-FINAL DRAFT-

RADIOGRAPHIC ABNORMALITIES, BLADDER INTERVENTIONS, AND BLADDER SURGERY IN THE FIRST DECADE OF LIFE IN CHILDREN WITH SPINA BIFIDA

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Introduction/Objective:

Spina bifida (SB) patients are at increased risk for hydronephrosis (HN), bladder storage and emptying problems, and renal failure that may require multiple bladder surgeries to address. We use early renal/bladder ultrasound (RBUS) and fluoroscopic urodynamic images (FUI) to guide therapies (clean intermittent catheterization (CIC), anticholinergic use (AC), and/or surgical interventions (SI)). We analyzed initial and 10-year radiologic findings, renal function (RF), and CIC, AC and SI rates for children followed proactively and consistently.

Materials/Methods:

We retrospectively reviewed all born with SB between 2005 and 2009, presenting to our institution within 1 year of birth. Outcomes at 8-11 years old included final RBUS results, CIC use, AC use, any SIs prior to final follow-up, and final RF. We excluded those without follow-up past age 8, and/or no RBUS or FUI within first year of birth. All RBUS and FUI were performed at our institution. Imaging was independently reviewed by 4 pediatric urologists blinded to radiologists' interpretation. McNemar's test was used to compare initial findings (RBUS results, FUI, CIC, AC) with final outcomes at 8-11 years of age (RBUS, CIC, AC, SI, and RF). FUI was too infrequent at the final (8-11 years) window, and not included. Serum creatinine and cystatin-C were used to estimate GFR.

Results:

Of 98 children, we excluded 16 without adequate follow-up (left referral area), and 20 for lack of available imaging within 1 year of birth (born elsewhere). 62 children remained for analysis: (48 % male, 76 % shunted). Median age at last follow-up was 9.6 years. Upon initial imaging, 74 % of children had HN (≥ SFU grade 1), this decreased to 5 % at 10 years ($p<0.0001$). Initially, 9 % had ≥ SFU grade 3 HN, this decreased to 2 % ($p=0.13$). CIC and AC

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increased from 61 % and 37 %, to 87 % and 86 %, respectively ($p=0.001$ and <0.0001, respectively). With follow-up, 55 % had a SI and 23 % an augmentation. Of children with a serum creatinine/cystatin-C at 8-11 years old, one had confirmed CKD (stage 2).

Discussion:

This study was limited by a small sample size, retrospective nature, and selection bias toward patients with prolonged follow-up. Possible confounders, i.e. bladder capacity/compliance and desire for continence were not analyzed and may influence SI.

Conclusions:

Despite a high incidence of HN initially among children with SB, this was low grade and resolved in the first decade of life. Additionally, the 8-11 year incidence of kidney disease and upper tract changes was low in this cohort due to aggressive medical management.

Introduction:

Renal failure is less common than it was historically in the spina bifida (SB) patient, contributing to the longer expected survival of SB patients [1]. Using early, frequent monitoring with renal-bladder ultrasound (RBUS), flurourodynamic imaging (FUI), and serum studies, we are attempting to determine early signs of pending renal failure. Clean intermittent catheterization (CIC), anticholinergics (AC), and surgical interventions (SI) are used proactively and/or expectantly to avoid what was once considered inevitable [2-4]. Although this success is laudable, what is unclear is the incidence and significance of radiologic abnormalities in infancy and later childhood. Further, there are no reliable methods of predicting who will develop chronic kidney disease (CKD) and/or require urologic surgical intervention (SI).

Despite the controversies between expectant and proactive management in the urologic literature, most agree that routine and early clinical monitoring with periodic RBUS with routine or "as needed" urodynamic testing helps to identify those patients needing early intervention [5-11]. For those patients considered at risk for obstructive nephropathy, the three tools at a pediatric urologist's disposal for intervention include CIC, AC, and/or SI. These are considered efficacious and well-tolerated [2, 12-15].

Rather than expectant management, our group employs a proactive approach. For those born with SB, we institute early CIC (three times each day) based on elevated postvoid residuals following myelomeningocele closure. We believe early CIC is easier for patients and families to accept and tolerate, while leaving open the option of ending CIC if residuals are consistently below 10ml for 48 hours prior to leaving the hospital. RBUS is performed within the first week of birth, and flurourodynamics are ideally pursued at 3 months of age.

The incidence and significance of radiologic abnormalities within 1 year of life in the SB population is unknown. Also with routine follow up, it is unclear whether initial findings upon RBUS and/or FUI persist. This information may be clinically useful, and potentially reassuring when counseling families of children born with SB.

In this study, we sought to evaluate radiologic studies performed, and CIC and AC status within 1 year of life, and later at 8-11 years of age (in addition to SI and RF) in all patients initially managed at our institution with the diagnosis of SB. We hypothesized a high incidence of initial hydronephrosis (HN) and vesicoureteral reflux (VUR),

with improvement in these parameters and an overall low incidence of chronic kidney disease (CKD) later in life in the setting of modern medical management.

Material and Methods

After IRB approval under IRB number 1605024102, we collected a cohort of children with SB followed at our institution who were born between August 2005 and August 2009. We collected all subsequent radiology studies performed at our institution. Those without either RBUS or FUI available for review within 1 year of birth were analyzed as a separate group. We presumed these (20) patients were either born elsewhere, and moved after first year of life, or were late referrals due to a lack of knowledge. We evaluated patient demographics and clinical characteristics, focusing on RBUS findings, FUI radiologic findings, CIC use, and AC use within 1 year of birth. For outcomes, we collected RBUS, CIC use, and AC use by 8-11 years of birth, SI by 8-11 years of age, and serum creatinine and cystatin-C, with calculated GFR.

All relevant RBUS and FUI images were independently reviewed by four pediatric urologists and blinded to radiologists' interpretation. Each renal unit on RBUS was assigned a grade of HN by each reviewer as described in the SFU grading scheme [16]. All FUIs were graded for degree of VUR (grade 0-5 per renal unit), bladder shape (round, oblong, or trabeculated), and open or closed bladder neck prior to void [17]. We then made final determinations of HN or VUR grade based upon majority consensus with mean grade if equal dissent was noted.

All charts were reviewed for any evidence of CIC or AC use, both in the first year of life, and then at 8-11 years of life to assess for 10 year outcomes. A three year window was used to assess for 10 year outcomes to maximize study enrollment, while ensuring similar follow-up length. The last outcome in the time-window was used when multiple visits occurred. At 8-11 years of life, we collected all available serum creatinine and cystatin-C values with associated measured height, gender, creatinine, and BUN. Using the bedside Schwartz and CKD-Epi CC equations, we sought to most accurately estimate GFR, and CKD stage[18, 19].

For each patient in the cohort, we collected initial predictors (RBUS findings, FUI findings, CIC use, AC use) and final outcomes (RBUS findings, CIC use, AC use, SI incidence, and RF). To assess for potential selection bias, we compared baseline characteristics and 10 year outcomes for those with and without initial imaging as a subgroup analysis. We compared the incidence of HN, bilateral HN, and high grade HN in the initial study (predictor) and the final study (outcome) using McNemar's test to correct for correlations within the sample (i.e. changes were compared within each patient, rather than for the group as a whole). Again, using McNemar's test, we compared the

incidence of CIC use, AC use, and SI initially (predictors), and then at the final time point (outcomes). Next, we evaluated SI differences by HN status, VUR status, and initial vesicostomy status (present or not present). Catheterizable channels were most commonly performed for ease of independent CIC. Vesicostomies were performed for refractory upper tract deterioration despite maximal medical management. A critical p-value of 0.05 was used to assess for statistical significance. Lastly, we evaluated RF at the final time point (8-11 years of age) using both the bedside Schwartz equation and the CKD-Epi CC equation (when a serum cystatin-C was available).

Results

Of 98 patients, we excluded 16 without follow-up past 8 years old, and 20 for lack of either RBUS or FUI in the first year of life, leaving 62 children for analysis. In this group, 48 % were male, 66.1 % had lumbar or lumbosacral defect and 76 % were treated with a ventriculoperitoneal shunt for hydrocephalus (Table 1). In addition, 52 % were community ambulators. Median follow-up time was 9.6 years.

We then compared those with (62) and without (20) imaging in the first year of life (Table 1). There was a higher proportion of patients with a diagnosis of lipomeningocele ($p=0.02$) in the group without imaging. The two groups were otherwise similar in makeup other than age at initial radiologic evaluation. When comparing hydronephrosis incidence, VUR status, CIC/AC rates, surgical incidence, and estimated GFR, we found no meaningful differences in any of these outcomes However, there was a higher rate of AC use in those with initial imaging ($p=0.01$). Those (20) patients without imaging in the first year of life were likely not recognized until sometime (months, or years) after birth, given the higher proportion of lipomeningocele.

Ultrasound

Fifty-seven children (92 %) in the cohort had a renal bladder ultrasound in the first year of life (Table 2). Of the 15/57 (26 %) with no evidence of HN on the initial RBUS, three (20 %) subsequently underwent a vesicostomy. All of these vesicostomies were performed after the first year of life for worsening bladder compliance despite CIC/AC. Three (20 %) of those without initial HN were ultimately treated a bladder augmentation (Table 3).

Within the first year of life, 74 % of children had some degree of HN (≥ grade 1), which decreased to 5 % at 10 years ($p<0.0001$) (Table 3). Initially, 9 % had SFU grade 3 or higher HN, with 2 % demonstrating these grades at 10 years ($p= 0.13$).

The most common finding upon initial ultrasound was low grade (SFU grade 1-2) HN (37/57, 65 %). In these patients, 11 % had a vesicostomy performed and 24 % underwent bladder augmentation. Few patients had initial high grade (grade 3-4) HN (5, 9 %). Of these, 2 (40 %) were treated with a vesicostomy and 1 (20 %) with a bladder augmentation. Only 1 of these patients had persistent HN (high grade). This patient had no interval SIs, the HN resolved with an empty bladder, and there was no increase in grade from the initial antenatal ultrasound. Regardless of initial HN status, 23 (40%) had no bladder surgery (vesicostomy, catheterizable channel,

augmentation, or bladder chemodeinervation) performed by 8-11 years of age. Presence and grade of HN upon initial RBUS were not associated with risk of surgery.

Flurourodynamic Images

Fifty-nine patients (95 %) had FUI within the first year of life, with 46/59 (78%) having no evidence of VUR. Of these, 5 (11 %) required vesicostomy. 20/46 (44 %) did not require any SI.

Of the 13 patients (22 %) with VUR on their initial study, roughly half (6, 46 %) had high grade VUR (grade 3 or above). Three patients (50 %) with initial high grade VUR subsequently underwent a vesicostomy. One patient (14 %) with initial low grade VUR underwent a vesicostomy. 5 patients (11%) without evidence of VUR received a vesicostomy. When compared to those without VUR on their initial study, those with VUR had an increased risk of vesicostomy, but this was not statistically significant (31 % vs. 11 %, p=0.10). There was no clear trend toward no bladder surgery for those without vs. with VUR (44 % vs. 23 %, p=0.21). Similarly, these patients had similar rates of bladder augmentation (31 % vs. 22 %, p=0.48).

Clean Intermittent Catheterization and Anticholinergic Use

CIC and AC increased from 38 (61 %) and 23 (37 %) in the first year of life to 54 (87 %) and 53 (86 %) at 10 years, respectively (p=0.001 and <0.0001, respectively) (Table 2).

Surgical Intervention

With diligent follow-up, 34 (55 %) patients had at least one SI, with 14 (23 %) undergoing bladder augmentation. All patients treated for vesicostomy were due to failure to achieve a safe bladder despite maximal medical therapy. We first compared those initially treated with a vesicostomy with those that were not. We saw no difference in the rates of catheterizable urinary channels, bladder augmentation, onobotulinum toxin injection, or hydronephrosis on final imaging. There was an increased risk for bladder augmentation in the vesicostomy group, but this did not reach statistical significance (p=0.21). There was an increased risk of ureteral reimplantation in the vesicostomy group (p=0.012), which may be due to the higher rate of early VUR in this group.

We then focused on those that were initially treated with a vesicostomy. 40 % (4/10) went on to have a bladder augmentation (with catheterizable channel). One patient received a catheterizable channel only, and 2 had a

vesicostomy takedown (without catheteriziable channel), with no further SI. At 8-11 years of age, 30 % (3/10) continue to drain their bladder with a vesicostomy. Only 30 % of the vesicostomies were performed before 1 year of age. All those treated with an initial vesicostomy now either remain with a vesicostomy or are CIC dependent (via urethra or catheterizable channel). Conversely, of the 52 patients that did not receive a vesicostomy, 11 (21 %) void spontaneously, and have not required any surgery (including onobotulinum toxin). Those treated with a vesicostomy trended towards an increased risk of requiring a bladder augmentation (40 %, 4/10 vs. 19 %, 10/53, p=0.21). Those that remained with their vesicostomy at 10 years (30 %), were due to parental/family preference for ease of care.

Renal Function

Thirty-three children (53 %) in the cohort had a serum creatinine and height available at final follow-up. Using the bedside Schwartz formula, we found a median eGFR of 126 ml/min/1.73 m2 (IQR 102-157). All values were ≥90 ml/min/1.73 m2. Twenty children with available serum cystatin-C in the 8-11 age range had a median GFR of 100 mL/min/1.73 m2 (IQR 89-112). Of those, 5 had a GFR 60-89 mL/min, but only one showed evidence of renal scarring on ultrasound. None showed evidence of albuminuria. In other words, only 1 patient had definitive evidence of stage 2 CKD. No children required hemodialysis nor renal transplant.

Discussion

We present 10-year results of renal and bladder outcomes for children with SB. We found many had early HN (72 %). However, the majority of these findings were unilateral (52 %), and/or low grade (88 %). Vesicoureteral reflux was less common (22 %). Over half of the children (57 %) underwent bladder surgery in the first 10 years of life. We found that a vesicostomy, a marker of a hostile bladder, tended to be a positive predictor of later bladder augmentation, but this was not statistically significant (4/10 (40 %), vs. 10/53 (19 %), p=0.21). No child developed renal failure.

A previous retrospective review of 84 children with SB imaged at age 6 months or less, found only 7 % had HN, much lower than our finding [11]. In this study, patients were categorized into "high" or "low" risk based upon evidence of retention or HN. Those considered high risk at any point received further evaluation with voiding cystourethrogram and urodynamics study, and appropriate intervention, including, but not limited to CIC, AC, vesicostomy, and/or antibiotic prophylaxis for VUR. With diligent follow-up, there was a 45 % conversion rate from low to high risk, prompting the above stated studies and intervention(s). Tarcan et al. confirmed in their study that those once considered low risk, can at any time become high risk, necessitating urodynamics and further treatment (32 %) [6].

Wang et al. reviewed nationwide trends in chronic renal insufficiency (CRI) and urologic surgery over time within the SB population [20]. Interestingly, SB admissions with the diagnosis of CRI has progressively increased from 6 % in 1998 to 12 % in 2011. Yet, admissions related to urologic surgeries in this population remained stable from 2.0 % in 1998 to 1.8 % in 2011. This study assessed a large administrative dataset of 427,616 SB hospital admissions, but remains difficult to interpret, given reliance upon accurate diagnostic and procedure codes.

Alabi et al. recently reviewed the Ntional Spina Bifida Registry (2009-2013) for surgical procedures and other health outcomes (fecal continence, urinary continence, skin breakdown, and ambulatory status) [21]. They noed that 81.5 % (3801) had surgical data. Interestingly the most frequent procedures were neurologic, with the urologic typically occurring later in life. Overall, the rates of fecal and urinary incontinence and skin breakdown increased with age, whereas the ability to ambulate declined with age. Also the incidence of urologic surgery remained roughly 10 % of total surgeries, regardless of whether myelomeningocele or nonmyelomeningocele. This study was

different in it's large number of patients and more generalized surgical data. In contrast, our study strictly followed patients from birth at our instituions, and focused upon urologic imaging and surgical procedures.

As mentioned, our study included those with initial imaging (RBUS or FUI) within the first year, and consistent follow up until at least age 8. To check for bias, we compared those with and those without imaging in the 1st year. Those without imaging in the first year (possibly born elsewhere or discovered/referred later) were more likely to have lipomeningocele (statistically significant), but otherwise fairly similar in radiologic, surgical, and renal function outcomes. This would suggest that the consistent, long-term follow up is likely more important than obtaining early imaging.

Limitations of our study include the relatively small cohort as only 68 of these had perinatal radiology study. In addition, patients' charts were retrospectively reviewed. Despite our centralized, standardized follow-up model with a regularly scheduled multidisciplinary clinic visits, some patients may be seen at other institutions for their care. In addition, this is relatively short-term follow-up and may be insufficient length of time to observe deterioration of renal function. Differences between providers undoubtedly exist and were not evaluated in our study. Our study also did not include urodynamic findings (not easily available), and patients' and families' desire for continence. As we did not assess the indications for surgery, both of these factors very likely contributed toward a decision to perform bladder surgery.

Conclusion

These data are an important contribution to the urologic care of patients with spina bifida and will be useful in counseling families. We found that although hydronephrosis is common upon the initial ultrasound, it is usually low grade, and not associated with an increased rate of surgical intervention in the first decade of life. Those treated with a vesicostomy trended towards an increased risk for bladder augmentation (relative risk 2.1, absolute risk increase of 21 %). Finally, about half (55 %) had SI in the first decade of life for variable reasons. Routine, regular clinical follow up may be a driver toward long-term renal health with prompt evaluation, and, if necessary, early medical or surgical intervention.

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Table 1. Baseline characteristics and non-urologic clinical history.

	With imaging in First Year (n=62)	Without imaging in First year (n=20)	P values
Male	**30 (48 %)**	**10 (50 %)**	**0.99**
Myelomeningocele	**59 (95 %)**	**15 (75 %)**	**0.02**
Lipomeningocele	**3 (5 %)**	**5 (25 %)**	
Myelomeningocele level			
Thoracic Defect	**3 (5 %)**	**0**	**0.43**
Lumbar or lumbosacral defect	**41 (66 %)**	**11 (55 %)**	
Sacral Defect	**15 (24 %)**	**4 (20 %)**	
Community ambulators	**32 (52 %)**	**14 (70 %)**	**0.20**
Median age at first ultrasound	**10 days**	**4.8 years**	**<0.00001**
Median age at first Flurourodynamics	**19 days**	**4.8 years**	**<0.00001**
Shunt Incidence for Hydrocephalus	**47 (76 %)**	**12 (60 %)**	**0.25**
Initial Flurourodynamics Findings (n=59)		*	
Any Vesicoureteral Reflux	13 (22 %)	*	
Bilateral Vesicoureteral Reflux	8 (14 %)	*	
High grade Vesicoureteral Reflux (≥ grade 3)	6 (10 %)	*	
Open bladder neck	38 (64 %)	*	
Oblong or trabeculated bladder shape on cystogram	26 (44 %)	*	

*Patients in this cohort did not routinely get flurourodynamics.

Table 2. Incidence of hydronephrosis, clean intermittent catheterization, anticholinergics, and bladder surgery

N=57*	**First year of life**	**Final time point**	***p-value*****
Any Hydronephrosis	**42 (74 %)**	**3 (5 %)**	***<0.0001***
Bilateral Hydronephrosis	**22 (39 %)**	**2 (4 %)**	***<0.0001***
Any High Grade Hydronephrosis (> SFU Grade 2)	**5 (9 %)**	**1 (2 %)**	***0.13***
N=62			
Clean Intermittent Catheterization Status	**38 (61 %)**	**54 (87 %)**	***0.001***
Anticholinergic Use	**23 (37 %)**	**53 (86 %)**	***<0.0001***
Bladder surgery#	**3 (5 %)^**	**34 (55 %)**	***<0.0001***

*5 patients in this cohort did not have an ultrasound within the first year of life.

**Calculated using McNemar's test.

Defined as vesicostomy, vesicostomy takedown, catheterizable channel, bladder chemodenervation, or bladder augmentation.

^ All were vesicostomies.

Table 3. Ten-year outcomes stratified by hydronephrosis upon initial renal ultrasound (n=57)

	All	No Hydronephrosis	SFU Grade 1-2	SFU Grade 3-4
	57	15 (26 %)	37 (65 %)	5 (9 %)
10 year outcomes				
Vesicostomy	9 (16 %)	3 (20 %)	4 (11 %)	2 (40 %)
Catheterizable bladder channel	25 (44 %)	7 (47 %)	16 (43 %)	2 (40 %)
Bladder augmentation	13 (23 %)	3 (20 %)	9 (24 %)	1 (20 %)
Botox injection	8 (14 %)	4 (27 %)	4 (11 %)	0
Ureteral reimplantation	4 (7 %)	0	3 (8 %)	1 (20 %)
No bladder surgery	23 (40 %)	5 (33 %)	16 (43 %)	2 (40 %)

Conflicts of Interest

There were no conflicts of interest amongst the authors of this manuscript.