



Original Research

Complications After Dual Placement of a Baclofen Pump and Ventricular Shunt in Individuals With Severe Brain Injury



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KEYWORDS

Baclofen;
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shunt

Abstract Objective: To assess the complications of dual placement of an intrathecal baclofen (ITB) pump and a ventriculoperitoneal shunt (VPS) in people with severe brain injury.

Design: Case series.

Setting: Referral center, ambulatory, and hospitalized care.

Participants: Referred sample (N=9) composed of 5 men and 4 women with severe brain injuries (5 traumatic brain injuries, 3 subarachnoid hemorrhages, 1 intracerebral hemorrhage) and a mean disease duration of 6 ± 4.5 years (range, 0.5-11.4y).

Intervention: Both systems (ie, an ITB device and a VPS system) were implanted in all participants.

Main Outcome Measures: We assessed the number and type of complications that occurred after implantation of the second system, as well as subsequent interventions.

Results: The ITB delivery system was implanted after the VPS system in 5 patients (ITB group), and the VPS system was the second implanted system in 4 groups (VPS group). Seven complications occurred in 7 patients after implantation of the second system, 4 in the ITB group and 3 in the VPS group. Three of the complications were drug-related, 2 were procedure-related, and 2 were device-related. The complication occurred within 4 days after implantation of the second system in 6 patients.

Conclusions: Complications are frequent in patients who undergo implantation of both an ITB delivery device and a VPS system. Drug-related complications were more common.

List of abbreviations: ITB, intrathecal baclofen; VPS, ventriculoperitoneal shunt.

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Complications occurred more often when an ITB device was implanted as the second system. The critical period is the first 4 days.

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Intrathecal baclofen (ITB) is a well-established treatment option in patients with severe spinal or supraspinal spasticity in neurologic disorders of any etiology, such as cerebral palsy, spinal cord injury, traumatic brain injury, and multiple sclerosis.¹⁻¹⁹ It is commonly administered to patients not responding sufficiently to oral baclofen or when nontolerable side effects to oral antispastic medication occur.

Patients with spasticity of cerebral origin may develop disturbances of the cerebrospinal fluid circulation. Disorders of the cerebrospinal fluid circulation usually require implantation of a valved tubing system to divert cerebrospinal fluid into other body cavities. The annual incidence rates range from 30 to more than 300 per 100,000 population depending on age, etiology, and geographic region.²⁰ Posttraumatic hydrocephalus might occur in as many as 14% of patients with severe traumatic brain injury or 36% in cases with a preceding decompressive craniotomy.²¹⁻²³

Both ITB devices and ventriculoperitoneal shunt (VPS) systems are associated with a risk of complications. In a retrospective analysis of 116 patients with an implanted ITB system, 32 complications occurred in 25% (29 out of 116) of the patients within an 11-year observational period (23 catheter-, 4 pump-, and 5 procedure-related).¹⁹ The cumulative complication rate at 5 years was 32% in 14,455 individuals with VPS placement in California, with significantly higher rates of shunt complications revealed in children (48% compared with 27% in adults). In addition, young age, male sex, low socioeconomic status, and obstructive hydrocephalus were associated with an increased risk of shunt complications.²⁴ According to a meta-analysis, the rate of shunt failure was 31% in the first year and 5% per year thereafter in children younger than 17 years of age.²⁵

In patients who require both an ITB device and a VPS system, possible interactions and cumulative complications remain unclear. Based on small case series and retrospective data analyses, there is evidence for interactions and higher complication rates when an ITB delivering system is implanted and a VPS system already exists or vice versa.^{26,27}

The aim of this study was to assess complications occurring systematically in consecutive patients undergoing successive implantation of both an ITB device and a VPS system or vice versa. Furthermore, we sought to elucidate possible interactions between these systems.

Methods

A total of 116 consecutive patients were treated with an ITB device at the Department of Neurology between January 1, 2006 and December 31, 2018. Of these patients, 9 (8%)

underwent placement of both an ITB device and a VPS system and were eligible for inclusion in the final retrospective analysis. Five patients had the VPS system implanted first followed by the implantation of the ITB delivering system (ITB group). In the remaining 4 patients, the ITB device was implanted before the VPS system (VPS group).

Demographic information (sex, age), clinical details, and information on occurring complications were collected for all included patients (table 1). In patients who underwent a continuous ITB trial before implantation of the permanent ITB device, the implantation date of the intrathecal catheter connected to an external pump was used for further analysis. In patients who underwent an ITB bolus trial before implantation of the permanent ITB device, the implantation date of the permanent system was used for the final analysis. In patients who only underwent an implantation of an intrathecal catheter connected to an external pump (but no implantation of a permanent ITB device), the implantation date of the intrathecal catheter connected to an external pump was used for calculation. In 1 patient, lumbar drainage was applied for evaluation purposes before implantation of the VPS and, in this case, the date of implantation of the lumbar drainage was used for calculation. In an earlier publication, complications were divided into drug-related (baclofen), procedure-related, and device-related problems.¹⁹ Procedure-related complications were defined as those associated with surgical intervention occurring within the first months after surgical intervention, such as cerebrospinal fluid leakage, subcutaneous seroma, subdural hygroma, subdural or intraventricular hemorrhage, or infections. Device-associated problems included complications related to the catheter or pump of the ITB device or complications related to the VPS system. They were classified as "early" within the first 2 months or "late" if they occurred more than 2 months after the surgical intervention. In addition, the administered baclofen dosage and shunt settings were recorded on the day of the complication. According to our previously published study, patients with a suspected complication underwent a detailed evaluation comprising the clinical situation, response to ITB, laboratory testing and imaging (ie, x-ray, computed tomography with or without contrasting agent, magnetic resonance imaging, or fluoroscopy), and surgical exploration in further unclear cases.¹⁹ The duration of follow-up was defined as the period from the implantation date of the second system until the last consultation.

Surgical interventions

ITB delivery systems are comprised of an intrathecal catheter connected to an external or implanted pump. The

Table 1 Demographic and clinical details of patients with an implanted ITB device and VPS

Patient No.	Pathology	Group	Complication	Time 1st Device to Complication (d)	Time 2nd Device to Complication (d)	Baclofen Dose (μg per d)	Shunt Setting (mmH_2O)	Intervention	Hospital Stay (d)	Outcome	Follow-up (mo)
1	ICH	VPS	Procedure-related	39	-	Minimal flow	-	Non-surgical (compression bandage)	101	Resolved	3.4
2	TBI	VPS	Device-related	-	109	150	80	Surgical (change of valve setting)	55	Resolved	72.8
3	SAH	ITB	Device-related	-	2	144	130	Non-surgical (repositioning of catheter)	67	Resolved	112.6
4	TBI	VPS	Procedure-related	-	0	160	-	Non-surgical (IV \S antibiotics)	59	Resolved	2.0
5	TBI	ITB	Drug-related	-	2	144	145	Non-surgical (reduction ITB dose)	222	Resolved	7.4
6	TBI	ITB	Procedure-related	-	4	216	100	Surgical (external ventricular drainage) and non-surgical (IV \S antibiotics)	110	Death*	3.7
7	TBI	ITB	Drug-related	-	4	384	85	Non-surgical (reduction ITB dose)	140	Resolved	20.2
8	SAH	VPS	Device-related	2	-	84	-	Surgical (implantation port-a-cath)	112	Resolved	3.7
			Drug-related	-	3	650	120	Non-surgical (pause in ITB administration)	68	Death \dagger	3.7
9	SAH	ITB	None	-	-	-	-	-	-	-	-

Abbreviations: ICH, intracerebral haemorrhage; IV, intravenous; SAH, subarachnoid haemorrhage; TBI, traumatic brain injury.

* Died owing to complication.

\dagger Death not related to complication.

Table 2 Complications occurring in patients with an implanted ITB device and VPS

Complications	ITB Group	VPS Group	Total No. of Patients
Drug-related	Impaired vigilance Bradycardia, hypotonia	Status epilepticus	3
Procedure-related	Intraventricular hemorrhage with occlusive hydrocephalus and ventriculitis	Infection of lumbar drainage preceding of VPS-implantation	2
Device-related			2
Early	Dislocation of intrathecal catheter of ITB device (fourth cervical vertebra instead of tenth thoracic vertebra)		
Late		Subdural hemorrhage over right hemisphere	

insertion of a temporary intrathecal catheter^a via the lumbar route at the lumbar space followed by subcutaneous tunneling and the connection to an external pump (CADD [before 2011]^b or Crono Five [since 2011]^c) was carried out by the attending neurologist in an inpatient setting at the Department of Neurology. The standardized catheter tip level for the intrathecal catheter was the lower thoracic vertebra column with the 10th thoracic vertebra being the primary target (controlled by x-ray). All other surgical interventions regarding the ITB device (ie, implantation of the permanent ITB device system, replacement surgery owing to end of battery life, revision surgery after a device-related complication) were performed at the Department of Neurosurgery.

Statistical analysis

Data were summarized in cross tables. The mean, standard deviation, and range were calculated for time intervals. We used SPSS, version 24.0^d for data analysis. According to Austrian law on research, retrospective observational studies do not require ethics committee approval.

Results

Demographic and clinical details of the 9 patients (5 men, 4 women; mean age, 36.6±11.8y; age range, 25-62y) who had both an ITB delivery and a VPS system implanted are summarized in [table 1](#). The mean disease duration was 6±4.5 years (range, 0.5-11.4y). The indication for the implantation of the ITB device was severe medically refractory spasticity in 7 patients and paroxysmal sympathetic hyperactivity in 2 patients. Reasons for implantation of a VPS system included posttraumatic hydrocephalus in 8 patients and hydrocephalus after nontraumatic subarachnoid hemorrhage in 1 patient.

In the 5 ITB group patients, the VPS was implanted 4.1±3.5 month (range, 1.1-8.8mo) after severe brain injury; the ITB device was implanted 12±10.5 months (range, 3-24.6mo) later. In the 4 patients in the VPS group, the ITB delivery system was implanted 5.5±2.2 months (range, 3.4-7.5mo) after the initiating event; the VPS system was implanted 10.6±16.7 months (range, 0-35.3mo) later. Six patients underwent a continuous ITB trial before

implantation of the permanent ITB device. Two patients had only undergone the continuous ITB trial with an intrathecal catheter connected to an external pump and did not receive a permanent ITB system. One patient died during the follow-up period owing to a severe complication as described below; in the other patient, the implantation of the permanent ITB device was refused by the patient's relatives. One patient underwent an ITB bolus trial before implantation of the permanent ITB device.

Complications

A total of 9 complications (3 drug-related, 3 procedure-related, 3 device-related) occurred in 8 out of 9 studied patients. One patient sustained 2 complications (first after ITB device implantation, second after VPS implantation), 1 patient experienced only 1 complication after implantation of the first system (ITB device), and 1 patient had no complications. Thus, 2 complications were detected in 2 patients after implantation of the first system, both of whom were in the VPS group, after implantation of the ITB device). In 1 patient, the complication was procedure-related (leakage), which was resolved after compression bandage with no further complications after implantation of the VPS. In the other patient, the complication was device-related. This patient experienced dislocation of the catheter during the continuous ITB trial, which was replaced by an intrathecal port-a-cath for the continuous ITB trial, then the ITB device and later the VPS system were implanted, followed by a second complication.

Seven complications were recorded in 7 patients after implantation of the second system, including 4 complications in the ITB group and 3 in the VPS group. Three complications were drug-related (2 in the ITB group, 1 in the VPS group), 2 were procedure-related (1 in the ITB group, 1 in the VPS group), and 2 were device-related (1 in the ITB group, 1 in the VPS group). The complications are described in detail in [table 2](#). In 6 patients, the complications occurred an average of 2.7±1 days (range, 1-4d) after implantation of the second system (4 in the ITB group, 2 in the VPS group). The remaining patient experienced a complication 3 months and 25 days after VPS implantation (VPS group; dysfunction of VPS with consecutive subdural hemorrhage). The mean duration of hospital stay after a

complication was 119.3 ± 91.0 days (range, 49-273d) from the complication until discharge in the 7 patients.

The mean follow-up duration of the 9 studied patients was 3 ± 3.7 years (range, 0.3-10.6y). Two patients died during follow-up after implantation of the second system. One patient in the ITB group died owing to intraventricular hemorrhage with consecutive occlusive hydrocephalus and subsequent fulminant ventriculitis 3 months and 20 days after the second implantation (ITB device). The other patient in the VPS group died 2 months and 8 days after implantation of the VPS owing to sepsis (related to an underlying disease).

Discussion

This study provides a systematic assessment of complications in 9 out of 116 (8%) consecutive patients who underwent implantation of both an ITB device and a VPS system. Seven complications occurred in 7 patients, approximately half in the ITB group and half in the VPS group. Nearly half of the complications were drug-related. More than 80% of the complications were encountered within the first 4 days.

Different mechanisms of interaction between the 2 intrathecal systems might explain the complications observed in our study population, including enhanced cerebrospinal fluid circulation in a normally functioning VPS system resulting in baclofen overdose and intoxication (all 3 drug-related complications) and overdrainage of the VPS system subsequently resulting in subdural hemorrhage (late device-related complication) and intraventricular hemorrhage (procedure-related complication). Two complications cannot be explained by an interaction between the 2 systems. An accidentally dislocated intrathecal catheter of the ITB device appears to be solely device-related, and the infection of the lumbar drainage preceding the implantation of VPS solely procedure-related.

Only 1 small case series with 3 children and a retrospective data analysis addressing complication rates and possible interactions in both an implanted ITB delivering and a VPS system has been published.²⁶ Fulkerson et al discuss 3 potential serious interactions of the 2 devices. In the first case, complete obstruction of the proximal VPS catheter resulted in a VPS dysfunction and subsequent progressive worsening of paresis and hypotonia. The authors discuss that a dysfunction of the VPS might alter the cerebrospinal fluid clearance and thus the pharmacology of ITB. The clearance of ITB decreased with the VPS dysfunction, leading to elevated levels of ITB and a subsequent clinical picture of baclofen overdose or intoxication. In the second case, the patient developed feeding difficulties 2 days after implantation of an ITB device. A computed tomography scan showed a marked ventricular dilation despite an apparently functioning VPS, which could be solved with neck-wrapping. The authors hypothesize that ventricular size might change after any new access to a system acting at the thecal space, even with a functioning VPS. In the third case, the patient presented with drainage from the lumbar wound approximately 2 weeks after implantation of the ITB device. Investigations revealed increased ventricular size and shunt disconnection. In the subsequent shunt revision surgery, a proximal obstruction

of the shunt was found. Based on this case, the authors suggest that testing the function of a patient's shunt before implantation of an ITB device is mandatory. The 3 cases described by Fulkerson et al could all be considered VPS-related, as they included an obstruction of the VPS leading to a worsening of paresis and hypotonia, a ventricular dilation despite functioning VPS leading to feeding difficulties, and a ventricular dilation owing to a shunt obstruction followed by shunt disconnection. Interestingly, these 3 specific complications did not occur in our series of a larger study population. Owing to use of different VPS systems in the year 2006, we cannot exclude methodological differences in our study, which comprises 2007 through 2018. Moreover, the comparability of the 2 study populations is limited, as all patients described by Fulkerson et al received the VPS first, followed by the ITB device. In our study population, roughly half had the ITB device implanted first, and the other half received the VPS system first.

Four patients from our study group presented with the clinical picture of a baclofen overdose or intoxication induced by different mechanisms. In 3 patients, the complications were drug-related; in 1 patient, the complication was device-related. In the fourth patient, the intrathecal catheter of the ITB device was accidentally placed at the level of the fourth cervical vertebra instead of the intended 10th thoracic vertebra. The impaired vigilance in this patient could be explained by the different level of the neural axis exposed to ITB. Higher baclofen concentrations might be measured at the cervical location of the catheter tip with its proximity to the brainstem based on the lumbar-to-brain gradient. In the other 3 patients with clinical signs of overdose or intoxication of baclofen, the "normally" functioning VPS system might have led to altered or enhanced cerebrospinal fluid circulation, resulting in higher baclofen concentrations as the 2 systems accessed the thecal space. Thus, clinical signs of overdose or intoxication require a reduction and often also a slower titration of the daily baclofen dosage.

Two encountered complications, namely subdural hemorrhage in a patient in the VPS group and intraventricular hemorrhage in a patient in the ITB group, were most likely caused by overdrainage. The implantation of a second system also acting in the cerebrospinal fluid system might have altered cerebrospinal fluid circulation and drainage. In the patient who had intraventricular hemorrhage in the ITB group, spinal fluid leaks around the intrathecal baclofen device might also have played a role. This has been described in children as well as adults.²⁸

Abousamra et al focused on infections in patients with both implanted systems, which occurred in 5 out of 31 (16%) children in their study.²⁷ For that purpose, cerebrospinal fluid was obtained from the side access port and from the VPS reservoir. Three out of 5 children had 1 system infected, and 2 had both systems infected. We found a comparable rate of infections in our patient series (2 out of 9 patients, 22%), which were considered procedure-related complications. Both patients had a cerebrospinal fluid infection with *Klebsiella pneumoniae* diagnosed after a lumbar puncture. In 1 patient, the infection occurred after implantation of lumbar drainage to evaluate VPS purposes; in the other patient, the infections occurred after

Table 3 Recommendations to prevent complications*Recommendations*

1. Functional testing of first implanted system before implantation of a second system
2. Start with a lower daily baclofen dosage and slow titration of daily baclofen dosage after implantation of a second system to prevent baclofen overdose ("start slow and go slow")
3. Pay attention to signs of overdrainage necessitating adjustment of shunt setting
4. Close monitoring of patients for drug-, procedure-, and device-related complications during the first 4 days after implantation of a second system (critical period)

implantation of an external pump connected to an intrathecal catheter for ITB delivery and resulted in ventriculitis in both. The infection was successfully treated in 1 patient, but resulted in the death of the other patient approximately 4 months later.

Implications for clinical care

Patients with both an implanted ITB device and a VPS system appear to be prone to a higher complication rate, as both systems have access to the thecal space. Implanting each device separately is already associated with a risk of complications,^{19,24} but implantation of 2 intrathecal systems appears to be associated with an even higher risk.

Based on our findings, we suggest the following strategies to prevent complications as much as possible: (1) functional testing of the initially implanted system before implantation of the second system; (2) starting with a lower daily baclofen dosage and slow titration of the daily baclofen dosage after implantation of a second system to prevent baclofen overdose and intoxication based on enhanced cerebrospinal fluid circulation ("start slow and go slow"); (3) attention to signs of overdrainage necessitating an adjustment of the shunt setting; and (4) close monitoring and observation of patients after implantation of the second system for drug-, procedure-, and device-related complications during the critical period of the first 4 days (summarized in [table 3](#)).

Study limitations

Limitations of our study included the retrospective character of the data analysis and the heterogeneous patient population with the need for both an ITB device and a VPS system.

Conclusions

To our knowledge, this is the first study to systematically assess complications in patients undergoing both placement of an ITB device and a VPS system. After implantation of a second system with access to the thecal space, complications occurred in as many as 80% of the patients. Enhanced cerebrospinal fluid circulation and overdrainage were the possible mechanisms of interaction between the 2 systems explaining the majority (71%) of complications. The common clinical denominator in both the ITB and VPS groups appears to be the risk of baclofen overdose and

intoxication, as drug-related complications were the most commonly detected problems.

Further larger prospective multicenter studies are necessary to investigate the role of these 2 implanted systems with access to the thecal space to support these preliminary findings.

Suppliers

- a. Codman; Johnson & Johnson Medical Devices Companies.
- b. CADD; Smiths Medical.
- c. Crono Five; Canè S.p.A.
- d. SPSS, version 24.0; IBM Corp.

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