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Comparison between the retropubic and transobturator approaches in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications

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ABSTRACT

Objective: This study aimed to compare the effectiveness and complications between the retropubic and transobturator approaches for the treatment of female stress urinary incontinence (SUI) by conducting a systematic review.
Materials and Methods: We selected all randomized controlled trials (RCTs) that compared retropubic and transobturator sling placements for treatment of SUI. We estimated pooled odds ratios and 95% confidence intervals for intraoperative and postoperative outcomes and complications.
Results: Six hundred twelve studies that compared retropubic and transobturator approaches to midurethral sling placement were identified, of which 16 were included in our research. Our study was based on results from 2646 women. We performed a subgroup analysis to compare outcomes and complications between the two approaches. The evidence to support the superior approach that leads to better objective/subjective cure rate was insufficient. The transobturator approach was associated with lower risks of bladder perforation (odds ratio (OR) 0.17, 95% confidence interval (CI) 0.09-0.32), retropubic/vaginal hematoma (OR 0.32, 95% CI 0.16-0.63), and long-term voiding dysfunction (OR 0.32, 95% CI 0.17-0.61). However, the risk of thigh/groin pain seemed higher in the transobturator group (OR 2.53, 95% CI 1.72-3.72). We found no statistically significant differences in the risks of other complications between the two approaches.
Conclusions: This meta-analysis shows analogical objective and subjective cure rates between the retropubic and transobturator approaches to midurethral sling placement. The transobturator approach was associated with lower risks of several complications. However, good-quality studies with long-term follow-ups are warranted for further research.

ARTICLE INFO

Key words:
stress urinary incontinence; retropubic tape; transobturator tape; meta-analysis; systematic review

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INTRODUCTION

Stress urinary incontinence (SUI) is a major health problem that affects millions of women throughout the world. It is estimated to affect 15% to 35% of women in the general population (1).

Since it was first described by Ulmsten et al. (2) in 1996, the tension-free vaginal tape (TVT) has been considered as the first-line approach for the treatment of SUI. Although the TVT procedure was shown to have a high and stable cure rate in the medium and long terms (3, 4), complications such as bladder perforation, retropubic hematoma related to the passage of the sling through the retropubic space (5), and voiding dysfunction (6) have been reported. To minimize these complications, in 2001,

Delorme (7) described a new route of inserting the tape, which the author called transobturator taping (TOT), in which the tape was inserted through the obturator foramina.

In 2003, de Leval (8) introduced a modified technique called TVT-O, in which the tape is inserted in a reverse route, in through a vaginal incision and out through the obturator foramen (inside out).

Both the TOT and TVT-O procedures proved to have high success rates in short and medium term follow-ups and to be associated with few perioperative complications (9, 10). However, the use of transobturator slings is associated with specific complications such as thigh pain (11). Furthermore, whether the TOTs (both TOT and TVT-O) are equal to the TVT in effectiveness for the treatment of SUI is controversial. Some studies showed that the TOTs were as effective as the TVT (12, 13), but some trials proved that the TVT was superior than the TOT in terms of outcomes (14).

However, current researches were often driven by local norms and individual surgeon preferences instead of evidence-based medicine. Proper comparisons of effectiveness and associated complications between TVT and TOTs are currently limited.

The objectives of this systematic review were to determine and compare effectiveness between the TOTs and TVT in randomized controlled trials (RCTs) and to explore complication rates.

MATERIALS AND METHODS

A prospective protocol for this systematic review was developed. The study inclusion and exclusion criteria, statistical method, approach to estimating study quality, and outcomes are described in the sections that follow. This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Cangzhou People Hospital. Written informed consent was obtained from all participants.

Sources

All RCTs that compared retropubic and transobturator midurethral sling placement in the treatment of SUI were collected. We searched literatures from 2001 to 2011 using the following online databases: PubMed, Springer, OVID, EBSCO, SAGE Journals, and Web of Science. We also found meeting abstracts from 2001 to 2011 on the Web sites of the International Continence Society, the American Urogynecologic Society, and Society for Urodynamics and Female Urology.

Our search strategy included the Medical Subject Heading term "urinary incontinence" and other "free" keywords such as "retropubic," "transobturator," "tension-free vaginal tape," "TVT," "TVT-O," "TOT," "Monarc," "SPARC," and "midurethral sling." These search terms were used singly and in combination. There were no language restrictions on our searches. Two reviewers collaboratively performed our literature research. The corresponding author of each RCT included in the analysis was contacted.

Inclusion/Exclusion Criteria

All prospective RCTs that compared TOTs (TOT or TVT-O) and TVT in the treatment of urodynamically proven SUI were included. The following inclusion criteria were used: (i) prospective randomized studies that compared between the retropubic and transobturator approaches to tension-free midurethral polypropylene sling placement for SUI; (ii) clearly defined objective and/or subjective outcome measures; and (iii) clearly defined follow-up periods. Studies were excluded on the basis of the following criteria: (i) duplicate reports, in which case the report containing the most complete data was included; (ii) patients who had previously undergone anti-incontinence surgery; (iii) the rate of loss to follow-up was higher than 15% in general; (iv) fewer than 40 included cases; (v) the operation method included TVT-secure; and (vi) animal experiments.

Data Abstraction

The quality of the research studies and data abstraction were evaluated independently by two reviewers (Feng S and Qinglu S) according to Cochrane guidelines 4.2.2 and the quality-control standards set by Jada et al. (15). In case of any dissents between the two reviewers, a third member (Hongbo Z) participated in a discussion

to reach a consensus. We collected the following information: (i) the quality of the trials (allocation concealment, randomization method, blinding, power calculation, and intention-to-treat analysis); (ii) the participants' characteristics (number, type of sling used, and type of SUI, either isolated or mixed); (iii) follow-up duration and number of patients lost to follow-up; (iv) outcomes, namely subjective and/or objective cure; (v) intraoperative (bladder perforation and retropubic/vaginal hematoma) and postoperative complications (thigh/groin pain, de novo urgency or urge incontinence, transient voiding dysfunction, long-term voiding dysfunction, and tape erosion).

Statistical analysis

Statistical analysis was performed using the RevMan 5.0.24 software. For the dichotomous data in our review, we assessed statistical heterogeneity using the following criteria: "P≤0.05 or I2≥50%" was considered to represent statistically significant heterogeneity, and the Mantel-Haenszel random effects model was used to estimate odds ratios (ORs) and 95% confidence intervals (95% CIs). The Peto fixed effects model was used if "P>0.05 and I2<50%."

We assessed publication bias using funnel plots. Subgroups were established prior to the analysis of the objective/subjective outcomes, according to two perspectives as follows: (i) women with isolated and mixed incontinence and women with isolated incontinence, and (ii) "TVT vs. TOT" and "TVT vs. TVT-O." The subgroups established prior to the analysis of the complications included only "TVT vs. TOT" and "TVT vs. TVT-O."

RESULTS

Characteristics of the studies

Our search identified 612 reports, of which 588 were excluded on the basis of their titles/abstracts because of several shortcomings, including the following: lack of a comparative study design, a retrospective design, midurethral slings made of autogenous materials, non-randomized study design, association with other pelvic operations, and fewer than 40 study subjects. The remaining trials were assessed in detail. Three were excluded because neither the objective nor subjective cure criteria were defined (16-18). One was excluded because of lack of a clear explanation of the randomization method (19). Another was excluded because of a high rate of loss to follow-up (20). Three were excluded because of duplicate reports (21-23). Sixteen prospective randomized studies (24-39) were included in the review. The included studies used different objective cure criteria, singly or in combination, such as negative cough stress test result in the urodynamic testing (24-27, 29-39), and 1-hour pad test <1 g (28,29,34), <2 g (32,38), and <3 g (30). Twelve trials reported subjective cure rates (24-30, 32-35, 39). Different subjective measures such as the visual analogue scale, Incontinence Impact Questionnaire, Urogenital Distress Inventory, and other validated questionnaires were also used. Patient satisfaction of the subjective cure was described as "satisfied," "very satisfied," or "dry."

We randomized 2646 women to undergo midurethral sling placement for SUI using either TOTs (TOT/TVT-O) or TVT. Nine trials included women with either isolated or mixed SUI (25-27, 30-32, 34, 35, 39). Seven trials included women with isolated SUI only (24, 28, 29, 33, 36-38). Ten trials compared between TVT-O and TVT (24-26, 29, 34-39); 5 trials compared between TOT and TVT (27, 28, 31-33); and 1 trial included both TOT and TVT-O (30). Perioperative cystoscopy was performed for all the patients in 7 trials (25-28, 30, 31, 38); cystoscopy was used only for the TVT group in the remaining trials. Five of the trials reported allocation concealment (26, 28, 32, 33, 38). Thirteen trials had computer-generated randomization (24-28, 30-37), whereas the other trials used quasi-randomization. Only one trial had a single-blind design (24). Power calculation was performed in 10 trials (25-28, 31, 33, 34-36, 38); intention-to-treat (ITT) analysis was performed in only 1 trial (25). In all the trials, the general rates of loss to follow-up were not higher than 15%. The mean follow-up periods ranged from 6 to 36 months. The details of the included trials are shown in Table-1.

Effectiveness

We performed the first subgroup analysis according to different types of SUI ("isolated and

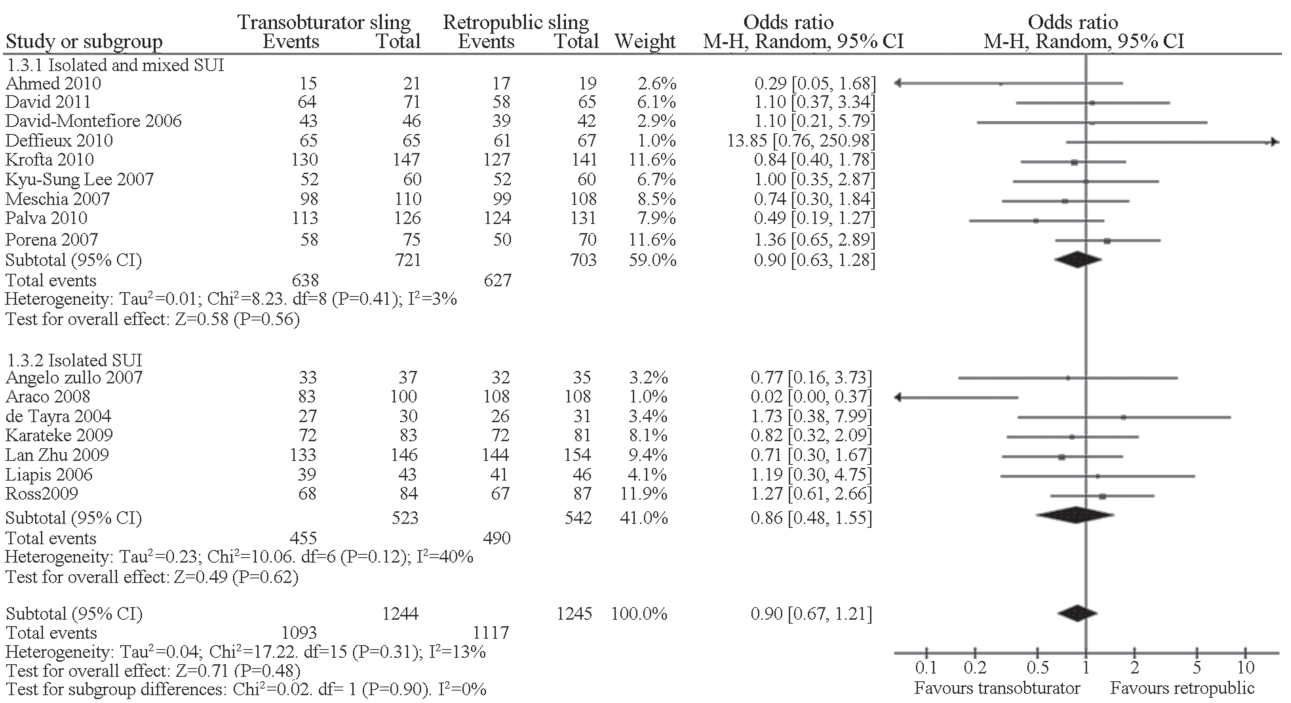
Table 1 - Basic data of research from literatures.

Author	Year	Country	Follow-up duration (month)	Research quality	Retropubic group	Transobturator group
Zhu et al	2008	China	14.5	A	35 (TVT)	34 (TVT-O)
Karateke et al	2009	Turkey	14	A	83 (TVT)	84 (TVT-O)
Palva et al	2010	Finland	36	B	136 (TVT)	131 (TVT-O)
Deffieux et al	2010	France	24	B	67 (TVT)	67 (TVT-O)
Porena et al	2007	Italy	31	B	70 (TVT)	75 (TOT)
Ross et al	2009	Canada	12	B	105 (TVT)	94 (TVT-O)
Liapis et al	2006	Greece	12	B	46 (TVT)	43 (TVT-O)
Wang et al	2011	China	12	B	32 (TVT)	36 (TVT-O)
David et al	2011	Switzerland	12	B	65 (TVT)	70 (TVT-O/TOT)
Lee et al	2006	Republic of Korea	13	B	60 (TVT)	60 (TVT-O)
David-Montefiore et al	2006	France	24	B	42 (TVT)	46 (TOT)
Ahmed et al	2010	Egypt	20	B	19 (TVT)	21 (TVT-O)
de Tayrac et al	2004	France	12	B	31 (TVT)	30 (TVT-O)
Krofta et al	2010	Czech	12	B	149 (TVT)	151 (TVT-O)
Meschia et al	2007	Italy	6	B	114 (TVT)	117 (TVT-O)
Angelo et al	2007	Italy	12	B	35 (TVT)	37 (TVT-O)
Zhu et al	2009	China	6	B	160 (TVT)	155 (TVT-O)
Araco et al	2008	Britain, Italy	12	B	120 (TVT)	120 (TVT-O)
Total					1369	1371

mixed SUI" and "isolated SUI"). When compared with the TVT group, the objective cure rate in the transobturator group was equivalent to that of the "isolated and mixed SUI" subgroup (OR 0.90, 95% CI 0.63-1.28), as well as that of the "isolated SUI" subgroup (OR 0.86, 95% CI 0.48-1.55). The differences in combined objective cure rate were not statistically significant (OR 0.90, 95% CI 0.67-1.21). When the transobturator and TVT groups were compared in terms of subjective cure, the "isolated and mixed SUI" (OR 0.91, 95% CI 0.68-1.23) and "isolated SUI" subgroups had equivalent results (OR 1.17, 95% CI 0.71-1.93), while differences in combined subjective cure were not statistically significant (OR 0.97, 95% CI 0.76-1.26). Figure-1 provides the objective cure rates of the transobturator group (TVT-O and TOT) in comparison with those of the TVT group in the first subgroup analysis.

We performed another subgroup analysis based on different anti-incontinence approaches ("TVT-O vs. TVT" and "TOT vs. TVT"). One study (30) was excluded in the meta-analysis because of the use of combined TVT-O and TOT in the transobturator group. When compared with TVT, the objective cure of SUI was equivalent between the TVT-O (OR 0.77, 95% CI 0.51-1.15) and TOT groups (OR 1.07, 95% CI 0.68-1.68), and the combined objective cure was not statistically significant (OR 0.86, 95% CI (0.63-1.16). The subjective cure in the transobturator group (TVT-O and TOT) in comparison with that in the TVT group

Figure 1 - Meta-analysis of objective cure of SUI between transobturator and TVT approaches in the first subgroup analysis.



was also not statistically significant (TVT-O vs. TVT: OR 0.97, 95% CI 0.71-1.33; TOT vs. TVT: OR 1.05, 95% CI 0.37-2.99, and total: OR 1.02, 95% CI 0.77-1.34). Figure-2 provides the objective cure rates of the two approaches (TVT-O and TOT) in comparison with that of the TVT in the subgroup analysis. The funnel plots indicated symmetrical distribution of the studies, indicating a low likelihood of publication or reporting bias (Figure-3).

COMPLICATIONS

We excluded one study (30) in the analysis of complications because it used the combination of TVT-O and TOT in the transobturator group.

All the trials provided data on bladder perforation. In comparison with TVT, TVT-O and TOT were associated with statistically significantly lower risk of bladder perforation as follows: TVT--O group (OR 0.18, 95% CI 0.08-0.38), TOT group (OR 0.17, 95% CI 0.06-0.49), combined TVT-O and TOT (OR 0.17, 95% CI 0.09-0.32).

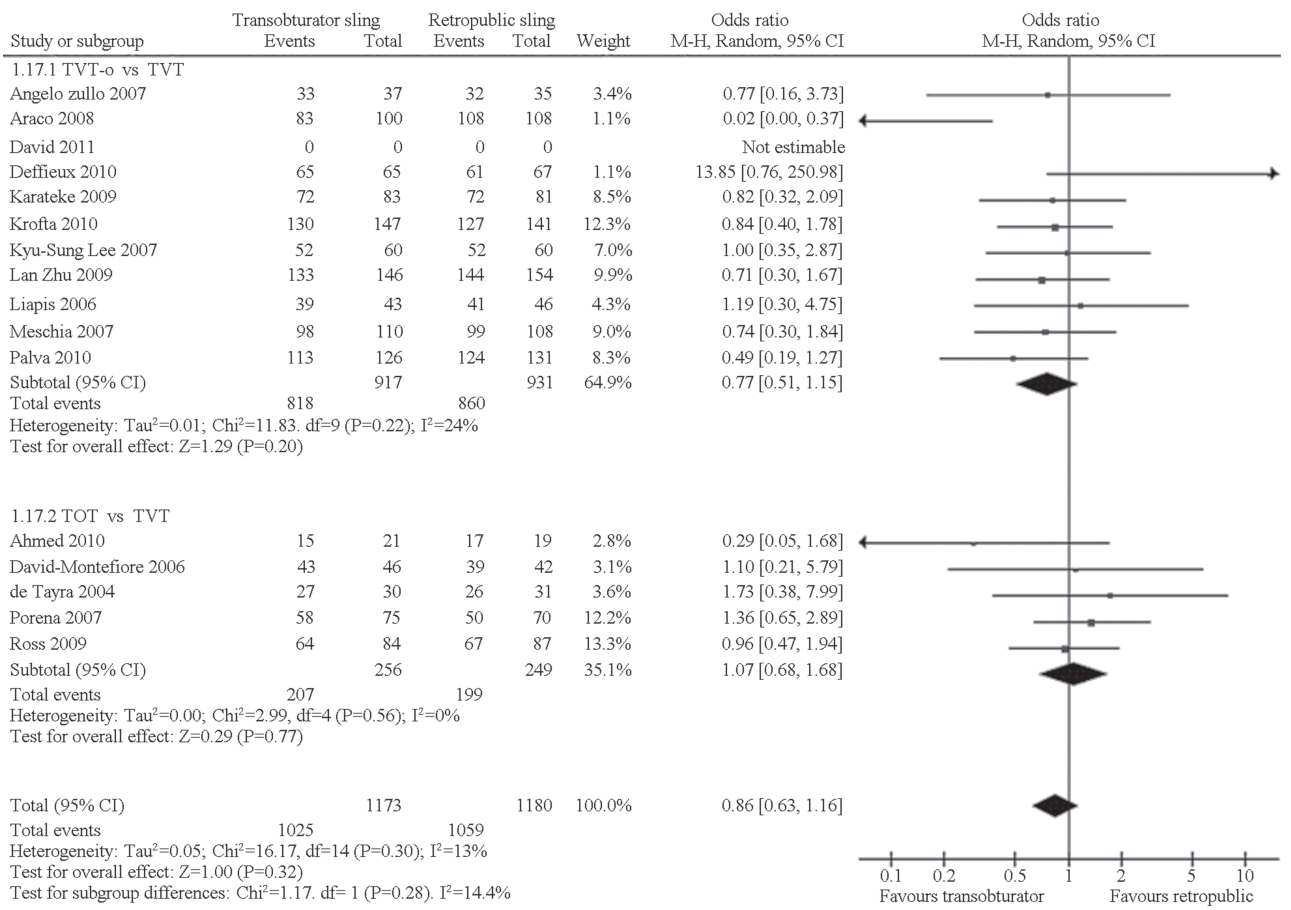
All trials reported data on retropubic/vaginal hematoma. In the subgroup analysis, the risk of hematoma was lower in both the TVT-O (OR 0.42, 95% CI 0.19-0.93) and TOT groups (OR 0.13, 95% CI 0.03-0.53) than in the TVT group.

Eleven trials (25-28, 31, 32, 34-37, 39) represented data on thigh/groin pain. The description and criteria of pain in each trial were not accordant. The TVT-O group seemed to be associated with a higher risk of pain than the TVT group (OR 2.8, 95% CI 1.81-4.45). However, no statistically significant difference was found between the TOT and TVT subgroups (OR 1.85, 95% CI 0.88-3.90). The risk of thigh/groin pain was higher for the combined TVT-O and TOT group (OR 2.53, 95% CI 1.72-3.72).

Thirteen trials (24-27, 29, 31, 33, 34-39) provided data on transient voiding dysfunction. The risks of transient voiding dysfunction were equivalent (TVT-O vs. TVT: OR 1.26, 95% CI 0.89-1.77 and TOT vs. TVT: OR 0.73, 95% CI 0.29-1.86).

Eleven studies (25-29, 31, 33, 34, 36, 38, 39) provided data on long-term voiding dysfunction. In the subgroup analysis, the risk of long--term voiding dysfunction was lower in the TVT-O group (OR 0.23, 95% CI 0.10-0.52) and equivalent

Figure 2 - Meta-analysis of the objective cure of the two approaches (TVT-O and TOT) in comparison with TVT.



between the TOT (OR 0.54, 95% CI 0.19-1.49) and TVT groups.

Eleven studies (24, 25, 28, 29, 31, 33, 34, 36-39) described postoperative symptoms of de novo urgency/urge incontinence. The risks were equivalent between the transobturator and retropubic groups (TVT-O vs. TVT: OR 0.96, 95% CI 0.56-1.65 and TOT vs. TVT: OR 1.03, 95% CI 0.41-2.60).

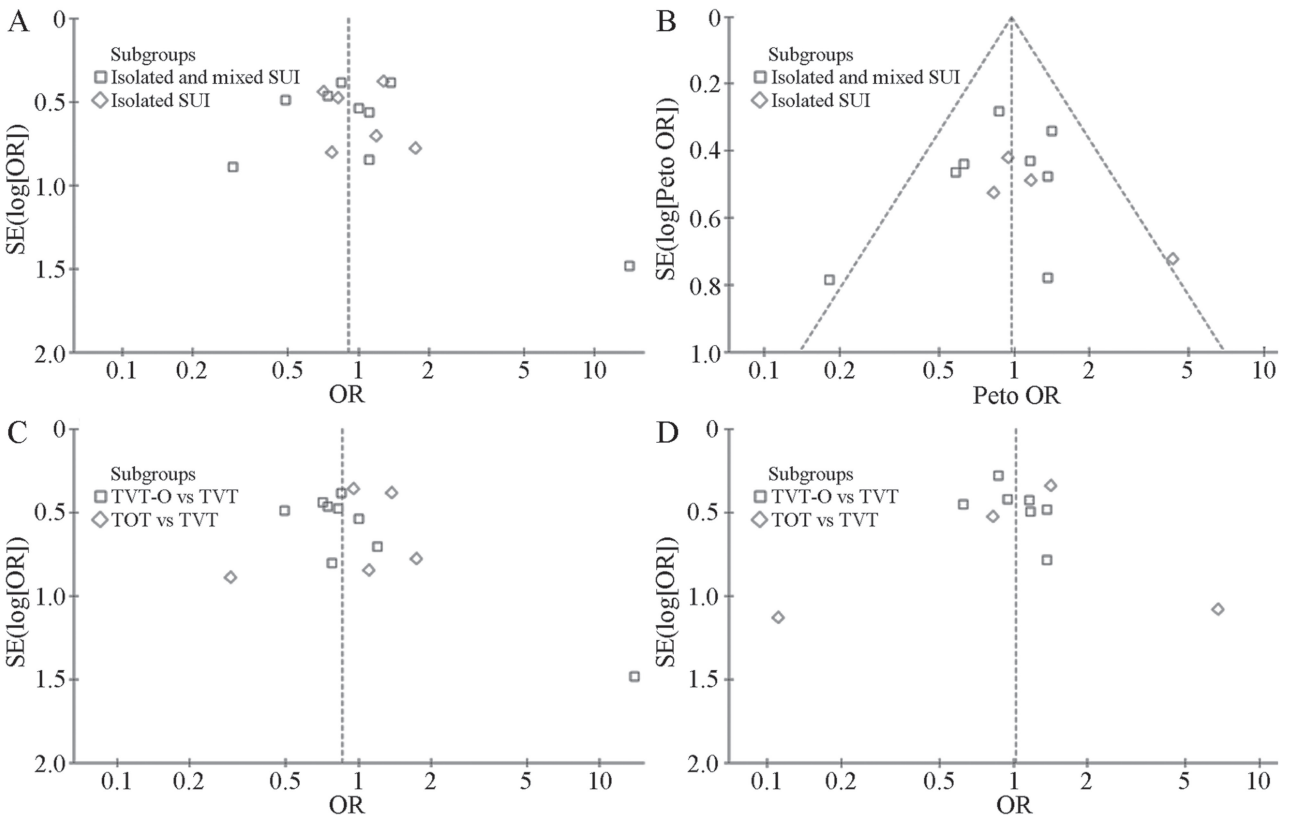
All the trials reported data on tape erosion. The risks of tape erosion were equivalent (TVT-O vs. TVT: OR 0.95, 95% CI 0.45–1.98 and TOT vs. TVT: OR 2.40, 95% CI 0.54-10.62).

Figure-4 provides a summary of the complications associated with the two tapes (TVT-O and TOT) in comparison with the TVT.

DISCUSSION

This systematic review has several superiorities. To ensure the accordance of baseline participant characteristics, we included only prospective and RCTs trials. To minimize the likelihood of publication or reporting bias, we set no language restrictions on our searches and sought both published and unpublished studies. Two reviewers independently estimated the quality of the studies according to Cochrane guidelines 4.2.2 and quality-control standards set by Jada et al. To obtain the most accurate results possible, we performed a subgroup analysis from two angles, namely (1) “isolated and mixed SUI” and “isolated SUI,” and (2) “TVT-O vs. TVT” and “TOT versus TVT.”

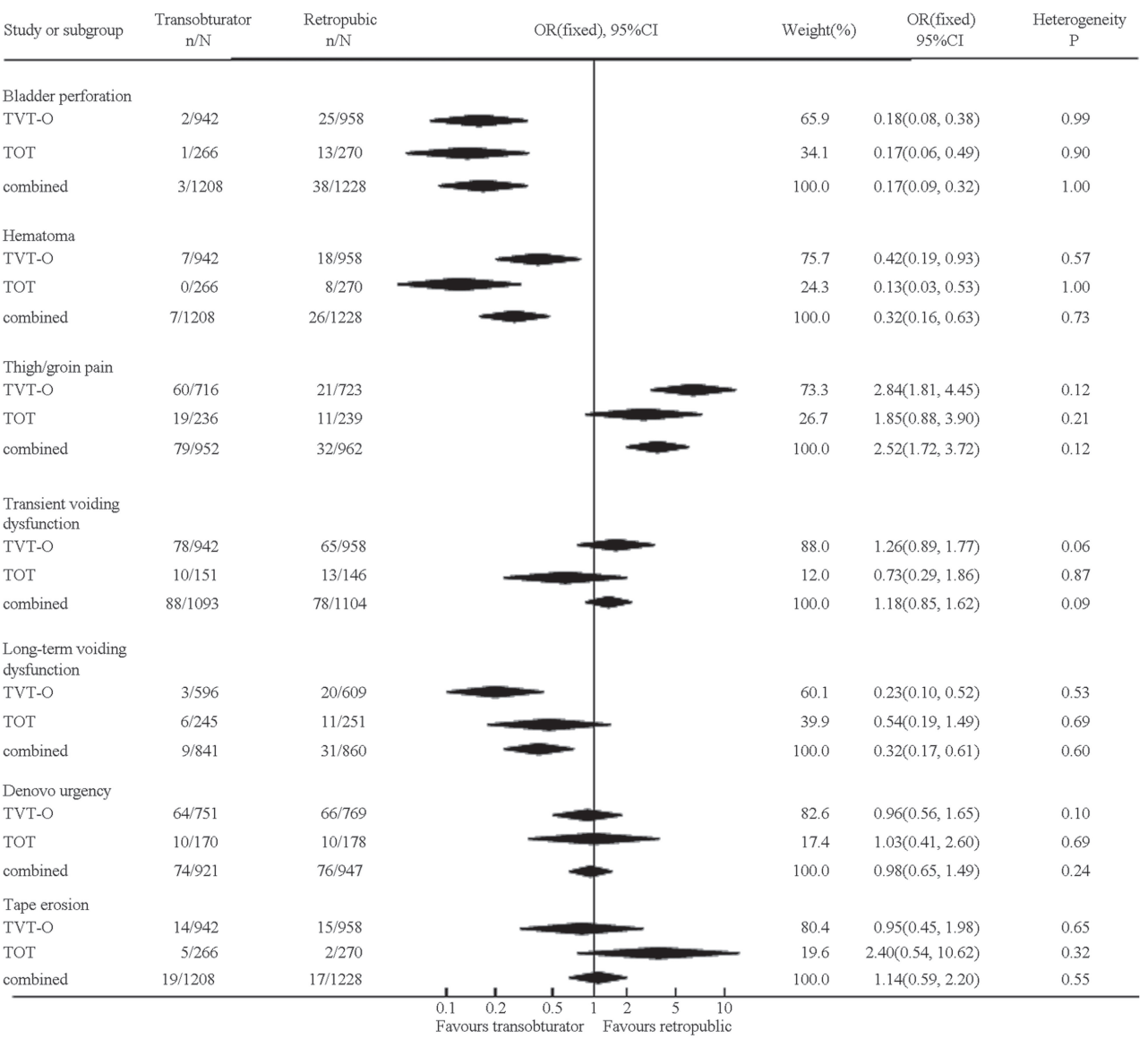
Figure 3 - A and B: Funnel plot of included trials to study the objective/subjective cure of SUI between transobturator and retropubic procedures in the first subgroup analysis C and D: Funnel plot of included trials to study the objective/subjective cure of SUI with procedures by TVT-O/TOT versus TVT.



We found no statistically significant difference in either objective or subjective cure between the transobturator and retropubic approaches for the treatment of female SUI. The funnel plots of the outcomes in the two subgroup analyses were evenly distributed, indicating a less likelihood of publication bias and higher confidence in the results. These results are consistent with those of most of the included trials (24-31, 33-37, 39). However, these findings cannot demonstrate the equivalent effectiveness of the two approaches. Although we compared between the transobturator and retropubic approaches in the "isolated and mixed SUI" and "isolated SUI" subgroups, the comparison between the two approaches in women with intrinsic sphincter deficiency (ISD) was ignored because of the lack of sufficient relative trials. In fact, several studies (14, 40) proved that the transobturator approach was inferior to the retropubic approach in the treatment of ISD in women. Thus, further research in this field is warranted.

Both the TVT-O and TOT approaches are recognized as associated with lower risks of bladder perforation and retropubic hematoma than the TVT. This review confirms the above-mentioned standpoint. However, some RCTs avoided the systematic use of cystoscopy with transobturator procedures (24, 29, 32-37, 39), and all the 3 cases of bladder perforation during the transobturator procedure were reported by the trials in which perioperative cystoscopy was routinely used for all the patients (26, 27). Thus, the real bladder perforation rate during transobturator procedures may be a little higher. Although previous research (41) suggests that systematic use of cystoscopy was

Figure 4 - Complications of the two procedures (TVTO and TOT) in comparison with TVT.



not necessary for transobturator approach, surgeons must be aware of the risk of bladder perforation, even with the transobturator procedure.

We found that the transobturator approach, especially the TVT-O procedure, was associated with a lower risk of long-term voiding dysfunction than the TVT. This result may be explained by the following, as reported by Juma (42) and Morey (43): the orientation of the transobturator tension-free midurethral sling was more similar to the natural hammock shape, as compared with the TVT procedure. As a result of lower shearing force to the urethra, the transobturator tape is more appropriate for women with slow urine flow rate.

Although we concluded that the risk of thigh/groin pain was higher in the transobturator group, the result was not persuasive owing to the lack of unified definition and description of the duration of pain. Some authors have reported that the hammock nature of the transobturator procedure decreases the risk of de novo urgency or urge incontinence (42). However, we found only insufficient evidence to sup-

port that claim, or that one approach leads to a lower risk of tape erosion.

Our study has potential limitations. First, the quality of the included trials was not good enough. For example, only one of the 16 trials had a single--blind design (24) and intention-to-treat analysis was performed only in one study (25). That may be a source of heterogeneity. Second, the criteria of objective and subjective cure, and complications such as pain were not consistent. These negative factors may cause bias and heterogeneity. Among our trials, the last one had the longest follow-up period of 36 months. The follow-up periods were too short to appropriately reflect long-term outcomes and complications.

In conclusion, the transobturator and retropubic approaches were equally effective for the treatment of SUI. In particular, the transobturator approach was associated with a decreased risk of complications. However, good-quality studies with long-term follow-up are warranted for further research.

CONFLICT OF INTEREST

None declared.

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