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ORIGINAL PAPER

Short-term postnatal renal outcome after vesico-amniotic shunting in boys with posterior urethral valves diagnosed prenatally

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ABSTRACT

Introduction: The most common interventions in lower urinary tract obstruction are vesico-amniotic shunting (VAS) and serial amnioinfusions; however, their outcome remains uncertain. The aim of the study was to assess the kidney function as well as clinical complications in boys at the age of 6 months with posterior urethral valves (PUV), who underwent prenatal VAS and survived the neonatal period.

Material and methods: The study group consisted of 14 boys and the mean time of the VAS procedure was 22 weeks of gestational age (GA). Children were born in 34 GA (29–39) with average birth weight of 2860 g. Four fetuses needed amnioinfusion. In the study we assessed physical development, prevalence and aetiology of urinary tract infections (UTIs), number of hospitalizations, estimated glomerular filtration rate, presence of hypertension, albuminuria, proteinuria and acidosis.

Results: Average body weight at 6 months of life was 7.2 kg. 86% of children had at least one UTI; the same percentage were given antibacterial prophylaxis. 36% underwent urinary diversion. Median number of hospitalizations was 4. One patient required chronic renal replacement therapy, and one needed a short course of peritoneal dialysis. Median serum creatinine level was 0.65 mg/dl with estimated glomerular filtration rate (eGFR) 50.6 ml/min/1.73 m^2. Average serum cystatin C level was 1.50 mg/l with eGFR 48.5 ml/min/1.73 m^2. 43% developed acidosis. 71% had elevated albuminuria with a median urine albumin-to-creatinine ratio of 581.64 mg/g. 28.5% had overt proteinuria.

Conclusions: Growth at the age of 6 month of infants with PUV after prenatal VAS was barely satisfactory. More than half had impaired kidney function, but the need for renal replacement therapy was uncommon.

KEY WORDS:

urinary tract diseases, urethral obstruction, fetal therapies, neonatal diseases.

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INTRODUCTION

Posterior urethral valves (PUV), as a reason for severe obstruction of the urinary tract, were first described in 1802 by Langenbeck. Before the era of prenatal interventions the majority of fetuses with serious urinary tract obstruction (LUTO) died *in utero* or in the neonatal period, mainly because of severe pulmonary hypoplasia, but also kidney damage [1]. On the other hand, children with milder LUTO were often diagnosed postnatally (after the first febrile urinary tract infection (UTI)) and had a chance to survive, even with preserved kidney function.

Nowadays, prenatally diagnosed PUV are still a negative prognostic factor regarding maintaining kidney function. It has been proven that these cases presented the most severe malformations [2, 3]. Also, the analysis of long-term outcomes in these children showed that 24–45% developed renal failure in childhood or adolescence [4]. Other unfavourable prognostic factors include: presentation before 24 weeks of intrauterine life, renal dysplasia, poor corticomedullary differentiation in ultrasound and vesicoureteric reflux [4].

Even though there is a technical possibility for prenatal intervention in suspicion of PUV, its outcome remains uncertain. The most common interventions in LUTO are vesico-amniotic shunting (VAS) and serial amnioinfusions, which aim to prevent pulmonary hypoplasia and preserve kidney function. Moreover, several attempts have been made to remove obstruction *in utero* by prenatal fetoscopy. However, such interventions are not yet favoured, due to their questionable long-term effects [2, 5, 6].

It is worth mentioning that the early survival rate in children with prenatally suspected PUV was 21–75% with no advantage of any prenatal intervention. What is more, in our previous research VAS led to unfavourable neonatal outcomes, with a 56% 28-day survival rate [7].

The aim of the study was to assess the function as well as clinical complications in boys at the age of 6 months with PUV, who underwent prenatal VAS and survived the neonatal period.

MATERIAL AND METHODS

Thirty-three fetuses were the initial group qualified for *in utero* intervention. Twenty-three pregnancies ended with successful delivery. Three boys died in the neonatal period. Five patients were lost to follow-up. One patient was dismissed from the study after delivery due to erroneous sex determination [7]. Finally, the study group was composed of 14 boys who were observed for six months (Table 1).

The inclusion criteria were: VAS procedure upon standard clinical picture of megacystis, reduced amniotic fluid index, singleton male fetus and favourable outcome of the early neonatal period. Exclusion criteria comprised: multiple syndromic malformations, female gender or death within the first days of life.

TABLE 1. Detailed clinical characteristics of the study group

Patient	Keyhole sign	Megacystis	Week of intervention	Amnioinfusion	Gestational age	Birth weight [kg]	Apgar score	Birth length [cm]	Urinary diversion	UTI	UTI prophylaxis
1	1	1	13	1	33	2.2	6	43	0	1	1
2	1	1	23	0	38	3.08	9	55	1	1	1
3	0	0	17	0	34	2.6	8	49	0	1	1
4	1	1	28	0	33	2.5	8	46	0	1	0
5	0	0	24	1	37	4.44	10	57	0	1	1
6	1	1	21	0	36	3.5	7	49	1	0	1
7	0	0	20	0	37	3.18	10	51	1	0	1
8	1	1	17	0	33	2.13	9	46	0	1	1
9	0	1	24	0	33	2.56	7	49	0	1	1
10	1	1	23	0	29	1.85	5	41	1	1	1
11	1	1	30	0	39	4.1	9	55	0	1	0
12	1	1	18	0	35	2.05	5	53	0	1	1
13	1	1	23	0	38	3.05	9	53	0	1	1
14	1	1	24	0	35	2.55	8	47	1	1	1

0 – no, 1 – yes, UTI – urinary tract infections

TABLE 2. Anthropometric data of the study group

Parameters	Median	Minimum	Maximum	25th quartile	75th quartile
Z-score weight	–1.52	–3.68	2.03	–2.60	–0.48
Z-score length	–1.42	–3.61	4.81	–2.28	–0.05
Z-score BMI	–1.41	–3.14	2.07	–2.03	–0.77

The vesico-amniotic shunting procedure was performed with the shunt (diameter 2 mm, length 12 cm; Rocket KCH Fetal Bladder Catheter, Washington, United Kingdom). In the fetal urine, selected prognostic markers were assessed: sodium (normal < 100 mmol/l), chloride (normal < 90 mmol/l) β2-microglobulin (SO-314.501 LIAISON β2-microglobulin; normal < 4.0 mg/l), concentration and osmolarity (normal < 200 mOsm/kg/water).

Mean time of VAS was 22 gestational age (13–30). Children were born in the 34th week of pregnancy (29–39) with mean birth weight of 2860 g (1850–4440 g). Four fetuses needed amnioinfusion during the pregnancy. During the neonatal period all boys underwent cystoscopic PUV removal (10) or urinary tract avulsion (4).

At the end of the 6th month, as the interim analysis of the group planned to be followed up later on, we assessed: physical development measuring children's length, weight and body mass index (BMI), presence of UTI, number of hospitalizations, need for antibacterial prophylaxis, and presence of hypertension. Kidney function was assessed by the Schwartz equation (0.413 × (ht/cm/Scr) and by the Siemens (Date Behring) equation ($70.69 \times (\text{cysC})^{-0.931}$) based on serum creatinine and cystatin C level respectively [8]. Presence of albuminuria (albumin/creatinine ratio – ACR), proteinuria and acidosis was assessed as other markers of early kidney damage.

Statistical data were analysed with the Statistica 12 PL package. All parameters were tested for normal distribution using the Shapiro-Wilk test and were presented as the median and range. Nominal variables were presented as numbers or percentages. For detection of relations between prenatal and early clinical parameters Spearman correlation coefficient values were calculated. For multiple relations logistic regression analysis was applied.

RESULTS

At the age of 6 months the median serum creatinine level was 0.65 mg/dl (range 0.2–5.3), estimated glomerular filtration rate (eGFR) at 50.6 ml/min/1.73 m^2 (range 5.06–130.09). When compared with the normative eGFR values for age, it was found that only 36% had normal eGFR. It was confirmed by the analysis with cystatin C: median serum cystatin C level was 1.50 mg/l (range 0.92–3.53), with eGFR 48.5 ml/min/1.73 m^2 (range 22–76) [9]. One patient was on chronic renal replacement therapy. None of the patients was oliguric. In reference to the ability of regulation of acid balance, 43% of the infants developed acidosis that required pharmacological intervention (natrium bicarbonate with oral formulations). Furthermore, proteinuria was present in the majority of cases, even taking into account higher albumin excretion in the first year of life. Seventy-one percent of infants had elevated albuminuria with a median urine albumin-to-creatinine ratio of 581.64 mg/g (range 0.19–3240), and 28.5%, significantly, had overt proteinuria. We found no clear correlation of kidney function or proteinuria with prenatal clinical data, presence of amnioinfusion or the technical aspect of postnatal surgery.

Analysing the presence of high blood pressure according to the normative values for 6-month-old infants, hypertension was found in only two of the boys (2/14). After deeper analysis of the pharmacotherapy, we concluded that there was no simple way to assess whether the patient was hypertensive or not. This difficulty arose from the conservative urologic treatment with doxazosin – an α-blocker relaxing the urethral sphincter and bladder neck, simultaneously lowering the blood pressure. 10/14 patients (71%) were treated with doxazosin. One of them had elevated BP despite the treatment. One out of four not treated with doxazosin developed hypertension.

Mean body weight in the 6th month of life was 7.2 kg (range 5.8–9. 8). Median Z-score of body weight was –1.52, of height/length – 1.42, of BMI – 1.41. Medians and interquartile ranges of Z-scores are illustrated in Table 2. Children increased their birth weight by 1.64 × (range 0.57–2.62). Median length was 66.5 cm (range 63–80) and it rose on average 18.5 cm (range 11–28 cm) from birth.

After analysis of correlations, we found no clear correlation of the anthropometric and developmental data with birth age degree of proteinuria or timing and technical aspect of prenatal and postnatal surgery procedures. Logistic regression analysis revealed no impact of urological treatment (fulguration only or fulguration with urinary diversion) on kidney function or physical development assessed by Z-scores of body weight, length and BMI in the 6th month of life (OR 0.82; 0.96; 0.59, respectively). No correlations were found between growth and presence of UTI and number of hospitalisation.

Glomerular filtration rate estimated by creatinine was strongly correlated with body weight Z-score, $r = 0.67$, $p = 0.007$. Glomerular filtration rate estimated by cystatin C as muscle-independent kidney function index was strongly correlated with body weight Z-score, $r = 0.78$, $p = 0.007$. Glomerular filtration rate estimated by creatine was also positively associated with Z-score BMI ($r = 0.66$, $p = 0.009$), but not GFR estimated by cystatin C.

When the presence of UTI in the first 6 months of life were analysed, we found that a very high number (86%) had at least one UTI (range 0–4), despite the antibiotic prophylaxis given in most of the patients (86%). For the prophylaxis amoxycillin (1/3 usual dose), trimethoprim + sulfamethoxazole and nitrofurantoin derivatives (> 6 week of age) were used. The median age of first infection was 1.5 months. All infections required hospitalisation, but we registered similar aetiology of the infection as in other children with urinary tract malformation in our centre (unpublished data). Additionally, the all-cause hospitalization index was high (4; range 0–9). Only one child was not admitted to the hospital after initial discharge.

DISCUSSION

The study revealed that most of the children who had undergone prenatal LUTO intervention for PUV and survived the first 28 days of life remained in an acceptable physical condition at the age of 6 months. However, the majority of them had kidney function impairment, such as renal insufficiency or proteinuria. Moreover, the patients suffered from non-optimal physical growth, frequent hospitalizations (due to recurrent UTIs), chronic kidney disease (CKD) management and a need for urological treatment.

To date, few prognostic markers are used to assess the usefulness of prenatal intervention in preservation of kidney function and the ability of the child to live through the neonatal period. Prognostic markers should allow the obstetricians and urologists to assess the chance of survival and enable the prediction of long-term kidney function. Although controversial, specific test results may reflect fetal glomerular and tubular kidney function. For example, urine sodium < 100 mEq/l, chloride < 90 mEq/l, osmolality < 200 mOsm/l and β2-microglobulin < 6 mg/l are considered as positive prognostic factors. Ruano *et al*., however, suggested a staging system based on fetal ultrasound and biochemistry at 18–30 weeks, as a tool enabling reasonable choices of fetal therapy and intervention strategy [10].

In general, prenatal intervention is supposed to give a chance for normal development and possibly preservation of kidney function after birth. However, a recent meta-analysis showed that early prenatal detection and intervention did not have a significant influence on the final outcome with regard to CKD progression and dialysis or transplant use [11]. In this aspect, because prenatal interventions carry risks for both the mother and the fetus, in each case the decision must be made individually and with caution. In our observation, only about one-third of survivors after prenatal LUTO intervention with subsequent postnatal surgery had well-preserved kidney function in the 6th month of life. To our understanding, the biomarkers of impaired kidney function are not only elevated serum creatinine and cystatin C, but also overt proteinuria and acidosis, which are indicators of tubular dysfunction. A recent study from Vasconcelos *et al*. indicated that baseline creatinine, nadir creatinine (the lowest value) and proteinuria could serve as predictors of CKD development [12]. During the study period, 37.6% out of 173 patients with PUVs followed for 83 months (±70 months) developed CKD stage ≥ 3.

In a retrospective study from 2011, Deshpande *et al*. analysed the data of 15 PUV patients who had had elevated serum creatinine before the treatment of LUTO, which resulted in a decrease of serum creatinine [13, 14].

In this research, 73% of the total serum creatinine decrease occurred within the first 2 months of life. Also, the authors suggested that the nadir serum creatinine was reached by the age of 6 months. Based on these results, the kidney function assessment in the 6th month of life can provide important and realistic information about prevalence of kidney damage in children with prenatally diagnosed and managed PUV.

However, the majority of studies assessed the kidney function at an older age (after the 1st year of life). For example, Uthup *et al*. retrospectively analysed 30 children with PUV after at least 5 years from surgery. They found that 86.7% had decreased GFR estimated by creatinine (< 90 ml/min/1.73 m^2), while 20% had a severe reduction in eGFR (< 30 ml/min/1.73 m^2). Also, all children who were diagnosed with PUV prenatally had decreased eGFR (< 90 ml/min/1.73 m^2) [15].

Yadav *et al*. similarly reported that 30% of children in longer observation (at least 12.5 years) had eGFR < 60 ml/min/1.73 m^2. The study was conducted in a group of 46 boys half of whom were diagnosed prenatally. Poor outcome was associated with significantly higher nadir serum creatinine in the first year of life, bilateral vesicoureteric reflux and breakthrough UTIs. Interestingly, the long-term outcome did not differ among boys diagnosed pre- and postnatally [11, 16]. This observation was also reported in the study by Vasconcelos *et al*. Their survival analysis showed no differences in incidence of hypertension and proteinuria, CKD stage ≥ 3 and 5 and incidence of death [12]. Based on the data from this group of 173 patients, the authors concluded that the declining rates of renal function in patients with PUVs are not attenuated by an early diagnosis or an intervention after antenatal diagnosis. Moreover, Joseph *et al*. claimed that prenatally diagnosed PUV had a good functional outcome [17]. In this retrospective review they included 81 patients with antenatal hydronephrosis who had endoscopic valves ablation at a mean (SD) intervention age of 124 (147 days) and had a minimum 6-month follow-up period. They reported that only 15% of patients had nadir creatinine > 1.2 mg/dl with a trend towards higher creatinine on follow-up. From these results one might get the impression that prenatally diagnosed PUV are associated with a good renal outcome. However, the authors themselves stressed that an ultrasound is not specific for PUV, and they discounted other signs of severe PUV presence, such as keyhole sign and enlarged bladder, which are more significant for the presence of severe PUV. For this reason, their pa-

tients' kidney function preservation outcome seems so favourable. When the choice of early postnatal procedures is considered, a study of Kim *et al.* should be mentioned. They reported that vesicostomy was more beneficial in the recovery of renal function and is not inferior in terms of bladder function, even in patients with severe PUV disorder [18]. In the present study we analysed prenatally diagnosed patients. Nonetheless, we strongly support the statement that patients requiring prenatal intervention might have significant kidney injury. It should be emphasised that the selection of patients subjected to the prenatal intervention should be very meticulous. Patients with severe oligohydramnios, leading to pulmonary hypoplasia, should not be subjected to any interventions other than amnioinfusion to improve lung growth and pulmonary survival.

Hypertension is another evident complication of kidney failure. We decided to assess this parameter while planning the study. However, it turned out to be considerably problematic – the boys from our study group were treated with α-antagonists (doxazosin in a dose of 0.1 mg/kg) *per* standard from the first month of age. Therefore, in fact we could not objectively determine the real prevalence of hypertension in the study group. Therapy with an α-antagonist may potentially act to facilitate relaxation of the bladder base and the proximal urethral sphincter, decreasing the bladder outlet resistance. Scarce and old data suggest that α 1 adrenergic blockers have proven to be safe and resulted in significant improvement in bladder emptying in patients after ablation of PUV. In this group of 40 children (mean age 15 months, from 1 day to 9 years) only one reacted with hypotension, but they observed 85% reduction in post-void residual function [19]. Although very promising, the results arising from this heterogenous group are difficult to implement widely as a recommendation. Nevertheless, this treatment, even without an evidence base, is gaining in popularity. In hypertensive patients with chronic kidney disease, especially with overt proteinuria, the medication of choice, in absence of contraindications, should be an angiotensin converting enzyme inhibitor. It has been proven that by its nephroprotective effect it slows down the progression of kidney damage [14]. In this light, although α-adrenergics also have a hypotensive effect, especially in proteinuric patients, a change of treatment option should be considered in favour of angiotensin-converting enzyme inhibitors (ACEI) – especially considering the lack of strong data confirming long-term favourable outcomes of α-blocker therapy. That is true for children with CKD, but the scarcity of data concerning infants below 6 months of age with a tendency to electrolyte imbalance made us decide not to put all the normotensive boys on ACEI.

Impaired kidney function is commonly associated with poorer physical growth in CKD; it is related, among other conditions, to mineral and bone disorder, acid-base imbalance, decreased appetite and polyuria. Balanced growth is essential in children with CKD for their general health condition, life span, but also a plan for renal replacement therapy, including kidney transplantation. Six-month observation, otherwise short, enabled the confirmation of some influence of PUV on the development of infants. Most boys from the study group did not double their body weight and body weight Z-scores were below the average. Their length gains up to 6th month of life were acceptable, but the Z-scores were also below the average for the population. We found a link between physical growth and kidney damage – there was a strong positive correlation between eGFR and body weight, both for serum creatinine and cystatin C equations. Length gains were independent of eGFR. We found no association between the type of urological treatment and kidney function and physical development. About one-third of children in our group, apart from transurethral resection of PUV, also had urinary diversion. This observation is consistent with data suggesting that the type of primary surgical treatment (fulguration and vesicostomy or high urinary diversion) did not influence progression of renal failure or body growth in children with PUV. Regardless of the surgical or medical treatment, which can greatly influence mortality, renal failure developed in almost 50% of the children with PUV [20]. Similar results were also presented by Narasimhan *et al*. They followed up 37 patients after transurethral fulguration of urinary diversion. At the end of the first year, children from the first group had a similar growth velocity compared to the vesicostomy group, though in general they showed retarded growth compared to healthy counterparts. The modality of treatment chosen did not seem to affect the renal functions or somatic growth in the short-term follow-up. In other authors' observations the growth retardation ratio varied between 40–52% [21]. Uthup *et al.* assessed that about 30% of children with PUV had growth retardation when assessed at least 5 years after surgery [15]. However, this less significant growth retardation could be an effect of the fact that in this study only cases diagnosed postnatally were included. In the present study only 28% of participants gained weight, as is expected in physiological development in the 1st year of life (doubling birth weight in the 4th month). In our opinion physicians cannot expect normal growth velocity in children with prenatally diagnosed PUV unless they have completely maintained kidney function. However, the low birth weight can influence some of the clinical parameters of boys with PUV – longer neonatal intensive care unit stay, lower eGFR on admission. Taken together, this made the prognosis of patients in the study of Sarhan *et al.* worse [22].

The other aspect of the present study is the burden of recurrent UTI, which could jeopardize the efforts to maintain kidney function in an organ already damaged by congenital malformation. Harper *et al.* reported an increased risk of UTI in PUV with almost 50% incidence of febrile UTI with dilating vesico-ureteric reflux as the only predictive factor [23]. They observed three distinct time periods for presenting a febrile UTI with a decrease in infection rate after the first 40 days of life, then

at 240 days of life. Our study assessed that until 6 months of life 86% of patients had at least one UTI and received chronic prophylaxis, and 64% of boys had recurrent UTI. We found no correlation between presence of recurrent UTI and eGFR. However, recurrent UTI was the main reason for hospitalizations. Bilgutay *et al*. recorded in 104 patients with PUV that presence of recurrent UTIs, although associated with the need for multiple operations, was not a reason for poor renal outcomes [15, 24]. This observation is consistent with our study – there was no correlation between kidney function and recurrent UTI in the 6th month of life. Recurrent UTI theoretically put the patient at risk of frequent hospitalizations and the need for antibiotic treatment, with associated post-antibiotic administration complications. Frequent antibiotic administration could cause diarrhoea, candidiasis, and bowel dysfunctions, which could also be a factor affecting growth. We found that there was no correlation between frequent UTIs and prophylaxis and deterioration of growth.

CONCLUSIONS

The majority of children who survived prenatal interventions for PUV had impaired kidney function. The need for renal replacement therapy in the first 6 months of life was very uncommon. Weight gain in this group was impaired, while length gains remained satisfactory. The survival was burdened with a risk of recurrent UTI and hospitalizations, which might have influenced the development of the child, as the CKD does. Kidney damage occurred in boys, despite using early diagnosis and intervention. The aim of the prenatal diagnostics and interventions should not be only saving lives, but also maintaining optimal health condition and minimally affecting growing pattern.

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DISCLOSURE

The authors declare no conflict of interest.

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