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Baseline Urinary Imaging in Infants Enrolled in Urologic Management to Preserve Initial Renal Function (UMPIRE) Protocol for Children with Spina Bifida

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Abstract

PURPOSE: The lifetime risk of renal damage among children with spina bifida (SB) is high, but only limited baseline imaging data are available for this population. We therefore queried a large, prospective cohort of infants with SB to define their baseline imaging characteristics.

PATIENTS AND METHODS: The Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE) is an iterative quality-improvement protocol that follows a cohort of newborns at nine US centers. Using descriptive statistics, we described the initial baseline imaging characteristics, specifically renal bladder ultrasound (RBUS), cystogram and DMSA scan.

RESULTS: Data on 193 infants from 2015–2018 were analyzed. RBUS was normal in 55.9% of infants, while 40.4% of infants had Society for Fetal Urology (SFU) grade 1–2 hydronephrosis in at least one kidney, 3.7% of infants had SFU grade 3–4 hydronephrosis in either kidney, and

Conflict of Interest: None relevant to this research.

21.8% of infants had bilateral hydronephrosis (SFU grade 1 or higher). There was no vesicoureteral reflux in 84.6% of infants. Of the one third of enrolled infants who had a DMSA renal scan, 92.4% had no renal defects and 93.9% of infants had a difference in differential function of <15%.

CONCLUSIONS: The majority of infants born with SB have normal baseline imaging characteristics and normal urinary tract anatomy at birth. This proactive protocol offers careful scheduled surveillance of the urinary tract with the goal of lifelong maintenance of normal renal function and healthy genitourinary development.

Keywords

Urology; Pediatric; Spina Bifida; Ultrasound; Vesicoureteral reflux

INTRODUCTION

In individuals with spina bifida (SB), the bladder usually has abnormal innervation from the malformed spinal cord. Indeed, 90% of patients with SB receive treatment for signs and symptoms of neurogenic bladder. (1) Abnormal bladder function in SB predisposes to chronic kidney disease. (2,3,4,5) The goal of the urologist is to protect the upper tracts, but many patients go on to develop renal impairment despite regular care. (6–8) There is controversy about optimal bladder management, and both proactive and reactive treatment pathways have been recommended. (9–10). There is also uncertainty about how best to provide long term follow up for these patients. Most reviews of SB management suggest renal ultrasound during the birth hospitalization and emphasize the importance of ongoing surveillance of the upper tracts without defining minimum intervals. (6–7) In a recent survey of 79 urologists and urology nurses, 95% recommended renal ultrasound at the initial hospitalization, and 52% also recommended an initial in-hospital cystogram; however, no follow-up imaging recommendations were gathered. (7) No multicenter large studies have been performed to define optimal urologic management, including the selection of imaging studies and minimum intervals for these studies.

In order to define optimal management strategies for newborns and young children from birth to 5 years of age with SB, we started a prospective, multicenter trial with a protocol for proactive bladder management. The Centers for Disease Control and Prevention (CDC) initiated a collaborative effort with nine SB centers in the United States that are currently participating in the National Spina Bifida Patient Registry (NSBPR). This collaborative effort, the Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida (UMPIRE) is one of the first and one of the largest prospective, multicenter studies to follow a large number of newborns from birth through early childhood, and monitor their renal imaging and functional outcomes over time. Through the course of the five years of funding for this prospective protocol, data on serial imaging, urodynamics, and kidney function are being collected. Details of the specific timing of these studies have been previously described. (11).

The purpose of this manuscript is to describe the baseline genitourinary imaging characteristics of the patients in this protocol to better understand renal appearance and

function around the time of birth. Baseline imaging includes renal bladder ultrasound (RBUS) obtained during the newborn period, and an evaluation for vesicoureteral reflux (VUR) and renal defects on a dimercaptosuccinic acid (DMSA) nuclear medicine scan. This baseline imaging, as one of the first analyses of this proactive protocol, will help inform optimal bladder management and allow us to compare our outcomes over time.

METHODS

Study Participants:

In 2015, nine NSBPR centers (Appendix 1) implemented a consensus-based, iterative, quality-improvement protocol, which was approved by each site's institutional review board (IRB). The UMPIRE protocol hasbeen described in-depth previously. (11) Eligibility criteria for the protocol included having the myelomeningocele form of SB and patient age ≤ 3 months if delivered at a study center. For those participants who transferred care to a protocol institution, the patient with myelomeningocele could be up to six months of age if the patient's care followed the protocol since birth, with no more than minor deviations. The goal was to enroll all eligible individuals followed at the nine sites. Of 272 eligible newborns, 228 (83.8%) were enrolled.

Study Interventions:

As outlined in the UMPIRE protocol, RBUS is specified to be obtained within one week after birth or prior to neo-natal intensive care unit (NICU) discharge. In this analysis, we included the first RBUS test in the first 59 days of life.

Cystogram was obtained either by voiding cystourethrogram (VCUG) or in conjunction with the baseline video-urodynamic studies ideally performed by 3 months of age. Studies obtained during the first five months of age were included in the analysis.

Baseline DMSA scan was performed at age 3 months. Due to difficulties in DMSA isotope production, some centers were unable to provide DMSA scans as specified per protocol. Therefore, infants were included in the DMSA scan sub-analysis if they had a DMSA during the first five months of age.

Baseline Imaging Grading

Hydronephrosis was graded by the Society of Fetal Urology (SFU) classification. (12) The International Reflux Study (IRS) grading scheme was used to grade VUR. (13). Renal defects were graded by segments affected using the Randomized Intervention for Children with Vesicoureteral Reflux (RIVUR) study grading system. Differential renal function from the DMSA scan was also recorded. (13)

Statistical Analysis

This analysis includes infants who were enrolled from the start of data collection in February 2015; who were at least 4 months old by the end of April 2018; and who completed their 3-month visit with results and demographic information entered into the electronic medical record by the end of April 2018. Descriptive statistics were performed

using SAS version 9.4© (Cary, NC) to present demographic and imaging results for this population. (11) Fisher's exact test was used to test ttheassociation between hydronephrosis and VUR.

RESULTS

Demographics

A total of 228 infants were enrolled in UMPIRE during this time period; 193 infants (84.6%) met inclusion criteria for this analysis. Baseline demographics for the enrolled 193 infants are displayed in Table 1. Approximately half of study participants were female (48.7%); a majority were Non-Hispanic white (60.1%); and slightly more than half (51.8%) had any private insurance.

Renal ultrasound

Baseline RBUS data were available for 190 (98.4%) of the 193 infants. The median age at baseline RBUS was 3 days (range: 0–58 days); 76.3% of infants had their baseline RBUS within the first 7 days of life. Two of the 190 infants had a solitary kidney, both with SFU grade 2. The distribution of SFU grading by each kidney for the 188 infants with both kidneys is reported in Table 2. The majority of infants had normal (grade 0) kidneys or low-grade (grade 1-grade 2) hydronephrosis. Overall in the 188 infants, seven (3.7%) infants had SFU grade 3 or 4 in at least one kidney, 76 (40.4%) infants had SFU grade 1 or 2 in at least one kidney, and 105 infants (55.9%) had two normal kidneys. Forty-one (21.8%) infants had bilateral hydronephrosis SFU grade 1 or higher.

Cystogram

Of the enrolled infants, 184 of the 193 (95.3%) had a baseline cystogram. The median age at baseline cystogram was 85 days (range: 1–171 days). One hundred thirty-three infants (72.3%) had video-urodynamics, while 51 (27.7%) had voiding cystourethrogram. Table 3a displays the distribution of IRS grading by each kidney for the 182 infants with both kidneys.

Of the 182 infants with both kidneys, 154 (84.6%) had no VUR into either kidney and 28 (15.4%) infants had VUR grade 1 or above into at least one kidney. Sixteen infants (8.8%) had bilateral VUR: one infant with grade 5 / grade 5; one with grade 5 / grade 3; seven with grade 3–4 / grade 3–4; five with grade 3–4/ grade 1–2; and 2 with grade 1–2/ grade 1–2. None of the two infants with a solitary kidney had VUR into the solitary kidney.

We examined for association between hydronephrosis and VUR in Table 3b. We categorized hydronephrosis into absent, low grade (SFU grades 1–2) and high grade (SFU grades 3–4), and VUR grade into absent, non-dilating (grades 1–2), and dilating (grades 3–5). Given the small numbers of hydronephrosis and VUR in this study, we were unable to determine an association (Fischer's exact test, p=0.19).

DMSA scan

Results for DMSA renal scan were only available for 66 of the 193 (34.2%) enrolled infants. Of the 9 participating centers, only 5 were able to perform DMSA at all, and only 3 were able to obtain DMSA on the majority of their enrolled infants. For the 66 infants with both kidneys who had a DMSA, the distribution of RIVUR grading is shown in Table 4A. RIVUR grade 0 (i.e., no renal defects) was noted in 97.0% of left and 95.5% of right kidneys. No infants had both kidneys affected and only five infants (7.6%) had one kidney affected. None of the 2 infants with a solitary kidney underwent DMSA scan.

A comparison of differential kidney function is shown in Table 4B. Sixty-two infants (93.9%) had a difference in differential function of less than 15%. Four infants had a difference exceeding 15%.

Of the five infants who had an abnormal DMSA findings in a single kidney, two infants had VUR. The infant with 3–4 segments affected had bilateral VUR (grade 5 ipsilateral, grade 3 contralateral). This infant had SFU-2 ipsilateral hydronephrosis and no contralateral hydronephrosis. The infant with 1–2 segments affected had ipsilateral unilateral grade 2 VUR and no hydronephrosis. The other three infants with 1–2 kidney segments affected had SFU 1–2 hydronephrosis in the affected kidney.

One of the infants with the abnormal DMSA was reported to have had a urinary tract infection (UTI) shortly before the DMSA scan. While the urine culture was positive, and the patient was treated, the only symptom was fever >100.4. In the absence of any other symptoms, this event did not meet protocol definition of UTI. (11)

DISCUSSION

Our data demonstrate that the vast majority of newborns with SB have essentially normal kidneys at birth, with no clinically significant findings on baseline imaging. High grade SFU hydronephrosis, VUR, and renal defects were quite rare. Differential function by DMSA was overall maintained in the normal range, with little evidence for congenital dysplasia. Over fifty years ago, there were reports that the majority of infants with SB have normal kidneys at birth. (1–4) Prior studies have also been limited by their relatively small sample size, retrospective nature and/or varied indications for imaging. A report from 1965 suggested that 95% of newborns with SB had normal excretory urograms at birth. A study of 83 infants with SB <6 months of age found that only 6/83 (7%) had hydronephrosis on screening ultrasound. (14) VUR has been reported in about 20% infants with SB. (4, 6)

Despite previous reports of overall reassuring early imaging, the prevalence of chronic kidney disease (CKD) among adults with SB is relatively high. (2,3) More individuals with SB are surviving into later adulthood. Given the morbidity and cost of CKD, the availability of healthcare for individuals with SB to preserve normal kidney function is not only important for the individual, but also for healthcare costs at the population level.

The goal of our protocol is to determine which patients are at risk for renal deterioration and how to best prevent it. As an initial step, we performed this descriptive analysis of baseline

imaging data from a recent large, geographically diverse cohort of infants with SB. Our newborn spina bifida population today and our current imaging are different from 50 years ago in many ways, and we could not assume that their kidneys would also be the same. With increased perinatal survival today, those with baseline imaging in the past may have been a less severely affected cohort. Maternal diet has changed; since 1998, the U.S. Food and Drug Administration began requiring folate fortification of cereals and grain products. (16) The effect of prenatal myelomeningocele repair on in-utero kidney development has yet to be elucidated. (17)

Currently, there are no specific guidelines regarding type, timing and frequency of imaging in infants and children with SB. This protocol aims to define baseline imaging findings and determine, over time, the frequency and impact of that imaging on the child's urologic and renal outcome. The protocol includes obtaining a DMSA renal scan at baseline and then again at age 5 years. A retrospective study from Argentina showed abnormal DMSA scan was present in 30% at baseline; half had never had a UTI.(4) Previous studies have suggested that in the SB population, ultrasound may not be the optimal method for assessing renal scarring over time. (15) Limitations to RBUS include body habitus related issues such as obesity and scoliosis in older patients. In a recent study comparing renal ultrasound and DMSA in adult patients, in 40% of cases without scarring on ultrasound, scars were present on DMSA. (15)

The incidence of CKD is high in adults with SB, and the variability in urologic management may contribute to the disease burden. Our goal is to determine how to best prevent CKD by testing a standardized urologic protocol starting at birth. This proactive protocol is one of the first interventional protocols to prospectively define and evaluate the urologic and renal management of children with SB. The protocol offers careful, scheduled surveillance of the urinary tract with serial imaging studies and urodynamics from birth to five years of agewith the goal of predicting and subsequently treating those infants at risk for upper tract deterioration and intervening prior to the onset of deterioration. This study describes the baseline imaging of this scheduled surveillance.

These findings should be considered within the context of their limitations. We did not combine analysis of baseline imaging and urodynamics, as urodynamic data are subject to varied interpretations. Indeed, we previously found that many urodynamic data points were variable to the point of being unreliable. Therefore, during this project, our urodynamic definitions and interpretations have gone through iterative clarifications. Additionally, we developed a review process for each urodynamic tracing. This process is currently being formally tested and will be the subject of a future publication. Our goal is that these definitions and review process can increase the validity of urodynamics presented from multi-center studies. We felt that the discussion of the urodynamics review process would overwhelm the discussion on baseline imaging.

Although the 9 participating institutions are from all regions of the United States, they are also all tertiary care centers with established, multidisciplinary SB clinics. As such, they may not represent a level of care that is accessible to all individuals with SB; these findings may not be generalizable beyond the participating institutions. Even within this cohort, not

all institutions were able to offer DMSA scans due to difficulties with acquisition of the necessary radioisotope. Although DMSA data on those patients who were able to undergo nuclear renal scans were quite reassuring, particular caution should be applied to generalizations of the DMSA data. Similarly, it is worth noting that UMPIRE was designed as a single-arm study; thus, the lack of a defined control group may limit or even prevent some comparisons. However, this iterative quality improvement protocol design has been previously shown to be highly effective in the study of similar congenital conditions. (14)

CONCLUSIONS

In this study, the majority of infants born with SB have normal or nearly normal baseline renal imaging. UMPIRE is one of the first prospective interventional protocols specifically designed to measure and optimize the urologic management of newborns and young children with SB. During the course of the five year proactive UMPIRE protocol, we hope to demonstrate that our protocol with specific scheduled imaging, urodynamic and other measured parameters can maintain normal renal function in patients with SB. (11) Given the reassuring baseline imaging data, proactive protocols that focus on long-term renal outcomes and prevention of CKD are important.

Acknowledgments

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Appendix 1:: Nine Participating Centers

Children’s Hospital Los Angeles (Los Angeles, CA)

Duke University Medical Center (Durham, NC)

Lurie Children’s Hospital (Chicago, IL)

Monroe Carell Jr. Children’s Hospital at Vanderbilt (Nashville, TN)

Oregon Health Sciences University (Portland, OR)

Seattle Children’s Hospital (Seattle, WA)

Texas Children’s Hospital (Houston, TX)

University of Alabama-Birmingham (Birmingham, AL

Primary Children’s Hospital (Salt Lake City, UT).

Abbreviation Key

UMPIRE	Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida

NSBPR	National Spina Bifida Patient Registry
SB	Spina Bifida
RBUS	Renal bladder ultrasound
VCUG	Voiding cystourethrogram
VUR	Vesicoureteral Reflux
SFU	Society for Fetal Urology
IRS	International Reflux Study
DMSA	Dimercaptosuccinic acid nuclear medicine scan
RIVUR	Randomized Intervention for Children with Vesicoureteral Reflux
UTI	Urinary tract infection

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Table 1.

Baseline demographics for 193 infants participating in the Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida 2015–2018

	N	%
Sex		
Female	94	48.7
Male	99	51.3
Race/Ethnicity		
Non-Hispanic White	116	60.1
Non-Hispanic Black	15	7.8
Hispanic or Latino	54	28.0
Other	8	4.1
Insurance		
Any private	100	51.8
Public only	82	42.5
Public and supplementary	7	3.6
Uninsured	2	1.0
Unknown	2	1.0
Prenatal Closure		
Yes	41	21.2
No	152	78.8
Circumcision[1]		
Yes	45	45.5
No	54	54.5

1. Males only

Table 2.

Baseline renal ultrasound SFU grade by kidney[1] for 188 infants participating in the Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida 2015–2018

	Left Kidney		Right Kidney	
Society of Fetal Urology (SFU) Grading of Infant Hydronephrosis	**n**	**%**	**n**	**%**
SFU Grade 0, no renal sinus splitting	126	67.0	126	67.0
SFU Grade 1, urine in pelvis barely splits sinus	31	16.5	38	20.2
SFU Grade 2, urine fills intra-renal pelvis +/− major calyces dilated	25	13.3	19	10.1
SFU Grade 3, urine fills intra-renal pelvis, major and minor calyces uniformly dilated, parenchyma preserved	5	2.7	5	2.7
SFU Grade 4, urine fills intra-renal pelvis, major and minor calyces uniformly dilated, parenchyma thin	1	0.5	0	0.0

[1]Excludes the two infants who had a solitary kidney.

Table 3a.

Cystogram IRS Grading by kidney for 182 infants[1] participating in the Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida 2015–2018

	Left Kidney		Right Kidney	
International Reflux Study grade	**N**	**%**	**N**	**%**
Grade 0	160	87.9	160	87.9
Grade 1	2	1.1	4	2.2
Grade 2	6	3.3	6	3.3
Grade 3	5	2.8	5	2.8
Grade 4	7	3.9	6	3.3
Grade 5	2	1.1	1	0.6

Excludes the 2 infants who had a solitary kidney.

Table 3b:

RBUS hydronephrosis association with VUR:

		VUR Grade			
		Grade 3–5	**Grade 1–2**	**No reflux**	**Total**
Hydronephrosis Grade	Grade 3–4	2 (28.6%)	0	5 (71.4 %)	7
	Grade 1–2	8 (10.8%)	2 (2.7%)	64 (86.5%)	74
	No hydronephrosis	7 (7.1%)	8 (8.2%)	83 (84.7%)	98
	Total	17	10	151	179

Fisher’s exact for any difference p-value= 0.19

Table 4A.

Dimercaptosuccinic acid (DMSA) scans, defects by RIVUR grade by kidney for 66 infants[1] participating in the Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida 2015–2018

	Left Kidney		Right Kidney	
Randomized Intervention for Children with Vesicoureteral Reflux (RIVUR) Grade	**N**	**%**	**N**	**%**
0, no kidney segments affected	64	97.0	63	95.4
1, 1–2 segments affected	1	1.5	3	4.6
2, 3–4 segments affected	1	1.5	0	0.0

[1]Excludes the 2 infants who had a solitary kidney.

Table 4B

DMSA scans distribution of differences in differential function between the two kidneys for 66 infants[1] participating in the Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida 2015–2018.

Differences in function between kidneys	N	%
0–9.9%	52	78.8
10–14.9%	10	15.1
15–19.9%	3	4.6
20–24.9%	1	1.5

1. Excludes the 2 infants who had a solitary kidney.