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Original Research

Long-Term Dosing of Intrathecal Baclofen in the Treatment of Spasticity After Acquired Brain Injury

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Abstract

Background: Intrathecal baclofen (ITB) often is used to treat severe spasticity of cerebral origin. Although literature exists regarding the efficacy of ITB, there has been minimal investigation related to dosing in the adult-acquired brain injury population, particularly at long-term duration.
Objective: To investigate long-term dosing of ITB in adult patients with spasticity of cerebral origin due traumatic brain injury (TBI), stroke, and hypoxic-ischemic encephalopathy (HIE).
Design: Retrospective cohort study.
Setting: An academic outpatient rehabilitation clinic.
Patients: Forty-two adult patients with spasticity secondary to TBI, stroke, or HIE treated with ITB for greater than 3 years.
Methods: Medical records and device manufacturer records of included patients were reviewed to obtain demographic data, dosing information, dates of pump and catheter placements, and revisions.
Main Outcome Measure: Average daily ITB doses and mean change in ITB dose over 1, 2, and 3 years. Goal of ITB treatment (active function versus comfort/care/positioning) also was compared.
Results: Of 42 total patients, spasticity was attributed to either TBI (n = 19), stroke (n = 11), or HIE (n = 12). The mean (standard deviation) age was 35.21 (10.17), 56.7 (13.1), and 35.1 (12.4) years for the TBI, stroke, and HIE groups, respectively ($P < .001$). There was a significant difference in the goal of therapy with "improving functional independence," accounting for 27.8%, 72.8%, and 0% in the TBI, stroke, and HIE groups, respectively ($P = .002$). The mean duration of ITB therapy was 8.5 (5.0), 7.8 (3.4), and 9.1 (4.6) years in the TBI, stroke, and HIE groups, respectively ($P = .79$). The mean daily ITB dose was 596.9 (322.8) μg/d, 513.2 (405.7) μg/d, and 705.2 (271.7) μg/d for the TBI, stroke, and HIE groups, respectively ($P = .39$). In the subset of the cohort with ITB therapy for more than 5 years, the mean percent change in daily ITB dose between time of chart review and 1, 2, and 3 years previously was 7.3% (13.6), 12.7% (16), and 24.7% (50.3), respectively. A complex dosing pattern was used more frequently in those with stroke (36.4%) compared with the TBI and HIE (9.7%) groups ($P = .04$).
Conclusion: Despite the long-term use of ITB therapy in this cohort, the mean daily dose of ITB continued to require adjustments. There was no significant difference in the mean daily dose between patients with a diagnosis of TBI, stroke, or HIE. A complex dosing pattern was used more frequently in patients with stroke.
Level of Evidence: To be determined.

Introduction

Spasticity is a known complication after injuries to the central nervous system. This phenomenon results from reduction in descending inhibitory influences, which affects control of motor neurons and interneurons [1] and leads to a velocity-dependent increase in tonic stretch reflexes [2]. Baclofen is a gamma-aminobutyric acid B receptor agonist that is used widely to treat spasticity. Oral baclofen has been shown to have depressant effects on the central nervous system, which can lead to sedation [3] and may limit use in patients with traumatic brain injury (TBI), stroke, or hypoxic-ischemic encephalopathy (HIE), in whom optimizing cognition is often an important goal.

As such, focal delivery of baclofen to the subarachnoid space with an intrathecal baclofen (ITB) pump is used frequently to treat severe spasticity of cerebral

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origin [1]. The efficacy of ITB treatment in reducing spasticity after TBI, stroke, and HIE has been described. Several studies have demonstrated that ITB is effective in reducing spasticity, spasm frequency, and/or reflex score in these patient populations [4-13]. In addition, 2 prospective studies of patients with stroke have shown improvement in function and quality of life with ITB treatment [6,13].

Although literature exists regarding efficacy of ITB, there has been minimal investigation related to dosing in the adult-acquired brain injury population, particularly provided over a long-term duration. Previous studies have reported a wide range of average daily ITB doses for managing spasticity of cerebral origin, including rates from 265 to 628.5 μg/d [4,5,8-11,13]. These studies are limited by small sample sizes [5,9,10,14], heterogeneous populations [10,11], and short follow-up time frames [5,8,9,11,13]. In addition, no previous studies have investigated changes in ITB dose over time in the TBI, stroke, and HIE population; thus, relative dose stability is unknown. Furthermore, potential differences in ITB dosing between these diagnoses have not been studied.

In the present study of adult patients with chronic spasticity of cerebral origin caused by TBI, stroke, or HIE, we aimed to determine (1) whether there is a difference in dosing between diagnoses and (2) long-term dose stability as measured by the change in ITB dose over a 3-year period. We hypothesized that (1) there would be differences in dosing between diagnoses with greater daily doses in patients with TBI and HIE and (2) doses would remain relatively stable at long-term follow-up, indicated by $<$10% changes annually.

Methods

This retrospective cohort study was conducted at an urban, academic outpatient rehabilitation clinic, following approval from our local institutional review board. The electronic medical record was queried for Current Procedural Technology codes related to ITB pump refill procedures to identify consecutive patients undergoing ITB therapy at the study site. The medical records of the identified patients were screened for eligibility. Patients were included if they were $\geq$18 years of age; had spasticity secondary to TBI, stroke, or HIE; and had received ITB therapy for greater than 3 years. Medical records and device manufacturer records were reviewed to obtain demographic information, dosing information, goal of therapy, dates of pump and catheter placements, and revisions. The goal of therapy was obtained through chart review and classified as either to "improve functional independence" or to "improve comfort, position, and ease care" by the investigators. The primary outcome measures were the mean ITB dose at last follow-up and annual change in ITB dose over the previous 3 years. Secondary outcomes included pump and catheter lifespan and complications.

Data Analysis

The total number of years of ITB therapy was calculated by subtracting the initial implantation date from the date of the most recent ITB pump refill. The duration from acquired brain injury to ITB pump implantation was calculated by subtracting the date of injury from the date of implantation. Patient-years of ITB treatment were calculated by summing the years of ITB therapy for all the patients in the study. Pump and catheter life were calculated by determining the time between implantations for each component. The long-term dose stability was evaluated by calculating the absolute change in dose between the dose at the time of chart review, and 1, 2, and 3 years earlier. Long-term dose stability analysis was performed with the subset of subjects who had received ITB therapy longer than 5 years ($n = 31$). This ensured that dosing data used was at least 2 years post-ITB implantation, as a previous investigation established relative dose stability beyond 2 years postimplantation [15].

Statistical Analysis

Means and standard deviations (SDs) were calculated for demographic and dosing data. Analysis of variance was used to compare the dosing patterns between patients with diagnoses of TBI, stroke, and HIE. The χ^2 test was performed to compare categorical variables between the 3 aforementioned groups. Given the multifocal pattern of injury associated with both TBI and HIE, a subanalysis was performed comparing TBI and HIE with the stroke group. Statistical significance was defined as a P value of less than .05. IBM SPSS Statistics Version 22 (IBM Corp., Armonk, NY) was used for all analyses.

Results

Two hundred twenty charts were reviewed, and 42 patients met study inclusion criteria. Of the 178 screened patients who were not included, 163 had spasticity due to conditions other than TBI, stroke, or HIE, primarily cerebral palsy and spinal cord injury. The other 15 excluded patients had spasticity secondary to TBI, stroke, or HIE but had received ITB therapy for less than 3 years.

Patient characteristics grouped by diagnosis are shown in Table 1. The numbers of patients with diagnosis of TBI, stroke, and HIE were 19, 11, and 12, respectively. There was a statistically significant difference in age between the TBI, stroke, and HIE groups with stroke patients, on average, older than the other 2

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