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ASUNTO: Autorización del trabajo de investigación del Dr. Miguel Ángel López González.

DR. ISIDRO AVILA MARTÍNEZ
SECRETARIO DE SERVICIOS ESCOLARES
DE LA FACULTAD DE MEDICINA
Presente.

Estimado Dr. Avila Martínez:

Me permito informar a usted que el **Dr. Miguel Ángel López González**, alumno del curso de especialización en **Neurocirugía** en el **Instituto Nacional de Neurología y Neurocirugía**, presenta el trabajo de investigación intitulado ***"Ventriculoperitoneal shunt of continuous flow vs valvular shunt for treatment of hydrocephalus in adults".***

De conformidad con el artículo 23 capítulo 5º. de las Normas Operativas del Plan Unico de Especializaciones Médicas (PUEM) se considera que cumple con los requisitos para validarlo como el trabajo formal de Investigación que le otorga el derecho de la diplomación como especialista.

Sin otro particular de momento, reciba un cordial saludo.

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03-449	7613	Fagundes-Pereyra	Meningeal melanocytoma of the posterior fossa:
03-455	7618	Hamani	Correspondence of microelectrode mapping with MRI
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Ventriculoperitoneal shunt of continuous flow vs valvular shunt for treatment of hydrocephalus in adults

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Abstract

Background: Shunting for hydrocephalus is the neurosurgical procedure most frequently associated with long-term complications. We developed an alternative to valvular shunts based on a simple shunt procedure whose functioning depends on a peritoneal catheter with a highly precise cross-sectional internal diameter of 0.51 mm. Preliminary studies have shown that the shunt of continuous flow (SCF) is superior to valvular shunts for the treatment of hydrocephalus in adults. Here, we show the long-term performance of the SCF in adult patients with hydrocephalus secondary to a comprehensive variety of neurological disorders.

Methods: In a 5-year period, ventriculoperitoneal shunting was performed on 307 patients with hydrocephalus; 114 of them were treated with the SCF and 193 controls were treated with a conventional valvular shunt. Patients were followed from 1 to 5 years after surgery; endpoint observation was considered at surgical reintervention because of shunt failure.

Results: At the end of the observation period (44 ± 17 months), the failure rate of the shunting device was 14% for the SCF and 46% for controls ($P < .0002$). Shunt endurance was 88% in patients with SCF and 60% in controls. Along the study, signs of overdrainage developed in 40% of patients treated with valvular shunt, but they were not observed in patients with SCF.

Conclusions: The design of the SCF was calculated according to the mean rates of cerebrospinal fluid production; it takes simultaneous advantage of the intraventricular pressure and the siphon effect and complies with the principle of uninterrupted flow, maintaining a fair equilibrium that prevents under- and overdrainage. The SCF is a simple, inexpensive, and effective treatment for hydrocephalus in adults.

Keywords: Cerebrospinal fluid; Hydrocephalus; Intraventricular pressure siphon effect; Shunt of continuous flow; Shunt overdrainage; Valvular shunts

1. Introduction

Shunting for hydrocephalus is fraught with high failure rates [1,3,18]. During the last 50 years, several shunts have been developed; each new design is more sophisticated and expensive than its predecessor [4,5,10,34]. However, it is a widespread notion that most shunting devices are far from satisfactory [9,37], and the treatment of hydrocephalus continues as a challenge to modern medicine [11,28,47]. The search for modifiable factors causatively related to shunt failure has been disappointing [30]. We departed in our studies from the idea that the fundamental principles upon which the shunting devices have been elaborated might not be adequate for alternative drainage of cerebrospinal fluid [42]. All shunts currently available share 2 main characteristics: their functioning is in a valvular fashion and the valve opens in response to the intraventricular pressure (IVP). We have questioned the appropriateness of these 2 fundamentals in dealing with the pathophysiology of hydrocephalus: First, the intermittent accumulation and drainage of cerebrospinal fluid through a valvular shunt produces a nonphysiological on-off phenomenon of fluid

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transit, with long periods of stasis. Second, in human beings, the IVP widely varies within physiological parameters, depending on postural changes of the subject, which wander constantly from the horizontal to the vertical planes [19,23]. These highly variable parameters indicate that any fixed cipher of IVP should not be taken as a unique gate for cerebrospinal fluid drainage. In addition, the fluid within any tubing that connects the ventricular cavity with the peritoneal cavity is inevitably exposed, when the subject is standing, to the force of gravity that greatly increases the flow, leading to the most conspicuous complication of ventriculoperitoneal shunts, overdrainage. This problem is so common that it has been considered that all available shunts overdrain [14,16,30].

Our investigations have addressed each of these drawbacks and resulted in a rather unsophisticated design: a ventriculoperitoneal shunt procedure, containing a peritoneal catheter 1 m long with a highly precise internal diameter (ID) of 0.51 mm; this peculiar catheter, attached to a conventional ventricular catheter, achieves the goal of uninterrupted cerebrospinal fluid flow, whose amount approaches the constant production of cerebrospinal fluid (around 0.35 mL/min) with momentary but limited variations of flow velocity and amount imposed by the hydrodynamic forces acting in relation to the combination of IVP and the force of gravity, both differing in accordance to postural changes. Nonetheless, uninterrupted drainage is maintained.

Preliminary studies have shown that the ventriculoperitoneal shunt of continuous flow (SCF) is superior to valvular shunts for the treatment of hydrocephalus in adults [44,45]. This benefit is extended to difficult cases such as hydrocephalus secondary to chronic inflammatory disorders of the subarachnoid space [24,45] or to neoplasms of the posterior fossa. Here, we report our long-term experience with the SCF in a large number of adult patients with hydrocephalus.

2. Methods

In a long-term prospective study, 307 adult patients with hydrocephalus were surgically treated: 114 were treated with the SCF and 193 controls were treated with a conventional valvular shunting procedure (Pudenz-type shunt, Biomed or Radionics, USA). Patients were allocated alternately into either group regardless of the primary pathology that originated the hydrocephalus; patients initially selected for the SCF who did not sign the informed consent were included in the control group. Patients in whom the primary pathology would not allow adequate neurological recovery after shunting, such as malignant tumors of the posterior fossa, were not included. The study included patients treated from March 1997 to October 2002; in this way, minimal follow-up was 1 year at the time of data analysis, in January 2004. Follow-up was from 14 to 78 months, a mean of 42 ± 11 months, 44 ± 17 months for patients with the SCF, and 44 ± 18 months for controls. Age was 40 ± 14 years (from 16 to 79) for SCF and 41 ± 15 years (from 17 to 78) for controls. Male-female ratio was 49:65 for SCF and 107:86 for controls. Short-term results from 54 SCF patients and from 80 controls included in this study have been reported in preliminary studies with short follow-up [45]: 12 patients initially selected to receive the SCF and 23 controls died due to progression of the primary pathology. They were excluded from the study; only those patients who died from causes attributable to progression or complications from hydrocephalus were included in the analysis.

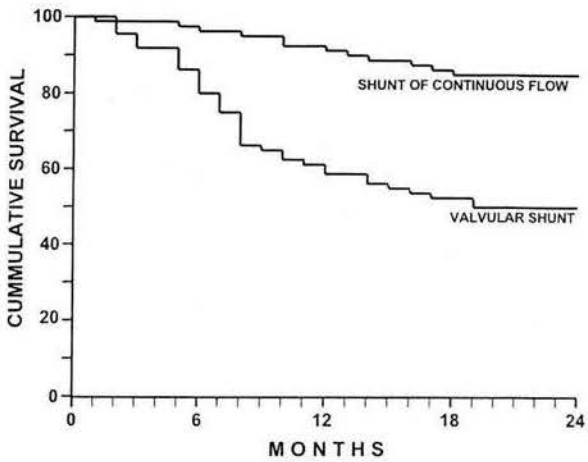

Fig. 1. Kaplan-Meier plot of shunt survival rate after surgery. A significant difference was observed between patients treated with the SCF and control patients treated with a valvular shunt ($P < .0003$).

Table 1
Etiopathogenesis of hydrocephalus in 307 shunted patients

	SCF (%)		Valvular shunt (%)	
		Withdrawn[a]		Withdrawn
Chronic arachnoiditis	55 (48)	9 (8)	105 (55)	58 (30)
Neoplasm	46 (4,1)	4 (3)	60 (31)	21 (10)
Normotensive	7 (6)	2 (2)	12 (6)	5 (3)
Subarachnoid	6 (5)	1 (1)	16 (8)	5 (3)
Hemorrhage	114 (100)	16 (14)	193 (100)	89 (46)

[a] Number of cases in whom the shunting device was withdrawn or changed because of failure.

Diagnosis of the primary pathological process underlying hydrocephalus is shown in Table 1. Endpoint observation was considered at surgical reintervention for changing the shunting device due to obstruction, infection, or overdrainage. Because most reports indicate that complications secondary to shunting occur within a period of 2 years after surgery, a Kaplan-Meier analysis of shunt permanence was made on those patients who completed at least 2 years after surgery; that included 104 (91%) patients with SCF and 170 (88%) controls (Fig. 1).

2.1. Shunting procedure

Surgical implantation of the SCF or the conventional shunt was identical; under general anesthesia, a trephination

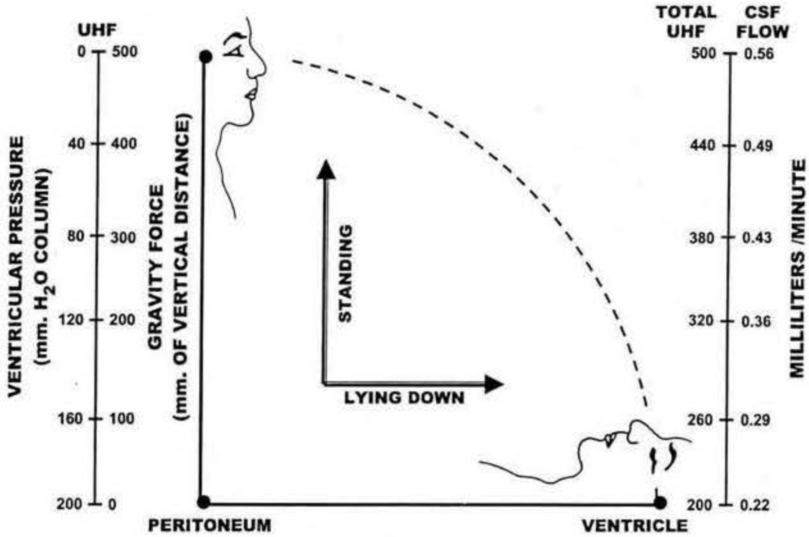

Fig. 2. Cerebrospinal fluid drainage through the ventriculoperitoneal SCF varies within expected limits according to the 2 different parameters of hydrokinetic forces influencing the amount and velocity of flow (IVP and siphon effect). When the subject is standing, the ventricular pressure is negligible and the main acting force is the siphon effect. In contrast, when the subject is lying down, the siphon effect is negligible and the main acting force is the ventricular pressure. Intermediate postures would produce a variable combination of these 2 main forces. For instance, when the subject is inclined at about 45°, he would have a combination of 80 mm H_2O of ventricular pressure plus 300 mm of vertical distance between the proximal and the distal ends of the shunt, located in the ventricular and the peritoneal cavities, respectively. This combination generates 380 UHF, which will result in a drainage of 0.43 mL/min through the SCF. Adapted from ref [45] with permission.

was made on the nondominant side of the cranial cavity and the ventricular catheter installed into the corresponding lateral ventricle. Afterward, in the case of SCF, the ventricular catheter was directly connected to the peritoneal catheter; in the case of controls, the ventricular catheter was connected to the valvular system that was joined to the peritoneal catheter. The peritoneal catheter was guided subcutaneously to the peritoneal cavity; cerebrospinal fluid drainage was corroborated before its final insertion into the peritoneal space. Drainage capacity of the SCF under experimental conditions that simulate physiological circumstances is shown in Fig. 2.

3. Results

At the end of the observation period, the SCF remained functional in 98 (86%) patients after a mean follow-up of 44 ± 17 months, equivalent to 4586 months of shunting endurance from a maximum possible of 5221 months (88% endurance). In controls, the shunt remained functional in 104 (54%) patients after a mean follow-up of 44 ± 18 months ($P < .002$ when compared to SCF) equivalent to 5586 months of shunt endurance from a maximum possible of 9286 months (60% endurance). Shunt survival rates according to the primary pathology are shown in Table 1.

Failure of the surgical device occurred in 16 (14%) patients with SCF, from 1 to 21 months after surgery, a mean of 12.7 ± 4.6 months with a median of 12 months; reasons for shunt withdrawal were obstruction in 13 patients and bacterial colonization in 3 patients. Failure of the shunting device occurred in 89 (46%) controls, from 1 to 36 months after surgery, a mean of 9.4 ± 7.3 months, with a median of 8 months; reasons for shunt withdrawal were obstruction in 55 patients, overdrainage accompanied by the slit ventricle syndrome in 18 patients, and bacterial colonization in 16 patients. In most cases, the shunting device was replaced by a similar one. During the study, 78 patients (40%) from the control group had had at least one episode of overdrainage that was clinically symptomatic, which required medical attention at the emergency department; however, in most cases, the shunting device was not removed. This circumstance was not seen in any case from the SCF group. Along the study, 2 patients (2%) from the SCF group died from causes related to failure of the shunting procedure; in both cases, it was occlusion of the catheter with progression of hydrocephalus; in the control group, 10 patients (5%) died from causes related to failure of the shunting procedure: 2 of them developed subdural hematoma, 2 ascending transtentorial herniation, and 6 infection due to bacterial colonization of the shunt.

4. Conclusions

All parameters favor the results obtained in patients with SCF over those treated with valvular shunt; shunt failure rate in patients with SCF was 14%, in contrast with 46% in controls. In addition, during follow-up, clinical and radiological signs of overdrainage were observed in nearly half of those patients treated with valvular shunt, but they were not observed in any case of SCF. Results obtained in controls are similar to those reported in several other studies with the use of valvular shunts [2,18,29,35,47,50]. Most studies concur that the failure rate of valvular shunts within the first 2 years is between 30% and 50%, irrespective of the type of shunt design used [13,15,26,31]. Complications of shunting remain distressingly common [18,26,30,48]; recent studies have shown that long-term shunt revision rates are similar to those reported over the past 2 decades [9,31].

Two main hydrokinetic forces influence the fluid drainage through a device that connects the ventricular with the peritoneal cavities in human beings: the injection force, which corresponds to the IVP, and the gravity force (GF), which corresponds to the siphon effect [20] imposed upon any fluid that drains through a tubing into a recipient located underneath. The condition of bipedalism in human beings produces, during long periods, a substantial differential of planes between the cerebral ventricles and the peritoneal cavity. Thus, any direct connection between these 2 anatomical sites is subjected, unavoidably, to the force of gravity acting upon the fluid running through this connection [22]. Along the last 4 decades of research on hydrocephalus, several shunting devices have been produced, most of them designed in valvular fashion that opens and closes in response to presettled values of the injection force. Although the siphon effect has long been recognized [8,18,35,36,46], its magnitude on the performance of ventriculoperitoneal shunts has been minimized; its only technical manipulation has been by attempts directed to its neutralization with the so-called antisiphon devices [5,16]. However, their performance has been unsatisfactory [18,25].

In experimental models, which simulate physiological conditions in human beings [40-42], we have shown that the GF acting on a ventriculoperitoneal connection affects the fluid drainage twice as much as the injection force imposed by the IVP (Fig. 2): When the subject is sitting or standing, the IVP would be zero [18,33], whereas the GF would be around 500 mm H_2O [22,45,48], for a total of 500 units of hydrokinetic force (UHF); in contrast, when the same subject is lying down, the mean IVP would be around 200 mm H_2O [7,40], whereas the GF would be 0, for a total of 200 UHF (Fig. 2). The differential pressure that can develop because of the siphoning effect can be more than 5 times greater than the IVP necessary to open most valves [48]. Within physiological conditions, the IVP and the GF have opposite dynamics: the IVP diminishes from the horizontal to the vertical posture, whereas the gravity effect increases from the horizontal to the vertical posture (Fig. 1) [40,45].

From all parameters that intervene in the complicated process of cerebrospinal fluid physiology, the most predictable is cerebrospinal fluid production, whose values have been settled between 500 and 600 mL daily at a constant rate between 0.35 and 0.40 mL/min, with some circadian variations [7,12]. This rate is fairly maintained regardless of intracranial pressure, arterial tension, blood flow, systemic hydration, or intracranial pathology [7,12]. Apparently, the only pathological condition that significantly increases the cerebrospinal fluid production is papilloma of the choroid plexus [24]. Thus, it seems reasonable to use the constant parameter of cerebrospinal fluid production as the backbone of instrument performance for the SCF [44]. In contrast with production, cerebrospinal fluid absorption mechanisms largely exceed those of production [7,12,38,45].

In the paradigm used as theoretical framework, we selected the ID of the peritoneal catheter, with a highly precise measure of 0.51 mm, as the sole mechanism of flow resistance for the SCF; it has a drainage capacity of 0.0011 mL/min per UHF [40,42]. The mean extremes of parametric fluctuations in human beings vary from 200 UHF when lying down to 500 UHF when standing (Fig. 1); the drainage through the SCF in these 2 opposite situations is 0.22 and 0.56 mL/min, respectively (Table 2). The mean production of cerebrospinal fluid in human beings (0.35 mL/min) resides between these 2 values (Fig. 2).

As our previous experiences with SCFs of slightly different ID have shown, the principal feature of the SCF is the achievement of uninterrupted flow at all times. Minimal variations of ID alter drastically this delicate equilibrium; centesimals of millimeter upward or downward of the central measure of 0.51 mm may lead to overdrainage or underdrainage, respectively [21,41,44,45]. At the beginning of our studies, the first SCF that resulted in better performance than controls had an ID of 0.41 mm; permanence of the shunt after a mean follow-up of 9 months was achieved in 96% of patients [44]. However, at long-time follow-up, clinical and radiological evidence of normotensive hydrocephalus developed in some cases [41];

Table 2
Comparisons of drainage capacity under experimental conditions through SCF with catheter of 1 m long of different IDs

Cross-sectional ID (mm)	Drainage capacity (mL/min per UHF)	Drainage at 500 UHF of GE (mL/min)	Drainage at 200 UHF injection pressure (mL/min)	Daily flow[a] [illegible]
0.41	0.00062	0.31	0.12	298 + 85 = 356
0.46	0.00091	0.47	0.19	451 + 91 = 542
0.51	0.00112	0.56	0.22	538 + 106 = 644
0.55	0.00178	0.69	0.28	662 + 134 = 796

The SCF used in the present study had a catheter with ID of 0.51 mm; comparisons of daily flow with catheters of 0.41, 0.46, and 0.55 mm showed a difference in daily drainage of −81%, −19%, and +19%, respectively. UHF indicates units of hydrokinetic force measured as mm of an H_2O column.
Abbreviation: GE, gravity effect.

[a] Considering 16 hours at 500 UHF of GE plus 8 hours at 200 UHF of injection pressure (to simulate two thirds of the day in the erect posture and one third in the supine posture).

the same occurred, although less frequently, in a subsequent study, when we cautiously increased the ID to 0.46 mm [45]. Nonetheless, it was relevant in those 2 previous studies [41,45] that, similarly to this report, signs of overdrainage were never seen (Fig. 3). After those experiences, a further increase of 5 centesimals of millimeter was decided to achieve 0.51 mm ID (Table 2), the one used in this study and in related preliminary reports [45]. In contrast with our initial experiences, no cases of remnant hydrocephalus were observed as evidence that underdrainage was prevented.

The absence of artificial mechanisms on the SCF avoids dysfunction due to mechanical failure, as well as shunt occlusion due to fluid stasis. Both complications are frequent with valvular shunts [30,49]. Because the sole resistance mechanism of flow resides in the peritoneal catheter of 1 m long, some differences are found among individuals according to his/her personal height and the site on the peritoneal cavity where the distal end of the catheter was surgically implanted, which impose a distinctive distance between the proximal and distal ends of the shunt. In addition, geographic differences in altitude and atmospheric pressure slightly affect the GF acting on the fluid transit. Nonetheless, they were not sufficient to alter the long-term performance of the SCF as seen by multivariate analysis that considered stature of the patient, weight, site of residence in regards to sea level, and occupation (in regards to mean times standing and lying along the day). It should also be considered the remnant individual capacity for endogenous absorption of cerebrospinal fluid that surely intervenes in the homeostatic maintenance of intracranial pressure in shunted individuals; however, their precise ciphers might vary widely from one patient to another. Our results emphasize the importance of physiological compensatory mechanisms that participate in the endogenous pursuit for intracranial homeostasis, provided that under- and overdrainage through the artificial shunt, as well as lasting interruptions of flow, are essentially prevented, which is the case of the SCF.

The fact that uninterrupted flow is maintained most of the time through the SCF may explain the low rate of bacterial contamination; fluid stasis and accumulation of organic detritus along a shunting device greatly favor bacterial colonization [6,18,27,32], which may be eluded by the constant transit of fluid. Thus, the cerebrospinal fluid moves through a valvular shunt only a minimal time, whereas most of the time, it remains static, favoring 2 potential and frequent complications, bacterial colonization and shunt occlusion [29,37].

The ample capacity for fluid transit through valvular shunts may also induce retrograde passage of cerebrospinal fluid from the subarachnoid space to the ventricular cavities in moments of overdrainage. Whereas this phenomenon may not have noticeable consequences in many patients, it could represent a serious source of complications in some pathologies. For instance, in patients with chronic arachnoiditis, the cell and protein contents in ventricular cerebrospinal fluid are usually low, whereas a high content of activated immune cells and protein are found in subarachnoid cerebrospinal fluid [24,39]; retrograde passage of this fluid to the ventricular cavities due to overdrainage may induce severe ventriculitis and cerebritis. In addition, because of the abnormal composition of subarachnoid cerebrospinal fluid that passes through the shunt, its occlusion in these patients is particularly frequent [27,43].

Although our studies were made in adult patients, occasional experiences have shown us that children older than 3 years (after constant deambulation starts) benefit from SCF. The SCF is not useful in newborns because their conspicuous horizontal posture does not promote the participation of the GF [45]. In adult patients who remain in bed for long periods (eg, during occasional sickness), we recommend significant intervals of sitting posture or bed inclination at 45° to promote the GF on the shunt performance.

The simplicity of the SCF is such that it is difficult to conceive so many advantages (not least of them the cost [17]) over sophisticated valvular shunts. However, we believe that the single most important feature of SCF, the uninterrupted transit of cerebrospinal fluid, conciliates the artificial diversion of cerebrospinal fluid transit with many

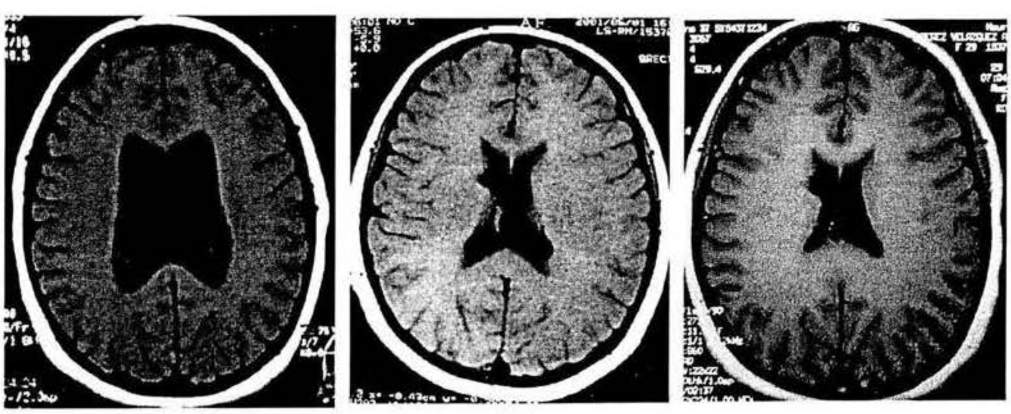

Fig. 3. Ventricular size in a patient with hydrocephalus. Left panel, before shunting. Central panel, 4 months after shunting with the SCF. Right panel, 38 months after shunting. Note the sustained evidence of normal ventricular size after shunting.

physiological features and provides a simple means for treatment of a complex pathology.

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Commentary

The authors have presented an appropriate topic. The original shunt by Pudenz et al in the late 1940s was based upon a distal catheter that had slit valves, only to prevent retrograde flow, and the opening pressure of those valved catheters was variable enough to say it was not a part of the decision to use them. This type of shunt was used initially for ventriculoatrial shunts and then was converted to ventriculoperitoneal some years later when this change seemed reasonable. I used those valveless shunts rather extensively and felt they were very good. This shunt had the same effective physiological status as defined very well by the authors in the current manuscript, and they describe the basic physiology as the primary responsible factor! The fact that the shunts have a potential for continuous flow of the spinal fluid does not mean that spinal fluid flows continuously, but such is the capability if something occurs, such as a sudden increase in intracranial pressure when the person is upright and coughs, etc. Although not emphasized, such a normal response in patients does increase the flow momentarily, and this increase is accommodated by the shunt that the authors advocate (SCF).

Dr Sotelo and colleagues have added a very significant contribution to the neurosurgical literature concerning hydrocephalus and shunt types, which emphasizes the unrealistic approach of having a shunt with a set or multiple sets of functioning intracranial pressures for the shunt, when there is very little evidence that the shunt pressures and the intracranial pressure are well-defined as to what is needed for intracranial pressure. The basic thought in the manuscript, that if we recognize that there are basic neurophysiologic mechanisms that will control the pressure satisfactorily if there is no opening pressure built into the shunt, is a valid observation.

I felt that the authors might well have emphasized the fact that the change in intracranial pressure when a shunted person assumes a prone or supine position from an upright position is due primarily to a volume change of the venous volume in the head initially, and this then gradually causes a loss of ventricular fluid volume. The initial fall has been assumed to be secondary to venous volume exchange for a long time, originally pretty well proven. The fall thereafter in hydrocephalus patients with ventriculoperitoneal shunts is due to excessive loss of spinal fluid into the peritoneal cavity–the overshunted syndrome.

I congratulate Dr Sotelo and colleagues for their persistence and continued contributions to this arena in neurosurgery.

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In a randomized study, Sotelo et al compare their simple small bore catheter shunt, which they call an SCF, to a standard Pudenz-type valve shunt of unknown opening pressure. The results in favor of the SCF shunt are remarkable (obstruction: SCF 11%, valve 28%; infection: SCF 3%, valve 8%; overdrainage: SCF 0%, valve 9%). The comparison is almost too good and certainly has to be verified by a larger multicenter randomized study. Why should there be such a difference in infection rate. Despite all their explanations, as far as I know, infection is caused by bacteria. If their data hold up in a larger study, the SCF would be a significant advance particularly because the cost of the SCF is considerably lower than that of a shunt with a valve.

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A friend is one before whom I may think aloud.

— Ralph Waldo Emerson
http://www.quotationspage.com/quote/34205.html