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# Intrathecal Baclofen Pump in Post-stroke Rehabilitation: Our Experience

Ramnarayan. R*

Consultant Neurosurgeon
New Hope Hospital, Kilpauk
Chennai, India

*Author for correspondence: Ramnarayan R,
Consultant Neurosurgeon
New Hope hospital, Kilpauk
Chennai, India, E-mail: r.ramnarayan65@gmail.com

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**Abstract:**

Stroke is a common problem affecting the middle age and elderly people. Loss of function of one side especially the right side causes severe crippling effect. The main reason for this is the spasticity which appears after a stroke. The usual treatments for spasticity are not very useful in many patients. Here we describe our experience of intrathecal baclofen pump insertion for this problem.

**Keywords:** Stroke; Intrathecal; neurological

## Introduction

Stroke is classically characterized as a neurological deficit attributed to an acute focal injury of the central nervous system by a vascular cause, including cerebral infarction, intracerebral haemorrhage, and subarachnoid haemorrhage, and is a major cause of disability and death worldwide [1]. It may be either ischaemic or haemorrhagic in origin. Studies have shown that annually 15 million people worldwide suffer a stroke. Of these, 5 million die and another 5 million are left permanently disabled, placing a burden on family and community [2].

Post stroke spasticity is a major health problem in patients who survive stroke. Spasticity is usually assessed using the Modified Ashworth scale. [3] described that among the more frequent long-term complications following stroke are spasticity-related disabilities. Although spasticity alone occurs in up to 60% of stroke survivors, disabling spasticity affects only 4-10%. Spasticity further interferes with important functions of daily life when it occurs in association with pain, motor impairment, and overall declines of cognitive and neurological function. Post stroke spasticity (PSS)-related disability is emerging as a significant health issue for stroke survivors. Data on phases of the PSS continuum revealed evidence of PSS in 4% to 27% of those in the early time course (1-4 weeks post stroke), 19% to 26.7% of those in the post acute phase (1-3 months post stroke), and 17% to 42.6% of those in the chronic phase (>3 months post stroke). Data also identified key risk factors associated with the development of spasticity, including lower Barthel Index scores, severe degree of paresis, stroke-related pain, and sensory deficits [4]. Urban et al [5] looked at 301 patients with clinical signs of central paresis due to a first-ever ischemic stroke were examined in the acute stage and 6 months later. At both times, the degree and pattern of paresis and muscle tone, the Barthel Index and the EQ-5D score were evaluated. Spasticity was assessed on the Modified Ashworth Scale. Two hundred eleven patients (70.1%) were reassessed after 6 months. Of these, 42.6% (n=90) had developed spasticity. A more severe degree of spasticity was observed in 15.6% of all patients. The prevalence of spasticity did not differ between upper and lower limbs, but in the upper limb muscles, higher degrees of spasticity were more frequently (18.9%) observed than in the lower limbs (5.5%). Regression analysis used to test the differences between upper and lower limbs showed that patients with more severe paresis in the

proximal and distal limb muscles had a higher risk for developing spasticity.

Treatment of this spasticity can be done with pharmacological measures or physical measures. The usual drug used for this is baclofen given orally. But oral baclofen causes significant side effects in 10 to 75% of patients. Moreover when baclofen is administered orally, only a small portion of the original dose crosses the blood brain barrier and enters the CSF. In order to bypass the oral route, baclofen may be administered intrathecally by infusion directly to the CSF. Candidates for intrathecal baclofen (ITB) infusion are patients with spasticity who have intractable spasticity uncontrolled by drug therapy, or who experience intolerable side effects from oral baclofen.

## Material and Methods

This is a retrospective case note study from 2016 to 2019. Records of eleven patients with stroke hemiplegia of more than one year duration were taken out as part of this study. Seven of them were men and four women. Six of them had right hemiplegia and five had left hemiplegia. Eight had ischaemic stroke and three had haemorrhagic stroke. Five of them had aphasia which improved with time. Clinical assessment at our centre showed modified Ashworth scale (MAS) 3 to 4 in all cases. In nine patients the upper limbs were more or equally affected than the lower limbs [Table 1]. All patients had undergone trial intrathecal baclofen injection of 50µg. the MAS was assessed before the procedure and hourly four times after the LP. The subjective feeling of improvement of the patient and an increase in the MAS by 1 was taken as positive trial. One patient developed severe headache during the trial and so he was not offered the pump surgery. Finally ten patients underwent intrathecal baclofen pump insertion (Synchromed II) under general anaesthesia. The per-operative period was uneventful. Patients were then called back after one month and three months to assess the MAS score. At both these periods the Stroke Specific Quality of Life (SSQOL) was also assessed

| Age/Sex | Side | Aetiology | MAS Preop | | MAS 3/12 Postop | | SSQOL | |
|---|---|---|---|---|---|---|---|---|
| | | | UL | LL | UL | LL | preop | 3 mon postop |
| 68/M | Right | Infarct | 3 | 4 | 1 | 2 | 175 | 87 |
| 66/M | Left | Infarct | 4 | 2 | 2 | 1 | 212 | 174 |
| 71/F | Left | Infarct | 3 | 3 | 0 | 0 | 138 | 58 |
| 53/M | Right | Haemorrhage | 2 | 3 | 1 | 2 | 209 | 129 |
| 60/F | Right | Infarct | 3 | 3 | 0 | 0 | 187 | 95 |
| 62/M | Left | Infarct | No Surgery | | No Surgery | | No Surgery | |
| 48/M | Right | Infarct | 4 | 3 | 1 | 1 | 167 | 68 |
| 54/F | Left | Infarct | 4 | 4 | 2 | 1 | 195 | 89 |
| 59/M | Right | Haemorrhage | 4 | 3 | 2 | 1 | 218 | 198 |
| 57/M | Left | Haemorrhage | 4 | 2 | 2 | 1 | 234 | 212 |
| 64/F | Right | Infarct | 3 | 3 | 0 | 0 | 176 | 165 |

## Results

All the ten patients who underwent surgery had benefit of reduction of MAS score three months after surgery. In three patients the reduction was significant to become normal. The upper limb spasticity also had improved in most of the cases. However the results in patients with haemorrhage were not that good compared to those with infarcts. The Stroke specific Quality of life score (SSQOL) also showed improvement in most patients. In two patients with haemorrhage and two with infarcts, however the quality of life did not improve much at three months and they continued to be crippled.

## Discussion

Intrathecal baclofen has been shown to have a definite antispastic effect in many studies. Our study looked at patients who had undergone the same for spastic hemiplegia following stroke. Francesco [6] opined that clinicians often fail to recognize the potential enhancement in the function of these individuals if they gain better control of their spastic limbs. Some patients may not tolerate the systemic side effects of oral medications, such as drowsiness and sedation. ITB therapy offers the advantage of effectively decreasing severe, diffuse spasticity without causing untoward effects on arousal and cognition. Maythaler et al [7] did a randomized, double-blind, placebo-controlled crossover design of either intrathecal normal saline or 50 microgram baclofen for 21 patients with stroke of more than 6 months. During trial all the patients had definite reduction of spasticity. Seventeen patients underwent continuous intrathecal baclofen infusion and followed up for 12 months also showed continued reduction in spasticity. So they opined that intrathecal infusion of baclofen is capable of maintaining a reduction in the spastic hypertonia resulting from stroke.

Spasticity reduction should have some benefit for the patient. Two studies looked at the walking speed and antispastic gait after ITB. One study [8] measured triceps and quadriceps Ashworth scores, gait analysis at preferred and maximal speed measured by a motion analysis system with 2 force plates, and electromyographic recording of leg muscles before and 4 hours after ITB. The slopes of the moment-angle curves were measured on the hemiplegic side at the onset of ankle and knee flexion to assess muscle stiffness during walking. Pre- and post-ITB spatiotemporal, kinetic, and kinematic data were compared by using a nonparametric test. They found that the Ashworth scores of the quadriceps and triceps of all subjects decreased significantly after ITB. Maximal walking speed

increased significantly, with a significant increase in stride length, but the preferred walking speed was unchanged. The conclusion was that ITB improved walking and reduced muscle stiffness at both the ankles and knees on the spastic hemiplegic side and the post-ITB reduction in muscle stiffness might be attributed to decreased spasticity. The second study in ten patients who had ITB following stroke, customary walking speed was measured from the time required to walk 50ft (15m) at a self-selected pace. This study suggested that suggests that ITB therapy, in combination with physical therapy, may improve walking speed and functional mobility in ambulatory individuals with post stroke spastic hemiplegia.

[9] assessed the effects of intrathecal baclofen (ITB) therapy for the treatment of post stroke spastic hemiparesis on quality of life, functional independence, and upper, lower extremity (UE, LE) motor functions in 26 patients. They found that at 12 months patients demonstrated improvement in most functional parameters like MAS scores in both upper and lower limbs, SSQOL, gait distance and velocity and personal self care. A similar study by Ivanhoe and others [10] also showed that there was significant improvement in function, QOL, and spastic hypertonia at 3 and 12 months after implant, without adversely affecting muscle strength of the unaffected limbs. They also opined that ITB therapy is a safe and efficacious treatment for spastic hypertonia resulting from stroke. [11] did a multicentre, randomised, controlled, open-label trial (SISTERS Trial) comparing intrathecal baclofen therapy (ITB) versus conventional medical management (CMM) for severe poststroke spasticity. Of 60 patients randomised to ITB (n=31) or CMM (n=29), 48 patients (24 per arm) completed the study. The primary analysis showed a significant effect of ITB therapy over CMM and this supports the use of ITB therapy as an alternative to CMM for treatment of generalised poststroke spasticity in adults. Kofler and coworkers however cautioned that ITB has some limitations also. They found that ITB may reduce spasticity in a dose-dependent manner irrespective of its origin. Although not primarily antinociceptive in humans, ITB may alleviate pain if arising from increased muscle tone. A functional benefit may result if ITB can uncover "subclinical" motor control that had been suppressed by spasticity. However, when a patient uses antigravity patterns for ambulation in the absence of more complex motor control, ITB may cause the loss of residual walking ability, which becomes a major limitation for patients with hemiplegic stroke.

## Conclusion

ITB can be a very useful method of treating post stroke spasticity in patients. It does improve the use of the spastic limbs and also quality of life.

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