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Clinical Follow-Up Study for Sphera Duo® Hydrocephalus Shunt

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Abstract

Cerebral hydrodynamics complications in shunted patients are due to malfunction of the system. The objective of this retrospective, single-center, single-arm cohort study is to confirm safety and performance of Sphera® Duo when used in adult patients suffering from hydrocephalus, pseudotumor cerebri or arachnoid cysts. Data were generated by reviewing 55 adult patient's charts that were submitted to a ventriculoperitoneal shunt surgery and followed for one year after surgery. The result shows us that 85.4% of the patients improved the neurological symptoms and the reoperation rate was 12.5% in the first year after surgery.

Keywords: Ventriculoperitoneal shunt; Complications; Reoperation; Outcome

Introduction

Hydrocephalus, pseudotumor cerebri and aracnoid cysts are the main causes of cerebral hydrodynamics disturbance in adults. The surgical treatment is attained through the implantation of ventricular (to peritoneum, atrium or pleural cavity) shunt system, neuroendoscopy or both for neurological improvement [1,2].

In 1997, the United Kingdom Shunt Registry showed in 13,206 adults with hydrocephalus submitted to ventriculoperitoneal shunt (VP) implantation that 22% of all patients required reoperation within five years [3].

Cerebral hydrodynamics complications in shunted patients are due to malfunction of the system. If the shunt malfunctions and if the mechanism causing the cerebral hydrodynamics disturbance is still active, symptoms of hydrocephalus, pseudotumor cerebri or arachnoid cyst recur, and a shunt revision or other drainage procedure are required [1,2,4,5].

Malfunction may be caused by infection or mechanical failure. Approximately 40% of standard shunts malfunction occur within the first year after placement and 5% per year malfunction in subsequent years [4].

The objective of this study was to confirm safety and performance of Sphera® Duo when used in adult patients suffering from hydrocephalus, pseudotumor cerebri or arachnoid cyst.

Methods

This is a retrospective, single-center, single-arm cohort study approved by the Institutional Ethics Committee. The data are generated by reviewing 55 adult patient's charts who were submitted to a VP shunt surgery for the treatment of cerebral hydrodynamics disturbs (hydrocephalus, pseudotumor cerebri or arachnoid cyst), from January 2015 to July 2016 at Instituto de Psiquiatria do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo. The SPHERA DUO® (HPBio, Brazil) shunt was used in all cases.

The SPHERA DUO® is a fixed pressure valve which works through a sequential double coil spring mechanism, seat and ruby sphere. According to the characteristic of the springs, three ranges of pressure difference ensure a flow of 21 mL/h, which corresponds to the physiological CSF production: low (3 to 7 cm H_2O), medium (7 to 11 cm H_2O) and high (11 to 14 cm H_2O).

Primary endpoints

Frequency and severity of complications or side effects occurring in one year observation period following implantation are recorded.

Secondary endpoints

Clinical improvement after one year of shunt implantation: resolution of the intracranial hypertension syndrome (hydrocephalus, pseudotumor cerebri or arachnoid cyst) or improvement of Normal Pressure Hydrocephalus (NPH) triad (gait apraxia, memory alterations and urinary incontinence).

Study population

Inclusion criteria: Patient has received ventriculoperitoneal, ventriculoatrial or ventriculopleural shunt by implanting the SPHERA DUO® hydrocephalus shunt system.

Patient has been followed according the institutional pre-established routine in-patient and out-patient visits.

Age > 16 years old

Exclusion criteria: The patient received only the shunt (not the entire system - ventricular and peritoneal catheter) to treat a diagnosed over drainage in the previous implanted shunt of another brand.

The patient was treated by ventriculitis with Extraventricular Drainage (EVD) shortly before the implantation of the SPHERA DUO® hydrocephalus derivation system

Surgical procedure

The standard VP shunt implantation technique applied in

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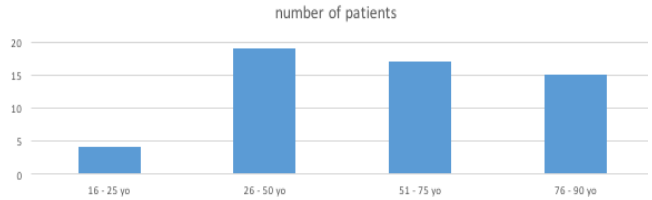

Figure 1: Distribuition of the age of the patients by range 16-25, 26-50, 51-75 and 76-90 years-old (yo).

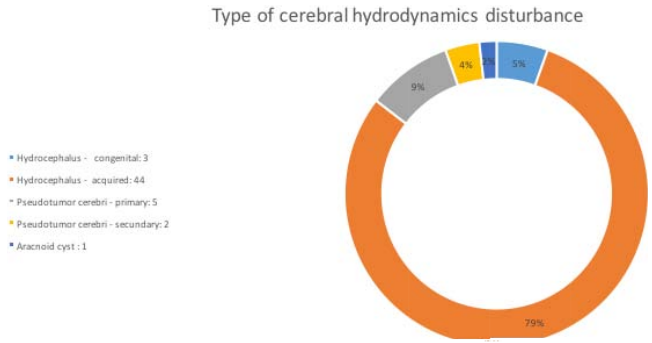

Figure 2: Types of cerebral hydrodynamics disturbance: total amount (legend) and percentage (graph).

our service is composed of cranial and abdominal approaches and is not different from the technique described by Choux et al. [4]. After initial approaches, we perform identification of peritoneum and catheterization of lateral ventricles. Simultaneously we create a subcutaneous tunnel to allow the passage of distal catheter. The whole system is attached and wounds are closed with tight suture.

Results

In the period of 1 year and 6 months (from January 2015 to July 2016), 252 surgeries were performed by the Group of Cerebral Hydrodynamics. Of these, 55 were included in this study according to the established criteria for structuring this cohort.

Twenty-five patients are male (45%) and 30 female (55%). The distribution of ages is represented in (Figure 1), with the youngest patient being 16 years old and the oldest being 90 years old. The most commonly treated cerebral hydrodynamic disorder is acquired hydrocephalus, accounting for 80% of cases (Figure 2), and normal pressure hydrocephalus constitutes about 60% of this sample (Figure 3). Thirty-seven valves were of medium pressure (67%), 13 of high pressure (23%) and 5 (10%) of low pressure valves were implanted according to (Table 1).

Six patients with NPH were reoperated due to overdrainage, with replacement of medium pressure valves by high pressure ones. Overdrainage was detected in neuroimaging (tomography) examinations associated with headache and worsening of the neurological condition (memory, gait or urinary incontinence). One patient was reoperated because the distal catheter was outside the peritoneum in abdominal subcutaneous tissue.

In the 12-month follow-up period, there were no cases of wound dehiscence, superficial infection or meningitis. There were no deaths related or not to surgery during the follow-up period.

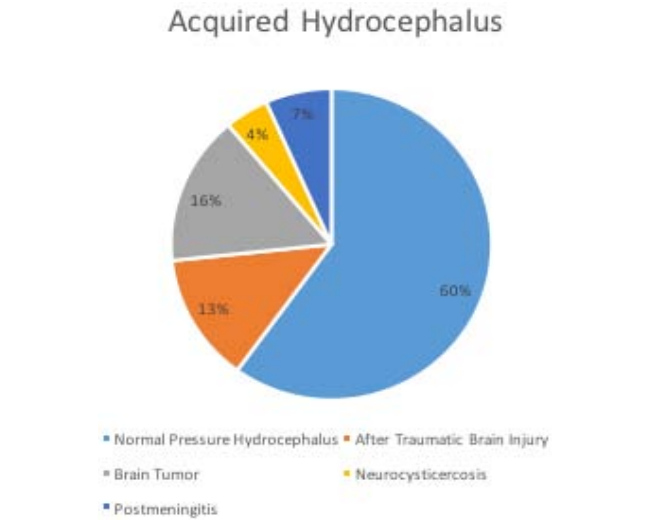

Figure 3: Causes of the acquired hydrocephalus in the sample.

Table 1: Diagnosis, classification and pressure of the valve implanted.

Hydrocephalus	Acquired	Low pressure value	4
		Medium pressure value	25
		High pressure value	8
	Congenital	Medium pressure value	2
		High pressure value	2
Pseudotumor Cerebri	Primary	Medium pressure value	5
		High pressure value	3
	Secundary	Medium pressure value	5
Arcanoid Cyst		Low pressure value	1

Seven patients (12.5%) were reoperated in the follow-up period. One patient had to undergo the distal revision because the distal catheter migrated from the peritoneal cavity to the subcutaneous space and six patients with NPH were reoperated. Of these, five patients had the valve changed from medium to high pressure and one from low to medium pressure by hyperdrainage detected to cranial tomography by subdural collections larger than 1 cm. The latter patient has NPH, had multiple previous abdominal surgeries not related to the neurological problem, and also has pulmonary artery hypertension; having been submitted to ventricular-pleural shunt.

Patients presented radiographic improvement detected by the reduction of the Evans index, but less prominent in patients with NPH.

Forty-seven patients (85.4%) presented clinical improvement of the neurological symptoms that led to the implantation of the derivation (triad of NPH or intracranial hypertension in cases of hypertensive hydrocephalus, cerebral pseudotumor or arachnoid cyst), seven (12.7%) presented progression of NPH symptoms and one (1.9%) remained on neurological examination unchanged one year after surgery.

Discussion

Shunt infection is a common complication, occurring in

approximately 5 to 15% of procedures. This may lead to ventriculitis, may promote the development of loculated compartments of Cerebrospinal Fluid (CSF), and may contribute to impaired cognitive outcome and death. The risk of shunt infections appears to be higher in newborns compared with older infants, children and adults [1-5].

Most shunt infections occur in the first six months after shunt placement. This is an important consideration in deciding when to tap shunts to evaluate a fever, especially when there is no clinical or radiographic evidence of mechanical shunt failure. Increasing abdominal pain associated with peritoneal signs and/or fever is a common presentation of shunt infection in patients with VP shunts. Abdominal ultrasound may demonstrate pseudo cyst. Shunt infection must be considered in a child with a shunt who develops persistent fever. Antibiotics should be started, but this treatment alone is often not effective. In most cases, an infected shunt must be removed, and an external ventricular drain must temporarily be placed [4-8].

Perioperative antibiotic prophylaxis reduces the risk of infection. In two meta-analyses, prophylactic antibiotics in the perioperative period reduced the risk of shunt infection by approximately 50%. The use of antibiotic-impregnated catheters also appears to lower the risk of infection. Whether prophylactic antibiotics are beneficial after the perioperative period remains uncertain. In our study we didn't have any case of infection probably because we adopt a strict protocol using perioperative antibiotics, two gloves and the same staff always perform de VP shunt implantation [4,5].

Mechanical shunt failure is another important cause of shunt failure. Like shunt infection, it is most common during the first year after shunt placement. The majority of shunt failures result from obstruction at the ventricular catheter. Fractured tubing is the cause of shunt failure in approximately 15% of cases. Other causes include shunt migration (partial or complete) and excessive CSF drainage (over drainage). Mechanical failure requires prompt recognition and surgical intervention [2,8-11].

Over drainage can cause functional shunt failure, which causes subnormal ICP (particularly in the upright position) and which is associated with characteristic neurological symptoms such as postural headache and nausea. Over drainage greatly reduces the size of the ventricles causing the catheter to lie against the ependyma and choroid plexus, and these tissues block the holes in the catheter [8-11]. Over drainage can lead to slit-ventricle syndrome, which is characterized by small or slit-like ventricles, coupled with transient episodes of symptoms of raised ICP. Changes in shunt design to address the problem of over drainage include valves designed to open at different pressures and selected based upon the patient's characteristics; anti-siphoning devices to minimize the siphon effect caused by changes in posture; and valves that regulate by flow rather than by pressure differences [8-11].

Six of 27 NPH patients (22.2%) in this study presented over drainage after shunting. They were submitted to reoperation. The pressure of the valve was changed medium to high in 5 cases and low to medium in one. All of them recover the neurological status prior to over drainage. The reoperation could be avoided with implantation of programmable valve or with antisifon device, but none of them developed subdural hematoma [6-8].

Other less common complications are related to the end site of CSF drainage. Potential complications in patients with VP shunts include perforation of viscus and intestinal obstruction. Patients with VA shunts may develop thrombosis associated with the atrial catheter, cor pulmonale, or very rarely may develop glomerulonephritis ("shunt nephritis"), which is related to chronic infection. Patients with ventriculopleural shunts may develop pleural effusions which occasionally produce symptoms[9]. One case in this study needed distal shunt revision because the distal cateter went out from the peritoneal cavity to subcutaneous space. After reoperation the patient recover the neurological status. This problem could be avoided with appropriate surgical technique. A thigh suture in reto abdominal muscle aponeurosis is indicated in obese patients.

The routine performance of a brain computed tomography (CT scan) in follow-up is of undetermined clinical utility. While ventricular size may decrease postoperatively, studies have mixed results in associating this with postoperative improvement. Thus, CT scan cannot be considered a reliable indicator of shunt functioning. CT scan may also detect a subclinical subdural effusion or hematoma.

Regular follow-up and attention to symptoms is required. When patients experience neurologic deterioration, a brain CT scan should be performed to exclude the possibility of subdural hematoma and check the catheter position. A shunt series of a plain x-ray films that visualize the entire shunt system should be performed, looking for visible obstruction. An abdominal ultrasound may also detect obstruction of the shunt tip [10,11].

Conclusion

Sphera Duo® shunt system is safe when used in adult patients suffering from hydrocephalus, pseudotumor cerebri or arachnoids cyst. 85.4% of the patients improved the neurological symptons and the reoperation rate was 12.5% in the first year after surgery.

Conflicts of Interest

Authors declare no additional conflicts of interest. All Sphera Duo® valves used in this study were provided by Hp Bio Company according to respective material acquisition policies in Public Health System in Brazil.

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