Original Article

Renal transplantation into optimized abnormal lower urinary tract – Impact on graft outcomes, patient survival, and complications

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ABSTRACT

Introduction: Literature regarding the outcomes of renal transplant in patients with abnormal lower urinary tracts (LUTs) is conflicting. The study aimed to determine the graft outcomes and complications of renal transplantation in an optimized abnormal LUT as compared to those with a normal LUT.

Materials and Methods: In this single-center retrospective-matched cohort study, we identified 31 patients with an optimized abnormal LUT in our transplant database between 2006 and 2016 (Group A) and selected an equal number of matched controls (Group B). The primary outcome was graft survival, and secondary outcomes were overall survival and complications.

Results: The median age was 24 years (range: 12–45), and the median duration of follow-up was 36 months in both groups. On Kaplan–Meier analysis, the estimated mean graft survival was 106 months (confidence interval [CI]: 91-120) in Group A versus 128 months (CI:117-139) in Group B ($P = 0.47$, log-rank analysis). On subgroup analysis of Group A, augmented bladders had the poorest mean survival (81 months, CI: 56–106), $P = 0.09$). The mean estimated patient survival was comparable between Group A and B (109 months, CI: 96–122 versus 139 months, CI: 134–144), $P = 0.13$). Infective complications (27 episodes vs. 1) and re-admissions (77 vs. 30) were significantly higher in Group A ($P = 0.04$ and $P < 0.01$). Clean intermittent catheterization was a risk factor for infections (63% vs. 37%, $P = 0.033$, odds ratio: 5).

Conclusions: The graft and overall survival was comparable at 3 years in both groups. Infective complications were higher in Group A.

INTRODUCTION

An abnormal lower urinary tract (LUT) is the cause for end-stage renal disease in up to 15% of adults and 20%–30% of the pediatric population.[1] The LUT may be abnormal due to neuro-vesical dysfunction, bladder outlet obstruction, posterior urethral valve (PUV), urethral stricture, or acquired bladder disease. The transplanted renal kidney is likely to have the same fate as the native kidney in patients with an untreated abnormal LUT. How safe is it to do a renal transplant in patients with a treated abnormal LUT is a matter of debate. Some investigators contend that despite treatment for an abnormal urinary tract, these patients are suboptimal candidates for renal transplantation;[2] on the other hand, others have reported patient and graft survival similar to that of the general transplant population, but with a higher incidence of infections.[3-6] In a country like India, where transplantation is self-financed and largely living

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donor-driven, and patients are exposed to a highly infectious milieu, (making infections the most common cause of mortality rather than malignancy[7]) a realistic assessment of posttransplant outcomes is necessary to aid clinicians in the clinical management and prognostication of this patient group in the Indian subcontinent.

In order to test our hypothesis that increased infectious complications in these optimized LUT patients leads to higher incidence of graft dysfunction and mortality in Indian setting, we compared the graft survival, patient survival and complications in patients with an optimized abnormal LUT (Group A) with matched controls having normal LUTs (Group B) at a single center in India.

MATERIALS AND METHODS

This retrospective cohort study compared the outcomes of renal transplantation in patients with an optimized abnormal LUT to a control group of patients matched for age, sex, and transferred estimated glomerular filtration rate, (eGFR) at a single tertiary center.

Definitions

Patients in the abnormal LUT group were categorized as follows:

1. Abnormal bladders (small capacity, poorly compliant, thick-walled with or without reflux, augmented, or native bladders) on clean intermittent self-catheterization (CISC)
2. Abnormal native bladders not on CISC
3. Urinary diversion (ileal conduit)
4. Urethral stricture (posturethroplasty; pre- or post-renal transplantation).

Patient selection

From our renal transplant database, we selected patients with an abnormal LUT as defined above (Group A) who were transplanted between January 1st, 2006, and December 31st, 2016. Group B consisted of patients with a normal urinary tract who underwent a renal transplant in the same period and were matched for age, sex, and transferred eGFR and selected by stratified random sampling. In order to determine transferred eGFR, we measured the split function of the donor kidneys by Tc-99 m diethylenetriaminepentaacetic acid renal scintigraphy using Gates protocol,[8] and calculated the total donor eGFR using the chronic kidney disease epidemiology creatinine 2009 equation.[9] We then calculated the percentage of eGFR likely to have been transferred to the patient by the donor kidney based on the percentage split function of the transplanted kidney.

The primary outcome was a comparison of graft survival in Group A and Group B. Graft survival was defined as the time interval between the date of renal transplant and the documentation of eGFR <15 mL/min/1.73 m^2.

The secondary outcomes were a comparison of patient survival and complications between Group A and Group B:

1. Patient survival was defined as the time from renal transplant to death from any cause
2. Complications included:
   - Infective complications (pyelonephritis, epididymo-orchitis, wound infection)
   - Surgical complications (urinary leak, arterial/venous graft vessel thrombosis)
   - Rejection (biopsy-proven acute cellular rejection, acute antibody-mediated rejection, and chronic rejection).

The study was approved by the Institutional Review Board and Ethics Committee of our institution (Ethics Committee approval number: 11148 dated January 24, 2018).

Statistical analysis

Data were entered using EpiData software version 2.0.8.56 (EpiData Association, Odense, Denmark) and screened for outliers and extreme values using Box-Cox plot and histogram. Association between variables was reported using Chi-square/Fisher's exact test as appropriate. Graft survival was reported using Kaplan–Meier curves and comparison of survival curves between the normal and the abnormal LUT groups was done using Log Rank (Mantel-Cox) analysis.

Post hoc analysis

The trend of e-GFR at 1 month, 1 year, and 3 years was studied and reported using generalized estimating equation. $P < 0.05$ was considered statistically significant. The association of infective complications with CISC, persistent vesicoureteral reflux (VUR), and augmented bladder was checked using odds ratio (OR). All analysis was done using Statistical Package for Social Sciences version 16.0 (SPSS Inc., Chicago, IL, USA).

Preoperative evaluation and operative protocol for patients with abnormal lower urinary tracts undergoing renal transplant

All prospective kidney transplant recipients at the study institution underwent an assessment comprising a detailed clinical history, physical examination, and investigations that included urine culture and abdominal sonography. In addition, patients with an abnormal LUT underwent micturating cystourethrogram, uroflow, and pressure flow studies (except in patients with stricture urethra).

Patients with an abnormal bladder with poor compliance on filling cystometry were treated with anticholinergics, CISC or augmentation cystoplasty or ileal conduit as clinically indicated and subjected to renal transplant once they were documented to have normal bladder compliance after treatment. In our study, all bladder augmentation was done before renal transplant (median time duration of 36 months, range: 6 weeks–16 years). As per institutional

protocol, patients with a compliant reservoir and an easily catheterizable passage were considered to have safe LUTs for renal transplant.

Patients with a stricture urethra underwent substitution urethroplasty pre- or post-transplant. Patients with bladder outlet obstruction due to primary bladder neck obstruction were taken up for transurethral incision of prostate 3–6 weeks after renal transplant. Patients who had symptomatic bilateral vesicoureteric reflux with recurrent urinary tract infection (UTI) underwent pretransplant nephrectomy.

Renal transplant technique

Patients underwent right/left iliac fossa transplantation. The renal vein was anastomosed end to side to the external iliac vein and the renal artery to the external iliac (end to side) or internal iliac artery (end-to-end). The ureter was anastomosed to the bladder by an extra-vesical (Roy Calne's) technique. Routine ureteric stenting was not done. Patients with an ileal conduit underwent uretro-ileal anastomosis by Bricker's technique.

Technique for ureteric re-implant in augmented bladders

Seven patients underwent Roy Calne's extravesical re-implantation. Two patients underwent ileocolonic re-implant by Goodwin's technique, while one patient underwent a ureteroureterostomy (second transplant) and another Politano-Leadbetter method of re-implantation.[10-12]

Follow-up protocol

Patients follow-up in a dedicated transplant clinic thrice weekly for the first 2 months, twice weekly from months 3 to 4, and once weekly from months 5 to 6. Thereafter, they follow-up once in 3 months for the remainder of the 1st year, once in 6 months for the 2nd year, and once yearly thereafter.

RESULTS

Patient characteristics

There were 923 patients who underwent renal transplants during the studyperiod. Group A (optimized abnormal LUT) consisted of 31 patients who had received 32 renal transplants. There were an equal number of controls (renal units) (n = 32) matched for age, sex, and transferred eGFR (Group B). The median age of the study population was 24 years (range: 12–45), and the median duration of follow-up was 36 months in both groups. All patients in Group B underwent living donor-related transplant compared to 94% in Group A. The majority of patients in Group A had a neurogenic bladder (25%) or PUV (25%) as the primary cause of obstructive uropathy. The other causes for an abnormal LUT were: stricture urethra (21%), dysfunctional voiding (10%), postradical cystectomy and urinary TB (6%), and bladder outlet obstruction (13%). In Group B, the etiology of native kidney disease was unknown in 96% of the patients because kidneys were not amenable for biopsy at the time of presentation. The two groups were comparable in terms of age, sex, transferred eGFR, and donor's age [Table 1].

Surgical interventions done to make the lower urinary tract safe before transplantation:

In order to make the bladder safe and the lower tract suitable for renal transplantation, patients in the study group underwent reconstructive procedures such as augmentation cystoplasty (11) (ileocystoplasty [8], colocystoplasty [2], ureterocystoplasty [1]), Ileal conduit (3), bladder neck incision (4), and substitution urethroplasty (7). Twelve patients underwent a pretransplant nephrectomy for symptomatic VUR [Appendix Table 1].

Graft function and survival

The median duration of follow-up was 36 months in both groups. On Kaplan–Meier survival analysis, median graft survival was not reached; however, the estimated mean graft survival was 106 months (95% confidence interval [CI]: 91–120) in Group A versus 128 months (95% CI: 117–139) in Group B. However, on log-rank analysis, this difference was not statistically significant [P = 0.47, Appendix Figure 1].

There was no significant difference in graft survival between the subgroups of Group A, though the augmented bladder group showed a trend toward poorer graft survival [mean estimated graft survival in augmented bladders was 81 months, 95% CI: 56–106 months vs. other abnormal LUT subgroups, for whom it was 116 months, 95% CI: 105–127, P = 0.09, Appendix Figures 2 and 3].

Overall survival

The mean estimated overall survival between the groups was comparable (109 months, 95% CI: 96–126 vs. 139 months, CI: 124–144, P = 0.13) [Appendix Figure 4].

Table 1: Patient characteristics

Patient characteristics	Abnormal lower urinary tract (Group A, n=32)	Normal lower urinary tract (Group B, n=32)
Median age of the recipient in years (range)	24 (12-45)	25 (14-43)
Sex ratio (male: female)	25:7	25:7
Median transferred eGFR (ml/min/1.73 m^2)	52 (34-83)	53 (33-74)
Median donor age (years)	41 (23-60)	42 (20-64)
Live/deceased donor	30:2	32:0
Pretransplant UTI (%)	20 (62)	0

eGFR=Estimated glomerular filtration rate, UTI=Urinary tract infection

Postoperative complications

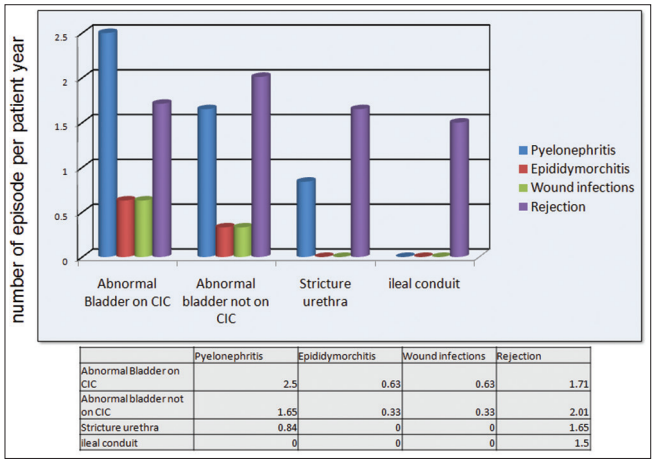
Infective complications (wound infections: 4 vs. 1, pyelonephritis: 19 vs. 0 episodes and epididymo-orchitis: 4 vs. 0 episodes, $P = 0.04$), and re-admission rate (number of hospital admissions divided by number of patients at risk, 2.4 vs. 0.9, $P < 0.01$) were significantly higher in Group A. Of the pyelonephritic episodes, 64% were caused by extended-spectrum beta-lactamase (ESBL) producing organisms and 10% by carbapenem-resistant organisms (CRO). The biopsy-proven rejection rate was comparable (25% vs. 19%) in both groups [Table 2].

In Group A, patients with an abnormal bladder on CISC had a higher rate of infective complications (OR: 5, $P = 0.03$), while patients who received an ileal conduit had the least complications [Figure 1 and Table 3].

Post hoc analysis

Graft function at follow-up

The median eGFR at 1 and 3 years in Group A was 96 and 71 ml/min/1.73 m^2, respectively and in Group B was 80 and 74 ml/min/1.73 m^2, respectively ($P = 0.13$). There was a trend toward a steeper fall in GFR beyond 1 year in Group A which could translate into poorer graft survival in the long term [Figure 2]. All study patients who are alive are under regular follow-up with us as per protocol. There is no loss to follow-up.



	Pyelonephritis	Epididymorchitis	Wound infections	Rejection
Abnormal Bladder on CIC	2.5	0.63	0.63	1.71
Abnormal bladder not on CIC	1.65	0.33	0.33	2.01
Stricture urethra	0.84	0	0	1.65
ileal conduit	0	0	0	1.5

Figure 1: Complications and readmission rate in the abnormal lower urinary tract, a subgroup analysis. CIC-Clean intermittent catheterization, LUT-lower urinary tract

Clean intermittent self-catheterization through Mitrofanoff versus native urethra

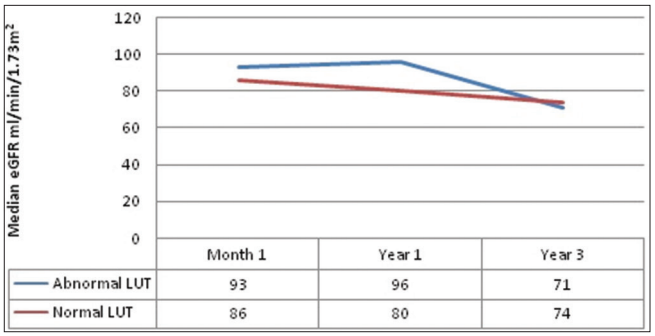
Did it make a difference to the infective complication? In our study population, the incidence of pyelonephritis in those performing CISC through a Mitrofanoff was 75% (3/4), while patients on CISC through a normal urethra were 60% (6/10). Patients performing CISC through normal urethra also had 4 episodes of epididymorchitis.

DISCUSSION

The majority of the data from higher-income countries suggest equivalent graft outcomes in patients undergoing renal transplantation after optimizing an abnormal urinary tract as compared to those with normal LUT.[5,13-15] However, some studies show an increase in the incidence of infectious complications in optimized abnormal LUT group.[6,16,17]

We compared the results of our study with other comparative cohort studies which included patients with an optimized abnormal LUT and matched controls undergoing renal transplant[5,6,16-18] [Appendix Table 2].

Our study included patients in the second to fifth decades of life, most of the other studies have included the pediatric



	Month 1	Year 1	Year 3
Abnormal LUT	93	96	71
Normal LUT	86	80	74

Figure 2: Comparison of estimated glomerular filtration rate between the study and control groups. LUT-lower urinary tract

Table 2: Overall complications

Complication	Abnormal LUT (Group A, *n*=32) *n* (%)	Normal LUT (Group B, *n*=32) *n* (%)	*P*
Surgical			
Urinary leak	0	0	-
Postoperative hemorrhage	0	1 (3)	-
Graft thrombosis	0	1 (3)	-
Infective			
Wound infection	4 (12.5)	1 (3)	0.04
Pyelonephritis (number of episodes)	19	0	
Epididymo-orchitis (number of episodes)	4	0	
Re-admissions n (rate)	77 (2.4)	30 (0.9)	<0.01
Biopsy proven rejection episodes (acute cellular and antibody mediated)	8 (25)	6 (19)	0.12

LUT=Lower urinary tract

Table 3: Infective complications in abnormal bladder on clean intermittent self-catheterization versus the other abnormal lower urinary tract subgroups

Abnormal LUT (*n*=32)	Infective complications		OR
	Yes	No	
On CISC	10	4	5
Normal voiding	6	12	

OR=Odds ratio, CISC=Clean intermittent self-catheterization, LUT=Lower urinary tract

population except a study by Neild *et al.*[5] The underlying etiology of the abnormal urinary tract has a bearing on renal transplant outcomes. Patients with VUR without a history of any UTI or treated bladder outlet obstruction have a better outcome compared to patients with poorly compliant, overactive bladder with sphincter dysynergia in case of neurovesical dysfunction. As in other studies,[5,6,16,17] PUV and neurogenic bladder were the most common underlying etiologies of abnormal LUT in our study. Other studies[3,6] also included stricture urethra and other causes of bladder neck obstruction.

The median duration of follow-up in our study was 3 years, whereas, in other studies, it varied from 3 to 7.5 years. Comparison in terms of graft and overall survival is only possible if, graft or overall survival is reported as estimated mean/median survival using survival curves and not actual survival calculated as proportions at various time frames.

Two comparative studies by Neild *et al.*[5] from Europe and Traxel *et al.*[18] from the USA found a similar infective complication rate between the optimized abnormal and normal urinary tract groups and infections did not contribute to graft loss. However, studies from the developing countries showed contrary results. Aki *et al.*[16] from Turkey, Basiri *et al.*[17] from Iran, Saad *et al.*[6] and Ali-El-Dein[19] from Egypt, showed that there was a higher rate of infective complications in patients with an abnormal urinary tract.

In the present study, the optimized abnormal LUT group had higher infective complications with significantly higher re-admissions. Patients who were on CISC had a five times higher risk of developing infective complications. In a subgroup analysis, the augmented bladders had a higher rate of infective complications and a trend toward poorer graft survival compared to the other abnormal LUT groups. This can be a reflection of the highly infectious milieu that patients are exposed to in lower-income countries. Persistent reflux and recurrent pyelonephritis were a direct cause of graft loss and mortality in one patient, in our study. The similar suggestions have been made by another group in Indian setting.[20]

Hatch *et al.*[21] compared outcomes of renal transplantation between urinary diversion and augmented bladders. He showed no difference in graft outcomes and comparable infection rates. Rigamonti from Italy also compared renal transplantation into urinary diversion versus augmented bladders and showed similar infection rates.[19] However, in the present study, we noted that patients with a urinary diversion (ileal conduit) had fewer infective complications as compared to augmented bladders. On analysis, we could attribute this discrepancy to the fact that, the augmented group in our study had higher infective complications as compared to other two studies mentioned above.[21,19] CISC was an added factor for increased infective complications in the augmented bladder group. CISC introduces bacteria into a reservoir which is lined by intestinal mucosa, which unlike urothelium, is unable to provide an effective barrier against bacterial translocation into the bloodstream.[22] In addition, 74% of all pyelonephritic episodes were caused by drug-resistant bacteria (ESBL producing organism or CRO). Infections caused by drug-resistant organisms are not only more severe but result in higher re-admissions, prolonged hospital stay and spiraling costs – all important considerations in a resource-poor setting.

Thus, urinary diversion may offer a safer option as compared to bladder augmentation and CISC in a resource-poor country, in terms of reducing postoperative infections, treatment costs and a possibly better graft function in long-term, in those patients in whom both the treatment modalities are acceptable options, according to our study results.

Thus, transplantation in an optimized abnormal LUT in this setting requires specialized care and efforts to reduce infective complications. Neild *et al.*[5] suggested the use of prophylactic antibiotics for the first 6 months to reduce the incidence of UTI. Our cohort of patients, especially the group with augmented bladders was also started on prophylactic antibiotics. One patient had recurrent epididymorchitis (3 episodes) in the augmented bladder group and subsequently was started on CISC with a sterile catheter for each use and cyclical antibiotic prophylaxis. This resulted in resolution of symptoms at 2-year follow-up.

Comparative retrospective cohort studies by Neild *et al.*[5] from Europe, Saad *et al.*[6] from Egypt and Traxel *et al.*[18] from the USA showed no difference in graft survival between the two groups at 10 years. Studies from other developing countries differed in their results. However, Aki *et al.*[16] from Turkey showed that at a median follow-up of 13 years, the graft survival was 10% lower in the optimized abnormal LUT group. In a similar study from Iran by Basiri *et al.*,[17] the graft survival was poorer in the patients with an abnormal LUT (66% vs. 80%). These studies cannot be compared as they reported survival at varying durations of follow-up rather than actuarial survival (using Kaplan–Meier estimates).

In the current study, the mean estimated graft survival and overall survival in the group with an abnormal urinary

tract was similar to the control group though there was a trend toward poorer graft survival in the abnormal LUT group. There was a steeper fall in the eGFR beyond 1 year in the study group which could translate into a poorer graft survival on longer follow-up. This finding was also demonstrated by Neild *et al*.[5] They showed that there was no difference in graft survival between the two groups at 10 years, although the graft survival was better for normal bladders at a longer follow-up.

The limitations of the study are that it was a retrospective cohort study and the follow-up was not long enough to highlight differences between the two groups in terms of graft survival. The strengths of the study were that the study group was compared with matched controls and the follow-up was complete. Hence, at intermediate-term follow-up, patients with optimized abnormal LUT undergoing renal transplantation have similar graft and overall survival. However, they have higher infective complications, higher costs of treatment, higher number of readmissions, and a trend toward poorer graft survival in the long-term. These observations can be used to manage and prognosticate the renal transplant recipients with optimized abnormal LUT in Indian setting.

CONCLUSIONS

The graft and overall patient survival in patients with an abnormal LUT were comparable to those with a normal LUT at a median follow-up of 36 months. Augmented bladder showed a trend toward lower graft survival which is associated with higher rates of infective complications. CISC was a risk factor for infective complications.

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Conflicts of interest
There are no conflicts of interest.

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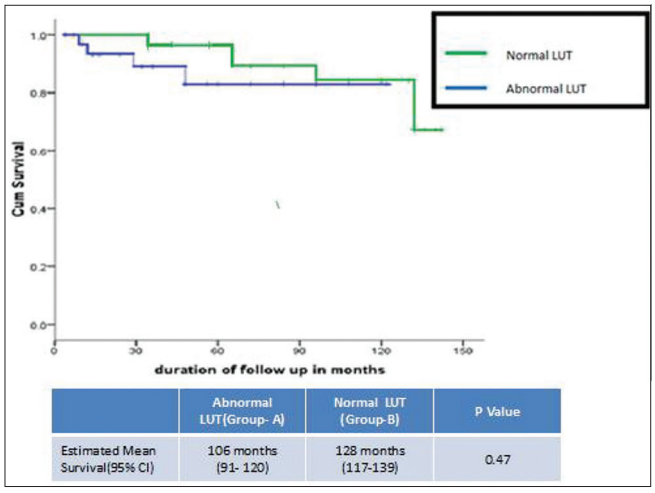
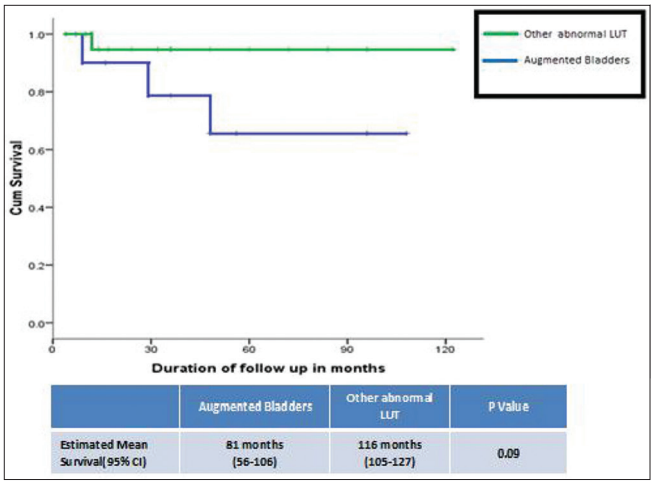
APPENDIX



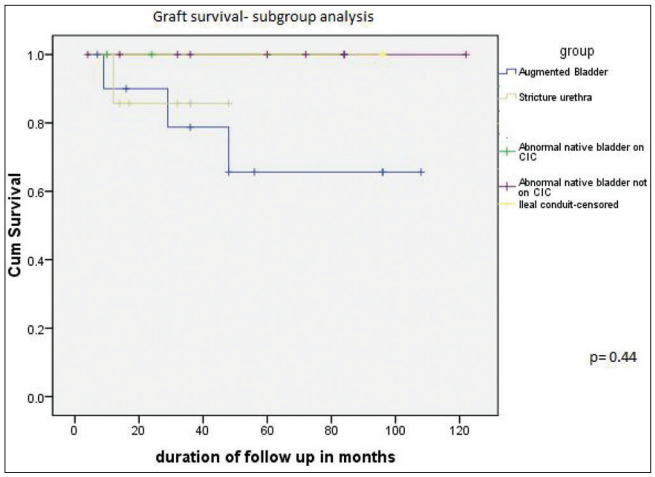
	Abnormal LUT(Group- A)	Normal LUT (Group-B)	P Value
Estimated Mean Survival(95% CI)	106 months (91- 120)	128 months (117-139)	0.47

Appendix Figure 1: Kaplan–Meier curve showing the graft survival between the study and control groups. Cum survival-cumulative survival, LUT-lower urinary tract

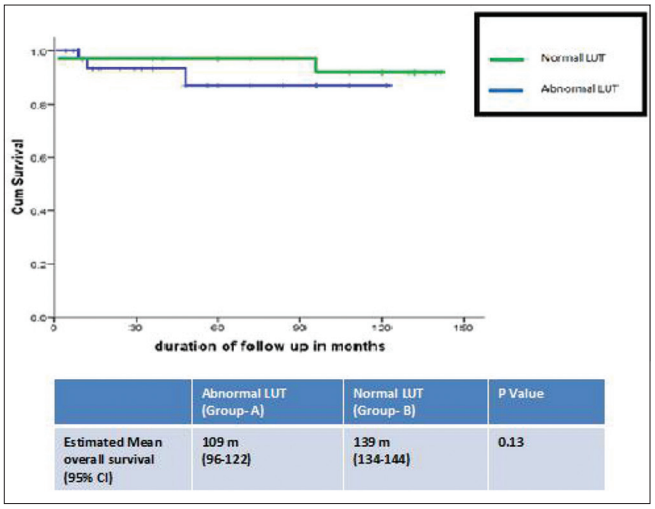


	Augmented Bladders	Other abnormal LUT	P Value
Estimated Mean Survival(95% CI)	81 months (56-106)	116 months (105-127)	0.09

Appendix Figure 2: Graft survival in augmented bladders versus other abnormal lower urinary tract. Cum survival-cumulative survival, LUT-lower urinary tract



Appendix Figure 3: Graft survival–subgroup analysis. Cum survival-cumulative survival, LUT-lower urinary tract, CIC – clean intermittent catheterisation



	Abnormal LUT (Group- A)	Normal LUT (Group- B)	P Value
Estimated Mean overall survival (95% CI)	109 m (96-122)	139 m (134-144)	0.13

Appendix Figure 4: Kaplan–Meier curve showing the overall survival between the Abnormal and normal LUT. Cum survival-cumulative survival, LUT-lower urinary tract

Appendix Table 1: Preoperative surgical interventions in the abnormal urinary tract

Group A Pretransplant procedures	Abnormal bladders on CISC (*n*=14)	Abnormal bladders not on CISC (*n*=8)	Urinary diversion (*n*=3)	Stricture urethra (*n*=7)
Augmentation cystoplasty	14	0	0	0
Ileal conduit	0	0	3	0
Pretransplant nephrectomy	9	1	2	0
EIU	0	0	0	1
Substitution urethroplasty	0	0	0	6

EIU=Endoscopic internal urethrotomy, CISC=Clean intermittent self-catheterization

Appendix Table 2: Comparison of graft, patient survival, and infective complications between other comparative cohort studies

Patient characteristics and outcomes	Neild 2004	Basiri 2007	Traxel 2007	Aki KT 2015	Saad 2016	Present study 2018
Place	UK	Iran	Ohio	Turkey	Egypt	India
Number in the study group	73	43	17	25	29	32
Mean (SD)/median age (years)	32	13.2±2.2	6.4 (2-20.5)	13 (10-17)	5(+/-12.5)	24 (12-45)
Most common Etiologies	PUV Neurogenic bladder	Neurogenic Bladder PUV	Neurogenic bladder PUV Voiding dysfunction	Neurogenic bladder PUV	PUV VUR Neurogenic bladder	Neurogenic bladder PUV
Median follow up (months)	86	36	90	63	54	36
Primary outcome: Actual/ estimated graft survival	66% versus 61%	66% versus 80%	NA	76% versus 89%	93% versus 91%	Est mean graft survival 106 versus 128 months
Secondary outcome: Actuarial/ mean estimated overall survival	86%	NA	NA	NA	NA	109 versus 139 months
Infective complication (%/rate)	33% versus 31%	15% versus 3%	0.22 versus 0.28 infection/patients year	15% versus 3%	24% versus 12%	27 versus 1 episodes

SD=Standard deviation, PUV=Posterior urethral valve, VUR=Vesicoureteral reflux, NA=Not available