Novel Method for Controlling Cerebrospinal Fluid Flow and Intracranial Pressure by Use of a Tandem Shunt Valve System

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Introduction

In general, cerebrospinal fluid (CSF) shunt valves control intracranial pressure (ICP) rather than fluid flow or other aspects [1–4]. There are various kinds of shunt valves, including fixed pressure and programmable valves. Fixed pressure valves usually have low, medium or high pressure settings. The choice of valve pressure is based on preoperative ICP, clinical course, cerebral ventricle size, age and the lifestyle of the patient [5–8].

Programmable valves with or without anti-siphon devices were subsequently developed [9–16]. CSF flow is regulated by adjusting the pressure via a magnetically controlled valve. However, CSF dynamics are complicated because production and absorption rates of CSF may vary in any given patient. Consequently, the existing shunt systems cannot correspond to each of these situations. With regard to ICP, treatment in vivo involves not only setting the shunt’s valve pressure but also taking into consideration the CSF flow rate, which is a very important parameter [17, 18]. Even with anti-siphon devices attached to some valves and despite their advantages, there is still no perfect valve system in neurosurgery as devices with these attachments still fail to adequately control pressure requirements as well as CSF flow rates at the same time. In clinical practice, we sometimes see a patient with an over-drainage problem even though an anti-siphon device is used.

Key Words
Hydrocephalus · Programmable valve · Siphon · Tandem · Cerebral spinal fluid

Abstract

Objective: Programmable shunt valve systems have improved the management of patients with hydrocephalus. However, associated problems such as over-drainage and slit-like ventricles, even in patients with anti-siphon devices installed, still remain unresolved. Methods: We conceived a novel tandem shunt valve system to overcome the problems with existing shunt valve systems. Experiments were performed in vitro and a manometer was used to measure the results. Results: Manometric measurements in vitro with the tandem shunt valve system demonstrated that it effectively controlled the final pressure under varying flow rates. This novel system was applied to 2 intractable cases (over-drainage and slit-like ventricles) with good results. Interpretation: The tandem shunt valve system has therapeutic potential not only for over-drainage and slit-like ventricles, but also for uncontrollable hydrocephalus, by precisely controlling the cerebral spinal fluid flow rate.
To overcome the difficulties of the existing shunt valve systems in achieving adequate CSF pressure and flow control, we contrived a novel tandem shunt valve system. We performed in vitro experiments using a manometer, and report the first clinical application of the novel tandem shunt system in humans.

Materials and Methods

An in vitro system with a manometer was built to measure pressure and flow rates of water in open and closed systems using the Codman (Codman; Johnson & Johnson, Raynham, Mass., USA) Hakim programmable valve (CHPV) and the Strata programmable valve (Medtronic, Minneapolis, Min., USA), as shown in figures 1 and 2, respectively. One single (fig. 1a and 2a) and 2 single-shunt valves connected in series (the tandem shunt system; fig. 1b and 2b) were connected to the manometer to check the pressure.

In vitro Closed System with Water Bath
In the closed single shunt valve system experiment, as shown in figure 1a, we measured the pressure in the original bath to be 400 mm H₂O with a closed valve (V1). We conducted 3 changes to V1, the valve pressure of the CHPV, and took 5 measurements each at V1 = 50, 100 and 200 (these values are in mm H₂O for the CHPV). Figure 1b shows the setup in a closed tandem shunt valve system. If we set V1 = 50 and V2 = 50, the total pressure setting of the valves is V1 + V2 = 100. Other combinations of V1 and V2 were taken, and 6 are reported below.

In vitro Open System with Manometer
An open system represents the real-world environment. Unlike in figure 1, the system detailed in figure 2 does not have a clamp at the endpoint to keep the system closed. In our experiment, we have the Strata valve directly connected to the manometer and a scale at the other end to measure the volume of water (fig. 2). In our single valve open system experiment (fig. 2a), the manometer was set to 400 mm H₂O and the Strata valve used had 5 programmable valve (V1) settings (0.5, 1.0, 1.5, 2.0 and 2.5). Unlike the CHPV, these valve settings are not in mm H₂O, but are referred to as performance levels (PLs) by Strata, and we took manometer readings at each PL. An electric flow meter was also used to measure the volume of water every 30 s for each PL. The same measurements for the open tandem shunt valve system (fig. 2b) were also taken, but for different combinations of PLs. This experiment helped us illustrate the effects of a tandem shunt valve system in hydrocephalus cases.
Results

In vitro Closed System with Water Bath

In the single shunt valve system experiment, when $V_1$ was adjusted to 50, the final measurement in the manometer equaled around 350 mm H$_2$O (fig. 3a). When $V_1 = 100$, the final manometer reading was around 300 mm H$_2$O. Subsequently, a $V_1$ adjustment of 200 resulted in a final manometer reading of around 200 mm H$_2$O. Based on these results, we can conclude that the original water bath pressure = $V_1$ pressure value + final manometer reading ($M_1$) as shown in figure 3a, where the average results of 5 measurements at $V_1 = 50, 100$ and 200 were taken. In the closed tandem shunt valve system experiment, when the final manometer reading was 300 mm H$_2$O, the sum of $V_1 + V_2$ always equaled around 100. We conducted further experiments that measured 5 manometer readings at different combinations of $V_1$ and $V_2$, (such that $V_1 + V_2 = 100, 150, 200, 250, 300$ and 400) and averaged the results (fig. 3b). Based on our experiment, the final manometer pressure = original water bath pressure – ($V_1$ pressure + $V_2$ pressure) + final manometer reading ($M_1$).

In vitro Open System with Manometer

In an open system, at any value of $V_1$, the manometer represents the same value as $V_1$. At a PL of 0.5 on the Strata valve, the final manometer reading was approximately 30 mm H$_2$O after we had allowed the system to run for some time. Subsequent PL settings were measured, and their final pressure manometer readings are as follows: $1.0 \equiv 40$ mm H$_2$O, $1.5 \equiv 100$ mm H$_2$O, $2.0 \equiv 170$ mm H$_2$O and $2.5 \equiv 200$ mm H$_2$O (fig. 4).
Figure 4 also shows the calculated flow rate (ml/min) curve over time. At the highest PL setting of 2.5, we achieved a lower flow rate as expected.

Figure 2b shows 2 valves connected in series in an open system (tandem system). In our tandem valve open system experiment, we varied V1 and V2 and measured the final manometer readings for each combination (table 1). Interestingly, in the tandem system, the final pressure was almost equal to the highest pressure setting of one of the valves in the system. In a single valve system, the flow rate changed depending on the valve pressure (fig. 4). On the other hand, the flow rate in the tandem system depends on the total pressure of each shunt valve setting (fig. 5). Furthermore, based on our experiments, we concluded that in an open system (along with reducing the flow rate) we could control pressure because the final pressure reading on the manometer was always equal to the highest pressure value of either V1 or V2.

We assessed all combinations of tandem shunt valve pressures. The result was that the flow rate depended on the total valve pressure in the system (fig. 5). Of considerable significance in table 1 is the experiment with Strata PL 1.0 + 1.0 and Strata PL 2.0. We would expect the final manometer pressure to be the same for these 2 experiments (because the PL totals are the same) but they are actually 50 and 170 mm H2O, respectively. There are 2 significant points here: (1) flow rate, and (2) final pressure. In figure 5, if we compare the rate of decrease between the 2 experiments, we find that the curves follow similar flow rates, which indicates that even at different pressures we can control the flow rate. In fact, at PL 1.0 + 1.0, the final pressure of 50 mm H2O is quite similar to that of a single valve with PL 1.0 where the pressure is 40 mm H2O (as shown in table 1), but it exhibits flow rates similar to PL 2.0. Similarly, upon comparing the experiments PL 2.0 + 0.5 with PL 2.5, the same property exists.

In conclusion, we can decrease flow rate without a major change in pressure using a tandem shunt valve system. After obtaining these in vitro results, we implemented tandem shunt valve systems in 2 shunt cases where problems associated with shunt implants, such as slit-like ventricles and/or intractable hydrocephalus, were present.

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**Table 1. Results comparing the single shunt valve with the tandem shunt valve in the open system**

| Single valve (V1) Strata PL | Tandem valve (V2) Strata PL | Final pressure (mm H2O) |
|---------------------------|---------------------------|--------------------------|
| 0.5                       | –                         | 30                       |
| 1.0                       | –                         | 40                       |
| 1.0                       | 1.0                       | 50                       |
| 1.5                       | –                         | 100                      |
| 2.0                       | –                         | 170                      |
| 2.0                       | 0.5                       | 180                      |
| 2.5                       | –                         | 200                      |

In the tandem system, with V1 at 1.0 and V2 at 1.0 the final pressure (50 mm H2O) is always close to the final pressure (40 mm H2O) when V1 is at 1.0 in a single valve system.
**Case 1**

A 6-year-old girl with a malignant glioma received a bilateral ventricle-peritoneal (V-P) shunt (CHPV) for obstructive hydrocephalus. Although the patient’s ICP was controlled by the shunt system (valve pressure was 150 mm H2O), hydrocephalus developed during chemotherapy and radiotherapy. The lateral ventricle size and abdominal circumference increased due to a peritoneal fluid collection caused by tumor tissue dissemination through the V-P shunt tract. The shunt valve pressure was adjusted from 150 to 180 mm H2O to solve this over-drainage problem. However, this caused acute hydrocephalus with deteriorating consciousness. The shunt valve pressure was then decreased from 180 to 140 mm H2O. Although the ventricular size decreased and her level of consciousness improved, the fluid collection in the peritoneal cavity rapidly increased, which caused dyspnea due to high peritoneal pressure. We informed her parents about the 2 paradoxical problems that needed to be solved simultaneously: (1) finding the best V-P shunt valve pressure to prevent the hydrocephalus, and (2) reducing the amount of peritoneal fluid collection containing the brain tumor tissue and debris. To solve the opposing problems of obtaining sufficient CSF drainage to treat the hydrocephalus but not so much that it would cause peritoneal fluid collection, we tested the therapeutic possibility of the tandem shunt system by adding another adjustable valve (CHPV) with anti-siphoning to the current setup. The new tandem shunt system was a connection from the lateral ventricle CHPV (1st valve) connected to the CHPV (2nd valve) with a siphon guard to the peritoneal cavity. The PL of the new tandem shunt system was adjusted to 2.5 (1st valve) and 0.5 (2nd valve) to the peritoneal cavity. The PL of the new tandem shunt system was adjusted to 2.5 (1st valve) and 0.5 (2nd valve), but there was no remarkable change in his condition. After a few days, his second shunt valve PL was adjusted from 0.5 to 1.0, his general condition improved dramatically and he was able to keep head-up position over several hours.

**Discussion**

Intraventricular CSF, shunt valve opening pressure and intra-abdominal pressure are, through common use in neurosurgery and convention, called ICP, valve pressure and abdominal pressure, respectively. If we also consider the tube connecting the head to the abdomen, a difference in water pressure is present, conventionally referred to as hydrostatic pressure. If we assume (ICP + hydrostatic pressure) – (valve pressure + abdominal pressure) = 0, then this simplifies to ICP = (valve pressure + abdominal pressure) – hydrostatic pressure.

The difference in pressure causes fluid flow; however, other parameters to consider include the coefficient of viscosity caused by protein in the CSF, resistance between the inner wall shunt tube and CSF flow (tube diameter), the positioning of the shunt valve (forehead or back of the head), the intra-abdominal tube length, and so on. All these parameters contribute to complicated flow dynamics, but a simpler approach is to only use pressures to help...
us describe fluid flow in a shunt system. In our in vitro experiment, we kept all other parameters the same and only changed the pressure via valve settings and, in the tandem shunt valve system, an additional shunt valve. This tandem system allowed us to precisely control the pressure and flow rate. Until now, CSF flow rate was always the result of the shunt’s valve pressure, but there has been no study to control the CSF flow rate and ICP individually. Our in vitro experiment showed that the tandem system was able to control CSF flow rate and ICP independently of each other.

ICP automatically changes when the position of the head and abdominal changes (e.g. compare heights of standing versus sleeping person); these changes cause a siphon effect, which makes it extremely difficult to control ICP with only a single shunt system [19–21].

Even with an anti-siphon system in place, controlling CSF flow is still difficult. However, with the tandem shunt valve system in place, we were able to create a low CSF flow rate environment without increasing the ICP. In a single valve shunt system, it was impossible to create such an environment while maintaining a constant ICP even with an anti-siphon system installed because (as shown in our experiments) CSF flow is always directly related to the pressure setting at the valve. However, in the tandem valve shunt system, the most significant finding was that the final pressure was equal to the highest valve pressure of the 2 valves (fig. 6). This means that in practice, the system has the possibility to control the ICP without increasing the pressure that is required by the patient.

Figure 6 demonstrates the mechanism behind the tandem shunt valves. It is used to show that the final pressure is equal to the highest valve pressure of the 2 tandem valves. M, V1 and V2 represent ICP in the body, and the pressure settings at the shunt valve, respectively. Walls (V1 and V2) added to M1 and M2 as shown in figure 6 show that regardless of where the highest wall is placed, the final water level at the highest wall will always be the same as the water level in column M. This demonstrates that the final pressure always equals the final pressures setting of either V1 or V2. In clinical practice, ICP is controlled by the height of the highest setting of the 2 shunts.

Assuming a PL of 3.0 was required for a patient in a single shunt valve system using the Strata valve, this could only be done by using 2 Strata valves; the first (V1) connected to another Strata (V2) shunt valve with the following V1 + V2 patterns available: (2.5 + 0.5, 2.0 + 1.0, 1.5 + 1.5). Each of these patterns result in: (1) achieving the PL of 3.0; (2) setting up the final ICP so that it would be controlled at 2.5, 2.0 and 1.5 (the highest valve pressure of the 2 valves). With only a single valve, the PL of 3.0 would not be possible because the maximum PL is 2.5. Furthermore, we were able to control the pressure while changing the flow rate with the tandem shunt valve system using the Strata valves.
While the Strata valve has only 5 settings, the CHPV has settings from 30 to 200 in increments of 10. If we try to create a 250 environment with the CHPV, as required by the patient, it would be impossible to do so with only 1 valve. In a tandem system, there are 8 patterns available: (200 + 50, 190 + 60, 180 + 70, 170 + 80, 160 + 90, 150 + 100, 140 + 110, and 130 + 120) with the CHPV shunt valve connected to another CHPV directly; thus, creating a tandem shunt valve system. Each pattern could set up the final ICP controlled at 200, 190, 180, 170, 160, 150, 140, and 130, respectively. The outcomes would result in the same condition as the Strata example, that is, flow rate would be adjustable while keeping ICP controlled at the highest pressure setting of either V1 or V2. Because of the different combinations available, we could select the best shunt valve pressure pair depending on the condition of the patient.

With the above mechanism, the tandem shunt valve systems (PL 2.5 + 1.0) prevent ICP increasing, thereby decreasing CSF flow as opposed to the single valve system PL 2.5, which is extremely important in treating slit-like ventricles. We can prevent an increasing ICP and limit flow rate at the same time, which is particularly useful in treating cases of over-drainage. Our case studies have demonstrated that this control is only possible with a tandem shunt valve system in place and not with a single valve system. This new tandem shunt valve system prevents falls in ICP and can adjust CSF flow at the same time. Tandem shunt systems that enable the measurement of new shunts equipped with the tandem system function that enables the measurement of CSF flow rate will be required in the future.

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