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A Retrospective Study to Investigate the Clinical Performance and Safety of BMI CSF Shunting System in Patients Who Needed Cerebrospinal Fluid Drainage Therapy

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Abstract

Background: Despite BMI Cerebrospinal Fluid (CSF) Shunting System has been on the market for decades, no studies have been carried out. This retrospective study examined its clinical performance and safety, and attempted to discern risk factors.

Methods: Medical records from 232 patients with External Ventricular Drainage (EVD) placement and 35 patients with Ventriculoperitoneal (VP) shunt placement were reviewed for 1 year and 2 years postoperatively, respectively.

Results: The incidence of device malfunction was 22.9% for VP shunt in 2 years and 25.4% for EVD in 1 year. The most common cause of device malfunction was over drainage for VP shunt; and distal displacement and infection for EVD. The incidence of complications was 2.9% in the VP shunt group and 27.6% in the EVD group, while that of device-related infections were 0.0% and 7.3%, respectively. No one in the VP shunt died in 2 years postoperatively, while 2 patients (0.9%) in the EVD group died in 1 year postoperatively. No factors were found to influence the VP shunt survival; while age, catheter diameter, type of hydrocephalus, and Glasgow Coma Scale (GCS) score before surgery were found to have significant impact on EVD function.

Conclusion: Compared to other similar device, BMI EVD showed comparable clinical performance and VP shunt showed superior clinical performance. Both devices were safe, with limited device-related infections reported. Our study sheds some light on the long-term outcome of BMI CSF Shunting System. Further study on a larger population is warranted to verify the predictors of device survival we identified in this analysis.

Keywords: BMI CSF Shunting System; Hydrocephalus; Clinical performance; Safety; Retrospective

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Introduction

Shunting of the Cerebrospinal Fluid (CSF) remains the treatment of choice for the majority of patients with hydrocephalus. Such procedure provides an immediate and effective treatment necessary to avoid the resulting neurological damage if the condition is left untreated. Unfortunately, shunt surgery is associated with an excessive rate of complications. It is reflected in the high risk of experiencing one or more reoperations. Together with the high incidence of hydrocephalus, the treatment constitutes a significant medical and economic problem [1]. Therefore, it is a proclaimed goal to reduce the incidence of shunt revisions.

Several retrospective studies have reported comparable results according to rates of revision and infection, patient specific and intraoperative risk factors, and causes of shunt failure [2-9]. Other studies have investigated the benefits of applying different procedural strategies [10-12] and the use of specific shunt hardware to avoid certain complications in high-risk patients [13-15]. Conversely, only few studies have addressed whether shunt surgery has improved over the past few decades resulting in decreased revision rates and prolonged shunt survival. Most of these studies conclude this does not seem to be the case [16-18] while only one study describes better outcomes for recently shunt-treated pediatric patients [19].

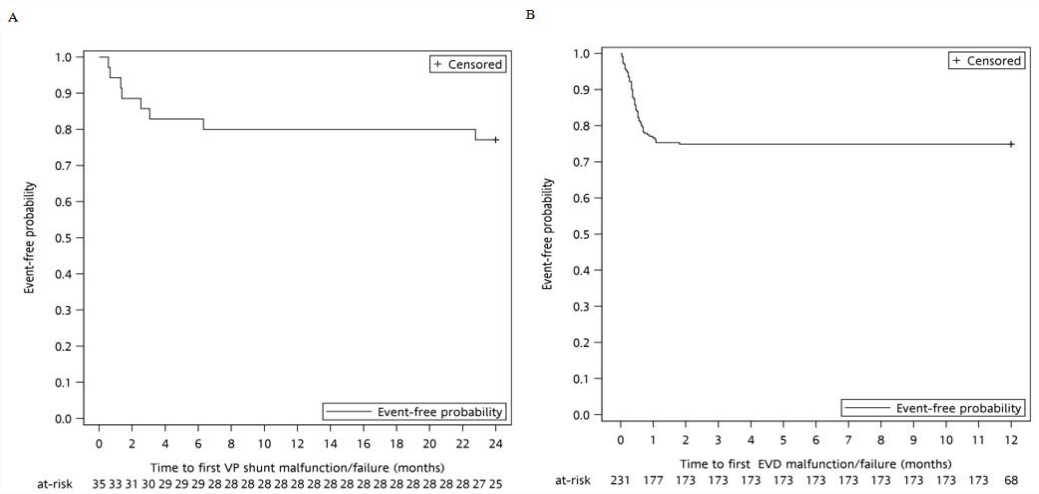

Figure 1: Kaplan-Meier analysis of time to first device malfunction (A. VP shunt; B. EVD).
Abbreviations: VP: Ventriculoperitoneal; EVD: External Ventricular Drainage

BMI CSF Shunting System (Wellong Instruments Co., Ltd. Taiwan), including Ventriculoperitoneal (VP) shunt and External Ventricular Drainage (EVD) coupled with external monitoring system, has been on the market for decades. However, no studies have been carried out until then to investigate its clinical performance and safety. The purpose of this retrospective study is to evaluate its clinical performance and safety in the real-world setting, and to investigate the risk factors that may cause the postoperative complications.

Material and Methods

Patient population: The study was approved by the institutional review board of Linkou Chang Gung Memorial Hospital in Taiwan. Each patient's written informed consent was waived due to the retrospective nature of the study.

We respectively reviewed the medical records and operative reports covering a 1-year period for patients who underwent BMI EVD placement after 2015 and data covering a 2-year period for patients who used BMI VP shunt after 2012 for the management of hydrocephalus. A total of 232 patients with EVD placement and 35 patients with VP shunt placement were identified and enrolled. Patients were excluded for the following reasons: had meningitis from community acquired organisms (e.g., *Streptococcus pneumoniae*, *Neisseria meningitidis*, *Listeria monocytogenes*, and *Haemophilus Influenzae*) or blood-borne infectious diseases (e.g., HIV, HBV, Creutzfeldt-Jakob disease, and syphilis).

Study objectives: The primary outcome of interest was the clinical performance of BMI CSF shunting system in terms of VP shunt survival and EVD malfunction rates. Secondary objectives included the safety of BMI CSF shunting system and risk factors affecting BMI CSF shunting system survival.

Data elements and classifications: Information was collected on each patient regarding age, sex, diagnosis, neurological examination, underlying illness, secondary complications, antibiotics treatment, hospital stay, follow-up, and further management. Follow-up in neurosurgery clinics was specifically reviewed for periodic shunt assessment, persistent or new onset symptoms, and any neurological deficits in terms of visual/motor/cognitive deficits. Any further hospital admissions and surgeries after initial VP shunt or EVD insertion were also studied.

Diagnosis: Patients were categorized as having (1) Normal-Pressure Hydrocephalus (NPH), (2) High-Pressure Hydrocephalus, or (3) congenital/infantile hydrocephalus for etiologies grouped into different categories (i.e., traumatic brain injury, subarachnoid hemorrhage, Subarachnoid Hemorrhage [SAH], intracranial hemorrhage, aneurysm or vascular malformation, brain tumors/colloid and other types of cysts, Reye syndrome or similar encephalopathy, meningitis, stroke/infarcts, post-cranial surgery hydrocephalus, Arnold–Chiari or Dandy–Walker malformations, idiopathic type, and prior CSF drainage therapy failure).

Procedural and in-hospital records: Data regarding 0medical histories, device model, pre- and post-procedural Glasgow Coma Scale (GCS) assessment, surgeon's educational level, surgical duration, antibiotics use, and duration of hospitalization were captured.

Post-procedural follow-up: A period of 2-year and 1-year follow-up record after the placement of VP shunt and EVD, respectively, were gathered. Cardinal events included BMI CSF Shunting System malfunction and adverse events (e.g., new onset or worsening of neurologic symptoms and device-associated meningitis/infections) as well as its severity and resolution. Clinical malfunction was determined based on the occurrence of revision surgery, clinical judgment of the physician, and the indication for surgery or shunt pressure adjustment. Surgical findings, as documented in operative reports of the revision surgery, were categorized into the following groups: proximal defect or obstruction, proximal displacement, distal defect or obstruction, distal displacement, valve defect, over drainage, infections, revision due to open abdominal surgery, and no abnormal findings.

Statistical analysis: Patients using VP shunt and EVD were analyzed separately. All statistical analyses were performed using SAS® software, version 9.4. (SAS Institute Inc., Cary, NC, USA); and were mainly descriptive to present number of observations, mean, standard deviations, range, and 95% Confidence Interval (CI) for continuous data and frequency and percentage for categorical data. Multiple logistic regressions was used to determine various factors affecting BMI CSF Shunting System survival. Kaplan–Meier curves were used to present the duration from CSF drainage therapy to first

Table 1: Patients' characteristics.

Parameters		VP shunt N=35	EVD N=232
Age, mean ± SD (years)		52.1 ± 22.98	56.4 ± 17.25
Type of subjects, n (%)	Adult	31 (88.6)	225 (97.0)
	Pediatric	4 (11.4)	7 (3.0)
Male, n (%)		18 (51.4)	137 (59.1)
Asian, n (%)		34 (97.1)	232 (100.0)
Smoker, n (%)		2 (5.7)	32 (13.8)
Comorbidities, n (%)	Hypertension	15 (48.4)	141 (62.7)
	Diabetes	8 (25.8)	45 (20.0)
	Cardiovascular disease	4 (12.9)	56 (24.9)
	Obesity (BMI ≥ 30 kg/m^2)	4 (12.9)	16 (7.1)
	Dyslipidemia	3 (9.7)	9 (4.0)
	Atherosclerosis	0 (0.0)	3 (1.3)
Hydrocephalus type, n (%)	Normal-pressure	32 (91.4)	46 (19.8)
	High-pressure	1 (2.9)	169 (72.8)
	Congenital/infantile	0 (0.0)	14 (6.0)
Etiology, n (%)	Intracranial hemorrhage	7 (20.0)	116 (50.0)
	Subarachnoid hemorrhage	3 (8.6)	54 (23.3)
	Traumatic brain injury	5 (14.3)	20 (8.6)
	Aneurysm/vascular malformation	6 (17.1)	7 (3.0)
	Brain tumor or cyst	9 (25.7)	4 (1.7)
	Stroke/infarcts	3 (8.6)	17 (7.3)
	Meningitis	2 (5.7)	2 (0.9)
	Others	0 (0.0)	12 (5.2)
GCS before operation	14-15 (mild or no injury)	18 (51.4)	73 (31.5)
	9-13 (moderate injury)	10 (28.6)	52 (22.4)
	3-8 (severe injury)	5 (14.3)	107 (46.1)
Best GCS after operation	14-15 (mild or no injury)	24 (68.6)	103 (44.4)
	9-13 (moderate injury)	10 (28.6)	57 (24.6)
	3-8 (severe injury)	0 (0.0)	71 (30.6)

SD: Standard Deviation; VP: Ventriculoperitoneal; EVD: External Ventricular Drainage; BMI: Body Mass Index; GCS: Glasgow Coma Scale

malfunction. Statistical significance was defined at probability of Type I error of α=0.05.

Results

Patients' characteristics: Patient demographics and admission characteristics are shown in Table 1. A total of 35 (31 adults and 4 pediatric cases) patients with VP shunt placement and 232 (225 adults and 7 pediatric cases) patients with EVD placement were identified. The mean age was 52.1 ± 22.98 years, ranging from 0.2 to 85.0 years for the VP shunt group; and 56.4 ± 17.25 years, ranging from 0.2 to 88.8 years for the EVD group. Male patients accounted for 51.4% (n=18) of the VP shunt population and 59.1% (n=137) of the EVD population. For both VP shunt and EVD cohorts, hypertension (48.4% and 62.7%, respectively) and diabetes (25.8% and 20.0%, respectively) were the most common comorbidities; however, cardiovascular disease (24.9%) was also one of the most common comorbidities for the EVD cohort.

The types of hydrocephalus were mostly normal-pressure hydrocephalus (n=32, 91.4%) for the VP shunt group and high-pressure hydrocephalus (n=169, 72.8%) for the EVD group. The most common admitting diagnoses/etiology (≥ 10%) for the VP shunt group included brain tumor or cyst (n=9, 25.7%), intracranial hemorrhage (n=7, 20.0%), aneurysm/vascular malformation (n=6, 17.1%), and traumatic brain injury (n=5, 14.3%); while that for the EVD group included intracranial hemorrhage (n=116, 50.0%) and subarachnoid hemorrhage (n=54, 23.3%).

Table 2: Summary of devise malfunction.

Parameters		VP shunt N=35	EVD N=232
Device malfunction, n (%)		8 (22.9)	59 (25.4)
Time to first malfunction	median (months)	NA	NA
	mean ± SD (months)	18.7 ± --	1.5 ± --
Operational findings, n (%)	Proximal defect or obstruction	0 (0.0)	7 (3.0)
	Proximal displacement	0 (0.0)	1 (0.4)
	Distal defect or obstruction	1 (2.9)	9 (3.9)
	Distal displacement	0 (0.0)	29 (12.5)
	Over drainage	3 (8.6)	0 (0.0)
	Infection	0 (0.0)	20 (8.6)
	Other	4 (11.4)	8 (3.4)

SD: Standard Deviation; NA: Not Available; VP: Ventriculoperitoneal; EVD: External Ventricular Drainage

On presentation, 5 (14.3%) patients in the VP shunt group and 107 (46.1%) in the EVD group were comatose (GCS ≤ 8). After surgery, none in the VP shunt group were comatose; however, 71 (30.6%) patients in the EVD group were still at comatose state.

Clinical performance: Results of device malfunction are presented in Table 2. The incidence of device malfunction was 22.9% (8/35) for VP shunt in 2 years postoperatively and 25.4% (59/232) for EVD in 1 year postoperatively. Revision was performed in all of these cases. Kaplan-Meier curves showed that the VP shunt failure rates at 6 months and 1 year were approximately 20% and that of EVD at 6 months was around 25% (Figure 1), with the mean time to malfunction of 18.7 and 1.5 months, respectively, while the median time was not yet achieved.

The most common cause of device malfunction was over drainage (37.5%, 3/8) for VP shunt; and distal displacement (49.2%, 29/59) and infection (33.9%, 20/59) for EVD.

Multiple logistic regression analysis was performed to identify factors affecting BMI CSF Shunting System survival (Table 3). GCS 9-13 before the surgery was associated with a lower risk of EVD malfunction versus comatose (GCS 3-8) (odds ratio [OR]=2.611, 95% CI=1.090 to 6.257, P=0.031) but such finding was not observed for GCS 14 to 15 *vs.* GCS 3 to 8. However, older age (OR=0.971, 95% CI=0.946 to 0.995, P=0.021), smaller catheter diameter (OR=0.307, 95% CI=0.103 to 0.910, P=0.033), and high-pressure hydrocephalus (versus infantile hydrocephalus, OR=0.064, 95% CI=0.006 to 0.702, P=0.025) were associated with a lower risk of EVD malfunction. Regarding VP shunt, no factors were found to influence the shunt survival significantly and this could be due to relatively small numbers in subcategories, resulting in a low statistical power.

Safety: The safety profile of BMI CSF Shunting System is shown in Table 4. The incidence of complications was 2.9% (n=1) in the VP shunt group and 27.6% (n=64) in the EVD group. The incidence of device-related adverse events (AEs) was 2.9% (n=1, dysphagia) in the VP shunt group and 27.2% (n=63) in the EVD group, with 3 EVD-

Table 3: Multiple logistic regression analysis for identifying factors affecting BMI CSF Shunting System survival.

		VP shunt N=35		EVD N=232	
Factors		**Estimate (P-value#)**	**OR (95% CI)**	**Estimate (P-value#)**	**OR (95% CI)**
Age		-0.001 (0.999)	0.999 (0.088, 11.342)	-0.030 (0.021*)	0.971 (0.946, 0.995)
Male		-15.45 (0.783)	<0.001 (<0.001, >999.999)	0.246 (0.556)	1.279 (0.563, 2.909)
Smoker		-50.16 (0.841)	<0.001 (<0.001, >999.999)	0.177 (0.738)	1.194 (0.423, 3.370)
Comorbidities	Obesity	-33.95 (0.896)	<0.001 (<0.001, >999.999)	-0.138 (0.832)	0.871 (0.242, 3.131)
	Hypertension	-12.95 (0.926)	<0.001 (<0.001, >999.999)	0.454 (0.290)	1.575 (0.679, 3.655)
	Diabetes	12.586 (0.954)	>999.999 (<0.001, >999.999)	-0.278 (0.597)	0.758 (0.271, 2.118)
	Dyslipidemia	12.432 (0.959)	>999.999 (<0.001, >999.999)	0.718 (0.418)	2.050 (0.361, 11.641)
	Atherosclerosis	--	--	-13.20 (0.987)	<0.001 (<0.001, >999.999)
	Cardiovascular disease	-3.109 (0.976)	0.045 (<0.001, >999.999)	0.848 (0.064)	2.334 (0.951, 5.729)
VP shunt model	84-288-02512H *vs.* 84-288-02512M	81.383 (0.912)	>999.999 (<0.001, >999.999)	--	--
	84-288-02512L *vs.* 84-288-02512M	14.061 (0.824)	>999.999 (<0.001, >999.999)	--	--
Prior EVD placement		-29.95 (0.722)	<0.001 (<0.001, >999.999)	--	--
EVD catheter diameter	1.5 mm *vs.* 2.1 mm	--	--	-1.181 (0.033*)	0.307 (0.103, 0.910)
Duration of surgery	< 30 *vs.* ≥ 90 min	--	--	-12.35 (0.993)	<0.001 (<0.001, >999.999)
	30-59 *vs.* ≥ 90 min	31.543 (0.957)	>999.999 (<0.001, >999.999)	0.440 (0.354)	1.553 (0.612, 3.940)
	60-89 *vs.* ≥ 90 min	-14.53 (0.823)	<0.001 (<0.001, >999.999)	0.990 (0.053)	2.692 (0.989, 7.331)
Surgeon	register *vs.* neurosurgeon	1.288 (0.994)	3.626 (<0.001, >999.999)	-0.285 (0.524)	0.752 (0.313, 1.807)
Antibiotics use during surgery and hospitalization		58.472 (0.765)	>999.999 (<0.001, >999.999)	15.160 (0.987)	>999.999 (<0.001, >999.999)
Duration of antibiotics	1 week *vs.* >1 week	-28.43 (0.742)	<0.001 (<0.001, >999.999)	0.620 (0.229)	1.859 (0.676, 5.113)
Type of hydrocephalus	normal-pressure hydrocephalus *vs.* infantile hydrocephalus	--	--	-0.373 (0.552)	0.689 (0.202, 2.350)
	high-pressure hydrocephalus *vs.* infantile hydrocephalus	--	--	-2.755 (0.025*)	0.064 (0.006, 0.702)
GCS before operation	14-15 *vs.* 3-8	-1.966 (0.990)	0.140 (<0.001, >999.999)	-0.139 (0.780)	0.870 (0.327, 2.313)
	9-13 *vs.* 3-8	15.096 (0.908)	>999.999 (<0.001, >999.999)	0.960 (0.031*)	2.611 (1.090, 6.257)
GCS after operation	14-15 *vs.* 3-8	--	--	0.385 (0.456)	1.469 (0.535, 4.034)
	9-13 *vs.* 3-8	--	--	0.956 (0.069)	2.602 (0.930, 7.279)
	14-15 *vs.* 9-13	46.781 (0.825)	>999.999 (<0.001, >999.999)	--	0.565 (0.218, 1.460)

#P-value by Chi-square test, *Statistical significance

VP: Ventriculoperitoneal; EVD: External Ventricular Drainage; CI: Confidence Interval; OR: Odds Ratio; GCS: Glasgow Coma Scale

treated patients (1.3%) experiencing serious adverse events (SAEs) of infection, postoperative wound infection, and impaired healing. The most common AEs in the EVD group were pyrexia (n=20, 8.6%), infection (n=17, 7.3%), pneumonia (n=12, 5.2%), urinary tract infection (n=8, 3.4%), and central nervous system infection (n=7, 3.0%). Device-related infection was noted in 17 EVD-treated patients (7.3%) but none in VP shunt-treated patients. No one with VP shunt placement died within 2 years of follow up, while 2 patients using EVD (0.9%) died in 1 year postoperatively.

Discussion

In this study, we retrospectively presented data on VP shunt and EVD operated patients during 2012 to 2016. Overall, our study demonstrates the clinical performance and safety of BMI CSF Shunting System and identify some potential risk factors of device survival.

Shunt failure is common in patients who receive CSF shunt insertion, and the incidence increases with time [20,21]. However, according to the Kaplan-Meier analysis of time to first shunt malfunction in this study, the occurrence of shunt failure was not increased as time went by. Most revisions occurred within 6 months in accordance with the literature [5,22,23]. The probability of 2-year shunt survival in our study was 77.1%, which was considerably higher than the overall VP shunt survival rate in 2 years (around 52% to 67%) reported by previous studies from other parts of the world [18,24-30], and also from recent reports [31,32]. Also, the median time from shunt placement to first shunt failure was not reached in our study, showing a remarkably longer shunt survival time than other studies [31,32]. Regarding the clinical performance of BMI EVD, the overall EVD malfunction rate in our study was 25.4%. In comparison, Bogdahn et al. [33], Abla et al. [34], and Herrick et al. [35] have reported EVD survival probabilities of 19% to 26%, 14.9%, and 19.4%, respectively,

Table 4: Summary of safety outcomes.

Parameters		VP shunt N = 35, n (%)	EVD N = 232, n (%)
Device-related AEs		1 (2.9)	63 (27.2)
Device-related SAEs		0 (0.0)	3 (1.3)
Complications		1 (2.9)	64 (27.6)
Types of AEs†	Dysphagia	1 (2.9)	--
	Pyrexia	--	20 (8.6)
	Infection	--	17 (7.3)
	Pneumonia	--	12 (5.2)
	Urinary tract infection	--	8 (3.4)
	Central nervous system infection	--	7 (3.0)
	Hydrocephalus	--	3 (1.3)
	Death	--	2 (0.9)
	Cellulitis	--	2 (0.9)
	Postoperative wound infection	--	2 (0.9)
	Brain death	--	1 (0.4)
	Impaired healing	--	1 (0.4)
	Vasospasm	--	1 (0.4)

†Presented as Medical Dictionary for Regulatory Activities (MedDRA) 21.0 preferred term (PT)
SD: Standard Deviation; AE: Adverse Event; SAE: Serious Adverse Event; VP: Ventriculoperitoneal; EVD: External Ventricular Drainage

these results were comparable to our observation.

Meticulous surgical technique and improved asepsis might be considered as factors for the lower rate of VP shunt failure. Besides, Linkou Chang Gung Memorial Hospital is one of the biggest medical centers that provide the best medical care in Taiwan. Another plausible explanation for this observation could be that shunt failure typically implies a symptomatic shunt failure requiring revision. Patients who might become shunt independent later on would continue to be asymptomatic, even if their VP shunt was not functioning. Such patients were not considered as having shunt failure, and hence, it might have led to an erroneously low failure rate. All these factors can be influential to study outcome; however, they were not standardized and assessed properly in this retrospective study.

Given that BMI VP shunt is a non-programmable shunt, over drainage accounted for the most common cause of VP shunt malfunction in our study (37.5%, 3/8) and neither obstruction nor infection were reported to cause VP shunt failure in our study. This observation was not in accordance with previous reports that investigated programmable shunts equipped with programming valves which can cause shunt obstruction, infection, migration, and CSF ascites [36-39]. Our results reveal that neurosurgeons may need to set the valve pressure in a cautious way when placing BMI VP shunt.

Postoperative device-related infections have been considered a major problem of CSF drainage surgery due to its significant consequences for the patient and as a complication costly to treat. Despite the positive development in techniques and procedures to prevent infection through the past few decades, the problem still deserves our attention. BMI VP shunt in our study did not report any infections and only one case with complications was noted over the 2 years after shunt placement, which was superior to other studies showing an average infection rate of 5% to 9% that mostly fell within 4 weeks postoperatively [6,7,9,40]. Infection is also regarded as the most common complication of EVD placement, with rates reported to range from 5% to 27.7% [33,41,42]. The rate of EVD-related infection (7.3%) in our study was also relatively low comparing to most of the previous reports.

Our study reported a complication rate of 27.6% and a mortality rate of 0.9% for EVD cases, both of which were lower than observations from other studies which showed a complication rate ranging from to 33% to 46.7% [41,43,44] and mortality rate ranging from 4.6% to 46.9% [33,34,41,42].

In the present retrospective file review, the impact of various factors like patient demographics, past medical history, and inpatient management on device survival was analyzed. BMI CSF Shunting System, especially VP shunt, showed favorable clinical performance regardless of different types of patients or inpatient management. No factors were found to influence the rate of VP shunt failure significantly. This could be due to relatively small numbers in subcategories, resulting in a low statistical power. Factors like sex and co-morbid conditions did not influence the frequency of EVD failure in this study as well; however, younger age seemed to be an independent risk factor of the EVD survival and infantile hydrocephalus was linked to a higher risk of EVD malfunction. Such observations were also established in other studies investigating EVD-related complications [43]. The rate of revision was found to be dependent on age and infantile diagnosis [4,8], and neonates and infants were noted to have a higher rate of device failure [45]. Although some plausible theories go as "elderly patients had fragile and atrophic brain parenchyma and surgical intervention in such patients may probably associated with a higher risk of iatrogenic trauma inflicted to the nearby tissues", it was not observed in real-world practice from previous studies and our study. However, it still cannot be said with certainty, given that we did not have enough data from pediatric patients for comparison.

Another finding noted in our study was that the rate of EVD malfunction was found to be related to catheter diameter the smaller catheter was associated with the better EVD survival, compared to the bigger catheter. A plausible explanation is that it was hard to have delicate control of the flow speed using a big catheter; besides, there can be treatment selection bias when choosing the catheter for patients with different conditions. Neurosurgeons tend to use big catheters for patients with more severe brain trauma to evacuate the cerebral hemorrhage immediately, relieve pressure on the brain, and prevent blood clot causing obstruction. Therefore, it was very likely that the severity of patients' condition contributed to different outcomes observed between small and big catheters, and we presented our conclusions with the understanding that they are derived from nonrandomized data, with inevitable variables.

An intriguing finding noted in our study was that patients with GCS 9-13 before operation were more likely to have EVD malfunction than those with GCS 3-8. However, the association between GCS score and EVD malfunction was not observed in GCS 14-15 versus. This finding requires further investigation as the results were made out of imbalanced populations, with the lack of data from patients with GCS 3-8. For patients at comatose state (GCS 3-8), neurosurgeons take conservative treatment measure like ICU stay for further observation rather than doing brain surgery immediately as it can put patients in even higher risks. Only under stable condition will patients with GCS 3-8 undertake the CSF shunting procedure. Compared to patients

at comatose state, the treatment priority for patients with moderate brain injury (GCS 9-14) is usually the brain surgery to draining the bleeding as majority of such patients are suffering from structural brain damage.

In our study, we did not find prolonged antibiotic therapy (>1 week) to be the significant factor that lead to EVD malfunction, which was contrary to previous reports. While the role of short-term prophylactic antibiotics in neurosurgery is well-established [46], many studies have also shown that prolonged use of antibiotics can promote anti-microbial resistance and serve as a means of "natural selection" for more virulent pathogens [47]. Infection with such organisms can prove to be detrimental for shunting system survival [48-50]. Additionally, some evidence also suggests that prolonged use of antibiotics can impair the natural process of suppurative inflammation and result in the formation of conglomerate micro-abscesses [51]. These can impede CSF flow through the shunt system, ultimately culminating in shunting system failure.

In all, the association of above factors with worsened shunt survival observed in our study needs to be explored further through larger prospective studies. Our study was subject to a number of limitations, which must be kept in mind before reaching a conclusion. Given the retrospective nature, certain clinical information is not complete in all the subjects, including etiology of hydrocephalus, valve type, valve settings, onset and duration of symptoms, and neurologic status at the examination. At the investigational hospital, surgical procedures were performed by more than ten different neurosurgeons. However, in the present study, we did not compare the shunt failure rate among different neurosurgeons. Moreover, preference of surgical methods was not analyzed separately; therefore, the influence of surgical procedure on subsequent device survival could not be assessed. Among the patients included in the study, not all patients had regular follow-up after the surgery, which may lead to under-detection of device complications. In addition, some patients who had undergone were excluded from the analysis due to unavailability of medical records and missing data, which may result in possible selection bias. Lastly, BMI VP shunt was newly introduced in the investigational hospital in 2012. There were no enough cases using VP shunt in our study. Also, based on the imbalanced number of adult and pediatric patients, little could we know if a pediatric case was associated with higher risks of device failure as the previous reports.

Conclusion

Despite the limitations of being a retrospective study, it bears significant value as it is the first study to gather and analyze data of patients with hydrocephalus undergoing BMI CSF Shunting System placement in a real-world setting. Compared to previous reports, EVD showed comparable clinical performance and VP shunt showed superior clinical performance. Both EVD and VP shunt were safe, with limited or no device-related infections reported. Our study sheds some light on the long-term functional outcome of BMI CSF Shunting System survival; however, further study on a larger population is warranted to verify the predictors of device survival we identified in this analysis.

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Authors Contribution

Chieh-Tsai Wu and Po-Chuan Hsieh conceived and designed the study. Chieh-Tsai Wu, Hsiu-Ling Chang, and Chen-Ying Liu collected and analyzed the data. Chieh-Tsai Wu, Hsiu-Ling Chang, and Chen-Ying Liu interpreted the data, discussed the results, and contributed to the final manuscript.

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