Original Article

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Effect of Intrathecal Baclofen Pump on Scoliosis in Children With Cerebral Palsy: A Meta-Analysis

Soolim Lee, MD, Cheolhwan Hyun, MD, Kyungmin KIM, MD, Hyo Eun Kwon, MD, Minwoo Woo, MD, Seong-Eun Koh, MD, PhD

Department of Rehabilitation Medicine, Konkuk University School of Medicine & Konkuk University Medical Center, Seoul, Korea

Objective To systematically review the effect of intrathecal baclofen pump insertion in children with cerebral palsy (CP) with respect to scoliosis.

Methods A systematic literature search was conducted in PubMed, Embase, Cochrane Library, and Google Scholar databases up to June 2022. The inclusion criteria were as follows: (1) studies with a quantitative study design; (2) studies with a study group of children with CP; (3) studies comparing scoliosis in children with and without an intrathecal baclofen pump; and (4) studies with Cobb's angle as a parameter.

Results Of the 183 studies found, four studies, all of which were retrospective comparative studies, met the aforementioned inclusion criteria. All studies were homogeneous (I^2=0%, p=0.53) and intrathecal baclofen pump insertion accelerated the progression of scoliosis (standard mean difference=0.27; 95% confidence interval=0.07–0.48).

Conclusion Intrathecal baclofen pumps have been used to alleviate spasticity in children with CP, thus aiding their daily activities and movements. However, their advantages and disadvantages should be reviewed after sufficient time considering the pumps' negative effect on the course of scoliosis.

Keywords Cerebral palsy, Baclofen, Scoliosis

INTRODUCTION

Cerebral palsy (CP) refers to a disorder of movement and posture with "non-progressive, but often changing motor impairment syndromes secondary to lesions or anomalies of the brain, arising in the early stages of its development [1,2]." The three subtypes of CP are named after the types of motor dysfunction: spastic, dyskinetic, and ataxic [3].

Spastic CP is observed in 70%–80% of patients with CP [4]. Spasticity has long affected patients' quality of life, hampering their basic activities of daily living [1].

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Corresponding author: Seong-Eun Koh
Department of Rehabilitation Medicine, Konkuk University School of Medicine & Konkuk University Medical Center, 120-1 Neungdong-ro, Gwangjin-gu, Seoul 05030, Korea. Tel: +82-2-2030-5346, Fax: +82-2-2030-5375, E-mail: kohse@kuh.ac.kr
ORCID: Soolim Lee (https://orcid.org/0000-0002-2355-5928); Cheolhwan Hyun (https://orcid.org/0000-0001-9552-6846); Kyungmin KIM (https://orcid.org/0000-0001-8198-2955); Hyo Eun Kwon (https://orcid.org/0000-0003-3806-4387); Minwoo Woo (https://orcid.org/0000-0002-5299-4452); Seong-Eun Koh (https://orcid.org/0000-0002-0446-1889).

Various methods, including both medical and surgical treatments, have been introduced to ease the pain and burden of patients with CP. Oral medications, including benzodiazepines, dantrolene, gabapentin, alpha-2 adrenergic agonists, and baclofen, have been commonly used to control spasticity [5]. Along with oral medication, posterior rhizotomy and intrathecal baclofen (ITB) pump insertion have been utilized as neurosurgical interventions to control spasticity in children with CP [6].

The ITB pump was first devised in the 1980s [7]. In addition to CP, ITB pump insertion can be considered in various disease groups, including stroke, spinal cord injury, brain injury, and multiple sclerosis [8]. Compared to oral baclofen, intrathecal pumps had a direct effect on gamma-aminobutyric acid receptors in the spinal cord, which enabled a significantly lower dosage to be used [7].

There are no accurate statistical data with regard to the use of ITB in CP. In Vender et al. [9]'s paper, two surgeons performed ITB pump insertions on 108 children with CP over 5 years. In a meta-analysis, which includes 48 papers, selective dorsal rhizotomy (SDR) was performed in 54% and ITB pump was performed in 29% for the purpose of controlling spasticity in children with CP [10].

Although there are complications, such as infection, wound dehiscence, cerebrospinal fluid leakage, and overdose or withdrawal symptoms of baclofen, baclofen pump has been used so far to alleviate spasticity. Along with the pump's effect on spasticity, ITB pump insertion has been shown to reduce the probability of additional orthopedic surgery [11,12].

Until now, the ITB-related meta-analysis in CP was limited to the comparison of the influence on spasticity and superiority with rhizotomy rather than on the risk of scoliosis progression [10,13-16]. In terms of spasticity, there were studies that showed that it was helpful in CP patients, and there were no uniform studies on long-term effect [15]. When compared with SDR and extracorporeal shockwave therapy, ITB was a less invasive method for treating spasticity in children with CP [14]. As the number of cases using ITB pump in CP increased, studies on various effects and side effects caused by the pump began. The impact on scoliosis after pump insertion had controversial conclusions, with some studies suggesting that ITB pumps accelerate scoliosis progression and others suggesting the opposite [17-24].

Regarding the fact that the prevalence of scoliosis in CP patients reaches as high as 76% [12] and the rate of scoliosis progression varies with the growth of children, it is important to identify how ITB pump insertion affects scoliosis in determining its usefulness. Therefore, given that two theories coexist with regard to the influence of an ITB pump on scoliosis, this study aimed to analyze how ITB pumps affect the progression of scoliosis in patients with CP.

MATERIALS AND METHODS

The Preferred Reporting Items for Systematic Review and Meta-Analyses checklist was used in this study (Supplementary Material) [25].

Literature search and study selection

In a systematic review of the literature, we selected studies that used ITB pumps and analyzed scoliosis in children with CP.

The search was performed using PubMed, Embase, Cochrane Library, and Google Scholar databases from inception to June 2022 using the following keywords: (cerebral palsy) AND ("intrathecal baclofen pump" or "intrathecal baclofen" or "continuous baclofen") AND ("scoliosis" or "Cobb's angle"). Abstracts were reviewed to select eligible studies.

The inclusion criteria were as follows:

1) Studies with a quantitative study design
2) Studies with study group of children with CP
3) Studies comparing scoliosis in children with and without ITB pumps
4) Studies with Cobb's angle as a parameter

Studies comparing the effectiveness of ITB pumps with other procedures or studies comparing its effect on spasticity, not scoliosis, were excluded.

Analysis and data extraction

After the search, we documented the details of the selected studies, including patient group, study design, publication year, and results. Among them, four studies compared the extent of scoliosis in children with CP using Cobb's angle as an objective tool between the two groups, one with an ITB pump and one without an ITB pump [19,20,22,23].

In case of Lins et al. [19] study, 19 patients with ITB and 39 without were initially included in the study. For these two groups, differences such as pelvic fixation during surgery, degree of blood loss, and fixation method were compared. Indicators to determine the progress of scoliosis, including Cobb's angle between the ITB insertion group and the no ITB insertion group, were only compared between those with serial annual radiograph follow-up before surgery. Therefore, 12 patients without serial radiographs were excluded, and 15 patients who underwent ITB insertion and 31 who did not were included in this meta-analysis.

All four studies calculated the annual change in Cobb's angle to evaluate the speed of scoliosis progression. Both the mean±standard deviation (SD) values were presented in three studies [19,22,23]. Although the SD value was not presented in one study [20], the value could be derived through a graph using Adobe Acrobat XI (Adobe, San Jose, CA, USA).

Statistical analysis

The annual change in Cobb's angle was statistically analyzed to examine the effect of ITB pumps on scoliosis. The heterogeneity of the study was calculated using the I^2 test to observe variation across studies. The 95% confidence intervals (CIs) and two-tailed p-values were provided. R metapackage was used for statistical analysis and graphics (http://www.r-project.org).

RESULTS

Search results

Study selection was performed, as shown in Fig. 1. A total of 183 studies were initially reviewed, four of which met all the inclusion criteria [19,20,22,23]. Two individual authors carefully reviewed the full English text. The study data and results are presented in Table 1.

Outcomes

The total number of patients included in this meta-analysis was 387, which included 181 children with ITB pump insertion (experimental group) and 197 without (control group).

Lins et al. [19] and Walker et al. [20] concluded that ITB pump accelerates the progression of scoliosis. Rushton et al. [22] and Shilt et al. [23] showed no statistically significant difference between the ITB insertion group and one without with regard to scoliosis.

Three papers [19,22,23] showed no significant difference in baseline age between the control and pump groups. In the study by Walker et al. [20], children in the pump group were approximately two years older than those in the control group. However, the age at final follow-up was 13.9±3.2 years in the control group (n=91) and 14.3±3.4 years in the pump group (n=91), without statistically significant difference (p=0.458).

In the current meta-analysis of four papers, the mean±SD of annual Cobb's angle change was used as a parameter for scoliosis progression. Pooled analysis revealed

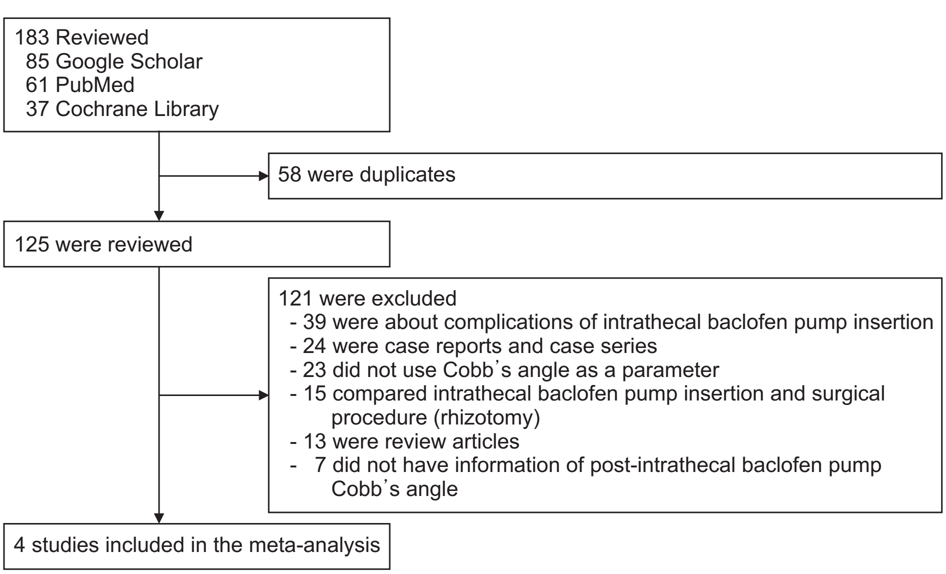

Fig. 1. Flowchart of study selection.

Table 1. A summary of the effect of intrathecal baclofen pump insertion on Cobb's angle

Study	Study design	Sampling	Gross motor function classification system	Group	Group characteristics and follow-up period	Cobb's angle at presentation, final follow-up, mean annual Cobb's angle progression
Lins et al. [19]	Single-center, retrospective review	Patient with cerebral palsy undergoing posterior spinal fusion	4 and 5	Pump (n=15) Control (n=31)	Age at baseline, yr (p=0.4531) Pump (n=15): 10.2±3.9 Control (n=31): 9.3±3.6 Follow-up period, yr Pump (n=15): 3.1±1.6 Control (n=31): 2.6±1.4	Cobb's angle at presentation (p=0.0384) Pump (n=15): 22.0±17.2 Control (n=31): 35.1±20.7 Cobb's angle at final follow-up (p=0.25) Pump (n=15): 60.0±20.3 Control (n=31): 66.7±23.4 Mean annual Cobb's angle progression (p=0.0346) Pump (n=15): 14.8±9.1 Control (n=31): 9.5±6.7
Walker et al. [20]	Retrospective, case matched review	Cerebral palsy	Level 2 (n=2), level 3 (n=34), level 4 (n=46), level 5 (n=100)	Pump (n=91) Control (n=91)	Age at baseline, yr (p<0.001) Pump (n=91): 8.75±3.10 Control (n=91): 6.42±2.80 Follow-up period, yr (p<0.001) Pump (n=91): 5.5±2.1 Control (n=91): 7.5±3.2	Cobb's angle at presentation (p=0.090) Pump (n=91): 21.4±12.9 Control (n=91): 27.1±14.3 Cobb's angle at final follow-up (p=0.498) Pump (n=91): 48.6±24.3 Control (n=91): 54.3±31.4 Mean annual Cobb's angle progression (p=0.05) Pump (n=91): 6.0±9.9 Control (n=91): 3.8±4.5
Rushton et al. [22]	Retrospectively matched cohort study	Quadriplegic spastic cerebral palsy	5	Pump (n=25) Control (n=25)	Age at baseline, yr (p=0.16) Pump (n=25): 9.4±4.2 Control (n=25): 9.2±2.0 Follow-up period, yr (p=0.16) Pump (n=25): 4.3 (1.0–7.8) Control (n=25): 3.5 (1.0–7.5)	Cobb's angle at presentation (p=0.06) Pump (n=25): 25.6±22.4 Control (n=25): 29.7±21.9 Cobb's angle at final follow-up (p=0.39) Pump (n=25): 76.1±29.8 Control (n=25): 69.1±29.2 Mean annual Cobb's angle progression (p=0.72) Pump (n=25): 13.6±9.1 Control (n=25): 12.6±7.6

Table 1. Continued

Study	Study design	Sampling	Gross motor function classification system	Group	Group characteristics and follow-up period	Cobb's angle at presentation, final follow-up, mean annual Cobb's angle progression
Shilt et al. [23]	Controlled clinical trial	Cerebral palsy	4 and 5	Pump (n=50) Control (n=50)	Age at baseline, yr (p=0.15) Pump (n=50): 9.8±3.7 Control (n=50): 9.7±3.9 Follow-up period, yr (p=0.56) Pump (n=50): 2.7±1.4 Control (n=50): 3.0±1.6	Cobb's angle at presentation (p=0.06) Pump (n=50): 15±13 Control (n=50): 13±13 Cobb's angle at final follow-up (p=0.38) Pump (n=50): 28±20 Control (n=50): 27±21 Mean annual Cobb's angle progression (p=0.39) Pump (n=50): 6.6±11.3 Control (n=50): 5.0±6.1

Values are presented as mean±standard deviation or mean (range).

homogeneity (I^2=0%, p=0.53) as shown in Fig. 2. The forest plot (Fig. 2) suggests that the annual change of Cobb's angle is greater in the experimental group with ITB pump insertion than in the control group, implying that ITB pump insertion accelerates annual Cobb's angle progression in children with CP. The fixed-effects model revealed a standardized mean difference (SMD) of 0.27 (95% CI, 0.07–0.48). The random-effects model showed an identical SMD considering the homogeneity of the four studies.

A funnel plot analysis is shown in Fig. 3. All studies included in the meta-analysis are symmetrically located in both sides. Diagonal lines of Fig. 3 represent an area where 95% of points lie without publication bias, and all the four studies included in this meta-analysis lied within this area, suggesting that the ITB pump group showed accelerated annual Cobb's angle change compared to the control group. Egger test (p=0.655) also did not show any publication bias.

DISCUSSION

The four studies [19,20,22,23] included in this meta-analysis were divided into two groups with conflicting conclusions. In two studies [19,20], ITB pump insertion accelerated scoliosis, while no statistically significant difference in annual Cobb's angle change was found in the remaining two [22,23]. The current meta-analysis included a total of 181 and 197 children with and without ITP pump insertion, respectively. Children with CP and ITB pump insertion showed greater annual changes in the Cobb's angle than those with CP without ITB pump insertion. Data synthesis and meta-analysis showed that the four studies were homogeneous, and a funnel plot confirmed that there was no publication bias.

Until now, the available systematic review of ITB pump in children with CP has focused mainly on whether there is an improvement in spasticity. In 2000, the American Academy for Cerebral Palsy and Developmental Medicine performed a systematic analysis of 17 studies after screening papers from 1956 to March 2000 [26]. Twenty-six out of the 32 measures of spastic signs, such as muscle tone, range of motion, and functional level, showed improvement after ITB pump application. In particular, ITB pump was found to be more effective in controlling spasticity in the lower extremities; however, its effect was not yet clear in the upper extremities. The functional level

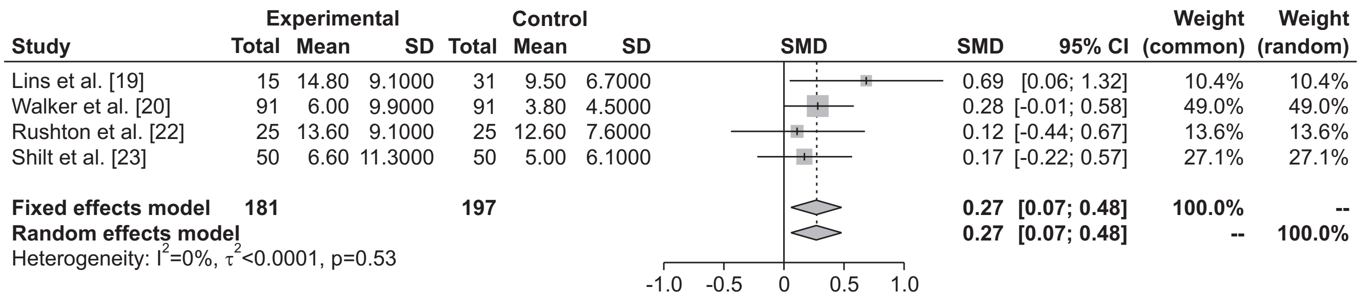

Fig. 2. Forest plot of change in annual Cobb's angle in the intrathecal baclofen pump insertion and control groups. SD, standard deviation; SMD, standardized mean difference; CI, confidence interval.

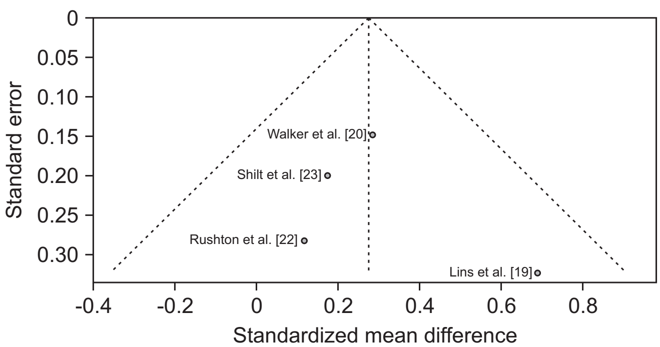

Fig. 3. Funnel plot of estimate of fixed effects model. Diagonal lines refer to lines where 95% of points exist when publication bias is absent.

and caregiver burden improved. Complications were also described in this systematic review, most of which were medical problems, such as hypotonia, device-related events, seizure, and headache, whereas there was no mention of scoliosis [26].

There have been limited studies showing the relationship between spasticity and ITB pump in CP children, but studies on the factors that may affect scoliosis acceleration in CP children are abundant. In children with CP, Willoughby et al. [27], using Gross Motor Function Classification System (GMFCS) 1 as the reference value, reported that GMFCS 4 had odds ratio (OR) of 15.3 (95% CI, 6.6–35.5) and GMFCS 5 had OR of 23.4 (95% CI, 9.9–55.6). Also, 18% of GMFCS 4 and 48% of GMFCS 5 children had scoliosis, with Cobb's angle being larger than 40 degrees. In a population-based study including 962 CP patients [28], GMFCS 4 showed a hazard ratio of 15 (95% CI, 9–30), GMFCS 5 of 53 (95% CI, 28–100) when compared to GMFCS 1 and 2. These large population-based studies [27,28] suggest that GMFCS is an important prognostic factor for scoliosis progression. In the four papers included in the current meta-analysis, all children had GMFCS levels of 4 and 5; thus, we ruled out the impact of GMFCS level on the progression of scoliosis. Given that age and GMFCS level of patients were similar in the four studies, homogeneous and meaningful conclusions could be drawn.

Further, in another study by Gu et al. [29] with 110 nonambulatory spastic tetraplegic CP children, age and Cobb's angle >40 degrees at age 12 years were correlated with aggravation of scoliosis in a multivariate regression model. Given that Walker et al. [20] found no significant difference in age at last follow-up and the other three papers [19,22,23] also reported no significant difference in age at baseline, we ruled out the impact of age on scoliosis progression and ITB pump insertion. Three out of the four studies [20,22,23] reported no statistical difference between ITB pump and non-ITB pump groups with regard to the initial Cobb's angle. In the remaining one study [19], the initial Cobb's angle was more severe in the control group (35.1±20.7) than in the ITB pump insertion group (22.0±17.2). We predicted that the control group would show acceleration of scoliosis, but in reality, the rate of acceleration of scoliosis was faster in the ITB pump group. In addition, since the initial cobb's angle was less than 40 degrees in all studies, with age under 12 years [19,20,22,23], we could rule out the effect of Cobb's angle at presentation on scoliosis progression. Thus, we concluded that ITB pump insertion was the only variable in our study with greater clinical significance. Therefore, this meta-analysis has been a clinically significant study in analyzing the effect of pump insertion on scoliosis progression.

The association between ITB pump insertion and scoliosis has not yet been clearly elucidated. In addition, it is unclear how to distinguish between the natural course of scoliosis progression and the effect of the ITB pump. A possible mechanism is that hypotonia caused by baclofen increases instability and worsens scoliosis [30,31]. Therefore, it is meaningful to compare a control group without ITB insertion and an ITB pump insertion group, as in this meta-analysis. This study demonstrated that pump insertion resulted in the acceleration of scoliosis.

This study has some limitations. In this study, since Cobb's angle was measured annually in patients with CP who were mainly about to undergo surgery, most of them progressed in the direction of aggravating scoliosis. Since the study was conducted on children with GMFCS levels of 4 or 5 and most of the patients who underwent baclofen pump insertion generally presented poor clinical manifestations, the annual scoliosis progression rate recorded by the Cobb's angle might have been higher than that in the natural course of the disease. In addition, although a significantly larger number of procedures is currently performed than in the 1980s, the total number of patients who underwent pump procedures in this systematic review was limited to 181 due to the procedure's invasiveness and the inclusion criteria. Despite these limitations, this systematic analysis is meaningful as it analyzed the effect of ITB pump insertion from a new perspective of scoliosis rather than spasticity, with Cobb's angle as an objective indicator.

Our study supports the view that ITB pumps may accelerate the rate of scoliosis progression in children with CP. Managing scoliosis is clinically important because it affects the maintenance of a sitting or standing posture, the performance of activities of daily living, and the caregiver burden [31,32]. Future studies are needed to reveal the clinical and long-term effects and mechanisms of scoliosis of the ITB pump through case-control studies with a larger sample size. In the meantime, the ITB pump should be carefully applied to appropriate patients at the right time, considering its advantages and disadvantages between spasticity control and scoliosis exacerbation.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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None.

AUTHOR CONTRIBUTION

Conceptualization: Koh SE. Methodology: Kwon HE. Formal analysis: Hyun C, Woo M. Project administration: Lee S, Koh SE. Visualization: KIM K. Writing – original draft: Lee S. Writing – review and editing: Lee S, KIM K, Koh SE. Approval of final manuscript: all authors.

SUPPLEMENTARY MATERIALS

Supplementary materials can be found via https://doi.org/10.5535/arm.22108.

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