Early outcomes of the transobturator male sling based on body mass index

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Introduction: *Little is known regarding factors that contribute to the long term success or failure of the transobturator male sling for stress urinary incontinence. The objective of this study was to compare the outcomes of the transobturator male sling for stress urinary incontinence based on body mass index (BMI).*

Materials and methods: *A retrospective review was performed of 31 transobturator male slings placed at a single institution from 2008 to 2010. Success of the procedure was defined as resolution of leakage or great improvement of leakage by the Patient Global Impression of Improvement scale and lack of urinary leakage on postoperative physical exam. Patients were divided into one of three groups: ideal weight (BMI 18.5-24.9 kg/m^2), overweight (25-29.9 kg/m^2), and obese (> 30 kg/m^2). Outcomes and complications were compared between groups.*

Results: *Etiology of urinary incontinence was radical prostatectomy in 28 patients and a transurethral procedure for infection or benign prostatic hypertrophy (BPH) in 3 patients. Successful treatment of incontinence was significantly higher in the ideal weight (7/8 or 88%) and overweight group (13/14 or 93%) in comparison to the obese group (4/9 or 44%), (p = 0.019). Postoperative complications were similar between groups.*

Conclusions: *Obese patients had lower success rates after transobturator sling in comparison to ideal and overweight patients. We feel this may be due to increased intra-abdominal pressure transmission to the bladder, urethra, and sling itself. These patients may be better candidates for an artificial urinary sphincter or should be counseled to undergo pre-preoperative weight loss to improve sling outcomes.*

Key Words: male sling, stress urinary incontinence, post-prostatectomy incontinence, obesity

Introduction

The most common cause of stress urinary incontinence (SUI) in men is iatrogenic injury during prostate surgery.[1] Approximately 1 in 6 men will be diagnosed with prostate cancer during his lifetime and more than 2 million men in the United States who have been diagnosed with prostate cancer are alive today.[2] Mean continence 12 months after robotic assisted radical prostatectomy, which has become the mainstay of the surgical treatment for prostate cancer, is 91%.[3] Post-prostatectomy urinary incontinence lasting longer than 12 months will affect 25-33% of patients treated with radical prostatectomy.[4,5] With such large numbers of men suffering from post-prostatectomy incontinence, many will present to a urologist desiring treatment. It has been estimated that up to 10% of these men seek surgical intervention for his stress incontinence.[5] In addition, many men undergoing other urologic procedures, such as transurethral treatments for benign prostatic hypertrophy (BPH), may develop postoperative stress urinary incontinence (SUI) and will desire definitive treatment.

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Placement of an artificial urinary sphincter (AUS) is the gold standard for treatment of male SUI with a high degree of patient satisfaction.[6] However, AUS placement may be unattractive to many men because of the potential for infection of the implant, mechanical failure, and the desire to avoid a mechanical device.[4] Since 2006, the transobturator male sling has emerged as an additional treatment option for male SUI. The male sling offers a less invasive treatment option for men, without the encumbrance of having to operate a mechanical device, thus allowing for the most natural return to normal micurition. In addition, in the event of a sling failure, an AUS can be placed successfully. This makes a male sling an attractive first line option for patients with mild to moderate urinary incontinence without the elimination of the future option of an AUS.[6]

Long term efficacy and factors that contribute to male sling failure have yet to be determined. No current studies reviewing outcomes of transobturator male slings have assessed how BMI effects sling outcome. Over the past few decades, the body mass index (BMI) of men undergoing radical prostatectomy has increased.[7] It is known from experience with incontinence in the female population that obesity is an independent risk factor for urinary incontinence as well as for treatment failure of midurethral slings in women with stress urinary incontinence.[8] In addition, studies have shown that after radical prostatectomy, obese men have increased rates of stress urinary incontinence in comparison to normal weight men as well as a longer duration of postoperative incontinence.[9,10] We present an early review of trends in outcomes of treatment of male SUI after transobturator male sling based on BMI.

Materials and methods

After IRB approval by our institution, a non-funded retrospective chart review was performed of all men who underwent placement of transobturator male sling (AdVance Sling, American Medical Systems, Minnetonka, MN, USA) at a single institution by a single provider from September 2008 to June 2010. All patients had SUI for greater than 1 year after radical prostatectomy or a transurethral procedure for treatment of BPH or infection. Preoperative confirmation of SUI was made by positive urinary leakage during cough and valsalva on physical examination in the supine position. In addition, flexible cystourethroscopy was performed to ensure coaptation of the external urinary sphincter in all patients and patency of the urethrovesical anastomosis in those patients status post radical prostatectomy. Multi-channel urodynamics was performed at the discretion of the treating surgeon for patients with symptoms concerning for overactive bladder, incomplete emptying, or small bladder capacity. Patients who did not have coaptation of their external sphincter on cystoscopy or those who had severe urinary incontinence were counseled to undergo placement of an AUS.

All procedures were performed by a fellowship trained urologist according to previously described techniques.[11] Patients were discharged home on the day of surgery unless medically contraindicated. A voiding trial was performed in the post anesthesia care unit (PACU). Any patient with the inability to void greater then 50% of their bladder capacity or post void residual > 200 mL was considered to be in urinary retention and discharged home with a Foley catheter. A voiding trial was scheduled for these individuals 1-5 days later. Patients were seen for follow up at 2 weeks with a uroflow and post void residual (PVR) and at 6 weeks postoperatively with a uroflow and PVR if the 2 week study was equivocal for obstruction, at 6 months, and then annually there after. Success of the procedure was defined as "very much better" or "much better" on the 5 point patient global impression of improvement inventory (PGI-I) and lack of stress urinary leakage on post operative physical exam. The postoperative cough stress test was performed in the upright position with a full bladder. All other results were considered failures.

BMI was calculated based on the following formula: weight in kilograms/(height in meters) x (height in meters). Patients were divided into three groups: ideal weight (BMI 18.5-24.9 kg/m^2), overweight (BMI 25-29.9 kg/m^2), obese (BMI > 30 kg/m^2). The sling outcomes and complication rates were compared between the three groups.

All statistical calculations were computed using Stata/SE v 10.0 (College Station, TX) for Mac OS X. Continuous variables were analyzed using the Kruskal-Wallis test. Analysis of categorical data was performed using the chi-squared and fisher-exact tests where appropriate.

Results

All patients were able to be followed up after surgery. Overall patient demographics are presented in Table 1. A total of 31 men underwent sling placement. The mean age was 71 years (49-85). Etiology of SUI was open or robotic radical prostatectomy in 28 men, holmium laser enucleation of the prostate in 2 men, and transurethral unroofing of a prostatic abscess in 1 man. Mean pad usage per day was 4 (1-20) and mean VLPP on urodynamics was 71 cm H_20 (30-134). The mean

TABLE 1. **Overall demographic information**

Mean patient age (yr)	71 (49-85)
Mean BMI (kg/m^2)	28 (21-42)
Mean pads per day	4 (1-20)
Mean valsalva LPP (cm H_20)	71 (30-134)
Previous incontinence procedure	2
Previous radiation	1
Mixed incontinence	8
Etiology of incontinence	
Radical prostatectomy	28
HoLEP	2
Transurethral resection of prostatic abscess	1

BMI = body mass index; LPP = leak point pressure
HoLEP = holmium laser enucleation of the prostate

BMI was 28 kg/m^2 (20.7-42.1). There were 8 patients in the ideal weight group, 14 in the overweight group and 9 in the obese group. There was no statistically significant difference in the demographics between the three groups separated by BMI category, Table 2. Length of hospital stay was 0-1 days. Mean follow up was 390 days (188-805).

The preoperative urodynamic parameters between the three groups is presented in Table 3. There was no statistically significant difference seen in valsalva leak point pressure, presence of detrusor overactivity, post void residual (PVR), Qmax, or bladder capacity between the different BMI groups.

On final analysis, overall successful treatment of SUI was analyzed utilizing PGI-I because so few failures failed the cough stress test and no one who was a success failed the cough stress test. It was thus felt that the PGI-I provided a more accurate representation of successes and failures. Success was achieved in 77% (24/31) of patients. When broken down by BMI category, the ideal weight group was successful in 88% (7/8), the overweight category had success in 92% (13/14), and the obese category had success in 44% (4/9) of patients, (p = 0.019, Table 4).

There was no statistically significant difference in operative time, blood loss, or urinary retention rates between the three BMI groups, Table 4. In addition, no patient experienced mesh extrusion, erosion, or de novo irritative urinary symptoms postoperatively. One patient still complained of a minor persistent perineal pain at 6 weeks post surgery which subsequently resolved. Minor complications included 9 episodes of postoperative urinary retention (29%). Eight patients had resolution of their retention 3-14 days after surgery and 1 patient required sling loosening under general anesthesia. No major perioperative complications including cardiovascular events, wound infections, or blood transfusions were noted.

Two men had undergone previous incontinence procedures. One patient had a bone anchored male sling and one had a previous transobturator sling. The bone-anchored sling was removed at the time of transobturator sling placement. The redo transobturator sling was placed over, and distal to, the previous sling that had been placed too proximally on the urethra at an outside institution. A third patient had a prior penoscrotal urethrotomy for pendulous urethral stricture disease performed at an outside institution. He had the stricture repaired and urethrotomy reversed before sling placement for pre-existing SUI. One patient had undergone adjuvant radiotherapy for prostate cancer

TABLE 2. **Demographics by BMI category**

	BMI < 25	**BMI 25-30**	**BMI > 30**	**p value**
Age (yr)	72.6	73.7	64.9	0.13
Etiology				0.35
RRP/RARP	7 (87.5%)	14 (100.0%)	7 (77.8%)	
HoLEP	1 (12.5%)	0 (0.0%)	1 (11.1%)	
Abscess unroofing	0 (0.0%)	0 (0.0%)	1 (11.1%)	
Gleason score	6.5	6.6	7	0.42
Nerve sparing	3	3	3	0.51
Pads per day	3.6	4.9	3.9	0.66

BMI = body mass index; RRP = radical retropubic prostatectomy; RARP = robot-assisted radical prostatectomy
HoLEP = holmium laser enucleation of the prostate

TABLE 3. **Urodynamic parameters by BMI category**

	BMI < 25	BMI 25-30	BMI > 30	p value
Valsalva LPP (cm H_20)	66.3	66.8	81.2	0.61
Detrusor overactivity	1 (12.5%)	2 (14.3%)	4 (44.4%)	0.06
Preop Qmax	17.7	14.3	16.6	0.89
Preop PVR	37.3	8.2	4.8	0.75
Bladder capacity	408	324	259	0.26

BMI = body mass index; PVR = post void residual

TABLE 4. **Postoperative outcomes by BMI category**

	BMI < 25	BMI 25-30	BMI > 30	p value
OR time (mins)	83.3	88.5	93	0.67
EBL (mL)	45	58	72	0.31
Postop retention	1 (12.5%)	5 (35.7%)	2 (22.2%)	0.59
Successful surgery	7 (87.5%)	13 (92.9%)	4 (44.4%)	0.019

BMI = body mass index; OR = operating room; EBL = estimated blood loss

after radical prostatectomy. Table 5 outlines which BMI group each of these patients belonged to and the sling outcome for each of these patients who were at "high risk" for sling failure.

Discussion

Historically male slings have fallen short of the success of the gold standard of treatment of SUI, the AUS. The perineal bone anchored sling had low a success rate of 39.5% for treatment of male SUI. In addition, many patients experienced significant postoperative perineal pain, complication rates as high as 58.8%, and re-operative rates up to 26.9% after the bone anchored sling.[12-14] In contrast to the bone-anchored male sling, which provides bulbar urethral compression, the newer generation of transobturator male sling is thought to improve continence by elevating the bulbomembranous urethra and increasing functional urethral pressure and length.

TABLE 5. **High risk patients**

Risk factor	BMI category	Outcome
Previous sling surgery	1	Success
Previous sling surgery	2	Success
Previous urethral surgery	2	Success
Pad usage > 10/day	2	Success
Pad usage > 10/day	2	Failure
Previous radiation	3	Failure

BMI = body mass index

Our overall success rate of 77% is similar to that previously reported in the literature. Comparisons between studies are difficult, however, secondary to lack of a uniform definition of success of the sling or cure of SUI. Bauer et al reported a cure rate of 77.1% at 12 months which included 51.4% of patients (36/70) who were completely dry.[15] Cornel et al reported success in 44% (15/33) and cure in only 9% patients at 12 months follow up.[16] It is interesting to note in that study that patient satisfaction was seen in 54.5% of patients at 12 months which again highlights the difficultly in defining cure and success after the procedure, not only between various studies but between patients and providers as well.[16] Gill et al had similar patient determined success rates with 51.4% (18/35).[17] Rehder et al reported cure in 73.7% (87/113) patients at 1 year follow up as well as a statistically significant decrease in pad use and increase in quality of life.[18] Finally, Christine et al placed a salvage transobturator male sling for recurrent leakage after AUS placement with a 79% (15/19) continence rate.[3]

Our complication rate was also similar to previously reported data. We report 9/31 (29%) patients with postoperative urinary retention, including 1 patient who required reoperation for sling loosening. In addition, 1 patient continued to report perineal discomfort at 6 weeks post surgery. Bauer et al reported only on complications after male sling placement.[19] As in our review, no severe intraoperative complications such as rectal or bladder perforation or major bleeding occurred in their study.[19] Their reported postoperative urinary retention rate was also similar to our experience at 21.3% (49/230) with 1 patient requiring incision of the sling.[19] Overall, the authors concluded that without urinary retention, the complication rate after male sling was very low at 2.6%.[19] In our data, without urinary retention, our complication rate is also quite low at 6.5% (2/31): 1 patient with perineal pain and 1 patient requiring sling loosening. This is in contrast to the overall AUS complication rate of 35%.[20] There was no difference in rates of urinary retention between the three BMI groups ($p = 0.59$).

Little data exists regarding what factors contribute to sling failure. Bauer et al hypothesized that prior treatment affecting the mobility of the sphincter region and posterior urethra (radiotherapy, stem cells, and bulking agents) would be expected to have a negative impact on sling outcome; however, no statistically significant difference was seen in their study.[15] It has also been reported by other authors that no cure has been obtained after male sling in patients who had previous radiotherapy.[15,18] Fischer et al found that a 400 cc pad test weight cutoff predicted whether a sling would or would not fail.[21] Gill et al found that patients with perceived success had significantly lower preoperative pad use than those with therapeutic failure.[18] In addition, it has been reported on multivariate analysis that failure is associated with previous urethral stricture surgery and a 24 hour pad test > 200 g/day.[22] Finally, other authors have reported incomplete closure of the sphincter, no sling tunneling, and use of resorbable sutures (< 4) were significant predictors for sling failure.[23]

Thus, it appears that the optimal candidates for transobturator male sling are patients with mild to moderate incontinence, no previous bulking therapies, no history of urethral stricture disease, and no history of prior radiotherapy who have good coaptation of the urethral sphincter on cystoscopy. We feel that preoperative pad usage may be a poor predictor of post-operative outcomes as pad usage is very subjective; some patients may wait until the pad is completely soaked to change it while others change the pad when it is slightly damp. However, pad weights may be a useful adjunct in determining severity of urinary incontinence and could be used for pre and post-operative evaluation at the discretion of the surgeon.

No study has previously reported the effect of BMI on male sling outcomes for the treatment of SUI. We found a striking and statistically significant difference between men who were ideal or overweight compared with those who are obese in regards to success of the procedure. The ideal and overweight patients had a success rate of 88% and 93% respectively. This is in stark contrast to the obese patients who had a success rate of only 44%. We hypothesize this tendency is due to increased intra-abdominal pressure transmission to the bladder, urethra, and sling itself in the obese population. The surgeon who performed all procedures did not feel that it was technically more challenging to perform the surgery in the obese population. This is highlighted by the lack of a significant difference in operative time between the three groups.

It is known from the treatment of SUI in females that obesity is an independent risk factor for treatment failure after midurethral sling placement.[8] Our finding of increased risk of early male sling failure in the obese population suggests that these patients may also be at increased risk of male sling failure based on weight. Obese patients should thus be counseled to undergo lifestyle changes, including weight loss, prior to an incontinence surgery to increase their chance of a successful surgical outcome or possibly consider an AUS.

A near significant number of patients in the obese category had detrusor overactivity (DO) on urodynamics (44.4%) when compared to the ideal and overweight groups (12.5% and 14.3% respectively), ($p = 0.06$). We feel it is unlikely that DO contributed to the increased failure rate of the obese patients as only two failed patients had DO compared with 5 patients throughout all groups who had DO on urodynamics, all of whom had a successful surgery. As can be seen in Table 3, there was no significant difference between VLPP, bladder capacity, preoperative PVR, or preoperative Qmax between the three BMI groups at baseline. Thus, we do not feel there were any urodynamic findings that may explain the higher failure rate in the obese category.

The patients included in the study do represent a heterogenous group including 1 patient with previous adjuvant radiation, 1 patient with pendulous urethral stricture disease, 2 patients with previous anti-incontinence procedures, as well as 2 patients with pad usage of ≥ 10 pads per day. Table 5 outlines which BMI group each of these patients belonged to and their sling outcome. As can be seen, only the patient with

adjuvant radiotherapy after prostatectomy was in the obese category. He was a failure and thus radiation exposure may have been a confounding factor in his failure.

The limitations of our study include small sample size, the retrospective nature, and short follow up. Unfortunately, because of small sample size we were unable to perform a multi-variate analysis to determine if BMI > 30 kg/m^2 is an independent predictor of sling failure. Further research defining a uniform way to determine success after the male sling as well as larger studies allowing for multivariate analyses examining which patient factors contribute to success or failure after male sling would be helpful for the future. Finally, the long term durability of the male sling has yet to be determined.

Conclusion

Obese patients with a BMI greater than 30 kg/m^2 have a worse outcome after transobturator male sling for SUI in comparison to ideal and overweight patients at short term follow up. This patient population may be better served with an AUS as a definitive treatment of their SUI. Alternatively, lifestyle changes and weight loss could be considered in this group prior to undergoing surgical therapy with a sling. Further longitudinal follow up of our cohort will hopefully strengthen the findings presented here.

Disclosure

Dr. Christopher E. Wolter is a meeting participant for Allergan and a lecturer for Coloplast. □

References

1. Comiter CV. Male incontinence surgery in the 21st century: past, present, and future. *Curr Opin Urol* 2010;20(4):302-308.
2. American Cancer Society. What are key statistics about prostate cancer? June 30, 2010.
3. Coelho RF, Chauhan S, Palmer KJ, Rocco B, Patel MB, Patel VR. Robotic-assisted radical prostatectomy: a review of current outcomes. *BJU Int* 2009;104(10):1428-1435.
4. Christine B, Knoll LD. Treatment of recurrent urinary incontinence after artificial urinary sphincter placement using the AdVance male sling. *Urology* 2010;76(6):1321-1324.
5. Kumar A, Litt ER, Ballert KN, Nitti VW. Artificial urinary sphincter versus male sling for post-prostatectomy incontinence – what do patients choose? *J Urol* 2009;181(3):1231-1235.
6. Litwiller SE, Kim KB, Fone PD, White RW, Stone AR. Post-prostatectomy incontinence and the artificial urinary sphincter: a long-term study of patient satisfaction and criteria for success. *J Urol* 1996;156(6):1975-1980.
7. Motamedinia P, Korets R, Spencer BA, Benson MC, McKiernan JM. Body mass index trends and role of obesity in predicting outcome after radical prostatectomy. *J Urol* 2008;72(5);1106-1110.
8. Stav K, Dwyer PL, Roamilia A, Schierlitz L, Lim YN, Lee J. Risk factors of treatment failure of midurethral sling procedures for women with stress incontinence. *Int Urogynecol J* 2010:21(2):149-155.
9. van Roermund JG, van Basten JP, Kiemeney LA, Karthaus HF, Witjes JA. Impact of obesity on surgical outcomes following open radical prostatectomy. *Urol Int* 2009;82(3):256-261.
10. Sugaya K, Oda M, Nishijima S et al. Risk factors for duration of urinary incontinence after radical prostatectomy. *Nihon Hinyokia Gakkai Zasshi* 2002;93(3):444-449.
11. Rehder P, Gozzi C. Transobturator sling suspension for male urinary incontinence including post-radical prostatectomy. *Eur Urol* 2007;52(3):860-866.
12. Castle EP, Andrews PE, Itano N, Novicki DE, Swanson SK, Ferrigni RG. The male sling for post-prostatectomy incontinence: mean follow up of 18 months. *J Urol* 2005;173(5):1657-1660.
13. Mourcade P, Wagner B, Charles T, Lang H, Jacqmin D, Saussine C. Treatment of postoperative male urinary incontinence by bone anchored male sling. *Prog Urol* 2008(6):390-394.
14. Styn NG, McGuire EJ, Latini JM. Bone-anchored sling for male stress urinary incontinence: assessment of complications. Urology 2011;77(2):469-473.
15. Bauer RM, Mayer ME, Gozzi 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.
16. Cornel EB, Elzevier HW, Putter H. Can advance transobturator sling suspension cure male urinary postoperative stress incontinence? *J Urol* 2010;183(4):1459-1463.
17. Gill BC, Swartz MA, Klein JB et al. Patient perceived effectiveness of a new male sling as treatment for post-prostatectomy incontinence. *J Urol* 2010;183(1):247-252.
18. Rehder P, Mitterberger MJ, Pichler R, Kerschbaumer A, Glodny B. The 1 year outcome of the transobturator retroluminal positioning sling in the treatment of male stress urinary incontinence. *BJU Int* 2010;106(11):1668-1672.
19. Bauer RM, Mayer ME, May F et al. Complications of the advance transobturator male sling in the treatment of male stress urinary incontinence. *Urology* 2010;75(6):1494-1498.
20. Kim SP, Sarmast Z, Daignault S, Faerber GJ, McGuire EJ, Latini JM. Long term durability and functional outcomes among patients with artificial urinary sphincters: a 10-year retrospective review from the University of Michigan. *J Urol* 2008;179(5):1912-1916.
21. Fischer MC, Huckabay C, Nitti VW. The male perineal sling: assessment and prediction of outcome. *J Urol* 2007;177(4):1414-1418.
22. Cornu JN, Sebe P. Ciofu C, Peyrat L, Cussenot O, Haab F. Mid-term evaluation of the transobturator male sling for post-prostatectomy incontinence: focus on prognostic factors. *BJU Int* 2010;108(2):236-240.
23. Soljanik I, Gozzi C, Becker AJ, Stief CG, Bauer RM. Risk factor of treatment failure after retrourethral transobturator male sling. *World J Urol* 2011;Epub ahead of print.