until SVS becomes obvious. However, some prerequisites for the development of SVS can be recognized earlier. One key feature is the reduction of the compensatory capacity. Overdrainage induces very small ventricles or a “contracting skull” resulting in a premature suture closure, which can often be seen years before SVS develops.

Our data up to now have shown that head growth is within the physiological range following shunt treatment with the Paedi-GAV. Only in premature children with subependymal bleeding does the average head circumference reach levels below the 50th percentile. Yet by definition, some of these children were in a microcephalic state. Even in these children, however, the ventricles were not siltlike and the sutures closed at an appropriate time, likely excluding overdrainage as the underlying cause. Our explanation for the combination of small heads and normal-sized ventricles is that the bleeding destroyed the brain’s subependymal cellular matrix, which is vital for its development.

We have not yet seen any early signs for the development of prerequisites for SVS. Skin macerations in some premature children occurred as a consequence of an inadequate skin closure technique and were not the result of overstretching of the skin by a large valve design. The dimensions of the Paedi-GAV and the clinical results after we changed our operative technique strengthened our belief that this device may be safely implanted in premature children who weigh more than 1500 g.

Conclusions

The Paedi-GAV is an effective and safe shunt for the specific demands of young children. Our data confirm its qualification for inclusion in a randomized controlled trial with other shunts to study whether pediatric gravitational valves might, like their adult counterparts, reduce the incidence of hydraulic mismanagement and resultant shunt failures.

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References


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