Sling surgery for the treatment of urinary incontinence after transurethral resection of the prostate: evaluation of literature and new data on the Virtue® male sling

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Introduction

One of the most frequently performed surgical procedures for the treatment of obstructive symptoms following benign prostate enlargement is the transurethral resection of the prostate (TURP). Complication rates following a TURP are generally low but are frequently encountered due to large numbers of surgery being performed. Stress urinary incontinence (SUI) is a common complication following a TURP, occurring in 1.8% to 5.0% of the patients (1-4). SUI in these cases is usually caused by damage to the proximal part of the (rhabdo) sphincter distal to the seminal colliculus (or verumontanum) (5).
It is known that SUI has a significant impact on the quality of life (QoL) and when conservative treatment (e.g. pelvic floor physiotherapy) fails, surgical procedures can be considered. The two most common surgical options are the implantation of an artificial urinary sphincter (AUS) or the use of a male sling (6).
Throughout history, multiple surgical techniques have been developed for the treatment of male urinary incontinence. In 1947, Foley introduced an externally worn urethral cuff and subsequent modifications by Kaufman in 1973 led to the first fully internal AUS. Since, the AUS is considered to be the gold standard in the surgical management of urinary incontinence following prostate surgery (7;8). Documented AUS success rates are generally high and vary between 59% and 91.4% (9;10). When complications occur however, surgical revision is often required and AUS explantation rates due to mechanical failure, infection or erosion can be as high as 36% (11;12).
In the search for a less invasive procedure, synthetic male slings have gained popularity in the treatment of mild to moderate SUI. The concept of the male sling for the treatment of SUI is based on a combination of less invasiveness, fewer postoperative complications and a significant cost reduction. Present studies on the efficacy and complication rates of different types of male slings show success rates varying from 40% to 91%, with generally lower complication rates when compared to AUS surgery (13;14). Nevertheless, the majority of these studies only describe male slings after a radical prostatectomy (RP) and little is known on the efficacy of male slings in post-TURP patients specifically.
The Virtue® is a relatively new sling, introduced in 2012 by Coloplast (Humlebaek, Denmark) for the treatment of male SUI. This quadratic male sling combines perineal urethral compression with proximal urethral relocation, making it a hybrid sling. The monofilament polypropylene mesh contains two inferior (trans-obturator) extensions and two superior (prepubic) extensions (15;16).
The first part of this study provides an overview of the available literature regarding male slings in post-TURP patients. Secondly, a prospective study was conducted in a cohort of 8 patients at the department of Urology at the Leiden University Medical Center to assess the effects of the Virtue® sling on patients suffering from post-TURP SUI.

Material and methods

The first part of this paper consists of a review of literature regarding the efficacy of synthetic male slings in patients suffering from post-TURP SUI. The review started with an electronic database search of PubMed, Embase, Web of Science, Cochrane and Cinahl using the search strategy shown in figure 1. One author screened the articles by title, abstract or by full article, when necessary, to select studies that met the predefined selection criteria. Selection criteria were defined as: language (English, German, French or Spanish), mean topic (male sling for urinary incontinence following prostate surgery, including TURP), type (case study, cohort study or randomized controlled trial) and availability of the results (published in peer reviewed journal).

(((("male sling"[tw] OR "male slings"[tw]) AND ("Urination Disorders"[Mesh] OR "Anuria"[tw] OR "Enuresis"[tw] OR "Hematuria"[tw] OR "Haematuria"[tw] OR "Oliguria"[tw] OR "Polyuria"[tw] OR "Urinary Incontinence"[tw] OR "Urinary Retention"[tw] OR "Prostatectomy"[Mesh] OR Prostatectom*[tw] OR ("transurethral"[tw] AND "resection"[tw] AND prostat*[tw]) OR "turp"[tw] OR "Transurethral Resection of Prostate"[Mesh] OR "micturition"[tw] OR "urination"[tw] OR "Urination"[mesh])) OR (("urinary slings"[tw] OR "urinary sling"[tw] OR "urethral sling"[tw] OR "urethral slings"[tw] OR "midurethral sling"[tw] OR "midurethral slings"[tw] OR "periurethral sling"[tw] OR "periurethral slings"[tw] OR "suburethral sling"[tw] OR "suburethral slings"[tw] OR "bulbourethral sling"[tw] OR "bulbourethral slings"[tw] OR "transobturator sling"[tw] OR "transobturator slings"[tw] OR "pubourethral sling"[tw] OR "pubourethral slings"[tw] OR (("sling"[tw] OR "slings"[tw]) AND ("urinary"[tw] OR "urethral"[tw] OR "urogenital"[tw] OR "midurethral"[tw] OR "periurethral"[tw] OR "suburethral"[tw] OR "bulbourethral"[tw] OR "subpubic"[tw] OR "anteropubic"[tw] OR "transobturator"[tw] OR "pubourethral"[tw]))) AND ((("Urination Disorders"[Mesh] OR "Anuria"[tw] OR "Enuresis"[tw] OR "Hematuria"[tw] OR "Haematuria"[tw] OR "Oliguria"[tw] OR "Polyuria"[tw] OR "Urinary Incontinence"[tw] OR "Urinary Retention"[tw] OR "micturition"[tw] OR "urination"[tw] OR "Urination"[mesh]) AND ("Male"[mesh] OR "male"[tw] OR "Men"[mesh] OR "man"[tw] OR "men"[tw] OR "boy"[tw] OR "boys"[tw])) OR "Prostatectomy"[Mesh] OR Prostatectom*[tw] OR ("transurethral"[tw] AND "resection"[tw] AND prostat*[tw]) OR prostat*[tw] OR "Prostate"[Mesh]))))

Figure 1 Search Strategy

The second part of the paper is a prospective clinical trial performed at the Department of Urology of the Leiden University Medical Center as part of a European study on the Virtue® male sling. All patients that underwent surgery using the Virtue® male sling as surgical treatment for post-TURP SUI between January 2012 and November 2013 were included after written informed consent was obtained (n = 8). Exclusion criteria were previous anti-incontinence surgery or prostate cancer. All 8 patients underwent a cystoscopy and urodynamic investigation at baseline to evaluate sphincter function and to rule out detrusor instability and bladder neck strictures. All procedures were performed by a single surgeon using the surgical technique described by Rhee (17).

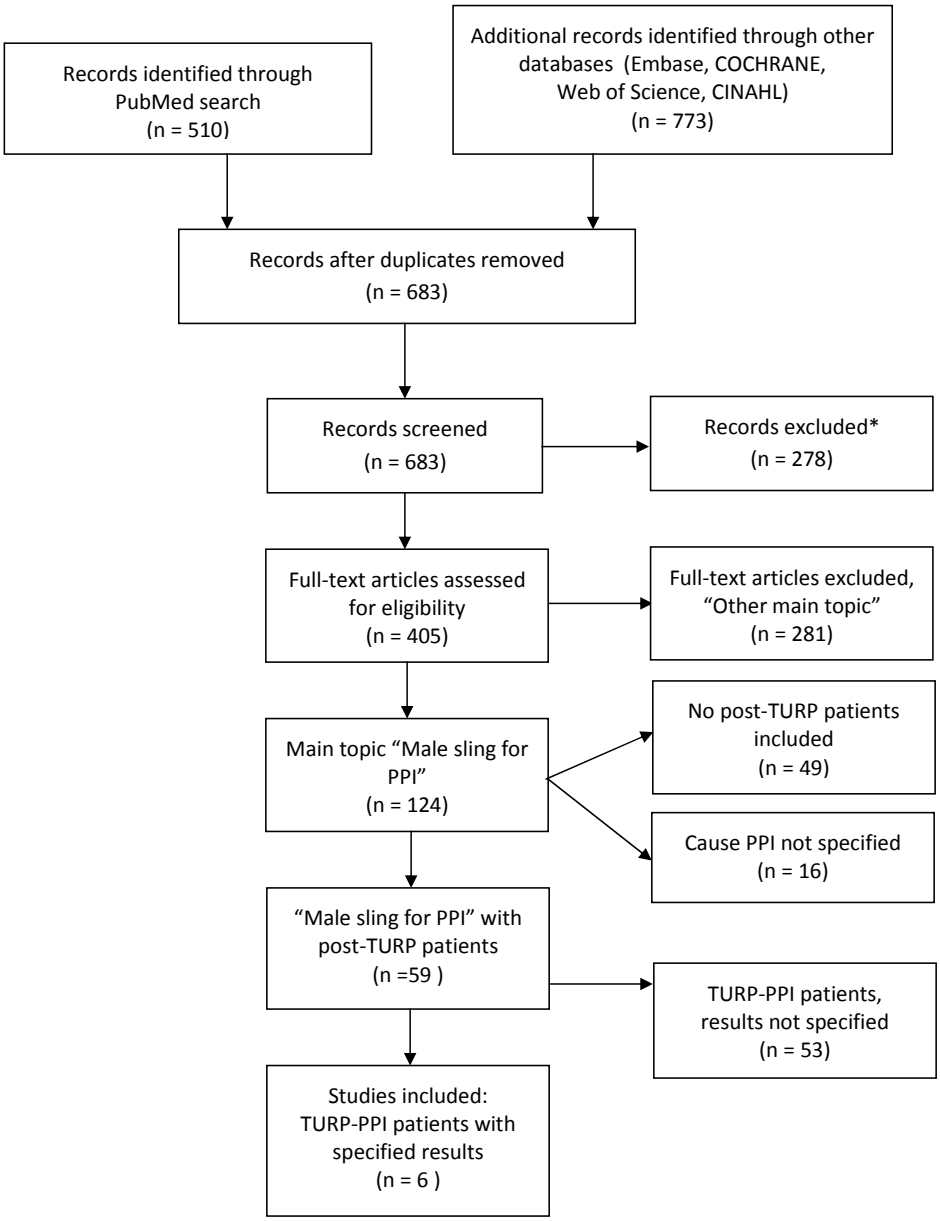

Figure 2 PRISMA flow chart

*Exclusion criteria: animal study, female study, pediatric study, editorial comment, author replies, conference abstract, not "peer-reviewed journal," other language (not English, French, German, Spanish). PPI, postprostatectomy incontinence; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (www.prisma-statement.org).

A pre- and postoperative pad test was used to evaluate continence after surgery. Success was defined as no pad use (0 pads per day; PPD) or the use of one dry "safety pad" only. Improvement was defined as a pad reduction of 50% or more compared to the preoperative situation. In addition, a questionnaire consisting of 40 multiple-choice questions was used for evaluation. The first part included a visual analogue scale (VAS) and specific questions assessing patients' satisfaction regarding the surgery, as well as the usage of pads. The second part consisted of the Dutch translation of the King's Health Questionnaire (KHQ). The KHQ is a validated, condition-specific (urinary incontinence) quality of life questionnaire and is recommended by the European Association of Urology (EAU) as a specific tool for the evaluation of incontinence (18-20). The preoperative questionnaire was identical to the postoperative questionnaire, except for the questions concerning the sling surgery itself. Patients were asked to complete questionnaires preoperatively and 1, 3, 6 months and 1 year postoperatively. The secondary outcomes of our study were QoL, pain and surgery satisfaction measured using the KHQ and VAS questionnaires.

Statistical analysis was performed using SPSS Statistics (Version 20, IBM Corporation, Armonk, NY). The results of the systematic review on slings following a TURP and other prostate related surgery were processed in crosstabs and compared using Fisher exact tests. The pre- and postoperative comparison of the KHQ, VAS, and pad usage was performed with paired two-tailed *t*-tests. $P<0.05$ indicated statistical significance.

The questionnaire used is part of the standard follow-up program for incontinence patients in this center and hence did not require approval by the medical ethics comity.

Results

The first part of this study consisted of a systematic literature search regarding male slings in patients post-TURP. The search strategy retrieved 1283 records of which 59 included patients with post-TURP SUI. Combined, the 59 studies included 2736 patients of which 230 had post-TURP SUI (8,4% of all patients). Six of the 59 studies differentiated between post-RP and post-TURP patients and were eligible for inclusion (see PRISMA flow-chart in figure 2) (21-25). The 6 included studies reported on a combined total of 23 patients. Postoperative success was defined as total continence, a pad reduction of 50% or more, daily loss of urine <2grams, or a subjective improvement in continence stated in an interview. In these 6 studies, post-TURP sling success rates ranged from 0-100% and were significantly lower compared to success rates in patients who did not undergo a TURP (mean 78.3% vs. 95.0%; $p=0.009$, $p<0.05$).

Table 1 Pads per Day

Patients	Preoperative Pads/Day	Postoperative Pads/Day			
Age		1 month	3 months	6 months	12 months
68	>6	0	0	0	0
58	5-6	0	1-2	1-2	1-2
74	5-6	1-2	1-2	1-2	1 sp
74	5-6	1-2	1-2	1-2	1-2
73	1-2	1 sp	1-2	1 sp	1 sp
61	1-2	1-2	1-2	1-2	1-2a
60	1-2	3-4	1-2	1-2	b
75	1-2	0	0	0	0

sp = dry security pad, a: type pad preop "large", 12mo "regular", b: patient had received AUS

The second part of this paper described 8 patients who received the Virtue® sling as surgical treatment for post-TURP SUI between January 2012 and November 2013. No adverse events were observed during or in the 12 months following surgery. The response rate was 100%, but 1 patient was excluded from further analysis after 9 months when he received an AUS because of persistent incontinence. At 12 months postsurgery 4 patients were considered cured, meaning no pad usage or use of 1 dry security pad only. Another 2 patients were considered improved, whereas the 1 remaining patient had no change in PPD, even though pad size was reduced from large to regular. All patients (n=4) who had severe SUI (>5 PPD), experienced a postoperative improvement. Two of these patients had more than 50% pad reduction and the other 2 stated to be completely dry (Table 1).

The pre- and postoperative VAS scores evaluating the influence of SUI on daily life (scored from 0 "not at all", to 10 "very much") were compared using a paired-samples *t*-test. The results showed a significant decrease in the impact of SUI at all intervals in comparison to the preoperative situation. At the 1 month interval, 6 patients (75%) experienced postoperative pain. After 12 months, this number had decreased to 1 patient reporting residual postoperative pain, scoring a 3 (out of 10) on the VAS. Six patients (75%) stated they would apply for surgery again in hindsight.

The next part of the evaluation consisted of the KHQ, which the patients completed at 4 specific points during follow-up (1, 3, 6 and 12 months postoperatively). After 1 month a significant improvement was observed in 3 of 10 subcategories, namely 'incontinence impact', 'physical limitations' and 'severity measures'. After 3 and 6 months the KHQ showed significant improvement in 4 of 10 (40%) and 5 of 10 (50%) of the subcategories, respectively. The only difference between the 3-month and the 6-month interval was the subcategory 'severity measures', which did not show improvement

after 3 months. At the end of 12 months, a significant improvement was seen in 6 of 10 (60%) subcategories, including 'incontinence impact', 'general health' and 'physical limitations' (table 2). The patient that had received an AUS 9 months postoperatively was excluded from the 12 -month follow-up.

Table 2 KHQ preoperative and 12-month scores

Domain	Mean	Std. Deviation	P[a]
General health			
Preoperatively	31.25	17.68	
12 Months	46.43	22.49	**0.008**
Incontinence impact			
Preoperatively	83.33	25.12	
12 Months	23.81	25.19	**0.023**
Role limitations			
Preoperatively	64.58	22.60	
12 Months	14.29	17.82	**0.008**
Physical limitations			
Preoperatively	54.17	29.21	
12 Months	9.52	8.91	**0.007**
Social limitations			
Preoperatively	38.89	31.57	
12 Months	4.76	12.59	0.050
Personal relationships			
Preoperatively	40.48	34.50	
12 Months	16.67	19.24	**0.037**
Emotions			
Preoperatively	41.67	27.05	
12 Months	7.94	13.93	0.059
Sleep/energy			
Preoperatively	31.62	37.81	
12 Months	14.29	14.99	0.386
Severity measures			
Preoperatively	50.35	15.25	
12 Months	21.03	11.55	**0.012**
Symptom severity			
Preoperatively	12.57	5.16	
12 Months	9.67	2.42	0.268

P <0.05 was considered statistically significant, a: paired two-tailed *t*-test

Discussion

The first part of this study identified 23 patients described in 6 previous studies that had undergone sling surgery for post-TURP SUI. The postoperative success rate was 78.3% (18 of 23 patients). The second part of this paper prospectively analysed the effects of the Virtue® male sling in 8 patients with post-TURP SUI. After 1 year, 4 of 8 patients did not require the use of pads and were considered cured. Another 2 patients had a pad reduction of over 50% and were considered improved.

To date, there are few studies that evaluate the results of the Virtue® male sling. The cure rates found in earlier studies are comparable to those found in the current cohort. In accordance with our results, Comiter et al. also experienced equal improvement rates for patients with mild, moderate and severe preoperative SUI. These findings are in contrast to papers on other slings that associate higher preoperative incontinence rates with lower postoperative continence rates (13-16).

In general, male slings appear to be less effective in the treatment of post-TURP SUI in comparison to SUI following a RP. Incontinence following a prostatectomy may be caused by either sphincter dysfunction or bladder dysfunction. Incontinence following a TURP is usually caused by damage to the proximal part of the (rhabdo) sphincter distal to the seminal colliculus (verumontanum) (5). However, the mechanisms for either trans-obturator or bone-anchored slings are not yet fully understood. In theory, trans-obturator slings such as the AdVance™ (American Medical Systems, Minnetonka, MN), function through relocation of the bulbar urethra in the pelvis, which then leads to angulation and lengthening of the membranous bulbar urethra (26). In contrast, a bone-anchored sling such as the InVance™ (American Medical Systems) is believed to achieve continence by exerting pressure on the bulbar urethra, resulting in an increase in outflow resistance (27).

The Virtue® male sling combines perineal urethral compression with proximal urethral relocation. Results of the current study show that, in contrast to other slings in current literature, the Virtue® male sling appears to be as effective in patients post TURP as in patients with a RP in their medical history. These findings support our hypothesis that the dual design of the Virtue® sling is more suited for post-TURP SUI than other conventional male slings that work through either compression or relocation of the urethra (13;14).

There are certain limitations to this study that need to be addressed. The first limitation is the fact that 3 out of the 6 (50%) selected articles included in our review did not differentiate between cure and improvement rates, which makes a comparison to our results more difficult. This lack in uniformity and the absence of a clear definition of success (and improvement) remains a problem when comparing different studies and techniques. Second, the clinical part of this study was performed in a single center

setting and included only 8 patients. Nevertheless, our review revealed that at present no studies describing a similar group of patients are known, making this study the largest cohort of its kind. Nevertheless, more extensive research, with larger cohorts and longer follow-up, should be performed before viable conclusions may be drawn.
In conclusion, little is currently known about the effects of sling surgery in patients suffering (mild to severe) SUI after a TURP. Although the Virtue® male sling seems to be an efficient and safe device in the treatment of this complication, long-term follow-up and larger cohorts are needed to further confirm these results.

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