Who Needs a Revision? 20 Years of Cambridge Shunt Lab

Zofia Czosnyka, Marek Czosnyka, John D. Pickard, and Aswin Chari

Abstract Shunt testing independent of manufacturers provides knowledge that can significantly improve the management of patients with hydrocephalus. The Cambridge Shunt Evaluation Laboratory was created 20 years ago. Thanks to financial support from the Department of Health (1993–1998), all shunts in use in the UK were systematically evaluated, with "blue reports" being published. Later new devices were tested as they appeared in public domain.

Twenty-six models have been evaluated. The majority of the valves had a non-physiologically low hydrodynamic resistance that may result in over-drainage, both related to posture and during nocturnal cerebral vasogenic waves. A long distal catheter increases the resistance of these valves by 100–200 %. Drainage through valves without a siphon-preventing mechanism is very sensitive to body posture. Shunts with siphon-preventing accessories offer a reasonable resistance to negative outlet pressure. Bench parameters were used to test shunt performance in vivo using infusion tests. A criterion for correctly performing a shunt procedure was established. Pressure measured in the shunt prechamber during the plateau phase of infusion should not remain more than 5 mmHg above the le shunt's operating pressure plus hydrodynamic resistance of the valve multiplied by the infusion rate. "Critical levels" for every shunt and every performance level have been used in the shunt testing wizard of ICM+ software.

Keywords Hydrocephalus • Shunt • Laboratory • Infusion test • In vivo functioning

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Introduction

Shunting remains the mainstream strategy for the management of communicating hydrocephalus. Although approximately 70 % of properly diagnosed patients with hydrocephalus improve after implantation of any model of shunt, the remaining 30 % may suffer further complications, frequently caused by inadequate shunt performance. To help the neurosurgeon to choose from the many types of shunt available, information about the hydrodynamic properties of each shunt should be available. The amount of technical information provided by the manufacturer varies. In the mid-1990s, the ISO standard (ISO 7197) was aimed at regulating the minimal requirements for the description of the hydrodynamic properties of the shunt, but this has not been fully implemented by all manufacturers.

Over the years, a number of independent laboratories, usually supported by academic institutions, set the standard for shunt testing in vivo. The testing of shunts in Europe originated in the laboratory of Dr A Ashoff in Heidelberg over two decades ago [2]. The Cambridge Shunt Evaluation Laboratory was established almost 20 years ago thanks to a grant from the Department of Health. Over this period, 26 shunts have been evaluated according to the ISO 7197 standard. Under the initial grant (1993–1998), all shunts in use in the UK were systematically evaluated in "blue reports" published by the Medical Devices Agency. New devices were tested as they appeared in the marketplace (or as prototypes), and these results have been published in academic journals. This paper is a shortened version of a more extensive study published in January 2014 [3], which summarises 20 years' experience from the Shunt Lab and places additional emphasis on using data from the laboratory for shunt testing in vivo.

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Materials and Methods

The shunt testing rig [5] is controlled by a standard IBM-compatible personal computer that reads and zeroes the balance periodically (every 15 s) to calculate the drainage rate (see Fig. 1). In this way the weight of the outflowing fluid is measured incrementally, which cancels the influence of vaporisation from the outlet container. The computer analyses the pressure waveform recorded from the pressure transducer and controls the rate of the infusion pump. The effect of changes in atmospheric pressure is compensated for by using the reference barometer. The shunt and pressure transducer are placed on the same level. The water column in the fluid container (H), the degree of the shunt submersion and the level of the outlet tubing (O) may be changed according to the test protocol.

The testing protocol agrees with, but also extends beyond, the requirements of the International Standard Organization Hydrocephalus Valves Testing Standard (ISO/DIS 7197). The protocol has been kept essentially fixed for all previously tested shunts; therefore, comparison between different models is possible using retrospective data sets. Three shunts of the same type are tested simultaneously, filled with deionised and de-aerated water. The shunts are mounted onto three identical cross-calibrated rigs and the testing protocol starts. The initial tests are used to observe whether the shunt commences to work properly immediately after it was first filled with water. When the calculated parameters are stable for two consecutive tests, the testing procedure recommences. Before each test the shunt is inspected for air bubbles, and if necessary, gently flushed. Each pressure transducer and the reference barometer are zeroed and recalibrated with the reference water column.

Usually, tests start with assessment of the valve at a constant, medium setting (for set or adjustable valves). The shape of the pressure–flow curve, its stability in time and the basic hydrodynamic parameters (closing and opening pressure, hydrodynamic resistance of the valve) are tested over an 18-day period. Next, the influence of a change in bath temperature, the changing residual resistance to CSF outflow, the external pressure, the magnitude of the pulse waveform in inlet pressure, the influence of the outlet negative pressure and distal drains of various lengths are tested. Then,

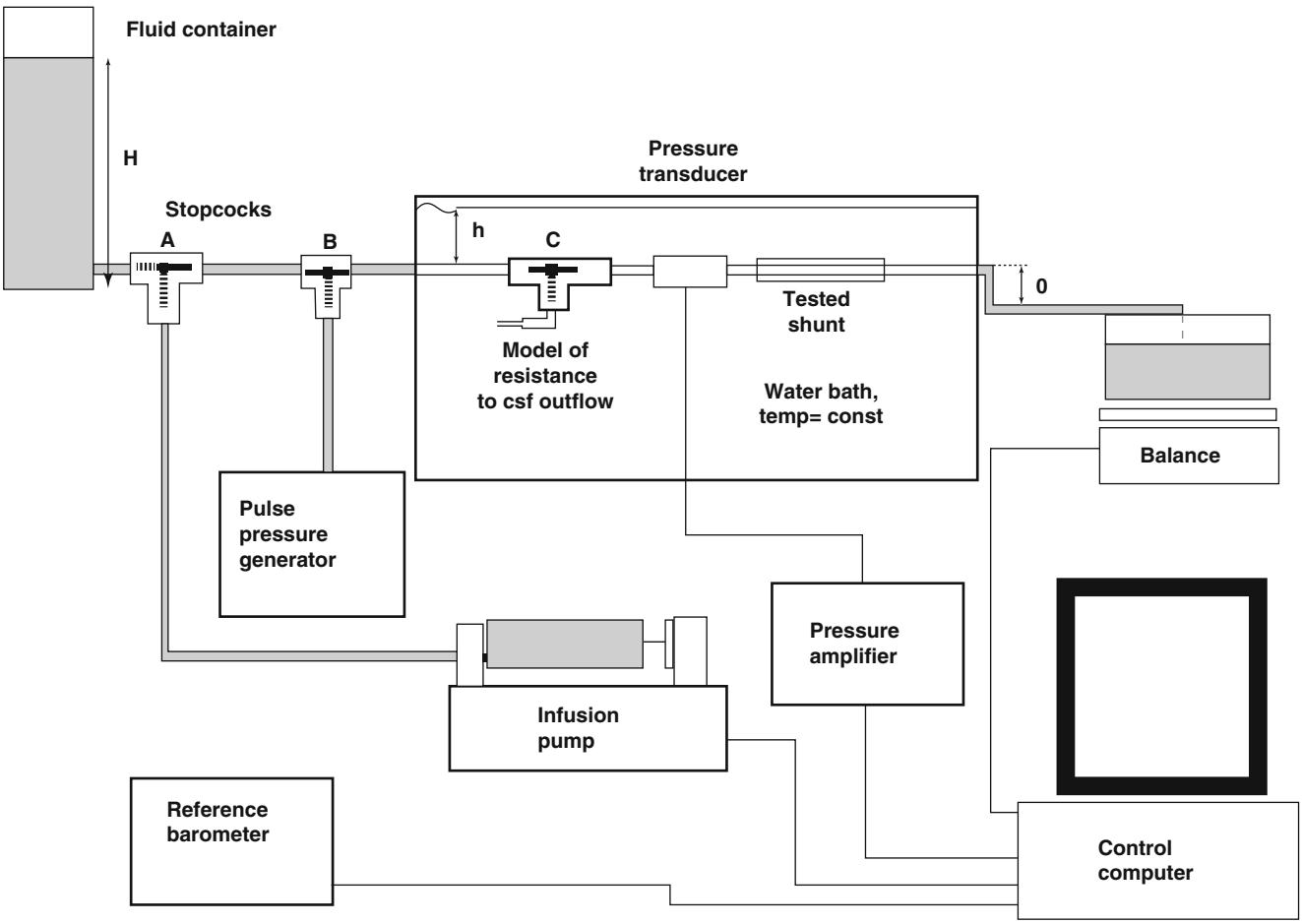

Fig. 1 Scheme of a shunt testing rig. A description is found in the text

the variability of hydrodynamic parameters with different performance levels is assessed. The valves are exposed to a magnetic field in 3-T MRI and the safety, stability of performance level and volume of artefact on gradient echo and spin echo (T1) scans are assessed. For adjustable valves, basic hydrodynamic parameters are tested before and after MRI. Finally, the reflux, the durability of the junctions and the drift of the pressure–flow performance over the whole testing period are assessed.

Results

Synopsis of Hydrodynamic Properties of Contemporary Shunts

Eighteen non-programmable and 8 programmable valves reveal common hydrodynamic properties of contemporary shunts.

For different constructions, pressure flow performance curves may have different shapes varying from completely linear (above the opening pressure) to absolutely non-linear (e.g. flow-regulating valves such as the Orbis-Sigma or Diamond). In some valves a wide hysteresis of the performance curve can be noticed, suggesting that measured differential pressure might be dependent on the direction of flow changes through the shunt; silicone valves show particularly significant hysteresis, whilst ball-on-spring valves are less susceptible. Ball-on-spring valves usually show better convergence of pressure–flow performance characteristics than membrane valves. Some constructions, such as distal-slit valves, may change their performance dramatically, if distal conditions change (wet or dry end, touching tissue at the outlet or the outlet being suspended in fluid).

Hydrodynamic resistance is calculated for pressures greater than the valve opening pressure and is a well-defined parameter for valves with a relatively linear pressure–flow performance curve; it cannot be evaluated for the Orbis-Sigma or Diamond valves (for these valves, stabilising the flow, hydrodynamic resistance is very high; theoretically infinite). The majority of the contemporary classic differential shunts show low resistance to flow as low as 1.05 mmHg/(ml/min), which is substantially lower than the physiological resistance to CSF drainage, measured at 6–10 mmHg/(ml/min) in normal subjects [1]). Low resistance is likely to result in over-drainage of CSF. Exceptions are the Medtronic Lumbo-Peritoneal Shunt, Codman Uni-Shunt, Sinu Shunt, and to some extent the Holter Valve, the latter two of which have been discontinued. The resistance of the Uni-Shunt, however, may be strongly affected by conditions for flow at the distal end (e.g. in a peritoneal cavity).

Any repetitive variations of proximal pressure have a tendency to decrease the nominal operating pressure of shunts with unidirectional valves. This may lead to over-drainage in situations with regular vasogenic ICP waves or high respiratory fluctuations – particularly often seen in lumbo-pleural implantation. For this reason, lumbo-pleural shunts should be chosen from models of greater hydrodynamic resistance.

Long distal catheters increase the resistance of the majority of classic differential valves towards normal physiological values. It is important to remember that the resistance of the catheter is the inverse of the fourth power of its inner diameter and that it is directly proportional to its length (Poisseuille's Law). Therefore, a 1-m long catheter with a 1-mm inner diameter having a resistance of around 5 mmHg/(ml/min), while a similar length catheter of 1.2 mm inner diameter has a resistance of around 2.5 mmHg/(ml/min).

By comparison, the resistance of the ventricular catheter is not greater than 1 mmHg/(ml/min). The number of patent holes in a ventricular catheter does not usually change the resistance of the tubing as the resistance is mainly affected by the tube itself.

All valves with membrane siphon-preventing devices are sensitive to external pressure. External pressure exerted by tense skin or a scar on the skin increases the operating pressure of the valve. Increased external pressure (cap, headband) may close CSF drainage completely. This manoeuvre is used in shunt testing in vivo to reveal the patency of the ventricular drain. All constructions without membrane siphon-preventing devices are not sensitive to external pressure up to 50 mmHg.

Negative outlet pressure decreases operating pressure by the same value in all valves without siphon-preventing mechanism. When the resistance of the shunt system is low (4–6 mmHg/ml/min), a negative outlet pressure of 15 mmHg may accelerate the drainage rate to a non-physiological value of 2–4 ml/min. Over-drainage may also occur when a low resistance valve is subjected to the repetitive cycling of proximal pressure (exceptions are Orbis-Sigma, Diamond Valve and valves fitted using the Codman SiphonGuard). Another rarely mentioned cause of over-drainage may be the "pumping" of the proximal reservoir of the shunt, which is commonly performed in emergency departments when shunt dysfunction is suspected.

All adjustable valves can be reset in vivo by applying an external magnetic field. Most settings cover a range of operating pressures from 0 to 20 cmH_2O (0–15 mmHg). The number of steps varies from 5 to 20. In almost all valves, the levels are equally spaced. In all valves except the Codman Hakim Programmable Valve, verification of the setting may be conveniently performed without the need for radiography, using an external compass placed over the valve. Both measurement and adjustability may be affected if the valve rotates under the skin.

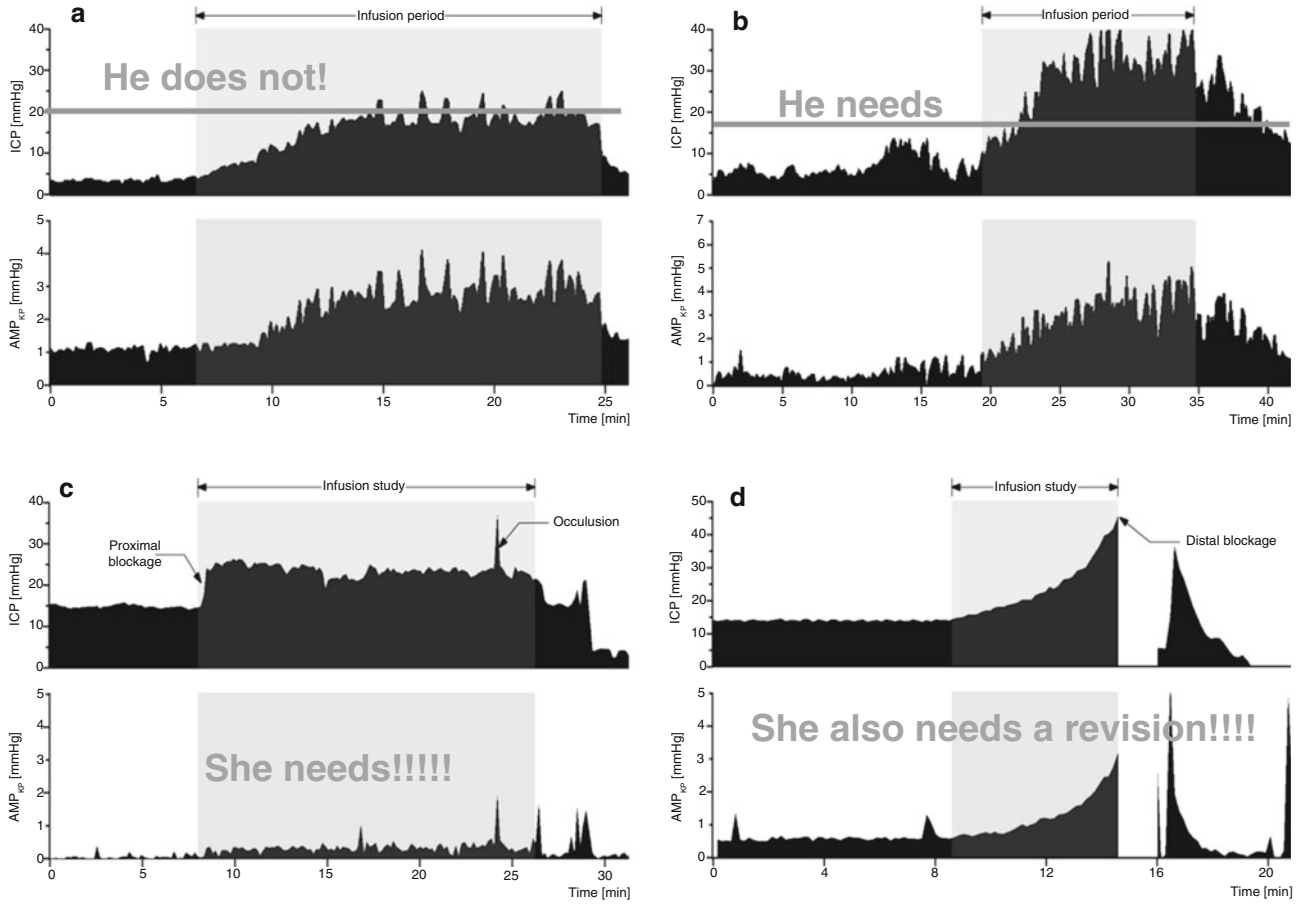

Fig. 2 Who needs a revision? Examples of the infusion studies performed in shunted patients (see the text for a more detailed explanation. X-axis: time in minutes, period of constant rate infusion indicated by the grey zone. (**a**) A properly functioning shunt, (**b**) an underdraining shunt, (**c**) ventricular blockage, (**d**) distal (abdominal) dysfunction (possible compartmentalisation)

Magnetic fields can undesirably influence adjustable valve settings. The Sophy, Strata and Codman Hakim Programmable valves can be readjusted by relatively weak fields (around 40 mT). Newer valves (Polaris, ProGAV, ProSA) have mechanisms intended to prevent accidental readjustments, even in MRI scanners (up to 3 T). All the new valves tested were safe for MRI up to 3 T (translational and torque forces are safe, heating is minimal), but cause significant distortion of the MR image.

Shunt Testing In Vivo

In more than 2000 tests performed in patients exhibiting adverse clinical symptoms with shunts in situ, underperformance was revealed in almost 1200 cases. These patients underwent revisions and the majority improved after surgery. Figure 2 presents a summary of possible infusion test findings [6]. In panel A, the test performed into the shunt prechamber shows pressure below the critical level of the implanted shunt gray (horizontal line, this level is established in Shunt Lab for every model and every performance level). Therefore, the shunt is performing properly. In contrast, in panel B, the shunt is underperforming. In panel C, a shunt with a ventricular blockage (no pulse amplitude [AMP], very fast rise of the pressure during the test) is shown and in panel D, a distal blockage with a gradual rise in the pressure in the limited abdominal compartment is shown.

Discussion

From the point of view of cerebral hydrodynamics, a hydrocephalus shunt represents a strong non-linear element. Influence of its non-linearity may have an impact not only on the constant drainage of CSF, but also on cerebrospinal physiology.

The market is quite stable, with the larger manufacturers such as Medtronik PS Medical, Codman, Integra, Sophysa and Miethke well established. The average price of the shunt

varies from £300 to £1200 in the UK. Surprisingly, the prices are higher in the developing countries. Some local lower-cost constructions are available and have been reported to serve their purposes well [4]. The behaviour of a valve revealed during testing is of relevance to the surgeon and may not be adequately described in the manufacturer's product leaflet. This information is also useful for shunt testing in vivo.

Disclosure Cambridge Shunt Lab had R-D agreements (short term) with various shunt manufacturers (J&J, Medtronic, Integra, Miethke, Sophysa etc.) to cover the costs of shunt testing.

MC has a consultancy agreement with Codman J&J and lecture contracts with Integra.

JDP was a member of the Scientific Advisory Board for Medtronic and Codman J&J.

Conflict of Interest We declare that we have no conflict of interest.

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