Baseline Urinary Tract Imaging in Infants Enrolled in the UMPIRE Protocol for Children with Spina Bifida

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Purpose: The lifetime risk of renal damage in children with spina bifida is high but only limited baseline imaging data are available for this population. We evaluated a large prospective cohort of infants with spina bifida to define their baseline imaging characteristics.

Materials and Methods: The UMPIRE Protocol for Young Children with Spina Bifida is an iterative quality improvement protocol that follows a cohort of newborns at 9 United States centers. Using descriptive statistics, we report the initial baseline imaging characteristics, specifically regarding renal bladder ultrasound, cystogram and dimercaptosuccinic acid nuclear medicine scan.

Results: Data on 193 infants from 2015 to 2018 were analyzed. Renal-bladder ultrasound was normal in 55.9% of infants, while 40.4% had Society for Fetal Urology grade 1 to 2 hydronephrosis in at least 1 kidney, 3.7% had grade 3 to 4 hydronephrosis in either kidney and 21.8% had grade 1 or higher bilateral hydronephrosis. There was no vesicoureteral reflux in 84.6% of infants. One-third of enrolled infants underwent dimercaptosuccinic acid nuclear medicine renal scan, of whom 92.4% had no renal defects and 93.9% had a difference in differential function of less than 15%.

Conclusions: The majority of infants born with spina bifida 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.

Abbreviations and Acronyms

CKD = chronic kidney disease
DMSA = dimercaptosuccinic acid nuclear medicine
IRS = International Reflux Study
RBUS = renal-bladder ultrasound
RIVUR = Randomized Intervention for Children with Vesicoureteral Reflux
SB = spina bifida
SFU = Society for Fetal Urology
UMPIRE = Urologic Management to Preserve Initial Renal Function
UTI = urinary tract infection
VCUG = voiding cystourethrogram
VUR = vesicoureteral reflux

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In individuals with spina bifida the bladder usually has abnormal innervation from the malformed spinal cord. Indeed, 90% of patients with spina bifida receive treatment for signs and symptoms of neurogenic bladder.[1] Abnormal bladder function in patients with spina bifida predisposes to chronic kidney disease.[2–5] The goal of the urologist is to protect the upper tracts, although renal impairment subsequently develops in many patients despite regular care.[6–8]

There is controversy about optimal bladder management, and proactive and reactive treatment pathways have been recommended.[9,10] There is also uncertainty about how best to provide long-term followup for these patients. Most reviews of spina bifida 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] A recent survey of 79 urologists and urology nurses revealed that 95% recommended renal ultrasound at the initial hospitalization and 52% also recommended an initial in hospital cystogram.[7] However, no followup imaging recommendations were gathered. No large multicenter studies have been performed to define optimal urological management, including the selection of imaging studies and minimum intervals for these studies.

To define optimal management strategies for newborns and young children with SB from birth to age 5 years, we started a prospective multicenter trial with a protocol for proactive bladder management. The Centers for Disease Control and Prevention initiated a collaborative effort with 9 SB centers in the United States that are currently participating in the National Spina Bifida Patient Registry. This program, the UMPIRE Protocol for Children with Spina Bifida, is among the first and largest prospective multicenter studies to follow a large number of newborns from birth through early childhood and to monitor renal imaging and functional outcomes through time. During the course of the 5 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 reported previously.[11]

We describe the baseline genitourinary imaging characteristics of patients in this protocol to better understand renal appearance and function around the time of birth. Baseline imaging includes RBUS obtained during the newborn period, and evaluation for VUR and renal defects on DMSA 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 outcomes through time.

METHODS

Study Participants

Nine National Spina Bifida Patient Registry centers implemented a consensus based, iterative, quality improvement protocol in 2015 (see Appendix). The study was approved by the institutional review board of each site. The UMPIRE Protocol for Children with Spina Bifida has been described in depth previously.[11] Eligibility criteria for the protocol included having the myelomeningocele form of SB and patient age 3 months or less if delivered at a study center. For those participants who transferred care to a protocol institution the patient with myelomeningocele could be up to 6 months old if patient care followed the protocol since birth with no more than minor deviations. The goal was to enroll all eligible individuals followed at the 9 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 1 week after birth or before discharge from the neonatal intensive care unit. In this analysis we included the first RBUS in the first 59 days of life.

Cystogram was obtained either by VCUG or in conjunction with the baseline videourodynamic studies, ideally performed by age 3 months. Studies obtained during the first 5 months of life 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 offer DMSA scans as specified per protocol. Therefore, infants were included in DMSA subanalysis if they underwent scanning during the first 5 months of life.

Baseline Imaging Grading

Hydronephrosis was graded according to SFU classification.[12] The IRS system was used to grade VUR.[13] Renal defects were graded by segments affected using the RIVUR trial grading system. Differential renal function from the DMSA scan was also recorded.

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 the 3-month visit with results and demographic information entered into the electronic medical record by the end of April 2018. Descriptive statistical analysis was performed using SAS® 9.4 software to present demographic and imaging results for this population.[11] Fisher exact test was used to analyze the association between hydronephrosis and VUR.

RESULTS

Demographics

A total of 228 infants were enrolled in the UMPIRE Protocol for Children with Spina Bifida during this

period, of whom 193 (84.6%) met inclusion criteria for this analysis. Baseline demographics for the enrolled infants are displayed in table 1. Approximately half of study participants were female (48.7%), the 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 infants (98.4%). Median age at baseline RBUS was 3 days (range 0 to 58), with 76.3% of infants undergoing the baseline RBUS within the first 7 days of life. Two of the 190 infants had a solitary kidney (SFU grade 2 in both). Distribution of SFU grading by each kidney for the 188 infants with 2 kidneys is outlined in table 2. The majority of infants had normal (grade 0) kidneys or low grade (1 to 2) hydronephrosis. Overall, of 188 infants 7 (3.7%) had SFU grade 3 or 4 hydronephrosis in at least 1 kidney, 76 (40.4%) had grade 1 or 2 hydronephrosis in at least 1 kidney and 105 (55.9%) had 2 normal kidneys. A total of 41 infants (21.8%) had bilateral SFU grade 1 or higher hydronephrosis.

Cystogram

Of the 193 enrolled infants 184 (95.3%) had a baseline cystogram available. Median age at baseline cystogram was 85 days (range 1 to 171). A total of 133 infants (72.3%) underwent videourodynamics, while 51 (27.7%) underwent VCUG. Table 3 displays the distribution of IRS grading for each kidney in infants with 2 kidneys.

Of 182 infants with 2 kidneys 154 (84.6%) had no VUR into either kidney and 28 (15.4%) had grade 1 VUR or higher into at least 1 kidney. A total of 16 infants (8.8%) had bilateral VUR, of whom 1 had grade 5 reflux in both kidneys, 1 had grade 5 and grade 3, 7 had grade 3 to 4 in both kidneys, 5 had grade 3 to 4 and grade 1 to 2, and 2 had grade 1 to 2 in both kidneys. Neither of the infants with a solitary kidney had VUR into the kidney.

Table 4 outlines the association between hydronephrosis and VUR. We categorized hydronephrosis into absent, low grade (SFU grade 1 to 2) and high grade (3 to 4), and VUR into absent, nondilating (grade 1 to 2) and dilating (3 to 5). Given the small number of hydronephrosis and VUR cases in this study, we were unable to determine an association (Fisher exact test, $p = 0.19$).

DMSA Scan

Results for DMSA renal scan were available for only 66 of the 193 enrolled infants (34.2%). Of the 9 participating centers only 5 were able to perform DMSA scan, and only 3 were able to obtain scan results in the majority of enrolled infants. For the 66 infants with 2 kidneys who underwent DMSA scan the distribution of RIVUR grading is shown in table 5. RIVUR grade 0 (no renal defects) was noted in 97.0% of left and 95.5% of right kidneys. No infant had both kidneys affected, and only 5 (7.6%) had 1 kidney affected. Neither infant with a solitary kidney underwent DMSA scan.

A comparison of differential kidney function is outlined in table 6. A total of 62 infants (93.9%) had a

Table 1. *Baseline demographics for 193 infants participating in UMPIRE, 2015 to 2018*

	No. Pts (%)
Gender:	
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 + supplementary	7 (3.6)
Uninsured	2 (1.0)
Unknown	2 (1.0)
Prenatal closure:	
Yes	41 (21.2)
No	152 (78.8)
Circumcision:*	
Yes	45 (45.5)
No	54 (54.5)

* Males only.

Table 2. *Baseline renal ultrasound SFU hydronephrosis grading by kidney for 188 infants participating in UMPIRE, 2015 to 2018*

	No. Pts (%)	
SFU Grade	Lt Kidney	Rt Kidney
0 (no renal sinus splitting)	126 (67.0)	126 (67.0)
1 (urine in pelvis barely splits sinus)	31 (16.5)	38 (20.2)
2 (urine fills intrarenal pelvis with or without major calyces dilated)	25 (13.3)	19 (10.1)
3 (urine fills intrarenal pelvis, major + minor calyces uniformly dilated, parenchyma preserved)	5 (2.7)	5 (2.7)
4 (urine fills intrarenal pelvis, major + minor calyces uniformly dilated, parenchyma thin)	1 (0.5)	0 (0.0)

Data exclude 2 infants who had a solitary kidney.

Table 3. *Cystogram IRS grading by kidney for 182 infants participating in UMPIRE, 2015 to 2018*

	No. Pts (%)	
IRS Grade	Lt Kidney	Rt Kidney
0	160 (87.9)	160 (87.9)
1	2 (1.1)	4 (2.2)
2	6 (3.3)	6 (3.3)
3	5 (2.8)	5 (2.8)
4	7 (3.9)	6 (3.3)
5	2 (1.1)	1 (0.6)

Data exclude 2 infants who had a solitary kidney.

Table 4. *RBUS hydronephrosis association with VUR*

Hydronephrosis	No. VUR Grade/Total No. (%)		
	3–5	1–2	None
Grade 3–4	2/7 (28.6)	0/7 (0)	5/7 (71.4)
Grade 1–2	8/74 (10.8)	2/74 (2.7)	64/74 (86.5)
None	7/98 (7.1)	8/98 (8.2)	83/98 (84.7)
Totals/av*	17/179 (9.5)	10/179 (5.6)	151/179 (84.4)

$p = 0.19$ for any difference (Fisher exact test).
* Total percentage equals less than 100 due to rounding.

difference in differential renal function of less than 15%. Four infants had a difference exceeding 15%.

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

One of the infants with an abnormal DMSA scan reportedly had a UTI shortly before the test. While the urine culture was positive and the patient was treated, the only symptom was fever greater than 100.4F. In the absence of any other symptoms this event did not meet protocol definition of UTI.[11]

DISCUSSION

Our data demonstrate that the 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 scan was overall maintained in the normal range, with little evidence of congenital dysplasia.

More than 50 years ago there were reports that the majority of infants with SB had normal kidneys at birth.[1–4] Previous studies have been limited by the relatively small sample sizes, retrospective nature and/or varied indications for imaging. One report from 1965 suggested that 95% of newborns with SB had normal excretory urography at birth.[14] In that study of 83 infants younger than age 6 months with SB only 6 (7%) had hydronephrosis on screening ultrasound. In addition, VUR has been reported in about 20% of infants with SB.[4,6]

Table 5. *DMSA scan distribution of RIVUR grading by kidney for 66 infants participating in UMPIRE, 2015 to 2018*

RIVUR Grade	No. Pts (%)	
	Lt Kidney	Rt Kidney
0 (no kidney segment 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)

Data exclude 2 infants who had a solitary kidney.

Table 6. *DMSA scan distribution of difference in differential renal function for 66 infants participating in UMPIRE, 2015 to 2018*

% Difference in Function between Kidneys	No. Pts (%)
0–9.9	52 (78.8)
10–14.9	10 (15.1)
15–19.9	3 (4.6)
20–24.9	1 (1.5)

Data exclude 2 infants who had a solitary kidney.

Despite previous reports of overall reassuring early imaging, the prevalence of 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 health care for individuals with SB to preserve normal kidney function is important not only for the individual, but also regarding health care costs at the population level.

The goal of our protocol is to determine which patients are at risk for renal deterioration and how best to prevent it. As an initial step, we report 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 the 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. Also, maternal diet has changed. Since 1998, the United States Food and Drug Administration has required folate fortification of cereals and grain products.[15] Finally, the effect of prenatal myelomeningocele repair on kidney development in utero has yet to be elucidated.[16]

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, through time, the frequency and impact of that imaging on patient urological and renal outcomes. The protocol includes obtaining a DMSA renal scan at baseline and then again at age 5 years. A retrospective study from Argentina revealed an abnormal DMSA scan in 30% of patients with SB at baseline, with half of patients never having had a UTI.[4] Previous studies have suggested that in the SB population ultrasound may not be the optimal method for assessing renal scarring through time.[17] 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 scan in adults scars were present on DMSA scan in 40% of cases without scarring on ultrasound.[17]

The incidence of CKD is high in adults with SB, and the variability in urological management may contribute to the disease burden. Our goal was to determine how best to prevent CKD by testing a standardized urological protocol starting at birth. This proactive protocol is among the first interventional programs to prospectively define and evaluate the urological 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 age 5 years with the goal of predicting and subsequently treating those infants at risk for upper tract deterioration and intervening before 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 since urodynamics data are subject to varied interpretations. Indeed, we previously found that many urodynamic data points were variable, rendering the results 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 the review process can increase the validity of urodynamics presented from multicenter studies. We believe that 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, and our 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 noteworthy that the UMPIRE Protocol for Children with Spina Bifida 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 previously been shown to be highly effective in the study of similar congenital conditions.[14]

CONCLUSIONS

In this study the majority of infants born with SB had normal or nearly normal baseline renal imaging. The UMPIRE Protocol for Children with Spina Bifida is among the first prospective interventional protocols specifically designed to measure and optimize the urological management of newborns and young children with SB. During the course of the 5-year proactive trial we hope to demonstrate that our protocol with specific scheduled imaging and 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.

Appendix. *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)

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EDITORIAL COMMENT

The UMPIRE Protocol for Children with Spina Bifida is a single arm, prospective study following newborns with spina bifida at 9 institutions using a consensus based, urological management protocol (reference 11 in article). The authors describe the baseline imaging results of the first 228 newborns enrolled. Most infants were born with relatively normal kidneys. Specifically 55.9% had no hydronephrosis, while 40.4% had SFU grade 1 to 2 hydronephrosis in 1 or both kidneys and 3.7% had grade 3 to 4 hydronephrosis. The majority of patients (84.6%) had no VUR, while 15.4% had unilateral and 8.8% had bilateral VUR. Of the 66 patients with a DMSA scan 92.4% had no defects.

Although the degree of hydronephrosis could be underestimated since some patients underwent RBUS during the period of physiological oliguria of the newborn, it is reassuring that most newborns had relatively normal imaging at birth. Based on imaging alone (without considering retention or bladder pressures), few patients would require clean intermittent catheterization or prophylactic antibiotics (reference 11 in article). It will be interesting to see how the imaging may change as patients age, and how consistently a change in renal function or scarring is correlated with a change in RBUS or VCUG findings.

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