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ORIGINAL PAPER

Intrathecal baclofen therapy: complication avoidance and management

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Abstract
Purpose Intrathecal baclofen (ITB) therapy is an accepted treatment modality for spasticity and dystonia. Several complications related to ITB have been described, including mechanical malfunctions, infections, cerebrospinal fluid fistula, and baclofen withdrawal or overdose. In this study, we present our institutional experience with ITB therapy, emphasizing complication avoidance and lessons learned.
Methods The charts of 87 patients treated with ITB therapy were retrospectively reviewed. The primary surgical technique, complication type and timing, method of treatment, and outcome were analyzed.
Results Thirteen out of 76 (17.1%) patients primarily treated at our department had 25 complications. The first complication occurred 17.5–30.9 months (mean 24.2±6.7) after the pump implantation. Additional four patients with pumps placed elsewhere had six complications and were subsequently treated by our group. The main complications were: catheter fracture (11), subcutaneous fluid collection (5), lumbar wound/CSF infection (3), lumbar catheter or connector protrusion (3), pump malfunction (3), distal catheter migration outside the thecal sac (2), and baclofen withdrawal (1). Of the patients in the NYULMC group, six were treated by a single surgical procedure, six underwent multiple surgical procedures, and one was managed conservatively. In retrospect, changing the surgical technique, or adding an abdominal binder may have prevented 17 complications (54.8%). There were two deaths that were unrelated to the ITB therapy.
Conclusion ITB therapy is associated with complications, many of which require additional surgery. Some of these complications are avoidable by adhering to a strict surgical technique and a proper criterion for patient selection.

Keywords Intrathecal baclofen therapy · Complications · CSF leak · Intraventricular baclofen

Introduction

Intrathecal baclofen (ITB) systems have been effectively used since the mid-1980s for treating patients with severe spasticity [29]. The therapeutic advantage of ITB systems has especially been seen in cases with medically refractory spasticity. Common indications for ITB therapy include cerebral palsy, traumatic brain injury, spinal cord injury, diffuse anoxic brain injury, hereditary diseases such as Rett syndrome, and other etiologies leading to severe and unmanageable spasticity [17, 19, 25]. Several studies have supported the use of ITB systems for the treatment of dystonia too [5, 27]. Although some patients may not regain complete functionality or remission of pain, ITB therapy has shown to positively affect the quality of life and ease patient daily treatment by their caregivers.

While ITB is an effective treatment option, there are still significant complications associated with the intricate surgical technique and prolonged duration of treatment.

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Complications may range from constitutional symptoms related to the Baclofen drug (such as diarrhea or vomiting), to equipment failure, and infections [5, 31].

In this study, we present our institutional experience with ITB therapy, emphasizing complication avoidance and lessons learned.

Methods

All cases undergoing ITB pump-related procedures at the Department of Neurosurgery at New York University Langone Medical Center (NYULMC) between July 1998 and December 2008 were included in this series. Data were retrospectively collected from the surgical and follow-up charts at the Pediatric Neurosurgical Division at NYULMC, as well as from the preoperative and follow-up charts at the Hospital of Joint Disease, NY, NY. IRB approval was given prior to data collection.

The current series includes two subgroups: patients that underwent primary implantation of an ITB pump at the NYULMC, and those who were implanted elsewhere and were treated for ITB-related complications at our center. As a routine, all patients who underwent a primary implantation of ITB pumps were referred by a neurologist specializing in spasticity, rehabilitation, or movement disorders. The patients underwent presurgical neurological and physical therapy evaluations, and were followed by the same neurologist postoperatively. Pre- and postoperative Ashworth spasticity scores were available for only a subset of patients, and as the focus of this paper was not the degree of spasticity improvement, we did not include the scoring in the current paper.

The goals for ITB therapy in the current series were increasing the functionality of patients who were cooperative and awake, as well as palliative treatment, aiding the primary caregivers in the routine treatment of patients who were not cooperative or in chronic vegetative state (such as following diffuse anoxic brain injury).

ITB pump implantation was routinely preceded by an ITB trial, and only patients responding favorably to the trial were offered a permanent pump.

Implantation procedure

The site of pump placement is decided after discussion with the patient and/or their caretaker about their daily activities, posture of the body, and previous procedures such as gastrostomy, VP shunt, etc. Following preoperative prophylactic antibiotics (typically Ancef or Clindamycin), patients undergo general endotracheal anesthesia and are placed in either a left or right lateral decubitus position depending upon the site of the pump placement. For placement of the intrathecal catheter, a Touhy needle is used to enter the lumbar thecal sac through a vertical incision at the level of the lower lumbar spine (L4-L5 or L3-L4). The needle is then angulated upward. As a routine, fluoroscopy is not used; however, for select patients, such as those with spinal fusion, or for patients with scoliosis, fluoroscopy is recommended, and rarely, a laminectomy may be necessary to access the spinal canal. Upon entering the lumbar cistern, the catheter along with guidewire is advanced to the planned spinal level (approximately lower thoracic spine in paraparetic cases, and upper thoracic spine in tetraparetic cases). The height of the intrathecal catheter is estimated by presurgical measurement of the distance to the desired level. The subcutaneous tissue is dissected until the fascia is reached and a purse-string suture is placed around the needle, which is then withdrawn. The guidewire is then withdrawn too and spontaneous cerebrospinal fluid (CSF) flow is noted. The purse-string suture is then tied around the intrathecal catheter, thus preventing a pericatheter CSF leak. The intrathecal catheter is cut so that only about 4–5 cm of stump remains, and is attached to a straight connector and to the primary tube (that later attaches to the pump). A silicone covering is placed over the connection site and secured with ties. The primary tube is tunneled from the abdominal wall wound (at the level of the pump site—either subcutane, or subfascia) to the spinal subcutaneous pocket, and pulled so that the tubing lies loose with a small loose loop in the pocket, and the connector lies in the subcutaneous tract slightly lateral to the spinal midline incision.

For pump placement, a 10-cm horizontal skin incision is made slightly under the level of the lower rib. The subcutaneous tissue is then divided to create a pocket. If a subfascial pocket is desired, then the rectus sheath is identified and divided horizontally to create a subfascial pocket [24]. It is important to verify hemostasis prior to placement of the pump. All pumps implanted were Medtronic Synchromed EL or Synchromed II pumps, including 10, 18, 20, and 40 cc volumes. The pump is soaked in bacitracin solution and filled with baclofen. It is then connected to the primary catheter, a tie is placed over the connection site to protect against detachment, and the pump is placed in the pocket. Careful attention is paid to avoid any kinking or malposition of the catheter. The pump is placed such that the tubing lies posterior to the pump to prevent inadvertent tubing injury when filling the pump. Fascia, subcutaneous tissue, and skin are then closed in layers. Lastly, the pump is programmed to reflect catheter lengths, pump volume, and required daily dose.

Postoperative course

Following surgery, antibiotics are continued for 24 h, and patients are referred to rehabilitation or discharged home within 1–2 days.

Data analysis

Data was tabulated using Excel software. Data is presented as mean ± SD.

Results

A total of 87 patients were included in the current series. There were 59 males and 27 females between the ages of 5 and 27 years (16±10). Of these patients, 76 received their first ITB pump implant at NYULMC (NYULMC group), and 11 were referred to NYULMC for an ITB pump-related complication after being primarily treated elsewhere (non-NYULMC group). The indications for ITB pump are presented in Table 1. Seventy-seven (88.5%) patients were treated with the goal of functional improvement, while therapy for ten (11.5%) patients was directed as palliative care. Thirty-four (39%) patients underwent surgical procedures for non-complicated indications such as battery expiration/pump size upgrade (29), pump removal (3), and catheter revision for spinal surgery (2). No major intraoperative complications occurred.

Complications

There were a total of 25 complications noted in 13 (17%) patients primarily treated at NYULMC. The first complication in all patients occurred between 17.5 and 30.9 months (24.2±6.7) after pump implantation. Four patients in the non-NYULMC group had a total of six complications, which were treated at our institution. Complications included catheter fracture (11), subcutaneous fluid collection (5), lumbar wound/CSF infection (3), lumbar catheter or connector protrusion (3), pump malfunction (3), distal catheter migration outside the thecal sac (2), catheter disconnection (1), intrathecal catheter flipping (1), baclofen withdrawal (1), and idiopathic system malfunction (1; Table 2).

Table 1 Indications for ITB

Indication for ITB pump implantation	No. of cases
Cerebral palsy (including two patients with dystonia)	61
Traumatic brain injury (TBI)	6
Hereditary spasticity	6
Idiopathic spasticity	4
Rett syndrome	3
Hypoxic-ischemic encephalopathy (HIE)	2
Congenital viral infection	2
Other	3
Total cases	87

Amongst the NYULMC group, one patient was treated conservatively with no surgical treatment, six patients were treated successfully with one surgical procedure, and the remaining six patients required multiple surgical procedures. Of the four patients in the non-NYULMC group, two patients were treated with one surgical procedure, one patient was treated with two surgical procedures, and one patient underwent one surgical revision for a complication at NYULMC and a separate revision for another complication at another institution.

Preventable complications

Of the 25 complications in the NYULMC group of patients, 17 complications in a total of nine patients were presumed as being preventable. None of the six complications noted in the non-NYULMC group were attributed to preventable factors. In these scenarios, stricter criteria for patient selection, emphasis on postoperative care, or a re-envisioned surgical technique are thought to be the key in the prevention of such complications in the future.

Two patients (nos. 4 and 13) suffered multiple catheter-related complications due to severe dystonia. Both patients experienced fluid collections resulting from catheter fractures as well as a secondary complication due to either migration of the catheter outside the thecal sac or disconnection of the catheter. These complications were attributed to the fact that both patients were noted to be severely writhing due to excessive truncal dystonic movements. To avoid catheter malfunction in severely dystonic patients, intraventricular baclofen should be considered.

Two patients experienced catheter-related complications that could have been prevented with use of alternate surgical technique. One patient (no. 8) was initially treated for a complication at another institution, but came to NYULMC for revision of a spinal fluid collection. Upon exploration of the hardware, it was noted that there was no purse-string suture at the catheter exit site. This enabled the catheter to coil and migrate inside the thecal sac and cause the fluid collection. In the second patient (no. 12), the suture at the catheter–pump connection site had eroded through the catheter. This complication could have been prevented with the use of a sutureless silicon cap at the catheter–pump connection.

Equipment protrusions were preventable too, and were seen in three patients (nos. 6, 7, and 9). Protruding equipment included the pump (one patient) and the spinal right angle fixator (two patients). All three patients were required to undergo surgical revisions and removal of equipment to treat their complications (removal of right angle fixator in the two cases, and removal of all hardware in the third). In retrospect, the cause of protrusions was attributed to either the right angle fixator or subcutaneous

Table 2 Complications, treatment, and possible preventive measures

ITB Complications and Treatment in Total Series

			Infection		Mechanical		Other	Preventive Measure(s)
Pt	Sex	Age @ 1st ITB	Type	Treatment	Type	Treatment	Type	
NYULMC Group								
1	M	4			Abd SC Fluid Collection[+]	Placed Abd binder		Maintain Abdominal Binder
2	M	7			Spinal Catheter Fracture	Catheter Replacement		
					Pump Malfunction	Pump Replacement		
3	M	5	Lumbar Wound Infection s/p unrelated spinal surgery	Equipment Removal				
4	F	6			Pump Catheter Fracture	Catheter Replacement		Use of sutureless silicon cap at pump catheter connection
					Spinal Catheter Regression	Catheter Replacement		Use of Intraventricular Baclofen
5	M	5			Catheter Fracture[a]	Equipment Removal[a]		
6	M	15			Right Angle Fixator Protrusion	Wound Revision and Removal of Fixator		Avoid use of Fixator
7	M	15			Right Angle Fixator Protrusion preceded by local infection	Wound Revision, Removal of Fixator, and Oral Antibiotics		Avoid use of Fixator
8	F	22			Catheter "MicroFracture"[a]	Spinal Catheter Replacement[a]		
					SC Fluid Collection along catheter track	Spinal Catheter Replacement		Use of purse-string suture at spinal catheter exit site
9	M	8			Pump Protrusion	System Removal[a]		Subfascial pump placement in thin patients
10	F	23			Fluid Collection	Muscle plug and Spinal Catheter Replacement		Consider shunt if suspected hydrocephalus
					Caudal facing Spinal Catheter Tip	Spinal Catheter Replacement		Consider shunt if suspected hydrocephalus
			Meningitis	Antibiotics	Fluid Collection and CSF Leak at lumbar wound	Equipment Removal	Baclofen Withdrawal	Consider shunt if suspected hydrocephalus
11	M	9			Spinal Catheter Fracture	Spinal Catheter Replacement with Pump revision for Battery Expiry		
12	M	13			Pump Catheter Fracture	Pump Catheter Replacement and Pump Upgrade to Larger Volume		Use of sutureless silicon cap at pump catheter connection
					Pump Catheter Fracture	Pump Catheter Replacement and Pump Upgrade to Larger Volume		Use of sutureless silicon cap at pump catheter connection
13	F	3			Lumbar Fluid Collection	Fascial Sutures at Spinal Catheter		Use of purse-string suture at spinal catheter exit site

					Pump Catheter Fracture	Pump Catheter Replacement	Use of Intraventricular Baclofen and limited spinal incision
					Pump Catheter Disconnection	Pump Catheter Replacement	Use of Intraventricular Baclofen and limited spinal incision
					Pump Catheter Fracture	Complete Catheter Replacement	Use of Intraventricular Baclofen and limited spinal incision
					Spinal Catheter migration	Equipment Removal	Use of Intraventricular Baclofen and limited spinal incision
Non-NYULMC Group							
14	M	8	Lumbar Wound Infection	Complete Equipment Revision	Catheter Fracture	Complete Equipment Revision	
15	F	15			Pump Malfunction	Pump Replacement	
16	M	NA[b]			Pump Malfunction	Complete Equipment Revision	
					Catheter Fracture[a]	NA[a]	
17	F	NA[b]			Unknown system malfunction	Pump Catheter Replacement	

[a] Complication treatment was completed at other institutions for which full details were not available

[b] Initial ITB implantation was completed at other institutions for which full details were not available

SC Subcutaneous, *NA* Not applicable, *Abd* Abdominal, *s/p-* Status post

pump placement. Such complications can be avoided by avoiding use of the right angle fixator and implanting pumps subfascially especially in cachectic patients.

Of the preventable fluid collections seen in two patients—one was treatable by replacement of the abdominal binder (no. 1), while the other required several surgical revisions and eventually equipment removal due to hardware infection (no. 10). In the second case, recurring pseudomeningoceles were related to an increased CSF pressure and moderate hydrocephalus. We believe that early CSF diversion may have obviated the need for multiple wound revisions leading to further complications.

Discussion

Intrathecal baclofen is widely used for treating spasticity, increasing the functionality in these patients and their overall quality of life. While the efficacy of ITB therapy has been supported by various studies [2, 7, 18, 23, 26, 32], there is still a wide range of complications associated with the treatment. Approximately 20–30% of patients with baclofen pumps have complications [14, 22], these include baclofen-related complications (overdose and withdrawal), infections (surgical site infections, hardware infections, and meningitis), and hardware-related complications (malfunction, leaks, etc). The most frequent complications include infections, CSF leaks, and catheter malfunctions [7, 31, 32]. Rarely, baclofen withdrawal and overdose can also occur [9, 12, 19].

Upon revision of our patient series, we noted that some complications could have been prevented by meticulous care in patient selection, surgical technique, and postoperative follow-up. These complications can broadly be classified into: catheter-related (migration or disconnection) and equipment protrusion, CSF leaks and infection.

Catheter migration or disconnection

Catheter-related complications are the most common device-related complications [13, 33]. Many studies have stated that the majority of complications that required repeated surgeries involved the catheter, both at the thecal and the pump site [1, 3, 11, 16, 20, 31]. In the current series, several cases had catheter-related complications. As noted in the literature, these complications were recurrent [1, 3, 11, 16, 20, 31]. The most common presenting sign was spinal/abdominal fluid collections. These complications were seen to be a result of the patients' severe dystonia and truncal rotation. We recommend that patients suffering from severe dystonia and contortion should be counseled of the higher possibility of catheter-related complications. Previous studies have shown that intraven-

tricular baclofen can be effective in treating patients with secondary as well as heterodegenerative dystonia, the site of action being at the cortical level [5, 8]. Intraventricular baclofen should be offered to the patients who primarily present with severe dystonia. We also observed certain instances where the fluid collection was caused by the securing tie eroding through the catheter connection to the pump. Currently, there are sutureless catheter connectors available that can be used to prevent these complications. We also had cases where the lumbar fluid collection was due to lack of purse-string suture at the catheter exit site. Purse-string suture at the level of the fascia is important also to prevent extrathecal slippage and coiling of the catheter.

Equipment protrusion

Equipment protrusion is a rare complication [28, 30, 31]. We observed equipment protrusion including exposure of the pump or the right angle spinal fixator in three cases. All three patients were extremely thin. A subfascial implantation in very thin patients to allow greater tissue coverage of the equipment could have prevented this [24]. Additionally, placement of the right angle fixator above the spinal fascia does not seem to be important, and may be omitted. Currently, we place the right-angle adaptor only in patients with thick subcutaneous tissue, in which the surgical wound is large and additional fixation is needed.

Abdominal pocket fluid collection

Postoperative effusions are one of the less commonly seen complications of baclofen pump surgery [3, 14, 22, 26, 31]. It may be benign (such as a seroma), or due to under lying problems like CSF leak, catheter-related issues, or infection. If the patient does not present with any other symptom other than the fluid collection, it is best observed and abdominal binder applied. If the effusion persists, then further investigation such as fluid aspiration (under strict sterile conditions), and imaging (such as a CT scan following contrast injection through the pump—to exclude a leak) should be done. We had one patient who presented with fluid collection in the abdominal pocket. This was due to premature removal of the abdominal binder. We recommend wearing an abdominal binder for at least 6 weeks after implantation of the ITB pump system to prevent fluid collection.

CSF leaks

CSF leakage is one of the common complications encountered in ITB pump implantation [3, 13, 22, 26, 31]. CSF leaks may cause pseudomeningocele and impair wound healing, and may lead to an infection if the wound breaks down [10, 13, 22, 24]. We observed one patient with an external CSF leak. In this case, there was a large pseudomeningocele that developed 6 months after the ITB pump implantation. A local thecal catheter and wound revision was followed by external CSF leaks. This patient had moderate ventriculomegaly, and a high opening lumbar pressure. Eventually, this patient got infected, and the hardware was removed. Finally, a ventriculoperitoneal shunt was placed due to onset of symptoms of elevated intracranial pressure (ICP). "Occult hydrocephalus" was found in a subset of patients with spasticity, despite the absence of symptoms of elevated ICP [4, 6]. This may lead to CSF leaks and pseudomeningoceles. We recommend that CSF opening pressures should be routinely measured prior to implantation of the ITB pump (for example, during the baclofen test), and brain imaging should be performed to rule out ventriculomegaly. We also recommend that a ventriculoperitoneal shunt should be considered in patients with high CSF opening pressures and ventriculomegaly prior to ITB pump implantation, even in the absence of overt symptoms and signs of elevated ICP.

Infections

Reported rates of infection vary between 3.4% and 41.7%, and may include wound infections and meningitis [3, 10, 11, 13, 15, 21, 22, 31, 34]. Two cases in the current series had superficial wound infections. One of the cases was secondary to external CSF leak, and the other was due to equipment protrusion. Both infections were secondary to other complications. Thus, every effort should be done to avoid the primary complications, which in turn decreases the risk of infection.

Study limitations

The retrospective nature, lack of pre- and postoperative Ashworth spasticity scores for some of the patients, and lack of details regarding patients treated elsewhere (despite it being a small group) make this analysis incomplete. However, the study focuses on a single centers' experience treating children with ITB, and thus, the lessons learned from the current series may shed light on the causes and prevention of some of these complications.

Conclusions

ITB therapy is an effective functional and palliative treatment for spasticity and dystonia caused by cerebral palsy, TBI, hereditary diseases, and other etiologies.

Although many complications are still associated with the treatment, careful analysis of such complications reveals preventative methods that can be taken to avoid some of the complications.

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