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Research Article

# Clinical Experience with Continuous Intrathecal Baclofen Administration Using an External Pump as a Screening Method for Functional Assessment

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**Abstract**

**Objective:** To describe our clinical experience with continuous intrathecal baclofen (ITB) using an external pump as a screening method.

**Design:** Retrospective medical records review.

**Participants:** Forty-three patients with disabling spasticity due to different causes treated in our centre between 2002 and 2016.

**Interventions:** Patients received continuous ITB for 1 to 10 days via an intrathecal catheter connected to an external pump as a screening method.

**Outcome Measures:** Effect of ITB on spasticity was assessed using Modified Ashworth Score (MAS) or description of functional hindrance resulting from spasms given by the patient, changes in general function, duration of trial, optimal dose of ITB, adverse effects during trial and whether patients received pump implant.

**Results:** In 4 patients trial was discontinued before effect on spasticity could be determined, in the other 39 patients ITB had a positive effect on spasticity or hindrance due to spasms. Mean MAS before trial was higher than at the end of trial (2.4 versus 0.8, z = - 4.572, p = 0.000). Seven different functions were considered for assessment, number of functions per patient varied. In 34 patients effect on function could be determined. Thirty-one patients received pump implant. Post-lumbar puncture headache was the most frequent adverse effect (44%).

**Conclusion:** Screening with continuous ITB using an external pump has an important advantage over that with bolus of ITB when assessing effect on function. However, risks of an external pump are higher and its use should be carefully considered. Measures to reduce adverse events should be explored.

**Keywords:** Baclofen; Intrathecal Injection; Muscle Spasticity; Extra Corporal Pump; Function

## Abbreviations

6MWT: 6 Minute Walk Test; 10MWT: 10 Metre Walk Test; ADL: Activities of Daily Living; BBS: Berg Balance Scale; CP: Cerebral Palsy; CSF: Cerebrospinal Fluid; GABA: Gamma-Amino Butyric acid; HSP: Hereditary Spastic Paraplegia; ITB : intrathecal baclofen; MAS: Modified Ashworth Score; MS: Multiple Sclerosis; PGIC: Patient Global Impression of Change; QOL: Quality of Life; SCI: Spinal Cord Injury; SCI-SET: Spinal Cord Injury Spasticity Evaluation Tool; TUG: Timed Up and Go test; UMNS: Upper Motor Neuron Syndrome

## Introduction

Spasticity is a common problem in patients with Upper Motor Neuron Syndrome (UMNS). The prevalence ranges from 17-42.6% in stroke [1-3], 60-78% in Spinal Cord Injury (SCI) [4-6] and 40-84% in Multiple Sclerosis (MS) [7-10]. It can have negative impact on patients' life in many different ways, including reduced functional independence [2,4,7,10,11] and quality of life (QOL) [9,12-14]. As a consequence, since patients need more support emotionally as well as in daily activities, the caregiver burden increases [15]. In addition, healthcare costs rise due to need for more home care, hospital admissions or specialist referrals [7,15-17].

Treatment of spasticity is only initiated when the spasticity causes severe pain or is disabling, interfering with hygiene, daily care or mobility. Several treatment algorithms have been developed [18,19]. The first step in these treatment algorithms is the correction of trigger factors and physical therapy. If this has no satisfactorily effect, the next step is to make a distinction between focal or general spasticity. Local spasticity can be treated with local denervation of the muscle or nerve or with surgery. Treatment options for general spasticity consist of several oral antispasticity agents, either monotherapy or in case of insufficient effect, in combination with other agents. When these treatments have no or limited effect or when side effects are severe, intrathecal baclofen (ITB) can be considered, for both multifocal and general spasticity.




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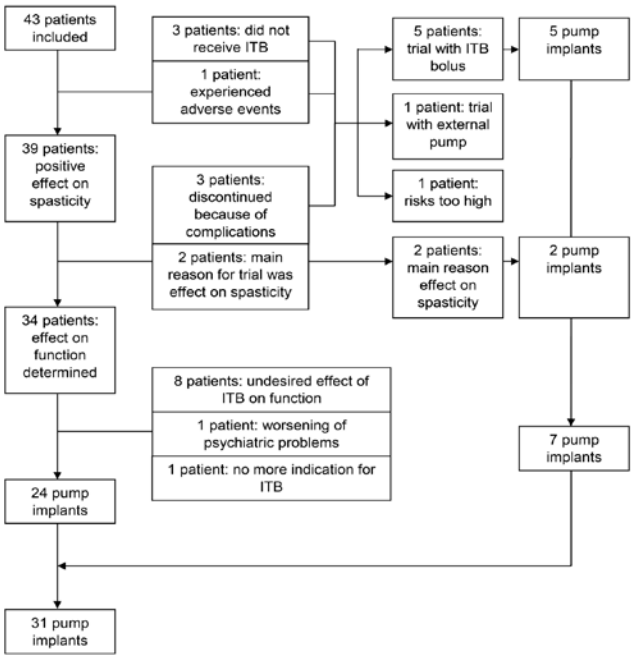


**Figure 1:** Procedural flowchart.

Baclofen is an agonist of Gamma-Amino Butyric acid (GABA), which is an inhibitory neurotransmitter. It is used as an oral drug to treat spasticity, however, because of the blood-brain barrier, most of the baclofen does not reach the spinal cord. It is reported that after oral intake, plasma baclofen levels are around eight times higher than that in cerebrospinal fluid (CSF) [20]. When it is injected directly into the intrathecal space, the blood-brain barrier is by-passed and the baclofen can be more effective with lower doses. Intrathecal baclofen is a widely accepted method and proven to be effective in reducing spasticity and in improving performance of activities of daily living (ADL) [21,22].

To determine whether ITB is a suitable treatment for a patient with spasticity or not, a bolus of baclofen is injected via lumbar puncture and its effect on spasticity is monitored. The effect starts after 30 to 120 minutes, is optimal between 4 and 6 hours and lasts between 6 and 8 hours [23]. Assessments of spasticity are carried out before the effect of Baclofen diminishes. In that short period it is challenging to evaluate the effect of ITB on function or on ambulation. In addition, the bolus cannot be titrated and small differences in effect on spasticity cannot be made.

An alternative procedure is to use an external pump to administer continuous ITB. To achieve this, an intrathecal catheter is placed and connected to an external pump, which controls the dose of Baclofen administered. The effect can be evaluated for a longer period of time and the dose can be adjusted. Besides evaluation of expected positive effects, negative effects on function such as transfers, standing and walking could also be observed.

Only 4 studies have described their experience with this screening method before pump implantation. They conclude that an external pump can be used to evaluate effect of ITB on function and walking ability in patients with Hereditary Spastic Paraplegia (HSP) [24], Cerebral Palsy (CP) [25] and patients with different causes of spasticity [26]. The method is also helpful to evaluate effect on the unaffected limbs in hemiparetic spasticity [27]. Three of these studies had a small number of patients, 1 in Heetla et al. [24], 3 in Harned et al. [27] and 7 in Bleyenheuft et al. [25], but Phillips et al. [26] included 57 patients.

**Table 1:** Patient characteristics.

| | | |
|---|---|---|
| **Mean age (SD)** | | 45.1 yrs (±11.9) |
| **Gender** | Male | 26 |
| | Female | 17 |
| **Diagnosis** | Multiple Sclerosis | 13 |
| | Spinal Cord Injury | 10 |
| | Cerebral Palsy | 6 |
| | Stroke | 4 |
| | Neuromyelitis Optica | 3 |
| | Traumatic Brain Injury | 1 |
| | Other | 6 |

The aim of this study is to describe our clinical experience with continuous ITB using the external pump as a screening method and to compare our method and results to that of previous studies.

## Methods

All patients who have had an external pump with continuous ITB between 2002 and 2016 as a screening procedure are included in this study. These patients were considered suitable for treatment with ITB, based on clinical evaluation. They were selected for trial with an external pump by rehabilitation physicians of the rehabilitation centre in agreement with neurosurgeons of the local general hospital. Patients were interviewed before the trial to find out which function, in their view, needed to improve or had to remain unchanged. Data was collected retrospectively from medical records. No patients were excluded.

The intrathecal catheters (Perifix® SoftTip) were placed by neurosurgeons or anesthesiologist of the local general hospital. From 2015 catheters were tunnelled under the skin to the lateral side of the patient, in order to make it more secure. The level of the tip of the catheter was determined depending on the level of SCI and desired effect. After placement of the catheter, the patients were directly transferred to the rehabilitation centre where the catheter was connected to the external pump and initial dose was started. Before 2015 this was the Crono five pump, since 2015 the CADD®-Solis pump has been used.

Depending on diagnoses and severity of spasticity, the initial dose was 1 mcg to 4 mcg of baclofen an hour. Oral antispasticity agents were continued. Before starting the pump, spasticity was assessed by rehabilitation physicians using the Modified Ashworth Score (MAS). In case of spasms, the patients were asked whether they caused functional hindrance. After starting the ITB, the assessments were carried out twice a day during trial. Change in functioning was observed by physiotherapists and nurses every day and opinion of the patient regarding the effect of ITB was asked and noted. Based on the combination of these findings the ITB dose was adjusted up to twice a day by the rehabilitation physician, with a maximum increment of

**Table 2:** Duration of trial.

| Duration of trial (Days) | No. of patients |
|---|---|
| 1 | 1 |
| 2 | 1 |
| 3 | 13 |
| 4 | 7 |
| 5 | 2 |
| 6 | 1 |
| 7 | 5 |
| ≥8 | 11 |

**Table 3:** Optimal ITB dose during trial.

| Optimal ITB dose (mcg/hr, rounded up) | No. of patients |
|---|---|
| 1 | 4 |
| 2 | 9 |
| 3 | 9 |
| 4 | 6 |
| 5 | 3 |
| 6 | 3 |
| 7 | 2 |
| 8 | 3 |
| 9 | 1 |
| No ITB | 3 |

1 mcg/hour each time.

During the trial, patients were monitored for vital functions and side effects such as headaches, nausea, puncture wound problems, CSF leakage and urinary retention. Aimed duration of the trial was no longer than one week. After removing the catheter, patients stayed in the rehabilitation centre for at least one day to continue monitoring. The internal tip of the removed catheter was sent for bacterial examination and patients measured their temperature twice a day for one week after discharge.

Outcome measures were duration of trial, optimal dose of ITB, effect of ITB on spasticity, functional hindrance due to spasms and general function, side effects and complications during trial and whether a pump was implanted or not after the trial.

For each patient relevant muscles, depending on spasticity, were determined and were assessed using MAS. Mean MAS before and at the end of trial was calculated for each patient. Wilcoxon Signed Ranked Test was used to compare the mean MAS before and at the end of trial. When one of the scores was missing for a patient, all scores of this patient were excluded. Analyses were performed with IBM SPSS Statistics 19.

## Results

Details of 43 patients included in this study are shown in Table 1. Main causes of spasticity were MS, SCI and CP, the 'other' causes included Primary lateral sclerosis, Metachromatic leukodystrophy and Autosomal Recessive Spastic Ataxia of Charlevoix Saguenay. Two patients had spasticity without a clear origin. Average duration of trial was five days and mean optimal ITB dose was 4mcg/h (Tables 2 & 3).

**Table 4:** Effect on Function.

| Function | Improved | Unchanged | Worsened |
|---|---|---|---|
| Sitting posture | 2 | - | - |
| Wheelchair riding | - | - | 1 |
| Transfers | 2 | 4 | 6 |
| Standing | 2 | 3 | 3 |
| Walking | 12 | 5 | 6 |
| ADL | 6 | 2 | 1 |
| Sleeping | 2 | - | 1 |
| *Pain* | *3* | - | - |

Figure 1 illustrates the procedural flowchart. Three of the patients did not receive ITB because of a suspected unsterile situation and trial had to be discontinued. In 2 of these patients the catheter connection dislodged and in 1 patient the bacterial filter was disconnected from the catheter at the time of arrival at the rehabilitation centre. Another patient experienced severe neck pain, headache, nausea and drowsiness at arrival and trial was discontinued before the effect on spasticity could be determined. In the other 39 patients, ITB had a positive effect on spasticity as measured by MAS or effect on disabling spasms.

MAS before trial and at the end of trial were reported in 27 patients. MAS before trial was higher than at the end of trial (2.4 versus 0.8, $z = -4.572$, $p = 0.000$). Ten of the 12 patients with no MAS reported had functional disabling spasms. In 5 of those, the spasms completely disappeared during trial, in the other 5, the spasms reduced and caused no functional hindrance. In two patients available data was limited, one patient had no more myoclonia after trial and 1 patient had less 'spasticity'.

In 3 of the 39 patients of whom effect on spasticity could be determined, the effect on function could not be determined because trial had to be discontinued due to a complication. In 2 patients this was because of a severe headache, in the other patient trial was discontinued because of a severely leaking catheter. In 2 patients effect was not reported because the main reason for trial was effect on spasticity, not on function.

In 34 patients effect on function could be determined. Table 4 shows the effect of ITB on seven different functions and severity of pain as indicated by the patients before start of the trial and the effect during trial. Most patients had indicated more than one function. In 26 assessments the function improved, 14 remained the same and 18 worsened during trial.

Twenty-four patients out of 34 received pump implant. Eight patients out of 10 who did not receive pump implant experienced an undesired effect of ITB on function, 1 patient discontinued because of worsening of psychiatric problems during trial. In 1 patient ambulation deteriorated after trial and spasms were less, so there was no longer an indication for ITB.

Five patients, out of 9 of whom the effect on function could not be determined, had a second trial with ITB bolus, after which they all

**Table 5:** Adverse Events.
There were no side effects or complications in 14 patients.

| Side effects | | Complications | |
|---|---|---|---|
| Minor headache | 17 | Severe headache | 2 |
| Nausea | 10 | Meningitis | 2 |
| Radiating pain | 2 | Catheter problems | 5 |
| Urinary retention | 2 | Severe reaction to ITB | 1 |

received pump implant. Both patients of whom the main goal was effect on spasticity continued with pump implantation. Two patients did not continue with implantation; 1 patient had severe headache and nausea during trial and did not want to risk experiencing it again in another trial. The other patient had a second trial with an external pump, but improvement on function was too little to proceed with implantation. 31 pumps in total were implanted after trial with an external pump or with ITB bolus.

Table 5 shows the incidence of adverse events, divided in 2 groups, side effects and complications. The difference between headache as a side effect or complication is whether it caused the trial to be discontinued. Two patients developed meningitis after trial which had no influence on their assessments. Both were treated successfully.

## Discussion

The objective of these trials was to assess effect of ITB on functioning. In the first years of trials, attempt was made to plan standard functional tests such as Timed Up and Go test (TUG), 10 Metre Walk Test (10MWT), Berg Balance Scale (BBS) and 6 Minute Walk Test (6MWT) for patients with the ability to walk and Timed Transfer Test for non-ambulatory patients. However, it proved to be impossible to plan these at the exact moment optimal dose of ITB was attained. In addition to that, no functional tests for ADL are available. As a consequence, effect on functioning was not objectively assessed. In the study by Phillips et al. [26] no standard functional tests were used either, functional mobility was assessed by a physical therapist. In addition, Heetla et al. [28] found that, although MAS shows a good dose-effect relationship with ITB, this relationship does not exist with TUG or patients' own impression of functioning using Patient Global Impression of Change (PGIC). TUG dose-effect relationships were both positive and negative, but all patients' impressions of functioning improved or did not change, indicating that standard tests of functioning do not always correlate with perceived functioning. This supports our belief that assessments by an experienced therapist or nurse and patients' opinion of effect on functioning are more important than functional tests and that they provide all information needed when deciding on pump implantation.

There are many findings that support the important role of self-assessment in spasticity treatment. For example, it is found that minor changes in spasticity relevant to daily life are better documented by the patients themselves [29] and clinical measurements and self-rated spasticity do not correlate well [30]. It is also found that patients interpret and express themselves relating to their spasticity in a way that might not conform clinical terms, which could be misunderstood by the physician [31]. A self-report questionnaire, Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET), has been developed to measure the impact of spasticity on daily life [32] and could be a helpful tool for the physician when making decisions about treating spasticity. Unfortunately, this questionnaire has thus far only been published in English, Turkish and Persian language. Currently, a project is underway to translate the SCI-SET into Dutch and study its validity and applicability.

Despite positive effect on spasticity in 39 cases, only 24 patients proceeded with pump implantation after trial with an external pump. This supports the earlier statement that the effect on spasticity is not the only factor in deciding on pump implantation. Eight patients discontinued with implantation because the ITB did not have the desired effect on function. In all of these patients, one of the main reasons to discontinue was worsening of transfers, standing or walking. These are functions that can improve by or rely on spasticity and loss of these functions can have a great impact on patients´ independence. Also, both desired and undesired effects on different functions can occur during trial. In trials with ITB bolus, there would be insufficient time for assessments and without the possibility to adjust the dose of ITB, the effects cannot be evaluated and experienced adequately. A trial with an external pump does allow the patients to experience the full effect of ITB on spasticity and function and does allow them to make an informed decision.

In 2 of the 43 cases, trial had to be discontinued due to a severe headache. Minor headaches occurred in 17 patients. This total incidence of 44% is considerably higher than incidences of 2.4-8.8% found by studies with ITB bolus trials [33,34], internal pump placements [33,34] and trials with external pump by Phillips et al. [26]. In the studies by Bleyenheuft et al. [25], Phillips et al. [26] and Harned et al. [27] the intrathecal catheters were tunnelled under the skin. We started to use this method from 2015, hoping this would have an effect on the incidence of headaches. Bleyenheuft et al. [25] also connected the catheter to a catheter-port system, with a minimal time between operation and assessments of 12 days. All patients had post-lumbar puncture headache, but only for the first few hours. It allowed the patients to rest and recover before ITB is given and before assessments begin. We considered using this method, however, a sizable number of our patients do not continue with implantation and they would have to have a second operation to remove an expensive catheter and catheter-port system.

To minimize the risk of infection, trials were kept as short as possible. In 11 trials duration was 8 days or longer. This is a considerable longer period than the other studies with a maximum duration of 3 [27] and 5 [26] days. Since 2009, in our centre, only 2 trials had duration longer than 5 days.

Two patients developed meningitis, both times this occurred after trial and the patient was already discharged. This emphasizes the important role of informing the patients about the risks, monitoring temperature after discharge and performing bacterial examination of the catheter tip.

Of the 9 patients of whom effect on function could not be determined, 7 eventually did have a pump implanted. Two patients were only interested in the effect on spasticity and 5 patients had a trial with ITB bolus after the trial with an external pump. Apparently, for these patients the trial with an external pump was not absolutely necessary. Considering the risks involved in a trial with an external

pump, the indication for the trial should be well considered. Trial with an external pump is indicated only when function has to be assessed. When the goal of ITB is to reduce spasticity or caregiver burden, trial with bolus of ITB is more appropriate. However, with literature research we could not find a decision algorithm for screening methods and the choice is still based on clinical evaluation.

## Study Limitations

One of the limitations of this study is the absence of functional tests measurements due to logistic problems, as explained previously. However, we believe assessments by an experienced therapist or nurse and patients' opinion are more important when deciding on pump implant, provided ITB had a positive effect on spasticity. Secondly, a different external pump was used before and after 2015, we do not believe this had any impact on results.

## Conclusion

Screening with an external pump with continuous ITB has an important advantage over screening with bolus of ITB when assessing improvement of function. However, risks of an external pump are higher and indication of placement should therefore be well considered. Also, procedures to reduce adverse events should be explored. When deciding on pump implantation, patients experience and preferences should be taken into consideration.

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