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Early pyeloplasty versus conservative management of severe ureteropelvic junction obstruction in asymptomatic infants☆

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ABSTRACT

Background: Ureteric-pelvic junction obstruction (UPJO) is the most common cause of antenatal and neonatal hydronephrosis and its management remains controversial. While conservative management is advocated for all, this strategy puts a quarter of these patients at risk for possibly irreversible renal damage.
Aim: In this study, we compare functional and anatomic outcomes in newborns and infants less than 1 year of age with high-grade unilateral UPJO, following early surgical pyeloplasty (ESP) versus conservative management (CM).
Materials and Methods: This was a single center prospective interventional study. Infants referred to our tertiary care pediatric surgery clinic between September 2016 and September 2018 with UPJO were considered. To be included patients must have been less than 1 year old, lack of clinical symptoms, suffer from severe hydronephrosis as defined by Society for Fetal Urology (SFU) grades 3 or 4, and have affected kidney Split Renal Function (SRF) above 40%. Patients with bilateral disease, structural anomalies, or an abnormal voiding cystourethrogram (VCUG) were excluded. Anatomical and functional outcomes were measured and compared at 6 and 12 months.
Results: Fifty-six patients were assigned to receive either ESP (n = 28) or CM (n = 28). At 6 months Cortical thickness, polar length, and SFU indices were significantly lower in the ESP group, while none of the outcomes were significantly different between the two groups at 12 months. Despite the two groups not being different at 12 months regarding differential renal function (DRF), there was a significant decrease of function in the CM group compared to baseline.
Conclusion: When considering treatment options for infants with high-grade UPJO, it appears that ESP hastens improvement of anatomic and functional indices, while CM may lead to a significant deterioration in renal function.

Ureteric-pelvic junction obstruction (UPJO) is the most common cause of antenatal and neonatal hydronephrosis [1]. The prevalence is estimated at one per 1500 live births with a male–female ration of 3–4 to 1 [2].The diagnosis is often made during prenatal ultrasonography screening; but those who do not receive prenatal care may present with pain, hematuria, urosepsis, failure to thrive, or a palpable abdominal mass. Neonatal hydronephrosis can be caused by a range of abnormalities including ureteropelvic junction obstruction (UPJO), vesicoureteral reflux (VUR), ureterovesical junction obstruction, or megacystis megaureter. Since the latter two are uncommon, patients with a normal voiding cystourethrogram (VCUG) are presumed to have UPJO [3,4] about half of those identified with antenatal hydronephrosis go on to be diagnosed with UPJO during infancy [3]. Newer imaging modalities have simplified diagnosis of obstruction, yet its clinical significance remains unclear. Many obstructions diagnosed during infancy improve without any intervention and those that remain do not always lead to renal function impairment. Further complicating the treatment plan, is the fact that current renal imaging modalities cannot reliably determine which patients are at risk for permanent kidney damage, and who will improve spontaneously [5].

Several options have been considered for the management of children with prenatally-diagnosed hydronephrosis but controversy

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persists regarding the optimal approach [6–8], the earliest and most aggressive option is fetal surgery. It aims to drain the fetal urinary system before any complications occur. The problem is that prenatal ultrasound poorly differentiates obstruction from other causes of hydronephrosis. But in pregnancies with persistent early onset oligohydramnios, prenatal intervention may be an option. Unfortunately, the less than perfect benefits come at an increased risk to both the fetus and the mother [9].

Most patients are treated after birth with either surgery or conservative management. While historically corrective surgery was the norm for UPJO, studies in the wake of widespread ultrasonography screening, pointed away from overaggressive management of every patient [10]. Based on the fact that many of those found to have UPJO eventually do well without treatment, current protocols focus on close conservative monitoring, and reserve surgical intervention only for those who develop significant renal drainage impairment or poor renal growth [5,11]. In this approach patients with mild to moderate obstruction are closely observed using ultrasonography and receive antibiotic prophylaxis in selected cases. The parents are educated about the importance of promptly treating urinary tract infections and cases with moderate to severe obstruction or vesicoureteral reflux receive antibiotics prophylactically [12]. Surgery is reserved for those with severe obstruction, who experience worsening of obstruction or complications during the observation period. Indications include SFU grade 3 or 4; continued expansion of the renal pelvis collection system; a renal cortex <5 mm; and a single-kidney with decrease in GFR [13]. More recently, investigators have once again questioned applying the conservative approach to all patients. They argue that waiting for often irreversible loss of function is unjustifiable, especially for cases with severe hydronephrosis [14]. Even systematic reviews have failed to reach a definite conclusion regarding the best approach to treating these patients [15,16]. Thus, there is great interest in finding characteristics that can help differentiate patients requiring surgery.

Several indices have been introduced to identify the need for surgical intervention. Symptom such as pain, the Anteroposterior diameter (APD) of the affected kidney, or a decrease in its function to below 40%of expected values are considered prime indications. However other studies have pointed to shortcomings of relying on APD and have suggested that the degree of calyceal dilatation and thinning of renal cortex may be more important [17]. To overcome such shortcomings more complex grading systems such as the Society for Fetal Urology (SFU) system have been described [18]. One such characteristic is degree of obstruction as defined by SFU. Many have suggested those with high-grade obstruction defined as SFU grades 3 and 4 are more likely to suffer irreversible kidney damage during CM [19].In this single center prospective study, we compare functional outcomes in newborns and infants less than 1 year of age with high-grade unilateral UPJO, following early surgical pyeloplasty (ESP) versus conservative management (CM).

1. Material and methods

All newborns and infants referred to our tertiary care pediatric surgery clinic with a positive prenatal or neonatal screening ultrasonography for UPJO between September2016 and September 2018 were considered. Inclusion criteria were age less than 1 year, lack of clinical symptoms, severe hydronephrosis as defined by Society for Fetal Urology (SFU) grade 3 or 4 by ultrasonography, and affected kidney Split Renal Function (SRF) above 40% as determined by radionuclide scan. Patients with SFU grades 1 or 2 were not included, because authors believe they are more likely to benefit from conservative management. Those with clinical symptoms, SRF less than 40%, or bilateral disease were excluded as the authors believe they may benefit from immediate surgical intervention. Furthermore, patients with recognized ureteral and kidney anomalies, structural anomalies, or an abnormal Voiding Cystourethrography showing reflux or posterior urethral valve were also excluded in favor of surgery.

Baseline SFU was determined using confirmatory ultrasonography at 1 week of age, or at time of referral for older infants. Radionuclide evaluation was done using Technetium-99 m diethylene triamine pentaacetic acid (Tc-99 m DTPA) (furosemide after 15 min) at 3 months of age or at time of referral for others followed by voiding cystourethrogram at 4 to 6 weeks of life, or immediately if diagnosed later during the first year of life.

Due to ethical implications, randomization was not feasible. Each individual patient's condition was described to the parents and acceptability of both treatment methods were clarified. Relevant pros and cons of each strategy was discussed. Through shared decision making with parents, it was determined whether each patient would be designated to the ESP or CM groups.

All patients in the ESP group received a standard open pyeloplasty procedure by the same surgical team. The extra peritoneal approach with supra costal incision above the 12th rib with 6–0 polyglactin interrupted and continuous sutures was used. An indwelling double J stent was placed at time of surgery and prophylactic antibiotics were initiated for all patients. Patients were seen in the clinic 1 week later to remove the sutures, and the stent was removed after 4 weeks.

Follow-up ultrasonography was performed at 6, and 12 months post-operatively. Urinalysis was carried out every month, prophylactic antibiotics were continued until Tc-99 m DTPA scan revealed lack of obstruction and three consecutive urine samples were found to be clear for infection. In this group post-operative Tc-99 m, DTPA scans were performed at 3, and 12 months after the operation, at the same center using the same protocol, to assess final SRF and drainage.

After undergoing baseline assessments, patients in the CM group were seen in the clinic every month to ask about development of concerning symptoms and to perform a urinalysis in order to rule out urinary tract infection. Ultrasonographic and DTPA exams in this group were both repeated at 6, and 12 months after start of management. Tc-99 m DTPA scan was conducted at the same center, using identical protocols. All patients in this group were taking daily prophylactic antibiotic. Delayed pyeloplasty was carried out for infants in this group if deterioration in SRF greater than 10% was detected or if any concerning symptoms developed.

Surgeons, radiologists performing the ultrasonography, and the data analyst were not blinded. However, the nuclear medicine specialist assessing renal function was blinded to the patient groups.

1.1. Statistical analysis

Functional outcomes were compared using chi square tests in Graph Pad Prism version 8 and SPSS version 25 and a p-value of less than 0.05 was considered statistically significant. The non-randomized study was approved by the institutional board of ethics and all parents signed an informed consent prior to their infant's inclusion in the study.

2. Results

Over the two-year course of the study, 82patients met the inclusion criteria, of which 26 were excluded due to presence of clinical symptoms ($n = 8$), bilateral disease ($n = 3$),presence of urinary tract structural anomalies ($n = 5$), or an abnormal voiding cystoureterography ($n = 10$). Eventually, 56 infants were divided into groups either receiving ESP ($n = 28$) or initial CM with close follow-up ($n = 28$). Mean age of patients at time of entering the study was 4.8 ± 2.1 months and 4.4 ± 1.8 months for the ESP and CM groups respectively (Fig. 1).

Sixty-six percent of patients were male, and 61% of the affected kidneys were on the left side. All included patients were classified as having severe obstruction on Tc-99 m DTPA scan with a baseline T1/2 > 20 min.

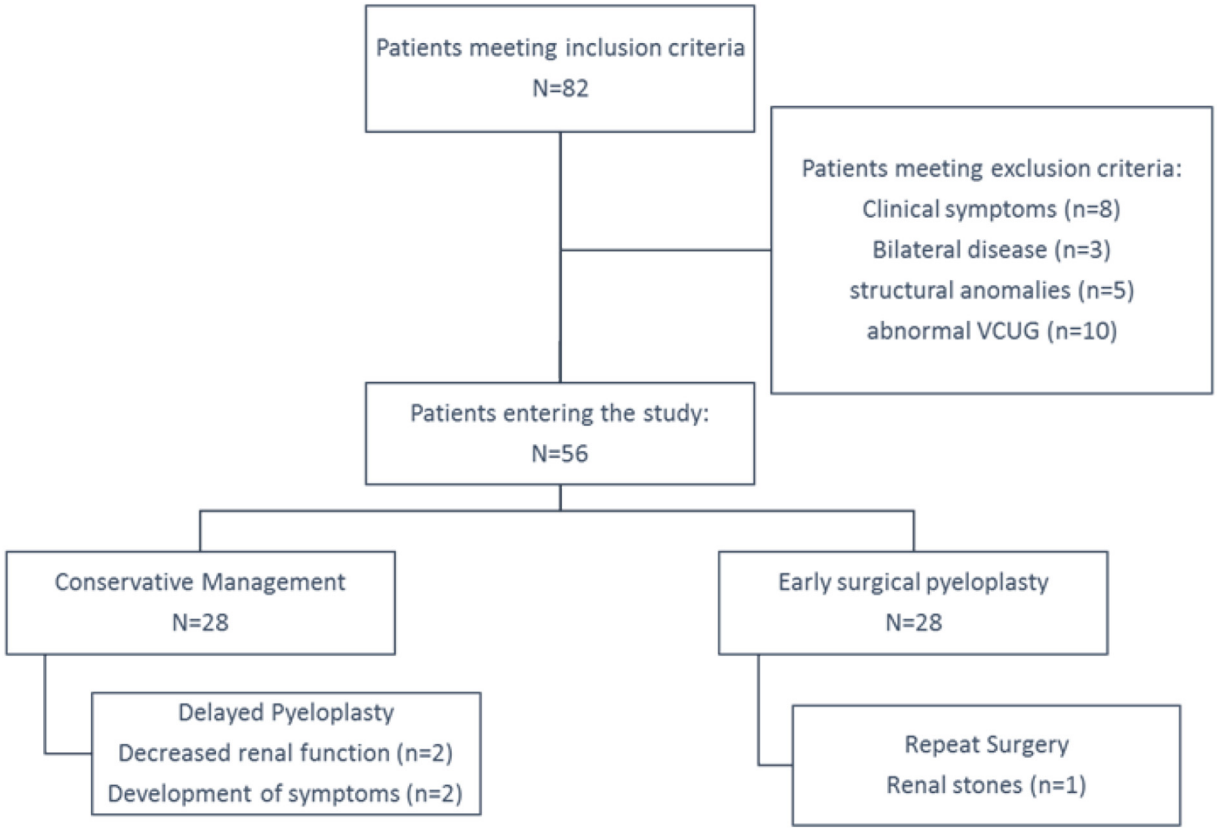

Fig. 1. Patient selection diagram.

Table 1
Baseline characteristics.

Variable	ESP	CM	p-Value
Age at time of inclusion (months)	4.821 ± 2.074	4.429 ± 1.773	0.5487
Gender			
Male	20 (71.4%)	17 (60.7)	0.3972
Female	8 (28.5 5)	11 (39.2)	
APD (mm)	25.50 ± 8.95	21.89 ± 4.63	0.0635
Cortical thickness (cm)	4.607 ± 1.343	4.804 ± 1.039	0.6469
Polar length(mm)	73.07 ± 13.10	68.21 ± 8.34	0.1038
SFU	3.536 ± 0.508	3.429 ± 0.504	0.5932
DRF%	49.00 ± 6.69	51.04 ± 5.84	0.2306
Laterality	9 (32.2%)	13 (46.4%)	0.274
Right	19 (67.8%)	15 (53.6%)	
LEFT			

As summarized in Table 1, baseline characteristics were not significantly different statistically in the two groups. Yet, given the small sample size, it is important to note the trend in pre-surgical APD in which the ESP group had larger mean APD but this value did not reach statistical significance at $p = 0.06$.

During follow up, one patient in the ESP group had to undergo redo pyeloplasty due to development of symptomatic renal stones.

In the CM group, two infants developed an impairment of renal function to levels below 40% on the nuclear scan, and two patients who developed urinary symptoms such as flank pain, fever >38.5, poor feeding and a positive urine culture at a level of ≥100,000 colony-forming units (cfu)/mL, all underwent delayed pyeloplasty (see Table 2).

Table 2
Follow-up characteristics.

	Characteristics	ESP (n = 28)	CM (n = 28)	p-Value
APD mm	After 6 month	19.50 ± 7.15	18.89 ± 3.07	0.6812
	After 1 year	15.25 ± 5.96	17.18 ± 3.65	0.1501
Cortical thickness (cm), polar length(mm), DRF %	After 6 month	5.714 ± 0.976	5.018 ± 0.866	0.0061
	After 1 year	6.143 ± 0.931	5.607 ± 1.166	0.0505
Polar length	After 6 month	76.11 ± 13.61	70.04 ± 8.02	0.0469
	After 1 year	77.54 ± 13.09	71.82 ± 9.34	0.0654
SFU	After 6 month	2.956 ± 0.474	3.179 ± 0.390	0.0352
	After 1 year	2.750 ± 0.441	2.929 ± 0.466	0.1465
DRF	After 3 month	49.25 ± 5.26	–	–
	After 6 month	–	48.64 ± 4.97	–
	After 1 year	48.07 ± 5.22	47.04 ± 8.25	0.5770
Renal scan T1/2 < 10 min	After 1 year	25 (89.3%)	20(71.4%)	

Table 2 summarizes the follow up findings in both groups.

Both groups showed a significant improvement of SFU scores, ($p < 0.0001$ in the ESP and $p = 0.0403$ in the CM group) at 1 year after start of management. The ESP group showed a significantly lower SFU score at 6 months compared to the CM group ($p = 0.0352$), but this difference was not seen after 12 months ($p = 0.1465$).

Analysis of APD again showed significant improvement in both groups compared to baseline at 6 and 12 months. In the CM group, APD diameter improved significantly from baseline to 6 month ($p < 0.001$) and from 6 month to 12 month ($p < 0.001$). The two groups did not appear to be significantly different regarding APD at 6 and 12 months. Although the original p value at baseline was 0.06 (initially skewed towards longer APDs for the EPS group), it was 0.68 and 0.15 at 6 and 12 months respectively.

The polar length significantly improved in the ESP group after 1 year ($p = 0.0294$), while the CM group showed a significant increase in polar length at 6 month ($p < 0.001$) and 1 year ($p = 0.001$). The polar length was found to be significantly larger in the ESP group at 6 months ($p = 0.0469$) but not at 1 year follow-up ($p = 0.065$) when compared to the CM group.

The index of cortical thickness significantly improved in both groups during follow up. However, the EPS group showed a greater improvement and was found to be significantly larger than the CM group at 6 month ($p = 0.006$). At 1 year, this tendency remained but the p-value increased to 0.0505.

The EPS group did not show a significant decrease in the DRF scan results at 1 year ($p = 0.408$). However, in the control group renal function significantly deteriorated both at 6 months ($p = 0.006$) and 1 year ($p = 0.021$). Despite this finding, the two groups were not found to be significantly different on head to head comparison of DRF-Tc-99 m DTPA results at 1 year ($p = 0.577$).The Tc-99 m DTPA scan was also used to determine the degree of obstruction in the affected kidney. At baseline, all patients were determined to have prolonged obstruction ($T1/2 > 20$ min). At 12 months, 25 patients (89.3%) in the EPS group had unobstructed drainage with $T1/2 < 10$ min, while the obstruction in the remaining three had partially resolved, meaning that while the obstruction had resolved more than 50% compare to the initial scan, T1/2 was between 10 and 20 minutes. In the CM group at one-year follow up, 20 patients were found to have unobstructed drainage (71.4%) while eight remained partially obstructed (28.6%).

Table 3 summarized these findings.

3. Discussion

Management of UPJO is complicated by our inability to reliably identify those who will benefit from early surgical intervention and those who will not. On the one hand, the original approach of aggressively treating every patient introduces risks associated with surgery to the many who would have spontaneously resolved. On the other hand, the "conservative management for all" approach puts some infants at risk for permanent loss of renal function [20]. A better approach is to offer a more personalized treatment to patients. We know that patients demonstrating high-risk characteristics like decreased DRF, symptomatic disease, and UTIs benefit from early aggressive surgical treatment. In this study, we looked at level of obstruction as described byTc-99 m DTPA, to determine whether patients demonstrating high-grade obstruction also benefit from early surgical intervention. Our results show when high-grade obstruction is present without any other worrying factors, using a conservative management approach appears to cause deterioration of some renal anatomy and function indices at 6 months and 1 year, that are not seen in the ESP group.

Effectiveness of pyeloplasty in preventing deterioration and even improving renal function has been known for many years [21,22] and this was historically the standard of treatment.

In 1990 Ransley et al. were one of the first groups to question a universal surgery approach and to offer APD as a prognostic determinant for selecting those who are likely to benefit from surgery [10]. Later, nuclear testing was introduced which has the ability to determine the function of each kidney independently and led to recognition of high-risk patients using SRF [23]. Long-term follow up of patients who had undergone conservative management indicates this approach is safe in about 75% of cases [5,24]. Therefore, current protocols have adopted an approach of initial conservative treatment of prenatally diagnosed UPJO [10,25,26]. Supporters of this approach argue that expectant management spares unnecessary surgery, and even if renal function deteriorates during the expectant period, the initial functional can be restored through delayed pyeloplasty [27,28].

In our study, while patients undergoing ESP did not experience a significant decline of renal function, those that underwent CM did. Although SRF was not found to be, significantly different between the groups at 1 year this may be attributed to the small sample size and the non-randomized study design.

The paradigm of conservative management for all has been challenged by some authors [14,29].A quarter of affected patients do benefit from the definite effects of surgery and waiting for possibly irreversible damage before initiating treatment is not warranted [30].

In 1999 Subramanian et al. noted that in some patients conservative management of antenatally detected UPJO leads to a greater loss of function which is not recovered after surgery [29].

In a 2002 study, Liang et al. demonstrated that ESP significantly reduced evidence of hydronephrosis in asymptomatic infants with SFU grades 3 and 4 obstructions when compared to conservative management at 6 and 12 months [31].

In another study, Kim and colleagues looked at the effects of ESP on parenchymal thickness of newborns with unilateral UPJO. They also reported that surgical intervention within the first year of life has a significant impact of kidney parenchymal growth [32].

Babu et al. have shown that while renal function is maintained in those undergoing ESP, those undergoing delayed pyeloplasty only regain a fraction of the lost function and so favor a surgical approach towards those presenting with high-grade hydronephrosis [14].

In this study, we found that anatomic and functional indices of the affected kidney are impacted by the method of treatment. Those undergoing ESP demonstrate an earlier improvement of indices at 6 months and maintain their renal function. On the other hand, those undergoing CM appear to make up for some of the deterioration by the first year of follow up but eventually demonstrate a significant decrease in kidney function. The improvement of indices in the CM group during the

Table 3
DTPA results during follow-up.

Follow-up	ESP		CM	
Initial (pre-surgery)	Prolonged obstruction		Prolonged obstruction	
3 months	Nonobstructed 85.7%	Partially obstructed 14.3%	–	–
6 months	–	–	Nonobstructed 46.4%	Partially obstructed 53.6%
1 year	Nonobstructed 89.3%	Partially obstructed 10.7%	Nonobstructed 71.4%	Partially obstructed 28.6%

second half of follow up may have been in part due to the fact that eventually, four patients in this group underwent delayed pyeloplasty. Two of these were patients who experienced reduced renal function on DTPA scan and the two suffered from flank pain and active urine analysis. Although comparison of renal function at 12 months did not reveal a significant difference between the two groups, this may have been due to worse (although not statistically significant) indices at baseline in the ESP group.

This is a small study and aims to document our experience with severe perinatal UPJO obstruction. The main drawbacks of this study are its small sample size and non-randomized design. Randomization was not ethically feasible. Despite these shortcomings, we believe our findings contribute to the current understanding of antenatal UPJO management.

4. Conclusion

In high-grade perinatal UPJO, ESP hastens improvement of anatomic and functional indices of the affected kidney, while a CM approach may lead to a significant deterioration in renal function. The authors believe that this risk must be considered and included in the shared decision-making conversation before a management approach is selected for each individual patient.

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Compliance with ethical standards

Conflict of interest

The authors declare that they have no conflict of interest.

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