Original Article

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Efficacy and Safety of Tension-Free Vaginal Tape-Secur Mini-Sling Versus Standard Midurethral Slings for Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis

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Purpose: To assess the efficacy and safety of tension-free vaginal tape (TVT)-Secur for stress urinary incontinence (SUI).
Methods: A literature review was performed to identify all published trials of TVT-Secur. The search included the following databases: MEDLINE, Embase, and the Cochrane Controlled Trial Register.
Results: Seventeen publications involving a total of 1,879 patients were used to compare TVT-Secur with tension-free obturator tape (TVT-O) and TVT. We found that TVT-Secur had significant reductions in operative time, visual analog score for pain, and postoperative complications compared with TVT-O. Even though TVT-Secur had a significantly lower subjective cure rate ($P<0.00001$), lower objective cure rate ($P<0.00001$), and higher intraoperative complication rate, compared with TVT-O at 1 to 3 years, there was no significant difference between TVT-Secur and TVT-O in the subjective cure rate (odds ratio [OR], 0.49; 95% confidence interval [CI], 0.22–1.08; $P=0.08$), objective cure rate (OR, 0.49; 95% CI, 0.22–1.09; $P=0.08$), or complications at 3 to 5 years. Moreover, TVT-Secur had significantly lower subjective and objective cure rates compared with TVT.
Conclusions: This meta-analysis indicates that TVT-Secur did not show an inferior efficacy and safety compared with TVT-O for SUI in 3 to 5 years, even though displaying a clear tread toward a lower efficacy in 1 to 3 years. Considering that the safety is similar, there are no advantages in using TVT-Secur.

Keywords: Urinary Incontinence, Stress; Suburethral Slings; Randomized Controlled Trial

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• **Conflict of Interest:** No potential conflict of interest relevant to this article was reported.

INTRODUCTION

The International Continence Society defines stress urinary incontinence (SUI) as the complaint of involuntary urine leakage during effort, exertion, sneezing, or coughing [1]. It results from hypermobility of the urethra and functional insufficiency of the urethral sphincter. SUI affects 4% to 35% of women, and the prevalence increases with age [2]. Ten percent of middle-aged women report daily or severe incontinence and at least one-third report leakage at least weekly [3].

SUI management is based on surgical options in case of failure of noninvasive therapies. Placement of a suburethral sling is the gold standard treatment for management of SUI associated with urethral hypermobility [4]. Tension-free vaginal tape

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(TVT) and tension-free obturator tape (TVT-O) are widely used for this indication, with a high success rate and few complications [5]. Nevertheless, neither is completely free of complications, mainly due to the blind course of the introducer devices. The TVT course may perforate the bladder, whereas TVT-O passage is associated with vaginal perforation and neurologic impairment, leading to protracted thigh pain and upper leg weakness [6]. Both routes occasionally are associated with life-threatening complications, including bowel perforation, major vessel disruption, and perineal gangrene [7]. In addition, voiding dysfunction and vaginal mesh exposures may also complicate midurethral slings (MUS) [8].

Single-incision slings (SIS) were optimized to overcome these complications. TVT-Secur was the first single-incision device, and was developed in 2006. This device can be placed using a retropubic or "U" approach, or a transobturator-like "hammock" approach [9]. The innovation was based on the use of shorter polypropylene laser-cut tape (8 cm × 1 cm) through a single vaginal incision in order to avoid the retropubic space, obturator foramen, or groin muscles, and their related nerves and blood vessels.

Moreover, TVT-Secur seemed to cause less postoperative pain and reduced operative time [10], but its effectiveness seemed to be lower in comparison with traditional MUS [11,12]. However, a number of studies reported satisfactory results, including at midterm [13]. The anchoring mechanism of TVT-Secur has been critically evaluated, with studies demonstrating a deterioration over time of the efficacy of this SIS, and calling for long-term studies of the surgical treatment of SUI [14]. Following these contrasting results, TVT-Secur was withdrawn from clinical practice by the manufacturer.

The goal of the present study was to perform a meta-analysis to evaluate the safety and efficacy of TVT-Secur compared with standard MUS in treating SUI, making the evidence available for the many women who had a TVT-Secur device implanted.

MATERIALS AND METHODS

Search Strategy

A systematic literature review was performed in August 2015. The MEDLINE, Embase, and Cochrane Controlled Trial Register databases were searched to identify relevant studies. Searches were restricted to publications in English. Two separate searches were done by applying a free-text protocol with the following search terms: stress urinary incontinence, suburethral slings, tension-free vaginal tape, and randomized controlled trials.

Inclusion Criteria and Trial Selection

Article selection proceeded according to the search strategy based on Preferred Reporting Items for Systematic Reviews and Meta-analysis criteria (Fig. 1). Only studies comparing TVT-Secur and standard MUS were included for further screening. Cited references from the selected articles retrieved in the search were also assessed for significant papers. Conference abstracts were not included because they were not deemed to be methodologically appropriate. Two independent reviewers completed this process, and all disagreements were resolved through consensus.

Quality Assessment

The methodological quality of each study was assessed according to how patients were allocated to the arms of the study, the concealment of allocation procedures, blinding, and the data loss due to attrition. The studies were then classified qualitatively according to the guidelines published in the *Cochrane Handbook for Systematic Reviews of Interventions 5.1.0* [15]. Based on the quality-assessment criteria, each study was rated and assigned to one of three quality categories: A, if all quality criteria were adequately met, the study was deemed to have a low risk of bias; B, if one or more of the quality criteria was only partially met or was unclear, the study was deemed to have a moderate

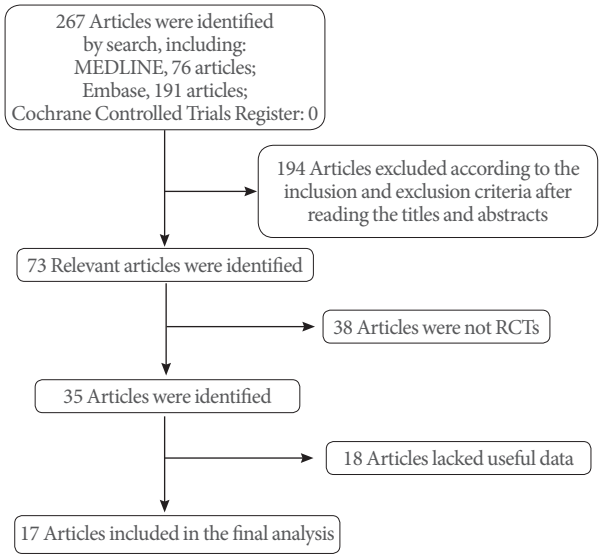

Fig. 1. The flow diagram of the study selection. RCT, randomized controlled trial.

risk of bias; or C, if one or more of the criteria were not met, or not included, the study was deemed to have a high risk of bias. Sensitivity analyses were then performed on the basis of whether these quality factors were adequate, inadequate, or unclear. Differences were resolved by discussion among the reviewers.

Data Extraction

Data extracted from each eligible study included the name of the clinical trial, number of patients in each group, the therapy that the patients received, and the country in which the study was conducted. Data including operative time, subjective cure rate, objective cure rate, visual analog score (VAS) for pain, bleeding greater than 100 mL, intraoperative complications, postoperative complications, reoperation for SUI, and *de novo* urgency were also extracted.

Statistical Analysis

The meta-analysis of comparable data was carried out with Review Manager 5.1.0 (The Cochrane Collaboration, London, UK). Due to the large number of plots, we combined 6 forest plots into 1 plot by using Adobe Photoshop CS (Adobe Systems, San Jose, CA, USA).

RESULTS

Characteristics of Individual Studies

The database search and reference lists of retrieved studies found 267 potential articles for our meta-analysis. Based on the inclusion and exclusion criteria, 194 articles were excluded after reading the titles and abstracts of the articles; 38 articles were not randomized controlled trials (RCTs), and 18 articles lacked useful data. In all, 17 articles [11,12,16-29] with 18 RCTs that compared TVT-Secur with standard MUS (TVT, TVT-O) were included in the analysis. The baseline characteristics of the studies included in our meta-analysis are listed in Table 1.

Quality of Individual Studies

All 18 RCTs were blinded, and all described the randomization processes that they had used. All included a power calculation to determine the optimal sample size (Table 2). The level of quality of each identified study was A to B (Table 2). The funnel plot provided a qualitative estimation of publication bias of the studies, and no evidence of bias was found (Fig. 2).

TVT-Secur Compared With TVT-O at 1 to 3 Years

Efficacy

Operative time (minute): Six RCTs represented 728 participants (360 in the TVT-Secur group and 368 in the TVT-O group) (Fig. 3). Based on our analysis, the pooled estimate of standardized mean difference (SMD) was –0.99, and the 95% confidence interval (CI) was –1.42 to –0.57 ($P < 0.00001$). This result suggests that TVT-Secur showed significant reductions in the mean operative time compared with TVT-O.

Subjective cure rate: Seven RCTs represented 791 participants (388 in the TVT-Secur group and 403 in the TVT-O group) (Fig. 4). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of odds ratio (OR) was 0.38, and the 95% CI was 0.27 to 0.54 ($P < 0.00001$). This result suggests that TVT-Secur showed a significantly lower subjective cure rate in comparison with TVT-O.

Objective cure rate: Eleven RCTs represented 1,076 participants (528 in the TVT-Secur group and 548 in the TVT-O group) (Fig. 4). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 0.26, and the 95% CI was 0.19 to 0.37 ($P < 0.00001$). This result suggests that TVT-Secur showed a significantly lower objective cure rate in comparison with TVT-O.

Safety

VAS pain score (postoperative day 1): Three RCTs represented 265 participants (131 in the TVT-Secur group and 134 in the TVT-O group) (Fig. 3). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of SMD was –2.15, and the 95% CI was –2.45 to –1.84 ($P < 0.00001$). This result suggests that TVT-Secur showed significant reductions in the VAS score compared with TVT-O.

Bleeding greater than 100 mL: Six RCTs represented 791 participants (402 in the TVT-Secur group and 389 in the TVT-O group) (Fig. 5). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 1.78, and the 95% CI was 0.98 to 3.22 ($P = 0.06$). This result suggests that TVT-Secur showed no significant difference in the rate of bleeding greater than 100 mL compared with TVT-O.

Table 1. Study and patient characteristics

Study	Therapy in experimental group	Therapy in control group	Country	Sample size		Duration of treatment (mo)	Inclusion population
				Experimental	Control		
Tommaselli et al. (2010) [16]	TVT-Secur	TVT-O	Italy	38	37	12	SUI lasting for at least 2 yr as diagnosed by clinical evaluation and urodynamics and age > 40 yr
Hinoul et al. (2011) [17]	TVT-Secur	TVT-O	Belgium, the Netherlands	97	98	12	All patients in whom SUI could be objectified during clinical and/or urodynamic examination
Wang et al. (2011) [18]	TVT-Secur	TVT-O	China	34	36	12	Women with SUI as diagnosed by clinical evaluation and urodynamics
Wang et al. (2011) [18]	TVT-Secur	TVT	China	34	32	12	Women with SUI as diagnosed by clinical evaluation and urodynamics
Masata et al. (2012) [19]	TVT-Secur	TVT-O	Czech Republic	129	68	24	Women with urodynamic SUI, failed conservative therapy, > 18 yr and agreed to postoperative follow-up
Hota et al. (2012) [20]	TVT-Secur	TVT-O	USA	43	44	12	Women with SUI with an impact on QoL, positive CST during urodynamics
Barber et al. (2012) [21]	TVT-Secur	TVT	USA	136	127	12	Women at least 21 yr of age with SUI on multichannel urodynamics, desire for surgical treatment, concurrent surgical treatment of prolapse
Andrada Hamer et al. (2013) [22]	TVT-Secur	TVT	Sweden	64	69	12	Primary SUI or MUI with predominant stress, > 18 yr of age and no wish for further pregnancy, ≥ 3-mL leakage on pad test, positive CST
Tommaselli et al. (2013) [11]	TVT-Secur	TVT-O	Italy	77	77	36	Women with SUI, diagnosed clinically and by urodynamics, age > 30 yr, failed PFMT
Tommaselli et al. (2015) [23]	TVT-Secur	TVT-O	Italy	77	77	63	Women with SUI, diagnosed clinically and by urodynamics, age > 30 yr, failed PFMT
Maslow et al. (2014) [24]	TVT-Secur	TVT-O	Canada	56	50	12	Women with symptoms of SUI and a positive cough test, which required surgical management
Oliveira et al. (2011) [25]	TVT-Secur	TVT-O	Portugal	30	30	12	Women with clinically and urodynamically proven SUI associated with urethral hypermobility
Ross et al. (2014) [26]	TVT-Secur	TVT	Canada	40	34	12	Women leaked urine with increased abdominal pressure, and were suitable for either type of surgery
Bianchi-Ferraro et al. (2013) [27]	TVT-Secur	TVT-O	Brazil	66	56	12	Women presenting SUI symptoms demonstrated by stress test and urodynamics
Bianchi-Ferraro et al. (2014) [12]	TVT-Secur	TVT-O	Brazil	66	56	24	Women presenting SUI symptoms demonstrated by stress test and urodynamics
Jeong et al. (2010) [28]	TVT-Secur	TVT-O	Korea	31	33	12	Women presenting SUI symptoms demonstrated by stress test and urodynamics
Neuman et al. (2011) [13]	TVT-Secur	TVT-O	Israel	79	73	36	A diagnosis of SUI based on the patient's personal history and a positive cough test with the bladder holding 300 to 400 mL
Pushkar et al. (2011) [29]	TVT-Secur	TVT-O	Russia	45	50	12	Women with primary SUI or MUI with predominant stress, age > 18 yr, positive CST

TVT, tension-free vaginal tape; TVT-O, tension-free obturator tape; SUI, stress urinary incontinence; QoL, quality of life; CST, cough stress test; MUI, mixed urinary incontinence; PFMT, pelvic floor muscle training.

Table 2. Quality assessment of individual study

Study	Allocation sequence generation	Allocation concealment	Blinding	Loss to follow-up	Calculation of sample size	Statistical analysis	Intention-to-treat analysis	Level of quality
Tommaselli et al. (2010) [16]	A	B	A	9	YES	Student t-test, Shapiro-Wilk test	YES	B
Hinoul et al. (2011) [17]	A	A	A	34	YES	Mann-Whitney test, chi-square test	YES	A
Wang et al. (2011) [18]	A	A	A	6	YES	Paired t-test, chi-square test	YES	A
Masata et al. (2012) [19]	A	A	A	0	YES	Fisher exact test	YES	A
Hota et al. (2012) [20]	A	A	B	6	YES	t-test, Mann-Whitney U-test, or chi-square test	YES	B
Barber et al. (2012) [21]	A	A	A	14	YES	Paired t-test, Wilcoxon rank-sum test	YES	A
Andrada Hamer et al. (2013) [22]	A	A	A	4	YES	Chi-square test, Wilcoxon test, Mann-Whitney test or Kruskal-Wallis test	YES	A
Tommaselli et al. (2013) [11]	A	A	B	9	YES	Mann-Whitney test, Wilcoxon test, or chi-square test	YES	B
Tommaselli et al. (2015) [23]	A	A	B	34	YES	Mann-Whitney test, Wilcoxon test, or chi-square test	YES	B
Maslow et al. (2014) [24]	A	A	A	2	YES	Chi-square test, Kruskal-Wallis test, Wilcoxon test, and Fisher exact test	YES	A
Oliveira et al. (2011) [25]	A	A	A	0	YES	Fisher exact test	YES	A
Ross et al. (2014) [26]	A	A	A	6	YES	Fisher exact test, Mann-Whitney U test and t-test	YES	A
Bianchi-Ferraro et al. (2013) [27]	A	A	A	5	YES	Mann-Whitney U-test, Student t-test, Fisher exact test	YES	A
Bianchi-Ferraro et al. (2014) [12]	A	A	A	7	YES	Mann-Whitney U-test, Student t-test, Fisher exact test	YES	A
Jeong et al. (2010) [28]	A	B	B	0	YES	Student t-test, chi-square test, and Fisher exact test	YES	B
Neuman et al. (2011) [13]	A	A	B	6	YES	t-test, chi-square test or Fisher exact test and McNemar test	YES	B
Pushkar et al. (2011) [29]	A	A	A	3	YES	t-test, chi-square test or Fisher exact test and the McNemar test	YES	A

A, all quality criteria met (adequate) - low risk of bias; B, one or more of the quality criteria only partly met (unclear) - moderate risk of bias; C, one or more criteria not met (inadequate or not used) - high risk of bias.

Intraoperative complications: Five RCTs represented 645 participants (325 in the TVT-Secur group and 320 in the TVT-O group) (Fig. 6). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 1.98, and the 95% CI was 1.15 to 3.42 (P=0.01). This result suggests that TVT-Secur showed significant increases in the rate of intraoperative complications compared with TVT-O.

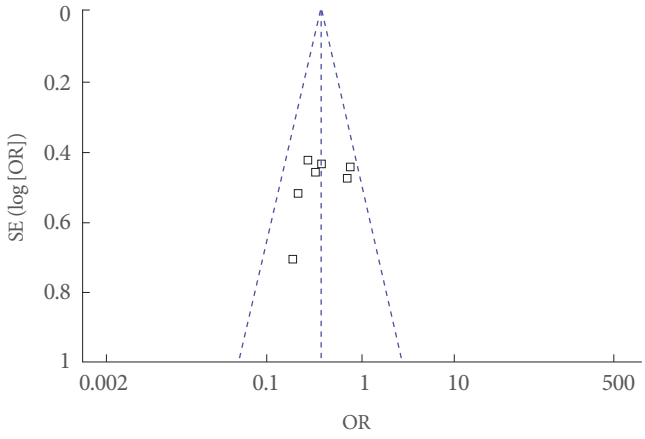

Fig. 2. Funnel plot of the studies represented in our meta-analysis. SE, standard error; OR, odds ratio.

Postoperative complications: Seven RCTs represented 780 participants (392 in the TVT-Secur group and 388 in the TVT-O group) (Fig. 6). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 0.67, and the 95% CI was 0.48 to 0.95 (P=0.03). This result suggests that TVT-Secur showed a significant decrease in the rate of postoperative complications compared with TVT-O.

De novo urgency: Eight RCTs represented 874 participants (439 in the TVT-Secur group and 435 in the TVT-O group) (Fig. 5). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 0.78, and the 95% CI was 0.50 to 1.91 (P=0.25). This result suggests that TVT-Secur showed no significant difference in the rate of *de novo* urgency compared with TVT-O.

Reoperation for SUI: Four RCTs represented 471 participants (229 in the TVT-Secur group and 242 in the TVT-O group) (Fig. 5). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 4.96, and the 95% CI was 2.37 to 10.35 (P<0.0001). This

Study of subgroup	TVT-Secur			TVT-O			Weight (%)	Mean difference	Mean difference
	Mean	SD	Total	Mean	SD	Total		IV, Fixed, 95% CI	IV, Fixed, 95% CI
Operation time									
Hinoul P 2011	18.9	7.0	96	16.0	6.0	92	5.3	2.00 [0.14, 3.86]	
Masata J 2012	11.4	3.7	64	8.3	3.5	68	12.0	3.10 [1.87, 4.33]	
Masata J 2012	10.8	4.4	65	8.3	3.5	68	9.9	2.50 [1.14, 3.86]	
Tommaselli GA 2010	7.1	2.1	37	11.3	2.9	38	13.9	-4.20 [-5.34, -3.06]	
Tommaselli GA 2013	7.8	2.5	64	12.0	3.1	66	19.5	-4.20 [-5.17, -3.23]	
Wang YJ 2011	15.4	1.4	34	16.2	1.5	36	39.4	-0.80 [-1.48, -0.12]	
Total (95% CI)			360			368	100	-0.99 [-1.42, -0.57]	
Heterogeneity: $Chi^2=150.77$, df=5 (P<0.00001); $I^2=97\%$									
Test for overall effect: Z=4.56 (P<0.00001)									
Pain VAS score									
Oliveria R 2011	2.3	2.3	30	4.5	2.6	30	6.0	-2.20 [-3.44, -0.96]	
Tommaselli GA 2010	2.1	1.1	37	4.5	2.3	38	14.1	-2.40 [-3.21, -1.59]	
Tommaselli GA 2014	0.7	0.2	64	2.8	1.4	66	79.9	-2.10 [-2.44, -1.76]	
Total (95% CI)			131			134	100	-2.15 [-2.45, -1.84]	
Heterogeneity: $Chi^2=0.45$, df=2 (P=0.80); $I^2=0\%$									
Test for overall effect: Z=13.80 (P<0.00001)									

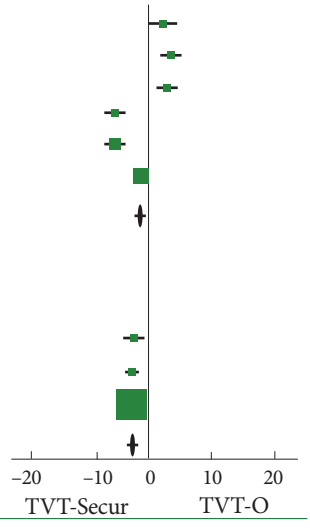

Fig. 3. Operative time, visual analog score (VAS) score (postoperative day 1) (TVT-Secur vs. TVT-O). TVT, tension-free vaginal tape; TVT-O, tension-free obturator tape; SD, standard deviation; IV, inverse variance; Fixed, fixed effect model; CI, confidence interval; df, degrees of freedom.

Study of subgroup	TVT-Secur		TVT-O		Weight (%)	Odds ratio	Odds ratio
	Events	Total	Events	Total		M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Subjective cure in 1-3 years							
Bianchi-Ferraro AM 2014	50	66	45	56	11.1	0.76 [0.32, 1.82]	
Hinoul P 2011	57	75	77	85	16.2	0.33 [0.13, 0.81]	
Masata J 2012	40	65	58	68	20.4	0.28 [0.12, 0.64]	
Masata J 2012	44	64	58	68	16.5	0.38 [0.16, 0.89]	
Maslow K 2014	32	52	44	50	16.2	0.22 [0.08, 0.60]	
Pushkar DI 2011	14	32	21	40	9.8	0.70 [0.28, 1.79]	
Wang YJ 2011	23	34	33	36	9.7	0.19 [0.05, 0.76]	
Total (95% CI)		388		403	100	0.38 [0.27, 0.54]	
Total events	260		336				
Heterogeneity, $Chi^2 = 6.93$, df = 6 (P = 0.33); $I^2 = 13\%$							
Test for overall effect: Z = 5.45 (P < 0.00001)							
Objective cure in 1-3 years							
Bianchi-Ferraro AM 2014	51	66	48	56	8.2	0.57 [0.22, 1.46]	
Hinoul P 2011	62	75	82	85	9.3	0.17 [0.05, 0.64]	
Hota LS 2012	20	42	40	44	14.2	0.09 [0.03, 0.30]	
Jeong MY 2010	22	31	28	33	5.5	0.44 [0.13, 1.49]	
Masata J 2012	45	65	63	68	13.2	0.18 [0.06, 0.51]	
Masata J 2012	44	64	63	68	13.3	0.17 [0.06, 0.50]	
Maslow K 2014	33	52	43	50	11.1	0.28 [0.11, 0.75]	
Oliveria R 2011	20	30	25	30	5.8	0.40 [0.12, 1.36]	
Pushkar DI 2011	20	32	38	40	8.8	0.09 [0.02, 0.43]	
Tommaselli GA 2010	31	37	31	38	3.4	1.17 [0.35, 3.87]	
Wang YJ 2011	23	34	33	36	7.2	0.19 [0.05, 0.76]	
Total (95% CI)		528		548	100	0.26 [0.19, 0.37]	
Total events	371		494				
Heterogeneity: $Chi^2 = 16.17$, df = 10 (P = 0.09); $I^2 = 38\%$							
Test for overall effect: Z = 7.79 (P < 0.00001)							
Subjective cure in 3-5 years							
Neuman M 2011	70	77	60	60	35.5	0.08 [0.00, 1.39]	
Tommaselli GA 2013	50	64	55	66	64.5	0.71 [0.30, 1.72]	
Total (95% CI)		141		126	100	0.49 [0.22, 1.08]	
Total events	120		115				
Heterogeneity: $Chi^2 = 2.28$, df = 1 (P = 0.13); $I^2 = 56\%$							
Test for overall effect: Z = 1.77 (P = 0.08)							
Objective cure in 3-5 years							
Neuman M 2011	70	77	58	60	32.6	0.34 [0.07, 1.72]	
Tommaselli GA 2013	50	64	57	66	67.4	0.56 [0.22, 1.41]	
Total (95% CI)		141		126	100	0.49 [0.22, 1.09]	
Total events	120		115				
Heterogeneity: $Chi^2 = 0.27$, df = 1 (P = 0.60); $I^2 = 0\%$							
Test for overall effect: Z = 1.75 (P = 0.08)							

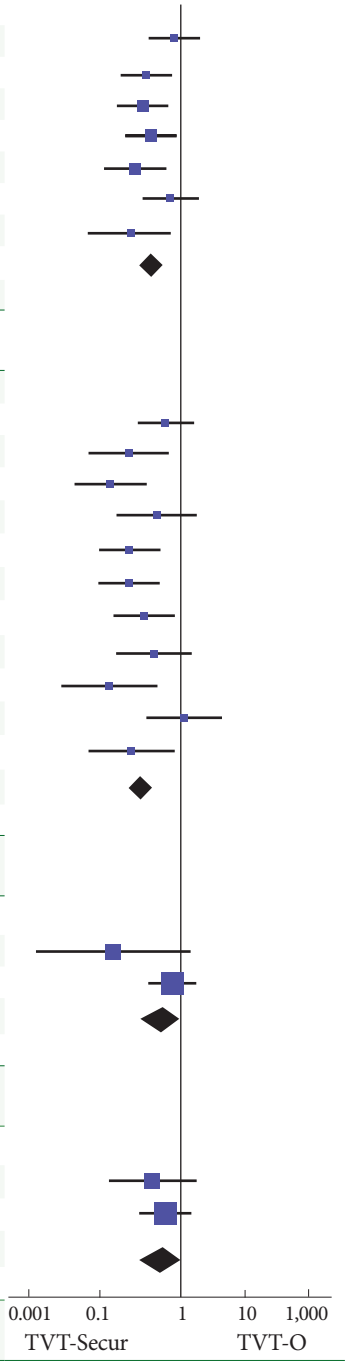

Fig. 4. Subjective and objective cure rate at 1–3 years and 3–5 years (TVT-Secur vs. TVT-O). TVT, tension-free vaginal tape; TVT-O, tension-free obturator tape; M-H, Mantel-Haenszel method; Fixed, fixed effect model; CI, confidence interval; df, degrees of freedom.

result suggests that TVT-Secur showed a significant increase in the rate of reoperation for SUI compared with TVT-O.

TVT-Secur Compared With TVT-O at 3 to 5 Years

Subjective cure rate

Two RCTs represented 267 participants (141 in the TVT-Secur

Study of subgroup	TVT-Secur		TVT-O		Weight (%)	Odds ratio	Odds ratio
	Events	Total	Events	Total		M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Bleeding greater than 100 mL							
Bianchi-Ferraro AM 2013	1	66	0	65	3.0	3.00 [0.12, 75.00]	
Hinoul P 2011	28	96	17	92	73.8	1.82 [0.91, 3.61]	
Masata J 2012	2	64	1	68	5.6	2.16 [0.19, 24.43]	
Masata J 2012	2	65	1	68	5.7	2.13 [0.19, 24.04]	
Neuman M 2011	1	77	0	60	3.3	2.37 [0.09, 59.28]	
Wang YJ 2011	0	34	1	36	8.6	0.34 [0.01, 8.71]	
Total (95% CI)		402		389	100	1.78 [0.98, 3.22]	
Total events	34		20				
Heterogeneity, $Chi^2 = 1.18$, df = 5 (P = 0.95); $I^2 = 0\%$							
Test for overall effect: Z = 1.90 (P = 0.06)							
Reoperation for SUI							
Hota LS 2012	8	42	0	44	5.1	21.93 [1.22, 393.21]	
Masata J 2012	8	64	0	68	5.5	20.61 [1.16, 364.91]	
Masata J 2012	7	65	0	68	5.6	17.56 [0.98, 314.11]	
Tommaselli GA 2014	15	58	9	62	83.8	2.05 [0.82, 5.15]	
Total (95% CI)		229		242	100	4.96 [2.37, 10.35]	
Total events	38		9				
Heterogeneity: $Chi^2 = 6.23$, df = 3 (P = 0.10); $I^2 = 52\%$							
Test for overall effect: Z = 4.26 (P < 0.0001)							
De novo urgency							
Bianchi-Ferraro AM 2014	1	66	2	56	4.5	0.42 [0.04, 4.71]	
Masata J 2012	8	64	13	68	23.3	0.60 [0.23, 1.57]	
Masata J 2012	5	65	13	68	24.7	0.35 [0.12, 1.05]	
Neuman M 2011	12	79	14	73	26.0	0.75 [0.32, 1.76]	
Oliveria R 2011	3	30	5	30	9.5	0.56 [0.12, 2.57]	
Tommaselli GA 2010	2	37	1	38	2.0	2.11 [0.18, 24.37]	
Tommaselli GA 2014	1	64	1	66	2.0	1.03 [0.06, 16.85]	
Wang YJ 2011	12	34	6	36	8.0	2.73 [0.89, 8.39]	
Total (95% CI)		439		435	100	0.78 [0.50, 1.19]	
Total events	44		55				
Heterogeneity: $Chi^2 = 8.19$, df = 7 (P = 0.32); $I^2 = 15\%$							
Test for overall effect: Z = 1.16 (P = 0.25)							

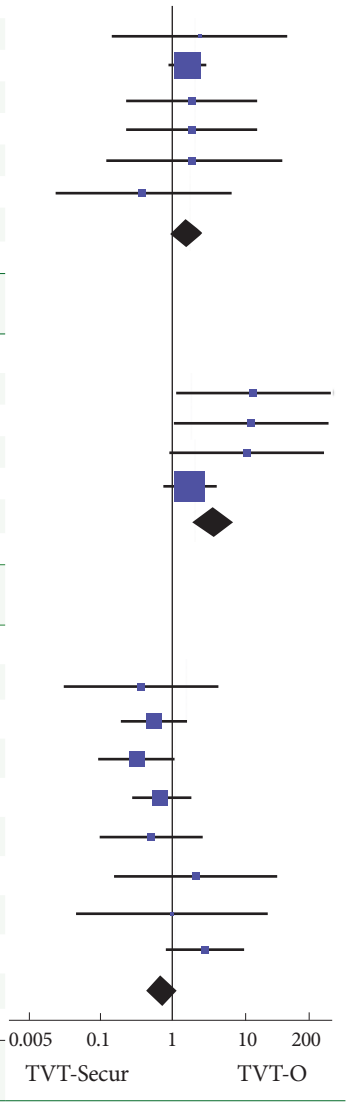

Fig. 5. Bleeding greater than 100 mL, reoperation for stress urinary incontinence (SUI), and *de novo* urgency (TVT-Secur vs. TVT-O). TVT, tension-free vaginal tape; TVT-O, tension-free obturator tape; M-H, Mantel-Haenszel method; Fixed, fixed effect model; CI, confidence interval; df, degrees of freedom.

group and 126 in the TVT-O group) (Fig. 4). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 0.49, and the 95% CI was 0.22 to 1.08 (P = 0.08). This result suggests that TVT-Secur showed no significant difference in subjective cure rate in comparison with TVT-O.

Objective cure rate

Two RCTs represented 267 participants (141 in the TVT-Secur group and 126 in the TVT-O group) (Fig. 4). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 0.49, and the 95% CI was 0.22 to 1.09 (P = 0.08). This result suggests that TVT-Secur showed no significant difference in objective cure rate in

Study of subgroup	TVT-Secur		TVT-O		Weight (%)	Odds ratio	Odds ratio
	Events	Total	Events	Total		M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Intraoperative complication in 1-3 years							
Bianchi-Ferraro AM 2014	4	66	4	56	21.4	0.84 [0.20, 3.52]	
Hinoul P 2011	30	96	18	92	66.6	1.87 [0.95, 3.66]	
Masata J 2012	7	64	1	68	4.6	8.23 [0.98, 68.88]	
Masata J 2012	2	65	1	68	5.0	2.13 [0.19, 24.04]	
Wang YJ 2011	1	34	0	36	2.5	3.27 [0.13, 83.03]	
Total (95% CI)		325		320	100	1.98 [1.15, 3.42]	
Total events	44		24				
Heterogeneity, $Chi^2 = 3.23$, df = 4 (P = 0.52); $I^2 = 0\%$ Test for overall effect: Z = 2.47 (P = 0.01)							
Postoperative complication in 1-3 years							
Bianchi-Ferraro AM 2014	20	66	32	56	30.5	0.33 [0.15, 0.69]	
Hinoul P 2011	30	96	24	92	21.3	1.29 [0.68, 2.43]	
Masata J 2012	3	64	10	68	11.7	0.29 [0.07, 1.09]	
Masata J 2012	6	65	10	68	11.2	0.59 [0.20, 1.73]	
Oliveria R 2011	5	30	9	30	9.5	0.47 [0.14, 1.61]	
Tommaselli GA 2010	3	37	6	38	6.9	0.47 [0.11, 2.04]	
Wang YJ 2011	15	34	13	36	8.9	1.40 [0.54, 3.65]	
Total (95% CI)		392		388	100	0.67 [0.48, 0.95]	
Total events	82		104				
Heterogeneity: $Chi^2 = 12.07$, df = 6 (P = 0.06); $I^2 = 50\%$ Test for overall effect: Z = 2.24 (P = 0.03)							
Postoperative complication in 3-5 years							
Neuman M 2011	10	79	6	73	41.3	1.62 [0.56, 4.70]	
Tommaselli GA 2013	8	64	9	66	58.7	0.90 [0.33, 2.51]	
Total (95% CI)		143		139	100	1.20 [0.58, 2.49]	
Total events	18		15				
Heterogeneity: $Chi^2 = 0.60$, df = 1 (P = 0.44); $I^2 = 0\%$ Test for overall effect: Z = 0.49 (P = 0.63)							

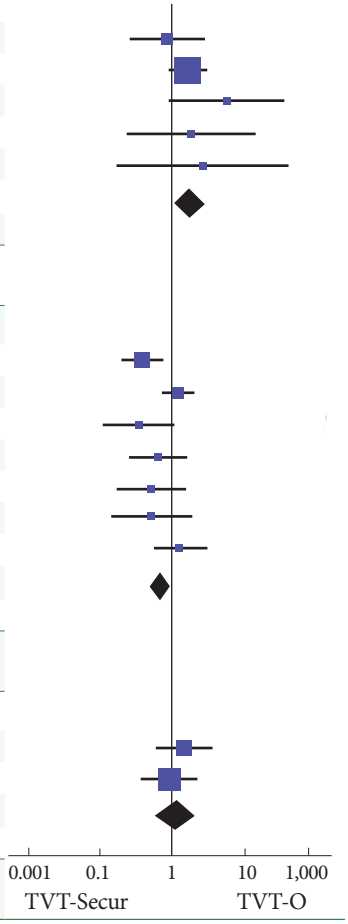

Fig. 6. Complications: intraoperative or postoperative complications at 1–3 years, postoperative complications at 3–5 years (TVT-Secur vs. TVT-O). TVT, tension-free vaginal tape; TVT-O, tension-free obturator tape; M-H, Mantel-Haenszel method; Fixed, fixed effect model; CI, confidence interval; df, degrees of freedom.

comparison with TVT-O.

Postoperative complications

Two RCTs represented 282 participants (143 in the TVT-Secur group and 139 in the TVT-O group) (Fig. 6). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 1.20, and the 95% CI was 0.58 to 2.49 (P = 0.63). This result suggests that TVT-Secur showed no significant difference in the rate of postoperative complications compared with TVT-O.

TVT-Secur Compared With TVT

Efficacy

Subjective cure rate: Three RCTs represented 444 participants (226 in the TVT-Secur group and 218 in the TVT group) (Fig. 7). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 0.59, and the 95% CI was 0.39 to 0.88 (P = 0.01). This result suggests that TVT-Secur showed a significantly lower subjective cure rate in comparison with TVT.

Objective cure rate: Three RCTs represented 248 participants (127 in the TVT-Secur group and 121 in the TVT group) (Fig. 7). According to our analysis, no heterogeneity was found

Study of subgroup	TVT-Secur Events	TVT-Secur Total	TVT Events	TVT Total	Weight (%)	Odds ratio M-H, Fixed, 95% CI
Subjective cure						
Andrada Hamer M 2013	28	60	47	61	40.8	0.26 [0.12, 0.57]
Barber MD 2012	72	129	77	127	56.3	0.82 [0.50, 1.35]
Ross S 2014	35	37	29	30	2.8	0.60 [0.05, 7.00]
Total (95% CI)		226		218	100	0.59 [0.39, 0.88]
Total events	135		153			
Heterogeneity, $Chi^2 = 5.87$, df = 2 (P = 0.05); $I^2 = 66\%$						
Test for overall effect: Z = 2.58 (P = 0.010)						
Objective cure						
Andrada Hamer M 2013	40	60	56	61	76.1	0.18 [0.06, 0.52]
Ross S 2014	27	33	25	28	20.2	0.54 [0.12, 2.39]
Wang YJ 2011	33	34	30	32	3.7	2.20 [0.19, 25.52]
Total (95% CI)		127		121	100	0.33 [0.15, 0.71]
Total events	100		111			
Heterogeneity: $Chi^2 = 4.01$, df = 2 (P = 0.13); $I^2 = 50\%$						
Test for overall effect: Z = 2.84 (P = 0.004)						

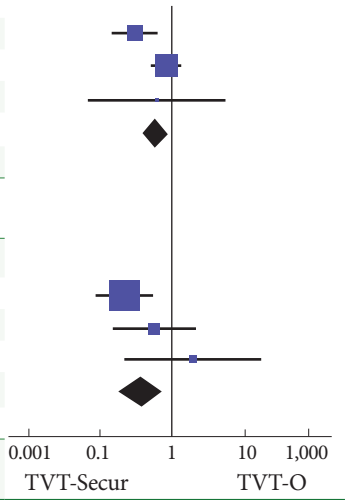

Fig. 7. Subjective and objective cure rate (TVT-Secur vs. TVT). TVT, tension-free vaginal tape; M-H, Mantel-Haenszel method; Fixed, fixed effect model; CI, confidence interval; df, degrees of freedom.

Study of subgroup	TVT-Secur Events	TVT-Secur Total	TVT Events	TVT Total	Weight (%)	Odds ratio M-H, Fixed, 95% CI
Andrada Hamer M 2013	8	60	7	61	23.9	1.19 [0.40, 3.51]
Barber MD 2012	7	136	10	127	39.0	0.63 [0.23, 1.72]
Ross S 2014	6	40	3	34	11.0	1.82 [0.42, 7.92]
Wang YJ 2011	16	34	12	32	26.0	1.48 [0.55, 3.96]
Total (95% CI)		270		254	100	1.12 [0.65, 1.91]
Total events	37		32			
Heterogeneity, $Chi^2 = 1.99$, df = 3 (P = 0.57); $I^2 = 0\%$						
Test for overall effect: Z = 0.41 (P = 0.68)						

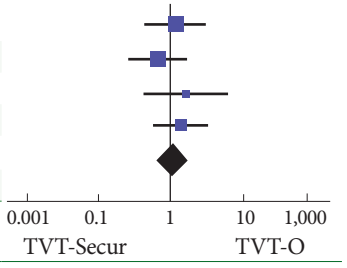

Fig. 8. Complications (TVT-Secur vs. TVT). TVT, tension-free vaginal tape; M-H, Mantel-Haenszel method; Fixed, fixed effect model; CI, confidence interval; df, degrees of freedom.

among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 0.33, and the 95% CI was 0.15 to 0.71 (P = 0.004). This result suggests that TVT-Secur showed a significantly lower objective cure rate in comparison with TVT.

Safety

Complications: Four RCTs represented 524 participants (270 in the TVT-Secur group and 254 in the TVT group) (Fig. 8). According to our analysis, no heterogeneity was found among the trials, and a fixed-effects model was thus chosen for the analysis. Based on our analysis, the pooled estimate of OR was 1.12, and the 95% CI was 0.65 to 1.91 (P = 0.68). This result suggests that TVT-Secur showed no significant difference in the rate of complications compared with TVT.

DISCUSSION

As a third-generation device, TVT-Secur was first used in 2006. The new so-called minimally invasive devices have been developed to limit groin pain after sling placement while aiming at comparable success results. TVT-Secur minimizes operative dissection and risk of injury of periurethral elements and pelvic organs, as well as the risk of nerve or adductor muscle damage.

However, TVT-Secur was withdrawn from clinical practice by the manufacturer due to poor efficacy.

Our study reveals that there was no evidence of significant differences between TVT-Secur and TVT-O for bleeding greater than 100 mL or *de novo* urgency. There were also no significant differences between TVT-Secur and TVT in complication rates. However, our study found that TVT-Secur has a higher reoperation rate for SUI and intraoperative complication rate compared with TVT-O. Some reports highlighted the risk of severe bleeding following TVT-Secur positioning [30,31]. Larsson et al. [31] recently reported an injury of the corona mortis, an anomaly of the vessels combining the obturator and epigastric arteries passing over the superior pubic ramus. Both cases required surgical intervention to remove clots, identify the site of bleeding, and perform hemostasis. Another report [16] thought that the severe blood loss (approximately 400 mL) experienced by one patient undergoing TVT-Secur was probably from the internal obturator muscle, and was treated conservatively by immediate compression of the muscle with vaginal packing. These data suggest that severe bleeding for TVT-Secur positioning is possible. In the TVT-Secur group, the main postoperative complication was *de novo* urgency, which may be related to tension difficulties with this kind of device. Higher *de novo* urgency rates (5%–35%) have been published [18,21], but were not significantly different from the rate observed in the TVT-O group.

Thigh pain is one of the most frequent complications of TVT-O, and TVT-Secur was associated with less postoperative pain [17]. Although we observed a statistical difference in postoperative pain, both groups presented average pain scores <3, which are considered mild according to the VAS [32]. TVT-Secur was associated with less thigh pain than TVT-O, possibly due to absence of involvement of the nerve or adductor muscles. However, all women were free from this symptom within a month following surgery. Moreover, operative time was significantly reduced in the TVT-Secur group.

Our meta-analysis indicated that TVT-Secur had significantly worse subjective and objective outcomes than standard MUS at 1 to 3 years. However, at 3 to 5 years, we found that there was no significant difference in subjective or objective cure rates in comparison with TVT-O. The subjective and objective cure rate of TVT-Secur is 69.7% and 70% at 1 to 3 years, and 59.7% and 78% at 3 to 5 years, respectively. Tommaselli et al. [23] recently reported that subjective success (63.8%) and objective cure rates (68.4%) over 5 years were lower for TVT-Secur than TVT-O, but not significantly. The reason may be that many patients with TVT-Secur who failed at 1 to 3 years may have had other operations, which were not included at 3 to 5 years of follow-up. Moreover, in comparison with the 36-month follow-up, TVT-Secur showed a greater decrease in subjective cure rate than TVT-O [23]. These data seem to indicate that the subjective cure rate of TVT-Secur decreases over time more than that of TVT-O, although not significantly. Indeed, a limitation of our study is the sample size of patients. With a larger sample size, the study may demonstrate a difference in outcomes between TVT-Secur and TVT-O at 3 to 5 years. As for objective cure rate, this discrepancy may be explained by the fact that objective evaluation may not reflect normal daily activities, and thus underestimates the incidence of recurrent SUI. The fact that TVT-Secur has been associated with lower cure rates deserves some consideration. The failure at 1–3 years is mainly linked to an incorrect positioning or early failure of the sling, and recurrences are probably due to insufficiency of the tape in avoiding SUI. As for the many women who had a TVT-Secur device implanted, reoperation is a problem. The clinical relevance of the decline of the efficacy of TVT-Secur, and the limited advantages of this device in the long-term, in particular, suggest that TVT-O may be a better choice, when all factors are considered.

In summary, TVT-Secur failed to demonstrate high clinical efficacy for SUI. Indeed, only 70.8% of patients treated with TVT-Secur remained cured, whereas 90.7% of patients treated with TVT-O remained cured after a median follow-up of 32 months. These results are influenced by previous incontinence surgery and a cystocele grade ≥ 2 [33]. Multivariate analysis also showed that only low Valsalva leak point pressure <60 cm H_2O was associated with a lower cure rate [34]. Therefore, these factors should be carefully evaluated when choosing a TVT-Secur procedure, to provide sufficient information to patients. TVT-O or TVT are still the first-line treatments for female SUI.

This meta-analysis includes studies in which all findings are from randomized double-blind, placebo-controlled trials. According to the quality-assessment scale that we developed, the quality of the individual studies in the meta-analysis was conforming. The results of this analysis acquire great importance from a scientific standpoint, but also for daily clinical practice. However, the number of included studies was not large. Longer-term safety, efficacy, and stability of TVT-Secur cannot be extrapolated from this article, as the sample size is limited. In addition, unpublished data were not included in the analysis. Besides, there is a discrepancy in the number of parameters used

in comparing the procedures. Nine parameters were evaluated for the analysis of TVT-Secur compared with TVT-O at 1 to 3 years. As the data were limited, a carefully structured analysis comparing TVT-S with TVT-O at 3 to 5 years could not be done, and only 3 parameters were evaluated. This may compromise the value of the study results, and these factors may have resulted in bias. More high-quality trials with larger samples are proposed to learn more about the efficacy and safety of the therapy for female SUI.

In conclusion, this meta-analysis indicates that TVT-Secur did not show an inferior efficacy and safety compared with TVT-O for SUI in 3 to 5 years, even though displaying a clear tread toward a lower efficacy in 1 to 3 years. Considering that the safety is similar, there are no advantages in using TVT-Secur.

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