Performance of fixed-pressure valve with antisiphon device SPHERA® in hydrocephalus treatment and overdrainage prevention

Desempenho da válvula de pressão fixa com antissifão SPHERA® no tratamento da hidrocefalia e na prevenção da ocorrência de hiperdrenagem

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ABSTRACT

Patients with hydrocephalus and risk factors for overdrainage may be submitted to ventricular shunt (VS) implant with antisiphon device. The objective of this study was to prospectively evaluate for two years the clinical and tomographic results of the implant of fixed-pressure valves with antisiphon device SPHERA® in 35 adult patients, with hydrocephalus and risk factors for overdrainage. Of these, 3 had congenital hydrocephalus in adult patients with very dilated ventricles (Evans index >50%), 3 had symptomatic overdrainage after previous VS implant (subdural hematoma, hygroma or slit ventricle syndrome), 1 had previous chronic subdural hematoma, 15 had normal pressure hydrocephalus with final lumbar pressure <5 cm H_2O after tap test (40 mL), 6 had pseudotumor cerebri, and 7 had hydrocephalus due to other causes. Clinical improvement was observed and sustained in 94.3% of the patients during the two-year period with no computed tomography (CT) evidence of hypo or overdrainage, and no immediate early or late significant complications.

Key words: hydrocephalus, pseudotumor cerebri, cerebrospinal fluid shunts.

RESUMO

Pacientes com hidrocefalia e fatores de risco para hiperdrenagem podem ser submetidos ao implante de derivação ventricular (VS) com mecanismo antissifão. O objetivo deste trabalho foi avaliar prospectivamente os resultados clínicos e tomográficos do implante de válvulas de pressão fixa com antissifão SPHERA® em 35 pacientes adultos, com hidrocefalia e risco de hiperdrenagem, acompanhados por dois anos. Destes, 3 apresentavam hidrocefalia congênita em adulto, com ventrículos muito dilatados (índice de Evans >50%); 3 tinham hiperdrenagem sintomática pós-derivação ventricular prévia (hematoma subdural, higroma ou síndrome dos ventrículos colabados; 1 apresentava hematoma subdural crônico pregresso; 15 apresentavam hidrocefalia de pressão normal com pressão lombar final <5 cm H_2O após *tap test* (40 mL); 6 apresentavam pseudotumor cerebral; e 7, devido a outras causas. A melhoria clínica foi detectada e sustentada em 94,3% dos pacientes no período de dois anos, sem indícios tomográficos de hipo ou hiperdrenagem e sem complicações significativas imediatas, precoces ou tardias.

Palavras-Chave: hidrocefalia, pseudotumor cerebral, derivações do líquido céfalorraquidiano.

Surgical treatment of hydrocephalus in adults is attained through the implantation of ventricular shunt (VS) systems, neuroendoscopy or through the association of both procedures, offering the possibility of significant neurological improvement[1].

The United Kingdom Shunt Registry showed in 13,206 adults with hydrocephalus submitted to VS implant that 22% of patients required reoperation within five years[2].

Patients with hydrocephalus and risk factors for overdrainage may be submitted to VS implant with antisiphon device. This valve-integrated device allows the patient, while in the orthostatic position, to increase the resistance to drainage of cerebrospinal fluid (CSF), reducing the siphoning effect that always occurs, thus avoiding overdrainage[2-6].

The objective of this study was to prospectively evaluate for two years the clinical performance of fixed-pressure valve with SPHERA® antisiphon device in the treatment of 35 adult patients, with hydrocephalus and high clinical susceptibility to overdrainage.

METHODS

After approval by the Ethics Committee, all patients admitted to the Cerebral Hydrodynamics Group, Division of

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Functional Neurosurgery of the Institute of Psychiatry, at Hospital das Clínicas, Faculty of Medicine, University of São Paulo (HC-FMUSP), from January 1st, 2009 to January 1st, 2010, with hydrocephalus and high risk for overdrainage, as the previously established inclusion criteria, were selected for the implant of a fixed-pressure valve, with antisiphon membrane mechanism (SPHERA®, HPBIO, São Paulo, Brazil) and clinical-radiological follow-up up to January 1st, in 2012.

The SPHERA® valve works through a coil spring mechanism, seat and ruby sphere. According to the characteristic of the spring, four strips of pressure difference ensure a flow of 21 mL/h, which corresponds to the physiological CSF production: extralow (1 to 3 cm H_2O), low (3 to 7 cm H_2O), medium (7 to 11 cm H_2O), and high (11 to 14 cm H_2O).

The body of the prosthesis measures 42 x 14 x 6.5 mm. Its proximal portion contains the valve mechanism, the central part is a chamber for digital pumping or puncture, and its distal part contains the antisiphon membrane mechanism (Fig 1). When the pressure distal to the antisiphon mechanism becomes negative, the membrane temporarily occludes the system, avoiding overdrainage. This occurs when the patient is in the orthostatic position (up to – 50 cm H_2O) or additionally during inspiration in patients with ventriculopleural shunt (up to – 8 cm H_2O), as seen in Fig 2.

Inclusion criteria included patient with more than 16 years of age; and some clinical and radiological conditions considered to have high risk for overdrainage by VS: congenital hydrocephalus in adults with very dilated ventricles (Evans index >50%); previous symptomatic overdrainage post-VS (subdural hematoma, hygroma or slit ventricle syndrome); previous chronic subdural hematoma (not related to VS); normal pressure hydrocephalus (NPH) with final lumbar pressure <5 cm H_2O after tap test (40 mL); and pseudotumor cerebri with VS indication.

Patients were evaluated for two years after surgery, through preestablished routine outpatient appointments with the Cerebral Hydrodynamics Group of HC-FMUSP: ten days after surgery for stitch removal, three months (cranial computed tomography scan – CT – requested), six months, one year and two years after surgery. The evaluation criteria of the patients were:

- clinical: comparison of pre and postoperative neurological assessment; postoperative infection; signs and symptoms of overdrainage or system malfunction (headache, postural headache, nausea, vomiting, visual alterations, altered level of consciousness);
- radiological: pre and postoperative CT, immediately after surgery and after three months (size of the ventricles, deviations of deep brain structures, patency and size of cisterns and cortical sulci, proximal catheter placement, subdural collections or hygroma).

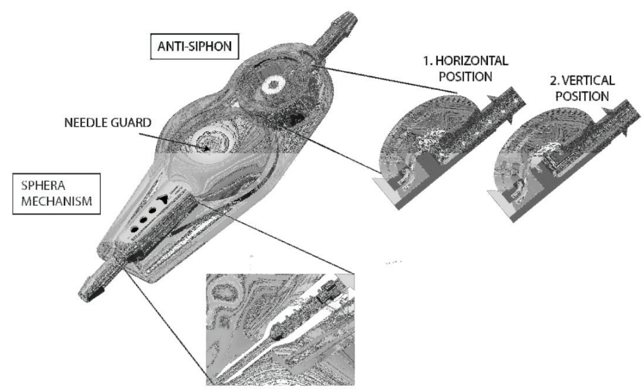

Fig 1. Illustrative picture of the SPHERA® valve: spring coil mechanism, seat and ruby sphere; chamber for digital pumping or puncture and membrane-type antisiphon mechanism (when the pressure distal to the antisiphon mechanism becomes negative, the membrane temporarily occludes).

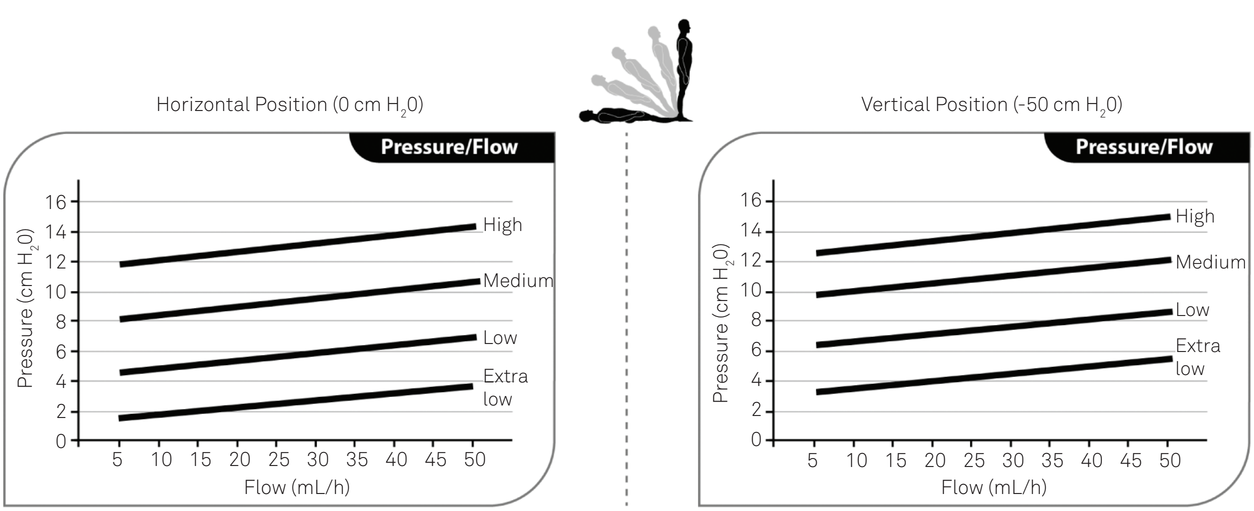

Fig 2. Pressure *versus* flow, SPHERA® valve (extralow, low, medium, and high pressure) in the horizontal and vertical positions.

RESULTS

The study included 35 patients, 21 men and 14 women. The age ranged from 16 to 86 years-old, with a mean of 51 years-old.

Table shows the distribution of procedures by the hydrocephalus etiology and pressure valve used, indicating that two patients underwent ventriculopleural shunt (VPS) and that three had symptomatic overdrainage after previous derivation.

Clinical assessment

After 24 months of follow-up, 33 patients showed clinical improvement (33/35=94.3%). A patient with hydrocephalus after traumatic brain injury by gunshot wound showed no alteration at the neurological assessment, and one with normal hydrocephalus pressure initially improved for one year, but showed a slight worsening in gait after two years of follow-up. In these two patients (2/35=5.7%), the valve worked normally at digital compression of the pumping chamber and there was a decrease in ventricular dimensions with no evidence of overdrainage (subdural collections).

Patients with pseudotumor cerebri showed improvement in headache, sight, and resolution of papilledema three months after surgery.

No patient had postural headache, nausea, vomiting or other signs of intracranial hypertension or hypotension during the two-year follow-up.

One patient with congenital hydrocephalus, who had undergone five previous derivations, the latter being the implant of the low-pressure SPHERA® valve, showed postoperative ventriculitis; he was submitted to system removal, intravenous antibiotic therapy for 21 days and reimplantation of a new SPHERA® system and showed improvement at the neurological assessment.

The two patients submitted to VPS showed improvement and had no complications.

Radiological assessment

The patients showed a reduction in ventricular size and no patient had subdural collections or hygroma.

The three patients who already had another valve and underwent surgery to treat the overdrainage condition showed an increase in ventricular dimensions and reduction of subdural collections associated with clinical improvement. Fig 3 shows the preoperative CT of one of these patients and the control CT three months after valve replacement. The resolution of bilateral subdural collection and ventricular increase was associated with improvement in postural headache, with no signs or symptoms of intracranial hypertension.

In patients who underwent brain magnetic resonance imaging (MRI) for reasons other than hydrocephalus control, it was observed that the tested valve did not produce artifacts in image acquisition.

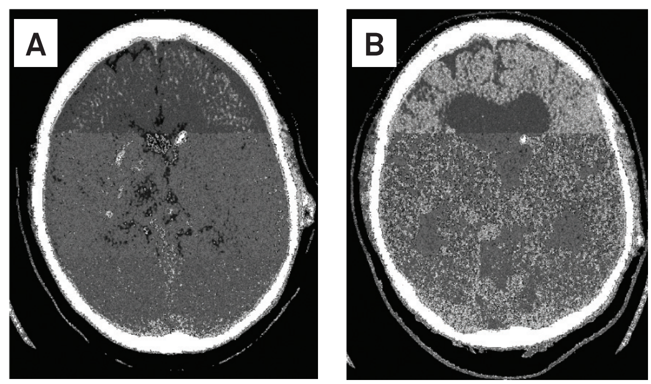

Fig 3. Patient with thalamic arteriovenous malformation to the right, and slit ventricle syndrome after prior ventricular shunt for three months with medium pressure PS Medical® valve (Medtronic). (A) Computed tomography without contrast, axial view, showing preoperative status: collapsed ventricles, bilateral subdural collections, and thalamic arteriovenous malformation to the right. (B) Computed tomography without contrast, axial view, three months after medium-pressure SPHERA® valve replacement: increased ventricular dimensions and resolution of bilateral collections.

Table. Etiology of cerebral hydrodynamic disease, number of cases, and valve pressure. Almost all patients underwent ventriculoperitoneal shunt, except two with congenital hydrocephalus. These patients underwent ventricular shunt to pleura as it was not possible to use the peritoneum as the distal place (previously treated peritonitis) and the atrium was tried before, without success. Three patients had ventriculoperitoneal shunt and hyperdrainage, one case with pseudotumor cerebri had slit ventricle syndrome, one normal pressure hydrocephalus had chronic subdural hematoma, and one patient with thalamic arteriovenous malformation had bilateral hypertensive subdural collections and slit ventricle syndrome.

Etiology	Number of patients	High pressure	Medium pressure	Low pressure
Pseudotumor cerebri	6	-	6	-
Normal pressure hydrocephalus	15	-	-	15
Thalamic arteriovenous malformation	2	-	2	-
Congenital hydrocephalus	3	1	2	1
Postmeningitis	4	-	3	1
Brain tumor	2	-	1	1
Subarachnoid hemorrhage	2	-	2	-
After traumatic brain injury	1	-	1	-
Total	35	1	17	18

DISCUSSION

The main complications related to VS include: infection (meningitis, ventriculitis, abdominal cyst), mechanical malfunction (system obstruction or disconnection), and overdrainage (subdural collections, collapsed ventricle syndrome, subdural hematomas). All these complications are severe, require reoperation, and may cause death[2,3,7-13].

Currently, there is a consensus that, whenever possible and indicated, one should avoid VS implantation when a high complication rate is identified in the long-term (mean of 60 months) of up to 51% of cases; in these cases, ventricular neuroendoscopic procedures are given preference[12,14-17].

To prevent infectious complications, the institutional adoption of protocols, such as first described by Choux, is what shows the most positive impact and control of these complications. Catheters impregnated with antibiotics or silver also seem to reduce infectious complications[18,19].

The prevention of mechanical malfunction is related to good surgical technique and proper choice of the type of valve and the distal site of VS implant. The frontal trepanation seems to be related to better positioning of the proximal catheter, due to puncture suitability offered by this site, as it accepts a wider range of introduction angles[20-22].

All implanted VS have a siphon effect when the patient is in the orthostatic position, since there is a pressure difference between the two extremities of the system that exceeds the valve opening pressure. The term "siphon effect" is more used to describe the physical phenomenon involved, ruled by well-known Law of Stevin (pf=p0+d.g.h).

The term overdrainage is commonly used to describe the physiopathological mechanism by which an internal or external CSF shunt generates specific radiological or one of the related clinical syndromes: CSF hypotension, intracranial hypertension due to the expanding effect of a hematoma, or by intermittent obstruction in the collapsed ventricle syndrome. The degree of overdrainage, and therefore the risk of clinical manifestations, is associated both with the intracranial pressure (negative) and with the intracranial CSF volume. Patients with pseudotumor, for instance, may have an overdrainage image with normal or slightly negative intracranial pressure. Overdrainage is associated with compensatory intracranial and intraspinal hemodynamic alterations, mainly venous ones at first. Clinical manifestations do not always occur, which depend on factors such as pre-VS brain turgor, degree of cerebral atrophy, pain sensitivity, and drainage speed.

To reduce overdrainage, the choice of the fixed-pressure valve opening pressure should be appropriate for the patient to ensure the necessary CSF flow to treat the hydrodynamic disorder, however without causing excessive drainage and symptomatic intracranial hypotension[2-6].

The programmable valves offer the possibility of adjustment after surgery without the need for reoperation. The flow-regulated shunt (Orbis-sigma valve) ensures a steady flow and, in theory, it would better adjust to each patient, but large samples have not shown a superior performance of this system[13].

On the other hand, the antisiphon mechanism can be implemented in series with any type of valves and works by increasing the resistance to flow, whenever the pressure differential (p0=ventricular - pf=distal site) increases, preventing overdrainage and reducing the siphon effect. A number of siphon regulatory devices has been developed over the past two decades. Basically, there are two types of antisiphon mechanisms: gravity (spheres or parts that move with the force of gravity, hindering and reducing flow) and membrane (thin, flexible membrane that occludes the system when the pressure difference increases due to a decrease in distal pressure)[2].

Many factors can influence the dynamics of CSF drainage, and these can be both hydrodynamic and related to individual physiological characteristics, which make their knowledge essential when choosing the most appropriate drainage system for each patient and even to identify probable causes of hypo – or overdrainage. The main forces acting on the flow drained through the VS system are the intracranial pressure (ICP), intra-abdominal pressure (IAP), and hydrostatic pressure (HP), and the correlation between these forces results in the perfusion pressure (PP), which can be calculated using the following formula: PP=HP+(ICP-IAP)[5].

Large increases occur, especially in hydrostatic pressure gradients, when the patient sits down or stands up, causing excessive CSF drainage. Kajimoto et al.[5] evaluated the association between postural changes and CSF pressure in VPS systems implanted in 13 patients with hydrocephalus, with no incidence of overdrainage. For that purpose, they simultaneously measured the pressures of the various compartments in the supine and sitting positions. With the patients in the supine position, ICP, IAP, and HP were 4.6±3, 5.7±3.3, and 3.3±1 mmHg, respectively. As a result, the PP was only 2.2±4.9 mm Hg. However, when patients sat down, the IAP increased to 14.7±4.8 mmHg, and ICP decreased to – 14.2±4.5 mmHg. The increase in IAP and decrease in ICP compensated the HP in 67% (42.9±3.5 mmHg), and consequently the PP (14±6.3 mmHg) corresponded to only 33% of HP. They demonstrated that the high IAP and low ICP have preventive effects and that high HP has promoting effects on overdrainage. In addition, they observed that only a small fraction of individuals with VS becomes symptomatic, due to the effects of CSF overdrainage[5].

The gravitational antisiphon mechanism reinforces this protective physiological mechanism, so that the weight of the spheres would simulate an even greater increase in IAP. However, such mechanism should be implemented strictly in the vertical position to work properly. It has a rate of general complications identified in the long-term follow-up (mean of 60 months) of up to 21% of cases, of which 5% are related to hypodrainage[12].

The individual's physiological characteristics also make it difficult to determine not only the vertical level of CSF in the cranial-spinal compartment, but also of the fluid level in the cavity where it is absorbed. Thus, it is difficult to precisely calculate the vertical hydrostatic difference between both compartments. Among the main physiological characteristics that influence the vertical hydrostatic gradient are the child's growth, increase in the compliance of the cranial-spinal compartment (such as spinal stenosis, Chiari malformation I, pseudotumor cerebri, and a large intracranial mass lesion). In addition, weight loss increases the compliance of the peritoneal cavity (favoring overdrainage), and extreme constipation can decrease intraperitoneal compliance (resulting in increased IAP). Therefore, two individuals of the same height may have differences in vertical hydrostatic gradient, either by a difference in the cranial-spinal compartment, or by one in the abdominal compartment. It is possible that overdrainage prevention can be more effective with a certain antisiphon device than another. Moreover, even during sleep, and episodically, vasogenic brain alterations can cause an increase in intracranial pressure and, thus, result in overdrainage (e.g., Lundberg's B waves).

These physiological characteristics may explain why many patients with healthy cranial-spinal compartment and peritoneal cavity appear to tolerate a VPS, with or without the use of an antisiphon mechanism, supporting the conclusions of Kajimoto et al.[5], whereas in other patients with altered compliances hydrocephalus can be extremely difficult to treat through VPS (with no incidence of overdrainage), despite the use of several concomitant antisiphon mechanisms.

In this study, we purposely selected patients with overdrainage or patients with hydrocephalus and high susceptibility to overdrainage to test the performance of the SPHERA® valve. The membrane antisiphon mechanism ensured therapeutic success in 94.3% of the patients and showed tomographic resolution of patients with overdrainage. The only complication detected in this sample was infectious, not related to the functional performance of the valve.

The choice of the medium-pressure valve for pseudotumor cases and low-pressure valve for NPH was adequate hydrodynamic to treat these hydrodynamic disorders. The healing process did not hinder the performance of the membrane antisiphon mechanism. The case of NPH, which showed a slight worsening in gait after the first year of improvement, presented no radiological signs of hypo – or overdrainage; it seems that the worsening was due to disease progression unrelated to hydrocephalus due to functional alteration of the VS.

The membrane antisiphon mechanism has two advantages. The technical advantage exists because the valve can be placed in any position in the skull to function properly, differently from the gravity mechanism, in which the vertical positioning of the sphere is critical to proper operation of the system. Another benefit is in the antisiphon protection, regardless of position (supine or standing position). The antisiphon membrane can be used in ventricular-pleural shunts, in which cases the inspiratory pressure gradients, even when patients are lying down, can cause overdrainage.

In conclusion, the fixed-pressure valve with anti-siphon device SPHERA® can be used to treat patients with hydrocephalus and prevent overdrainage. Clinical improvement was observed and sustained in 94.3% of the patients for a two-year period, with no tomographic evidence of hypo – or overdrainage and no significant immediate complications, either early or late ones.

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