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Clinical Study

# Posterior Urethral Valve: Is Complete Endoscopic Valve Incision Sufficient?

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**Keywords**
Endoscopic valve incision
Posterior urethral valve
Urethral ratio

**Abbreviations**
**APD** - Antero-posterior diameter of the renal pelvis
**BNI** - Bladder neck incision
**CRF** - Chronic renal failure
**ESRD** - End-stage renal disease
**EVI** - Endoscopic valve incision
**MCUG** - Micturating cysto-urethrogram
**PTK** - Parenchymal thickness of kidney
**PUV** - Posterior urethral valve
**PVRV** - Post-void residual volume
**UDS** - Urodynamic study
**UR** - Urethral ratio
**UTI** - Urinary tract infection
**VUR** - Vesico-ureteric reflux

## Abstract

***Background:*** *After adequate endoscopic incision of posterior urethral valve (PUV), normalization of posterior urethra on micturating cysto-urethrogram (MCUG) is expected. This study examines if normalization of urethra is correlating with check urethro-cystoscopy, improvement of renal function tests, imaging of upper renal tracts and urodynamics studies in all patients.*

***Methods and Material:*** *Fifteen consecutive patients with PUV from June 2011 to May 2012 were included in this prospective study. Renal function tests, ultrasonography and MCUG were done in all patients at diagnosis. Urethral ratio (UR) was calculated by dividing posterior urethral diameter with anterior urethral diameter in oblique MCUG films. However, it was seen that each MCUG yields a range of UR and hence we labelled the least UR as the 'best UR', and the maximum one as 'worst UR'. Pre-operative urodynamic studies were also done in these patients. All the investigations were repeated 12 weeks after adequate endoscopic valve incision (EVI). All the patients were assessed for the need of any further management. Statistical significance was calculated using Mann-Whitney U-test.*

***Results:*** *The median age at presentation was 21 months (range 8 d - 7 yr). Pre and post EVI values of renal function tests did not differ significantly. Reduction of hydronephrosis and VUR was not significant; but reduction of bladder wall thickness and hydroureter was significant. The mean pre-EVI 'best UR' was 3.58 (range 1.6 - 8.3; SD 1.86) and the mean post-EVI 'best UR' was 1.7 (range 1 - 3.3; SD 0.61). This difference was significant ($p<0.001$). Post-EVI urodynamic abnormalities were seen in 71.43% of patients in whom urodynamic study (UDS) was done. Two thirds of patients needed some form of bladder management even after adequate EVI.*

***Conclusions:*** *Following adequate EVI, there is a significant reduction in the 'best UR'. Adequate EVI however does not correlate with improvement in renal imaging, renal function tests and urodynamic parameters.*

## INTRODUCTION

Posterior urethral valves (PUV) are the most common cause of lower urinary tract obstruction in male infants, with an incidence ranging from 1/3000 to 1/8000 male births.[1] It is now agreed that primary endoscopic valve incision (EVI) is the treatment of choice for PUV. One-third of boys with PUV progress to end stage renal disease (ESRD).[2] Some surgeons believe that progression of bladder dysfunction and the ultimate ESRD are the results of inadequate endoscopic treatment of PUV. They contend that if valve incision were adequate, further progression of renal and bladder dysfunction would not take place.[3,4] Another school of thought suggests that the basic pathology is an embryological field defect in the urinary tract, which persists despite adequate EVI. According to this school, bladder is the most affected organ in this field defect and hence proper bladder management would preserve the upper tracts in most of these patients. Some workers believe that patients presenting with gross upper tract dilatation, highly deranged renal function tests and urosepsis, would ultimately land up in ERSD. This may be because of teratogenic insult not only at the site of the origin of Wolffian ducts, but also at the site of nephrogenesis.[5]

In the past, adequacy of treatment was judged by surgeons by mere inquiries and observation of the urinary stream. Check cystoscopy has always been considered as the gold standard for documentation of complete ablation of valves.[6] Recently, some authors have stated that adequate EVI is indicated by post procedural normalization of the UR.[3,7] However, there are differing opinions as regard to the correlation of these changes with the changes in the postoperative general condition, voiding status, improvement in renal function and drainage patterns of the upper urinary tract.[3,6]

In this study, we aimed to evaluate whether adequate EVI alone, as suggested by normalization of urethral ratio on MCUG and confirmed by check urethro-cystoscopy, is also associated with improvement in bladder function, upper urinary tracts and renal function tests in PUV patients.

## MATERIALS AND METHODS

Fifteen consecutive patients with classical PUV managed in the Department of Pediatric Surgery over a period of one year (from June 2011 to May 2012) were included in this prospective study. Renal function tests and ultrasonography was done in all of them at diagnosis. Those with urinary tract infections (UTI) were treated with suitable antibiotics and catheterisation.

Urethral ratio (UR) was calculated in all the patients by dividing posterior urethral diameter with anterior urethral diameter in oblique MCUG films. The diameter of posterior urethra was measured transversely at a point half way between the bladder neck and the distal end of membranous urethra. The transverse diameter of anterior urethra was measured at the point of maximum distension at bulbar urethra. We realized early in the study that the UR varies with changing dimensions of the anterior urethra in correlation with the changes in voiding pressure during different phases of micturition. So, a range UR was available for each MCUG. We labelled the one with least value as 'best UR' and the maximum one as 'worst UR'. (Fig. 1) The difference between 2 values were analysed by using paired sample t-test. For 7 MCUGs, only a single micturating film was available and hence instead of two values of UR, only one value was available in them. Pre-operative urodynamic studies (UDS) were also performed in 5 patients.

PUV were endoscopically incised using a hook electrode through an appropriate size urethro-cystoscope at 5, 7 and 12 o'clock positions. UR was recalculated on MCUG performed 12 weeks post procedure in the same fashion. Two criteria were to be fulfilled to label an adequate EVI: (1) Post-EVI, UR of $<3$ was considered as radiological normalisation of posterior of urethra; and (2) evidence of adequate valve incision at check urethro-cystoscopy. If either of these two criteria

were not met, EVI was done once again. If adequate treatment of PUV was ascertained, renal function tests, ultrasonography and UDS were done. UDS was not done in infants (n=7), in those with high-grade VUR (n=4) and 2 other patients in whom pre-EVI catheterization was not successful.

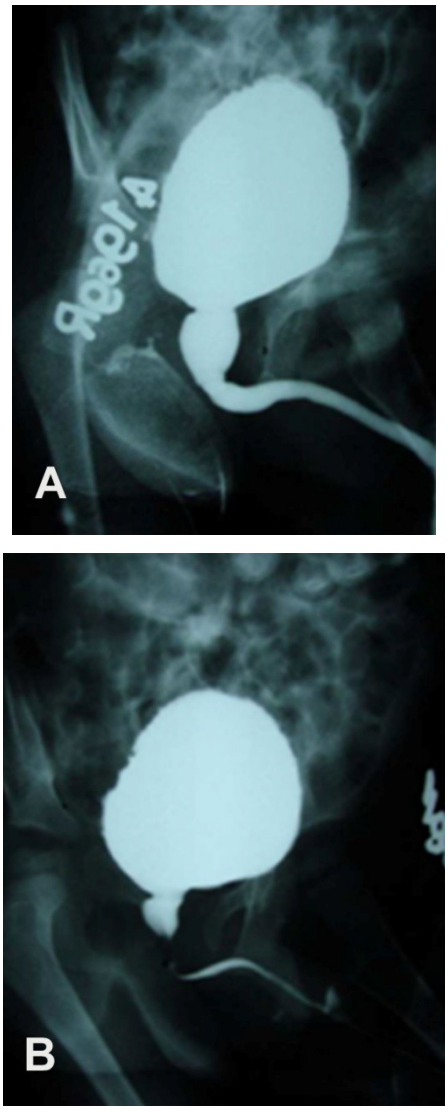


***Fig. 1: Concept of 'best' and 'worst' urethral ratio***
*MCUG showing the 'best' (A) and 'worst' (B) urethral ratios in the same patient after endoscopic valve incision*

Patients with persistently abnormal bladder functions were considered to be the candidates for treatment with anti-cholinergics and/or bladder neck incision (BNI).

Mann-Whitney U-test was done to evaluate the statistical significance of the difference noted between the pre- and post-ablation values of blood urea, serum creatinine, antero-posterior diameter of renal pelvis (APD), parenchymal thickness of kidney (PTK), diameter of ureters and bladder wall thickness. Same test was used to evaluate the statistical significance of difference between pre- and post-ablation values of 'best UR'. $P$ - value $< 0.05$ was considered significant.

## RESULTS

The median age at presentation was 21 months (range of 8 days to 7 years). There were 4 neonates, 3 infants, 5 were between 1-5 years, and 3 were pre-schoolers. Only 2 patients were antenatally diagnosed, while 2 presented with febrile UTI. All others had obstructive urinary symptoms.

The mean pre-EVI blood urea was 31.8mg/dl (range 12-66 mg/dl; SD 15.58) and the mean post-EVI blood urea was 30.67 mg/dl (range 16-72 mg/dl; SD 16.27). The mean pre-EVI level of serum creatinine in these patients was 0.8 mg/dl (range 0.3- 2.5 mg/dl; SD 0.63) and the mean post-EVI serum creatinine was 0.53 mg/dl (range 0.1- 1.3 mg/dl; SD 0.29). Pre- and post-EVI values of blood urea and serum creatinine were not found to be statistically different ($P = 0.42$ and 0.83 respectively). Only 1 patient had post-op creatinine of more than 1 mg/dl. Pre- and post-EVI PTK was available for 26 renal units, APD in 24, ureteric diameter in 21 and bladder wall thickness in 11 patients. The mean improvements in pre- and post-EVI values of these sonographic parameters are shown in Table 1.

By Mann-Whitney U-test pre- and post- EVI values of PTK and APD did not differ significantly ($P$=0.4 and 0.35 respectively). However, sonographic parameters of the 21 ureters and 11 bladders showed significant difference between the pre- and post-EVI values ($P$=0.003 and 0.024 respectively).

Post-void residual volume (PVRV) was significant in 6/15 (40%) patients before treatment and it was significant in only 2/15 (13.33%) of patients after adequate valve ablation. By applying the Fisher's exact test, we found this difference was not statistically significant ($P$=0.21).

Table 1. Ultrasound findings in PUV patients

| Parameter | n | Mean percentage improvement | SD % | *P* value† |
|---|---|---|---|---|
| PTK (mm) | 26* | 11.02 | 41.97 | 0.41 |
| APD (mm) | 24* | 11.15 | 49.53 | 0.35 |
| Ureteric diameter | 21* | 13.37 | 23.90 | 0.003 |
| Bladder wall thickness | 11 | 15.66 | 21.81 | 0.024 |

** Numbers indicate renal / ureteric unit*
*† Calculated by Mann-Whitney U- test.*
*PTK- Parenchymal thickness of kidney; APD-Antero-posterior diameter of renal pelvis*

The mean pre-EVI 'best UR' was 3.58 $\pm$ 1.86 (range 1.6-8.3). The mean post-EVI 'best UR' was 1.7 $\pm$ 0.61 (range 1-3.3). After analysing the two set of values, the difference was significant ($P$<0.001). (Table 2)

VUR was seen in 4/30 (13.3%) ureteric units before treatment, with two patients having unilateral grade-V VUR and one with bilateral grade-V VUR. Five out of 30 (16.67%) units had VUR after adequate EVI. The patient who had bilateral grade-V VUR at presentation had complete resolution of VUR post-EVI, while those with unilateral grade-V VUR at presentation showed no change; instead one of these developed grade-V VUR on the contralateral side too. Two patients with no VUR at presentation developed unilateral VUR later, grade III and V (one each). Most (80%) of patients needed single procedure for adequate EVI by our criteria, while a repeat EVI was needed in 2 patients and 4 times in 1 child.

Table 2: The pre- and post-EVI 'best urethral ratios'

| Pt. No. | Pre-EVI | Post-EVI | Decrease† (%) |
|---|---|---|---|
| 1 | 3.4 | 2.2 | 35.29 |
| 2 | 3.5 | 1.9 | 45.71 |
| 3 | 1.6 | 1 | 37.5 |
| 4 | 2.5 | 1.6 | 36 |
| 5 | 2.1 | 1.5 | 28.57 |
| 6 | 3 | 1 | 66.67 |
| 7 | 6 | 2 | 66.67 |
| 8 | 8.3 | 1 | 87.95 |
| 9 | 5.6 | 3.3 | 41.07 |
| 10 | 2.5 | 2 | 20 |
| 11 | 2.4 | 1.3 | 45.83 |
| 12 | 2.6 | 1.6 | 38.46 |
| 13 | 2.5 | 1.4 | 44 |
| 14 | 2.5 | 2.3 | 8 |
| 15 | 5.2 | 1.5 | 71.15 |

*(Mann-Whitney U-test, p-value < 0.001)*
*EVI- Endoscopic valve incision*
*†Calculated by the formula: difference between pre and post EVI ratios/Pre-EVI ratio x 100*

Urodynamic studies were done in 5 pre-EVI and in 7 post-EVI patients. Comparison of pre- and post-EVI UDS findings was available in only 5 patients. (Table 3) Post-EVI UDS was done in 2 more patients in whom pre-EVI UDS was not possible. One patient out of these 2 had normal study and another had overactive bladder. Five patients developed episodes of febrile UTI during the course of study and they were all managed conservatively.

We finally assessed all outcomes in our study individually for every patient to decide whether any further treatment was needed in them or not. The further treatments required by our patients were oxybutynin (n=5) and bladder-neck incision (BNI) (n=3). Indications for oxybutynin were overactive bladder, low capacity bladder and progression of VUR with trabeculated bladder on MCUG. Indications for BNI were bladder neck hypertrophy, back-pressure changes in the bladder on MCUG or check urethro-cystoscopy and significant PVRV after adequate EVI. BNI was

combined with oxybutynin medication in 2 patients. Surprisingly, the only patient with chronic renal failure (CRF) in our study is doing well on CRF medications alone. Four other patients are also doing well and required no further treatment until this date. Out of these 4 patients, one has dilated cardiomyopathy and is also undergoing treatment for that.

Table 3: Outcome of urodynamic studies

| Sr. No. | Bladder status | |
|---|---|---|
| | **Pre-EVI** | **Post-EVI** |
| 1 | Low capacity high pressure | Same as pre EVI |
| 2 | Low capacity | Same as pre EVI |
| 3 | Low capacity high pressure | High pressure overactive |
| 4 | High pressure | Normal study |
| 5 | High pressure | Overactive bladder |

## DISCUSSION

Although it has been well documented that bladder management following EVI is the most important aspect of PUV management, there are reports claiming that adequate EVI is sufficient in most of them and inadequate EVI is the chief cause of progressive damage of the upper tract.[1-4, 8-15] Also, opinions differ regarding the optimum investigation for the confirmation of adequate EVI. While some authors consider the repeat MCUG to be sufficient, others consider check urethro-cystoscopy as the gold standard. This study was an attempt to find whether adequate EVI alone is sufficient in PUV patients.

Prior to this study, UR has been described in 3 papers in the literature. One study[1] observed post-EVI UR of 3 or less as a marker of adequate EVI, while a cut-off of 2.5-3 was suggested by another study.[7] Yet another study emphasized the importance of the UR calculated 3 months after EVI and observed that those within 2 standard deviations of their post-EVI UR fared better than others and required no further treatment. However, they did not mention any cut-off value as marker of complete EVI.[3] Smeulders retrospectively reviewed 31 patients.[6] Repeat MCUG was suggestive of residual valves in 10, but no residual leaflets were identified on check urethro-cystoscopy in 4. In 20 patients, the valves that appeared completely ablated on MCUG had persistent valve leaflets on cystoscopy and they required further ablation in 10. They concluded that positive predictive value of repeat MCUG was 56% and negative predictive value was 50%.

In our study, post-EVI value of mean+2SD of best UR was 2.93 and that of mean+1SD was 2.32. So, our results matched with the observations of Gupta.[7] Although our observation of difference of pre- and post-EVI 'best UR' was statistically significant, 8 (53.33%) of our patients had UR less than 3 at presentation. So we could infer from our findings that UR, though was a good marker of adequate EVI in our study, it was not a good diagnostic tool. Also, as 14/15 patients in our study had maximum post adequate EVI, UR of less than mean+1SD (2.32), we consider 2.3 as a good cut-off value. Our observation of 'best' vs. 'worst' UR emphasizes the importance of calculating UR at the time of peak flow as the distension of anterior urethra is maximum at that point of time. So, it is very important to use fluoroscopy which can freeze a frame from the recorded act of voiding. Video-urodynamic study is perhaps the most ideal method.

Smith *et al.* observed that the incidence of CRF increases with age.[8] In their study of long-term follow-up, 34% had CRF at 10 years of age, which increased to 51% at the age of 20 years. However, in most of their patients bladder management strategy constituted only of double voiding. In our study, 4/15 (26.67%) patients had serum creatinine of more than 0.8mg/dl at presentation, which decreased to 1/15 (6.67%) after adequate EVI.

We studied change in hydronephrosis and hydroureter separately. We observed statistically significant reduction in hydroureter following

adequate EVI, but not in hydronephrosis. We can say from our observation that the resolution of hydroureter precedes that of hydronephrosis, after EVI. Dunohoe *et al.* found persistent hydronephrosis in 20/71 (28.2%) patients in their study.[17] However, their follow-up period in these cohort was variable. They further performed video-urodynamics and started some form of bladder management in all these patients. On subsequent follow-up, there was further improvement and only 7 patients had residual hydronephrosis. Extrapolating these findings to our study, we can say that further follow-up after early establishment of appropriate bladder management in our series would yield us similar outcomes.

Most of the investigators have identified bladder dysfunction as the most important cause for worsening of CRF with age.[9-14] Parkhouse *et al.* identified four factors responsible for poor outcome: presentation before 1 year of age, proteinuria, bilateral VUR and day-time urinary incontinence. They were probably the first to speculate that bladder dysfunction even after resolution of obstruction is a major determinant of bad outcome.[9] Role of bladder dysfunction in ESRD has been stressed in the literature.[10-14] Different studies have observed bladder dysfunction on UDS in 50-90% of PUV after adequate EVI.[15,18,19] In this study, we found that overall bladder dysfunction was present in all patients at presentation. This improved by only 20% after adequate EVI. We did post EVI UDS in 7 patients in our study and observed bladder dysfunction in 5 patients. So, based on our UDS findings, 71.43% of patients needed attention of bladder dysfunction even after adequate EVI. Common abnormalities observed in our study were low bladder capacity, high pressure bladder and detrusor overactivity. This was in contrast to the observations made by Menon *et al,* according to whom most of the patients do not need any further treatment after adequate EVI.

In our study, PVRV was significant after adequate EVI in 2 (20%) patients aged more than 1 year and in none aged less than 1 month. Pre- and post-EVI difference in PVRV was not statistically significant ($P$=0.21). Incidence of significant PVRV after EVI has been variously reported in the literature, ranging from 12.5 to 81.43%.[20-22] Abraham *et al*. found significant improvement in PVRV after administration of terazosin following EVI.[23] One of our previous study showed encouraging improvement in bladder function after BNI; however, it was statistically insignificant. This could be a fallacy due to a small sample size.[24] We continue to perform BNI in patients with significant PVRV after EVI.

Ten out of 15 (66.67%) of our patients needed some form of bladder management strategies even after documentation of complete EVI. We applied multivariate logistic regression for all the biochemical and radiological parameters between those patients who needed some treatment after adequate EVI and those who did not. We observed that no parameter was statistically significant and thus no single parameter was indicative of the need for further treatment.

We believe in aggressive management of any bladder abnormality in our follow-up patients of PUV. Once we have documented complete EVI on check urethro-cystoscopy, we perform regular MCUG and UDS in these patients (besides USG and renal function tests) to promptly address any issue. Based on this principle, we observed that two thirds of our patients in this study needed some form of bladder management after 3 months of adequate EVI. We are of the opinion that the remaining one third of the patients in our series may also need bladder management in the future. We will keep a close follow-up of all the patients in our study and take prompt actions as and when required.

There were a few limitations in this study. A larger sample size and longer follow-up are needed to

make meaningful conclusion. This could not be achieved as the study duration was only one year. It is difficult to predict as to how much time is required for voiding dysfunction and other parameters to improve after successful EVI. For these reasons, we tried to assess the improvement after 12 weeks of adequate EVI. UDS was not done in infants because of technical difficulties. UDS was also not done in patients with high grade VUR as it was fallacious without video-urodynamics, which was not available in our center.

## CONCLUSIONS

UR is not a static figure on a particular MCUG. A single MCUG would produce a range of UR and hence we propose to coin the terms 'best UR' and 'worst UR'. Cut-off values for 'best UR' of 2.5-3 should be considered as a marker of adequate EVI. Resolution of hydroureter precedes that of hydronephrosis in these patients. Two thirds of the patients need some form of bladder management even after adequate EVI and hence UR, though a good marker of adequate EVI, is not a indicator of completion of therapy in these patients. Therefore, we conclude that adequate EVI measured by normalization of UR may not improve renal function tests, imaging of upper renal tracts and urodynamics studies in all patients of PUV. Most of these patients may need some form of bladder management after EVI.

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