Effect of the Intrathecal Baclofen Screening Test on the Spatiotemporal Gait Motion Parameters of Patients with Cervical Spinal Cord Injuries Who Exhibited Diffuse Spasticity: A Report of Three Cases

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We examine the quantitative changes in the gait motion of patients with cervical spinal cord injuries (CSCIs) before and after the intrathecal baclofen (ITB) screening test. The subjects were three patients with CSCI, who exhibited spasticity in the lower extremities. They could all walk 10 or more meters with/without aids. All patients were subjected to the ITB screening test, in which they had gabalon (50 μg) injected into their spinal column via paramedian puncture at the L3–4 level. The subjects had their ankle clonus; patellar tendon reflex; and modified Ashworth scale, Berg balance scale, Spinal Cord Independence Measure, and 10-meter walk test (10MWT) assessed before and 5 hours after the ITB screening test. At 5 hours after the ITB screening test, all of the patients exhibited deceased spasticity in static position, and improved balance. There were no differences in the abilities of any of the patients to perform ADL. One patient did not change the spatiotemporal gait motion parameters (walking time, step count, and step length in the 10MWT). Therefore, the pomp implantation for ITB therapy was not performed. Two patients who had suffered CSCI more than 20 years ago exhibited a reduced walking time, increased step count, and step length. Out of the two patients one received the pomp of implantation after ITB screening test, and the other was planned to operate. The spatiotemporal gait motion parameters might be one of the useful tests to decide the pomp implantation for CSCI patients who hope improvement of gait ability.

Keywords: intrathecal baclofen, cervical spinal cord injury, gait ability, spatiotemporal gait motion parameter, spasticity

Introduction

Spasticity of cerebral and/or spinal cord origin is a functional disorder that can lead to secondary complications, inhibit movement or activities of daily living (ADL), and have a negative influence on physical performance.1–3) Intrathecal baclofen (ITB) therapy is useful for treating uncontrolable spasticity of cerebral and/or spinal cord origin, and the ITB screening test is performed to estimate the effect of ITB therapy before pump implantation. Previous reports on the effect of ITB therapy or the ITB screening test on patients with spasticity mainly focused on changes in quality of life (QOL), such as care or nursing requirements,4–6) and were based on static clinical studies, such as assessments of spasticity using the Ashworth scale7–9) or evaluations of metabolic function.10) Furthermore, Leary et al.11) suggested that ITB therapy might improve the functional intelligibility of speech in selected individuals with cerebral palsy. In addition, several dynamic clinical studies involving patients with spastic motion have reported improvements in their ability to perform ADL.8,10) Although, a few studies involving patients with spastic motion have reported changes in gait motion6,10) no detailed quantitative investigations of gait motion (e.g.; spatiotemporal parameter) that only involved spinal cord injury patients have been performed. In this study, we examined the quantitative changes in the gait motion of patients with cervical spinal cord injuries (CSCIs) who could walk independently with/without aid before and after the ITB screening test. We recommended the pomp implantation for patients who improved spatiotemporal gait motion parameters, if CSCI patients demanded improvement of gait ability.

Case Presentation

I. Case 1

A 51-year-old male was admitted to the Department of Neurosurgery in our hospital for improvement of spastic gait. Four years ago, he tumbled downstairs in which he received CSCI. Two years ago, C3–6 laminoplasty was performed to improve spastic gait. He had spasticity in lower extremity, however he could walk independently without aid or cane, and carries out ADL independently. His characteristics before the ITB screening test are shown in Table 1. We performed the ITB screening test in which 50 μg gabalon were injected into the spinal column by paramedian puncture at the L3–4 level.

We examined following parameter assessed before and 5 hours after the ITB screening test (Table 2). Two of the investigators served as evaluators throughout the study. The evaluators participated in a training session before the start of the data collection, and any difficulties with scoring items were discussed to obtain a consensus. The degree of spasticity was evaluated using the modified Ashworth scale (MAS) (mean score for eight sites: the hip extensors, hip adductors, knee extensors, and the ankle plantar flexors in the bilateral lower limbs). The MAS is scored on a scale of 1 to 5, and hence, the final score ranges from 8 to 40.

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The scoring criteria for the MAS are not very specific. The patellar tendon reflex was evaluated on a 6-grade scale (−, ±, +, 2+, 3+, or 4+), and the degree of ankle clonus was evaluated on a 5-grade scale (−, ±, +, 2+, or 3+). The Berg balance scale (BBS)\(^{(1)}\) was used to measure balance. The BBS consists of 14 items, which are scored on a scale of 0 to 4, and hence, the final score ranges from 0 to 56. A score of 0 is given if the participant is unable to perform the task, and a score of 4 is awarded if the participant is able to complete the task based on the criteria assigned to it. The scoring criteria are highly specific. The Spinal Cord Independence Measure (SCIM)\(^{(2)}\) was used to measure the subjects’ abilities to perform ADL. The SCIM is comprised of 17 variables, and the scoring criteria are highly specific. The final score ranges from 0 to 100. The 10-meter walk test (10MWT) was used to assess the spatiotemporal gait motion parameters (the time that it takes the subjects to walk 10 meters, step count, and step length). This test has been used in gait studies of patients with neurological movement disorders.\(^{(3)}\) The assessor walked beside the patient and began timing with a digital stopwatch (S321-4000, SEIKO Ltd., Tokyo) when their first foot crossed the start line. Timing was stopped when their foot crossed the 10-meter line, although the patient continued to walk further 2 meters. A rest period was provided after each of the 3 trials.

He displayed decreased MAS scores and reduction in patellar tendon reflexes and ankle clonus after the ITB screening test, compared with those obtained before the ITB screening test (Table 2). The BBS scores were mildly increased after the ITB screening test. However, there were no differences in the SCIM scores between before and after the ITB screening test. In the 10MWT, there was no change in time, step count, or step length between before and after the ITB screening test.

Obvious improvement of spatiotemporal gait motion parameters was not observed. Although, he hoped smooth gait with baclofen injection, he felt frustrated in gait motion. Therefore, the pomp implantation for ITB therapy was passed with his intent, this time. We also did not recommend the pomp implantation for ITB therapy.

### II. Case 2

A 64-year-old male was admitted to the Department of Neurosurgery in our hospital for improvement of spastic gait, and decreased of spasticity. Twenty-five years ago, he met with a traffic accident in which he received CSCI. C3–7 laminotomy was performed. However, 2 years ago, he tumbled downstairs, and myelopathy in limb was developed. Conservative treatment and rehabilitation therapy were continued. He had spasticity in lower extremity, however he could walk

### Table 1  Subjects’ characteristics before the intrathecal baclofen (ITB) screening test

| Case 1 | Case 2 | Case 3 |
|--------|--------|--------|
| Age (years) | 51 | 64 | 59 |
| Gender | M | M | M |
| Body mass index | 22.8 | 28.4 | 26.1 |
| Years post CSCI | 2 | 27 | 20 |
| Surgical history | Laminoplasty (C3–6) | Laminoplasty (C3–7) | Preservation |
| Modified Frankel grade | D3 | D1 | D2 |
| MMT | U/E | 4 | 4 | 5 |
| L/E | 5 | 4 | 2 |
| PTR | 4– | 3– | 3– |
| ATR | 4– | 3– | + |
| Bladder disturbance | + | – | – |
| Clonus Patellar | + | + | – |
| Ankle | + | 2+ | – |
| ROM | Bil hip flex, add # | Bil hip flex, add # | Bil ankle DF # |
| Assitive device | Walker | Double T-cane |

M: male, CSCI: cervical spinal cord injury, MMT: manual muscle testing, U/E: upper extremity, L/E: lower extremity, PTR: patellar tendon reflex, ATR: Achilles tendon reflex, ROM: range of motion, Bil: bilateral, add: adduction, DF: dorsal flexion, flex: flexion.

### Table 2  Clinical data including gait parameters obtained before and after the intrathecal baclofen (ITB) screening test

| Case 1 | Case 2 | Case 3 |
|--------|--------|--------|
| MAS (points) | Before ITB | 20 | 16 | 24 | 14 | 24 | 12 |
| PTR | 4– | + | 3– | ± | 3– | ± |
| Ankle clonus | 4– | + | 3– | – | + | – |
| BBS (points) | 42 | 45 | 13 | 18 | 16 | 19 |
| SCIM (points) | 98 | 98 | 60 | 60 | 80 | 85 |
| 10MWT (sec)* | 14.6 ± 0.6 | 13.6 ± 0.7 | 68.2 ± 1.7 | 48.8 ± 0.9 | 51.3 ± 1.7 | 38.6 ± 0.6 |
| Step count* | 16.3 ± 0.6 | 16.0 ± 1.0 | 55.3 ± 1.5 | 42.6 ± 2.1 | 34.3 ± 0.6 | 32.3 ± 0.6 |
| Step length (cm)* | 62.5 ± 1.3 | 62.7 ± 1.1 | 18.2 ± 1.3 | 23.6 ± 1.7 | 29.3 ± 1.6 | 31.3 ± 1.4 |

MAS: modified Ashworth scale, PTR: patellar tendon reflex, BBS: Berg balance scale, SCIM: Spinal Cord Independence Measure, 10MWT: 10-meter walk test, *mean value ± standard deviation.
independently with a walker, and carries out ADL independently. His characteristics before the ITB screening test are shown in Table 1. We performed the ITB screening test with 50 μg gabalon injection into the spinal column. The method and procedure to measure physical function before/after the ITB screening test were as same as Case 1. He displayed decreased MAS scores and loss of their patellar tendon reflexes and ankle clonus after the ITB screening test, compared with those obtained before the ITB screening test (Table 2). The BBS scores were mildly increased after the ITB screening test. There were no differences in the SCIM scores between before and after the ITB screening test. In the 10MWT, he showed reduced walking time, increased step count, and step length, however he experienced discomfort during the forward swing of the leg. He showed decline of spasticity in static position and improvement of spatiotemporal gait motion parameters. He achieved a sense of contentment in static position and gait motion. Therefore, we recommended the pomp implantation for ITB therapy, and he was taking a positive slant on surgery.

III. Case 3
A 59-year-old male was admitted to the Department of Neurosurgery in our hospital for improvement of spastic gait, and decreased of spasticity. Twenty years ago, he fell on to the floor in which he received CSCI. Conservative treatment and rehabilitation therapy were continued, and he could walk independently without aid or cane. As the spasticity progresses, he needed double T-cane from 5 years ago, however he carried out ADL independently. His characteristics before the ITB screening test are shown in Table 1. We performed the ITB screening test with 50 μg gabalon injection into the spinal column. The method and procedure to measure physical function before/after the ITB screening test were as same as Case 1. He displayed decreased MAS scores and loss of their patellar tendon reflexes and ankle clonus after the ITB screening test, compared with those obtained before the ITB screening test (Table 2). The BBS scores and the SCIM scores were mildly increased after the ITB screening test. In the 10MWT, he showed reduced walking time, increased step count, and step length. However, he experienced discomfort during the forward swing of the leg. He showed decline of spasticity in static position and improvement of spatiotemporal gait motion parameters. He achieved a sense of contentment in static position and gait motion. Therefore, we recommended the pomp implantation for ITB therapy, surgery was performed. After the pomp implantation, he was content with his gait motion.

Discussion
After the ITB screening test, all of the CSCI patients exhibited reduced lower extremity muscle tone in the static position, however none of them displayed marked improvements in their abilities to perform ADL. Several studies have reported improvements in basic motion or ADL abilities after ITB therapy or the ITB screening test.\textsuperscript{5,8,9,10} In addition, previous reports have suggested that reductions in muscle tone in the static position led to improvements in ADL abilities\textsuperscript{5,8,9,10} In these studies, the improvements were mainly associated with sleeping, hygiene, feeding, dressing, or self-care. However, our three patients were relatively self-sufficient and could walk by themselves before the ITB screening test. Therefore, we suggest that patients who possess relatively high ADL abilities might not see any marked improvement in their ADL abilities after the ITB screening test.

Previous studies involving a limited numbers of subjects support the hypothesis that antispasticity drugs might be useful for treating gait-related muscle hypertonia.\textsuperscript{14,15} While, some reports about oral baclofen treatment failed to demonstrate any improvement in the walking ability of ambulatory spastic patients.\textsuperscript{16,17} However, a few studies have reported changes in gait motion among patients with spastic motion after ITB therapy or the ITB screening test.\textsuperscript{5,6,8,10,18,19} In the abovementioned studies, the subjects’ spastic gaits were caused by cerebrovascular disorder, cerebral palsy, spinal cord injury, or multiple sclerosis. Thus, the cause of spastic motion differs among subjects. Although baclofen injections are generally indicated for patients with spastic motion due a diverse range of causes, the effect of baclofen treatment might vary among patients with different conditions. Recently, several studies that only involved patients with acquired brain injuries have examined the effects of ITB therapy on gait motion, and case studies have described the treatment and outcomes of patients with spastic paraparesis due to cerebral palsy, hereditary spastic disease, etc.\textsuperscript{5,6,18,19} However, no investigations of gait motion after ITB therapy or the ITB screening test that only involved spinal cord injury patients with ability to walk have been performed. Leary et al.\textsuperscript{5} reported that decrease in walking time and step count in the 10-meter test were observed in a cerebral palsy patient after ITB injection. Furthermore, Horn et al.\textsuperscript{10} reported that 28 patients with acquired brain injuries showed significant improvements in gait speed and step width after ITB injection. Meanwhile, in our study there were two cases in which the patients’ spatiotemporal gait motion parameters improved after the ITB screening test and another in which they did not. Previous studies of gait motion after ITB injection in patients with acquired brain injuries reported that there were some cases in which no changes in gait parameters occurred and others in which improvements were achieved.\textsuperscript{5,10} Thus, the effects of baclofen treatment on spastic gait vary. Our results for CSCI patients were similar to those of previous studies. Furthermore, in the present study the amount of time that had passed since the injury occurred was longer in the two cases in which improvements were achieved than in the case in which no change occurred. A previous study reported that in patients with cervical spinal cord disorders increasing spasticity of the antigravity muscles resulted in antigravitational positions being adopted.\textsuperscript{19} Patients with a long history of spinal cord disorder often adopt abnormal gaits such as a spastic gait.\textsuperscript{20} Therefore, muscles other than the primary antigravity muscles might suffer secondary muscular weakness and muscular atrophication. Thus, we suggested that patients with a long
history of spinal cord disorder might suffer discomfort during the forward swing of the leg due to muscular weakness or atrophication, in spite of improvements in their spatiotemporal gait motion parameters.

In conclusion, we suggested that when a sense of contentment in gait motion after ITB screening test and improvement of the spatiotemporal gait motion parameters were observed, it might be useful for CSCI patients who hope improvement of gait ability to recommend the pomp implantation for ITB therapy. Moreover, it might be important for patients with a long history of CSCI who are due to be injected with baclofen to improve their gait to undergo rehabilitation before receiving ITB injections. In addition, rehabilitation therapy to regain the ability to perform ADL including an appropriate gait motion might be necessary prior to dosage adjustment after the initial ITB injection.

Conflicts of Interest Disclosure

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices in the article.

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