Features of the Sinushunt® and its influence on the cerebrospinal fluid system

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Objectives: A new cerebrospinal fluid (CSF) shunt system, Sinushunt®, has recently been introduced. CSF is shunted from the ventricles to the transverse sinus. The Sinushunt is not a classical differential pressure shunt; instead, it opens as soon as there is a positive pressure over the shunt and the flow is dependent on the resistance of the system, which is high compared with traditional CSF shunts. The objective of this study was to characterise the features of the Sinushunt and to evaluate its influence on the CSF system.

Methods: Five brand new Sinushunts with distal catheters were tested. An automated, computerised experimental apparatus based on regulation of pressure, built into an incubator at 37 °C, was used. Opening pressure, resistance, and anti-reflux properties were determined.

Results: The mean (SD) opening pressure was highly dependent on the pressure in the sinus: $P_{open} = 1.3$ (0.6) mm Hg with $P_{sinus} = 0.0$ mm Hg, and $P_{open} = 7.5$ (0.6) mm Hg for $P_{sinus} = 6.5$ mm Hg. The mean (SD) resistance of the shunts was 7.9 (0.3) mm Hg/ml/min and not clinically significantly affected by the sinus pressure. In one shunt there was reflux, and in another two shunts there was a very small, but similar, tendency.

Conclusions: This study confirms that the resistance of the Sinushunt is comparable to the physiological values in humans. However, the optimal post-operative resistance for different hydrocephalus types is unknown, and randomised clinical trials are needed to confirm improved outcome and reduced complication rate for the Sinushunt compared with traditional low resistance ventriculoperitoneal shunts. A weakness of the anti-reflux system of the Sinushunt must be suspected and has to be further investigated.

Ventriculoperitoneal cerebrospinal fluid (VP CSF) shunts are the standard treatment for patients with hydrocephalus. Recently, a new CSF shunt system based on older principles, placing the distal catheter in the transverse sinus instead of the abdominal cavity, was reported.¹ The advantage of this new CSF shunt system is mainly prevention of complications related to over drainage associated with VP shunts, by avoiding the distal hydrostatic component in the upright position.²

The flow profile of the Sinushunt® is characterised by a linear correlation between the pressure difference between the ventricle and sinus and the resulting CSF flow. The Sinushunt is marketed in Europe and is a realistic alternative for the neurosurgeon. However, only case series¹ have been published thus far, and there are no randomised trials comparing this new technique with the traditional VP shunt in patients with hydrocephalus. Furthermore, in vitro data regarding the features of the Sinushunt are only provided by the manufacturer.

The resistance of the Sinushunt has been adapted to the CSF outflow resistance over the arachnoid villi in healthy individuals.³ The purpose of this study was to confirm that the features of the Sinushunt corresponds to the data given by the manufacturer, to discuss the advantages and disadvantages of this new shunt technology, and to investigate its influence on the CSF system.

METHODS

Shunts

Sinushunts supplied by the manufacturer were tested (fig 1). The shunts were tested with their distal catheter. To confirm reproducibility five shunts were tested.

The in vitro test

The in vitro experimental set up has previously been described.⁴ In summary, a computerised system collects data

and regulates the pressure. Flow is calculated from the pressure drop over a glass constriction with known resistance. The pressure drop over the constriction and the pressure over the hydrocephalus shunt are measured with differential pressure transducers (LPM8000, Druck, Leicester, UK).

The shunt was mounted on a support and submerged into 100 mm of water corresponding to a subcutaneous scalp tissue pressure of 7.4 mm Hg. A study on rats determined the tissue pressure around an implanted shunt to be 64 mm H₂O.⁵ Suspecting that it can be slightly higher in humans, we chose 100 mm H₂O. Outflow from the shunt is led into an overflow container with a constant water level at the zero pressure level, or at 6.5 mm Hg level when testing with a distal pressure component corresponding to a normal sinus pressure, P_{sinus} . The experimental apparatus was built into an incubator at 37°C.

The proximal pressure, corresponding to intracranial pressure (ICP) was in cycles increased from 0 to 18.5 mm Hg (shunt 1) or from 0 to 22.1 mm Hg (shunt 2–5) and back to 0 again over a time period of 1 hour (fig 2). The test cycles were automatically repeated 10 times on each shunt with a pressure calibration between every cycle. On five cycles P_{sinus} was set to 0 and on five cycles to 6.5 mm Hg. One of the 50 measurements was omitted owing to suspected air bubbles in the shunt system.

Calculation of resistance, R_{shunt} , and opening pressure, P_{open} , is shown in fig 2. The resistance of the tubing in the experimental apparatus without shunt and shunt tubing was measured to be $R_{tubing} = 2.6$ (0.1) mm Hg/ml/min ($n = 12$).

Abbreviations: CSF, cerebrospinal fluid; ICP, intracranial pressure; VP, ventriculoperitoneal

Figure 1 The Sinushunt consists of a connector (1), two unidirectional valves (2), a pre chamber (3), a resistance tube made of titanium (4), and a distal catheter (5). Picture supplied by CSF Dynamics A/S.

RESULTS

P_{open} was highly dependent on the sinus pressure, $P_{open} = 1.3$ (0.6) mm Hg (mean (SD), $n = 25$) with $P_{sinus} = 0.0$ mm Hg, and $P_{open} = 7.5$ (0.6) mm Hg (mean (SD), $n = 24$) for $P_{sinus} = 6.5$ mm Hg.

There was a small, but significant, difference in R_{shunt} with respect to the two levels of sinus pressure (10.5 mm Hg/ml/min versus 10.6 mm Hg/ml/min) (one way analysis of variance: $p = 0.046$, $n = 49$). However, the difference had no clinical significance and the subsequent analysis was therefore based on all measurements together. Resistance for the five shunts with tubing was $R_{shunt} = 10.5$ (0.3) mm Hg/ml/min (mean (SD), $n = 49$). This leads to a shunt resistance of 7.9 (0.3) mm Hg/ml/min after subtraction of the tubing resistance related to the experimental apparatus. There were significant (one way analysis of variance: $p < 0.01$, $n = 49$) differences in resistance between shunts. However, the maximum differences between R_{shunt} mean values were < 0.6 mm Hg/ml/min (fig 3).

Test with $P_{sinus} = 6.5$ mm Hg revealed a clear backflow through one of the shunts for an ICP interval of approximately 4.0–6.5 mm Hg (fig 4). This interval corresponds to a negative pressure interval of 0.0–2.5 mm Hg over the shunt.

DISCUSSION

The Sinushunts tested in this study produced very stable and reproducible results. Resistance was within specification and in the middle of the interval for normal values.³ The variation was small and well within what we believe is clinically relevant (fig 3). P_{open} was directly dependent on the distal pressure—that is, the P_{sinus} . Our results show a minor difference between P_{sinus} and P_{open} . This is explained by the method of linear extrapolation that we use for defining P_{open} . On pressures where the flow is close to 0, there was an

Figure 2 Flow versus pressure for a typical shunt. Black line represents test with $P_{sinus} = 0.0$ mm Hg and gray line test with $P_{sinus} = 6.5$ mm Hg. Note that there was a flow through the shunt when the ICP exceeded P_{sinus} . The linear regression for determining $1/R_{shunt}$ (slope) and the pressure limit over which the shunt was open, P_{open} (defined as the crossing of the abscissa), is shown for the $P_{sinus} = 0.0$ measurement. Resistance, R_{shunt} , was determined for fully open shunts (static resistance¹⁸), using the flow interval of 0.6–1.2 ml/min.⁴

Figure 3 There were no clinically relevant differences between the resistances of the five shunts tested. Error bars show 95% confidence interval.

intermediate phase where the pressure and flow curve was not linear (fig 2). A positive flow through the shunt was typically shown as soon as $ICP > P_{sinus}$ (fig 4).

Influence on CSF dynamics

In contrast to traditional VP shunts, the Sinushunt uses no valve mechanism to regulate the opening pressure for control of the ICP. Flow through the shunt started when the differential pressure over the shunt was positive—that is, when the ICP exceeded the sinus pressure. The resistance of the Sinushunt was of the same magnitude as the resistance of normal pathways of a human. The resistance of the sinus shunt was approximately three times higher than that of a Delta shunt. The Sinushunt works in parallel with arachnoid villi and reduces the ICP by reducing total resistance. It is described by the Dawson equation:⁶

$$ICP = P_{sinus} + R_{out}q_f$$

Where q_f is the CSF formation rate. For a shunted patient, the post-operative $R_{out} = R_{postop}$ and can be estimated from shunt

Figure 4 Flow versus ICP for all five shunts with a simulated $P_{sinus} = 6.5$ mm Hg. As long as there is a negative pressure gradient over the shunt—that is, when $ICP < P_{sinus}$, the anti-reflux valves should keep a zero flow. For one shunt there was a clear backflow through the shunt for an ICP interval spanning a couple of mm Hg beneath the $P_{sinus} = 6.5$ mm Hg. For two other shunts, there was a tendency to backflow in the similar ICP interval. For high negative pressures ($P_{sinus} - ICP > 3$ mm Hg) all anti reflux valves worked properly. For all shunts the positive flow through the shunt starts at $ICP \approx P_{sinus}$ —that is, as soon as there is a positive differential pressure over the shunt.

resistance, R_{shunt} , and normal pathways resistance, described by the pre-operative resistance, R_{preop} , as:

$$\frac{1}{R_{postop}} = \frac{1}{R_{preop}} + \frac{1}{R_{shunt}}$$

Thus, as shown in fig 5, the expected post-operative resistance will depend on both the pre-operative resistance and the resistance of the Sinushunt. Expected post-operative ICP can be estimated according to that post-operative resistance and the Dawson equation.

In contrast to a regular differential pressure VP shunt, the function of the Sinushunt is thus to reduce ICP by a moderate reduction of the total resistance to outflow. Pre- and post-operative measurement of resistance with an infusion technique^{7,8} is regularly performed in hydrocephalus patients and with this technique it would be possible to confirm the in vitro results presented in this study.

The main advantages of the Sinushunt compared with more conventional shunts are that the siphoning problem caused by the distal hydrostatic component in the upright position is avoided by shunting into the sinuses, and that the more physiological sinus pressure, rather than the abdominal pressure, is used as distal reference.

Pathophysiology

If the pathophysiology of hydrocephalus is solely due to an increased resistance to outflow and a subsequent increased ICP, the Sinushunt has the potential to work well. In this case, the shunt would normalise the hydrodynamics of the patient. For high pressure hydrocephalic patients with a high R_{preop} this definition fits reasonable well and they may be good candidates for the Sinushunt. We therefore suggest that an infusion test where both R_{preop} and pre-operative ICP are determined should be performed before choosing the Sinushunt. Janny *et al*⁹ have shown that high ICP can be a consequence of high P_{sinus} ; for those patients, shunting with a Sinushunt would not be effective for reducing ICP. Preferably, the pre-operative P_{sinus} should also be measured, but as this is not a simple procedure it is not likely to be used as a standard pre-operative investigation.

For normal pressure hydrocephalus patients, the hydrodynamic pathophysiology is not as clear. Even if studies indicate that an elevated outflow resistance is a predictor for positive outcome of shunt surgery,^{10–12} it has also been shown that patients with a normal outflow resistance and normal or slightly raised ICP will benefit from shunting.^{10,11,13} Furthermore, it has been shown that even in cases of unchanged ICP after shunting, patients have clinical improvement.⁷ Most of the current shunts have a resistance to outflow that is lower than normal physiological values¹⁴

Figure 5 Estimated post-operative resistance after shunt insertion versus pre-operative resistance. The graphs represent values for insertion of a Sinushunt and of a typical Delta shunt with $R_{shunt} = 2.6$ mm Hg/ml/min. The normal R_{shunt} range [4.8–10.5 mm Hg/ml/min] for human³ is shown by the shaded area.

(fig 5), which may indicate that the function of the standard shunts today is not to normalise the hydrodynamics. As the optimal post-operative range of resistance in hydrocephalus patients is unknown, it is impossible to postulate if one should aim at low (traditional differential pressure VP shunt) or normal (Sinushunt) post-operative resistance. For instance, a patient operated on with a Sinushunt may improve post-operatively, but we do still not know if the patient would show even more improvement with a VP shunt system (or vice versa). In a previous study with another ventricle to sinus shunt, only one patient of four (with low or normal pressure hydrocephalus) improved and it was concluded that its use in normal and low pressure hydrocephalus must still be evaluated.¹⁵ Randomised studies are urgently needed to clarify this intricate topic.

Reflux

In one of the five shunts, there was reflux, a flow of fluid toward the inflow catheter, within a physiological range of differential pressures between the ventricle and the sinus (fig 4). In another two shunts, there was a similar tendency to reflux, however probably without clinical significance. In the worst case scenario, reflux could cause blood to flow from the venous sinus through the shunt and into the CSF of the ventricles.¹⁶ A more likely scenario is that refluxed blood clogs the titanium tube in the shunt and obstructs the CSF outflow. Our sample of five shunts was too small to make any statement about the likelihood of occurrence of reflux in other samples of the Sinushunt.

When testing the shunts with high negative pressures over the shunt—that is, $P_{sinus} > ICP$, all valves closed and there was no backflow. The problem with a high pressure test is that the unidirectional valves use the negative pressure as a driving force to close. The valves therefore get more effective the higher the negative pressure. We found this dysfunction by continuous variation of ICP during a constant small distal pressure. The ISO 7197 standard¹⁷ for shunts prescribes a reflux test with static distal pressures of 10, 50, and 500 mm H₂O (0.8, 3.8, and 38 mm Hg) and a maximum allowed reflux of 0.02 ml/min. The first pressure level should have detected a non-permitted reflux in the dysfunctional valve, while the other four shunts would have passed the ISO reflux test. However, for improved testing we suggest that the manufacturers use continuous pressure variation test, similar to the one used in this study.

CONCLUSIONS

This study confirms that shunt resistance was comparable to the physiological values previously given by Ekstedt.³ There was minimal variability in the resistance. A weakness of the anti-reflux system of the Sinushunt must be suspected and further investigations are needed. As VP shunts are still the golden standard, and as the pathophysiology of hydrocephalus is not unequivocal, and the optimal post-operative resistance for different hydrocephalus types is unknown, clinical trials comparing traditional shunt systems with the Sinushunt are needed.

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REFERENCES

- 1 **Borgesen SE**, Gjerris F, Agerlin N. Shunting to the sagittal sinus. *Acta Neurochir Suppl* 2002;**81**:11–14.
- 2 **Aschoff A**, Kremer P, Benesch C, *et al.* Overdrainage and shunt technology. A critical comparison of programmable, hydrostatic and variable-resistance valves and flow-reducing devices. *Childs Nerv Syst* 1995;**11**:193–202.
- 3 **Ekstedt J**. CSF hydrodynamic studies in man. 2. Normal hydrodynamic variables related to CSF pressure and flow. *J Neural Neurosurg Psychiatry* 1978;**41**:345–53.
- 4 **Lundkvist B**, Eklund A, Koskinen LOD, *et al.* An adjustable CSF shunt. Advice for clinical use. *Acta Neurol Scand* 2003;**108**:38–42.
- 5 **Hassan M**, Higashi S, Yamashita J. Risks in using siphon-reducing devices in adult patients with normal-pressure hydrocephalus: bench test investigations with Delta valves. *J Neurosurg* 1996;**84**:634–41.
- 6 **Gjerris F**, Borgesen SE. Current concepts of measurement of cerebrospinal fluid absorption and biomechanics of hydrocephalus. *Adv Tech Stand Neurosurg* 1992;**19**:145–77.
- 7 **Lundkvist B**, Eklund A, Kristensen B, *et al.* Cerebrospinal fluid hydrodynamics after placement of a shunt with an antisiphon device: a long-term study. *J Neurosurg* 2001;**94**:750–6.
- 8 **Czosnyka M**, Batorski L, Laniowski P, *et al.* A computer system for the identification of the cerebrospinal compensatory model. *Acta Neurochirurgica* 1990;**105**:112–16.
- 9 **Janny P**, Chazal J. Intracranial pressure and sagittal sinus pathology. *J Neurosurg* 1981;**54**:424.
- 10 **Vanneste JA**. Diagnosis and management of normal-pressure hydrocephalus. *J Neural* 2000;**247**:5–14.
- 11 **Boon AJ**, Tans JT, Delwel EJ, *et al.* Dutch normal-pressure hydrocephalus study: prediction of outcome after shunting by resistance to outflow of cerebrospinal fluid. *J Neurosurg* 1997;**87**:687–93.
- 12 **Kahlon B**, Sundberg G, Rehnstrom S. Comparison between the lumbar infusion and CSF tap tests to predict outcome after shunt surgery in suspected normal pressure hydrocephalus. *J Neural Neurosurg Psychiatry* 2002;**73**:721–6.
- 13 **Malm J**, Kristensen B, Karlsson T, *et al.* The predictive value of cerebrospinal fluid dynamic tests in patients with idiopathic adult hydrocephalus syndrome. *Arch Neurol* 1995;**52**:783–9.
- 14 **Czosnyka Z**, Czosnyka M, Richards HK, *et al.* Laboratory testing of hydrocephalus shunts – conclusion of the UK Shunt evaluation programme. *Acta Neurochir (Wien)* 2002;**144**:525–38 (discussion 538).
- 15 **Hash CJ**, Shenkin HA, Crowder LE. Ventricle to sagittal sinus shunt for hydrocephalus. *Neurosurgery* 1979;**4**:394–400.
- 16 **El Shafei IL**, El Shafei HI. The retrograde ventriculosinus shunt: concept and technique for treatment of hydrocephalus by shunting the cerebrospinal fluid to the superior sagittal sinus against the direction of blood flow. Preliminary report. *Childs Nerv Syst* 2001;**17**:457–65 (discussion 466).
- 17 ISO-7197. Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components. In: *ISO Standards*. Geneva: International Organization for Standardization, 1997:1–16.
- 18 **Czosnyka M**, Czosnyka Z, Whitehouse H, *et al.* Hydrodynamic properties of hydrocephalus shunts: United Kingdom Shunt Evaluation Laboratory. *J Neural Neurosurg Psychiatry* 1997;**62**:43–50.

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