

## Articles

# Effectiveness and complication rates of tension-free vaginal tape, transobturator tape, and tension-free vaginal tape-obturator in the treatment of female stress urinary incontinence in a medium- to long-term follow up

## Meta-analysis of randomized controlled trials

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### ABSTRACT

**الأهداف:** تقييم فعالية وأعراض الشريط المهبلي الخالي من التوتر والشريط السداسي والشريط السداسي المهبلي الخالي من التوتر في المتابعة المتوسطة والطويلة المدى.

**الطريقة:** أجري بحث باستخدام قاعدة البيانات وقاعدة بيانات كوكرين ومحرك قوقل وموقع جمعية الحصر العالمي خلال الفترة من أغسطس حتى ديسمبر 2012م في مستشفى قوانغتشو الأول للشعب، قوانغتشو، الصين. تم اختيار تجارب عشوائية لمقارنة فعالية وأعراض الشريط المهبلي الخالي من التوتر والشريط السداسي والشريط السداسي المهبلي الخالي من التوتر.

**النتائج:** اشتملت الدراسة على 40 دراسة. كانت معدلات شفاء أعراض الشريط المهبلي الخالي من التوتر والشريط السداسي الذاتية (نسبة الخطر 95%؛ 0.99) فترة الفحة 1.04-0.93، ومعدل العلاج (RR: 0.96؛ 95% CI 0.70-1.32). ولكن قلل الشريط المهبلي الخالي من التوتر خطورة الأربية وألم الفخذ (RR: 0.33؛ 95% CI: 0.18-0.59). كان معدل الشفاء الموضوعي (RR: 1.02؛ 95% CI: 0.97-1.06)، ومعدل العلاج الموضوعي للشريط السداسي المهبلي الخالي من التوتر (RR: 1.02؛ 95% CI: 0.99-1.06) كان مشابه للشريط السداسي المهبلي الخالي من التوتر ولكن كان هنالك خطورة عالية للثقوب المثانة (RR: 2.29؛ 95% CI: 1.18-4.45). الشريط السداسي والشريط السداسي المهبلي الخالي من التوتر (RR: 0.99؛ 95% CI: 0.93-1.06) ومعدل العلاج الموضوعي (RR: 1.01؛ 95% CI: 0.95-1.07) لكن انخفضت خطورة معدل التآكل المهبلي (RR: 0.16؛ 95% CI: 0.03-0.89).

**خاتمة:** كانت معدلات الشفاء الذاتية والموضوعية لسلس البول المجهد متشابه بين الشريط المهبلي الخالي من التوتر والشريط السداسي والشريط السداسي المهبلي الخالي من التوتر في المتابعة المتوسطة وطويلة المدى. كان الشريط المهبلي الخالي من التوتر أعلى نسبة في الإصابة بثقوب المثانة بالمقارنة مع TVT-O وأقل نسبة خطورة للأربية وألم الفخذ بشكل أكثر من TOT وكان TVT-O أقل خطورة من معدلات تآكل المهبل من TOT.

**Objectives:** To evaluate the effectiveness and complications of tension-free vaginal tape (TVT), transobturator tape (TOT), and tension-free vaginal tape-obturator (TVT-O) in a medium- to long-term follow up.

**Methods:** We searched PubMed, EMBASE, Cochrane database, ClinicalTrials.gov, Google Scholar, and the International Continence Society (ICS) website from August to December 2012 in Guangzhou First People's Hospital, Guangzhou, China. Randomized controlled trials (RCTs) comparing the effectiveness and complications of TVT, TOT, and TVT-O were selected.

**Results:** Forty RCTs were included. The TVT and TOT had similar subjective (risk ratio [RR]: 0.99; 95% confidence interval [CI]: 0.93-1.04), and objective cure rates (RR: 0.96; 95% CI: 0.70-1.32). However, TVT had a reduced risk of groin/thigh pain (RR: 0.33; 95% CI: 0.18-0.59). The subjective (RR: 1.02; 95% CI: 0.97-1.06) and objective cure rates (RR: 1.02; 95% CI: 0.99-1.06) of TVT-O were similar to TVT, but TVT had a higher risk of bladder perforations (RR: 2.29; 95% CI: 1.18-4.45). The TVT-O and TOT had similar subjective (RR: 0.99; 95% CI: 0.93-1.06), and objective cure rates (RR: 1.01; 95% CI: 0.95-1.07). However, TVT-O had a lower risk of vaginal erosion rates (RR: 0.16; 95% CI: 0.03-0.89).

**Conclusion:** The subjective and objective cure rates of stress urinary incontinence were similar among TVT, TOT, and TVT-O in a medium- to long-term follow up. The TVT had a higher risk of bladder perforation than TVT-O, and a lower risk of groin/thigh pain than TOT, and TVT-O had a lower risk of vaginal erosion rates than TOT.

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Stress urinary incontinence (SUI) is defined by the International Continence Society (ICS), as the involuntary leakage on effort or exertion, or on sneezing or coughing, and has an adverse impact on patient's physical, psychological, and social well-being.<sup>1</sup> The observed prevalence of SUI ranged from 4-14% in younger women, and 12-35% in older women.<sup>2</sup> Presently, treatment strategies for SUI include conservative treatment and surgical treatment, in which surgery is the most effective treatment for patients with serious SUI. Minimally invasive sling procedures have revolutionized the surgical management of female SUI. Since the tension-free vaginal tape (TVT) was first reported by Ulmsten et al<sup>3</sup> in 1996, it has been widely used popularly over the last decade due to its good efficacy and easy performance. The TVT was increasingly considered to be the standard of surgical treatment for female SUI. However, the TVT procedure has various and possible serious complications, including injuries of the bladder, bowel, vascular and nerve, urine retention,<sup>4</sup> de novo urgency, and urge incontinence.<sup>5</sup> To avoid the retropubic route related complications, Delorme et al<sup>6</sup> reported a new surgery in 2001; the transobturator tape (TOT) procedure. It inserted the tape passing through the obturator foramen, and the tape was introduced from the skin of the groin into the obturator foramen, and came out in the vaginal incision after the initial anterior vaginal incision and dissection.<sup>7</sup> The advantages of TOT include high success rates, easy performance, and avoiding the blind passage into the retropubic space.<sup>8</sup>

Even though the TOT procedure is considered to be safe and reliable, it may cause injuries of the urethra and bladder.<sup>9</sup> Subsequently, deLeval et al<sup>10</sup> developed a novel surgical procedure in 2003; the tension-free vaginal tape-obturator (TVT-O). The tape was passed from inside to outside through the obturator foramen with a newly designed specific surgical instrument. As an index finger is not placed in the vaginal incision to guide the needle coming from the outside, the TVT-O is easier than TOT.<sup>11</sup> Moreover, the European Association of Urology (EAU) Guideline states that cystoscopy is no longer required, only if difficulty is encountered during TVT-O procedure. However, the American Urological Association (AUA) Guideline states that cystoscopy should always be performed.

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The third-generation midurethral slings as single-incision mini-slings can be performed more easily, but these have a relatively lower patient-reported cure rates, objective cure rates, and higher reoperation rates at short-term follow-up. When compared with the third-generation midurethral slings,<sup>12</sup> standard midurethral slings hinder the development of these surgeries. Therefore, TVT, TOT, and TVT-O are the major surgery for female SUI. Although Latthe et al,<sup>13,14</sup> Long et al,<sup>11</sup> and Ya-Fei et al<sup>15</sup> had performed meta-analyses to compare the effectiveness and complications of transobturator with retropubic tape, it seemed that the conclusions about the effectiveness and complications were not complete because of cohort studies, short follow-up (less than 12 months), a lack of comparison between objective cure rates and subjective cure rates, or no direct comparison between TVT-O and TOT. So potential bias could not be minimized.

Currently, some meta-analyses indicated that the short-term efficacy of transobturator or retropubic routes was similar, and the risk of bladder injuries was lower in transobturator tapes. However, these studies did not compare the effectiveness and complications of transobturator with retropubic tapes at a medium- to long-term follow up. Our aim is to conduct the latest meta-analysis among TVT, TOT, TVT-O based on RCTs, so as to assess the effectiveness and complications of these 3 procedures in a medium- to long-term follow-up.

**Methods. Strategy and procedures for literature search.** A comprehensive literature search was performed using PubMed, EMBASE, Cochrane database, ClinicalTrials.gov, Google Scholar, and ICS website. The search was performed using the Medical Subject Heading (MeSH) terms "urinary incontinence, stress", "surgical mesh" and "suburethral slings" in combination with the following "free text" search terms: intravaginal slingplasty, transobturator sling, TVT-Obturator, transobturator tape, tension-free vaginal, tension-free vaginal tape, TVT, TOT, TVT-O, Monarc, retropubic sling, retropubic tape, and midurethral sling. Additionally, hand searches of the references and citation lists of all relevant reviews were performed, the conference proceedings and abstracts from the ICS, and the International Urogynecological Association (IUGA) annual meetings were also searched. We attempted to contact the corresponding authors to obtain complete data from these clinical trials. Subsequently, the searches were pooled and the following limits were used: humans, gender (female), and at least 12 months follow-up. We restricted the search to studies published in English. A literature search was performed independently by 2 authors.

**Inclusion criteria.** All prospective RCTs of female SUI comparing midurethral tape by transobturator (TOT or TVT-O) with TVT (retropubic tape), or between TOT and TVT-O were included. The mixed incontinence with predominant SUI was eligible for inclusion. The primary or secondary endpoints were objective cure rate, subjective cure rate, or the incidence of complications with at least 12 months follow-up.

**Exclusion criteria.** Studies were excluded when: there is no RCTs; RCTs focusing on special populations, such as the elderly or obese patients; patients who underwent modified TVT-O or TVT procedures; and neurologic bladder, or psychiatric disease.

**Assessment of study eligibility.** All assessments of the quality of trials and data extraction were performed independently by 2 authors using a prespecified data abstraction form. Data extracted included study characteristics, treatment (type of device), duration of follow-up, subjective and/or objective outcomes (definitions of cure), preoperative complications, and postoperative complications. The third author's opinion was used in case of any controversy.

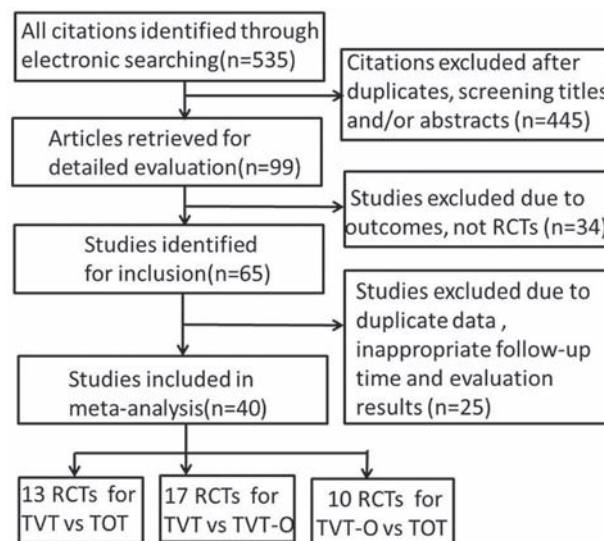
**Data collection and quality assessment.** The studies were differentiated using the level of the Centre for Evidence-based Medicine (CEBM): systematic review with homogeneity of RCTs (level 1a), individual RCT with narrow confidence interval (level 1b), systematic review with homogeneity of cohort studies (level 2a), and individual cohort study (including low quality RCT; for example, <80% follow-up)(level 2b).<sup>16</sup> The methodological quality of the selected RCTs was assessed according to the Jadad score.<sup>17</sup> A numerical score between 0 and 5 was assigned as a rough measure of trial design and reporting quality, with 0 being the weakest, and 5 being the strongest.<sup>17</sup> Two points was assigned if the method to generate the sequence of randomization was described and it was appropriate (computer generated, table of random numbers), and one point was given if the method to generate the sequence of randomization was not described; 2 point was given the method of double blinding was described and it was appropriate (identical placebo), and one point was given if the word "double blind" was mentioned and the method of blinding was inappropriate;<sup>17</sup> one points were given if the number and the reasons for withdrawal in each group be stated. The high-quality study has an overall score of  $\geq 3$ .<sup>17</sup>

**Statistical analysis.** Meta-analysis was performed using Review Manager 5.1.4 (The Cochrane Collaboration, Oxford, United Kingdom). Dichotomous data were presented as a risk ratio (RR)

with 95% confidence interval (CI). Meta-analysis was performed using the fixed effect model or the random effect model. The fixed effect model was used for calculations in the absence of evidence of heterogeneity, and the random effect model was used if heterogeneity was obvious. Statistical heterogeneity was assessed by the Chi-square test and  $I^2$  test with significance set at  $p < 0.10$  and  $I^2 < 50\%$ . Publication bias was evaluated through visual inspection of funnel plots for asymmetry. Sensitivity analyses were limited to studies of higher quality so as to reconfirm a similar result. A probability of  $p < 0.05$  was considered to be statistically significant.

**Results. Literature search results.** The literature search outcomes were summarized in Figure 1. Forty RCTs that met the criteria for inclusion were used to perform the meta-analysis. The characters and quality of the 40 RCTs were shown in supplemental table. Specifically, 13 RCTs compared TVT with TOT (Table 1);<sup>4,18-29</sup> 17 RCTs compared TVT with TVT-O (Table 2);<sup>21,30-43</sup> 10 RCTs compared = (Table 3);<sup>21,44-50</sup> among these studies, 4 RCTs were published as congress abstracts,<sup>18,23,48,50</sup> 17 studies were high quality RCTs.<sup>4,19,21,26-29,31,33,35-37,42,43,46,47,49</sup>

**Randomized controlled trials comparing TVT with TOT.** Thirteen RCTs comparing TVT with TOT were included,<sup>4,18-29</sup> and 10 studies reported subjective cure rate.<sup>4,18-23,25,26,28</sup> The subjective cure rates for TVT was



**Figure 1** - Study selection process for meta-analysis. RCTs - randomized controlled trials, TVT - tension-free vaginal tape, TOT - transobturator tape, TVT-O - tension-free vaginal tape-obturator

**Table 1** - Details of randomized controlled trials comparing tension-free vaginal tape (TVT) and transobturator tape (TOT) in the treatment of stress urinary incontinence (SUI).

Study reference	Cases	Follow-up (months)	Subjective measure	Subjective cure rate n (%)	Objective measure	Objective cure rate n (%)	Level of evidence	Jaded score	Operative complications
de Tayrac et al, <sup>4</sup> France, 2004	31 TVT 30 TOT	12	Self-evaluated Very satisfied	20 (64.5%) 18 (60.0%)	Negative cough stress test	26 (83.9%) 27 (90.0%)	1b	3	Bladder injury: 3 vs. 0; De novo urge: 2 vs. 2; voiding difficulties: 7 vs. 5; urinary retention: 2 vs. 0; hematoma: 0 vs. 1
Riva et al, <sup>18</sup> Italy, 2006	66 TVT 65 TOT	12	NR	62 (94.0%) 59 (91.0%)	NR	60 (91.4%) 59 (91.3%)	2b	0	Bladder injury: 1 vs. 0; De novo urge: 2 vs. 2; voiding difficulties: 1 vs. 0; urinary retention: 1 vs. 2; vaginal erosion: 1 vs. 2; thigh pain: 0 vs. 2; reoperation: 0 vs. 2
Ross et al, <sup>19</sup> Canada, 2009	96 TVT 86 TOT	12	Questionnaire	88 (92.6%) 85 (98.8%)	1-hour pad test	67 (77.0%) 68 (81.0%)	1b	3	Groin pain: 5 (90) vs. 13 (85); vaginal mesh extrusions/erosions: 1 (90) vs. 1 (85)
Wang et al, <sup>20</sup> China, 2010	40 TVT 48 TOT	12	UDI-6 and IIQ-7 Post-operative <10	36 (90.0%) 44 (91.4%)	Cough stress test and 1-hour pad test <2 g	38 (95.0%) 45 (93.7%)	2b	2	Bladder injury: 3 vs. 1; vaginal erosion: 1 vs. 2; voiding dysfunction: 8 vs. 6; thigh pain: 3 vs. 8
Scheiner et al, <sup>21</sup> Switzerland, 2012	65 TVT 34 TOT	12	Patient's global impression	57 (87.7%) 28 (82.4%)	Negative cough and negative short-pad test	58 (93.6%) 31 (91.2%)	1b	3	Bladder perforation: 3 vs. 0; vaginal erosions: 1 vs. 4; voiding difficulty: 2 vs. 0; thigh pain: 1 vs. 3
Freeman et al, <sup>22</sup> UK, 2011	85 TVT 95 TOT	12	No reported SUI	55 (65.5%) 59 (63.4%)	No leakage cough test	75 (88.0%) 84 (90.0%)	1b	2	Bladder perforation: 2 vs. 0; groin pain: 1 vs. 8; voiding difficulty: 5 vs. 5; UTI: 7 vs. 2; De novo OAB symptoms: 4 vs. 4; tape extrusion: 2 vs. 3
Porena et al, <sup>23</sup> Italy, 2005*	47 TVT 42 TOT	13.4	NR	33 (70.2%) 33 (78.6%)	NR	41 (93.6%) 40 (97.6%)	1b	2	Bladder perforations: 1 vs. 0; hematoma: 2 vs. 0; vaginal erosion: 0 vs. 2; voiding dysfunction: 3 vs. 1; De novo urgency: 5 vs. 1
Enzelsberger et al, <sup>24</sup> Germany, 2005	52 TVT 53 TOT	15	NR	NR	Negative stress test	45 (86.0%) 45 (84.0%)	2b	0	Bladder injury: 7 vs. 0; De novo urgency: 5 vs. 6; hematoma: 7 vs. 0; vaginal erosion: 1 vs. 1; voiding difficulties: 4 vs. 3
Mansoor et al, <sup>25</sup> France, 2003	54 TVT 48 TOT	17	Self-questionnaire	50 (93.0%) 46 (96.0%)	NR	NR	1b	2	Bladder perforations: 5 vs. 0; urinary retention: 5 vs. 1
Barber et al, <sup>26</sup> USA, 2006	88 TVT 82 TOT	18.2 ± 6	NR	50 (58.8%) 48 (62.3%)	NR	73 (92.4%) 62 (87.3%)	1b	3	Vaginal erosion: 5 vs. 1; thigh pain: 2 vs. 3; urinary retention: 5/85 vs. 2/77; reoperation: 1/85 vs. 0/77
El-Hefnawy et al, <sup>27</sup> Egypt, 2010	19 TVT 21 TOT	19.7 ± 7	NR	NR	Negative stress test	18 (94.7%) 17 (81.0%)	1b	3	Bladder injury: 0 vs. 1; UTI: 1 vs. 1; vaginal erosion: 0 vs. 1; thigh pain: 1 vs. 3; suprapubic hematoma: 2 vs. 0
Porena et al, <sup>28</sup> Italy, 2007*	70 TVT 75 TOT	35	No leakage reported	50 (71.4%) 58 (77.3%)	No leakage stress test	63 (90.0%) 67 (89.3%)	1b	3	Bladder injury: 2 vs. 1; vaginal erosion: 0 vs. 3; suprapubic hematoma: 1 vs. 0; voiding dysfunction: 3 vs. 2
Ballester et al, <sup>29</sup> France, 2012	34 TVT 37 TOT	≥48	NR	NR	No leakage stress test	27 (79.4%) 32 (86.5%)	1b	3	De novo urgency: 7 vs. 10

\*same study, different follow-up times, vs - versus, NR - not reported, UTI - urinary tract infection, UDI - urinary distress inventory, IIQ - Incontinence Impact Questionnaire, OAB - overactive bladder



**Table 2** - Details of randomized controlled trials comparing tension-free vaginal tape (TVT) and tension-free vaginal tape-obturator (TVT-O) in the treatment of stress urinary incontinence (SUI).

Study reference	Cases	Follow-up (months)	Subjective measure	Subjective cure rate	Objective measure	Objective cure rate	Level of evidence	Jaded score	Operative complications
Liapis et al, <sup>30</sup> Greece, 2006	46 TVT 43 TVT-O	12	Non-validated questionnaire	34 (73.9%) 33 (76.7%)	Negative cough test and negative 1-hour pad test	41 (89.1%) 39 (90.7%)	2b	1	Bladder perforation: 3 vs. 0; urinary retention: 4 vs. 1; UTI: 3 vs. 1; vaginal erosion: 1 vs. 0
Zullo et al, <sup>31</sup> Italy, 2007*	35 TVT 37 TVT-O	12	NR	NR	Negative cough test	32 (91.4%) 33 (89.2%)	1b	3	Bladder/vaginal injury: 3 vs. 0; hematoma: 1 vs. 0; urinary retention: 1 vs. 0; De novo urgency: 3 vs. 0; UTI: 2 vs. 1
Araco et al, <sup>32</sup> Italy, 2008	108 TVT 100 TVT-O	12	Quality of life questionnaire	NR	Negative cough stress test	108 (100.0%) 83 (83.0%)	1b	2	Bladder/vaginal perforation: 3 vs. 6; vaginal erosions: 1 vs. 3; hematomas: 6 vs. 0; reoperation: 19 vs. 17
Rinne et al, <sup>33</sup> Finland, 2008	134 TVT 131 TVT-O	12	Patient satisfied	120 (90.0%) 122 (93.0%)	Negative cough test	128 (95.5%) 122 (93.1%)	1b	3	De novo urgency: 2 vs. 3; bladder perforation: 2 vs. 0; voiding difficulty: 1 vs. 2; thigh pain: 0 vs. 1; UTI: 19 vs. 22; tape erosion: 0 vs. 1
Aniuliene, <sup>34</sup> Lithuania, 2009	114 TVT 150 TVT-O	12	No signs of SUI	97 (85.1%) 117 (78.0%)	NR	108 (94.6%) 142 (94.6%)	2b	2	Bladder perforation: 1 vs. 0; hematoma: 1 vs. 0; urinary retention: 18 vs. 5; UTI: 5 vs. 1
Karateke et al, <sup>35</sup> Turkey, 2009	81 TVT 83 TVT-O	12	Patient's satisfaction rate	76 (93.9%) 76 (91.5%)	Cough stress test	72 (88.9%) 72 (86.7%)	1b	3	Bladder injury: 3 vs. 0; tape erosion: 4 vs. 2; voiding difficulty: 8 vs. 6
Deffieux et al, <sup>36</sup> France, 2010**	69 TVT 69 TVT-O	12	No referred leakage at interview	63 (91.3%) 61 (88.4%)	Negative stress test	65 (94.2%) 67 (97.1%)	1b	3	Bladder injury: 4 vs. 2; vaginal erosion: 0 vs. 1; voiding dysfunction: 6 vs. 2; thigh pain: 2 vs. 2; repeat surgery: 2 vs. 1
Krofta et al, <sup>37</sup> Czech Republic, 2010	141 TVT 147 TVT-O	12	No leakage of urine after surgery	111 (78.7%) 112 (76.2%)	Negative cough stress test and 1-hour pad test	127 (90.1%) 130 (88.4%)	1b	3	De novo urgency: 4 vs. 20; bladder injury: 1 vs. 0; tape erosion: 2 vs. 2; urinary retention: 1 vs. 1; thigh pain: 6 vs. 8; UTI: 5 vs. 8; hematoma: 1 vs. 0
Teo et al, <sup>38</sup> UK, 2011	41 TVT 29 TVT-O	12	Improvement scale	35 (85.4%) 26 (89.7%)	24-hour pad test	33 (80.5%) 25 (86.2%)	2b	2	Vaginal erosion: 3 (57) vs. 1 (50); voiding difficulty: 3 (66) vs. 1 (61); thigh pain: 1 (59) vs. 14 (53)
Wang et al, <sup>39</sup> China, 2009***	115 TVT 118 TVT-O	12	NR	NR	Negative stress test	103 (89.6%) 106 (89.8%)	1b	2	Tape erosion: 3 vs. 3; urinary retention: 6 vs. 4; thigh pain: 4 vs. 12; hematoma: 2 vs. 2; De novo urgency: 9 vs. 6
Scheiner et al, <sup>21</sup> Switzerland, 2012	65 TVT 37 TVT-O	12	Patient's global impression	57 (87.7%) 29 (78.4%)	Negative cough and negative short-pad test	58 (93.6%) 33 (89.2%)	1b	3	Bladder perforation: 3 vs. 0; vaginal erosion: 1 vs. 0; voiding difficulty: 2 vs. 1; thigh pain: 1 vs. 1
Lee et al, <sup>40</sup> Korea, 2007	60 TVT 60 TVT-O	13	Patient very satisfied	56 (93.4%) 57 (95.0%)	Negative cough stress test	52 (86.8%) 52 (86.8%)	2b	1	De novo urgency: 0 vs. 4; bladder perforation: 2 vs. 0; groin pain: 1 vs. 8; voiding difficulty: 6 vs. 8; thigh pain: 5 vs. 8
Zhu et al, <sup>41</sup> China, 2007***	28 TVT 27 TVT-O	27.6	NR	NR	No leakage exerting strong abdominal	26 (92.6%) 25 (92.9%)	1b	2	NR
Deffieux et al, <sup>36</sup> France, 2010**	65 TVT 67 TVT-O	24	No referred leakage	55 (84.6%) 56 (83.6%)	Negative stress test	61 (93.8%) 65 (97.0%)	1b	3	NR
Wang et al, <sup>39</sup> China, 2009***	35 TVT 30 TVT-O	36	NR	NR	Negative stress test	29 (82.9%) 25 (83.3%)	2b	2	NR
Palva et al, <sup>42</sup> Finland, 2010	131 TVT 126 TVT-O	36	Questionnaire	NR	Negative cough test	124 (94.6%) 113 (89.7%)	1b	3	De novo urgency: 8 (130) vs. 7 (125)
Angioli et al, <sup>43</sup> Italy, 2010*	35 TVT 37 TVT-O	60	Overall satisfaction of patients	23 (65.7%) 21 (56.8%)	Negative stress test	25 (71.4%) 27 (72.9%)	1b	3	Tape erosion: 1 vs. 2; pelvic pain: 1 vs. 0; De novo urgency: 1 vs. 2

\*, \*\*, \*\*\* same study, different follow-up times, vs - versus, NR - not reported, UTI - urinary tract infection

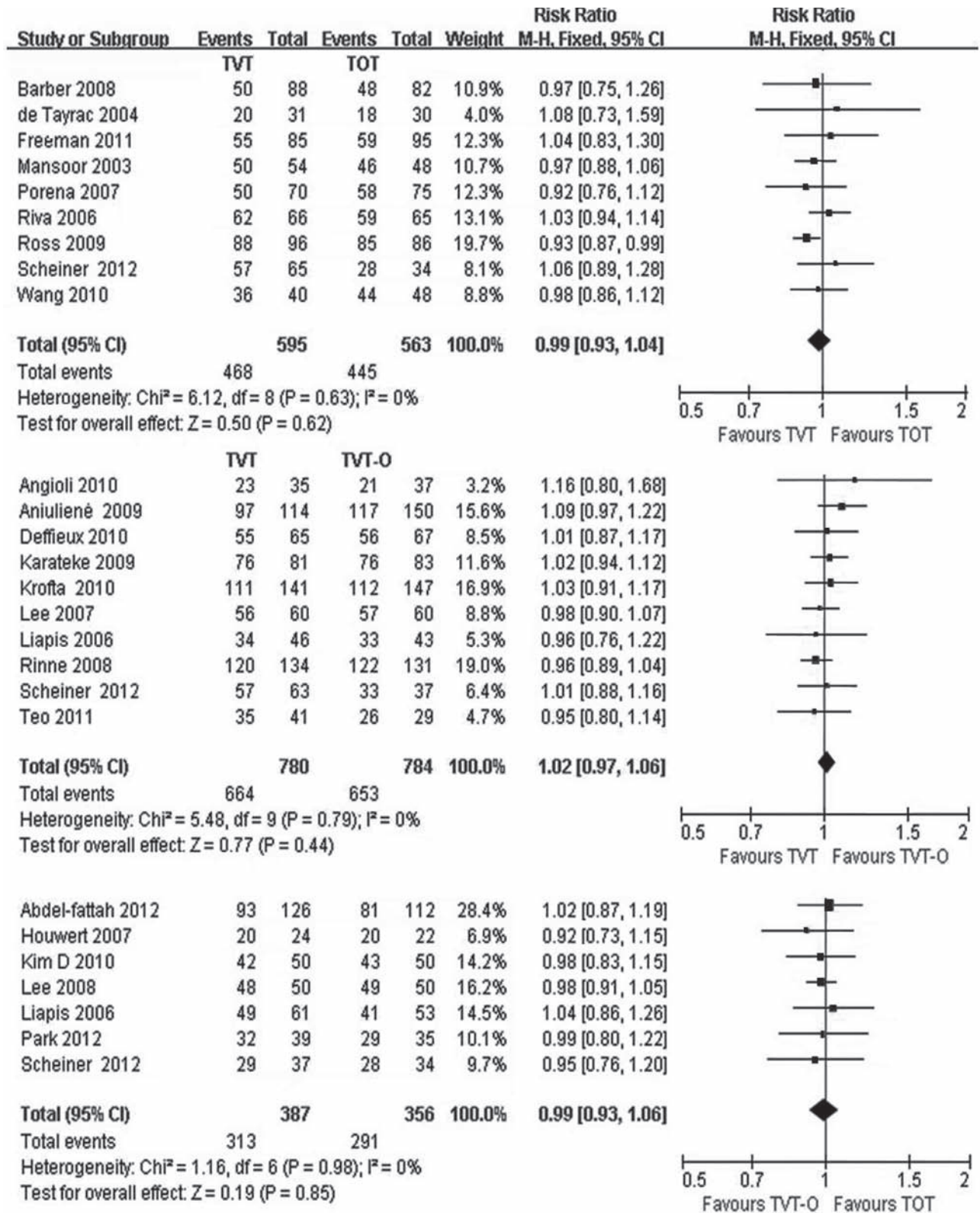
**Table 3** - Details of randomized controlled trials comparing tension-free vaginal tape-obturator (TVT-O) with transobturator tape (TOT) in the treatment of stress urinary incontinence.

Study reference	Cases	Follow-up (months)	Subjective measure	Subjective cure rate	Objective measure	Objective cure rate	Level of evidence	Jaded score	Operative complications
Lee et al, <sup>44</sup> South Korea, 2008	50 TVT-O 50 TOT	12	Subjective satisfaction	48 (96.0%) 49 (98.0%)	Negative cough stress test	43 (86.0%) 46 (92.0%)	2b	1	De novo urgency: 2 vs. 1; voiding difficulty: 8 vs. 12; thigh pain: 7 vs. 9
Scheiner et al, <sup>21</sup> Switzerland, 2012	37 TVT-O 34 TOT	12	Patient's global impression	29 (78.4%) 28 (83.4%)	Negative cough and negative short-pad test	31 (91.2%) 33 (89.2%)	1b	3	Vaginal erosion: 4 vs. 0; voiding difficulty: 0 vs. 1; thigh pain: 3 vs. 1
Liapis et al, <sup>45</sup> Greece, 2008	61 TVT-O 53 TOT	12	A simple questionnaire	49 (80.0%) 41 (77.0%)	Negative cough stress test; 1-hour pad test <1	53 (87.0%) 48 (90.0%)	2b	1	Bladder perforation: 0 vs. 0; hematoma: 0 vs. 0; retention: 3 vs. 2; thigh pain: 3 vs. 1; De novo urgency: 8 vs. 6; UTI: 3 vs. 2
Abdel-fattah et al, <sup>46</sup> UK, 2010*	152 TVT-O 147 TOT	12	Patient reported success rates	121 (81.2%) 111 (77.6%)	1-hour pad test	114 (94.2%) 96 (88.1%)	1b	3	Repeat surgery: 2 (152) vs. 9 (147)
Park & Kim, <sup>47</sup> Korea, 2012**	39 TVT-O 35 TOT	12	NR	NR	No urine leakage stress test	35 (89.7%) 32 (91.4%)	1b	3	NR
Houwert et al, <sup>48</sup> Netherlands, 2007	24 TVT-O 22 TOT	12	Losing urine upon physical exercise	20 (83.0%) 20 (91.0%)	NR	NR	2b	2	Vaginal erosion: 1 vs. 0; repeat surgery: 1 vs. 2
Abdel-fattah et al, <sup>49</sup> UK, 2012*	126 TVT-O 112 TOT	36	Patient reported success rate on the PGI-I	93 (73.8%) 81 (72.3%)	NR	NR	2b	3	UTI: 3 vs. 1; vaginal erosion: 0 vs. 2; voiding dysfunction: 1 vs. 1; repeat surgery: 7 vs. 15
Kim & Jang, <sup>50</sup> Korea, 2010	50 TVT-O 50 TOT	36	Does not experience any loss of urine upon physical activity	42 (84.0%) 43 (86.0%)	NR	NR	2b	2	NR
Park & Kim, <sup>47</sup> Korea, 2012**	39 TVT-O 35 TOT	36	Patient's satisfaction	32 (82.1%) 29 (82.8%)	No urine leakage on stress test	33 (84.6%) 30 (85.7%)	1b	3	Bladder perforation: 0 vs. 0; voiding difficulty: 1 vs. 1; thigh pain: 1 vs. 0; vaginal discharge: 0 vs. 1

\*,\*\*same study, different follow-up times, vs - versus, NR - not reported, UTI - urinary tract infection, PGI-I - Patient Global Impression of Improvement

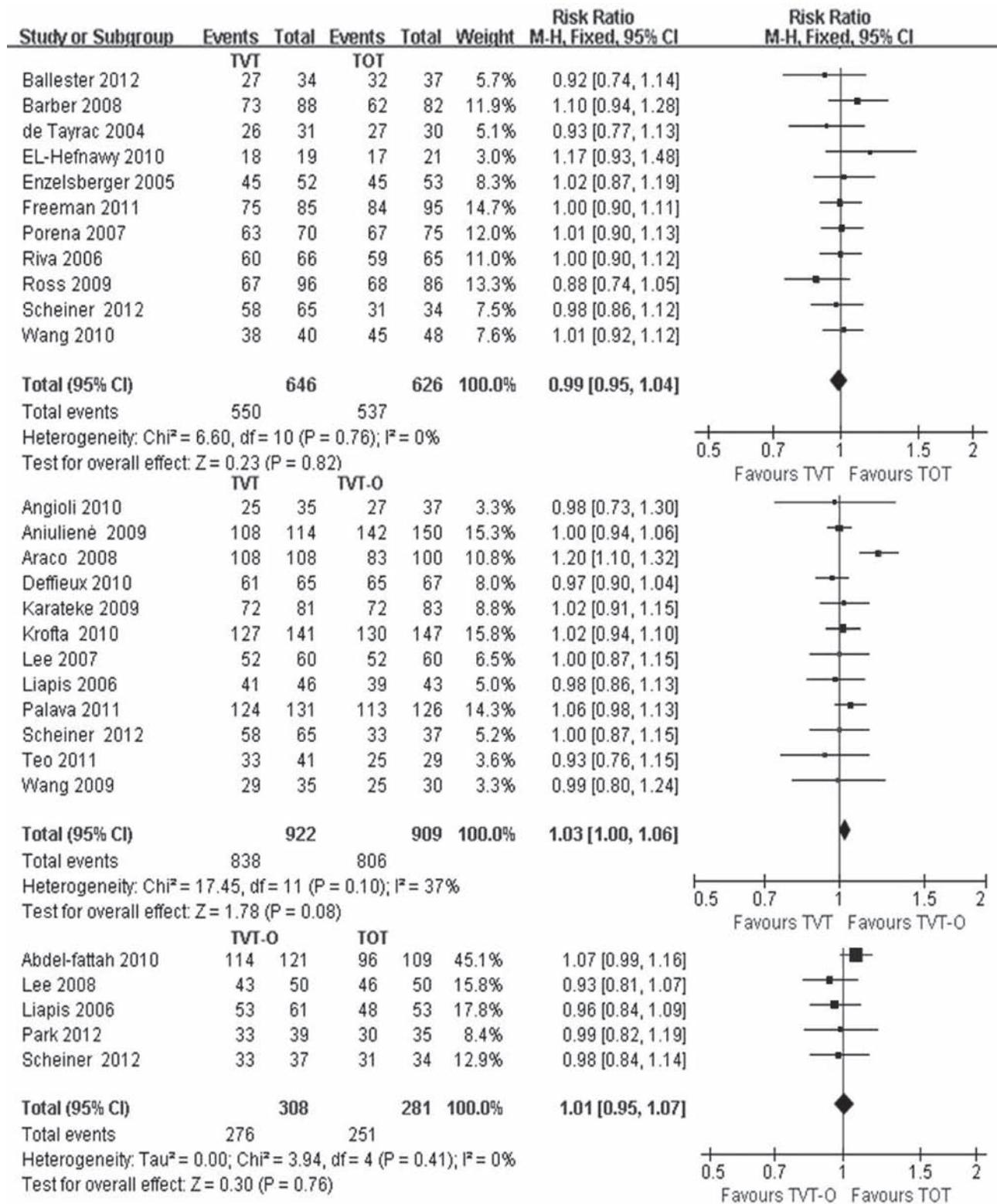
78.7% (468/595) and for TOT was 79% (445/563), and there was no statistically significant difference (RR: 0.99; 95% CI: 0.93-1.04,  $p=0.62$ , **Figure 2**). Low quality studies<sup>18,20,22,23,25</sup> were excluded. Sensitivity analyses of high quality studies<sup>4,19,21,26,28</sup> reconfirmed a similar result (RR: 0.97; 95% CI: 0.89-1.05;  $p=0.41$ ) (Forest plot not shown). Eleven studies<sup>4,18-22,24,26-29</sup> showed the objective cure rates of TVT and TOT. The objective cure rates were 85.1% (550/646) for TVT, and 85.8% (537/626) for TOT, and there was no statistically significant difference (RR: 0.99; 95% CI: 0.95-1.04;  $p=0.82$ , **Figure 3**). Further sensitivity analyses of high quality studies<sup>4,19,21,26-29</sup> showed a similar result (RR: 1.00; 95% CI: 0.94-1.06;  $p=0.99$ ) (Forest plot not shown). With regard to complication rates, the risk of bladder perforations (RR: 4.42; 95% CI: 1.89-10.34;  $p=0.0006$ ), voiding difficulties/urinary

retention (RR: 1.66; 95% CI: 1.05-2.64;  $p=0.03$ ) and hematoma (RR: 4.11; 95% CI: 1.18-14.24;  $p=0.03$ ) were significantly higher in TVT, whereas groin/thigh pain was significantly more common in TOT operations (RR: 0.33; 95% CI: 0.18-0.59;  $p=0.0002$ , **Figure 4**). In addition, there were no significant difference in vaginal erosion (RR: 0.63; 95% CI: 0.30-1.32;  $p=0.22$ ), de novo urgency (RR: 1.03; 95% CI: 0.61-1.74;  $p=0.90$ ), urinary tract infection (RR: 2.97; 95% CI: 0.81-10.92;  $p=0.10$ ), and reoperation rate (RR: 0.63; 95% CI: 0.10-3.83;  $p=0.62$ ). Other assessable complications were shown in overlapping figures. However, sensitivity analyses of high-quality RCTs<sup>4,19,21,26-29</sup> showed different results with regard to the risk of bladder perforations (RR: 2.38; 95% CI: 0.68-8.34;  $p=0.18$ ), voiding difficulties/urinary retention (RR: 1.89; 95% CI: 0.91-3.94;  $p=0.09$ ), and hematoma (RR: 1.88; 95% CI: 0.42-8.44;  $p=0.41$ ) (all Forest plots not shown).



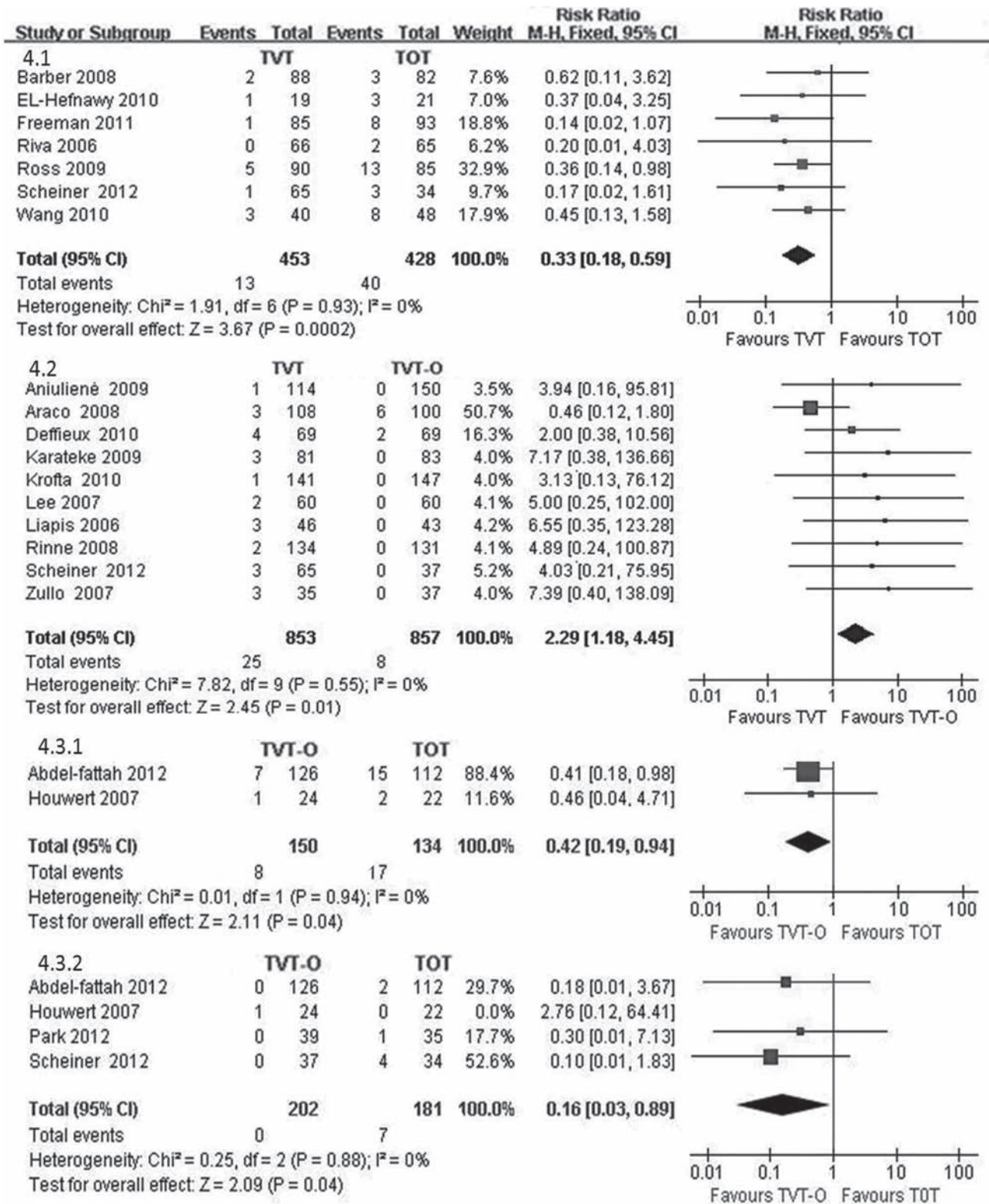
**Figure 2** - Forest plots of subjective cure rate of stress urinary incontinence with midurethral tapes by TVT versus TOT, TVT versus TVT-O, TVT-O versus TOT. TVT - tension-free vaginal tape, TOT - transobturator tape, TVT-O - tension-free vaginal tape-transobturator





**Figure 3** - Forest plots of objective cure rate of stress urinary incontinence with midurethral tapes by TVT versus TOT, TVT versus TVT-O, TVT-O versus TOT. TVT - tension-free vaginal tape, TOT - transobturator tape, TVT-O - tension-free vaginal tape-transobturator.





**Figure 4 -** Forest plots of several complication rates of stress urinary incontinence with midurethral tapes by TVT versus TOT, TVT versus TVT-O, TVT-O versus TOT. Outcome: 4.1 groin/thigh pain; 4.2 bladder perforations; 4.3.1 reoperation rate; 4.3.2 vaginal erosion. TVT - tension-free vaginal tape, TOT - transobturator tape, TVT-O - tension-free vaginal tape-transobturator. CI - confidence interval

**Randomized controlled trials comparing TVT to TVT-O.** A total of 17 RCTs addressed this comparison<sup>21,30-43</sup> including 6 duplicate studies. The subjective cure rates of TVT was 85.1% (664/780), and 83.3% (653/784) for TVT-O in 10 studies<sup>21,30,33-38,40,43</sup> (RR: 1.02; 95% CI: 0.97-1.06;  $p=0.44$ , Figure 2), and there was no statistically significant difference. Sensitivity analyses of higher quality studies<sup>21,33,35-37,43</sup> reconfirmed a similar result (RR: 1.02; 95% CI: 0.97-1.08;  $p=0.43$ ) (Forest plot not shown). Thirteen studies reported objective cure rates.<sup>21,30,32,34,35-43</sup> The objective cure rates of TVT was 90.9% (864/950), and 88.8% (831/936) for TVT-O, but the heterogeneity test showed a moderate difference among individual studies (heterogeneity Chi-squared=17.53;  $p=0.13$ ,  $I^2=32\%$ ). Therefore, a random-effect model for the pooled analysis was selected. Interestingly, the difference was not statistically significant (RR: 1.02; 95% CI: 0.99-1.06;  $p=0.22$ , Figure 3). Further sensitivity analyses of higher quality studies<sup>21,35-37,42,43</sup> showed a similar result (RR: 1.02; 95% CI: 0.98-1.06;  $p=0.42$ ) (Forest plot not shown).

With regard to complication rates, the prevalence of intraoperative bladder perforation (RR: 2.29; 95% CI: 1.18-4.45;  $p=0.01$ ; Figure 4), hematoma (RR: 2.91; 95% CI: 1.15-7.36;  $p=0.02$ ), and voiding difficulties/urinary retention (RR: 1.86; 95% CI: 1.23-2.82;  $p=0.004$ ) were significantly lower in the TVT-O group. However, groin/thigh pain was significantly more common in TVT-O group (RR: 0.44; 95% CI: 0.27-0.72;  $p=0.001$ ). In addition, the risk of vaginal erosion (RR: 0.91; 95% CI: 0.48-1.73;  $p=0.78$ ), de novo urgency (RR: 0.71; 95% CI: 0.44-1.13;  $p=0.15$ ), urinary tract infection (RR: 1.05; 95% CI: 0.67-1.64;  $p=0.84$ ), and reoperation rate (RR: 1.09; 95% CI: 0.61-1.93;  $p=0.78$ ) were similar between the 2 surgical treatments. Other assessable complications were shown in overlapping figures. However, sensitivity analyses of high quality RCTs:<sup>21,31,33,35-37,42,43</sup> showed different results in the prevalence of hematoma (RR: 2.41; 95% CI: 0.63-9.17;  $p=0.20$ ), voiding difficulties/urinary retention (RR: 1.51; 95% CI: 0.75-3.00;  $p=0.25$ ) and groin/thigh pain (RR: 0.83; 95% CI: 0.38-1.83;  $p=0.65$ ) (all Forest plots not shown).

**Randomized controlled trials comparing TVT-O to TOT.** Ten RCTs addressed this comparison<sup>21,44-50</sup> including 2 duplicate studies, and 7 RCTs compared the subjective cure rates of TVT-O with TOT,<sup>21,44-50</sup> and the subjective cure rates of TVT-O were 80.9% (313/387), and 81.7% (291/356) in TOT. There was no statistically significant difference (RR: 0.99; 95%

CI: 0.93-1.06;  $p=0.85$ ; Figure 2). Sensitivity analyses of higher quality studies<sup>21,47,49</sup> reconfirmed a similar result (RR: 1.00; 95% CI: 0.89-1.12;  $p=0.99$ ) (Forest plot not shown). Five studies reported objective cure rate.<sup>21,44-47</sup> The objective cure rates of TVT-O were 89.6% (276/308) and 89.3% (251/281) in TOT, and the difference was not statistically significant (RR: 1.01; 95% CI: 0.95-1.07;  $p=0.76$ ; Figure 3). Sensitivity analyses of higher quality studies<sup>21,46,47</sup> showed a similar result (RR: 1.04; 95% CI: 0.97-1.11;  $p=0.31$ ).

With regard to complication rates, the reoperation rate was significantly higher in TOT (RR: 0.42; 95% CI: 0.19-0.94;  $p=0.04$ ; Figure 4) compared with TVT-O. However, there were no significant difference in vaginal erosion (RR: 0.30; 95% CI: 0.08-1.10;  $p=0.07$ ), groin/thigh pain (RR: 0.74; 95% CI: 0.25-2.18;  $p=0.59$ ), voiding difficulties/urinary retention (RR: 0.84; 95% CI: 0.44-1.63;  $p=0.61$ ), and de novo urgency (RR: 1.27; 95% CI: 0.51-3.17;  $p=0.61$ ). Other assessable complications showed overlapping figures. But sensitivity analyses of high quality RCTs:<sup>21,46,47,49</sup> showed a different result in the risk of vaginal erosion (RR: 0.16; 95% CI: 0.03-0.89;  $p=0.04$ ; Figure 4) (all Forest plots not shown). There were also few higher quality studies to compare complication rates of TVT-O with TOT.

**Publication bias.** A funnel plot indicated a symmetrical distribution of these studies used in meta-analysis. Funnel plots of all the studies were generated for all the evaluated comparisons (all funnel plots not shown). Only one study<sup>32</sup> comparing objective cure of TVT with TVT-O lay outside the 95% CI in our meta-analysis. After removing this study, the heterogeneity test showed no difference (Chi-squared=3.65,  $p=0.98$ ,  $I^2=0\%$ ), hence, it suggested a low likelihood of publication bias.

**Discussion.** The TVT, TOT, and TVT-O have gained widespread popularity in the treatment of female SUI, based mainly on high success rates and safety at short-term follow-up. Some recent meta-analyses comparing TVT with TOT, or TVT-O had been published.<sup>13-15,51</sup> Latthe et al,<sup>13,14</sup> reported that the subjective and objective cure rates between TOT or TVT-O and TVT were not significantly different. Novara et al<sup>51</sup> showed the equivalent subjective and objective cure rates between TOT or TVT-O and TVT in sensitivity analyses. But these meta-analyses<sup>13,14,51</sup> of RCTs were established over a short-term follow-up. Ya-fei et al<sup>15</sup> only demonstrated a similar objective cure rate between TVT-O and TVT. This study<sup>15</sup> did not compare the subjective cure rate of TVT-O with

TVT. Our meta-analysis of RCTs is the first to assess extensively the effectiveness and complication rates of three midurethral tapes (TVT, TOT and TVT-O) in a medium- to long-term follow up (at least 12 months). Moreover, 17 RCTs were judged as high quality trials by the Jadad score. To further reduce clinical heterogeneity, the TVT was also compared with TOT and TVT-O separately. Therefore, the most rigorous TOMUS trial<sup>52</sup> was not part of our analysis. Our results showed that the subjective and objective cure rates of TVT, TOT, and TVT-O had no difference in female SUI in a medium- to long-term follow up. These findings were further confirmed in sensitivity analyses and consistent with recent studies,<sup>13,14,51</sup> basing on short-term follow-up. However, a potential heterogeneity could be included, because some studies used different criteria to evaluate subjective and objective cure rates. Although negative cough stress test was used in our studies to evaluate objective cure rates, the evaluation of subjective cure rate was different.

With regard to complications, low complication rates were reported in all included studies. Our meta-analysis showed that the incidence rates of bladder perforation, hematoma, and voiding difficulties/urinary retention were significantly higher in the TVT group than TVT-O/TOT. Groin/thigh pain was significantly more common in TVT-O/TOT group than TVT. However, further sensitivity analyses based on high quality RCTs showed that the risk of bladder perforations was also significantly higher in TVT group than TVT-O. The incidence of bladder perforations was similar between TVT and TOT, but this result was not consistent with recent studies,<sup>13,14,51</sup> and it may be because the bladder perforation as intraoperative complication was less reported in a medium- to long-term follow-up. In comparing TVT with TVT-O/TOT, the incidence rates of hematoma, voiding difficulties/urinary retention, de novo urgency, and groin/thigh pain did not show different results. In comparing TVT-O with TOT, it showed that the incidence of voiding difficulties/urinary retention, de novo urgency, and groin/thigh pain showed similar results, but these results are not consistent with Latthe et al's studies.<sup>13,14</sup>

Although we reconfirmed that their operation rate was significantly higher in the TOT group than TVT-O, there was only one high quality RCT. Therefore, this report was insufficient to pool results. In addition, the risk of vaginal erosion was significantly lower in TVT-O group than TOT. However, these results were more likely to be determined from large national registries and voluntary reporting registries or databases for reporting complications.

There are several limitations in our meta-analysis. Firstly, the studies have provided few high quality RCTs and major complications. Secondly, the evaluation standard of subjective and objective cure rates was highly variable among the RCTs. Thirdly, we restricted the language, because we cannot find satisfactory RCTs with other languages. Finally, patients lost to follow-up were directly deleted in our analyses, which would affect more realistic estimations of the results.<sup>51</sup>

In conclusion, the current evidence in our meta-analysis showed that the subjective and objective cure rates were similar among TVT, TOT, and TVT-O for female SUI in a medium- to long-term follow up. The TVT had a higher risk of intraoperative bladder perforation than TVT-O. Groin/thigh pain was significantly more common in TOT than TVT. The TVT-O had a lower vaginal erosion rate than TOT. Finally, no significant differences could be found in other complications comparing these 3 mid-urethral tapes. However, statistically speaking, clear definitions and standardization of outcome measures used, complete clinical parameters, and high quality RCTs with long-term follow-up are clearly needed for future studies.

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