Risk factors for baclofen pump infection in children: a multivariate analysis

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OBJECTIVE Intrathecal baclofen infusion systems to manage severe spasticity and dystonia are associated with higher infection rates in children than in adults. Factors unique to this population, such as poor nutrition and physical limitations for pump placement, have been hypothesized as the reasons for this disparity. The authors assessed potential risk factors for infection in a multivariate analysis.

METHODS Patients who underwent implantation of a programmable pump and intrathecal catheter for baclofen infusion at a single center between January 1, 2000, and March 1, 2012, were identified in this retrospective cohort study. The primary end point was infection. Potential risk factors investigated included preoperative (i.e., demographics, body mass index [BMI], gastrostomy tube, tracheostomy, previous spinal fusion), intraoperative (i.e., surgeon, antibiotics, pump size, catheter location), and postoperative (i.e., wound dehiscence, CSF leak, and number of revisions) factors. Univariate analysis was performed, and a multivariate logistic regression model was created to identify independent risk factors for infection.

RESULTS A total of 254 patients were evaluated. The overall infection rate was 9.8%. Univariate analysis identified young age, shorter height, lower weight, dehiscence, CSF leak, and number of revisions within 6 months of pump placement as significantly associated with infection. Multivariate analysis identified young age, dehiscence, and number of revisions as independent risk factors for infection.

CONCLUSIONS Young age, wound dehiscence, and number of revisions were independent risk factors for infection in this pediatric cohort. A low BMI and the presence of either a gastrostomy or tracheostomy were not associated with infection and may not be contraindications for this procedure.

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KEY WORDS infection; baclofen pump; children; spasticity

Intrathecal baclofen (ITB) therapy has been used to treat spasticity in adults since the 1980s and in children since 1993, when Albright and colleagues1 published their findings on the first series of 37 pediatric patients implanted with baclofen pumps. In that series, the authors found an overall infection rate of 19% without perioperative antibiotics and 5% with perioperative antibiotics. Subsequent studies have found infection rates in children with baclofen pumps that range from 3% to 40%, although most studies report an infection rate of approximately 9%.2,3,6,8 These infections are associated with high rates of morbidity, including multiple surgeries, long hospital stays, intravenous antibiotic administration, and high overall costs.

Since the original study by Albright et al.,1 subsequent studies have confirmed that the overall complication and the infection rates are both higher in the pediatric population than in adults.3,12 Various reasons for this have been postulated, including poor wound healing in children with severe spasticity (Vender et al.12 reported that 16% of children had wound revisions vs 5% of adults), a higher percentage of gastrostomy tubes, more frequent revisions, and higher rates of urinary and fecal incontinence in children treated with ITB therapy.4,12 The placement of the large pump subcutaneously versus subfascially has also been identified as a risk factor for subsequent infection.18 To date, to our knowledge, no large multivariate analysis of risk factors for baclofen pump infections in children has

ABBREVIATIONS BMI = body mass index; ITB = intrathecal baclofen; PCH = Primary Children’s Hospital; TBI = traumatic brain injury; VP = ventriculoperitoneal.


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been published. To address this important knowledge gap, we evaluated independent risk factors to identify those that are predictive of baclofen pump infection in children.

**Methods**

**Study Design**

This single-center, retrospective cohort study was approved by the Primary Children’s Hospital (PCH) Privacy Board and the University of Utah Institutional Review Board with a waiver of consent. Clinical data were abstracted by a paper and electronic chart review conducted by a physician specializing in neurosurgery; 2 other physicians reviewed 10% of the charts to ensure the accuracy of data abstraction.

**Study Population**

The study population included consecutive children 17 years of age or younger who underwent baclofen pump and intrathecal catheter implantation at PCH between January 1, 2000, and March 1, 2012, and who had at least 1 year of clinical follow-up after surgery. The cohort was assembled by interrogating the pediatric neurosurgical database and cross-referencing with a billing database to ensure a consecutive sample of patients during the defined study period.

**Primary Outcome**

The primary outcome variable was a documented infection of the infusion pump or catheter during the 13-year study period. Infection was defined as culture-positive (CSF, wound specimen, or exposed hardware).

**Risk Factors**

Each variable or risk factor was defined a priori in a data dictionary to minimize measurement bias. Preoperative risk factors that were examined included age, sex, race, height, weight, body mass index (BMI), and the presence of a gastrosity, tracheostomy, previous spinal fusion, or ventricuropereitoneal (VP) shunt. The documented diagnosis or indication for the baclofen pump insertion was also recorded as cerebral palsy, chromosomal or genetic disorder, posttraumatic brain injury, or other. Of note, 1 preoperative variable we could not accurately assess because of the retrospective nature of this study was the exact reason for the pump revision. Indications for revision include concern for infection or symptoms of baclofen withdrawal. Because there was significant variability in documentation, the reason for revision was not included in our analysis.

Intraoperative risk factors were abstracted from the anesthesia record and the operative note as dictated by the surgeon. These variables included surgeon, number of people scrubbed during the entire case, the administration of antibiotics prior to skin incision, and the specific antibiotic prophylaxis used. We also recorded whether an additional procedure was performed during the same anesthesia period, which included orthopedic fusion, tracheostomy, or gastrostomy. The location of the catheter tip was categorized as in the ventricle, cervical, thoracic, or lumbar subarachnoid space, and the site of spinal access was recorded as cervical, thoracic, or lumbar. The anatomical placement of the pump was recorded as either subcutaneous or subfascial. Access into the thecal sac was defined as either percutaneous or via laminectomy. The pump model (3 over the course of the study) was also recorded.

Postoperative risk factors were abstracted from the inpatient and outpatient medical records. The patient’s discharge disposition was recorded as home, nursing facility, inpatient rehabilitation service, or other. The variable wound dehiscence was originally abstracted as none, superficial (suprafascial), deep (subfascial), open erosion, or exposure of the hardware, but it was analyzed in the multivariate model as a dichotomized variable: none versus any (superficial, deep, and open erosion combined) to minimize any effects from retrospective documentation errors. The total number of revision procedures was collected for each patient during the study period as well as the number of revisions within 6 months of initial pump placement. The number of revisions within 6 months was also analyzed as a categorical variable (none, 1, and more than 1 revision within 6 months of pump placement).

**Statistical Analysis**

Each of the clinical risk factors was compared with the outcome using a chi-square analysis for categorical variables and a t-test for continuous variables. All variables were tested and found to be parametric. The p values were reported for all analyses, and any variables with a significant (p < 0.05) or nearly significant (p < 0.10) association with infection were included in the multivariate analysis. Because of significant covariance between the total number of revisions and the total number of revisions within 6 months of pump placement, we only included the total number of revisions within 6 months of pump placement, because it was not dependent on length of follow-up. Stepwise logistic regression was used to determine which variables were independently associated with baclofen pump infection (p < 0.05). All statistical analyses were conducted using SAS version 9.3 (SAS Institute).

**Results**

**Patient Sample**

A total of 261 patients underwent implantation of a programmable pump and intrathecal catheter for baclofen infusion during the study period. Seven patients were excluded because of incomplete charts; thus, our cohort included 254 patients (149 male and 105 female; mean age 9.3 years). The indication was spasticity in the context of cerebral palsy (75%), traumatic brain injury (TBI) (17%), or chromosomal disorder (6%), and other (1%) diagnoses. The majority of the patients were white (81.1%), and the mean BMI was 17.5 kg/m². Forty-four percent of the cohort had a gastrostomy, 6% had a tracheostomy, and 12% had a preexisting VP shunt (Table 1).

Surgical implantation of the ITB system was preceded by multidisciplinary evaluation, including neurology, neurosurgery, rehabilitation medicine, and physical therapy, and an ITB bolus trial. No patients in this cohort underwent a catheter trial. Two surgeons performed all of the
surgeries. Prophylactic antibiotics were used in 98.8% of the cases. Ninety-four percent of patients had the intrathecal catheter placed via needle puncture in the lumbar spine, with the catheter tip most commonly positioned in the midthoracic spine (98%). The majority of patients (69.7%) had subfascial placement of the pump, and the most common pump used was the Medtronic Synchromed II 20-ml pump (45%; Medtronic) (Table 1). Overall, 58.3% of our cohort had a baclofen pump revision during the study period.

Twenty-five patients (9.8%) had a baclofen pump infection, including 1 patient who had exposed hardware with negative cultures but was treated and counted as having an infection in this study. Of the 24 patients with positive cultures, 19 of these infections were *Staphylococcus* species (methicillin-resistant *S. aureus* n = 5; methicillin-sensitive *S. aureus* n = 11; *S. epidermis* n = 2; and *S. capitata* n = 1). The other infections seen were due to *Pseudomonas* species (n = 2), *Propionibacterium acnes* (n = 1), *Enterococcus faecalis* (n = 1), and documented Gram-negative bacilli (n = 1). Overall, 7 patients (2.8%) had wound dehiscences; only 1 patient had a wound erosion with visible hardware (0.4%). CSF leaks occurred in 10 (3.9%) patients, and the mean number of revisions within 6 months of pump placement for the entire cohort was 0.22 (Table 1).

**Univariate Analysis**

Univariate analysis demonstrated a significant association between infection and young age (when age was ana-
lyzed as a continuous variable) \( (p = 0.003) \), shorter height \( (p = 0.03) \), and lower weight \( (p = 0.004) \). Although BMI showed a trend toward association with infection, this was not statistically significant \( (p = 0.09) \). The preoperative presence of a gastrostomy, tracheostomy, previous spinal fusion, or VP shunt was not associated with baclofen pump infection. No intraoperative factors were found to be statistically significant. The postoperative factors significantly associated with infection included both overall wound dehiscence and a dichotomized wound dehiscence (present or absent) \( (p < 0.001) \), CSF leak \( (p = 0.01) \), total number of revisions \( (p < 0.001) \), and number of revisions within 6 months of pump placement \( (p < 0.001) \) (Table 2).

Because age was statistically significant, we examined it more closely as a categorical variable (Fig. 1). We found an infection peak in the 4- to 6-year age group that steadily decreased by age 10 \( (p = 0.02) \). When number of revisions was analyzed as a categorical variable, there was a significant increase in number of infections with each revision \( (p < 0.001) \) (Fig. 2).

### Multivariate Analysis

A predictive model was developed using multivariate logistic regression. The significant and near-significant variables from the univariate analysis (i.e., categorical age, BMI, the dichotomized variable of wound dehiscence, CSF leak, and the categorical variable revisions within 6 months of pump placement) were included in the model. The univariate statistical threshold for inclusion in the multivariate analysis was \( p \leq 0.1 \), which included BMI \( (p = 0.09) \). Because height and weight covary, these could not be independently entered into the multivariate logistic model regression. Similarly, revisions within the first 6 months of pump placement were included, and total numbers of revisions were not.

Overall, the logistic regression model had excellent discrimination with a c-statistic of 0.94. Age was independently associated with baclofen pump infection \( (p = 0.05) \), but this association was dominated by the age group of 4–5 years versus 10 years or older \( \text{OR} 14.1; 95\% \text{CI} 2.2–90.3 \). A higher number of revisions within 6 months of initial surgery was significantly associated with infection \( (p < 0.001) \). In the multivariate model, patients with 0, 1, and more than 1 revision had infection rates of 3.5%, 37.5%, and 77.8%, respectively. Wound dehiscence was also independently associated with infection \( (OR 11.8; 95\% \text{CI} 1.0–144.9; p = 0.05) \). BMI and postoperative CSF leak were not independently associated with a baclofen pump infection (Table 3).

We then examined the 4- to 5-year-old age group in more detail. We found a significantly larger proportion of 20-ml or smaller pumps were placed in 4- and 5-year-old patients compared with all other age groups combined \( (p = 0.001) \). When we reanalyzed pump model versus infection within only the 4- to 5-year-old age group, however, we again found no association \( (p = 0.82) \).

### Discussion

We present a retrospective cohort study of 254 children who underwent insertion of a baclofen pump and intrathecal baclofen.
cal catheter. Twenty-five children had a subsequent infection after pump placement, for an overall infection rate of 9.8%. Univariate analysis showed that age between 4 and 5 years, BMI (p = 0.09), wound dehiscence, CSF leak, and revisions within 6 months of pump placement were all associated with higher rates of infection. Multivariate analysis of significant and near-significant univariate variables demonstrated that age, number of revisions within 6 months of initial pump placement, and wound dehiscence were independent risk factors for infection in this cohort. Conversely, factors such as BMI, tracheostomy, gastrostomy, and concomitant spinal fusion were not independent risk factors for baclofen pump infection.

The reported infection rates for baclofen pump infection in the literature range from 3% to 40%. The infection rate of 9.8% in our pediatric cohort is consistent with the findings from the most recent study by Motta and colleagues, who found a 9.3% infection rate when they conducted a retrospective review of 430 pediatric patients with ITB pump placement.

**Patient Age**

In our cohort, young age was significantly and independently associated with an increased risk for baclofen pump infection (p = 0.05). This differs from a previous single-center retrospective study of 139 pediatric patients. Specifically, in our cohort, patients who were 4 or 5 years old at the time of initial surgery had a 20.3% infection rate driving this association (OR 14.1; 95% CI 2.2–90.3). Infection was not significantly associated with any other age category. That younger patients are more vulnerable to implanted CNS hardware infections is not novel or surprising, and is consistent with many pediatric CSF shunt studies.

What is novel, however, is that the youngest group of children (less than 4 years of age) did not have the highest infection rate (8.6%) (Fig. 1). In fact, the infection rate for the children younger than 4 years old was consistent with those seen for those 8 years old and older (3.8%–8.3%). This finding cannot be discounted as spurious because of low numbers, because the group of patients younger than age 4 years had a sample size of 35 and represented 14% of the overall cohort. One possible explanation is that this period of time in a child’s life with spasticity is usually free from multiple orthopedic procedures and repeated hospitalizations awaiting further growth and development, which may decrease the risk for iatrogenic infections. Of note, in this cohort, we did not find infection risk to be correlated with pump size.

Although these data may be interpreted to support baclofen pump implantation before the age of 4 years to mini-
mize infection risk, the severity and functional impact of spasticity and dystonia may not be clear at such a young age, lower-risk therapies may not have been adequately trialed, and candidacy for alternative neurosurgical therapies, including selective dorsal rhizotomy, may not be resolved.

### Number of Revisions and Wound Dehiscence

The increased rate of infection with each revision within the first 6 months of pump placement was relatively dramatic: Children with zero revisions had a 3.5% infection rate, those with 1 revision had a 37.5% rate (OR 22.6; 95% CI 3.3–154.5), and those with 2 or more revisions had a 77.8% infection rate (OR 116.5; 95% CI 22.1–613.2). This finding is consistent with previous studies that also demonstrated a statistically significant increased rate of infection in patients undergoing multiple surgeries for revision of the ITB catheter or pump. This finding is also consistent with previous studies in children with CSF shunts, demonstrating CSF shunt infections increasing logarithmically with each successive shunt revision.\(^\text{10}\)

The multivariate model found that wound dehiscence was independently associated with baclofen pump infection, but CSF leak was not. Our retrospective data collection and analysis only allowed us to determine that there is an independent, significant association (which is different than causation) between wound dehiscence and baclofen pump infection. However, not all patients with wound dehiscences subsequently had infections and not all patients with infections had dehiscences. In terms of timeline, the diagnosis of wound dehiscence preceded that of the infection in all cases of dehiscence. This may indicate that while a CSF leak through a baclofen pump wound may be salvageable by over-sewing the incision to stop the leaking, a wound dehiscence is not less likely salvageable and probably may require pump removal, treatment with antibiotics, and reimplantation. This finding is contrary to that of Hester and colleagues,\(^\text{7}\) who reported successful pump salvage for superficial wound dehiscences that were treated with a course of oral antibiotics. The clinical bottom line is that when a wound dehiscence is clinically diagnosed, quick surgical attention and surveillance for infection is mandated. This is clinically quite self-evident, but this study is the first to scientifically link these variables.

### Other Nonsignificant Variables

A previous retrospective study of 139 patients over a period of 15 years found no significant differences in sex, weight, or site of implantation in those patients who developed an infection, concordant with our findings. Using the National Nosocomial Infection Surveillance definition for infection, they found, contrary to our analyses, that patients with infection were more likely to have spasticity or dystonia from TBI or genetic disorders infection (p < 0.001).\(^\text{3}\)

At the conception of the study, we expected to find a significant correlation between a low BMI and baclofen pump infection; however, despite indicating a significant association with height and weight and near significance with BMI within the univariate analyses, the multivariate analysis found no significant association between BMI and infection. This variable may have been mitigated by the change in the pump placement to subfascial from subcutaneous, although this variable was not associated with infection either. This finding differs from the results of a previous study, which found an association between subcutaneous pump placement and infection in a retrospective review of 430 children.\(^\text{8}\)

We hypothesized that children with a gastrostomy or tracheostomy might have a higher infection rate, but neither variable was significantly associated with infection. This result differs from those of a previous baclofen pump study of 163 patients that demonstrated associations between both tracheostomy and gastrostomy and increased infection rates.\(^\text{4}\) One possible explanation for this difference is that our cohort included more patients (and, therefore, more power) and examined more potential risk factors. The previous study also found that urinary and fecal incontinence correlated with pump infection.\(^\text{4}\) We did not examine this variable because, retrospectively, we could not reliably quantify the degree of incontinence.

### Limitations

The main limitations of this study are that it represents only a single center and is retrospective in design; however, the large cohort and robust analyses set it apart from the previous literature. Our original intent was to also examine Ashworth scores as a potential predictor of the severity of the spasticity for baclofen pump infection, but we found considerable variability among practitioners assigning Ashworth scores and decided that these values were not documented accurately or reliably enough for analysis. In addition, the frequency of percutaneous baclofen pump refill and any potential association with pump infection was not analyzed. Finally, we were unable to stratify surgical revision in our cohort by indication (concern for infection vs symptoms of baclofen withdrawal).

### Conclusions

Pediatric patients with spasticity who undergo placement

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**TABLE 3. Multivariate logistic regression analysis of risk factors for baclofen pump infection**

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at procedure, yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;4</td>
<td>1.6 (0.2–16.2)</td>
<td>0.05</td>
</tr>
<tr>
<td>4–5</td>
<td>14.1 (2.2–90.3)</td>
<td></td>
</tr>
<tr>
<td>6–7</td>
<td>6.1 (0.6–61.4)</td>
<td></td>
</tr>
<tr>
<td>8–9</td>
<td>3.2 (0.3–38.3)</td>
<td></td>
</tr>
<tr>
<td>≥10</td>
<td>Referent</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>1.0 (0.9–1.1)</td>
<td>0.92</td>
</tr>
<tr>
<td>CSF leak</td>
<td>0.2 (0.03–1.7)</td>
<td>0.15</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>11.8 (1.0–144.9)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of revisions w/in 6 mos of pump placement</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Referent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>22.6 (3.3–154.5)</td>
<td></td>
</tr>
<tr>
<td>&gt;1</td>
<td>116.5 (22.1–613.2)</td>
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* Boldface type indicates statistical significance.
of ITB pumps have high rates of infection (approximately 9%). Multivariate analysis of the risk factors for infection showed that a young age of 4–5 years, wound dehiscence, and multiple surgical revisions were significantly associated with an increased risk for infection. Conversely, factors such as BMI, tracheostomy, and gastrostomy were not associated with increased infection risk. These results argue that, if possible, deferring ITB therapy until children are older than 6 years may decrease the risk for infection, but that, conversely, factors such as low BMI and preexisting tracheostomy and gastrostomy may not be contraindications for surgery. Lastly, changes in practice that decrease the frequency of revision may be the most important way to decrease infections in this vulnerable population.

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References

Disclosures
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