ORIGINAL ARTICLE

Effect of Intrathecal Baclofen Bolus Injection on Lower Extremity Joint Range of Motion During Gait in Patients With Acquired Brain Injury

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ABSTRACT. Horn TS, Yablon SA, Chow JW, Lee JE, Stokic DS. Effect of intrathecal baclofen bolus injection on lower extremity joint range of motion during gait in patients with acquired brain injury. Arch Phys Med Rehabil 2010;91:30-4.

Objectives: To evaluate lower extremity joint range of motion (ROM) during gait before and after intrathecal baclofen (ITB) bolus administration, and to explore the relation between changes in ROM and concurrent changes in gait speed and muscle hypertonia.

Design: Case series.

Setting: Tertiary care rehabilitation center.

Participants: Adults (N=28) with muscle hypertonia due to stroke, trauma, or anoxia.

Interventions: 50-μg ITB bolus injection via lumbar puncture (75 and 100μg in 2 cases).

Main Outcome Measures: Ashworth score, self-selected gait speed, and sagittal plane ROMs in hip, knee, and ankle joints before and 2, 4, and 6 hours after ITB bolus.

Results: A significant decrease in the mean Ashworth score on the more involved side (2.0 to 1.3) and an increase in gait speed (41 to 47cm/s) were noted at different intervals after ITB bolus injection. Ankle ROM significantly increased on the more involved (13° to 15°, $P<.01$) and less involved (22° to 24°, $P<.05$) sides. ROM significantly improved, significantly worsened, or showed no significant change in 42%, 34%, and 24% of individual joints, respectively. The peak change in ROM did not coincide with the peak decrease in Ashworth score. Peak changes in ROM and speed coincided more often ($P<.001$) in participants who increased gait speed after ITB bolus compared with those who decreased speed. The absolute change in ROM after ITB bolus injection correlated better with the concurrent changes in speed ($r=.41$, $P<.001$) than with the baseline speed ($r=.18$, $P<.05$).

Conclusions: ITB bolus injection produces variable changes in joint ROM during gait, with significant improvements in the ankles only. Timing and magnitude of peak changes in ROM are associated with concurrent changes in speed but not muscle hypertonia.

Key Words: Brain injuries; Gait; Muscle hypertonia; Rehabilitation.

CONTINUOUS INTRATHECAL baclofen infusion therapy effectively reduces lower extremity spastic hypertonia in ambulatory and nonambulatory patients with ABI resulting from trauma or stroke.[1,2] Screening protocols for determining clinical response to baclofen administration before pump implantation typically use manual evaluation of muscle stiffness after ITB bolus injection. The implications of change in muscle hypertonia after a bolus or continuous ITB administration on functional activities, such as walking, are less clear. This is not surprising considering that the contribution of muscle tone to gait impairment after stroke remains controversial.[3-7] In addition, transient changes in gait after ITB bolus injection may be subtle and not readily discernible by clinical or observational gait assessment. Thus, computer-assisted motion analysis has been used to better understand changes in various gait parameters after bolus[8] and continuous[9] ITB administration.

Our recent investigation of walking performance in 28 pump candidates with ABI revealed a consistent decrease in the lower extremity Ashworth score after ITB bolus injection.[8] The effects on speed and other time- and distance-based gait parameters were unrelated to the decrease in Ashworth score, however, and greatly varied in terms of timing and magnitude of changes between 2 and 6 hours of ITB bolus administration. In this follow-up investigation, we examined the changes in lower extremity joint ROM during ambulation in the same 28 participants.

We generated 3 hypotheses based on previous results. First, we predicted that joint ROM during gait would increase after ITB bolus injection, as may be observed with other antispasticity treatments such as botulinum neurotoxin chemodenervation[10,11] and dorsal rhizotomy.[12,13] Second, assuming a positive correlation between changes in sagittal plane ROM and gait speed in patients after stroke,[14] we postulated a temporal relation between changes in ROM and speed after ITB bolus injection. That is, the improvement in ROM during gait would coincide with the largest increase in speed after ITB bolus administration. Lastly, providing that the latter relation between ROM and speed holds true, changes in ROM during gait should not be associated with changes in the resting Ashworth score, since we previously found no association between

List of Abbreviations

ABI	acquired brain injury
ITB	intrathecal baclofen
ROM	range of motion

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changes in speed and muscle hypertonia after ITB injection in the same sample.[8]

METHODS

Participants

Twelve men and 16 women, ranging in age from 19 to 56 years (mean ± SD, 35±12y), were recruited from a spasticity and motor disorders clinic led by one of the investigators. The etiology of ABI included stroke (13 participants), trauma (12 participants), and hypoxic encephalopathy (3 participants). The average time ± SD postinjury was 45±34 months. Additional descriptive information about the sample has been provided elsewhere.[8] All participants had experienced persisting motor impairments associated with muscle hypertonia despite prior administration of oral antispasticity agents, botulinum toxin chemodenervation injections, or both. ITB was thus considered a potential treatment option with the goal of improving overall motor function, including gait. Each participant had been scheduled for bolus injection before enrollment in this study as a part of the screening for possible ITB pump implantation. Additional criteria for referral were (1) muscle hypertonia resulting from ABI; (2) age 16 years or older; (3) no known allergy to baclofen; (4) ability to safely walk independently or with some assistance; and (5) no fixed contracture in the lower extremity joints. The study was approved by the institutional review board for human research, and each participant signed the informed consent before enrollment in the study.

Evaluation Protocol

On day 1, a physical therapist evaluated muscle hypertonia in hip flexor, hip extensor, knee flexor, knee extensor, and ankle plantarflexor muscle groups using the Ashworth score on a scale of 1 to 5.[15] Each participant then underwent baseline gait evaluation using the video-based motion analysis protocol. The next morning, participants received a 50-μg bolus of baclofen injected into the lumbar intrathecal space. Two participants received 75 and 100μg, respectively, because of equivocal clinical responses from a previous 50-μg bolus. Clinical assessment of muscle hypertonia and computerized gait analysis were repeated at 2, 4, and 6 hours after the bolus injection. The same therapist measured the Ashworth score across all evaluation points in a given patient. The reflective markers attached to body segments were kept in place between 2 and 6 hours after the injection. To minimize the occurrence of postlumbar puncture headache, participants rested in bed except when gait data were being acquired.

Gait Data Acquisition and Processing

Spherical reflective markers 2.5cm in diameter were affixed with adhesive tape to bony landmarks on the lower extremity in accordance with the Helen Hayes biomechanical model.[16] After the baseline assessment, the locations of the reflective spheres were marked on the patient's skin with indelible ink. Participants walked at a self-selected speed, either barefoot or with preferred footwear, and with their customary assistive device, if any. Video images were acquired at a sampling frequency of 60 fields/s using a 6-camera motion capture system.[a] Data acquisition started after participants had taken a few steps and terminated before they reached the end of a 4-m walkway. At least 5 walking trials, comprising 2 to 5 gait cycles each, were recorded during every evaluation session, providing 10 to 25 total gait cycles for analysis.

Images of the reflective markers were computer digitized to derive their 3-dimensional positions for each walking trial. The raw data were normalized to 1% interval of each gait cycle. Normalized data were then averaged to produce mean hip, knee, and ankle joint angle curves for each evaluation session. In addition to previously reported temporospatial outcome measures,[8] maximum flexion and extension angles for the hip, knee, and ankle joints were calculated (Orthotrak gait modeling software[a]) and used to derive joint ROM values for the more and less involved sides.

Data were processed for group and individual analyses. For the group analysis, the greatest difference from baseline was defined as the participant's peak response, and the evaluation session at which it occurred (2, 4, or 6h) was defined as time of peak response. Peak response was considered to be the most representative individual outcome and thus most suitable for the before-after group comparison. Considering variable changes in ROM across participants, joints, and evaluation time points, individual ROM data were transformed into categorical outcomes. For that purpose, baseline, 2-, 4-, and 6-hour data of each participant were submitted to the analysis of variance with planned post hoc comparison to determine the statistical significance of each participant's response to ITB bolus injection.[8] Depending on whether the level of significance was reached ($P<.05$) and the direction of ROM change, 1 of 3 possible outcome categories (significant improvement, significant worsening, no significant change) was ascribed to each joint (hip, knee, ankle) on both sides for each evaluation session (2, 4, and 6h postbolus). ROM was considered improved when the absolute deviation from the normative data[a] decreased after the injection. The reverse indicated ROM worsening. The frequencies of the 3 possible ROM outcomes were tabulated for each joint across all participants and compared between the 3 evaluation time points after ITB injection.

Statistical Analysis

To examine changes in joint ROM after ITB bolus injection across the entire group (hypothesis 1), the paired *t* test was applied to test the difference between baseline and peak response values for each joint. For descriptive purposes, the frequency of individual ROM outcomes was related to the time of postbolus evaluation using the chi-squared statistic. The chi-squared statistic was also used to determine whether the timing of peak changes in ROM coincided with peak changes in speed (hypothesis 2) and Ashworth score (hypothesis 3). As per a priori planned comparisons, the magnitude of change in ROM at the time of peak change in speed was compared between the subsets of participants who increased speed and those who decreased speed, by using analysis of variance and controlling for joint and side, as appropriate. Correlations between ROM and speed, and between ROM and Ashworth score were explored in secondary analyses using the Pearson product-moment correlation and the Spearman rank correlation, respectively. A *P* value of less than .05 was considered significant. Statistical analyses were performed using Prism 3.0[b] and SAS[c] software.

RESULTS

Range of Motion During Gait Before Intrathecal Baclofen Bolus

Mean ROM results per joint and side are presented in table 1 for all 28 ABI participants along with normative values. On average, baseline ROM was within normal limits only at the hip joint on the less involved side. At the more involved hip, ROM was 10°, or approximately 2 SD, below normal. Knee ROM was 35° (7 SD) below normal on the more involved side and 12°