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Does Intrathecal Baclofen Therapy Increase Prevalence and/or Progression of Neuromuscular Scoliosis?

Kevin R. Walker, MD[a,b,*], Susan A. Novotny, PhD[a], Linda E. Krach, MD[c,d]

[a]*Gillette Children's Specialty Healthcare, 200 University Ave East, St. Paul, MN 55101, USA*
[b]*Department of Orthopaedic Surgery, University of Minnesota, 2512 South 7th Street, Suite R200, Minneapolis, MN 55454, USA*
[c]*Courage Kenny Rehabilitation Institute, 800 E. 28th Street, Minneapolis, MN 55407, USA*
[d]*Department of Physical Medicine and Rehabilitation, University of Minnesota, 410 Church St. SE, Minneapolis, MN 55455, USA*

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Abstract

Study Design: Retrospective, case-matched review.
Objectives: Compare a group of individuals with cerebral palsy (CP) who had intrathecal baclofen (ITB) pumps to a group of individuals with CP who did not have ITB pumps in order to determine if there was a difference in the prevalence of new-onset neuromuscular scoliosis, an increased rate of progression of preexisting neuromuscular scoliosis, or an increased rate of posterior spine fusion surgery in skeletally immature individuals with CP who had ITB pumps.
Summary of Background Data: Various authors report conflicting findings, with some reporting an increased incidence or prevalence of scoliosis in individuals with CP who have ITB pumps whereas others report no difference in the rate of scoliosis between groups.
Methods: Retrospective chart and radiographic case-matched study in which individuals were matched by gender and Gross Motor Function Classification Scale (GMFCS) level.
Results: We found no difference in the rates of new-onset neuromuscular scoliosis for those with CP and ITB pumps and those without ITB pumps. However, we did see a higher rate of progression as well as an increased rate of posterior spine fusion surgery in individuals with CP who had ITB pumps than for those with CP who did not have an ITB pump.
Conclusions: We continue to recommend ITB pump therapy for individuals with severe spasticity associated with CP (GMFCS IV and V). There is a significant risk of complications for individuals in general. The risk of neuromuscular scoliosis is relatively high in this population. Our findings suggest that individuals with CP who have ITB pumps and who do or do not have preexisting scoliosis should be monitored closely for either developing new neuromuscular scoliosis or progression of preexisting scoliosis.

Keywords: Cerebral palsy; Intrathecal baclofen pump; Neuromuscular scoliosis; Posterior spine fusion

Level of Evidence: Level III; case-control study

Introduction

Penn first described the application of intrathecal baclofen (ITB) for individuals with spinal spasticity [1,2]. Albright expanded its use to children with spasticity of cerebral origin shortly thereafter [3,4]. ITB therapy using an implantable, programmable pump has now been widely adopted in the treatment of children with spasticity due to cerebral palsy (CP) [5-9]. Many authors have reported high levels of overall satisfaction among family members and caregivers of patients with ITB pumps [10-12]. However, a number of authors have also reported the occurrence of associated complications that may require revision surgery, including infection, pump failure, pump hypermobility, and catheter-related problems such as broken or disconnected catheters [13-19]. Moreover, the primary group of individuals who receive ITB therapy consists of individuals classified as Gross Motor Function Classification System (GMFCS) levels 4 and 5 [20]. This population is also at an

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*Corresponding author. Gillette Children's Specialty Healthcare, 200 University Ave East, Saint Paul, MN 55101, USA. Tel.: (651) 229-3948; fax: (651) 312-3188.
E-mail address: walke009@umn.edu (K.R. Walker).

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increased risk for developing progressive neuromuscular scoliosis [21-23]. It is unclear from the literature whether those with CP who are receiving ITB therapy have a greater chance of developing scoliosis or have a higher rate of scoliotic curve progression, compared with those with CP not receiving ITB therapy. In one of the earliest studies on the effect of ITB therapy on scoliosis, Segal reported that four of their five participants had marked progression of their scoliosis within one year of pump insertion [15]. In another small study, Sansone also reported rapid progression of scoliosis following insertion of ITB pumps in four participants [24]. Ginsberg and Lauder compared the rate of curve progression before and after ITB pump insertion in 19 nonambulatory individuals with spastic quadriplegia and reported an increased rate of progression after pump insertion [25]. However, this was a retrospective study with no control group.

The aim of this study was to determine whether the development of new scoliosis, the rate of curve progression of preexisting scoliosis, and the occurrence of associated posterior spine fusion was greater in skeletally immature children and adolescents with CP who received ITB therapy, compared with a case-matched group with CP who did not have ITB pumps. It was hypothesized that a significantly greater proportion of those with CP and an ITB pump developed neuromuscular scoliosis and/or experienced a significantly greater progression of preexisting scoliosis, compared with individuals with CP who did not have an ITB pump. Because progression to a large curve magnitude may be treated by performing posterior spine fusion surgery, it was further hypothesized that a significantly greater proportion of individuals with CP who are treated with an ITB eventually undergo spinal fusion surgery, compared with children with CP who do not receive an ITB pump.

Material and Methods

A retrospective, case-matched study was conducted at a tertiary-level pediatric specialty hospital to assess whether management of spasticity with ITB in children and adolescents with CP impacted the development and/or progression of scoliosis. Individuals with a diagnosis of CP and an ITB pump (ie, ''pump'') surgically implanted over a 13-year period were compared to gender- and GMFCS level–matched individuals with CP without ITB pumps (ie, ''control'') as described below. The inclusion criteria for individuals with pumps were as follows: (1) static encephalopathy with onset prior to one year of age; (2) placement of an ITB pump prior to skeletal maturity; (3) no previous spinal fusion; (4) existing initial baseline radiograph prior to pump placement; and (5) clinical follow-up and spinal radiographs available for a minimum of two years after the initiation of ITB therapy. The inclusion criteria for controls were as follows: (1) static encephalopathy with onset prior to one year of age; (2) no previous spinal fusion; and (3) clinical follow-up and spinal radiographs available for a minimum of two years from date of match to the ITB participant. The study was approved by the University of Minnesota's Institutional Review Board.

Medical records were used to identify a list of individuals who received ITB pumps as well as a list of potential gender- and GMFCS-matched Controls. Baseline age for Pump participants was defined as age at ITB pump implantation, and efforts were then made to select the Control patient most similar in chronological age to the Pump patient in addition to matching gender and GMFCS level. When the target chronological age fell between two clinical visits for the matched Control, the earlier of the two dates was selected. For all individuals, demographic, surgical, and radiographic information were acquired from the medical record.

Surgical and radiographic data from clinical visits were collected for each individual during the entire 13-year study period, or until (1) the patient had a spinal fusion; (2) the Pump patient had an ITB pump surgically removed; or (3) the Control patient had an ITB pump surgically placed. For those who had one of these surgical events, the date of their last clinic visit prior to surgery was used as their final follow-up visit. For individuals who were lost to follow-up, their last clinic visit was used as the final follow-up. Surgical information included types of surgery (eg, ITB pump placement or removal, or spinal fusion) and dates of the surgery. For individuals who underwent spinal fusion, the intrathecal catheter was maintained so that it was patent and functioning at the conclusion of the procedure.

To determine whether ITB management influenced the development of scoliosis, baseline and follow-up radiographs were analyzed for the presence of scoliosis (ie, spinal curvature $\geqslant 10^{\circ}$) as well as curve magnitude and curve pattern. All spinal radiographs were obtained with the patient in the seated positon. The magnitude of the curve or curves was determined using the Cobb method. For those with more than one curve, the largest curve was used to assess curve magnitude. Curve pattern (single, double or multiple) was also noted. The annual rate of change of curve magnitude was calculated as the change in curve magnitude between the final follow-up visit and baseline visit, divided by the difference in years between these respective clinic dates.

Statistics

Chi-square tests with Fisher exact tests for categorical variables, and paired *t* tests for continuous variables were used to determine whether the incidence of scoliosis, curve magnitude and progression, demographics, and the incidence of posterior spine fusion were different between Pump and Control groups. To determine if ITB management influenced the progression of preexisting scoliosis, or the need for spinal fusion, subanalyses were performed using those with baseline scoliosis and those requiring