

# Incontinence-specific quality of life measures used in trials of sling procedures for female stress urinary incontinence: a meta-analysis

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## Abstract

**Purpose** We conducted this review to summarize the short-term and long-term efficacy of several midurethral sling procedures on quality of life (QoL) improvement based on incontinence-specific QoL measures in clinical trials among women with stress urinary incontinence (SUI). **Methods** We searched MEDLINE (January 1966 to March 2015), EMBASE (January 1988 to March 2015), and the Cochrane Incontinence Group Specialised Register (March 2015). Only randomized controlled trials (RCTs) were eligible in this analysis.

**Results** We identified 13 different condition-specific instruments in the included 31 RCTs; the Urogenital Distress Inventory (UDI), the Incontinence Impact Questionnaire (IIQ), and Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire-12 (PISQ-12) were the most frequently used methods to measure QoL among women with SUI. We found that the improvement in sexual function (as assessed by PISQ-12) score was significantly higher in the single-incision slings group than in the TO-TVT group (WMD 1.06; 95 % CI 0.58–1.54); the post-operative pain visual analogue scale scores in the single-incision slings group was significantly lower than that in the TO-TVT

group (WMD  $-1.59$ ; 95 % CI  $-2.28$  to  $-0.89$ ). TO-TVT-treated patients had significantly greater reductions in total UDI scores (WMD 2.28; 95 % CI 1.77–2.80) and total IIQ scores (WMD 0.89; 95 % CI 0.26–1.52) than TVT-treated patients. The reduction in the total UDI score was significantly higher in the RP-TVT group than in the TO-TVT group (WMD  $-1.00$ ; 95 % CI  $-1.65$  to  $-0.35$ ). Subgroup analysis of the total UDI score showed a significantly greater improvement in TO-TVT-treated patients than in TVT after long-term follow-up ( $>30$  months), but no differences were detected after short-term follow-up (12–15 or 6 months).

**Conclusions** Our meta-analysis indicated that consistent use of the UDI and IIQ with or without the PISQ-12 might promote options for comparisons between trials. Single-incision slings were associated with significantly higher improvement in sexual function and lower post-operative pain compared with standard midurethral slings, and the long-term efficacy of TO-TVT was superior to the TVT procedure in terms of reducing the distress caused by incontinence symptoms.

**Keywords** Stress urinary incontinence · Randomized controlled trial · Quality of life · Sling

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## Introduction

Urinary incontinence (UI) is an important health problem resulting in psychological, social, and hygienic impairment, thus affecting the lives of the patients as well as their families. The prevalence of UI increases significantly with age. Three common subtypes of UI are stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed urinary incontinence (MUI). SUI is the

most common type of UI, affecting an estimated half of all incontinent women, with a mean prevalence of 4.7 % [1, 2]. A systematic review estimated that the prevalence of SUI during pregnancy was up to 41 % and increased with gestational age [3].

SUI is associated with quality of life (QoL), and women experiencing SUI have signs of a lower QoL. Treatments for women with SUI are designed to improve symptoms and incontinence-related QoL. Clinical trials are designed to evaluate treatments, and it is therefore important to measure treatment-related change, not only in symptoms but also in QoL. Therefore, in clinical trials of such treatments, the inclusion of a measure of QoL is particularly important.

In the past several decades, a variety of questionnaires for measuring the impact of SUI on QoL have been developed and tested. Subjective QoL results of SUI using condition-specific QoL questionnaires might differ because there are a plethora of measurement instruments that vary in terms of their scope and content. The use of a standardized outcome measurement for incontinence-specific QoL should be strongly encouraged in order to combine and compare results of trials. The standardization committee of the International Continence Society (ICS) suggested that reliable and sensitive QoL questionnaires should be used in evaluating treatments for SUI. However, they did not recommend the use of specific QoL measures, nor did they give specific guidance on the best way to select measures [4].

Trials on SUI and QoL are scattered and inconsistent and vary widely in the QoL measurement, which limits comparing and combining data from studies with different measures. Therefore, despite the large amount of research, a meta-analysis of the trials on QoL studies in women with SUI is still lacking. Furthermore, several midurethral sling (MUS) procedures, such as tension-free vaginal tape (TVT), TVT obturator (TVT-O), tension-free vaginal tape SECUR (TVT-S), and pubovaginal sling (PVS), have been used for the treatment of female SUI; however, which method is best for improving patient QoL is not known. The first aim of the present study was to collect all clinical randomized controlled trials (RCTs) conducted in women with SUI and to critically discuss the measurement and evaluation of QoL in women with UI. Therefore, we can provide information that is likely to be helpful in both choosing the appropriate QoL instruments for clinical trial research and combining and comparing published studies. The second aim of study was to compare different midurethral sling procedures on QoL improvement over short-term and long-term follow-ups using measurement instruments that vary in terms of their scope and content.

## Materials and methods

### Search strategy and selection criteria

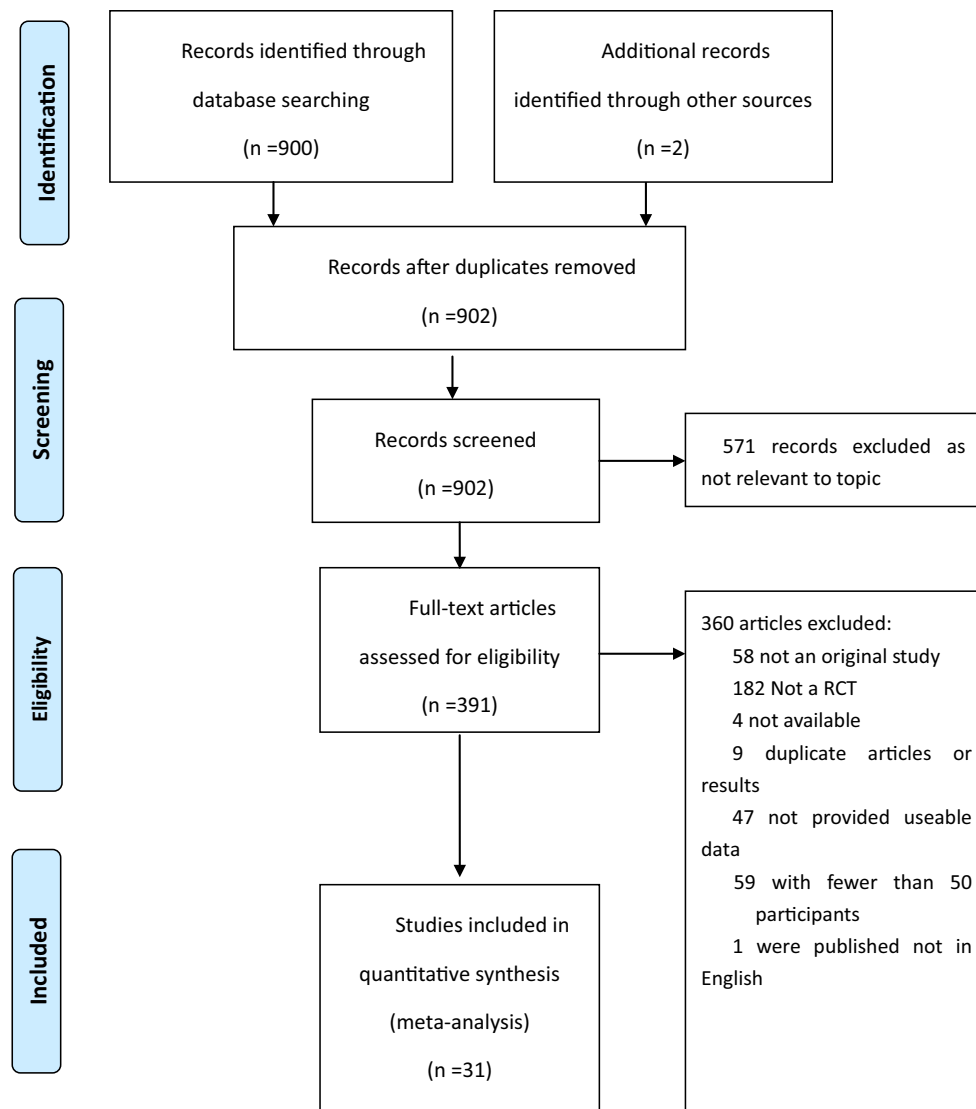
We searched MEDLINE (January 1966 to March 2015), EMBASE (January 1988 to March 2015), and the Cochrane Incontinence Group Specialised Register (March 2015), which contains trials identified from the Cochrane Central Register. Search terms consisted of the following key words: “stress urinary incontinence”, “SUI”, “quality of life”, “QoL”, “health-related quality of life”, and “HRQoL”. The reference lists of relevant articles were searched for other possible relevant studies. We adapted our search strategy to suit each database.

Only RCTs that reported the improvement in QoL of women with SUI were eligible in this meta-analysis. When a study reported the results from different subpopulations, we treated them independently. Studies involving women with urethral hypermobility, intrinsic sphincter deficiency, and mixed incontinence with a predominantly stress component were included. Quasi-randomized studies, prospective observational studies, and retrospective reviews were excluded. Studies that did not provide useable data, had duplicate results or overlapping data, or had fewer than 50 participants were excluded. When there were multiple publications from the same population, only the one with largest sample size or the most complete follow-up data was included. Two of the authors independently performed the literature search and screen. Any disagreements were resolved by discussion or involvement of a third author. Figure 1 shows the flow diagram for selecting studies for this meta-analysis.

### Data collection and methodological quality assessment

Two of the authors examined titles, abstracts, and articles independently with identical case definitions, data abstraction forms, and selection criteria. Disagreements were resolved by discussion or involvement of a third author. In addition, attempts were made to contact the authors for any clarification or missing data. The following data were extracted from the eligible studies: characteristics of studies (setting, location, and study design), patient characteristics, inclusion criteria, medical treatment, follow-up procedures, and QoL measures before and after medical treatment.

The authors assessed the methodological quality of the trials' focuses on allocation concealment, blinding, incomplete outcome data, and selective outcome reporting with the Cochrane Collaboration's risk-of-bias method [5]. The results of the quality assessment analysis of the trials are presented in Fig. 2.



**Fig. 1** PRISMA 2009 flow diagram for literature search and study selection. PRISMA diagram showing the different steps of systematic review, starting from literature search to study selection and

exclusion. At each step, the reasons for exclusion are indicated. doi:[10.1371/journal.pone.0052562.g001](https://doi.org/10.1371/journal.pone.0052562.g001)

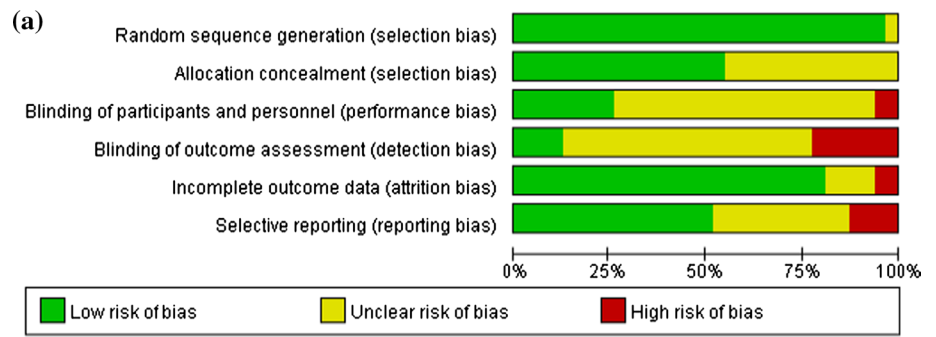
## Types of slings procedures

Sling procedures included single-incision slings and standard midurethral slings, retropubic tension-free vaginal tape (RP-TVT), and transobturator tension-free vaginal tape (TO-TVT). Single-incision slings included TVT-Secur (Gynecare, Bridgewater, NJ, USA), U-type single-incision slings, and H-type single-incision slings. TO-TVT was further subdivided by type of transobturator sling into inside-out (TVT-O), outside-in (TOT), modified TVT-O (scheduled to undergo the same surgical procedure using the modified less invasive technique), biological material TOT, and synthetic material TOT.

## Primary outcome

The primary outcomes were the features and frequency in clinical trials of a range of incontinence-specific QoL questionnaires and QoL improvement measured and evaluated using these QoL questionnaires. These questionnaires included multidimensional questionnaires and single questions or single items, which covered different scope and content including distress caused by incontinence symptoms, sexual function in women with SUI, post-operative pain, severity, and improvement of symptoms.

**Fig. 2** Risk-of-bias graph



(b)

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Abdel-Fattah M 2012	?	?	?	?	?	+
Abdel-Fattah M 2014	+	+	?	?	-	-
Aigmuller T 2014	+	+	-	-	+	?
Ballester M 2012	+	?	?	?	+	+
Barber MD 2012	+	+	+	+	+	?
David-Montefiore E 2006	+	?	?	?	+	+
deTayrac R 2004	+	+	?	?	+	?
Djehdian LM 2014	+	+	+	?	+	+
Kim JJ 2010	+	?	?	?	+	+
Laurikainen E 2014	+	+	?	-	+	+
Maslow K 2014	+	+	+	+	+	+
Meschia M 2007	+	+	?	?	+	+
Mostafa A 2012	+	+	?	?	+	?
Mostafa A 2013	+	+	?	?	+	?
Palva K 2010	+	+	?	?	+	+
Paparella R 2010	+	+	?	?	+	-
Porena M 2007	+	?	?	?	+	?
Ross S 2009	+	+	+	+	+	+
Scheiner DA 2012	+	?	?	?	-	?
Schellart RP 2014	+	?	?	?	+	-
Schierlitz L 2008	+	?	?	?	+	+
Schierlitz L 2012	+	?	?	?	+	?
Schweitzer K 2012	+	+	+	-	?	?
Schweitzer KJ 2015	+	+	+	-	?	+
Tang X 2014	+	?	?	?	?	+
Tommaselli GA 2013	+	+	+	-	+	?
Tommaselli GA 2016	+	?	+	-	+	-
Ugurlican FG 2013	+	+	?	?	+	+
Wang F 2010	+	?	-	+	+	+
Wang WY 2008	+	?	?	-	+	+
Zhang Y 2011	+	?	?	?	+	?

## Statistical analysis

We calculated risk ratios (RRs) for binary outcomes and weighted mean differences (WMD) for continuous outcomes. We used the Chi-square test and  $I^2$  scores ( $I^2 > 50\%$  was regarded as substantial heterogeneity) to assess the degree of statistical heterogeneity [6]. A random effects model was used to aggregate individual effect sizes in order to take into account the heterogeneity of the risk estimates and to provide more conservative estimates compared with the fixed effects model [7]. We investigated potential sources of heterogeneity with subgroup analyses according to follow-up duration (months), disease severity (with urethral hypermobility, with intrinsic sphincter deficiency, and with a mix of urethral hypermobility and intrinsic sphincter deficiency), disease type (with and without mixed incontinence), and mean age of participants in clinical trials.

To establish the robustness of the outcome by sensitivity analyses, we applied a fixed effects model, used the trim-and-fill method, and excluded studies with fewer participants. All analyses were performed using the software STATA version 12.0 (StataCorp LP, College Station, TX, USA) and Review Manage 5.1. All *P* values were two-sided. A *P* value  $< 0.05$  was considered to be statistically significant.

## Results

### Characteristics of eligible studies

Figure 1 illustrates the flow of literature through the search and assessment process. We retrieved 962 candidate articles from all searches. A total of 31 RCTs met the inclusion criteria and were included in the meta-analysis [8–38]. Table 1 shows the characteristics of the trials. The means (SD) age of the participants was 55.74 (5.449) years old, and the mean (SD) longest duration of follow-up was 19.34 (15.90) months.

The risk of bias was assessed using a risk-of-bias graph (Fig. 2). Most RCTs had good sequence generation, allocation concealment, and incomplete outcome data; however, reporting of blinding methods and selective reporting in most RCTs were generally poor.

### Condition-specific instruments to assess QoL in women with SUI

A total of 13 different condition-specific instruments were identified in this meta-analysis. In our study, the Urogenital Distress Inventory (UDI), Incontinence Impact Questionnaire (IIQ), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) were the most frequently used in measuring QoL among women with SUI.

The most frequently used combination of incontinence-specific QoL measures was the IIQ with the UDI (reported in 13 trials). The details of these reported condition-specific questionnaires are presented in Table 2.

### Summary of main results

Five RCTs, which used the same questionnaire (PISQ-12), reported the comparison of single-incision slings and TO-TVT on sexual function; improvement in the PISQ-12 score was significantly higher in the single-incision slings group than in the TO-TVT group (WMD 1.06; 95 % CI 0.58–1.54) over a mean follow-up of 12 months (Fig. 3a). The mean pain visual analogue scale (VAS) score during the first three post-operative days in the single-incision slings group was significantly lower than that in TO-TVT group (WMD  $-1.59$ ; 95 % CI  $-2.28$  to  $-0.89$ ) (Fig. 3a). Five RCTs compared single-incision slings and TO-TVT with a patient-reported success rate defined as “very much improved/much improved” on the PGI-I, and we did not detect a difference between the two groups over a mean follow-up of 12 months (Fig. 3a). Only one study compared single-incision slings and TO-TVT with the KHQ; the improvement in total KHQ score was significantly lower in the single-incision slings group than in the TO-TVT group (WMD  $-3.09$ ; 95 % CI  $-5.58$  to  $-0.60$ ) (Fig. 3a). We did not detect differences in total score improvement with the UDI, IIQ, Incontinence Questionnaire Short Form (ICIQ-SF), or the International Consultation of Incontinence Questionnaire–Frequency of Lower Urinary Tract Symptoms (ICIQ-FLUTS) between the single-incision slings group and the TO-TVT group (Fig. 3a). After excluding RCTs that evaluated TVT-Secur, single-incision mini-slings (SIMS) still had significantly improved PISQ-12 sexual function scores (WMD 0.95; 95 % CI 0.45–1.46).

Six RCTs compared TVT and TO-TVT with the UDI; our results showed that TO-TVT-treated patients had significantly greater reductions in UDI (WMD 2.28; 95 % CI 1.77–2.80) than TVT-treated patients over a mean follow-up of 12 months (Fig. 3b). Six RCTs compared TVT and TO-TVT with the IIQ; our results showed that TO-TVT-treated patients had significantly greater reductions in IIQ (WMD 0.89; 95 % CI 0.26–1.52) than TVT-treated patients over a mean follow-up of 12 months (Fig. 3b). Three RCTs compared TVT and TO-TVT with the pain VAS score; we did not detect a difference between the two groups (Fig. 3b).

Four RCTs compared RP-TVT and TO-TVT with the UDI; the reduction in the total UDI score was significantly higher in the RP-TVT group than in the TO-TVT group (WMD  $-1.00$ ; 95 % CI  $-1.65$  to  $-0.35$ ) (Fig. 3c). Four RCTs compared RP-TVT and TO-TVT with the IIQ, and no difference was detected between the two groups. Only two RCTs compared TVT and TO-TVT with the pain VAS score, and there was no difference between the two groups (Fig. 3c).

**Table 1** Characteristics of included studies

References	Design	Participants	Comparisons	Follow-up duration	Loss to follow-up (%)	Outcome measures instruments
Abdel-Fattah et al. [26]	RCT	341 women with urodynamic SUI who had previously failed or declined pelvic floor muscle treatment	TVT-O versus TOT	36 months	30.21	PGI-I, VAS, ICIQ-SF, KHQ, PISQ-12
Abdel-Fattah et al. [16]	RCT	83 women with MUI symptoms and predominant SUI symptoms; mean age was 54.45 (SD = 11.06)	TVT-O versus TOT	36 months	20.48	KHQ, PISQ-12
Aigmuller et al. [15]	RCT	569 women who had planned primary surgery for urodynamically verified SUI without concomitant prolapse surgery or hysterectomy; mean age was 59.17 (SD = 11.02)	RP-TVT versus TO-TVT	3 months	15.64	KHQ, PGI-S, PGI-I, IOQ
Ballester et al. [25]	RCT	88 women with SUI proven by clinical and urodynamic examinations	RP-TVT versus TO-TVT	48 months	19.32	UDI, IIQ
Barber et al. [24]	RCT	263 women with urodynamic SUI who desired surgical treatment for their incontinence; mean age was 54.6 (SD = 10.87)	SIMS versus RP-TVT	12 months	0.00	PISQ-12, PGI-I
David-Montefiore et al. [37]	RCT	88 women with SUI; mean age was 55.02 (SD = 11.31)	RP-TVT versus TO-TVT	4–6 weeks	0.00	UDI, IIQ
de Tayrac et al. [38]	RCT	61 women who had urodynamically proved genuine SUI; mean age was 54.14 (SD = 12.12)	TVT versus TOT	12 months	0.00	VAS
Djehdian et al. [14]	RCT	130 women with SUI confirmed by a positive cough stress test, the presence of urine leakage >2 g, and urodynamic stress incontinence; mean age was 53.13 (SD = 9.82)	SIMS versus TO-TVT	12 months	7.69	I-QoL, UDI-6, VAS
Kim et al. [31]	RCT	115 women with urodynamic SUI for at least 3 months; mean age was 55.96 (SD = 8.98)	U-type TVT-Secur versus H-type TVT-Secur	12 months	0.00	I-QoL, VAS, BFLUTS-SF
Laurikainen et al. [13]	RCT	268 women who had a history of stress urinary incontinence and an indication for surgical treatment of their incontinence, a positive cough stress test; mean age was 53.48 (SD = 9.99)	RP-TVT versus TVT-O	60 months	5.22	UDI-6, IIQ-7, VAS, UISS
Maslow et al. [12]	RCT	106 women who had symptoms of stress urinary incontinence and a positive cough test; mean age was 48.73 (SD = 8.80)	TVT-O versus TVT-Secur	12 months	3.77	UDI-6, IIQ-7
Meschia et al. [36]	RCT	231 women with SUI and urethral hypermobility; mean age was 57.01 (SD = 9.55)	TVT versus TVT-O	6 months	5.63	VAS, ICIQ-SF, W-IPSS, PGI-S, PGI-I
Mostafa et al. [22]	RCT	137 women admitted for surgical treatment of urodynamic SUI as a sole procedure; mean age was 61.05 (SD = 7.72)	SIMS versus TO-TVT	4–6 months	0.00	VAS, KHQ, ICIQ-SF, PGI-I, UPS, ICIQ-FLUTS
Mostafa et al. [19]	RCT	137 women with urodynamic SUI who failed or declined pelvic floor muscle training; mean age was 50.01 (SD = 10.17)	SIMS versus TO-TVT	12 months	4.38	KHQ, PISQ-12, ICIQ-SF, ICIQ-FLUTS, UPS
Palva et al. [30]	RCT	267 women with a history of stress incontinence and indication for surgical treatment of incontinence; mean age was 55.96 (SD = 8.98)	TVT versus TVT-O	36 months	3.75	UISS, VAS, UDI-6, IIQ-7, EQ-5D
Paparella et al. [29]	RCT	70 women suffering from clinical and urodynamic SUI with urethrovesical junction hypermobility; mean age was 60.03 (SD = 7.77)	Biological TOT versus synthetic TOT	24 months	0.00	KHQ, VAS, PISQ-12

Table 1 continued

References	Design	Participants	Comparisons	Follow-up duration	Loss to follow-up (%)	Outcome measures instruments
Porena et al. [35]	RCT	148 women with stress or mixed urinary incontinence (stress component clinically predominant) associated with urethral hypermobility; mean age was 61.19 (SD = 10.33)	TVT versus TOT	31 months	2.03	UDI-6, IIQ-7
Ross et al. [32]	RCT	199 women who elected surgical management of SUI and who had visualized leaking urine from the urethra with cough; mean age was 50.55 (SD = 8.89)	TVT versus TOT	12 months	8.54	UDI-6, IIQ-7
Scheiner et al. [21]	RCT	149 women with urodynamically confirmed SUI or mixed urinary incontinence with a predominant component of SUI; mean age was 59.78 (SD = 12.12)	RP-TVT versus TVT-O versus TOT	12 months	30.87	KHQ, VAS
Schellart et al. [11]	RCT	193 women who were indicated for surgical correction of symptomatic SUI; mean age was 53 (SD = 10.97)	SIMS versus TO-TVT	12 months	0.00	PGI-I, VAS, UDI-6, PGI-S
Schierlitz et al. [34]	RCT	164 women diagnosed with urodynamic SUI and intrinsic sphincter deficiency with or without concomitant pelvic organ prolapse repair; mean age was 60 (SD = 11.17)	TVT versus TO-TVT	6 months	15.85	UDI-6, IIQ-7
Schierlitz et al. [20]	RCT	164 women who had failed conservative management for SUI and who were diagnosed with intrinsic sphincter deficiency on urodynamic studies; mean age was 60 (SD = 11.17)	TVT versus TO-TVT	36 months	10.37	UDI-6, IIQ-7
Schweitzer et al. [23]	RCT	156 women with SUI who completed conservative therapy	SIMS versus TO-TVT	12 months	5.92	PISQ-12
Schweitzer et al. [9]	RCT	156 women with clinically proven SUI; mean age was 49.85 (SD = 9.86)	SIMS versus TO-TVT	12 months	30.77	UDI-6, IIQ-7, PGI-I, PGI-S, PISQ-12
Tang et al. [10]	RCT	94 women with demonstrable SUI for whom conservative therapy had failed; mean age was 50.58 (SD = 8.82)	TVT-O versus TVT-Secur	24 months	13.83	IIQ-7, PISQ-12
Tommaselli et al. [18]	RCT	110 women with SUI diagnosed by clinical evaluation and urodynamics and previously failed pelvic floor muscle training; mean age was 61.05 (SD = 7.72)	Modified TVT-O versus TVT-O	12 months	11.82	I-QoL, PISQ-12, PGI-S
Tommaselli et al. [8]	RCT	154 women with SUI diagnosed by clinical evaluation and urodynamics and previously failed pelvic floor muscle training; mean age was 58.65 (SD = 7.99)	TVT-O versus TVT-Secur	60 months	22.08	I-QoL, PGI-S, PGI-I
Ugurlucan et al. [17]	RCT	100 women with clinically or urodynamically proven SUI for whom conservative treatment had failed; mean age was 53.95 (SD = 11.47)	Biological TOT versus synthetic TOT	12 months	0.00	UDI, IIQ, KHQ
Wang et al. [28]	RCT	140 women with urodynamically proven SUI; mean age was 59 (SD = 11.21)	TVT versus TOT	12 months	0.00	UDI, IIQ
Wang et al. [33]	RCT	69 women diagnosed with SUI; mean age was 52 (SD = 10.92)	TVT versus TVT-O	14.5 months	0.00	UDI, IIQ

Table 1 continued

References	Design	Participants	Comparisons	Follow-up duration	Loss to follow-up (%)	Outcome measures instruments
Zhang et al. [27]	RCT	156 female patients with SUI for at least 3 months; mean age was 62.02 (SD = 4.44)	Modified TVT-O versus TVT-O	1 month	0.00	I-QoL

*TVT* tension-free vaginal tape, *TVT-Secur* single-incision TVT, *TO-TVT* transoburator TVT, *RP-TV* retropubic TVT, *TVT-0* inside-out TO-TVT, *TOT* outside-in TO-TVT, *UDI* Urogenital Distress Inventory, *I/Q* the Incontinence Impact Questionnaire, *KHQ* King's Health Questionnaire, *I-QoL* the Incontinence Quality of Life questionnaire, *PGI-I* Patient Global Impression of Improvement questionnaire, *VAS* visual analogue scale, *PGI-S* the Patient Global Impression of Severity questionnaire, *PISQ-12* Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire, *ICIQ-SF* the International Consultation of Incontinence Questionnaire Short Form, *UPS* urgency perception scale, *ICIQ* the International Consultation of Incontinence Questionnaire, *UISS* the Urinary Incontinence Severity Score, *BFLUTS* Bristol Female Lower Urinary Tract Symptoms Questionnaire, *W-IPSS* Women Irritative Prostate Symptoms Score, *IQQ* the Incontinence Outcome Questionnaire, *ICIQ-FLUTS* the International Consultation of Incontinence Questionnaire—Frequency of Lower Urinary Tract Symptoms

The number of RCTs that compared TVT-O and TOT was small. Of this small number, only two RCTs reported results with the KHQ score, two reported results with the PISQ-12, two reported results with the PGI-I, and one reported results with the VAS. No differences in the improvement of QoL were detected between these groups (Fig. 3d).

Only one RCT compared biological TOT and synthetic TOT, modified TVT-O and TVT-O, U-type single-incision slings and H-type single-incision slings, and there were no differences in improvement of QoL detected between these groups (Fig. 3e).

The meta-analysis results across all binary outcomes, for example having 18-point improvement in KHQ total score, success defined as very much/improved by PGI-I, having 20-point increase in I-QoL total score, having eight-point increase in VAS total score, were presented in Fig. 4, and there were no difference between TVT-Secur and TO-TVT, TVT-O vs TOV, TVT-Secur and RP-TV on these binary outcomes.

### Subgroup analysis

We performed a subgroup analysis of all RCTs that used the UDI by follow-up duration (months) due to a high level of heterogeneity ( $I^2 = 83.9\%$ ,  $P < 0.001$ ). Analysis of total UDI scores showed a significantly higher improvement in TO-TVT-treated patients than in TVT-treated patients after a long-term follow-up (>30 months) (WMD 2.80; 95 % CI 1.56–4.04), but after a short-term follow-up (12–15 and 6 months), no significant differences were detected between the two groups (Fig. 5).

Subgroup analysis by disease severity and disease type showed that the improvement in sexual function score (as assessed by the PISQ-12) was significantly higher in the single-incision sling group than in the TO-TVT group for patients with urethral hypermobility (WMD 2.10; 95 % CI 0.52–3.68), with mixed incontinence (WMD 1.00; 95 % CI 0.44–1.56), and without mixed incontinence (WMD 1.23; 95 % CI 0.28–2.18); however, no trial reported the results among patients with intrinsic sphincter deficiency. The post-operative pain VAS scores in the single-incision sling group was significantly lower than that in the TO-TVT group among both patients with mixed incontinence (WMD -1.59; 95 % CI -2.28 to -0.89) and without mixed incontinence (WMD -0.66; 95 % CI -1.01 to -0.32). Only one trial reported the results among patients with mixed urethral hypermobility and intrinsic sphincter deficiency, and there was no evidence of a significant difference in post-operative pain VAS scores between both groups (Table 3).

TO-TVT-treated patients had significantly greater reductions in total UDI scores than TVT-treated patients in the subgroup of urethral hypermobility (WMD 1.95; 95 % CI 0.59–3.32); in the other subgroups, there was no significant difference in the improvement of total UDI scores between both groups (Table 3).



**Table 2** Incontinence-specific questionnaires reported (among the papers which reported using such a measure,  $n = 31$ )

QoL measure	Description of measure	Domains	Score	Number of studies (%)
UDI and UDI-6	The UDI is used to evaluate the distress caused by incontinence symptoms. The UDI-6 is the short form that was developed by selecting the items that would correctly predict the long form total score	Three subscales: irritative symptoms (6 items), obstructive/discomfort (11 items), and stress symptoms (2 items). The UDI-6 has a single domain: distress caused by UI	0–300 for UDI, 0–100 for UDI-6 (high scores are low QoL)	15
IIQ and IIQ-7	Asks about 30 activities and evaluates the impact UI has had on these activities. The IIQ-7 is the short form that was developed by selecting the items that would correctly predict the long form total score	Four subscales: physical activity (6 items), travel (6 items), social relationships (10 items), and emotional health (8 items). The IIQ-7 has a single domain: life impact caused by UI	0–400 for IIQ, 0–100 for IIQ-7 (high scores are low QoL)	14
PISQ-12	Evaluating sexual function in women with pelvic organ prolapse and/or UI in clinical and research settings	Three domains: behavioural/emotive domain (4 items), physical domain (5 items), and partner-related domain (3 items).	0–48 (higher scores indicate better sexual function)	9
VAS	The VAS is a well-established subjective measurement of post-operative pain and is also used in assessing urinary symptoms	Subjects were asked to describe the subjective burden of incontinence on a 100-mm VAS	0–10 (0 corresponding to no symptoms and 10 to the maximum severity)	8
PGI-I and PGI-S	The PGI-I and PGI-S are global indexes of severity and improvement that summarize the severity or improvement. The PGI-I is commonly used subjectively to assess subjective cure rate of SUI	Both are single questions with four and seven response categories, respectively. Both are single-question global indexes for UI	Success is defined as “very much improved” or “much improved” on the PGI-I. 1–4 for PGI-S (1 corresponding to normal and 4 to severe)	8
KHQ	A condition-specific QoL questionnaire for the assessment of symptom severity of UI	General health perception (1 item) plus eight QoL domains: incontinence impact (1 item), role limitations (2 items), physical limitations (2 items), social limitations (3 items), personal relationships (2 items), emotions (3 items), sleep/energy disturbance (2 items), severity measures (5 items)	Eight domains, with scores for each ranging between 0 and 100 (high scores are greater impairment)	8
I-QoL	Focusing on incontinence and its emotional impact	Three subscales: avoidance and limiting behaviours (8 items), psychological impact (9 items), and social embarrassment (5 items)	0–100 (high score is high QoL)	5
ICIQ-SF	The ICIQ-SF is used to diagnose the frequency and severity of UI	Three scored items: assessment of frequency (0–5), severity (0–6) and perceived impact of incontinence (0–10), and an unscored self-diagnostic item	High scores are severe symptom	4
UISS	The UISS has been widely used in clinical practice, to assess symptom severity and impact of urinary incontinence on everyday life	The UISS questionnaire consists of 10 questions with a three-point scoring system (0 = not at all, 1 = sometimes, 2 = often)	0–20 (high scores are severe symptom)	2
UPS	Patient-reported subjective assessment of urinary urgency in clinical studies of overactive bladder (OAB) syndrome treatments	The UPS is a single-item, three-response question	1–3 (higher score indicates can completely hold urine)	2
W-IPSS	The W-IPSS was developed to evaluate irritative and obstructive bladder symptoms	Two subscales: irritative (3 items) and obstructive (4 items) bladder symptoms	0–35 (high scores are severe symptom)	1

Table 2 continued

QoL measure	Description of measure	Domains	Score	Number of studies (%)
BFLUTS	The BFLUTS is ideal for measuring changes following therapeutic intervention and can identify those women who wish treatment for their symptoms	The BFLUTS has three domains: symptoms, sexual matters, and lifestyle impact. The BFLUTS-SF has three subscale scores for incontinence, voiding and filling symptoms, and a combined symptom score, plus subscales for sexual function and QoL	BFLUTS: no individual items. BFLUTS-SF has a composite score for symptoms	1
IOQ	The IOQ is a valid and reliable instrument for assessing patient-reported outcomes after surgery for SUI and can be used if baseline or pre-operative data are unavailable	The IOQ consists of one multi-item subscale (15 items), six single questions about pain, and six non-scoring questions	For all scores, high values indicate inferior outcomes, and lower values indicate superior outcomes	1

TVT tension-free vaginal tape, *TVT-Secur* single-incision TVT, *TO-TVT* transoburator TVT, *RP-TVT* retropubic TVT, *TVT-0* inside-out TO-TVT, *TOT* outside-in TO-TVT, *UDI* Urogenital Distress Inventory, *IIQ* the Incontinence Impact Questionnaire, *KHQ* King's Health Questionnaire, *I-QoL* the Incontinence Quality of Life questionnaire, *VAS* visual analogue scale, *PGI-I* Patient Global Impression of Improvement questionnaire, *PGI-S* Patient Global Impression of Severity questionnaire, *PISQ-12* Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire, *ICIQ-SF* International Consultation of Incontinence Questionnaire Short Form, *UPS* urgency perception scale, *ICIQ* the International Consultation of Incontinence Questionnaire, *UISS* the urinary incontinence severity score, *BFLUTS* Bristol Female Lower Urinary Tract Symptoms Questionnaire, *IOQ* the Incontinence Outcome Questionnaire, *W-IPSS* Women Irritative Prostate Symptoms Score

**Fig. 3** Meta-analysis results across all continuous outcomes (WMD). *TVT* tension-free vaginal tape, *TVT-Secur* single-incision TVT, *TO-TVT* transoburator TVT, *RP-TVT* retropubic TVT, *TVT-0* inside-out TO-TVT, *TOT* outside-in TO-TVT, *UDI* Urogenital Distress Inventory, *IIQ* the Incontinence Impact Questionnaire. *VAS* visual analogue scale, *KHQ* King's Health Questionnaire, *PISQ-12* Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire, *ICIQ-SF* Incontinence Questionnaire Short Form

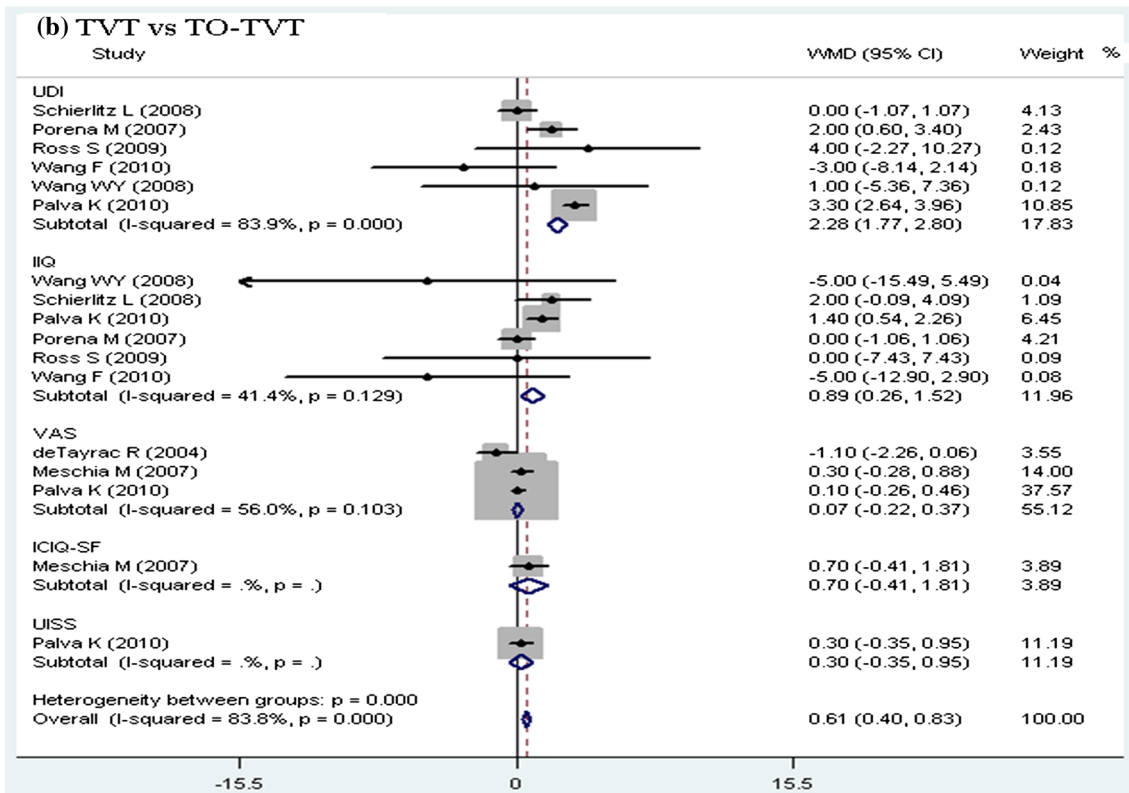
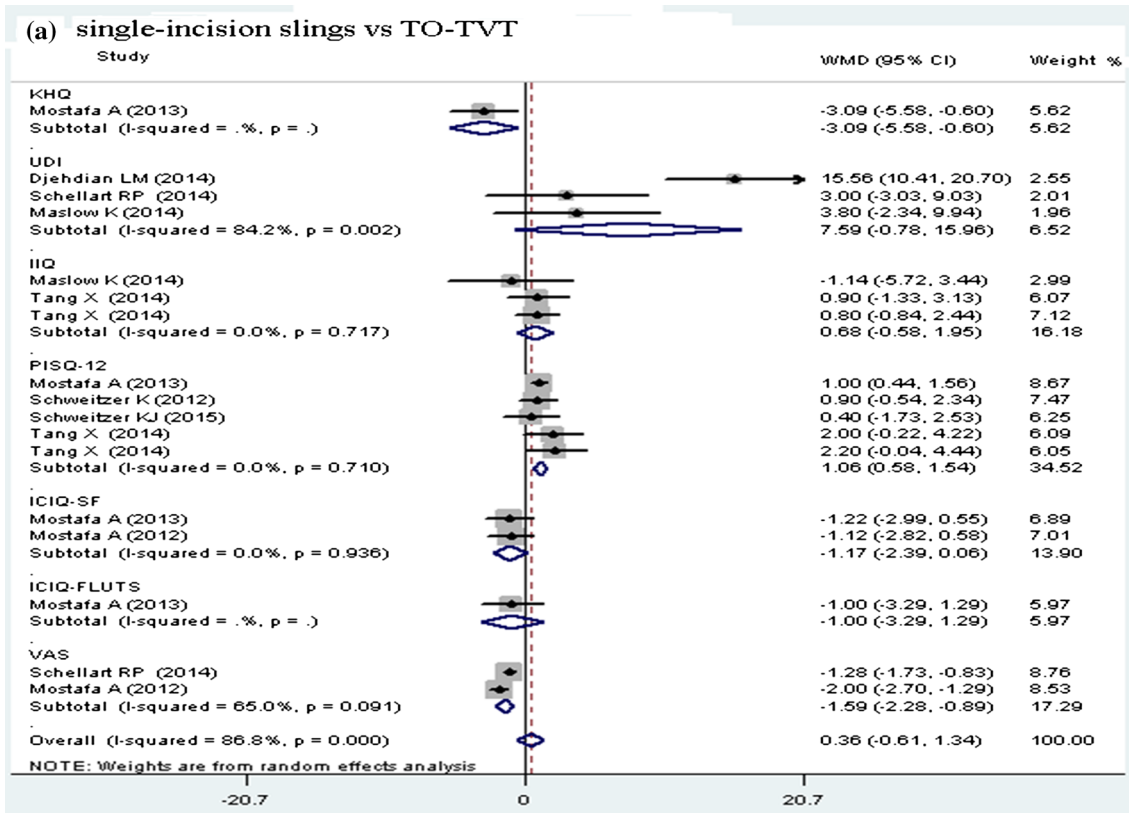
### Evaluation of publication bias

We assessed funnel plot asymmetry using Egger's linear regression test. The results showed that there was no publication bias in all main outcomes and subgroup analyses ( $P > 0.05$ ).

### Discussion

Health-related QoL in women with SUI is increasingly considered an essential outcome for clinical trials and patient management. During the past several decades, a variety of incontinence-specific questionnaires for measuring the impact of SUI on health-related QoL have been developed and tested. Subjective QoL of women with SUI using incontinence-specific questionnaires might differ because there are excessive measurement instruments that vary in terms of their scope and content. In this meta-analysis, we identified 13 different condition-specific instruments from 31 RCTs of women with SUI. Our results revealed that the UDI and IIQ were the most frequently used tools for measuring QoL among women with SUI, and the two instruments were commonly combined, as in 13 of the trials. The UDI is used to evaluate the distress or "bother" caused by incontinence symptoms. The IIQ uses approximately 30 activities to evaluate the impact that UI has on these activities [39]. The two instruments both had good clinical face validity and measurement properties and were the most appropriate for use in measuring the QoL among women with SUI [40]. The PISQ-12 is often used to complement these QoL measures by evaluating sexual function in women with pelvic organ prolapse and/or SUI in clinical and research settings [41]. The short forms of the IIQ (IIQ-7) [42] and UDI (UDI-6) [42] are becoming more common in order to reduce the burden of questionnaires on patients; in this study, only 2 RCTs (25, 37) reported the results of the long forms of the IIQ (14.29 %) and UDI (13.33 %). Therefore, we recommend that researchers consider using the short forms of the IIQ (IIQ-7) and UDI (UDI-6) with or without the PISQ-12 as their first choice of QoL measurement in trials of incontinence treatments.

The Incontinence Quality of Life questionnaire (I-QoL) evaluates the effects of UI in the three domains of avoidance and limiting behaviour, social embarrassment, and



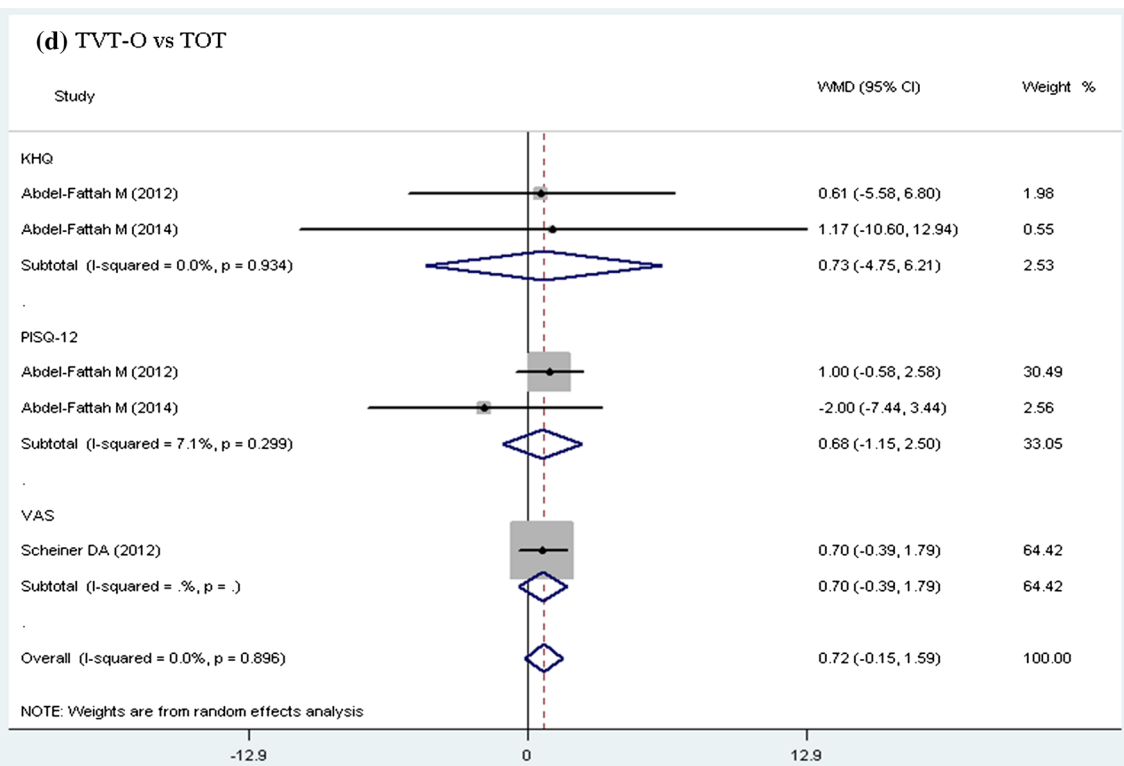
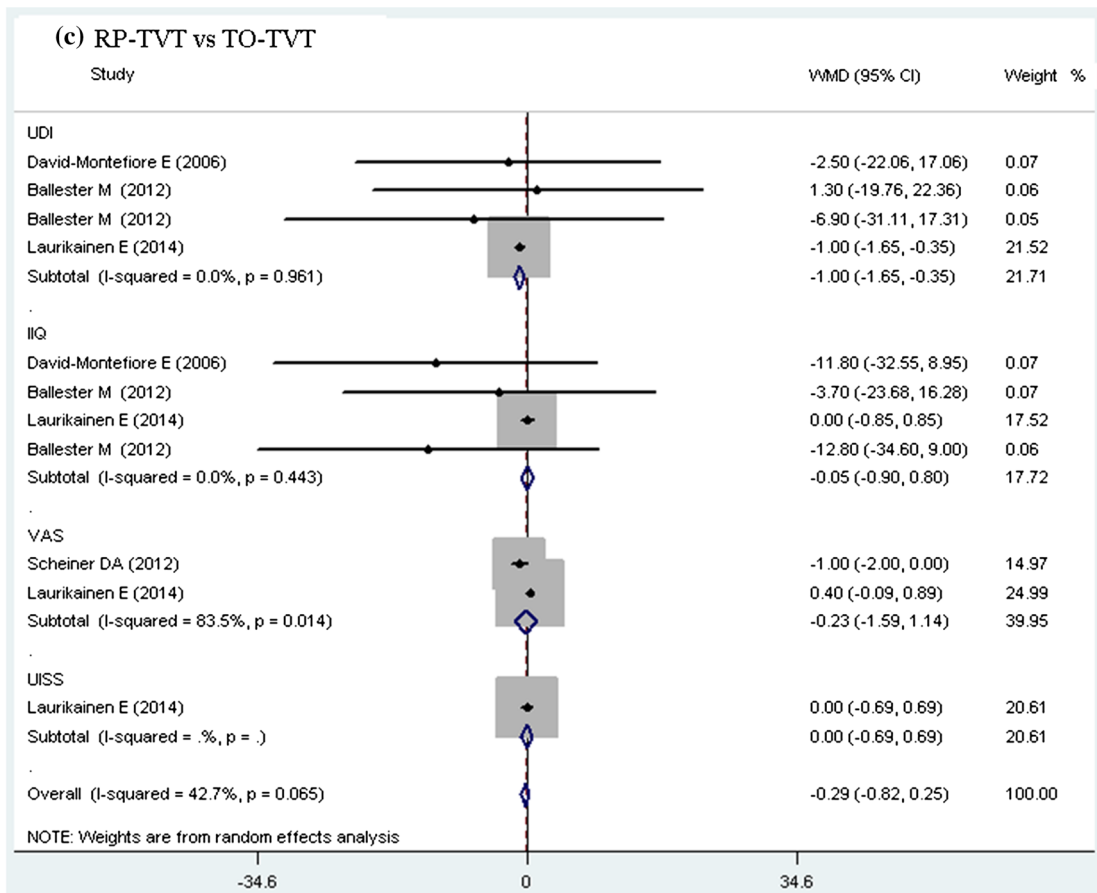


Fig. 3 continued

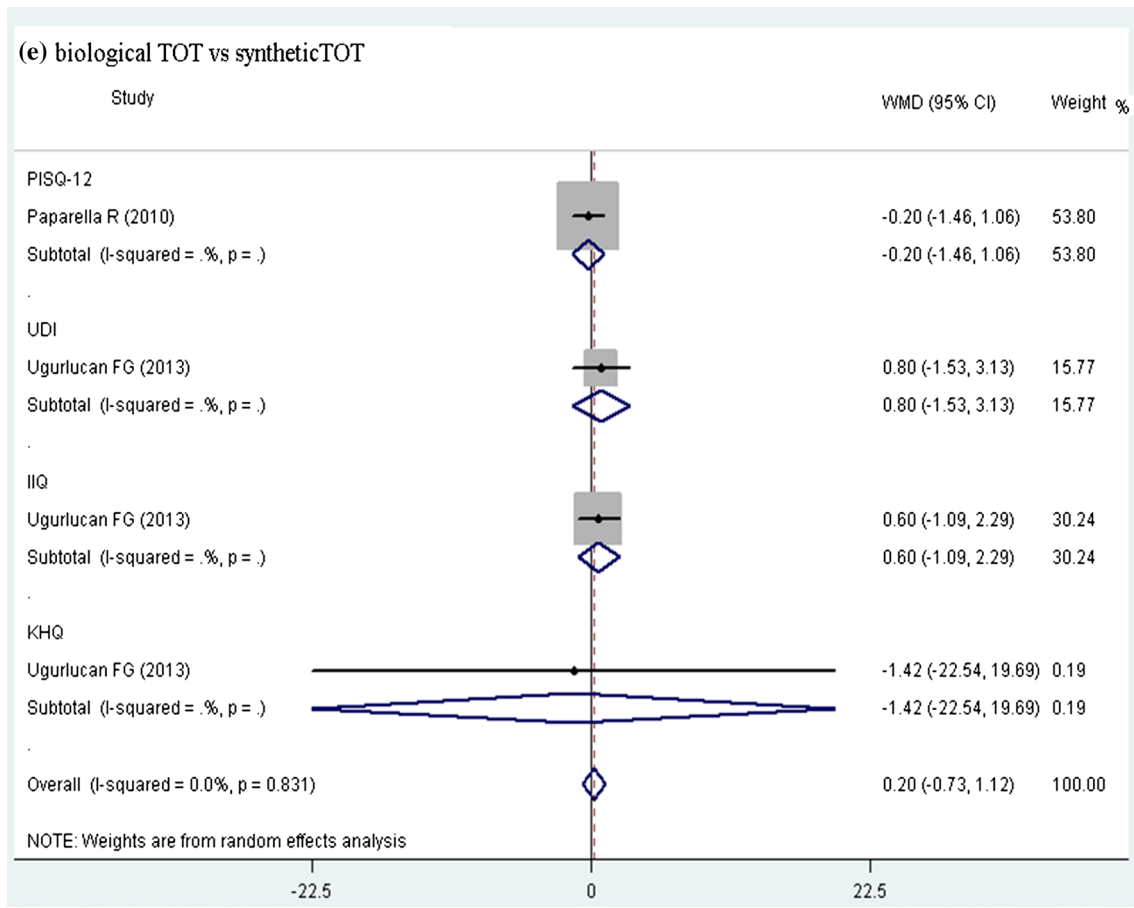
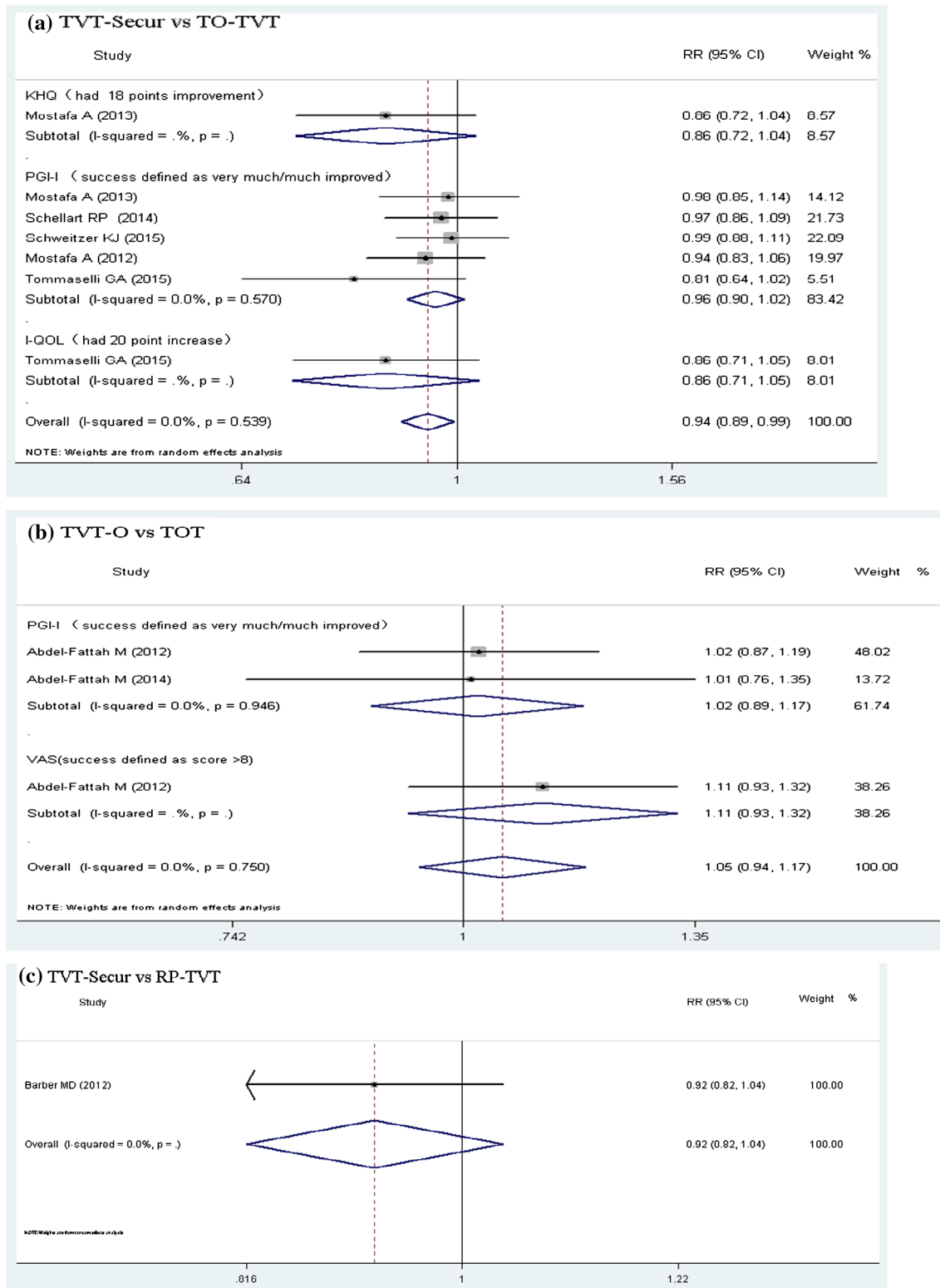


Fig. 3 continued

psychosocial impact, and it was endorsed by the International Consultation on Incontinence [43]. The I-QoL is available in a number of languages and has been shown to be a reliable and valid measure of QoL suitable for use in a variety of international settings [44]. Although only 5 of 31 RCTs in this study reported the results of the I-QoL, we still recommend the I-QoL as an important continence-specific measure of QoL in a clinical trial setting. Despite the availability of QoL questionnaires, new questionnaires continue to appear; for example, the Incontinence Outcome Questionnaire (IOQ) [45] and International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) [46] were also reported in this meta-analysis. The reasons for developing additional questionnaires are not clear but could be related to the limited range of languages available in previously developed questionnaires. However, we recommend translation of the commonly used instruments, for example, the UDI-6, IIQ-7, I-QoL, into different languages as the best choice.

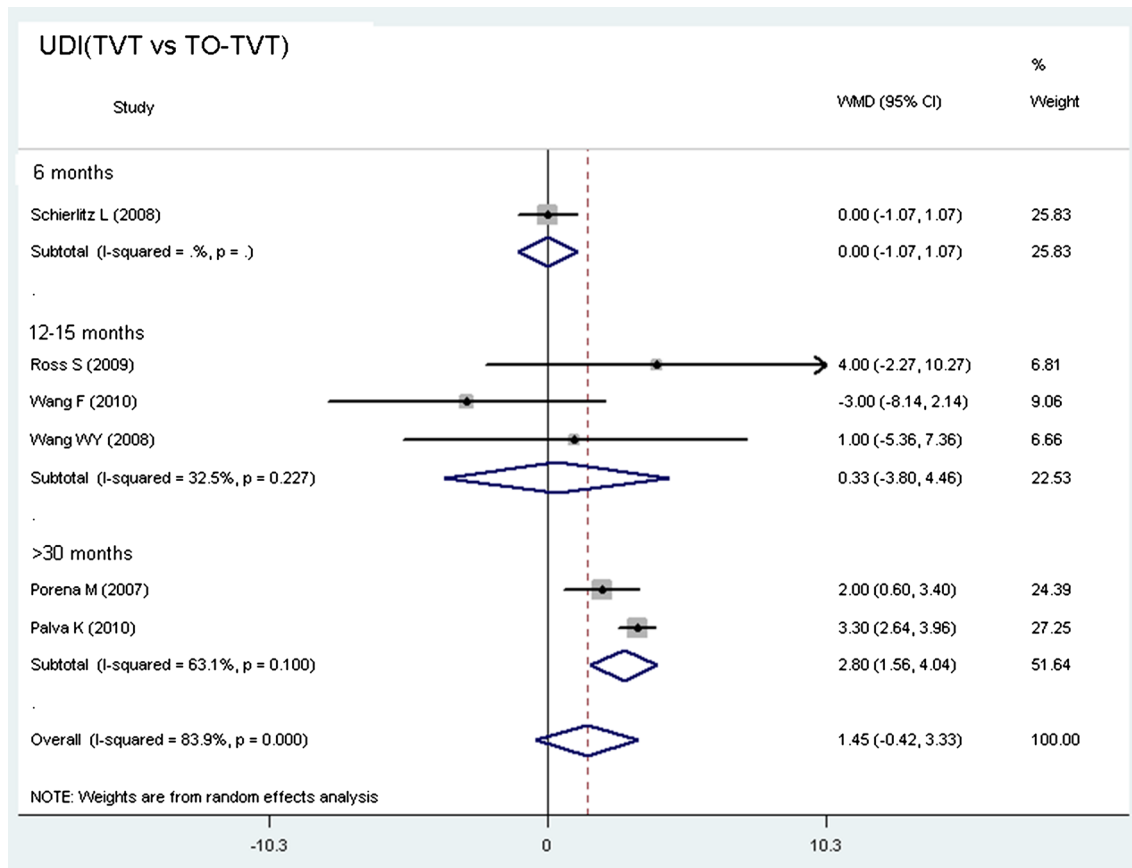
Midurethral slings have been shown to be effective in treating female SUI. However, associated adverse events include bladder and bowel injury, groin pain, and

haematoma formation. In an effort to maintain efficacy while eliminating some of the side effects, a new generation of slings has been developed, called “single-incision slings” or “mini-slings”. Our meta-analysis revealed that single-incision slings were associated with significantly higher improvement in sexual function and lower post-operative pain than standard MUS. A meta-analysis performed by Mostafa [47] was inconsistent with our results, which did not detect significant differences in total PISQ-12 scores between SIMS and standard MUS. Two recently published RCTs were added into our analysis, so our results might be more reliable [9, 10]. Furthermore, after excluding RCTs evaluating TVT-Secur (one type of single-incision sling) [10], SIMS still had significant improvement in PISQ-12 sexual function scores. The result that single-incision slings are associated with significantly lower post-operative pain was identified by another meta-analysis [48]. Meanwhile, distress caused by incontinence symptoms (evaluated by the UDI), the impact of SUI on physical, social, and emotional activities (evaluated by the IIQ), the frequency and severity of symptoms (evaluated by the ICIQ-SF), and the subjective success rate (evaluated by the PGI-I) were all



**Fig. 4** Meta-analysis results across all binary outcomes (RR). *TVT* tension-free vaginal tape, *TVT-Secur* single-incision TVT, *TO-TVT* transobturator TVT, *RP-TVT* retropubic TVT, *TVT-O* inside-out TO-TVT, *TOT* outside-in TO-TVT, *UDI* Urogenital Distress Inventory,

*I-QoL* the Incontinence Quality of Life questionnaire, *PGI-I* Global Impression of Improvement questionnaires, *VAS* visual analogue scale, *KHQ* King’s Health Questionnaire



**Fig. 5** Subgroup analysis of the decrease in UDI score compared TVT with TO-TVT according to follow-up duration (months)

not significantly different between the two groups. Only one study [19] reported that midurethral slings were associated with higher improvement on the KHQ total scores than single-incision slings, but this result should be interpreted with caution due to the insufficient research data.

TVT was the first synthetic MUS introduced, and prospective studies have shown long-term cure rates >77 % with TVT for SUI [49]. TO-TVT was introduced to minimize the complications of the retropubic slings, which include injury to the bladder, major vessels, and bowel. TO-TVT has shown similar safety and efficacy to TVT in a meta-analysis [50]. In our meta-analysis, TO-TVT had significantly greater reductions in total UDI scores and total IIQ scores than TVT, but no difference was detected on the post-operative VAS pain score. Considering the high level of heterogeneity among the trials, we performed a subgroup analysis by follow-up duration. Interestingly, the long-term efficacy of the TO-TVT procedure was superior to that of TVT in terms of reducing the distress caused by incontinence symptoms, but the short-term efficacy was not significantly different between the two groups. When compared with RP-TVT, the TO-TVT procedure was significantly associated with a higher reduction in the distress

caused by incontinence symptoms, but there were no significant differences in other incontinence-specific QoL measures (IIQ, VAS, UISS). Other comparisons were also performed in this meta-analysis, including biological TOT versus synthetic TOT, modified TVT-O versus TVT-O, and U-type single-incision slings versus H-type single-incision slings, and we detected no differences in improvement of QoL between these groups. However, these results should be interpreted with caution due to the small number of trials.

This meta-analysis had a number of strengths. RCTs are the gold standard in the assessment of surgical interventions. Systematic reviews based on RCTs are the cornerstone of evidence-based medicine because they can reduce bias and random errors and provide the highest quality of evidence. Furthermore, we included only RCTs with more than 50 participants, which improves the efficiency of the work without an appreciable loss of power.

This review also had several limitations. First, some RCTs included in this meta-analysis reported results using the median and range, and we estimated standard deviations (variances) using the formula  $\text{range}/4$  for

**Table 3** Subgroup analysis results across all outcomes according to disease severity and disease type

Comparisons	Questionnaire	Studies	WMD/ RR	LCI	UCI	Z	P	Heterogeneity		
								Q	p	I <sup>2</sup> (%)
Single-incision slings versus TO-TVT										
With UH	IIQ	3	0.68	-0.58	1.95	1.06	0.290	0.66	0.717	0.00
With UH	PISQ-12	2	2.10	0.52	3.68	2.61	0.009	0.02	0.901	0.00
With UH	UDI	1	3.80	-2.34	9.94	1.21	0.225	-	-	-
With UH	PGI-I (success defined as very much/ much improved)	1	0.81	0.64	1.02	1.81	0.071	-	-	-
With UH	I-QoL (had a 20-point increase)	1	0.86	0.71	1.05	1.49	0.135	-	-	-
Mix of UH and ISD	UDI	1	15.56	10.41	20.70	5.93	0.000	-	-	-
Mix of UH and ISD	VAS	1	-0.40	-1.10	0.30	1.12	0.262	-	-	-
With MI	ICIQ-FLUTS	1	-1.00	-3.29	1.29	0.86	0.391	-	-	-
With MI	ICIQ-SF	2	-1.17	-2.39	0.06	1.87	0.062	0.01	0.936	0.00
With MI	KHQ	1	-3.09	-5.58	-0.60	2.43	0.015	-	-	-
With MI	PISQ-12	1	1.00	0.44	1.56	3.49	<0.001	-	-	-
With MI	UDI	1	3.00	-3.03	9.03	0.98	0.329	-	-	-
With MI	VAS	2	-1.59	-2.28	-0.89	4.46	<0.001	2.85	0.091	0.65
With MI	PGI-I (success defined as very much/ much improved)	3	0.96	0.90	1.04	1.02	0.309	0.27	0.875	0.00
With MI	KHQ (had an 18-point improvement)	1	0.86	0.72	1.04	1.54	0.123	-	-	-
Without MI	IIQ	3	0.68	-0.58	1.95	1.06	0.290	0.66	0.717	0.00
Without MI	PISQ-12	4	1.23	0.28	2.18	2.55	0.011	1.97	0.579	0.00
Without MI	UDI	2	9.80	-1.72	21.32	1.67	0.095	8.28	0.004	0.88
Without MI	VAS	3	-0.66	-1.01	-0.32	3.75	0.000	0.78	0.679	0.00
Without MI	PGI-I (success defined as very much/ much improved)	2	0.90	0.80	1.02	1.62	0.105	3.25	0.071	0.59
Without MI	I-QoL (had a 20-point increase)	1	0.86	0.71	1.05	1.49	0.135	-	-	-
RP-TVT versus TO-TVT										
Mix of UH and ISD	UDI	3	-2.34	-14.67	9.99	0.37	0.710	0.25	0.882	0.00
Mix of UH and ISD	IIQ	3	-9.18	-21.19	2.84	1.50	0.134	0.46	0.796	0.00
With UH	UDI	1	-1.00	-1.65	-0.35	3.01	0.003	-	-	-
With UH	IIQ	1	0.00	-0.85	0.85	0.00	1.000	-	-	-
With UH	VAS	1	0.40	-0.09	0.89	1.60	0.109	-	-	-
With UH	UISS	1	0.00	-0.70	0.70	0.00	1.000	-	-	-
With MI	VAS	1	-1.00	-2.00	0.00	1.95	0.051	-	-	-
With MI	UDI	3	-2.34	-14.67	9.99	0.37	0.710	0.25	0.882	0.00
With MI	IIQ	3	-9.18	-21.19	2.84	1.50	0.134	0.46	0.796	0.00
Without MI	VAS	1	0.40	-0.09	0.89	1.60	0.109	-	-	-
Without MI	UDI	1	-1.00	-1.65	-0.35	3.01	0.003	-	-	-
Without MI	UISS	1	0.00	-0.70	0.70	0.00	1.000	-	-	-
Without MI	IIQ	1	0.00	-0.85	0.85	0.00	1.000	-	-	-
TVT versus TO-TVT										
Mix of UH and ISD	UDI	1	-3.00	-8.14	2.14	1.14	0.252	-	-	-
Mix of UH and ISD	IIQ	1	-5.00	-12.90	2.90	1.24	0.215	-	-	-
With ISD	IIQ	2	-6.76	-23.91	10.39	0.77	0.440	152.02	0	99.30
With ISD	UDI	2	0.07	-0.80	0.94	0.16	0.876	0.06	0.83	0.00
With UH	ICIQ-SF	1	0.70	-0.41	1.81	1.24	0.215	-	-	-
With UH	UDI	2	1.95	0.59	3.32	2.80	0.005	0.09	0.763	0.00
With UH	VAS	2	-0.31	-1.67	1.05	0.44	0.658	4.48	0.034	77.70
With UH	IIQ	2	-0.05	-1.11	1.01	0.09	0.925	0.86	0.353	0.00



**Table 3** continued

Comparisons	Questionnaire	Studies	WMD/ RR	LCI	UCI	Z	P	Heterogeneity		
								Q	p	I <sup>2</sup> (%)
With MI	UDI	3	0.69	-0.54	1.93	1.10	0.270	5.33	0.07	62.50
With MI	IIQ	3	-4.50	-14.58	5.58	0.87	0.382	230.05	0	99.10
Without MI	ICIQ-SF	1	0.70	-0.41	1.81	1.24	0.215	-	-	-
Without MI	IIQ	4	0.04	-2.89	2.96	0.02	0.981	3.99	0.263	24.80
Without MI	UDI	4	1.77	-1.26	4.80	1.14	0.253	6.20	0.102	51.60
Without MI	UISS	1	0.30	-0.35	0.95	0.90	0.367	-	-	-
Without MI	VAS	3	-0.02	-0.56	0.52	0.07	0.941	4.55	0.103	56.00
TVT-O versus TOT										
With MI	KHQ	2	-40.26	-116.54	36.02	1.03	0.301	131.52	0	0.99
With MI	PISQ-12	2	0.31	-2.17	2.79	0.24	0.809	1.47	0.226	0.32
With MI	VAS	1	0.70	-0.39	1.79	1.26	0.206	-	-	-
With MI	PGI-I (success defined as very much/ much improved)	2	1.02	0.89	1.17	0.26	0.797	0.00	0.946	0.00
With MI	VAS (success defined as score > 8)	1	1.11	0.93	1.32	1.16	0.246	-	-	-
Biological versus synthetic TOT										
With UH/without MI	PISQ-12	1	-0.20	-1.46	1.06	0.31	0.756	-	-	-
With UH/with MI	KHQ	1	-1.43	-22.54	19.69	0.13	0.895	-	-	-
With UH/with MI	UDI	1	0.80	-1.54	3.14	0.67	0.502	-	-	-
With UH/with MI	IIQ	1	0.60	-1.09	2.29	0.70	0.485	-	-	-
U-type versus H-type TVT-Secur										
With UH/without MI	VAS	1	-0.17	-1.00	0.66	0.40	0.400	-	-	-

TVT tension-free vaginal tape, SIMS TO-TVT transobturator TVT, RP-TVT retropubic TVT, TVT-O inside-out TO-TVT, TOT outside-in TO-TVT, UDI Urogenital Distress Inventory, IIQ the Incontinence Impact Questionnaire, VAS visual analogue scale, KHQ King's Health Questionnaire, PISQ-12 Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire, ICIQ-SF Incontinence Questionnaire Short Form, UH urethral hypermobility, PGI-I Patient Global Impression of Improvement questionnaire, I-QoL the Incontinence Quality of Life questionnaire, UISS the Urinary Incontinence Severity Score, ICIQ-FLUTS the International Consultation of Incontinence Questionnaire-Frequency of Lower Urinary Tract Symptoms, ISD intrinsic sphincter deficiency, MI mixed incontinence, WMD weighted mean differences, RR risk ratios, LCI lower confidence interval, UCI upper confidence interval

moderately sized samples ( $15 < n \leq 70$ ) and the formula range/6 for larger samples ( $n > 70$ ), which may affect the pooled results. Second, lack of blinding in the RCTs can be a source of bias. The assessors' blinding methods were poorly documented, and only four RCTs reported detailed blinding procedures. Blinding of participants was also poor (8 of 31 RCTs).

## Conclusions

Our meta-analysis indicated that consistent use of the short forms of the IIQ (IIQ-7) and UDI (UDI-6) with or without the PISQ-12 might promote options for comparisons between trials. We can conclude that the single-incision slings procedure is superior to TO-TVT in terms of improving sexual function and lowering post-operative pain scores. The RP-TVT procedure is superior to TO-TVT in terms of reducing distress caused by incontinence symptoms. The long-term efficacy of the TO-TVT procedure

was superior to that of TVT in terms of reducing the distress caused by incontinence symptoms, but the short-term efficacy was not significantly different between the two groups.

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**Conflict of interest** The authors declare that they have no possible conflicts of interest in the manuscript, including financial, consultant, institutional, and other relationships that might lead to bias or a conflict of interest.

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