

Ventriculo-peritoneal shunt performance under hyperbaric conditions

E. T. HUANG, K. R. HARDY, J. M. STUBBS, R. A. LOWE, and S. R. THOM

Institute for Environmental Medicine, Department of Emergency Medicine, Department of Epidemiology and Biostatistics, Center for Epidemiology and Biostatistics, University of Pennsylvania School of Medicine; and Leonard David Institute of Health Economics, University of Pennsylvania, Philadelphia, Pennsylvania

Huang ET, Hardy KR, Stubbs JM, Lowe RA, Thom SR. Ventriculo-peritoneal shunt performance under hyperbaric conditions. *Undersea Hyper Med* 2000; 27(4):191-194.—A novice scuba diver with an implanted ventriculo-peritoneal (VP) shunt inquired about the performance characteristics of his shunt while diving. A literature search revealed no information regarding shunt performance under hyperbaric conditions. The manufacturer could not certify that the shunt would function under pressure. Therefore, four VP shunts were tested according to the manufacturer's testing protocol at 1 and 4 atm abs in a multiplace hyperbaric chamber. The pressure (in mm of H₂O) required to establish flow through the shunts was recorded. Trials at 1 atm abs ($n = 12$) and 4 atm abs ($n = 12$) show that all shunts performed within the pressure range specified by the manufacturer.
ventriculo-peritoneal shunt, performance, hyperbaric, diving, fitness to dive

This investigation was initiated in response to a recent inquiry by one of our patients. A novice scuba diver asked whether he could expect his implanted ventriculo-peritoneal (VP) drainage catheter to function normally under hyperbaric conditions. A literature search failed to reveal information on how the shunt would function underwater, and the manufacturer was unable to state that the shunt would function within its certified parameters when subjected to hyperbaric conditions. Additionally, the manufacturer did not have any literature regarding shunt function in a hypobaric environment such as aboard commercial airline flights pressurized to 8,000 feet above sea level. They did not believe, however, that an intracranial shunt was a contraindication to flying (J. Bertrand, Medtronic, personal communication, October 2000).

The patient population that may require hyperbaric oxygen (HBO₂) therapy includes those with a history of hydrocephalus and an implanted VP drainage catheter. Our search of the literature revealed no documented case reports of shunt malfunction during HBO₂ therapy, and indeed there have been no complications with patients with VP shunts in our clinical practice at the University of Pennsylvania. Davis and Bove's textbook (1) on diving medicine acknowledges that there are individuals with intracranial shunts who currently dive. He recommends that those who choose to dive with a shunt do so in locations where there is medical support in case the shunt should become occluded.

Theoretically, the presence of a VP shunt should not represent a contraindication to HBO₂ therapy. The body is subjected to higher-than-atmospheric pressure in a hyper-

baric environment. Pressure is equally distributed throughout the body, not focused on one particular point in the shunt system. Figure 1 illustrates the positioning of the intracranial shunt in the body with its proximal and distal catheters in the ventricle and the peritoneum. Increased pressure will compress all fluid-filled compartments of the body equally, so that the change in intracranial pressure will be equal to the change in intraperitoneal pressure. Only air-filled spaces such as the sinuses, the middle ear, and hollow viscera will have different pressures. As the shunt system and the valve mechanism are filled with cerebral spinal fluid (CSF), it will be subjected to the same pressure changes as the ventricles and the peritoneum. There should be no change in the pressure gradient across the shunt mechanism at all. The shunt should theoretically function as well under hyperbaric conditions as normobaric conditions.

Nevertheless, the only way to determine if the shunt would function properly under hyperbaric conditions was to test the shunt and determine if there was any deterioration of its performance in a hyperbaric environment. Clinical HBO₂ therapy (2) is conducted at pressures between 2.0 and 3.0 atm abs. The Divers Alert Network (3) reports that 70% of recreational scuba divers remain above 90 feet of seawater (fsw) throughout their dive, a pressure of 3.7 atm abs. We reasoned that testing of VP shunts at a pressure of 4 atm abs, or the equivalent of 99 fsw, should provide data to encompass the majority of these possible scenarios.

METHODS

We obtained four Performance Level One Delta Valve

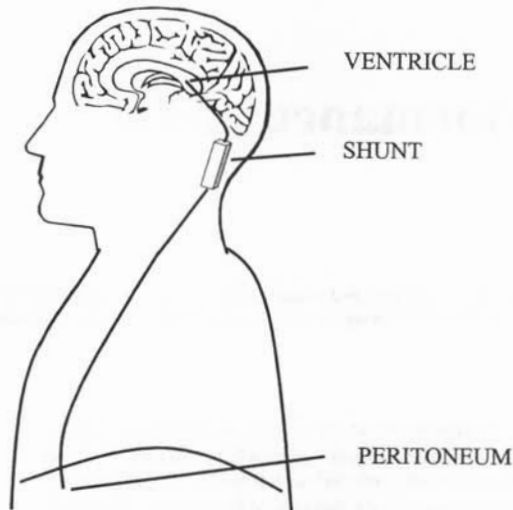


FIG. 1—Layout of ventriculo-peritoneal shunt.

shunts (Medtronic PS Medical, Inc., Goleta, CA), the same VP shunt that is used by our patient, for testing. We used the testing protocol (4) supplied by Medtronic, Inc. to determine performance characteristics of the shunts. Figure 2 shows a schematic diagram of the testing apparatus. Each shunt was attached with i.v. tubing to a three-way stopcock and then submerged in a water bath. The second port of each stopcock was connected to individual pressure manometers graduated in 2-mm increments. The third port of each stopcock was attached to infusion pumps running normal saline. Two Gemini PC-2TX infusion pumps (Alaris Medical Systems, San Diego, CA) were used to deliver a set flow of saline through the testing apparatus. The manufacturer has certified these pumps to operate properly in hyperbaric conditions. The four shunts were tested simultaneously using separate infusion pumps (two pumps with two channels each) and manometers set up in identical fashion. The testing sequence was as follows:

1. The zero level of the manometer was set on the same plane as the water level of the water bath to zero each manometer.
2. The shunts were placed in the water bath and the system was flushed with saline solution.
3. The flow rate for each infusion pump was set at 50 ml/h to run through all shunts simultaneously.
4. After the pressure reading on each manometer had stabilized at 50 ml/h, the flow rate was reduced to 5 ml/h.
5. A pressure reading was obtained at five separate flow rates (5, 10, 20, 40, and 50 ml/h). A stable reading was determined if there was no change after 30 s.
6. After the reading was obtained at 50 ml/h, the pumps were paused and the system was re-calibrated.
7. Steps 3–6 were repeated twice for a total of three measurements.

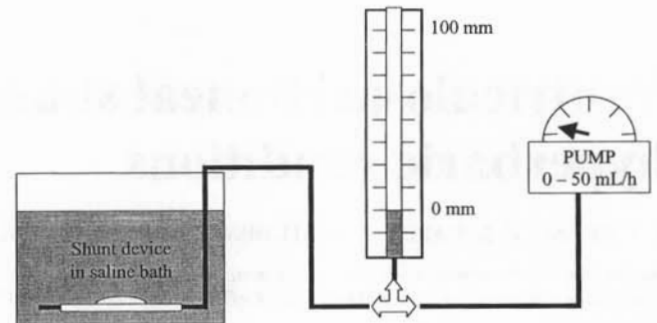


FIG. 2—Experimental setup.

Three measurements were obtained at 1 atm abs and three measurements at 4 atm abs. The mean pressure required to establish flow across the shunt was calculated for each flow rate at 1 and 4 atm abs. In addition, 95% confidence intervals (CIs) were calculated. Because of the small number of runs at each flow rate, and because the data were clustered, standard formulas to calculate CIs would not have yielded accurate results. Therefore, 95% CIs were calculated using a bias-corrected bootstrapping technique with adjustment for clustering (5). In addition, the proportion of runs with pressures outside of the manufacturer's specified tolerance range was calculated, along with the 95% CI. In this case, adjustment for clustering was made by calculating the design effect of clustering (estimated at 3) and reducing the sample size appropriately. All calculations were performed using STATA software, version 6.0.

RESULTS

The measurements from all runs are recorded in Table 1. Figure 3 shows the average performance of all four shunts at 1 and 4 atm abs. The solid lines in the figure represent the high and low performance limits that are specified by Medtronic, Inc. (6). Of the 120 flows measured under different conditions, none (95% CI, 0–8.8%) required pressures outside of the manufacturer's recommended range.

DISCUSSION

The physiologic considerations when evaluating the function of the VP shunt focus on three separate points of the shunt system. The proximal point is the ventricle, the middle point is the valve mechanism, and the distal point is the peritoneal cavity where the shunt empties. Normal CSF production *in vivo* is about 500 ml per day, or about 20 ml/h (7). Increased intracranial pressure (ICP) will drive CSF from the ventricle through the shunt mechanism and into the peritoneum. A freely patent conduit between ventricle and peritoneum leads to over-drainage of CSF, which may result in changes of cranial size and volume, slit ventricles, negative pressure

Tables 1: Pressure (in mmH₂O) Required for Function of Each Shunt at Various Flow Rates

Run	1 atm abs, ml/h					4 atm abs, ml/h					
	5	10	20	40	50	5	10	20	40	50	
Shunt 1	1	38	42	48	56	58	30	34	36	41	44
	2	34	38	44	52	55	30	30	35	41	44
	3	35	38	46	53	54	32	34	37	44	44
Shunt 2	1	35	37	44	55	58	30	33	37	45	47
	2	35	36	44	55	58	34	37	45	52	56
	3	37	40	47	55	60	35	38	44	54	55
Shunt 3	1	26	28	32	38	50	26	28	32	38	37
	2	30	30	33	37	42	26	28	32	38	40
	3	28	30	34	43	44	26	28	32	38	40
Shunt 4	1	33	35	41	49	50	26	28	36	41	42
	2	28	30	36	43	47	26	28	34	41	40
	3	29	30	40	46	50	25	28	32	41	42
Mean (95% CI)	32 (30-36)	35 (31-39)	41 (36-46)	49 (43-55)	52 (48-58)		29 (26-32)	31 (29-35)	36 (34-41)	43 (40-48)	44 (41-51)

syndromes, intolerance of CSF pressure elevations, and subdural hematomas (8).

The VP shunt valve is a device designed to avoid over-drainage of fluid. The Delta Valve tested in this paper uses a membrane pressure valve in series with a normally closed siphon control mechanism to maintain intraventricular pressure within the normal physiologic range. Medtronic representatives have stated that pressure applied directly on the valve mechanism itself will increase the amount of pressure required to achieve flow through the valve. In physiologic terms, this would translate into higher ICP before CSF would begin to drain, and patients could re-develop hydrocephalus with its attendant symptomatology.

Although a hyperbaric environment increases pressure uniformly across the shunt system and not on any one

component of the system, Medtronic, Inc. could not certify that the shunt would function properly in a hyperbaric environment. The company tests each shunt individually to certify that it will function within a specific range of pressures at various flow rates. Using their testing protocol, the results of this study show that the pressure required to establish flow across the valve for all four shunts falls within the manufacturer's acceptable range, at pressures of 1 and 4 atm abs, for each of the three measurements and each of the flow rates.

Because four shunts were tested 3 times each, our data are subject to a clustering effect which makes it more likely that our results appear more similar than if they had been tested on 12 separate shunts. Although none of the runs in this study required pressures outside of the manufacturer's recommended range, the 95% CI for this proportion extends to 8.8%. In other words, there is a 95% probability that, were this experiment to be repeated, the proportion of runs with pressures outside the recommended range would be under 8.8%. Thus, the sample size of this study leaves some uncertainty about the potential for pressures outside of the recommended range.

Some individual variation was found between runs at each flow rate. This variation could be because of small bubbles that were passing through the testing apparatus. If these bubbles became trapped in the shunt mechanism or in the tubing, the mechanical effects of the bubbles may affect the quality of measurements. The tests at 4 atm abs were conducted after the tests at 1 atm abs, so air

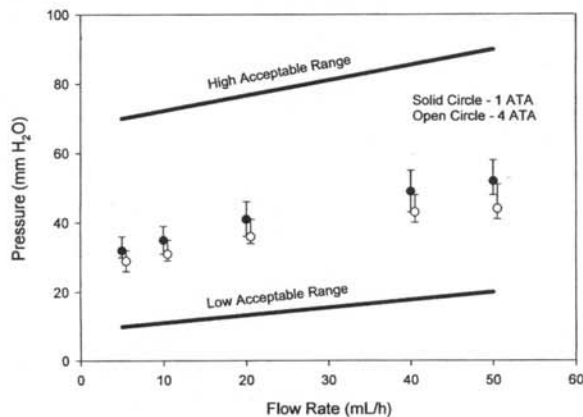


FIG. 3—Performance characteristics of all four shunts at 1 atm abs ($n = 12$) and 4 atm abs ($n = 12$) showing mean pressure with 95% CI.

bubbles that were present earlier may have decreased in size and been flushed out of the system by the time the latter tests were run, resulting in more accurate and more precise measurements.

The Delta Valve is not the only VP shunt on the market, but none of the competing brands were tested. Future research ideas include minimizing the clustering effect by testing more shunts, and testing other manufacturer's shunt mechanisms to determine their performance characteristics under hyperbaric conditions.

These results indicate that the Delta Shunt system functions within specified parameters in a laboratory hyperbaric setting. Treating patients with a VP shunt has not been a problem clinically. Our results indicate that there is low suspicion that VP shunts would malfunction in the hyperbaric environment.

We thank our Chamber Systems Supervisor, Charles E. Hires, for his assistance during the tests. We also thank Lisa Kirkpatrick and Jeff Bertrand of Medtronic, Inc. for providing the shunts and answering technical questions. Medtronic, Inc. did not provide any additional

financial support for this project.—*Manuscript received July 2000; accepted November 2000.*

REFERENCES

1. Davis JE, Bove AA. Medical evaluation of sport diving. In: Bove AA, ed. *Diving medicine*, 3rd ed. Philadelphia: WB Saunders 1997:354.
2. Hampson NB, chairman and editor. *Hyperbaric oxygen therapy 1999 committee report*. Kensington, MD: Undersea and Hyperbaric Medical Society, 1999.
3. Vann R, Ugucioni D, editors. *Report on decompression illness and diving fatalities*, 2000 ed. Durham, NC: Diver's Alert Network, 2000:86.
4. *Pressure/Flow Test Technical Bulletin*. Goleta, Ca: Medtronic PS Medical, 1997.
5. Efron B, Tibshirani RJ. *An introduction to the bootstrap*. New York: Chapman & Hall, 1993.
6. *Delta Valves and Shunt Assemblies: Instructions for Use*. Goleta, Ca: Medtronic PS Medical, 1999.
7. Guyton AC, Hall JE, eds. *Medical physiology*, 10th ed. Philadelphia: WB Saunders, 2000:711.
8. Faulhauer K, Schmitz P. Overdrainage phenomena in shunt treated hydrocephalus. *Acta Neurochir* 1978; 45:89-101.