

Long-term safety and efficacy of intrathecal baclofen (ITB) therapy for control of intractable spasticity

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Abstract

In 1988 intrathecal baclofen administration (ITB) using an implantable computer controlled pump was introduced in our centre as an adjunctive therapy for intractable spasticity.

OBJECT: *To investigate the long-term effectiveness, the prevalence of adverse events (AE) and user satisfaction in patients suffering from intractable spasticity using the implanted pump.*

METHODS: *A prospective, monocentre study was conducted in patients who had been enrolled for ITB therapy and were willing to participate. All adverse events and complications were recorded. A questionnaire was constructed to determine complications, technical failures and personal experiences of the patients.*

RESULTS: *The results from 52 patients are included in this study. Patient diagnosis included cerebral encephalopathy, spinal cord injury, multiple sclerosis and others. During 297.3 recipient-years of pump operation, 68 treatment-associated adverse events occurred (i.e. once in 4.4 years). Forty-one (60%) AEs were device-related; 35 catheters, and 6 pumps. The most common device-related AEs were catheter migration (46%) and disconnection or kink (39%). ITB-therapy related AEs (27, or 40% of all AEs) included intrathecal baclofen-infusion related (17/27 or 63%), and patient-related problems (10/27 or 37%). User satisfaction was high. Most patients (88%) reported that expectations with respect to spasticity treatment were met, and would opt for this therapy again. Ninety-two percent of users would advise ITB to fellow-sufferers.*

CONCLUSIONS: *Intrathecal baclofen therapy is a safe and effective long-term*

treatment for severe otherwise intractable spasticity. Despite the risk of an AE, the experiences of the patients are positive, and satisfaction was high.

1 Introduction

Spasticity often arises below the level of injury as a result of the loss of modulating influences on reflex activities, and can be debilitating for patients with respect to rehabilitation and self-care [1]. Mild forms of spasticity can be treated well with a combination of physiotherapy and oral medication. In about 30% of patients with severe generalized spasticity insufficient beneficial effects can be achieved with conventional therapies. Great progress in the treatment of spasticity has been made since we are able to administer drugs close to where the deregulating mechanism has occurred in the spinal cord. Infusion of even small doses of baclofen into the subarachnoid space has been shown to dramatically reduce spinal spasticity [2-4]. In 1988 intrathecal baclofen (ITB) infusion therapy with an implantable pump was introduced in our centre.

The objective of this study was to determine the long-term results of the ITB-therapy in patients with severe intractable spasticity treated in our centre with respect to effectiveness, adverse events, complications and advantages. In addition, the experiences of patients themselves were collected.

2 Methods

A cross-sectional descriptive study was conducted. The study was approved by the local Medical Ethics Committee. We analyzed results from patients who were implanted with a pump system at the neurosurgical department of

hospital Medical Spectrum Twente, and treated at MST or Rehabilitation Centre Het Roessingh, Enschede. All patients included in this study gave written informed consent.

Patients eligible for ITB-therapy had severe spasticity (Ashworth score ≥ 3) located mainly in the trunk and legs, due to spinal cord injury, multiple sclerosis, cerebral encephalopathy, stroke, and others. Furthermore, patients should be refractory to oral baclofen or experience intolerable side-effects at effective doses.

A questionnaire was constructed to determine the personal experiences of the patients with ITB-therapy system. The items addressed were related to expectations, advantages and disadvantages and willingness to undergo the implant-procedure again with their present knowledge. Patients' medical records were used to complete the data with respect to spasm outcome, complications and technical failures. Adverse events were defined as ITB-therapy related problems that required clinical treatment, hospitalization or surgery.

2.1 ITB-therapy procedure

ITB-therapy is applied through a well established protocol. Potential candidates for ITB-therapy first undergo an ITB-test phase, during which the patient's response to intrathecal baclofen is determined. For this the patient is given an intrathecal catheter under local anesthesia. Bolus injections of baclofen are then injected at increasing concentrations (25 μg , 50 μg , 75 μg , and 100 μg) until a strong effect on spasticity is noted. Patients who respond well to ITB-therapy will have the programmable pump implanted. The pump is surgically placed in a subcutaneous pocket and connected to the catheter which is tunneled from the lumbar region insertion site to the pump pocket site. Medication is injected into the pump reservoir through a refill septum, and when activated the pump delivers the medication as programmed to the intrathecal space through a silicone catheter. Post-operatively the intrathecal baclofen infusion is optimized in such a way that muscle tone is close to normal and the frequency and severity of spasms are reduced as much as possible without causing baclofen related side-effects.

The pump is refilled percutaneously about every 2-3 months, depending on patient daily dosage requirements, and drug concentration used.

2.2 Implant

In our centre we use the SynchroMed system (Medtronic Inc, Minneapolis, MN, USA), and consists of an implantable, programmable, battery-powered device that stores and delivers medication according to instructions received from the programmer. The implanted pump can be non-invasively interrogated and programmed using a two-way radio-frequency link.

3 Results

Between 1988 and 2002 in our centre 80 patients were implanted with an ITB-pump. Fifty-two patients could be traced and agreed to participate in this study. Total recipient-years of operation were 297.3 years. The mean ITB-follow-up period was 6 years (range 1.5 to 15.8 years). During this period 36 pumps were replaced as a result of 'low-battery' alarm (i.e. device's end-of-life). The average life-time of Medtronic's SynchroMed pump was calculated to be 4.8 years. 38 patients (73%) still receive ITB-therapy for reduction of spasticity.

3.1 Complications and adverse events

During the total operation time a total of 68 AEs that needed clinical treatment were reported. Twenty patients (38%) never had an AE; 15 (29%) had one AE, 7 (13%) had two AEs, and 10 (19%) had 3 or more AEs. The chance on an AE is about once every 4.4 pump-operation years. NB, the 'end-of-life' replacements are not included in this number.

Most AEs, 41 in total (60%), were device-related. Six (15%) were related to problems with pumps (unexplained alarm, repositioning, and malfunction). All other device-related AEs, 35 or 85%, were due to catheter problems. Of these, catheter migration was reported most frequently (19 or 54%) followed by disconnection or kink (16 or 45%).

Twenty-seven (40%) of AEs were related to ITB-therapy. Of these, seventeen (63%) were due to baclofen infusion rate problems and cerebrospinal fluid leaks, and 10 (37%) due to skin-related problems (irritation, infection, perforation).

3.2 Patients' experiences

Of all participating patients, 36 (69%) returned the users questionnaire. With respect to control of severe spasticity expectations were met in 88%. Other ITB-related advantages reported

were improved self-care (50%), reduced overall need of care (44%), reduced pain (59%), improved social activities (66%), functional gain (44%), and mood (64%).

Overall, ninety percent of patients reported that the implanted ITB-system had a positive influence on one or more aspects in life. Almost ninety percent of patients would choose for ITB-therapy again. Ninety-two percent of patients would recommend ITB-therapy to fellow-sufferers from uncontrolled spasticity.

4 Discussion and Conclusions

Our study on long-term use of intrathecal infusion of baclofen with an implanted pump-system shows that this therapy is a safe and effective treatment for severe otherwise intractable spasticity. ITB-therapy related adverse events that need medical attention happen once every 4 to 5 years. Most frequent reported AEs were catheter problems (disconnection, kink or migration), and is in agreement with previously reported results [3][4]. Despite the risks, the experiences of the patients are positive, and satisfaction was high. In fact ITB-users are very content with it.

References

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