Intrathecal baclofen for the treatment of spasticity

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Summary

Spasticity is a clinical condition characterized by a velocity-dependent increase of muscle tone due to “parapyramidal” disturbance of the inhibitory afferents to the second motor neuron.

Intrathecal baclofen (ITB) is at present the most effective treatment for generalized spasticity provided that an accurate assessment of patients to be candidates for ITB is made. The most important patient selection criterion is lack of positive response to any oral antispastic drug or appearance of undesired side effects of such oral treatment.

Spasticity should not be treated in patients in whom it may be helpful to maintain posture due to their very poor muscle strength. When assessing a spastic patient alternative treatments such as Botox and peripheral neurotomies must also be considered, particularly in cases of predominantly focal spasticity.

According to our experience, it is advisable to divide spastic patients into two different groups: the first group including wheel-chaired and bed-ridden patients, the second group comprising spastic patients who are still able to move. In each of these two groups treatment goals vary and require different protocols for the patients’ evaluation. Assessment of patients is completed with the functional index measurement (FIM) scale in order evaluate changes in patients’ quality of life caused by variations in the motor performance.

Currently, treatment of spasticity with ITB is the most effective way of reducing spasticity regardless of its cause.

Keywords: Neuromodulation; wheel-chair; spasticity; baclofen; intrathecal; pump; bedridden patient; ITB.

Introduction

Spasticity is a clinical condition characterized by a velocity-dependent increase of muscle tone due to “parapyramidal” disturbance of the inhibitory afferents to the second motor neuron. Increase of tendon reflexes and appearance of muscle spasms are almost constantly accompanying findings.

Also, spasticity is always flanked by variable muscle weakness [1, 4, 14].

Spasticity is a clinical sign of many neurological disorders and is caused by lesions at either the cerebral or spinal level. It could be considered a positive sign of the CNS’ ability to compensate for a focal or generalized loss of muscle strength, and hence spasticity should not be treated in all patients because it could be beneficial in many. Patients affected by spasticity experience variable deterioration in their quality of life mainly because of a worsening motor performance [3, 10, 24]. Intrathecal baclofen is at present the most effective treatment for diffuse spasticity [1, 3–7, 11–14]. The difference in effectiveness between oral and intrathecal administration of baclofen (ITB) is due to a significantly higher drug concentration that can be achieved in the CSF by ITB. In addition, there is a 4 to 1 gradient in drug distribution between the caudal and rostral parts of the spinal cord following ITB, thus providing for a beneficial effect at the spinal level without undesired side effects in the brain [18].

Patient selection

The most important criterion for patient selection is a negative response to oral antispastic drug treatment as this can be demonstrated by poor reduction of spasticity and appearance of undesired side effects. If spasticity must be treated but patients do not respond to any oral therapy, intrathecal baclofen is currently the most effective treatment.

However, spasticity should not be treated in patients in whom it represents a transitional phase of the disease’s progression as in amyotrophic lateral sclerosis; in such cases, any treatment of spasticity will result in a reduction of muscle strength. Spasticity should also be left untreated in those patients in whom it may be helpful to maintain posture, particularly in patients with poor muscle strength.
When treating a spastic patient, alternative treatments such as botulinum toxin A (Botox™) injection and peripheral neurotomies should be considered, especially in cases of focal spasticity.

Special caution should be exercised in patients with hypersensitivity, in whom even a very small dose of baclofen may cause hypotonia and muscle weakness. If needed, additional focal treatments of residual spasticity with either Botox or peripheral neurotomies may be applied in order to improve motor performance.

In our experience, it is advisable to divide spastic patients into two groups: the first group includes wheelchaired and bed-ridden patients, the second group includes spastic patients who are still able to move.

The goals of antispastic treatment in the two groups are different. In the first group, the decrease of spasticity aims to offer better sleep, nursing and posture while in the second group, the treatment of spasticity aims to improve the patient’s motor performance.

These two different targets require different protocols for the evaluation and management of patients. In both groups, clinical assessment and grading are based on the same evaluation scales i.e. Ashworth Spasticity Scale, Penn’s Muscle Spasms Scale and Osteotendinous Reflex Scale. In the second group of the still-moving spastic patients, an additional computerized gait analysis is performed. Such careful evaluation of movement patterns of various muscle groups during gait is done with and without antispastic therapy in order to determine the level of required treatment.

Analysis of gait is performed using the Elite System, in which the following parameters can be recorded:

1. recruiting pattern of affected muscles during altered gait
2. temporal phase of gait
3. stance reaction forces and
4. movements of hip, knee and ankles during gait

The assessment of patients is completed with the FIM evaluation scale in order to analyse the degree of change in patients’ quality of life due to variations in motor performance. The complete battery of tests described above is performed during the following stages: a) before treatment, b) during bolus test of intrathecal baclofen, c) at peak effect, and d) during long-term treatment.

**Bolus test of intrathecal baclofen**

The screening test of intrathecal baclofen administration is made through lumbar puncture; if necessary, the test is repeated with an increased baclofen dosage (10, 25, 50, 75 and 100 µg) at each test. The test is normally considered positive when a decrease of spasticity of about two degrees on the Ashworth Scale is achieved for at least two hours during the day of test. This common assumption is valid for wheel-chaired and bed-ridden patients while for walking patients the reduction of spasticity could be even less pronounced but should be accompanied by an appreciable improvement in patient’s motor performance. A positive intrathecal baclofen test is a sufficient indication for the implantation of a pump.

### The choice of administration device

There are two types of administration devices (pumps) that can be used for intrathecal chronic drug delivery. All systems consist of an intradural spinal catheter connected to an administration device. The administration device can be either a constant-flow gas-propelled pump or an electronically programmable pump.

In the gas-propelled pump, the solution flow is constant as it is based on the pressure of gas in the “high-pressure” chamber, which compresses the drug reservoir. When the drug concentration needs to be changed, also dosage can be adjusted. In the electronically programmable pump, the change of daily dosage is achieved by resetting the parameters of function. Main advantage of the programmable pump is that functional parameters can easily be altered via an external programmer without any need to change the drug concentration. The pros of the constant flow pumps include low price, low weight, and smaller size. However, the relatively high cost of baclofen in Europe discourages frequent changes of daily dosages because in any such change the existing drug in the pump must be discarded and be replaced by new drug with the adjusted concentration.

### Surgical procedure

In our department, implantation of an intrathecal administration pump is usually performed under local anaesthesia with exception of children and particularly non-cooperative individuals. It takes around 30 minutes without major discomfort for the patient. A large series of catheters can be used as proximal intradural catheters. They are all inserted at a low lumbar level with the tip positioned upwards, usually to the level of the first lumbar vertebra (L1). Unlike other groups, we do not think that the level of the catheter tip is crucial in extending the effect of baclofen upwards.