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Factors Associated With Pressure Ulcers in Individuals With Spina Bifida

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Abstract

Objective—To describe factors associated with pressure ulcers in individuals with spina bifida (SB) enrolled in the National Spina Bifida Patient Registry (NSBPR).

Design—Unbalanced longitudinal multicenter cohort study.

Setting—Nineteen SB clinics.

Participants—Individuals with SB (N=3153) enrolled in 19 clinic sites that participate in the NSBPR.

Interventions—Not applicable.

Main Outcome Measures—Pressure ulcer status (yes/no) at the annual visit between 2009 and 2012.

Results—Of 3153 total participants, 19% (n=603) reported ulcers at their most recent annual clinic visit. Seven factors—level of lesion, wheelchair use, urinary incontinence, shunt presence,

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above the knee orthopedic surgery, recent surgery, and male sex—were significantly associated with the presence of pressure ulcers. Of these factors, level of lesion, urinary incontinence, recent surgery, and male sex were included in the final logistic regression model. The 3 adjusting variables—SB type, SB clinic, and age group—were significant in all analyses (all $P < .001$).

Conclusions—By adjusting for SB type, SB clinic, and age group, we found that 7 factors—level of lesion, wheelchair use, urinary incontinence, shunt presence, above the knee orthopedic surgery, recent surgery, and male sex—were associated with pressure ulcers. Identifying key factors associated with the onset of pressure ulcers can be incorporated into clinical practice in ways that prevent and enhance treatment of pressure ulcers in the population with SB.

Keywords

Pressure ulcer; Rehabilitation; Risk factors; Spinal cord injuries

Spina bifida (SB) is a neural tube defect that occurs when the spinal column of a developing fetus does not close properly in utero. It affects approximately 3.1 individuals per 10,000 children and adolescents in 10 regions of the United States according to a population-based study.¹ Myelomeningocele is the most severe form of SB, in which the vertebrae and spinal canal do not close before birth. Meningocele and lipomyelomeningocele are milder forms. Resulting sequelae of an open neural tube defect may include impairments in mobility, cognition, urinary and fecal continence, and an accumulation of secondary conditions, which may require numerous medical and surgical interventions throughout the life span.²

Pressure ulcers result from prolonged pressure to soft tissue, skin, and muscle. They may occur in individuals who have impairments in sensation or motor function. Each year, more than 2.5 million people develop pressure ulcers in the United States.³ Between 1999 and 2005, the overall pressure ulcer prevalence rate was 15% for hospitalized individuals in 9 international pressure ulcer surveys,⁴ and 4% in hospitalized children in 2003.⁵ In individuals with SB, skin wounds are reported as one of the primary diagnoses associated with hospitalizations.⁶ Pressure ulcers can lead to serious complications such as infection, sepsis, leg amputation, and even death.

The annual prevalence rate of pressure ulcers and other causes of skin breakdown in individuals with myelomeningocele reported in the literature for all ages is between 15% and 77%,⁷⁻¹¹ and in adults with SB it is 34%,¹² a much higher rate than in the general population. The wide variations in the rates may be attributed to the differences in population age and inclusion criteria over different studies.

Although there are many published articles describing risk factors for skin breakdown including pressure ulcers, there has been a lack of studies focusing exclusively on this topic in the population with SB. A recent cohort study over a 13-year period found that age, wheelchair use, bare feet, obesity, and reduced executive functioning are key risk factors for wound development.¹³ Another small questionnaire-based study of 87 adults with myelomeningocele showed a higher prevalence of pressure ulcers in individuals with memory deficits, Chiari II malformation, and sensory deficit.¹⁴ For young adults with

myelomeningocele, the number of ulcers has also been found to be associated with motor and educational level.¹⁵

Understanding factors associated with pressure ulcers in this population is critical to help them maintain or improve their health. Using results from a prospective study with an adequate sample size will provide a scientific basis to help influence clinical care. This study aims to explore factors associated with pressure ulcers in individuals enrolled in the National Spina Bifida Patient Registry (NSBPR) in the United States between 2009 and 2012.

Methods

Study population

The sample is composed of participants with SB from 19 clinic sites who participated in the NSBPR between 2009 and 2012. After institutional review board approval and obtaining informed consent/assent from parents and patients, the clinics collected longitudinal data on individuals with SB.¹⁶ At the initial visit, basic demographic and diagnostic information as well as information on surgical procedures were collected from each patient. At the initial visit and each subsequent annual visit, information on insurance status, anthropometric measurements, surgeries and procedures, education and employment, and treatments and outcomes was also collected. Depending on when a patient was enrolled, a patient may have had from 1 to 4 submitted annual reports. By the end of 2012, a total of 3738 participants were enrolled in the NSBPR. Of these, 585 participants aged <2 years at enrollment were excluded because mobility status is variable in this age group and for this reason they were not typically evaluated as a cohort. The final analytical data set was composed of 3153 participants' 5593 annual reports (see supplemental tables S1 and S2, available online only at <http://www.archives-pmr.org/>).

Variables

SB type and level of lesion—Participants were classified into 2 SB types: myelomeningocele or non-myelomeningocele, which included the diagnoses of meningocele, lipomyelomeningocele, or fatty filum. Each patient's level of lesion was determined on their both right and left sides on the basis of the presence of antigravity strength of muscle groups: hip flexors, quadriceps, dorsiflexors, and plantar flexors. The functional level of lesion was classified into 5 categories—1, sacral, 2, low-lumbar, 3, mid-lumbar, 4, high-lumbar, and 5, thoracic in the order of increasing severity—and used as a continuous variable (1–5) in the analysis. For asymmetric level of lesions, the higher spinal level (ie, more severe) was selected.

Pressure ulcer status—At each annual visit, participants were asked if there have been any pressure ulcers in the past 12 months or since the previous clinic visit.

Surgeries—Six surgical types were considered as potential factors. Chiari II decompression and shunt placement surgeries that occurred from birth to the time of the annual visit were considered as (history) binary indicators. Orthopedic, urology, and tethered cord release surgeries that occurred from the 12 months before enrollment to the

time of each annual visit were considered as (partial history) binary indicators. Orthopedic surgeries were divided into 2 categories: above the knee and below the knee. Procedures addressing scoliosis, kyphosis, hip flexion contracture, and hip subluxation/dislocation were classified as above the knee procedures. Correction of knee flexion contracture, external tibial torsion, ankle valgus deformity, equinus contracture, clubfoot deformity, congenital vertical talus, and congenital deformity of foot were considered as below the knee procedures. Lastly, to consider the effect of recent hospitalization on pressure ulcers, a summary variable reflecting any recent surgery since the previous annual visit was also created as a binary variable (yes/no).

Bladder/bowel incontinence—Participants were asked if they were wet during the day with or without interventions for bladder incontinence and if they experienced involuntary stool leakage for bowel incontinence. If they responded yes to either question, they were assigned to the incontinence group for bladder and bowel, respectively.

Ambulatory ability—Participants were grouped into 4 ambulatory categories and then regrouped into 2 groups: community ambulators or wheelchair users. Community ambulators were defined as those who are able to walk indoors and outdoors for most of their activities regardless of whether they use assistive device or braces. Individuals in this group could use a wheelchair, but only for long trips in the community. Otherwise, individuals were classified as wheelchair users.

Insurance type, age group, and race/ethnicity—Medicaid, Medicare, and state high-risk health care plans were classified into public insurance, and all other types of insurance were classified as private. Participants were classified into 1 of 3 groups at each annual visit: group 1 included patients aged 2 to <10 years, group 2 included patients aged 10 to 20 years, and group 3 included patients aged >20 years; age group was treated as a continuous variable (Groups 1–3) in the analysis. With regard to race/ethnicity, participants were classified into non-Hispanic white, non-Hispanic black, Hispanic or Latino, or Asian.

Data analysis

The study population was described by their general characteristics at the most recent annual clinic visit. To examine any association between pressure ulcer status and a candidate factor, multiple logistic regressions were run treating pressure ulcer status as a dependent variable and any given factor as a primary independent variable by using all data. SB type, SB clinic, and age groups were adjusted in the analyses, as we assumed that the variation of ulcers would be explained by SB types, ages, and the unobserved clinic level effects; for example, clinics may treat wounds differently or have a patient population that differs significantly from that in other clinics. We note that a clinic with a sample of size $n=42$ was set as the reference. To account for repeated measurements per patient over multiple years, generalized estimating equation (GEE) analysis was performed with a compound symmetry correlation structure. The GEE is robust for the misspecification of the covariance structure and is more efficient for large sample sizes compared to the number of repeated measures. For the factors that had significant associations ($P<.05$) in the analyses, the adjusted prevalence of pressure ulcers was calculated over various age groups by SB type.

In addition, we developed the final model to select the joint model, balancing model complexity, and model fit by applying quasi-likelihood information criteria (QIC).¹⁷ The QIC method is a model selection method for GEE models. Including all the significant factors initially, the final model was developed as the one that led to the smallest QIC by comparing several GEE candidate models. All data analyses were performed with SAS version 9.3.18,^a

Results

Pressure ulcer prevalence

The final analytical data set was composed of 3153 participants with at least 1 completed initial and annual visit report forms. During the study period, 1036 pressure ulcers occurred in 825 participants (26%). Table 1 lists the general characteristics of participants by pressure ulcer status at the most recent annual clinic visit. Approximately 19% (n=603) of participants reported a pressure ulcer in the past 12 months. The myelomeningocele group had a higher prevalence of pressure ulcers. The prevalence of pressure ulcers increased with a higher level of lesions, gradually increasing from 7% (n=63) in participants with sacral level lesions to 31% (n=169) in participants with thoracic level lesions. In comparison with community ambulators, wheelchair users had an 11% higher prevalence of pressure ulcers. Participants with bladder incontinence were 1.1% more likely to experience pressure ulcers than did participants with bowel incontinence, and overall, ulcers were more common in participants with any incontinence. The prevalence of pressure ulcers was higher in those with a history of neurologic and orthopedic surgeries, non-Hispanic black participants, men, those aged 10 years, and those with public insurance only. The mean age was 6.3 ± 2.1 years for patients aged 2 to <10 years, 14.9 ± 2.8 years for patients aged 10 to 20 years, and 27.8 ± 8.8 years for patients aged >20 years.

The location of ulcers was most frequent in the areas of the foot, lower limb, or posterior pelvis for all age groups and SB types (fig 1). Participants with myelomeningocele had more ulcers than did participants with non-myelomeningocele. Although participants aged 2 to <10 years had more ulcers on the lower limb than on the posterior pelvis, those aged 10 years had more ulcers on the posterior pelvis than on the lower limb.

Pressure ulcer factors

The results of multiple logistic regression using the GEE are summarized in table 2. Adjusting for SB type, SB clinic, and age groups, the factors significantly associated with pressure ulcers were level of lesion, ambulation status, bladder incontinence, shunt placement, above the knee orthopedic surgery, recent surgery, and male sex. For each increase in the functional level of lesion, the odds of pressure ulcers were increased by 34% ($P < .001$). The odds were 74% higher ($P < .001$) in wheelchair users and 22% higher ($P = .02$) in participants with bladder incontinence. The odds of a pressure ulcer were increased by 49% ($P < .001$) in participants with a history of shunt placement and by 53% ($P = .02$) in

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participants with a history of above the knee orthopedic surgery. In men, the odds were 17% ($P=.04$) higher than those in women. No significant associations were found between pressure ulcer and bowel incontinence, Chiari II decompression, urology surgery, tethered cord release, below the knee orthopedic surgery, race/ethnicity, or insurance type. The 3 adjusting variables—SB type, SB clinic, and age groups—were all significant in all analyses (data not shown). To facilitate the interpretation of these results, we illustrated the adjusted prevalence of the pressure ulcer status for the 7 significantly associated factors by their values (yes/no) from the fitted model over various age groups in figure 2. Overall, the prevalence of pressure ulcers in participants with myelomeningocele was higher than that in participants with non-myelomeningocele. Also, as the age increased within both myelomeningocele and non-myelomeningocele groups, the prevalence of pressure ulcers increased gradually. For example, in wheelchair users with myelomeningocele, the pressure ulcer prevalence was 29% in the age group of 2 to 10 years, 42% in the age group of 10–20 years, and 55% in the age group of >20 years. In their peers with non-myelomeningocele conditions, the pressure ulcer prevalence was 18%, 27%, and 39%, respectively. In participants with myelomeningocele with shunt placement, the adjusted prevalence of pressure ulcers was 7% higher in the age group of 2 to 10 years, 9% higher in the age group of 10 to 20 years, and 10% higher in the age group of >20 years as compared with those who were not shunted.

Our final model included level of lesion, urinary incontinence, recent surgery, and male sex, adjusting for SB type, SB clinic, and age groups (see table 2). Higher level of lesion and male sex including SB type, age group, and SB clinic were still significantly associated with pressure ulcers (all $P<.05$): the odds of pressure ulcer were 55% higher for the myelomeningocele group (odds ratio [OR], 1.55; 95% confidence interval [CI], 1.17–2.04) and 68% higher for one age group increase (OR, 1.68; 95% CI, 1.48–1.92) (not shown in table 2). The ORs for 18 clinics versus the referred clinic are presented in figure 3 (ORs, 0.08–1.16). The ORs excluding 1.00 in the 95% CI are significant.

Discussion

Pressure ulcers were more common in individuals with a higher level of lesions in the study, which is consistent with the findings of Ottolini et al.¹³ In general, higher lesion levels are generally associated with higher degrees of paralysis and sensory loss, which may explain the higher rates of pressure ulcers. Wheelchair use was also associated with ulcers, which is not surprising because prolonged sitting and immobility may predispose to pressure ulcers. Among demographic factors, male sex was associated with the occurrence of pressure ulcers. Similar findings for higher risk of ulcers in men were reported among palliative home care clients,¹⁹ adults in acute care hospitals,²⁰ and individuals with spinal cord injury,²¹ where a higher level of care requirements¹⁹ and poor nutrition²⁰ compared to women were discussed as possible reasons. After neurological surgeries, we found that ulcers were more likely to occur in the shunted group.¹³ Bladder incontinence was another factor associated with ulcers, whereas bowel incontinence was not. Work by others has suggested that urinary incontinence may be a more accurate predictor than fecal incontinence in individuals with spinal cord injury,^{22,23} and it has been well demonstrated that incontinence and moisture are strongly associated with pressure ulcers. For orthopedic

ulcers during an annual visit unless they were routinely examined by clinicians. Finally, we did not adjust for multiple testing such as Bonferroni correction because this study was exploratory in nature and we did not posit a strong assumption of no association between pressure ulcers and a factor.

Conclusions

Recent pressure ulcers were present in 19% of the total sample at the mean age of 14 years, present in 22% for myelomeningocele and 9% for non-myelomeningocele. Factors with statistically significant associations with pressure ulcers were level of lesion, wheelchair use, urinary incontinence, presence of shunt, recent surgery, and male sex. Of these, level of lesion, urinary incontinence, recent surgery, and sex were also included in the final model. Approximately 75% to 85% of individuals born with SB are now surviving into adulthood, likely owing to advances in medical and surgical care.^{27,28} This elevates the importance of dealing with the morbidity associated with pressure ulcers in a longer living population. When considering prevention and treatments for pressure ulcers, more importance should be placed on the factors identified in these models of association.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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List of abbreviations

CI	confidence interval
GEE	generalized estimating equation
NSBPR	National Spina Bifida Patient Registry
OR	odds ratio
QIC	quasi-likelihood information criteria
SB	spina bifida

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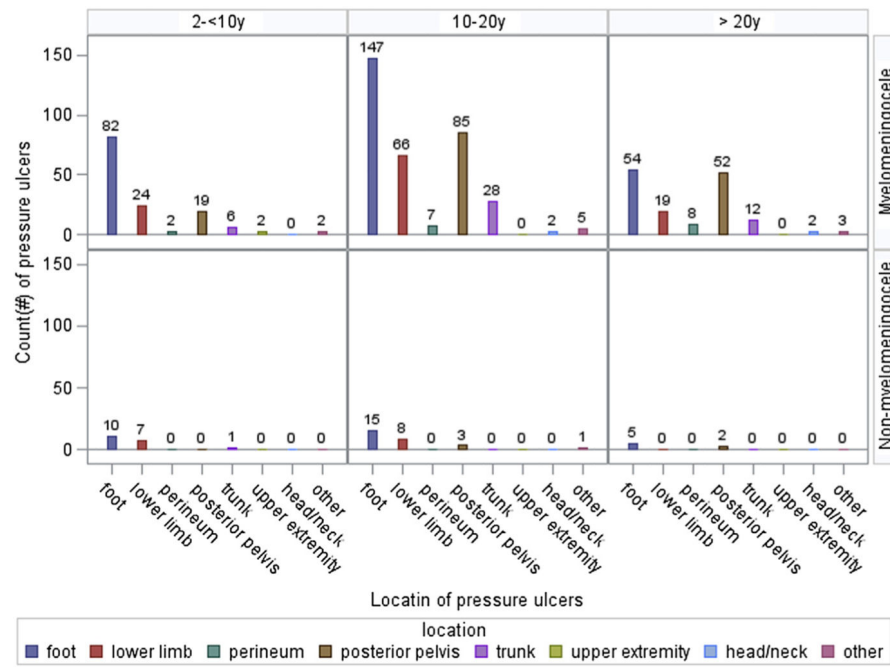


Fig 1. Count (#) of pressure ulcers by location for myelomeningocele (top) and others (bottom) at the most recent annual clinic visit.

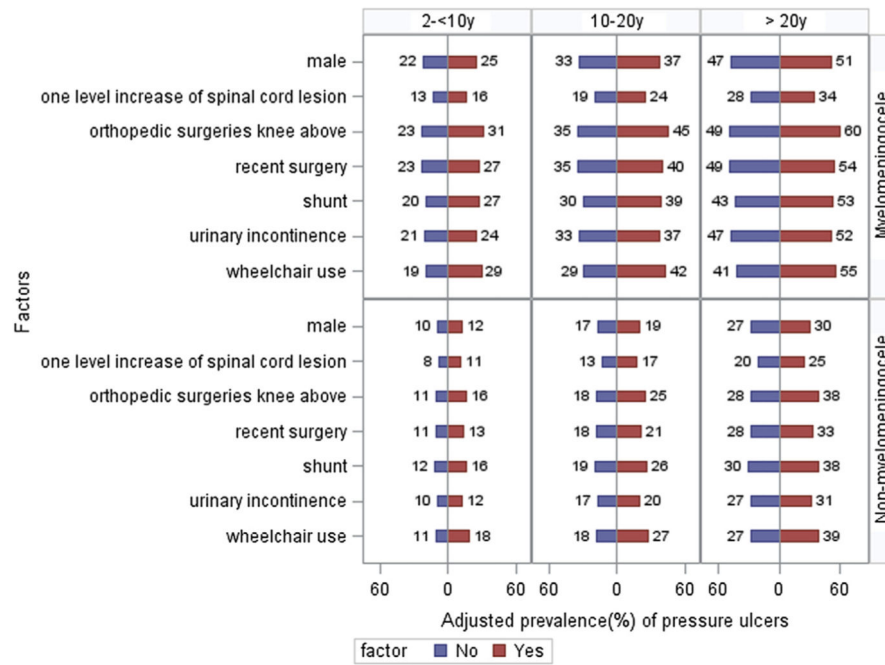


Fig 2. Adjusted prevalence (%) of pressure ulcers by associated factors over various age groups for myelomeningocele (top) and others (bottom), adjusting SB clinic. Adjusted prevalence was calculated using GEE analysis. Each model included the factor of interest, age group, SB type, and SB clinic.

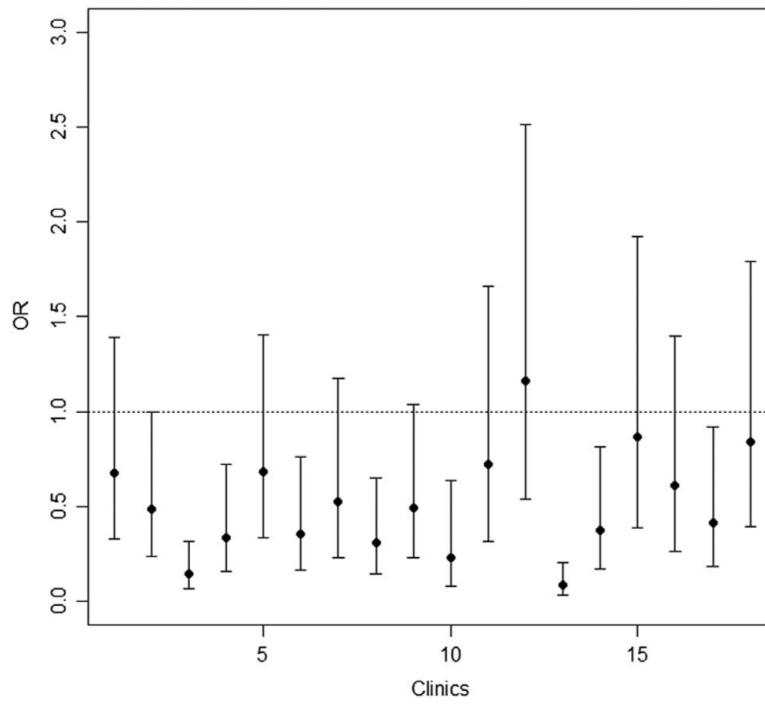


Fig 3.
OR (95% CI) for SB clinics in the final model.

Table 1

Sample distribution of factors at the most recent annual clinic visit by pressure ulcer status

Factor	n (%)	Pressure Ulcer Status	
		Yes	No
	3153 (100)	603 (19.1)	2550 (80.9)
SB type			
Myelomeningocele	2566 (81.4)	553 (21.5)	2013 (78.5)
Others	587 (18.6)	50 (8.5)	537 (91.5)
Level of lesion *			
Sacral	886 (28.1)	63 (7.1)	823 (92.9)
Low-lumbar	565 (17.9)	89 (15.8)	476 (84.3)
Mid-lumbar	867 (27.5)	215 (24.8)	652 (75.2)
High-lumbar	285 (9.0)	67 (23.5)	218 (76.5)
Thoracic	550 (17.4)	169 (30.7)	381 (69.3)
Wheelchair use			
Yes	1421 (45.1)	360 (25.3)	1061 (74.7)
No	1732 (54.9)	243 (14.0)	1489 (86.0)
Incontinence			
Urinary			
Yes	1851 (58.7)	375 (20.3)	1476 (79.7)
No	1302 (41.3)	228 (17.5)	1074 (82.5)
Stool			
Yes	1662 (52.7)	319 (19.2)	1343 (80.8)
No	1491 (47.3)	284 (19.1)	1207 (81.0)
Neurologic surgery			
Chiari II			
decompression [†]			
Yes	235 (7.5)	64 (27.2)	171 (72.8)
No	2918 (92.6)	539 (18.5)	2379 (81.5)
Shunt [†]			
Yes	2077 (65.9)	473 (22.8)	1604 (77.2)
No	1076 (34.1)	130 (12.1)	946 (87.9)
Tethered cord			
release [‡]			
Yes	142 (4.5)	31 (21.8)	111 (78.2)
No	3011 (95.5)	572 (19.0)	2439 (81.0)
Orthopedic surgery [‡]			
Above the knee			
Yes	120 (3.8)	35 (29.2)	85 (70.8)
No	3033 (96.2)	568 (18.7)	2465 (81.3)
Below the knee			
	211 (6.7)	50 (23.7)	161 (76.3)

Factor	n (%)	Pressure Ulcer Status	
		Yes	No
Yes			
No	2942 (93.3)	553 (18.8)	2389 (81.2)
Urology surgery [‡]			
Yes	285 (9.0)	60 (21.0)	225 (79.0)
No	2868 (91.0)	543 (18.9)	2325 (81.1)
Recent surgery			
Yes	649 (20.6)	149 (23.0)	500 (77.0)
No	2504 (79.4)	454 (18.1)	2050 (81.9)
Race/ethnicity			
Non-Hispanic white	2059 (65.3)	413 (20.1)	1646 (79.9)
Non-Hispanic black	256 (8.1)	59 (23.1)	197 (76.9)
Hispanic or Latino	651 (20.7)	103 (15.8)	548 (84.2)
Asian	130 (4.1)	14 (10.8)	116 (89.2)
Unknown	57 (1.8)	14 (24.6)	43 (75.4)
Sex			
Male	1494 (47.4)	299 (20.0)	1195 (80.0)
Female	1659 (52.6)	304 (18.3)	1355 (81.7)
Age group (y) [*]			
2-<10	1177 (37.3)	144 (12.2)	1033 (87.8)
10-20	1420 (45.0)	321 (22.6)	1099 (77.4)
>20	556 (17.6)	138 (24.8)	418 (75.2)
Insurance type			
Public	2066 (65.5)	414 (20.0)	1652 (80.0)
Private	1087 (34.5)	189 (17.4)	898 (82.6)

NOTE. Values are n (%). The mean ages for each age group were 6.3±2.1, 14.9±2.8, 27.8±8.8y in an order.

* Treated as a continuous variable in the main analysis.

[†] Any surgery history from birth to the last annual visit.

[‡] Any surgery history from enrollment to the last annual visit.

Table 2

OR (95% CI) from multiple logistic regression models and the final model, controlling for SB type, SB clinic, and age groups

Factor	Multiple Logistic Regression Models		Final Model	
	OR (95% CI)	P	OR (95% CI)	P
Level of lesion	1.34 (1.27–1.43)	<.001	1.34 (1.26–1.42)	<.001
Wheelchair use	1.74 (1.47–2.06)	<.001	NA	
Urinary incontinence	1.22 (1.04–1.43)	.02	1.15 (0.98–1.35)	.09
Stool incontinence	1.05 (0.90–1.23)	.51	NA	
Chiari II decompression	1.08 (0.83–1.40)	.57	NA	
Tethered cord release	1.21 (0.85–1.73)	.29	NA	
Shunt	1.49 (1.17–1.90)	<.001	NA	
Above the knee orthopedic surgery	1.53 (1.06–2.20)	.02	NA	
Below the knee orthopedic surgery knee	1.23 (0.93–1.63)	.14	NA	
Urology surgery	1.24 (0.97–1.60)	.09	NA	
Recent surgery	1.26 (1.06–1.49)	.01	1.18 (0.99–1.40)	.06
Race/ethnicity			NA	
Non-Hispanic white	Reference	NA	NA	
Non-Hispanic black	0.97 (0.72–1.30)	.84	NA	
Hispanic or Latino	0.91 (0.72–1.16)	.44	NA	
Asian	0.96 (0.59–1.55)	.85	NA	
Sex: male	1.17 (1.00–1.37)	.04	1.18 (1.01–1.39)	.04
Public insurance	1.15 (0.97–1.36)	.11	NA	

Abbreviation: NA, not applicable.