Observational Study

Rising Complication Rates after Intrathecal Catheter and Pump Placement in the Pediatric Population: Analysis of National Data Between 1997 and 2006

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Background: Intrathecal delivery of baclofen (ITB) is effective at controlling spasticity. However, it requires the placement of a catheter into the intrathecal space, and a pump with a reservoir for the medication. The process of placing the catheter and pump are prone to complications.

Objectives: The objective of this paper is to determine factors contributing to rising complication rates after intrathecal catheter/pump placement in a national sample of pediatric patients.

Study Design: This was a retrospective observational database study.

Methods: We queried the Kids' Inpatient Database for all children greater than 4 years old and under 20 years old for the years 1997, 2000, 2003, and 2006 who had an intrathecal catheter and pump placed. We then compared demographics and hospital characteristics of patients with and without complications. We performed univariate and multivariate analyses to determine the relative contribution of various factors to the development of complications.

Results: We identified 2,843 patients who met our criteria, and 514 of these patients had one or more complications after placement of intrathecal pump/catheter. There were 1.14 complications per patient. The complication rate was 10.2% in 1997, and increased to 21.9% in 2006. Mechanical complications were the most common type of complication in this population, account for nearly two-thirds of all complications occurring. Age, hospital type, hospital size, and admission source were independent predictors of complications.

Limitations: We did not have access to ASA status, operative details, and access to patient charts.

Conclusions: Complication rates after placement of intrathecal pump/catheters have increased in the pediatric population between 1997 and 2006 mainly due to an increase in mechanical complications.

Key words: Intrathecal, baclofen, catheter, pediatric, kids, complications, spasticity

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Many conditions in the pediatric population are associated with spasticity. These include cerebral palsy, traumatic brain injury, paraplegia, spastic hemiparesis, and other neurological conditions. Intrathecal baclofen has been used to control spasticity since the first reports by Penn and Kroin in 1984 (1,2). Prior to this, available therapeutic options included physical therapy, orthopedic surgeries, oral baclofen, botox injections, and rhizotomy (3). Physical therapy and orthopedic surgeries were only mildly effective. Oral baclofen improved cerebral spasticity mildly, but it was associated with many systemic side

effects, and its activity was limited because of its poor lipid solubility and poor central nervous system (CNS) penetration (4,5). Rhizotomy was effective, but had permanent and nonlocalized sequelae. With the advent of intrathecal baclofen (ITB), the anti-spastic GABA-B agonist could be delivered directly to the intrathecal space without the associated systemic side effects of oral baclofen (6-11). This method of controlling spasticity has been shown to be cost-effective and to offer functional benefits (12,13). However, delivering baclofen to the intrathecal space requires a special pump and catheter system to be surgically implanted (14). Many reports have described the complications associated with surgical implantation of intrathecal catheter systems and guidelines in adult as well as pediatric patients (15-32). However, there is limited information on how complications are changing over the years.

In this study, we used a large existing database to determine the complication rates associated with intrathecal catheter and pump placement for infusing baclofen in the pediatric population from 1997 to 2006. We also classified the complications and attempted to identify factors contributing to complications so that measures may be developed to reduce these complications in the future.

Methods

Data source

Data were obtained from the Kids' Inpatient Database (KID) from the years 1997, 2000, 2003, and 2006. These are the years for which the KID database is available. The KID is a data set of national pediatric inpatient hospitalizations from the Healthcare Cost and Utilization Project (HCUP), sponsored by the Agency for Healthcare Research and Quality (AHRQ). It contains discharge level data on more than 10 million hospitalizations of patients younger than 20 years old from 38 states across the country. States represented in the 2006 sample include Arkansas, Arizona, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana, Kansas, Kentucky, Massachusetts, Maryland, Michigan, Minnesota, Missouri, North Carolina, Nebraska, New Hampshire, New Jersey, Nevada, New York, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, and West Virginia. Patient Selection

We identified patients in the KID that were ≥ 4 years of age who had an intrathecal catheter and implantable infusion pump by using the International Classification of Diseases, Ninth Revision (ICD-9) procedure codes 03.90 (insertion of catheter into spinal canal for infusion of therapeutic or palliative substance), 03.91 (injection of anesthetic into spinal canal for analgesia), 03.92 (injection of other agent into spinal canal), and 86.06 (insertion of totally implantable infusion pump). Baclofen is not recommended for use in children under 4 years of age, thus we limited our search to children older than 4.

We separated these patients further by diagnosis codes 338.0-338.4 (pain syndromes), 340 (multiple sclerosis), 342.1 (spastic hemiplegia), 342.8-342.9 (other hemiplegias), 343.0-343.9 (cerebral palsy), 344.0-344.9 (other paralysis including quadriplegia and paraplegia), 728.8 (other disorders of muscle, ligament, and fascia), 781.0 (abnormal involuntary movements), 781.2-781.3 (gait abnormalities), 806.0 (spinal cord injury), and 952.0 (spinal cord injury).

We defined postoperative complications using ICD-9 codes, including mechanical complications of nervous system device (996.2), infection and inflammatory reaction due to prosthetic device (996.6), other complications of prosthetic device (996.7), immediate postoperative complications (997.0), postoperative respiratory complications (997.3), postoperative shock (998.0), postoperative hematoma or hemorrhage (998.1), accidental puncture or laceration during a procedure (998.2), postoperative wound disruption (998.3), retained foreign body (998.4), postoperative infection (998.5), persistent postoperative fistula(998.6), Staphylococcus infection (041.1), and other postprocedure complications (998-7-998-9).

Statistical Analysis

Hospitalizations were examined by age, race, sex, length of stay (LOS), cost of hospitalization (COH), hospital size (large, medium, small), hospital location (West, Northeast, South, Midwest), hospital teaching status, children's hospital status, admission source, and payer source. Children's hospital (CH) status is derived from the National Association of Children's Hospitals and Related Institutions (NACHRI) hospital type, and included general hospital (GH), children's unit in a general hospital (CUGH), children's specialty hospital (CSpecH), and children's general hospital (CGenH). Admission source included emergency rooms, other hospitals, home, and other facilities. Patient level data included demographic information, admission source, race, sex, and payer source.

Hospital level data included hospital size, rural or urban location, hospital teaching status, hospital census region, and NACHRI hospital type.

Results are presented in percentages or median with 25% - 75% interquartile range. Fisher's exact test was used to compare categorical data. Mann-Wilcoxon Rank-Sum test was used to compare age, LOS, and cost among the groups. Univariate analysis indicated that age, hospital type, admission source, and hospital size contributed to the development of complications. Multiple logistic regression was then performed using age, hospital type, admission source, hospital size, and hospital region as independent factors and the presence of complication as the dependent factor. For this analysis, the admission source was coded into a binary system where emergency department (ED) admissions were categorized as 0 and non-ED admissions were categorized as 1. Odds ratio (OR) was generated with 95% confidence intervals (CI) for the data from the multiple logistic model. For all analyses, statistical significance was set at $P < 0.05$. Statistical analyses were performed with SAS, version 9.1 (SAS Institute, Cary, NC).

Results

General characteristics

From the database, we identified 2,843 patients who were ≥ 4 years old and received an intrathecal catheter/pump for the diagnoses of interest in 1997, 2000, 2003, and 2006. The median age of all patients was 12 years (Table 1). The median length of stay was 3 days (interquartile range 2 - 5 days). The median cost of hospitalization was $30,842 (interquartile range $17,372 – $46,894).

Among the identified patients, 58.8% of them were male, and 49.7% were white. Most patients were admitted from home, and fewer than 5% were admitted from the ED. Most were covered by private payers. Less than 1% were self-pay patients. As for hospital sizes, 47.2% of patients received care at large hospitals, 26.8% at medium hospitals, 21.9% at small hospitals, and 4% of them were missing data on hospital size. Teaching hospitals accounted for 82.6%; 92.7% were in urban areas; 71.9% had their procedures at children's hospitals even though children's hospitals comprise less than 2% of the hospitals in the KID. Only 22.5% were at general hospitals, and hospital type data were missing on 5.5%.

Table 1. *Patient demographics for all patients with intrathecal pumps/catheters in 1997, 2000, 2003, 2006.*

	Median (25% - 75%)	
Age	12 (8 - 16)	
LOS (days)	3 (2 – 5)	
Cost ($)	30,842 (17372 – 46, 894)	
	# Patients	**Percent of total**
Total	2,843	100%
Gender		
Female	1,155	40.6%
Male	1,257	58.8%
Missing	17	0.6%
Admit Source		
ER	130	4.6%
Hospital	57	2.0%
Facility	56	2.0%
Court	1	0%
Home/other	2,521	88.7%
Missing	78	2.7%
Payer		
Medicare	9	0.3%
Medicaid	1,178	41.4%
Private	1,478	52.0%
Self pay	26	0.9%
No charge	2	0.1%
Other	137	4.8%
Missing	13	0.5%
Race		
White	1,414	49.7%
Black	245	8.6%
Hispanic	235	8.3%
Asian/Pacific	30	1.1%
Native American	9	0.3%
Other	68	2.4%
Missing	842	29.6%

ER - Emergency Room

Complications

Of the 2,843 patients, 514 (18%) had one or more of the complications described in the methods section (Table 2). Among the patients who had complications, there were 1.14 complications per patient. This corresponds to the rates described in the literature (21,22).

Table 2. *Difference in patient-level factors of children with and without complications.*

	Complications	No Complication	P-value
Number patients	514	2329	-
Age (years)	13 (10 - 16)	12 (7 - 16)	**<0.001**
LOS (days)	4 (2 - 8)	3 (2 - 5)	**<0.001**
Cost ($)	37,081 (21,858 - 63,945)	29,431 (16,153 - 45,250)	**<0.001**
	Number	**Number**	
Gender			
Female	202 (39.3%)	953 (40.9%)	0.49
Male	308 (59.9%)	1363 (58.5%)	0.5
Missing	4 (0.8%)	13 (0.6%)	0.53
Admit Source			
ER	45 (8.8%)	77 (3.3%)	<0.001
Hospital	11 (2.1%)	48 (2.1%)	0.8
Facility	9 (1.8%)	47 (2.0%)	0.7
Court	0	1 (0%)	0.003
Home/other	437 (85%)	2090 (89.7%)	0.5
Missing	12 (2.3%)	66 (2.8%)	0.55
Payer			
Medicare	3 (0.6%)	6 (0.3%)	0.2
Medicaid	197 (38.3%)	982 (42.4%)	0.11
Private	277 (53.9%)	1199 (51.5%)	0.3
Self pay	2 (0.4%)	24 (1.0%)	0.2
No charge	0	2 (0.1%)	-
Other	28 (5.4%)	109 (4.7%)	0.5
Missing	7 (1.4%)	7 (0.3%)	0.006
Race			
White	235 (45.7%)	1181 (50.7%)	0.04
Black	34 (6.6%)	207 (8.9%)	0.1
Hispanic	35 (6.8%)	202 (8.7%)	0.19
Asian/pacific	8 (1.6%)	22 (0.9%)	0.23
Native American	0	9 (0.4%)	-
Other	8 (1.6%)	60 (2.6%)	0.2
Missing	194 (37.7%)	648 (27.8%)	<0.001

LOS-length of stay, Cost-cost of hospitalization, ER-emergency room

There was no trend in the rate of complications per patient over the 4 years studied. A goodness of fit curve shows an exponential increase in complication rates (R2 = 0.93) (Fig. 1).

Table 2 also shows differences in patient-level factors of patients with and without complications. The median age of children who had complications was one year greater than those who did not have a complication ($P < 0.001$). The median cost of hospitalization for children that had a complication was $7,650 greater than children without complications ($P < 0.001$). The median length of stay was one day greater in children that had complications than those who did not (4 days versus 3 days, $P < 0.001$). More patients who had com-

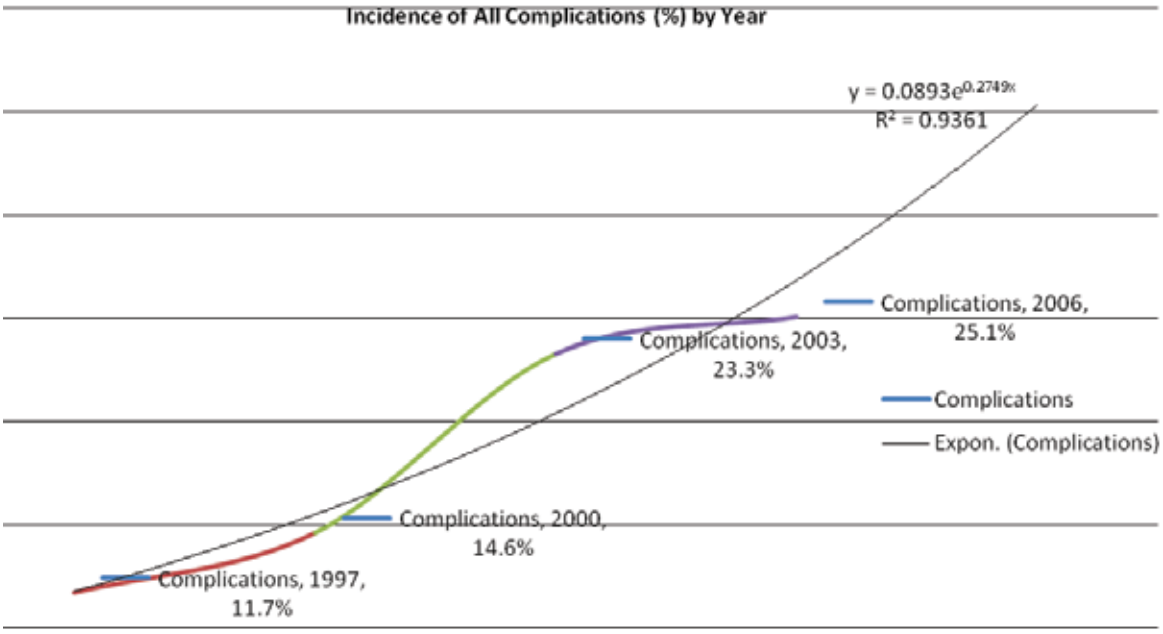

Fig. 1. *Goodness of fit curve showing exponential increase in incidence of all complications by year from 1997 to 2006.*

plications were admitted from the ED (8.8% vs. 3.3%, $P < 0.001$). There was no difference in complication rates based on payer source.

More patients with complications had received care at urban hospitals ($P = 0.04$), at large hospitals (P = 0.01), and at teaching hospitals ($P = 0.07$), though this last comparison did not reach significance (Table 3). There were regional variations, with hospitals in the Midwest accounting for more complications ($P = 0.001$) and hospitals in the South and Northeast accounting for fewer complications ($P < 0.05$). Complications occurring at CGenH or at CUGH accounted for more than 60% of all complications. Nearly half of all patients treated at CSpecH had complications, which is nearly 5 times the percentage of patients experiencing complications at GH (Table 4). However, nearly 5% of the children were missing data on hospital type, with more data missing from children with complications than those without complications ($P = 0.001$).

There was no increase in the percent of patients treated at CH (defined here as CGenH, CSpecH, and CUGH combined) versus GH over the years considered. In 1997, 22% were treated at GH compared with 27% in 2006. In 1997, 78% were treated at CH compared with 79% in 2006. The most frequent primary diagnosis associated with placement over all 4 years was quadriplegia, and this did not change over the 4 years we considered.

The combined complication rate increased from 10.2% of all cases in 1997 to 21.9% of all cases in 2006. Mechanical complications of the device were the most common complications in each of the 4 years studied (Fig. 2). The incidence of mechanical complications increased 2.5-fold between 1997 and 2006 (6.6% vs. 16.8%). The incidence of wound disruption and respiratory complications increased by 60%, while the incidence of Staphylococcus infections increased by 90%. The incidence of hemorrhage increased by 40%. However, all postoperative infections decreased by 50% from 1997 to 2006.

Multiple logistic regression showed CH status and age to be associated with increased complication rates, with OR 1.29 (1.16 – 1.43) and OR 1.06 (1.04 - 1.08), respectively ($P < 0.001$ for both). Hospital size and admission source were inversely related with complication rates, with OR 0.67 (0.58 – 0.77) and OR 0.83 (0.75 – 0.91), respectively ($P < 0.001$ for both).

Table 3. *Difference in hospital-level factors of children with and without complications.*

	Complications (Number)	No Complication (Number)	P-value
Hospital size			
Small	142 (27.6%)	481 (20.7%)	**<0.001**
Medium	131 (25.5%)	632 (27.1%)	0.48
Large	217 (42.2%)	1126 (48.3%)	**0.01**
Missing	24 (4.7%)	90 (3.9%)	0.38
Location			
Rural	3 (0.6%)	91 (3.9%)	**<0.001**
Urban	487 (94.7%)	2148 (92.2%)	**0.04**
Missing	24 (4.7%)	90 (3.9%)	0.38
Teaching			
Nonteaching	80 (15.6%)	302 (13.0%)	0.13
Teaching	410 (79.8%)	1937 (83.2%)	0.07
Missing	24 (4.7%)	90 (3.9%)	0.38
Region			
Northeast	57 (11.1%)	385 (16.5%)	**0.002**
Midwest	185 (36.0%)	667 (28.6%)	**0.001**
South	112 (21.8%)	642 (27.6%)	**0.006**
West	160 (31.1%)	635 (27.3%)	**0.08**
Missing	0	0	-
CH Type			
GH	64 (12.5%)	569 (24.4%)	**<0.001**
CGenH	177 (34.4%)	790 (33.9%)	0.8
CSpecH	66 (12.8%)	80 (3.4%)	**<0.001**
CUGH	163 (31.7%)	778 (33.4%)	0.47
Missing	44 (8.6%)	112 (4.8%)	0.001

GH – General Hospital (Non-children's), CGenH – Children's General Hospital (Freestanding), CSpecH – Children's Specialty Hospital, CUGH – Children's Unit in a General Hospital

Table 4. *Incidence of all complications over four years, divided by hospital type.*

	Complications	No Complications	% with complications
GH	64	569	10.1%
CGenH	177	788	18.3%
CSpecH	66	74	47.1%
CUGH	163	778	17.3%
Missing	44	112	28.2%

GH – General Hospital (Non-children's),
CGenH – Children's General Hospital (Freestanding),
CSpecH – Children's Specialty Hospital,
CUGH – Children's Unit in a General Hospital

Discussion

The core finding in our study is a doubling of complication rates in a national sample of pediatric inpatients between 1997 and 2006 after placement of intrathecal pumps/catheters. Having a complication increases total median hospitalization cost by more than $7,500 and increases median length of hospital stay by one day. Complication rates have been shown to be stable regardless of experience, beyond a baseline threshold, and specialties of the practitioners placing the pump (33). In this study, we evaluated the effect of factors other than individual practitioners on the development of complications. This is a unique addition to the existing literature on this topic. It is clear

from the literature that intrathecal pumps offer immense benefit to patients and caregivers (5,8). Therefore, the increase in complication rate over the past 10 years concerns us. There has been a trend toward receiving care at large, teaching hospitals in urban areas over the years. Looking at all 4 years, children that had complications were 3.7 times more likely to be treated at a children's specialty hospital, and only half as likely to be treated at a general hospital (Table 4). This phenomenon can be due to the possibility that complex cases in children prone to complications anyway may be more frequently transferred from general hospitals to children's hospitals, where expertise tends to be more concentrated. Thus, the shift noted in this study could simply be a surrogate of the general state of the health of the patients being treated. However, this alone does not explain a rise in complication rates.

The most common complication throughout the years was mechanical complications. Comparing data from studies is difficult because of varying classification systems, but most authors see mechanical complications as the most frequent complication (16,34). However, we report in our study that an alarming increase in mechanical complications occurred from 1997 to 2006, which accounts for most of the doubling of all complication rates over the 4 years studied. In 1997, 6.6% of all pump placements experienced mechanical complications. By 2006, this had nearly tripled to 16.8% of all pump placements. Mechanical complications include pump flipping, catheter kinking, catheter disconnection and catheter coiling (35). Catheter complications are more common than pump complications (35-37).

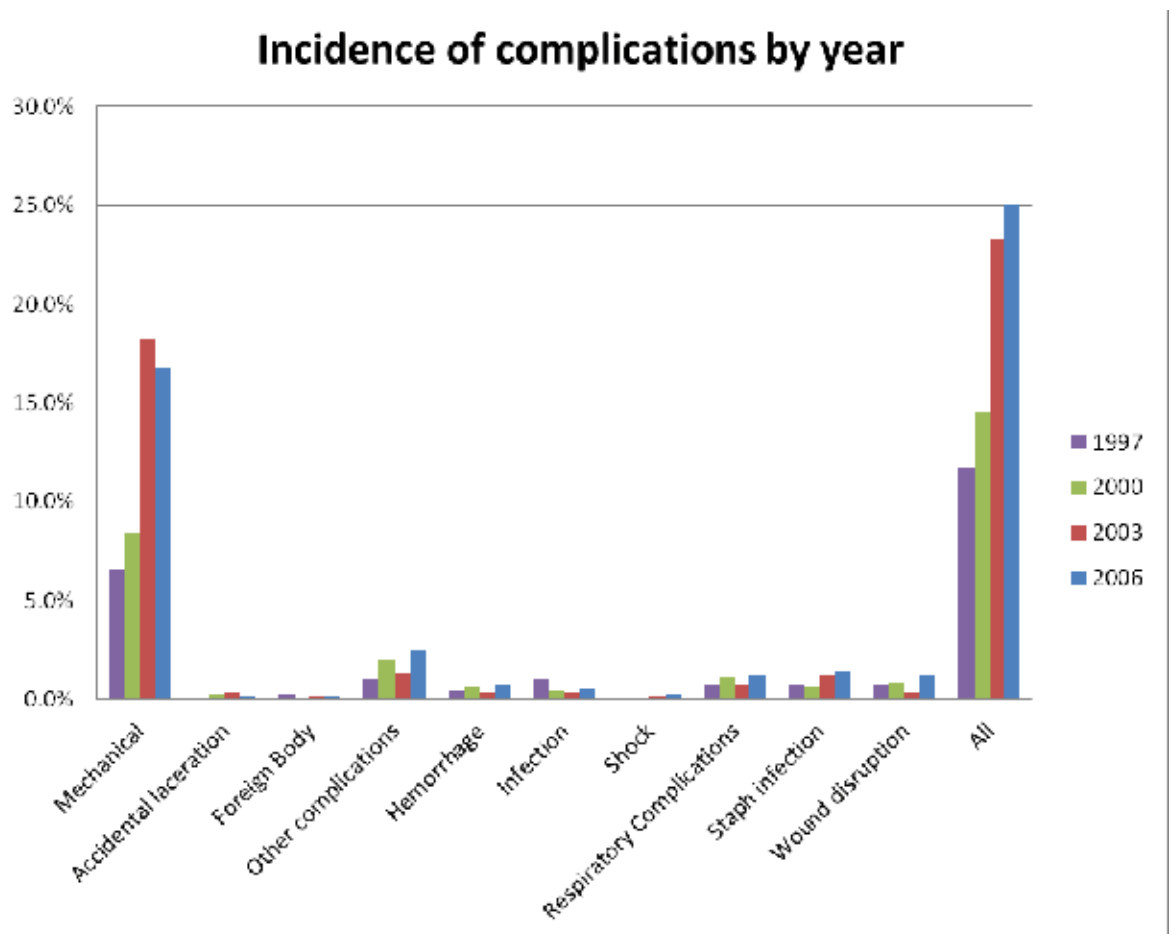

Fig. 2. *Incidence of complications by year.*

However, the KID does not record specific details of complications occurring in each case.

The literature suggests a difference in mechanical complications whether a one-piece or 2-piece catheter system is utilized (33). We do not know whether the catheters placed in the patients in our study were one- or 2-piece systems. Because the proximal and distal portions of a 2-piece are connected, they are prone to kink, disconnect, and tear at the point of joining (29). One-piece systems are less prone to these problems. However, 2-piece catheters allow for a more robust anchoring technique with more secure suturing without occluding the catheter. It could be hypothesized that the use of one of these 2 systems increased over the years, explaining the increase in mechanical complications noted in our study.

Further, there has been an increase in the popularity of subfascial rather than subcutaneous positioning of the pump itself. However, subfascial positioning can lead to greater mechanical shear and increased complication rates (35). It is possible that the increase in subfascial placements of pumps over the years could explain the increase in mechanical complications as well.

Catheter problems occur more frequently with catheters inserted below the L3-4 level (20). Because we do not have access to intraoperative documentation, it is possible that more catheters were placed below the L3-4 level over the years which could help explain the rise in complication rates.

There was also an increased incidence of mechanical complications in children with dystonia (15,34). It is possible that there was an increase in children with dystonia receiving ITB therapy over the years. However, in our study, this appears not to be true and that the primary indications for children to receive ITB remained stable over the years.

The rate of Staphylococcus infections increased from 0.7% in 1997 to 1.2% in 2006. Postoperative infections affected fewer than 10 patients in this sample. This is significantly lower than the currently published rates of 3.4% to 41.7% (34). This is very likely due to the fact that pocket infections and skin infections develop over time and this database is a snapshot during the patient's admission and it does not follow patients for any prolonged period of time.

Another significant finding is that children who had complications after placement of an intrathecal pump/catheter have higher costs of hospitalization and a longer length of stay than children who do not. While the increase in length of stay will vary by the type of complication experienced, the fact that the median length of stay increased by one day and the median cost by more than $7,500 indicates that having a complication is a very expensive and time consuming problem. In this large database alone, the 514 patients who experienced complications accumulated $4 million more in hospital charges than those patients who did not.

The strengths of this study include a large sample size from most of the country spanning a decade. The data collected by the AHRQ is robust and accurate. There were thousands of participating hospitals contributing to the database. There was internal consistency within the methods and analysis across the years, due to consistency within the database structure itself. Weaknesses of the study include its retrospective nature and its reliance on a database not designed specifically to answer the question at hand. There is missing clinical data of interest including American Society of Anesthesiologists physical status, types of the catheter system, further definitions of mechanical complications, intraoperative management, perioperative antibiotic use, and specific details of insertion level and pump placement locations.

Future prospective studies would need to consider these factors to better identify the causes for the increased complication rates after placement of an intrathecal pump/catheter.

Conclusion

Complication rates after placement of intrathecal pump/catheters have increased in the pediatric population between 1997 and 2006 mainly due to an increase in mechanical complications

Disclosure

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Author contributions: NV participated in the study design, data collection, data analysis, and manuscript preparation. ZZ participated in the study design, data analysis, and manuscript preparation.

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