Durability of Retropubic Suburethral Sling Procedure and Predictors for Successful Treatment Outcome in Women With Stress Urinary Incontinence

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OBJECTIVE To investigate the long-term durability of retropubic suburethral sling procedure for female stress urinary incontinence (SUI) and to identify urodynamic factors that might predict long-term successful outcomes.

MATERIALS AND METHODS In total, 286 women who underwent a retropubic suburethral sling for SUI were enrolled in this retrospective survey. Most patients received uroflowmetry, postvoid residual volume study and standardized video urodynamic testing preoperatively and 6 months postoperatively in half of them. Surgical results, demographic characteristics, preoperative and postoperative urodynamic parameters, and postoperative clinical manifestation were retrospectively analyzed. Urodynamic parameters that predict a failure outcome were investigated.

RESULTS The median follow-up period was 10 years (4-29 years). The overall subjective cure rate was 80.8%. The success rates of the sling procedures at 3, 5, 10, 15, and 20 years were 89.2%, 87.7%, 78.8%, 68.6%, and 60.0%, respectively. Vaginal delivery and greater parity had negative influence on cure rate ($P = .004$ and .013, respectively). A significant interaction was detected from the baseline to 6 months between successes and failures for maximum flow rate (Qmax) ($P = .007$), voided volume ($P = .020$), and bladder outlet obstruction index ($P = .001$). Univariate analysis revealed significant decrease of Qmax, volume, and voiding efficiency; and increase of postvoid residual volume, detrusor pressure, and bladder outlet obstruction index in patients with successful outcome. However, multivariate logistic regression failed to find predictive factors for a failure suburethral sling procedure.

CONCLUSION Retropubic suburethral sling has a durable long-term effect for SUI. Slightly increased bladder outlet resistance after retropubic suburethral sling might be helpful for achieving long-term dryness. UROLOGY 131: 83–88, 2019. © 2019 Elsevier Inc.

Stress urinary incontinence (SUI) is a common and disturbing problem affecting 29%-75% of women at some point in their lives.[1] Surgical management for this problem has existed for over 100 years. There have been approximately 200 different surgical procedures described as yet.[2] According to the International Consultation on Incontinence Guidelines in 2013, the surgical treatments of female SUI may include the use of midurethral slings, bulking agents, and colposuspension.[3] Midurethral sling operations have been widely accepted as a routine surgical treatment for female SUI, which is minimally invasive, effective, and safe.[4-7]

Ideal and proper sling placement is often described as "tension-free",[8] but the precise physiological mechanism underlying successful sling surgery remains unclear. In practice, it has never been biomechanically validated that successful sling surgery is truly "tension-free." Overtensioning of the sling may cause varying degrees of bladder outlet obstruction (BOO), leading to obstructive voiding symptoms. On the contrary, a sling that is placed too loosely may result in incomplete resolution of SUI and a second sling is necessary to achieve continence.

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This study was approved by the Research Ethics Committee of the hospital. Informed consent was waived due to the retrospective data analysis in nature. All methods were performed in accordance with the relevant guidelines and regulations.

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Furthermore, with ageing, the initial sufficient tension and proper support on the urethra might become ineffective after decades. Despite that tension is very important in sling procedure, the standard intraoperative evaluation of sling tension is still lacking.[9]

In fact, some patients do experience subclinical BOO after successful SUI surgery. Some investigators have reported increased urethral resistance after successful Burch colposuspension.[10-12] They suggest that the cure of SUI depends partly on creating obstructive voiding, a compensatory abnormality. Correspondingly, others have reported decreased urine flow rates, increased residual urine volume, and increased detrusor pressure at maximum flow rate (Pdet.Qmax) after success pubovaginal sling.[13,14] Investigators of the Stress Incontinence Surgical Treatment Efficacy Trial also demonstrated that urodynamic changes after pubovaginal sling are accompanied by higher postoperative voiding pressures at 2 years.[15] Hence, a successful sling procedure might be necessary to associate with relative increase of urethral resistance and accompanied by a mean increase in Pdet.Qmax with a concomitant decrease in flow rate.

The currently available urodynamic evidence concerning successful outcomes of sling surgery is limited to preoperative factors analysis.[16] Postoperative urodynamic testing is often performed to assess surgical failures. Data are needed for the interpretation between surgical outcome and postoperative status. In this study, we retrospectively analyzed the preoperative and postoperative videourodynamic studies (VUDS), and further correlate the changes of urodynamic parameters with surgical outcomes. We also try to identify the urodynamic parameters after suburethral sling surgery that might predict the early treatment failure or long-term cure rate.

MATERIAL AND METHODS

In this study, we retrospectively reviewed the data of patients who received retropubic suburethral sling alone for female SUI with more than 2 years' follow-up between 1989 and 2014. Because this study was a real life retrospective analysis, therefore, we didn't set any exclusion criteria such as previous SUI surgery, a history of pelvic radiation, or previous pelvic surgery. Patients who received repeat sling procedure after the first sling surgery failure were not included in the final analysis. All patients underwent standardized videourodynamic testing preoperatively as the baseline and about half of them had the study postoperatively within 6 months. Patients were encouraged to receive postoperative VUDS for evaluation of their postoperative voiding condition regardless of their initial treatment outcome. Urodynamic studies included noninstrumented uroflowmetry, filling cystometry, and a video pressure flow study using a standardized research protocol. The patients were enrolled in this study since 1989, before that, there was no ICS standardization. However, all the performed urodynamic study and terminology in this study were in accordance with that recommended by the International Continence Society-recommended Good Urodynamic Practice Guidelines.[17]

The retropubic suburethral sling procedures in this study were performed by a single surgeon. The sling was positioned in the midurethra or proximal urethra depending on the videourodynamic findings. The sling was placed a little bit proximally to elevate the proximal urethra in patients with type 2 SUI and those with a hypermobile bladder base, while it was placed at the midurethra with mild tension in those with type 3 SUI with a nonmobile bladder base.[18] The sling ends were pulled to the retropubic lower abdomen bilaterally. After the cough test during operation, the sling was placed with adequate tension to overcome the increase of abdominal pressure by several vigorous coughs and mild elevation of the midurethrea without obstructing bladder outflow in the cystoscopic feature. This suburethral sling technique has been used by the authors for more than 20 years and the initial and long-term results are satisfactory comparable to the commonly used commercial slings.[18-20] Successful outcome of the suburethral sling was defined as negative cough and Valsalva stress test, no self-reported SUI symptoms, and no retreatment for SUI. Subjective cure of the procedure was confirmed if a patient reported successful outcome as mentioned above at the latest clinic visit or telephone interview. Surgical results, demographic characteristics, urodynamic parameters, and postoperative clinical manifestation such as difficult urination, urgency frequency, or persistent or recurrent SUI were analyzed.

The urodynamic parameters for evaluation in this study includes maximum flow rate (Qmax), corrected Qmax (CQmax), voided volume (Vol), postvoid residual (PVR), voiding efficiency (VE), Pdet.Qmax, and BOO index (BOOI). The CQmax was obtained by formulaic calculations: $Qmax = Qmax/(Vol + PVR)^{1/2}$. The VE was obtained by formulaic calculations: $VE = Vol/(Vol + PVR)$. The BOOI was obtained by formulaic calculations: $BOOI = Pdet.Qmax - 2 \times Qmax$, despite the fact that this is an index described for men.[21]

For analysis, preoperative and postoperative UDS parameters were compared within successful group and within failure group firstly. Secondary, the changes of urodynamic parameters after operation were compared between successful and failure groups. Patient demographics and urodynamic characteristics were evaluated for association with SUI cure rate using the Pearson's chi-squared test for categorical variables and paired *t* tests/Student's *t* test for numerical variables. Multivariable logistic regression models were used to evaluate the possible confounding effects among predictors on the outcome of sling surgery. All statistical tests were performed using a significance level of 95%. A value for $P < .05$ was considered statistically significant. SPSS software (version 16.0, Chicago, IL) was used for the statistical analyses.

RESULTS

Baseline Demographics and Postoperative Clinical Manifestations

A total of 434 women who received retropubic suburethral sling procedures between 1989 and 2014 were retrieved. Although this is a retrospective analysis of treatment outcome, medical record of all patients have been documented in electronic file of the hospital. Therefore, the subjective reported successful results and changes of the outcome in the long-term follow-up can be retrieved from0 the chart. For patients who have not returned for long time, telephone interview0 or office visit was scheduled and the treatment outcome was assessed. Excluding 129 patients who had concomitant pelvic organ prolapse surgery and

Table 1. Baseline demography of patients with retropubic suburethral sling procedure

	Total	Successes	Failures	*P* Value
No.	286	231 (80.8%)	55(19.2%)	
Operation age	58.1±11.7	57.7±12.2	58.5±11.8	.645
Parity*	3 (2, 4)	3 (2, 4)	4 (3, 5)	.013
Vaginal delivery*	3 (2, 4)	3 (2, 4)	4 (3, 5)	.004
Menopause	227	185 (80.1%)	42 (76.4%)	.335
Hysterectomy Hx	92	71 (77.2%)	21 (38.2%)	.288
POP operation Hx	19	13 (5.6%)	6 (10.9%)	.158
SUI operation Hx	32	24 (10.4%)	8 (14.5%)	.380

POP, pelvic organ prolapse; SUI, stress urinary incontinence.
Continuous variable: Student's *t* test.
Categorical variable: Pearson's chi-squared test.
* Data are presented as median with interquartile range (IQR).

19 000patients who received repeat suburethral sling operation, a total of 286 patients were finally followed up for long-term durability. Patients who had concomitant pelvic organ prolapse surgery were excluded because the complexity of surgery might interfere the therapeutic efficacy of a single suburethral sling. Patients who received repeat sling operation had already been enrolled and considered failure from the first sling operation.

The average age at the time of surgery was 58.1 years old (range 24-80), and the median follow-up was 10 years (range 4-29). At the latest clinic visit during follow-up, 231 of 286 patients (80.8%) declared themselves cured. The 231 patients in the successful group and 55 in the failure group were comparable at baseline with respect to demographics, clinical, and urodynamic characteristics. Baseline demographics and clinical characteristics of the study group are summarized in Table 1, including age, parity, vaginal delivery, menopausal status, operation history for hysterectomy, SUI, and pelvic organ prolapse. Vaginal delivery and greater parity had negative influence on SUI-specific cure rate ($P = .004$ and .013, respectively). No significant deterioration of objective cure rates was observed over time. The success rates of sling procedures at 3, 5, 10, 15, and >20 years were 90.5% (n = 286), 89.2% (n = 263), 79.8% (n = 138) 68.6% (n = 62), and 60.0% (n = 22), respectively. (Fig. 1A) There was no significant difference of the survival curves between patient groups with ≥50 (n = 217) and ≤50 (n = 69) years old ($P = .13$). (Fig. 1B)

Besides SUI, reinterventions due to refractory urgency urinary incontinence (UUI), difficult voiding, and sling erosions were observed in our study. Urodynamic detrusor overactivity was noted in 46 (16.1%) patients preoperatively, and 21 (7.3%) remained to have urgency or UUI after suburethral sling procedure refractory to antimuscarinic therapy, including 11 in successful group (3.8%) and 10 in failure group (18.2%). Patients with postoperative OAB were treated with antimuscarinics. The 21 patients with refractory UUI underwent intravesical Botox injection with OAB symptoms improved. A total of 11 (3.9%) patients eventually received cutting the suburethral sling at the midline without removing the sling underneath the urethra because of de novo obstructive voiding symptoms after the initial sling procedure. Most sling cutting procedures (n = 6, 54.5%) were performed within the first month postoperatively, from 2 days to 3.7 years. The continence rate after sling cutting was 90.9% (10/11). After sling cutting, the VE was around 60%, and no more urethral hypermobility could be demonstrated on

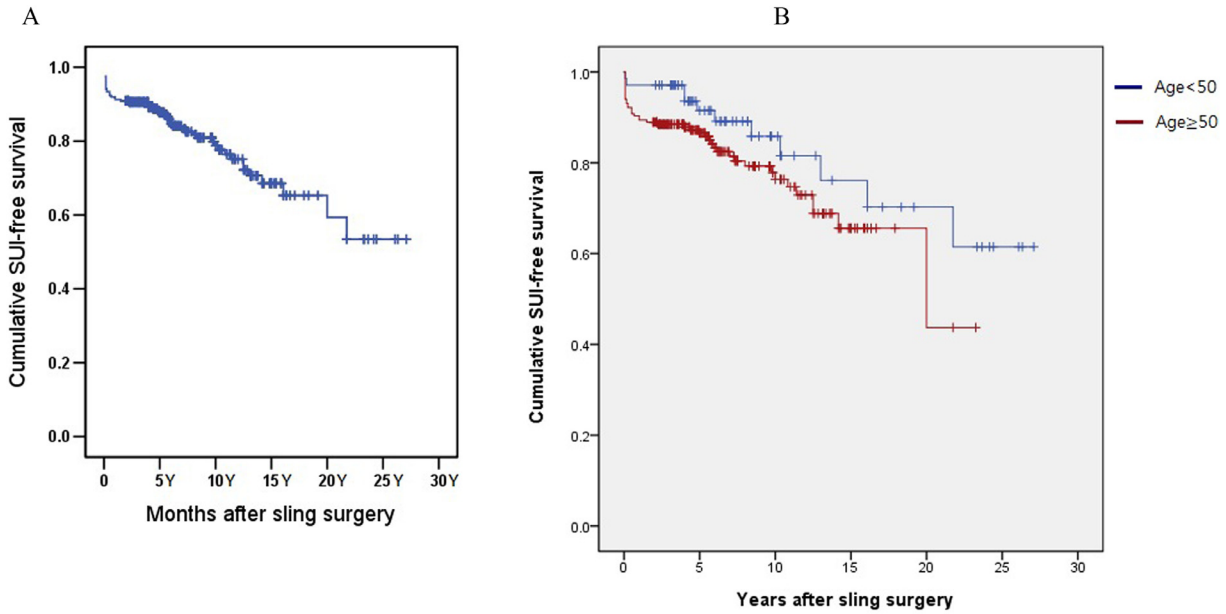

Figure 1. Cumulative stress urinary incontinence (SUI)-free survival after suburethral sling procedures in (**A**) overall patients, and (**B**) between patients with age ≥50 (n = 217) and ≤50 (n = 69) years old ($P = .13$). (Color version available online.)

postoperative VUDS. Complication of sling erosion was 1.05% (n = 3) in the long-term follow-up.

Changes of the Urodynamic Parameters After Sling Procedures

Table 2 shows the urodynamic parameters at baseline and after sling surgery and stratified by outcome status (successful vs failure outcome). The urodynamic parameters include uroflowmetry variables and video pressure flow study parameters. Because the data were retrospectively retrieved, only 266 patients (217 with successful and 49 failed outcome) had available preoperative and postoperative uroflowmetry data. There was no significant difference in all baseline urodynamic parameters between patients who had successful and failed surgical outcome. The postoperative parameters also showed no significant difference between groups, except a greater PVR was noted in the successful group ($P = .044$).

In the patients that underwent suburethral sling procedure, the mean Qmax values significantly decreased from baseline to 6 months by 6.88 mL/s among successes and 2.72 mL/s among failures, respectively ($P = .007$). The postoperative Vol decreased and PVR increased among successes, whereas no changes were noted among failures. An increase of BOOI between baseline and 6 months after surgery were noted in successful group, but not in failures. Women who achieved successful outcomes had significantly greater increases in BOOI from the baseline to 6 months compared with women who were classified as failures (19.9 ± 26.9 vs 3.4 ± 20.3, $P = .001$). The change of Pdet after operation was significantly increased in patients with successful outcomes but was not in those who were classified as failures; however, the difference did not reach statistical significance between groups (5.14 ± 14.6 vs 1.0 ± 11.1, $P = .128$).

Prediction of Long-Term Cure Rate With Urodynamic Parameters

Multivariate logistic regression model performed to evaluate the association between the changes of urodynamic parameters and successful outcome of sling procedures is displayed in Table 3. The logistic regression model revealed significant independent factors for SUI-specified outcome, including Qmax, Vol, and BOOI. Although univariate analysis revealed significant decrease of Qmax, decrease of Vol, and increase of BOOI after suburethral sling procedure might predict successful outcome, the odds ratio was too small for a clinically relevant prediction. Multivariate analysis also showed no significant predictor to predict a failure sling outcome. These results suggest that patients with a successful long-term outcome might have an increase of bladder outlet resistance after operation, however, single urodynamic parameter change after suburethral sling operation cannot predict the long-term success.

DISCUSSION

This study demonstrates that retropubic suburethral sling has a durable long-term effect on female SUI. The subjective cure rate was 80.8% at a median of 10-year follow-up. Women who had more parity or vaginal delivery were likely to have failure surgical outcome. Increased bladder outlet resistance as manifested by increased PVR, BOOI, and decreased Qmax and VE after sling surgery were associated with SUI-specific surgical success. In patients who

Table 2. Changes of urodynamic parameters: noninvasive uroflowmetry and pressure flow study

	Successful Outcome					Failure Outcome						
	N	Baseline	Post-op	Difference	P^1	N	Baseline	Post-op	Difference	P^1	P^2	P^3
Qmax (mL/s)	217	23.3 ± 12.5	16.4 ± 9.2	−6.88 ± 12.7	<.001	49	18.4 ± 10.7	15.7 ± 7.7	−2.72 ± 8.47	.035	.007	.524
C Qmax	217	1.27 ± 0.64	0.94 ± 0.48	−0.34 ± 0.69	<.001	49	1.19 ± 0.72	0.95 ± 0.40	−0.24 ± 0.62	.012	.372	.925
Vol (mL)	217	319 ± 163	256 ± 149	−62.5 ± 181	<.001	49	268 ± 148	271 ± 156	3.06 ± 164	.897	.020	.682
PVR (mL)	217	32.4 ± 70.6	70.4 ± 92.9	38.0 ± 972	<.001	49	23.1 ± 60.0	44.3 ± 73.3	21.2 ± 92.3	.114	.269	.044
VE	217	0.89 ± 0.21	0.78 ± 0.22	−0.11 ± 0.26	<.001	49	0.92 ± 0.18	0.85 ± 0.22	−0.07 ± 0.27	.087	.297	.053
Pdet.Qmax	98	15.4 ± 13.7	20.6 ± 13.9	5.14 ± 14.6	.001	35	19.8 ± 11.8	20.8 ± 12.4	1.0 ± 11.1	.599	.128	.466
BOOI	98	−26.3 ± 27.3	−6.4 ± 20.5	19.9 ± 26.9	<.001	35	−15.1 ± 24.2	−11.7 ± 19.8	3.4 ± 20.3	.328	.001	.730

BOOI, bladder outlet obstruction index (calculated by Pdet − 2× Qmax); CQmax, corrected Qmax; Pdet.Qmax, detrusor pressure at Qmax; PVR, post-void residual; Qmax, maximum flow rate; VE, voiding efficiency; Vol, volume.
P^1: difference between baseline and post-op 6 months, by paired *t* test.
P^2: difference of the changes of parameters between successes and failures, by Student's *t* test.
P^3: difference of post-op parameters between successes and failures, by Student's *t* test.

Table 3. Multivariable logistic regression analysis of changes of the urodynamic parameters from preoperative to postoperative associated with retropubic suburethral sling failure

	Univariate			Multivariate		
	OR	95% CI	*P* Value	OR	95% CI	*P* Value
Qmax (mL/s)	0.97	0.943-0.998	.036	0.947	0.840-1.068	.375
Corrected Qmax	0.800	0.491-1.303	.370	0.982	0.155-6.211	.984
Vol (mL)	0.998	0.996-1.00	.024	0.997	0.992-1.003	.358
PVR (mL)	1.002	0.999-1.005	.269	0.997	0.987-1.008	.601
Voiding efficiency	0.531	0.162-1.741	.296	0.465	0.006-35.4	.729
Ped.Qmax(cm H_2O)	1.023	0.993-1.054	.132	1.019	0.986-1.053	.255
BOOI	1.031	1.011-1.051	.002	-	-	-

have very low urethral resistance, mild increase of the sling tension might increase the effective therapeutic duration. In patients who develop lower Qmax or increased PVR volume, they might be less likely to fail the operation in long-term follow-up.

Several studies have demonstrated that the increased urethral resistance after incontinence surgery is associated with SUI-specific success.[10-15] An increase in urethral resistance after sling surgery, including increased Pdet. Qmax, increased PVR, and decreased Qmax have been reported in patients with a successful surgical outcome. The results of these studies suggest that the success of SUI surgeries depends in part on creating obstructive voiding. Compared with a cohort of 56 women with normal urodynamic tracing (mean Pdet 17.3 ± 8.23 cm H_2O, Qmax 24.1 ± 7.81 mL/s, Vol 488.6 ± 114.3 mL, PVR 19.4 ± 28.8 mL, VE 6.4 ± 4.94%),[22] the patients with successful outcome had mildly increased Pdet and PVR, and deceased Qmax and VE, indicating a mildly increase of urethral resistance after the sling operation has developed. The successful midurethral slings could be slightly obstructive because of increased tension overlying the urethra, in addition to the kinking effect on the vaginal wall and proximal urethra. However, this obstructive effect is subclinical, patient usually will not perceive voiding difficulty after the sling procedure.

The postoperative UDS data regarding the more minimally invasive midurethral slings are also in accordance with Burch colposuspension and pubovaginal sling. The changes of UDS parameters in terms of an increase in voiding pressure and a reduction of the corresponding flow rate are consistent. Sander et al reported that the spontaneous flow curve changed to a more obstructive pattern in 40%, with significantly decrease in Qmax, CQmax, average flow rate, and significantly increased PVR.[23] Ward and Atherton also found significant changes in the uroflowmetry variables compatible with the above studies.[24,25] These studies suggest that Burch colposuspension, pubovaginal slings, and midurethral slings are effective to cure SUI, partly because of increased outlet resistance. Besides, a little more tension seems to be good for long-term success as an aspect of providing sufficient urethral support when patient is getting older and the urethral resistance is reduced.

Although the slight obstructive voiding pattern is observed after successful sling surgery, the accurate definition of this mild form of female BOO is lacked. A few methodologies of identifying women with BOO exist, but the diagnosis of the female BOO is not standardized.[26-30] The difficulty in using precise cutoff criteria to define BOO in women is clearly stated. However, women can void by simply relaxing the pelvic floor without a detrusor contraction. Consequently, in order to avoid overdiagnosis of women with BOO, the clinical symptoms and the UDS measures are both essential for classifying the obstruction. We need not only the careful assessment of voiding condition, such as force to stream, weak stream, prolong voiding, and residual urine sensation; but also the VUDS findings to get the complete picture to identify the true female BOO. In our study, the mean Qmax after operation was slightly lower and the mean Pdet.Qmax was slightly higher than the normal women. Besides the 11 patients with obstructive voiding symptoms that received sling cutting, most patients with a successful outcome did not report voiding symptoms at follow-up visit. A subclinical increase of urethral resistance might develop after the successful suburethral sling procedure, which might also ensure a longer durability of suburethral sling.

In comparison with other studies regarding UDS parameter changes after continence surgery, this study has a longer follow-up period with a median time of 10 years. Because the operations were performed by the same urologist, all patients received a uniform surgical procedure. However, this is also the weakness of this study because the results might not be generalized. Although the standardized urodynamic practice guidelines recommended by International Continence Society was published in 2002, all the procedure of urodynamic study and the terminology of parameters used in this study were all in accordance with the ICS recommendations, with rigorous quality control. Moreover, different discriminations between the UDS results were adopted in our study. First, the UDS results were stratified by outcome status. Significant difference of UDS parameter changes after surgery was only observed in successful group. In other words, an adequate bladder outlet resistance might be essential to achieve long-term successful SUI-specific outcome. This could further explain the finding of previous sling studies that reported an increase of the maximal urethral closure pressure and PVR in successfully treated patients, and a low maximal urethral closure pressure predicts the failure of sling surgery.[7,31,32]

Limitation of this study is the BOOI, which was developed to measure urethral resistance in male BOO but not for female SUI. In this study, we aimed to point out that an increase of urethral resistance seems to provide a long-term sling durability. Because the increased urethral resistance after sling procedure is subclinical and not a true BOO, categorizing the BOO condition by Blaivas nomogram[26] cannot differentiate the minor change of the urethral resistance. Using the BOOI by Abrams-Griffiths nomogram[21] will be more appropriate for demonstration of the changes of urethral resistance after sling procedure. In addition, although the enrollment criteria were patients who had sling operation for at least more than 2 years, after completion of the study, all patients had been followed up for ≥4 years. Because most of the failure occurred in the initial years after operation, therefore, we evaluated the consecutive success rated at 3, 5, 10, 15, and 20 years to demonstrate the change of success rate with time.

CONCLUSION

The findings of this study suggest that, for suburethral sling operations, slightly increased urethral resistance as measured by increased Pdet.Qmax, increased BOOI, decreased Qmax, decreased VE, and increased PVR are associated with long-term successful sling outcomes. It is therefore arguable whether "tension-free" is the principle for successful sling surgery. Nonetheless, a little tension, which slightly increased bladder outlet resistance, seems to be essential for achieving long-term dryness.

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