NKR 33 Urininkontinens, PICO 8: Bør kvinder med stress urininkontinens tilbydes MUS-RP frem for MUS-TO?

Review information

Authors

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Characteristics of studies

Characteristics of included studies

Aigmuller 2014

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age, years (SD)*: 59.8 (11.50) ● *BMI, mean (SD)*: 28.1 (6.0) ● *Parity, mean (SD)*: 2.2 (1.14) Control ● *Mean age, years (SD)*: 59.5 (10.5) ● *BMI (SD)*: 28.4 (5.1) ● *Parity, mean (SD)*: 2.22 (1.2) **Included criteria:** Primary surgery for urodynamically verified SUI (positive cough stress test at bladder filling of 300 mL) without concomitant prolapse surgery or hysterectomy. **Excluded criteria:** Detrusor overactivity. A predominant complaint of overactive bladder, significant concomitant surgery (ie. hysterectomy, prolapse surgery), previous incontinence surgery other than colporrhy, and residual urine > 100 mL. **Pretreatment:** No differences between groups at baseline.
Interventions	**Intervention Characteristics** Intervention ● Description: Midurethral sling TVT. Cystoscopy was performed with all retropubic placements but not at all transobturator insertions. Control ● Description: Midurethral sling TVT-O. Cystoscopy was performed with all retropubic placements but not at all transobturator insertions.

Outcomes	*Inkontinensrelateret livskvalitet, KHQ incontinence impact, mean final, SD* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: KHQ incontinence impact, (item 2) ● **Data value**: Endpoint *De novo urgency incontinence, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Change from baseline *Underlivssmerter, antal personer (obs smerter ikke beskrevet nærmere, antager underlivssmerter)* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint
Notes	*NKR 33 Urininkontin* on 07/09/2019 05:11 **Included** 5 års opfølgelse på Aigmüller 2014 *NKR 33 Urininkontin* on 24/09/2019 22:34 **Outcomes** Reoperationer fordelt på årsag:TVT 6 reoperationer:3 pga vaginal erosion, 1 vaginal erosion + samtidig Burch kolposuspension, 1 TVT-O (7mdr postop pga rec SUI), 1 blærecancer.TVT-O 5 reoperationer:2 pga vaginal erosion, 1 TVT (3mdr postop pga rec SUI), 1 Botox (39 mdr postop pga OAB), fjernelse pga clitorissmerter. Regarding pain:Results are reported as tape related pain. No differentiation on location og pain (abdominal or groin).

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: randomized according to a computer generated random list allocating trial identification number and treatment group. Randomization was by fax through the central office.
Allocation concealment (selection bias)	Low risk	Judgement Comment: computer generated random list allocating trial identification number and treatment group.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Patients, surgeons, and physicians performing follow-up exams were not blinded to the type of surgery. Oplysninger fra Aigmuller 2014
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: Patients, surgeons, and physicians performing follow-up exams were not blinded to the type of surgery. Oplysninger fra Aigmuller 2014

Incomplete outcome data (attrition bias)	High risk	Judgement Comment: Lost to follow-up in TVT group: 124/285. Lost to follow-up in TVT-O group: 99/269.Reasons for lost to follow-up are not reported.Unbalanced lost to follow-up between groups.There were no significant differences in baseline characteristics between patients who were available for 5-year follow-up and those who were not. No intention-to-treat analysis. High dropout rate at 5 years follow-up. Data available for 56% in the tvt group and 63% in the TVT-O group. Only per protocol analyses
Selective reporting (reporting bias)	Low risk	Judgement Comment: Protocol at clinicaltrials.gov. outcomes at 5 years only stated as continence and quality of life. reporting of complications not stated in the protocol, but reported in the manuscript
Other bias	Low risk	Judgement Comment: The tape manufacturer had no role in the study and did not provide funding or products for the study Baseline comparability:Both groups were comparable at baseline.

Alkady 2009

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age, years (range)*: 48 (32-62) ● *Parity, mean (range)*: 5 (2-10) Control ● *Mean age, years (range)*: 50 (30-65) ● *Parity, mean (range)*: 6 (1-13) **Included criteria:** Visible SUI and proven urodynamically as genuineUrethral hypermobility at the physical examinationMixed urinary incontinence without urodynamically proven contractionAbsence of a contractile urinary bladder or obstruction **Excluded criteria:** Acute cystitisPredominant urge incontinenceUrodynamic detrusor instabilityMaximum flow (Qmax) less than 15ml/s/and or positive residual urine of more than 20% of the volume voidedGenital prolapse of IV, V **Pretreatment:** No differences between groups at baseline.
Interventions	**Intervention Characteristics** Intervention ● Description: TVT procedure: All TVT procedures were performed as was previously reported by Ulmsten et al. [24], except that the operation was carried out with the patient under general or epidural anaesthesia. After bilateral paraurethral dissection of the vaginal wall, the trocar and special polypropylene tape were placed through the urogenital diaphragm into the retro-pubic space close to the back of the pubic bone up to the abdominal incision. The same procedure was performed on the other side. Cystoscopy was subsequently carried out to verify the absence of bladder injury. Then tape was adjusted without tension in a U-shaped form around the mid urethra. The vaginal and abdominal incisions were then closed by vicryl-O suture after cutting the abdom-inal ends of the tape in the subcutaneous tissue. A foley catheter was inserted into the bladder at the end of the procedure and removed at 12-16 interval hours after surgery. Control ● Description: TVT-O procedure: It was carried out as firstly described by Jean de Leval [18] either under general or epidural anaesthesia. The patient was placed in lithotomy position and thighs in hyperflexion. The operative field was cleaned and drapped with betadine solu-tion with care

	being taken to keep the groin folds in the operative field. A16Fr foley catheter was inserted into the bladder. The point where the needles will exit at the skin level were identified by tracing a horizontal line at the level of the urethral meatus. The exit points were located 2cm above this line and 2cm outside the thigh folds. A 5mm skin incision was made at each exit point. A 1-cm median sagittal incision was made in the anterior vaginal wall starting 1 cm from the external urethral meatus. A bilateral paraurethral dissection of the vagina was done through intro-duction of fine dissection scissors through the blade-initiated dissection path towards the upper part of the ischio-pubic ramus, on a horizontal plane with a 45º angle relatively to the urethral sagittal plane to perforate the obturator membrane with the tip of the scissors. The introduce was then pushed in the performed dissection pathway until it reached and perforated the obturator membrane. The assembled device is gently slipped along the gutter of the introducers so as to pass through the obturator foramen. At this step, the handle of the passer must be aligned in a parallel manner with the sagittal axis of the vulval slit. The pointed tip of the tube appears at the previously incised skin exit points at the level of the thigh folds. The tube was pulled from the supporting passer, which was removed by a backwards-rotational movement, until the first centimeter of the tape become exter-nalized. The same technique was applied to the left side. It is important to take care not to twist the tape. When both tubes have been extracted through the skin incisions, the ends of the tape were cut. The tape was then aligned under the junction between the mid and distal urethra and the tension of the tape was adjusted by exerting a traction on its two ends and by interposing a pair of scissors between the tape and the urethra so to leave a space avoiding any tension on the tape. The plastic sheaths were then removed simultaneously. The tape ends were cut in the subcutaneous layer and the incisions were closed with vicryl-O suture. No cystoscopy was required for the procedure. Foley catheter has been left in place for 12-16 hours and for complet-ing 24 hours of the preoperative period in those cases involving complementary surgery. Once the woman was able to void easily and the residual volume was less than 100mL, she was discharged.
Outcomes	*Reoperation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Infektion, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Hæmatom, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Blæreperforation* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *De novo urgency incontinence, antal personer* ● **Outcome type**: Adverse Event

	● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Change from baseline *Patientoplevet effekt, very satisfied or satisfied, antal personer* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Women were randomized using numbered, opaque, sealed envelops containing computer- generated random allocations in a ratio of 1:1 in balanced blocks of 10."
Allocation concealment (selection bias)	Low risk	Judgement Comment: Women were randomized using numbered, opaque, sealed envelops containing computer-generated random allocations in a ratio of 1:1 in balanced blocks of 10
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information of blinding of participants and surgeons, blinding of surgeons not possible
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No informations of blinding of outcome assessors. Patient perceived effect was self-evaluated.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No attrition in both groups.
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to a protocol. The study reports on all the outcomes stated in the methods section. No reporting on quality of life or abdominal or leg pain.
Other bias	Unclear risk	Judgement Comment: No informations of conflicts of interest. Baseline comparability:Both groups comparable at baseline.

Aniuliene 2009

Methods	Details Cystoscopy and cough test were routinely performed only in the TVT group. Antibiotic prophylaxis was applied for all patients during surgery. Foley catheter was left for 12 hours in the TVT group and for 6 hours in the TVT-O group after operation. Power calculation Not reported Intention to treat analysis Not reported

Participants	N = 264 TVT-O (transobturator inside out) = 150 TVT (bottom up tension-free vaginal tape) = 114 Characteristics Gender – Female/N (% female) 264/264 (100%) Age (years)- Mean ± SD TVT-O = 49 ± 9.5 TVT = 51 ± 10.1 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI (years) – Mean ± SD TVT-O = 7.5 ± 2.4 TVT = 6.5 ± 3.1 Detrusor overactivity – n/N (%) Not reported Inclusion criteria 1] Women with stress urinary incontinence 2] Patient's agreement to buy a TVT or TVT-O set (there is no compensation from territorial patients funds in Lithuania) Exclusion criteria 1] Urogenital prolapse greater than stage II 2] Urinary retention 3] Overactive bladder 4] Mental disease
Interventions	Interventions Surgical procedures (TVT and TVT-O) were performed by the same surgeon using the standardised Gynecare protocol
Outcomes	Patient satisfaction with treatment Not reported Self reported rate of absolute symptom reduction per day Not reported Continence status at 12 months Scale used – "Results were estimated according to the following criteria: excellent - no signs of SUI, imperative urination or dysuria; good - no signs of SUI, very mild imperative urination, no dysuria; moderate - no signs of SUI, imperative urination with minimal leakage, very mild dysuria; bad - SUI, imperative urination, a woman uses inlays." Excellent TVT-O = 117/150 (78%) TVT = 97/114 (85.1%) Good TVT-O = 25/150 (16.7%) TVT = 11/114 (9.7%) Moderate TVT-O = 5/150 (3.3%) TVT = 3/114 (2.6%) Bad TVT-O = 3/150 (2%) TVT = 3/114 (2.6%) Incontinence-specific quality of life Not reported Adverse effects of treatment Peri-operative Suprapubic haematoma TVT-O = 0/150 (0%) TVT = 1/114 (0.9%) Wound bleeding in vagina TVT-O = 3/150 (2%) TVT = 2/114 (1.8%) Bladder perforation TVT-O = 0/150 (0%) TVT = 1/114 (0.9%) Urinary retention* TVT-O = 5/150 (3/3%) TVT = 18/114 (15.8%) Symptoms of irritated bladder TVT-O = 5/150 (3/3%) TVT = 6/114 (5.3%) Post-operative Urinary tract infection* TVT-O = 1/150 (0.7%) TVT = 5/114 (4.4%) Fever >38°C TVT-O = 1/150 (0.7%) TVT =0/114 (0%) Psychological outcomes Not reported Clinical measures Not reported *Most common adverse effects in peri-operative and post-operative categories used for meta-analyses Continence status, Peri-operative adverse effects & Post-operative adverse effects
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: unclear - no mention of randomisation in methods, although author does stated 'prospective randomised study' in abstract A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: unclear
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: unclear - no mention of randomisation in methods, although author does stated 'prospective randomised study' in abstract A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: unclear
Blinding of participants and personnel (performance bias)	High risk	D1 - Was follow-up appropriate length: yes D2 - Were outcomes defined precisely: no - how 'signs of SUI' 'imperative urination' and 'dysuria' (variables that form composite measure of continence status) were measured is not described D3 - Was a valid and reliable method used to assess outcome: unclear D4 - Were investigators blinded to interventions: unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: high
Blinding of outcome assessment (detection bias)	Unclear risk	B1 - Did groups get same level of care: unclear B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: unclear Level of bias: unclear
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: unclear C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: yes Level of bias: low
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Aniuliene 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age, years (SD)*: 50 (8.9) ● *BMI, mean (SD)*: 28.5 (3.5) ● *Parity, mean (SD)*: 2.1 (1.1) Control ● *Mean age, years (SD)*: 67 (9.5) ● *BMI (SD)*: 28.2 (3.8) ● *Parity, mean (SD)*: 2.5 (1.2) **Included criteria:** History of SUI with a demonstrable impact of SUI upon coughing and Valsalva tests during urodynamic (cystometry and uroflowmetry) testing **Excluded criteria:** Previous suburethral sling, predominant overactive bladder symptoms, prolapse (cystocele) greater than stage 2, elevated postvoid

	residual (PVR >100 mL), urinary retention, progressive neurological disease, psychiatric disease and evidence of systematic infection **Pretreatment:** Statistical significant difference in mean (SD) age between groups:TVT: 50 (8.9)TVT-O: 67 (9.5) p<0.05Statistical significant difference in no. of participants with presence of menopause between groups:TVT: n= 38 of total N = 76 TVT-O: 55 of total N = 78 p<0.05
Interventions	**Intervention Characteristics** Intervention ● Description: TVT-Exact (retropubic). Cystoscopy during operation was routenly performed only in the TVT-Exact group. Antibiotic prophylaxis was performed for all operations during surgery. Surgical procedures (TVT-Exact and SLING-IUFT) were performed by the same surgeon, using standardized protocols. Control ● Description: Midurethral sling- SLING-IUFT (transobturator). Antibiotic prophylaxis was performed for all operations during surgery. Surgical procedures (TVT-Exact and SLING-IUFT) were performed by the same surgeon, using standardized protocols.
Outcomes	*Blæreperforation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Bensmerter, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Scale**: Bensmerter ● **Direction**: Lower is better ● **Data value**: Endpoint *Hæmatom, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *De novo urgency incontinence, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Change from baseline *Patientoplevet effekt, Excelent or good, antal personer cured or improved* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint

Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Women were randomized by 1:1 to midurethral sling- SLING-IUFT (transobturator) and TVT-Exact (retropubic) operations.The envelopes were sealed at the same day of surgery. Patients were not blinded to the procedure postoperatively as they were made aware of differences between procedures. Judgement Comment: No information of how the allocation sequence was generated
Allocation concealment (selection bias)	Low risk	Judgement Comment: The envelops were sealed at the same day of surgery.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Patients were not blinded to the procedure postoperatively as the were made aware of differences between procedures. Surgical procedures (TVT and TVT-O) were performed by the same surgeon, using standardized protocols. A nonblinded clinical trial. One surgeon performed all operations
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: A non blinded clinical trial.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No participants were lost to follow-up.
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to a protocol. The study reports on all the outcomes stated in the methods section. No reporting of quality of life. Doubt about whether the results in Table 3 are self-reported subjective cure rate.
Other bias	Unclear risk	Judgement Comment: Baseline comparability:Groups comparable at baseline. no information of conflicts of interests

Araco 2008

Methods	Country/ies where the study was carried out Italy Study type Randomised controlled trial Aim of the study "We compared TVT-O with TVT in SUI1 and SUI2 patients to evaluate the efficacy of both techniques, the eventual urodynamic changes and complications rates in each subgroup of patients." Study dates January 2004 to March 2007 Source of funding Not reported. Details Two surgeons performed the procedures within an inpatient setting, both of whom had previously performed more than 40 TVT-O and TVT each. Oral anticoagulants were discontinued 7 days before surgery where appropriate. NICE guidelines were adopted for preoperative testing, Standard prophylaxis measures of deep vein thrombosis and infections were implemented. All patients underwent spinal anaesthesia. No additional doses of antibiotics were administered unless an infection or an intra-operative complication was present. Ketorolac was usually given on

	patient's request as an analgesic. Early mobilisation was encouraged 1–3 h postoperatively, and elastic bands or garments were maintained for 6–12 h postoperatively. Urinary catheter was removed 6–12 h after surgery. After removal, if a urinary residual greater than 100cc was present, the patient performed intermittent catheterisation. If she still failed to resume normal voiding after 3 weeks, a permanent bladder obstruction was considered and tape resection planned. Patients without complications were discharged 24 h after the operation. Power calculation Sample size of the study was determined assuming a significance level (α) of 0.05 and a desired power of the experiment of 87–90% (87%: drop-out of 25%, 90% absence of drop-out). For all these reasons, the study enrolled 240 subjects. Intention to treat analysis - Not reported
Participants	N = 240 TVT-O (transobturator inside out) = 120 TVT (bottom-up tension-free vaginal tape) = 120 Characteristics Gender – Female/N (% female) 240/240 (100%) Age (years) - Mean ± SD TVT-O SUI1 = 53.2 ± 4.9 TVT-O SUI2 = 54.0 ± 5.1 TVT SUI1 = 53.6 ± 3.4 TVT SUI2 = 54.5 ± 7.9 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI (years) – Mean ± SD TVT-O SUI1 = 4.4 ± 1.1 TVT-O SUI2 = 5 ± 1.4 TVT SUI1 = 4.8 ± 1.9 TVT SUI2 = 5 ± 1.7 Detrusor overactivity – n/N (%) Not reported Incontinence-specific quality of life Scale used - Incontinence Quality of Life Questionnaire (I-QOL) - Mean ± SD (N) TVT-O SUI1 = 54 ± 13.5 (50) TVT-O SUI2 = 32 ± 7.3 (50) TVT SUI1 = 52 ± 16.5 (50) TVT SUI2 = 32 ± 7.3 (58) Inclusion criteria 1] Symptomatic SUI grade 1 (loss of urine during excessive strains) and grade 2 (loss of urine during minor strains) Exclusion criteria 1] SUI grade 3 (loss of urine at rest) 2] Overactive bladder 3] Associated prolapses 4] Neurovegetative disorders 5] Recurrent SUI 6] Rehabilitative or medical therapies for SUI (i.e. pelvic floor muscle training or duloxetine)
Interventions	TVT-O procedure was performed using the TVT Obturator System (Gynecare Ethicon, Somerville, NJ, USA). TVT procedure was performed using the TVT kit (Gynecare Ethicon, Somerville, NJ, USA).
Outcomes	Patient satisfaction with treatment Not reported Self reported rate of absolute symptom reduction per day Episodes of incontinence: Not reported Continence status at 12 months Scale used – "Incontinence cure was evaluated with the postoperative ambulatory urodynamic tests 1 year after and failures defined as the persistency of SUI on that occasion." TVT-O SUI1 = 50/50 (100%) TVT-O SUI2 = 33/50 (66%) TVT SUI1 = 50/50 (100%) TVT SUI2 = 58/58 (100%) Incontinence-specific quality of life at 12 months Scale used - Incontinence Quality of Life Questionnaire (I-QOL) - Mean ± SD (N) TVT-O SUI1 = 104 ± 6.3 (50) TVT-O SUI2 = 73 ± 31.0 (50) [this is as reported in paper but SD of 31.0 seems out of keeping with other reported SDs] TVT SUI1 = 96 ±5.7 (50) TVT SUI2 = 104 ±5.8 (58) Adverse effects of treatment Peri-operative Bladder obstructions* TVT-O SUI1 = 0/50 (0%) TVT-O SUI2 = 0/50 (0%) TVT SUI1 = 12/50 (24%) TVT SUI2 = 0/58 (0%) Vaginal perforations TVT-O SUI1 = 2/50 (4%) TVT-O SUI2 = 4/50 (8%) TVT SUI1 = 0/50 (0%) TVT SUI2 = 0/58 (0%) Bladder perforations TVT-O SUI1 = 0/50 (0%) TVT-O SUI2 = 0/50 (0%) TVT SUI1 = 1/50 (2%) TVT SUI2 = 2/58% (3%) Haematomas TVT-O SUI1 = 0/50 (0%) TVT-O SUI2 = 0/50 (0%) TVT SUI1 = 3/50 (6%) TVT SUI2 = 3/58 (6%) Post operative Detrusor overactivity TVT-O SUI1 = 2/50 (4%) TVT-O SUI2 = 1/50 (2%) TVT SUI1 = 2/50 (4%) TVT SUI2 = 0/58 (0%)

	Re-catheterisations TVT-O SUI1 = 8/50 (16%) TVT-O SUI2 = 9/50 (18%) TVT SUI1 = 7/50 (14%) TVT SUI2 = 8/58 (14%) Vaginal erosions TVT-O SUI1 = 2/50 (4%) TVT-O SUI2 = 1/50 (2%) TVT SUI1 = 0/50 (0%) TVT SUI2 = 1/58 (2%) Reoperations TVT-O SUI1 = 0/50 (0%) TVT-O SUI2 = 17/50 (34%) TVT SUI1 = 15/50 (30%) TVT SUI2 =4/58 (7%) Psychological outcomes Not reported Clinical measures at 12 months Postvoid residual volume (ml) - Mean ± SD (N) TVT-O SUI1 = 19 ± 15 (50) TVT-O SUI2 = 20 ± 13 (50) TVT SUI1 = 52 ± 44 (50) TVT SUI2 = 19 ± 14 (50) * Most common adverse effects in peri-operative and post-operative categories used in meta-analyses Continence status, Peri-operative adverse effects & Post-operative adverse effects.
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: "two surgeons explained experimental nature of the trial, obtained the informed consent signed and presented 2 identical closed envelopes to patients, one containing the paper 'TVT' and the other 'TVT-O'. After choosing and opening of the envelope, further stratification was performed with a sampling chart." A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: unclear --> A stratified randomisation was carried out. Results are reported separately for SUI grade 1 and SUI grade 2 populations randomised to TVT-O or TVT. Patients were classified according to the SUI system on the basis of urodynamics studies (McGuire classification: SUI1 = abdominal leak-point pressure (ALPP) greater than 90cm water, SUI2 = ALPP of 60–90 cam water, SUI3 = intrinsic sphincter deficiency and ALPP less than 60 cm water).
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: "two surgeons explained experimental nature of the trial, obtained the informed consent signed and presented 2 identical closed envelopes to patients, one containing the paper 'TVT' and the other 'TVT-O'. After choosing and opening of the envelope, further stratification was performed with a sampling chart." A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: unclear
Blinding of participants and personnel (performance bias)	Unclear risk	B1 - Did groups get same level of care: yes B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: no Level of bias: unclear
Blinding of outcome assessment (detection bias)	Low risk	B1 - Did groups get same level of care: yes B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: no Level of bias: unclear D4 - Were investigators blinded to interventions: unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: low
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: yes - 100/120 in TVT-O and 108/120 in TVT were assessed at 12 month follow up Level of bias: low Outcome: Unclear exactly which urodynamic measures were used to determine incontinence cure (continence status)
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Deffieux 2010

Methods	France Study type Randomised controlled trial Aim of the study "To compare the retropubic procedures (both using the same macroporous monofilament polypropylene sling), with emphasis being placed on cure rates and intraoperative and post-operative complications, with a minimum follow-up of 24 months." Study dates January 2005 to December 2007 Source of funding Not reported The method of anaesthesia was left to the discretion of each surgeon. Vaginal incision was made in the same fashion in both groups. The polypropylene sling was identical in both procedures. For both procedures, the surgeons were instructed to place the slings "tension-free". Beyond this no other standardisation of the sling tension was imposed. No per-operative cough stress test was required. All patients, including those in the TVT-O group, underwent an intraoperative cystoscopy to check for the presence of lower urinary tract injury. Power calculation The sample size calculation (SPSS analysis) was performed assuming a bladder injury rate of 8% for TVT and 0.5% for TVT-O. With α equal to 5% and 80% power (1-β) the sample size should be 180 patients, with 90 patients in each group, to reveal a 7.5% difference. The number of subjects included in the trial did not reach this figure because of insufficient enrolment in some centres. Intention to treat analysis Not reported
Participants	N = 149 TVT-O (transobturator inside out) = 74 TVT (botton-up retropubic tension-free vaginal tape) = 75 Characteristics Gender – Female/N (% female) 149/149 (100%) Age (years)- Mean ± SD TVT-O = 52.8 ± 9.8 TVT = 54.6 ± 10.9 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI – Mean ± SD Not reported Detrusor overactivity – n/N (%) Not reported Mixed urinary incontinence - n/N (%) TVT-O = 20/74 (27%) TVT = 26/75 (35%) Inclusion criteria 1] Isolated or mixed urodynamic stress incontinence (USI; according to the International Continence Society classification) 2] Indication for surgical treatment of USI 3] Positive cough stress test (cough stress test was performed during cystometry in sitting position, volume 200 – 300 ml) 4] At least 18 years of age Exclusion criteria 1] Concomitant pelvic organ prolapse surgery 2] Concomitant hysterectomy 3] Previous incontinence surgery 4] Pregnancy 5] Anticoagulation therapy

	6] Higher than first stage urogenital prolapse 7] Patient unable to understand the purpose of the trial.
Interventions	TVT-O (Johnson and Johnson, Ethicon, Gynecare) procedures were all performed using the vaginal approach from inside to outside, as described by de Leval. TVT procedures were all performed using the vaginal approach in accordance with the technique described by Ulmsten and the manufacturer (Johnson and Johnson, Ethicon, Gynecare).
Outcomes	Patient satisfaction with treatment at 24 months Scale used - subjective cure rate = "no referred leakage at interview" TVT-O = 56/67 (83%) TVT = 55/65 (84%) Self reported rate of absolute symptom reduction per day Not reported Continence status at 24 months Scale used - objective cure rate = negative stress test TVT-O = 65/67 (97%) TVT = 61/65 (94%) Incontinence-specific quality of life Not reported Adverse effects of treatment Tape erosion Not reported Retention Not reported Voiding dysfunction Not reported De novo OAB symptoms Not reported Psychological outcomes Not reported Clinical measures Not reported
Notes	NICE guideline; Critical Appraisal Skills Programme. Cohort study checklist. Items 1-7

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The patients were randomized using sealed opaque envelopes, following computer-generated random allocations, with a ratio of 1:1 in balanced blocks of four."
Allocation concealment (selection bias)	Low risk	Quote: "The envelopes were opened just before each participant's surgical procedure."
Blinding of participants and personnel (performance bias)	High risk	Quote: "Blinding of the surgeon or the participants was not possible post-operatively because of the different incisions required for each procedure (shamed incisions are not ethically justified)." Judgement Comment: No blinding.
Blinding of outcome assessment (detection bias)	High risk	Quote: "Blinding of the surgeon or the participants was not possible post-operatively because of the different incisions required for each procedure (shamed incisions are not ethically justified). Post-void" Judgement Comment: The operating surgeon was the objective outcome assessor and the patients were the subjective outcome assessor
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: 8/75 TVT and 9/74 TVT-OVery little incomplete outcome data. Missing outcome data is balanced between intervention and control groups.
Selective reporting (reporting bias)	Low risk	Judgement Comment: Prespecified primary and secondary outcomes are reported. Protocol not located, it seems that all relevant outcomes are presented.
Other bias	Unclear risk	Judgement Comment: None detected

Feng 2018

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age, years (SD)*: 52.24 (7.54) ● *BMI, mean (SD)*: 25.19 (2.57) ● *Parity, mean (SD)*: 2.92 (1.58) Control ● *Mean age, years (SD)*: 53.26 (6.33) ● *BMI (SD)*: 24.51 (2.20) ● *Parity, mean (SD)*: 3.23 (1.73) **Included criteria:** Women aged 40-75 years diagnosed with SUI. SUI and urethral hypermobility was diagnosed based on symptoms, signs and urodynamic investigation. **Excluded criteria:** Previous MUS surgery or genitourinary tract surgery. Recently UTI. Requiring concomitant surgery (hysterectomy or prolapse surgery). Poor general status for surgery. MUI. **Pretreatment:** No differences between groups at baseline.
Interventions	**Intervention Characteristics** Intervention ● Description: Midurethral sling TVT-E were performed according to the manufacture's manual. (Johnson and Johnson, Ethicon, Gynecare) and Ulmsten et al.'s paper, through the vaginal route under general anesthesia. the trocar in the TVT surgeri consists of a non-sterile reusable instrument that was 3 mm in diameter with a single-use trocar handle, which was more ergonomic than the TVT device. Hemostatic forceps were placed between the underside of the urethra and the medium of the sling to prevent dysuresia. Control ● Description: Midurethral sling TVT-A performed as descriped by Leval et al. We made a medial sagitaal insicion of the vaginal wall starting from the location of 1 cm. proximal to the urethral meatus and contonuing caudally for 1 cm, followed by a paraurethral dissection which was continued to the pubic ramus without perforating the obturator membrane with the guide. And the guide was then removed after the obturator membrane was perforated by the trocar. The handle of the helical passer was dropped to a vertical position and rotate around the inferior pubic ramus. Also, bone contact was maintained during the whole process the ensure the right passage around the bony structure, with the tip of the passer exiting at the skin level 0.5-1 cm lateral of the crural plicae, which is more medial than the exit points in the TVT-obturator operations.
Outcomes	*Inkontinensrelateret livskvalitet, ICIQ-UI-SF, mean final, SD* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: ICIQ-UI-SF ● **Range**: 0-21 ● **Direction**: Lower is better ● **Data value**: Endpoint

Reoperation, antal personer
- **Outcome type**: Adverse Event
- **Reporting**: Fully reported
- **Direction**: Lower is better
- **Data value**: Endpoint

Patientoplevet effekt, PGI-I, antal personer cured or improved
- **Outcome type**: Dichotomous Outcome
- **Reporting**: Fully reported
- **Scale**: PGI-I
- **Direction**: Higher is better
- **Data value**: Endpoint

Blæreperforation, antal personer
- **Outcome type**: Adverse Event
- **Reporting**: Fully reported
- **Direction**: Lower is better
- **Data value**: Endpoint

Bensmerter, antal personer
- **Outcome type**: AdverseEvent
- **Reporting**: Fully reported
- **Scale**: Bensmerter
- **Direction**: Lower is better
- **Data value**: Endpoint

De novo urgency incontinence, antal personer
- **Outcome type**: Adverse Event
- **Reporting**: Fully reported
- **Direction**: Lower is better
- **Data value**: Change from baseline

dysparauni, antal personer
- **Outcome type**: Adverse Event
- **Reporting**: Fully reported
- **Direction**: Lower is better
- **Data value**: Endpoint

Seksualfunktion, PISQ 12, mean final, SD
- **Outcome type**: Continuous Outcome
- **Reporting**: Fully reported
- **Scale**: PISQ 12
- **Data value**: Endpoint

Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: To avoid a selective bias, all enrolled patients were divided into two groups: TVT and TVT-O using the random scheme generated from SPSS.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information of allocation concealment
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: The surgeons and patients were not blinded to the treatment. Patients reporting on self-reported questionnaires and outcomes. Same for both groups.
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: The outcome assessment was done at subsequent outpatient visit by investigators who were blinded to the grouping.Patients were not blinded and some outcomes are self-reported effects/outcomes. Outcome assessors were blinded
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Lost to follow-up in TVT group: 17/74Lost to follow-up in TVT-O group: 16/74Reasons for drop-outs/lost to follow-up not reported.Per protocol analysis. No intention-to-treat analysis.
Selective reporting (reporting bias)	Low risk	Judgement Comment: Protocol available online, reports on all the predefined outcomes, complications were not specified in categories. No reporting of abdominal or pelvic pain, only groin pain reported
Other bias	Low risk	Judgement Comment: The authors declare no conflicts of interests. Baseline comparability:Both groups were comparable at baseline.

Jakimiuk 2012

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** There were no significant differences in age and body mass index between the two groups. **Included criteria:** Women aged 40 - 80, SUI confirmed with 1-hour pad-weighing test and positive results of urodynamic tests, maximum bladder volume over 300 ml, patients without urinary tract infection. **Excluded criteria:** BMI over 33 kg/m2, pathology in the reproductive organ or in lower pelvis which should be qualified for surgical treatment, bladder pathology, hysterectomy with or without salpingectomy in the past, neurological urinary incontinence, overactive bladder, hypotony of detrusor muscle or any form of mixed incontinence, pregnancy, radiotherapy of pelvis in the past, hypersensitivity to anesthetic drugs, post voiding volume >150ml, pelvic organ prolapse, myocardial infarction or hemorrhagic or ischemic stroke within past 6months prior to randomization, auto immunologic disorders, cancer disease, family of investigator **Pretreatment:** There were no significant differences in age and bodymass index between two groups.
Interventions	**Intervention Characteristics** Intervention ● Description: Midurethral sling TVT. In the TVT group, cystoscopy was routinely performed. In both procedures the needles and wovenpolypropylene tape were Gynecere products (GynecereEthicon Inc., Somerville, NJ, USA). The procedures wereconducted under spinal anesthesia.

	Control ● Description: Midurethral sling TVT-O. In both procedures the needles and wovenpolypropylene tape were Gynecere products (GynecereEthicon Inc., Somerville, NJ, USA). The procedures wereconducted under spinal anesthesia.
Outcomes	*Inkontinensrelateret livskvalitet, KHQ incontinence impact, mean final, SD* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: KHQ incontinence impact, (item 2) ● **Range** ● **Direction**: Lower is better ● **Data value**: Endpoint *Patientoplevet effekt, antal personer med significant improvement* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint *Blæreperforation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Underlivssmerter, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Infektion, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Hæmatom, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization was done through a web page secured with a 128-bit code."
Allocation concealment (selection bias)	Low risk	Quote: "The randomization was done through a web page secured with a 128-bit code."
Blinding of participants and personnel (performance bias)	Unclear risk	Quote: "Every patient had extra skin incisions for masking the type of procedure (“sham operation”). Each patient had 4 skin incisions in localization typical for needle introduced in TVT and TVT-O procedure." Judgement Comment: Patients were blinded (sham incisions for masking the type of procedure), no information of blinding of surgeons.
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: Quality of life and patient perceived effect were self-reported, patients were blinded to the type of operation.
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: 4 paitents were lost to follow-up, they all came from the TVT group. No intention to treat analyses.
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to at protocol. The study reports on all the outcomes stated in the methods section. No reporting of reoperations
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias. A grant from the ministry of science was mentioned in acknowledgement, no information of whether the manufacturers were sponsoring equipment. Baseline comparability:Groups comparable at baseline.

Karateke 2009

Methods	Turkey Study type Randomized controlled trial Aim of the study "This prospective randomised trial was designed to compare the use of TVT and TVT-O for surgical treatment of SUI in terms of cure rates, complications and factors influencing cure rate." Study dates December 2004 to March 2006 Source of funding Not reported Metzenbaum scissors were placed between tape and urethra prior to removal of plastic covers. Cough test was not used in both groups. Cystoscopy was routinely performed only in the TVT group. Although diagnostic cystoscopy was not used, the signs suggesting bladder perforation (such as leakage through surgical abdominal or vaginal cuts) were recorded in TVT-O group. When bladder injury occurred, an indwelling catheter was placed on 72h. If postoperative post-void residual volume was > 100 ml, the patient carried out intermittent self-catheterisation at home until a post-void residual volume of < 80 ml on two consecutive measurements was obtained. Spinal and general anaesthesia was used according to the patient and anaesthesiologist's preference. Power calculation

	Preliminary power analysis indicated that a sample size of 152 patients (76 for TVT group and 76 for TVT-O group) provided a statistical power (1– β) of at least 80% at α = 0.05 for the detection of 16% differences of cure rates between the two groups. To compensate for dropouts (estimated 10%), study aimed to recruit 84 patients per group. Intention to treat analysis Not reported
Participants	N = 164 TVT (bottom-up tension-free vaginal tape) = 81 TVT-O (transobturator inside out) = 83 Characteristics Gender – Female/N (% female) 164/164 (100%) Age (years)- Mean ± SD TVT = 49.31 ± 5.00 TVT-O = 49.08 ± 4.93 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI – Mean ± SD Not reported Detrusor overactivity – n/N (%) Not reported Incontinence-specific quality of life Scale used - Incontinence Impact Questionnaire (IIQ-7) TVT = 13.83 ± 3.88 TVT-O = 13.83 ± 3.88 Inclusion criteria Patients suffering from urinary incontinence with urodynamically proven SUI Exclusion criteria 1] Urogenital prolapse greater than stage 1 2] Detrusor overactivity 3] Symptoms of overactive bladder 4] Urinary retention (peak flow rate < 15 ml/s) 5] Previous anti-incontinence surgery including anterior colporrhaphy 6] Neurological bladder
Interventions	TVT-O was performed according to the original technique by de Leval (2003) except for mid-urethral transverse incision instead of vertical one. TVT was performed according to the original technique by Ulmsten (1995).
Outcomes	Patient satisfaction with treatment at 12 months Scale used – "Patients were asked to rate their overall satisfaction with the surgical outcome, with the three possible choices being very satisfied, satisfied or not satisfied." Very satisfied TVT = 68/81 (84.0%) TVT-O = 69/83 (83.1%) Satisfied TVT = 8/81 (9.9%) TVT-O = 7/83 (8.4%) Not satisfied TVT = 5/81 (6.2%) TVT-O = 7/83 (8.4%) Self reported rate of absolute symptom reduction per day Episodes of incontinence: Not reported Continence status at 12 months Scale used – "Cure of SUI was defined as no leakage of urine during cough stress test (performed at maximum cystometric capacity after the filling line was removed) at urodynamic testing." Cured TVT = 72/81 (88.9%) TVT-O = 72/83 (86.7%) Failed TVT = 9/81 (11.1%)* TVT-O = 11/83 (13.3%)* *failed data calculated from reported cure rates Incontinence-specific quality of life at 12 months Scale used - Incontinence Impact Questionnaire (IIQ-7) TVT = 6.94 ± 3.40 (81) TVT-O = 6.88 ± 3.38 (83) Scale used - Urogenital Distress Inventory (UDI-6) [reported as UDI 1–2 scores, UDI 3–4 scores, UDI 5–6 scores] UDI 1–2 TVT = 1.60 ± 0.93 (81) TVT-O = 1.54 ± 0.91 (83) UDI 3–4 TVT = 0.89 ± 0.87 (81) TVT-O = 1.00 ± 1.06 (83) UDI 5–6 TVT = 0.93 ± 1.19 (81) TVT-O =0.76 ± 1.11 (83) Adverse effects of treatment Peri-operative Bladder perforation TVT = 3/81 (3.7%) TVT-O = 0/83 (0%) Haematoma TVT = 4/81 (4.9%) TVT-O = 2/83 (2.4%) Post-operative Fever TVT = 4/81 (4.9%) TVT-O = 1/83 (1.2%) Tape erosion TVT = 4/81 (4.9%) TVT-O = 2/83 (2.4%)

	Voiding difficulty TVT = 8/81 (9.9%) TVT-O = 6/83 (7.2%) De novo detrusor overactivity - 12 months TVT =12/81 (14.8%) TVT-O = 10/83 (12.0%) De novo urge incontinence - 12 months TVT = 6/81 (7.4%) TVT-O =5/83 (6.0%) Psychological outcomes Not reported Clinical measures Not reported Patient satisfaction with treatment, Continence status, Incontinence QOL, Peri-operative adverse effects & Post-operative adverse effects.
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: yes - pre-determined computer-generated randomisation code. A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: yes - pre-determined computer-generated randomisation code. A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Blinding of participants and personnel (performance bias)	Unclear risk	B1 - Did groups get same level of care: unclear B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: unclear Level of bias: unclear
Blinding of outcome assessment (detection bias)	Low risk	D4 - Were investigators blinded to interventions: yes D5 - Were investigators blinded to confounding factors: unclear Level of bias: low
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes - all patients received intervention to which they were randomised C3 - Were groups comparable for missing data: yes - 83/84 in TVT-O and 81/83 in TVT group were assessed at 12 months. Level of bias: low
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Krofta 2010

Methods	Czech Republic Study type Randomized controlled trial Aim of the study "The current randomised, non-blinded study was undertaken to prospectively compare the TVT procedure with TVT-O, concerning the effectiveness and safety." Study dates January 2005 to December 2006 Source of funding None reported The TVT-O procedure was performed under spinal or local anaesthesia supplemented by intravenous analgosedation. Hydrodissection was performed

	routinely only in case of local anaesthesia. The Gynecare Winged Guide was regularly used but the cough test and cystoscopy were not. To avoid excess tension during the plastic sheath removal, Babcock forceps were used to grasp the tape in the middle and create a small, 5mm-long tape loop. The TVT procedure wasperformed under local anaesthesia supplemented by intravenous analgosedation. Cystoscopy was routinely performed and a cough test was performed with the patient coughing repeatedly with a bladder volume of 300 ml. In both groups, for all patients, a bladder catheter (16-French Foley) was kept in place for 24h. After catheter removal, patients were instructed to urinate 3 times before a bladder scan was performed to measure postvoid residual volume (PVR). When the PVR was > 100 ml or there was complete retention, a Foley catheter was inserted for 24h. Patients were discharged when PVR < 100 ml. All subjects received intravenous prophylactic antibiotic treatment with 2g cefazoline, administered at the beginning of surgery. Power calculation A preliminary power calculation indicated that a sample size of 172 women (86 in each group) would lend a statistical power (1-β) of at least 80% at α = 0.05 for the detection of 15% differences of cure rates between the TVT and TVT-O group. Anticipating the drop out at the level of 10% of patients in each arm, we planned to include at least 190 patients. Intention to treat analysis Not reported
Participants	N = 300 TVT-O (transobturator inside out) = 151 TVT (bottom-up tension-free vaginal tape) = 149 Characteristics Gender – Female/N (% female) 300/300 (100%) Age (years)- Mean ± SD TVT-O = 57.82 ± 10.35 TVT = 57.19 ± 10.65 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI – Mean ± SD Not reported Detrusor overactivity – n/N (%) Not reported Incontinence-specific quality of life Scale used - VAS TVT - O = 7.91 ± 1.82 (151) TVT = 7.86 ± 1.61 (149) Scale used - Incontinence Questionnaire-Short Form (ICIQ-UI SF) TVT-O = 13.76 ± 4.78 (151) TVT = 13.28 ± 15.83 (149) Scale used - CONTILIFE Daily activities TVT-O = 22.38 ± 5.96 TVT = 19.82 ± 5.29 Effort activities TVT-O = 16.22 ± 2.62 TVT = 17.62 ± 3.48 Self-image TVT-O = 18.39 ± 5.51 TVT = 17.56 ± 4.82 Emotional impact TVT-O = 24.95 ± 6.52 ± SD Not reported Duration of SUI – Mean ± SD Not reported Detrusor overactivity – n/N (%) Not reported Incontinence-specific quality of life Scale used - VAS TVT - O = 7.91 ± 1.82 (151) TVT = 7.86 ± 1.61 (149) Scale used - Incontinence Questionnaire-Short Form (ICIQ-UI SF) TVT-O = 13.76 ± 4.78 (151) TVT = 13.28 ± 15.83 (149) Scale used - CONTILIFE Daily activities TVT-O = 22.38 ± 5.96 TVT = 19.82 ± 5.29 Effort activities TVT-O = 16.22 ± 2.62 TVT = 17.62 ± 3.48 Self-image TVT-O = 18.39 ± 5.51 TVT = 17.56 ± 4.82 Emotional impact TVT-O = 24.95 ± 6.52 Society pelvic organ prolapse quantification system 8] Concomitant operations
Interventions	TVT-O procedure (Gynecare® TVT Obturator System, Ethicon, USA) was performed according to the original technique described by de Leval (2003). TVT procedure (Gynecare® TVT Ethicon, USA) was performed according to the technique described by Ulmsten (1996)

Outcomes	Patient satisfaction with treatment at 12 months Scale used – "Patients were also asked to rate their overall satisfaction after the operation with three possible choices: very satisfied, satisfied, or not satisfied." Very satisfied TVT-O = 120/151 (79.5%) TVT = 120/149 (80.5%) Satisfied TVT-O = 25/151 (16.6%) TVT = 21/149 (14.1%) Not satisfied TVT-O = 2/151 (1.3%) TVT = 0/149 (0%) Patient satisfaction with treatment at 12 months Scale used – "Patients were also asked to rate their overall satisfaction after the operation with three possible choices: very satisfied, satisfied, or not satisfied." Very satisfied TVT-O = 120/151 (79.5%) TVT = 120/149 (80.5%) Satisfied TVT-O = 25/151 (16.6%) TVT = 21/149 (14.1%) Not satisfied TVT-O = 2/151 (1.3%) TVT = 0/149 (0%) urine leakage frequency before and after the surgery was identical or worse." Cured TVT-O = 112/151 (74.2%) TVT = 111/149 (74.5%) Improved TVT-O = 31/151 (20.5%) TVT = 27/149 (18.1%) Failed TVT-O = 4/151 (2.6%) TVT = 3/149 (2%) Incontinence-specific quality of life at 12 months Scale used - Visual Analog Scale (VAS) - 0 = no symptoms, 10 = maximum symptoms TVT-O = 2.16 ± 1.88 (147) TVT = 2.14 ± 1.45 (141) Scale used - Incontinence Questionnaire-Short Form (ICIQ-UI SF) TVT-O = 3.5 ± 3.47 (147) TVT = 3.00 ± 4.92 (141) Scale used - CONTILIFE Daily activities TVT-O = 10.62 ± 4.21 TVT = 10.32 ± 5.14 Effort activities TVT-O = 10.52 ± 2.19 TVT = 9.64 ±3.25 Self-image TVT-O = 10.31 ± 4.21 TVT = 9.07 ± 3.52 Emotional impact TVT-O = 11.91 ± 6.29 TVT = 10.39 ± 4.97 Sexuality TVT-O = 5.07 ± 1.97 TVT = 5.57 ± 1.37 Well-being TVT-O = 1.91 ± 1.12 TVT = 1.48 ± 0.83 Adverse effects of treatment Peri-operative Bladder perforation TVT-O = 0/151 (0%) TVT = 1/149 (0.7%) Severe urinary retention TVT-O = 1/151 (0.6%) TVT = 1/149 (0.7%) Retropubic haematoma TVT-O = 0/151 (0%) TVT = 1/149 (0.7%) Suprapubic discomfort TVT-O = 0/151 (0%)* TVT = 6/149 (4.5%) Inner thigh discomfort TVT-O = 8/151 (5.4%) TVT = 0/149 (0%) Post-operative Tape erosion TVT-O = 2/151 (%) TVT = 2/149 (%) De novo urgency* TVT-O = 20/151 (%) TVT = 9/149 (%) Anticholinergic use postoperatively TVT-O = 15/151 (%) TVT = 7/149 (%) Urinary tract infection TVT-O = 8/151 (5.4%) TVT = 5/149 (3.4%) Psychological outcomes Not reported Clinical measures Postoperative retention of urine (24h) - PVR > 100 ml TVT-O = 10/151 (6.6%) TVT = 4/149 (2.7%) *Most common adverse effects in peri-operative and post-operative ctageories used in meta-analyses Patient satisfaction with treatment, Continence status, Incontinence QOL, Peri-operative adverse effects & Post-operative adverse effects.
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: yes A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: yes A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Blinding of participants and personnel (performance bias)	High risk	B1 - Did groups get same level of care: yes B2 - Were participants blinded: no
Blinding of outcome assessment (detection bias)	High risk	B3 - Were clinical staff blinded: no Level of bias: unclear D4 - Were investigators blinded to interventions: yes D5 - Were investigators blinded to confounding factors: unclear Level of bias: low
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: yes - 147/151 (97.4%) in TVT-O and 141/149 (94.6%) were assessed at 12 months Level of bias: low
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Laurikainen 2007

Methods	Finland Study type Randomized controlled trial Aim of the study To compare the TVT procedure with the TVT-O, using the same tape for both, in terms of cure rate, peri-operative complications. Study dates March 2004 to November 2005 Source of funding Not reported Women were positioned on the operating table according to the procedure. For TVT the angle of the thighs in the stirrups was to be 70o while for TVT-O it was to be betwenn 90o and 110o. Both procedures were performed under local anaesthesia, using 75-135ml prilocaine plus adrenalin diluted to 0.25%. Light intravenous sedation was used to enable the patient to perform the intraoperative cough stress test. The cough stress test was performed with a bladder volume of 300ml, with the goal of adjusting the tape to allow a drop of urine to escape from the outer meatus of the urethra on strong coughing. Cystoscopy was performed twice during the TVT procedure (one each passing of the needle) and once during the TVT-O procedure. Power calculation Sample size calculation was based on a 95% success rate with TVT and that a 10% difference in either success rate or complication rate would be clinically relevant. With 70% power to show a 10% difference, the sample size should be 160 patients, 130 in each arm. Intention to treat analysis Not reported

Participants	N = 267 TVT = 136 TVT-O = 131 Characteristics Gender – Female/N (% female) 267/267 (100%) Age (years)- Mean ± SD TVT = 53 ± 10 TVT-O = 54 ± 10 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI – Mean ± SD TVT = 7 ± 6 TVT-O = 10 ± 7 Detrusor overactivity – n/N (%) Not reported Inclusion criteria 1] history of stress urinary incontinence 2] indication for surgical treatment of stress incontinence 3] positive cough stress test 4] Detrusor Instability Score (DIS) 7 or less Exclusion criteria 1] previous incontinence surgery 2] postvoid residual urine volume > 100mL 3] lower urinary tract anomaly 4] current urinary tract infection or more than 3 UTI eppisodes in past year 5] urogenital prolapse of more then 2nd degree (Baden-Walker) 6] BMI > 35 7] previous radiation treatment of the pelvis 8] active malignancy 9] anticoagulant therapy 10] hemophilia 11] neurogenic disease whihc can be associated with bladder disorders 12] anticholinergic medication 13] duloxetine medication 14] inability to understand the purpose of the trial 15] patient immobile
Interventions	TVT was performed as decribed by Ulmsten and TVT-O as described by de Leval and in both case Gynecare (Ethicon, Johnso & Johson) wass used.
Outcomes	Patient satisfaction with treatment Not reported at 12 months Self reported rate of absolute symptom reduction per day Not reported Continence status at 12 months* Scale used - objective cure rate = negative stress test TVT = 128/136 (94.1%) TVT-O = 122/131 (93.1%) Incontinence-specific quality of life Scale used = UDI-6 (score at 12 months) TVT: 7 ± 2 TVT-O: 7 ± 2 Scale used = IIQ-7 (score at 12 months) TVT: 7 ± 1 TVT-O: 7 ± 1 Adverse effects of treatment Peri-operative Bladder injury TVT: 1/136 (0.7%) TVT-O: 0/131 (0%) Vaginal perforation TVT: 2/136 (1.5%) TVT-O:/3/131 (2.3%) Groin pain TVT: 2/136 (1.5%) TVT-O: 21/131 (16%) Urinary tract infection TVT: 11/136 (8%) TVT-O: 17/131 (13%) Hematoma TVT: 1/136 (0.7%) TVT-O: 0/131 (0%) Wound infection TVT: 1/136 (0.7%) TVT-O: 0/131 (0%) Post-operative Urinary tract infection* TVT: 19/134 (14.2%) TVT-O: 22/131 (16.8%) De novo urgency TVT: 2/134 (1,5%) TVT-O: 3/131 (2.3%) Retention symptoms TVT: 1/134 (0.7%) TVT-O: 2/131 (1.5%) Tape erosion TVT: 0/134 (0%) TVT-O: 1/131 (0.8%) Pain TVT: 0/134 (0) TVT-O: 1/131 (0.8%) Psychological outcomes Not reported Clinical measures at 12 months Post-void residual volume (ml) - Median (interquartile range) TVT-O = 00.00 (00.00 – 10.25) TVT = 10.00 (00.00 – 50.00) *Data on most common adverse effects for both peri-operative and post-operative categories used in meta-analyses Continence status, Incontinence QOL, Peri-operative adverse effects & Post-operative adverse effects.
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: yes - computer generated A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low Rinne 2008: Judgement Comment: Patients were randomized into the groups by using computer-generated random allocations in ratio of 1:1 in balanced blocks of four. The investigator called an independent randomization center.
Allocation concealment (selection bias)	Low risk	A1 - Was there appropriate randomisation: yes - computer generated A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low Rinne: Judgement Comment: Independent randomization center, low risk
Blinding of participants and personnel (performance bias)	Low risk	B1 - Did groups get same level of care: Yes B2 - Were participants blinded: Unclear B3 - Were clinical staff blinded: unclear Level of bias: unclear. Rinne 2008: Judgement Comment: No information of blinding of participants or surgeons, blinding of surgeons not feasible Palva 2010: Judgement Comment: It is unlikely that the awareness of the operation type affects the patients satisfaction or scores, though it is not described that they were blinded to the operation type. Judgement Comment: The operator was not blinded to the intervention operation.
Blinding of outcome assessment (detection bias)	High risk	D4 - Were investigators blinded to interventions: yes - pad test performed by nurse blinded to treatment allocation D5 - Were investigators blinded to confounding factors: unclear Level of bias: low Rinne 2008: Judgement Comment: The one year follow-up visit was performed by a study nurse and an independent physician or the operating surgeon, high risk.
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: yes Level of bias: low Rinne 2008: Judgement Comment: Lost to follow-up 2/136 in TVT group (reason not specified) Lost to follow-up 1/132 in TVT-O group (changed to TVT during surgery)Reasons for not completing the study not reported. Palva 2010: Quote: "Two hundred and seventy three patients were randomized, and 267 patients received the allocated operation: 136 in the TVT group and 131 in the TVT-O group. Five patients dropped out between randomization and surgery. One TVT-O operation was altered to a TVT procedure due to technical difficulties with the TVT-O procedure. At the 36-month follow-up, 257 patients (96%) were evaluated and only 10 patients were lost to follow-up." Judgement Comment: Dropout: 5/136 in intervention group, 6/132 in control group. LAuriokainen 2014: Quote: "Overall, 254 women returned to the clinics for their 5-yr follow-up visit. Thus 94.8% of the women (254 of 268) could be assessed per protocol. Fourteen women were not available for assessment: 5 in the TVT group (5 of 136) and 9 in the TVT-O group (9 of 132). One woman had died, two women had moved abroad, six women refused to return to the clinic, and five women had undergone a repeat incontinence operation." Judgement Comment: Reasons for missing outcome date probably unlikely to be related to true outcomes, though five women had undergone a repeat incontinence operation, and not stated which primary group? Missing outcome data balanced in no across groups, but unclear what reasons for and which group?
Selective reporting (reporting bias)	Low risk	Judgement Comment: Protocol at clinicaltrials.gov. Reports on all the outcomes stated in the protocol. Complictions not specified in details in the protocol

Other bias	Low risk	Judgement Comment: Baseline comparability:Both groups comparable at baseline. The authors declare no conflicts of interest. the study appears to be free of other sources of bias

Lee 2007

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention TVT ● *Mean age* : 54.4 (11) ● *Mean parity years*: 2.5 (1.2) ● *Menopause %*: 19 (31.7) ● *Mean symptom duration (years)*: 7.3 (5.7) ● *SUI Grade (range 1-3)*: 1.6 (0.5) control TVT O ● *Mean age* : 54.4 (11) ● *Mean parity years*: 2.5 (1.2) ● *Menopause %*: 19 (31.7) ● *Mean symptom duration (years)*: 7.3 (5.7) ● *SUI Grade (range 1-3)*: 1.6 (0.5) **Included criteria:** female patients with urodynamically proven SUI who underwent surgery **Excluded criteria:** Patients with predominant urge incontinence or pelvic organ prolapse were excluded from study **Pretreatment:** There was no significant difference in the preoperative characteristics of patients who under-went TVT or TVT-O
Interventions	**Intervention Characteristics** Intervention TVT ● *Description* : We used the TVT technique according to the description of Ulmsten et al. cystoscopy wasperformed only during the TVT procedure. ● *Length of follow-up*: 13 months Control TVT O ● *Description* : We used the TVT technique according to the description of Ulmsten et al and theTVT-O technique according to the description of de Leval of the obturator route of tape insertion12 with the patient under intravenous and local anesthesia. ● *Length of follow-up*: 13 months
Outcomes	*Bensmerter/ leg pain (LFU min. 6 months)* ● **Outcome type**: Continuous Outcome ● **Measure names**: ["Time"] ● **Reporting**: Not reported

Dage med inkontinens episoder/days with incontinence episodes (LFU min. 6 months)
- **Outcome type**: Continuous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported

Inkontinensrelateret livkvalitet (Incontinence related QOL) (LFU min. 6 months)
- **Outcome type**: Continuous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Fully reported
- **Range**: 0-100
- **Direction**: Higher is better
- **Data value**: Endpoint

De novo inkontinens efter operation (De novo incontinence after operation) (LFU min. 6 months)
- **Outcome type**: DichotomousOutcome
- **Measure names**: ["Time"]
- **Reporting**: Fully reported
- **Unit of measure**: amount of people with incontinence
- **Direction**: Lower is better
- **Data value**: Endpoint

Stranguri med residualurin (stranguri with residual urine) (LFU min. 6 months)
- **Outcome type**: DichotomousOutcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported

Re-operation (reoperation) (LFU min. 6 months)
- **Outcome type**: DichotomousOutcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported

Underlivssmerter (pelvic pain) (LFU min. 6 months)
- **Outcome type**: ContinuousOutcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported

Infektion (Infection) (30 dage/30 days)
- **Outcome type**: DichotomousOutcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported

Hæmatom (hematoma) (30 dage/30 days)
- **Outcome type**: Dichotomous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Fully reported

- **Direction**: Lower is better
- **Data value**: Endpoint

Blæreperforation (bladder perforation) (Peropeativt/during surgery)
- **Outcome type**: Dichotomous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Fully reported
- **Direction**: Lower is better
- **Data value**: Endpoint

Operationstid (Surgery time) (Peropeativt/during surgery)
- **Outcome type**: Continuous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Fully reported
- **Scale**: hours
- **Range**: 0-24
- **Direction**: Lower is better
- **Data value**: Endpoint

Dyspareuni (dyspareuni) (30 dage/30 days)
- **Outcome type**: Dichotomous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported
- **Direction**: Lower is better
- **Data value**: Endpoint

Ændring i seksual funktion (Change in sexual function) (30 dage/30 days)
- **Outcome type**: Dichotomous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported
- **Data value**: Endpoint

Antal tilfælde af inkontinens (Incontinence episodes) (LFU min. 6 months)
- **Outcome type**: Continuous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Not reported

Underlivssmerter (pelvic pain) (LFU min. 6 months)
- **Outcome type**: Dichotomous Outcome
- **Measure names**: ["Time"]
- **Reporting**: Fully reported
- **Unit of measure**: No of patients reporting pain
- **Direction**: Lower is better
- **Data value**: Endpoint

	Grad af inkontinens (Severity of urinary incontinence) (LFU) ● **Outcome type**: Continuous Outcome ● **Measure names**: ["Time"] ● **Reporting**: Not reported *Livskvalitet - pt'er tilfredse med operation (QOL - Patients satisfied with surgery) (LFU)* ● **Outcome type**: Dichotomous Outcome ● **Measure names**: ["Time"] ● **Reporting**: Fully reported ● **Unit of measure**: No of patients "very satisfied" with surgery ● **Direction**: Higher is better ● **Data value**: Endpoint
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: Patients were alternately assigned
Allocation concealment (selection bias)	Unclear risk	Judgement comment: No information of allocation concealment
Blinding of participants and personnel (performance bias)	High risk	Judgement comment: No information of blinding of surgeons and participants, blinding of surgeons not feasible.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement comment: No information of blinding of outcome assessors
Incomplete outcome data (attrition bias)	Low risk	Judgement comment: No dropouts
Selective reporting (reporting bias)	Low risk	Judgement comment: No refernce to a protocol, the study reports on all outcomes stated in the methods section.
Other bias	Low risk	Judgement comment: The study appers the be free from other sources of bias

Liapis 2006

Methods	Greece Study type Randomized controlled trial Aim of the study "To compare prospectively the TVT-O procedure concerning the effectiveness, safety and simplicity with the TVT procedure." Study dates November 2003 to October 2004 Source of funding Not reported TVT-O "The patient is placed in gynecological position with thighs in hyperflexion. A 16-Fr Foley catheter is inserted into the bladder. The points were the needles will exit at the skin level are identified by tracing a horizontal line at the level of the urethral meatus. The exit points are located 2 cm above this line and 2 cm outside the thigh folds. A skin incision ismade at each exit point. A median sagittal incision of the vaginal wall is started 1 cm distal to

	the urethral meatus and about 2 cm long. A fine dissection path is created with dissection on a horizontal plane with a 45° angle relatively to the urethral sagittal plane, towards the upper part of ischio-pubic ramus. The Gynecare TVT Winged Guide is inserted into the dissected tract until it passes the inferior pubic ramous. The correct TVT Helical Presser is inserted into the dissected tract following the channel of the TVT Winged Guide. The device is pushed inward slightly and passes the obturator membrane and then comes out through the incision of skin. The technique is repeated on the patient's other side ensuring that the tape lies flat under the urethra without tension." TVT Additional detail not reported. Power calculation Not reported
Participants	N = 89 TVT-O (transobturator inside out) = 43 TVT (bottom-up tension-free vaginal tape) = 46 Characteristics Gender - Female/N (% female) 89/89 (100%) Age (years)- Mean ± SD TVT-O = 52 ± 10.2 TVT = 53 ± 9.1 Incontinence episodes/day - Mean ± SD Not reported Duration of SUI (years) - Mean ± SD TVT-O = 4.4 ± 3.1 TVT = 4.7 ± 3.4 Detrusor overactivity - n/N (%) Not reported Inclusion criteria "All patients included in the study had SUI without evidence of bladder over-activity" Exclusion criteria 1] Evidence of detrusor instability 2] Other gynaecologic disease requiring hysterectomy or other gynaecologic operation 3] Previously failed surgcal treatment
Interventions	TVT-O was performed using the Gynecare TVT Winged Guide and the correct TVT Helical Presser. TVT was performed according to the technique described by Ulmsten (1996)
Outcomes	Patient satisfaction with treatment at 12 months Scale used - "Subjective cure, improvement and failure were assessed with the use of a simple questionnaire" Cured TVT-O = 33/43 (76.7%) TVT = 34/46 (73.9%) Improved TVT-O = 7/43 (16.2%) TVT = 10/46 (21.7%) Failed TVT-O = 3/43 (6.9%) TVT = 2/46 (4.3%) Self reported rate of absolute symptom reduction per day Episodes of incontinence: Not reported Episodes of urgency: Not reported Continence status at 12 months Scale used - "Objective cure was defined as a negative cough stress test during multi-channel urodynamic examination and a 1-hour pad test giving a weight of less than 1 g. Objective improvement was defined as a negative cough stress test and a 1-hour pad test weight of less than 5 g. Failure was defined as a positive cough stress test and urine leakage more than 5 g in the 1-hour pad test." Cured TVT-O = 39/43 (90%)* TVT = 41/46 (89%)* Improved TVT-O = 3/43 (7.6%)* TVT = 3/46 (6.5%)* Failed TVT-O = 1/43 (2.5%)* TVT = 2/46 (4.3%)* *Only % reported, n calculated byNCC-WCH Incontinence-specific quality of life Not reported Adverse effects of treatment Peri-operative Bladder perforation TVT-O = 0/43 (0%) TVT = 3/46 (6.5%) Urinary retention (> 100 ml)* TVT-O = 1/43 (2.3%) TVT = 4/46 (8.7%) Post-operative Urinary infection TVT-O = 1/43 (2.3%) TVT = 3/46 (6.5%)

	Vaginal erosion TVT-O = 0/43 (0%) TVT = 1/46 (2.2%) De novo instability at 12 months TVT-O = 4/43(9.3 %)** TVT = 4/46 (8.6%)** De novo urgency at 12 months*** TVT-O = 6/43 (13.9%)** TVT = 5/46 (10.8%)** **Only % reported, n calculated by NCC-WCH *** Most common adverse effects in peri-operative and post-operative categories used in meta-analysis Psychological outcomes Not reported Clinical measures Not reported Patient satisfaction with treatment, Continence status, Peri-operative adverse effects & Post-operative adverse effects.
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: unclear - "All patients were randomly assigned to an operation from the outpatient department of the hospital" A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: unclear
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: unclear - "All patients were randomly assigned to an operation from the outpatient department of the hospital" A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: unclear
Blinding of participants and personnel (performance bias)	Unclear risk	B1 - Did groups get same level of care: unclear B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: unclear Level of bias: unclear
Blinding of outcome assessment (detection bias)	Unclear risk	D4 - Were investigators blinded to interventions: unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: unclear
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: unclear Level of bias: unclear
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Meschia 2007

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age, years (SD)*: 56 (9) ● *BMI, mean (SD)*: 25.6 (3) ● *Parity, mean (range)*: 2 (0-6) Control

	● *Mean age, years (SD)*: 58 (10) ● *BMI (SD)*: 26.1 (3) ● *Parity, mean (range)*: 2 (0-5) **Included criteria:** SUI and urethral hypermobility **Excluded criteria:** Previous anti-incontinence surgery. Vaginal prolapse requiring treatment. Co-existing pelvic pathology. Known bleeding diathesis or current anti-coagulant therapy. Detrusor overactivity and urethral hypo mobility (delta Qtip < 20 degrees from the horizontal with straining). **Pretreatment:** No differences between groups at baseline.
Interventions	**Intervention Characteristics** Intervention ● Description: Midurethral sling TVT Control ● Description: Midurethral sling TVT-O
Outcomes	*Inkontinensrelateret livskvalitet, ICIQ-UI-SF, mean final, SD* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: ICIQ-UI-SF ● **Range**: 0-21 ● **Direction**: Lower is better ● **Data value**: Endpoint *Reoperation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Patientoplevet effekt, subjective cure, antal personer* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint *Blæreperforation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Bensmerter, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported

	● **Scale**: Bensmerter ● **Direction**: Lower is better ● **Data value**: Endpoint
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: Women with SUI and urethral hypermobility were randomized to treatments according to a centralized computer-generated random list. Researchers randomized participants by a telephone system to one of the treatment groups.
Allocation concealment (selection bias)	Low risk	Judgement Comment: Computer generated allocation sequence administred by a telephone system.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information of blinding of surgeons and participants. Blinding of surgeons not feasible
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No informations of blinding of outcome assessors. Quality of life and subjective cure rate were self-reported, participants assumed not blinded.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: 6 dropouts in the TVT group, 7 dropouts in the TVT-O group, reasons for dropout not stated. No intention to treat analyses.
Selective reporting (reporting bias)	Low risk	Judgement Comment: No reference to a protocol, reports on all the outcomes stated in the methods section. No reporting of abdominal or pelvic pain
Other bias	Unclear risk	Judgement Comment: No information of conflicts of interests. Baseline comparability: Groups comparable at baseline.

Scheiner 2012

Methods	Switzerland Study type Randomized controlled trial Aim of the study To compare retropubic tension-free vaginal tape (TVT) with transobturator out-in (TOT) and in-out (TVT-O) for female stress urinary incontinence. Study dates January 2006 to October 2009 Source of funding "No funding received" Experienced gynaecologists performed the procedures according to the original methods (not described), preferably under analgesia and sedation. The first 10 procedures were observed by a urogynaecologist. Cefazolin or clindamycin (in case of penicillin allergy) was given as prophylactic single-shot antibiotic. Cystoscopy was mandatory for every procedure. To determine appropriate tape tension a cough test was performed, and Metzenbaum scissors were placed as a spacer between tape and urethra to ascertain a tension-free position. An indwelling catheter was placed in case of concomitant prolapse surgery, intraoperative bladder injury or increased intraoperative bleeding with need

	of intra-vaginal packing. Power calculation Equivalence for all techniques in regard to efficacy and continence was assumed, but fewer obstructions in the two transobturator approach groups (TVT-O and TOT). A postoperative Qmax of 25 and 30 ml/s (SD ± 10) in the TVT and transobtruator groups, respectively. Based on 0.8 power to detect this difference, a total of 200 patients was estimated (P = 0.05, two-sided). Intention to treat analysis Not reported
Participants	N = 160 TVT-O = 40 TOT = 40 TVT = 80 Characteristics Gender – Female/N (% female) 160/160 (100%) Age (years) - Mean ± SD TVT-O = 59.3 ± 12.1 TOT = 56.6 ± 10.3 TVT = 57.8 ± 13.0 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI – Mean ± SD Not reported Detrusor overactivity – n/N (%) Not reported Overactive bladder dry - n/N (%) TVT-O = 13/40 (32.5%) TOT = 9/40 (22.5%) TVT = 25/80 (31.3%) Overactive bladder wet - n/N (%) TVT-O = 3/40 (7.5%) TOT = 2/40 (5.0%) TVT = 8/80 (10.0%) Incontinence-specific quality of life at baseline Scale used - Visual Analogue Scale on incontinence impact (0 = no urinary complaints, 10 = unbearable urinary complaints) - mean ± SD, N TVT-O = 7.1 ± 2.6, 37 TOT = 7.7 ± 1.9, 38 TVT = 7.5 ± 2.1, 74 Scale used - King's Health Questionnaire (higher scores, greater impairment) General Health Perception - mean ± SD, N TVT-O = 33.6 ± 26.4, 37 TOT = 42.9 ± 24.7, 38 TVT = 36.1 ±21.8, 74 Scale used - King's Health Questionnaire (higher scores, greater impairment) Incontinence impact - mean ± SD, N TVT-O = 68.6 ± 31.3, 37 TOT = 82.9 ± 26.0, 38 TVT = 75.9 ± 24.5, 74 Scale used - King's Health Questionnaire (higher scores, greater impairment) Overactive bladder - mean ± SD, N TVT-O = 48.7 ± 39.6, 37 TOT = 44.6 ± 33.3, 38 TVT = 46.9 ± 31.7, 74 Inclusion criteria 1] Urodynamically confirmed SUI 2] Mixed urinary incontinence with predominant component of SUI 3] Women with concomitant sling insertion to prolapse repair were eligible Exclusion criteria 1] Missing urodynamic assessment 2] Previous sling procedure 3] Predominant overactive bladder syndrome 4] Post-void residual volume above 100 ml 5] Pregnancy or considering further pregnancy 6] Known or suspected coagulopathy 7] Known allergy to local anaesthetics 8] Unable to understand German 9] Unable or unwilling for follow up
Interventions	Tension-free vaginal tape (TVT), transobturator outside-in (TOT), transobturator inside-out (TVT-O). Further details not reported.
Outcomes	Patient satisfaction with treatment at 12 months - n/N (%) "Patient's global impression of improvement (cured)" TVT-O = 29/27 (78.4%) TOT = 28/34 (82.4%) TVT = 57 (87.7%) Self reported rate of absolute symptom reduction per day Not reported Continence status at 12 months - n/N (%) "Both a negative cough (supine position) and a negative short-pad test [weight gain < 3g, performed with a bladder filling at 300ml" TVT-O = 33/37 (89.2%) TOT = 31/34 (91.2%) TVT = 58/65 (93.6%) Incontinence-specific quality of life at 12 months Scale used - Visual Analogue Scale on incontinence impact (0 = no urinary complaints, 10 =

	unbearable urinary complaints) - mean ± SD, N TVT-O = 1.3 ± 1.8, 28 TOT = 1.2 ± 1.7, 28 TVT = 0.7 ± 1.3, 47 Scale used - King's Health Questionnaire (higher scores, greater impairment) General Health Perception - mean ± SD, N TVT-O = 25.0 ± 2.08, 28 TOT = 22.3 ± 19.6, 28 TVT = 22.3 ± 18.4, 47 Scale used - King's Health Questionnaire (higher scores, greater impairment) Incontinence impact - mean ± SD, N TVT-O = 10.7 ± 18.6, 28 TOT = 11.9 ± 22.6, 28 TVT = 8.5 ± 14.7, 47 Scale used - King's Health Questionnaire (higher scores, greater impairment) Overactive bladder - mean ± SD, N TVT-O = 4.9 ± 14.5, 28 TOT = 5.2 ± 19.3, 28 TVT = 3.9 ± 13.0, 47 Adverse effects of treatment Bladder perforation TVT-O = 0/40 (0%) TOT = 0/40 (0%) TVT = 3/80 (3.75%) Vaginal perforation TVT-O = 4/40 (10%) TOT = 6/40 (15%) TVT = 1/80 (1.25 %) Haemorrhage TVT-O = 0/40 (0%) TOT = 0/40 (0%) TVT = 1/80 (1.25%) Tape loosening within first week TVT-O = 0/40 (0%) TOT = 1/40 (2.5%) TVT = 1/80 (1.25%) Tape release within 12 months by complete incision, including partial excision TVT-O = 1/40 (2.5%) TOT = 0/40 (0%) TVT = 2/80 (2.5%) Second sling insertion TVT-O = 0/40 (0%) TOT = 1/40 (2.5%) TVT = 1/80 (1.25%) Vaginal tape exposure TVT-O = 0/40 (0%) TOT = 4/40 (10%) TVT = 1/80 (1.5%) Thigh or groin pain TVT-O = 1/40 (2.7%) TOT = 3/40 (8.3%) TVT = 1/80 (1.5%) Female sexual dysfunction (in sexually active women; not associated with tape exposure) TVT-O = 0/25 (0%) TOT = 5/29 (17.2%) TVT = 1/52 (1.9%) Psychological outcomes Not reported Clinical measures Not reported
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: Yes - computer generated A2 - Was there adequate concealment: Unclear - not reported A3 - Were groups comparable at baseline: Unclear - not reported Level of bias:
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: Yes - computer generated A2 - Was there adequate concealment: Unclear - not reported A3 - Were groups comparable at baseline: Unclear - not reported Level of bias:
Blinding of participants and personnel (performance bias)	Unclear risk	B1 - Did groups get same level of care: unclear B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: unclear Level of bias: unclear
Blinding of outcome assessment (detection bias)	Unclear risk	D4 - Were investigators blinded to interventions: unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: low
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: yes Level of bias: low
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Teo 2011

Methods	United Kingdom Study type Randomized controlled trial Aim of the study To evaluate the effectiveness and complications of TVT and TVT-O for USI in women Study dates February 2005 to September 2007 Source of funding None reported Intra-operative cystoscopy with a 70 degree cystoscope was used in all studies, included twice after each trocar pass during the TVT procedure and one at the end of the TVT-O procedure. Urethral catheterization was used intra-operatively but not postoperatively. Cough testing was used to guide TVT tension. Power calculation Using a 65% objective cure rate for TVT 100 women were required per study arm to detect a 20% difference in the cure rate with 80% power. Significance was considered at 0.05 Intention to treat analysis ITT analysis considered women lost to follow-up considered as treatment failures for subjective and objective outcomes.
Participants	N = 127 TVT = 66 TVT-O = 61 Characteristics Gender – Female/N (% female) 127/127 (100%) Age (years)- Mean ± SD TVT = 52.4 ± 11.8 TVT-O = 50.9 ± 11.4 Incontinence episodes/day [reported as leakage episodes/day] – Median (Range) TVT = 3 (0 - 13) TVT-Secur = 3 (0 - 16) Duration of SUI (years) Not reported Detrusor overactivity Not reported Inclusion criteria 1] sole diagnosis of SUI 2] no previous continence surgery Exclusion criteria 1] uterovaginal prolapse greater than stage I on the Pelvic Organ Prolapse Quantification staging system 2] voiding dysfunction (defined as maximal flow rate less than 15 mL per second or post-void residual urine volume 100 ml or greater.
Interventions	TVT procedure was not described in detail TVT-O was performed as described by de Leval 2005 but local (not general) anaesthetic was used.
Outcomes	Patient satisfaction with treatment Not reported Self reported rate of absolute symptom reduction per day Not reported Continence status at 12 months Object cure - defined as "24 hour pad test < 5gm" TVT: 33/41 (80.5%) TVT-O: 25/29 (86.2%) Incontinence-specific quality of life Not reported Adverse effects of treatment Peri-operative Bladder perforation TVT = 0/66 (0%) TVT-O = 0/61 (0%) Vaginal injury* TVT = 0/66 (0%) TVT-Secur = 3/61 (4.9%)

	Post-operative Leg pain* TVT: 1/66 (1.7%) TVT-O: 14/61 (23.0%) Vaginal tape erosion TVT: 3/66 (5.9%) TVT-O: 1/61 (1.6%) Psychological outcomes Not reported Clinical measures Not reported Continence status, Peri-operative adverse effects & Post-operative adverse effects
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: Yes - computer generated A2 - Was there adequate concealment: Yes - opaque envelopes used A3 - Were groups comparable at baseline: Yes
Allocation concealment (selection bias)	Low risk	A1 - Was there appropriate randomisation: Yes - computer generated A2 - Was there adequate concealment: Yes - opaque envelopes used A3 - Were groups comparable at baseline: Yes
Blinding of participants and personnel (performance bias)	High risk	B1 - Did groups get same level of care: Yes B2 - Were participants blinded: No B3 - Were clinical staff blinded: No Level of bias: Serious
Blinding of outcome assessment (detection bias)	Unclear risk	D4 - Were investigators blinded to interventions: Unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: low
Incomplete outcome data (attrition bias)	High risk	C1 - Was follow-up equal for both groups: Yes C2 - Were groups comparable for dropout: No C3 - Were groups comparable for missing data: No Level of bias: Serious
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Ugurlucan 2013

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age, years (SD)*: 50.6 (8.0) ● *BMI, mean (SD)*: 30.4 (4.3) ● *Parity, mean (SD)*: 3.06 (1.3) Control ● *Mean age, years (SD)*: 51.1 (9,3) ● *BMI (SD)*: 30.9 (4.9) ● *Parity, mean (SD)*: 3.58 (1.54)

	Included criteria: Not reported **Excluded criteria:** Not reported **Pretreatment:** No differences between groups at baseline.
Interventions	**Intervention Characteristics** Intervention ● Description: Midurethral sling TVT. The same surgeon peformed all of the surgecal procedures. The operations were performed with spinal or general anesthesia according to patient preferences in accordance with original technique described by Ulmsten and de Leval. For TVT operations Gynecare TVT, for TVT-O operations Gynecare TVT Obturator system tension- free support for incontinence was used. Cystoscopi was routinely performed in all of the TVT-procedures and in suspected cases during TVT-O operations. Foley catheter was introduced during all of the operations and kept for 24 hours in cases of isolated midturethraal sling operations, and kept for three days if anterior colporrhaphy was included. The residual urine volume was measured afte rthe Folley catheter was removed and the patients were discharged when the residual urine volumen was less than 100 ml. In case of urinary retention, the catheter was inserted and kept in place for an additional 24 hours. Control ● Description: Midurethral sling TVT-O. The same surgeon peformed all of the surgecal procedures. The operations were performed with spinal or general anesthesia according to patient preferences in accordance with original technique described by Ulmsten and de Leval. For TVT operations Gynecare TVT, for TVT-O operations Gynecare TVT Obturator system tension- free support for incontinence was used. Cystoscopi was routinely performed in all of the TVT-procedures and in suspected cases during TVT-O operations. Foley catheter was introduced during all of the operations and kept for 24 hours in cases of isolated midturethraal sling operations, and kept for three days if anterior colporrhaphy was included. The residual urine volume was measured afte rthe Folley catheter was removed and the patients were discharged when the residual urine volumen was less than 100 ml. In case of urinary retention, the catheter was inserted and kept in place for an additional 24 hours.
Outcomes	*Antal tilfælde af inkontinens, mean pr. dag* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Blæreperforation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Bensmerter, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Scale**: Bensmerter ● **Direction**: Lower is better ● **Data value**: Endpoint *De novo urgency incontinence, antal personer* ● **Outcome type**: Adverse Event

	● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Change from baseline
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: No information of how the allocation sequence was generated
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: The patients were randomly assigned and 19 patients underwent TVT-O and the remaining 17 underwent TVT operation. Not reported or specified details on randomization.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: The same surgeon performed all of the surgical procedures. No information of blinding og participants.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No information of blinding of outcome assessors. Number of incontinence episodes were self-reported.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No dropouts
Selective reporting (reporting bias)	Low risk	Judgement Comment: The study reports on all the outcomes stated in the methods section. The majorities of outcomes were not directly patient important. No reporting of quality of life or patient perceived effect.
Other bias	High risk	Judgement Comment: Other operative treatments were not similar in the two groups. A lot of other urogynaecological operations were performed in the two groups . Only 4 and 3 participants in the TVT and TVT-O received sling operations only

Wang 2009

Methods	China Study type Randomized controlled trial Aim of the study "To compare the two surgical approaches to treat Chinese women with SUI to assess complications (primary end point) and cure rates at intermediate term follow-up (secondary end point)." Study dates January 2004 to December 2007 Source of funding Not reported All patients received prophylactic antibiotics with one preoperative dose of 500 mg of intravenous levofloxavin. All operations were performed by the same surgeon. The two procedures were performed under local anaesthesia supplemented by an intravenous sedative, unless patients were also undergoing vaginal

	hysterectomy or pelvic floor repair. In these cases, they were given general or spinal anaesthesia Cystoscopy was performed in the TVT group, before the tape was pulled upward, because of the risk of bladder perforation. Cystoscopy was not performed in the TVT-O group owing to the minimal risk of bladder perforation with this procedure. Power calculation Not reported Intention to treat analysis Not reported.
Participants	N = 315 TVT-O (transobturator inside out) = 155 TVT (bottom up tension-free vaginal tape) = 160 Characteristics Gender – Female/N (% female) 315/315 (100%) Age (years) - Mean ± SD TVT-O = 54.8 ± 12.5 TVT = 55.0 ± 11.9 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI (years) – Mean ± SD TVT-O = 8.5 ± 8.8 TVT = 10.3 ± 9.3 Detrusor overactivity – n/N (%) Not reported Inclusion criteria Women with demonstrable severe SUI, or mild or moderate SUI and failure of conservative therapy. Exclusion criteria 1] Pregnancy 2] Urinary tract infection 3] Urge incontinence 4] Postvoid residual volume > 100 ml 5] Past history of neurological disease, urogenital malignancy, fistula or pelvic radiotherapy
Interventions	TVT-O procedures were performed in accordance with the technique described by de Leval (2005) with Gynecare needles and woven polypropylene tapes (Ethicon Inc, Somerville, NJ, USA) TVT procedures were performed in accordance with the technique described by Ulmsten (1996) with Gynecare needles and woven polypropylene tapes (Ethicon Inc, Somerville, NJ, USA)
Outcomes	Patient satisfaction with treatment Not reported Self reported rate of absolute symptom reduction per day Episodes of incontinence: Not reported Episodes of urgency: Not reported Continence status at 12 months Scale used – Cured = "when the cough test was negative". Improved = "when the frequency of involuntary passage of urine and urine weight by the 1-h pad test were decreased by more than 50%". Failed = "frequency of involuntary passage of urine and urine weight by the 1-h pad test were decreased by less than 50% or worse than that before surgery" Cured TVT-O = 106/118 (89.8%) TVT = 103/115 (89.6%) Improved TVT-O = 9/118 (7.6%) TVT = 10/115 (8.7%) Failed TVT-O = 3/118 (2.5%) TVT = 2/115 (1.7%) Incontinence-specific quality of life Not reported Adverse effects of treatment Peri-operative Haematoma TVT-O = 2/146 (1.4%) TVT = 2/154 (1.3%) Wound infection TVT-O = 0/146 (0%) TVT = 0/154 (0%) Urinary retention* TVT-O = 4/146 (2.7%) TVT = 6/154 (3.9%) Post-operative De novo urinary urgency TVT-O = 6/146 (4.1%) TVT = 9/154 (5.8%) Tape erosion TVT-O = 3/146 (2.1%) TVT = 3/154 (1.9%) Groin/thigh pain* TVT-O = 12/146 (8.2%) TVT = 4/154 (2.6%)

	Psychological outcomes Not reported Clinical measures Post-void residual volume < 100 ml 12 h after surgery TVT-O = 119/146 (81.5%) TVT = 130/154 (84.4%) *Most common adverse effects in peri-operative and post-operative categories used in meta-analysis Continence status, Peri-operative adverse effects & Post-operative adverse effects
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: yes A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: yes A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Blinding of participants and personnel (performance bias)	Unclear risk	B1 - Did groups get same level of care: yes B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: unclear Level of bias: unclear
Blinding of outcome assessment (detection bias)	Unclear risk	D4 - Were investigators blinded to interventions: unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: low
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: unclear Level of bias: low
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Wang 2011

Methods	China Study type Randomized controlled trial Aim of the study To compare the efficacy and possible post-operative complications of the TVT-Secur with TVT and TVT-O procedures Study dates October 2008 to December 2009 Source of funding No funding reported During the U procedure, 50mL normal saline was injected into the bladder before withdrawing the inserter. This was then retracted and observed for blood. If blood was observed a cystoscopy was ordered to identify any bladder injury. Unlike TVT or TVT-O, the TVT-Secur was inserted as close to the urethra as possible to maintain the necessary pull-out force between the two ends. Power calculation A sample-size calculation showed objective cure rates for SUI, which included 90% for TVT and 88% for TVT-O and assuming a cure rate of 55% for

	TVT-Secur, 90 patients would be needed (30 in each group) to detect a difference of 35% in cure rates among the three procedures with 90% power and α value of 0.05. Assuming a drop-out rate of 20% study aimed to recruit 108 patients in total. Intention to treat analysis Not reported
Participants	N = 102 TVT = 32 TVT-O = 36 TVT-Secur = 34 Characteristics Gender – Female/N (% female) 102/102 (100%) Age (years)- Mean ± SD TVT = 56.6 ± 9.6 TVT-O = 56.0 ± 9.1 TVT-Secur = 57.3 ± 9.5 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI(years) – Mean ± SD TVT = 6.1 ± 5.5 TVT-O = 4.4 ± 3.6 TVT-Secur = 4.8 ± 4.4 Detrusor overactivity – n/N (%) Not reported Inclusion criteria Not reported Exclusion criteria 1] previous surgical procedure for SUI
Interventions	TVT was performed as described by Ulmsten et al. TVT-O was performed as described by De Leval. For TVT-Secur the hammock position was selected for patients with a higher ALPP (≥ H2O) and were performed as recommended by the manufacturer or as described by Tartaglia. All procedures were performed by experienced surgeons who had received the appropriate training.
Outcomes	Patient satisfaction with treatment Not reported Self reported rate of absolute symptom reduction per day Not reported Continence status at 12 months Negative cough stress test and the absence of urine leak by patients report - n/N (%) TVT = 30/32 (93.8%) TVT-O = 33/36 (91.7%) TVT-Secur = 23/34 (76.6%) Incontinence-specific quality of life at 12 months Not reported Adverse effects of treatment Bladder perforation TVT = 1/32 (3.1%) TVT-O = 0/36 (0%) TVT-Secur = 1/34 (2.9%) Patients with > 100ml blood loss TVT = 2/32 (6.3%) TVT-O = 1/36 (2.8%) TVT-Secur = 0/34 (0%) Complete retention TVT = 1/32 (3.1%) TVT-O = 1/36 (2.9%) TVT-Secur = 0/34 (70%) Thigh pain TVT = 0/32 (0%) TVT-O = 5/36 (13.9%) TVT-Secur = 0/34 (0%) Psychological outcomes Not reported Clinical measures Not reported
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: Yes - computer A2 - Was there adequate concealment: Yes - Seale, opaque envelopes used A3 - Were groups comparable at baseline: yes Level of bias: low
Allocation concealment (selection bias)	Low risk	A1 - Was there appropriate randomisation: Yes - computer A2 - Was there adequate concealment: Yes - Seale, opaque envelopes used A3 - Were groups comparable at baseline: yes Level of bias: low
Blinding of participants and personnel (performance bias)	Unclear risk	B1 - Did groups get same level of care: Yes B2 - Were participants blinded: unclear B3 - Were clinical staff blinded: unclear Level of bias: unclear
Blinding of outcome assessment (detection bias)	Unclear risk	D4 - Were investigators blinded to interventions: Unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: low
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: Yes C2 - Were groups comparable for dropout: Yes C3 - Were groups comparable for missing data: Yes Level of bias: low
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Zhang 2016

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age, years (SD)*: 55 (12) ● *BMI, mean (SD)*: 25 (3) ● *Parity, mean (SD)*: 2 (1.3) Control ● *Mean age, years (SD)*: 51 (12) ● *BMI (SD)*: 25 (4) ● *Parity, mean (SD)*: 2 (1.2) **Included criteria:** SUI with urethral hypermobility was diagnosed using symptoms, signs and urodynamic investigations according to the ICS standardization. Patients who were diagnosed with SUI with urethral hyper mobility and in whom conservative treatment had failed were included. **Excluded criteria:** Patients with intrinsic sphincter deficiency, defined as a Valsalva leak-point pressure of < 60 cm H2O, were excluded. Other exclusion criteria were MUI, POP>stage 1 and previously hysterectomy or pelvic reconstruction surgeries. **Pretreatment:** No differences between groups at baseline.
Interventions	**Intervention Characteristics** Intervention ● Description: Midurethral sling TVT

	Control ● Description: Midurethral sling TVT-O
Outcomes	*Patientoplevet effekt, PGI-I, subjective cure* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint *Reoperation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Infektion, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Hæmatom, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Blæreperforation, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Bensmerter, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Scale**: Bensmerter ● **Direction**: Lower is better ● **Data value**: Endpoint *Dysparauni, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint

	Seksualfunktion, PISQ 12, mean final, SD ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: PISQ 12 ● **Data value**: Endpoint *Underlivssmerter, antal personer* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: An independent statistician generated the random allocation sequence according to the SAS schedule
Allocation concealment (selection bias)	Low risk	Judgement Comment: An independent statistician generated the random allocation sequence according to the SAS schedule. The patients were enrolled by study surgeons at the outpatient department and were allocated to the TVT or TVT-O group according to random assignments sealed in an envelope.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: The surgeons and patients were not blinded to the treatment.
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: At the postoperative visit, all of the patients were evaluated by an independent investigator by an interview, pelvis examinations, and self-administered PFIQ-7 and PISQ-12 questionnaires. The investigator was blinded to the patients' assignments
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Lost to follow-up in TVT group: 12/70Lost to follow-up in TVT-O group: 8/70Reasons for withdrawn or lost to follow-up not reported. Intention to treat analyses, imputation method not stated.
Selective reporting (reporting bias)	Low risk	Judgement Comment: Protocol available online. In this protocol the objective is to compare long term efficacy, quality of life and sexual fuction between patients undergoing tension free vaginal tape (TVT) and inside-out transobturator tape (TVT-O) procedure. Reports on all expected outome in relation to the objective.
Other bias	Low risk	Judgement Comment: The authors declare no conflicts of interests Baseline comparability:Both groups comparable at baseling.

Zhu 2007

Methods	China Study type Randomized controlled trial Aim of the study "To compare the two approaches and determine whether the TVT-O procedure could be recommended for widespread use in Chinese women with mild or moderate SUI." Study dates January 2004 to September 2005 Source of funding Not reported All operations were performed by the same surgeon. The two procedures were performed under local anaesthesia supplemented by an intravenous sedative, unless patients were also undergoing hysterectomy when they were given general or spinal anaesthesia. In the TVT group, after needles were in place but before the tape was pulled upward, cystoscopy was performed because of the risk of bladder perforation. Cystoscopy was not performed in the TVT-O group owing to the minimal risk of bladder perforation with this procedure. Power calculation Not reported Intention to treat analysis Not reported
Participants	N = 55 TVT-O (transoburator inside out) = 27 TVT (bottom-up tension-free vaginal tape) = 28 Characteristics Gender – Female/N (% female) 55/55 (100%) Age (years)- Mean ± SD TVT-O = 53.3 ± 11.5 TVT = 56.2 ± 12.5 Incontinence episodes/day – Mean ± SD Not reported Duration of SUI – Mean ± SD Not reported Detrusor overactivity – n/N (%) Not reported Inclusion criteria 1] Mild or moderate SUI not improved by conservative therapy Exclusion criteria 1] Pregnancy 2] Urinary tract infection 3] Urge incontinence 4] Post void residual volume > 100 ml
Interventions	TOT was performed according to the technique described by Delorme (2001). TVT was performed according to the technique described by Ulmsten (1996). In both procedures the needles and woven polypropylene tape were Gynecare products (Gynecare, Ethicon Inc, Somerville, NJ, USA).
Outcomes	Patient satisfaction with treatment Not reported at 12 months Self reported rate of absolute symptom reduction per day Not reported at 12 months Continence status Not reported at 12 months Incontinence-specific quality of life Not reported at 12 months Adverse effects of treatment Peri-operative Bladder injury TVT: O/28 (0%) TVT-O: 0/27 (0%)

	Urethral injury TVT: O/28 (0%) TVT-O: 0/27 (0%) Bowel injury TVT: O/28 (0%) TVT-O: 0/27 (0%) Blood loss > 200ml TVT: O/28 (0%) TVT-O: 0/27 (0%) Post-operative Not reported at 12 months Psychological outcomes Not reported Clinical measures Not reported Peri-operative adverse effects
Notes	NICE guidelines manual. Appendix D: Methodology checklist: Randomised controlled trials

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A1 - Was there appropriate randomisation: yes A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Allocation concealment (selection bias)	Unclear risk	A1 - Was there appropriate randomisation: yes A2 - Was there adequate concealment: unclear A3 - Were groups comparable at baseline: yes Level of bias: low
Blinding of participants and personnel (performance bias)	High risk	B1 - Did groups get same level of care: yes B2 - Were participants blinded: no B3 - Were clinical staff blinded: no Level of bias: unclear
Blinding of outcome assessment (detection bias)	Unclear risk	D4 - Were investigators blinded to interventions: unclear D5 - Were investigators blinded to confounding factors: unclear Level of bias: high
Incomplete outcome data (attrition bias)	Low risk	C Attrition bias C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: yes Level of bias: low
Selective reporting (reporting bias)	Unclear risk	No judgement comment in original NKR
Other bias	Unclear risk	No judgement comment in original NKR

Zullo 2007/

Methods	Italy Study type Randomized controlled trial Aim of the study "This prospective randomised trial compared use of TVT and transobturator suburethral tape from inside to outside (TVT-O) for surgical treatment of SUI in terms of complications (primary end point) and short-term success rate (secondary end point)." Study dates July 2004 to May 2005 Source of funding Not reported. Cystoscopy was routinely performed only in the TVT group.

	A short-term antibiotic prophylaxis was performed 2 hours prior to surgery (cefazolin 2 g). All surgical procedures were performed under lumbar epidural anaesthesia. When bladder injury occurred, an indwelling catheter was placed for 48 hours. If postoperative postvoid residual volume > 100 ml, the patient carried out intermittent self-catheterisation at home until postvoid residual < 80 ml on two consecutive measurements was obtained. Power calculation "We believed that that incidence of intraoperative and postoperative complications would be 39% (higher value reported in the literature) in the TVT group and 7% in the TVT-O group. Based on 0.9 power to detect a significant different (p = 0.05, 2-sided), 35 patients were required for each study group. To compensate for non-evaluable patients (estimated 10%) we planned to enroll 38 patients per group." Intention to treat analysis "All 72 patients were treated in an intention-to-treat basis."
Participants	N = 72 TVT-O (transobturator inside out) = 37 TVT (bottom-up tension-free vaginal tape) = 35 Characteristics Gender - Female/N (% female) 72/72 (100%) Age - Mean ± SD TVT-O = 53.4 ± 10.7 TVT = 52.8 ± 11.8 Incontinence episodes/day - Mean ± SD Not reported Duration of SUI -Mean ± SD Not reported Detrusor overactivity Not reported (see exclusion criteria) Incontinence-specific quality of life Scale used - Visual Analog Scale (VAS) to quantify perception of symptom severity by standardised question "Can you quantify the influence of urinary incontinence on your daily life?" TVT-O = 8.2 ± 2.8 (37) TVT = 8.6 ± 3.4 (35) Inclusion criteria 1] SUI with no contraindications to vaginal surgery and signed informed consent. Exclusion criteria 1] Urogenital prolapse greater than stage 1 2] Detrusor overactivity 3] Symptoms of overactive bladder 4] Intrinsic urethral sphincter deficiency 5] Urinary retention 6] Previous anti-incontinence surgery 7] Neurogenic bladder 8] Psychiatric disease
Interventions	Surgical procedures were performed by the same two experienced surgeons, according to the techniques of Ulmsten (1995) and De Leval (2003).
Outcomes	Patient satisfaction with treatment Not reported Self-reported rate of absolute symptom reduction per day Episodes of incontinence Not reported Episodes of urgency Not reported Continence status at 12 months Scale used - Cure = no leakage of urine during the stress test at urodynamic testing TVT-O = 33/37 (89%) TVT = 32/35 (91%) Incontinence-specific quality of life at 12 months Scale used - Visual Analog Scale (VAS) to quantify perception of symptom severity by standardised question "Can you quantify the influence of urinary incontinence on your daily life?" TVT-O = 0.9 ± 0.7 (37) TVT = 1.1 ± 0.9 (35) Adverse effects of treatment Peri-operative Bladder injury* TVT-O = 0/37 TVT = 2/35 Vaginal perforation TVT-O = 0/37 TVT = 1/35 Retropubic haematoma TVT-O = 0/37 TVT = 1/35 Postoperative Fever TVT-O = 0/37 TVT = 2/35 Urinary tract infection TVT-O = 1/37 TVT = 2/35 Severe pain (pain requiring analgesic 1 wk after surgery) TVT-O = 1/37 TVT = 0/35

	Urinary retention TVT-O = 0/37 TVT = 1/35 Tape erosion TVT-O = 0/37 TVT = 0/35 Frequency at 12 months TVT-O = 0/37 (0%) TVT = 2/35 (6%) Urgency at 12 months* TVT-O = 0/37 (0%) TVT = 3/35 (9%) Psychological outcomes Not reported Clinical measures Not reported *Most common adverse effects in peri-operative and post-operative categories used in meta-analyses Continence status, Incontinence QOL, Peri-operative adverse effects & Post-operative adverse effects.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: Patients were randomly allocated to the TVT or TVT-O procedure using a pre- determined, computer-generated randomisation code.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information of allocation concealment
Blinding of participants and personnel (performance bias)	High risk	B1 - Did groups get same level of care: yes B2 - Were participants blinded: no B3 - Were clinical staff blinded: no Level of bias: unclear
Blinding of outcome assessment (detection bias)	Low risk	Judgement comment: All follow-up examinations were performed by physicians not involved in the study protocol
Incomplete outcome data (attrition bias)	Low risk	C1 - Was follow-up equal for both groups: yes C2 - Were groups comparable for dropout: yes C3 - Were groups comparable for missing data: yes Level of bias: low Not described if intention to treat was used but apparantly no patients excluded from analysis.
Selective reporting (reporting bias)	Low risk	Jugdement comment: All outcomes seem to be reported. But no trial protocol.
Other bias	Low risk	Jugdement comment: None detected

Footnotes

Characteristics of excluded studies

Abdel Fattah 2019

Reason for exclusion	Wrong study design

Aigmuller 2014a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Albo 2012

Reason for exclusion	wrong comparator: TOT (outside-int)

Alvarez 2014

Reason for exclusion	abstract - full text ej tilgængeligt

Amin 2018

Reason for exclusion	Wrong study design

Andonian 2007

Reason for exclusion	wrong comparator: TOT (outside-int)

Angioli 2010a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Aniuliene 2009a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Araco 2008a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Ballester 2012

Reason for exclusion	wrong comparator: TOT (outside-int)

Barber 2008

Reason for exclusion	wrong comparator: TOT (outside-int)

Barry 2008

Reason for exclusion	wrong comparator: TOT (outside-int)

Bianchi Ferraro 2014

Reason for exclusion	Wrong outcomes

Bicudo Furst 2018

Reason for exclusion	Wrong study design

Brubaker 2011

Reason for exclusion	wrong comparator: TOT (outside-int)

Cavkaytar 2015

Reason for exclusion	Wrong study design

Costantini 2014

Reason for exclusion	Wrong study design

Costantini 2016

Reason for exclusion	wrong comparator: TOT (outside-int)

Darabi Mahboub 2014

Reason for exclusion	abstract - full text ej tilgængeligt

Darai 2007

Reason for exclusion	wrong comparator: TOT (outside-int)

David Montefiore 2006

Reason for exclusion	wrong comparator: TOT (outside-int)

Deffieux 2010a

Reason for exclusion	allerede inkluderet i NKR fra 2016

El Hefnawy 2010

Reason for exclusion	wrong comparator: TOT (outside-int)

Freeman 2011

Reason for exclusion	wrong comparator: TOT (outside-int)

Huang 2018

Reason for exclusion	Wrong study design

Imamura 2018

Reason for exclusion	Wrong study design

Imamura 2019

Reason for exclusion	Wrong study design

Karateke 2009a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Kenton 2015

Reason for exclusion	Wrong study design

Kenton 2015a

Reason for exclusion	wrong comparator: TOT (outside-int)

Krofta 2010a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Laurikainen 2007a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Laurikainen 2014a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Lee 2007a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Liapis 2006a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Mahboub 2014

Reason for exclusion	abstract - full text ej tilgængeligt

Masata 2015

Reason for exclusion	abstract - full text ej tilgængeligt

Maslow 2014

Reason for exclusion	Wrong outcomes

Nyyssonen 2014

Reason for exclusion	wrong comparator: TOT (outside-int)

Palos 2018

Reason for exclusion	wrong comparator: TOT (outside-int)

Palva 2010a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Porena 2007

Reason for exclusion	wrong comparator: TOT (outside-int)

Rechberger 2009

Reason for exclusion	wrong intervention: intravaginal sling plasty

Richter 2010

Reason for exclusion	wrong comparator: TOT (outside-int)

Ross 2009

Reason for exclusion	wrong comparator: TOT (outside-int)

Ross 2016

Reason for exclusion	wrong comparator: TOT (outside-int)

Salem 2014

Reason for exclusion	abstract - full text ej tilgængeligt

Scheiner 2012a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Schierlitz 2008

Reason for exclusion	wrong comparator: TOT (outside-int)

Schierlitz 2012

Reason for exclusion	wrong comparator: TOT (outside-int)

Seklehner 2015

Reason for exclusion	Wrong design: metaanalysis/systematic review

Shirvan 2014

Reason for exclusion	wrong comparator: TOT (outside-int)

Song 2018

Reason for exclusion	Wrong study design

Tammaa 2014

Reason for exclusion	abstract - full text ej tilgængeligt

Tang 2014

Reason for exclusion	Wrong outcomes

Tanuri 2010

Reason for exclusion	wrong comparator: TOT (outside-int)

Tarcan 2014

Reason for exclusion	Wrong comparator

Tarcan 2014a

Reason for exclusion	wrong comparator: TOT (outside-int)

Teo 2011a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Tommaselli 2015

Reason for exclusion	Wrong outcomes

Wadie 2013

Reason for exclusion	wrong comparator: TOT (outside-int)

Wai 2013

Reason for exclusion	wrong comparator: TOT (outside-int)

Wang 2006

Reason for exclusion	wrong comparator: TOT (outside-int)

Wang 2009a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Wang 2010

Reason for exclusion	wrong comparator: TOT (outside-int)

Wang 2011a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Wein 2019

Reason for exclusion	Wrong study design

Zhu 2007a

Reason for exclusion	allerede inkluderet i NKR fra 2016

Zhu 2014

Reason for exclusion	abstract - full text ej tilgængeligt

Zhu 2015

Reason for exclusion	abstract - full text ej tilgængeligt

Zullo 2007

Reason for exclusion	allerede inkluderet i NKR fra 2016

Zyczynski 2012

Reason for exclusion	Wrong study design

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

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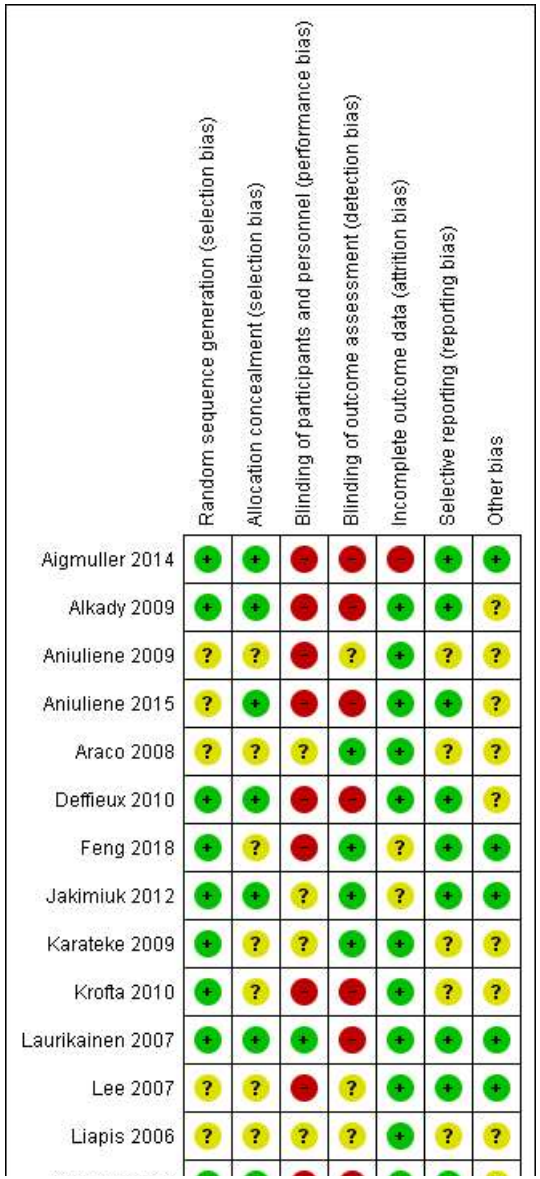
Data and analyses

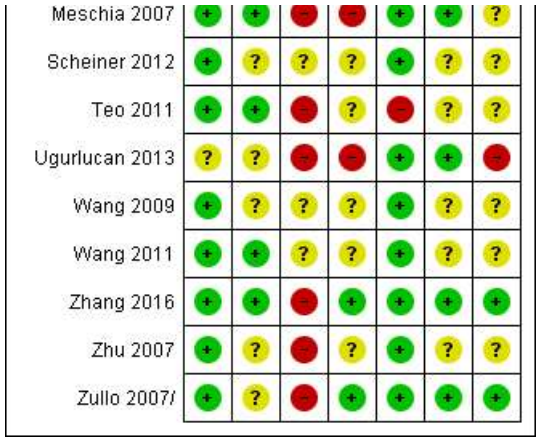
1 TVT vs TVT-O

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Inkontinensrelateret livskvalitet (incontinence quality of life)	13	2060	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.24, 0.04]
1.2 Patientoplevet effekt (patient perceived effect) antal personer med klinisk relevant forbedring	18	2653	Risk Ratio (IV, Random, 95% CI)	1.03 [1.00, 1.07]
1.3 Reoperation	13	2091	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.72, 1.79]
1.4 Antal tilfælde af inkontinens (Incontinence episodes) mean pr. dag	1	36	Mean Difference (IV, Fixed, 95% CI)	0.30 [-0.65, 1.25]
1.5 De nove urgency	14	2082	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.55, 1.07]
1.6 Bensmerter (leg pain), antal personer	9	1312	Risk Ratio (M-H, Random, 95% CI)	0.27 [0.11, 0.66]
1.7 Underlivssmerter (pelvic pain) antal personer	2	212	Risk Ratio (M-H, Random, 95% CI)	2.62 [0.63, 10.99]
1.8 Infektion (infection), antal personer	9	1497	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.54, 2.18]
1.9 Hæmatom (haematoma) antal personer	12	2083	Risk Ratio (M-H, Random, 95% CI)	1.52 [0.69, 3.35]
1.10 Blæreperforation (bladder perforation) antal personer	21	3308	Risk Ratio (M-H, Random, 95% CI)	4.53 [2.32, 8.86]
1.11 Dysparauni, antal personer	4	402	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.24, 2.38]
1.12 Ændring i seksualfunktion (change in sexual function)	4	654	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.17, 0.32]
1.13 Ændring i seksualfunktion (change in sexualfunction) antal personer med seksuel dysfunktion	1	102	Risk Ratio (M-H, Fixed, 95% CI)	0.28 [0.05, 1.48]

Figures

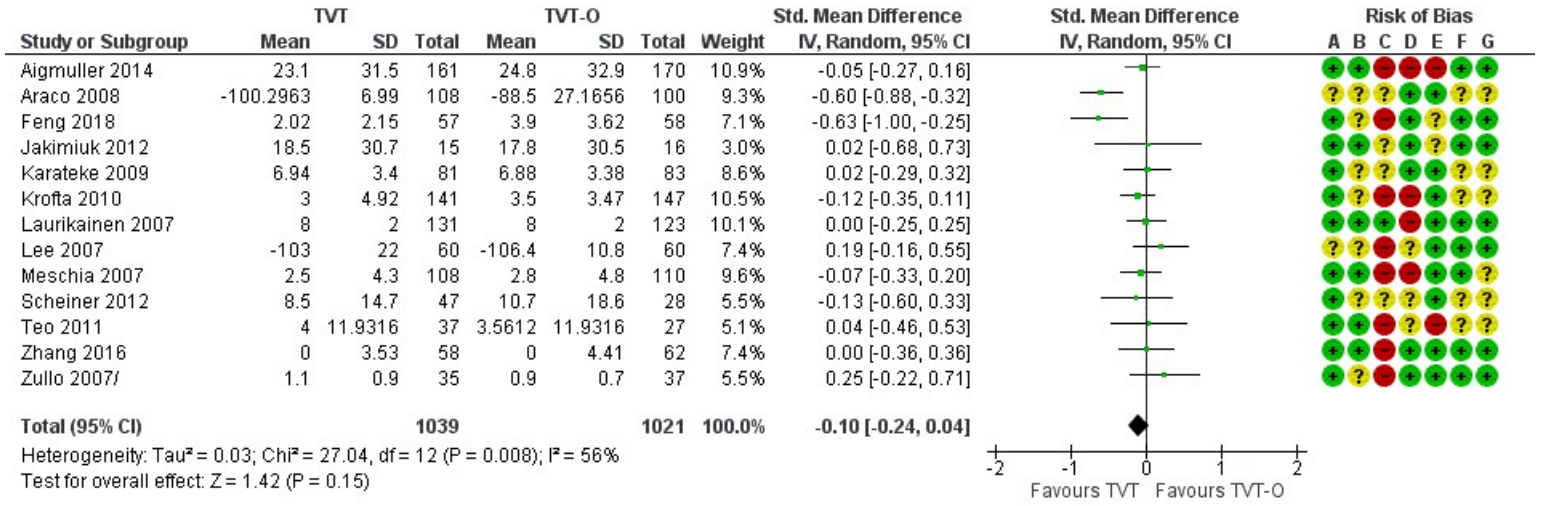
Figure 1





Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

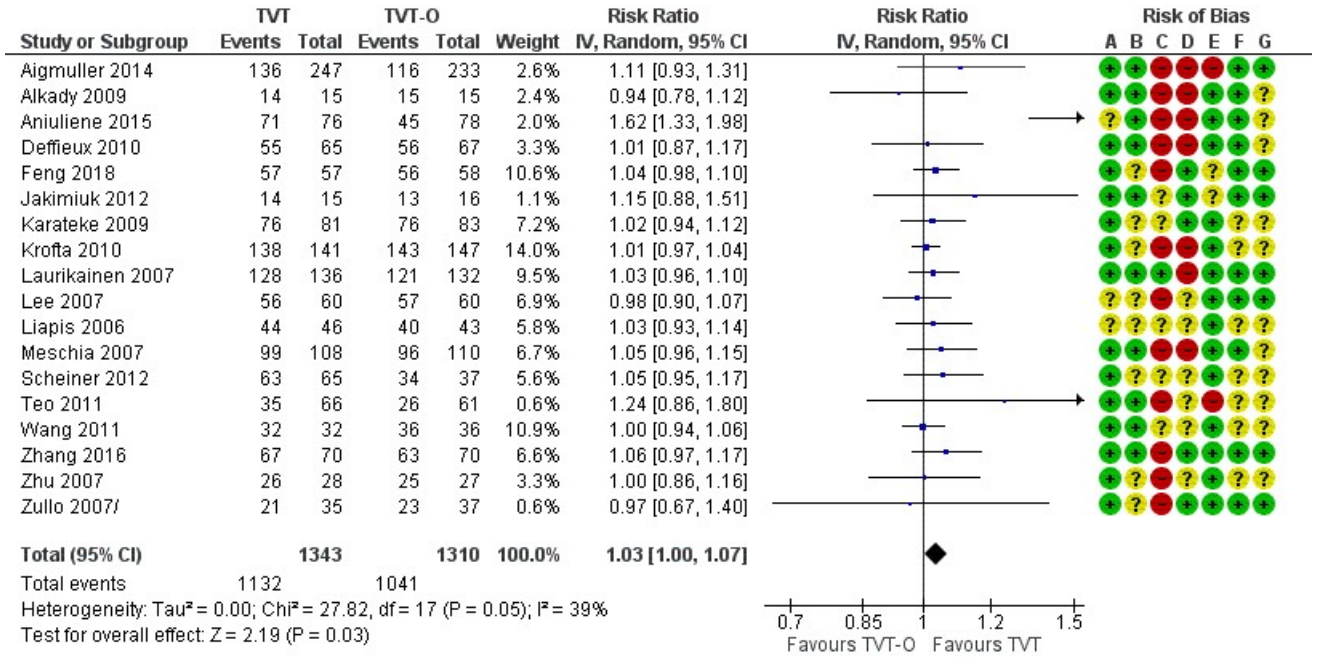
Figure 2 (Analysis 1.1)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.1 Inkontinensrelateret livskvalitet (incontinence quality of life).

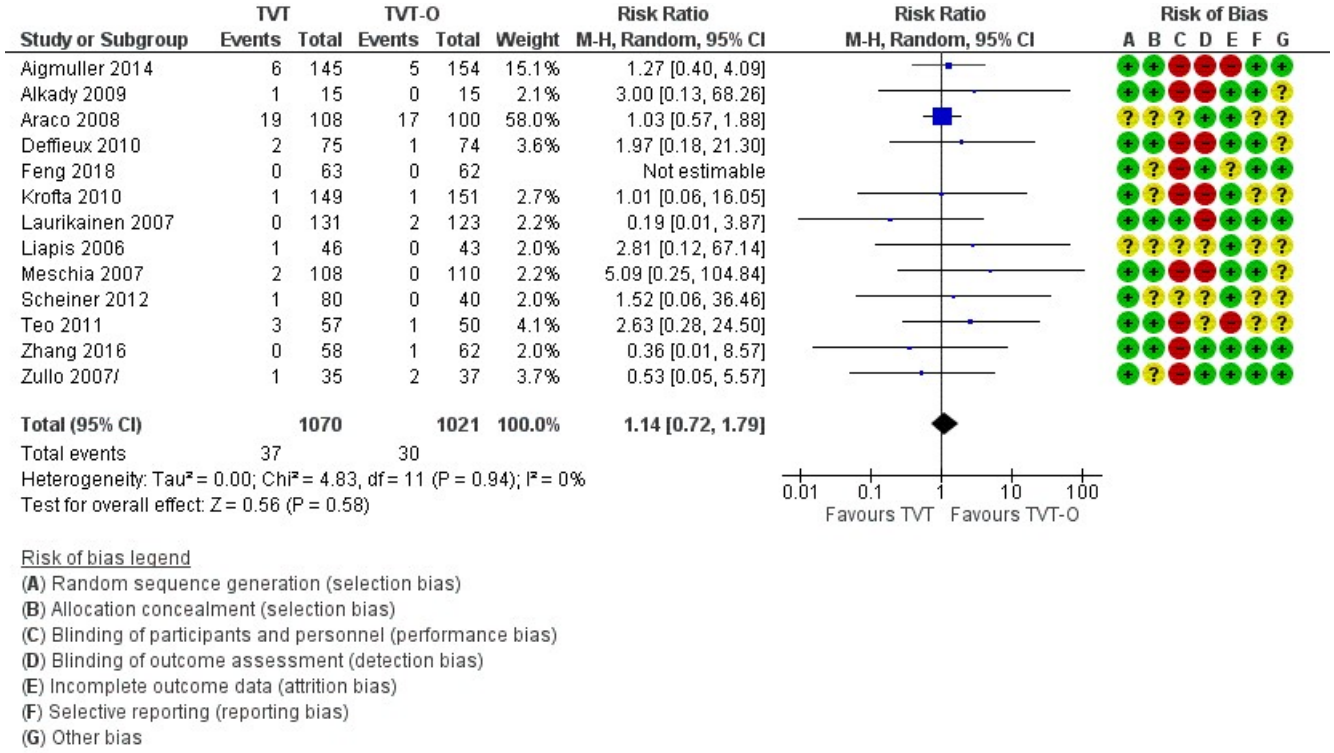
Figure 3 (Analysis 1.2)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

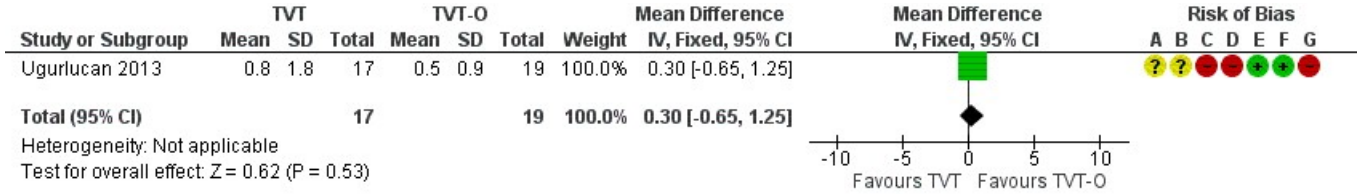
Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.2 Patientoplevet effekt (patient perceived effect) antal personer med klinisk relevant forbedring.

Figure 4 (Analysis 1.3)



Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.3 Reoperation.

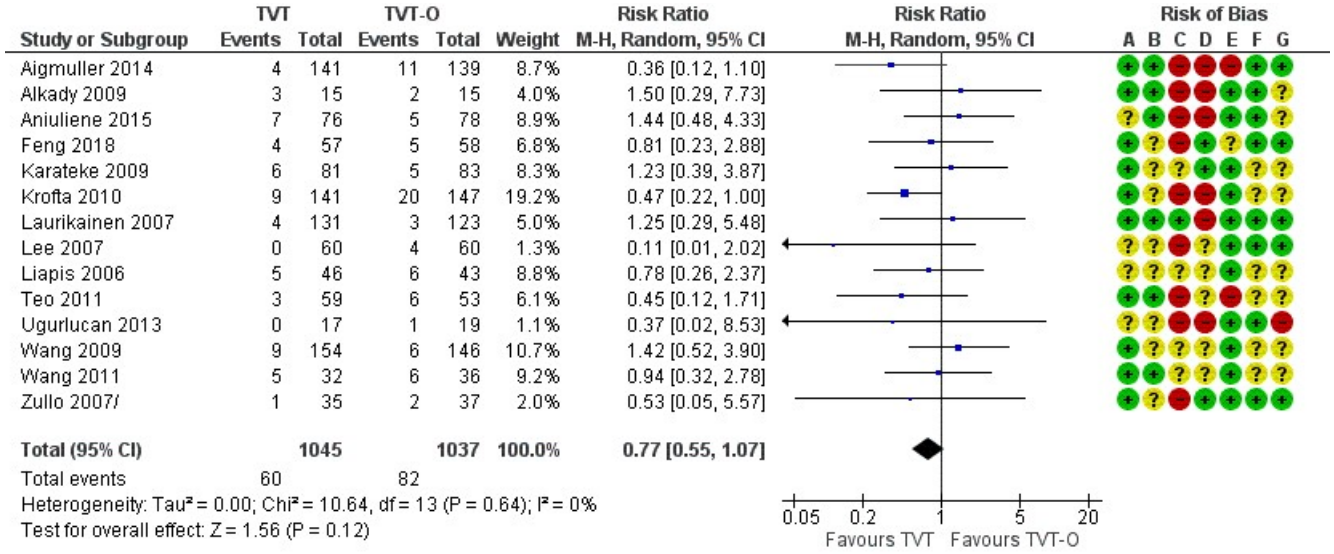
Figure 5 (Analysis 1.4)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.4 Antal tilfælde af inkontinens (Incontinence episodes) mean pr. dag.

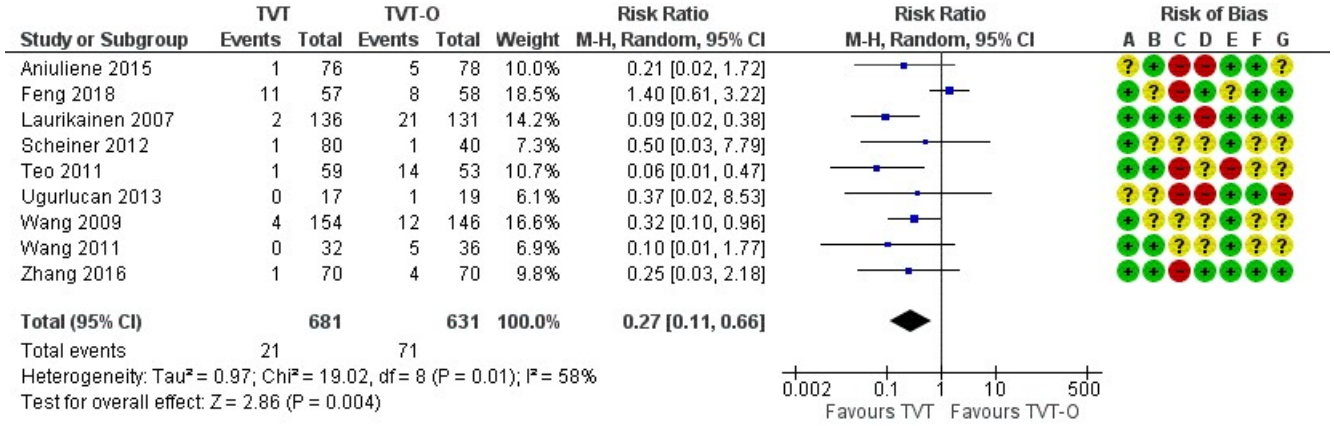
Figure 6 (Analysis 1.5)



Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.5 De nove urgency.

Figure 7 (Analysis 1.6)



Risk of bias legend
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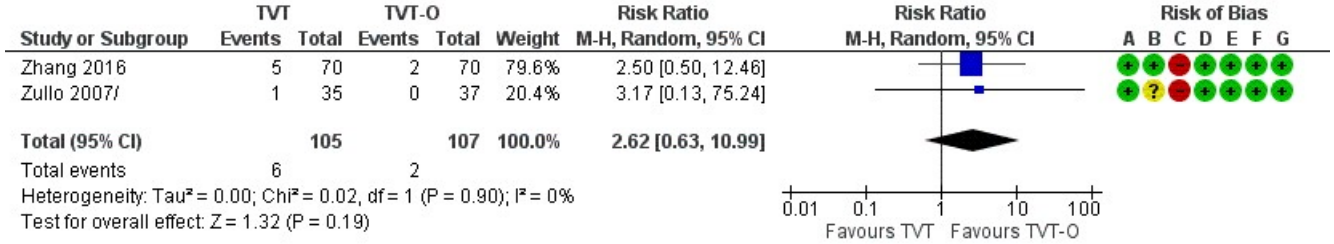
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.6 Bensmerter (leg pain), antal personer.

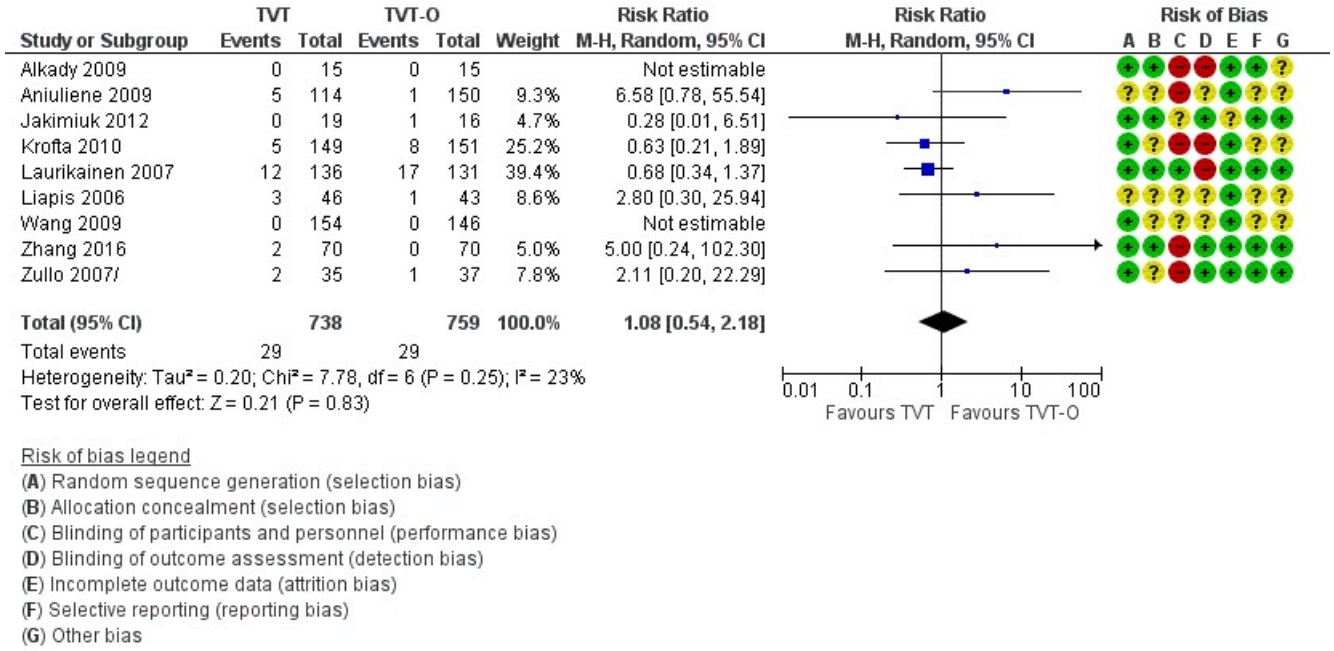
Figure 8 (Analysis 1.7)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.7 Underlivssmerter (pelvic pain) antal personer.

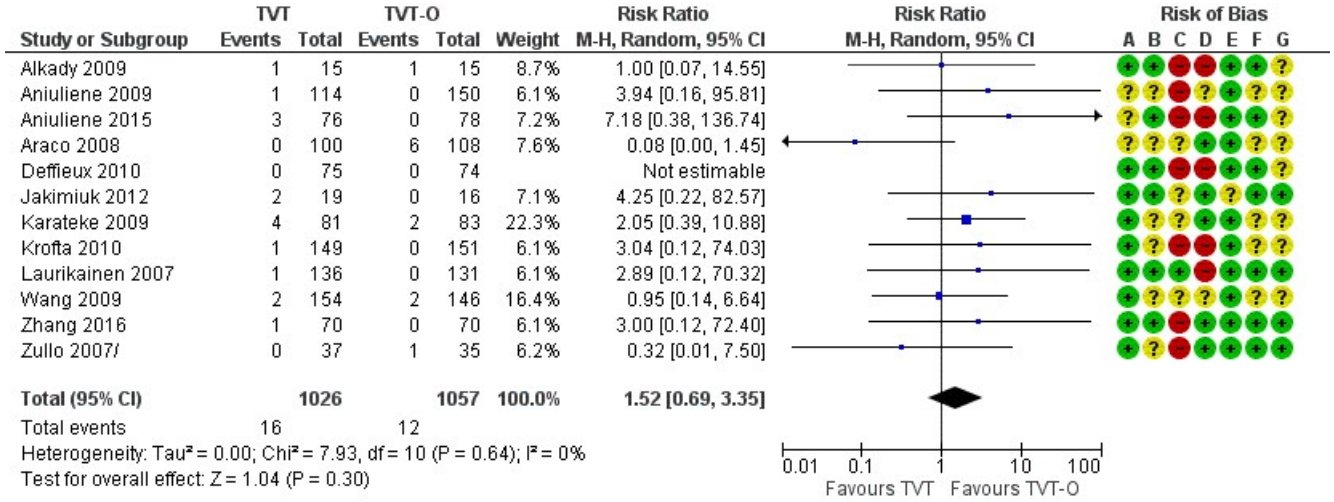
Figure 9 (Analysis 1.8)



Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.8 Infektion (infection), antal personer.

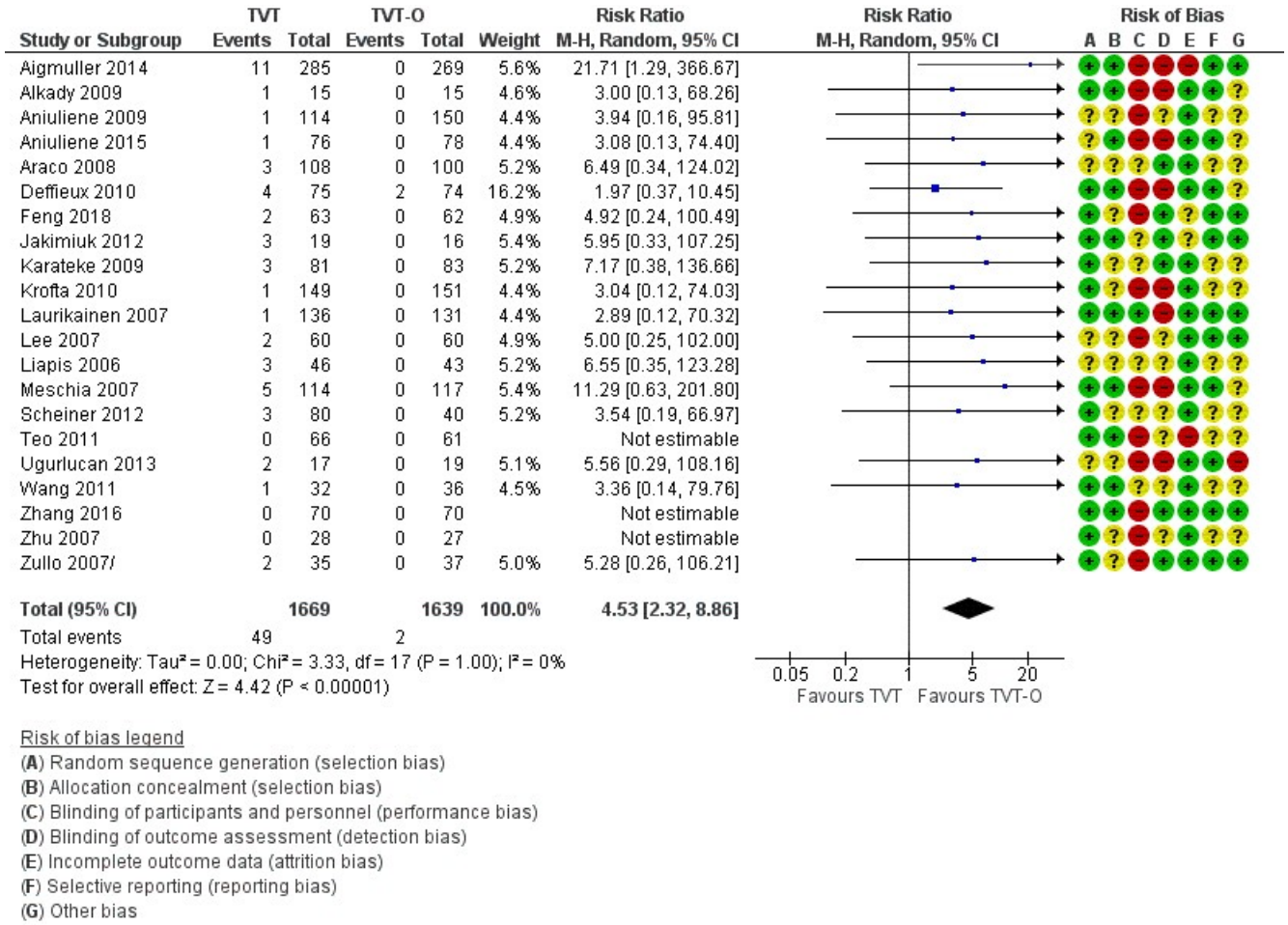
Figure 10 (Analysis 1.9)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

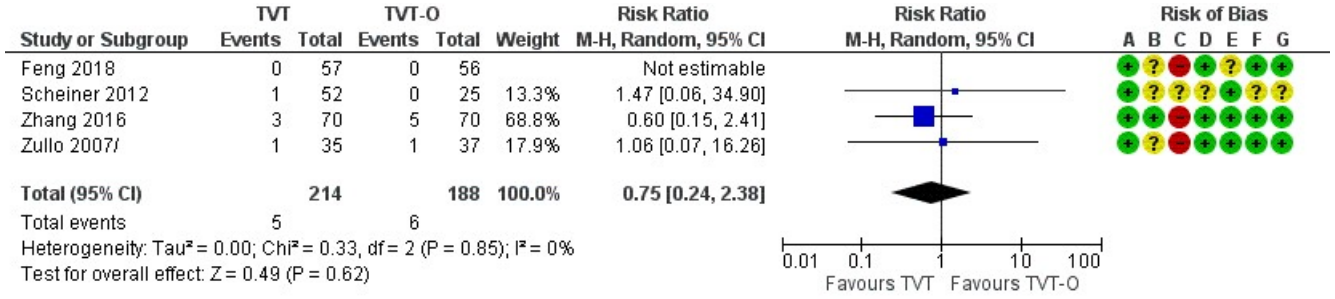
Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.9 Hæmatom (haematoma) antal personer.

Figure 11 (Analysis 1.10)



Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.10 Blæreperforation (bladder perforation) antal personer.

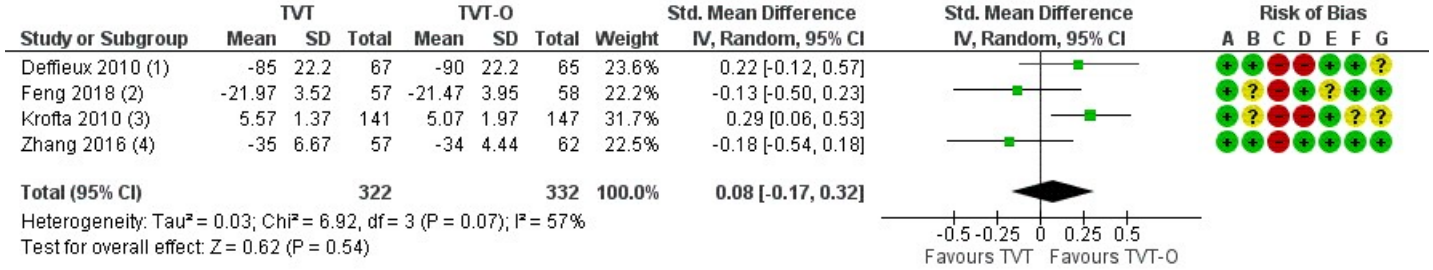
Figure 12 (Analysis 1.11)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.11 Dysparauni, antal personer.

Figure 13 (Analysis 1.12)

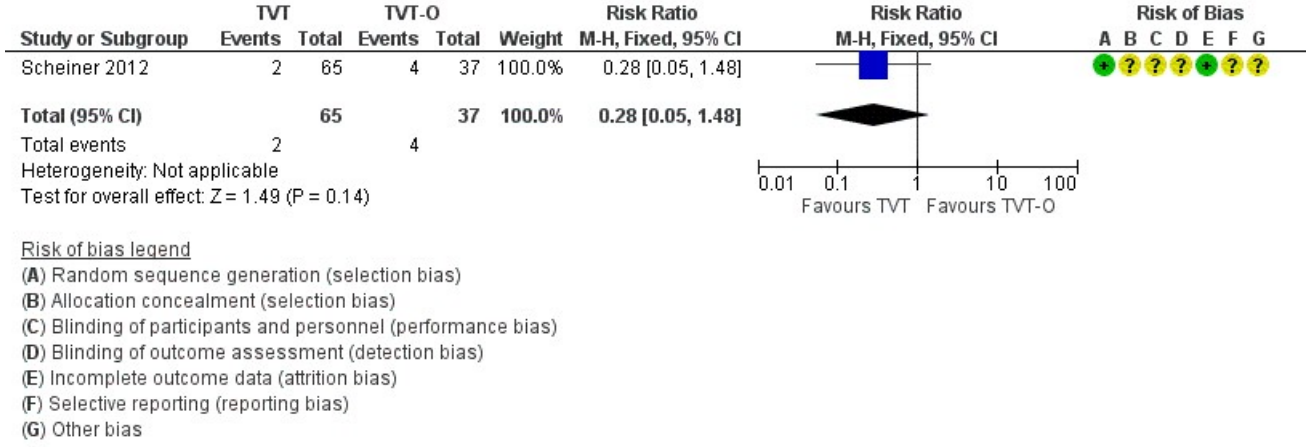


Footnotes
(1) Målt på VAS
(2) Målt med PISQ-12
(3) Målt med Contillife subscale sexuality
(4) Målt med PISQ-12

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance...
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.12 Ændring i seksualfunktion (change in sexual function).

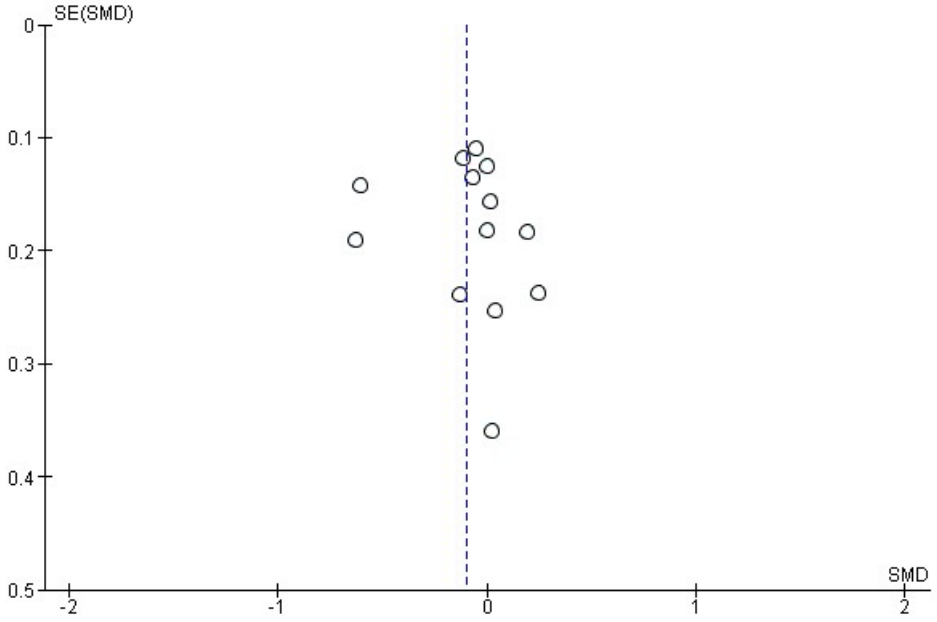
Figure 14 (Analysis 1.13)



Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

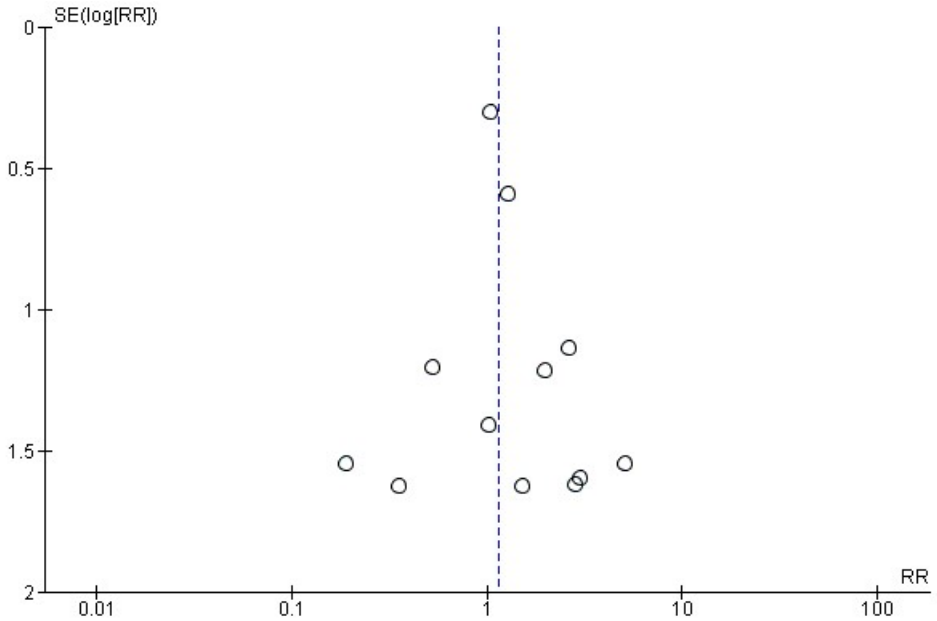
Forest plot of comparison: 1 TVT vs TVT-O, outcome: 1.13 Ændring i seksualfunktion (change in sexualfunction) antal personer med seksuel dysfunktion.

Figure 15 (Analysis 1.1)



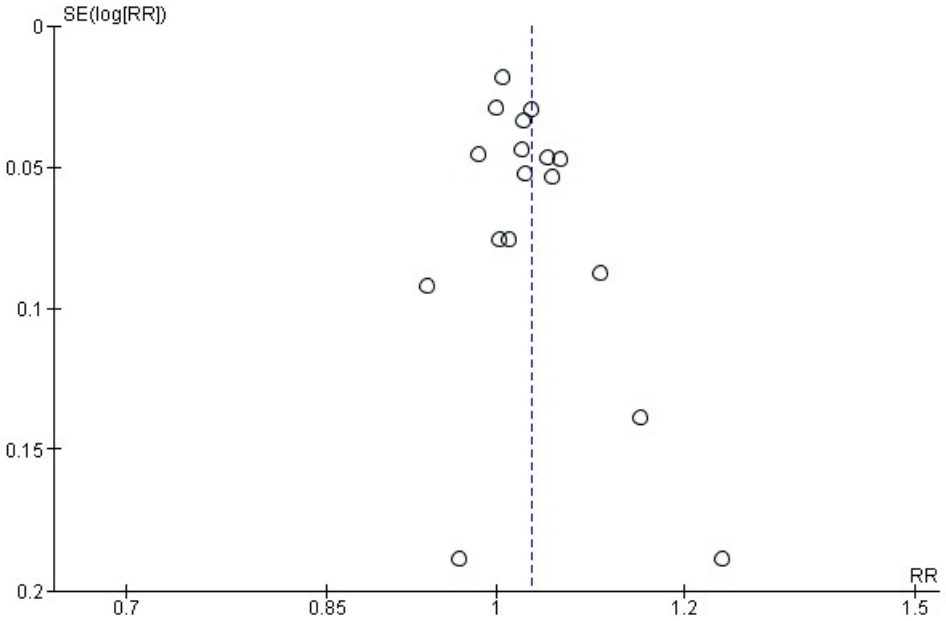
Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.1 Inkontinensrelateret livskvalitet (incontinence quality of life).

Figure 16 (Analysis 1.3)



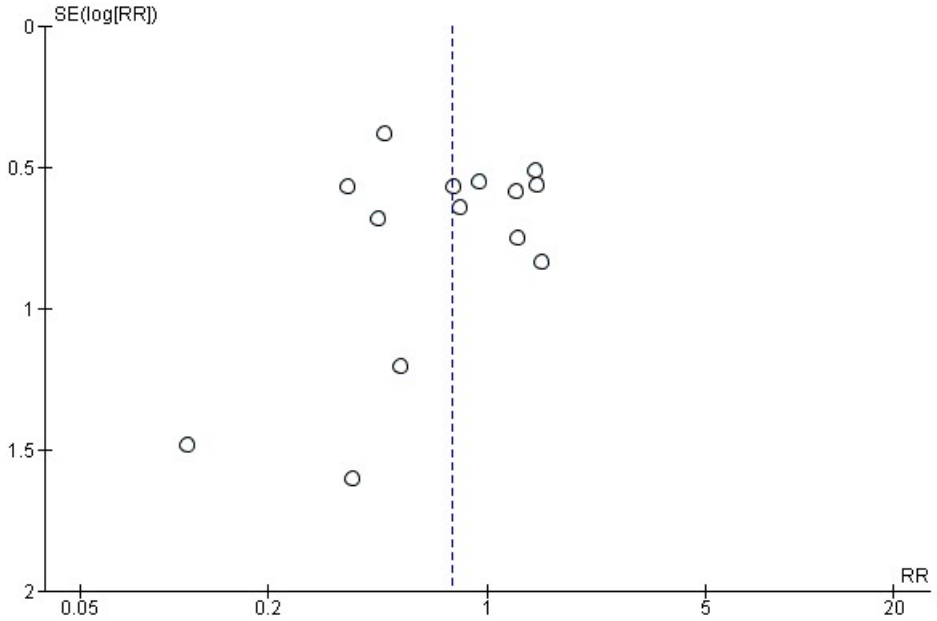
Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.3 Reoperation.

Figure 17 (Analysis 1.2)



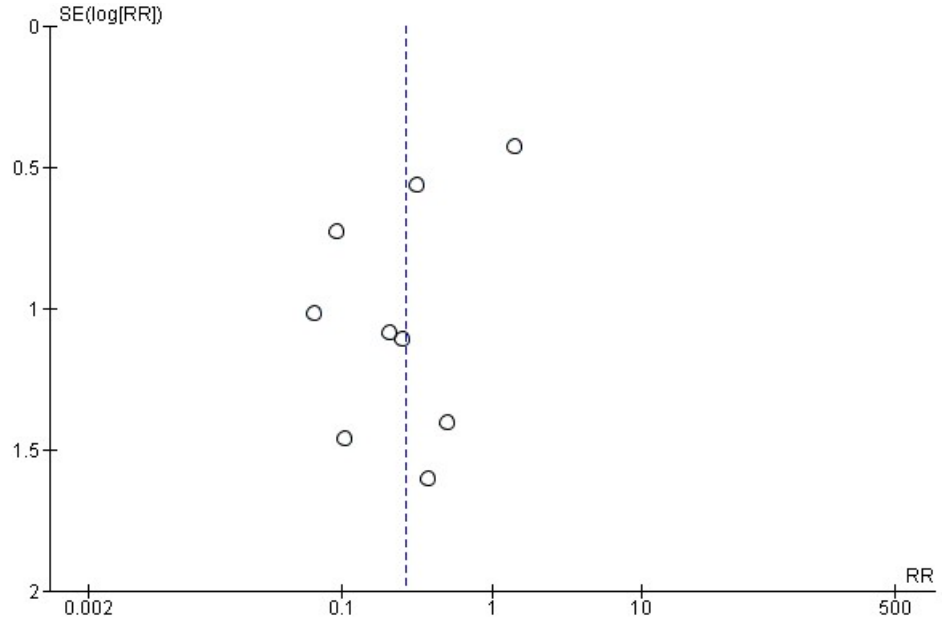
Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.2 Patientoplevet effekt (patient perceived effect) antal personer med klinisk relevant forbedring.

Figure 18 (Analysis 1.5)



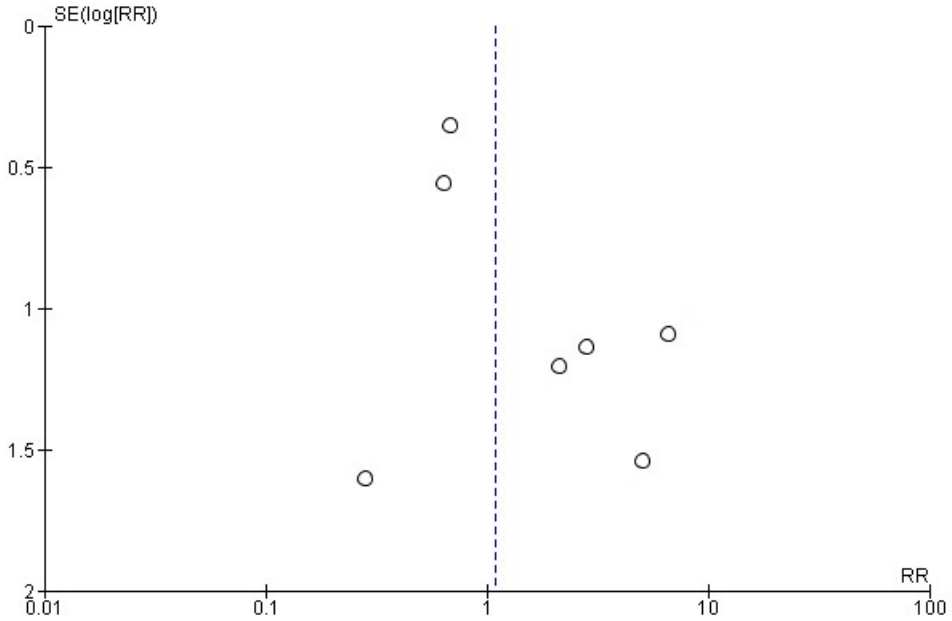
Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.5 De nove urgency.

Figure 19 (Analysis 1.6)



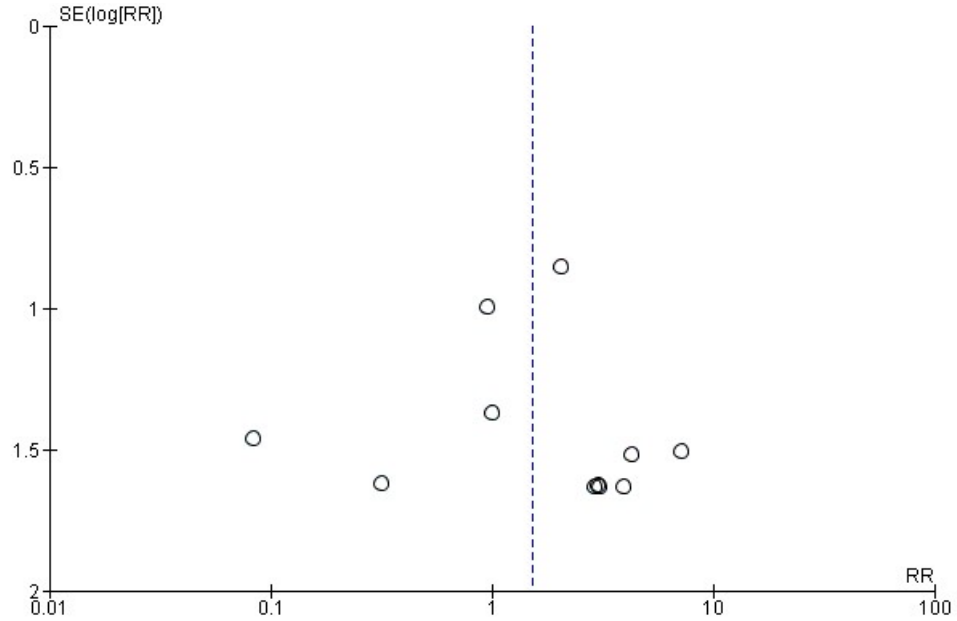
Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.6 Bensmerter (leg pain), antal personer.

Figure 20 (Analysis 1.8)



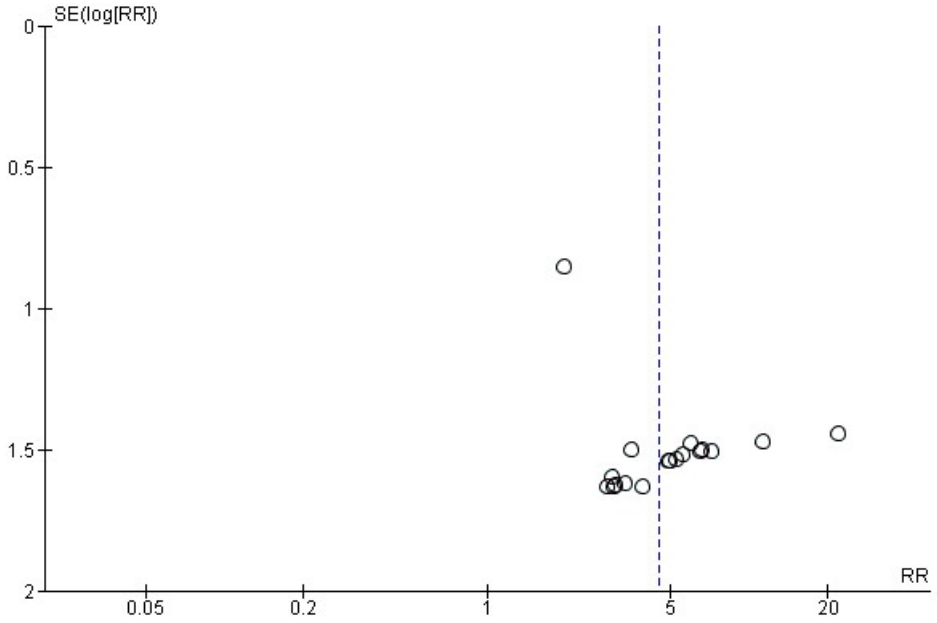
Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.8 Infektion (infection), antal personer.

Figure 21 (Analysis 1.9)



Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.9 Hæmatom (haematoma) antal personer.

Figure 22 (Analysis 1.10)



Funnel plot of comparison: 1 TVT vs TVT-O, outcome: 1.10 Blæreperforation (bladder perforation) antal personer.