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RESEARCH ARTICLE

Comparison of long-term efficacy and revision rate of a valve mechanism without an antisiphon versus a valve mechanism with an incorporated antisiphon in pediatric patients: presentation of data of a single-center retrospective analysis

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ABSTRACT

Purpose: Hydrocephalus remains the most frequently encountered pathological entity that is referred to pediatric neurosurgeons. The implantation of a ventriculoperitoneal shunt constitutes the most commonly used treatment modality to manage this entity. The purpose of our study was centered on the comparison of two different adjustable shunt systems, namely Codman Medos-Hakim and pro-GAV 2.0 (without and with anti-siphon device respectively), on the basis of their long-term need for a revision, due to obstruction (malfunction).

Methods: Seven hundred and seventy-eight patients undergoing primary shunt implantation between 2013 and 2023 were analyzed for 1-year revision rate, as well as 5-year revision rate, observing patient age, sex, etiology of hydrocephalus, and underlying cause of revision.

Results: All aforementioned data were recorded to all of the participants of our survey. The female patients that were included were 202, whereas their male counterparts were 248. The total number of patients that underwent revision after primary shunt implantation were 113, regardless of the type of the initial valve mechanism. Overall, 99 patients underwent revision surgery after primary implantation. Pro-GAV valve was implanted in 311 patients, and pro-GAV 2.0 valves were implanted in 139 patients. Our preliminary results suggest that there was a significant difference between the two shunt valves concerning 1-year revision rate, as well as 5-year revision-free survival. Most notably, the statistical difference between the two valve systems was more pronounced when the comparison was based on the long-term functionality (5year survival) of the different valve systems.

Conclusion: Based on the parameters that were compared to our patient population, it seems that the long-term efficacy of the Pro-GAV 2.0 valve system is superior to the corresponding long-term functionality of the Medos-Hakim valvular system. Based on the fact that the main differentiating factor between these two shunt systems is based on the presence or no of an anti-siphon device, we could support the hypothesis that the incorporation of an anti-siphon device increases the revision-free survival of any shunt system. According to the target variables we analyzed there is a significant difference between the two shunt valves.

Keywords: anti-siphon device, valve malfunction, shunt over drainage, slit ventricle syndrome.

Introduction

There are several historical bibliographic reports centered on the issue of excessive drainage of brain fluid [1–7]. In the contemporary era of neurosurgery, Fox et al have reported the first results based on ICP monitoring data in shunted patients. They concluded that their findings could be explained on the basis of the siphoning action of shunts. Siphoning might be responsible for persistent headaches related to postural changes, as well as with cases of subdural hematoma formation. Their initial recommendation included the insertion of higher-pressure valves for patients that were expected to be upright most of the time of their waking period [8]. Portnoy contributed to this “mechanistic model” by the innovation of an “antisiphon device” to prevent siphoning [4,9].

Moreover, chronic over-drainage was etiologically related with recurrent shunt obstruction, secondary to small ventricular size as a therapeutic-prophylactic measure, sub-temporal craniectomies were carried out [10,11]. In 1982 Hyde-Rowan and coworkers first defined the entity of “slit ventricle syndrome” as the clinical picture characterized by a triad: intermittent or chronic headaches, small ventricles on CT scan or ventriculogram, and slow refill of the palpable valve mechanism. These characteristic episodes, usually lasting from 10 to 90 min, were considered to be secondary to ventricular catheter obstruction that was episodic as well. They were not convinced that sub-temporal craniectomies could be beneficial in the long-term, and they suggested that other prophylactic measures should be employed to prevent slit

ventricles. Among them, they recommended the avoidance of low-pressure valves, valve upgrading or in-line ASD implantation whenever a slit ventricle was encountered [12]. In 1993, Rekate proposed a subclassification of SVS divided into five distinct syndromes by adding the so-called “shunt failure with small ventricles” and “intracranial hypertension with working shunt” types [13].

Nowadays, different classifications and algorithms have been adopted, regarding the entity of SVS [14,15] nevertheless, the most accepted concepts of shunt over-drainage are related to what has become described as “over-drainage syndromes” [16] or lately “shunt related headaches” [17]. There are reports who mention that a possible equivalence between these different classifications may exist [18]. Rekate considered shunt over-drainage to be an entity characterized by the appearance of severe headache, in patients harboring a CSF shunt system, along with normal or smaller than normal ventricles. The five previously described subcategories have nowadays been re-named: severe intracranial hypotension or low-pressure headaches (analogous to spinal headaches), intermittent obstruction of the ventricular catheter (“slit ventricle syndrome” itself), intracranial hypertension with small ventricles and a failed shunt, intracranial hypertension with a working shunt and headaches unrelated to shunt function (“shunt-related migraine”) [17].

Abbreviations

CT: computed tomography

MRI: magnetic resonance imaging

CSF: cerebrospinal fluid

ASD: anti-siphon device

Aim of the study-Methodology

To the best of our knowledge, there are not enough bibliographic reports centered on the entity of shunt over-drainage-slit ventricle syndrome as well as several relevant pathophysiologic models that attempt to elucidate its underlying mechanism have been developed. Nevertheless, clinical trials based on long-term data regarding the relevant success rate (avoidance of revision of the shunt system) of shunt systems that include or not an anti-siphon device are lacking.

Our study does attempt neither to provide a pathophysiologic mechanism which could explain the development of the entity of slit ventricle syndrome and its consequences, nor to present the ICP patterns of shunt over-drainage. On the contrary, it is a retrospective analysis based on the long-term data of a large tertiary pediatric neurosurgery department. We analyzed the results from the use of two different shunt types, one that incorporates an anti-siphon device (Pro-GAV2.0), and another one that it does not include such a device (Codman, Medos-Hakim). The long-term results regarding the one-year and five-year revision rates of both shunts systems are analyzed. Moreover, we performed another statistical analysis based on the data that were collected from patients who underwent more than one revision rate in the set time intervals (one year and five years after shunt insertion).

Materials and methods

PATIENTS

In our study, a total of 778 patients were included, all of which had undergone a surgery for ventriculoperitoneal or ventriculo-

atrial shunt insertion. These operations were performed between 2013 and 2023 and the corresponding data were retrospectively evaluated. Inclusion criteria were implantation of a Codman Medos-Hakim or pro-GAV 2.0 valves. Exclusion criteria from our study included the implantation of other valvular types, as well as an operation that did not incorporate the implantation of a valve was excluded. The total cohort of patients in primary situation consisted of pediatric patients as defined by a patient age of <16 years. Among participants, 455 were male (58,4%).

In the primary situation, implementation of the shunt catheter was routinely performed in the frontal area of the right lateral ventricle. In order to evaluate any possible association between the type of the selected valve with the number of shunt revisions and complications, we collected and analyzed the relevant data, regarding revision rate: 1-year revision rate and 5-year revision rate.

Regarding our follow-up protocol, the entity of revision-free shunt survival was defined as a follow-up period without an event of any kind of shunt revision surgery.

In our subpopulation of patients that were presenting an uneventful clinical course, a radiological examination of the shunt system was performed immediately after the operation using an X-ray of the abdomen, as well as an MRI of the head. Whenever possible, an ultrasound through the anterior fontanelle was utilized. Apart from that, on a regular basis, an MRI scan of the head was carried out once a year. In case that further relevant major clinical events were reported, they were investigated, in addition with the

standard follow-up control that was conducted in the further process.

EPIDEMIOLOGY-DEMOGRAPHICS AND HYDROCEPHALUS ETIOLOGY

An attempt was made to register the most common underlying pathophysiologic substrates that were recorded and implicated in the pathogenesis of hydrocephalus. Based on that data, we were able to identify several subcategories of patients. In accordance with the relevant experience that was based on

other pediatric neurosurgical clinics, post-hemorrhagic hydrocephalus which was attributed to intraventricular hemorrhage due to immaturity seemed to represent the most common underlying mechanism (37,5%). Apart from that, other less frequently encountered pathological conditions included the existence of infra/supratentorial neoplastic lesions (27,5%), as well as myelomeningocele (9%).

Table 1. Patients' Epidemiological data

Variable	No. of patients (%)
Gender	
Male	455 (58,4%)
Female	333 (41,6%)
Etiology of hydrocephalus	
Infantile posthemorrhagic hydrocephalus	292
Neoplasm (Supra/infra-tentorial)	214
Myelomeningocele	72
Congenital Hydrocephalus (i.e aqueductal stenosis)	90
Arachnoid Cysts	33
Post-meningitis	20
Posttraumatic	19
Idiopathic Intracranial Hypertension	12
Chiari Malformation	13
Dandy-Walker syndrome	13
Patient age at primary shunt placement	
< 1 year	421
< 1 month	201
1-6 months	148
6-12 months	72
1-10years	266
>10 years	91

STATISTICAL ANALYSIS

Categorical variables were expressed as absolute and relative frequencies. For the comparison of proportions chi-square tests

were used. Chi-square test for homogeneity was used for the comparison of proportions within each subsample (i.e., 1 year and 5 years). All reported p values are two-tailed.

Statistical significance was set at $p < 0.05$ and analyses were conducted using STATA statistical software (version 13.0).

PATIENT COHORT

The analyzed patient population of 778 patients underwent 1601 surgeries during their 5-year follow-up. That is, in more details, all of these patients were operated on in primary, whereas 501 patients underwent one or more revisions during their follow-up. Data on revision surgeries were available for all patients. More precisely, 195 (38.9%) patients underwent one valve revision during a one-year follow-up, whereas during a 5-year follow-up period, one revision was performed in 78 patients (15.6%). When the first patient subpopulation was considered, 135 patients (69.2%) were harboring a Codman Medos-

Hakim valvular mechanism, whereas, on the contrary, 60 patients were harboring a Pro-GAV 2.0 (30.8%). Regarding the second patient subpopulation, 56 patients (71.8%) were harboring a pro-GAV 2.0 valve, whereas the remaining 22 patients of that group (28.2%) were harboring a Codman Medos-Hakim valve type. The percentage of patients harboring a Codman Medos-Hakim valvular mechanism was significantly greater compared to those harboring a Pro-GAV 2.0, in both subsamples ($p < 0.001$ for 1 and for 5 years). Also, comparing the subsamples of 1 and 5 years regarding the type of mechanism, it was found that Pro-GAV 2.0 was used in a significantly greater percentage than a Codman Medos-Hakim valvular mechanism ($p < 0.001$). (Fig.1).

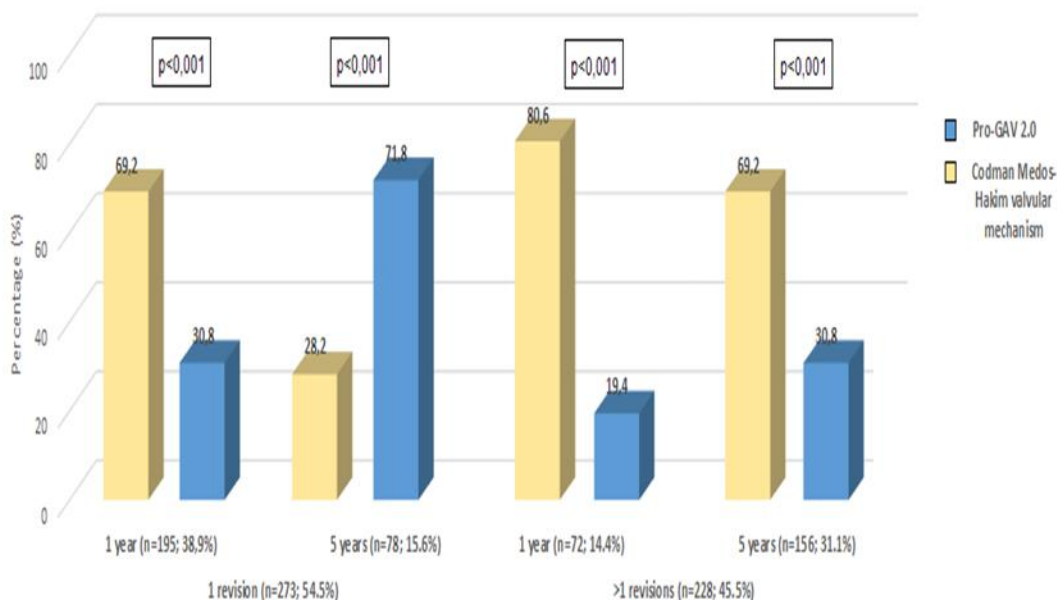


Fig.1 Schematic representation of the results of our statistical analysis, comparing the percentage of patients harboring both valve types who underwent one revision at one and five years after the initial operation

Another subgroup of participants was composed, based on patients that underwent more than one revision during their follow-up.

More precisely, 72 (14.4%) patients underwent more than one revision during a follow-up period of one year. In total, they

underwent 160 revisions of the offending valvular mechanism. Among them, 58 (80.6%) were harboring a Codman Medos-Hakim valvular mechanism, whereas in 14 patients (19.4%) a Pro-GAV 2.0 valve was utilized. Apart from that, another subpopulation of patients was under follow-up and it was composed of 156 patients (31.1%). These participants underwent more than one valve revision during their long-term (5-year) follow-up was encountered. Namely, these patients underwent as a group a total number of 390 operations (valve revisions). Among them, 108

patients (69.2%) were harboring a Codman Medos-Hakim valvular mechanism, whereas only 48 patients (30.8%) were harboring a Pro-GAV 2.0 valve. The percentage of patients harboring a Codman Medos-Hakim valvular mechanism was significantly greater compared to those harboring a Pro-GAV 2.0, in both subsamples ($p < 0.001$ for 1 and for 5 years). On the contrary, when the subsamples of 1 and 5 years were compared regarding the type of mechanism, no significant differences were found ($p = 0.074$) (Fig.2).

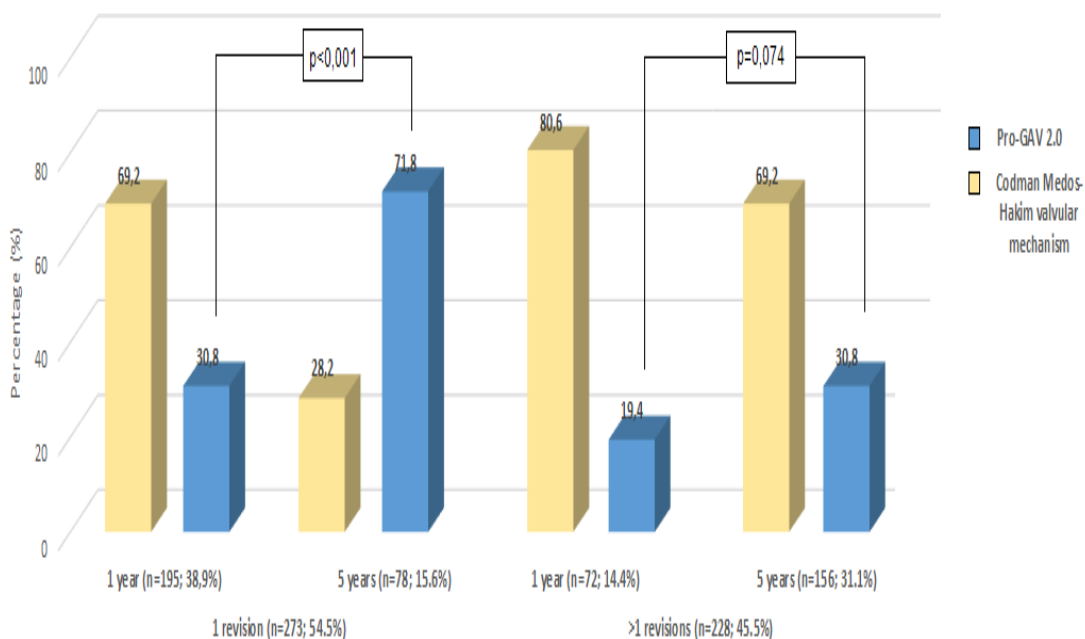


Fig. 2. Schematic representation of the results of our statistical analysis regarding patients who underwent more than one revision during a follow-up period of one and five years. We analyzed the results when patients harboring Codman Medos-Hakim and Pro-GAV 2.0 were compared. Also, we analyzed the data based on the subsamples of 1 and 5 years regarding the type of mechanism.

Discussion

The major differentiating feature among the selected valve types is related with the existence or no of an anti-siphon device, as they are both programmable. A lot of efforts have been performed to counteract the phenomenon of shunt over-drainage, along with the development of SVS, mainly centered

on the utilization of antisiphon and/or gravitational devices, as a therapeutic measurement against symptomatic over drainage. Based on published data, we have mentioned that, until recently, active prophylaxis for the prevention of shunt over drainage was not considered as worthwhile [19-23]. It is well known that in cases where

during the first months of life a reduction in the size of the ventricles exist, this is accompanied by a multiplied rate of symptomatic over drainage. This could consist an indication for a primary (at the time of first implantation) or secondary (at the time of shunt revision) intervention, in order to avoid the development of such a complication [24-26]. It seems that the strategy of exchange of the type of valvular mechanism, in order to prevent chronic over drainage, is well tolerated. Apart from that, there are reports that indicate an improvement regarding the clinical outcome, in terms of ventricular width, symptom relief and revision rate. In children suffering from hydrocephalus, the application of preventive strategies with adjustable differential pressure valves and integrated gravitational units seems to have a positive effect in terms of shunt survival [27,28].

it seems that ASD insertion is inherently related with a considerable decrease, regarding the relevant rates of central catheter malfunction due to obstruction. This fact could be attributed to the additional resistance that is exercised from the ASD against the flow of CSF, in addition to the conventional valvular mechanism. A gravity-dependent underlying mechanism is proposed in the literature as the offending substrate for these cases of proximal catheter obstruction [29]. Our results enhance the concept that gravity-driven shunt over-drainage is the main underlying pathophysiology associated with proximal shunt obstruction and enhance the validity of previous reports which highlighted the use of ASDs as an effective means in our effort to ameliorate proximal shunt obstruction rates [30,31].

The concept of drainage of excess CSF via a shunt device remains the most effective and widely used alternative in our therapeutic armamentarium regarding the management of hydrocephalus, irrespective of its underlying pathophysiology. This is currently the case, irrespective of the high failure rates associated with shunt insertion [32], along with their relevant long-standing adverse effects [33-36]. The incorporation of an ASD to a shunt system, aiming to decrease over-drainage, has been a well-established practice for several decades in the surgical treatment algorithm of these patients [37-40].

The ultimate goal of the prototype ASD was to eliminate the siphoning effect that happens when patients that harbor a CSF shunt adopt a standing posture, due to the pressure slopes between the cranial and peritoneal cavity.

Despite the superb contributions that are based on the published reports from many authors, centered on the issue of shunt over-drainage in the several last decades, severe forms of shunt over-drainage syndrome continue to exist and an active prevention policy that is universally accepted among most centers is currently lacking. In order to overcome this obstacle, universally agreed-upon diagnostic criteria and classifications are necessary, probably based on a better understanding of the pathophysiological mechanisms and relationships among them.

Our survey seems to be in accordance with these findings, based on the fact that the shunt revision rates (valve dysfunction and revision) are statistically related with the utilized valve type, and more precisely with the existence or no of an anti-siphon device that is incorporated into the shunt system.

This is in accordance with the statistically significant difference that was registered between the two different shunt types that were utilized in our patients, as the valve type that included an anti-siphon device was associated with a statistically significant reduction of the shunt revision, in the short and long-term follow-up (one and five years respectively). One limitation of our study is based on the fact that both valve types were used to all patients, independently of their underlying pathophysiology. This means that there is no double-blinded division of the affected patients in order to create two groups of patients that they were only differentiated based on the selected valve type. In order to enhance the scientific validity of our study the two subgroups should be equally matched to all other parameters such as age, patient sex and underlying pathology related to the hydrocephalus. Although the lack of this match weakens our ability to extract more safe results that could be more globally accepted, the statistical significance of our results should be seriously taken into consideration. Our basic tenet was to provide pilot data that would be able to further guide clinical and laboratory studies centered on the determination of the potential role of valves that harbor anti-siphon devices to reduce the long-term rates of shunt malfunction. Multi-center, double-blinded prospective studies, based on larger patient populations and based on patient populations that are better matched, would add more relevant data to the scientific community.

Conclusions

Although there is an increased bulk of evidence and pathophysiologic theories

regarding the entity of shunt over drainage mainly in the last decades, this entity continues to exist and represents a clinical problem that is difficult to manage, especially when we are confronted with its more severe forms. This issue, along with its counterpart, which is the slit ventricle syndrome, is even more difficult in the last half century, is even more difficult to manage due to the absence of universal agreement regarding its terminology and to the lack of an active prevention policy in most centers. A prerequisite is the establishment of universally agreed-upon diagnostic criteria and classifications. These should be based on a better understanding of the pathophysiological mechanisms and their intimate relationships.

The incorporation of an anti-siphon device in a shunt system, either therapeutically, after the development of clinical manifestations of the slit-ventricle syndrome, or prophylactically, seems to be of paramount importance in the management of this entity. Our study manifested that the one-year and five-year revision rate of the valvular mechanism was significantly different between the two different systems that were tested, in favor of the system that harbored an anti-siphon device (Pro-GAV2.0). Based on the fact that the main differentiating factor between the two tested valve systems was the presence (or not) of an anti-siphon device, we could conclude that the difference in our data should be attributed to this device. To the best of our knowledge, although there are enough reports that attempt to elucidate the possible role of an anti-siphon device, there is relatively lack of evidence regarding the long-term efficacy and functionality of specific valve types with and without an anti-siphon.

Moreover, our survey is based solely on a pediatric population, which shares different pathophysiologic mechanisms for the development of hydrocephalus, compared with their adult counterparts.

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