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CLINICAL OUTCOMES OF PRIMARY VALVE ABLATION VERSUS URINARY DIVERSION IN INFANTS WITH POSTERIOR URETHRAL VALVES: A PROSPECTIVE COHORT STUDY

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ABSTRACT

BACKGROUND: Posterior urethral valves (PUV) are a major cause of lower urinary tract obstruction in male infants, leading to significant morbidity. Primary valve ablation (PVA) and urinary diversion (UD) are commonly used interventions depending on disease severity and clinical stability.

OBJECTIVE: : To compare the short-term clinical outcomes of PVA versus UD in male infants aged ≤1 year with PUV.

METHODOLOGY: :A prospective cohort study was conducted including 110 infants equally allocated to PVA (n=55) and UD (n=55). Outcomes were assessed at a 3-month follow-up and included recurrent urinary tract infections (UTIs), glomerular filtration rate (GFR), serum creatinine, albumin excretion, and proteinuria.

RESULTS: Mean age of participants was 6.89±3.07 months, albumin excretion 24.50±10.13 mg/day, and GFR 76.46±18.34/ml/min/1.73m2. Duration of surgery in PVA was 25.40±5.47 and 129.94±18.44 minutes in UD. Recurrent UTIs were reported in 19.1% of all the participants. In the PVA group, slow stream was reported in 32%, straining in 14% and Urine dribbling in 21% of participants. The UD group reported an OR of 2.22 times higher risk of recurrent UTIs at follow-up. GFR (P<0.001), Albumin excretion (P<0.001), creatinine level (P=0.009), UTIs (P=0.04) and proteinuria (P=0.01) were significant. Albumin excretion r=-0.288, P=0.002, and GFR r=-0.346, P<0.001 had a significant association with child age.

CONCLUSION; Albumin excretion, Glumerular filtration rate, creatinine and proteinuria were improved in both groups, without a significant difference between groups. Recurrent UTIs were reported two times higher in the UD group. Prognosis cannot be determined at short follow-up. The study limitation was a short follow-up, a single-centre investigation and a lower sample size.

KEYWORDS: :Posterior urethral valves, primary valve ablation, urinary diversion, proteinuria, chronic kidney disease, pediatric urology

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INTRODUCTION

Posterior urethral valves (PUV) are a congenital condition affecting the male urinary tract and characterised by membranous folds in the posterior urethra. PUVs are categorised as Type I as plicae colliculi, Type II as bicuspid leaflets and Type III situated at the caudal verumontanum.[1] It is the most common cause of lower urinary tract obstruction in paediatric male patients associated with congenital causes. It can lead to urinary tract infections, poor urine stream, urine dribbling, and, in severe cases, unilateral or bilateral renal damage.[2] Lower urinary tract obstruction is one of the most common cause of obstruction in new-borns and infants, and its prevelance ranges as 1 in 5,000 to 1 in 25,000 pregnancies, while 40% of such infants are affected by Chronic Kidney Diseases (CKDs).[3,4] Delay in the treatment or not treating at all, PUVs can lead to life-threatening complications like kidney damage and renal failure before adulthood. Thus, crucial care and management are required to alleviate clinical symptoms and improve the Quality of life.[5] Management interventions for PUV include valve Ablation and vesicostomy, depending on the severity of the condition and age of the child.[6] interventions in PUV are proposed to preserve long-term bladder and renal functions, while the empirical evidence has reported varied significance and clinical significance of different treatment interventions.[7] Some studies have suggested the beneficence of vesicostomy, while other studies conclude no definitive difference between vesicostomy and Ablation procedures.[5,7]

PVA is a surgical procedure carried out through a cystoscope and incision of the urethral valves, and relieves the urethral obstruction. The minimally invasive technique aims to restore kidney function and prevent long-term complications in children with PUV. If PVA is not applicable due to the low age of the child or other complications, vesicostomy may be recommended as a temporary option, by developing an opening in the bladder.[6,9] Thus, urinary diversion is performed for the short term.[10] It has been estimated that 1/3rd of boys with PUV develop end-stage renal disease (ESRD) and require eventual dialysis or renal transplant.[11,12]

The decision about the initial surgical intervention is often multifactorial and is both surgeon- and institution-dependent. The overall goal is decompression of the bladder and upper

tracts.[13] Urinary diversion can be performed in several ways, including bladder catheterisation, cystostomy, nephrostomy, ureteral stent, urostomy and continent urinary diversion. Thus, studies have evaluated the effectiveness of progressive urethral dilation (PUD) in children with PUVs, before application of PVA, but the findings vary; some studies reported PUD as non-significant and non-consistent with urinary outcomes when applied before PVA, while other studies considered and reported its several limitations.[14]

The systematic review concluded increased renal insufficiency with primary diversion, although in longer followup no significant difference was found in PUV and UD.[12] Thus the 4.8 years follow up did not found any significant association in outcomes related to end stage renal disease.[15] In the same way the matched study of UD versus PVA did not found any defunctionalisation of bladder, considered as a myth to be associated with UD.[16] Based on the literature evidence, the current study has tried to evaluate if any differences in the outcomes of PVA versus UD can be addressed in treatment of posterior urethral valves.

The current study aimed to compare the effectiveness of primary valve Ablation (PVA) versus urinary Diversion (UD) in boys with posterior urethral valves (PUV) under the age of one year reporting to Khyber Teaching Hospital (KTH), Peshawar. The study hypothesised that there is a significant difference in surgical outcomes of PVA and UD in paediatric patients less than one year old, determined by the predictors of chronic kidney disease

METHODOLOGY:

The study was conducted at the department of Urology, from February 2025 to September 2025, recruiting n=110 boys under the age of 01 year. Sample size was calculated with a 95% confidence level; reference values of chronic kidney disease (CKD) prevalence of 60% in UD and 33% in PVA groups.[17] The study power was 80%, resulting in n=55 children in each group of UD and PVA. Children reporting to the Urology Outpatients Department of KTH were assessed and advised to undergo further laboratory and radiographic investigations, if required. The consultants on duty recommended PVA or UD as an intervention based on the clinical signs and symptoms, and Patients' prognostic needs. Patients were non-randomly allocated to one of the treatment groups. PVA was advised for infants with stable renal function, having a good response to initial drainage, and in the absence of sepsis or severe infection. UD was advised to patients with severe renal dysfunction, poor drainage, and a history of recurrent urinary tract infections. Infants were enrolled in the study through verbal and written consent of the parents and caregivers, following the Declaration of Helsinki guidelines. Inclusion criteria were under the age of one year, male gender, diagnosed with PUV through hospital reports and consultant confirmation and being advised to one of the procedure groups of PVA or UD. Patients were excluded from the study with renal failure, sigmoid diverticulosis and completed or planned radiotherapy sessions. Thus, children with comorbidities and an anal sphincter were also excluded, as such conditions may aggravate the renal and urethral symptoms and. can lead to confounding bias in the outcomes.

Patients were followed up periodically for three months post-intervention, and outcomes were recorded and assessed after completion. The Questionnaire included number of UTIs reported after discharge, and during three months of followup after the procedure. Symptoms of voiding dysfunction were assessed and reported from patients in the PVA group, while serum albumin and Glomerular Filtration Rate (GFR), creatinine levels and proteinuria were recorded from laboratory reports for all the infants. Referring to empirical evidence, the presence and absence of CKD were determined by Albumin-to-Creatinine Ratio of >30mg/day and GFR <60/ml/min1.73m^2 consecutively for more than three months. The recurrent UTI was determined by the presence of 50,000 colony-forming units (CFUs) per ml of Uropathogenic microorganisms from quantitative culture reported on more than one occasion during the study period. The voiding dysfunction in children with PVA procedure was assessed through subjective history taken from the parents, which included a history of slow stream of urine, splitting or spraying, intermittency, hesitancy, straining or crying on urination and terminal dribble. For the sociodemographic characteristics of the participants, subjective history included area of residence (rural/urban), academic level of parents, and monthly income of the family, categorised as lower, middle income and high income groups. The academic level of parents was categorised as illiterate, primary school education, Secondary school, and qualification level equal to or more than matriculation. Results of the Labs at follow-up visits and data analysis were blinded, and none of the laboratory technicians or the statisticians knew about the treatment groups. The clinicians were not blinded, as patients' treatment group was recommended by doctors on duty.

Data was analysed through Statistical Package for the Social Sciences (SPSS) version 27. Data normality was tested for continuous variables of age, duration of surgery, Albumin excretion, glomerular filtration rates, creatinine and proteinuria levels through the Shapiro-Wilk test. Descriptive statistics were used for all the variables, including patient characteristics, sociodemographic and clinical parameters. Signs of voiding dysfunction were illustrated in figures. For hypothesis testing Mann-Whitney U test was applied. ~~Pearson~~ Spearman correlation was applied to look for linear association between the study variables of age, GFR and Albumin excretion, the level of significance was P<0.05. The Wilcoxon signed-rank test was used as a non-parametric test for creatinine level, proteinuria, GFR. and Albumin excretion. Results of the study have been reported in American Psychological Association (APA) style tables and figures. Footnotes have been provided for the abbreviations used in the tables.

The Prospective cohort study was approved by the Institutional Research and Ethical Review Board (IERB) by letter No.656/DME/KMC on 05/09/2024 at KTH Peshawar.

RESULTS

The mean age of the study participants was 6.89±3.07 months, the minimum age was reported as 2 months, and the maximum was 12. The skewness value of 0.66 and kurtosis of -1.186 showed the data were normally distributed for age, Duration of surgery, mean GFR and Albumin excretion values have been reported in Table 1. Thus, the time duration for the UD surgical procedure was reported to be almost five times more than the PVA. The sociodemographic characteristics of the studied participants, area of residence, family income and academic level of parents have been presented in Table 1.

Table 1: Sociodemographic characteristics and clinical presentation of the study participants

Variables		Mean and SD, Frequency	Frequency (%)
Age		6.89±3.07	110
Albumin Excretion mg/day		24.50±10.13	110
Glomerular Filtration Rate mL/min		76.46±18.34	110
Duration of surgery	PVA	25.40±5.47	55
	UD	129.94±18.44	55
The monthly income of the family	Lower income	67	60.9%
	Middle income	31	28.2%
	High income	12	10.9%
The education status of the father	Illiterate	12	10.9%
	Primary school	43	39.1%
	Secondary school	24	21.8%
	Matriculation or above	31	28.2%
Education Status of Mother	Illiterate	25	22.7%
	Primary school	30	27.3%
	Secondary school	30	27.3%
	Matriculation or above	25	22.7%

Sociodemographic characteristics of the infant's families showed 61% of lower-income families, and 50% of participants as illiterate or had a primary school education.

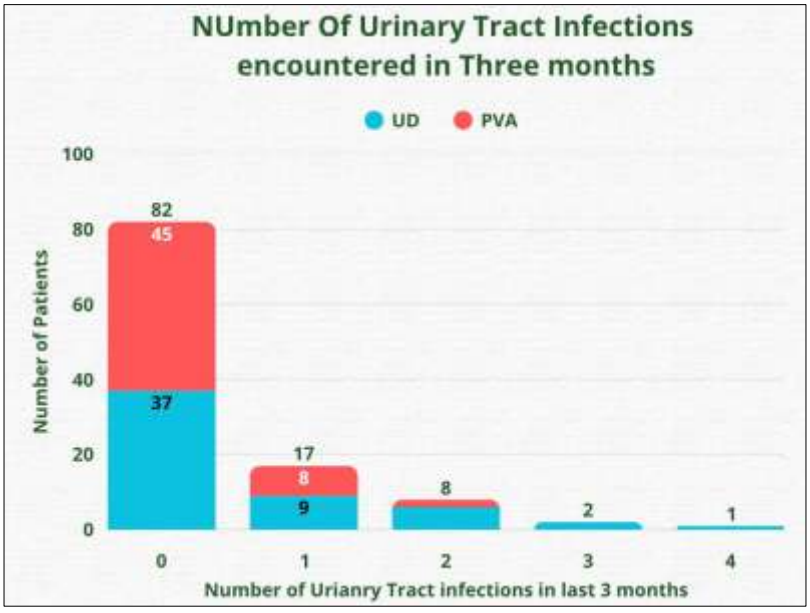

Figure 1: Number of Urinary Tract Infections reported in infants during three three-month study periods

Figure 1 illustrates the frequency of recurrent UTIs reported in infants during the three-month study The total number of positive UTIs was reported as 28 cases, including 10 cases in the PVA and 18 cases in the UD group. Descriptive statistics showed a 14% increase in recurrent UTI cases in the UD group, with a clinically significant difference from the PVA, and the odds of UTI were 2.2 times higher in the UD procedure.

Spearman correlation was applied to examine the association between sociodemographic characteristics and their relationship with CKD determinants, specifically albumin excretion and GFR. Age was found statistically significant with albumin excretion, with P=0.002, and the correlation value was -0.288, a moderate negative correlation, stating that an increase in age was associated with a decrease in albumin excretion. Thus age of the child was also found in a significant moderate positive association with GFR, with P <0.001, and a correlation coefficient of 0.346.

The Chi-square test results showed no significant difference for urine slow stream, P=0.289, urine dribbling, P=0.578 and urine straining, P=0.089, between the two treatment groups. Recurrent UTIs were reported 43.6% in UD and 25.5% of PVA, with a chi-square significant difference of P=0.04.To assess the occurrence of CKD in surgical groups PVA and UD, data normality was evaluated. The Shapiro-Wilk test values were reported as <0.05, thus stating non-normal distribution of data for the four variables of albumin excretion and GFR.

The alternate Hypothesis that there will be a significant difference in the clinical predictors related to CKD in treatment procedures of UD versus PVA group was rejected, and the null hypothesis was retained that showing no significant difference between the treatment procedures.Thus, the Mann-Whitney U test showed no significant difference in values of GFR P=0.487 and albumin excretion P=0.776.

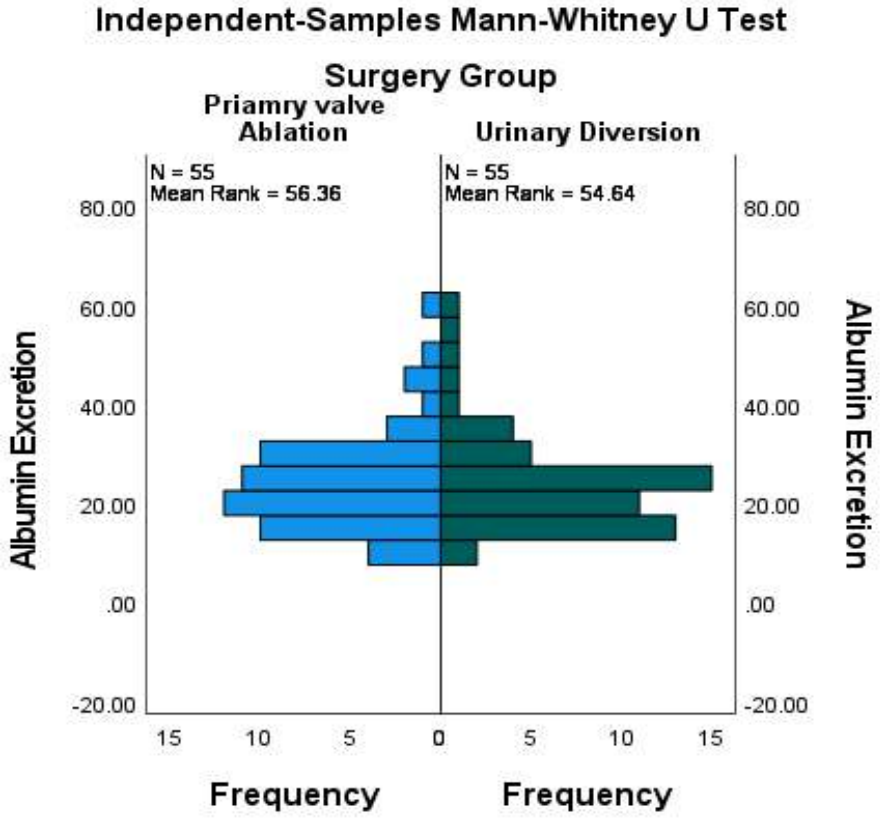

Figure 2: Mann-Whitney U test figure for Albumin excretion

Mean rank for PVA was 56.36 versus 54.64 in the UD group, thus showing no clear descriptive difference, as well the level of significance was P>0.05as illustrated in Figure 2.

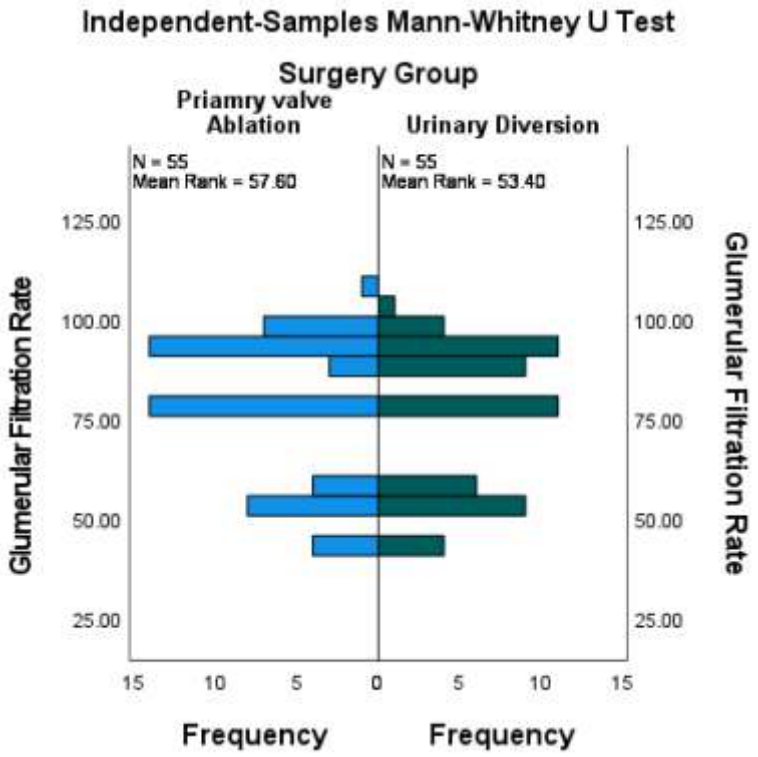

Figure 3: Mann-Whitney U test figure for Glomerular Filtration Rate

Thus, for GFR, the Mean rank value was reported as 57.60 in PVA and 53.40 in the UD group, with no significant difference by level of significance found as P=0.487, as illustrated in Figure 3.

The creatinine level decreased in 50 patients after the procedure, increased in 30 patients, and remained unchanged in 30 patients. The change was statistically significant (P = 0.009) at the 0.05 level, with an effect size of −0.249, indicating a small-to-medium change in mean creatinine levels following the procedure. The Mann–Whitney U test, applied as a non-parametric test to compare the effectiveness of UD and PVA in lowering creatinine levels, showed no significant difference between the two groups (P = 0.920), indicating comparable effectiveness at three-month follow-up.

Similarly, proteinuria decreased in 60 patients, increased in 20 patients, and remained unchanged in 30 patients, with a statistically significant difference observed between pre- and post-procedure values (P < 0.01). However, no significant difference was found between the treatment groups in reducing proteinuria (P = 1.00).

Glomerular filtration rate (GFR) decreased in 15 participants and increased in 95 participants, with no participants showing unchanged values, and this difference was statistically significant (P < 0.001) based on the Wilcoxon signed-rank test, although no significant difference was observed between the two interventions using the Mann–Whitney U test (P = 0.891).

Additionally, mean albumin excretion showed a statistically significant reduction (P < 0.001), with 75 cases reporting decreased levels at three-month follow-up, while 35 cases showed an increase and no cases showed unchanged values; however, no significant difference was observed between the UD and PVA groups in altering albumin excretion levels (P = 0.939).

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Table 2: Comparison table of Urinary diversion and primary valve ablation in the mean differences of chronic kidney disease predictors

Urinary Diversion Group			Primary valve ablation group		
Variables	Renal Parameters before	Renal Parameters after	Renal parameters before	Renal parameters After	Sig
GFR (mg/day)	75.41±18.27	89.20±20.29	77.50±18.51	91.18±21.60	<0.001*
Albumin Excretion /ml/min1.73m²	24.41±10.41	22.63±11.51	24.58±9.93	22.90±10.98	<0.001*
Creatinine (mg/dl)	0.40±0.19	0.32±0.19	0.40±0.20	0.33±0.20	0.009*
Number of UTIs	0.58±0.97	0.11±0.31	0.20±0.44	0.09±0.29	0.04*
Proteinuria (mg/day)	173.45±73.91	120±34.12	181.27±68.25	127±37.39	0.01*

At three months follow-up, findings of the study reported significant differences in GFR (P<0.001), Albumin excretion (P<0.001), Creatinine level (P=0.009), number of UTIs reported (P=0.04), and level of proteinuria (P=0.01) as reported in Table 2.

Results of the current study stated that there was no significant difference between the PVA and UD groups in terms of voiding dysfunction symptoms of urinary slow stream, urine straining, and urine dribbling, although recurrent UTIs were significantly reported in the UD group. The Mann-Whitney test accepted the null-hypothesis that there is no significant difference in terms of the outcomes of PVA and urinary diversion groups and rejected the researcher's hypothesis that the outcomes of PVA versus UD in one-year-old infants may differ in terms of the surgery outcomes of voiding dysfunction and chronic kidney diseases.

DISCUSSION

The study was conducted in infants under the age 01 years, with a mean age of 6.89±3.07 months. Post-treatment clinical parameters significantly improved for GFR (P<0.001), Albumin excretion (P<0.001), Creatinine levels (P=0.009), Number of UTIs (P=0.04) and proteinuria (P < 0.01). There was no significant difference reported for outcomes between the grous, except the UTI reported OR=2.2 times higher risk in the UD group.

Findings of the current study accepted the null hypothesis, and did not report any significant difference in outcomes of PVA versus UD, except the risk of UTI which was found two times higher in infants treated with UD. One of the possible factors is the study duration; previous research studies which have assessed outcomes of PVA or UD, in the treatment of PUV, have been carried out and followed for longer durations. The followup duration has been ranged from six month, three years, and 4.8 years to five years respectively,[15,18–21] as compared to the current study. The Age of the child with PUV by which complication may occur has been reported as 4.9±3.2 years for voiding dysfunction, 5.5 years to 15 years for CKD.

PUVs are a challenge in pediatric urology, with long-lasting impacts on the renal and general health of the child, so it requires immense care from birth to adulthood, to gain better clinical outcomes.[22] It affirms the possibility that complications in PUV may occur with growing age, and the child population of less than

one year old in the current study may not experience such complications at an early age.[23] The straining, dribbling and slow stream of urine have been the common complications addressed by previous studies as well [2, 16]. Thus, empirical evidence has reported the severity of complications in UD as compared to PVA over time. [17] recurrent UTIs have been reported in 54.4% of children with PUV after they were treated, and thus affirming findings of the current study in which 43.6% of UTIs were found in UD and 25.5% in PVA.[2]

Concluding the effectiveness of PVA versus UD, it has been affirmed from the empirical evidence that in short-term goals, UD may result in more complications than PVA, but long-term follow-up has neglected any significant differences.[8]

The current study helped to address the short term outcomes difference within PUV and UD for paediatric patients under the age of one year, although the short follow up duration, and looking for complication within the age group of one year is a limitation, as the empirical evidence has concluded that complications in children with PUV may appear with growing age, thus concluding the effectiveness of a treatment intervention at an early age, and observation of three months may not be feasible.[2,17] Decision of the surgeon and consultant to allocate the patient into a specific treatment group may be considered as a limitation or selection bias, although the study was not a randomised controlled trial, and patient allocation in a treatment group was based on Good Clinical Practice Guidelines. Allocation in treatment groups was based on the patients' benefits from the intervention. Furthermore, the patients were enrolled in the study after their treatment allocation, thus neutralising the risk of the investigator bias as well. However, the risk of confounding by indication persists in the current study, and allocation of patients into treatment groups without a standard approach may have caused allocation of more severe patients into one group compared to the other. While a lower sample size may reduce the generalizability of the findings to wider population groups, as well as the subjective history from parents may have caused recall bias. Future research studies should focus on longitudinal, prospective cohort studies to look for the occurrence of complications related to CKD and voiding dysfunctions in patients treated with PUV, as well as individual patient characteristics and pre-intervention health and morbidities status, which are also important and should be considered. The study can be repeated with an enhanced sample size to look for the mean difference and significance of PVA versus UD, in a diverse population.

CONCLUSION

Posterior urethral valve is a congenital condition affecting boys and is one of the leading causes of urinary tract complications and recurrent urinary tract infections. The findings of the current study did not report a significant difference in the outcomes of PVA versus UD in terms of chronic kidney disease predictors of Glomerular filtration rate, Albumin excretion, Creatinine levels and proteinuria. UTIs were found two times higher in the UD groups as compared to PVA at three months follow-up. Voiding dysfunction, including dribbling, straining, and a slow stream of urine. In contrast, recurrent UTIs were significantly more reported in the UD group, at twice the rate. The alternative hypothesis of a significant difference between primary valve ablation and urinary diversion was rejected, as the study did not find any significant difference between the outcomes. Predictors of CKD, Albumin excretion, and Glomerular filtration rate were not found to be associated with any of the treatment measures, PVA or UD. Findings of the current study have been limited by short follow-up, smaller sample size and non-random allocation of the patients to treatment groups. Future studies should focus on prospective cohort designs to carry out follow-up and prognostic measures for longer durations.

CONFLICT OF INTEREST: the authors declare no conflict of interest related to this publication

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