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Intrathecal baclofen therapy for spasticity: A compliance-based study to indicate effectiveness

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Abstract

Background: Intrathecal baclofen (ITB) therapy using a programmable battery-based pump is a well-recognized option in the treatment of patients with refractory spasticity. Improvements in clinical scale scores for muscle spasticity among this heterogeneous group of patients may not reflect the functional benefits of this therapeutic option. The aim of our study is to report the efficacy of ITB therapy by setting the patient's compliance at the 2-year follow-up after pump implantation as an indicator of treatment efficacy, as appreciated by the patients or their caregivers.

Methods: A cohort of 31 patients admitted for ITB therapy was studied. Treatment and follow-up expenses were supported by national health services. Compliance to follow-up visits 2 years after implantation was used as an indicator of treatment efficacy.

Results: Twenty-seven patients (mean age: 28.8 ± 19.3 years) were included in the study. At the 2-year post-implantation set point, 20 patients continued to comply with the treatment program. Those 20 patients reported at least moderate improvements in their symptoms, which justified treatment compliance.

Conclusion: At the 2-year follow-up post-implantation set point, nearly 3 of 4 patients (74.1%) continued to comply with the treatment, indicating treatment efficacy.

Key Words: Baclofen, compliance, intrathecal therapy, neuromodulation, spasticity

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INTRODUCTION

The use of oral baclofen (B-[4-chlorophenyl]-γ-amin obutyric acid) has been established for the treatment of generalized spasticity. The oral form of the drug has shown clinical benefits for some patients;[7,8,18] however, others did not respond and/or they developed intolerable systemic adverse effects, leading to unsatisfactory results.[6,12,15] Thus, intrathecal baclofen (ITB) therapy using implanted pumps was introduced with the aim of delivering the drug directly to the site of action, while reducing the dosage and minimizing the risk of systemic side effects. Continuous ITB therapy has shown promising efficacy in the management of refractory spasticity. This patient population includes those with refractory spasticity secondary to a variety of etiologies,

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such as spinal cord injury, cerebral palsy, multiple sclerosis, and familial spasticity syndrome.[1,3,5,9-11,16,19,21]

The outcomes from this type of therapy are often assessed by a set of muscle spasticity clinical scales such as the Ashworth scale.[2] Such assessments may not reflect the functional improvements associated with this therapeutic option,[13,14] which may result in a biased conclusion regarding the clinical outcomes of this treatment modality. In this study, we set patient compliance at the 2-year follow-up after pump implantation as an indicator of treatment efficacy, as appreciated by the patients themselves or by their caregivers.

MATERIALS AND METHODS

A cohort of 31 consecutive patients with refractory spasticity managed in our center between 2005 and 2012 were included in the study. Our patients were admitted for an ITB therapy trial. The trial included intrathecal administration of baclofen using a lumbar puncture. A total of 27 patients benefited from the trial and underwent surgical implantation of the battery-based programmable ITB pump (SynchroMed II; Medtronic, Inc., Minneapolis, MN, USA) by the senior author (AA), who followed a standard operative and postoperative protocol. All patients were subsequently referred to a specialized outpatient clinic for medication refilling and to adjust infusion doses. Surgery, implants, medications, and follow-up visits were supported by national health services. All expenses were covered (e.g., surgery, medication, etc.), including transportation. All patients' data, including their diagnoses, baclofen doses, responses to therapy, follow-up period, and intra and postoperative complications, were collected prospectively; these data were then reviewed and assessed at the time of the study. Programmable ITB pump efficacy was determined based on each patient's compliance at the 2-year follow-up visit following pump device implantation; this served as an indicator of functional efficacy or satisfaction by the patients themselves or their caregivers.

RESULTS

Of the 31 enrolled patients, 4 patients were excluded from the study. The reasons included minimal objective improvement (n = 2) or patient/caregiver dissatisfaction with the baclofen trial (n = 2).

A total of 27 patients (15 males and 12 females) underwent ITB pump insertion. The patients' ages ranged from 7–70 years (mean: 28.8 ± 19.3 years).

The documented etiologies of spasticity included cerebral palsy in 8 patients (29.6%), traumatic spinal cord injury in 5 patients (18.5%), familial spasticity syndrome in 5 patients (18.5%), inherited spasticity syndromes (e.g., Pelizaeus–Merzbacher disease, pantothenate kinase-associated neurodegeneration, mitochondrial diseases, etc.) in 4 patients (14.8%), myelopathic spondylosis in 2 patients (7.4%), demyelinating disease in 2 patients (7.4%), and spinal cavernoma in 1 patient (3.7%).

In a questionnaire-based survey, 22 patients reported good functional improvement, whereas 5 patients reported moderate improvement, as indicated by the patients themselves or by their caregivers. Baclofen doses ranged from 60–800 μg/day (mean: 253.4 ± 149.5 μg/day). No intraoperative complications were encountered in our cohort. Recurrent infection at the implantation site occurred in one patient, mandating hardware removal.

At the 2-year post-implantation set point, 20 patients (74.1%) continued to comply with the treatment. Treatment failure was defined as refill discontinuation or hardware removal, which occurred in 7 patients (25.9%). This was the result of a patient or caregiver's request indicating unsatisfactory functional improvement (n = 5), infection at the implantation site (n = 1), and death related to recurrent pneumonia (n = 1).

DISCUSSION

In 1984, Penn and Kroin[17] first reported the usage of ITB pump therapy in the management of spinal spasticity. Subsequently, several studies involving cerebral palsy patients have demonstrated that ITB improves muscle spasticity, functional outcomes, patient care, athetosis, dystonia, and the need for orthopedic surgery. Other studies have also shown similar results among patients with spasticity of other etiologies, such as spinal cord injury, multiple sclerosis, familial spasticity syndrome, and dystonia.[1,3,5,9-11,16,19,21]

A variety of objective clinical scoring systems has been reported in the literature, including the spasm score, expanded disability status scale (EDSS), ambulation index (AI), incapacity status scale (ISS), health-related quality of life by the sickness impact profile (SIP), and Hopkins symptom checklist (HSCL);[21] the Ashworth and modified Ashworth scales are the most widely used.[2,4]

Such objective clinical scales may not take into consideration the functional improvements noted in this heterogeneous group of patients because the disappearance of muscle spasticity may not necessarily represent functional improvement.[13,14] Therefore, patient satisfaction is an essential parameter to measure in addition to scores on these objective clinical scoring systems.

Rawlins[19] evaluated the functional improvements observed in 50 patients based on preoperative goals that were set by either the patients themselves, their caregivers, or by their healthcare practitioners. He reported that all 50 patients achieved certain short-term goals within 3 months of pump implantation, whereas 78% achieved long-term goals. Boviatsis *et al.*[5] reported an increase

in the Barthel index score (BIS) among 22 patients with either cerebral or spinal spasticity, with scores improving from 34.6 to 62.9 and 17.1 to 50.7, respectively.

In our cohort, compliance at 2 years following implantation of the pump device was used as an indicator of treatment efficacy. Given that the treatment plan requires frequent follow-up visits for pump refilling, adjustment, and maintenance, compliance is a strong indication of appreciated functional improvement, as noted by the patients themselves or by their caregivers. Two years after ITB pump implantation, 74.1% of the patients reported at least moderate improvements in their symptoms, meriting compliance with therapy. In this cohort group, all expenses were covered by the national health services. As such, compliance may truly reflect the functional benefit observed in these patients.

Treatment discontinuation occurred in 7 patients (25.9%). Five patients had stopped therapy as per the patient or caregiver's request, as related to treatment dissatisfaction, even in the presence of at least a moderate improvement response among all 7 patients.

ITB pump implantation is generally a safe and well-tolerated procedure. Complications such as mild sedation, dizziness, blurring of vision, seizures, drug overdose, respiratory depression, hypotension, bradycardia, coma, hallucination, hyperthermia, and hardware malfunction have been reported in the literature.[1,3,5,9-11,16,19-21] None of these complications were encountered in our cohort of patients. Neither baclofen toxicity nor deprivation have been observed in any of our patients during the 2-year follow-up period. Such conditions may result in a major impact on patients' satisfaction and compliance with the treatment. It is extremely important to avoid such life-threatening conditions. Therefore, patient and caregiver awareness and education as well as hotline access to medical facilities were provided to all patients in our program. Furthermore, in the literature, the infection rate reportedly ranges from 0.7–1.7%.[16,20] In our series, only one patient had wound infection at the implant site, possibly related to the percutaneous aspiration of seroma around the battery; this occurred at a local medical facility and required hardware removal.

CONCLUSION

ITB therapy using battery-based programmable pumps is a relatively safe and effective treatment modality for refractory spasticity. At the 2-year follow-up post-implantation set point, nearly 3 of 4 patients (74.1%) continued to comply with treatment, which is ultimately an indicator of treatment efficacy.

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REFERENCES

1. Albright AL, Gilmartin R, Swift D, Krach LE, Ivanhoe CB, McLaughlin JF. Long-term intrathecal baclofen therapy for severe spasticity of cerebral origin. J Neurosurg 2003;98:291-5.
2. Ashworth B. Preliminary trial of carisoprodol in multiple sclerosis. Practitioner 1964;192:540-2.
3. Azouvi P, Mane M, Thiebaut JB, Denys P, Remy-Neris O, Bussel B. Intrathecal baclofen administration for control of severe spinal spasticity: Functional improvement and long-term follow-up. Arch Phys Med Rehabil 1996;77:35-9.
4. Bohannon RW, Smith MB. Interrater reliability of a modified Ashworth scale of muscle spasticity. Phys Ther 1987;67:206-7.
5. Boviatsis EJ, Kouyialis AT, Korfias S, Sakas DE. Functional outcome of intrathecal baclofen administration for severe spasticity. Clin Neurol Neurosurg 2005;107:289-95.
6. Corston RN, Johnson F, Godwin-Austen RB. The assessment of drug treatment of spastic gait. J Neurol Neurosurg Psychiatry 1981;44:1035-9.
7. Dario A, Tomei G. A benefit-risk assessment of baclofen in severe spinal spasticity. Drug Saf 2004;27:799-818.
8. Duncan GW, Shahani BT, Young RR. An evaluation of baclofen treatment for certain symptoms in patients with spinal cord lesions. A double-blind, cross-over study. Neurology 1976;26:441-6.
9. Gooch JL, Oberg WA, Grams B, Ward LA, Walker ML. Care provider assessment of intrathecal baclofen in children. Dev Med Child Neurol 2004;46:548-52.
10. Guillaume D, Van Havenbergh A, Vloeberghs M, Vidal J, Roeste G. A clinical study of intrathecal baclofen using a programmable pump for intractable spasticity. Arch Phys Med Rehabil 2005;86:2165-71.
11. Hsieh JC, Penn RD. Intrathecal baclofen in the treatment of adult spasticity. Neurosurg Focus 2006;21:e5.
12. Jones RF, Lance JW. Bacloffen (Lioresal) in the long-term management of spasticity. Med J Aust 1976;1:654-7.
13. Landau WM. Clinical neuromythology II. Parables of palsy pills and PT pedagogy: A spastic dialectic. Neurology 1988;38:1496-9.
14. Landau WM. Spasticity: The fable of a neurological demon and the emperor's new therapy. Arch Neurol 1974;31:217-9.
15. McDowell FH. Treatment of spasticity. Drugs 1981;22:401-8.
16. Ordia JI, Fischer E, Adamski E, Chagnon KG, Spatz EL. Continuous intrathecal baclofen infusion by a programmable pump in 131 consecutive patients with severe spasticity of spinal origin. Neuromodulation 2002;5:16-24.
17. Penn RD, Kroin JS. Intrathecal baclofen alleviates spinal cord spasticity. Lancet 1984;1:1078.
18. Penn RD. Medical and surgical treatment of spasticity. Neurosurg Clin N Am 1990;1:719-27.
19. Rawlins PK. Intrathecal baclofen therapy over 10 years. J Neurosci Nurs 2004;36:322-7.
20. Stempien L, Tsai T. Intrathecal baclofen pump use for spasticity: A clinical survey. Am J Phys Med Rehabil 2000;79:536-41.
21. Zahavi A, Geertzen JH, Middel B, Staal M, Rietman JS. Long term effect (more than five years) of intrathecal baclofen on impairment, disability, and quality of life in patients with severe spasticity of spinal origin. J Neurol Neurosurg Psychiatry 2004;75:1553-7.