Long-term Success Durability of Transobturator Male Sling

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OBJECTIVE To determine the long-term outcome of transobturator sling for male stress urinary incontinence (SUI) clustered according to preoperative SUI severity, and to identify predictors of treatment success durability and failure occurrence in long-term follow-up.

METHOD A nonconcurrent study was conducted on all transobturator male sling cases performed from August 2006 to June 2012 by a single surgeon. Preoperative SUI severity was clustered into mild (≤2 ppd), moderate (3-4 ppd) or severe (≥5 ppd). Success was defined as complete dryness with 0 pads used (cured), and a patient with ≥50% improvement, satisfied without further procedures needed. Otherwise it was considered a treatment failure. Clinical variables significantly associated with long-term treatment success were determined. Time-to-event (Kaplan-Meier) and Multiple-Cox regression analysis were performed to determine predictors of long-term treatment outcome.

RESULTS A total of 215 patients (mild-59, moderate-94, and severe-62) with a mean follow-up of 56.4 ± 41.6 months were included. On long-term follow-up, 150 (69.8%) patients-maintained treatment success and 96 (44.7%) were dry. The long-term outcome success clustered according to SUI severity as mild, moderate, and severe was 84.7%, 72.3%, and 51.6%, respectively. Kaplan-Meier with Log-rank test and Multiple Cox-regression determined that both concomitant urge incontinence and preoperative SUI severity were independent predictors of long-term durability of treatment success and failure occurrence. Preoperative SUI severity was the only predictor of long-term cure sustainability.

CONCLUSION The time to event analysis with an average of ~5 years postoperative follow-up has determined that the preoperative severity and presence of concomitant urge incontinence were independent predictors for long-term outcome. UROLOGY 133: 222–228, 2019. © 2019 Elsevier Inc.

The main pathophysiology of male stress urinary incontinence (SUI) is sphincter deficiency due to prostate surgery and/or iatrogenic sphincter insult or trauma to the pelvic floor.[1,2] According to the 2019 American Urological Association Guideline on postprostatectomy urinary incontinence, the Artificial Urinary Sphincter (AUS) is the preferred treatment for men with moderate to severe SUI after radical prostatectomy; while male slings are an accepted approach for mild to moderate SUI.[3]

To date, the reported midterm outcome of the transobturator male sling, described as overall treatment success, ranges from 73% to 89.4%, with dry rates ranging from 51% to 77%.[4-8] However, the latest European Urology Association guideline on the management of male incontinence stated that there is limited evidence that fixed male slings cure or improve postprostatectomy incontinence in patients with mild-to-moderate incontinence[9] (level 3 evidence). Further evaluation is necessary to identify factors that predict long-term outcome; specifically, long-term success durability for different degrees of baseline SUI.[10]

We hypothesize that success durability is affected by the severity of the preoperative SUI. We postulated that this should be the basis of patient counseling and selection to ensure a favorable long-term outcome. We aim to report the outcome of transobturator male sling for the treatment of male SUI and determine the success durability according to baseline SUI. We also aim to identify independent predictors for overall treatment failure at long-term follow-up.

METHODOLOGY

The study was approved by our institutional research ethics board (REB# 18-10-WC-0236) and study reporting was in compliance with RECORD statements.[11] We retrospectively analyzed a prospectively maintained database of adult male patients who underwent transobturator male sling (AdVance Boston Scientific,

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Minnetonka, MN) from August 2006 to June 2012 by a single. Details of the surgical technique were previously described.[12] We included patients that had at least 1 postoperative follow-up. No patients were excluded on the basis of incontinence etiology or severity, radiation history, or any other complicating factors; however, redo cases were excluded from the analysis to avoid double counting and overestimate of the significance of certain clinical variables as a predictor of long-term outcomes. At our institution, patients with severe incontinence are counseled toward an AUS but we do not refuse male sling placement if patients otherwise meet criteria and choose to pursue this option.

The recorded data included patient demographics, diabetes, smoking status, history of pelvic radiation, prior SUI treatments (eg, bulking agent injection), concomitant Urge Urinary Incontinence (UUI), pre- and postoperative pad usage, treatment satisfaction as verbalized by the patient at their clinic follow-up and categorized as binary response, surgery-related complications, and subsequent continence procedures.[12] All the collected data were internally validated by a research group member that randomly counter-verified 15% of the total data set extracted.

For the purpose of this study, we defined the durability of success over time in terms of cure (defined as complete dryness with 0 wet pads) and improvement (defined as both a ≥50% improvement in pad use, patient satisfaction with the surgical outcome and without further procedures). The treatment outcomes were assessed at each follow-up visit until the latest clinic follow-up. Baseline SUI severity was clustered into mild (≤2 ppd), moderate (3-4 ppd) or severe (≥5 ppd).

Descriptive statistics were appropriately applied in summarizing categorical data as count and percentage for categorical data, while mean and standard error of means were used for continuous data. Bivariate analyses with Fisher's-exact test and one-way analysis of variance were performed to determine the difference between preoperative SUI severity clustered groups. Kaplan-Meier survival analysis was performed to examine the cumulative incidence of treatment outcome of overall success and cure. Time to event analyses for the cure and overall success (cure + improved) clustered according to preoperative SUI severity was evaluated with the log-rank test. The event of treatment failure was defined as a failure to sustain the condition of cure or treatment success. In addition, patients who had treatment failure after sling placement continued to be counted as such throughout the analysis. Mean duration of follow-up was individually captured to perform time to event analyses, censoring data at the time of latest clinical evaluation assessment, need for an additional anti-incontinence procedure or sling removal, recurrence of SUI or <50% improvement and nonsatisfaction with treatment outcome.

Significant clinical variables associated with treatment success on long-term follow-up were identified using Fisher's-exact test and independent *t*test as appropriate. Variables associated with increased risks of treatment failure at long-term follow-up were identified using multiple-Cox proportional hazards models to generate adjusted hazard ratios and corresponding 95% CI. IBM SPSS Statistics for Windows (Version 22.0. Armonk, NY: IBM Corp.) was used for all the statistical analyses with <.05 set for statistical significance.

RESULTS

A total of 215 patients with SIU (59 mild, 94 moderate, and 62 severe) that had surgery, with a mean follow-up of 56.4 ± 41.6 months were included for analysis. At last clinic follow-up visit, 150 patients (69.8%) were determined to have

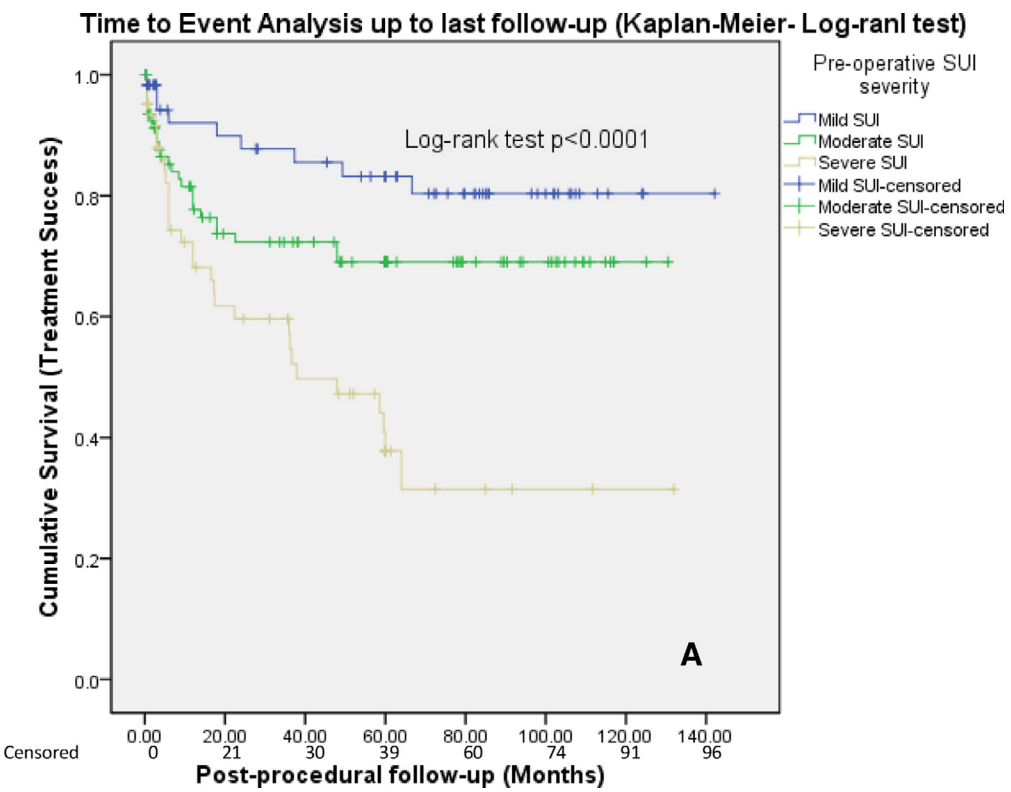

Figure 1. (A) Time to event analysis (Kaplan-Meier test) overall success. (B) Time to event analysis (Kaplan-Meier test) cure condition. (Color version available online.)

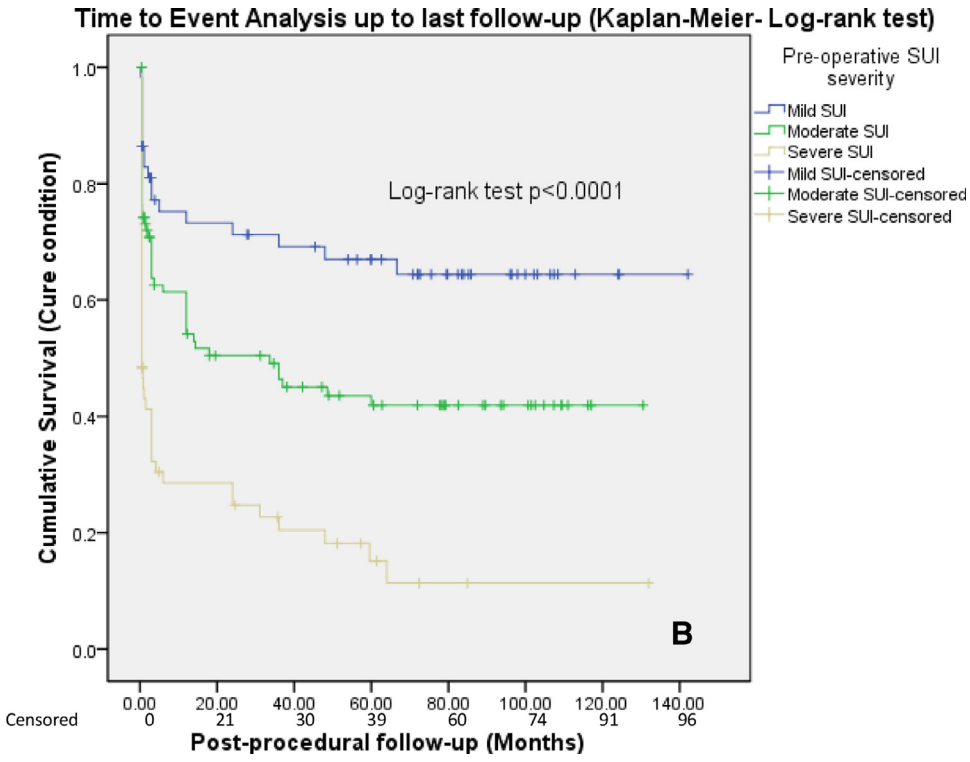

Figure 1. Continued

postprocedural success and 96 patients (44.7%) were considered cured. Supplementary Table 1 summarizes the overall patient characteristics clustered according to baseline SUI severity as mild, moderate, and severe. Summarizing, the perioperative variables were comparable between the 3 groups (mild, moderate, and severe SUI) except for the presence of concomitant UUI (18.6%, 22.3%, 41.9%, respectively; *P*= .008). Cure on latest follow-up was 67.8%, 46%, and 19.4%, respectively (*P* <.0001); while the overall success was 84.7%, 72.3%, and 51.6%, respectively (*P* <.0001).

The Kaplan-Meier survival curves for the length of time after male sling placement until treatment failure were presented for the clustered preoperative SUI severity groups (Fig. 1A: overall treatment success; Fig. 1B: cure). There was a significant difference in overall treatment success sustainability and cure between the treatment groups (log-rank test *P* <.0001 and *P* <.0001, respectively). Furthermore, the determined estimated overall success durability was 93.49 months (95%CI 83.588-103.391), while the overall average cure sustainability was 62.33 months (95%CI 52.979-71.676). Table 1 summarizes the estimated mean durability of overall treatment success and cure sustainability for each clustered preoperative SUI severity group. Specifically, mild preoperative SUI was estimated to have an average of 119.22 months (105.61-132.84) treatment success durability and 96.12 months (79.20-113.05) sustainability of cure.

Bivariate analysis showed that concomitant UUI (*P* = .001) and SUI severity clusters (*P*<.0001) were significantly associated with overall treatment success. While the pelvic radiation (*P*= .044), concomitant UUI (*P* = .003) and SUI severity clusters (*P* <.0001) were significantly associated with failure or lack of success (Table 2). Multiple Cox regression determined that both concomitant UUI (HR 2.033, 95%CI 1.226-3.370) and preoperative severe SUI (HR 3.686, 95%CI 1.723-7.888) were independent predictors of overall treatment failure at long-term follow-up. Baseline moderate to severe SUI (HR 1.918, 95%CI 1.127-3.264; HR 3.694, 95%CI 2.135-6.392, respectively) were independent predictors for failure of long-term cure (Table 3).

A total of 61 patients (28.4%) in the group that failed underwent at least 1 subsequent continence procedure at an average of 32.2 months (standard error of means 3.66) after the original sling placement. This included 17 (7.9%) who elected to have a redo male sling, 18 (8.4%) who had an AUS placed, and 18 (8.4%) who were injected with urethral bulking agents. In addition, 4 (1.9%) patients had placement of an Interstim device (Medtronic, Minneapolis, MN) or intravesical onabotulinum toxin A injection for urge incontinence; while 3 (1.4 %) patients underwent sling explant due to chronic urinary retention (>3 months) and 1 patient due to the development of surgical site infection and subsequent mesh infection.

The overall complication rate was low. Intraoperative corpus spongiosum and urethral injuries occurred in 7 (3.3%) of the patients. None of these required canceling the procedure nor affected the long-term outcome. Acute urinary retention after sling placement was found in 34 (15.8%) patients, which resolved within the first 2-3 weeks in all but 3 patients. Twelve patients (5.6%) complained of mild transient scrotal or groin pain; this persisted more than 3 months in 1 patient but did not require further intervention. Urinary tract infection was found in 2 patients, and 1 developed a surgical site infection and subsequent mesh infection that required sling explant. All reported surgical complications were category 1 except for the surgical site infection and chronic urinary retention, which required sling explant (Clavien grade 3b).

Table 1. Time to event analysis estimated treatment outcome durability

Preoperative SUI Severity	Mean Overall Treatment Success Durability (mo)				Mean Cure Outcome Condition Durability (mo)			
			95% Confidence Interval				95% Confidence Interval	
	Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	Lower Bound	Upper Bound
Mild UI	119.222	6.946	105.608	132.836	96.121	8.635	79.197	113.045
Moderate UI	91.852	6.195	79.709	103.994	60.287	6.615	47.322	73.253
Severe UI	59.191	8.428	42.673	75.710	23.438	6.016	11.647	35.230
Overall	93.490	5.052	83.588	103.391	62.327	4.770	52.979	71.676

DISCUSSION

Our study presents the long-term outcomes of the transobturator sling (AdVance) for the treatment of male SUI. At a mean follow-up of 56.4 months, the overall treatment success of 69.8% in our cohort is consistent with the literature; however, the sustained cure rate of 44.7% was relatively lower than previous reports.[6-10] We believe that given our strict criteria of cure as complete dryness (0 wet pads), we present a more realistic representation of long-term cure sustainability of the transobturator sling for the treatment of male SUI. Furthermore, our study has determined that the treatment success durability of patients with mild preoperative SUI is estimated to be nearly 10 years, with cure being sustained over an average of 8 years. This implies that this group of patients can achieve long-term treatment success with the transobturator male sling.

The long-term outcome is associated with the preoperative SUI severity and concomitant UUI; nevertheless, the time to event analysis and multiple Cox regression determined that both concomitant UUI and preoperative severe SUI were independent predictors for poor overall long-term success. Radiation therapy following radical prostatectomy increases the risk of urge urinary incontinence,[14-16] which implies that patients with a history of pelvic radiation and or overactive bladder seem to have a poor outcome after sling placement.[17-19] We postulate that concomitant UUI itself is a distinct characteristic that cannot be addressed or may even be aggravated by sling placement.[13] Our univariate and multivariate analyses suggest that concomitant UUI may have been a masked cofactor in patients who failed secondary to pelvic radiation. A relevant study has suggested that the subgroup of radiated patients may achieve good results with complications comparable to nonradiated patients.[20] Hence, given this findings, it is reasonable to emphasize the importance of preoperative concomitant UUI evaluation, while not disregarding its etiology secondary to the history of radiation.

Consistent with prior reports, our time to event analysis has determined that preoperative moderate to severe SUI is the only independent predictor for failure of cure in long-term follow-up.[4,8,20] Based on this finding, we support the current guideline's recommendation that the transobturator male sling is an appropriate option only for patients with baseline mild SUI, as they may benefit with a better long-term outcome.[3,9]

In our previous report, we included urodynamic evaluations and relevant variables as part of the evaluation in predicting outcomes.[12] In our current study, we aimed to include all patients with and without a urodynamic study, focused on the clinical presentation in an effort to make the predictors more pragmatic for routine clinical evaluation and initial consult discussion. Prior reports have shown that the urodynamic study variables did not correlate well with the postprostatectomy incontinence surgical outcome.[21] Compared to our previous midterm outcome

Table 2. Bivariate analysis for clinical variables associated with long-term last follow-up

		Success			Cure		
Variables		No	yes	*P* Value	No	Yes	*P* Value
Diabetes	No	53 (30.3%)	122 (69.7%)	1.00	96 (54.9%)	79 (45.1%)	0.861
	Yes	12 (30%)	28 (70%)		23 (57.5%)	17 (42.5%)	
Smoking	Smoker	39 (35.8%)	70 (64.2%)	0.077	67 (61.5%)	42 (38.5%)	0.075
	Nonsmoker	26 (24.5%)	80 (75.5%)		52 (49.1%)	54 (50.9%)	0.075
Race	White	47 (30.1%)	109 (69.9%)	0.963	82 (52.6%)	74 (47.4%)	0.332
	Black	15 (31.3%)	33 (68.8%)		31 (64.6%)	17 (35.4%)	
	Other	3 (27.3%)	8 (72.7%)		6 (54.5%)	5 (45.5%)	
Prostatectomy	No	8 (36.4%)	14 (63.6%)	0.624	14 (63.6%)	8 (36.4%)	0.500
	Yes	57 (29.5%)	136 (70.5%)		105 (54.4%)	88 (45.6%)	
Pelvic Radiation	No	48 (28.2%)	122 (71.8%)	0.273	88 (51.8%)	82 (48.2%)	0.044
	Yes	17 (37.8%)	28 (62.2%)		31 (68.9%)	14 (31.1%)	
Prior SUI Management (PFPT, bulking agent injection)	No	58 (30.4%)	133 (69.6%)	1.00	108 (56.5%)	83 (43.5%)	0.385
	Yes	7 (29.2%)	17 (70.8%)		11 (45.8%)	13 (54.2%)	
History of Vesicourethral Anastomosis Stenosis	No	47 (27.5%)	124 (72.5%)	0.098	90 (52.6%)	81 (47.4%)	0.128
	Yes	18 (40.9%)	26 (59.1%)		29 (65.9%)	15 (34.1%)	
Concomitant urgency symptoms	No	37 (23.6%)	120 (76.4%)	0.001	77 (49%)	80 (51%)	0.003
	Yes	28 (48.3%)	30 (51.7%)		42 (72.4%)	16 (27.6%)	
Intraop complication	No	61 (29.3%)	147 (70.7%)	0.202	115 (55.3%)	93 (44.7%)	1.00
	Yes	4 (57.1%)	3 (42.9%)		4 (57.1%)	3 (42.9%)	
Intraop to 3-month post-op complications	No	50 (31.3%)	110 (68.8%)	0.614	92 (57.5%)	68 (42.5%)	0.346
	Yes	15 (27.3%)	40 (72.7%)		27 (49.1%)	28 (50.9%)	
Pre-op SUI severity	Mild	9 (15.3%)	50 (84.7%)	<0.0001	19 (32.2%)	40 (67.8%)	<0.0001
	Moderate	26 (27.7%)	68 (72.3%)		50 (53.2%)	44 (46.8%)	
	Severe	30 (48.4%)	32 (51.6%)		50 (80.6%)	12 (19.4%)	
		mean (SEM) SD (65)	mean (SEM) SD (150)		mean (SEM) SD (119)	mean (SEM) SD (96)	
Age at sling surgery	(y)	67.86 (1.07) 8.605	67.73 (0.72) 8.843	0.924	67.70 (0.78) 8.528	67.86 (0.93) 9.066	0.890
BMI at sling surgery	(kg/m^2)	28.8 (0.45) 3.666	28.18 (0.31) 3.802	0.270	28.70 (0.34) 3.714	27.96 (0.39) 3.803	0.155
Interval from prostatectomy to sling	(y)	5.97 (0.74) 5.599	5.33 (0.40) 4.612	0.447	5.32 (0.49) 4.973	5.76 (0.52) 4.869	0.535
Interval from radiation to sling	(y)	6.30 (1.31) 5.699	6.01 (1.10) 5.923	0.866	6.30 (1.02) 5.967	5.69 (1.46) 5.471	0.745

SUI, stress urinary incontinence.

Table 3. Multiple Cox regression adjusted hazard ratio (HR) and corresponding 95%CI of predictors for treatment failure up to last follow-up

Treatment Success Predictors	Adjusted HR	95% CI for HR		Cure Condition Predictors	Adjusted HR	95% CI for HR	
		Lower	Upper			Lower	Upper
Mild SUI	1 (ref)			Mild SUI	1 (ref)		
Moderate SUI	1.986	0.929	4.247	Moderate SUI	1.918	1.127	3.264
Severe SUI	3.686	1.723	7.888	Severe SUI	3.694	2.135	6.392
Concomitant UUI	2.033	1.226	3.370	Concomitant UUI	1.341	0.908	1.981
				Pelvic radiation	1.370	0.904	2.076

report, we have observed no increase in complications as we continued to follow our patients over time.[12] The most common early postoperative complication observed (15.8% of our patients) was acute urinary retention, which is consistent with the literature.[9,12] Long-term urinary retention is rare.[22,23] Furthermore, previous reports have described that acute postprocedural urinary retention was a good indicator of a successful outcome.[24,25] In our cohort, a number of patients experienced initial cure, then failed in a relatively short time. This most likely represents sling slippage, as patients reported recurrent leakage immediately after an increase in physical activity within a month of sling placement.[26] While for the patient with late failure no well-defined etiology can be explained, we postulate that interim intrinsic sphincter deficiency development, de novo or progression of overactive bladder, or urethral atrophy, may be the causative entities, as seen on delayed presentation after AUS implantations.[27]

Our study has the strength of reporting a relatively large cohort with long-term follow-up of a range of baseline SUI severity that was treated with transobturator male sling by a single surgeon. As such, we utilized the new approach of time to event analysis in determining the sustainability of cure and long-term success durability of the AdVance sling. Furthermore, we evaluated concomitant UUI, which was a significant predictor for long-term success durability, a cofactor that was not previously described. Given the sparse literature on this important clinical factor, we recommend future studies to consider and further assess its impact on long-term treatment success durability. Similar to any retrospective study, ours has the limitation of potential bias on the basis of study design, nonutilization of standard or validated questionnaires (ie, ICIQ-SF) to assess patient-reported outcomes, and limited generalizability due to a single surgeon series. Furthermore, we did not report pad weight, as this is not a standard approach of assessment in our institution; instead, we used daily pad count as a measure of SUI severity. Although objectively this is not as accurate, previous studies have determined it as a suitable surrogate marker of patient-perceived outcomes.[28] A recent study also determined that the preoperative SUI defined as pads per day was predictive of AUS surgical outcome[29]; hence, we found it to be an acceptable and clinically pragmatic approach.

CONCLUSION

Our study described the long-term outcome of transobturator male sling for SUI, which was clustered according to preoperative SUI severity. We have determined that the preoperative SUI severity is an independent predictor for long-term success durability and cure sustainability; specifically, severe preoperative SUI was determined to have the highest probability of eventual treatment failure. Furthermore, our study has highlighted the importance of preoperative evaluation of the presence of concomitant UUI, which was determined to be an important covariable that has a negative impact on long-term success durability.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.07.032.

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