

'Comparison of Patient Reported Outcome Measures for Direct Visual Internal Urethrotomy and Non-Transecting Urethroplasty for Short Bulbar Stricture'

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Abstract

Background:

To evaluate the functional and sexual outcomes of Primary DVIU and Non- transecting bulbar urethroplasty (NTA) for short segment (<2 cm) bulbar urethral strictures using the Modified USS PROM.

Methods:

The USS PROM questionnaire comprising of a six-item LUTS domain, a LUTS-specific QOL question, and a peeling's voiding picture score was used. To achieve a holistic approach to the evaluation of stricture surgery outcomes a six-item IIEF and four-item version of MSHQ-EjD domains, completed the questionnaires. All cases of short bulbar urethral stricture who underwent primary DVIU and NTA between September 2018 and September 2019 and consented to filling out the questionnaires were enrolled into the study.

Results:

The LUTS score for the NTA at 12 months is significantly better (1.93 ± 2.13 Vs 8.76 ± 5.92 , $p=0.000$). The Peeling score of the NTA is significant better at 6 months (1.59 ± 0.56 Vs 2.26 ± 0.96 , $p=0.000$) and 12 months (1.41 ± 0.68 Vs 2.67 ± 0.73 , $p=0.000$). Erectile function score at 12 months for NTA is significantly better than DVIU (24.37 ± 3.2 Vs 21.143 ± 2.86 , $p=0.001$). The Ejaculatory function score at 6 months is significantly better for the NTA. Finally the Uroflowmetry (Qmax) is significant in NTA group at 12 months (26.7 ± 4.08 Vs 15.35 ± 5.16 , $p =0.000$).

Conclusion:

NTA shows superior outcomes in almost all domains of USS- PROM, both in terms of voiding and sexual function. This should be the preferred first choice treatment for short segment bulbar stricture.

Trail Registration- CTRI /2020/02/023578

Introduction:

Urethral stricture has many causes and is characterized by fibrosis of the urethral mucosa and underlying spongiosum. It is the common cause of voiding difficulty in younger and middle-aged men.¹ Stricture can affect any part of the male urethra but most often occurs in the bulbar segment². The optimal management of bulbar strictures continues to generate much debate³. For many years, traditionally the first line surgical management of these patients, has been Direct visual internal urethrotomy (DVIU). Despite its popularity the failure rate of DVIU is reported to be at least 50 %, and for majority of the patients DVIU should be considered as a temporizing measure until definitive reconstruction can be planned⁴. Excision and primary anastomosis (EPA) has been the treatment of choice if patient fail to respond to the first-line management by DVIU⁵. Recently, there have been increasing concerns that

urethral transection may adversely affect urethral blood supply resulting in urethral ischaemia and sexual side effects⁶.

Non-transecting urethroplasty avoids urethral mobilisation and transection of healthy bulbospongiosum and thereby has the potential to avoid the risks of urethral ischaemia and sexual side effects⁷. The published reports of non-transecting bulbar urethroplasty are promising in terms of success and sexual satisfactory rates^{5,8}. The purpose of this study was to evaluate the functional and sexual outcomes of DVIU and Non transecting bulbar urethroplasty for short segment (< 2 cm) bulbar urethral strictures from the patients point of view, using Modified USS PROM, as subjective assessment is particularly important in urethral stricture management where the goal is enhancing the quality of life⁹.

Materials And Methods:

Following the approval by the Institutional Ethics Board and CTRI (CTRI /2020/02/023578) approval, an observational study of all men undergoing non-transecting urethroplasty and primary DVIU for a short segment urethroplasty was performed between September 2018 to September 2019. Stricture length was assessed by preoperative retrograde urethrogram, micturating cystourethrogram, intraoperative endoscopic assessment and also after dorsal stricturotomy in cases of urethroplasty. Techniques employed in Non-transecting urethroplasty group were: Heineke-Mickulicz (H-M) technique, Non-transecting Excision of the Stricture and mucosal Anastomosis (NTABU), Augmented non-transecting anastomotic bulbar urethroplasty (ANTABU) technique and Dorsal Onlay Buccal graft Urethroplasty. Primary was defined as no prior intervention including dilatation/DVIU/urethroplasty. Urethrotomy was performed using a single incision at 12 o'clock position with a cold knife. A modified PROM questionnaire in the patient's own language was completed at pre- op, 6 months, 12 months post-surgery. Recurrence of stricture was defined as any intervention including self-dilatation, dilatation, DVIU, urethroplasty. As an institutional protocol any patient that fails to respond for DVIU was advised urethroplasty. Patients with, traumatic aetiology, age < 18 years, not sexually active, those not willing to participate in filling of questionnaires, and those with lost to follow-up were excluded from the analysis.

Scoring the modified patient-reported outcome measure (PROM)

LUTS Domain

- The LUTS domain comprised of six summative questions derived from the International¹⁰

Consultation on Incontinence Questionnaire Male LUTS (ICIQ MUTS) module, addressing hesitancy, stream, strain, intermittency, incomplete emptying, and post- micturition dribble to generate a total score between 0 (least symptomatic) and 24 (most symptomatic).

- • Peeling's voiding picture¹¹: an illustration of a man voiding wherein the respondent circles an integer between 1 (best) and 4 (worst) corresponding to their own uroflow pattern at that point in time.

- A Likert-type LUTS-specific QoL¹² question asks, “Overall, how much do your urinary symptoms interfere with your life?”

The EQ visual analogue scale (EQVAS) and EQ-5D descriptive system, of the original USS- PROM, were excluded during evaluation in the present study questionnaire.

Sexual function Domain

- Erectile function was assessed by the modified six-item International Index of Erectile Function (IIEF) 16 questionnaire addressing the various aspects of erection.
- Ejaculatory function was addressed by the four-item version of Male Sexual Health Questionnaire to assess Ejaculatory Function (MSHQ-EjD)¹³ wherein the last question evaluated the bother/satisfactory state of the patient.

Uroflowmetry was performed at baseline excluding the patients on suprapubic catheter, 6 month and at 1 year post-operatively for objective assessment during follow up.

Statistical analysis of LUTS domain, MSHQ-EjD bother/satisfactory score was done using Mann-Whitney test. Erectile function score, MSHQ-EjD, Qmax are analysed using ANOVA test.

Results:

Image 1(A-F)-

Figure 1: A. LUTS Score; B. Peeling Voiding Picture Score; C. Erectile Function Score; D. Ejaculatory Function Score; E. Ejaculatory Function-Bother Score; F. Uroflowmetry (Qmax).

Table 1
Study Population Baseline Characteristics:

	Nontransecting Urethroplasty (N = 29)	DVIU (N = 24)
AGE (mean ± SD)	46.79 ± .79	51 ± .20
Stricture location:		
PROXIMAL BULBAR	8	6
PROXIMAL AND MID BULBAR	9	4
MID BULBAR	7	8
MID AND DISTAL BULBAR	3	3
DISTAL BULBAR	2	3
Stricture etiology:		
IDIOPATHIC	14	10
IATROGENIC	9	11
INFLAMMATORY	6	3
Stricture length (mean ± SD):	1.31 ± .50	1.16 ± .44
Previous intervention :		
None	21	24
DVIU	6	-
Dilatation	1	-
Multiple DVIU/ Dilatations	1	-
Urethroplasty	-	-

Table 2
Statistical Analysis Of Variables:

		URETHROPLASTY (N = 29) Mean ± SD	VIU (N = 24) Mean ± SD	P VALUE
LUTS score	BASELINE	16.90 ± 5.1	16.63 ± 4.4	0.879
	6 MONTHS	3.31 ± 2.14	5.54 ± 5.88	0.605
	1 YEAR	1.93 ± 2.13	8.76 ± 5.92	0.000
Peeling voiding picture score	BASELINE	3.41 ± 0.56	3.46 ± 0.50	0.838
	6 MONTHS	1.59 ± 0.56	2.26 ± 0.96	0.007
	1 YEAR	1.41 ± 0.68	2.67 ± 0.73	0.000
Erectile function score	BASELINE	19.37 ± 3.45	18.25 ± 2.38	0.181
	6 MONTHS	23 ± 3.63	22.16 ± 3.43	0.398
	1 YEAR	24.37 ± 3.2	21.143 ± 2.86	0.001
Ejaculatory function score	BASELINE	11.31 ± 2.2	10.58 ± 1.12	0.165
	6 MONTHS	13.41 ± 1.18	12.33 ± 1.49	0.005
	1 YEAR	14.00 ± 1.0	11.76 ± 1.78	0.000
Ejaculatory function- bother/satisfaction score	BASELINE	2.28 ± 1.36	2.21 ± 0.83	1.000
	6 MONTHS	1.00 ± 0.75	1.33 ± 0.86	0.165
	1 YEAR	0.55 ± 0.68	1.57 ± 0.87	0.000
Qmax	BASELINE	5.03 ± 1.20	4.48 ± 1.70	0.192

	URETHROPLASTY (N = 29) Mean ± SD	VIU (N = 24) Mean ± SD	P VALUE
6 MONTHS	25.81 ± 2.83	18.55 ± 4.15	0.000
1 YEAR	26.7 ± 4.08	15.35 ± 5.16	0.000

Table 3
Luts and Sexual Function Domain Subgroup Analysis – Non Transecting Urethroplasty Group

		H-M (N = 4) Mean	NTABU (N = 17) Mean	ANTABU/ DORSAL ONLAY BMG (N = 8) MEAN
LUTS score	BASELINE	18.25	17.29	15.37
	6 MONTHS	2	3.7	3.12
	1 YEAR	0.75	1.94	2.5
Peeling voiding picture score	BASELINE	3.25	3.41	3.5
	6 MONTHS	1.5	1.588	1.62
	1 YEAR	1	1.47	1.5
Erectile function score	BASELINE	21.5	20.35	16.25
	6 MONTHS	26.5	22.94	21.35
	1 YEAR	28	24.11	23.125
Ejaculatory function score	BASELINE	12.25	11.23	11
	6 MONTHS	14.25	13.29	13.25
	1 YEAR	14.5	13.94	13.87
Ejaculatory function- bother score	BASELINE	1.75	2.29	2.5
	6 MONTHS	0.75	0.941	1.25
	1 YEAR	0.5	0.52	0.625
Qmax	BASELINE	5.1	4.83	5.44
	6 MONTHS	27.9	26.24	23.85
	1 YEAR	28.8	27.5	24.02

SUPPLEMENTARY TABLE 1: SURGICAL SATISFACTORY RATES - CROSS TABULATION

SUPPLEMENTARY TABLE 2: LUTS AND SEXUAL FUNCTION DOMAIN SUBGROUP ANALYSIS – NON TRANSECTING URETHROPLASTY GROUP WITH AND WITH OUT PRIOR INTERVENTIONS

On statistical analysis the LUTS score of the nontransecting urethroplasty procedures at 6 months is significantly better by the end of study (1.93 ± 2.13 Vs 8.76 ± 5.92 , $p = 0.000$), the peeling score is significant at 6 months (1.59 ± 0.56 Vs 2.26 ± 0.96 , $p = 0.000$) and 12 months (1.41 ± 0.68 Vs 2.67 ± 0.73 , $p = 0.000$). The erectile function score is significant at 12 months (24.37 ± 3.2 Vs 21.143 ± 2.86 , $p = 0.001$), Ejaculatory function score and bother/satisfaction score are significant at 12 months (14.00 ± 1.0 Vs 11.76 ± 1.78 , $p = 0.000$), (0.55 ± 0.68 Vs 1.57 ± 0.87 , $p = 0.000$). Improvement of Uroflowmetry (Qmax) is significant in the urethroplasty group at 6 months (25.81 ± 2.83 Vs 18.55 ± 4.15 , $p = 0.000$) and 12 months (26.7 ± 4.08 Vs 15.35 ± 5.16 , $p = 0.000$)

From the 29 patients in the nontransecting urethroplasty group, 8 patients had history of prior DVIU/Dilatations and 5 of them underwent ANTABU/Dorsal onlay BMG, 3 underwent NTABU. 1 patient with a history of multiple DVIU, who had undergone ANTABU required reintervention at 12 months post procedure. 2 patients who underwent ANTABU had post-micturition dribble which was not bothersome. 28 patients were satisfied/very satisfied with the procedure and 1 patient was unsatisfied. Out of 24 patients who underwent Primary DVIU, 11 patients required reintervention by the end of study and were unsatisfied/very unsatisfied.

Discussion:

DVIU is relatively easy procedure to learn, straight forward to perform and can be performed on outpatient basis. These attributes have made DVIU as the procedure of choice among urologists for treating short segment structures, despite poor long-term success rates¹⁴. EPA has been the surgical treatment of choice for short segment bulbar urethral strictures, if patients fail to respond to the first-line management by DVIU with long-term success rates of 90 to 98.6%¹⁵.

The present study demonstrates that nontransecting urethroplasty offers better surgical dividends in primary or failure after DVIU. Transection the urethra and corpus spongiosum for short segment bulbar strictures was challenged at the American Urological Association meeting in 2009¹⁷. The debate in favour or against transection with EPA and non-transecting techniques is based on stricture aetiology and the success rates and complications. The pathophysiology differs between non-traumatic and traumatic causes. In non-traumatic strictures the corpus spongiosum is well preserved with minimal scarring of around 10% involving the urethral wall, unless there has been any prior interventions¹⁸. Whereas, in fall-astride injuries there is usually full-thickness spongiofibrosis with no remaining vascularised spongiosal tissue.

Hence EPA for non-traumatic strictures inevitably transects healthy tissues and is reported to be associated with an 18-22.5% incidence of sexual dysfunction.^{19,20}

Jordan and colleagues²¹ were the first to promote the idea of vessel sparing bulbar urethroplasty which gave inception for the Non-transecting bulbar urethroplasty techniques³ with the aim to avoid the potential morbidity associated with transection of spongiosum.

The primary goal in stricture management is restoration of unimpeded flow of urine with minimal sexual side effects²². The most pronounced obstructive symptoms in urethral stricture disease are a weak stream, dribbling, and incomplete emptying.²³

In our study, there is significant improvement of LUTS score and peeing voiding picture score, uroflowmetry (Qmax) in nontransecting urethroplasty group compared to Primary DVIU group. The difference in LUTS score is not statistically significant at six months but worsening in LUTS score and Qmax are noted in DVIU group by the end of 12 months. This suggests that more durable and long-term outcomes can be achieved with Non-transecting Urethroplasty rather than DVIU for short segment bulbar strictures. There is a growing interest in Sexual dysfunction following Surgery for Urethral Strictures, but outcomes in most studies are heterogenous²⁴

We found statistically significant improvement of erectile function scores in Non transecting urethroplasty group at 12 months. Probable explanation for the improvement of Erectile function could be recovery of neuropraxia, decrease in tissue inflammation following surgical manipulation and psychosomatic recovery and the elimination of a supra-pubic catheter after surgery, improvement of body image as well as psychological factors are contributing to possible explanations for the improvement in erectile function^{25,26}. Preservation of healthy spongiosum also is aiding factor to improved sexual function.

Ejaculatory function scores recovered in both the groups with Non transecting urethroplasty group having statistically better scores at the end of 12 months. The significant improvement of ejaculatory score in the urethroplasty group can be asserted to resection of scarred and non-contractile part of the urethra/spongiosum which improves the rhythmic ejaculatory mechanism by restoring the continuity of the musculature²⁷ and the improvement of ejaculatory function in DVIU group can be ascertained to resolution of urethral obstruction²⁶. The studies on Ejaculatory function are sparse for both Non-transecting Urethroplasty and DVIU. In addition to Erectile and Ejaculatory function, decreased penile sensitivity and cold glans syndrome after surgery can lead to decreased sexual satisfaction²⁸. No patient in the study had de novo erectile dysfunction or complained of altered glans sensitivity/turgidity. Similar observations have been reported by retrospective studies performed in Non-transecting fashion for short segment bulbar stricture^{3,5}.

The satisfaction rates in Non transecting urethroplasty group is 96.5% which is similar to existing literature^{3,5}. One patient in the group with past history of multiple endoscopic interventions and underwent ANTABU required an endoscopic dilatation and was not satisfied with the surgical outcome.

2 patients (8%) who underwent ANTABU in the urethroplasty group had postmicturition dribble which was not bothersome. Post micturition dribble could be because of impaired function of perineal nerve branches from the surgical dissection^{23,24}. Similar rates of Post micturition dribble (13.8 %) also noted by Ivaz et al.⁵

Eleven patients (46%) of the primary DVIU group required reintervention and are unsatisfied with the outcome. It was observed that the patients who were very satisfied and satisfied after surgery had good maximum flow rate, low LUTS score and improved sexual function score. The patients who were not satisfied with the surgery had low flow rate, high LUTS score and modest Sexual function score. Hence assessing the subjective outcomes PROM can help achieve a holistic approach for patient follow-up and for preoperative decision making of the patient.

The success rate of Non transecting urethroplasty is 96.5% in our study. Similar success rates are noted in other studies^{3,5}. As most strictures recur in the first year post urethroplasty²⁹, we believe that subjective and objective stricture free rate of 96.5% at 12 months augurs well for a satisfactory outcome in the longer term. Most of the studies published on the outcomes of DVIU are conglomerate of variable lengths and aetiologies, hence they may not provide a complete picture of DVIU outcome. The success rate of Primary DVIU in our study is 54% and is of a homogenous group of primary DVIU for short segment bulbar stricture.

Among the nontransecting urethroplasty techniques, H-M, NTABU showed superior outcomes in all the domains and better satisfactory rates. Even though it is hard to comment on superiority of one technique over the other as the sample size is less, we believe when chosen for the right case H-M, NTABU techniques have satisfactory outcomes.

History of previous DVIU/Dilatations increases the complexity of the inevitable urethroplasty³⁰. The patients in the nontransecting urethroplasty group with previous interventions with DVIU/Dilatations had to undergo relatively more complex reconstructions and had inferior LUTS, SEXUAL FUNCTION outcomes when compared to those who had no prior interventions.

During the last three decades urethroplasty has improved in efficacy and safety, while DVIU is increasingly considered ineffective in the long term.³¹

The fact that DVIU has a low success rate is a strong argument for opting for the more effective and refined urethroplasty techniques with minimal side effects.

The shortcomings of our study include firstly, short duration of follow-up, small number of patients, secondly even though a prospective study, it is non-randomised and lastly, the absence of a descriptive health profile generating system like the EQ-5D.

Conclusion:

In our study, better outcomes in terms of voiding and sexual function seen in patients who underwent NTA compared to DVIU for primary short segment bulbar urethral stricture of non-traumatic aetiology. DVIU should be reserved for patients who are very poor surgical candidates or as a makeshift procedure until a definitive procedure in the form of urethroplasty is performed.

Declarations

- **Ethics approval and consent to participate** – Institutional ethical committee approval was taken and the trial was registered with CTRI (CTRI /2020/02/023578)
- **Consent for publication**- Consents have been taken as per the institutional proforma.
- **Availability of data and materials**- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request
- **Competing interests**- The authors declare that they have no competing interests
- **Funding**- Not Applicable
- **Authors' contributions** –

MS- Interpretation of patient data and manuscript writing.

SJR- Interpretation of patient data and manuscript writing.

AC- Concept analysis and major contributor in writing the manuscript.

JDLR- Review and statistics.

PL- Review and statistics

SP- Statistical analysis

BSR- Statistical analysis

SP- Data collection

AC- Data Collection

All authors read and approved the final manuscript

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Figures

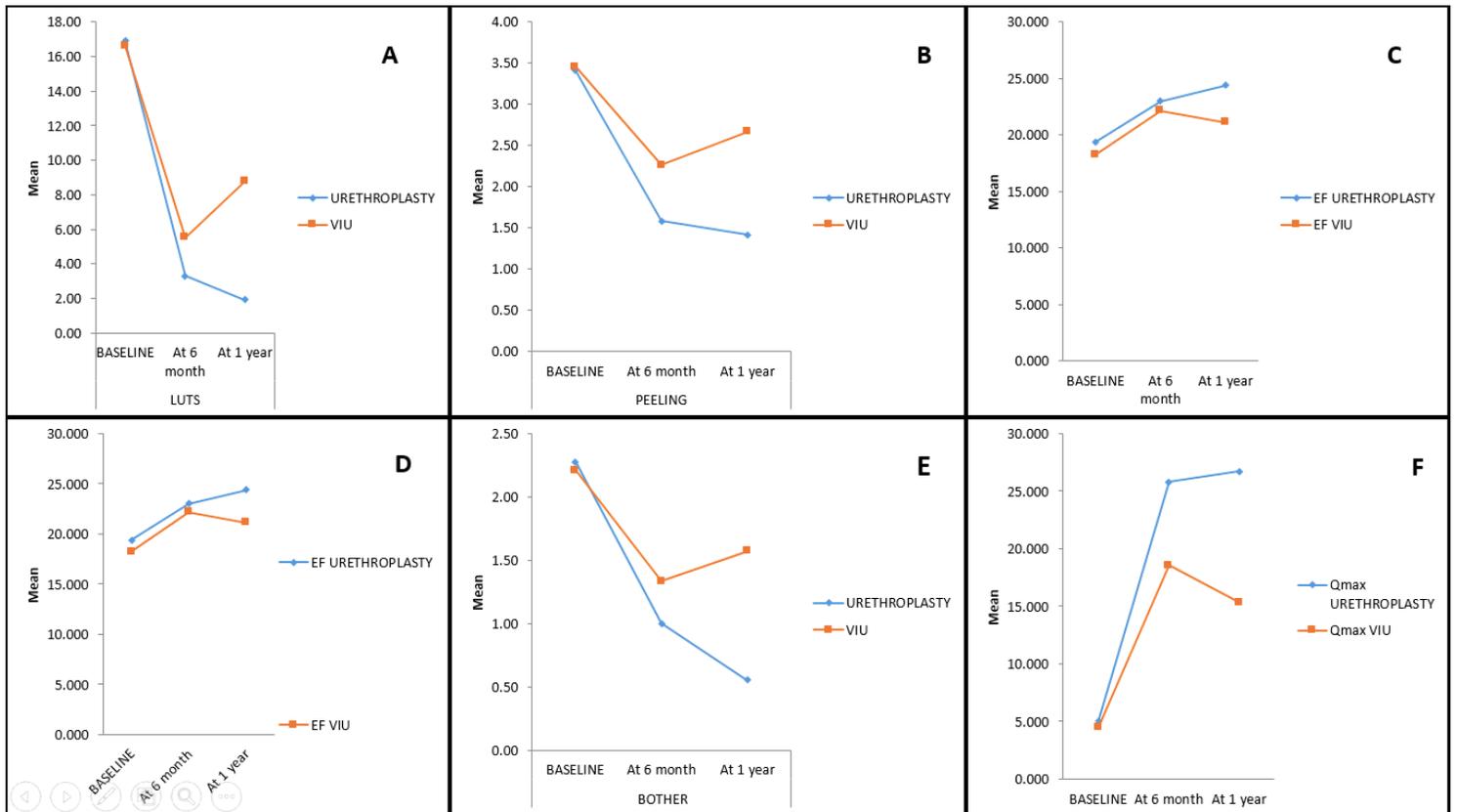


Figure 1

(A-F) – Colour images. A. LUTS Score; B. Peeling Voiding Picture Score; C. Erectile Function Score; D. Ejaculatory Function Score; E. Ejaculatory Function-Bother Score; F. Uroflowmetry (Qmax).

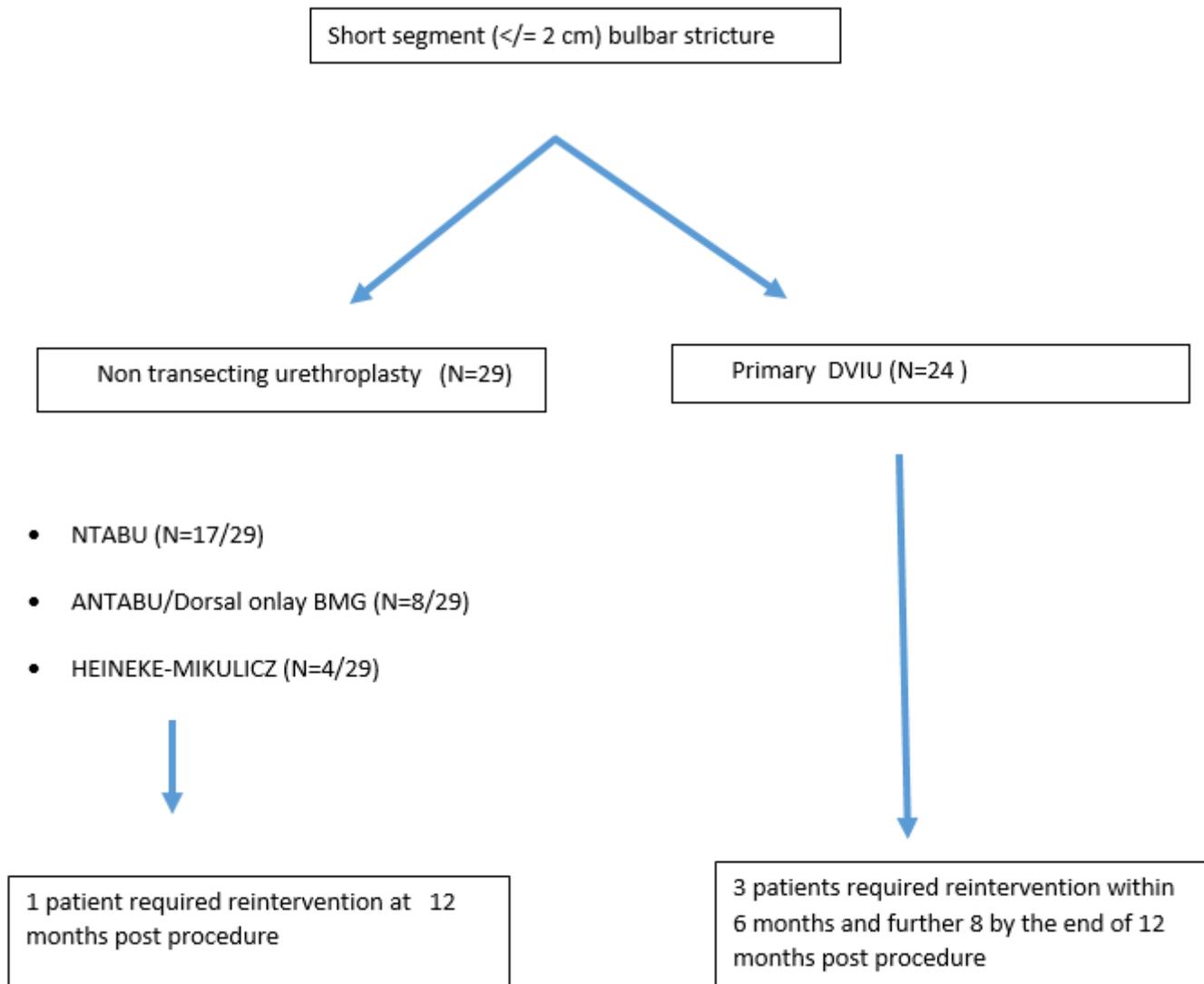


Figure 2

Flowchart reflecting patient groups in the study

Supplementary Files

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