

Identification of complications in paediatric cerebral palsy treated with intrathecal baclofen pump: a descriptive analysis of 15 years at one institution

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Abstract

Purpose Intrathecal baclofen (ITB) treatment is used with increasing frequency in the cerebral palsy population. We describe the complications of ITB treatment, the incidence of complications, and our experience with their treatment.

Methods In a period of 15 years, 341 paediatric patients with cerebral palsy treated with ITB were evaluated. Device problems associated with the catheter or pump, or infection and complications such as cerebrospinal fluid (CSF) leak and postdural spinal headache, were reviewed. Infection was classified as early (≤ 90 days) or late (> 90 days) according to the time of onset.

Results The infection rate was 6.9% per procedure (50/720) and 14.6% per patient (50/341) over a mean 6.3 ± 3.9 years. There was a positive correlation between the risk of infection and preoperative comorbidities including epilepsy/seizure history, feeding tube, and mixed type cerebral palsy ($p < 0.05$, $p = 0.03$, $p = 0.01$, respectively). Eighty-five (24.9%) patients experienced 90 CSF leak episodes; 61 of these 85 patients had headache complaints as a result of CSF leak. There was a positive correlation between the risk of early infection and CSF leak ($p < 0.05$).

Conclusions The most common complication related to ITB was associated with pump and catheter problems. The rate of complications with the use of ITB is relatively high; however, based on the literature reports, it is the most effective treatment for severe spasticity and dystonia in patients with severe cerebral palsy.

Level of Evidence: III

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Keywords cerebral palsy; complication; intrathecal baclofen

Introduction

The intrathecal baclofen pump was developed in the 1990s, and efficacy was confirmed in children with cerebral palsy (CP) by Albright et al.¹⁻³ Because baclofen has low lipid solubility, it has a limited ability to cross the blood-brain barrier. When giving baclofen orally, very high doses are required for severe spasticity, and, even with high doses, tolerance develops.³ In cases of persistent spasticity not alleviated by oral therapy or other conservative treatment modalities, baclofen may be administered intrathecally.⁴ Penn and Kroin⁵ reported that after intrathecal administration to treat severe spasticity, muscle tone was immediately reduced. With intrathecal administration, the problem of poor absorption across the blood-brain barrier was overcome, and very low baclofen doses were able to achieve a much higher cerebrospinal fluid (CSF) concentration. Intrathecal baclofen (ITB) treatment has been found to be safe and effective in severe spasticity, and its use has also been documented to be effective in children with CP.⁶⁻¹⁰

Although ITB is an effective treatment option, there are complications associated with the surgical technique and long-term treatment requiring an implanted mechanical device. The complications include side effects associated with baclofen (such as overdose and withdrawal), CSF leakage, postdural spinal headache, infection, wound dehiscence and seroma, which may be seen in the early postoperative period, and mechanical problems such as pump and catheter problems that may occur in the late period.¹¹⁻¹⁵ The next step in ITB pumps is to improve results in children with CP, decrease complication rates, and increase quality of life with these complications.

The aim of this study was to describe the rates of complications after treatment of 341 paediatric patients with CP treated consecutively with ITB to evaluate risk factors over a 15-year period.

Methods

This study was a retrospective chart review begun after approval by our hospital's institutional review board. Paediatric patients with CP treated with ITB between 2004 and 2018 were included. Implantation was performed by experienced paediatric orthopaedists. The adjustment and refilling of the test dose were carried out by the physiatrist. Complications were managed by the paediatric orthopaedist.

A separate intrathecal injection as a trial to evaluate the outcome was recommended prior to implants.¹⁶ We realized early on that for spastic quadriplegia Gross Motor Function Classification System (GMFCS) IV and V, very little clinical information is gained from these trials whilst incurring risk of a CSF leak; therefore, we only carried out trials for a small number of ambulatory children. The catheter insertion site varied between the L1 and L5 intrathecal space. After obtaining good backflow, the CSF pressure was measured with a manometer. The catheter tip was adjusted according to the clinical situation using fluoroscopic control. If the aim was primarily for lower extremity spasticity reduction, the catheter tip was placed at mid to lower thoracic levels (T6–T10). If the goal was to reduce upper extremity spasticity or dystonia, the catheter tip was placed at C5–T1 levels. A SynchroMed II pump (SynchroMed, Medtronic Inc., Minneapolis, MN) was implanted subcutaneously and anchored to the abdominal fascia or between the external and internal oblique muscles. The trial was a separate procedure in which the effectiveness of baclofen was evaluated by injecting baclofen as a single dose into the intrathecal space prior to placement of an ITB catheter. This review includes several catheter and pump versions, and we have not made any separation for the specific model of either the catheter or the pump.

Gross Motor Function Classification System level, type of spasticity, seizure history, feeding-tube status, and inpatient events were recorded from review of the medical record. Intrathecal baclofen trials, primary ITB applications, and posterior spinal fusion (PSF) interventions were recorded during ITB treatment period. Complications such as CSF leaks, headache, mechanical problems related to pump or catheter, infections, drug associated with side effects, pump malfunction, wound dehiscence, and seroma were recorded. Because of these complications, catheter or pump replacement or revisions, catheter removal procedures, treatment methods, and dates were recorded. Pump replacement due to an expiring battery was not considered a complication.

Infection was classified as early (≤ 90 days) or late (> 90 days) according to the time of onset.¹⁷ Cerebrospinal fluid leak was recorded as posterior when it was under the lumbar incision or posterior wound, anterior if it was

around the pump or anterior wound, and on either side if it caused swelling on both sides. To make the differential diagnosis between CSF leak swelling or infection abscess, we routinely aspirated under sterile conditions in cases where infection vs. CSF leak was unclear. Often, it was immediately clear that there was completely clear fluid indicating a likely CSF leak or grossly purulent material indicating infection; however, samples were always sent for gram staining and culture. Usually CSF leaks were seen in the first two weeks after a dural puncture; however, some may occur later because of catheter fracture or disconnection. Cerebrospinal fluid leak was often accompanied by a complaint of spinal headache. The device problems included overdose or withdrawal of ITB; catheter fracture, kinking, occlusion, slippage, or pullout; and the pump failed, flipped, or became disconnected from the catheter. The occurrence of headache within five days after the ITB interventions, orthostatic pain, and agitation after sitting for 15 minutes or standing up to 15 minutes were symptoms used for the diagnosis of spinal headache.¹⁸ At the same time, spinal headache was considered when there was no other reason especially if a CSF leak was also present.

Statistical analysis

This study was a retrospective cohort study. Parametric and non-parametric analyses were performed. Descriptive and frequencies statistics were used to describe the population by mean and standard deviation. Chi-squared tests were used to compare GMFCS, complication type, spinal headache, CSF leak, infection, and reoperation status. Statistical analysis was performed using SPSS v25 (IBM, Armonk, NY, USA). Significance was set at $p < 0.05$.

Results

This review includes 341 patients with CP who were treated with ITB during a 15-year period (2004–2018). These 341 patients had 64 pre-implantation baclofen trials. Mean follow-up time was 6.3 ± 3.9 years (range six months to 15 years). The number of males (205) was higher than females (136). Demographic characteristics of the patients are presented in Table 1. The mean implantation age was 12.0 ± 4.4 years. Before primary ITB implantation, an intrathecal trial dose was performed in 64 of 341 (18.7%) patients. The C7–T1 level was where the catheter tip was most frequently placed (254 patients, 74%).

A total of 720 ITB procedures were recorded (Table 2). Overall, the mean complication rate was 0.44 per implant. The mean time between primary ITB and secondary ITB because of the complications was 3.8 ± 2.1 years. The mean time between primary ITB and replacement because of the end of the battery life was 5.2 ± 3.8

Table 1 Patient Gross Motor Function Classification System (GMFCS) level and type of cerebral palsy (CP).

Characteristics	Number	Percentage
GMFCS level		
I	1	0.3%
II	10	2.9%
III	79	23.2%
IV	111	32.6%
V	140	41.1%
Type of CP		
Dystonic	27	7.9%
Mixed	36	10.6%
Spastic	277	81.5%
Quadriplegic	236	
Diplegic	39	
Hemiplegic	2	

years. The mean time between replacement and second replacement in these patients was 4.7 ± 2.7 years. The PSF was accompanied by primary ITB pump implantation in 31 patients, and 94 patients had pump or catheter replacement or both during PSF not related to any malfunction.

Infection

The infection rate was 6.9% per procedure (50/720) and 14.6% (50/341) in the whole patient population over a mean 6.3 ± 3.9 years (range 0.5 to 15 years). These infections were treated with antibiotic administration and a total of 67 with operative irrigation and debridement. Eighteen (36%) patients required a pump removal and secondary ITB re-implantation for the infection. It was seen that seven (2%) of the late infections followed primary ITB and 13 (3.4%) followed secondary ITB procedures. Early and late infection risks did not increase after planned procedures because of the end of the battery life (respectively, $p = 0.492$ and $p = 0.239$), but secondary procedures because of the pump and catheter problems increased the risk of early and late infection (respectively, $p = 0.034$ and $p = 0.013$). Similarly, 19 patients had early infection and eight patients had CSF leak complaints, and there was a positive correlation between the risk of early infection and CSF leak ($p < 0.05$). There was a positive correlation between the risk of infection and preoperative comorbidities including epilepsy/seizure history, feeding tube, and mixed-type CP ($p < 0.05$, $p = 0.03$, $p = 0.01$, respectively). Only GMFCS V increased the incidence of infection ($p = 0.02$).

There were five early and two late period infections after 31 concurrent primary ITB and PSF. There were 10 early and seven late infections after 94 secondary concurrent ITB and PSF.

Cerebrospinal fluid leakage and postdural spinal headache

Eighty-five (24.9%) patients experienced 90 CSF leak episodes, and 61 of these 85 patients had headache

Table 2 The distribution of all intrathecal baclofen (ITB) procedures.

Procedures	Number	Percentage
Primary ITB	341	47.3%
Secondary ITB due to problems	132	18.3%
Secondary ITB concurrent PSF	153	21.3%
Secondary ITB due to battery end of life	94	13.1%
Total	720	

Note. PSF, posterior spinal fusion.

complaints as a result of CSF leak. Of the 83 (24.3%) patients, 95 were headache episodes. Sixty-one patients with headache (71.7%) had wound swelling as a sign of CSF leakage. The CSF leak episodes were seen in 85 patients and were due to three baclofen trials, 20 primary ITB implants, and 67 secondary ITB procedures. The interval between the CSF leak and the procedure was 13 (range 0 to 136) days. The time interval between the headache and the procedure was 8.4 (range 0 to 87) days. Some headache (24/85) complaints started without apparent swelling but were felt to be due to a significant CSF leak. There was a positive correlation between the risk of CSF leak and preoperative comorbidities including epilepsy/seizure history, feeding tube, mixed-type CP, and dystonic type CP ($p < 0.05$, $p = 0.01$, $p < 0.05$, $p < 0.05$, respectively). Gross Motor Function Classification System III and V increased the incidence of CSF leakage ($p = 0.02$ and $p = 0.04$).

Forty-one complaints of CSF leak or headache or both spontaneously resolved. Twenty-three patients with CSF leak and headache, one patient with only CSF leak, and two patients with only headache did not respond to conservative procedures, and a total of 33 epidural blood patches (EBP) were applied. The CSF leak was treated with a secondary ITB procedure in 20 patients (23.5%); two patients had cranioplasty cement used to close the spinal fusion laminectomy site and two patients had dura mater repair. An ITB revision was performed in a patient with CSF leak because of a pseudomeningocele. After CSF leakage, two patients had seroma formation in the pump pocket, and an abdominal wound exploration was performed.

Pump- and catheter-related complications

Catheter or pump problems or both were treated with secondary ITB procedures in 75/341 (21.9% of total patient population). Distribution of device problems associated with the catheter or pump and drug-related complications are presented in Table 3 and 4. Pumps migrated intraperitoneally, or perforated through the skin, and four patients developed wound dehiscence after PSF and ITB procedures. These wounds were treated with spinal wound exploration and vacuum-assisted closure.

Table 3 Complications of intrathecal baclofen (ITB) treatment including secondary ITB procedures and number of patients.

Complications	Number of ITB procedures	Number of complications	Number of patients
Withdrawal	0	10	10
Overdose	0	2	2
CSF leakage and/or headache	20	185	107
Pump and catheter problems	75	67	67
Wound dehiscence and/or seroma	3	6	6
Infection early (\leq 90 days)	8	30	30
Infection late ($>$ 90 days)	10	20	20
Total	132	320	150

Note. CSF, cerebrospinal fluid.

Table 4 Distribution of device problems associated with the catheter or pump.

Pump and catheter problems	Number of events
Catheter hub fracture	9
Catheter disconnection	16
Catheter kinking	11
Catheter occlusion	19
Catheter slippage	3
Catheter pullout	3
Pump failure	2
Pump flipping	4
Total	67

Discussion

This review focused on defining the complications encountered during the treatment of children with CP with ITB. In the literature, overall complication rates vary between 4% and 30%.^{14,19,20} These ratios may vary depending on the type of complication, characteristics of patients, type of disease, age, and duration of follow up.^{11,19,21} Stetkarova et al²² reported that the overall complication rate was 56% of patients receiving an ITB pump implant. In the current study, this rate was 44% of ITB pump implants. Although Motta and Antonello¹⁴ reported the most frequent complication as a pump problem, in our study, as Dickey et al²³ reported, the most frequent problem requiring a second operation was the pump's end of battery life (44.8%), followed by pump and catheter problems and CSF leak. In the current study, 150 patients (43.9%) had at least one complication or side effect. The problems encountered with pumps and catheters required unplanned secondary surgery, and these surgeries caused other complications such as a CSF leak or headache, or both, and infections. We believe that these high rates are a reflection of our long-term follow-up period and the inclusion of all complications, not only those requiring a surgical procedure. It should also be noted that we have not evaluated different pump or catheter models.

The most frequent second procedure was the end of the battery life in 127 patients (37.2%) with a mean six years' follow up. Twenty-six (20.4%) had battery depletion for the second ITB replacement. All were easily treated with 153 replacement procedures. In another study, the rate

of replacement required because of battery depletion was 33%, and the secondary replacement rate was 6.3%.¹⁴

Infection

In our study, the total infection rate was 14.6% (50/341) over a 6.3-year follow up with a mean of 2.3 procedures per patient. To treat the infections, we had a 5.5% (19/341) secondary ITB procedure rate and 67 irrigation events. Motta and Antonello¹⁴ reported an infection rate in children of 9.3% and another series reported 9%. Ghosh et al¹³ reported a 21.8% rate. The infection rate we reported in a previous study was 9.5%.²⁴ In the literature, it is generally misleading to compare the rates of infection because the incidence of infection is calculated per patient, not procedure.^{13,14,23,25}

Vender et al¹⁹ noticed a 9.7% rate of infection per ITB procedure. Gooch et al¹² found that the rate of patients requiring secondary procedures was 3.4%. Gerszten et al²⁶ reported this rate as 4.2%. Although the infection rate was 14.6% in our study, the infection rate per ITB procedure was 4.7%. Based on a previous study, we found that this rate was 2.4% for early infection and 2.7% for late infection and infection risk was the same for subcutaneous or subfascial pump implants.²⁴

In the literature, the rate of infection after pump replacement was found to be higher than that of the primary application.^{14,23,27} We found that secondary ITB procedures due to pump system problems increased the risk of infection, which is consistent with the literature. Vender et al¹⁹ stated that CSF leak was a risk factor for infection. In the study, there was a positive relationship between CSF leak and early infection.²⁸ Similarly, 19 patients had early infection and eight patients had CSF complaints, and there was a positive correlation between the risk of early infection and CSF leak in our study. We believe that early CSF leak diagnosis and treatment might reduce the risk of secondary infection and need for multiple secondary ITB procedures leading to further complications. Infections are more likely to be associated with the frequent medical comorbidities present in GMFCS V. Seizures and feeding tubes were more common in these patients, increasing the incidence of infection.

Cerebrospinal fluid leakage and postdural spinal headache

Each ITB implantation creates a wound hematoma and a risk of CSF leak, which may cause a spinal headache. After the needle forms a dural defect, CSF leaks into the epidural space resulting in a decrease in CSF pressure and volume. This reduction is responsible for the formation of spinal headache. Therefore, patients with CSF leak developed a headache 71.7% of the amount or pattern of CSF leakage after lumbar puncture. To reduce the risk of CSF leak, we keep all patients supine for 48 hours. We found a significant correlation between the risk of CSF leakage and the history of epilepsy/seizure, preoperative comorbidities such as feeding tube, mixed type CP, and dystonic type CP. We believe that abnormal and uncontrolled movement components of dystonia may make sealing of the dural puncture at the catheter entry site slower or less stable thereby causing an increased risk of CSF leakage. In 85 (24.9%) of our cases, 90 CSF leak episodes were documented which is higher than previously published rates.^{14,28} A study by Taira et al²⁹ reported the ratio of patients with CSF leak was 3.3% and another study gave a CSF leak rate of 3.9%.²⁸ Vender and colleagues¹⁹ declared that the rate of CSF leak and pseudomeningocele requiring reoperation in children with ITB was 12%. We attributed the high rate found in our study to the inclusion of not only those who were treated but also patients with spontaneous resolution. A study by Motta and Antonello¹⁴ reported that the incidence of CSF leakage was 13.7%, 35.5% of which needed at least one blood patch, and only three chronic CSF leakages required the system to be changed while the others cleared spontaneously. Similarly, in our study, 36% of patients with CSF leak required at least one EBP, but 20 (23.5%) patients required a secondary treatment. Four patients required surgical repair. In two patients with CSF leak, there was a seroma formation in the pump pocket and abdominal exploration was performed.

Neumann et al³⁰ found a headache incidence of 23% after intrathecal system insertion in the paediatric population; 79% received conservative treatment, and the others were completely resolved with EBP. The incidence of headache was 24.3% in our series, with 23 patients with CSF leak and headache; one patient with only CSF leak and two patients with only headache underwent EBP treatment.

Pump- and catheter-related complications

In our series, there were 75 (21.9%) patients with pump problems requiring a secondary ITB procedure. Gerszten et al²⁶ reported that incidence of catheter-related complication was 8.3%, and Taira et al²⁹ reported that it was

8.5%. In another study, 23% revision for malfunction secondary to the catheter problem has been reported.²⁶ Motta and Antonello¹⁴ found that this ratio was 15.1%. Campbell et al³¹ found a 17.6% rate of problems associated with the catheter. Ghosh et al¹³ found that the rate of mechanical complications requiring revision was 19.3% during a mean 38 months' follow up.

Programming error or device problems can cause overdose or withdrawal.^{32,33} In our study, 12 patients had symptoms or signs of withdrawal and overdose. Only three patients were followed up by monitoring in the intensive care unit. The problems of the other patients were not life threatening and were quickly solved with early diagnosis and making dose adjustments and bolus applications. Ghosh et al¹³ reported severely adverse effects associated with overdose in only one patient. Side effects in the literature are reported in case reports and are very rare complications.^{34,35}

In conclusion, the most common complications related to ITB are associated with pump and catheter problems. The rate of complications with the use of ITB is relatively high; however, based on the literature reports, it is the most effective treatment for severe spasticity and dystonia in patients with severe CP. On the basis of our current findings over a 15-year treatment period, a patient will need approximately 3.5 procedures with a total risk of infection of 14.6% and a 19.7% risk of pump and catheter problems. Most patients with CP should be strictly followed up because of complicated medical and surgical history. The surgeon who applies ITB treatment must know how to deal with multiple complications.

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COMPLIANCE WITH ETHICAL STANDARDS

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ETHICAL STATEMENT

Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors. This study was a retrospective chart review that received approval from Alfred I DuPont Children's hospital's institutional review board.

Informed consent: Informed consent was not required.

ICMJE CONFLICT OF INTEREST STATEMENT

None of the authors have any conflict of interest to declare.

AUTHOR CONTRIBUTIONS

AL: Study conception and design, data acquisition, data analysis and interpretation, drafting of the article, critical revision of the article for important intellectual content, final approval of the article, manuscript preparation.

KR: Data analysis and interpretation; drafting of the article, final approval of the article, provision of study materials or patients, statistical expertise, administrative, technical, or logistic support, collection and assembly of data, manuscript preparation.

CP: Data analysis and interpretation; drafting of the article, final approval of the article.

JPS: Study conception and design, drafting of the article, final approval of the article, manuscript preparation, performed measurements.

FM: Study conception and design, drafting of the article, critical revision of the article for important intellectual content, final approval of the article, manuscript preparation.

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