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Augmentation Uretero-enterocystoplasty Is an Effective Procedure in Protecting the Upper Urinary Tract Without Accelerating Deterioration of Renal Function

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Abstract

Background: Augmentation uretero-enterocystoplasty (AUEC) provides a low-pressure urinary storage capsule that can preserve renal function in patients with lower urinary tract dysfunction for whom conservative treatments have failed.
Objective: To summarize the effectiveness and safety of augmentation uretero-enterocystoplasty (AUEC) and evaluate whether it aggravates renal function deterioration in patients with renal insufficiency.
Design, setting, and participants: This was a retrospective cohort study of patients who underwent AUEC from 2006 to 2021. Patients were grouped according to whether they had normal renal function (NRF) or renal dysfunction (serum creatinine >1.5 mg/dl).
Outcome measurements and statistical analysis: Follow-up of upper and lower urinary tract function was assessed via review of clinical records, urodynamic data, and laboratory results.
Results and limitations: We included 156 patients in the NRF group and 68 in the renal dysfunction group. We confirmed that urodynamic parameters and upper urinary tract dilation were significantly improved for patients after AUEC. Serum creatinine declined during the first 10 mo in both groups and remained stable thereafter. The reduction in serum creatine was significantly greater in the renal dysfunction group than in the NRF group in the first 10 mo (difference in reduction 4.19 units; $p < 0.05$). A multivariable regression model showed that baseline renal dysfunction was not a significant risk factor for deterioration of renal function in patients who had undergone AUEC (odds ratio 2.15; $p = 0.11$). The main limitations are selection bias because of the retrospective design, loss to follow-up, and missing data.

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Conclusions: AUEC is a safe and effective procedure to protect the upper urinary tract and will not hasten deterioration of renal function in patients with lower urinary tract dysfunction. In addition, AUEC improved and stabilized residual renal function in patients with renal insufficiency, which is important in preparation for renal transplantation.

Patient summary: Bladder dysfunction is usually treated with medication or Botox injections. If these treatments fail, surgery to increase the bladder size using a portion of the patient's intestine is a possible option. Our study shows that this procedure was safe and feasible and improved bladder function. It did not lead to a further decrease in function in patients who already had impaired kidney function.

1. Introduction

The clinical manifestations of refractory lower urinary tract (LUT) dysfunction resulting from a progressive decline in bladder function may be caused by neurologic disorders, such as spinal cord injury and spina bifida [1]. Most of these patients present with detrusor overactivity, low bladder capacity and compliance, and even renal insufficiency. Conservative treatment, including anticholinergic drugs and intravesical botulinum toxin injections, is the first choice for patients with neurogenic bladder (NB) [2]. In some patients for whom conservative treatment has failed, augmentation cystoplasty (AC) combined with clean intermittent catheterization (CIC) is still considered a viable option for protecting the upper urinary tract (UUT) and improving quality of life.

The primary purpose of augmentation cystoplasty (AC) is to provide a low-pressure urinary storage capsule in an attempt to preserve renal function. A number of studies have demonstrated the benefits and complications of AC [3–5]. In addition, a recent study suggested that LUT reconstruction does not negatively affect graft function or survival [6].

Whether ureteroplasty and ureteral implantation to prevent reflux are necessary for AC remains controversial, as well as the optimal timing for performing AC. Some groups believe that AC is beneficial for patients with a preoperative creatinine level ≤2 mg/dl [7]. Other investigators have concluded that AC does not accelerate the progression of moderate to severe renal insufficiency to end-stage renal disease [3,6]. Here we present a large, single-center study involving patients with LUT dysfunction undergoing AC with simultaneous ureteroplasty and ureteral implantation to prevent reflux, termed augmentation uretero-enterocystoplasty (AUEC). The objective of our retrospective study was to summarize the efficacy and safety of AUEC, and evaluate whether AUEC aggravates renal function deterioration in patients with renal insufficiency.

2. Patients and methods

This retrospective study was approved by the ethics committee of the China Rehabilitation Research Centre (reference 2017-003-1). All patients with refractory LUT dysfunction who experienced failure of conservative treatment and underwent AUEC at the China Rehabilitation Research Centre between 2006 and 2021 were included. Of these patients, 68 had renal dysfunction (RD), defined as serum creatinine >1.5 mg/dl (1 mg/dl = 88.4 μmol/l).

Patients of any age and with any disease duration were included in the study. The indications for AUEC were comprehensively evaluated. Baseline and follow-up data, including patient demographics, videourodynamics (VUDS), renal ultrasound, magnetic resonance urography (MRU), radioactive nephrography, and all available laboratory test results were extracted from medical records. All patients had at least one follow-up visit during the study period. Intervention failure was defined as the absence of clinical improvement, or deterioration in serum creatinine and UUT dilation (UUTD), or a need for an additional surgical intervention.

2.1. *Inclusion and exclusion criteria*

The inclusion criteria for the AUEC intervention were as described in our previous study [3,8]: (1) intravesical pressure >40 cm H_2O or bladder compliance <10 ml/cm H_2O; (2) unacceptable urinary incontinence; (3) high-grade and/or low-pressure (<10 cm H_2O) vesicoureteral reflux (VUR) with UUTD; (4) VUR/UUTD grade ≥III or ureterovesical junction (UVJ) stenosis; and (5) no significant improvement in UUT function after use of an indwelling urethral catheter. Patients who declined to complete the survey or had invalid or missing data were excluded. UUTD, including hydronephrosis and/or ureteral dilation, was assessed via MRU using the classification system previously described [9–11]. VUR was graded according to the international grading system [12].

2.2. *Statistical analysis*

All statistical analyses were performed using Empower (www. empowerstats.com) and R (http://www.R-project.org). Continuous variables are expressed as the mean ± standard deviation or median (interquartile range). Results for categorical variables are presented as the frequency and percentage. Student's t test or a Mann-Whitney U test was used to identify significant differences in quantitative variables. A χ^2 test or Fisher's exact test was used for categorical variables. A two-tailed p value <0.05 was considered statistically significant.

General additive mixed models (GAMMs) are ideal tools for analyzing data from repeated measurements. GAMMs were applied to assess the relationship between follow-up duration and serum creatinine stratified by baseline renal function. Serum creatinine, VUDS, and UUTD were assessed at baseline and at follow-up visits. Variables such as age, sex, disease duration, etiology, VUR, ureteral stent indwelling time, and complications were recorded at baseline or the first postoperative follow-up evaluation, and entered into the adjustment model as fixed effects.

3. Results

A total of 224 consecutive patients (162 males and 62 females) with severe UUT or LUT dysfunction were eligible for inclusion in the study. Intervention failure occurred in 13/156 patients with normal renal function (NRF) at baseline, and no gradual improvement in serum creatinine or UUTD was observed in 11/68 patients with RD at baseline. Demographic and baseline data for the study cohort stratified by renal function are summarized in Table 1. Of the patients who completed baseline assessment, 66 had two, 39 had three, 17 had four, 75 had five, and 27 had six or more follow-up visits. The median disease duration was 12 yr (range 4–20) and mean follow-up was 32.3 mo (range 1–180).

Figure 1 shows the change in serum creatinine during follow-up for patients who underwent AUEC. A significant improvement was observed in the RD group at different time points during follow-up ($p < 0.05$). A similar trend for improvement was observed in the NRF group. GAMMs with curve-fitting provide a more accurate overview of the variation in serum creatinine in the two groups during follow-up (Fig. 2A,B). There were significant declines in serum creatinine in the two groups between 0 and 10 mo, which then remained stable in both groups thereafter. Interestingly, AUEC significantly reduced serum creatinine in patients with renal insufficiency, but the majority of these patients still had RD. The adjusted decline in serum creatinine over 10 mo was 0.48 units (95% confidence interval [CI] 0.06–0.90; $p = 0.03$]) in the NRF group and 4.71 units (95% CI 2.55–6.87; $p < 0.01$) in the RD group (Fig. 2D). There was a significant difference in serum creatinine reduction between the two groups at 10-mo follow-up (4.19 units; $p < 0.01$; Fig. 2D).

Univariate and multivariable regression analyses were carried out to assess whether risk factors were associated with procedural failure for patients who underwent AUEC (Table 2). Univariate and multivariable models adjusted for possible confounding factors showed that serum creatinine was not significantly correlated with the occurrence of intervention failure (univariate: odds ratio [OR] 1.00, 95% CI 1.00–1.01; $p = 0.09$; multivariable: OR 1.00, 95% CI 1.00–1.01; $p = 0.21$). Similarly, renal function was not significantly related to deterioration of UUT function in the multivariable regression model (OR 2.15, 95% CI 0.99–6.18; $p = 0.11$).

The degree of bilateral hydronephrosis was significantly higher for patients with RD than for patients with NRF (left: median 2.25 vs 1.80 cm; $p = 0.01$; right: median 2.00 vs 1.50 cm; $p < 0.01$). For patients with bilateral kidneys, renal pelvis separation significantly decreased after AUEC treatment (RD group: left 2.25 vs 1.01 cm, right 1.8 vs 0.94 cm; $p < 0.05$; NRF group: left 2.25 vs 1.01 cm, right 1.8 vs 0.94 cm; $p < 0.01$). Kidneys were visualized on ultrasonography to assess UUTD. UUTD was observed for 266/306 ureters in the NRF group and 132/134 ureters in the RD group. A quantitative improvement in UUTD grade was observed at last follow-up evaluation in comparison to baseline: the rate of high-grade (grade III–IV) UUTD decreased from 69.41% to 14.93% ($p < 0.01$) in the RD group and from 48.04% to 12.75% ($p < 0.01$) in the NRF group (Fig. 3).

Differences in urodynamic parameters, including maximal bladder capacity (MBC), bladder compliance (BC), and maximal detrusor pressure (MDP), are shown in Table 3. At the final follow-up visit, patients in both groups had experienced significant improvements in MBC and BC, and a significant decrease in MDP.

Some common complications occurred in patients undergoing AUEC, including bowel dysfunction in two patients (Clavien-Dindo grade II), metabolic acidosis in 21 patients (grade II), urinary tract infection in 14 patients (grade II), and bladder calculus in three patients (grade IIIa); all problems resolved after appropriate therapy.

4. Discussion

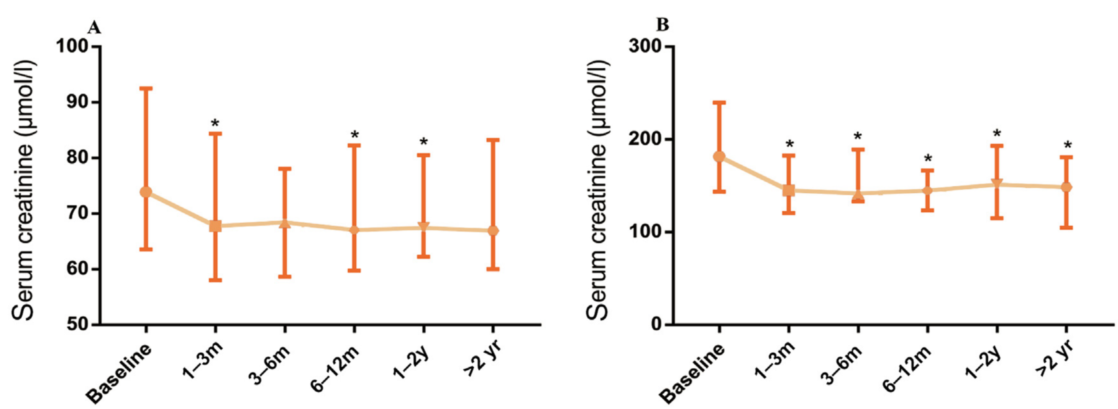
The primary aims of AUEC in patients with LUT dysfunction are to trim tortuous and obstructive ureters, decrease detrusor pressure, and increase bladder capacity and bladder compliance to ultimately prevent deterioration of UUTD. Currently, conservative treatment is preferred for management of bladder dysfunction; however, LUT reconstruction to preserve renal function is a viable option for patients for whom pharmacological treatments are not effective, and improvement and maintenance of renal function is a crucial metric in assessing this procedure.

Whether LUT reconstruction can affect renal function in individuals with LUT dysfunction is not clear. The general belief that severe renal insufficiency is a contraindication to LUT reconstruction, which might accelerate end-stage renal disease, has been controversial [13]. One study recommended against LUT reconstruction in patients with RD to avoid rapid deterioration of renal function [14]. In this case, the etiology of adverse outcomes appeared to depend on preoperative renal function. In 2015, a study with long-term follow-up confirmed that renal function improves in some patients after LUT reconstruction [15]; however, renal function deterioration was observed in more than half of patients who had renal insufficiency preoperatively. This was the first study to report on changes in renal function following LUT reconstruction in patients with preoperative RD. Other studies concluded that bladder reconstruction may hasten preoperative renal impairment to end-stage renal disease because of surgical trauma and complications [3,15–17]. By contrast, a correlation between postoperative deterioration in renal function and urinary reconstruction was not confirmed on other studies [4,6,18]. In a study of 30 patients who underwent gastrocystoplasty, only one experienced renal function deterioration [19]. In addition, several retrospective cohort studies of LUT reconstruction in patients with chronic renal insufficiency showed that augmentation had no effect on renal function deterioration in most patients [6,20]. Interestingly, our finding is consistent with the latter studies. In our cases series, most of the patients had end-stage NB, presenting with UUT dilatation (UUTD), tortuosity, or ureteral reflux with low pressure. There was no significant improvement in UUT function, including serum creatinine and UUTD, for these patients after 3-mo use of an indwelling urethral catheter. We

Table 1 – Demographic, clinical, and etiological characteristics of patients undergoing augmentation uretero-enterocystoplasty

Characteristics	Overall (n = 224)	Normal renal function (n = 156)	Renal dysfunction (n = 68)	p value
Age (yr) [a]	27.67 ± 13.97	28.39 ± 14.63	26.01 ± 12.26	0.24
Disease duration (yr) [b]	12.0 (4.0–20.0)	12.0 (3.88–20.0)	13.0 (4.0–20.0)	0.80
Serum creatinine (μmol/l) [a]	118.30 ± 78.83	78.60 ± 21.57	209.36 ± 86.72	<0.01
Left RPS median (cm) [b]	2.00 (1.20-2.80)	1.80 (1.10–2.60)	2.25 (1.63–3.58)	0.01
Right RPS median (cm) [b]	1.70 (0.80–2.40)	1.50 (0.50–2.30)	2.00 (1.52–3.00)	<0.01
Indwelling DJS time (d) [b]	28 (21–38)	28 (21–36)	28 (23–40)	0.55
Age category, n (%)				0.82
<18 yr	57 (25.45)	41 (26.28)	16 (23.53)	
≥18 yr	167 (74.55)	115 (73.72)	62 (76.47)	
Sex, n (%)				0.12
Male	162 (72.32)	108 (69.23)	54 (79.41)	
Female	62 (27.68)	48 (30.77)	14 (20.59)	
Etiology, n (%)				0.71
Neurogenic	184 (82.14)	129 (82.69)	55 (80.88)	
Non-neurogenic	9 (4.02)	7 (4.49)	2 (2.94)	
Idiopathic	31 (13.84)	20 (12.82)	11 (16.18)	
Vesicoureteral reflux, n (%)				0.93
No	88(39.29)	61 (39.10)	27 (39.71)	
Yes	136 (60.71)	95 (60.90)	41 (60.29)	
Ureter obstruction, n (%)				0.81
No	166 (74.11)	116 (74.36)	50 (73.53)	
Yes	58 (25.89)	40 (25.64)	18 (26.47)	
Ureter reimplantation, n (%)				0.33
No	27 (12.05)	21 (13.46)	6 (8.82)	
Yes	197 (87.95)	135 (86.54)	62 (91.18)	
Intervention failure, n (%)				0.08
No	200 (89.29)	143 (91.67)	57 (83.82)	
Yes	24 (10.71)	13 (8.33)	11 (16.18)	
Complications, n (%)				
No	181 (80.80)	131 (83.97)	50 (73.53)	0.07
Yes	43 (19.20)	25 (16.03)	18 (26.47)	

DJS = double-J stent; RPS = renal pelvis separation.
[a] Mean ± standard deviation.
[b] Median (interquartile range).



	Baseline	1–3m	3–6m	6–12m	1–2y	>2 yr
Median	73.9	67.75	68.45	67.05	67.45	66.95
Q1	63.58	58	58.65	59.78	62.25	60
Q3	92.5	84.38	78.05	82.28	80.53	83.23

	Baseline	1–3m	3–6m	6–12m	1–2y	>2 yr
Median	181.6	145	141.9	147.9	151.4	148.7
Q1	143.55	120.5	133.1	123.7	125.03	104.78
Q3	239.75	182.6	189	176.5	193.13	180.75

Fig. 1 – Changes in serum creatinine during follow-up for patients with (A) normal renal function and (B) renal dysfunction. Q1 = quartile 1; Q3 = quartile 3. * p < 0.05 in comparison to baseline.

hypothesized that AC, with a similar effect to an indwelling catheter, could not result in a satisfactory clinical benefit for these patients with UUT deterioration. Furthermore, some patients with UUTD (>3) had received AC in local hospital, but their UUT function was not well maintained. UUTD and renal function deteriorated gradually in these patients, who finally underwent ureteroplasty with effective results. Hence, our results confirm that AUEC can preserve or even improve renal function in patients with renal impairment. In addition, curve fitting analysis showed that renal func-

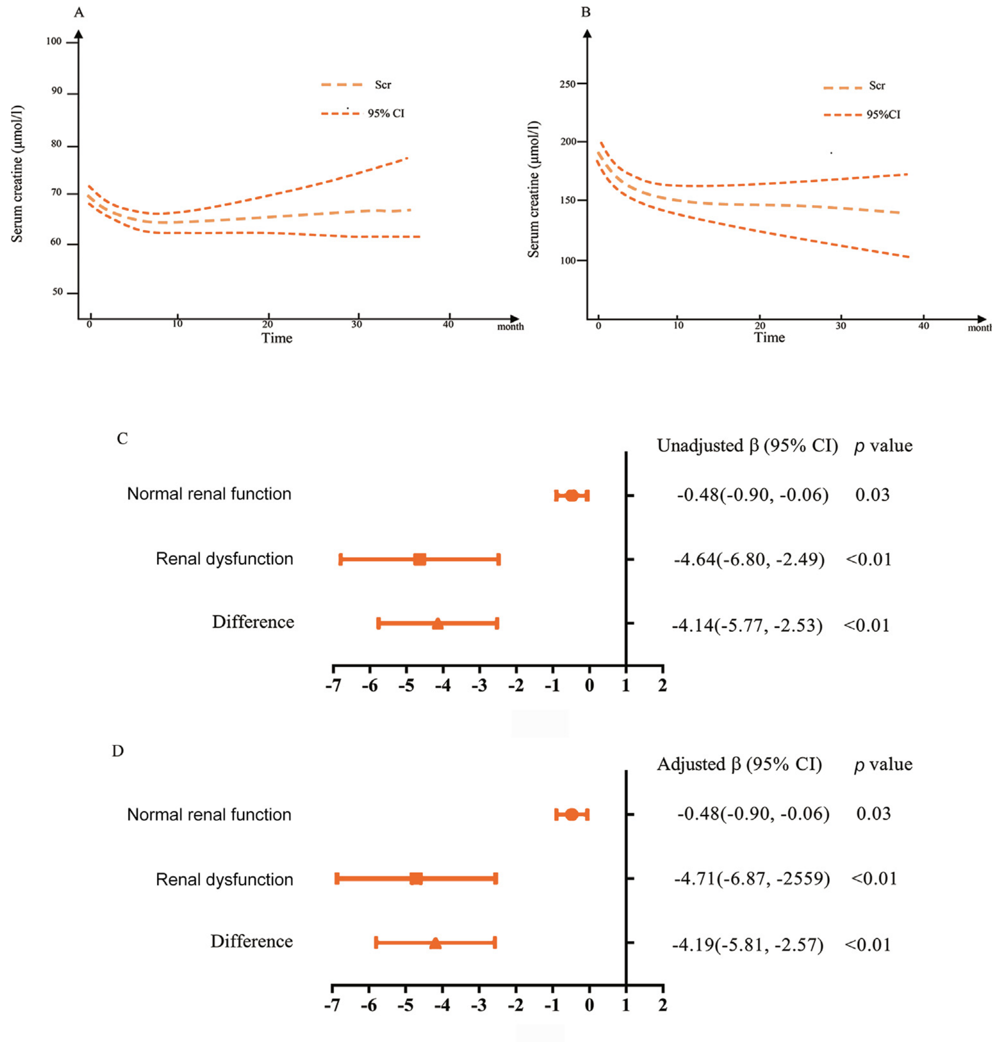


Fig. 2 – Smoothing analysis curves for serum creatinine (Scr) during follow-up for patients with (A) normal renal function and (B) renal dysfunction who underwent augmentation uretero-enterocystoplasty. (C) Unadjusted and (D) adjusted changes in Scr in the two groups during the first 10 mo. The model was adjusted for age, sex, disease duration, etiology, vesicoureteral reflux, ureteral stent indwelling time, and complications. CI = confidence interval.

tion improved over time in the first year after surgery for the groups with normal and abnormal renal function. Renal function in terms of serum creatinine remained stable, with no significant difference over time observed at 10 mo after surgery. In addition, our results confirm that intervention failure was not associated with baseline serum creatinine according to univariate and multivariable analyses. Even for the four patients with end-stage renal disease in our study, AUEC did not worsen renal function and it established a low-pressure, draining urinary storage reservoir to protect a subsequent kidney transplant. In our study, only 4/224 patients eventually received renal replacement therapy, two of whom underwent AUEC as a preparatory step before a future renal transplant. AUEC was performed safely before transplantation in these two patients and did not increase complications; it also facilitated better protection of the renal graft. Despite evidence that the timing of AC in relation to transplantation has no significant effect on the outcome of a renal transplant [21], in our opinion, establishment of a urinary storage capsule before transplantation would yield more benefits in patients with end-stage NB. First, performing augmentation before transplantation might be associated with lower rates of complications, specifically to the ureter, and of graft loss [22]. Second, the formation of fibrous bands or adhesion of periureteral tissue can cause ureteral stricture, curvature, and dilation in patients with advanced-stage NB. AUEC involving ureteroplasty can eliminate fibrous cords around the ureter and ameliorate obstruction to allow unobstructed drainage of urine from the renal unit and protect UUT function [23]. Our results are very encouraging and provide strong evidence of the efficacy of AUEC in protecting renal function in patients with preoperative renal insufficiency. However, although AUEC improved renal function in patients with renal insufficiency, it did not reverse their renal insufficiency.

Although some researchers believe that patients who undergo LUT reconstruction are at high risk of renal deterioration, risk factors contributing to such deterioration are often associated with pre-existing conditions rather than

Table 2 – Univariate and multivariable analysis of risk factors for the occurrence of intervention failure

Variable	Result [a]	OR (95% CI)	p value
Univariate analysis			
Age (yr)	27.67 ± 13.97	1.02 (0.99–1.05)	0.13
Serum creatinine (μmol/l)	118.30 ± 78.83	1.00 (1.00–1.01)	0.09
Disease duration (yr)	13.34 ± 10.90	1.05 (1.01–1.08)	0.01
Indwelling DJS time (d)	37.05 ± 25.03	0.98 (0.96–1.01)	0.16
Sex			
Male	162 (72.32)	Reference	
Female	62 (27.68)	0.49 (0.16–1.49)	0.21
Vesicoureteral reflux			
No	88 (39.29)	Reference	
Yes	136 (60.71)	0.61 (0.26–1.43)	0.26
Complications			
No	181 (80.80)	Reference	
Yes	43 (19.20)	0.83 (0.27–2.55)	0.74
Renal dysfunction			
No	156 (69.64)	Reference	
Yes	68 (30.36)	2.12 (0.90–5.01)	0.09
Etiology			
Neurogenic	184 (82.14)	Reference	
Non-neurogenic	9 (4.02)	0.9 (0.2–3.9)	0.84
Idiopathic	31 (13.84)	1.3 (0.4–4.0)	0.70
Multivariable analysis [b]			
Serum creatinine (μmol/l)	118.30 ± 78.83	1.00 (1.00–1.01)	0.21
Renal dysfunction			
No	156 (69.64)	Reference	
Yes	68 (30.36)	2.15 (0.99–6.18)	0.11

DJS = double-J stent; SD: standard deviation; OR = odds ratio; CI = confidence interval.
[a] Results are presented as mean ± standard deviation or n (%).
[b] Adjusted for age, sex, disease duration, etiology, vesicoureteral reflux, ureteral stent indwelling time, and complications.

LUT reconstruction per se [5]. Previous studies revealed that incomplete emptying and recurrent urinary tract infections are important risk factors for deterioration in renal function [24]. However, there are a limited number of similar studies and we found that no specific risk factors other than disease course were associated with deteriorating renal function for patients undergoing AUEC in the current study. It is widely accepted that UUT deterioration is associated with noncompliance with an intermittent catheterization schedule in some patients [17,25]. Because a number of patients with renal function deterioration can be asymptomatic, patients who void using a Valsava or Crede maneuver require vigilance. Therefore, we strongly recommend that patients who undergo AUEC should have regular follow-up. Furthermore, we believe that AUEC not only preserves residual renal function in patients with renal insufficiency and delays the occurrence of end-stage renal disease but also provides an optimal low-pressure urinary storage capsule suitable for future renal transplantation.

In addition to maintenance of renal function, improvement in bladder function is a key secondary metric in appraising benefits after LUT reconstruction. AC is a well-established reconstruction procedure that creates a urinary storage system with good capacity and low pressure [8,26]. Our results are consistent with those from previous studies, and satisfactory results were achieved in all patients; however, previous studies found that AC alone could not relieve obstructions at or above the UVJ [3,8]. Importantly, AUEC involves ureterolysis and ureteral tailoring, which ensures unobstructed drainage of urine from the renal unit and improves renal function [8]. Specific steps for this procedure can include the release of adhesive bands, straightening of tortuous ureters, and shortening of superfluous ureter length.

The major strengths of our study include the large sample size, analysis of renal function for a diverse population, and application of GAMM with curve-fitting analysis. The retrospective data are limited by selection bias, loss to follow-up, and missing data. In addition, serum creatinine measurements can vary for patients because of factors such as diet and muscle breakdown. Owing to technology and cost limitations, some of the patients in our study did not undergo repeat nephrography examinations, which is an issue. The absence of a comparison between AC and AUEC is probably another limitation of the study, and further comparative studies are necessary to validate the protective role of the two methods in a similar population.

5. Conclusions

Our results confirm that for most patients, AUEC improved renal function, which then remained stable during long-term follow-up. Moreover, AUEC did not hasten the deterioration of renal function in patients with renal insufficiency.

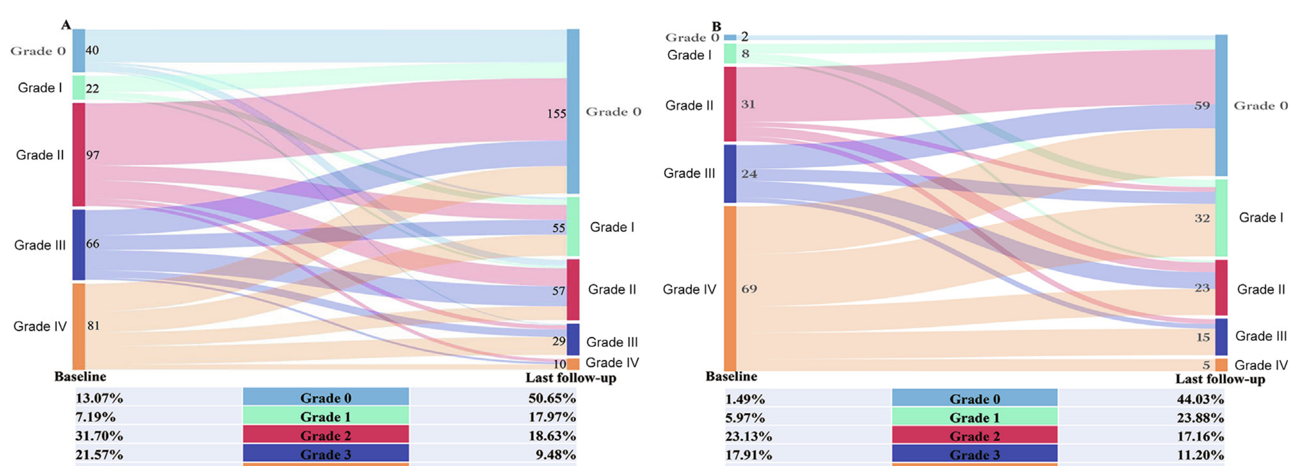


Fig. 3 – Sankey diagram of the grade distribution for upper urinary tract dilation in the groups with (A) normal renal function and (B) renal dysfunction.

Table 3 – Comparison of urodynamic findings at baseline before surgery and at the last follow-up visit

Parameter [a]	Normal renal function		Renal dysfunction	
	Baseline	Last follow-up	Baseline	Last follow-up
MBC (ml)	101.0 (44.0–192.5)	500.0 (450.0–550.0) [b]	82.0 (46.75–191.75)	500.0 (470.0–550.0) [b]
BC (ml/cm H_2O)	6.55 (3.13–12.81)	42.38 (33.31–58.75) [b]	5.64 (3.31–9.28)	44.73 (34.25–60.25) [b]
MDP (cm H_2O)	32.0 (16.0–48.0)	9.0 (6.0–15.0) [c]	34.5 (18.0–50.25)	10.5 (7.75-13.0) [c]

MBC = maximal bladder capacity; BC = bladder compliance; MDP = maximal detrusor pressure.
[a] Results are presented as the median (interquartile range).
[b] Significant improvement in comparison to baseline ($p < 0.01$).
[c] Significant decrease in comparison to baseline ($p < 0.01$) at the last follow-up.

AUEC can provide an optimal low-pressure urinary storage capsule to stabilize renal function in preparation for renal transplantation in the future.

In conclusion, AUEC is considered a safe and effective treatment for refractory LUT dysfunction and will not aggravate deterioration of renal function in patients with RD. It should be noted, however, that AUEC does not reverse renal insufficiency, although it can improve and maintain renal function.

Author contributions: Limin Liao had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Liao.
Acquisition of data: Wang, Zhou, Zhang, Li.
Analysis and interpretation of data: Wang, Zhou.
Drafting of the manuscript: Wang.
Critical revision of the manuscript for important intellectual content: Wang, Zhou, Liao.
Statistical analysis: Wang, Zhou.
Obtaining funding: Liao.
Administrative, technical, or material support: Liao.
Supervision: Liao.
Other: None.

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Ethics approval: This retrospective study was approved by the Ethics Committee of the China Rehabilitation Research Centre (reference 2017-003-1).

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