

# Clinical performance of fixed-pressure Sphera Duo<sup>®</sup> hydrocephalus shunt

Performance clínica da válvula de pressão fixa Sphera Duo<sup>®</sup>

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## ABSTRACT

**Introduction:** Cerebral hydrodynamics complications in shunted patients are due to the malfunction of the system. The objective of this retrospective, single-center, single-arm cohort study is to confirm the safety and performance of Sphera<sup>®</sup> Duo when used in adult patients suffering from hydrocephalus, pseudotumor cerebri or arachnoid cysts. **Methods:** Data were generated by reviewing 112 adult patient's charts, who were submitted to a ventriculoperitoneal shunt surgery and followed for one year after surgery. **Results:** The results show us that 76% of patients had their neurological symptoms improved and that the reoperation rate was 15% in the first year following surgery. **Discussion:** Sphera Duo<sup>®</sup> shunt system is an applicable shunt option in routine neurosurgical management of hydrocephalus by several causes. It has presented good results while mitigating effects of overdrainage. Overdrainage is especially important in adults with non-hypertensive hydrocephalus and can cause functional shunt failure, which causes subnormal ICP (particularly in the upright position) and is associated with characteristic neurological symptoms, such as postural headache and nausea. **Conclusion:** Sphera Duo<sup>®</sup> shunt system is safe when used in adult patients suffering from hydrocephalus, pseudotumor cerebri or arachnoid cyst.

**Keywords:** ventriculoperitoneal shunt; complications; reoperation; outcome.

## RESUMO

**Introdução:** As complicações da hidrodinâmica cerebral em pacientes com derivação ventriculoperitoneal são frequentemente relacionadas ao malfuncionamento do sistema. O objetivo deste estudo retrospectivo de coorte de centro único é avaliar a segurança e performance clínica do Sistema Sphera<sup>®</sup> Duo quando utilizado em adultos com hidrocefalia, pseudotumor cerebral ou cistos aracnoides. **Métodos:** Avaliamos os prontuários de 112 pacientes adultos submetidos a cirurgia de derivação ventriculoperitoneal e acompanhados por 1 ano após a cirurgia. **Resultados:** O resultado mostra que 76% dos pacientes melhoraram dos sintomas neurológicos e a taxa de reoperação foi de 15% no primeiro ano após a cirurgia. **Discussão:** O sistema de derivação Sphera Duo<sup>®</sup> é uma opção de shunt adequada a ser usada no tratamento neurocirúrgico da hidrocefalia por causas diversas. Ele demonstrou bons resultados clínicos enquanto reduziu riscos de hiperdrenagem. A hiperdrenagem é especialmente preocupante e mórbida em pacientes adultos com hidrocefalia não hipertensiva e pode levar a prejuízo clínico e disfunção da válvula, com sintomas de hipotensão craniana, como cefaléia ortostática e náuseas. **Conclusão:** O sistema de derivação Sphera Duo<sup>®</sup> é seguro para tratamento da hidrocefalia, pseudotumor cerebri ou cistos aracnoides em adultos.

**Palavras-chave:** derivação ventriculoperitoneal; complicações; reoperação; desfecho.

Hydrocephalus, pseudotumor cerebri and arachnoid cysts are the main causes of cerebral hydrodynamics disturbance in adults. Surgical treatment is based on the implantation of ventricular (peritoneum, atrium or pleural cavity) shunt system, neuroendoscopy, or both<sup>1,2</sup>.

Shunt surgeries have changed the curve of hydrodynamics diseases treatment, especially in infants. However, if they allowed treatment of several diseases, they have also turned

to be a problem themselves, resulting in many potential functional and infectious complications<sup>1-5</sup>.

Up to 80% of patients harboring a shunt may experience any kind of complications and approximately 50% may need a revision or undergo a surgery complication during life. Malfunction may be caused by infection or mechanical failure. Approximately 40% of standard shunts malfunctions occur within the first year after the procedure and 5% malfunction per year in subsequent years<sup>4</sup>.

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**Conflict of interest:** The authors declare no additional conflicts of interest. All Sphera Duo<sup>®</sup> valves used in this study were provided by HpBio Company, according to respective material acquisition policies in the Brazilian Public Health System.

Received on May 14, 2019; Accepted on August 28, 2019.

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. We describe the clinical results and its application in a daily neurosurgical practice.

## METHODS

This is a retrospective, single-center, single-arm cohort study approved by the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo Ethics Committee. There was ethical adherence and the study was registered with the protocol CAPPESQ 0348/09. Data are generated with the review of 112 adult patient's charts, who were submitted to a VP shunt surgery for the treatment of hydrocephalus, pseudotumor cerebri or arachnoid cyst, from June 2014 to December 2017, 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. This study was carried out at the Hospital das Clínicas, Universidade de São Paulo, São Paulo, Brazil.

SPHERA DUO® is a fixed pressure valve (Figure 1), 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 physiological CSF production: low (3 to 7 cm H<sub>2</sub>O), medium (7 to 11 cm H<sub>2</sub>O), and high (11 to 14 cm H<sub>2</sub>O).

### Primary endpoints

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



Figure 1. Sphera Duo Valve®, HpBio, São Paulo, Brazil.

## 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

- The patient has received a ventriculoperitoneal, ventriculoatrial or ventriculopleural shunt, by implanting the SPHERA DUO® hydrocephalus shunt system.
- Patient has been followed according to the institutional pre-established routine inpatient and outpatient 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 overdrainage in the previous implanted shunt of another brand.
- The patient was treated for 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 our service is composed of cranial and abdominal approaches and is not different from the technique described by Choux et al.<sup>4</sup> After initial approaches, we identify the peritoneum and perform the catheterization of lateral ventricles. Simultaneously, we create a subcutaneous tunnel to allow the passage of the distal catheter. The whole system is attached, and wounds are closed with a tight suture.

## RESULTS

### Sample

In the period of three and a half years (from June 2014 to December 2017), 252 surgeries were performed by the Group of Cerebral Hydrodynamics. Of these, 112 were included in this study respecting the established criteria for structuring this cohort.

Fifty were male (45%) and 62 were female (55%). The youngest patient was aged 16 years and the oldest, 90 years. The most commonly treated cerebral hydrodynamic disorder was acquired hydrocephalus, accounting for 93 cases (83%) (Figure 2), and normal pressure hydrocephalus constitutes about 60% of this sample (Figure 3). Ninety-four valves were

of medium pressure (84%), 13 of high pressure (11%) and 5 (5%) of low-pressure valves were implanted.

### Follow-up

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

Overall, eighty-six patients (76%) presented clinical improvement of neurological symptoms that led to the implantation of the shunt (triad of NPH or intracranial hypertension in cases of hypertensive hydrocephalus, cerebral pseudotumor or arachnoid cyst), twelve (11%) presented stability of symptoms and fourteen (13%) reported worsening of symptoms (Figure 3).

Seven patients were reoperated due to overdrainage (10%), with the replacement of medium pressure valves by high pressure ones. Overdrainage was detected in neuroimaging (tomography) examinations associated with headache and worsening of their neurological condition (memory, gait or urinary incontinence). One patient was reoperated because

the distal catheter was outside the peritoneum in the abdominal subcutaneous tissue. Four patients were reoperated due to an infection of the system; four patients were reoperated due to abdominal wall cysts or herniations; one patient was reoperated due to a malfunction of the shunt system (Figure 4).

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.

### DISCUSSION

Shunt complications are an everlasting matter in shunt surgery. The intent of current literature is to decrease complications and their consequences. The technology of shunt, its materials and the surgical techniques may decrease mechanical and infectious complications<sup>1-19</sup>.

Shunt infection is a common complication, occurring in approximately 5 to 15% of procedures. This may lead to ventriculitis, promote the development of loculated compartments of cerebrospinal fluid (CSF), and may impair life quality of patients harboring shunts.

Mechanical shunt failure is another important cause of shunt failure. Like shunt infection, it is most common during the first year after shunt placement. Shunt failures may result from obstruction at the ventricular catheter, migration (partial or complete) and excessive CSF drainage (overdrainage). Mechanical failure requires prompt recognition and management<sup>2-11</sup>.

Overdrainage is especially important in adults with non-hypertensive hydrocephalus and can cause functional shunt failure, which causes subnormal ICP (particularly in the upright position) and is associated with characteristic neurological symptoms, such as postural headache and nausea. Overdrainage greatly reduces the size of ventricles, causing the catheter to lie against the ependyma and choroid plexus, and these tissues block the holes in the catheter<sup>8-11</sup>. Overdrainage can lead to slit-ventricle syndrome, which is characterized by

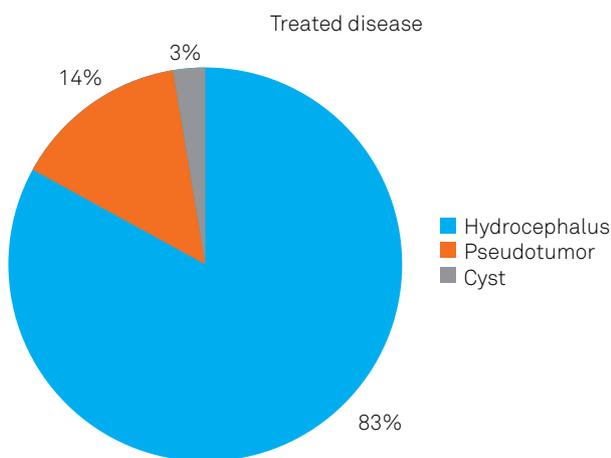


Figure 2. Types of cerebral hydrodynamics disturbance.

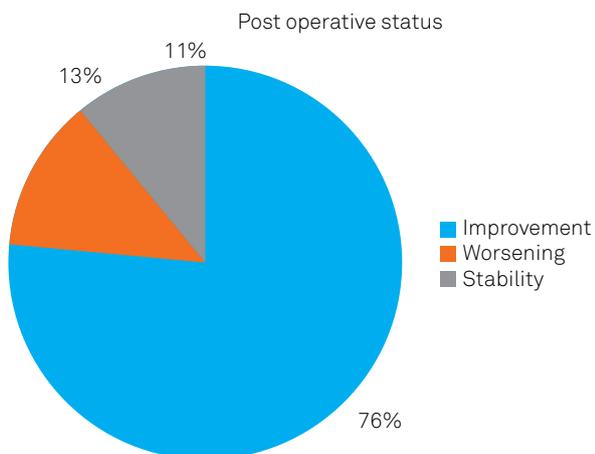


Figure 3. General clinical status at the 1-year after surgery follow-up.

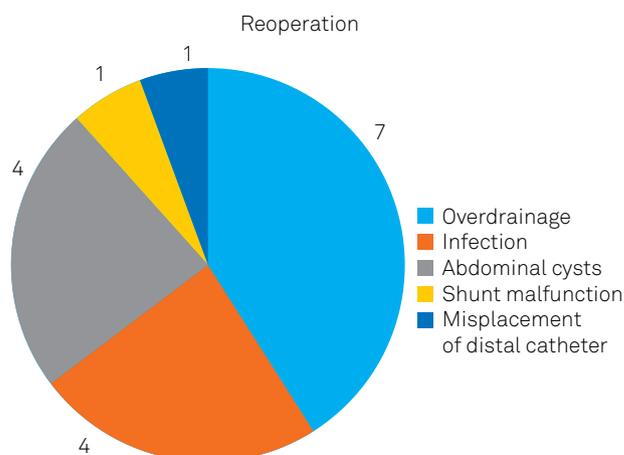


Figure 4. Causes for reoperation.

small or slit-like ventricles, coupled with transient episodes of symptoms of raised ICP. Changes in shunt, designed to address the problem of overdrainage, 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<sup>13-19</sup>.

We had a rate of complications of 12.5%, mainly due to overdrainage and need for valve replacement. The use of a programmable valve or anti-siphon system may mitigate such complications.

One case in this study needed distal shunt revision because the distal catheter went out from the peritoneal cavity to the

subcutaneous space. After reoperation, patient recovered the neurological status. This problem could be avoided with an appropriate surgical technique. A thigh suture in retro abdominal muscle aponeurosis is indicated for obese patients.

Our rate of symptom improvement was 76%, similar to that of other studies in literature<sup>2-8</sup>. This suggests the applicability and safety of the shunt.

In conclusion, Sphera Duo® shunt system is safe when used in adult patients suffering from hydrocephalus, pseudotumor cerebri or arachnoid cyst. Seventy-six percent of the patients had their neurological symptoms improved and the reoperation rate was 12.5% in the first year after surgery.

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