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Kazuhiko Tokoro
Shin-ichi Suzuki
Yasuhiro Chiba
Masako Tsuda

Shunt assistant valve: bench test investigations and clinical performance

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K. Tokoro (✉) · Y. Chiba · M. Tsuda
Department of Neurosurgery,
Kanagawa Rehabilitation Center,
516 Nanasawa, Atsugi-shi shi,
Kanagawa-ken 243–0121, Japan
e-mail: kazutokoro@aol.com
Tel.: +81-46-2492111
Fax: +81-46-2492290

S. Suzuki
Department of Neurosurgery,
Yokohama City University School of
Medicine, Yokohama, Kanagawa-ken,
Japan

Abstract *Background:* We tested the flow characteristics of a new siphon-reducing device, the Shunt Assistant Valve™ (SAV) combined with a Codman-Hakim™ (CH) programmable valve and studied 4 clinical cases. We discussed the efficacy of the SAV at preventing low pressure syndrome secondary to overdrainage. *Materials and methods:* In the horizontal position the closing pressure (CP) of the SAV was 0. The SAV was available in five different pressure ranges for the vertical position: 15, 20, 25, 30, and 35 cmH_2O. A bench test was performed in order to obtain pressure-flow curves for the SAV under various conditions. We investigated the simulation of the postural change of the flow performance of the new device. We implanted an SAV in 4 patients who already had an implanted CH valve. Postural changes of the shunt flow and intracranial pressure (ICP) were measured before and after the addition of the SAV. *Results:* Bench test: in the horizontal position the flow increased in proportion to the pressure difference. For all SAVs it reached 14 to 16 mL/min when the pressure difference was 50 cmH_2O. A tantalum sphere determined the CP of the SAV with a maximum in the vertical position. The flow in the vertical position was significantly decreased in comparison with the horizontal position. The external pressures did not influence the flow. Simulation: in adults shunt flow in the supine position was sufficient at both the low and the high ICP stages. When the SAV 20 and the CH valve (CP=8 cmH_2O) was used in the sitting position we found a reduction of the flow 70–80% compared with the flow-rate found for the CH valve alone. When the CP of the CH valve was adjusted up to 20 cmH_2O, we found a further reduction of the flow of 27–50% in the sitting position and overdrainage was effectively prevented. With this combination the flow in the sitting position significantly decreased in paediatric hydrocephalus and became zero, indicating the possibility of underdrainage in children. Clinical results: in 4 patients with overdrainage symptoms we found that these subsided after the additional implantation of the SAV. The ICP increased and the shunt flow decreased in both the supine and the sitting positions. *Conclusion:* The SAV effectively decreased the shunt flow in the erect position. Combined use of the SAV with the CH valve is an alternative treatment for patients with overdrainage, especially in patients in whom the increase of the CP of the CH valve alone had failed to control overdrainage.

Keywords Antisiphon · Hydrostatic valve · Overdrainage · Programmable/adjustable pressure valve · Shunt assistant valve · Siphon effect

Introduction

In accordance with the siphon effect, the shunt flow increases dramatically as long as patients with hydrocephalus remain standing or seated, resulting in the overdrainage of the cerebrospinal fluid (CSF). Controlling the overdrainage is the most important and difficult problem in the treatment of hydrocephalus. Programmable pressure valves have been widely used; however, the upgrading of the closing pressure (CP) of this valve does not always result in success [8, 13, 22, 24].

A new siphon-reducing device, the Shunt Assistant Valve™ (SAV), was produced by Christoph Miethke GmbH & Co. KG, Kleinmachnow, Germany (available through Kobayashi Medical Co. Ltd. in Japan). The SAV is used together with conventional differential pressure valves (DPV) or programmable pressure valves [9]. In the supine position the CP of the SAV is zero. As soon as the patient is upright the SAV gets into a vertical position and the CP increases due to the weight of a tantalum sphere, effectively preventing overdrainage.

We discuss the flow and siphon-reducing characteristics as well as the clinical performance of the SAV.

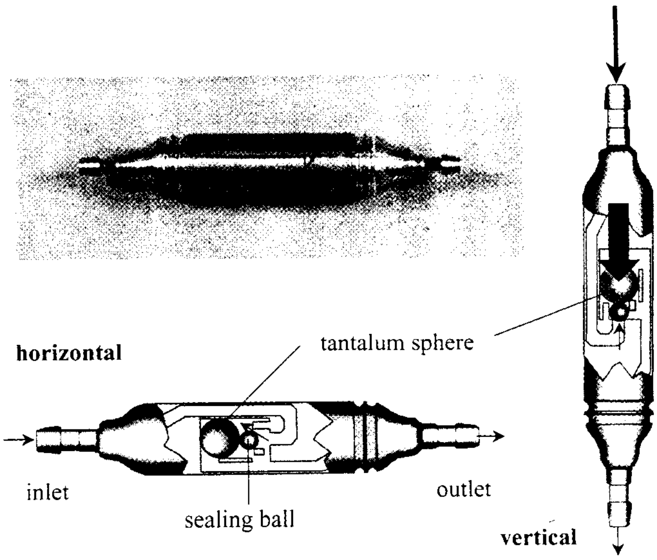


Fig. 1 Structure of the SAV. *Upper left* An SAV has a titanium casing with an outer diameter of 5.8 mm and is 25.4 mm long. The SAV has two different CP for the horizontal and the vertical positions. *Lower left* The CP of the SAV in the horizontal position is zero. *Right* In the vertical position a tantalum sphere compresses a sealing ball, increasing the CP

Materials and methods

Function of the SAV

The SAV has a titanium casing with an outer diameter of 5.8 mm and is 25.4 mm long (Fig. 1, upper left). The SAV is implanted together with a DPV. In adult patients it is preferably implanted in the thoracic region. The CP of the SAV is dependent upon its position. In the horizontal position the CP is zero and the shunt flow is only controlled by the DPV (Fig. 1, lower left). In the vertical position the weight of the tantalum sphere of the SAV compresses a sealing ball, resulting in an increased CP (Fig. 1, right). The SAV is available in five different ranges: the CP for the horizontal position is always zero; devices are available with a maximum CP in the vertical position of 15, 20, 25, 30 and 35 cmH_2O.

Bench test

SAVs with a CP of 20, 25, 30, and 35 cmH_2O combined with a Codman-Hakim™ (CH) valve were tested. The total length of the proximal and distal catheters of the Hakim™ programmable shunt system was 80 cm with the SAV and the CH valve. Pressure-flow curves of the SAV were measured with positive inlet pressures between 0 to 60 cmH_2O, or negative outlet pressures between –60 to 0 cmH_2O in 5 or 10 cmH_2O intervals. The CP of the CH valve was varied: 3, 8, 12, 16 and 20 cmH_2O. The temperature of the water was 20°C.

Simulation of the postural change of the shunt flow

A simulation of the postural changes of the shunt flow with reference to the postural changes of ICP and the bench test mentioned above was investigated according to the method of Tokoro et al. [20]. The positional changes of ICP in 13 adult patients with normal pressure hydrocephalus (NPH) and 4 paediatric patients before and after implantation of the conventional DPV are shown in Table 1 [20]. The intracranial pressure (ICP) was obtained by an external ventricular drain before the shunt operation and by puncturing the shunt valve after shunting. The ICP was referenced to the level of the foramen of Monro in all positions.

Patients

We studied 4 patients treated using the SAV. Positional changes of the shunt flow using radionuclide shuntography [17] and ICP were measured before and after the addition of the SAV.

Table 1 Positional change of ICP before and after shunt and assumed hydrostatic pressure

Patient	Posture	ICP before shunt	ICP after shunt	Assumed hydrostatic pressure
Adult	Supine	20 cmH_2O	3 cmH_2O	0 cmH_2O
Adult	Sitting	0 cmH_2O	–20 cmH_2O	50 cmH_2O
Child	Supine	27 cmH_2O	10 cmH_2O	0 cmH_2O
Child	Sitting	–2 cmH_2O	–16 cmH_2O	25 cmH_2O

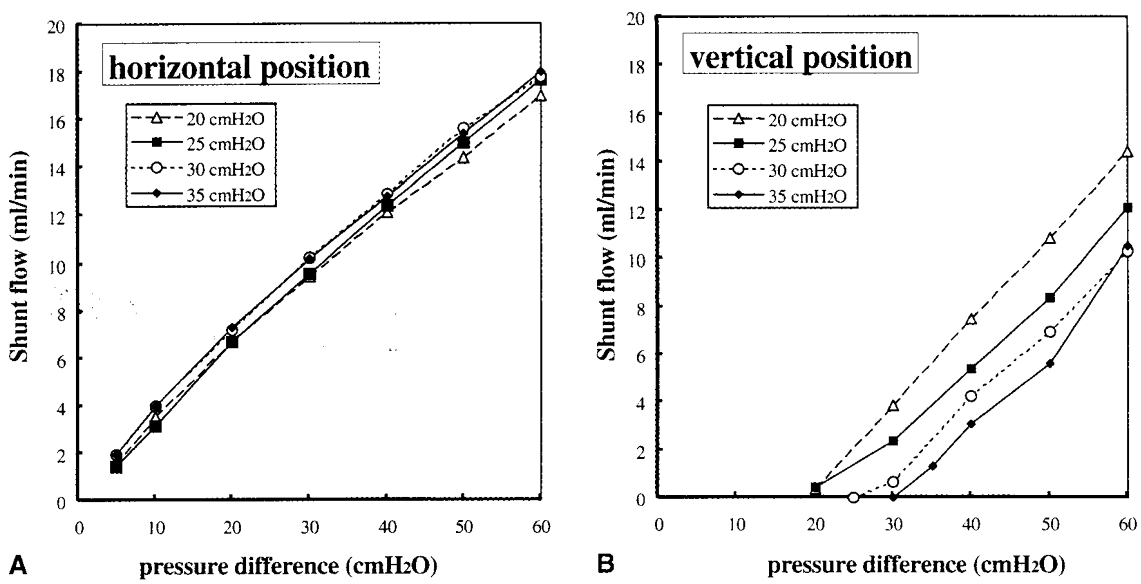


Fig. 2A, B Pressure-flow curves of the SAV. **A** CP in the horizontal position is 0. The flow increases in proportion to the pressure difference and reaches 16 mL/min when the pressure difference becomes 50 cmH_2O in all SAVs. **B** In the vertical position, CP of the SAV 20, 25, 30, and 35 becomes 20, 20, 25, and 30 cmH_2O respectively. In the vertical position the flow also increases in proportion to the pressure difference; however, it decreases significantly in comparison with the horizontal position

Results

Pressure-flow curves of the SAV

In the horizontal position the flow increased according to the pressure difference (PD). It reached 14 to 16 mL/min when the PD became 50 cmH_2O in all SAVs (Fig. 2A). CP in the horizontal position was 0. In the vertical position, CP of the SAV 20, 25, 30, and 35 became 20, 20, 25, and 30 cmH_2O respectively (Fig. 2B). In the vertical position flow also increased in proportion to the PD; it reached 10.9 mL/min (SAV 20), 8.5 mL/min (SAV 25), 7.0 mL/min (SAV 30), and 5.6 mL/min (SAV 35) when the PD became 50 cmH_2O (Fig. 2B). Shunt resistance was not influenced by the positions of the SAV (horizontal and vertical). There was no difference in the flow between positive inlet pressure and negative outlet pressure. The flow was not influenced by external pressures.

Pressure-flow curves of SAV with CH valve

Figure 3 shows the differences in performance between the CH valve alone and the combination of the CH valve and the SAV 20 in the horizontal and vertical positions. Whereas the CP was not affected by the SAV in the horizontal position, the flow was reduced to 80% of the flow of the CH valve alone due to the small amount of additional resistance of the SAV (Fig. 3A).

An increase in the CP of the CH valve resulted in an equal parallel shift of the pressure-flow curve to the right along the x-axis. When the PD was 20 cmH_2O in the horizontal position, flow decreased from 4.0 mL/min (CP=3 cmH_2O) to 0.6 mL/min (CP=20 cmH_2O). On the other hand, when the PD was 40 cmH_2O in the vertical position, the flow remained at 4.9 mL/min (CP=3 cmH_2O) and 1.0 mL/min (CP=20 cmH_2O) (Fig. 3B).

Simulation of the shunt

Figure 4 shows the simulation of the shunt flow in adults (Fig. 4A, B) and children (Fig. 4C, D) with the SAV 20 and the CH valve of 8 cmH_2O (Fig. 4A, C) and 20 cmH_2O (Fig. 4B, D). At the high ICP stage the shunt flow in adult NPH increased markedly in the sitting position when the CP of the CH valve was 8 cmH_2O and overdrainage was seen (Fig. 4A). When ICP became low after the shunt was inserted, the flow in the sitting position was reduced by 50%. Shunt flow in the supine position was sufficient at both the low and the high ICP stages. When the CP was upgraded to 20 cmH_2O, the flow decreased in the sitting position compared with a CP of 8 cmH_2O; however, overdrainage was still seen at the high ICP stage (Fig. 4B). At the low ICP stage, the flow in the supine position was zero and the flow in the sitting position became less than 1 mL/min.

At the high ICP stage the shunt flow in paediatric hydrocephalus was sufficient in the supine position (5 mL/min) when the CP of the CH valve was 8 cmH_2O and the flow in the sitting position decreased to 0.7 mL/min (Fig. 4C). Overdrainage was effectively pre-

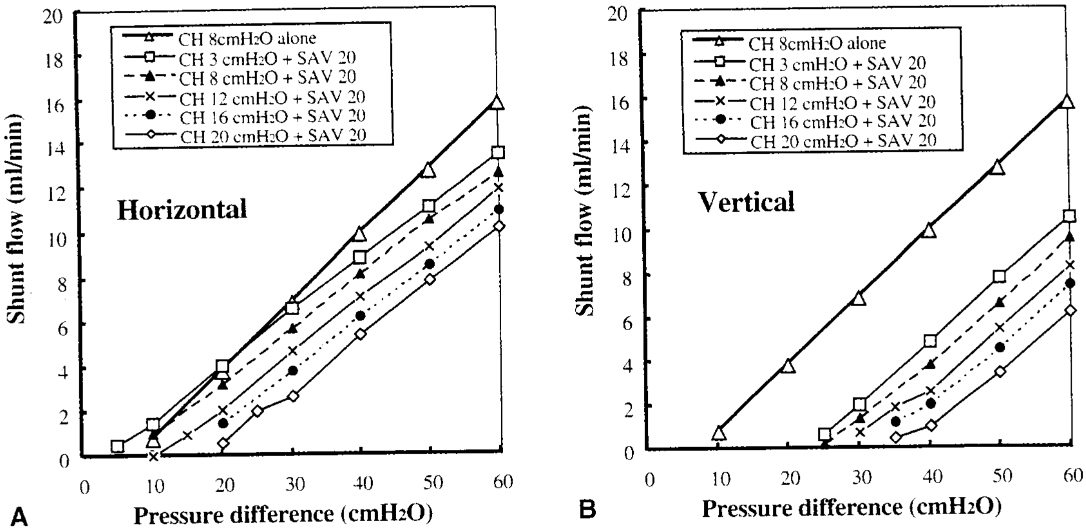
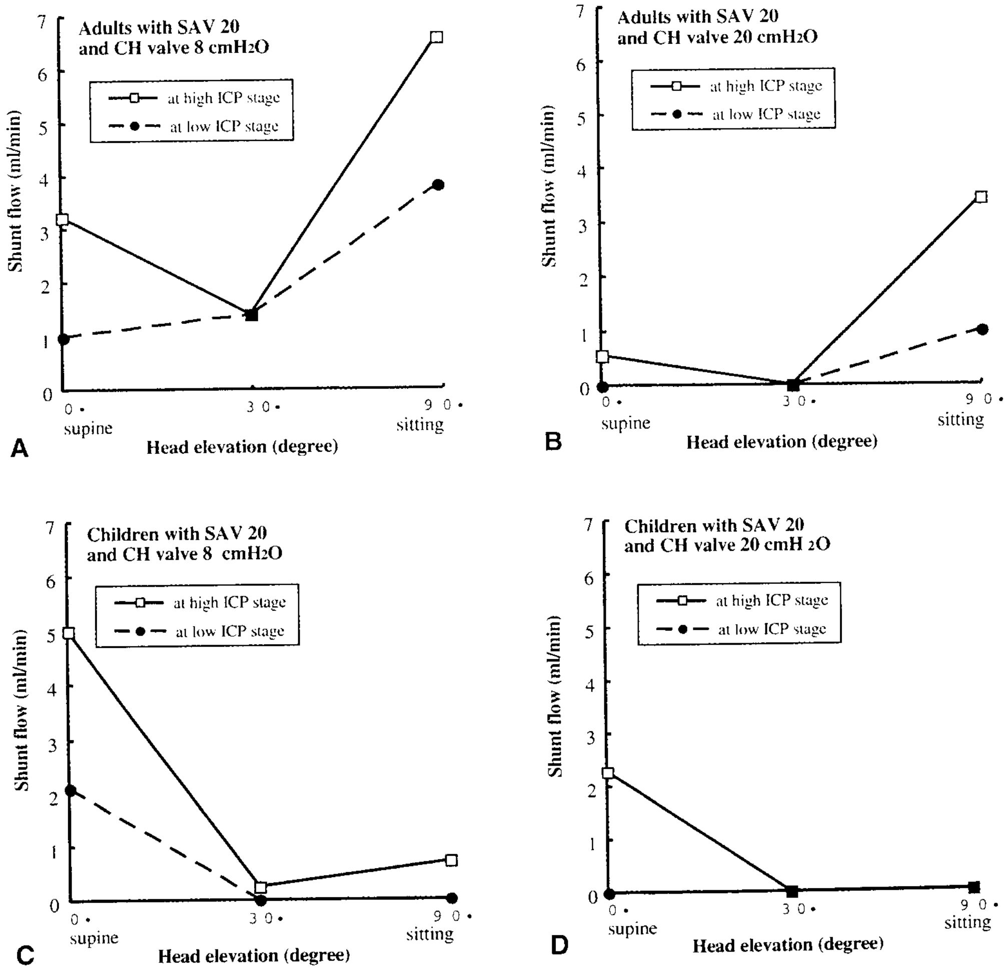


Fig. 3A, B Pressure-flow curves of the SAV with CH valve. **A** Horizontal position. The shunt flow in the supine position decreases to 80% of the CH valve alone. An increase in the CP of the CH valve results in an equal parallel shift of the pressure-flow curve to the right along the x-axis. When the pressure difference is 20 cmH_2O in the horizontal position, the flow decreases from 4.0 mL/min (CP=3 cmH_2O) to 0.6 mL/min (CP=20 cmH_2O). **B** Vertical position. In contrast, when the pressure difference is 40 cmH_2O in the vertical position, the flow remains at 4.9 mL/min (CP=3 cmH_2O) and 1.0 mL/min (CP=20 cmH_2O)

Fig. 4A–D Simulation of the postural changes of the shunt flow. **A** Adult with the SAV 20 and the CH valve of 8 cmH_2O. **B** Adult with the SAV 20 and the CH valve of 20 cmH_2O. **C** Child with the SAV 20 and the CH valve of 8 cmH_2O. **D** Child with the SAV 20 and the CH valve of 20 cmH_2O. See text for detail. *White square* high ICP stage; *black circle* low ICP stage



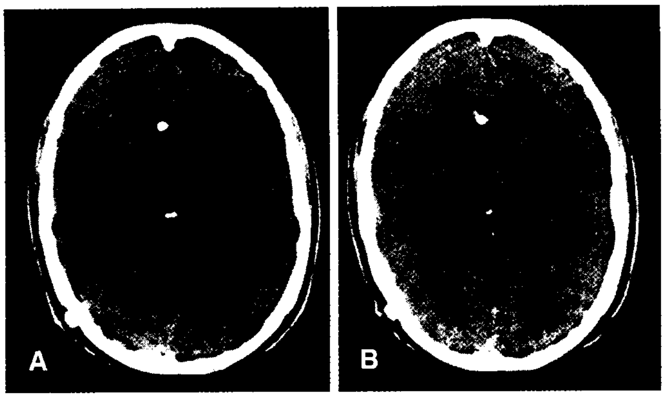
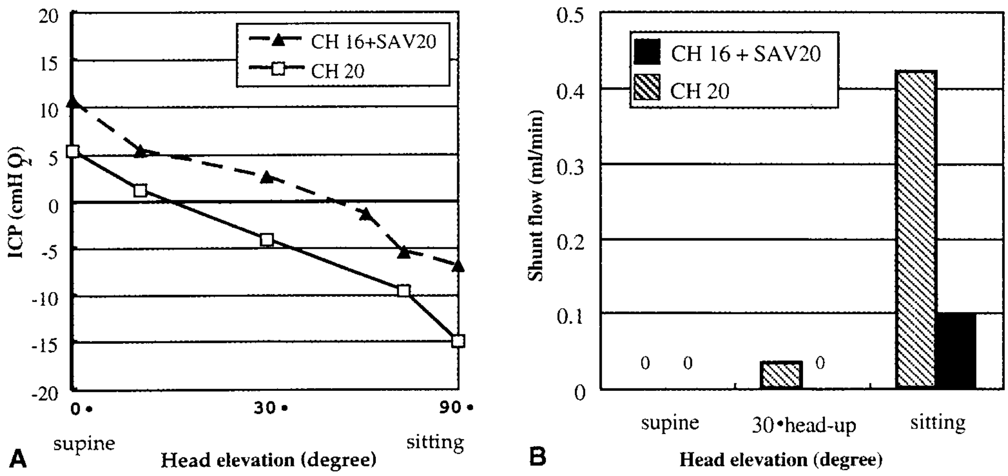


Fig. 5A, B CT scans of patient 1 before and after the additional implantation of the SAV 20. **A** CT scan before the addition of the SAV 20 showing the slit ventricle. **B** CT scan after the addition showing the small ventricles

vented. At the low ICP stage the flow was 2 mL/min in the supine position but became zero in the sitting position. When the CP was upgraded to 20 cmH_2O, the flow decreased in the supine position compared with a CP of 8 cmH_2O and the flow in the sitting position became zero even at the high ICP stage (Fig. 4D). At the low ICP stage, there was no flow in either the supine and or the sitting positions.

Fig. 6A, B Postural changes of the ICP (**A**) and the shunt flow **B**) before and after addition of the SAV 20 in patient 1. **A** *White square* before the addition of the SAV 20, ICP is 5 cmH_2O in the supine position, –4 cmH_2O in the 30° head-up position and –15 cmH_2O in the sitting position. After the addition of the SAV ICP increases to 11 cmH_2O in the supine position, 3 cmH_2O in the 30° head-up position and –7 cmH_2O in the sitting position. **B** *Shaded square* before the addition of the SAV 20, the shunt flow is zero in the supine position, 0.03 mL/min in the 30° head-up position and 0.42 mL/min in the sitting position. *Black square* after the addition of the SAV 20, the shunt flow becomes zero in the supine and 30° head-up positions and 0.01 mL/min in the sitting position



Clinical results

Up to now we have implanted the shunt assistant in 4 patients. Patient 1 was a 22-year-old woman with congenital hydrocephalus of spina bifida. She had undergone multiple shunt revisions and a CH valve was finally implanted. Because she complained of headaches and nausea when she stood up, we adjusted the CP to 20 cmH_2O. A CT scan (Fig. 5A) still showed a slit ventricle and her symptoms persisted. ICP was 5 cmH_2O in the supine position, –4 cmH_2O in the 30° head-up position, and –15 cmH_2O in the sitting position (Fig. 6A). The shunt flow was zero in the supine position, 0.03 mL/min in the 30° head-up position and 0.42 mL/min in the sitting position (Fig. 6B). We added the SAV 20 to the shunt system and the CP of the CH valve was decreased to 16 cmH_2O. After the insertion of the SAV her symptoms were relieved and a CT scan showed the small ventricles (Fig. 5B). ICP became elevated to 11 cmH_2O in the supine position, 3 cmH_2O in the 30° head-up position and –7 cmH_2O in the sitting position, and the shunt flow became zero in the supine and 30° head-up positions and 0.01 mL/min in the sitting position (Fig. 6).

Patient 2 was a 60-year-old man with subarachnoid haemorrhage and NPH and he had undergone multiple shunt operations including an LP shunt or VP shunts with CH valve or Delta valve of performance level 1.0. His NPH symptoms disappeared after implantation of the VP shunt using a standard low pressure valve; however, he complained of headaches and severe pain and tightness of both shoulders and upper extremities (reflux sympathetic dystrophy). The standing position brought on the symptoms, which were relieved in the supine position. Then his shunt valve was changed to a CH valve and the CP was increased from 8 to 20 cmH_2O step by step. A CT scan showed small ventricles and the low pressure syndrome persisted. ICP was 0 cmH_2O in the supine position, –7 cmH_2O in the 30° head-up position, and –14 cmH_2O in the sitting position. The shunt flow was zero in the supine position and 0.7 mL/min in the sitting position. We added the SAV 30 to the shunt system and the CP of the CH valve was initially decreased to 10 cmH_2O and finally to 3 cmH_2O. After the insertion of the SAV all his symptoms were relieved and a CT scan showed slightly dilated ventricles. ICP increased to 7 cmH_2O in the supine position, −3 cmH_2O in 30° head-up position, and −10 cmH_2O in the sitting position and the shunt flow was zero in the supine and 0.08 mL/min in the sitting position.

Patient 3 was a 21-year-old woman with postmeningitis and low pressure syndrome and the SAV 25 was added to her shunt system. The CP of the CH valve was changed from 20 to 18 cmH_2O. Patient 4 was a 67-year-old man with subarachnoid haemorrhage and chronic subdural haematoma and the SAV 20 was added to his shunt system and a conventional DPV (low pressure) was changed to the CH valve of 10 cmH_2O. All 4 patients had a good outcome.

Discussion

Subdural haematoma, slit ventricle syndrome, low pressure syndrome, craniosynostosis and obstruction of the ventricular catheter due to the overdrainage in CSF shunt system are the most serious complications in the treatment of hydrocephalus [5, 8, 14]. It is true that many patients can tolerate excessive negative ICP in the erect position; however, headaches and nausea secondary to low pressure syndrome have a detrimental effect on activity in the daily lives of these patients [5, 14].

All modern shunt systems have been designed to control overdrainage secondary to the siphon effect when patients are in the upright position. It is important to recognise that CSF physiology in the erect position differs from that in the supine position because CSF is mainly drained in the erect position by a siphon effect, not ICP [17, 20]. Mechanisms to prevent overdrainage are classified in five categories as follows:

1. A programmable pressure valve (Sophy™ valve, CH valve, and Strata™ valve) [1, 2, 7, 11, 13, 20, 22, 24]
2. An antisiphon system (antisiphon device: ASD, Delta™ valve, Novus™ valve, Integra Referential™ valve, and Strata™ valve) [1, 2, 4, 19, 20]
3. A flow-regulating valve (Orbis-Sigma™ valve, Diamond™ valve and SiphonGuard™) [1, 2, 4, 12, 18, 20]
4. A hydrostatic (or gravity) valve (Dual-Switch™ valve (DSV), SAV, and Paedi-Gravity Assisted valve (GAV™) [9, 16, 19, 21, 23]
5. Others (open ventricular shunt) [15]

Programmable pressure valves

There have been many reports that emphasise the efficacy of the programmable pressure valve at controlling overdrainage [8, 11, 13, 22, 24]. The fact that many neurosurgeons determine the CP of the CH valve according to the ICP obtained from the spinal or ventricular tap in the supine position is insignificant. Other more important factors, such as HP (siphon effect) and intra-abdominal pressure (IAP), have been ignored [8, 11]. Miyake et al. [11] determined the CP of the CH valve theoretically by directly measuring the IAP with the ideal ICP in the erect position (−7 to −14 cmH_2O). This is not always acceptable because their shunt system, which includes an Osaka telesensor, an on-off valve and two Ommaya reservoirs, is complex and the procedure increases the risk of infection. However, does the increase in the CP always prevent overdrainage and the siphon effect? The highest possible CP of the CH valve implies a pressure of 20 cmH_2O, which is much too high for the supine position but still too low for the erect position [21]. Good shunt function means a well-balanced combination of underdrainage in the supine position and overdrainage in the sitting position. The upgrading of the CP cannot always combat overdrainage when assuming the erect position in adults.

Children (infants) are different from adults because children have a higher ICP and a lower HP than adults. Therefore, shunt flow linearly correlates to the CP regardless of the patient's position and the upgrading of the CP markedly decreases shunt flow. A programmable pressure valve is more effective at preventing overdrainage in children than in adults [20].

Antisiphon systems

When using a shunt system with an ASD, the shunt flow is maximal in the supine position (0.11 mL/min) and decreases to nearly zero in the sitting position [17]. When used appropriately, the ASD is effective at preventing overdrainage.

However, the antisiphon systems including the ASD, Delta valve, Novus valve and the Integra Referential valve as well as the new Strata valve carry a risk of underdrainage [3, 6, 10, 17, 20]. The causes of underdrainage are divided into two categories

1. Overfunction of the device, which is related to the position of the device [6, 17, 20]
2. Occlusion of device due to increased subcutaneous pressure around the device [3, 6]

The latter is the fatal disadvantage of the structure of this system.

Hydrostatic valves

Miethke developed three types of hydrostatic valves: DSV, SAV, and Paedi-GAV [9, 16, 21, 23]. All these devices show a different CP according to the posture of the patient. The DSV has a low pressure chamber for the horizontal position and a high pressure chamber for the vertical position. A tantalum sphere regulates the CSF flow through these two chambers. The DSV is available in nine different combinations of the horizontal and the vertical CP that is suitable for adult hydrocephalus. The Paedi-GAV, which has a tantalum sphere for making additional increases to CP in the vertical position, is available in six combinations of the horizontal and the vertical CP. The opening characteristics offered are suitable for paediatric hydrocephalus. As the CP of these devices is not adjustable after surgery, the selection of the optimal combination of the horizontal and vertical opening pressure is an important problem, which can be solved by combined use with programmable valves.

Combined use of programmable pressure valve with siphon-reducing system

Most patients with hydrocephalus can obviously adapt to any shunt system. There are some patients who have a limited acceptance of unphysiological ICP-values. Once a slit-like ventricle secondary to longstanding overdrainage develops in children or adolescents, the treatment of low pressure syndrome or ventricular catheter occlusion becomes difficult even if a programmable pressure valve is used. If the upgrading of the CP is not sufficient to prevent overdrainage, combined use of the CH valve with other siphon-reducing systems, such as ASD, Delta chamber, SiphonGuard and SAV, is useful [9, 17, 18].

Since the flow through the ASD and the Delta chamber is highly influenced by the subcutaneous pressure, these systems are not recommended nowadays [3, 6]. The SiphonGuard has two CSF pathways; under the low pressure condition, the majority of CSF flows through a central primary pathway. Due to an increase in CSF flow a ruby ball closes the primary pathway and CSF is forced to flow through a high resistant spiral passage (secondary pathway), effectively reducing the CSF flow. A change in the two pathways does not depend on the posture of the patients. Since the primary pathway opens only for the DP ranged from CP to CP + 14 cmH_2O, the relationship between shunt flow and ICP is complex [18].

Out of the siphon-reducing devices the SAV is durable and is not affected by subcutaneous pressure. The action of the tantalum sphere is reliable. Combined use of the programmable pressure valve and the SAV presents a large dynamic range for controlling shunt flow in both the supine and erect positions. Precise and fine readjustment of the shunt flow can easily be carried out after implantation. Kiefer et al. [9] reported on the addition of the SAV to the existing valve in patients whose overdrainage symptoms could not be overcome by conservative treatment. They also used the CH valve together with the SAV as a primary procedure with good results. It is not necessary to implant the SAV and the programmable pressure valve as the first shunting procedure in all hydrocephalic patients. If the upgrading of the CP to the maximum pressure of 20 cmH_2O cannot control the overdrainage symptoms, we recommend adding the SAV to the existing valve. The manufacturer indicates that the optimal ICP in the sitting position is –5 cmH_2O. The CP of the SAV is said to be equal to the distance between the level of the foramen of Monro and the diaphragm minus the sum of the CP of the shunt valve and ICP in the erect position. Therefore, the SAV 20 or 25 is the most reasonable selection when the SAV is used together with the CH valve in adult patients with hydrocephalus. The SAV 35 in the erect position may be too high even for tall adult patients. For children the SAV 15 or 20 may be suitable for preventing underdrainage; however, the SAV is too large and hard to implant in a preschool child. A small paediatric version of the SAV is expected.

Conclusion

Combined use of the SAV with the CH valve is useful for preventing overdrainage in patients with hydrocephalus whose low pressure syndrome cannot be controlled by the upgrading of the CP of the CH valve.

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