Virtue male sling outcomes and application to a contemporary nomogram

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Introduction: *To report outcomes of our Virtue male sling series and evaluate predictors of surgical success and failure. We also retrofit the Male Stress Incontinence Grading Scale (MSIGS) refined nomogram, including the standing cough test (SCT), to assess its application to our cohort.*

Materials and methods: *A retrospective review was completed at a single institution over a 4 year period of all Virtue male slings implanted for stress urinary incontinence (SUI). Patient demographics including pad usage per day (PPD) and MSIGS were obtained on all patients after their bladders were filled cystoscopically. Failure was defined as > 1 PPD and/or conversion to another anti-incontinence procedure. Incidence, management and outcomes of complications were also evaluated.*

Results: *Forty-six men who underwent Virtue male sling at a median follow up of 15.6 months were analyzed with an objective success rate of 78% and a subjective success rate of 85%. Preoperative predictors of surgical success were ability to stop stream on physical exam, lack of total incontinence and no history of posterior urethral stricture. MSIGS alone was not predictive of sling success or failure. Penile numbness occurred in 11% of patients and reoperation with incision of the sutured together transobturator arms improved sensation in all patients.*

Conclusion: *Virtue male sling has high objective and subjective success rates with a manageable side effect profile. Evidence of residual sphincteric function appears to be more predictive of sling success rather than MSIGS.*

Key Words: male sling, contemporary nomogram

Introduction

Stress urinary incontinence (SUI) after prostate surgery can have a drastic negative impact on a patient's quality of life. Incontinence rates at 12 months after radical prostatectomy can be as high as 31% in contemporary studies.[1] Historically, 5% of patients who undergo radical prostatectomy will elect to have surgical repair of their SUI over a 15-year period.[2] Decision regarding which anti-incontinence procedure to undertake should be directed by severity of symptoms and patient preference.

There are a number of male slings on the market designed to mitigate the effects of SUI. The Virtue male quadratic sling (Coloplast, Humlebaek, Denmark)

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was introduced in 2012[3] for the treatment of mild to moderate male SUI. Reports of clinical outcomes with this device are sparse and reach heterogeneous conclusions. [4-8] Specifically, McCall et al reported a failure rate of 68% and abandoned doing the procedure thereafter[4] whereas Comiter et al reported objective success rate at 79% in their cohort.[8] Some predictors of success in these series have included preoperative pad weights, radiation history, and pads per day (PPD), among others. More recently, a male standing cough test (SCT) was introduced as means to quickly assess the degree of incontinence, on the validated male stress incontinence grading scale (MSIGS).[9] MSIGS has recently been incorporated into a formal nomogram to predict success of the AdVance Male sling (Boston Scientific, Marlborough, MA, USA).[10]

Herein we report our outcomes from a single institution and aim to test this nomogram in our population of male patients undergoing Virtue sling. We hypothesize that the nomogram will accurately predict failure in this population as it did in the AdVance sling population.

Materials and methods

A retrospective analysis of an IRB-approved database was reviewed. Patients with Virtue sling placement for SUI between September 2015 and April 2020 were included. Slings placed after an artificial urinary sphincter (AUS) were excluded.

Preoperative history collected at the office visit prior to surgery included International Prostate Symptom Score (IPSS), surgical and radiation history, as well as self-reported pad usage per day (PPD). PPD were divided into 0-3 and greater than or equal to 4, based on the method used in the nomogram.[10] Pad weights were not collected. While taking the patient's history, they were also questioned directly if on a normal day they would void voluntarily or were "totally incontinent" and did not voluntarily void. All patients then underwent office cystourethroscopy to evaluate for anterior or posterior urethral strictures. The bladder was filled with the cystoscope and the patient was then asked to stand and perform the SCT into a towel. MSIGS was then used to grade the severity of leakage. The patients were also asked to void, and the ability to stop the stream mid-void was assessed. The post void residual was then measured.

If a urethral stricture was identified at time of cystoscopy it was surgically repaired. We would then re-evaluate with cystoscopy at 4 months and if the urethra was patent and the patient had persistent SUI, he would be offered a sling.

Initial sling placement was performed as previously described.[8] Follow-up was performed at 6 weeks, 4 months, 1 year and then yearly thereafter. Failure at the last follow up visit was defined as > 1 PPD and/or conversion to another anti-incontinence procedure. In our series, we looked at success at last follow up, including those patients who underwent sling revision.

If patients had an early or delayed failure that was mild, as defined by some improvement of their symptoms of 2-3 PPD, they would be offered a sling revision as previously described.[11] If there was little to no improvement in incontinence compared to prior to sling placement, patients were offered an artificial urinary sphincter.

If patients complained of penile numbness that persisted at 3 month follow up, they were taken to the operating room for revision. The transobturator (TO) arm would be incised through a perineal incision at the midline where it was sewn together. Following this we would assess the coaptation via a retrograde leak point test and plicate the sling if needed. By waiting 3 months, it was felt the sling would have a chance to scar in prior to incising the TO arm.

For categorical data, frequency and percent are calculated whereas median and interquartile range (IQR) were calculated for continuous data. Baseline characteristics and results were stratified by success of Virtue sling and compared between success and failure patients using the Wilcoxon rank-sum test for continuous and Fisher's exact test for categorical data elements. Univariate and multivariate logistic regression was used to identify significant predictors for Virtue success. PPD were divided into <=3 PPD versus > 3 PPD. Statistical significance was defined as p value <= 0.05. SAS 9.4 (Cary, NC, USA) was used to conduct all analyses and generate graphs. Patient characteristics including MSIGS, radiation history, and self-reported PPD were input into the nomogram (msigs.shinyapps.io/nomogram/) to calculate the probability of success.

Results

Forty-nine Virtue slings were placed between January 2016 and January 2020. Three patients had previous AUS in place at time of sling placement and were excluded from the analysis. Thus, 46 men were included in this series. Median age was 70.6 years (52-84), and median follow up was 15.6 months, Table 1. There were 12/46 (26%) using 3 PPD or less and 15/46 (32.6%) were considered "totally incontinent"; 36/46 (78.3%) patients were considered a success as defined by 1 or less PPD at last follow up. In logistic regression models, Table 2, preoperative characteristics associated

TABLE 1. **Baseline characteristics, failure versus success / Data represent median (IQR) or n (%)**

	Sling failure (n = 10)	**Sling success (n = 36)**	**p value**	**All patients (n = 46)**
Age (y)	71.7 (66.2-79.3)	70.5 (65.8-74.2)	0.4	70.6 (65.8-75.2)
Body mass index	27.8 (25.4-33.8)	28.2 (25.8-31.6)	1.0	28.2 (25.7-32.1)
Follow up months	15.1 (13.7-31.8)	15.8 (5.5-26.1)	0.7	15.6 (5.9-28.1)
IPSS at baseline	12 (6-15)	10 (4-18)	0.7	10 (5-15)
BI score at baseline	6 (5.5-6)	5 (4-6)	0.04	5 (4-6)
MSIG	3 (2-4)	3 (2-3)	0.2	3 (2-3)
Stop stream				
No	5 (50.0%)	2 (5.6%)	0.0005	7 (15.2%)
Yes	5 (50.0%)	34 (94.4%)		39 (84.8%)
Valsalva				
No	9 (90.0%)	34 (94.4%)	0.6	43 (93.5%)
Yes	1 (10.0%)	2 (5.6%)		3 (6.5%)
History of posterior stricture				
No	6 (60.0%)	33 (91.7%)	0.01	39 (84.8%)
Yes	4 (40.0%)	3 (8.3%)		7 (15.2%)
Tobacco use				
No	9 (90.0%)	34 (94.4%)	0.6	43 (93.5%)
Yes	1 (10.0%)	2 (5.6%)		3 (6.5%)
DM				
No	10 (100.0%)	31 (86.1%)	0.2	41 (89.1%)
Yes	0 (0.0%)	5 (13.9%)		5 (10.9%)
Prior radiation				
No	6 (60.0%)	30 (83.3%)	0.1	36 (78.3%)
Yes	4 (40.0%)	6 (16.7%)		10 (21.7%)
Totally incontinent				
No	2 (20.0%)	29 (80.6%)	0.0008	31 (67.4%)
Yes	8 (80.0%)	7 (19.4%)		15 (32.6%)
Pad use at baseline				
≤ 1 ppd	0 (0.0%)	3 (8.3%)	0.3	3 (6.5%)
2 ppd	0 (0.0%)	6 (16.7%)		6 (13.0%)
3 ppd	1 (10.0%)	5 (13.9%)		6 (13.0%)
≥ 4ppd	9 (90.0%)	22 (61.1%)		31 (67.4%)
Total IPSS score at baseline	12 (6-15)	10 (4-18)	0.7	10 (5-15)
BI score at baseline	6 (5.5-6)	5 (4-6)	0.04	5 (4-6)
Nomogram probability of success	0.2 (0.1-0.3)	0.2 (0.2-0.5)	0.04	0.2 (0.2-0.5)

IPSS = International Prostate Symptom Score; BI = bother index; MSIG = Male Stress Incontinence Grading Scale; DM = diabetes mellitus; ppd = pad usage per day

with surgical success were: 1) Ability to stop stream on physical exam, 2) Lack of total incontinence, and 3) No history of posterior urethral stricture. On multivariate analysis, ability to stop stream and lack of radiation were predictors of success.

Failure (defined as > 1 PPD) occurred in 10/46 (21.7%) patients. Their individual risk factors are described in Table 3. Of those 10 patients, 3 indicated comfort with 2-4 PPD, and did not elect to have a sling revision or an AUS. Four went on to AUS and the

TABLE 2. **Univariate and multivariate results of logistic regression for probability of success**

Variable	Univariate OR (95%CI)	Multivariate p value	OR (95%CI)	p value
Age (cont.)	1.05 (0.95, 1.2)	0.4		
Body mass index (cont.)	1.04 (0.92, 1.2)	0.5		
No history of stricture	7.3 (1.3, 41.4)	0.02		
Stop stream	17.0 (2.6, 112)	0.003	30 (3.5, 264)	0.002
Lack of total incontinence	16.6 (2.9, 96)	0.002		
No history of radiation	3.3 (0.7, 15.5)	0.1	7.5 (1.06, 52)	0.044
Pad use at baseline (≤ 3 ppd vs. > 3)	5.7 (0.65, 50.3)	0.1		
IPSS BI at baseline (cont.)	0.38 (0.13, 1.1)	0.08		
MSIGS (cont.)	1.5 (0.8, 3.1)	0.2		
Total IPSS at baseline (cont.)	0.98 (0.89, 1.1)	0.7		
Irritability score (cont.)	0.94 (0.78, 1.1)	0.5		

ppd = pad usage per day; IPSS = International Prostate Symptom Score;
BI = bother index; MSIG = Male Stress Incontinence Grading Scale

TABLE 3. **Demographics of surgical failure**

Patient number	Total incontinence	MSIGS	Radiation	Ability to stop stream	Posterior urethral stricture	% chance of success per nomogram	Outcome
1	No, 4 PPD	1	Yes	Yes	No	24	AUS
2	No, 3 PPD	2	Yes	Yes	No	29	Dementia, lives with a suprapubic tube
3**	Yes	4	No	No	No	13	4 PPD incontinence. Dementia; no AUS placed
4	Yes	2	No	Yes	No	30	Happy at 2 PPD
5	Yes	4	No	Yes	No	13	Happy at 2 PPD
6	Yes	3	Yes	No	No	10	AUS
7	Yes	3	No	No	Yes	20	Happy at 4 PPD
8	Yes	2	No	No	Yes	29	Body habitus
9*	Yes	4	No	No	Yes	13	AUS*
10	Yes	4	Yes	Yes	Yes	6	AUS

*patient has success with the sling, but due to numbness, underwent revision and SUI recurred.
**patient was in retention postop, and after urethrolysis, he increased to 4 PPD incontinence.
MSIG = Male Stress Incontinence Grading Scale; PPD = pad usage per day; AUS = artificial urinary sphincter

TABLE 4. **Complications**

	Total (%)	Clavien-Dindo	Outcome
Skin rash	4 (9%)	1	Treated
Scrotal sensation changes	3 (7%)	1	Persists
Urinary tract infection	1 (2%)	2	Treated with ABX
Penile numbness	5 (11%)	3b	Revised, sensation improved in all
Bladder perforation	1 (2%)	2	Foley left in longer
Prolonged pain	6 (13%)	1	Resolved
Retention after Foley removal	2 (4%)	2, 3b	One resolved, one did not and underwent urethrolysis

remaining 3 patients who failed are not candidates for sphincter due to body habitus or functional capacity, Table 3.

The most common complications were neurologic in etiology, described as prolonged pain, scrotal sensation changes, and penile numbness, Table 4. All 5 patients (11%) who had persistent penile numbness at 3-month follow up underwent reoperation with incision of the TO arms where they were sutured together. With this maneuver, sensation improved in all patients; however, 1 patient had recurrent incontinence after the revision.

Six patients (13%) had immediate or delayed incontinence and underwent revision based on the criteria described in the methods. This was successful in all cases. Urinary retention occurred in 2 patients following catheter removal, of whom one required subsequent surgery for urethrolysis.

Discussion

Herein, we report on the outcomes of 46 patients undergoing Virtue male sling placement at a single institution. We report an overall 78% success rate defined as ≤ 1 PPD. We further report an overall post-operative patient satisfaction rate of 85% based on patient self-report of being content with their improved degree of SUI but not meeting our objective definition of surgical success. Overall morbidity was approximately 10% with the most common morbidity being neurologic changes in sensation. While the overall nomogram prediction did differ significantly between the success and failure groups, it is hard to make clinical decisions based on the findings being that both success and failure had a 20% chance of success. Given our overall objective success rate of 78%, the nomogram underestimated success for the Virtue sling. We believe this discrepancy to be multifactorial in how our SCT was executed as well as the mechanism of action of the Virtue quadratic sling as compared to the AdVance two-armed sling.

Our population had a higher MSIGS on average than that reported by Shakir et al.[10] In our preoperative work up, the bladder was filled with the cystoscope and then the SCT was performed instead of waiting 1 hour for the bladder to fill passively as originally described. This may have resulted in an overall higher MSIGS in our study, thus negatively impacting the nomogram chance of success. However, this simple one-step work up not only ensures there are no strictures, but also that the bladder is completely full for the SCT. We also prefer to ask the patient to stop the stream mid-void to ensure the ability to coapt the urethra. As we found in our series, patient ability to voluntarily close the sphincter has been shown previously to be a good preoperative prognosticator.[12] However, to our knowledge, this is the first series to report the ability to stop the stream mid-void, which is likely more indicative of a strong contraction, versus a visual assessment.

History of radiation is frequently described in the literature as being predictive of sling failure,[13] however we did not find this to be a risk factor in our cohort on univariate analysis. On multivariate analysis, in the presence of ability to stop the stream, the absence of radiation is favorable for success. Risk factors for surgical failure on univariate analysis included history of posterior stricture, total incontinence, and inability to stop a stream mid-void. Each of these risk factors likely reflects poor sphincteric function. The mechanism of the Virtue sling is two-fold including elevation of the urethra, and compression against the pubic bone. Comiter et al have previously shown that by using a retrograde leak point test, the tensioning of both the TO and the prepubic arms along with securing the arms together adds an additional 10 cm, 20 cm, and over 30 cm

of water above baseline, respectively.[3] Sling failures in patients with severely compromised sphincter function has led us to adjust our practice such that we no longer offer slings to those who do not void during the day ("totally incontinent") and those with any of the following: history of vesicourethral anastomotic stenosis, inability to stop urinating mid-stream, or radiation. In this population, the prepubic arm alone seems insufficient to prevent persistent incontinence, and the sling still requires some residual sphincter function for success. While it has been recently shown that patients with higher MSIGS have better outcomes with AUS over sling,[14] the way we obtain our MSIGS has been practice changing in that we believe to have identified a subset of patients with objectively more severe SUI that still appear to respond well to this sling.

Revisions in this population were not uncommon, at 24%. Unique to this sling is its larger surface area which allows for revision if a patient does not get to desired continence level. Moreover, all patients who underwent reoperation for sling tightening were successful. We do not offer revision to those demonstrating little to no improvement in continence after the initial sling placement. The second most common reason for revision was penile numbness. This complication does not always appear to be reported in the literature,[4,6,8] and our rates were not trivial at 11%. Patients experiencing this phenomenon in prior series presumably get grouped into the complication of "pain", however our patients primarily described numbness. This is likely due to the TO arms compressing the pudendal nerve. If numbness occurs, our practice is to wait until 3 months post-op as some patients will return to baseline SUI following surgery. We presume that 3 months will allow for the mesh to scar in and maintain continence but still allow for release of pudendal nerve entrapment as evidenced by all our patients who underwent revision showing improvement in numbness symptoms despite length from surgery.

Limitations of this study include its midterm follow up with median of 15 months along with small sample size that cannot properly assess the statistical significance of nomogram predications. Also, pad weights were not collected however those have recently been shown to be strongly correlated with PPD use and SCT outcomes.[15]

Conclusions

The Virtue male sling has high objective and subjective success rates with an acceptable and manageable side effect profile. It is especially useful in the patient population with some residual sphincteric function, despite their pad usage. While the nomogram predicting success of AdVance sling placement[10] did not accurately predict the success of the Virtue sling, it did predict a higher level of success in the success group. It appears that total incontinence, inability to stop the stream mid-void and history of posterior urethral stricture reliably predict sling failure. Further studies are needed to validate these findings. □

References

1. Ficarra V, Novara G, Rosen RC et al. Systematic review and meta-analysis of studies reporting urinary continence recovery after robot-assisted radical prostatectomy. *Eur Urol* 2012;62(3):405-417.
2. Nam RK, Herschorn S, Loblaw DA et al. Population based study of long-term rates of surgery for urinary incontinence after radical prostatectomy for prostate cancer. *J Urol* 2012;188(2):502-506.
3. Comiter CV, Nitti V, Elliot C, Rhee E. A new quadratic sling for male stress incontinence: retrograde leak point pressure as a measure of urethral resistance. *J Urol* 2012;187(2):563-568.
4. McCall AN, Rivera ME, Elliott DS. Long-term follow-up of the Virtue quadratic male sling. *Urology* 2016;93:213-216.
5. Abdullah A, Machkour F, Bouchet E, Plainard X, Descazeaud A. Efficacy of the VIRTUE male quadratic sling in the treatment of stress urinary incontinence: A retrospective study. *Prog Urol* 2019;29(10):490-495.
6. Ferro M, Bottero D, D'Elia C et al. Virtue male sling for post-prostatectomy stress incontinence: a prospective evaluation and mid-term outcomes. *BJU Int* 2017;119(3):482-488.
7. Sourial MW, Richard PO, Morisset J, Jundi M, Tu LM. Retrograde leak point pressure measurement improves outcomes of the Virtue male sling for postprostatectomy incontinence. *Can Urol Assoc J* 2017;11(7):E271-E276.
8. Comiter CV, Rhee EY, Tu LM, Herschorn S, Nitti VW. The virtue sling--a new quadratic sling for postprostatectomy incontinence--results of a multinational clinical trial. *Urology* 2014;84(2):433-438.
9. Morey AF, Singla N, Carmel M et al. Standing cough test for evaluation of post-prostatectomy incontinence: a pilot study. *Can J Urol* 2017;24(1):8664-8669.
10. Shakir NA, Fuchs JS, McKibben MJ et al. Refined nomogram incorporating standing cough test improves prediction of male transobturator sling success. *Neurourol Urodyn* 2018;37(8): 2632-2637.
10. Rubin RS, Xavier KR, Rhee E. Virtue quadratic male sling for stress incontinence-surgical guide for placement and delayed revision. *Transl Androl Urol* 2017;6(4):666-673.
11. Bauer RM, Mayer ME, Gratzke C et al. Prospective evaluation of the functional sling suspension for male postprostatectomy stress urinary incontinence: results after 1 year. *Eur Urol* 2009; 56(6):928-933.
12. Torrey R, Rajeshuni N, Ruel N, Muldrew S, Chan K. Radiation history affects continence outcomes after advance transobturator sling placement in patients with post-prostatectomy incontinence. *Urology* 2013;82(3):713-717.
13. Khouri RK Jr, Ortiz NM, Baumgarten AS et al. Artificial urinary sphincter outperforms sling for moderate male stress urinary incontinence. *Urology* 2020;141:168-172.
14. Yi YA, Keith CG, Graziano CE et al. Strong correlation between standing cough test and 24-hour pad weights in the evaluation of male stress urinary incontinence. *Neurourol Urodyn* 2020;39(1):319-323.