HHS Public Access

Author manuscript

J Neurosurg Pediatr. Author manuscript; available in PMC 2024 February 19.

Published in final edited form as:

J Neurosurg Pediatr. 2022 November 01; 30(5): 484–489. doi:10.3171/2022.7.PEDS22224.

Time to shunt failure in children with myelomeningocele: an analysis of the National Spina Bifida Patient Registry

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Previous Presentations

Portions of this work were presented at the AANS/CNS Section on Pediatric Neurosurgery Annual Meeting, Salt Lake City, UT, December 7–20, 2021.

Abstract

OBJECTIVE—Hydrocephalus is common among children with myelomeningocele and is most frequently treated with a ventriculoperitoneal shunt (VPS). Although much is known about factors related to first shunt failure, relatively less data are available about shunt failures after the first one. The purpose of this study was to use a large data set to explore time from initial VPS placement to first shunt failure in children with myelomeningocele and to explore factors related to multiple shunt failures.

METHODS—Data were obtained from the National Spina Bifida Patient Registry. Children with myelomeningocele who were enrolled within the first 5 years of life and had all lifetime shunt operations recorded in the registry were included. Kaplan-Meier survival curves were constructed to evaluate time from initial shunt placement to first shunt failure. The total number of children who experienced at least 2 shunt failures was calculated. A proportional means model was performed to calculate adjusted hazard ratios (HRs) for shunt failure on the basis of sex, race/ethnicity, lesion level, and insurance status.

RESULTS—In total, 1691 children met the inclusion criteria. The median length of follow-up was 5.0 years. Fifty-five percent of patients (938 of 1691) experienced at least 1 shunt failure. The estimated median time from initial shunt placement to first failure was 2.34 years (95% confidence interval [CI] 1.91–3.08 years). Twenty-six percent of patients had at least 2 shunt failures, and 14% of patients had at least 3. Male children had higher likelihood of shunt revision (HR 1.25, 95% CI 1.09–1.44). Children of minority race/ethnicity had a lower likelihood of all shunt revisions (non-Hispanic Black children HR 0.74, 95% CI 0.55–0.98; Hispanic children HR 0.74, 95% CI 0.62–0.88; children of other ethnicities HR 0.80, 95% CI 0.62–1.03).

CONCLUSIONS—Among the children with myelomeningocele, the estimated median time to shunt failure was 2.34 years. Forty-five percent of children never had shunt failure. The observed higher likelihood of shunt revisions among males and lower likelihood among children of minority race/ethnicity illustrate a possible disparity in hydrocephalus care that warrants additional study. Overall, these results provide important information that can be used to counsel parents of children with myelomeningocele about the expected course of shunted hydrocephalus.

Keywords

myelomeningocele; spina bifida; hydrocephalus; shunt revision; shunt failure; congenital

Among children with myelomeningocele, hydrocephalus is very common.[1] The published rates of hydrocephalus treatment vary between 40% and 90%; the rate of hydrocephalus treatment was 80% in a large national US sample.[1] The main treatment for hydrocephalus is the ventriculoperitoneal shunt (VPS). Widely cited data from randomized controlled trials show VPS failure occurring in 40%–50% of children within the first 2 years after placement.[2,3] Although numerous studies have examined factors related to initial shunt failure, relatively few studies have considered shunt failures after the first one. A prior study showed that the risk of subsequent revision is higher after each shunt revision.[4] These data potentially provide valuable insights into projections of a possible lifetime course of shunted hydrocephalus.

The goal of this study was to provide more complete information about VPS failure that can be used for counseling families. Specifically, we explored time to failure of VPS from initial placement to subsequent failures, evaluated possible associated variables, and estimated the probability of shunt failure in the first 10 years of life. Unlike previous studies, which modeled the likelihood of shunt failure in the setting of previous shunt failures, our goal was to provide information about the probability of having 1 or more shunt failure episodes at any time in the future, starting from the time of placement of the first shunt, typically in infancy.

Methods

Data for this study were obtained from the National Spina Bifida Patient Registry (NSBPR) funded by the Centers for Disease Control and Prevention (CDC). NSBPR began in 2009 with data collected by multidisciplinary spina bifida clinics across the United States. Data are collected annually and sent to a centralized data collection center at the CDC for quality control and analysis. All required NSBPR data elements are collected through a combination of patient interviews and review of medical records.[5] This process has been described in greater detail in previous reports.[1] Each site participating in NSBPR obtained local IRB approval for patient enrollment and data sharing with CDC.

Patients with a myelomeningocele diagnosis and a history of shunted hydrocephalus were included in this analysis. Any child with a missing date for 1 or more shunt operations was excluded to ensure that the lifetime record of all shunt surgical procedures was known as needed to perform time-to-event analysis for shunt failure. In addition, children who were not enrolled in NSBPR within the first 5 years of life were excluded, as enrollment later than that may lead to inaccurate reporting of surgical procedures that occurred early in life. All surgical procedures used to treat shunt infection were counted as 1 episode of shunt failure, i.e., a shunt infection episode was considered the same as a shunt failure. The enrollment diagram in Fig. 1 shows the inclusion and exclusion criteria that led to the final study cohort.

The specific variables collected for this study included month/year of initial shunt placement, month/year of all subsequent shunt surgical procedures, sex, race/ethnicity, functional level of lesion (FLOL) (as defined by NSBPR), and health insurance status at time of enrollment.[5]

Data Analysis

A proportional means model was used to estimate adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) for the association between any shunt failure and demographic factors (sex, race/ethnicity, insurance type) and FLOL. A robust variance estimate method was specified to account for the correlation among repeated measurements (shunt failure).[6] The proportional hazards assumption was tested visually using the Kaplan-Meier curve of each variable. All estimated HRs were presented with 95% CI. Statistical analysis was performed using SAS version 9.4 and SPSS Statistics version 27 (IBM Corp.). Kaplan-Meier survival analysis was used to create time-to-event curves depicting time from initial shunt placement to first shunt failure. Data were censored at the time of the most recent follow-up at a spina bifida clinic.

The total lifetime number of shunt revisions and the mean number of lifetime hydrocephalus operations undergone by the patients of each age (0 to 14 years) were calculated. For this analysis, subjects were assigned to an age category on the basis of their age at the time of their most recent NSBPR data entry, through 2019. For example, in the analysis of 10-year-old patients, we included only the 71 children who were 10 years old at the time of the most recent follow-up visit. Finally, the chi-square test was used to compare patients included in the survival analysis with those who did not meet the inclusion criteria.

Results

Of 10,253 patients in NSBPR, 1691 met the inclusion criteria for this study (Fig. 1). About half of the included patients were male (875 [51.7%]) and a majority were non- Hispanic White (1080 [64.1%]) (Table 1). Non-Hispanic Black and Hispanic patients represented 7.6% and 21.4% of the cohort, respectively. Nonprivate insurance was reported for 942 (55.7%) patients. FLOL was most commonly mid- and low-lumbar (28.4% and 28.6%, respectively). The excluded patients were more commonly female (52.4%) and had a higher proportion of thoracic-level FLOL (23.5%).

The median (interquartile range) length of follow-up for all included patients was 4.92 (2.66–8.00) years. Nine hundred thirty-eight (55.5%) patients experienced at least 1 shunt failure, 439 (26.0%) patients had at least 2 shunt failures, and 231 (13.7%) had at least 3 shunt failures. The median (95% CI) time from initial shunt placement to the first failure was 2.34 (1.91–3.08) years. Figure 2 shows the Kaplan-Meier survival curve for initial shunt failure. Post hoc analysis was performed using the Kaplan-Meier method to determine the median time from first shunt failure to second shunt failure. Considering only the 938 children who had a first shunt failure, we estimated that the median (95% CI) time to second shunt failure was 5.08 (4.00–6.42) years. Similarly, the estimated median (95% CI) time from second shunt failure to third shunt failure was 2.59 (1.92–4.42) years, with only 439 patients who had a second shunt failure. In the subset of 235 patients with 10 years of follow-up or longer, 61 (26.0%) had no shunt failures, 75 (31.9%) had exactly 1 shunt failure, 41 (17.4%) had exactly 2 failures, 27 (11.5%) had exactly 3 failures, and 31 (13.2%) had 4 or more failures.

Table 2 shows the HRs for experiencing 1 or more shunt failures, with the associations of sex, race/ethnicity, FLOL, and insurance status with shunt failure. Male children had a higher HR (95% CI) for shunt failures of 1.25 (1.09–1.44). In addition, compared with non-Hispanic White children, children of minority race/ethnicity had a lower HR for shunt failures (non-Hispanic Black children HR 0.74, 95% CI 0.55–0.99; Hispanic children HR 0.74, 95% CI 0.62–0.88). FLOL was not associated with shunt failure in any analysis.

Analysis of lifetime shunt revisions by age showed fewer total lifetime shunt revisions in younger patients, with increases in each year of life, as expected. Children younger than 1 year underwent a mean ± SD of 1.14 ± 0.81 shunt revisions. Children aged 13 years underwent a mean ± SD of 2.77 shunt revisions. Visual inspection of the averages, plotted by age, revealed a linear relationship (Fig. 3). Therefore, post hoc linear regression analysis

was performed (Fig. 3), which found an increase of 0.133 shunt revisions per year of life (R^2 = 0.96).

Discussion

We have conducted a longitudinal analysis of time to shunt failure in children with myelomeningocele by using a national data set. This is the first study of this large population to analyze shunt failures after the first failure. As such, it has the potential to inform counseling of families of children with myelomeningocele and hydrocephalus about what to expect as their children age.

Analysis of time from initial shunt placement to the first shunt failure showed an estimated median time to failure of 2.34 years. This result is consistent with the results reported in prior published studies, including the randomized Shunt Design Trial and Endoscopic Shunt Insertion Study.[2,3,7-9] Similarly, our analysis of time to subsequent shunt failures after the first and second shunt failures is similar to previously published data.[4] Overall, relatively few patients had more than 2 shunt failures (only 13.7% of the overall sample). These data support the notion that although shunt failure is relatively common among children with myelomeningocele, multiple shunt failures do not occur in the first several years of life for most children.

Previous studies have shown that there is an increased risk of recurrent shunt failure after shunt revision.[4,10] We used a proportional means model in an attempt to identify other factors that may affect the likelihood of multiple shunt failures. Male sex showed an association with all shunt failures (HR 1.25) (Table 2). In general, hydrocephalus is thought to be slightly more common in male infants.[10,11] Previous studies of risk factors for shunt failure have either not included sex as a variable or have shown no significant difference between male and female children.[2-4,10,12-14] However, in the large series that do report sex as an associated variable, the relationship between male sex and shunt failure was similar in magnitude (HR 1.1–1.5), but with 95% CIs that were not statistically signilicant.[4,12-14] The sample size of the present study is larger than the samples of most previous studies, thus increasing the power of the present study to show statistically significant associations. It is possible that male children manifest shunt failure with more obvious symptoms than female children. Other possibilities may be that male children are overdiagnosed with possible shunt malfunction or that female children are underdiagnosed. Because it is unclear why sex is a risk factor for shunt failure, more studies of this phenomenon are warranted.

Children of minority race/ethnicity also showed significantly lower probability of shunt failure compared with non-Hispanic White children. One possible explanation of this finding is that these children are underdiagnosed. Hispanic families are known to be at higher risk for socioeconomic disadvantage, may have low English proficiency, and may have challenges accessing healthcare.[15,16] These factors may have had a role in the present observations as well. Because untreated shunt failure has the potential for adverse developmental outcomes, this is an important potential disparity that requires further study. Non-Hispanic Black children also had a lower HR for shunt failure than White children. The same logic of disparity may apply, in that it is possible that social or structural factors may

lead to fewer shunt evaluations in minority children, or that there are unconscious biases that affect the likelihood of considering a diagnosis of shunt failure in a non-White child.[17] These observations warrant future study.

Our finding of a nearly linear increase in shunt revisions with each year of life provides another method for estimating the number of shunt operations in the 1st decade of life, an estimate that may also be useful for counseling families. These results are similar to the findings of a Monte Carlo simulation based on several large data sets of shunt failure.[18]

Limitations

Most participating clinics in NSBPR are multidisciplinary spina bifida clinics in tertiary medical centers, so these results may not apply to patients in all clinical settings. Patients with hydrocephalus of other etiologies may demonstrate different shunt performance dynamics. As with any large registry, there are inherent limitations, particularly pertaining to missing data. As shown in Fig. 1, nearly 6000 children with myelomeningocele and shunted hydrocephalus are included in NSBPR, but only 1691 had data that were complete enough for analysis in this study. Comparison of demographic variables and FLOL between the included and excluded patients showed significant differences in all variables (Table 1). This likely reflects differences in the population of patients included in NSBPR from time of their birth (as required in this study) compared with those enrolled later in life. However, we believe that our requirement of inclusion from birth allowed us to better understand shunt failures from birth onward. It is possible that some patients received care at another medical center not participating in NSBPR. If this were more common for minority patients, it could be a factor in the disparate rate of shunt revisions observed. We believe that this was most likely not a major factor because spina bifida and hydrocephalus care are highly specialized, and care is usually received at major medical centers.

The NSBPR considers the treatment of a shunt infection as a single episode, even if multiple procedures such as shunt removals, external ventricular drain placements and removals, and shunt replacement surgical procedures are performed. The objective of this analysis was to provide an overview of shunt failure; therefore, the analysis did not distinguish between shunt removals for shunt infection treatment and those for management of mechanical or obstructive etiologies.

In addition, the median length of follow-up was nearly 5 years. Although the survival analysis methodology intended to allow for varying durations of follow-up, one should use caution with interpreting the extreme end of the curve. As with any statistical analysis, errors of estimates increase as the number of patients in the analysis decreases.

Conclusions

This analysis demonstrated that the estimated median time to shunt failure after initial placement was 2.34 years in a large nationwide sample of children with myelomeningocele. Even though half of shunts failed after about 2.5 years, only about 26% experienced 2 or more failures and only about 14% experienced 3 or more failures. This information may be helpful when counseling patients and families about the risk of subsequent failure. Important

potential disparities based on sex and race/ethnicity were identified. Future research may assist in explaining these disparities.

Acknowledgments

The National Spina Bifida Patient Registry (NSBPR) is funded by the National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia (grant nos. DD000738, DD000740, DD000743, DD000774, DD001057, DD001062, DD001064, DD001093, DD001235, DD001237, DD001240, DD001262, DD001265, DD001266, DD001268, DD001270, DD001272, DD001274, DD001275, DD001278, DD001279, and DD001280). This study was funded by the CDC under the Cooperative Agreement for Improving the Care and Outcomes of People Living with SB—National Spina Bifida Patient Registry. We thank the many individuals with spina bifida and their family members who participated in this research, without whom the NSBPR would not be possible. The NSBPR has also been successful because of the contributions of the CDC, the Spina Bifida Association, and all of the spina bifida clinics that have been members of the NSBPR Coordinating Committee. The members of this committee during the collection of the data reported are listed in alphabetical order and were the Ann & Robert H. Lurie Children's Hospital of Chicago, IL; Boston Children's Hospital, Boston, MA; Children's Hospital and Research Center at Oakland, CA; Children's Hospital Colorado, Denver, CO; Children's Hospital Los Angeles, CA; Children's Hospital of Alabama, Birmingham, AL; Children's Hospital of Michigan, Detroit, MI; Children's Hospital of Philadelphia, PA; Children's Hospital of Wisconsin, Milwaukee, WI; Cincinnati Children's Hospital Medical Center, Cincinnati, OH; Cleveland Clinic, Cleveland, OH; Connecticut Children's Medical Center, Hartford, CT; District Medical Group Children's Rehabilitative Services, Phoenix, AZ; Duke University Medical Center, Durham, NC; Gillette Children's Specialty Healthcare, St. Paul, MN; Hershey Medical Center, Hershey, PA; Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, TN; Nationwide Children's Hospital, Columbus, OH; Oregon Health & Science University, Portland, OR; Primary Children's Medical Center, Salt Lake City, UT; Riley Hospital for Children, Indianapolis, IN; Seattle Children's Hospital, Seattle, WA; Shriners Hospitals for Children, Springfield, MA; St. Luke's Boise Medical Center, Boise, ID; Texas Children's Hospital, Houston, TX; Texas Scottish Rite Hospital for Children, Dallas, TX; University of California at San Francisco Benioff Children's Hospital, San Francisco, CA; University of Pittsburgh Medical Center, Pittsburgh, PA; and Upstate Medical University, Syracuse, NY.

ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
CI	confidence interval
FLOL	functional level of lesion
HR	hazard ratio
NSBPR	National Spina Bifida Patient Registry
VPS	ventriculoperitoneal shunt

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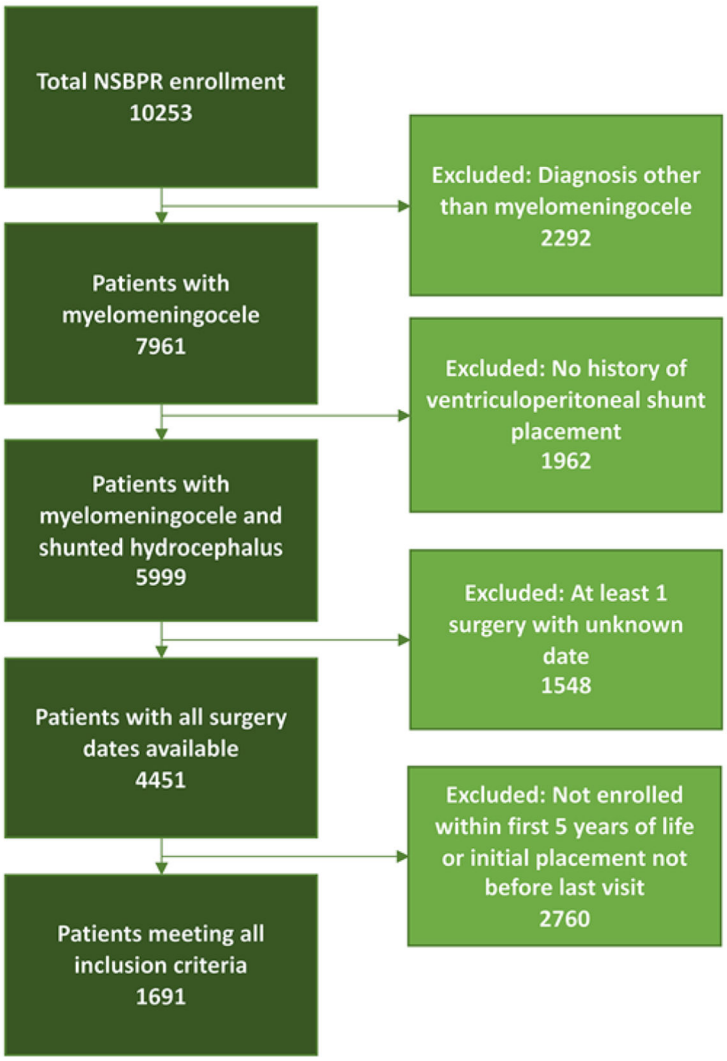

FIG. 1.
Study enrollment diagram.

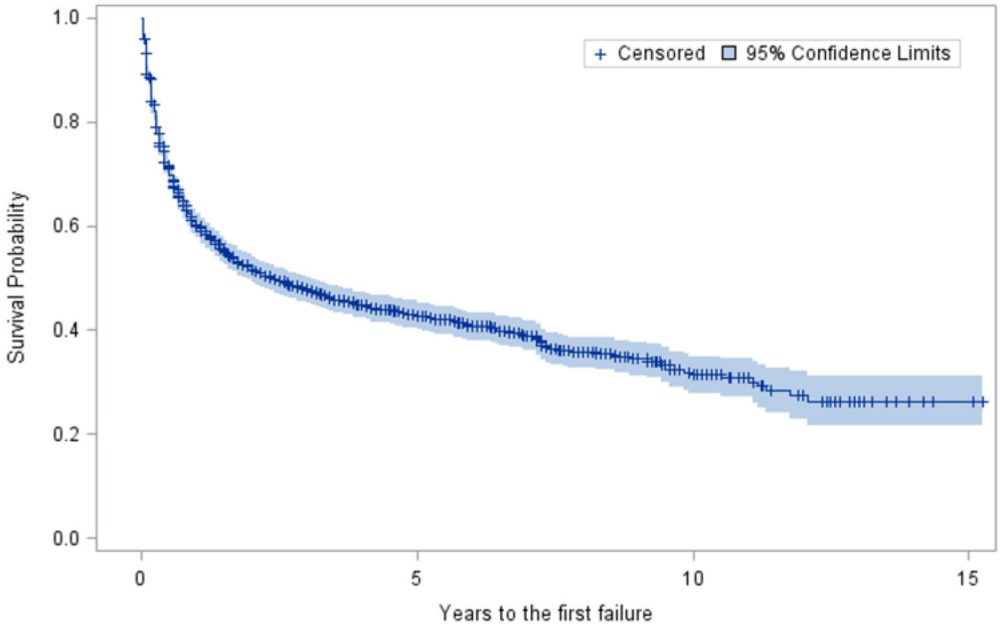

FIG. 2.
Kaplan-Meier survival curve for first shunt failure after initial shunt placement.

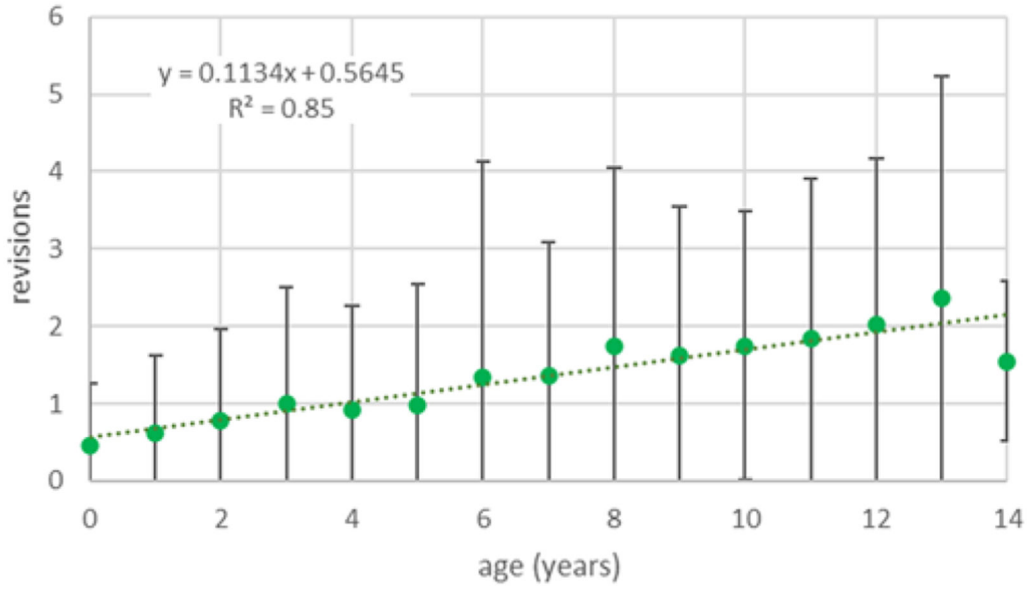

FIG. 3.

Average number of lifetime shunt revisions separated on the basis of patient age at most recent follow-up. The line of best fit (*dotted line*) demonstrates the approximately linear relationship between age and number of lifetime shunt revisions.

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TABLE 1.

Characteristics of patients who were included and excluded from analyses, NSBPR 2009–2019

Characteristic	Overall (n = 5999)	Included (n = 1691)*	Excluded (n = 4308)†	p Value
Sex				0.0041
Male	2925 (48.8)	875 (51.7)	2050 (47.6)	
Female	3074 (51.2)	816 (48.3)	2258 (52.4)	
Race/ethnicity (n = 5979)				0.0205
Non-Hispanic White	3827 (64.0)	1080 (64.1)	2747 (64.0)	
Non-Hispanic Black	479 (8.0)	128 (7.6)	351 (8.2)	
Hispanic	1338 (22.4)	360 (21.4)	978 (22.8)	
Other	335 (5.6)	118 (7.0)	217 (5.1)	
FLOL				<0.0001
Thoracic	1169 (19.5)	158 (9.3)	1011 (23.5)	
High-lumbar	798 (13.3)	254 (15.0)	544 (12.6)	
Mid-lumbar	1882 (31.4)	481 (28.4)	1401 (32.5)	
Low-lumbar	1202 (20.0)	483 (28.6)	719 (16.7)	
Sacral	948 (15.8)	315 (18.6)	633 (14.7)	
Health insurance (n = 5998)				0.0114
Any private	2502 (41.7)	749 (44.3)	1753 (40.7)	
Nonprivate	3496 (58.3)	942 (55.7)	2554 (59.3)	

Values are shown as number (%) unless indicated otherwise.

*The included patients had a diagnosis of myelomeningocele, history of shunted hydrocephalus, and available data on all VPS operations.

†The excluded patients had a diagnosis of myelomeningocele and history of shunted hydrocephalus, but they did not have complete data available for all VPS operations.

TABLE 2.

Estimated HRs for 1 or more shunt failures among patients with myelomeningocele and hydrocephalus, NSBPR 2009–2019

Characteristic	HR (95% CI)	p Value
Sex		**0.0013**
Male	**1.25 (1.09–1.44)**	
Female	Ref	
Race/ethnicity		**0.0027**
Non-Hispanic White	Ref	
Non-Hispanic Black	**0.74 (0.55–0.99)**	
Hispanic	**0.74 (0.62–0.88)**	
Other	0.80 (0.62–1.03)	
FLOL		0.38
Thoracic	1.08 (0.85–1.39)	
High-lumbar	1.21 (0.95–1.53)	
Mid-lumbar	0.98 (0.78–1.20)	
Low-lumbar	1.07 (0.86–1.34)	
Sacral	Ref	
Health insurance		0.50
Any private	Ref	
Nonprivate	0.95 (0.82–1.11)	

Boldface type indicates statistical significance ($p < 0.05$).