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Dual-Switch Valve: Clinical Performance of a New Hydrocephalus Valve

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Summary

The Dual-Switch valve (DSV) is the first construction on the market which changes between two different valve-chambers in parallel depending on the posture of the patient. In the lying position the valve acts like a conventional differential pressure valve, in the vertical position the high-pressure chamber only opens, when the pressure exceeds the hydrostatic pressure difference between the formanen of Monro and the peritoneal cavity.

The new device has been implanted in 32 adult patients with hydrocephalus of different etiology. The clinical results are excellent to good accompanied by a remarkable slight reduction of the ventricular size. Apart from one case with a nonsymptomatic transient hygroma, we saw no valve related complications like overdrainage, underdrainage or dysfunction. Contrary to conventional differential-pressure valves, adjustable devices and other hydrostatic constructions like the Anti-Siphon-device (ASD) or Deltavalve, the DSV reliably controls the IVP independently of the posture of the patient, the CSF viscosity or the subcutaneous pressure. In contrast to the Orbis-Sigma-valve (OSV) or the Diamond-valve, the DSV does not control the flow but the physiological IVP avoiding the increased risk of mechanical failure. The results of this study give strong evidence that the shunt-therapy of adult hydrocephalic patients can be significantly improved by the DSV.

Keywords: Dual-switch valve; hydrocephalus; overdrainage.

Introduction

Although the introduction of valve regulated shunts during the fifties has been a breakthrough in the treatment of hydrocephalus, we are still confronted with severe biomechanical problems. In the last years an increasing number of new devices has been presented aiming to avoid overdrainage related problems. But none of these devices can physiologically regulate the IVP of hydrocephalic patients independently of the posture, the CSF production rate or viscosity. Especially, sophisticated devices have a tendency to get blocked leading to underdrainage as well as to overdrainage [1,6].

With reference to the long list of overdrainage related complications like slit ventricles, obstruction of the ventricular catheter or hygromas/hematomas (Table 1), it seems very important to develop a valve which does reliably work in physiological limits in the lying position of the patient as well as in the standing position.

Materials and Methods

The dual-switch valve presents for the first time a construction which consequently takes into account that the hydrocephalic patient is in the horizontal position for only 8–12 hours, but for the rest of the day is in the upright position. Depending on the posture of the patient, the valve switches over between two autonomous valve chambers with a completely different opening pressure [4,9]. The valve, which has to be implanted in the subcutaneous tissue of the thoracic region, has opening pressures of 10, 13 or 16 cm of water for the lying and 30, 40 or 50 cm of water for the vertical position.

To investigate the clinical performance of the DSV a controlled prospective clinical trial was carried out. The study started in January 1995. The design of the study is shown in Table 2. In this study we used a DSV with an opening pressure of 13 cm of water (medium pressure) for the recumbent posture and 40 cm of water for the upright position. The clinical status before and after shunting was assessed according to the scale of Stein and Langfitt [10] and changes in the ventricular size were documented on follow-up CT with measurement of the Evans-Index. The DSV was implanted in 32 adult patients with different etiologies of the hydrocephalus (Table 3). The mean follow up was 17,3 months (12,5–25,4).

Results

The clinical outcome was excellent to good except in 3 cases with previous severe posttraumatic or posthemorrhagic brain damage. In the majority of cases we saw only minimal to slight reduction of the ventricular size (Fig. 1) accompanied by very satisfying clinical improvement (Fig. 2). There has been only one transient asymptomatic hygroma. One patient had a persisting hygroma due to a too inclined implantation in the upper part of the barrel-shaped thorax so that the high-pressure chamber was not activated in the upright position. After correction of the position of the valve, the hygroma resolved and the patient went back to work. At the beginning of the trial 3 revisions in 2 patients were necessary because of disconnections of the peritoneal catheter, probably due to sharp edges at the distal connectors of the DSV and thin peritoneal catheters. Changes in the design of the connectors and thicker catheters solved this problem.

Discussion

Worldwide there are more than 50 different valve constructions on the market. These valves can be

Table 1. *Sequelae of Overdrainage Reported in the Literature*

- Low intracranial pressure – syndrome (Foltz 1988)
- Slit-ventricle-syndrome (Epstein 1978)
- Subdural hygroma/hematoma (Anderson 1952)
- Craniosynostosis, hyperpneumatisation and thickening of the calvarium (Griscolm 1970)
- Aquaeductal stenosis, isolated IV. and lateral ventricle (Foltz 1966, Salmon 1970)
- Deteriotation of shunt-dependency (Epstein 1978)
- Precocious obstruction of ventricular catheter (Sainte-Rose 1993)
- Upper hind brain herniation (Emery 1965)

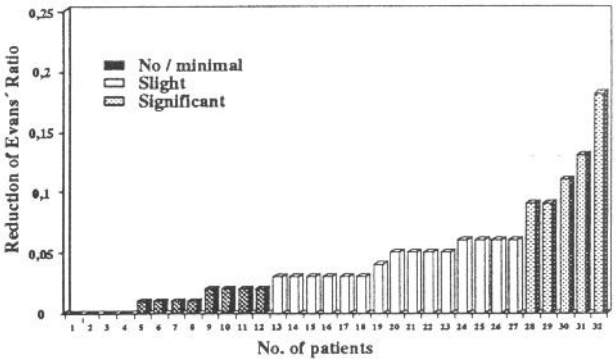

Fig. 1. Changes of Evans-Index after shunting with the DSV

Table 2. *Design of the Clinical Study*

Protocol
- Etiology of hydrocephalus
- Clinical status and CT before shunting
- Intraoperative measurement of ICP
- Clinical status and CT: 14 days, 3 and/or 6 months after surgery
- Registration of complications

Criteria of Inclusion
- Prospective study
- All kinds of hydrocephalus
- Patients older than 17 years
- Exspectation of life more than 1 year
- First implantation of revision
- VP-shunts, frontal burr-hole

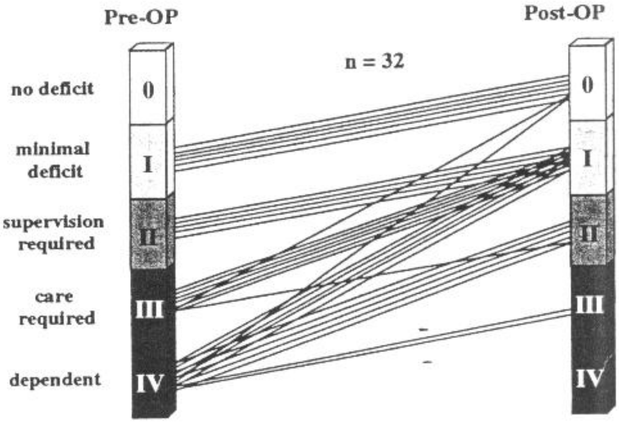

Fig. 2. Clinical improvemant according to Stein and Langfitt [10]

Table 3. *Patients with DSV*

n	Sex m	f	Age at operation (Years)	Etiology of Hc		Follow up (Months)
32	11	21	22–82	idiopath. NPH	9	14,5–27,4
			Mean	post-SAH	10	Mean
			56,3	posttraumat.	5	18,3
				Hc with MMC	2	
				Occl.-Hydroc. Tu./Hem.	2	
				Aqueduct. Stenosis	3	
				Pseudotumor c.	1	

divided into three groups: simple differential-pressure valves with only one opening pressure for the lying position, adjustable valves, again with an opening pressure for the lying position but with the possibility to adjust the pressure level after surgery and hydrostatic valves.

Valves belonging to the first group act similarly to the valves introduced in the fifties. Their opening performance depends on the lying position of the patient. The technical differences between valves of this type refer to the material, the kind of valve seat, the geometry or the flow characteristic. They are available with different pressure ranges beginning with 4 cm of water (very low) reaching up to 16 cm of water (very high). But independently of the chosen pressure range, these valves systematically lead to unphysiologic IVP as soon as the patient moves into the upright posture. These valves cannot keep the IVP within physiological limits due to the changes of hydrostatic pressure in the drainage-system. As many patients tolerate such negative values without clinical symptoms, it is quite understandable that such valves are still implanted. Most important for the clinical performance of the various valves of this group are the reliability of the valve-seat and the flow characteristics. A valve should definitely close if the differential pressure acting on the valve is lower than the opening pressure. Especially for the ventriculo-atrial drainage the safety against reflux has high priority. But besides these aspects there are no important differences in the physical performance of the various differential pressure valves on the market [2].

In principle, the same physics apply to the second group of valves, the so-called adjustable valves. The decisive difference with this group of conventional differential pressure valves lies in the possibility to change the valve performance between the different pressure ranges without surgery. Hereby, it is possible to reduce the negative IVP in the standing position of the patient by increasing the opening pressure of the device. On the other hand, this leads to an increased IVP in the lying position. The highest possible opening pressure of available adjustable valves implies a pressure of 20 cm of water. This pressure is much too high for the lying position and still too low for the standing position because the hydrostatic pressure of the adult patient is in the range of 235 to 250 cm of water. Neither in the horizontal position nor in the upright position the IVP is in physiological limits.

Therefore, adjustable valves can only be a compromise between a reduced negative IVP in the standing position and an increased IVP in the lying position.

The third group of valves represents the most sophisticated valves. There are very important technical differences between the different types of hydrostatic valves. All hydrostatic devices aim to reduce the flow through a shunt-system when the patient moves into the upright position.

The Orbis-Sigma valve [8] and the new Diamond valve [5] do not act depending on the posture of the patient but depending on the differential pressure acting on the system. These constructions aim to regulate a constant flow of about 20 ml/h, nearly independent of the differential pressure, by decreasing the opening while the pressure is increasing. In the standing position these devices can lead to overdrainage as soon as partial physiological absorption occurs or the production rate is lower than 20 ml/h. Both valves assume that the reason for an increased differential pressure on the valve must be a change in the position of the patient. The increased differential pressure is counteracted by a decrease of the opening area in the valve seat. This fact has two drawbacks: first, the reason for the increased differential pressure can be an increased production rate instead of changes of posture. In this case the opening area at the valve seat should not be smaller but larger and the flow should increase. Second, the delicate mechanism for the pressure induced flow regulation is very susceptible to mechanical complications. Very small changes in the opened area of the valve seat lead to dramatical changes of the flow. Therefore, debris or remnants of blood cells significantly influence the function of the valve.

The ASD and the Delta valve as well as the new Beverly valve directly depend on the subcutaneous tissue pressure which leads to unpredictable physical situations. Many authors [1,3,6] clearly demonstrated that the mechanism is extremely influenced by height of the positioning of the device and changes in the subcutaneous pressure by the development of a cellular capsule around the device or by the weight of the patients head lying on the device.

In contrast to other hydrostatic valves, the DSV always acts like two reliable differential pressure valves in parallel with different opening pressures depending on the position of the patient.

The results of the patients with the DSV in our series confirm that there is a remarkable difference between the physics of a lying and standing hydrocephalic patient. The fact that we saw – except one transient hygroma – no overdrainage related problems like symptomatic hygromas or hematomas in comparison to reports about other valves in the literature [7] together with the remarkable slight reduction of the ventricles produces strong evidence that the DSV presents a new possibility to improve the outcome of shunt-regulated patients with hydrocephalus avoiding underdrainage as well as overdrainage. In our opinion, the IVP and not the ventricular size defines the clinical outcome. If the IVP is kept within physiological limits, the individual clinical outcome and the ventricular size will show the optimal result for each individual patient.

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