Child's Nerv Syst (2002) 18:288–294
DOI 10.1007/s00381-002-0577-0

INVITED PAPER

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Clinical experiences with different valve systems in patients with normal-pressure hydrocephalus: evaluation of the Miethke dual-switch valve

Received: 31 August 2001
Published online: 15 May 2002

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Abstract *Objective:* In patients with normal-pressure hydrocephalus (NPH) and beginning brain atrophy the conventional differential pressure valve bears the disadvantage of opening abruptly when the patient moves into an upright position. In this way severe suction on the already atrophic brain could be induced. We wished to find whether this disadvantage, and especially the complication of the overdrainage, could be reduced or solved by a hydrostatic valve? *Methods:* In 115 patients diagnosed with NPH we implanted 36 Cordis standard valves (CSV), 19 Cordis-Orbis-Sigma valves type I (OSV), and 60 Miethke Dual-Switch valves (M-DSV). The patients were re-evaluated 7 months after surgical treatment. NPH was diagnosed from the clinical symptoms, the results of the CAT scan or MRI scan, the intrathecal infusion test, and the patients' recovery after a CSF tap test. *Results:* The clinical follow-up showed significantly better results for patients with an implanted M-DSV valve than in patients with a conventional differential pressure valve. We found clear differences in the incidences of overdrainage and subdural hematoma: 2 patients (6%) with a CSV, 3 patients (16%) with an OSV and 1 (2%) with a M-DSV exhibited clinical signs of overdrainage. Three patients (16%) with the OSV later developed subdural hematomas, for which neurosurgical treatment was necessary. One of these 3 patients (5%) died of an intraventricular hemorrhage. One patient with a CSV (3%) and 1 with a M-DSV (2%) had to be operated on a subdural hematoma. *Conclusion:* The clinical course in patients with NPH is influenced by the stage of the disease, the beginning of therapy and the implanted valve type. Although little clinical experience is so far available with the M-DSV, we have to underline the advantages of this valve for patients with NPH.

Keywords Clinical results · Hydrostatic valve · Normal pressure hydrocephalus · Overdrainage · Shunt operation

Introduction

Even though 40 years have passed since the beginning of valve-regulated shunt therapy for hydrocephalus internus, it is still beset by severe biomechanical problems caused by unphysiological valve constructions. These difficulties are reflected in the high number of available devices, with more than 200 different valves, which can be subdivided into three construction types: those in the first group, the so-called differential pressure valves, have a fixed opening pressure, which operates only when the patient is in a lying position. The second group is the group of programmable valves. These valves allow a noninvasive adjustment of the opening pressure. However, they also have the disadvantage of not taking any account of the patient's posture. Only the third group, the so-called hydrostatic valves, make any allowance for the fact that patients with ventriculoperitoneal shunts have completely different conditions of ventricular pressure [2, 21, 24].

Especially in patients with normal pressure hydrocephalus (NPH), conventional differential pressure valves have the disadvantage that they either open abruptly or remain open too long when the patient moves into the upright position. In this way they could induce suction on the already atrophic brain. We were anxious to find whether these disadvantages and the complications of the overdrainage could be reduced or solved by a hydrostatic valve.

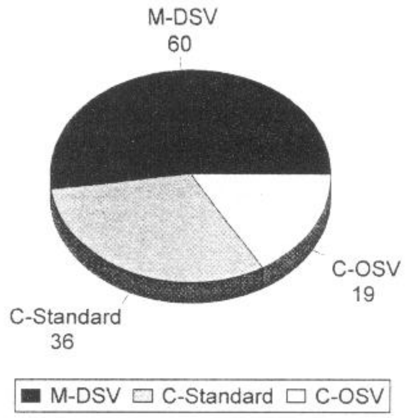

Fig. 1 Number and type of implanted valves (*C-Standard* Cordis standard; *C-OSV* Cordis-Orbis-Sigma valves; *M-DSV* Miethke dual-switch valves)

Patients and methods

In a prospective study, between May 1982 and December 1999, 115 patients with normal-pressure hydrocephalus were treated and re-evaluated by a ventriculoperitoneal shunt insertion, first in the Department of Neurosurgery in the hospital Berlin-Friedrichshain and from September 1997 onwards in the Department of Neurosurgery of the newly opened Unfallkrankenhaus Berlin. In 36 patients a Cordis standard valve, in 19 patients a Cordis-Orbis-Sigma valve, and in 60 patients a Miethke dual-switch valve was implanted (Fig. 1).

Cordis standard valves (CSV) were implanted between May 1982 and January 1991 and between October 1995 and March 1996, the type I Cordis-Orbis-Sigma valves (OSV) between February 1991 and September 1995, and the Miethke dual-switch valve (M-DSV) between March 1996 and December 1999.

All patients showed a ventricular enlargement, especially in the frontal part of the lateral ventricles, and a communicating hydrocephalus visualized on the CAT scan or MRI. The main symptom in the clinical examination was the gait ataxia. The symptoms of the patients, gait ataxia, dementia, urinary incontinence, headache and/or vertigo were classified according to the Kiefer scale for chronic hydrocephalus (Table 1) [10]. The course of disease was compared with the NPH Recovery Rate both postoperatively and after 7 months [13].

$$\text{NPH} - \text{R} - \text{R} = \frac{\text{clinical grading preoperatively} - \text{postoperatively}}{\text{clinical grading preoperatively}} \times 10$$

The comparison with the internationally established Black grading scale for shunt assessment [3] and our own NPH Recovery Rate [13] is illustrated in Table 2. The decision as to whether a shunt operation was indicated was made according to the clinical signs and the results of the intrathecal infusion test, with measurement of a pathologically increased resistance of over 13 Torr × min/ml [12]. The resistance to CSF outflow was the main criterion for

Table 1 Clinical grading in patients with normal-pressure hydrocephalus: Kiefer scale for chronic hydrocephalus

Symptoms	Grade	Score	Symptom
Mental	0	0	No clinical detraction
	1	1	Concentration disorders, forgetfulness
	2	3	Apathy, orientated only in parts and symptoms of grade
	3	5	Completely disoriented, skill disorders
Gait ataxia	0	0	No gait disorders
	1	0	Gait disorders only detectable in special tests (walking with eyes closed)
	2	2	Gait is atactic and wide based, but secure (without help)
	3	4	Walking is difficult and only possible with help
	4	5	Only a few steps with help of other persons
	5	6	Impossible to walk
Incontinence	0	0	No incontinence
	1	3	Temporary incontinence (e.g., at night)
	2	4	Permanent incontinence
	3	6	Incontinence of urine and stool
Headache	0	0	No headache
	1	1	Intermittent (e.g., at night) or permanent, slight headache
	2	4	Severe, constant headache
Vertigo	0	0	No vertigo
	1	1	Vertigo only under stress
	2	3	Intermittent vertigo
	2	4	Permanent vertigo

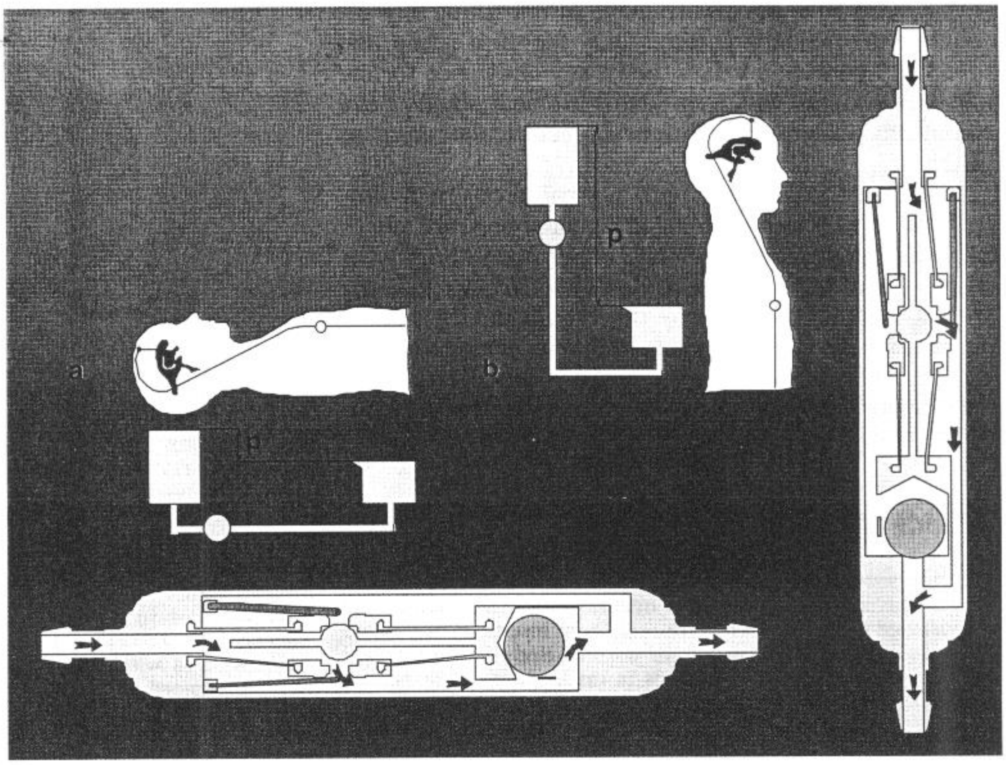

Fig. 2a, b Working principles of the Miethke dual-switch valve: **a** recumbent patient, **b** standing patient

Table 2 Comparison of the Black grading scale for shunt assessment and the NPH Recovery Rate

Black grading scale Grading	Description	NPH Recovery Rate Points
Excellent	Activity as before	>7 points
Good	Slight restriction	>5 points
Fair	Gradual recovery	>3 points
Transient	Temporary recovery	>2 points
Poor	No recovery or worse	Less than 2 points
Dead	Patient died of the operation	Not applicable

classifying patients into those with normal pressure hydrocephalus and those with cerebral atrophy. Our indication for shunt implantation was thus a pathologically increased outflow resistance together with clear recovery after CSF tap test. Patients whose outflow resistance was in the physiological range were diagnosed with cerebral atrophy and not treated surgically. The mathematical fundamentals, the standardized investigation procedure and the indications for the performance of a computer-aided infusion test have been described elsewhere, as have the pathophysiology, clinical symptoms and course of disease in NPH [12, 13, 14, 15, 16, 17, 18, 19].

Technical note

The Miethke dual-switch valve keeps the ICP within physiological limits, independent of the posture of the patient. It consists of two different chambers, one for the recumbent posture and one for the sitting or standing posture of the patient. This makes it possible to keep the ICP in physiological ranges whether the patient is lying down or in a standing position. The required valve chamber is activated by a heavy tantalum sphere, which prevents drainage through the low-pressure chamber as soon as the patient gets up. Only if the ICP increases up to critical values in the upright position will the high-pressure chamber open, counteracting any further rise in pressure (Fig. 2).

Recumbent patient

As long as a proper balance is maintained between the production and the resorption of CSF, the ICP remains in the physiological range and the valve is closed. As soon as the physiological CSF circulation is disturbed the ICP will increase. As the tantalum sphere opens the low-pressure chamber of the valve the CSF drainage through the valve prevents any further increase in ICP (Fig. 2a).

Standing patient

As soon as the patient gets up the tantalum sphere prevents the CSF drainage that would otherwise be caused by additional hydrostatic differential pressure. If the CSF circulation remains disrupted the ICP will increase and the high-pressure chamber of the valve will open. A critical rise in ICP and harmful and unintentional overdrainage through the valve are effectively avoided (Fig. 2b).

Results

The clinical follow-up (Fig. 3) according to the NPH Recovery Rate [13] showed a statistically significant

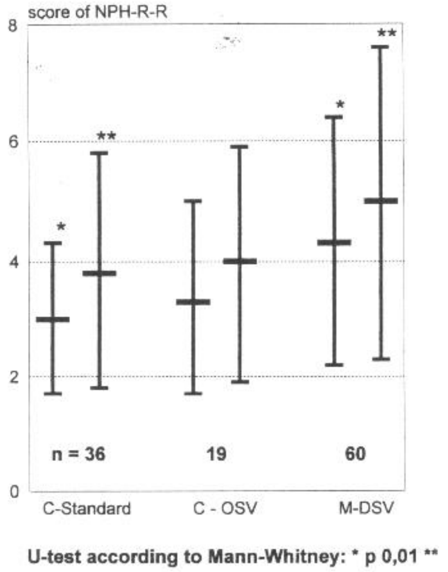

Fig. 3 NPH Recovery Rate, referred to postoperative status and condition 7 months after shunt placement, by valve type

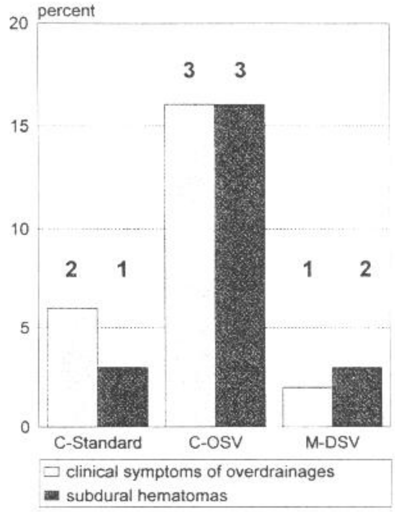

Fig. 5 Complications due to valve-related overdrainage plotted against valve types

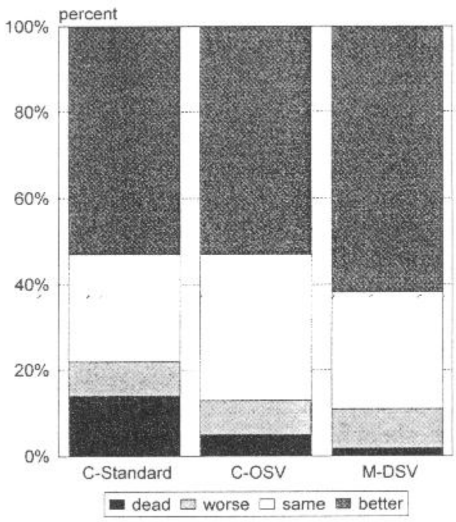

Fig. 4 Self-assessment of the patients, results 7 months after operation

($P<0.01$ using the Mann and Whitney U-test) improvement of outcome in patients with an implanted Miethke dual-switch valve postoperatively and also during follow-up after a mean time interval of 7 months, when the difference was even more highly significant. Self-assessments by the patients or their relatives also reflect these results (Fig. 4). Thus, the course of disease in patients with normal pressure hydrocephalus is dependent on the stage of disease, the beginning of therapy and the implanted valve type.

Complications arising from the operation or the shunt in the early stage after surgical treatment (5%) were chronic subdural hematomas in 4 cases and postpuncture intraventricular hemorrhages in 2. Two patients died as a result of the operation. One of these 2 patients was suffering from a vegetative state after a severe head injury. In the course of his illness he developed an intraventricular hemorrhage. The second one suffered from chronic subdural hemorrhage, which was treated with trepanation and removal of the hematoma, and subsequently the ventricular catheter was changed. Thus, the lethality in our own patient trial was 2%. Complications seen in the late stage after surgical treatment (9%) were infections of the ventricles in 7 cases (6%) and mechanical valve occlusion in 3. In the case of infection (2 cases of peritonitis, 2 of abdominal abscesses and 3 of ventriculitis) we removed the shunt. After recovery from infection we implanted a valve again in 5 patients. In the 3 cases of valve occlusion, or rather occlusion of the catheter, the shunt system was replaced. Therefore, late-stage morbidity was 14%. When the morbidity of the operation or rather the valve is compared with reference to the different valve types, we observed that the mechanical complications and infections of the valves did not differ in a statistically significant manner between the different valve types. However, clear differences were found between them in overdrainage and subdural hematomas (Fig. 5). Two patients (6%) with Cordis standard valves, 3 patients (16%) with Cordis-Orbis-Sigma valves, and 1 patient (2%) with a Miethke dual-switch valve showed clinical signs of overdrainage, such as queasiness, vomiting and headache, on neuroradiological examination.

The 3 patients (16%) with Cordis-Orbis-Sigma valves developed subdural hematoma in the course of disease and two (11%) of these had to be evacuated. One of these patients (5%) died of an intraventricular hemorrhage. Two of the patients with Miethke dual-switch valve (3%) also developed subdural hematomas. In 1 of these patients the subdural hematoma was resorbed within 1 month without accompanying clinical symptoms, but we had to remove the shunt in the other patient (Fig. 5).

Discussion

The breakthrough in shunt treatment can be traced back to the engineer Holter, who developed the first valve when his own child was suffering from hydrocephalus as a result of spina bifida. In 1949 the neurosurgeon Spitz implanted this valve for the first time. All the common valves work on the principle of differential pressure. This means that the passage through the valve is released when pressure difference between inlet and outlet of the valve rises over the specific opening pressure of the valve. Aschoff et al. [1, 2] described five different technical possibilities: slit, cross-slit, membrane, lip- and globe in both Conus and Orbis-Sigma valves and also a combined needle-and-membrane valve. There are now 195 different valve types, allowing 450 pressure levels and providing more than 1,200 different possibilities. All shunt systems consist of a tube system made of silicon and a one-way valve. Adjustment of the system to the individual requirement of the patient is made possible by the availability of different sizes of valves with graduated opening pressures. Besides these, there are the options of implanting the shunt system as a ventriculoarterial, a ventriculoperitoneal or a lumboperitoneal shunt, plus other, less common, versions. The anti-siphon device was developed to avoid the so-called siphon effect. This device consists of an extra valve, which is intended to avoid overdrainage distal to the pumping valve when the patient is in an upright position. None of these valves is subject to reliable quality control [1].

In patients with normal pressure hydrocephalus without brain atrophy we have found two clinically relevant overdrainage complications after implantation of a Cordis standard valve. Trost et al. [27] pointed out that many patients can tolerate negative intraventricular pressure values, which are actually physical characteristics of these valve types. However, other authors described overdrainages in standard valves. The Dutch multicenter study [4, 25] showed a statistically significant positive postoperative result with the implantation of low-pressure differential pressure valves in comparison with medium-pressure valves. But this advantage was accompanied by a high overdrainage rate of 71%, compared with 34% with the medium-pressure valves. In this study the clinical relevance of the high overdrainage rate was not described, but in our opinion this rate seems much too high. One reason for the implantation of standard valves is their low price, but even one overdrainage complication would cost the price of 30 or more valves with a negative balance. On the one hand, the significantly better results after implantation of a Miethke dual-switch valve are also based on our experience in diagnosis and therapy in patients with normal-pressure hydrocephalus over more than 12 years [11, 12, 13, 14, 15, 16, 17, 18, 19]; on the other hand, the better outcome is based on the construction of these valves, which takes account of the changes in patients' posture [24, 28]. Because of the good prognosis of patients with normal-pressure hydrocephalus without brain atrophy at the moment we also recommend the insertion of Miethke dual-switch valves in this group of patients. In most patients with normal-pressure hydrocephalus with beginning brain atrophy we have implanted Orbis-Sigma valves, Cordis standard valves and Miethke dual switch valves. Unlike the standard valves, the Orbis-Sigma valve makes regulation of a constant flow possible because this is how the differential pressure acts on the system. This is very important for patients with normal-pressure hydrocephalus and mild brain atrophy, so as to avoid overdrainage complications. Unfortunately, we had 3 cases of overdrainage altogether, with 3 chronic subdural hematomas, as complications of this type of valve. Weiner et al. [29] also report subdural hematomas as a clinical sign of overdrainage in patients with normal-pressure hydrocephalus after implantation of an Orbis-Sigma valve. In contrast to Czosnyka et al. [6], Decq et al. [7] found significantly lower overdrainage rates after Orbis-Sigma valve insertion than with conventional differential pressure valves. However, these studies did not exclusively evaluate patients with normal-pressure hydrocephalus, and therefore they are not completely comparable with our results. It remains to be seen whether the Orbis-Sigma-II valve will improve the benefit to the patient. The large number of cases of overdrainage and subdural hematoma suggests that the Cordis-Orbis-Sigma valve is not appropriate for patients with normal-pressure hydrocephalus. When Cordis differential pressure valves are used in patients with normal-pressure hydrocephalus they have the disadvantage of inducing suction on the already atrophic brain when the patients move into an upright position. An anti-siphon device could prevent this problem but, as a disadvantage, it would increase the resistance of the whole valve system at the same time. In 2 of our patients with this type of valve we observed clinical signs corresponding to overdrainage. With regard to the problem of the patients' posture the Miethke dual-switch valve [20], which changes between two different chambers in parallel, opened up new vistas. In our trial 2 patients with a Miethke dual-switch valve developed subdural hematomas, 1 of which showed up on the CAT scan as a small hematoma without corresponding clinical signs. The better result in the patients with a M-DSV is evident and finds its expression not only in the criteria of the NPH Recovery Rate (Fig. 3), but also in the self-assessment of the patient and his relatives (Fig. 4). Despite the scant clinical experience with the Miethke dual-switch valve, we want to emphasize the advantages of this valve for patients with normal-pressure hydrocephalus.

As complications after shunt placement in patients with normal-pressure hydrocephalus, Grumme and Kolodziejczyk [8] reported a lethality of 0–6% and an overdrainage rate of 6–20%. In our group of patients the lethality was 2% and the overdrainage rate was 6%. Our rates for obstruction and infection of the shunt were also very low, with 3% and 6%, compared with the international data. We think that a rate of 50% for shunt obstructions, as reported by Sotelo et al. [23], is much too high despite all critical quality control.

With the Sophy and Medos-Hakim valves the opening pressure can be regulated and adjusted by a percutaneous magnet. Patients with NPH also gave the Medos-Hakim valve a positive assessment. Serious disadvantages that must be mentioned are the large size of the valve and the external influence from magnetic fields such as are used in MRI, airport security systems, speakers and headphones. This type of valve was also unable to prevent overdrainage. In the case of the programmable valves, criteria for regulation of the valve pressure level had to be discussed. A short-term worsening of symptoms should not be taken as an indication for changing the opening pressure, and nor could an improvement of the symptoms be a positive feedback for valve adjustment. Changing the valve pressure level in relation to the ventricular width in the CAT scan must also be refused. We could not detect any dependence between the clinical improvement and the reduction of the ventricular width after shunt insertion. In patients with normal-pressure hydrocephalus no significant reduction in ventricular size has been seen after shunt insertion. Because of the atrophic process the brain of elderly patients loses a lot of its elasticity [5]. Histological studies in brains of cats have shown that ventricular enlargement induced by hydrocephalus causes axonal degeneration. According to Rubin and Hochwald [22], the reconstruction of the brain after a successful ventriculostomy is not based on regeneration of lost tissue, but rather on a compensated spreading of white matter, glia and the capillary vessel net. The damage of structure remains the same. Therefore the decisive factors for the restitution are the mechanism of compensation and the quantity of nondamaged structures. This is confirmed by the very extensive studies by Hakim [9] on the hydraulic characteristics of the neural tissue. Therefore, a reduction of the ventricular width in normal-pressure hydrocephalus in a chronic stage is hardly expected, because the bioplastic deformation has already caused degeneration of the parenchymatous tissue [26]. Only ICP-controlled valves would permit physiological drainage of cerebrospinal fluid. Unfortunately, these kind of valves are not yet technically perfect and thus they are not available for clinical use.

The course of disease in patients with normal-pressure hydrocephalus is influenced by the stage of disease (NPH with or without atrophy) at the time of therapy and the type of valve implanted. According to Lee et al. [11], an adequate shunt operation offers the chance of an improvement of cerebral blood flow and vasomotor activity in normal-pressure hydrocephalus patients. All these factors are correlated, with significantly better outcome in these patients. The low overdrainage rate of less than 3% and the good postoperative results are, in our opinion, the main reasons for presenting the Miethke dual-switch valve as the best valve for patients diagnosed with normal-pressure hydrocephalus.

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