AdVance™ Male Sling System

Clinical study summary

This document is a compilation and summary of several AdVance™ Male Sling System peer-reviewed journal articles. The information presented here is taken directly from the articles and represents the work and opinions of the authors. The reader is encouraged to refer to the full-text articles for complete study information.

Publications were selected for this clinical study summary based on the following criteria. All publications are related to the AdVance™ Male Sling System with study populations of at least 50 subjects. Only peer-reviewed journal articles are included. No publication was excluded based on whether the findings were favorable or unfavorable to the AdVance Sling. Foreign language and non-AdVance sling publications were excluded. If multiple publications existed for a clinical study population from a specific investigator and/or institution, the publication with the largest study population and/or longest follow-up was chosen. Throughout this summary, various authors use the terms “cured,” “improved” and “success rates.” Please refer to table 2 for definitions.

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Introduction

The AdVance™ Male Sling System is intended for the placement of a suburethral sling for the treatment of male stress urinary incontinence (SUI).[1] Since its commercial introduction in 2006, a number of clinical studies on the AdVance Sling have been conducted. Results from various independent research studies have been presented at urologic congresses and published in peer-reviewed journals.

Placement of a transobturator sling has been shown to be a viable procedure to treat post-prostatectomy SUI, providing durable results after more than three years of follow-up in several studies and nearly one thousand patients. This research has resulted in the AdVance Sling being the most widely studied male retrourethral transobturator sling (RTS). Overall, these clinical studies have demonstrated a success rate (see table 2 for definition of success) of 62% to 78%.[2-6]

NOTE: Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

Table 1. Article summary

Reference	Brief trial description	N	Follow-up	Clinical results
Rehder P, et al. 2012 *Eur Urol*[2]	Multi-center, prospective	156	40.1 months (mean)	▸ At 12 months, 76.9% success rate (53.8% cured, 23.1% improved) ▸ At 3 years, 76.8% success rate (53.0% cured, 23.8% improved) ▸ Pad usage was significantly decreased compared with baseline at 12 months and 3 years (P < 0.0001)
Li H, et al. 2012 *J Urol*[3]	Chart review and telephone survey	66 (63 at first office follow-up) (56 at second follow-up)	23.8 months (median)	▸ At initial follow-up, 87.3% quantitative success rate (50.8% cured, 36.5% improved) ▸ At 2 years, 62.5% quantitative success rate (39.3% cured, 23.2% improved) ▸ At 2 years, 53.6% patient determined success ▸ At initial follow-up, mean pad use of 0.8 ± 1.7 ▸ At 2 years, mean pad use of 1.7 ± 2.5
Bauer RM, et al. 2011 *BJUI*[4]	Single-center, prospective	137 (126 with follow-up)	27 months (median)	▸ 75.4% success rate (51.6% cured, 23.8% improved) ▸ Median pads per day decreased from 4.5 (1–24) to 1 (0–20) (P < 0.001) ▸ Median 1-hour pad test (urine loss) decreased from 110 grams (11–585) to 7.5 (0–320) grams (P < 0.001) ▸ Compared with 1-year follow-up data, no worsening over time was noticed and no additional complications were seen
Cornu JN, et al. 2011 *BJUI*[5]	Single-center, prospective	136	21 months (mean)	▸ 78% success rate (62% cured, 16% improved) ▸ Mean pad use decreased from 2.1 ± 1.2 (1–9) to 0.6 ± 1.0 (0–5) at last follow-up (P < 0.001) ▸ Results were sustainable over time
Zuckerman JM, et al. 2014 *Urol*[6]	Single-center retrospective review of a prospectively maintained database	102	36.2 months (mean)	▸ Success at 12 months 74% ▸ Cure at 12 months 58% ▸ Success at 24 months 63% ▸ Cure at 24 months 48% ▸ Success at final follow-up (30.3 months) 62% ▸ Cure at final follow-up (30.3 months) 40%
Soljanik I, et al. 2011 *Urol*[7]	Single-center, prospective	55	21 months (mean)	▸ AdVance Sling does not result in signs of compression or obstruction of the urethra ▸ Analysis of urodynamic parameters showed that only abdominal leak-point pressure changed significantly
Bauer RM, et al. 2010 *Urol*[8]	Single-center, prospective	230	17 months (median)	▸ Analysis of complications associated with the AdVance Sling showed that the main postoperative complication was transient acute urinary retention ▸ Severe intraoperative complications such as rectum or bladder perforation or major bleeding were not observed ▸ One misplacement of the sling across the urethra occurred
Sturm RM, et al. 2014 *Urol*[9]	Multi-center, retrospective medical record review	95	28 months (mean) – Ideal 12–49 months (range) – Ideal 29 months (mean) – Nonideal 12–51 months (range) – Nonideal	▸ Cure (ideal) 50% (36/72) ▸ Satisfaction (ideal) 92% (66/72) ▸ Cure (nonideal) 22% (5/23) ▸ Satisfaction (nonideal) 30% (7/23)
Davies TO, et al. 2009 *Urol*[10]	Single-center, prospective	13	6 months	▸ Valsalva leak-point pressure improved significantly (P=0.32) ▸ Detrusor voiding pressure, post-void residual urine volume, and maximal and average flow rates remained relatively unchanged

Patient selection

Within the publications, authors commented on and discussed various patient selection criteria. Patient selection statements were related to a variety of topics, including sphincter function, severity of incontinence and prior treatments. A summary of key patient selection statements is presented below.

AdVance™ Male Sling System Patient selection criteria[9]

Six (6) patient selection criteria for AdVance Sling (post-prostatectomy incontinence):

- **1** <4 pads/day or <300g daily pad weight
- **2** Intact appearing external urinary sphincter without segmental defects on cystoscopy; ability to volitionally contract their external urinary sphincter
- **3** No history of pelvic radiation or cryotherapy
- **4** No history of previous surgical procedures to treat incontinence
- **5** Volitional detrusor contraction when voiding
- **6** Post-void residual (PVR) urine volume <100 mL

	Patient meets all 6 criteria	Patient does not meet all 6 criteria	P value
N=95	72	23	
Mean daily preoperative **pad use** (range)	2.6 (1-4)	4.4 (1-9)	<.05
Mean daily preoperative **pad weight, g** (range)	131 (10-280)	520 (80-1200)	<.05
Mean daily postoperative **pad use** (range)	**0.6** (0-6)	2.4 (0-7)	<.05
Mean daily postoperative **pad weight, g** (range)	**16** (0-310)	201 (0-800)	<.05
Pad reduction percentage	**77%**	46%	
Pad weight reduction percentage	**88%**	61%	
Patient satisfaction	**92%**	30%	

Mean follow-up for patients who meet all 6 criteria: 28 months
Mean follow-up for patients who do not meet all 6 criteria: 29 months

Severity of incontinence

- Cure rates and improvement rates were higher in patients with mild or moderate incontinence compared to severe incontinence. Nevertheless, patients with severe incontinence have been treated successfully with the AdVance Sling.[2]
- The male transobturator AdVance Sling is a viable option for mild to moderate post-prostatectomy incontinence.[3,9]
- Cornu et al. propose that the AdVance Sling option be reserved for patients with mild to moderate incontinence.[5]
- Patients with mild to moderate incontinence may be good candidates for the Advance Sling.[9]

Risk factors associated with procedural outcome

Rehder conducted uni- and multivariate analysis to determine predictors of success.[2]

Univariate analysis showed that pretreatment pad usage and severity of incontinence were both significant predictors of success (P = 0.0355 and P = 0.0420, respectively).

- On multivariate analysis, only pad usage was an independent predictor of success.
- Previous irradiation (P = 0.0723) had no impact on outcome.

Zuckerman conducted uni- and multivariate analyses to determine factors that might predict cure.[6]

- At 24 months of follow-up, no variable was found to be predictive of being cured.
- Logistic regression predicting total success at 24 months, however, showed that having undergone a laparoscopic or robotic prostatectomy compared with an open procedure or no prostatectomy negatively influenced outcomes.
- At final follow-up, higher preoperative pad counts negatively predicted outcomes both in terms of overall success and cure.
- Neither of these variables significantly predicted outcomes on multivariate analysis.
- On multivariate Cox regression analysis, detrusor overactivity and an elevated mean detrusor pressure at peak flow (PdetQmax) were the only significant factors, and both negatively influenced continence outcomes.
- On multivariate Cox regression analysis, when the cohort was analyzed for overall success rather than cure, no variables were predictive of success.

Cornu conducted statistical analysis to determine pre-operative factors that were linked to postoperative status.[5]

- History of pelvic irradiation was associated with the failure group (P = 0.053) and not associated with the improved group.
- Previous surgery for urethral stenosis was associated with being improved rather than cured (P = 0.001) and also with failure (P = 0.013).
- Patients with preoperative 24-hour pad test > 200 grams were exposed to a worse outcome, showing failure more often than cure (P = 0.026) and improvement more often than cure, although this result was of limited significance (P = 0.091).

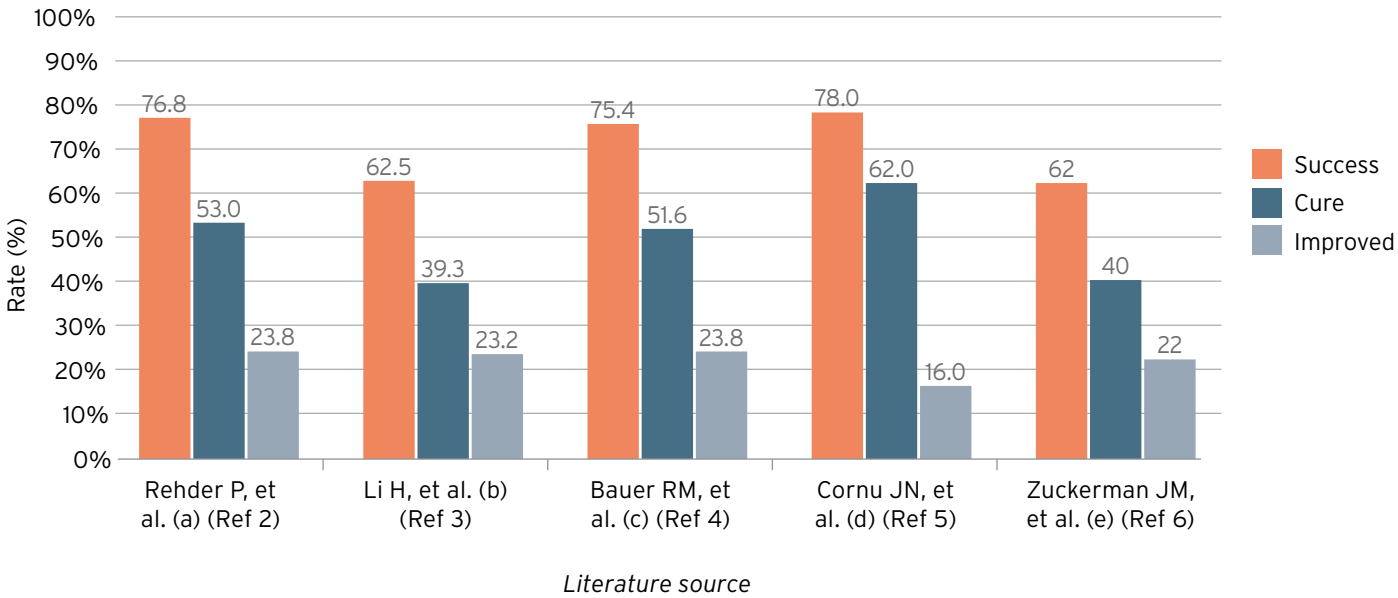
Soljanik commented on predictors of success. Although some authors select only patients with mild and moderate stress urinary incontinence to increase the RTS efficacy, multivariate analysis of risk factors for RTS failure revealed that intraoperative sling fixation and preoperative sphincter function are the main predictors for RTS success. In addition, incontinence severity was reported to have no influence on RTS outcome.[7]

Results

Success rates

Overall, success rates associated with implantation of the AdVance Sling range from 62% to 78%.[2-6]

Figure 1: Success rates



(a) 3 years; (b) 23.8 months; (c) 27 months; (d) 21 months; (e) 30 months

Table 2: Definitions for cure and improved

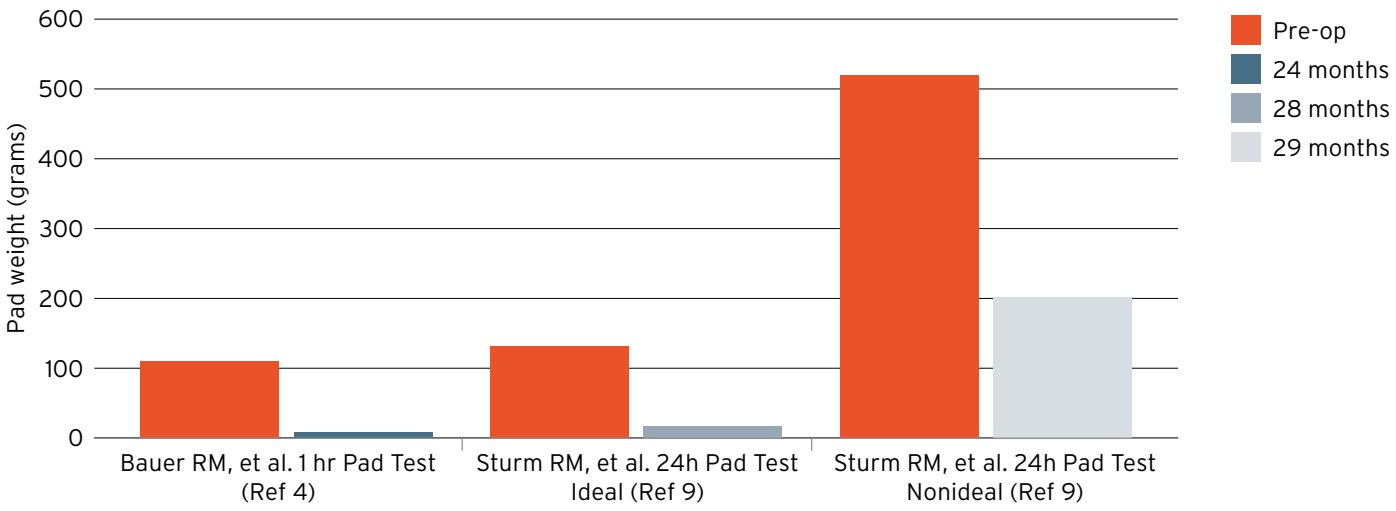
Reference		Definition
Rehder P, et al.[2]	Cure:	No pad or one dry pad for security reasons
	Improved:	One or two pads per day; reduction in daily pad usage of 50%
Li H, et al.[3]	Subjective Success:	PGI-I* responses of 'very much better' and 'much better' were considered subjective successes if no additional incontinence procedures were performed
	Success:	Quantitative included 'cure' and 'improvement'
	Cure:	Zero pads per day
	Improved:	A decrease from pre-sling pad use to 1 or 2 pads per day
Bauer RM, et al.[4]	Cure:	No pad use or one prophylactic (dry) pad
	Improved:	1 to 2 pads or reduction of pads ≥ 50%
Cornu JN, et al.[5]	Cure:	No pad usage
	Improved:	Decrease in pad use by > 50%
Zuckerman JM, et al.[6]	Success:	A dry safety pad or less (cured) or > 50% improvement in pads used per day and patient satisfaction with the surgical outcome (improved)
	Cure:	A dry safety pad or less
	Improved:	> 50% improvement in pads used per day and patient satisfaction with the surgical outcome

* PGI-I = Patient Global Impression of Improvement

Pad weight tests

Both 1- and 24-hour pad weights decreased after implantation of the AdVance Sling and these results were maintained over time.

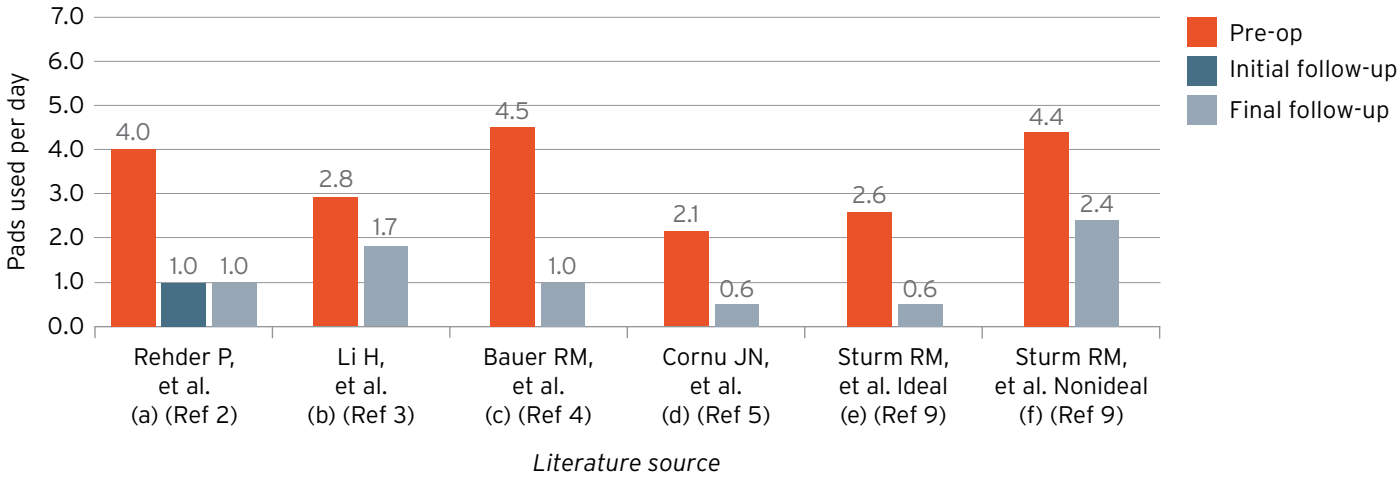
Figure 2: Pad weight results



Pads used per day

Pads used per day decreased significantly as shown in the following table.

Figure 3: Pads used per day results



(a) 12 months and 3 years; (b) 23.8 months; (c) 12 months; (d) 21 months; (e) 28 months; (f) 29 months

Quality of life and patient impressions of improvement

A variety of tools were used to assess the impact of incontinence on quality of life. The authors noted significant improvement in quality of life scores.

Table 3: Quality of life

Investigator	QOL measurement	QOL results	
		Pre-op	3 Years
Rehder P, et al.[2]	ICIQ-SF[a,b]	17.0	7.0
	I-QOL[c]	61.0	93.0
		Pre-op	Follow-up (median 27 months)
Bauer RM, et al.[4]	ICIQ-UI SF[a]	17	8 ($p < 0.001$)
	I-QOL[c]	54.5	63 ($p < 0.001$)
		Pre-op	1 Year

a International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-SF) – Improvement indicated by decreased score.
b Questions 1-3
c Incontinence Quality of Life Questionnaire (I-QOL) – Improvement indicated by increased score.

Urodynamic findings

In a group of 55 patients, Soljanik et al. prospectively evaluated urodynamic parameters before and after retrourethral transobturator sling placement and the impact of adverse preoperative urodynamic parameters on postoperative outcome.[7]

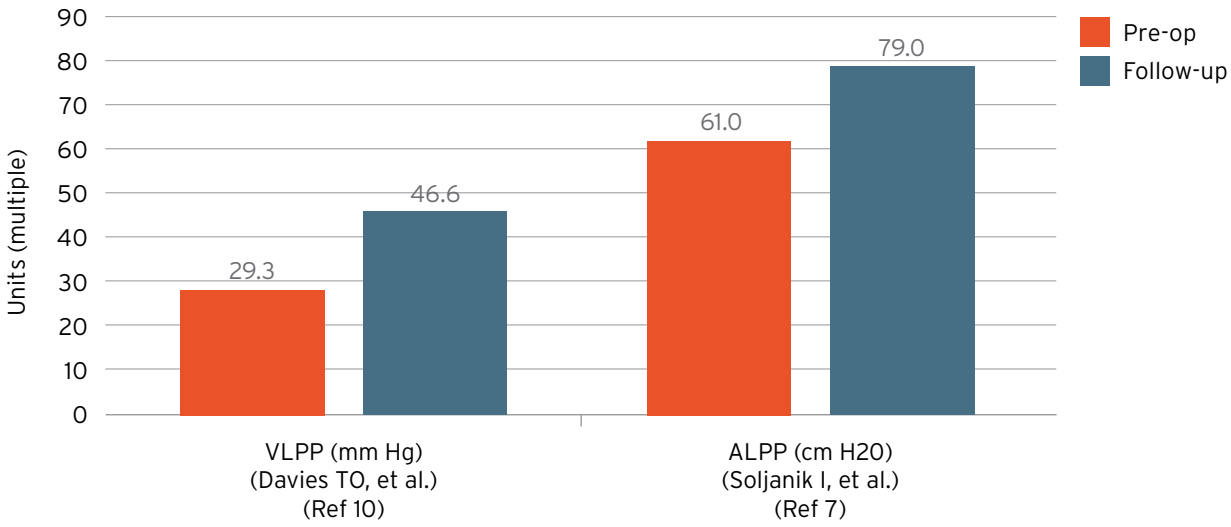
- Only abdominal leak-point pressure (ALPP) changed significantly (61 ± 14.2 vs. 79 ± 20.4 cm H2O) in patients who still had urine leakage postoperatively.
- All other evaluated urodynamic and uroflowmetry parameters remained unchanged or minimally differed without statistical significance.
- At the time of urodynamic assessment, no patient showed postvoid residual urine volume (PVR) >30 mL, de novo reduced bladder compliance or de novo hypo- or overactivity.
- No obstruction (bladder outlet obstruction index [BOOI] <20) was seen in 35 patients (63.6%) preoperatively and 42 patients (76.3%) postoperatively.
- Adverse preoperative urodynamic parameters were not associated with postoperative outcome.

Soljanik concludes that the detailed evaluation of urodynamic and uroflowmetry parameters revealed no differences between pre- and postoperative assessments, except for ALPP. These findings showed that retroluminal transobturator sling implantation has no influence on voiding function. No obstruction was found in urodynamic investigation postoperatively.

Davies et al. provides a comprehensive evaluation of urodynamic parameters. Urodynamic testing was performed at baseline and repeated at 6 months postoperatively. Postoperative results were relatively unchanged. There was no statistical difference between baseline and post-op detrusor voiding pressure, PVR, maximal uroflow and average uroflow. These results indicate that insertion of the AdVance Sling does not result in obstruction. The Davies et al. publication did not meet the study population criteria but was included because the topic was of specific interest (i.e., urodynamics).[10]

Valsalva leak-point pressure (VLPP) was noted to have improved significantly by Davies as illustrated in figure 4.[10] Soljanik found that only ALPP changed significantly.[7] An increase in VLPP or ALPP coincides with an improvement in continence status.

Figure 4: VLPP and ALPP



Literature source

Davies TO, et al. VLPP; Soljanik I, et al. ALPP

Adverse events and complications

The clinical study investigators reported a low incidence of severe or serious complications associated with implantation of the AdVance Male Sling. (Dashes (---) in the table below indicate no results were reported.)

Table 4: Adverse events

Adverse Events	Rehder P, et al.[2]	Li H, et al.[3]	Bauer RM, et al.[4]	Cornu JN, et al.[5]	Zuckerman JM, et al.[6]	Soljanik I, et al.[7]	Bauer RM, et al.[8]	Sturm RM, et al.[9]	Davies TO, et al[10]
Bleeding (major)	---	---	---	---	---	---	0%	---	---
Dysuria (mild)	4.5%	---	---	14.0%	---	---	---	---	---
Dysuria (requiring 24-hour catheterization)	---	---	---	1.5%	---	---	---	---	---
Erosion	0%	---	---	0%	---	---	---	---	---
Explantation of Sling	0.6%	---	1.6%[b]	0%	---	---	0.9%[b]	---	---
Infection	---	---	---	0%	---	---	---	---	---
Wound	0.6%	---	---	---	1.0%	---	0.4%	---	---
Urinary tract	0.6%	---	---	---	0.98%	---	0.4%[e]	---	---
Misplacement of Sling Across Urethra	---	---	0.7%	---	---	---	0.4%[f]	---	---
Pain	---	---	---	---	---	---	---	---	---
Perineal	50.0%[a]	---	---	10.0%	---	---	2.2%[g]	---	---
Persistent	---	5.4%	0.8%[c]	---	---	---	0.4%[h]	Ideal 2.8% Nonideal 4.3%	---
Scrotal and Groin	---	---	---	---	5.9%	---	0%	---	---
Perforation of Bladder or Rectum	---	---	---	---	---	---	0%	---	---
Perineal Hematoma	3.2%	---	---	0.7%	---	---	---	---	---
Perineal Paresthesia	---	---	---	1.5%	---	---	---	---	---
Rash, Fungal	---	3.0%	---	---	---	---	---	---	---
Short Period of Cure (<4 months) Followed by Return of Incontinence	---	10.7%	---	---	---	---	---	---	---
'Feeling something tear'	---	1.8%	---	---	---	---	---	---	---
Transected Sling Due to Slippage with Urethral Obstruction	---	---	---	---	---	---	0.4%	---	---
Urinary Retention prolonged (resolved by sling lysis)	---	---	15.1%[d]	---	0.98%	---	---	Nonideal 13.0%	---
Transient	9.0%	9.1%	---	---	10.82%	23.6%	---	Ideal 15.3% Nonideal 8.7%	15%
Immediate post-operative	0.6%	---	---	---	---	---	21.3%[i]	---	---
Urinary Urgency	0.6%	---	---	---	---	---	---	---	---
Voiding	---	---	---	---	---	---	---	---	---
Altered sensation during voiding	---	7.1%	---	---	---	---	---	---	---
Feeling of incomplete voiding	---	1.8%	---	---	---	---	---	---	---
Worsened Incontinence following AdVance Sling	---	---	---	3.68%	5.0%	---	---	Ideal 1.39% Nonideal 4.35%	---

a Mild
b One misplaced sling explanted 6 weeks post-op; one sling explanted in patient with pubic symphysitis due to Guillain-Barré Syndrome.
c Persistent light perineal discomfort
d Treated with suprapubic or transurethral catheter for a maximum of 10 weeks (range 4 days to 10 weeks).
e With fever
f No other intraoperative complications occurred.
g Mild perineal discomfort for 4–6 weeks; no pain medication needed.
h Persistent moderate perineal pain
i Postoperative urinary retention could be resolved conservatively in all except for 3 cases (1.3%). Two neobladder patients suffered from acute urinary retention after sling implantation and continued to apply intermittent self-catheterization due to residual urine. In one patient, the sling had to be transected due to obstruction after sling slippage.

Conclusions

Each author provided their own conclusions related to implantation of the AdVance Male Sling.

Authors	Conclusion
Rehder P, et al.[2]	"The transobturator retroluminal repositioning sling suspension provides durable outcomes to 3 years for SUI treatment and is accompanied by a low complication rate and an improved quality of life."
Li H, et al.[3]	"The AdVance Sling continues to be a safe and valid treatment option for PPI with more than half of our cohort reporting quantitative and subjective successes at an average 2-year follow-up. We demonstrated a decrease in quantitative measures, evidenced by increasing pad use and decreasing therapeutic durability in the majority of our patients. Although pad use increases, patient satisfaction persists as seen in the stable subjective success rates. These results emphasize key aspects of patient preference vs. therapeutic durability and should be discussed when counseling patients interested in pursuing the AdVance Sling."
Bauer RM, et al.[4]	"In conclusion, in a mid-term follow-up, the retroluminar transobturator male sling is an effective, safe and attractive treatment option for SUI after radical prostatectomy. Compared with 1-year data, results are stable over time. Complications occurred in the first 4 months after sling implantation. So far no further postoperative complications, such as erosions or infections, have been seen."
Cornu JN, et al.[5]	"In conclusion, the AdVance™ Male Sling is a valuable, safe and sustainable option for treating mild to moderate SUI after prostatectomy. These good and sustainable results are influenced by the degree of incontinence, previous urethral surgery and radiation therapy, therefore, these factors should be carefully evaluated when choosing treatment and giving information to patients."
Zuckerman JM, et al.[6]	"The AdVance sling continues to be a reasonable option in the treatment of male SUI. The procedure is reliably performed with minimal morbidity to the patient. The success in the early postoperative period rivals that after AUS placement; however, in our series we found a decrease in efficacy over time. That being said, 40% of patients were durably cured after an AdVance sling placement."
Soljanik I, et al.[7]	"RTS suspension is an effective and safe device for SUI treatment, without signs of urethral obstruction or any influence on voiding parameters, except for ALLP. Low ALPP, low bladder capacity, and low flow do not adversely affect the RTS outcome. Preoperative urodynamic evaluation has no predictive value on RTS outcome and should be reserved only for selected patients with symptoms of overactive bladder or to exclude neurogenic bladder dysfunction."
Bauer RM, et al.[8]	"The functional AdVance Sling offers an attractive minimally invasive treatment option for male patients with SUI due to nonintrinsic sphincter deficiency, that is, without direct sphincter lesions, after prostate surgery or ileal neobladder substitution. It is a safe option as the main complications are transient acute postoperative urinary retention, requiring only temporary recatheterization. In contrast to other surgical treatment options, severe complications and explantations are rare."
Davies TO, et al.[10]	"Our results have indicated that the AdVance Male Sling is a safe treatment of stress urinary incontinence in men after radical prostatectomy. The results of the present study with short-term follow-up have indicated excellent initial efficacy without significant obstruction. We await studies with larger cohorts and longer follow-up of this recently developed treatment."
Sturm RM, et al.[9]	"AdVance male urethral sling placement remains a viable option for the treatment of PPI. Proper preoperative patient selection, including those with an intact appearing external urethral sphincter, <300 g/day pad weight or <4 pad/day pad use, volitional detrusor contraction with voiding, a PVR urine volume <100 mL, and no history of previous pelvic radiotherapy, cryotherapy, or anti-incontinence surgical procedures may significantly influence successful surgical outcomes and patient satisfaction."

The AdVance™ Male Sling System is a viable treatment option for male post-prostatectomy SUI. Durable results have been demonstrated with more than 3 years of follow-up. The incidence of major complications is low.[2]

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

The AdVance™ Male Sling System is intended for the placement of a suburethral sling for the treatment of male stress urinary incontinence (SUI). These devices are contraindicated for patients with urinary tract infections, blood coagulation disorders, a compromised immune system or any other condition that would compromise healing, with renal insufficiency, and upper urinary tract relative obstruction. Possible adverse events include, but are not limited to, urinary retention, return to incontinence and pain.

References

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