FUNCTIONAL IMPROVEMENT IN PATIENTS WITH SEVERE SPINAL SPASTICITY TREATED WITH CHRONIC INTRATHECAL BACLOFEN INFUSION

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Accepted for publication: July 30, 2001

In this retrospective study we evaluated the efficacy and functional benefits of chronic intrathecal baclofen infusion in severe spinal spasticity.

Twenty patients with a diagnosis of severe intractable spinal spasticity were evaluated prior to implantation of a programmable pump for chronic intrathecal baclofen therapy and at follow up, which ranged from 12 to 36 months (mean 22.4 months).

The mean age of the patients was 39.1 years. The prevailing pathology was multiple sclerosis. All were unable to walk.

Patient assessment was based on the Ashworth Scale, the Spasms Frequency Scale, self-reported pain and Functional Independence Measure (FIM) scores. The Wilcoxon test was used for statistical analysis.

A statistically significant decrease in muscle tone, spasms and pain was observed in all the patients. The Ashworth score decreased from 4.4 to 1.8, the spasms frequency score from 2.5 to 0.5 and the self-reported pain score from 5.5 to 2.3. The FIM score also showed a statistically significant change (increasing from a mean of 33.8 to 58.7).

Two patients in employment were able to return to work. No severe side effects were observed.

Chronic intrathecal baclofen infusion was seen to produce a functional improvement in patients with severe spinal spasticity, particularly as regards bathing, comfortable wheelchair sitting and mobility.

KEY WORDS: Baclofen, intrathecal infusion, spinal spasticity.

FUNCTIONAL NEUROLOGY 2001;16: 311-315

INTRODUCTION

Chronic intrathecal baclofen infusion has been shown to be particularly indicated for severe spasticity of spinal origin, producing an improvement in symptoms (1,2). The results obtained by this treatment do not differ significantly between patients with spinal cord injury and those with multiple sclerosis (2). At present, intrathecal infusion pump implantation is regarded as a safe surgical technique.

Few studies, however, have evaluated functional improvement (3) or self-reported pain (4) after chronic intrathecal baclofen infusion.

The aim of this study was to demonstrate the possibility of obtaining a functional improvement through this therapy.
MATERIALS AND METHODS

Twenty patients (9 males, 11 females) all affected by severe progressive spinal spasticity that was not responsive to medical therapy and that interfered with their daily activities, were evaluated for chronic intrathecal baclofen infusion. Before beginning the study, all the patients signed the necessary informed consent form and approval was obtained from our institute’s ethics committee.

All the patients were in a stable neurological spastic condition of at least 12 months’ duration and all were unable to walk. The spasticity was caused by multiple sclerosis in 13 patients, by trauma in 4, by spinal tumors in 2 and by spinal myelitis in 1. All the patients but two had a spastic paraparesis; of these two patients, one was suffering from a cervical myelitis and the other had cerebral and spinal plaques caused by multiple sclerosis. Of the 13 patients with multiple sclerosis 7 had diffuse spinal plaques, 5 had diffuse spinal and cerebral plaques and one had only cerebral plaques; three patients also had tremors of the arms and one was suffering from nystagmus.

The presurgical treatment with oral anti-spasmodic drugs included a combination of baclofen, diazepam and tizanidine; this combination was progressively increased to a maximum dose of baclofen 50 mg, tizanidine 4 mg, and diazepam 10 mg in order to obtain the therapeutic effect; reduced consciousness emerged as a side effect of this oral therapy in seven patients. During the bolus screening prior to intrathecal baclofen treatment (25, 50, 75, and 100 µg at intervals of 48 hours) the administration of this drug per os was interrupted.

The patients’ neurological conditions were evaluated using the original Ashworth Scale (AS) to assess spasticity (5) and the four-point Spasm Frequency Scale (SFS) to assess spasms (6); the painful state was evaluated on the basis of self-reported pain (7) while physical disability was evaluated on the basis of the Functional Independence Measure (FIM) score (8).

These parameters were assessed before intrathecal therapy, 6 and 12 hours after bolus administration of intrathecal baclofen and every 6 months after pump implantation.

The bolus screening was administered by lumbar puncture performed at L3-L4 interspace. When a positive response was obtained (at least one point reduction in AS and/or SFS score), a continuous infusion pump (Synchromed Model 8616-18, Medtronic Inc., Minneapolis, USA) was implanted in the standard way (1).

The statistical analysis was performed using the Wilcoxon sign rank test (8) to evaluate differences between baseline values and those observed at the last follow up. Surgical complications and the side effects of intrathecal baclofen were also recorded.

RESULTS

The mean age of the patients was 39.1 years (range: 27-52 years).

Their clinical history of spasticity had a duration of at least 12 months (mean: 36.5 months); the patients were followed up for a mean of 22.4 months (range: 12-36 months) after implantation. The AS and SFS scores were seen to decrease by at least one point after the bolus test.

At the last follow up, the mean AS score was seen to have decreased from a preoperative value of 4.4±0.5 to a postoperative value of 1.8±0.7 (Fig. 1). The SFS score in thirteen patients had decreased from a preoperative value of 2.5±0.8 to a postoperative value of 0.5±0.4 (Fig. 2); these differences between baseline and follow-up spasticity were statistically significant (p < 0.01). The self-reported pain score had decreased from a preoperative score of 5.5±2.2 to a postoperative score of 2.3±1.9 (p < 0.05) (Fig. 3, see p. 314). A statistically significant change in the FIM score was also observed (an increase from a preoperative mean of
33.8±6.9 to a postoperative mean of 58.7±10.4 (p < 0.05) (Fig. 4). In particular the improvement regarded items C, E, I and J: bathing, dressing the lower body and transferring the body. On the contrary, the improvement seen in the patients with tetraparesis was only slight.

Two patients in employment were able to resume work. No differences emerged between the results of the patients with spinal cord injuries and those with multiple sclerosis.

After implantation five patients needed a progressive increase of the baclofen infusion. The mean daily dose of baclofen was 295 µgr (range: 90-830 µgr). Two patients with pain had an infusion of a mixture of baclofen and morphine (respectively 200 µgr + 0.3 mgr/day and 310 µgr + 0.5 mgr/day). Sedation provoked by previous oral antispasmodic drug intake was seen to improve in all patients. No side effects due to intrathecal baclofen administration were observed; one patient had a cerebrospinal fluid leak around the catheter that required surgical repair.

**DISCUSSION**

The chronic intrathecal infusion of baclofen by implanted pump for the treatment of spasticity associated with spinal disorders (2) is today a safe and accepted therapeutic tool (1,2): improvements in muscle tone and reductions of spasms are well documented (1); however the disappearance of spasticity does not necessarily equate with functional improvement (6), and few studies have focused on this aspect (3,7). In accordance with the literature (1), our data show improvements as regards muscle tone and spasms (Figs 1 and 2).

Moreover, in our small sample this surgical technique also led in the long-term to a significant improvement of FIM as well as self-reported pain scores.

Given their particularly severe clinical conditions it was felt that the two patients in our study who had tetraparesis could not be adequately assessed using disability scales such as the FIM (3).

The benefit in our patients suffering from paraparesis was reflected in almost all the indi-
individual FIM motor items but mainly in bathing, dressing the lower body and transferring the body (Fig. 4). In this study the functional results obtained did not differ between spinal cord injury and multiple sclerosis patients, but these findings could be due to what was, in relation to the progressive worsening that occurs in multiple sclerosis, a relatively short follow-up time (11).

Implantation is apparently more expensive than other procedures (12), thus the amount of functional improvement and quality of life (4) could be parameters useful for calculating the social cost-benefit ratio of this therapy.

Although expensive, chronic baclofen infusion makes it possible to personalise drug dosages and infusion programmes: this flexibility can be exploited to improve walking ability in ambulatory patients; moreover, in the presence of somatic and neuropathic pain due to spinal lesions a mixture of drugs (baclofen and morphine for example) can be intrathecally administered.

In fact, baclofen is an agonist of the GABA-B receptor and reduction of neuropathic pain has been reported (13).

In two of our patients suffering from a vertebral fracture, a mixture of morphine and baclofen resolved the back pain completely, yet our results in cases of neuropathic pain were not so satisfactory (14), showing wide differences among patients (Fig. 3).

In conclusion, we believe that the positive clinical results obtained following application of this technique should also be evaluated through functional assessment and in terms of life support tools in an attempt to determine the exact social cost-benefit ratio of this therapy.

REFERENCES


