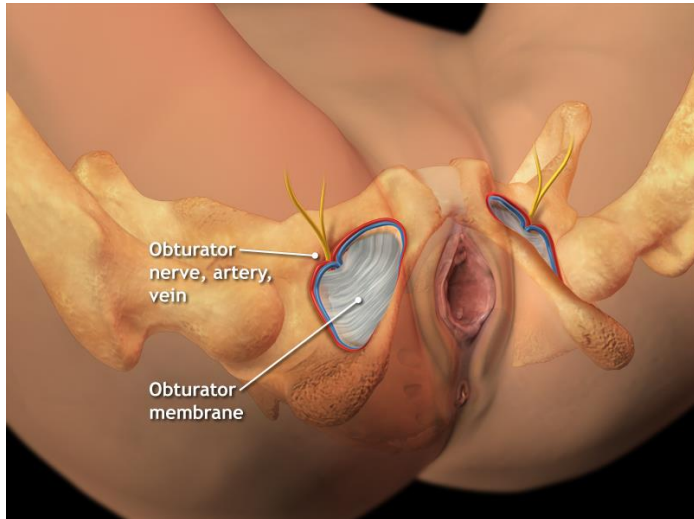
המרכז הרפואי האוניברסיטאי
ע"ש אדית וולפסון

# TOT / TVT-O (VS SIMS)

Dr. Maia Rosenberg

(Prof. Shimon Ginath)

אגף נשים וילדות
המרכז הרפואי האוניברסיטאי
ע"ש אדית וולפסון



THE CORRECTION OF STRESS INCONTINENCE BY SIMPLE VESICOURETHRAL SUSPENSION

VICTOR FRAY MARSHALL, M.D., F.A.C.S., ANDREW A. MARCHETTI, M.D., and KERMIT E. KRANTZ, M.D., New York, New York

From the Departments of Surgery (Urology) and Obstetrics and Gynecology of Cornell University Medical College and the New York Hospital, and the Department of Urology of the Memorial Hospital.

**Surg, Gynec & Obstet, 88: 509–518, 1949**

Urethrovaginal fixation to Cooper's ligament for correction of stress incontinence, cystocele, and prolapse

JOHN C. BURCH, M.D.

*From the Department of Obstetrics and Gynecology Vanderbilt University Medical School. Nashville, Tennessee*

Am. J. Obst. & Gynec. Volume 81 Number 2 February, 1961

**An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence**

U. Ulmsten, L. Henriksson, P. Johnson and G. Varhos

Department of Obstetrics and Gynecology, Akademiska Sjukhuset, Uppsala University, Uppsala, Sweden

Int Urogynecol J (1996) 7:81–86

**La bandelette trans-obturatrice : un procédé mini-invasif pour traiter l'in…me**

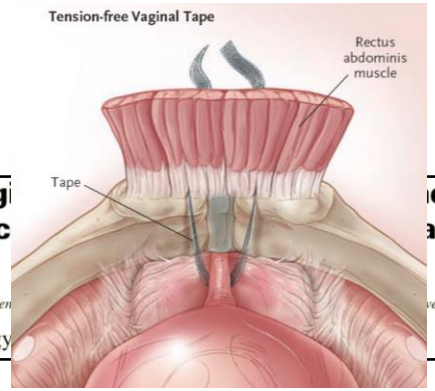
**Novel Surgi… Urinary Inc…**

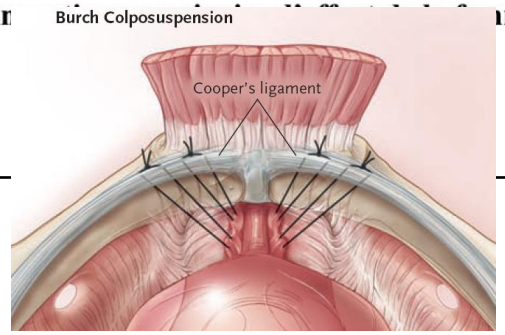
**…ent of Female Stress …aginal Tape Inside-Out**

Jean de Leval*

*Department of Urology, Cen… …veau – 1, B-4000 Liège, Belgium*

European Urology …




1949 – MMK

1961 – Burch

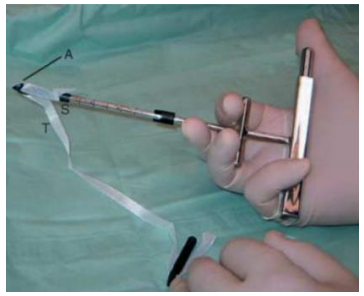
1996 – Ulmsten (TVT)

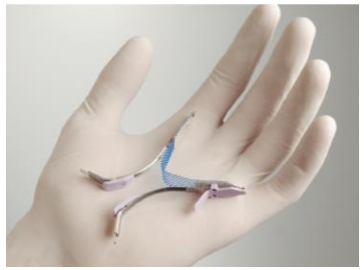
2001 – Delorme (TOT)

2003 – de Leval (TVT-O)

1945 1950 1955 1960 1965 1970 1975 1980 1985 1990 1995 2000 2005 2010 2015

אגף נשים ויולדות





Midurethral Tissue Fixation System sling – a 'micromethod' for cure of stress incontinence – preliminary report

Peter E. P. PETROS[1,2] and Peter A. RICHARDSON[1]

[1]*Department of Gynaecology, Royal Perth Hospital, and* [2]*University of Western Australia, Perth, Australia*

*Australian and New Zealand Journal of Obstetrics and Gynaecology* 2005; **45:** 372–375

**TVT SECUR System – tahuprostá podpora uretry u žen trpících stresovou inkontinencí moči – technika a první zkušenosti**

Martan A., Mašata J., Švabík K.

Gynekologicko-porodnická klinika VFN a 1. LF UK, Praha

Čes. Gynek.2007, 72, č. 1 s. 42-49

**The MiniArc® Sling System in the Treatment of Female Stress Urinary Incontinence**

**Annett Gauruder-Burmester, Gralf Popken**

*Department of Urogynecology, German Pelvic Floor Center (AGB), Berlin, and Department of Urology, Helios Klinikum Berlin Buch (GP), Berlin, Germany*

International Braz J Urol Vol. 35 (3): 334-343, May - June, 2009

***CONTASURE NEEDLELESS: TOT DE UNA SOLA INCISION PARA EL TRATAMIENTO DE LA INCONTINENCIA DE URINARIA DE ESFUERZO***

*Rafael Navazo, Jesús Moreno, Cristina Hidalgo, Miguel Angel Herraiz, José Antonio Vidart, Jesús Salinas y Angel Silmi.*

*Unidad de Suelo Pélvico. Universidad Complutense. Hospital Clínico San Carlos de Madrid. Madrid. España.*

Arch. Esp. Urol. 2009; 62 (9): 719-723

**One-Year Surgical Outcomes and Quality of Life after Minimally Invasive Sling Procedures for the Treatment of Female Stress Urinary Incontinence: TVT SECUR® vs. CureMesh®**

**Young Min Joo, Jin Ho Choe, Ju Tae Seo**

*Department of Urology, Cheil General Hospital, Kwandong University College of Medicine, Seoul, Korea*

Korean J Urol 2010;51:337-343

**Short-term outcomes with the Ajust™ system: a new single incision sling for the treatment of stress urinary incontinence**

**Michele Meschia · Pietro Barbacini · Roberto Baccichet · Arturo Buonaguidi · Marco Maffiolini · Luisa Ricci · Chiara Braghin · Valentina Brusati · Chiara Dell'Utri · Lorenzo Spreafico**

M. Meschia · P. Barbacini · V. Brusati, Department of Obstetrics and Gynecology, Ospedale "G. Fornaroli", Magenta, Milan, Italy

R. Baccichet · C. Braghin, Department of Obstetrics and Gynecology, Ospedale di Conegliano, Conegliano, Veneto, Italy

A. Buonaguidi · C. Dell'Utri, Department of Obstetrics and Gynecology, IRCCS Fondazione Policlinico Mangiagalli e Regina Elena, Milan, Italy

M. Maffiolini, Department of Obstetrics and Gynecology, Ospedale di Pieve di Coriano, Pieve di Coriano, Italy

L. Ricci · L. Spreafico, Department of Obstetrics and Gynecology, Ospedale di Montecchio Emilia, Montecchio Emilia, Italy

Int Urogynecol J (2011) 22:177–182

**What is the best indication for single-incision Ophira Mini Sling? Insights from a 2-year follow-up international multicentric study**

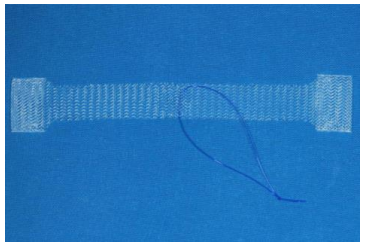
**Paulo Palma · Cassio Riccetto · Elaine Bronzatto · Rodrigo Castro · Sebastian Altuna**

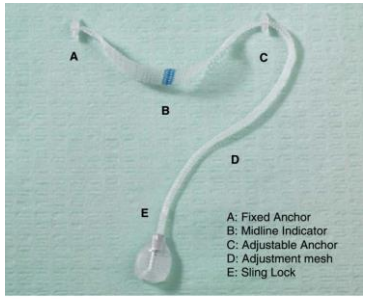
P. Palma · C. Riccetto · E. Bronzatto, Division of Female Urology, University of Campinas (UNICAMP), Campinas, Brazil

R. Castro, Department of Gynecology, Federal University of São Paulo (UNIFESP), São Paulo, Brazil

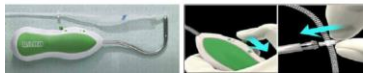
S. Altuna, Department of Gynecology, Austral University Hospital, Buenos Aires, Argentina

Int Urogynecol J 2014 Apr 16






Introducer and loading process of the adjustable anchor



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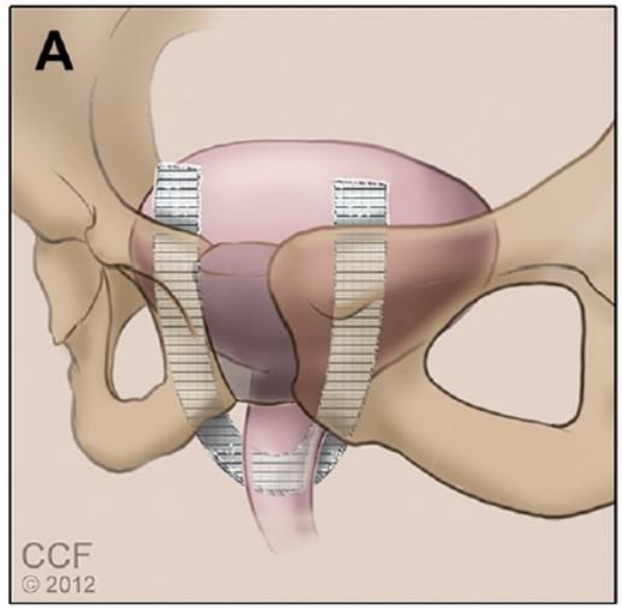
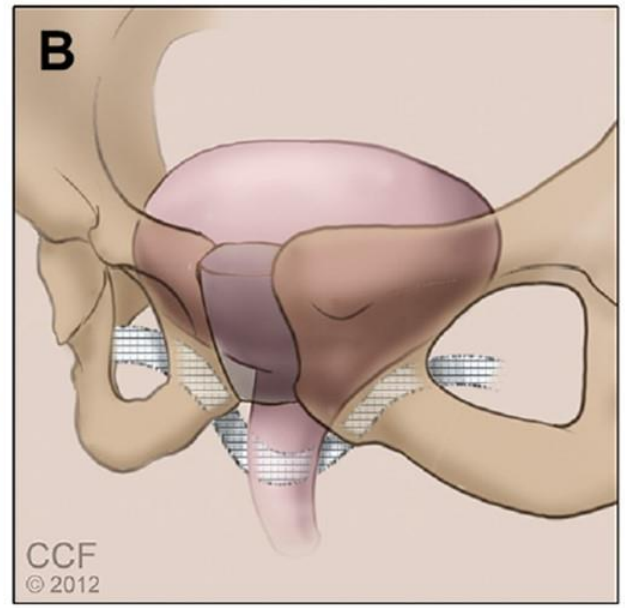
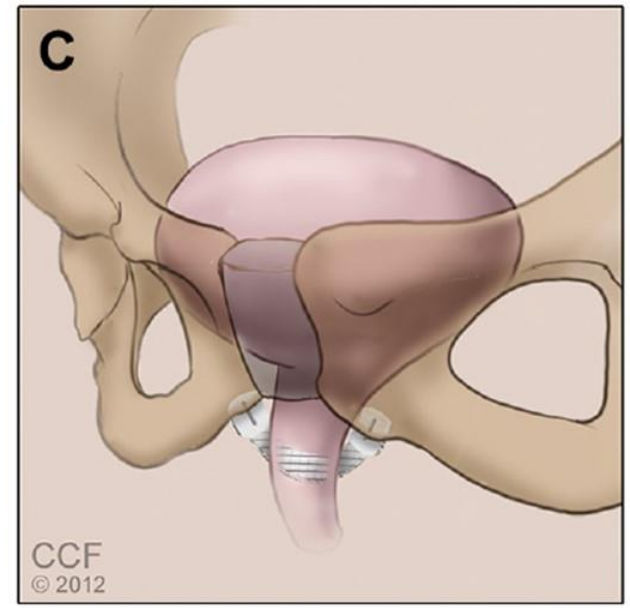


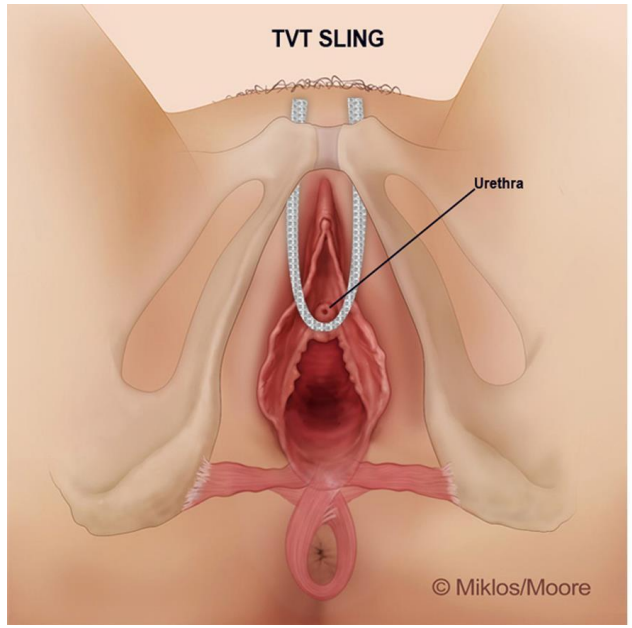

(*A*) Retropubic midurethral sling

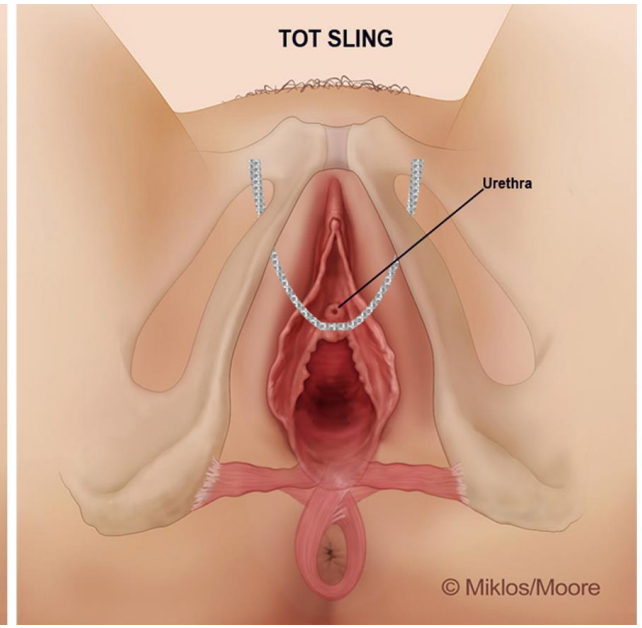


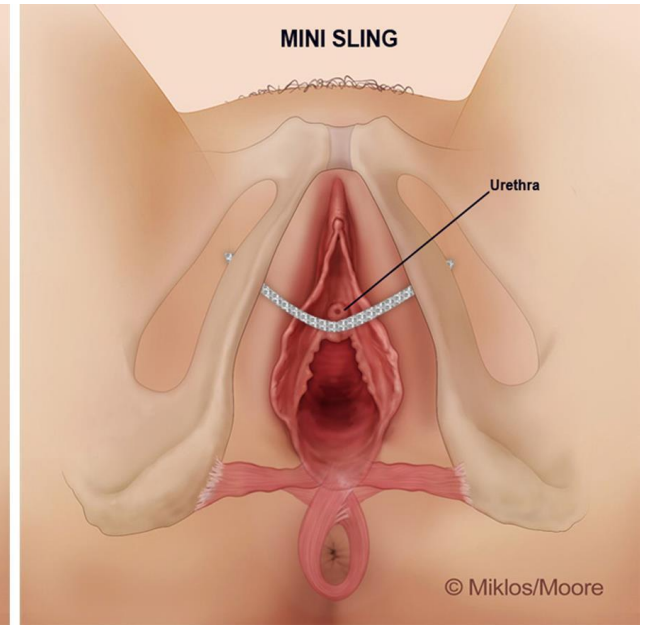

(*B*) Transobturator midurethral sling




(*C*) Single-incision sling



# Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up

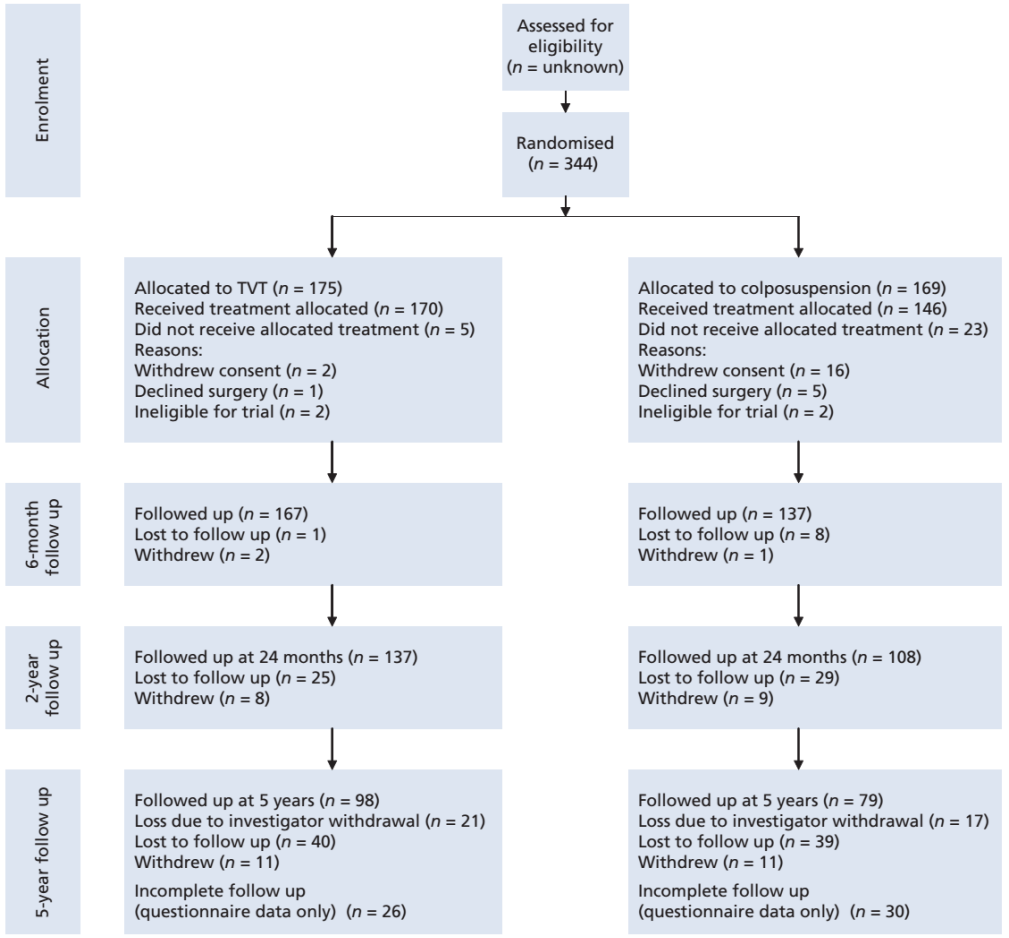
KL Ward, P Hilton on behalf of the UK and Ireland TVT Trial Group*

BJOG 2008;115:226–233

**14 – MC (UK, Ireland)**

- "No significant difference between TVT and colposuspension for the cure of USI at 5 years"

  Negative 1h pad test:
  - TVT: $^{58}/_{72}$ (81%)
  - Burch: $^{44}/_{49}$ (90%) *(P= 0.21)*




אגף נשים ויולדות

# Retropubic versus Transobturator Midurethral Slings for Stress Incontinence

Holly E. Richter, Ph.D., M.D., Michael E. Albo, M.D., Halina M. Zyczynski, M.D., Kimberly Kenton, M.D., Peggy A. Norton, M.D., Larry T. Sirls, M.D., Stephen R. Kraus, M.D., Toby C. Chai, M.D., Gary E. Lemack, M.D., Kimberly J. Dandreo, M.Sc., R. Edward Varner, M.D., Shawn Menefee, M.D., Chiara Ghetti, M.D., Linda Brubaker, M.D., Ingrid Nygaard, M.D., Salil Khandwala, M.D., Thomas A. Rozanski, M.D., Harry Johnson, M.D., Joseph Schaffer, M.D., Anne M. Stoddard, Sc.D., Robert L. Holley, M.D., Charles W. Nager, M.D., Pamela Moalli, M.D., Ph.D., Elizabeth Mueller, M.D., Amy M. Arisco, M.D., Marlene Corton, M.D., Sharon Tennstedt, Ph.D., T. Debuene Chang, M.D., E. Ann Gormley, M.D., and Heather J. Litman, Ph.D., for the Urinary Incontinence Treatment Network*

N Engl J Med 2010;362:2066-76

**TOMUS = Trial of Mid-Urethral Slings**

**14 – MC (USA)**

**43 – Surgeons**

## Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months

Michael E. Albo,*,† Heather J. Litman,‡ Holly E. Richter,§ Gary E. Lemack,‖ Larry T. Sirls,‡ Toby C. Chai,¶ Peggy Norton,‡ Stephen R. Kraus,** Halina Zyczynski,†† Kimberly Kenton,‡ E. Ann Gormley‡‡ and John W. Kusek‡ for the Urinary Incontinence Treatment Network

*From the University of California, San Diego, La Jolla, California (MEA), New England Research Institutes, Watertown, Massachusetts (HJL), University of Alabama at Birmingham, Birmingham, Alabama (HER), University of Texas, Southwestern, Dallas (GEL), and University of Texas at San Antonio, San Antonio (SRK), Texas, William Beaumont Hospital, Royal Oak, Michigan (LTS), University of Maryland, Baltimore (TCC), and National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda (JWK), Maryland, University of Utah, Salt Lake City, Utah (PN), University of Pittsburgh, Magee-Womens Hospital, Pittsburgh, Pennsylvania (HZ), Loyola University Chicago, Chicago, Illinois (KK), and Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire (EAG)*

THE JOURNAL OF UROLOGY® Vol. 188, 2281-2287, December 2012

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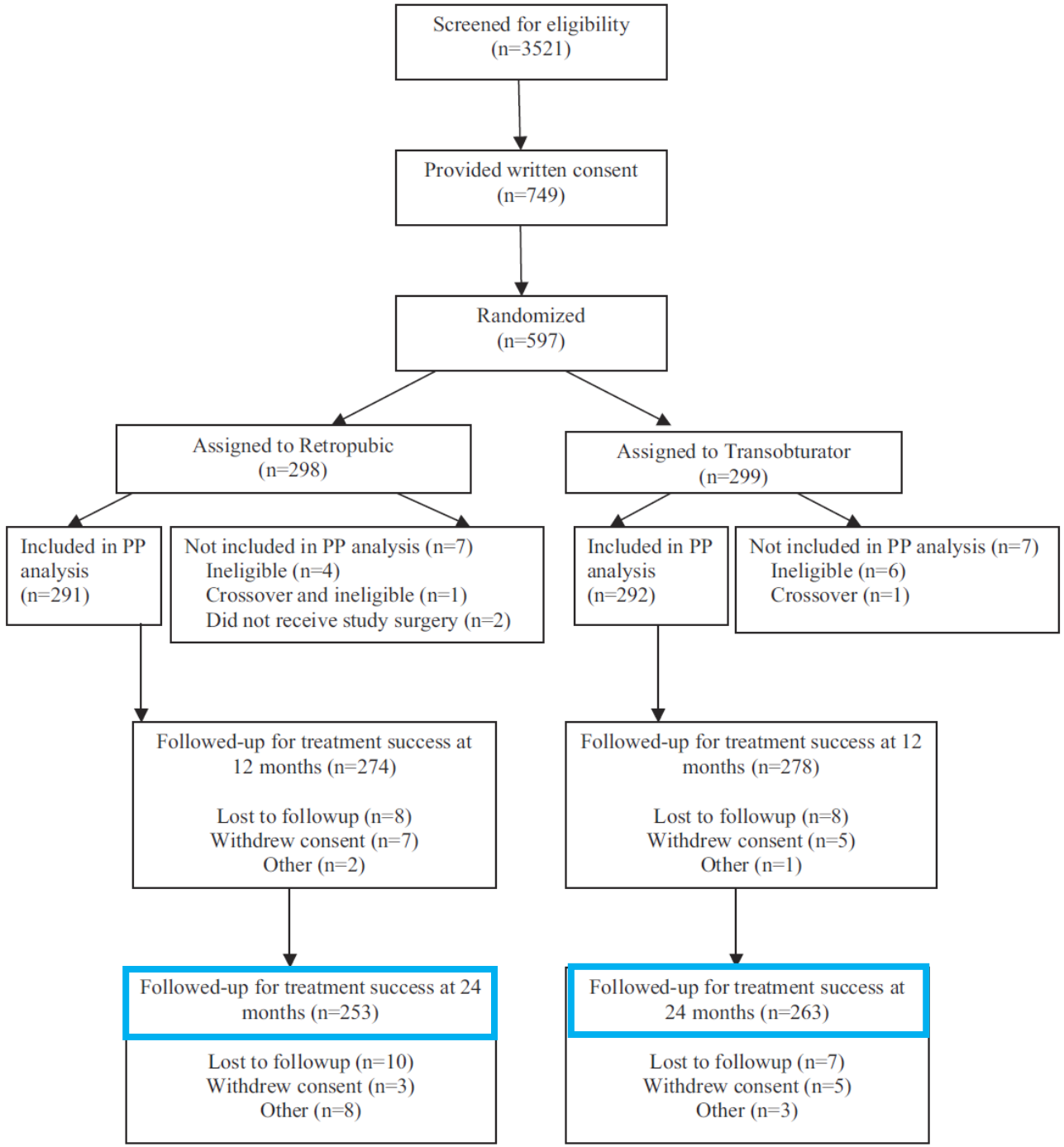
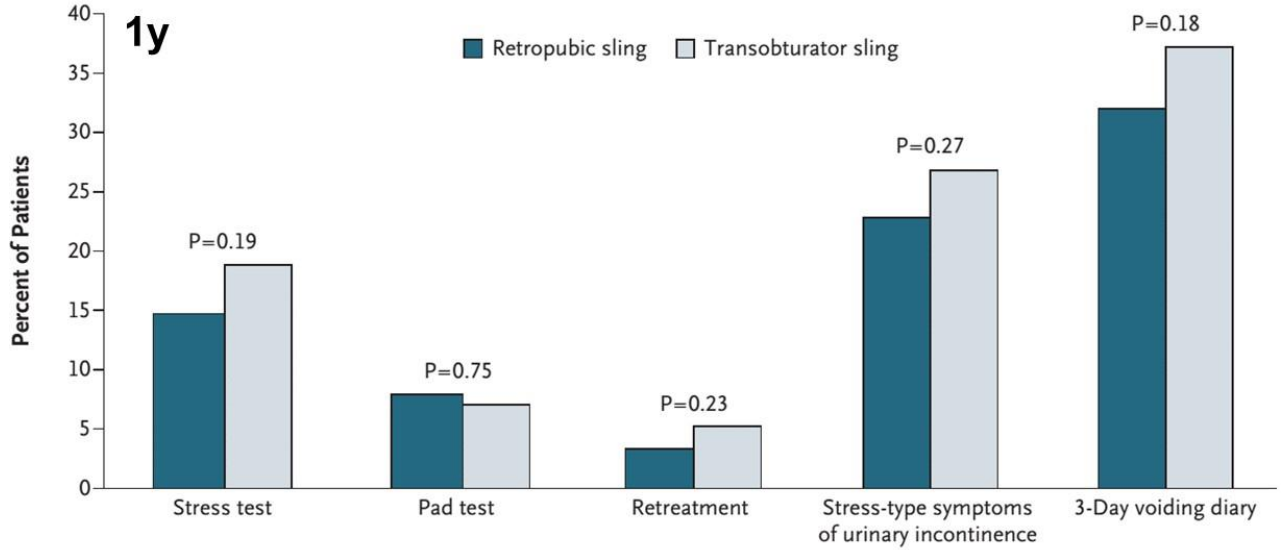
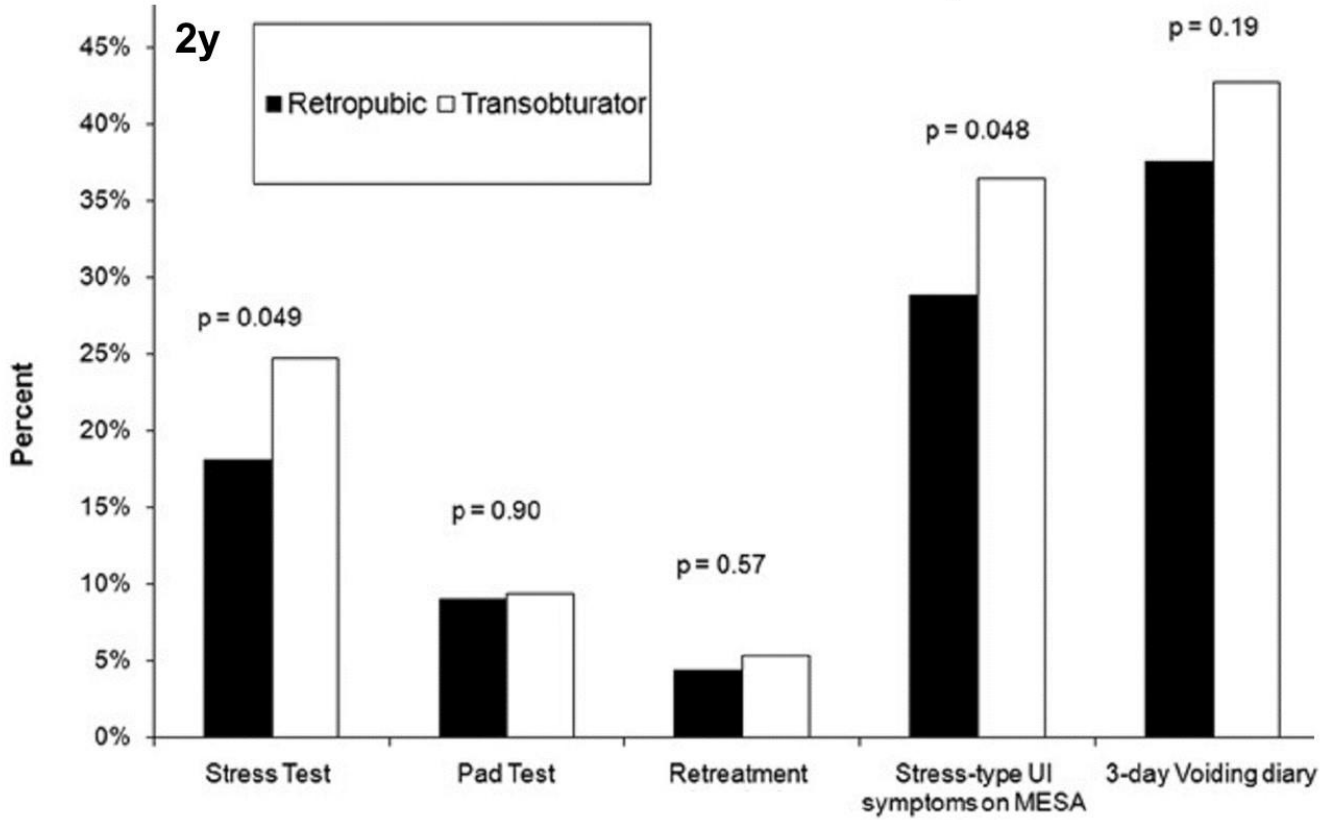




# Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis

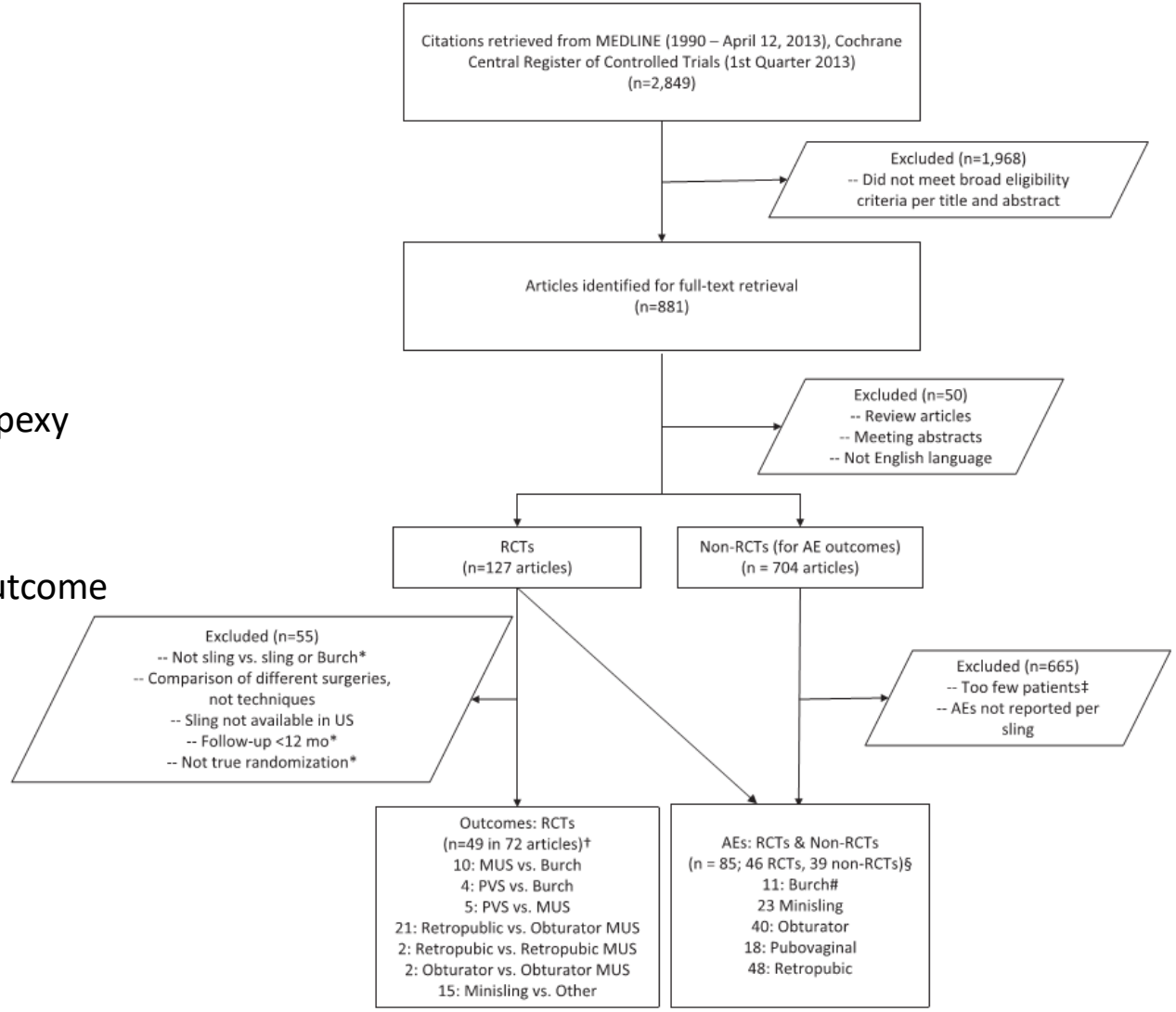
Megan O. Schimpf, MD; David D. Rahn, MD; Thomas L. Wheeler, MD, MSPH; Minita Patel, MD, MS; Amanda B. White, MD; Francisco J. Orejuela, MD; Sherif A. El-Nashar, MBBCh, MS; Rebecca U. Margulies, MD; Jonathan L. Gleason, MD; Sarit O. Aschkenazi, MD; Mamta M. Mamik, MD; Renée M. Ward, MD; Ethan M. Balk, MD, MPH; Vivian W. Sung, MD, MPH; for the Society of Gynecologic Surgeons Systematic Review Group

Am J Obstet Gynecol 2014;210:

- RCTs, 1990 – 2013
- F/U ≥12 months
- Comparison:

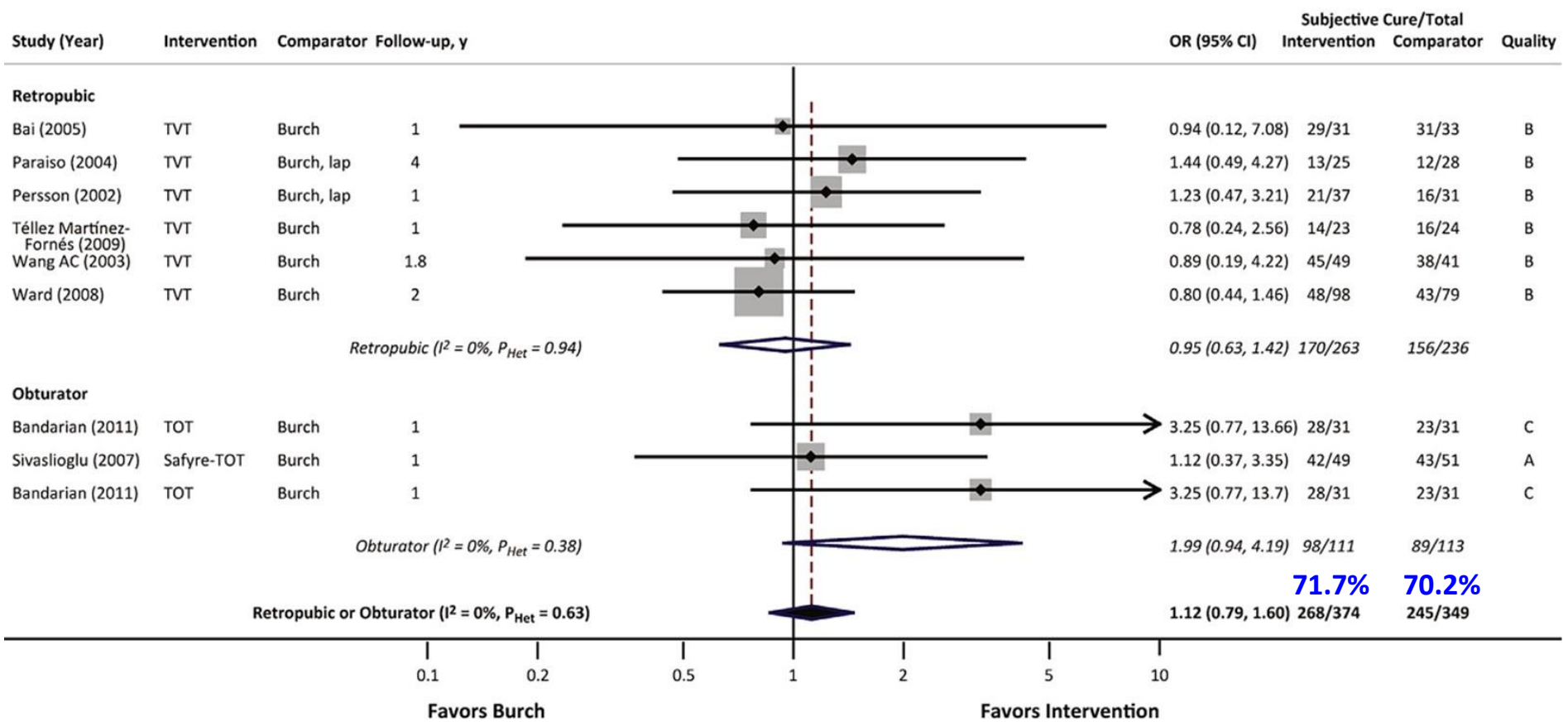
  Sling for SUI to another sling or Burch urethropexy
- Metaanalysis:

  ≥3 RCTs compared same surgeries for same outcome

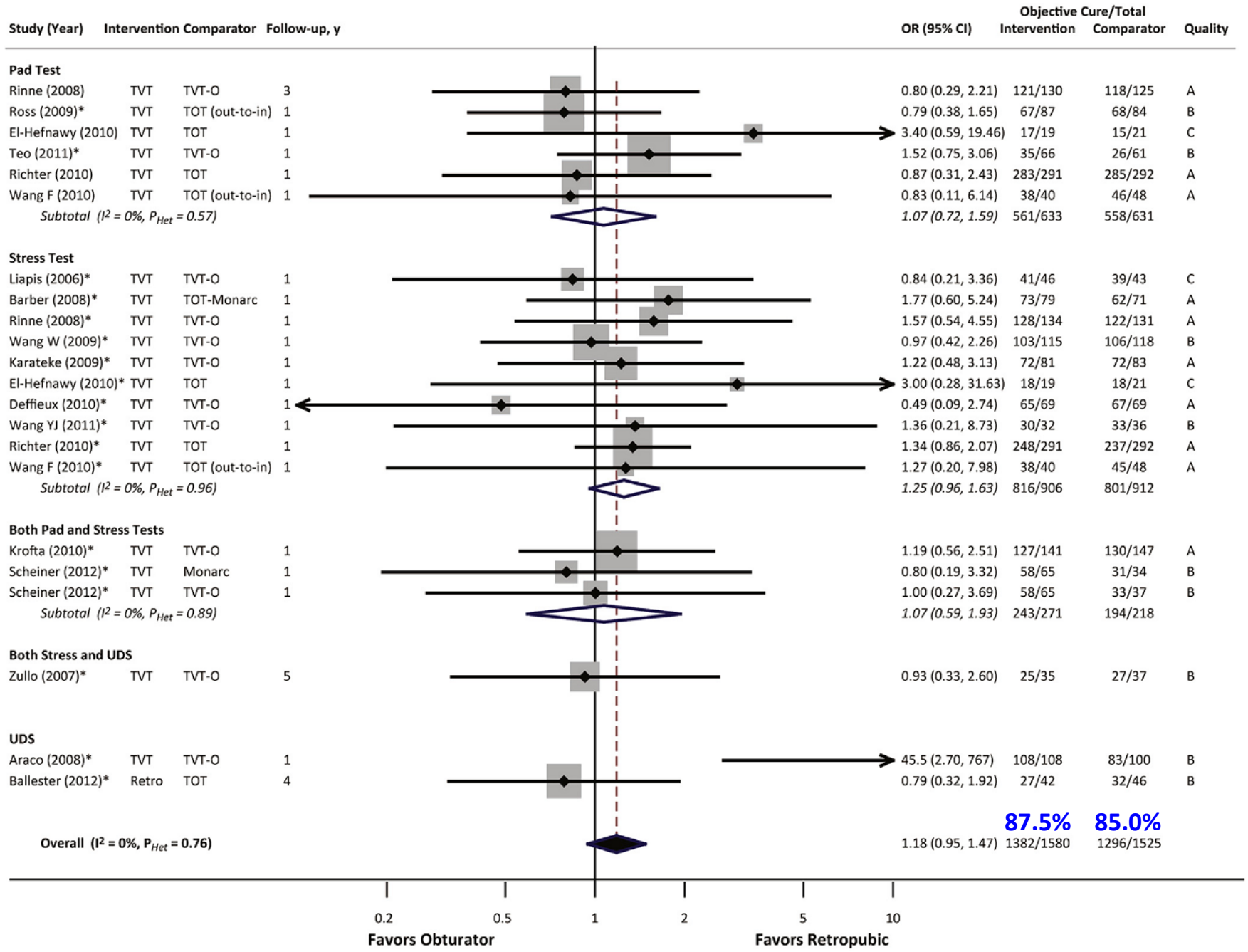



אגף נשים וילדות

## Metaanalysis for subjective cure: slings vs Burch urethropexy

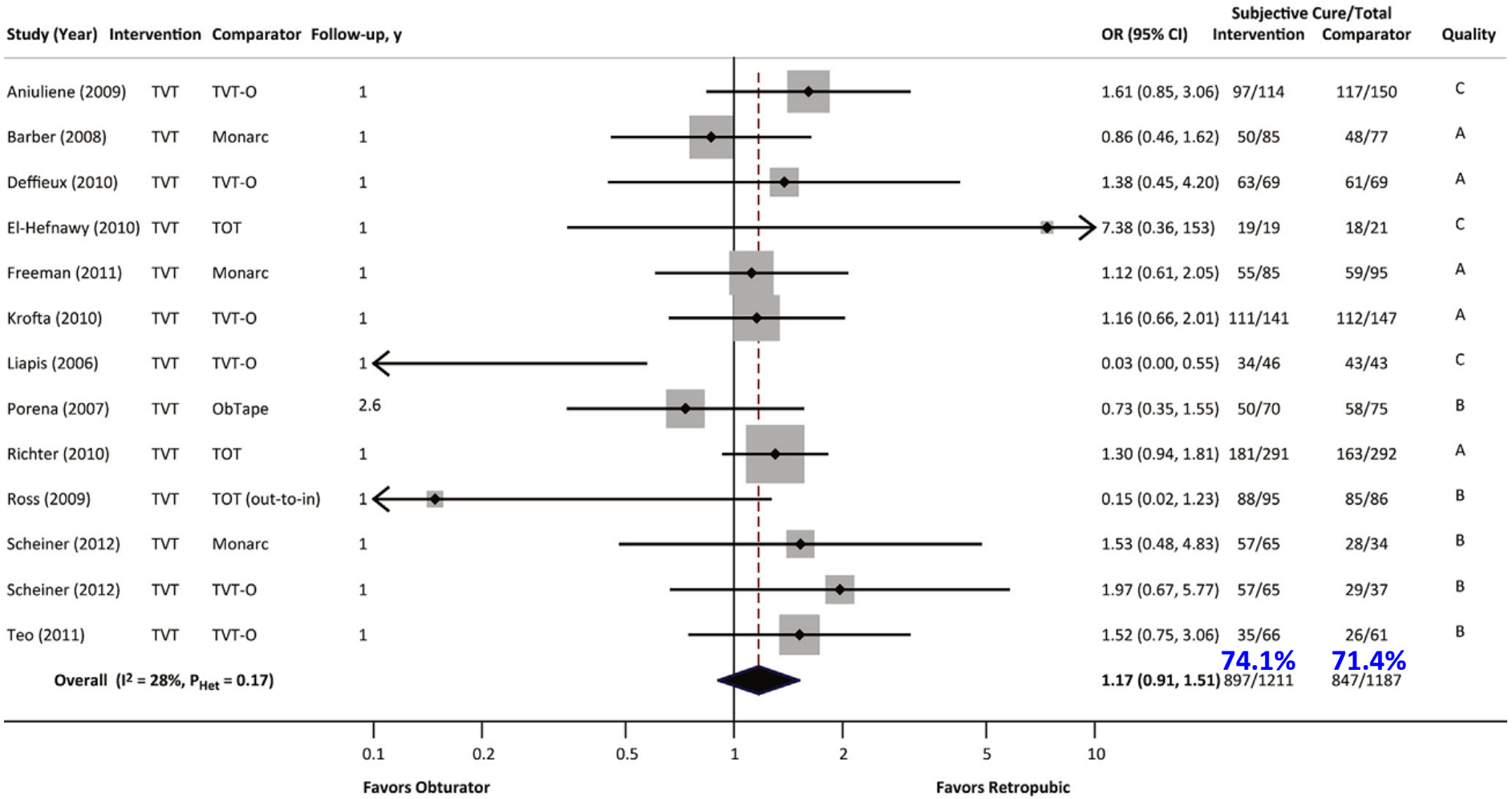


# Metaanalysis for objective cure: retropubic (retro) vs obturator midurethral slings



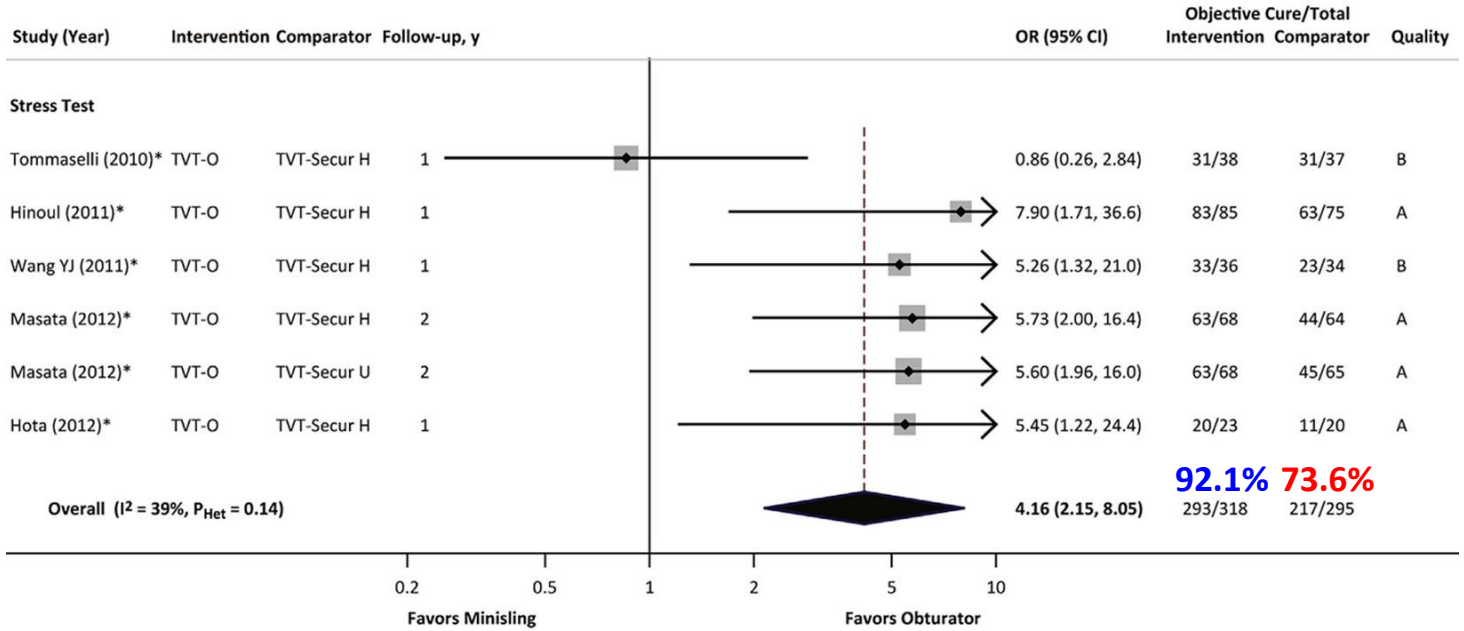

אגף נשים ויולדות

# Metaanalysis for subjective cure: retropubic vs obturator midurethral slings

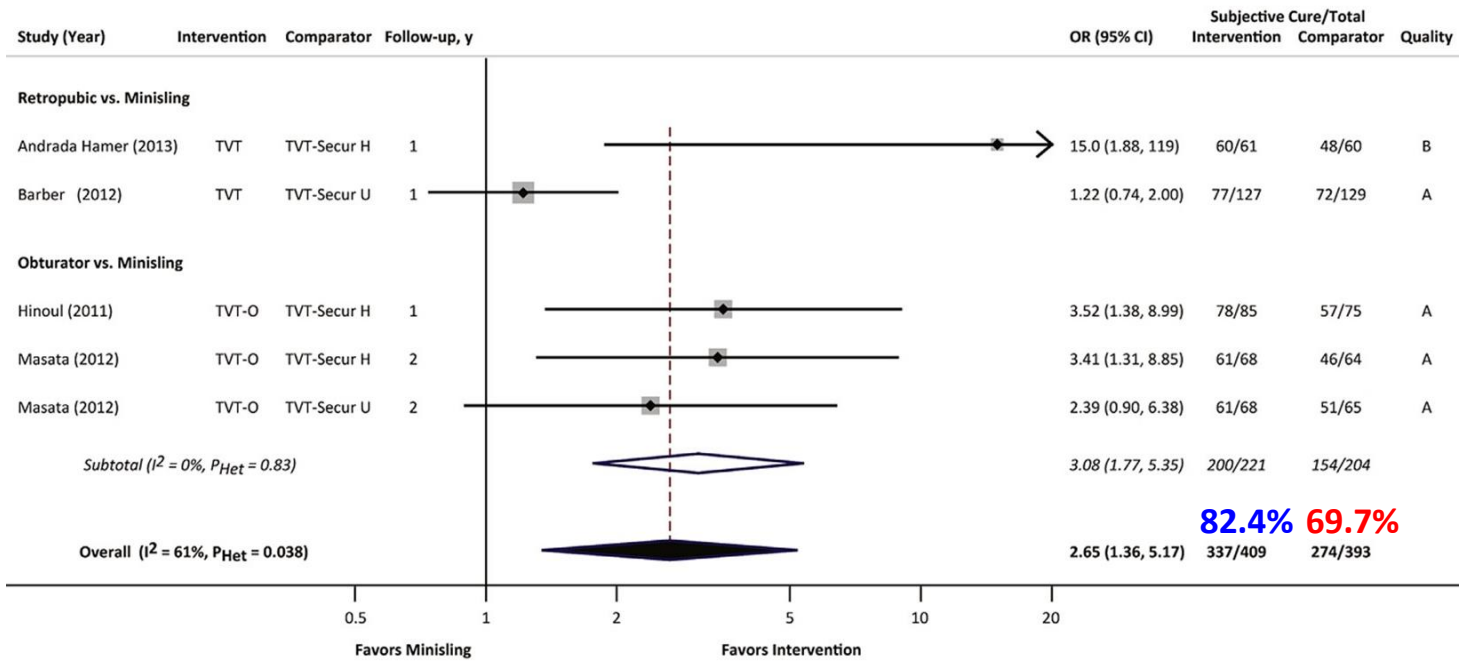



אגף נשים ויולדות

## Metaanalysis for objective cure: traditional midurethral sling (MUS) vs minisling




## Metaanalysis for subjective cure: traditional midurethral sling vs minisling




אגף נשים וילדות

# A systematic review and meta-analysis of single-incision mini-slings (MiniArc) versus transobturator mid-urethral slings in surgical management of female stress urinary incontinence

Binbin Jiao, MD[a,b], Shicong Lai, MD[a,b], Xin Xu, MD[a], Meng Zhang, MD[a,b], Tongxiang Diao, PhD[c,d], Guan Zhang, MD[a,b,*]

Jiao et al. Medicine (2018) 97:14

**Table 2**

**Study outcomes comparing MiniArc and Transobturator sling.**

| Outcomes | No. of studies | Sample size | | Heterogeneity (total) | | | | MD or RR (95% CI) | *P* (total) |
|---|---|---|---|---|---|---|---|---|---|
| | | MiniArc | Transobturator | $\chi^2$ | df | $I^2$, % | *P* | | |
| Objective cure rate | 4 | 393 | 443 | 0.14 | 3 | 0 | .99 | 0.98 (0.94, 1.03) | .48 |
| Subjective cure rate | 4 | 276 | 276 | 0.61 | 3 | 0 | .89 | 0.97 (0.91, 1.04) | .38 |
| Operation time | 11 | 810 | 924 | 85.34 | 10 | 88 | <.001 | −6.12 (−8.61, −3.64) | <.001 |
| Blood loss | 7 | 519 | 551 | 30.71 | 6 | 80 | <.001 | −16.67 (−26.29, −7.05) | .0007 |
| Urinary retention | 6 | 418 | 512 | 0.54 | 5 | 0 | .99 | 0.70 (0.50, 0.98) | .04 |
| Repeat of continence Surgery | 6 | 388 | 369 | 2.93 | 5 | 0 | .71 | 1.15 (0.46, 2.87) | .77 |
| Bladder perforation | 6 | 575 | 685 | 0.57 | 3 | 0 | .42 | 0.57 (0.20, 1.63) | .29 |
| Urinary tract infection | 5 | 359 | 464 | 2.09 | 4 | 0 | .72 | 0.76 (0.39, 1.46) | .41 |
| Postoperative groin pain | 5 | 384 | 405 | 8.79 | 4 | 54 | .07 | 0.42 (0.18, 0.98) | .04 |
| Vaginal mesh erosion | 5 | 474 | 585 | 3.76 | 3 | 20 | .29 | 2.05 (0.87, 4.86) | .10 |
| Postoperative pain | 3 | 98 | 97 | 34.39 | 2 | 94 | <.001 | −1.70 (−3.17, −0.23) | .02 |
| Hospitalization time | 3 | 140 | 110 | 27.83 | 2 | 93 | <.001 | −1.3 (−1.74, 0.86) | <.001 |
| De novo urgency | 6 | 271 | 268 | 1.06 | 5 | 0 | .96 | 0.64 (0.37, 1.11) | .11 |
| Sexual function | 2 | 103 | 117 | 0.11 | 1 | 0 | .74 | 4.42 (0.5, 39.39) | .18 |

**Table 1**

**Summary of comparative studies included in meta-analysis.**

| Study | Country | Study period | Study design | LE | Intervention | | Sample size | | Follow-up | Study quality |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Trial | Control | Trial | Control | | |
| Tieu 2016 | USA | 2008–2011 | RCT | 2a | MiniArc | Transobturator | 49 | 49 | 1 y | 3* |
| Schellart 2014 | The Netherlands | 2009–2011 | RCT | 2a | MiniArc | Transobturator | 97 | 96 | 1 y | 4* |
| Foote 2014 | Australia | Not mention | RCT | 2a | MiniArc | Transobturator | 25 | 25 | 2 y | 3* |
| Lee 2015 | Australia | 2009–2011 | RCT | 2a | MiniArc | Transobturator | 112 | 113 | 6 mo | 4* |
| Enzelsberger 2010 | Germany | Not mention | RCT | 2a | MiniArc | Transobturator | 45 | 45 | 1 y | 3* |
| Oliveira 2011 | Portugal | 2008 | RCT | 2a | MiniArc | Transobturator | 30 | 30 | 1 y | 4* |
| Castroviejo-Royo 2012 | Spain | 2005–2011 | Retrospective cohort study | 2b | MiniArc | Transobturator | 103 | 214 | 1 y | 7† |
| Tutolo 2016 | Belgium | 2003–2012 | Retrospective cohort study | 2b | MiniArc | Transobturator | 166 | 215 | 1 y | 7† |
| Lo 2014 | China | 2010–2011 | Retrospective cohort study | 2a | MiniArc | Transobturator | 85 | 55 | 6 mo | 7† |
| Sun 2012 | China | 2010–2011 | Retrospective cohort study | 2a | MiniArc | Transobturator | 43 | 42 | 1 y | 7† |
| Wu 2016 | China | 2005–2014 | Retrospective cohort study | 2a | MiniArc | Transobturator | 54 | 68 | 1 y | 7† |
| De Ridder 2010 | Belgium | 2007–2008 | Retrospective cohort study | 2b | MiniArc | Transobturator | 75 | 56 | 1 y | 9† |

## 5. Conclusions

This meta-analysis indicates that MiniArc is an effective method treating SUI. When compared with transobturator slings, it not only had a similar high cure rates, but also associated with lower complications. However, further larger, well-designed prospective RCTs with a larger patient series are required to confirm this conclusion.

אגף נשים וילדות

| Study | Country | Study period | Study design |
|---|---|---|---|
| Tieu 2016 | USA | 2008–2011 | RCT |
| Schellart 2014 | The Netherlands | 2009–2011 | RCT |
| Foote 2014 | Australia | Not mention | RCT |
| Lee 2015 | Australia | 2009–2011 | RCT |
| Enzelsberger 2010 | Germany | Not mention | RCT |
| Oliveira 2011 | Portugal | 2008 | RCT |

**Not blinded**
**Randomization ?**
**Heterogenicity**

אגף נשים וילדות

| | TO (Monarc™) group ($n = 49$) | SI (MiniArc™) group ($n = 49$) | $p$ value |
|---|---|---|---|
| Age (years), mean ± SD | 48.9 ± 9.4 | 52.9 ± 11.2 | 0.1 |
| Body mass index (kg/m$^2$), mean ± SD | 26.3 ± 4.7 | 28.4 ± 5.9 | 0.05 |
| Postmenopausal, *n* (%) | 18 (37) | 26 (53) | 0.15 |
| Parity, median (range) | 2 (0 – 4) | 2 (0 – 4) | 0.34 |
| Current smoker, *n* (%) | 2 (4) | 4 (8) | 0.7 |
| Incontinence episodes per day, mean ± SD | 2.4 ± 1.3 | 2.2 ± 1.4 | 0.2 |
| Pads per day, mean ± SD | 1.5 ± 1.0 | 1.1 ± 1.1 | 0.08 |
| Voids per day, mean ± SD | 6.9 ± 2.4 | 6.6 ± 2.2 | 0.5 |
| Urgency, *n* (%) | 28 (57) | 29 (59) | 1.0 |
| Urodynamics | | | |
| Maximal urethral closure pressure ($cmH_2O$), mean ± SD | 77.7 ± 24.3 | 85.3 ± 37.3 | 0.6 |
| Valsalva leak point pressure ($cmH_2O$), mean ± SD | 105.5 ± 43.6 | 113.5 ± 37.4 | 0.34 |
| Concomitant detrusor overactivity, *n* (%) | 3 (6) | 2 (4.7) | 0.89 |
| Overall preoperative POP stage, median (range) | 3 (1 – 4) | 3 (1 – 4) | 0.4 |
| Concomitant POP surgery, *n* (%) | 34 (69) | 29 (59) | 0.7 |
| Anterior colporrhaphy, *n* (%) | 19 (39) | 22 (45) | |

| Study | Country | Study period | Study design |
|---|---|---|---|
| Tieu 2016 | USA | 2008–2011 | RCT |
| Schellart 2014 | The Netherlands | 2009–2011 | RCT |
| Foote 2014 | Australia | Not mention | RCT |
| Lee 2015 | Australia | 2009–2011 | RCT |
| Enzelsberger 2010 | Germany | Not mention | RCT |
| Oliveira 2011 | Portugal | 2008 | RCT |

אגף נשים וילדות

# Randomized controlled trial comparing single-incision mini-sling and transobturator midurethral sling for the treatment of stress urinary incontinence: 3-year follow-up results

Ana L.G. Pascom MD | Lucyana M. Djehdian MD, PhD | Maria A.T. Bortolini MD, PhD | Zsuzsanna I.K. Jarmy-Di Bella MD, PhD | Carlos A. Delroy MD, PhD | Jose T.N. Tamanini MD, PhD | Rodrigo A. Castro MD, PhD

Department of Gynecology, Federal University of São Paulo, São Paulo, Brazil

*Neurourology and Urodynamics.* 2

| | | |
|---|---|---|
| Further SUI Surgery | SI 17% | TOT 4.9% |
| De novo urgency | SI 12.2% | TOT 4.9% |

**TABLE 2** Objective and subjective cure rates after 3 years of follow-up

| Analysis | SIMS | TOT | Absolute difference § (IC 90%) | *P* |
|---|---|---|---|---|
| Per protocol ($n = 82$) | | | | |
| Objective cure | 28/41 (68.3%) | 37/41 (90.2%) | 21.9 (7.8-36.1) | 0.027 |
| Subjective cure | 28/41 (68.3%) | 35/41 (85.4%) | 17.1 (2.1-32.1) | 0.115 |
| Intent to treat[a] ($n = 130$) | | | | |
| Objective cure | 28/69 (40.6%) | 37/61 (60.7%) | 20.1 (5.9-34.2) | 0.035 |
| Subjective cure | 28/69 (40.6%) | 35/61 (57.4%) | 16.8 (2.5-31.0) | 0.078 |
| Intent to treat[b] ($n = 130$) | | | | |
| Objective cure | 56/69 (81.2%) | 57/61 (93.4%) | 12.2 (2.9-21.6) | 0.066 |
| Subjective cure | 54/69 (78.3%) | 53/61 (86.9%) | 8.6 (2.2-19.5) | 0.252 |

אגף נשים וילדות

| Quality-of-life questionnaires | Preoperative ($n = 130$) | 12 mo[a] ($n = 120$) | 36 mo[a] ($n = 82$) | Between surgeries ($P$) | | |
|---|---|---|---|---|---|---|
| | | | | Preoperative | 12 mo | 36 mo |
| UI-specific quality-of-life instrument scores | | | | | | |
| Avoidance and limiting behavior | | | | | | |
| SIMS | 51.5 ± 23.4 | 87.2 ± 19.0 | 84.9 ± 21.8 | 0.971 | 0.033 | 0.021 |
| TOT | 50.2 ± 16.0 | 93.6 ± 10.4 | 89.6 ± 18.7 | | | |
| Psychosocial affect | | | | | | |
| SIMS | 66.7 ± 25.2 | 92.9 ± 17.2 | 89.8 ± 21.8 | 0.882 | 0.041 | 0.268 |
| TOT | 63.8 ± 20.1 | 98.3 ± 7.7 | 94.3 ± 15.1 | | | |
| Social embarrassment | | | | | | |
| SIMS | 42.1 ± 23.7 | 83.9 ± 25.5 | 78.0 ± 28.8 | 0.509 | 0.051 | 0.338 |
| TOT | 35.9 ± 13.8 | 92.4 ± 16.3 | 83.7 ± 26.4 | | | |
| Urogenital distress inventory short form scores | | | | | | |
| SIMS | 8.4 ± 2.7 | 2.6 ± 3.3 | 3.9 ± 4.2 | 0.087 | <0.001 | 0.026 |
| TOT | 9.2 ± 2.7 | 0.7 ± 1.3 | 2.1 ± 2.8 | | | |

אגף נשים וילדות

Cochrane Library

Cochrane Database of Systematic Reviews

**31 RCTs:**

- TVT-Secur
- MiniArc
- Ajust
- Needleless
- Ophira
- Tissue Fixation System
- CureMesh

# Single-incision sling operations for urinary incontinence in women (Review)

Nambiar A, Cody JD, Jeffery ST, Aluko P

Single-incision sling operations for urinary incontinence in women.

*Cochrane Database of Systematic Reviews* 2017, Issue 7. Art. No.: CD008709.

אגף נשים ויולדות

## Analysis 6.1. Comparison 6 Single-incision sling versus retropubic minimally invasive slings, Outcome 1 Number of women with urinary incontinence.

Review: Single-incision sling operations for urinary incontinence in women

Comparison: 6 Single-incision sling versus retropubic minimally invasive slings

Outcome: 1 Number of women with urinary incontinence

| Study or subgroup | Single-incision slings n/N | Retropubic slings n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 Bottom-up approach | | | | | |
| Abdelwahab 2010 SEC | 2/30 | 3/29 | | 10.8 % | 0.64 [ 0.12, 3.58 ] |
| Andrada Hamer 2012 SEC | 32/61 | 14/60 | | 27.5 % | 2.25 [ 1.34, 3.77 ] |
| Barber 2012 SEC | 57/129 | 50/127 | | 30.7 % | 1.12 [ 0.84, 1.50 ] |
| Basu 2010 ARC | 19/38 | 3/33 | | 17.4 % | 5.50 [ 1.79, 16.94 ] |
| Wang 2011 SEC | 11/34 | 2/32 | | 13.6 % | 5.18 [ 1.24, 21.57 ] |
| **Subtotal (95% CI)** | **292** | **281** | | **100.0 %** | **2.08 [ 1.04, 4.14 ]** |

Total events: 121 (Single-incision slings), 72 (Retropubic slings)

Heterogeneity: $Tau^2 = 0.38$; $Chi^2 = 15.96$, df = 4 (P = 0.003); $I^2 = 75\%$

Test for overall effect: Z = 2.08 (P = 0.038)

Test for subgroup differences: Not applicable

0.01 0.1 1 10 100

favours Single-incision slings favours retropubic slings

אגף נשים ויולדות

**Analysis 7.1. Comparison 7 Single-incision sling versus obturator minimally invasive slings, Outcome 1 Number of women with urinary incontinence.**

Review: Single-incision sling operations for urinary incontinence in women

Comparison: 7 Single-incision sling versus obturator minimally invasive slings

Outcome: 1 Number of women with urinary incontinence

| Study or subgroup | Single-incision sling n/N | Trans-obturator sling n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| 1 Inside-out TVTO | | | | | |
| Bianchi 2012 SEC | 13/66 | 9/56 | | 9.9 % | 1.23 [ 0.57, 2.65 ] |
| Friedman 2009 SEC | 16/42 | 3/42 | | 3.0 % | 5.33 [ 1.68, 16.95 ] |
| Hinoul 2011 SEC | 18/75 | 7/85 | | 6.6 % | 2.91 [ 1.29, 6.59 ] |
| Hota 2012 SEC | 23/42 | 4/44 | | 4.0 % | 6.02 [ 2.27, 15.95 ] |
| Mackintosh 2010 AJS | 1/14 | 0/13 | | 0.5 % | 2.80 [ 0.12, 63.20 ] |
| Masata 2012 SEC | 46/129 | 9/68 | | 11.9 % | 2.69 [ 1.40, 5.17 ] |
| Mostafa 2012 AJS | 10/69 | 6/68 | | 6.1 % | 1.64 [ 0.63, 4.27 ] |
| Oliveira 2011 ARC SEC | 14/60 | 5/30 | | 6.8 % | 1.40 [ 0.56, 3.52 ] |
| Seo 2011 SEC | 20/41 | 9/39 | | 9.3 % | 2.11 [ 1.10, 4.06 ] |
| Wang 2011 SEC | 11/34 | 3/36 | | 3.0 % | 3.88 [ 1.18, 12.73 ] |
| **Subtotal (95% CI)** | **572** | **481** | | **61.1 %** | **2.55 [ 1.94, 3.36 ]** |
| Total events: 172 (Single-incision sling), 55 (Trans-obturator sling) | | | | | |
| Heterogeneity: $Chi^2$ = 11.39, df = 9 (P = 0.25); $I^2$ =21% | | | | | |
| Test for overall effect: Z = 6.68 (P < 0.00001) | | | | | |

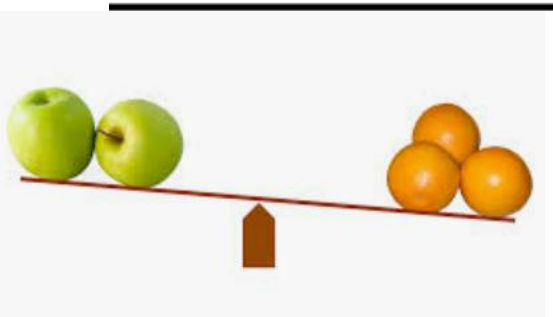
0.01 0.1 1 10 100

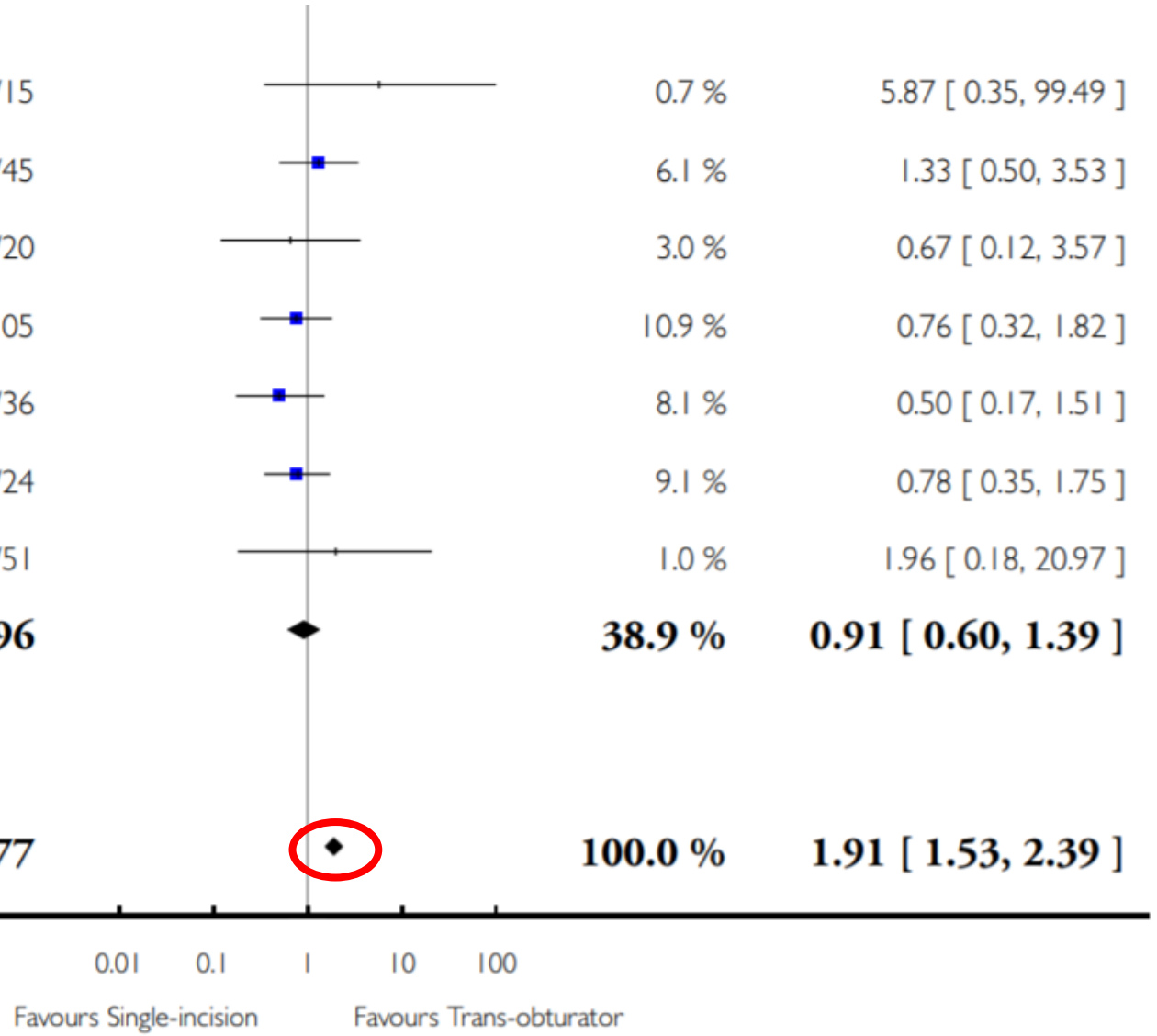
Favours Single-incision Favours Trans-obturator

אגף נשים וילדות

**Analysis 7.1. Comparison 7 Single-incision sling versus obturator minimally invasive slings, Outcome 1 Number of women with urinary incontinence.**

| | | | | | |
|---|---|---|---|---|---|
| 2 Outside-in TOT | | | | | |
| Djehdian 2010 OPH | 5/29 | 0/15 | | 0.7 % | 5.87 [ 0.35, 99.49 ] |
| Enzelsberger 2010 ARC | 8/45 | 6/45 | | 6.1 % | 1.33 [ 0.50, 3.53 ] |
| Kim 2010 SEC | 2/20 | 3/20 | | 3.0 % | 0.67 [ 0.12, 3.57 ] |
| Lee 2012 ARC | 8/100 | 11/105 | | 10.9 % | 0.76 [ 0.32, 1.82 ] |
| Sivaslioglu 2012 TFS | 4/36 | 8/36 | | 8.1 % | 0.50 [ 0.17, 1.51 ] |
| Smith 2011 ARC | 7/24 | 9/24 | | 9.1 % | 0.78 [ 0.35, 1.75 ] |
| Yoon 2011 NDL | 2/52 | 1/51 | | 1.0 % | 1.96 [ 0.18, 20.97 ] |
| **Subtotal (95% CI)** | **306** | **296** | | **38.9 %** | **0.91 [ 0.60, 1.39 ]** |
| Total events: 36 (Single-incision sling), 38 (Trans-obturator sling) | | | | | |
| Heterogeneity: $Chi^2 = 4.22$, df = 6 (P = 0.65); $I^2 = 0.0\%$ | | | | | |
| Test for overall effect: Z = 0.43 (P = 0.67) | | | | | |
| **Total (95% CI)** | **878** | **777** | | **100.0 %** | **1.91 [ 1.53, 2.39 ]** |






אגף נשים ויולדות

# Clinical outcome of single-incision slings, excluding TVT-Secur, vs standard slings in the surgical management of stress incontinence: an updated systematic review and meta-analysis

Aram Kim*, Min Seo Kim†, Young-Jin Park*, Woo Suk Choi*, Hyoung Keun Park*, Sung Hyun Paick*, Myung-Soo Choo‡ and Hyeong Gon Kim*

*Department of Urology, Konkuk University Medical Center, Konkuk University School of Medicine, †College of Medicine, Korea University, and ‡Department of Urology, Asan Medical Centre, Ulsan University College of Medicine, Seoul, Korea

*BJU Int* 2019; **123:** 566–584

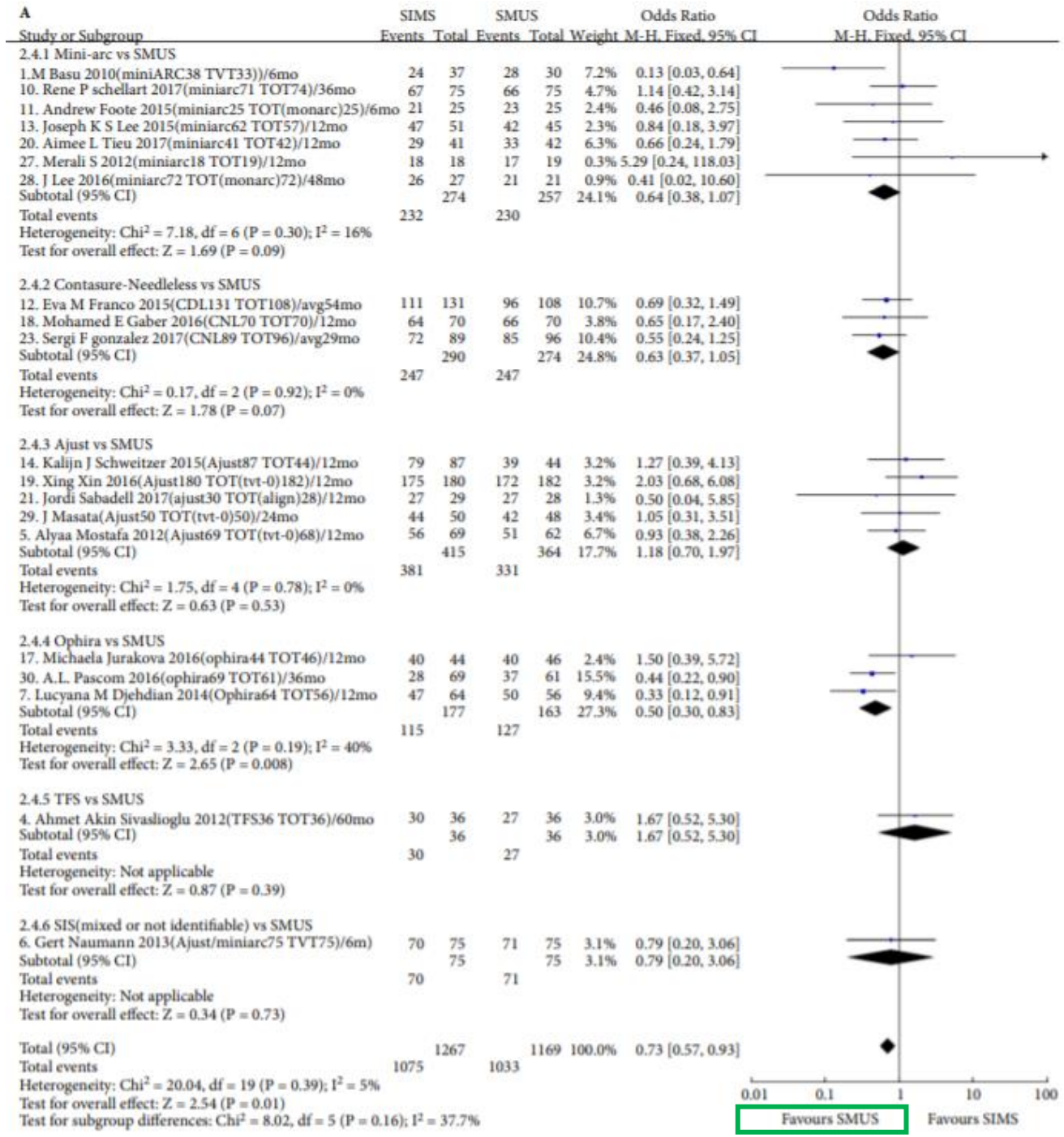
**29 RCTS:**

- **Mini-Arc**
- **Contasure-Needleless**
- **Ajust**
- **Ophira**
- **Tissue fixation system (TFS)**
- **Mixed / unidentifiable SIS**

אגף נשים ויולדות

# Objective cure rate:

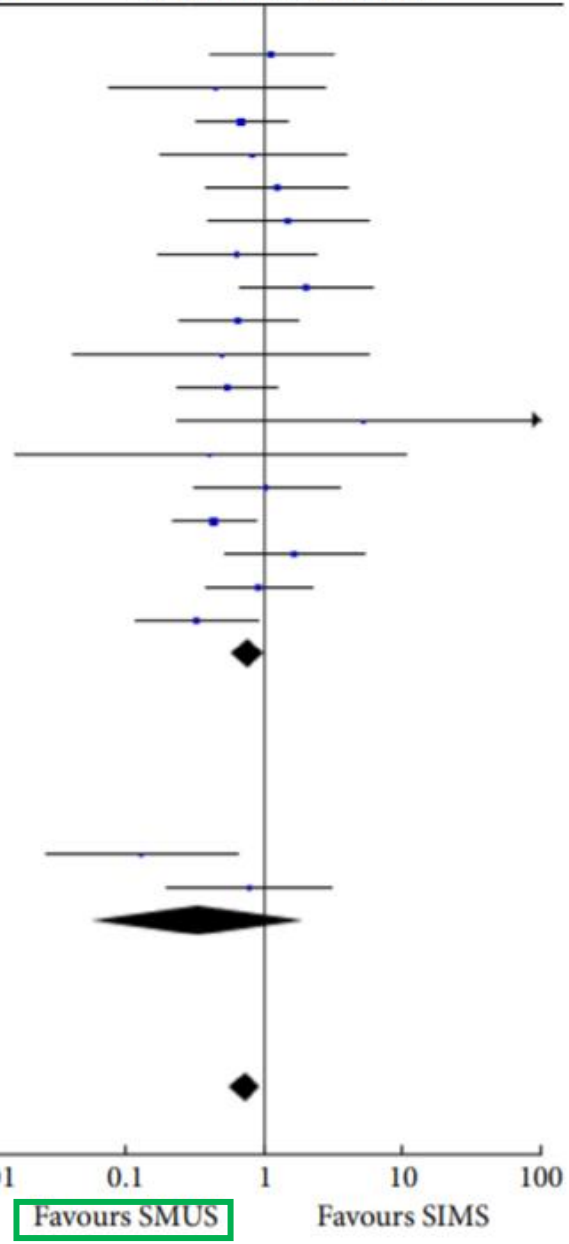
## Subgroup analysis based on the type of single-incision mini-sling




אגף נשים ויולדות

**B**

| Study or Subgroup | SIMS Events | SIMS Total | SMUS Events | SMUS Total | Weight | Odds Ratio M-H, Random, 95% CI |
|---|---|---|---|---|---|---|
| 2.6.1 SIMS vs TO-TVT | | | | | | |
| 10. Rene P schellart 2017(miniarc71 TOT74)/36mo | 67 | 75 | 66 | 75 | 6.3% | 1.14 [0.42, 3.14] |
| 11. Andrew Foote 2015(miniarc25 TOT(monarc)25)/6mo | 21 | 25 | 23 | 25 | 2.1% | 0.46 [0.08, 2.75] |
| 12. Eva M Franco 2015(CDL131 TOT108)/avg54mo | 111 | 131 | 96 | 108 | 10.5% | 0.69 [0.32, 1.49] |
| 13. Joseph K S Lee 2015(miniarc62 TOT57)/12mo | 47 | 51 | 42 | 45 | 2.8% | 0.84 [0.18, 3.97] |
| 14. Kalijn J Schweitzer 2015(Ajust87 TOT44)/12mo | 79 | 87 | 39 | 44 | 4.7% | 1.27 [0.39, 4.13] |
| 17. Michaela Jurakova 2016(ophira44 TOT46)/12mo | 40 | 44 | 40 | 46 | 3.7% | 1.50 [0.39, 5.72] |
| 18. Mohamed E Gaber 2016(CNL70 TOT70)/12mo | 64 | 70 | 66 | 70 | 3.9% | 0.65 [0.17, 2.40] |
| 19. Xing Xin 2016(Ajust180 TOT(tvt-0)182)/12mo | 175 | 180 | 172 | 182 | 5.5% | 2.03 [0.68, 6.08] |
| 20. Aimee L Tieu 2017(miniarc41 TOT42)/12mo | 29 | 41 | 33 | 42 | 6.5% | 0.66 [0.24, 1.79] |
| 21. Jordi Sabadell 2017(ajust30 TOT(align)28)/12mo | 27 | 29 | 27 | 28 | 1.1% | 0.50 [0.04, 5.85] |
| 23. Sergi F gonzalez 2017(CNL89 TOT96)/avg29mo | 72 | 89 | 85 | 96 | 9.3% | 0.55 [0.24, 1.25] |
| 27. Merali S 2012(miniarc18 TOT19)/12mo | 18 | 18 | 17 | 19 | 0.7% | 5.29 [0.24, 118.03] |
| 28. J Lee 2016(miniarc72 TOT(monarc)72)/48mo | 26 | 27 | 21 | 21 | 0.7% | 0.41 [0.02, 10.60] |
| 29. J Masata(Ajust50 TOT(tvt-0)50)/24mo | 44 | 50 | 42 | 48 | 4.5% | 1.05 [0.31, 3.51] |
| 30. A.L. Pascom 2016(ophira69 TOT61)/36mo | 28 | 69 | 37 | 61 | 12.2% | 0.44 [0.22, 0.90] |
| 4.Ahmet Akin Sivaslioglu 2012(TFS36 TOT36)/60mo | 30 | 36 | 27 | 36 | 4.9% | 1.67 [0.52, 5.30] |
| 5. Alyaa Mostafa 2012(Ajust69 TOT(tvt-0)68)/12mo | 56 | 69 | 51 | 62 | 8.0% | 0.93 [0.38, 2.26] |
| 7. Lucyana M Djehdian 2014(Ophira64 TOT56)/12mo | 47 | 64 | 50 | 56 | 6.3% | 0.33 [0.12, 0.91] |
| Subtotal (95% CI) | | 1155 | | 1064 | 93.7% | 0.77 [0.59, 1.00] |
| Total events | 981 | | 934 | | | |
| Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 15.38$, df = 17 (P = 0.57); $I^2 = 0\%$ | | | | | | |
| Test for overall effect: Z = 1.95 (P = 0.05) | | | | | | |
| 2.6.2 SIMS vs RP-TVT | | | | | | |
| 1.M Basu 2010(miniARC38 TVT33))/6mo | 24 | 37 | 28 | 30 | 2.7% | 0.13 [0.03, 0.64] |
| 6. Gert Naumann 2013(Ajust/miniarc75 TVT75)/6m) | 70 | 75 | 71 | 75 | 3.6% | 0.79 [0.20, 3.06] |
| Subtotal (95% CI) | | 112 | | 105 | 6.3% | 0.34 [0.06, 1.98] |
| Total events | 94 | | 99 | | | |
| Heterogeneity: $Tau^2 = 1.06$; $Chi^2 = 2.87$, df = 1 (P = 0.09); $I^2 = 65\%$ | | | | | | |
| Test for overall effect: Z = 1.20 (P = 0.23) | | | | | | |
| Total (95% CI) | | 1267 | | 1169 | 100.0% | 0.74 [0.57, 0.97] |
| Total events | 1075 | | 1033 | | | |
| Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 20.04$, df = 19 (P = 0.39); $I^2 = 5\%$ | | | | | | |
| Test for overall effect: Z = 2.22 (P = 0.03) | | | | | | |
| Test for subgroup differences: $Chi^2 = 0.82$, df = 1 (P = 0.37); $I^2 = 0\%$ | | | | | | |

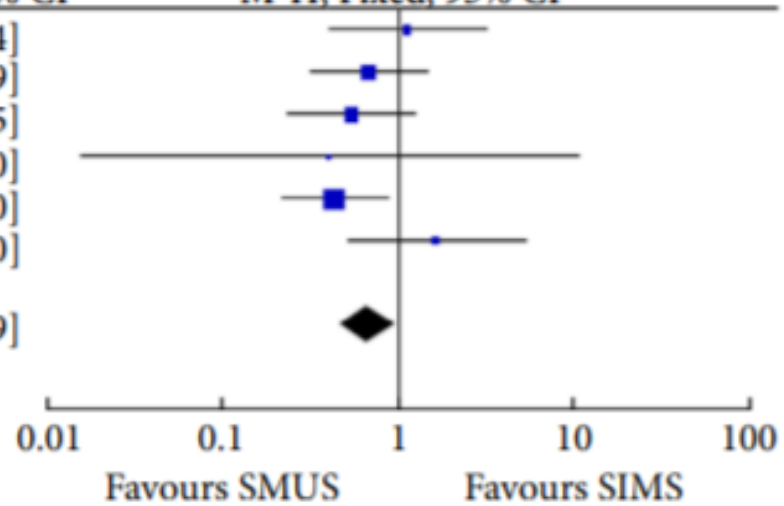


**C**

| Study or Subgroup | SIMS Events | SIMS Total | SMUS Events | SMUS Total | Weight | Odds Ratio M-H, Fixed, 95% CI |
|---|---|---|---|---|---|---|
| 10. Rene P schellart 2017(miniarc71 TOT74)/36mo | 67 | 75 | 66 | 75 | 10.4% | 1.14 [0.42, 3.14] |
| 12. Eva M Franco 2015(CDL131 TOT108)/avg54mo | 111 | 131 | 96 | 108 | 23.7% | 0.69 [0.32, 1.49] |
| 23. Sergi F gonzalez 2017(CNL89 TOT96)/avg29mo | 72 | 89 | 85 | 96 | 23.0% | 0.55 [0.24, 1.25] |
| 28. J Lee 2016(miniarc72 TOT(monarc)72)/48mo | 26 | 27 | 21 | 21 | 1.9% | 0.41 [0.02, 10.60] |
| 30. A.L. Pascom 2016(ophira69 TOT61)/36mo | 28 | 69 | 37 | 61 | 34.4% | 0.44 [0.22, 0.90] |
| 4. Ahmet Akin Sivaslioglu 2012(TFS36 TOT36)/60mo | 30 | 36 | 27 | 36 | 6.6% | 1.67 [0.52, 5.30] |
| Total (95% CI) | | 427 | | 397 | 100.0% | 0.68 [0.47, 0.99] |
| Total events | 334 | | 332 | | | |

Heterogeneity: $Chi^2 = 5.10$, $df = 5$ ($P = 0.40$); $I^2 = 2\%$

Test for overall effect: $Z = 2.04$ ($P = 0.04$)



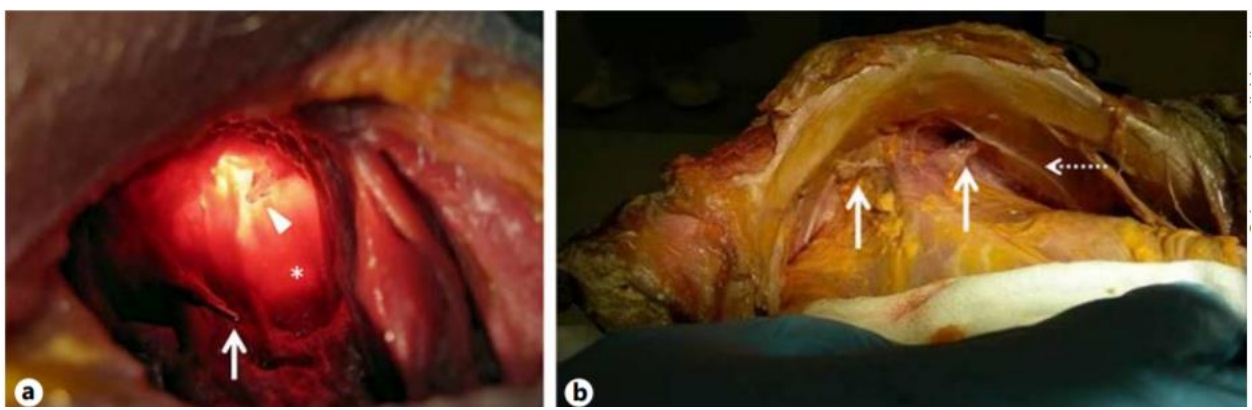

אגף נשים ויולדות

# Single-Incision Mini-Slings: Obturator Complex Pull-Out-Force Measurements

Florian Lenz[a] Sara Doll[b] Christof Sohn[c] Kerstin A. Brocker[c]

[a]Department of Obstetrics and Gynecology, St. Marien- and St. Annastiftskrankenhaus, Ludwigshafen, [b]Institute of Anatomy and Cell Biology, and [c]Department of Obstetrics and Gynecology, Medical School, University of Heidelberg, Heidelberg, Germany

Gynecol Obstet Invest 2016




אגף נשים וילדות

# Guideline of guidelines: urinary incontinence in women

**Table 7** Surgical treatment for SUI.

| Recommendation | ACOG | AUA/SUFU SUI | EAU | ICI | NICE |
|---|---|---|---|---|---|
| Inform women that any vaginal surgery has an impact on sexual function, which is generally positive | | | • | | |
| Open or laparoscopic colposuspension technique as option for women with SUI | • | • | • | • | • |
| Inform women undergoing colposuspension of longer operation time, hospital stay, recovery, and risk of POP and voiding dysfunction postoperatively | | | • | | |
| MUS as option for treatment of uncomplicated SUI | • | • | • | • | • |
| TMUS and RMUS have equivalent cure rates | • | | • | | |
| Do not offer TMUS unless there are specific clinical circumstances that retropubic space should be avoided | | | | | • |
| Do not use 'top-down' RMUS outside of a clinical trial | | | | | • |
| Do not use single-incision slings outside of a clinical trial | | | | | • |
| Single-incision slings may be offered, but patients should be warned about lack of long-term data | • | • | • | • | |
| Counsel women undergoing periurethral bulking about need for repeat injections | | • | | • | • |
| Do not recommend periurethral bulking agents to women seeking a permanent cure for SUI | | | | • | |
| May offer prophylactic anti-UI procedure at the time of POP repair after informed decision making | • | • | • | | |
| Do not offer anti-UI procedure at the time of POP repair in continent women | | | | • | • |
| AUS as an option for women with complicated SUI with warning of high complication and mechanical failure rate | | | | • | |
| Do not offer AUS to women with SUI unless prior surgery has failed | | | | | • |

↑ Efficacy

↓ Complications
↓ Cost

אגף נשים ויולדות


Thank
You!

# Mid-urethral sling operations for stress urinary incontinence in women

Abigail A Ford[1], Lynne Rogerson[2], June D Cody[3], Joseph Ogah[4]

[1]Obstetrics and Gynaecology, Bradford Royal Infirmary, Bradford, UK. [2]Gynaecology Department, St James University Hospital, Leeds, UK. [3]Cochrane Incontinence Review Group, University of Aberdeen, Foresterhill, UK. [4]University Hospitals of Morecambe Bay NHS Foundation Trust, Cumbria, UK

*Cochrane Database of Systematic Reviews* 2015, Issue 7. Art. No.: CD006375.

| | Participants (studies) | Retropubic tapes | Transobturator tapes | Relative effect (95% CI) |
|---|---|---|---|---|
| Bladder / Urethral perforation | 6372 (40 RCTs) | 4.9% | 0.6% | RR 0.13 (0.08 to 0.20) |
| Voiding dysfunction (≤5y) | 6217 (37 RCTs) | 7.2% | 3.8% | RR 0.53 (0.43 to 0.65) |
| De-novo urgency / urg. incont (≤1y) | 4923 (31 RCTs) | 8.2% | 8.0% | RR 0.98 (0.82 to 1.17) |
| Groin pain | 3226 (18 RCTs) | 1.4% | 6.6% | RR 4.62 (3.09 to 6.92) |
| Suprapubic pain | 1105 (4 RCTs) | 2.9% | 0.8% | RR 0.29 (0.11 to 0.78) |
| Vaginal tape erosion | 4743 (31 RCTs) | 2.0% | 2.2% | RR 1.13 (0.78 to 1.65) |
| Repeat incontinence surgery (≤1y) | 1402 (9 RCTs) | 1.9% | 3.1% | RR 1.64 (0.85 to 3.16) |
| Repeat incontinence surgery (>5y) | 695 (4 RCTs) | 1.1% | 10.0% | RR 8.79 (3.36 to 23.00) |