

# TVT versus TOT in the treatment of female stress urinary incontinence: a systematic review and meta-analysis

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**Background:** To evaluate the evidence available on the effects and safety of tension-free vaginal tape (TVT) versus transobturator tape (TOT) for female stress urinary incontinence therapy based on randomized controlled trials (RCTs).

**Methods:** PubMed, Cochrane, Embase, Wanfang, China National Knowledge Infrastructure, and Weipu database were searched up to July 2017 to identify relevant studies, including qualified RCT and quite-RCT and literature sources. Relative risks (RRs), mean difference (MD), and 95% CI were calculated in our review.

**Result:** Twenty-eight RCTs were involved in the meta-analysis with 2,505 patients in the TVT group and 2,477 patients in the TOT group. The aggregated results indicated that TOT significantly decreased the operative time (MD, -1.27; 95% CI: -1.77 to -0.76) and hospital stay (MD, -0.62; 95% CI: -1.08 to -0.17) when compared with TVT. Besides, the complications (RR, 0.86; 95% CI: 0.64–1.16) and blood loss (MD, -0.29; 95% CI: -0.71 to 0.14) were decreased in TOT but with no statistical significance; the change of VAS score (MD, 0.07; 95% CI: -0.05 to 0.19), IIQ-7 score (MD, 0.06; 95% CI: -0.03 to 0.15), and UDI-6 score (MD, 0.15; 95% CI: -0.19 to 0.48) were larger in TOT group than in TVT group, but still, with no statistical significance. However, there was no significant difference of cure rate (RR, 1.00; 95% CI: 0.96–1.04) and satisfied rate (RR, 1.00; 95% CI: 0.96–1.04) between the 2 groups.

**Conclusion:** TOT may have more valid effects than TVT in operative time and hospital stay. Besides, TOT method showed fewer complications and blood loss than TVT, but there was no significant difference between them. The scores of VAS, incontinence impact questionnaire short form-7 (IIQ-7), and urogenital distress inventory short form-6 (UDI-6) were higher in TOT than TVT, but still no significant difference was observed. However, more studies with higher quality and larger sample size that are multicentric and have longer follow-up in the form of RCTs are warranted to confirm the current findings.

**Keywords:** TVT, TOT, SUI, meta-analysis, randomized controlled trial

## Introduction

Stress urinary incontinence (SUI) is a common disease among middle and aged females, associated with obesity. It is estimated that about 10%–55% of females aged 15–64 have SUI,<sup>1</sup> and the prevalence increases with age.<sup>2</sup> The International Continence Society defines SUI as the complaint of involuntary urine leakage with effort, exertion, sneezing, or coughing;<sup>3</sup> it results from hypermobility of the urethra and functional insufficiency of the urethral sphincter. Ten percent of middle-aged women reported daily or severe incontinence and at least one-third reported leakage at least weekly.<sup>4</sup> The main pathogenic factors of SUI include age, menopause, hormone level, body mass index

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(BMI) and so on, and it is closely related to the number of pregnancies/childbirth, pelvic organ prolapse, chronic pelvic pain, history of pelvic surgery, diet, and lifestyle.<sup>5</sup>

Nonsurgical therapy and surgical therapy have been used for the treatment of SUI. The surgical therapy is mainly used in patients with ineffective nonsurgical therapy, moderate or severe SUI, bad living quality, and basin function lesion with pelvic organ prolapse.<sup>6</sup> The surgeries are of various types such as traditional open operation, minimally invasive surgery, tension-free vaginal tape (TVT), transobturator tape (TOT), and so on. The current gold standard for treating SUI is sling surgery. Many studies were conducted to identify the efficacy of these surgeries; however, no effective conclusions were drawn about the efficacy of TVT vs TOT in the treatment of SUI. We, therefore, conducted this meta-analysis of eligible randomized controlled trials (RCTs) to assess the effects and safety of TVT compared with TOT in the treatment of SUI.

## Methods

### Search strategy

The electronic databases of The Cochrane Library, PubMed, Embase, China National Knowledge Infrastructure, WangFang, and Weipu were systematically searched to identify relevant studies including all RCTs about the efficacy of TVT versus TOT in the treatment of bladder cancer up to July 2017. The databases were searched independently by 2 investigators, and a third investigator was involved to reach an agreement.

### Study selection

The studies that met the following criteria were included in our review: 1) RCT or quite-RCT (quite-RCT means the groupings are dependent on birth date, admission number, or the time of admission. It is a “randomized design” but does not state the randomization method); 2) the research subjects are females with SUI and with no other serious diseases; 3) TVT group and TOT group were involved with relevant interventions for the studies; and 4) the publications were available in English or Chinese.

The studies that met the following criteria were extracted: 1) repeated publications, or shared content and results; 2) faulty data; 3) case report, theoretical research, conference report, systematic review, meta-analysis, expert comment, or economic analysis; and 4) the outcomes were not relevant.

### Data extraction and quality assessment

Two reviewers independently extracted data based on pre-defined criteria. Differences were settled by discussion with a third reviewer. The analyses data were extracted from

all the included studies and consisted of 2 parts: general information and main outcomes. The authors' names, the detailed interventions of the 2 groups, the sample size, the percentage of male, the mean age, and the relative information from the Jadad were extracted as general information. Clinical outcomes, such as total operative time, blood loss, transfusion rate, hospital stay, and complications, were utilized to analyze the studies. The Jadad scoring checklist was used to assess the quality of involved studies. We evaluated all the RCTs through following 5 domains: allocation concealment; random sequence generation; blinding of participants and personnel; double-blind assessment; and incomplete outcome data. Domains were classified as “low quality and high bias risks” and “high quality,” with a score of  $<3$  and  $>3$ , respectively. The assessments were performed by 2 reviewers independently. Any arising differences were resolved by discussion.

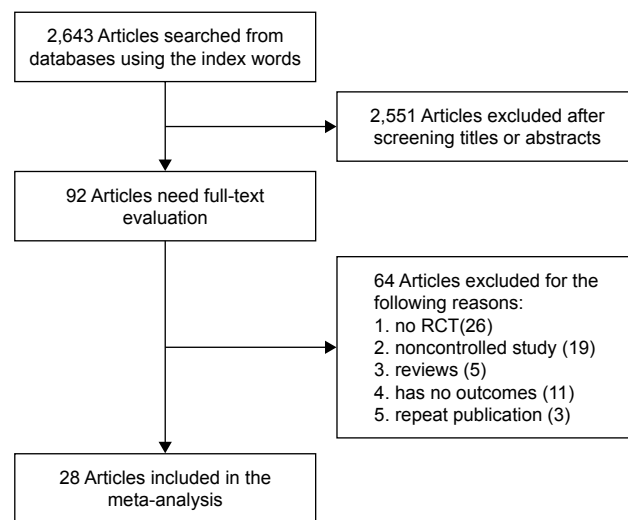
### Statistical analysis

All statistical analyses were performed using the STATA 10.0 software (StataCorp LLC, College Station, TX, USA).  $\chi^2$  and  $I^2$  tests were used to assess the statistical heterogeneity of clinical trial results and determine the analysis model (fixed-effect model or random-effect model). The heterogeneity was acceptable when the  $\chi^2$  test  $P$ -value was  $<0.05$  and the value of  $I^2$  was  $>50\%$  assessed by random-effects model. It was defined as homogeneous data when the  $\chi^2$  test  $P$ -value was more than 0.05 and the value of  $I^2$  was  $<50\%$  assessed by fixed-effects model. The continuous variables were expressed as the mean  $\pm$  SD and analyzed by mean difference (MD). The categorical data were calculated as percentages and analyzed by relative risk (RR) or odds ratio (OR). Complications, cure rate, and satisfaction rate were analyzed by RR and 95% CI. MD and 95% CI were calculated to analyze total operative time, blood loss, hospital stay, VAS score, IIQ-7 score, and UDI-6 score.

## Results

### Literature search

A total of 2,643 records were identified by the searches. During the preliminary screening of the titles and abstracts, 2,551 records were eliminated, leaving 92 records for further selection. After full-text screening, 64 records were excluded due to the following criteria: not RCTs (26), noncontrolled study (19), reviews (5), had no outcomes (11), and repeat publication (3). Finally, 28 records<sup>7–30</sup> were included in our meta-analysis with 2,505 patients in the TVT group and 2,477 patients in the TOT group. The detailed search process is presented in Figure 1.



**Figure 1** Flow diagram of the literature search and selection process.

**Abbreviation:** RCT, randomized controlled trial.

## Study characteristics

The main characteristics of all included studies are summarized in Table 1. The general information included treatment, number of patients, age and BMI, and the treatment of TOT

from inside to outside and from outside to inside. The age and BMI in the 2 groups were similar. The mean Jadad score of the included studies was 2.24, and a main score lower than 3 indicated low the quality of the included studies.

## Complications

Eleven studies with 2,515 patients (TVT group =1,279, TOT group =1,236) reported on complications. Based on the  $\chi^2$  test  $P$ -value ( $P=0.000$ ) and  $I^2$  test value ( $I^2=70.1\%$ ), random-effect model was chosen to analyze the complications. The pooled results showed that TOT decreased the incidence of complication compared with the TVT, but without statistical significance (RR, 0.86; 95% CI: 0.64–1.16, Figure 2).

## Cure rate

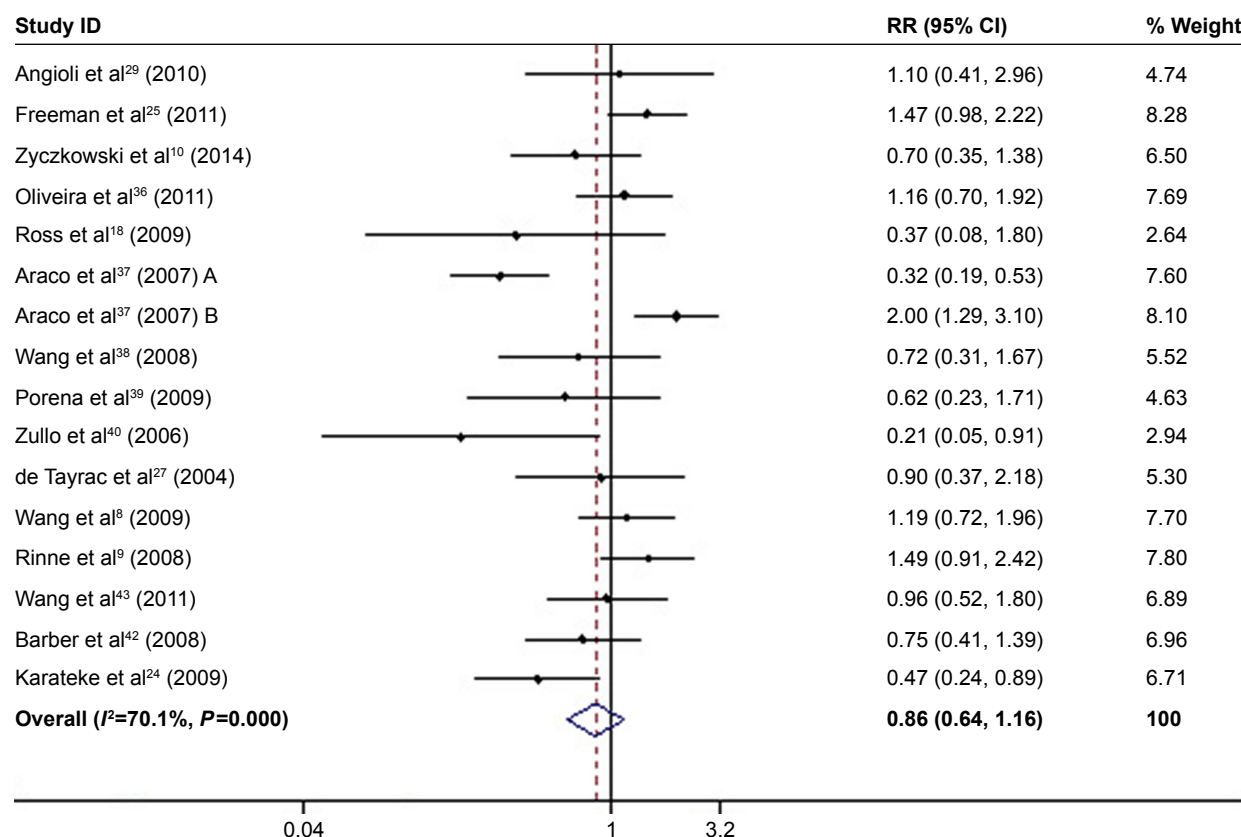
Ten studies with 1,991 patients (TVT group =982, TOT group =1,009) reported on cure rate. Based on the  $\chi^2$  test  $P$ -value ( $P=0.943$ ) and  $I^2$  test value ( $I^2=0.0\%$ ), fixed-effect model was chosen to analyze the cure rate. There was no significant difference of cure rate between the 2 groups (RR, 1.00; 95% CI: 0.96–1.04, Figure 3).

**Table 1** The basic characteristics and description of included studies

Study	Treatment		Number of patients		Age		BMI		Jadad score
Angioli et al <sup>29</sup> (2010)	TVT	TVT-O	35	37	–	–	–	–	3
Laurikainen et al <sup>21</sup> (2014)	TVT	Transobturator TVT	136	132	53.0	54.0	26.0	26.0	3
Kenton et al <sup>23</sup> (2015)	TVT	Transobturator midurethral slings	189	217	53.7	51.2	30.3	30.3	2
Ross et al <sup>17</sup> (2015)	TVT	TOT	105	93	52.2	50.3	28	28	2
Porena et al <sup>19</sup> (2007)	TVT	TOT	73	75	61.8	60.6	26.9	26.7	3
Freeman et al <sup>25</sup> (2011)	TVT	TOT	92	100	50	54	27	29	3
Hiroki et al <sup>30</sup> (2011)	TVT	TOT	38	45	59.8	62.6	23.1	24.6	2
Zyczkowski et al <sup>10</sup> (2014)	TVT	TOT	142	129	55.2	54.7	–	–	1
Wadie et al <sup>35</sup> (2012)	TVT	TOT	36	35	46.8	45.8	34	32	3
Schierlitz et al <sup>16</sup> (2012)	TVT	TOT	82	82	60	60	26	28	1
Zhang et al <sup>12</sup> (2011)	TVT	TVT-O	76	80	–	–	–	–	1
Oliveira R et al <sup>36</sup> (2011)	TVT	TVT-O	160	155	55	55	25	25	2
Ross et al <sup>18</sup> (2009)	TVT	TOT	105	94	51.8	50.1	28.1	27.8	3
Araco et al <sup>37</sup> (2007) A	TVT	TVT-O	50	50	53.6	53.2	28.1	28.1	3
Araco et al <sup>37</sup> (2007) B	TVT	TVT-O	58	50	54.5	54	27.8	28.1	3
Wang et al <sup>38</sup> (2008)	TVT	TVT-O	35	34	52	52	25	25	1
Porena et al <sup>39</sup> (2009)	TVT	TOT	47	42	60.9	61	27.7	25.8	1
Zullo et al <sup>40</sup> (2006)	TVT	Inside to outside TVT-O	35	37	52.8	53.4	25.7	26.5	3
de Tayrac et al <sup>27</sup> (2004)	TVT	TVT-O	31	30	53.6	54.7	25.2	24	3
Teo et al <sup>7</sup> (2011)	TVT	TVT-O	66	61	52.4	50.9	27	29	3
Wang et al <sup>8</sup> (2009)	TVT	Inside to outside TVT-O	154	146	55	54.8	25.2	24.7	1
Rinne et al <sup>9</sup> (2008)	TVT	TVT-O	134	131	53	54	26	26	2
Wang et al <sup>13</sup> (2011)	TVT	TVT-O	32	36	56.6	56	25.3	27.3	2
Deffieux et al <sup>26</sup> (2010)	TVT	Inside to outside TVT-O	75	74	54.6	52.8	26.3	26.3	3
Palva et al <sup>20</sup> (2010)	TVT	TVT-O	131	126	–	–	–	–	3
Krofta et al <sup>22</sup> (2009)	TVT	Inside to outside TVT-O	149	151	57.19	57.82	27.82	28.21	2
Wang et al <sup>41</sup> (2010)	TVT	TOT	70	70	60	58	24	24.6	1
Barber et al <sup>42</sup> (2008)	TVT	TOT	88	82	52	53	30	29	2
Karateke et al <sup>24</sup> (2009)	TVT	TVT-O	81	83	49.31	49.03	25.99	26.18	3

**Note:** – No data could be found.

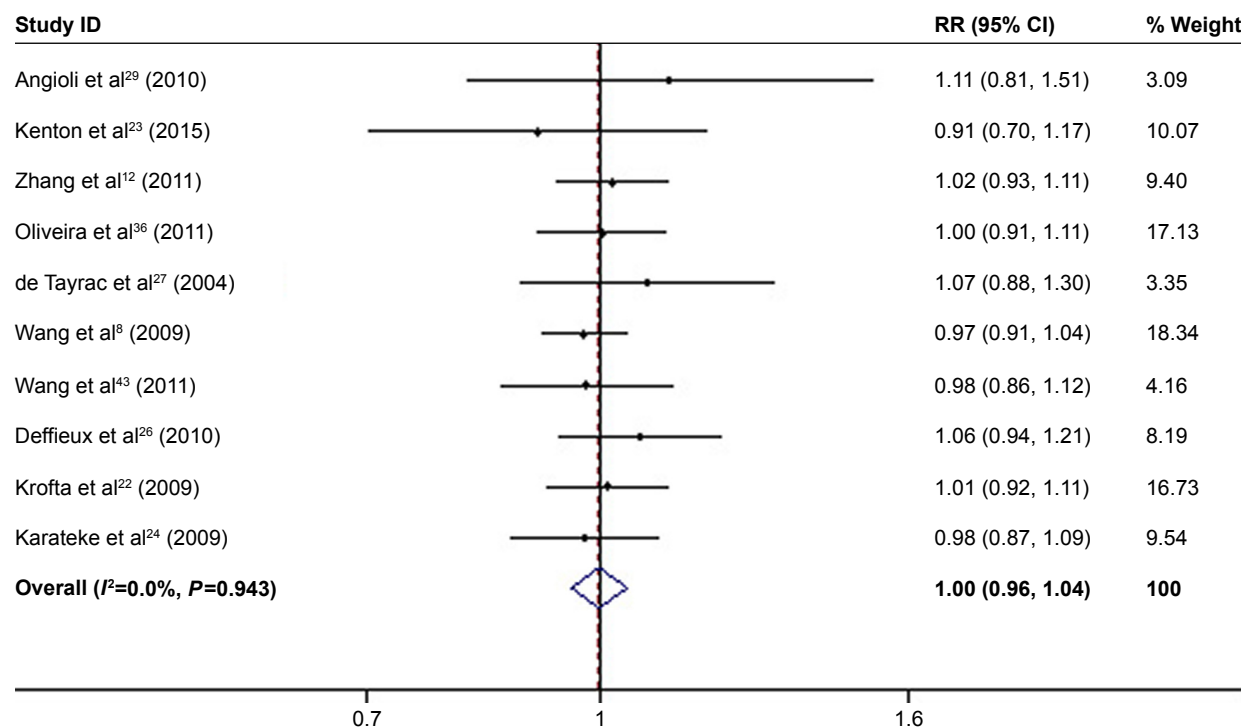
**Abbreviations:** BMI, body mass index; TOT, transobturator tape; TVT, tension-free vaginal tape; TVT-O, tension free vaginal tape obturator.



**Figure 2** Forest plot showing the efficacy of TVT versus TOT on complications.

**Note:** Weights are from random-effects analysis.

**Abbreviations:** RR, relative risk; TOT, transobturator tape; TVT, tension-free vaginal tape.



**Figure 3** Forest plot showing the efficacy of TVT versus TOT on cure rate.

**Abbreviations:** RR, relative risk; TOT, transobturator tape; TVT, tension-free vaginal tape.

## Satisfaction rate

Six studies with 1,128 patients (TVT group =569, TOT group =559) reported on satisfaction rate. Based on the  $\chi^2$  test  $P$ -value ( $P=0.790$ ) and  $I^2$  test value ( $I^2=0.0\%$ ), fixed-effect model was chosen to analyze the satisfaction rate. There was no significant difference of satisfaction rate between the two groups (RR, 1.00; 95% CI: 0.96–1.04, Figure 4).

## Operative time

Eleven studies with 2,861 patients (TVT group =1,440, TOT group =1,421) reported on operative time. Based on the  $\chi^2$  test  $P$ -value ( $P=0.000$ ) and  $I^2$  test value ( $I^2=97.3\%$ ), random-effect model was chosen to analyze the operative time. TOT significantly decreased the operative time compared with TVT (MD,  $-1.27$ ; 95% CI:  $-1.77$  to  $-0.76$ , Figure 5).

## Blood loss

Ten studies with 1,784 patients (TVT group =893, TOT group =891) reported on blood loss. Based on the  $\chi^2$  test  $P$ -value ( $P=0.000$ ) and  $I^2$  test value ( $I^2=94.7\%$ ), random-effect model was chosen to analyze the blood loss. TOT reduced the blood loss, but with no statistical significance compared with TVT (MD,  $-0.29$ ; 95% CI:  $-0.71$  to  $0.14$ , Figure 6).

## Hospital stay

Thirteen studies with 1,892 patients (TVT group =958, TOT group =934) reported on hospital stay. Based on the  $\chi^2$  test  $P$ -value ( $P=0.000$ ) and  $I^2$  test value ( $I^2=95.5\%$ ),

random-effect model was chosen to analyze the hospital stay. The hospital stay was significantly decreased in the TOT group compared with TVT group (MD,  $-0.62$ ; 95% CI:  $-1.08$  to  $-0.17$ , Figure 7).

## VAS score

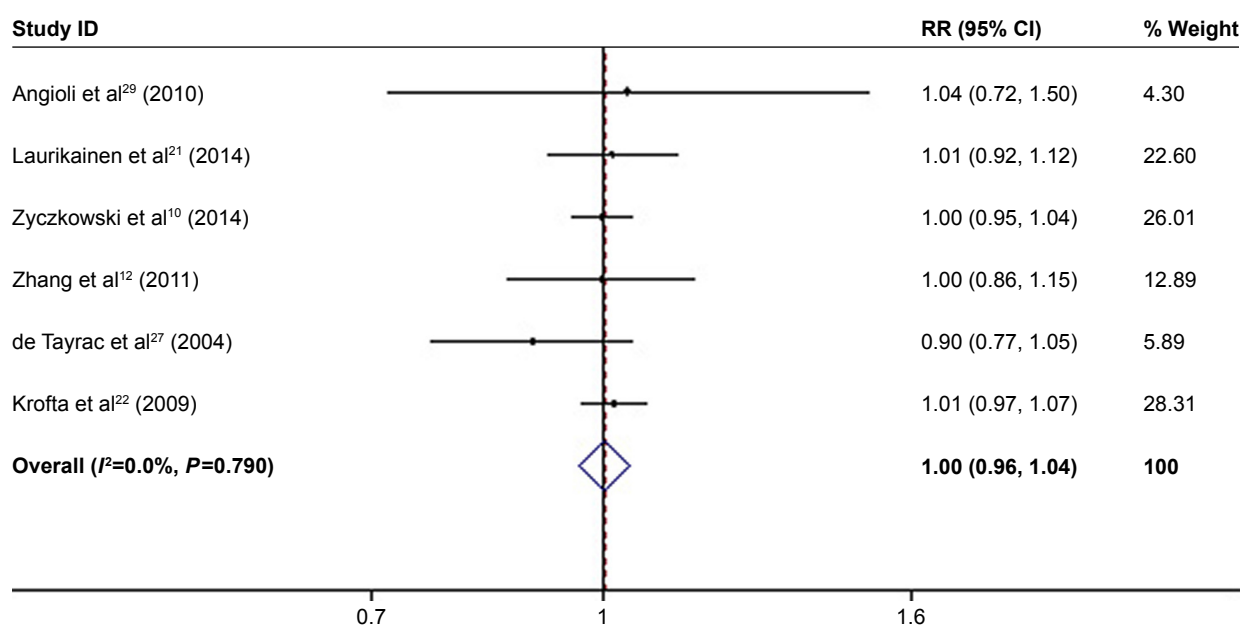
Five studies with 1,151 patients (TVT group =581, TOT group =570) reported on scores obtained on the VAS. Based on the  $\chi^2$  test  $P$ -value ( $P=0.000$ ) and  $I^2$  test value ( $I^2=92.1\%$ ), random-effect model was chosen to analyze the VAS score. The change in VAS score after the treatment was larger in TOT group than in TVT group, but without statistical significance (MD,  $0.07$ ; 95% CI:  $-0.05$  to  $0.19$ , Figure 8).

## IIQ-7 score

Eleven studies with 1,943 patients (TVT group =988, TOT group =955) reported on IIQ-7 score. Based on the  $\chi^2$  test  $P$ -value ( $P=0.100$ ) and  $I^2$  test value ( $I^2=37.5\%$ ), fixed-effect model was chosen to analyze the IIQ-7 score. The decrease in IIQ-7 score was more in TOT group than in TVT group, but without statistical significance (MD,  $0.06$ ; 95% CI:  $-0.03$  to  $0.15$ , Figure 9).

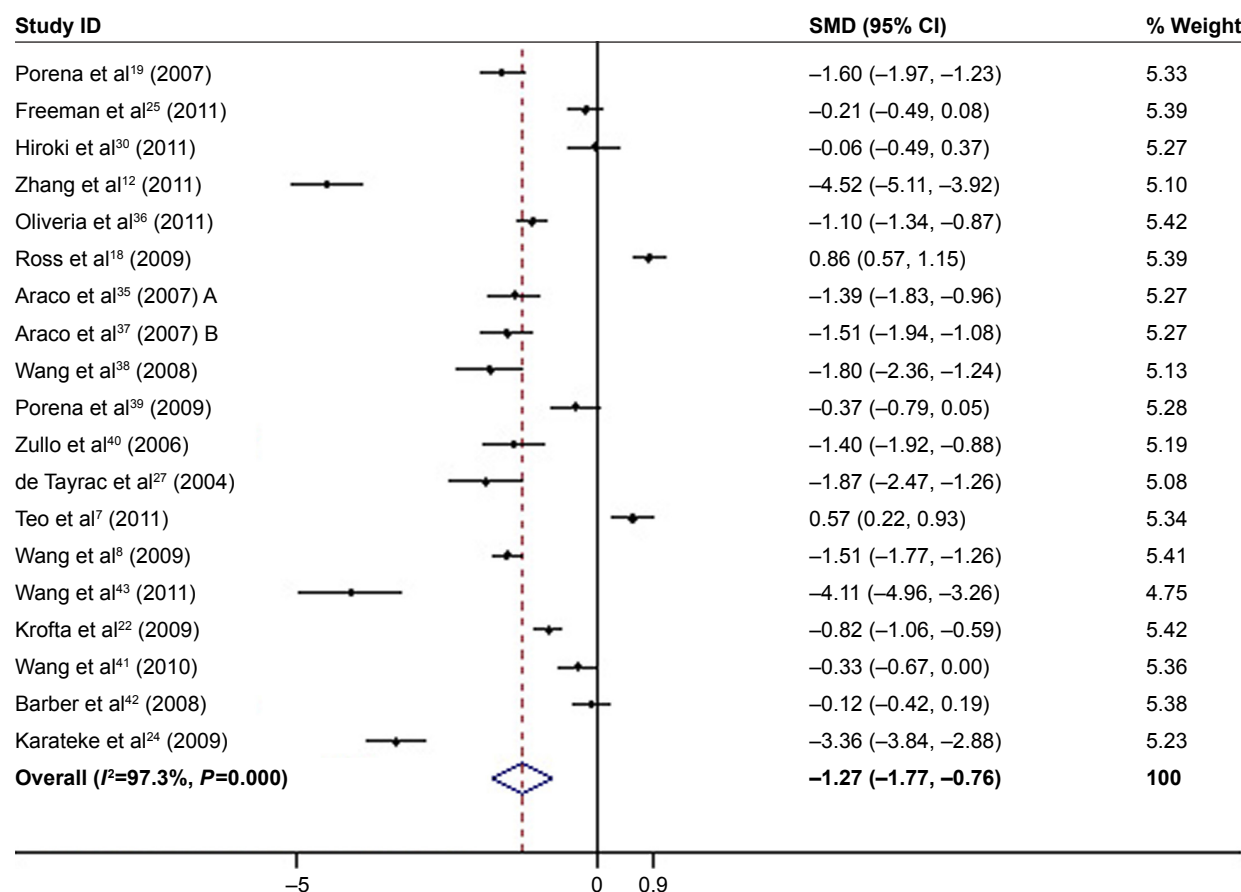
## UDI-6 score

Eleven studies with 1,779 patients (TVT group =907, TOT group =872) reported on UDI-6 score. Based on the  $\chi^2$  test  $P$ -value ( $P=0.000$ ) and  $I^2$  test value ( $I^2=91.7\%$ ), random-effect model was chosen to analyze the UDI-6 score.



**Figure 4** Forest plot showing the efficacy of TVT versus TOT on satisfaction rate.

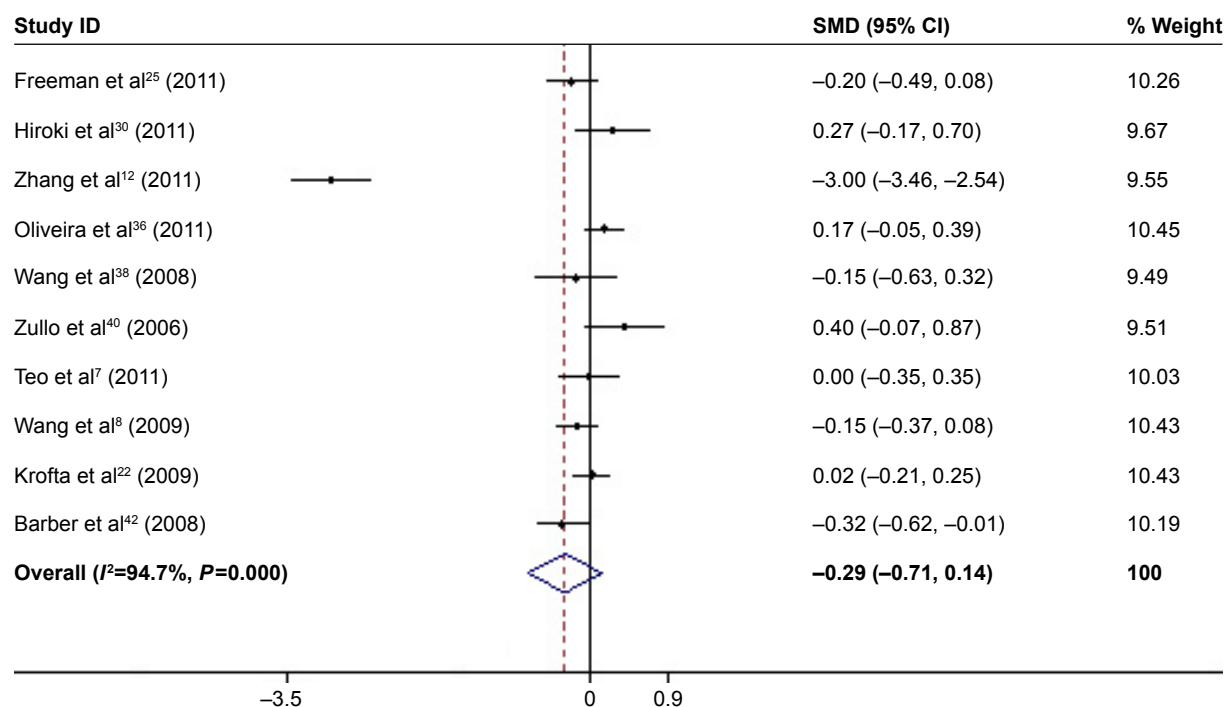
**Abbreviations:** RR, relative risk; TOT, transobturator tape; TVT, tension-free vaginal tape.



**Figure 5** Forest plot showing the efficacy of TVT versus TOT on operative time.

**Note:** Weights are from random-effects analysis.

**Abbreviations:** STD, Mean Difference; TOT, transobturator tape; TVT, tension-free vaginal tape.

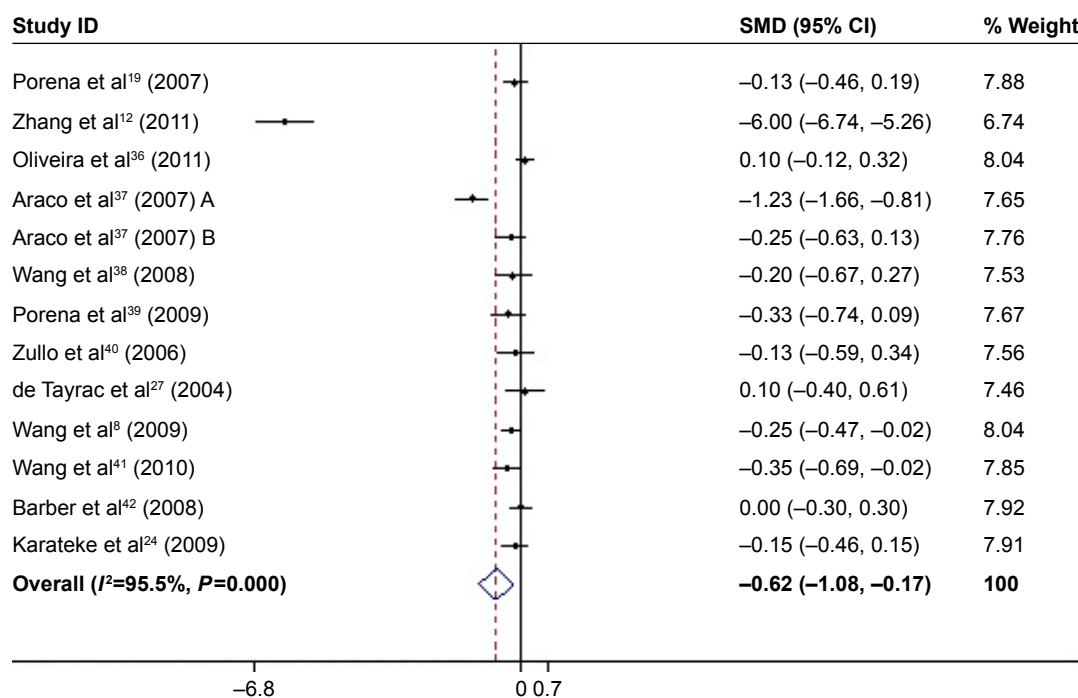


**Figure 6** Forest plot showing the efficacy of TVT versus TOT on blood loss.

**Note:** Weights are from random-effects analysis.

**Abbreviations:** STD, Mean Difference; TOT, transobturator tape; TVT, tension-free vaginal tape.





**Figure 7** Forest plot showing the efficacy of TVT versus TOT on hospital stay.

**Note:** Weights are from random-effects analysis.

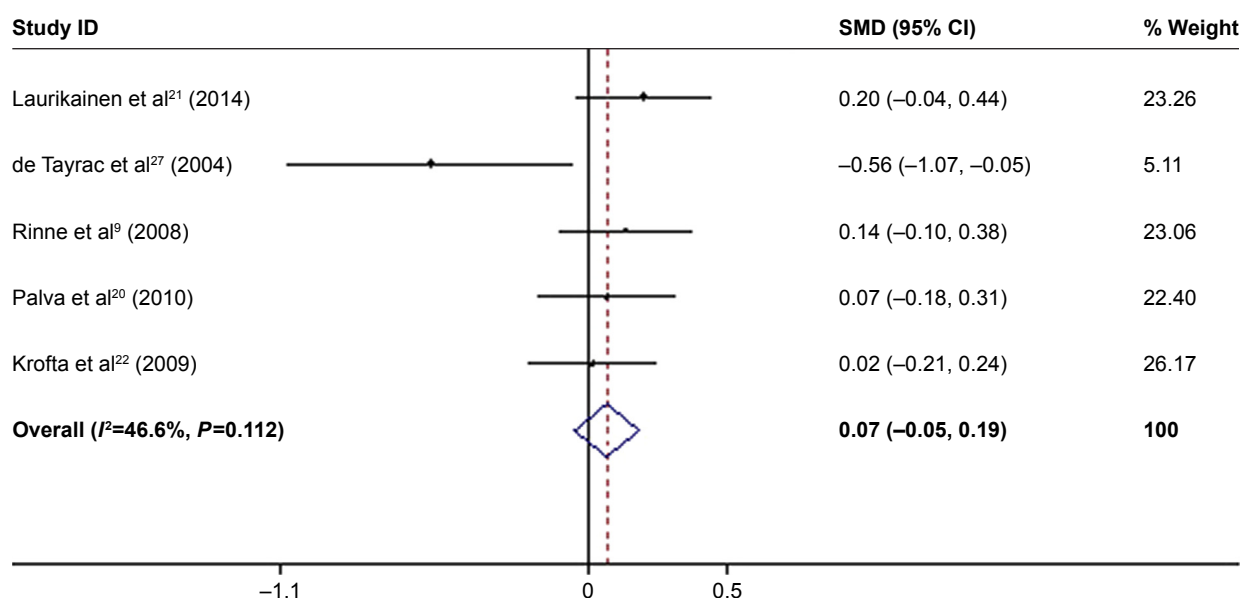
**Abbreviations:** STD, Mean Difference; TOT, transobturator tape; TVT, tension-free vaginal tape.

The change in UDI-6 score after the treatment was larger in TOT group than in TVT group, but without statistical significance (MD, 0.15; 95% CI: -0.19 to 0.48, Figure 10).

## Quality assessment and potential bias

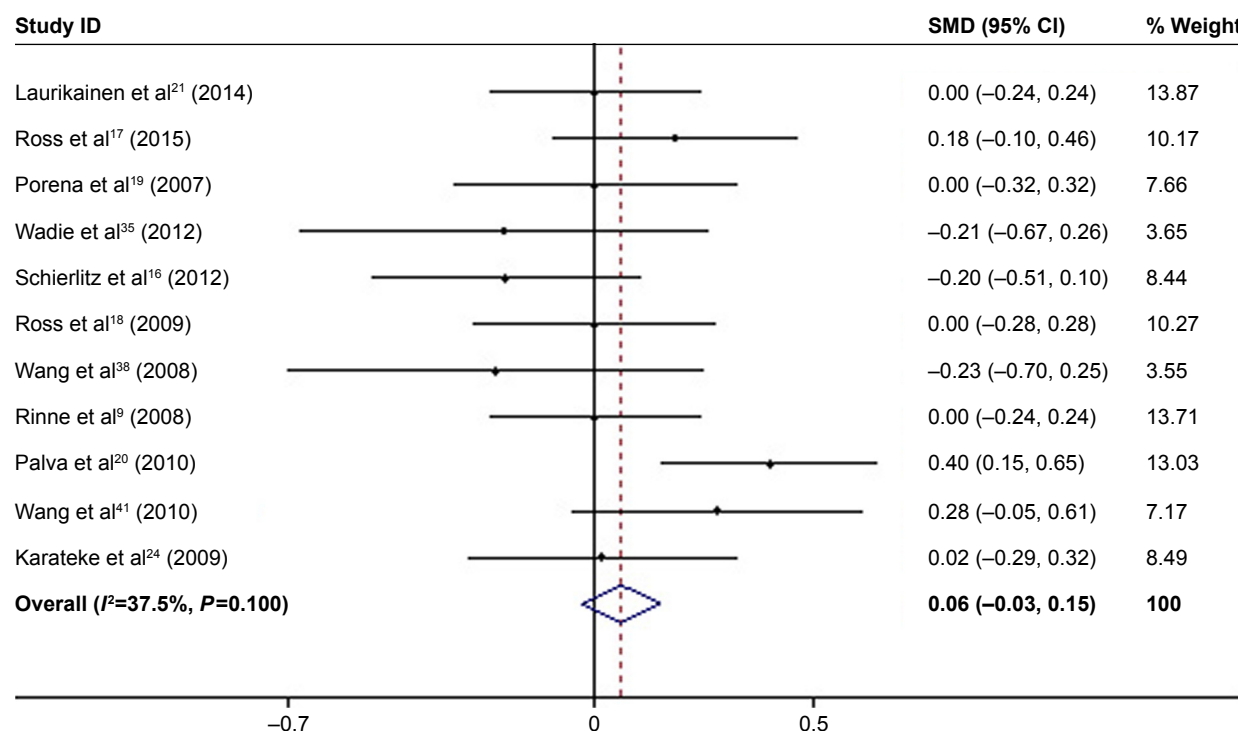
Based on the mentioned criteria, 28 articles were included in the meta-analysis. The quality assessment and potential bias

were assessed by funnel plot, Begg and Mazumdar's rank test, and Egger's test. The funnel plot for MD with regard to operative time in the included studies was notably unsymmetrical, suggesting significant publication bias (Figure 11). Moreover, significant asymmetry was detected using Begg and Mazumdar's rank test ( $Z=2.24$ ,  $P=0.025$ ). The Egger's test result showed that there was significant publication bias ( $P=0.033$ ).



**Figure 8** Forest plot showing the efficacy of TVT versus TOT on VAS score.

**Abbreviations:** STD, Mean Difference; TOT, transobturator tape; TVT, tension-free vaginal tape.



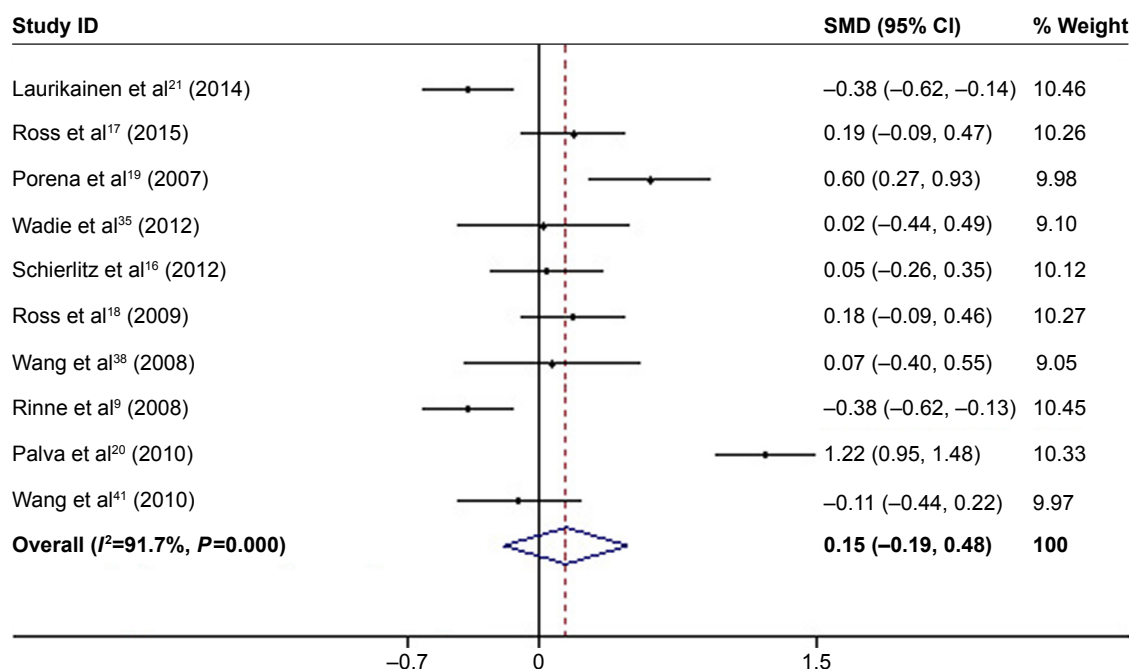
**Figure 9** Forest plot showing the efficacy of TVT versus TOT on IIQ-7 score.

**Abbreviations:** STD, Mean Difference; TOT, transobturator tape; TVT, tension-free vaginal tape.

## Discussion

Petros and Ulmsten<sup>31</sup> were the first to come up with the treatment TVT in 1995. TOT was proposed by some scholars in 2001, and another TVT inside-out (TVT-obturator system)

was proposed by de Leval<sup>4</sup> In previous studies, Maggiore et al<sup>32</sup> reported that objective and subjective cumulative cure rates of TVT and TOT (both out-in and in-out) were 61.6% (95% CI: 58.5%–64.8%) and 76.5% (95% CI: 73.8%–79.2%),



**Figure 10** Forest plot showing the efficacy of TVT versus TOT on UDI-6 score.

**Note:** Weights are from random-effects analysis.

**Abbreviations:** STD, Mean Difference; TOT, transobturator tape; TVT, tension-free vaginal tape.



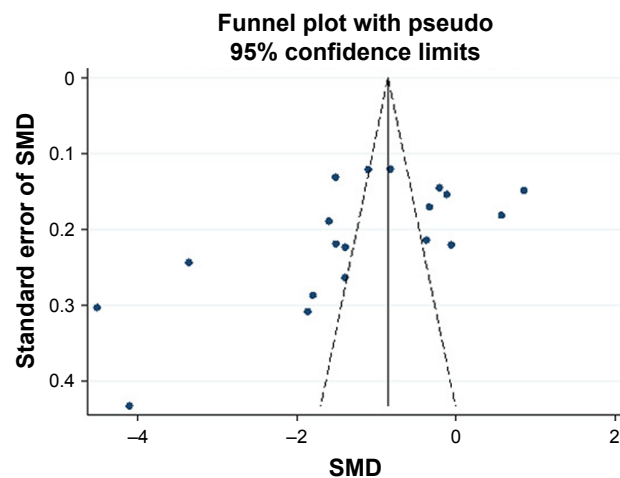


Figure 11 Funnel plot of publication bias.

and 64.4% (95% CI: 61.4%–67.4%) and 81.3% (95% CI: 78.9%–83.7%), respectively. Both TVT and TOT were associated with similar long-term objectives (OR, 0.87 [95% CI: 0.49–1.53]) and subjective (OR, 0.84 [95% CI: 0.46–1.55]) cure rates. In addition, it was shown that there was no significant difference in the complication rates when TVT was compared with TOT: TVT versus TOT (OR, 0.83 [95% CI: 0.54–1.28]), TOT-O versus TVT-O (OR, 0.77 [95% CI: 0.17–3.46]). Huang et al<sup>33</sup> found that TVT-Secur showed significant reduction in operative time, visual analog score for pain, and postoperative complications compared with TVT-O. 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 1–3 years; however, there was no significant difference between TVT-Secur and TVT-O in the subjective cure rate, objective cure rate, or complications at 3–5 years. Moreover, TVT-Secur had significantly lower subjective and objective cure rates compared with TVT.

The operative time in our systematic review and meta-analysis was significantly decreased in TOT group when compared with TVT group; TOT had shorter operative time with no routine cystoscopy. TOT would reduce the incidence of bladder perforation, which helps patients return to normal life as soon as possible, so the hospital stay was significantly shorter in TOT group.

The complications can be either intraoperative or postoperative. The intraoperative complications include necessity of blood transfusion, bladder injury, vaginal wall perforation, urethral injury, ureteral injury, bowel injury, cardiac arrhythmia, and so on. The postoperative complications are infections requiring antibiotics, urinary tract infections, cardiac or myocardial infarction, pulmonary, ileus, pelvic

abscess, necessity for blood transfusion, leg or obturator complication, hospital readmissions, emergency room evaluations, and so on. The incidence of bladder perforation or vaginal perforation was reported to be as high as 24%;<sup>34</sup> thus, TOT (in–out and out–in) appeared successively. In this review, we found that the complications were lower in TOT group than in TVT group, and the blood loss was also decreased in TOT group, but this showed no statistical significance. More studies are required to support the evidence.

The UDI-6 questionnaire is used to evaluate the urethral stimulant symptom, pressure symptoms, and obstructive symptoms in SUI patients. The IIQ-7 questionnaires evaluate four aspects including daily activities, physical activities, social activities, and psychological health of patients. The VAS is used to assess the pain in patients. The change in VAS score (MD, 0.07; 95% CI: –0.05 to 0.19), IIQ-7 score (MD, 0.06; 95% CI: –0.03 to 0.15), and UDI-6 score (MD, 0.15; 95% CI: –0.19 to 0.48) before and after the operation were larger in TOT group than in TVT group, but without statistical significance.

The cure rate in this review was same as the objective cure rate, and satisfaction rate was same as the subjective cure rates. We found that there was no significant difference in cure rate and satisfaction rate between the 2 groups, and the results were consistent with that of Leval et al.

However, there were several limitations in this analysis, such as the following: 1) only RCTs and quite-RCT were included; 2) there were differences in the inclusion and exclusion criteria for patients; 3) different patients with previous disease and treatments were unavailable; 4) some trials with low quality and low Jadad score were included in our study; 5) all the included studies were in English and/or Chinese only; 6) the technique of surgery between different studies was different; and 7) pooled data were used for analysis, and individual patient data was unavailable. Considering all the limitations mentioned above, more high-quality studies are needed to confirm our current findings.

## Conclusion

Our systematic review and meta-analysis suggested that TOT is better at decreasing operative time, the length of hospital stay, the incidence of complications, the blood loss, and leading to score reductions in VAS, IIQ-7, and UDI-6 compared with TVT, indicating TOT to be a more effective and safer method in the treatment of SUI. More detailed research with well-performed assays and larger sample size are warranted to verify these results.

## Disclosure

The authors report no conflicts of interest in this work.

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