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Prevalence and indication for changing the primary valve opening pressure in ventriculoperitoneal shunts – A single center five years overview

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ABSTRACT

Objective: Serious medical conditions of patients in neurosurgery often require ventriculoperitoneal shunting to normalize the intracranial pressure. Neurosurgeons select a valve opening pressure (VOP), whose exceeding causes the shunt to open to drain cerebrospinal fluid (CSF): In most cases a standard pressure is chosen. Whereas some patients fare well with the primary chosen VOP, others require one to several VOP changes. This study aims to evaluate the prevalence and indication for occurring valve pressure-adjustments.

Patients and methods: We obtained information about 343 ventriculoperitoneal shunt implantations in 321 adult patients from 2013 to 2018 in a single center with well-kept electronic health records regarding hydrocephalus types, hydrocephalus etiologies, primary VOP, valve pressure adjustment, time with shunt, time till VOP change, age, sex and shunt type. The data was analyzed using Kaplan-Meier estimator (KME) for the whole patient sample and for subgroups with the primary VOP adjustment defined as event. In the subgroup analysis different types of hydrocephalus, different hydrocephalus etiologies, valve types, both sexes and the patients' age had been compared by applying Peto-Pike's log-rank test and cox-regression.

Results: Of the 343 implanted VP shunts in 321 patients, 166 valve pressure adjustments in 101 V P shunts were required during the observed time with a resulting valve pressure-adjustment rate of 0.484 per valve implant. The time till median valve pressure-adjustment was 2.9 years and 38.3% one year after VP shunt placement for the general sample in Kaplan Meier-analysis. The subgroup comparisons between hydrocephalus types, hydrocephalus etiologies, valve types, sexes and the patients' age did not reveal significant differences applying Peto-Pike's log-rank test. But the primary chosen valve-pressure of 5 cmH_2O is associated with a lower percentage of valve-pressure adjustments, than other initial valve-pressures ($Chi^2 = 7.9$; df = 1; p = 0.0049).

Conclusion: This study reveals a valve pressure-adjustment rate of 38.3% after one year for the whole patient collective and similar adjustment rates for different types of hydrocephalus. The primary valve pressure of 5 cmH_2O is associated with a lower valve pressure-adjustment rate than other initial valve pressures and therefore 5 cmH_2O may be the preferred initial valve pressure for all patients receiving programmable VP shunt insertions with gravitational unit.

1. Introduction

The placement of a ventriculoperitoneal (VP) shunt is the most common and a well-established treatment for diverse types of hydrocephalus [1]. Although VP shunt placement is a routine surgery with a decreasing shunt failure rate in the past decades [2], multiple causes can affect the feasibility for the patients. One modifiable factor is the choice of the valve opening pressure (VOP), which is chosen preoperatively by the surgeon. The VOP marks the threshold, which causes the valve to open and to conduct the cerebrospinal fluid towards the peritoneum [3].

Some valves possess a fixed opening pressure and other valves have modifiable VOPs, which can be changed postoperatively and in the further follow-up via magnetic induction [4]. Under-drainage causing a distension of the ventriculi or over-drainage can cause nausea, vomiting, dizziness and other neurological symptoms [5]. Such symptoms are an indication for a postoperative valve-pressure adjustment in modifiable VP shunts and would require shunt revision in fixed pressure valves.

Whereas many studies exist about the examination of the shunt survival in adults or children [6–9], the examination of the prevalence and indication of valve-pressure adjustments in programmable valves have not been subject of frequent evaluation for general patient samples [5,10].

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Studies dealing with valve-pressure adjustments and their causes, are mostly conducted with NPH-patients [11,13–16]. Thus, knowledge about valve-pressure adjustments in other hydrocephalus types is rare [12].

An interesting aspect in regard towards valve-pressure adjustments in modifiable VP shunts is the number of adjustments per VP shunt until a suitable VOP is found. This may reveal how accurate the primary VOP has been chosen for the individual patient and the extent of possible over- and underdrainage complications.

The rate of primary valve-pressure adjustments could be helpful to explore the need for adjustments in different subgroups like type of hydrocephalus, examine for which patients a programmable or a fixed-pressure valve is suited best and lay open possible predictors for valve-pressure adjustments. This information may help to improve complications after VP shunt insertion.

Therefore, we examined the occurrence of valve pressure-adjustments in a general patient collective and in subgroups in a single center in a 5-year period.

2. Patients and methods

2.1. Patient selection and data

We performed a retrospective analysis of our database about in-patient VP shunt implantations in adults between 01/2013 and 07/2018. Approval was obtained by the local ethics board. The inclusion criteria were defined as age over 18 years, VP shunt implantation in our clinic and well-kept electronic patient-records. The electronic patient-records and operation protocols have been examined specifically in terms of date of VP shunt implantation, indication for VP shunt implantation, primary VOP, date of VOP adjustment, new VOP value, date of VP shunt removal, last patient contact, patient age, sex, shunt type and number of VP shunt implantation in a single patient. The patients' time with initial valve pressure begins with the day of VP shunt insertion and ends by valve pressure adjustment or any condition like catheter blockage, shunt infections, death causing a shunt removal. For all patients, whose shunts have not been adjusted or removed in the observed time frame, the last occurrence in the electronic patient-record was used for censoring in the survival analysis. The primary outcome of this retrospective study is the rate of valve pressure-adjustments in the general patient collective and in different subgroups.

2.2. Statistical procedures

Statistical analyses were calculated by using BiaS 11.05 (© epsilon 2017). P-Value of < 0.05 was considered statistically significant. Descriptive statistics were expressed as numbers (%) for categorial variables, for continuous, normally distributed variables as mean and standard deviation and as median and range for non-normally distributed variables. Chi tests were applied for univariate associations. Kaplan-Meier analysis was used to examine the rate of primary VOP changes for all patients and in subgroups (primary valve pressure, shunt type, type of hydrocephalus, sex) at different times. The subgroups' Kaplan-Meier curves were compared using log-rank (Cox-Mantel) test and Cox-regression.

3. Results

3.1. Patient demographics

This study reports about 343 shunts in 321 patients. 21 patients received two shunts and one patient received three shunts during the observed time-span. The median follow-up time after VP shunt insertion was 3.6 months. The mean age at time of the VP shunt placement was 57.76 years. 162 patients (50.5%) were between 18 and 60 years old and 159 patients (49.5%) were 60 years and older. 146 patients (45.5%) were male and 175 patients (54.5%) were female. The main types of hydrocephalus we examined were communicating hydrocephalus (160 shunts; 46.6%), obstructive hydrocephalus (92 shunts; 26.8%) and normal pressure hydrocephalus (NPH) (54 shunts; 15.7%). In 37 shunt insertions (10.8%) the hydrocephalus type was unknown, unspecified or of another type.

Hydrocephaly defined as communicating hydrocephalus cover different etiologies ranging from subarachnoid hemorrhage (SAH), neoplastic meningitis, infectious meningitis and craniocerebral injury (CCI). The obstructive hydrocephalus type's etiologies range from tumors – including primary central nervous system (CNS) tumors and metastases – over aqueduct stenosis, intracranial hemorrhage (ICH), compression by intracranial aneurysm to cysts.

The most often observed etiologies were SAH (112 shunts; 32.7%), tumor (62 shunts; 18.1%), idiopathic (54 shunts; 15.7%), postoperative conditions (17 shunts; 5.0%), CCI (15 shunts; 4.4%), ICH (15 shunts; 4.4%) and aqueduct stenosis (10 shunts; 2.9%).

Furthermore, among the etiologies, cases of benign intracranial hypertension (7 shunts; 2.0%), neoplastic meningitis (6 shunts; 1.7%), infectious meningitis (5 shunts; 1.5%), cysts (5 shunts; 1.5%), Dandy-Walker malformation (1 shunt; 0.3%) and Arnold-Chiari malformation (2 shunts; 0.6%) as well as unclear or mixed types (32 shunts; 9.3%) requiring VP shunting were registered (Table 1).

Among the shunt valve types proGAV® (Aesculap-Miethke, Potsdam, Germany) (274 shunts; 79.9%) was predominant from 2013 till 2017 and proGAV® 2.0 (Aesculap-Miethke, Potsdam, Germany) (64 shunts; 18.7%) from 2017 to 2018. In five shunt insertion protocols the valve type was not documented. The predominantly chosen primary valve-pressure was 5 cmH_2O (303; 88.3%) (Table 1).

Table 1
Group characteristics.

Demographics	General patient sample
Shunt insertions	343
Number of patients	321
Average age (years)	57.8
Sex	
Male	146 (45.5%)
Female	185 (54.5.%)
Etiologies	
SAH	112 (32.7%)
Tumor	62 (18.1%)
Idiopathic	54 (15.7%)
Postoperative	17 (5%)
craniocerebral injury	15 (4.4%)
ICH	15 (4.4%)
Aqueduct stenosis	10 (2.9%)
Benign intracranial hypertension	7 (2.0%)
Neoplastic meningitis	6 (1.7%)
Infectious meningitis	5 (1.5%)
Arnold-Chiari malformation	2 (0.6%)
Dandy-Walker malformation	1 (0.3%)
Mixed/unclear	32 (9.3%)
Type of hydrocephalus	
Communicating	160 (46.6%)
Obstructive	92 (26.8%)
NPH	54 (15.7%)
Mixed/unclear	37 (10.8%)
Shunt type	
proGAV®	274 (79.9%)
proGAV® 2.0	64 (18.7%)
Initial VOP	
5 cmH_2O	303 (88.3%)
other initial VOPs	31 (9.0%)
Unknown	9 (2.6%)
VOP adjustments per shunt	0.484

VOP = valve opening pressure, SAH = subarachnoid hemorrhage, ICH = intracranial hemorrhage, NPH = normal pressure hydrocephalus.

Table 2
Indications for valve pressure-adjustments.

Indication for pressure elevation	Number of adjustments	Indication for pressure reduction	Number of adjustments
Overdrainage	32	Underdrainage	38
Ventricular compression	14	Ventricular dilatation	19
Hygroma	7	Gait disorder	3
Headache, nausea, dizziness	8	Headache, nausea, dizziness	3
After cranioplastic craniotomy	4	Clinical improvement	4
Shunt insufficiency	2	Shunt insufficiency	4
SDH	1	CSF retention	2
ICH	2	Missing recovery	9
sunken craniectomy lesion	3	Swollen craniectomy lesion	2
Disturbance of vigilance	3	Disturbance of vigilance	6
	76		**90**

Indications for valve pressure-adjustments as mentioned in electronic patient records.
SDH = subdural hematoma, ICH = intracranial hemorrhage, CSF = craniospinal fluid.

3.2. Rate of change in primary valve pressure

Of the 343 implanted VP shunts, 101 (29.4%) shunts required a change of their primary VOP during the observed time interval and out of these, 41 shunts (12.0%) have been changed twice or more. In total 166 valve pressure-adjustments (90 downwards adjustments; 76 upwards adjustments) (Table 2) were done with a valve pressure adjustment rate of 0.5 adjustments per VP shunt implant. The initial mean valve pressure was 5.3 cmH_2O (range 1 cmH_2O to 17 cmH_2O) and the final mean pressure setting was 5.9 cmH_2O (range 0 cmH_2O to 20 cmH_2O). Whereas the initial and final median pressure was 5 cmH_2O. In the group with the primary valve pressure of 5 cmH_2O were 303 implanted valves. The mean pressure changed to 5.8 cmH_2O (range 0 cmH_2O to 20 cmH_2O). The other group with an initial valve pressure different from 5 cmH_2O contained 31 valve implants with a mean primary valve pressure of 8.1 cmH_2O (range 1 cmH_2O to 17 cmH_2O) and a final valve pressure of 6.42 cmH_2O (range 0 cmH_2O to 12 cmH_2O). For 9 valve implantations the initial valve pressure was not documented. The number of valve pressure-adjustments per shunt is portrayed in Fig. 3.

241 patients (70.3%) underwent censoring during the Kaplan-Meier analysis. The median time till valve pressure-adjustment was 2.9 years and the pressure adjustment-rate was 38.3% one year after VP shunt placement, 50.7% after three years and 58.4% after four years for the general patient sample (Fig. 1). The results for the observed types of hydrocephalus were a median time of > 1.5 years (non-computable) and a one-year adjustment rate of 38.4% for communicating hydrocephalus, for normal pressure hydrocephalus 2.5 years and 35.9% and for obstructive hydrocephalus 3.8 years and 38.5%. The comparison between male and female patients reveals a median time of 2.6 years and 40.1% one-year adjustment rate for shunts in male patients and 3.8 years and 37.0% for shunts in female patients. The valve type proGAV® had a median time for valve pressure-adjustment of 3.8 years and a one-year adjustment rate of 35.6% and 0.5 years and 86.5% for proGAV® 2.0. VP shunts with a primary VOP of 5 cmH_2O had a median survival of 3.8 years and one-year adjustment rate of 37.1%, whereas other primary VOPs' median survival and one-year survival rate were 0.7 years and 59.7% (Fig. 2).

3.3. Factors affecting the VP shunt survival rate

We compared the influence of age, sex, shunt type, type of hydrocephalus and primary VOP on the survival times by comparing the Kaplan-Meier curves using log-rank test (Cox-Mantel).

We found no significant difference in the log in between the sexes ($Chi^2 = 0.8$; $p = 0.36$),l between the valve types proGAV® and proGAV® 2.0 ($Chi^2 = 0.6$; $p = 0.43$), between normal pressure hydrocephalus, obstructive hydrocephalus and communicating hydrocephalus ($Chi^2 = 0.2$; $p = 0.89$) and no age-effect, when comparing patients younger than 60 years and patients with 60 or more years ($Chi^2 = 1.0$; $p = 0.32$) either. Only the initial VOP is a predictor for the probability that the VOP had to be adjusted ($Chi^2 = 7.9$; $p = 0.00497$). Patients with initial VOPs of other than 5 cmH_2O had a higher probability (relative hazards 2.1; 1.3–3.6 95% CI) that a valve pressure-adjustment was necessary than patients for whom 5 cmH_2O was chosen (Fig. 2). For example, VP shunts with an initial VOP of 5 cmH_2O in hydrocephalus after SAH have lower valve adjustment-rates than those with different initial VOPs, too ($p = 0.000037$). Afterwards the Cox-regression was applied to compare the both valve types and confirmed the result ($Chi^2 = 6.4$; $p = 0.012$).

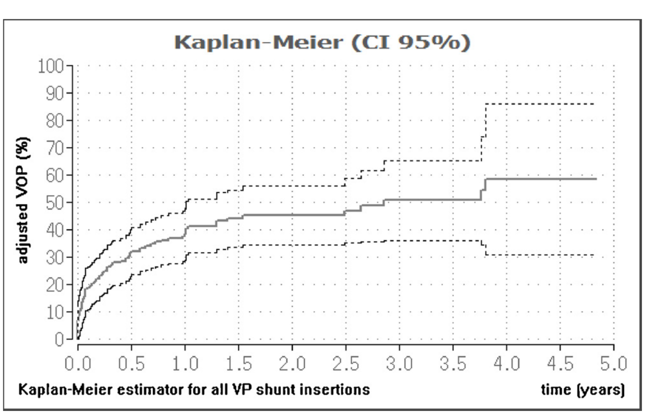

Fig. 1. Kaplan-Meier curve showing valve pressure-adjustment rate for the whole patient sample with 95% CI. CI = confidence interval.

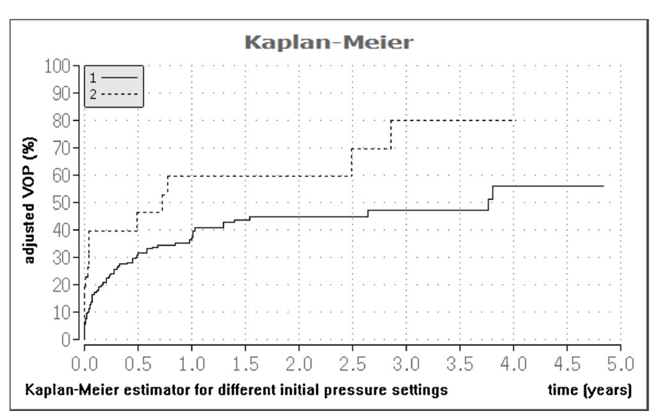

Fig. 2. Kaplan-Meier curve showing valve pressure-adjustment rates for 5 cmH_2O (1) and other initial VOPs (2). VOP = valve opening pressure.

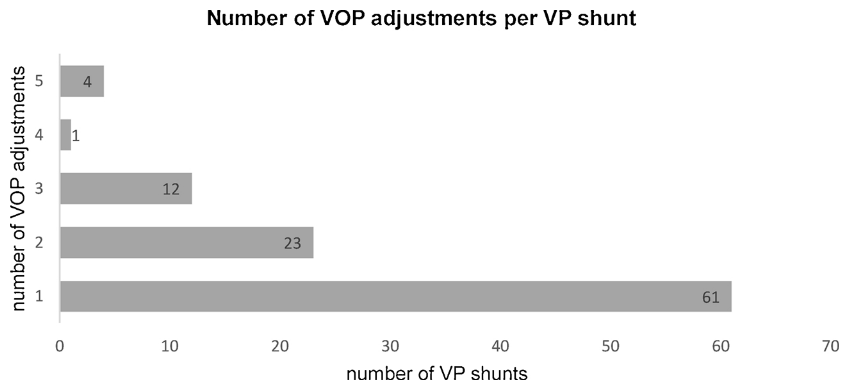

Fig. 3. Number of VOP adjustments per VP shunt; in total 101 adjusted VP shunts VOP = valve opening pressure, VP = ventriculoperitoneal.

4. Discussion

By presenting an analysis of the valve pressure-adjustments in VP shunts in a single institution, we aim to evaluate the need for pressure adjustments of VP shunts in general, the comparison with fixed and variable pressure valves for the whole patient collective and for different subgroups. Thereby we want to contribute to the process of finding the appropriate valve pressure setting and valve type for the individual patient. We examined 343 V P shunt insertion procedures between 2013 and 2018.

Our results show that the primary valve pressure needed to be changed in 38.3% of all VP shunt insertions after one year, in 50.7% after three years and in 58.4% after four years (Fig. 1). For communicating hydrocephalus (38.4%), obstructive hydrocephalus (38.5%) and NPH (35.9%), the valve pressure-adjustment rates after one year were in a close range.

The comparison of the observed Kaplan-Meier curves by applying Peto-Pike log-rank tests for sex, age, valve type, diverse types of hydrocephalus or etiology did not differ significantly. But the primary chosen VOP proved to correlate significantly with the valve pressure-adjustment rate in the observed inserted shunts. Patients for whom a VOP other than 5 cmH_2O was chosen tended to have an increased risk of need for valve pressure-adjustment in comparison to the standard pressure 5 cmH_2O. This may indicate that a VOP of 5 cmH_2O may be preferred prior to other valve-pressures for all patient collectives.

In the process of determining the appropriate individual valve pressure there are two often used approaches: First - the “European approach” - a low initial VOP is chosen, which is enabled by using anti-siphon devices to prevent overdrainage. Second – the “Pacific approach” - the initial VOP is high and can be lowered subsequently, until the patient lacks neurological symptoms. At first, studies considering the “European approach” are discussed.

For proGAV® valve insertions in idiopathic NPH (iNPH) Freimann et al. [11] conducted a study to investigate the ability of anti-siphon devices to improve the clinical outcome in shunt therapy. They compared 55 iNPH patients with proGAV® valves with gravitational unit with 45 iNPH patients with programmable Codman Hakim® valves without gravitational unit and found an adjustment rate of ∼56% (31 of 55 patients, 54 re-adjustments in total) with a mean observation period of approximately 29.4 months. The initial median valve pressure settings were 5 cmH_2O (quartiles 5 cmH_2O/ 5 cmH_2O) for the former and 14 cmH_2O (quartiles 13 cmH_2O/ 14 cmH_2O) for the latter and the final settings were 5 cmH_2O (quartiles 5 cmH_2O/ 2 cmH_2O) for the former and 12 cmH_2O (quartiles 10 cmH_2O/ 14 cmH_2O) for the latter These results are similar to our findings: For an observation period of approximately 29.4 months we found valve adjustment rates of ∼47% for the general patient sample (Fig. 1) and ∼53% for the NPH subgroup (data not shown). The proGAV® valves in NPH patients of our study have the same initial and final setting of 5 cmH_2O (quartiles 5 cmH_2O/ 5 cmH_2O). Freimann et al. conclude that the low-pressure setting enabled by adjustable VP shunts with anti-siphon device yield an improved outcome in comparison to VP shunts without anti-siphon device [11]. Thus, their results are more in favor of the “European approach”.

Gölz et al. [5] conducted a study about the indications for valve pressure-adjustments in 163 patients with iNPH of whom 111 patients received a proGAV® shunt. They concluded that the optimal valve pressure is in the range of 3–7 cmH_2O with 36% of the patients having a valve pressure of 5 cmH_2O. They observed 198 valve pressure-adjustments in a median follow-up time of 42 months. This is concordant to our finding, that 5 cmH_2O is the most common final VOP in NPH patients and in the general patient collective.

It was shown by Boon et al. [13] that low-pressure settings had slight advantages over medium-pressure settings in iNPH in terms of clinical outcome in Medos Hakim® spring ball valve shunts, despite occurring subdural effusions in 71% of the patients.

Furthermore, Meier et al. [14] found a better clinical outcome in fixed low-pressure GAV® shunts (5 cmH_2O) compared to medium-pressure shunts (10–13 cmH_2O) in iNPH. These results indicate, that low-pressure settings like 5 cmH_2O in this study might be beneficial in iNPH.

Studies by Reinprecht et al. [15] and Bergsneider et al. [16] concerning iNPH patients with Codman-Hakim® programmable valves describe the “Pacific approach” to find the right individual valve pressure setting: Starting with a valve pressure of 20 cmH_2O the pressure is reduced stepwise depending on the patients' clinical condition. Reinprecht et al. [15] resulted in a final valve pressure of 15 cmH_2O and a valve pressure-adjustment rate of 87% with more than 1.9 changes per patient in 37 patients. The 114 patients in the study by Bergsneider et al. [16] had a final valve pressure between 12–14 cmH_2O. The approach of Reinprecht et al. [15] and Bergsneider et al. [16] to start with a relatively high valve pressure and lowering it until the patients don't show symptoms causes more frequent valve pressure-adjustments than other approaches to determine the optimal valve pressure including our valve pressure adjustment-rate of 0.5 adjustments per implanted VP shunt.

Lee et al. [12] conducted a study to compare 57 programmable and 37 non-programmable Strata® valves by Medtronic, Inc. in hydrocephalus secondary to aneurysmal SAH. They concluded that programmable pressure valves yield a better postoperative outcome than fixed pressure and that valve pressure-adjustments during the follow-up can cause neurological improvements and help to find the patients' individual optimal valve pressure setting. Furthermore, programmable pressure valves proved to be more cost-effective than fixed-pressure valves, because despite the higher costs of programmable pressure valves, they were associated with a revision rate of 7% compared to 21.6% in fixed-pressure valves ($p = 0.0413$). Valve pressure adjustments occurred in 33 of 57 (57.9%) implanted programmable shunts, which meets approximately our findings. In 24 out of 33 (72.7%)

adjusted valves neurological and radiological improvements occurred and therefore programmable valves show lower rates of headaches, drowsiness, gait disturbance and drainage-related complications.

The above described findings supporting the “European approach” of valve pressure-adjustment by Freimann et al. [11], Boon et al. [13], Gölz et al. [5] and Meier et al. [14] indicate that an initial low valve opening pressure setting tends to have a better postoperative outcome compared to higher VOPs at least for NPH. According to Freimann et al. [11] low-pressure valve settings are made possible by using shunts with an anti-siphon unit like the proGAV® valve. Thus, preventing over-drainage complications. Since in our study the initial mean VOP different from 5 cmH_2O is 8.1 cmH_2O, these higher valve pressures may explain the higher probability of valve pressure-adjustment. Another possible explanation is the a-priori election of a non-standard valve pressure for patients with more severe medical conditions or non-standard types of hydrocephalus.

The “Pacific approach” represented by Reinprecht et al. [15] and Bergsneider et al. [16] requires more frequent valve-pressure adjustments in iNPH patients than the “European approach”.

Lee et al. [12] presented data showing a better clinical outcome and lower costs for programmable valves compared to non-programmable valves in post-SAH hydrocephalus. Out data additionally suggests that an initial valve pressure of 5 cmH_2O in programmable valves with gravitational unit might yield additional benefits in clinical outcome after shunt insertion for patients who suffered from SAH compared to other valve pressure settings, since less valve pressure-adjustments are necessary in this subgroup, too, for the initial pressure 5 cmH_2O ($p = 0.000037$). Therefore, programmable VP shunts might be generally preferred to fixed-pressure VP shunts.

Since the change of VP shunt insertions from the valve type proGAV® to valve type proGAV® 2.0 occured in the year 2017, the number of inserted proGAV® 2.0 valves and the follow-up time are too small to provide a long-term comparison.

The limitations of this study are the retrospective design, the availability of information only out of electronic patient records and operation protocols, the median follow-up time after VP shunt insertion of 3.6 months and high percentage of censoring (70.3%) in the Kaplan-Meier analysis, which may be due to the patients' early transportation to rehabilitation clinics in the aftermath of the VP shunt insertion, the bad prognosis of some patients for example after a severe SAH or treatments at other neurosurgical clinics. The VP shunt insertions had been performed by different neurosurgeons. Nonetheless, we believe that the relatively high number of shunt insertions and the observation period of up to five years make this study a valuable contribution to improve the patients' VP shunt therapy.

5. Conclusion

In conclusion, this study shows a valve-pressure adjustment in approximately 60% of the patients in a 5-year period and that a primary chosen VOP of 5 cmH_2O is associated with a lower probability of valve pressure-adjustment compared to other primary valve pressures. Further studies are needed to determine the rate of valve-pressure adjustments in other patient samples with special regards to the initial VOP and other predicting factors for valve pressure-adjustments.

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Declaration of Competing Interest

None.

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