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Fusco, F., Abdel-Fattah, M., Chapple, C.R. orcid.org/0000-0002-2960-9931 et al. (4 more authors) (2017) Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. European Urology, 72 (4). pp. 567-591. ISSN 0302-2838

https://doi.org/10.1016/j.eururo.2017.04.026

Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings and midurethral tapes in the surgical treatment of female stress urinary incontinence

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ABSTRACT

CONTEXT: Retropubic (RT-TVT) and transobturator miurethral (TO-TVT) mid-urethral sling (MUS) are popular surgical treatments for female stress urinary incontinence (SUI). The long-term efficacy and safety of the procedures is still a topic of intense clinical research and several randomized controlled trials (RCTs) have been published in the last years

OBJECTIVE: To evaluate the efficacy and safety of MUS compared with other surgical treatments for female SUI.

EVIDENCE ACQUISITION: A systematic review and meta-analysis of the literature was performed using the Medline, Scopus, and Web of Science databases to update our previously published analyses.

EVIDENCE SYNTHESIS: Twenty-eight RCTs were identified. In total, the meta-analyses included 15,855 patients. Patients receiving MUS had significantly higher overall (odds ratio [OR]: 0.59;p=0.0003) and objective (OR: 0.51; p=0.001) cure rates than those receiving Burch colposuspension (BC). Patients undergoing MUS and pubovaginal slings had similar cure rates. Patients treated with RT-TVT had higher subjective (OR: 0.83; p=0.03) and objective (OR: 0.82; p=0.01) cure rates than those receiving TO-TVT. However, the latter had lower risk of intraoperative bladder or vaginal perforation (OR 2.4;p=0.0002), pelvic hematoma (OR 2.61;p=0.002), urinary tract infections (OR 1.31;p=0.04) and voiding lower urinary tract symptoms (LUTS) (OR 1.66;p=0.002). Sensitivity analyses limited to RCTs with follow-up durations >60 mo demonstrated similar outcomes for RP-TVT and TO-TVT. No significant differences in efficacy were identified comparing inside-to-out and outside-to-in TO-TVT but vaginal perforations were less common with the former (OR 0.21;p=0.0002).

CONCLUSIONS: The present analysis confirms the superiority of MUS over BC. The studies comparing insertion of RT-TVT and TO-TVT showed higher subjective and objective cure rates for the RP-TVT but at the cost of higher risks of some complications and voiding LUTS. Efficacy of

inside-out and outside-in techniques of TO-TVT insertion was similar, although the risk of vaginal perforation was lower in the inside-to-out TO-TVT.

PATIENT SUMMARY:

Retropubic and transobturator midurethral slings are a popular treatment for female stress urinary incontinence. The available literature suggest that those slings are either more effective or safer than other older surgical procedures. Retropubic tapes are followed with slightly higher continence rates as compared with the transobturator tapes but are associated with higher risk of intra- and postoperative complications.

KEY WORDS: stress urinary incontinence, Burch colposuspension, pubovaginal sling, stress urinary incontinence, retropubic vaginal tape, tension free tape, transobturator tape

ABSTRACT WORD COUNT: 298

MANUSCRIPT WORD COUNT: 3511

TAKE-HOME MESSAGES

The present analysis confirms the superiority of MUS over Burch colposuspension. The studies comparing insertion of RT-TVT and TO-TVT showed higher subjective and objective cure rates for the RP-TVT but at the cost of higher risks of some complications and voiding LUTS. Efficacy of inside-out and outside-in techniques of TO-TVT insertion was similar, although the risk of vaginal perforation was lower in the inside-to-out TO-TVT

INTRODUCTION

Surgical treatment is often the preferred option for women with stress urinary incontinence (SUI) who have failed conservative management strategies [1].

Several different surgical procedures have been reported, with synthetic midurethral slings (MUS) being the most commonly adopted surgical procedures. Several systematic reviews and meta-analyses of randomized controlled trials comparing the different surgical approaches have been reported [2-6]. In our previous systematic review, we have shown that women treated with retropubic tension-free vaginal tapes (RP-TVT) had slightly higher objective continence rates than those treated with Burch colposuspension (BC) but they faced a higher risk of intraoperative complications. RP-TVT and pubovaginal slings (PVS) were similarly effective, although patients with PVS were more likely to experience postoperative storage lower urinary tract symptoms (LUTS). RP-TVT were associated with objective cure rates slightly higher than transobturator tension-free vaginal tapes (TO-TVT) but subjective cure rates were similar. TO-TVT, however, had a lower risk of bladder/vaginal perforations and postoperative storage LUTS [4].

Furthermore, concerns have been raised on the use of synthetic mesh for surgical treatment of female SUI and prolapse surgery. That was primarily due to the risk of complications –including mesh exposure/erosion, dyspareunia, infections, and pain. The FDA issued a series of statements concluding that serious complications associated with transvaginal mesh for pelvic organ prolapse (POP) repair and are not un-common nevertheless they emphasized that this does not apply to use of mesh for SUI or abdominal surgery. However, very recently, a Scottish population-based study, demonstrated that mesh surgical procedures for SUI were associated with lower risk of early postoperative complications and subsequent prolapse surgery, as well as similar risks of further incontinence surgery and later complications, as compared with open colposuspension [7]. In late 2015, various working groups worldwide reported on the use of transvaginal mesh in Scotland, England, and Europe (SCENIHR) in surgical treatment of SUI and POP [8-10]. All have emphasized the need of further research in the field. Therefore, we elected to

update our previous meta-analyses of the literature in the field of primary surgical treatment of female SUI.

MATERIALS AND METHODS

The updated systematic review of the literature was performed in July 2014 and last updated on 1st November 2016 using the Medline, Scopus, and Web of Science databases. The Medline search used a complex search strategy including both medical subject heading (MeSH) and free text protocols, as was done in the previous reviews [2-4]. Specifically, the MeSH search was conducted by combining the following terms retrieved from the MeSH browser provided by Medline: Urinary Incontinence, Stress, and Suburethral Slings. Multiple "free text" searches were also performed, searching for the following terms individually in the fields title and abstract of the records: Urinar*incont*, TVT, tension-free vaginal tape*, Tension-free vaginal sling*, Transobturator tape*, Trans-obturator sling*, TVT-obturator, TVT-O, TOT, suprapubic arc sling*, SPARC sling*, intravaginal slingplasty, IVS sling, Uratape, ObTAPE, Prepubic sling*, Prepubic TVT, Prepubic tape*, PelviLace, Ureter, Aris, In-Fast, Monarc, I-Stop, and BioArc. Subsequently, the search results were pooled, and the following limits used: humans, Entrez Date from 2009/08/01. No limitations regarding language of publication or type of publication were used. The searches on Scopus, and Web of Science used only the free-text protocol, with the same key words. Subsequently, the query results were pooled and the same temporal limit applied. Moreover, Cochrane Database of Systematic Review was searched using the key word "urinary incontinence". Hand-search of congress abstracts was not performed.

A total of 958 records were retrieved from Medline, 1789 from Scopus, and 1477 from Web of Science. Four of the authors reviewed the full texts to select the papers relevant to the review topic. Specifically, all the RCTs, discussing outcomes (ie, continence rates, satisfaction rates, complication rates) from the use of MUS as predominantly primary surgical treatment of SUI were

selected. RCTs reporting on the use of MUS exclusively in patients who had previously failed other surgical treatments were excluded. The selected papers were categorized according to the grade of evidence: an adequately sampled single RCT was considered to have level 1b evidence; a low-quality RCT to have level 2b evidence [11]. The quality of the retrieved RCTs was assessed using the Jadad score [12].

To evaluate the efficacy of the different procedures, both objective criteria (stress test, pad test, urodynamics) and subjective criteria (patients' perception of the clinical improvement, expressed by validated questionnaires, institutional questionnaires, or open interview) were considered. In the case of papers reporting patient outcomes through the use of mixed subjective and objective end points (eg, no referred leakage and negative stress test, no referred leakage and negative pad test), an overall continence rate was shown. Whenever multiple reports at different follow-up duration were available for a RCT, the figures from the reports with longest follow-up were considered.

Meta-analysis was conducted using Review Manager software v. 4.2 (Cochrane Collaboration, Oxford, UK). Specifically, statistical heterogeneity was tested using the chi-squared test. A value of $p < 0.10$ was used to indicate heterogeneity. In the case of a lack of heterogeneity, fixed-effects models were used for the meta-analyses. The results were expressed as weighted means difference (WMD) and standard deviations for continuous outcomes and as an odds ratio (OR) with a 95% confidence interval (CI) for dichotomous variables. In the comparisons of RP-TVT and TO-TVT, the large number of publications with appropriate data allowed us to perform subgroup analyses according to the device used. In this case, we differentiated retropubic TVT^{TM} vs inside-to-out trasobturator (TVT-O^{TM}), retropubic TVT^{TM} vs outside-to-in TO tapes (including different kits) and other retropubic vs other transobutaror tapes (reporting studies where either retropubic tapes different from TVT^{TM} were used or studies where both inside-to-out and outside-to-in TO tapes were used without differentiating the results). No covariate adjustments were performed, as usually done in the Cochrane collaboration systematic reviews of RCTs.

For all the comparisons, sensitivity analyses limited to RCTs of good methodological quality (i.e., those with a Jadad score ≥3) and to RCTs with follow-up duration ≥ 60 months were performed. The presence of publication bias was evaluated through a funnel plot, as previously reported [13]. The study complied with the recently reported Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [14].

RESULTS

Figure 1 summarizes the literature review process which lead to the identification of the 30 papers reporting data from 28 different RCTs used to update the meta-analysis (Figure 1).

Specifically, two papers compared MUS and BC [15, 16]; three papers compared MUS and PVS [17-19]; 20 papers compared RP-TVT and TO-TVT [20-39]; two papers compared RP-TVT and 2 different types of TO-TVT [40; 41]; 3 studies compared different TO-TVT [42-44].

Seventeen reports were from 15 high-quality RCTs [16, 19, 21-25, 27-29, 32-34, 38, 41-43].

Only 7 RCTs reported outcomes of surgery at a follow-up interval ≥ 60 mo [16, 19, 21, 34, 37-39].

In total, the metaanalyses included 15,855 patients.

Randomized controlled trials comparing midurethral tapes to Burch colposuspension

Supplemental Table 1 in the appendix summarizes the results of the only 2 new RCTs reporting continence, and complication rates following MUS or BC as primary treatment for stress urinary incontinence. Of note, all BCs in these 2 new RCTs had been performed laparoscopically.

Fig. 2 shows the forest plots concerning the meta-analyses of continence rates following MUS or BC.

MUS were associated with significantly higher cure rates compared to BC, considering success rates evaluated according to any definition of continence (8~~1.8~~2% vs 7~~3.6~~4%, respectively; OR:

0.59; 95% CI: 0.45–0.79; p = 0.0003; Fig. 2a), and objective continence rates (negative stress test: 79.7% vs 67.8%, respectively; OR: 0.51; 95% CI: 0.34–0.76; p = 0.001; Fig. 2b). Notably, stratifying the BC outcomes according to the surgical approach (open vs laparoscopic), the significant difference in favor of MUS pertained for "any definition of continence" and "objective continence rates". Similarly, there was some evidence of an effect in favor of MUS as compared to laparoscopic BC for "any definition of continence" but it did not meet conventional levels of statistical significance (OR,0.49 95%CI 0.23, 1.04, p=0.06 – Figure 2-A).

Subgroup analyses limited to the 3 studies with follow-up duration ≥60 months demonstrated better objective cure rate for MUS (OR: 0.54; 95% CI: 0.36–0.82; p = 0.004) but only a non-statistically significant trend for overall continence rate (OR: 0.39; 95% CI: 0.15–1.03; p = 0.06) and subjective continence rate (OR: 0.69; 95% CI: 0.45–1.06; p = 0.09)

Randomized controlled trials comparing midurethral tapes to pubovaginal slings

Supplemental Table 2 in the appendix summarized the results of the new RCTs reporting continence, and complication rates following MUS or PVS as primary treatment for stress urinary incontinence.

Fig. 3 shows the forest plots concerning the metaanalyses of cure, and complication rates.

On the whole, MUS and PVS were associated with similar effectiveness and similar prevalence of complications. However, there was there was some evidence of an effect in favor of MUS for re-operation rates but it did not meet conventional levels of statistical significance (3.9% vs 7.7%, respectively; OR 0.5; p=0.06 – Figure 3-G).

Only one single RCT had a follow-up duration ≥ 60 mo [19].

Randomized controlled trials comparing retropubic with transobturator tape

Supplemental Table 3 and 4 in the appendix summarize continence, complication, and reoperation rates of the RCTs comparing RP-TVT and TO-TVT as "primary" treatment for SUI.

Fig. 4 shows the forest plots concerning the metaanalyses of continence, complication, and reoperation rates.

Objective (86% vs 84%, respectively; OR: 0.82; 95% CI: 0.70–0.96; p = 0.01; Fig. 4b) and subjective (78% vs 74%, respectively; OR: 0.83; 95% CI: 0.70–0.98; p = 0.03; Fig. 4c) continence rates were superior in RP-TVT, whereas overall continence rate was similar with RP-TVT and TO-TVT. Considering "any definition of cure" there was no statistical significance between RP-TVT and TO-TVT groups (OR 1.16, 95%CI: 0.89-1.51, p=0.27 – Figure 4-A).

With regards to complications, risk of intraoperative bladder or vaginal perforation (4.8% vs 1.6%, respectively; OR 2.4; 95% CI 1.51 – 3.90; p = 0.0002; Fig. 4-D), pelvic hematoma (1.7% vs 0.3%, respectively; OR 2.61; 95% CI 1.41 – 4.82; p = 0.002; Fig. 4-E), urinary tract infections (10% vs 7.9%, respectively; OR 1.31; 95% CI 1.02 – 2.68; p = 0.04; Fig. 4-G) and voiding LUTS (9.2% vs 5.7%, respectively; OR 1.66; 95% CI 1.2 – 2.3; p = 0.002; Fig. 4-I) were significantly higher in RP-TVT. Conversely, the risk of vaginal erosion was lower in RP tapes (1.8% vs 2.8%, respectively; OR 0.64; 95% CI 0.44 – 0.92; p = 0.002; Fig. 4-F), which was mainly due to the higher risk of vaginal erosions in outside-to-in TO-TVT. Finally, rates of storage LUTS, clean intermittent self-catheterization (CISC)/recatheterization, and re-operation were similar in RP-TVT and TO-TVT tapes.

Table 1 summarizes sensitivity analyses performed on high quality RCTs. Such analyses reconfirmed advantages for RP-TVT in terms of objective cure rates (OR 0.76; p = 0.006) and risk of vaginal erosions (OR 0.56; p = 0.03), whereas bladder/vaginal perforations were less prevalent with TO tapes (OR 1.41; p = 0.002).

Further sensitivity analyses limited to the 5 RCTs with follow-up durations >60 mo [21, 34, 37-39] demonstrated similar outcomes for RP-TVT and TO-TVT in terms of objective cure rate, subjective cure rate, vaginal erosions, storage and voiding LUTS, and reoperation rates (see supplemental figure 1).

Randomized controlled trials comparing different transobturator midurethral tapes

Supplemental Tables 5 and 6 in the appendix summarize continence, complication, and reoperation rates of the RCTs comparing different TO-TVT tapes as the treatment for primary SUI.

Fig. 5 shows the forest plots concerning the metaanalyses of continence, complication, and reoperation rates.

No significant differences in efficacy were identified comparing inside-to-out and outside-to-in TO-TVT. Regarding complications, vaginal perforations were less common with the inside-to-out TO-TVT (2.6% vs 11.8%, respectively; OR 0.21; p = 0.0002). Moreover, there was also a non-statistically significant trend for vaginal erosions in favor of inside-to-out TO-TVT (OR 0.37; p = 0.06). All the other complications were similarly prevalent inside-to-out and outside-to-in TO-TVT.

No RCT has follow-up duration ≥ 60 mo.

Publication bias

Funnel plots of all the studies used in this meta-analysis were generated for all the evaluated comparisons. Only few studies lay outside the 95% CI with an even distribution about the vertical, suggesting little evidence of publication bias (data not extensively shown).

DISCUSSION

Surgical treatment is the standard approach for women with SUI who have failed conservative management **[**45**]**. More than 200 surgical procedures have been described over time. However, BC,

PVS and MUS are the most popular and effective surgical treatments for woman with SUI [46]. To date, MUS represent the most frequently used surgical intervention in Europe for women with SUI [45]**.** Current EAU guidelines recommend MUS in women with uncomplicated SUI as the preferred surgical intervention and BC (either open or laparoscopic) or autologous PVS in women with SUI if MUS cannot be considered **[**45**].** In 2010, in a previous systematic review and meta-analyses of RCTs evaluating the efficacy, complication, and reoperation rates of MUS compared with other surgical treatments for female SUI, Novara et al previously showed a statistically significant higher overall and objective cure rates in favor of MUS compared to BC, although at the cost of a statistically significant higher risk of bladder and vaginal perforations. The comparison between MUS and PVS showed similar overall and subjective cure rates although the safety profile was different. MUS were associated with higher risk of bladder perforation while the incidence of storage LUTS and the reoperation rate were higher among patients undergoing PVS [4]. The comparison between retropubic and trans-obturator routes for MUS placement showed a slightly higher objective cure rate in favor of the former although subjective cure rates were similar. Again, the safety profile was different: TO-TVT were associated with a lower risk of bladder and vaginal perforations, hematoma, and storage LUTS. Conversely, the incidence of vaginal erosion was higher among patients receiving TO-TVT and was mainly due to the higher risk of vaginal erosions in outside-to-in TO-TVT. The reoperation rate, the incidence of urinary tract infections, and the need for clean intermittent catheterization or re-catheterization was similar between the two techniques. Finally, based only on the evidences from three available RCTs, the meta-analysis demonstrated similar outcomes for the inside-out and outside-in procedures in terms of objective and subjective cure rates and safety profile [4].

Despite being based on many trials of good methodological quality, that meta-analysis had some limitations such as heterogeneity of outcomes measures and the lack of RCTs with long term follow-up as only two studies reported data at follow-up ≥ 60 months. Due to the fact that several RCTs have been published in the field since the publication of that report, we elected to update our

previous meta-analysis. The updated comparison among MUS and BC reconfirmed the superiority of MUS in terms of overall and objective continence rates as well as the equivalence in terms of subjective continence rates. Those results were mainly determined by the differences observed between MUS and open BC. Similarly, there was a trend towards more favorable outcomes with MUS compared to laparoscopic BC in all sub-analyses. Sensitivity analyses limited to the RCTs with follow-up duration ≥60 mo reconfirmed the advantages in terms of objective continence rates, whereas only non-statistically significant trend in favor of MUS was found for overall and subjective continence rates.

With regards of the comparison among MUS and PVS, the present analysis reconfirmed the absence of significant differences between both groups in terms of overall and subjective continence rates, as well as prevalence of pelvic hematoma, vaginal erosions, voiding LUTS. Conversely, the incidence of storage LUTS was significantly lower in patients treated with MUS. Notably, while the previous meta-analysis showed higher re-operation rate in patients receiving PVS, the present report showed a similar trend but did not reach statistical significance.

On comparing RP-TVT and TO-TVT, we found overall higher objective and subjective continence rates in patients treated with RP-TVT. However, although statistically significant, such difference in success rates were minimal (just 2% and 4% difference in objective and subjective cure rates, respectively) and probably of marginal clinical relevance if we consider the difference in complication rates. Interestingly, the study by Costantini et al. found that the long-term continence rate after MUS placement tended to decrease in patients who underwent TO-TVT, whereas remained stable for those who underwent RP-TVT [37]. Yet, our estimations including only RCTs with at least 5-year follow-up did not show any difference in objective or subjective cure rates between the retropubic and transobturator approaches. Except for vaginal erosions, our results showed the transobturator approach to be associated with lower risk of most intraoperative and postoperative complications, which is the main reasons why TO-TVT is now preferred by most surgeons for the primary surgical treatment of female over RP-TVT. Reassuringly, the above results

pertained on sensitivity analyses limited to the RCTs of highest methodological quality. In the end, retropubic approach might offer a slight advantage over the transobturator approach in terms of objective success rates but at the costs of higher complication rate.

With regard to the comparison between inside-out and outside-in TO-TVT, we found no statistically significant differences between the two surgical approaches in terms of continence rates, whereas the risk of vaginal perforation was lower in inside-to-out TO-TVT. Moreover, there was also a clear trend in favor of inside-to-out TO-TVT for vaginal erosions, although it did not reach statistical significance.

There has been a growing interest in the likehood of chronic pain and dyspareunia following MUS. In our review, only a limited number of RCTs reported on long-term pain following surgery for SUI. Kenton et al reported a few cases of long-term pain at 5-yr follow-up following RP-TVT or TO-TVT [47]. Interestingly, Khan et al. reported presence of scar pain also following autologous PVS, indicating that such risk is not limited to MUS [19]. Two recent studies reported 6.4% and 9% groin/inguinal pain/discomfort at 7 and 10-years follow-up respectively following TO-TVT [39,49]. Intractable suprapubic pain has been previously described following colposuspension and defined as post-colposuspension syndrome. Even less data are available on long-term prevalence of dyspareunia in patients receiving MUS for SUI. The available RCTs have reported just a few cases of de novo dyspareunia [32, 44]. However, the available literature seems to suggest improvements in sexual function for the sexually active patients treated with MUS for SUI [50-51].

The present study has several strengths. First, represents the most up-to-date and most comprehensive summary of the currently available evidence in surgical treatments of female SUI, including the most commonly adopted surgical treatments, with the only exception of the single-incision mini-sling. That choice was in line with the inclusion and exclusion criteria set at the moment of the original systematic reviews and meta-analyses [2-4]. Moreover, a recent systematic review and meta-analysis published by Mostafa el at. [48], demonstrating similar

outcome for mini-slings and traditional MUS. However, most of the available RCTs reported only short- or intermediate-term follow-up data. Secondly, the paper complies with the currently available standard to report systematic review and meta-analysis [14]. Finally, the review included a relatively high number of RCTs with long-term follow-up (≥60 months) which bridges a significant gap in the current literature. Taken together, those data corroborate the findings of the previous reports of ours with stronger results based on large number of patients included in analyses and, above all, larger number of studies with follow-up duration ≥60 months.

However, we acknowledge a number of limitations. First, a small percentage of the patients included in some RCTs had already received previous surgical treatments for SUI. However, such percentage was extremely low. Similar to our previous reports, the evaluation of subjective and objective outcomes was heterogeneous and not all studies utilized validated questionnaires. Although the number of studies with follow-up ≥ 60 months was higher with respect to previous meta-analysis, the short duration of the follow-up remains a limit of available literature as most studies report short- or intermediate-term follow-up. Limited data were available of potentially interesting outcomes such as long-term pain and dyspareunia. Moreover, the accuracy of complication reporting is limited in most RCTs, not complying with the standardized Martin criteria [52]. Finally, studies comparing MUS to other surgical treatments, such as bulking agent injections are lacking.

CONCLUSIONS

Overall, the literature summarized in this updated meta-analysis confirms the superiority of MUS over Burch colposuspension and PVS for the treatment of primary female SUI. MUS are significantly more effective than BC in terms of overall and objective continence rates. Although equivalent to PVS in terms of overall and subjective continence rates, MUS show a statistically significant lower incidence of storage LUTS. The studies comparing insertion of the MUS by the

retropubic and transobturator routes showed a slightly higher rate of objective cure rate in favor of the RP-TVT but at the cost of higher risks of intra-operative complications and voiding LUTS. No significant differences emerged from comparison of inside-out and outside-in techniques of TO-TVT insertion with regard to efficacy, although the risk of vaginal perforation and, in a lower extent, of vaginal erosions were more favorable in the inside-to-out TO-TVT. The heterogeneity in outcome measures and the lack of RCTs with long-term follow-up remain major limits of available literature.

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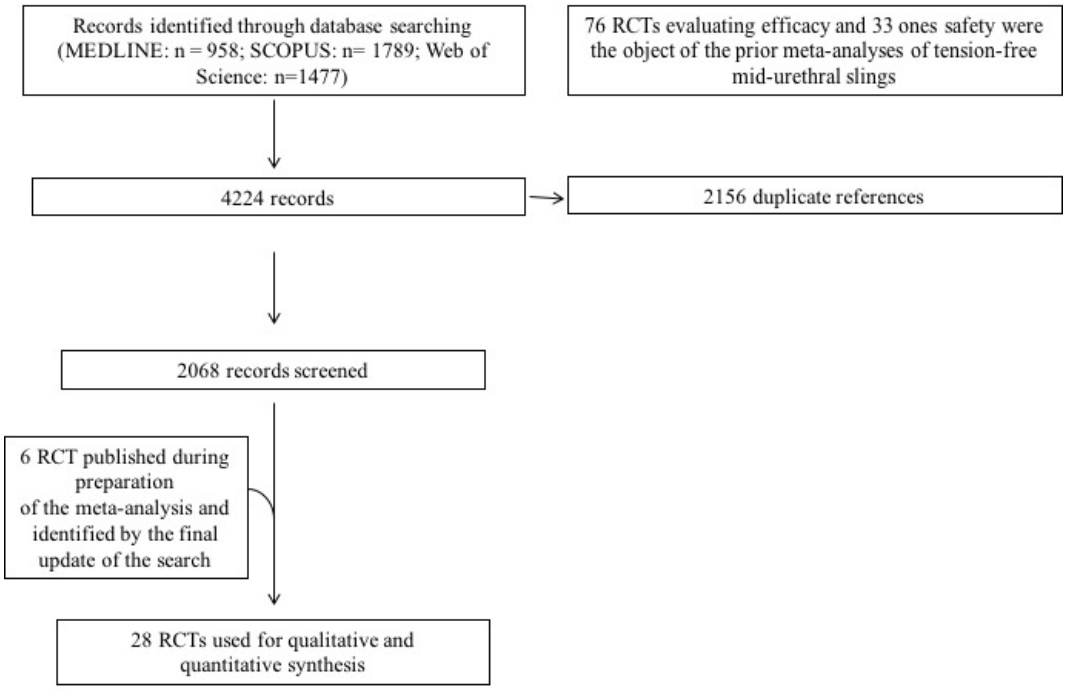
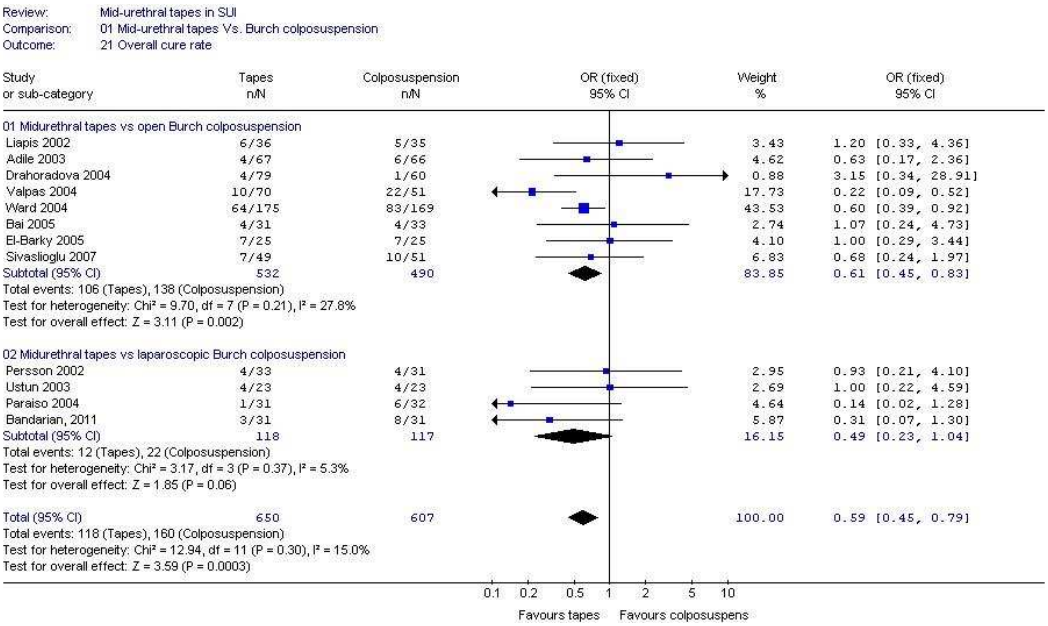
Figure 1: Fig. 1 – Flow diagram of the systematic review and meta-analysis.



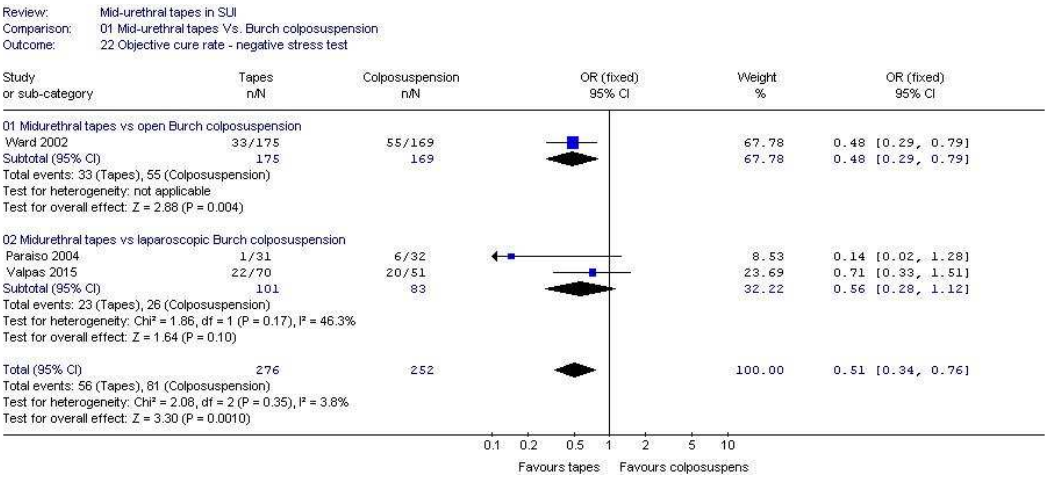
RCT = randomized controlled trial

Figure 2: Forest plots of comparisons after midurethral tapes and Burch colposuspension: Overall cure rate: continence rate according to (a) any definition of continence; (b) objective continence rate; (c) subjective continence rate;

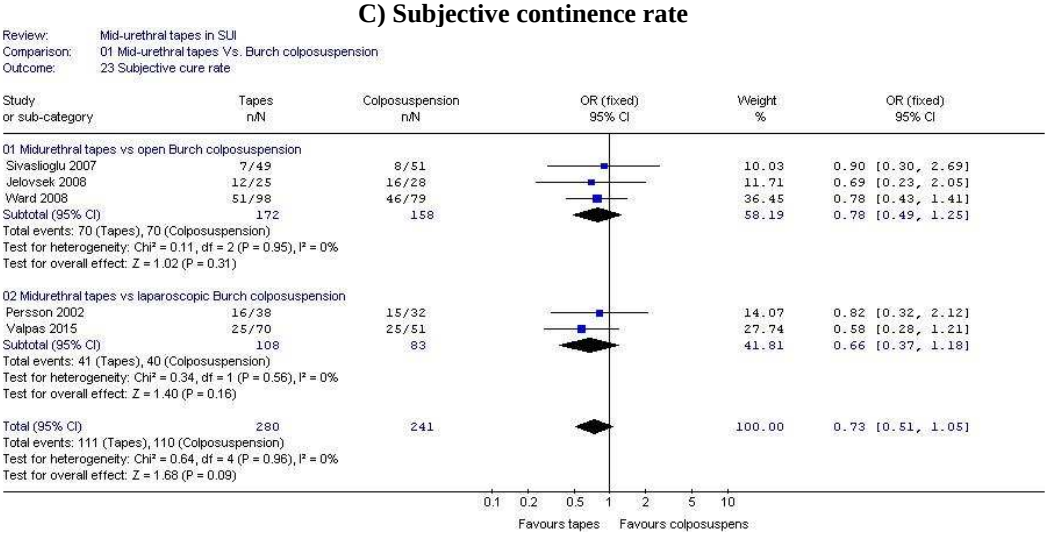
A) any definition of continence



B) Objective continence rate



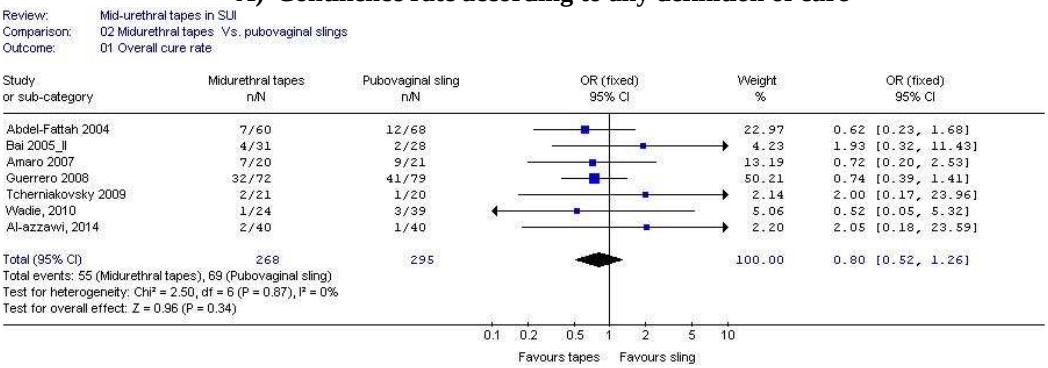
C) Subjective continence rate



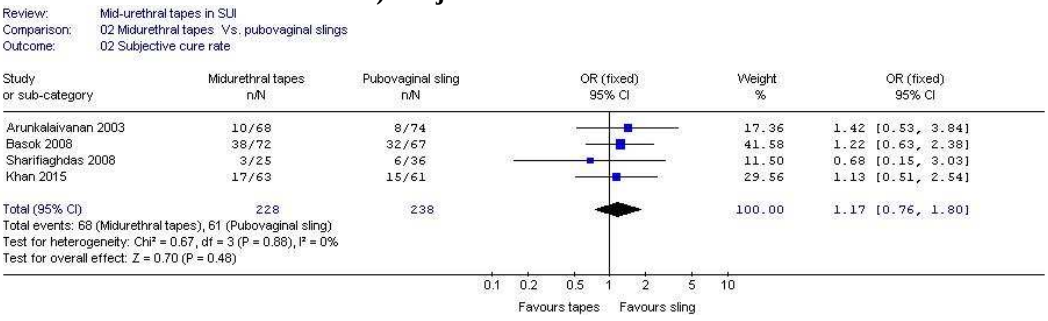
CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

Fig. 3 – Forest plots of comparisons after midurethral tapes and pubovaginal sling: (a) Continence rate according to any definition of continence; (b) subjective continence rate; (c) pelvic hematoma; (d) vaginal erosions: (e) storage lower urinary tract symptoms; (f) voiding lower urinary tract symptoms; (g) reoperation rate.

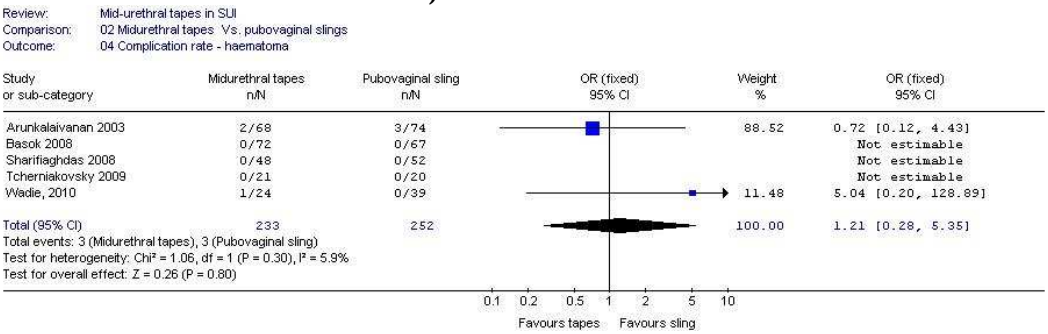
A) Continence rate according to any definition of cure



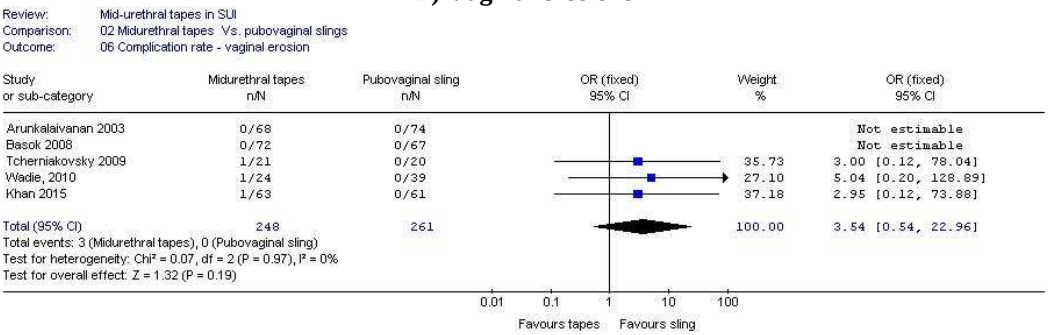
B) Subjective continence rate



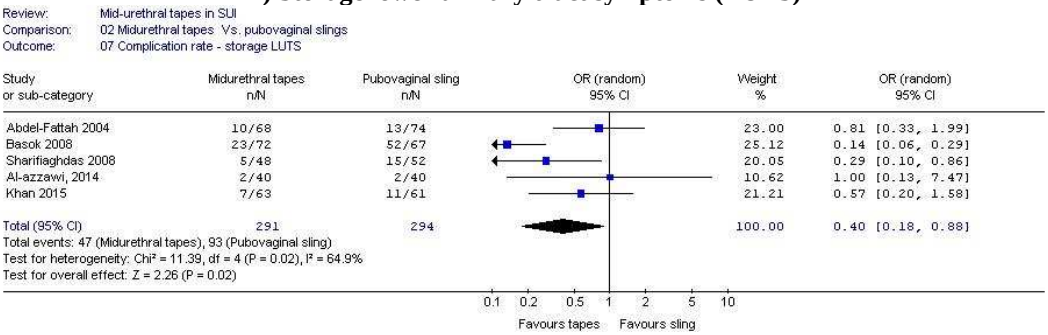
C) Pelvic hematoma



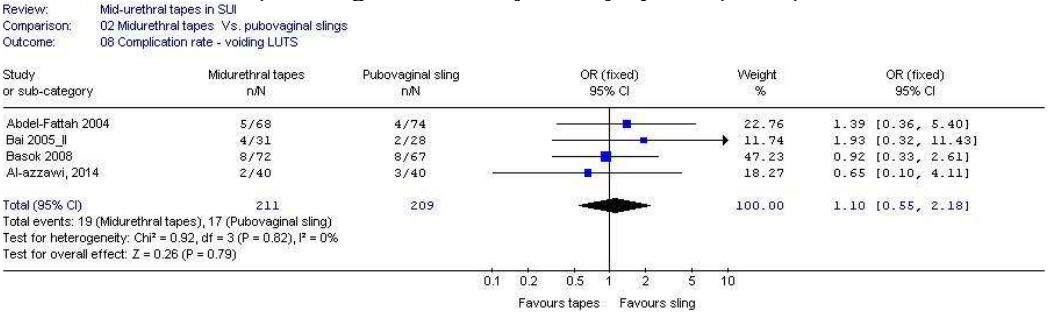
D) Vaginal erosions



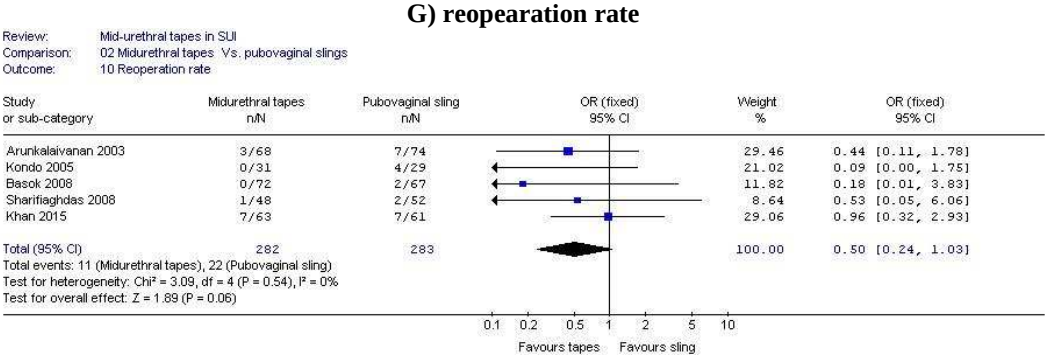
E) Storage lower urinary tract symptoms (LUTS)



F) Voiding lower urinary tract symptoms (LUTS)



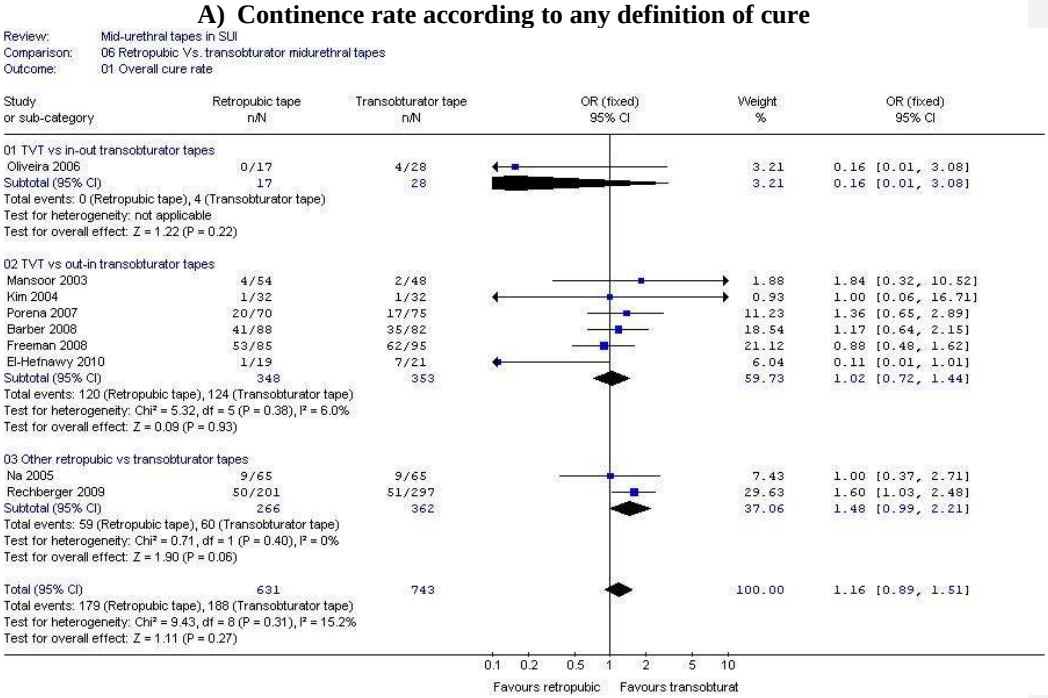
G) reopearation rate



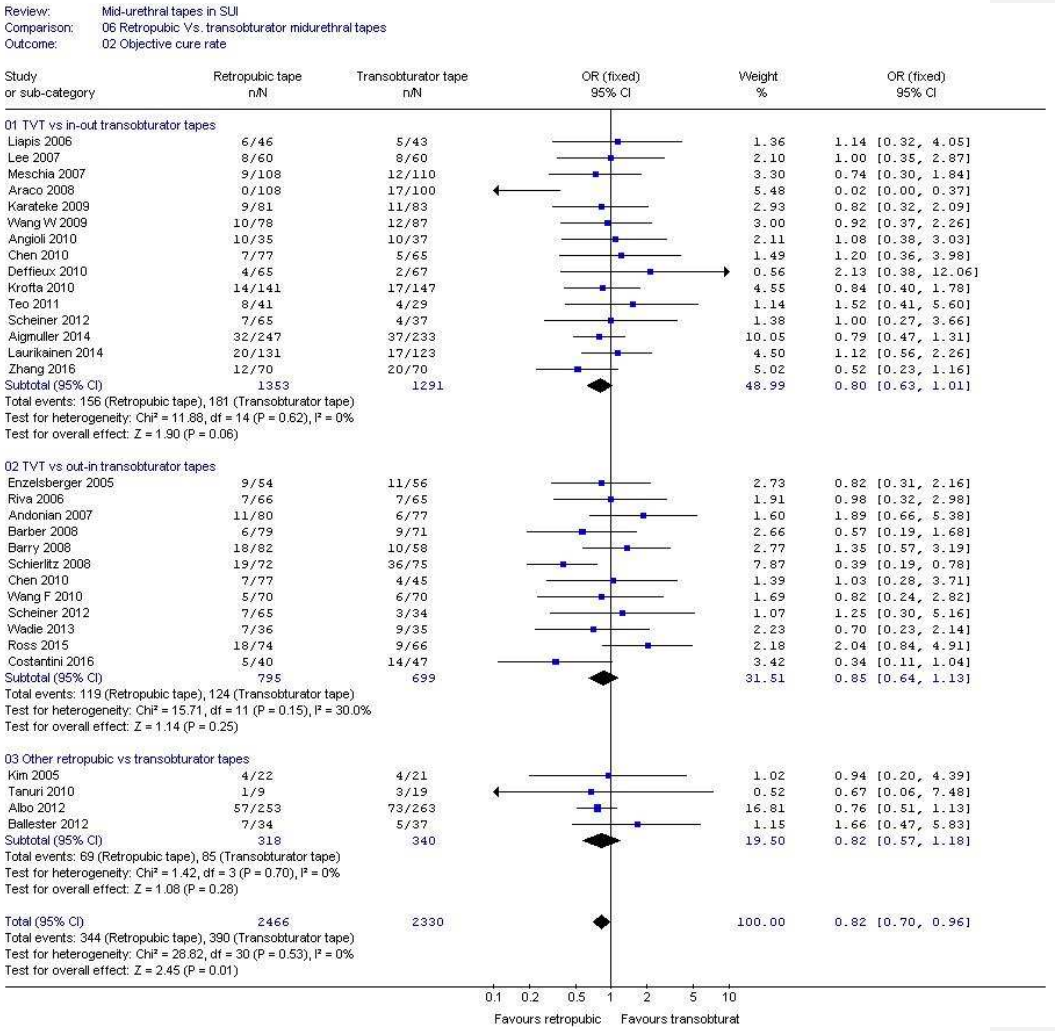
CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

Fig. 4 – Forest plots of comparisons after retropubic tape and transobturator tape. (a) Continence rate according to any definition of cure; (b) objective continence rate; (c) subjective continence rate (nonvalidated questionnaire); (d) bladder or vaginal perforation; (e) hematoma; (f) vaginal erosion; (g) urinary tract infection; (h) storage lower urinary tract symptoms (LUTS); (i) voiding LUTS; (j) need of clean intermittent catheterization or recatheterization; (k) reoperation rate.

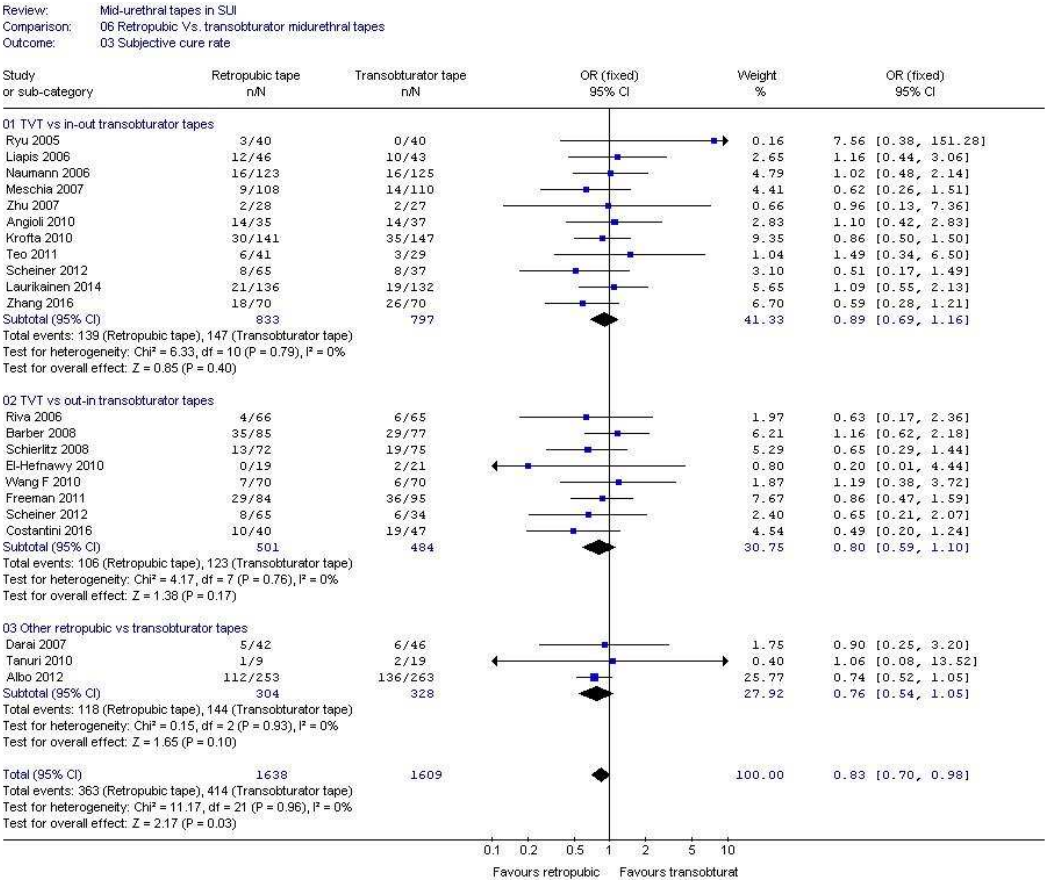
A) Continence rate according to any definition of cure



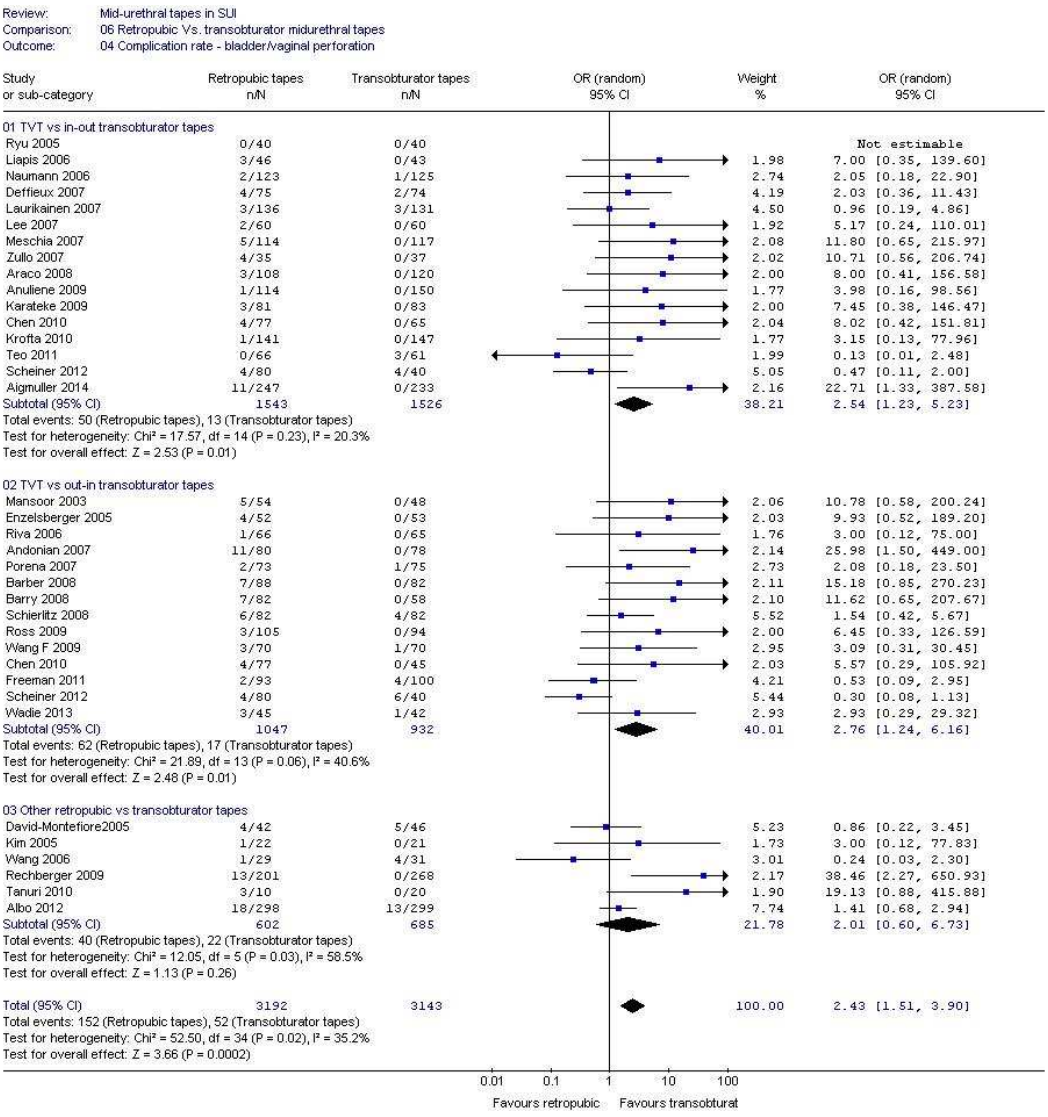
B) objective continence rate



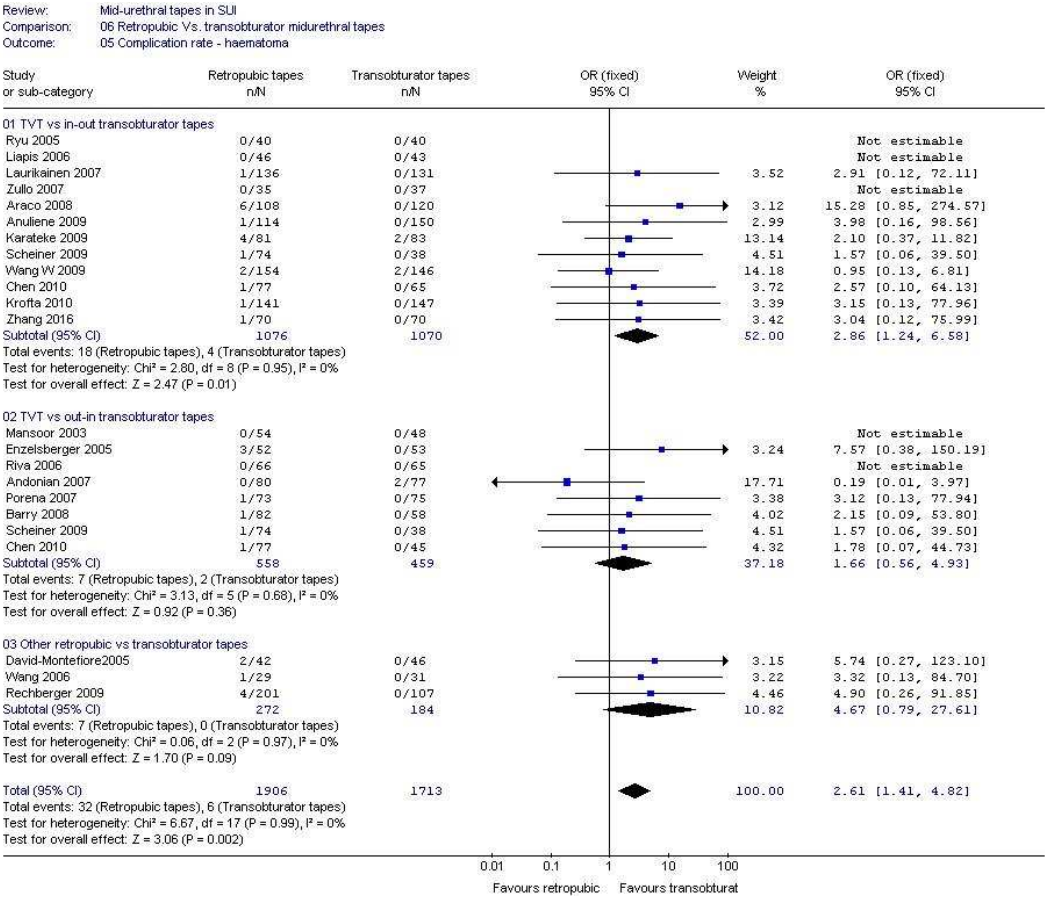
C) subjective continence rate



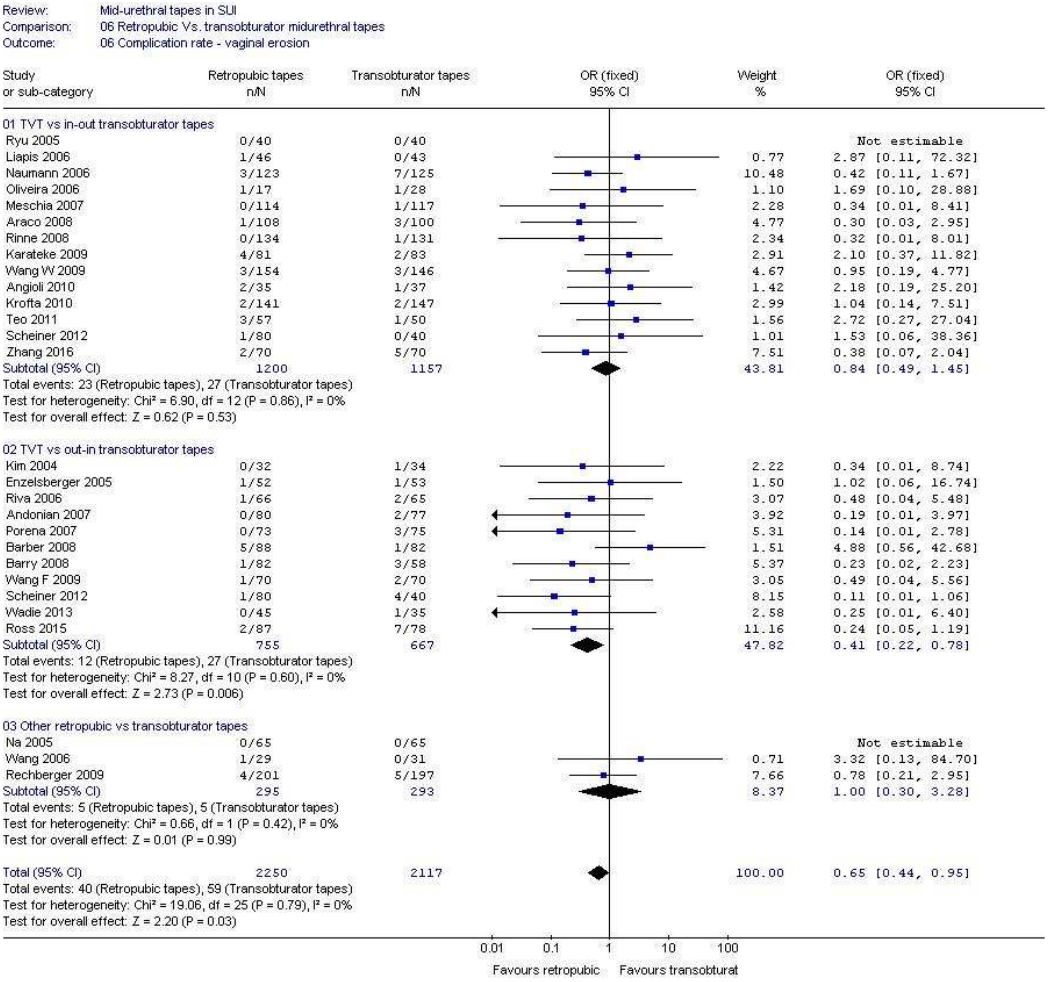
D) Intraoperative bladder or vaginal perforation



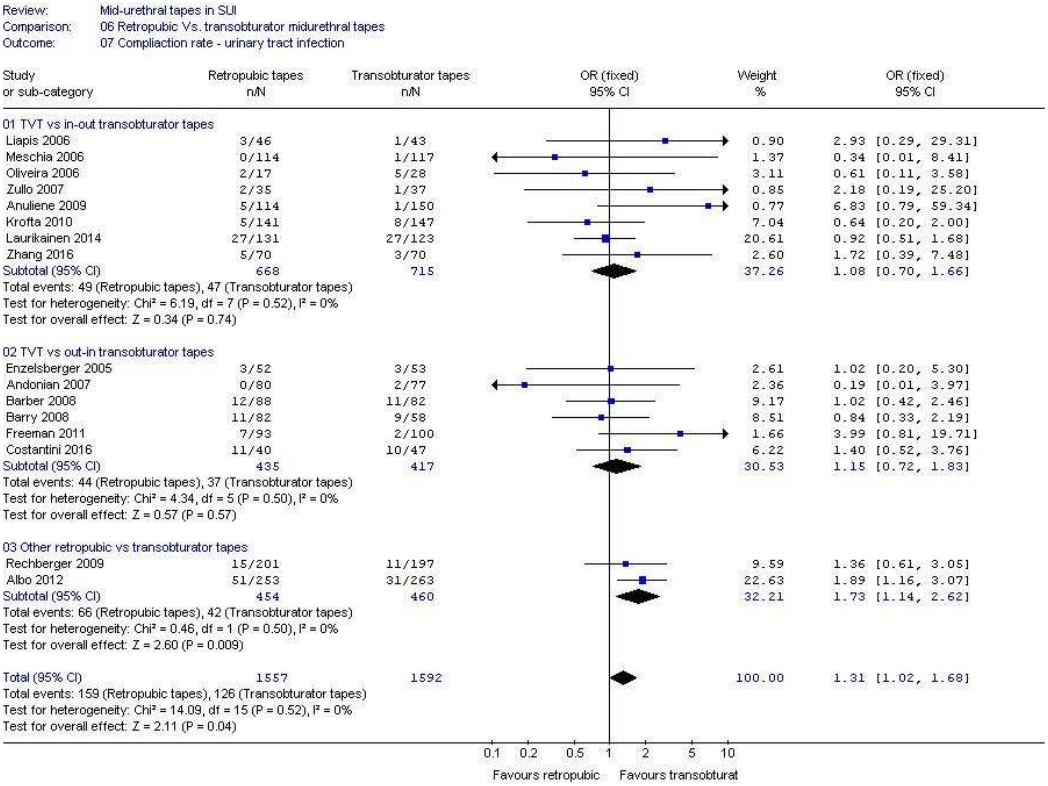
E) hematoma


Review: Mid-urethral tapes in SUI
Comparison: 06 Retropubic Vs. transobturator midurethral tapes
Outcome: 05 Complication rate - haematoma
Study or sub-category
Retropubic tapes n/N
Transobturator tapes n/N
OR (fixed) 95% CI
Weight %
OR (fixed) 95% CI
01 TVT vs in-out transobturator tapes
Ryu 2005 0/40 0/40 Not estimable
Liapis 2006 0/46 0/43 Not estimable
Laurikainen 2007 1/136 0/131 3.52 2.91 [0.12, 72.11]
Zullo 2007 0/35 0/37 Not estimable
Araco 2008 6/108 0/120 3.12 15.28 [0.85, 274.57]
Anuliene 2009 1/114 0/150 2.99 3.98 [0.16, 98.56]
Karateke 2009 4/81 2/83 13.14 2.10 [0.37, 11.82]
Scheiner 2009 1/74 0/38 4.51 1.57 [0.06, 39.50]
Wang W 2009 2/154 2/146 14.18 0.95 [0.13, 6.81]
Chen 2010 1/77 0/65 3.72 2.57 [0.10, 64.13]
Krofta 2010 1/141 0/147 3.39 3.15 [0.13, 77.96]
Zhang 2016 1/70 0/70 3.42 3.04 [0.12, 75.99]
Subtotal (95% CI) 1076 1070 52.00 2.86 [1.24, 6.58]
Total events: 18 (Retropubic tapes), 4 (Transobturator tapes)
Test for heterogeneity: Chi² = 2.80, df = 8 (P = 0.95), I² = 0%
Test for overall effect: Z = 2.47 (P = 0.01)
02 TVT vs out-in transobturator tapes
Mansoor 2003 0/54 0/48 Not estimable
Enzelsberger 2005 3/52 0/53 3.24 7.57 [0.38, 150.19]
Riva 2006 0/66 0/65 Not estimable
Andonian 2007 0/80 2/77 17.71 0.19 [0.01, 3.97]
Porena 2007 1/73 0/75 3.38 3.12 [0.13, 77.94]
Barry 2008 1/82 0/58 4.02 2.15 [0.09, 53.80]
Scheiner 2009 1/74 0/38 4.51 1.57 [0.06, 39.50]
Chen 2010 1/77 0/45 4.32 1.78 [0.07, 44.73]
Subtotal (95% CI) 558 459 37.18 1.66 [0.56, 4.93]
Total events: 7 (Retropubic tapes), 2 (Transobturator tapes)
Test for heterogeneity: Chi² = 3.13, df = 5 (P = 0.68), I² = 0%
Test for overall effect: Z = 0.92 (P = 0.36)
03 Other retropubic vs transobturator tapes
David-Montefiore2005 2/42 0/46 3.15 5.74 [0.27, 123.10]
Wang 2006 1/29 0/31 3.22 3.32 [0.13, 84.70]
Rechberger 2009 4/201 0/107 4.46 4.90 [0.26, 91.85]
Subtotal (95% CI) 272 184 10.82 4.67 [0.79, 27.61]
Total events: 7 (Retropubic tapes), 0 (Transobturator tapes)
Test for heterogeneity: Chi² = 0.06, df = 2 (P = 0.97), I² = 0%
Test for overall effect: Z = 1.70 (P = 0.09)
Total (95% CI) 1906 1713 100.00 2.61 [1.41, 4.82]
Total events: 32 (Retropubic tapes), 6 (Transobturator tapes)
Test for heterogeneity: Chi² = 6.67, df = 17 (P = 0.99), I² = 0%
Test for overall effect: Z = 3.06 (P = 0.002)
0.01
0.1
1
10
100
Favours retropubic
Favours transobturat

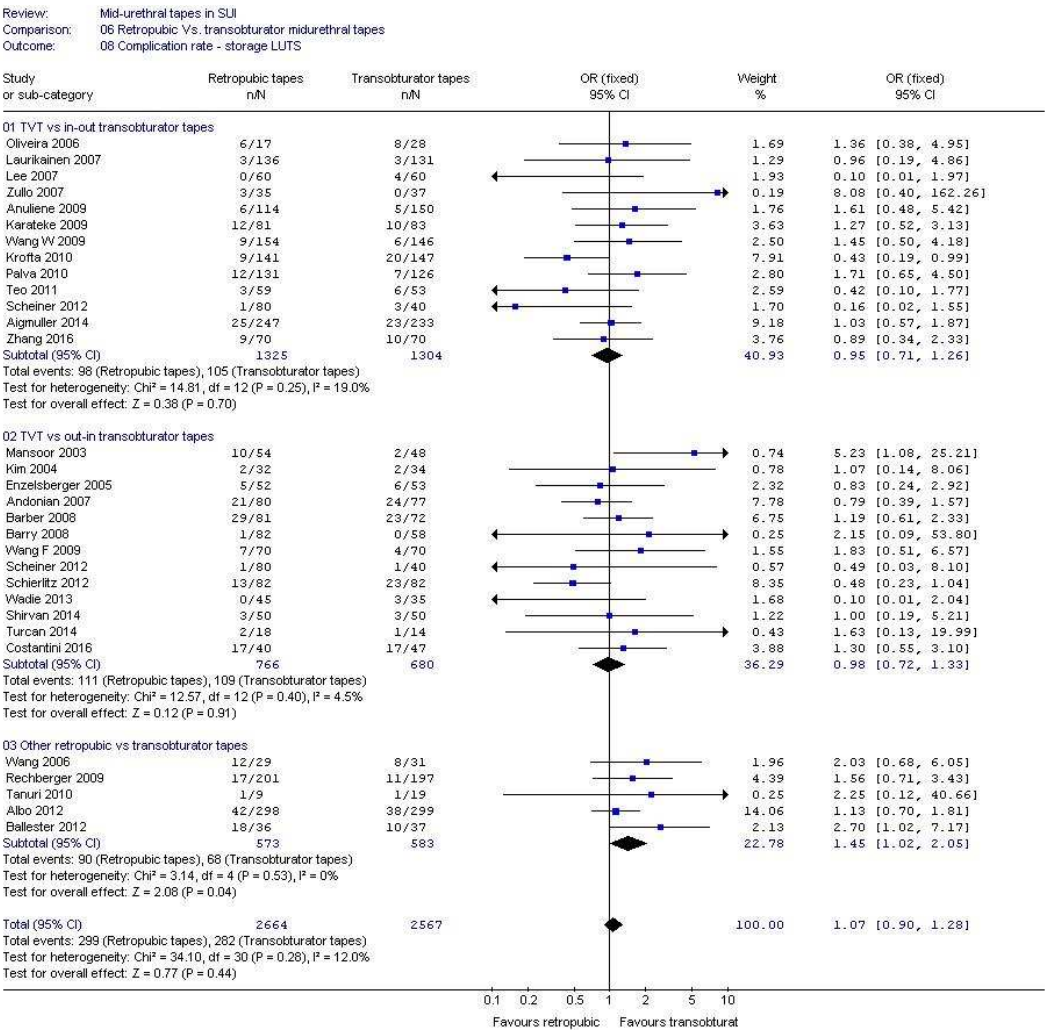
F) vaginal erosion



G) urinary tract infection

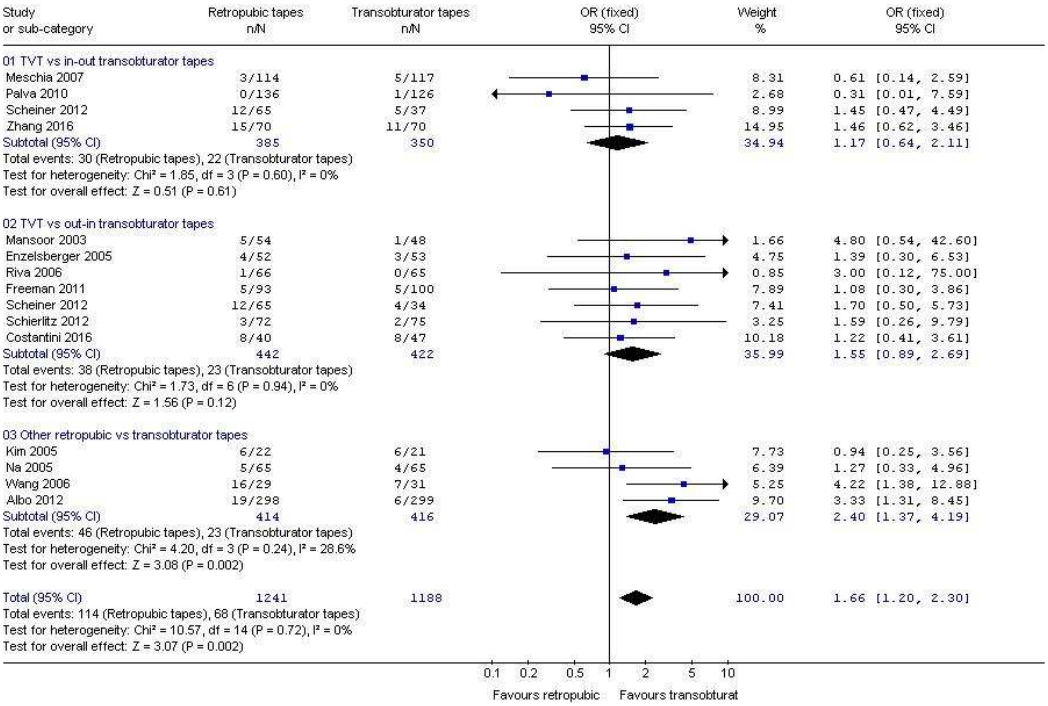


H) storage lower urinary tract symptoms (LUTS)

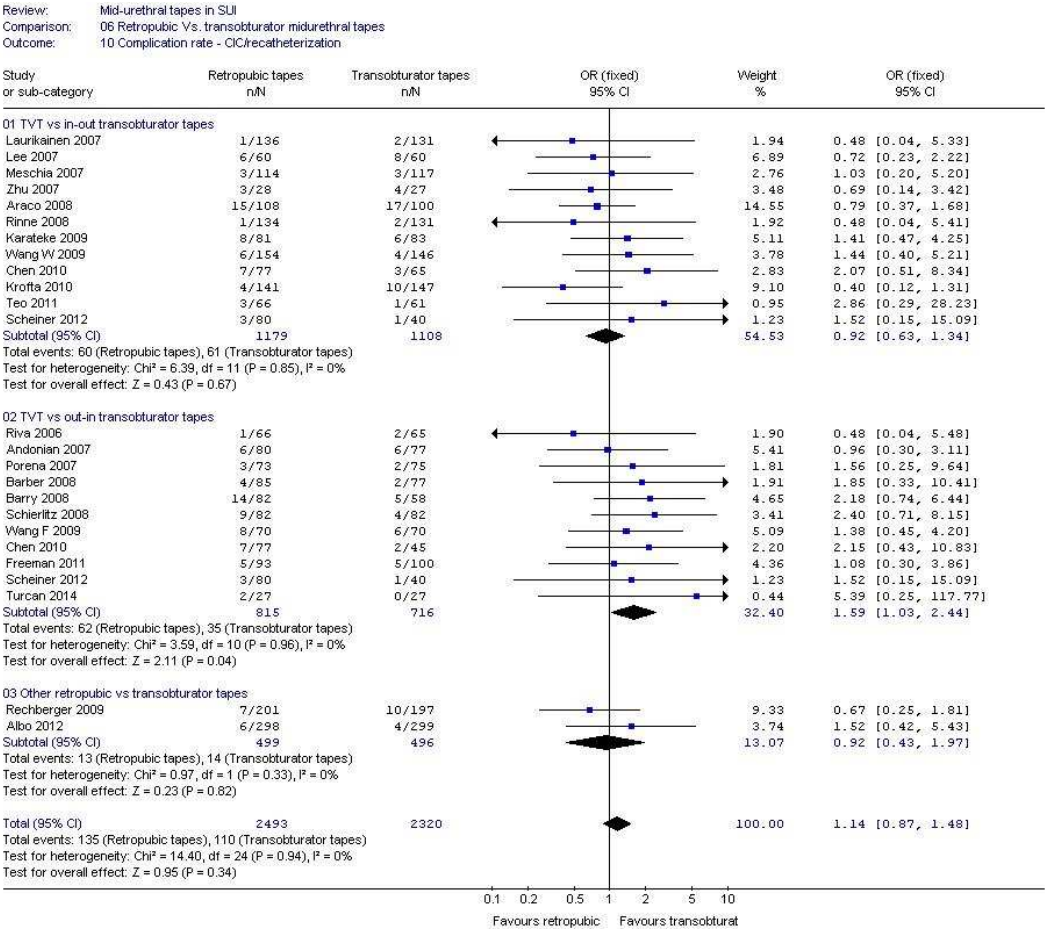


I) voiding LUTS

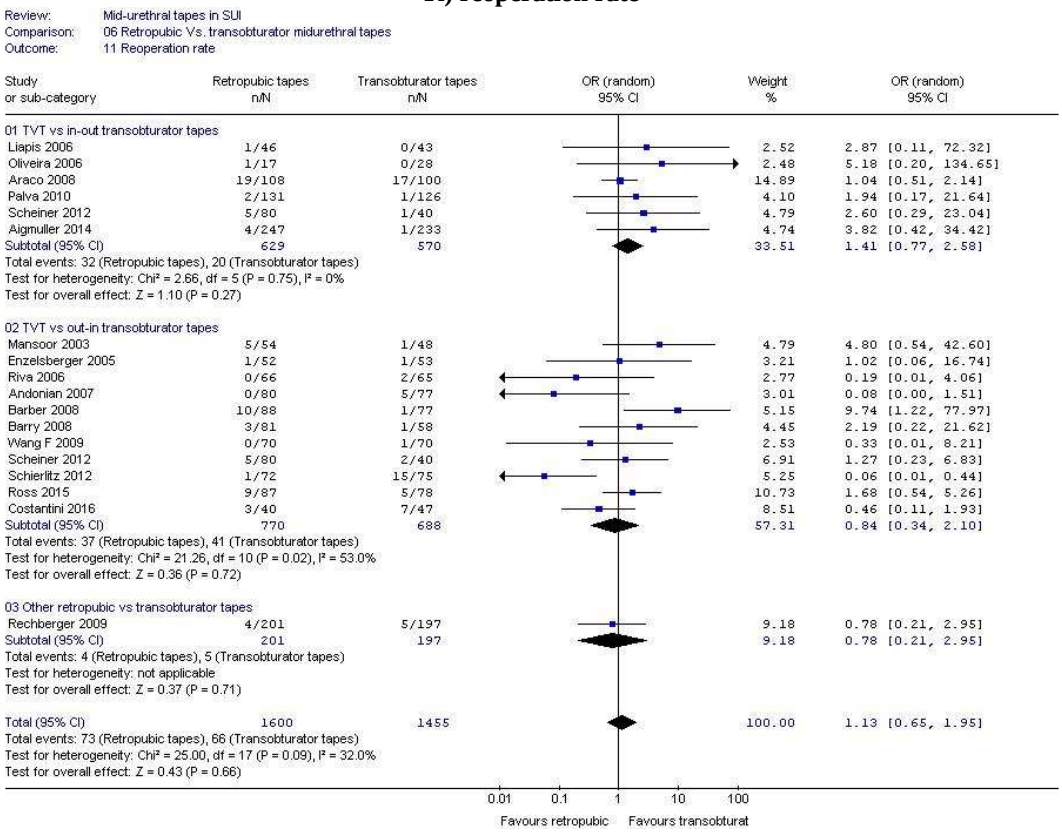
Review: Mid-urethral tapes in SUI
Comparison: 06 Retropubic Vs. transobturator midurethral tapes
Outcome: 09 Complication rate - voiding LUTS



J) need of clean intermittent catheterization or recatheterization



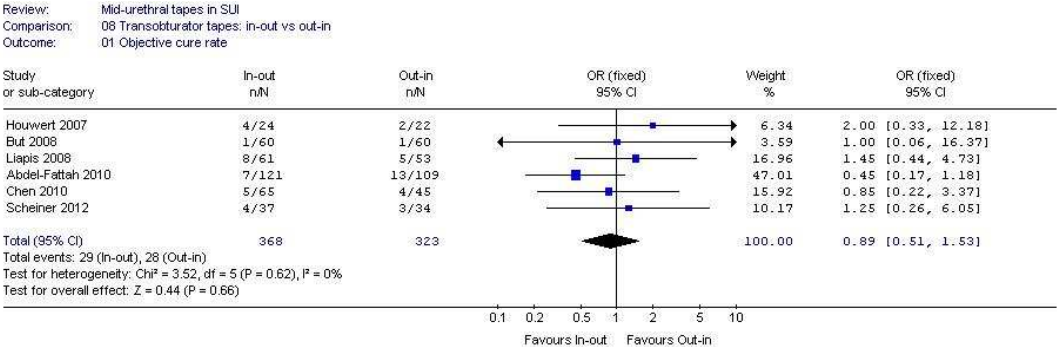
K) reoperation rate



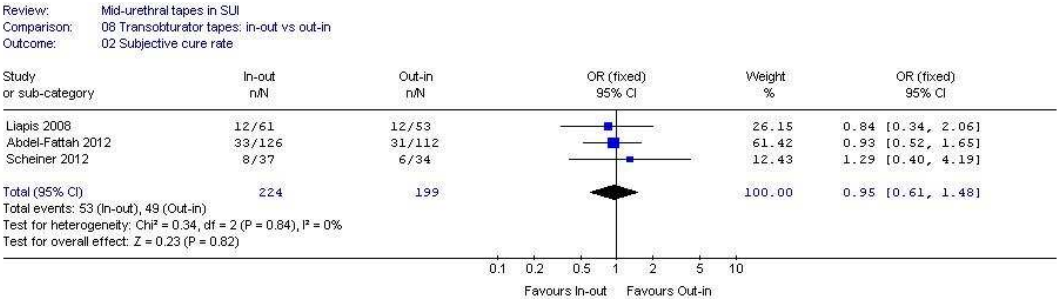
CI = confidence interval; CIC = clean intermittent catheterization; OR = odds ratio; SD = standard deviation; SUI = stress urinary incontinence; LUTS: lower urinary tract symptoms

Fig. 5 – Forest plots of comparisons after different transobturator tapes: (a) objective continence rate; (b) subjective continence rate; (c) vaginal perforation; (d) vaginal erosion; (e) urinary tract infection; (f) storage lower urinary tract symptoms; (g) voiding lower urinary tract symptoms; (h) need of clean intermittent catheterization or recatheterization.

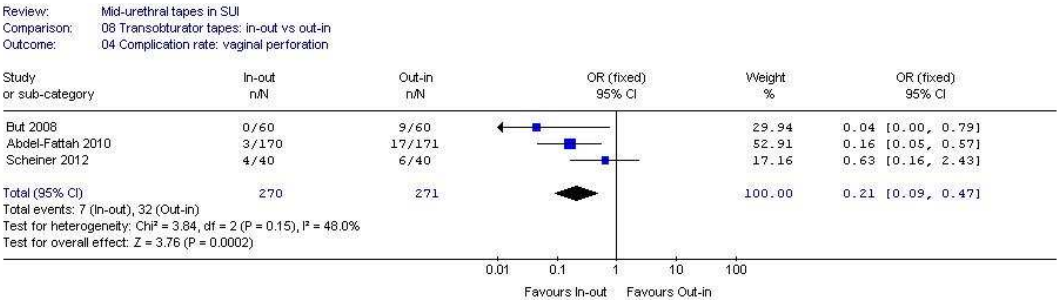
A) objective continence rate



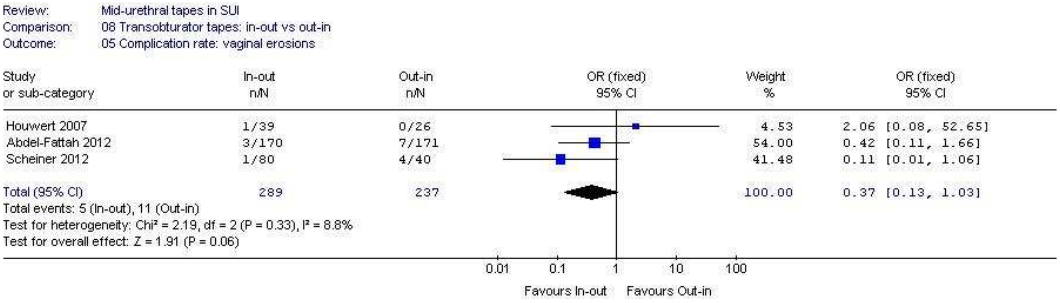
B) subjective continence rate



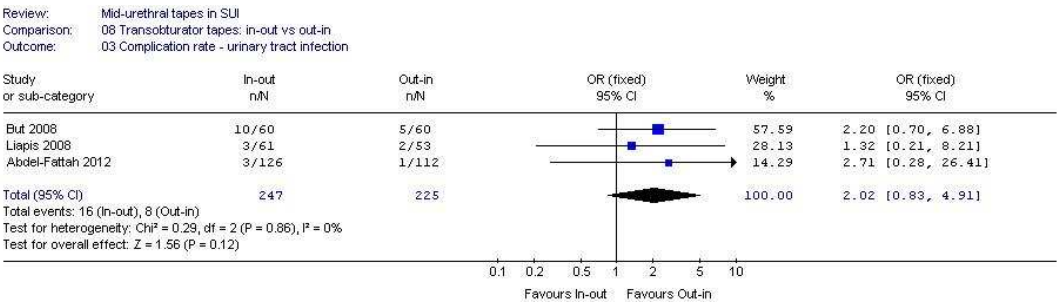
C) vaginal perforation



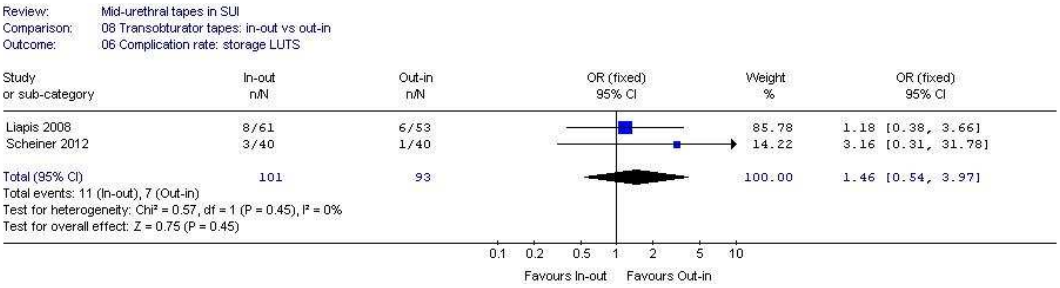
D) vaginal erosion



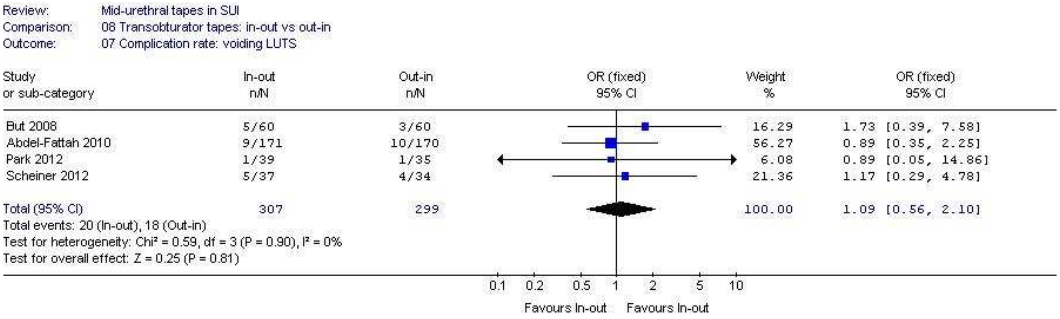
E) urinary tract infection



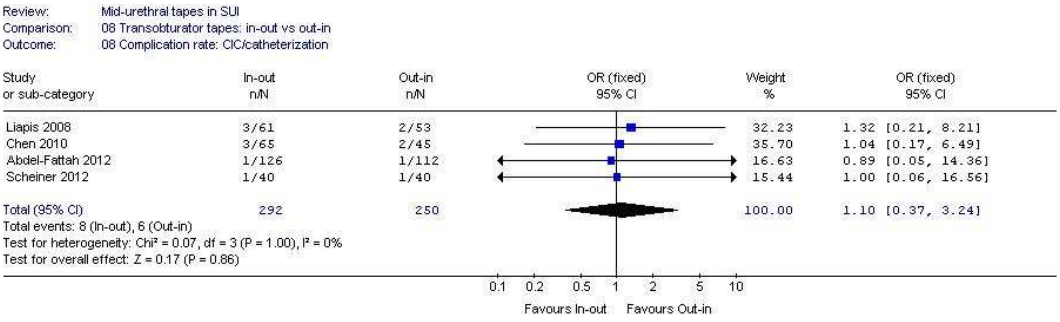
F) storage lower urinary tract symptoms



G) voiding lower urinary tract symptoms



H) need of clean intermittent catheterization or recatheterization.



CI = confidence interval; CIC = clean intermittent catheterization; OR = odds ratio; SD = standard deviation; SUI = stress urinary incontinence; LUTS: lower urinary tract symptoms

Table 1: Comparisons after retropubic and transobturator tapes . Meta-analysis of all the RCTs and sensitivity analyses for high quality RCTs

Retropubic vs transobturator tapes	All RCTs						High quality RCTs					
Continence rate												
	RCT	**Participants**	**OR**	**95%- CI of OR**	**P value**	**Difference in favor of**	**RCT**	**Participants**	**OR**	**95%- CI of OR**	**P value**	**Difference in favor of**
Any definition of continence	9	1374	1.16	0.89–1.51	0.27	None	3	355	0.96	0.42–2.17	0.92	None
Objective continence rate	31	4796	0.82	0.70–0.96	0.02	RP-TVT	16	3079	0.76	0.63–0.92	0.006	RP-TVT
Subjective continence rate	22	3247	0.83	0.70–0.98	0.03	RP-TVT	14	2361	0.85	0.7–1.03	0.77	None
Adverse events												
	RCT	**Participants**	**OR**	**95%- CI of OR**	**P value**	**Difference in favor of**	**RCT**	**Participants**	**OR**	**95%- CI of OR**	**P value**	**Difference in favor of**
Bladder/vaginal perforation	36	6335	2.5	1.87–3.36	<0.0001	TO-TVT	15	2993	2.41	1.56–3.71	0.002	TO-TVT
Hematoma	23	3619	2.61	1.41–4.82	0.002	TO-TVT	6	999	2.62	0.81–8.46	0.11	None
Vaginal erosion	28	4367	0.65	0.45–0.95	0.03	RP-TVT	13	1405	0.56	0.32–0.96	0.03	RP-TVT
Urinary tract infection	16	3149	1.31	1.02–1.68	0.04	TO-TVT	6	1302	1.28	0.93–1.78	0.13	None
Storage LUTS	31	52341	1.07	0.9–1.28	0.44	None	12	2531	1.07	0.76–1.5	0.70	None
Voiding LUTS	15	2429	1.66	1.2–2.3	0.002	TO-TVT	8	1038	1.59	0.85–2.97	0.15	None
CIC/recatheterization	24	4749	1.14	0.87–1.48	0.34	None	13	1510	1.33	0.81– 2.18	0.27	None
Reoperation rate	18	3126	1.13	0.65–1.95	0.66	None	8	778	1.33	0.46–3.87	0.6	None