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ORIGINAL ARTICLE

Outcome of isolated antenatal hydronephrosis: a prospective cohort study

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Abstract The purpose of this study was to report the outcome of infants with antenatal hydronephrosis. Between May 1999 and June 2006, all patients diagnosed with isolated fetal renal pelvic dilatation (RPD) were prospectively followed. The events of interest were: presence of uropathy, need for surgical intervention, RPD resolution, urinary tract infection (UTI), and hypertension. RPD was classified as mild (5–9.9 mm), moderate (10–14.9 mm) or severe (≥15 mm). A total of 192 patients was included in the analysis; 114 were assigned to the group of non-significant findings (59.4%) and 78 to the group of significant uropathy (40.6%). Of 89 patients with mild dilatation, 16 (18%) presented uropathy. Median follow-up time was 24 months. Twenty-seven patients (15%) required surgical intervention. During follow-up, UTI occurred in 27 (14%) children. Of 89 patients with mild dilatation, seven (7.8%) presented UTI during follow-up. Renal function, blood pressure, and somatic growth were within normal range at last visit. The majority of patients with mild fetal RPD have no significant findings during infancy. Nevertheless, our prospective study has shown that 18% of these patients presented uropathy and 7.8% had UTI during a medium-term follow-up time. Our findings suggested that, in contrast to patients with moderate/severe RPD, infants with mild RPD do not require invasive diagnostic procedures but need strict clinical surveillance for UTI and progression of RPD.

Keywords Fetal hydronephrosis · Prenatal diagnosis · Urinary tract infection · Vesicoureteral reflux · Outcome

The authors declare that they have no conflict of interest.

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Introduction

The introduction of routine fetal ultrasonography has improved the detection of many fetal anomalies, among them upper urinary tract dilatation, with affected infants representing one of the largest groups amenable to neonatal treatment [1]. Thus, over the past 15 years, there has been a continuous advance in the understanding of the pathophysiology and natural history of urinary tract anomalies [2, 3]. However, there are still many challenges and controversies regarding the definition and clinical significance of mild isolated renal pelvic dilatation. It is clear that all dilatations do not have the same clinical relevance; furthermore, their antenatal and postnatal evolution is variable [4]. Thus, there has been an abundant and somewhat controversial literature about the best work-up and follow-up after birth [5, 6]. A recent meta-analysis concluded that children with mild antenatal hydronephrosis may carry a risk for postnatal anomaly, but additional prospective studies are needed to determine the optimal treatment for these children [7]. Moreover, it has been pointed out that the current literature about antenatal hydronephrosis lacks a systematic analysis of clinical outcomes, which might provide further insight

into issues that remain unresolved and might highlight areas where consensus does exist [8].

This study was aimed at evaluating the clinical outcome of a cohort of infants with isolated antenatal hydronephrosis prospectively followed.

Patients and methods

Patients In this cohort study, 192 infants born consecutively at Hospital das Clínicas-UFMG (Belo Horizonte, Brazil) from May 1999 through June 2006 who were found to have isolated fetal renal pelvic dilatation (RPD) underwent systematic investigation for urinary tract anomalies and were prospectively followed. RPD was measured by assessment of the anteroposterior diameter (APD) of the renal pelvis. First, each fetus underwent a detailed anatomic study aimed at detecting other abnormalities or markers of aneuploidy. Only singleton fetuses with isolated RPD associated with normal amniotic fluid volume were included in the study. Fetuses with ureteral and bladder dilatation and associated malformations or aneuploidy were excluded. Our analysis was based on a database of 212 patients with isolated RPD admitted to our unit. Inclusion criteria were: presence of RPD equal to or greater than 5 mm on prenatal ultrasound after 28 weeks' gestation, at least 6 months of follow-up, and at least two postnatal ultrasound (US) scans. We excluded 20 patients from the analysis: six were lost to follow-up and 14 were not included in the analysis due to the presence of a duplex system with ureterocele (seven), hypoplastic kidney (five), horseshoe kidney (one), and posterior urethral valves (one). RPD was classified as mild (5–9.9 mm), moderate (10–14.9 mm) or severe (≥15 mm). For analysis purposes, when appropriate, the moderate and severe categories were merged into a single category.

Baseline data At admission, all children were maintained on antibiotic prophylaxis consisting of 50 mg of cephalexin as a single daily dose. After the children had reached 2 months of age, antibiotic prophylaxis was converted to 1–2 mg/kg trimethoprim, also as a single daily dose. The first postnatal US scan was performed at a median time of 13 days of life (interquartile (IQ) range 9–20 days). The postnatal US scans were performed by the same trained examiner using a Siemens machine (Sonoline Prima SLC, 5 MHz probe, Erlangen, Germany). After the initial US, patients underwent urinary tract imaging according to a systematic protocol described in detail elsewhere [9, 10]. Briefly, all infants were submitted to voiding cysto-urethrography (VCUG) within 3 months of life (95% between 18 days and 2 months of life). Reflux grade was classified at first VCUG according to the system proposed by the International Reflux Study Committee [11]. When a postnatal US scan demonstrated renal pelvis dilatation equal to or greater than 10 mm, renal scintigraphy [technetium-99m dimercapto-succinic acid (^{99m}Tc-DMSA) and technetium-99m diethylene triamine penta-acetic acid (^{99m}Tc-DTPA)] was performed after the first month. Independently of the initial magnitude of RPD, renal scintigraphy was also performed in all patients with vesicoureteral reflux (VUR) or patients with increasing RPD in subsequent US examinations.

Follow-up data After initial clinical and imaging evaluation, US scans, clinical examination, and laboratory reviews were scheduled at 6-month intervals. Briefly, the clinical approach consisted of full physical examination, including evaluation of growth and blood pressure performed at 6-month intervals. Urine cultures were obtained on the occasion of each 6-month follow-up visit, and it was recommended that urine samples be collected during any unexplained febrile episode. Urinary tract infection (UTI) was defined as growth of at least 100,000 cfu/ml in urine obtained by bag or from a mid-stream sample, with fever (38.0°C or more) and/or urinary symptoms. Urine specimens for culture were carefully collected at our hospital outpatient laboratory by trained technicians. For children with sphincter control a mid-stream sample was collected into a sterile container after thorough cleaning of the area around the urethral meatus with an antiseptic. For infants, to avoid fecal contamination, the urine specimen was collected with a sterile bag after complete cleaning of the entire perineal area. The bag was checked every 15 min to ensure a clean urine collection. The urine bag was promptly removed after urine had been voided into the bag, and the specimen was refrigerated or processed immediately.

Antibacterial prophylaxis was discontinued for patients without VUR at initial VCUG and with RPD <10 mm. In contrast, antibiotic prophylaxis was maintained until the end of the first year of life for patients with RPD >10 mm and until the resolution of reflux for patients with VUR. Plasma creatinine concentration was determined at baseline and yearly thereafter. Glomerular filtration rate was estimated by the method of Schwartz et al. [12]. Blood pressure was measured with a standard sphygmomanometer using a cuff of appropriate size as recommended by the Working Group of the National High Blood Pressure Education Program [13]. Reference values and definitions of normal blood pressure were based on The Fourth Report on High Blood Pressure in Children and Adolescents [14].

Outcomes The events of interest were: presence of uropathy, need for surgical intervention, RPD resolution, UTI, serum renal function, hypertension, and somatic growth.

Definitions Patients were divided into two groups according to presence of uropathy (non-significant findings vs

significant uropathy). Combined data obtained by VCUG, renal scintigraphy, and sequential US were regarded as the reference standard. Significant uropathy was defined as the presence of urinary tract abnormality such as VUR, megaureter, or ureteropelvic junction obstruction (UPJO). UPJO was defined as the presence of isolated hydronephrosis associated with an abnormal diuretic renogram pattern. The treatment for patients with apparent UPJO was a non-operative approach for renal units with good function (>40%) as ascertained by a DMSA scan, whatever the pattern on DTPA (if intermediate or obstructed). Renal units with <40% uptake were treated surgically by Anderson–Hynes dismembered pyeloplasty. In the absence of recognized uropathy, renal pelvis dilatation was labeled as idiopathic dilatation and regarded as a non-significant finding in the analysis. Extra-renal pelves were considered as a normal variant and were included in the group of non-significant findings. Those renal units with fetal renal pelvis dilatation not confirmed on postnatal ultrasound and negative findings on VCUG were labeled as transient dilatation and were also included in the group of non-significant findings.

RPD resolution was considered to have occurred with an APD diameter of the renal pelvis <5 mm on two consecutive renal sonograms. For analysis of serum renal function we considered only patients at least 24 months old at last visit. Hypertension was defined as values persistently above the 95th percentile for age, gender, and height on three consecutive visits [14]. For analysis of blood pressure (BP), we included only patients at least 24 months old at last visit.

Statistical analysis Patients with bilateral dilatation were categorized by the higher grade of APD. Survival analyses were performed by the Kaplan–Meier method in order to evaluate RPD resolution. Differences between subgroups were assessed by the two-sided log-rank test. The receiver-operating characteristic (ROC) plots were analyzed to determine the optimal cut-offs needed to define renal units with significant obstructive uropathy, which would require pyeloplasty or other surgical interventions. The chi-square test with Yates correction was used for the comparison of proportions. Relative risk (RR) and 95% confidence intervals (95% CI) were used for group risk comparison. Continuous data with normal distribution are reported as mean ± SD. The *t*-test and analysis of variance (ANOVA) were used for comparison of these variables. Continuous data without normal distribution are reported as the median and interquartile range between the 25th and 75th IQ. The non-parametric Mann–Whitney test was used for comparison of these variables.

Ethical aspects The study was approved by the Ethics Committee of UFMG, and the parents or persons responsible for the children gave written informed consent for the children to participate.

Results

Baseline findings

A total of 192 patients was included in the analysis (140 boys and 52 girls; male to female ratio 2.7:1). Ninety–five patients (49.5%) presented bilateral RPD, corresponding to 282 dilated fetal renal units. As shown in Table 1, of 192 infants, 114 were assigned to the group of non-significant findings (59.4%) and 78 to the group of significant uropathy (40.6%). Of 89 patients with mild dilatation, 16 (18%) presented a urinary tract anomaly, whereas 24 (40%) infants with moderate RPD and 38 (88%) with severe RPD had uropathy (chi-square=59.5, $P<0.001$). In addition, nine patients presented VUR in contralateral renal units without dilatation or with mild dilatation (Table 2). Of 16 patients with primary VUR, eight presented bilateral reflux with a total of 24 renal units. The distribution of the severity of reflux was as follows: grade I, four (17%), grade II, six

Table 1 Postnatal diagnosis in infants with isolated antenatal hydronephrosis according to the higher degree of fetal renal pelvic dilatation

Postnatal diagnosis	Mild (%) (5–9.9 mm)	Moderate (%) (10–14.9 mm)	Severe (%) (>15 mm)	Total Children
Non-significant findings				
Idiopathic dilatation	72 (67)	31 (29)	4 (4)	107
Extra-renal pelvis	1 (14)	5 (72)	1 (14)	7
Significant findings				
UPJO	6 (11)	17 (31)	32 (58)	55
VUR	9 (56)	5 (31)	2 (13)	16
Megaureter	1 (14)	2 (29)	4 (57)	7
Total	89 (47)	60 (31)	43 (22)	192

Table 2 Postnatal diagnosis in infants with isolated antenatal hydronephrosis according to the degree of fetal renal pelvic dilatation on contralateral side

Postnatal diagnosis	Normal (%) (>15 mm)	Mild (%) (5–9.9 mm)	Moderate (%) (10–14.9 mm)	Severe (%) (>15 mm)	Total Children
Non-significant findings					
Normal	92 (100)	0 (0)	0 (0)	0 (0)	92
Idiopathic dilatation	0 (0)	66 (82)	12 (15)	2 (3)	80
Extra-renal pelvis	0 (0)	1 (50)	0 (0)	1 (50)	2
Significant findings					
UPJO	0 (0)	0 (0)	0 (0)	6 (100)	6
VUR	5 (50)	4 (40)	1 (10)	0 (0)	10
Others	0 (0)	0 (0)	1 (50)	1 (50)	2
Total	97 (51)	71 (37)	14 (7)	10 (5)	192

(25%), grade III, ten (41.6%), grade IV, three (12.5%), and grade V, one (4%). Of 24 refluxing units, six (25%) presented congenital renal damage on DMSA scan.

The median RPD of renal units with a higher grade of dilatation was 10 mm (IQ range=7.8–14 mm). Of 95 bilateral cases, the median RPD of the contralateral units was 8 mm (IQ range=6.5–10 mm). There were ten patients (5%) with severe bilateral dilatation (>15 mm). There was a significant difference in median fetal RPD between idiopathic dilatation (8.4 mm, IQ range=7–11) and patients with uropathy (14.5 mm, IQ range=10.5–25) ($P<0.001$).

Clinical course

Median follow-up time was 24 months (IQ range=12–40 months). A total of 101 (52%) patients was followed up for more than 2 years and 34 (18%) for more than 4 years.

Surgical intervention Twenty-seven patients (14%) required surgical intervention for relief of the obstruction (pyeloplasty in 25 and ureteral reimplantation in two). The median age at surgery was 8 months (IQ range, 4–13). Only three children underwent surgery after age 18 months. All of them had increasing hydronephrosis at sequential US scans. Of 43 infants with severe RPD, 24 (56%) underwent surgery, whereas only three (5%) of 60 with moderate RPD required surgical intervention. In contrast, none of 89 infants with mild RPD needed any surgical procedures. A cut-off of 15 mm for RPD showed the best diagnostic performance in identifying patients who required surgical intervention. The calculated area under the curve was 0.94 (95% CI, 0.89–0.97), sensitivity was 89% (95% CI, 71%–97%) and specificity was 88% (95% CI, 83%–93%) (Fig. 1). The positive and negative likelihood ratios were 7.7 and 0.13, respectively.

RPD progression A total of 863 ultrasound scans was performed on 192 patients. The mean number of ultrasound scans performed per patient was 4 (IQ range=2–6). RPD progression was evaluated in 149 (77.6%) children clinically treated and without primary VUR. Of these 149 patients, 54 (36.2%) presented resolution of RPD within a median time of 49 months (95% CI, 36–62). Eight patients already presented a non-dilated renal pelvis on postnatal ultrasound. As expected, there was an association between the magnitude of fetal RPD and time for resolution. By survival analysis, the rate of resolution at 5 years of age was 60%, 44%, and 36% for mild, moderate, and severe RPD, respectively (Fig. 2).

Urinary tract infection Patients were maintained on antibacterial prophylaxis for a median time of 7.5 months (IQ range=6–16 months). There was a significant difference in median time of use of antibacterial prophylaxis between

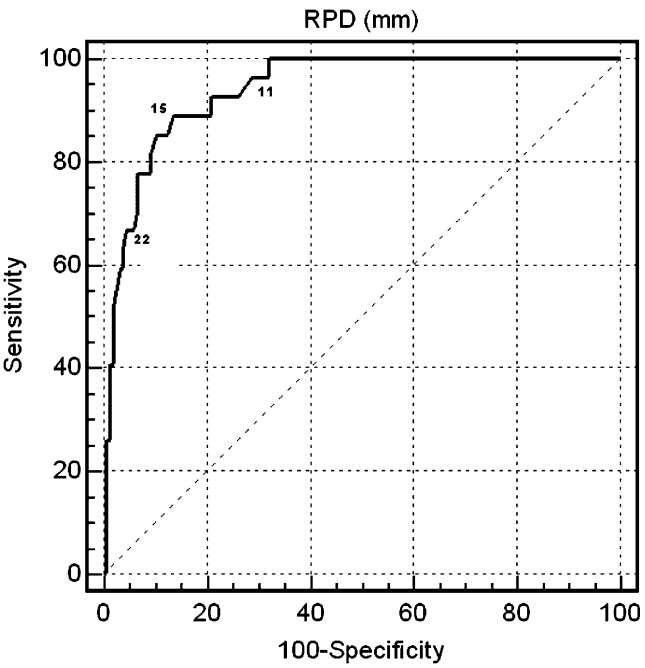
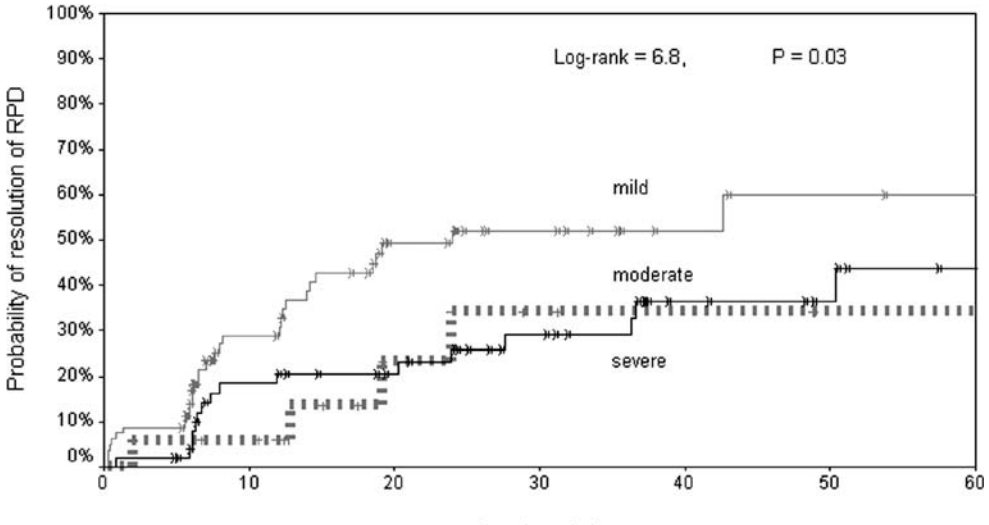


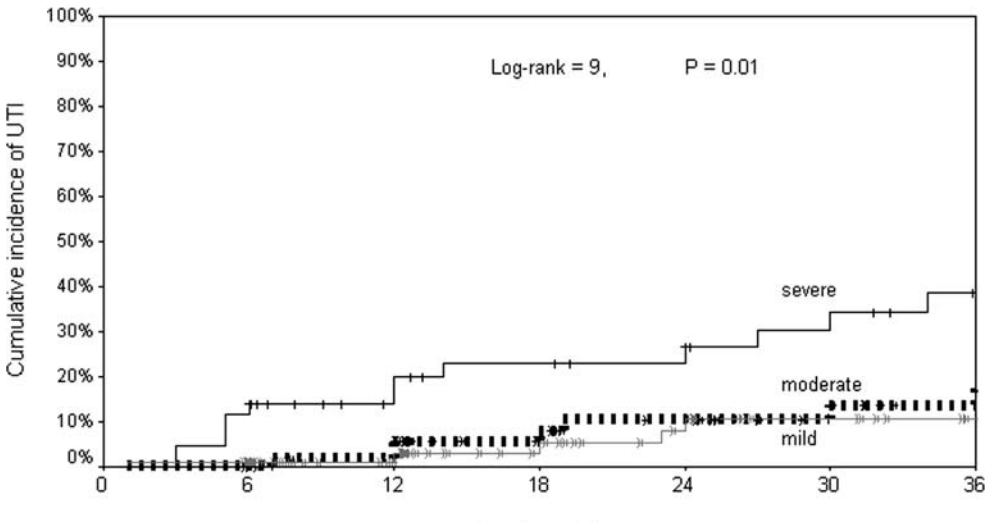
Fig. 1 Receiver-operating characteristic curve (ROC) based on the fetal RPD index as an indicator of the need for surgical intervention



Month	0	10	20	30	40	50	60
Mild	79	38	20	12	6	4	3
Moderate	53	38	31	22	12	9	7
Severe	17	15	7	5	4	2	1

Fig. 2 Kaplan–Meier survival curves showing the probability of resolution of urinary tract dilatation according to the magnitude of fetal RPD. *Numbers in the table* represent patients at risk at each time point

patients with mild RPD (6.7 months, IQ range=6–12), moderate RPD (12 months, IQ range, 6–24), and patients with severe RPD (13 months, IQ range=8–24) (P=0.01). During follow-up, UTI occurred in 27 (14%) of the 192 children followed. Twenty-four patients presented a single UTI and three presented two episodes. The median age at first episode of UTI was 14 months (IQ range=6–27). Twenty patients (74%) presented UTI while using antibiotic prophylaxis, and seven (26%) after discontinuation of prophylaxis (three with mild, two with moderate, and two with severe RPD). The incidence of UTI during follow-up was higher among infants with moderate/severe RPD (20%) than among patients with mild RPD (7.8%, RR=2.6, 95% CI, 1.2–5.8, P=0.01). The cumulative incidence of UTI was estimated at 39%, 18%, and 11% at 36 months of age for severe, moderate, and mild RPD, respectively (Fig. 3). Girls had a higher risk of UTI during follow-up than boys (RR= 2.15, 95% CI, 1.1–4.3, P=0.03).



Month	0	6	12	18	24	30	36
Mild	89	84	54	41	34	24	18
Moderate	60	57	52	39	34	27	21
Severe	43	37	29	24	21	17	13

Fig. 3 Kaplan–Meier survival curves showing the cumulative incidence of UTI according to the magnitude of fetal RPD. *Numbers in the table* represent patients at risk at each time point

Renal function Renal function estimated by glomerular filtration rate (GFR) was normal for all 101 children who were at least 24 months old at the end of follow-up. There was no significant difference in GFR according to fetal renal pelvic dilatation (Table 3).

Hypertension Blood pressure (BP) was recorded for 101 patients who were at least 2 years old at the end of follow-up. There was also no significant difference in median systolic or diastolic BP according to fetal renal pelvic dilatation (Table 3). Only one girl with bilateral UPJO developed sustained systolic hypertension with blood pressure above the 95th percentile for age, gender, and height.

Somatic growth At the end of follow-up, the mean height-for-age Z score (HAZ) and mean height-for-weight Z score (WHZ) were −0.005 (SD 1.1), and −0.11 (SD 1.1), respectively. There was also no difference in HAZ (P=0.45) or WHZ (P=0.33) between patients with normal, mild, moderate and severe RPD at admission.

Discussion

In this prospective cohort study we report on the clinical outcome of a group of infants with isolated antenatal hydronephrosis. Our study confirms that children with any degree of antenatal hydronephrosis are at greater risk of postnatal urinary tract anomaly, as pointed out by Lee et al. [7]. In our cohort of infants with isolated antenatal renal pelvic dilatation the prevalence of significant uropathy was approximately 40%. As expected, patients with severe RPD presented a higher prevalence of uropathy and need of surgical intervention, had a higher risk of UTI, and a slower rate of resolution of pelvic dilatation. Nevertheless, the clinical course of these patients is benign, although the length of follow-up is relatively short. It is important to point out the limitations associated with the clinical design of our study. The possible main weakness is the inevitable complexity involved in classifying patients into groups such as “significant uropathy” and “idiopathic pelvic dilatation”. It is clear that there is an intermediate zone between an idiopathic pelvic dilatation and an apparent UPJO. On the other hand, the prospective design of the study may increase the strength of our findings and possibly precludes a misclassification of patients.

At baseline, the clinical data for our series were similar to those reported in previous observational studies in which there was a predominance of boys [15]. The prevalence of significant uropathies ranged from 30% to 40% in other studies, as also observed in our series [15, 16]. There was a correlation between the magnitude of RPD and the presence of urinary tract obstruction. Our findings confirm our previous observation that an RPD threshold of 15 mm showed the best performance in discriminating between those patients who will require postnatal surgical intervention from those whose condition will benefit from conservative management [9]. Of note, recently in the larger published series, Coplen et al. [16] showed by ROC analysis that an RPD threshold of 15 mm discriminates obstruction in 80% of fetuses, with 73% sensitivity and 82% specificity. Gramellini et al. [17], on the other hand, demonstrated in a small sample (n=104) that a 12 mm cut-off had the greatest diagnostic accuracy (84%) in the third trimester for the prediction of neonatal nephrouropathy requiring surgery, with a positive predictive value of 52% and a sensitivity of 61%.

Recently, Lee et al. [7] performed a meta-analysis in order to determine whether the degree of antenatal hydronephrosis and related antenatal ultrasound findings were associated with postnatal outcome. They concluded that patients with moderate or severe antenatal hydronephrosis have a significant risk of postnatal anomaly, indicating that comprehensive postnatal diagnostic management should be performed. However, they pointed out that the outcome was not clear for infants with mild antenatal hydronephrosis and additional prospective studies are needed to determine the optimal management of these children. In our study 18% of infants with mild RPD presented urinary tract anomalies (most of them VUR) and 7.8% presented UTI during follow-up. In this group no children needed surgical procedures, and the median time for resolution of mild renal dilatation was estimated at 24 months by survival analysis.

In our series 14% of the children had breakthrough UTIs during follow-up, 70% of them in spite of the use of

Table 3 Glomerular filtration rate (GFR) and blood pressure (BP) at the end of follow-up according to the higher degree of fetal renal pelvic dilatation

Parameter	Mild (5–9.9 mm)	Moderate (10–14.9 mm)	Severe (>15 mm)	P
GFR ml/min—median (IQ range)	139.5 (116.9–179.7)	151.6 (112.3–163.8)	129.8 (121.8–149.7)	0.49
Systolic BP mmHg—median (IQ range)	90 (85–100)	98 (90–100)	90 (90–100)	0.21
Diastolic BP mmHg—median (IQ range)	55 (50–60)	60 (50–62)	56 (50–60)	0.86

prophylactic antibiotics. However, recurrent UTI was uncommon, and only three (1.5%) children presented more than one UTI episode. It is important to notice, nevertheless, that the accurate incidence of UTI is a difficult question to ascertain in a cohort consisting predominantly of infants. We are aware of the fact that the incidence of UTI could have been either overestimated in infants from whom urine was collected by bag or underestimated in patients with less obvious symptoms or when a urine sample was not collected in a timely fashion. Nevertheless, our data were collected prospectively, and clinical history and laboratory tests were thoroughly reviewed for this analysis. There have been few studies regarding the incidence of UTI in children with antenatal hydronephrosis. As in other series, infants with severe RPD had a higher incidence of UTI throughout follow-up [18]. Of note, however, the cumulative incidence of UTI was divergent during follow-up. In the first year of life, practically only infants with severe RPD had UTI, whereas children with mild/moderate RPD presented a similar incidence of episodes of UTI during their second and third year of life (Fig. 3). Alconcher and Tombesi [19] reported a 7% incidence of UTI in 70 infants with RPD between 5 mm and 15 mm followed for a mean time of 19.9 months. Of note, in their study, the incidence of UTI was not statistically different between children that had received prophylactic antibiotics and those that had not. In our study there was an association of occurrence of UTI with female gender and patients with severe fetal RPD. Nevertheless, 7.8% of children with mild RPD also presented UTI during follow-up. In a retrospective study of prenatally detected VUR, we have shown that, over a mean follow-up time of 66 months, UTI occurred in 12 (25%) of 47 conservatively treated children and in three submitted to surgery [20]. Dacher et al. [21] reported an incidence of 3.1% of UTI in the first 6 months of life in infants with a prenatal diagnosis of hydronephrosis and suggested possible explanations, such as failure to communicate the prenatal findings, failure to prescribe prophylactic antibiotics, failure to administer the prescribed medication, and the onset of infection in spite of adequate continuous antibiotic prophylaxis. We believe that, probably, a combination of the last two explanations can account for the relatively high incidence of UTI in our series. However, it is important to point out that the compliance issue was not evaluated in our study and may account for occasional failure of long-term prophylactic antibiotic programs [22].

After a median follow-up time of 24 months and a mean number of four US scans per patient, resolution of RPD was observed in 54 (36.2%) of 149 clinically treated children without primary VUR. As expected, according to our survival analysis, RPD improved faster in children with mild fetal RPD. Sidhu et al. [8] performed a systematic review and meta-analysis in order to identify the clinical outcomes of isolated antenatal hydronephrosis, defined by the authors as RPD with no associated abnormality. As in our analysis, they concluded that, in patients with isolated antenatal hydronephrosis and lesser degrees of pelvic dilatation, pelvic diameter decreases to the normal range or does not worsen in the vast majority of patients. In their meta-analysis, grade 1–2 pelviectasis was five-times more likely to stabilize than grade 3–4 pelviectasis. Cheng et al. [23] reported the ultrasonographic outcome of 57 patients with isolated antenatal hydronephrosis and demonstrated that during a mean follow-up time of 23 months, 82% of children presented normal renal pelvic diameter or mild pelviectasis. As in our series, deterioration of renal pelvic dilatation occurred in only three (5%) of 57 patients.

In conclusion, according to our findings, the risk of uropathy and its associated morbidity was remarkably correlated with the magnitude of fetal RDP. Our analysis suggested that infants with severe isolated renal pelvic dilatation (≥15 mm) should undergo comprehensive postnatal diagnostic treatment. Patients with moderate RPD (10–14.9 mm) also had a high prevalence of uropathy, although they rarely needed surgical intervention and the renal pelvic dilatation tended to resolve spontaneously. On the other hand, the majority of patients with mild fetal RPD (5–9.9 mm) had no significant findings during infancy. Nevertheless, our prospective study has shown that 18% of these patients presented uropathy and 7.8% had UTI during a medium-term follow-up time. Taken together, our findings suggested that invasive diagnostic procedures possibly are unnecessary for these patients who, however, need strict clinical surveillance for UTI and progression of RPD during infancy. Further prospective controlled studies addressing issues such as the role of VCUG and antibiotic prophylaxis are needed to determine the optimal treatment for these children.

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Conflict of Interest Statement: None.

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