



# Conservative management of primary non-refluxing megaureter during the first year of life: A longitudinal observational study

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## Keywords

Primary non refluxing megaureter; Urinary tract infection; Antibiotic prophylaxis; Hydro nephrosis; Megaureter; Prenatal diagnosis

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## Summary

### Introduction

There is a lack of prospective studies that include a selected population of patients with primary non-refluxing megaureter (PM). Thus, a longitudinal observational study was designed to follow from birth a selected population of children with PM; all were antenatally diagnosed. In this paper, the outcomes observed in the first year of life are presented.

### Objective

The primary aim was to follow the natural history of PM. The secondary aim was to monitor the onset of any potential complications such as urinary tract infections (UTIs), need for hospitalization and need for surgical correction.

### Study design

All children with antenatally diagnosed PM, born between January 2007 and December 2013, were prospectively followed with observational management: renal ultrasonography and clinical evaluation on a 3-month basis; urinalysis and culture in case of symptoms; and mercaptoacetyltriglycine (MAG3) nuclear scan once older than 1 month. Children presenting at birth with mild urinary tract dilatation were included in Group A; those with moderate-to-severe dilatation were included in Group B. Continuous antibiotic prophylaxis (CAP) was administered to Group B.

### Results

Forty-seven children (44 males, three females) with 58 PM were included in the study. The participants and their corresponding outcomes are shown in the summary Table. The presence of obstruction at renogram was a significant predictor of UTIs and hospitalization.

### Discussion

The strengths of this study were its prospective nature and its very consistent population. A limitation was the lack of control groups. The results regarding the negligible incidence of complications in Group A and the residual incidence of febrile UTIs (20%) and hospitalization (17%) in Group B, even with CAP, are in line with previous literature. In contrast, there was a higher risk of UTIs observed in children aged older than 6 months.

### Conclusions

Resolution or improvement is expected in all cases of PM with mild postnatal dilatation, and close to 60% of those with moderate or severe dilatation. Surgery is rarely performed on children younger than 1 year of age. It is safe to observe children with mild urinary tract dilatation without CAP, because the incidence of UTIs is negligible. In those presenting with moderate or severe urinary tract dilatation, despite CAP, a residual incidence of UTIs is seen, and symptomatic patients often require hospitalization. However, UTIs are well tolerated and do not seem to modify outcome. Cases showing obstruction on the MAG3 scan seem to be at higher risk of UTIs and hospitalization.

**Table** Outcomes and events of interest during the first year of life, in the overall population and in the two groups.

Group	Participants <i>n</i>	Primary non refluxing megaureter <i>n</i>	Outcome at 1 year of age				Events of interest			
			Resolved <i>n</i> (%)	Improved <i>n</i> (%)	Stable <i>n</i> (%)	Worsened <i>n</i> (%)	Afebrile UTIs (%)	Febrile UTIs (%)	Hospitalization (%)	Surgery (%)
A + B	47	58	11 (19.0)	30 (51.7)	14 (24.1)	3 (5.2)	3 (6.4)	7 (14.9)	6 (12.8)	2 (4.2)
A	13	17	6 (35.3)	11 (64.7)			2 (15.4)			
B	34	41	5 (12.2)	19 (46.3)	14 (34)	3 (7.3)	1 (2.9)	7 (20.6)	6 (17.6)	2 (5.9)

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## Introduction

The initial established approach for primary non-refluxing megaureter (PM) is non-operative management. Several retrospective studies [1–10] have been performed to review the natural history of PM and any complications that can potentially develop during conservative management. The first is the onset of UTIs. To our knowledge, there is only one paper with prospective features, a review of a prospectively maintained database, by Ranawaka [11]. Its population, however, is inconsistent regarding age at presentation (73% of the participants were antenatally detected, and the remaining were diagnosed after symptoms presented or incidentally). Therefore, prospective observational studies are lacking, including a selected population of patients with PM who are followed from birth.

On the other hand, several studies have been performed to investigate incidences of UTI and the subsequent need for antibiotic prophylaxis in children with antenatal hydronephrosis (HN) [12–19]. They mostly have a retrospective nature and the studied populations are often inconsistent, being formed by patients with upper urinary tract dilatation due to transient HN, transient hydro-ureteronephrosis (HUN), UPJ obstruction, uretero-vesical junction obstruction, and VUR. In effect, to date, there are no prospective studies determining the risk of UTI in a selected population of patients with PM.

In order to fill these gaps, a prospective study was designed, including a selected population of children with PM, all with antenatal diagnosis and all observed from birth. In this paper, the outcomes observed in the first year of life are presented.

Based on scientific evidence and clinical experience [5,20], it was hypothesized that observational management of PM is effective, but not necessarily free from complications, especially during the first year of life. To test this hypothesis, the primary aim of the study was to follow the natural history of PM. The secondary aim was to observe the onset of any potential complications such as UTIs, need for hospitalization and need for surgical correction.

## Materials and methods

Children with antenatally diagnosed HN or HUN, born between January 2007 and December 2013, were included in this study if their postnatal renal and bladder ultrasound confirmed HUN, and no VUR was seen on VCUG or voiding urosonography. Hydronephrosis was graded according to the Society for Fetal Urology classification [21]. Children presenting at birth with mild urinary tract dilatation (retrovesical ureter <10 mm and HN grade <3) were included in Group A. Children presenting with moderate to severe urinary tract dilatation (retrovesical ureter  $\geq 10$  mm or HN grade  $\geq 3$ ) were included in Group B. In case of bilateral PM, the most severely dilated side was considered for inclusion in the pertinent group. Continuous antibiotic prophylaxis (CAP) was only administered to children in Group B. All children were prospectively followed with observational management, which consisted of

renal ultrasonography and clinical evaluation performed on a 3-month basis until 1 year of age. The same operator always performed renal ultrasonography. Consistent with the guidelines put forth by the British Association of Paediatric Urologists (BAPU) [22], a mercaptoacetyl triglycine (MAG3) nuclear scan was performed on all patients over 1 month of age with moderate or severe urinary tract dilatation, always by the same operator. The MAG3 drainage curves were classified according to O'Reilly's classification: Type A (normal), Type B (obstructed), Type C (dilated, non-obstructed), Type D (partially obstructed) (Fig. 1)[23,24]. Urinalysis and urine culture were carried out in case of symptoms (fever, offensive or cloudy urine, failure to thrive, irritability, poor feeding). The recommended method to collect urine was a clean catch urine sample. If clean voided urine was unobtainable, a urine bag was used to collect urine [25]. Both an abnormal urinalysis and a positive culture were needed to give a diagnosis of UTI [26]. In every case with suspected contamination of the sample or with borderline results, a catheter urine specimen was obtained and urinalysis and culture were repeated to confirm a diagnosis of UTI. Febrile UTI (fUTI) was defined as a fever of 38 °C or greater, in the presence of a positive urinalysis and urine culture. Children with fUTI were hospitalized if younger than 3 months or systemically unwell [25]. Consistent with the guidelines put forth by the BAPU [22], observational management was switched to surgery in cases of massive or progressive hydronephrosis associated with documented obstruction and/or reduced function on MAG3, or in case of severe symptoms.

Events of interest during the first year of life were: development of UTIs (afebrile UTIs and fUTIs), need for hospitalization, and need for surgery. Morphologic parameters and the presence of obstruction at MAG3 renogram were tested as independent predictors of the main events of interest. Morphologic parameters included distal ureteral size ( $\geq 10$  mm or <10 mm) and degree of HUN (inclusion in Group A or B).

## Statistical analysis

Qualitative variables were summarized as frequency and percentage, and quantitative variables as median and range. The results were separately reported for the two groups (A and B) and stratified by MAG3 curve results (non-obstructed and obstructed). The Fisher's Exact Test was used to assess statistical significance of the differences between groups for qualitative variables. The Kaplan–Meier method was used to calculate the 1-year rates of UTI survival, fUTI survival, hospitalization survival and surgery survival. The Kaplan–Meier method was also used to estimate disease-free survival, cause-specific survival and overall survival at 1-yr of follow-up, after stratifying patients for all other factors. Statistical significance between curves was evaluated using the Log-rank test.

Multivariate analysis was performed using the Cox proportional hazards model to determine independent prognostic factors with significant impact of UTIs, fUTIs, hospitalization and surgery. The stability of the models was

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