TVT – edelleen ” The Gold Standard ”

Antti Valpas

LT, ylilääkäri
Etelä-Karjalan keskussairaala
Etelä-Karjalan Sosiaali- ja terveyspiiri (EKSOTE) Naisten- ja lastentautien osaamiskeskuksen palvelupäällikkö

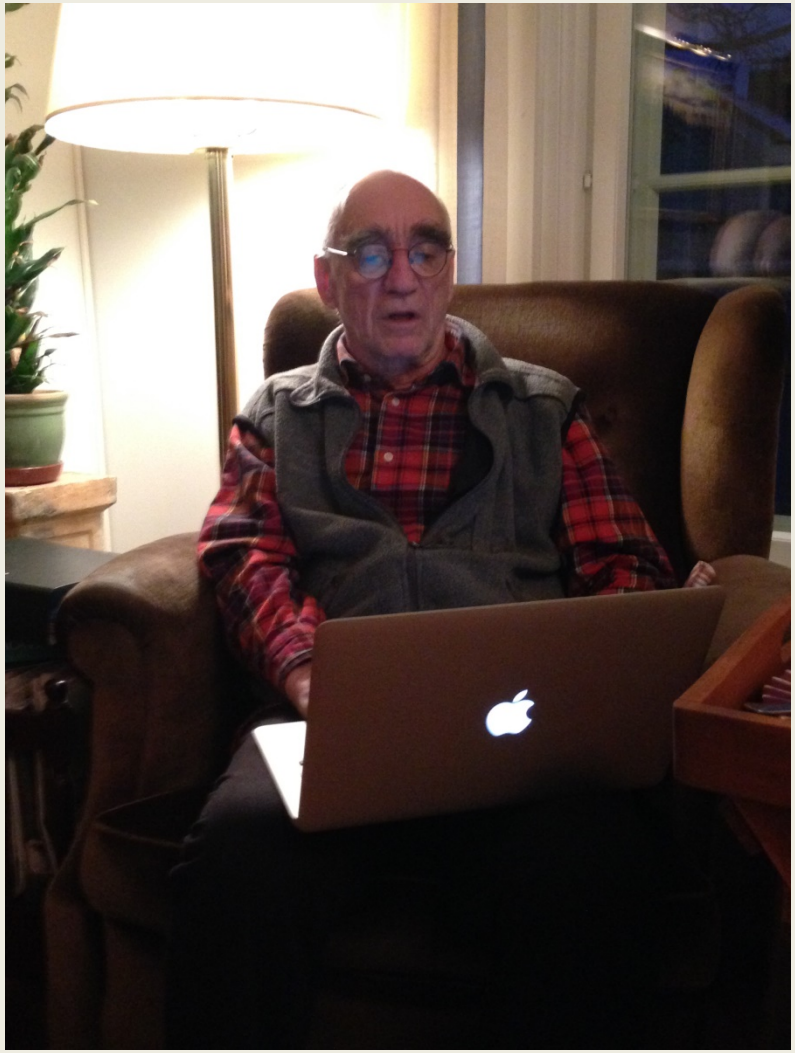
SGY 90- vuotta
15.11.2018
Finlandia-talo, Helsinki

Sidonnaisuudet

- LT, synnytys- ja naistentautien erikoislääkäri
- **Päätoimi**
  - Ylilääkäri Etelä-Karjalan keskussairaala
- **Sivutoimet**
  - Yksityislääkäri
- **Luottamustoimet terveydenhuollon alalla**
- **Toiminta terveydenhuollon ohjaukseen pyrkivissä hankkeissa**
- **Muut sidonnaisuudet**
  - n. kerran vuodessa osallistunut lääkealan yrityksen koulutukseen / koulutuksen suunnitteluun (Astellas)
  - NUGA – hallituksen jäsen

Prof. CG Nilsson

8.8.1944 - 8.10.2015

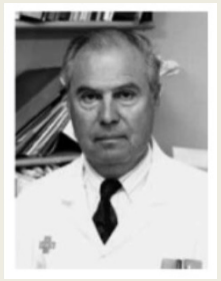


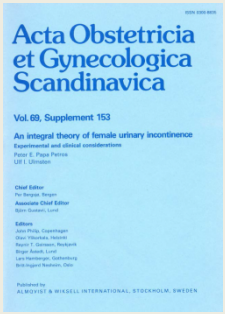
Esiintyvyys, kustannukset

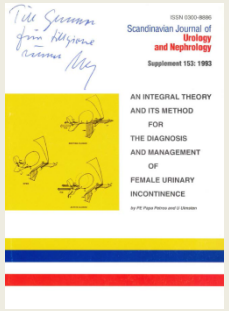
- n. 25 %:lla naisista esiintyy jonkinlaista tahatonta virtsan karkaamista; 7 %:lla haitta merkittävä
- tavallisin muoto on stress- l. ponnistusinkontinenssi
- Kustannukset Suomessa lähes 1 miljardi EUR (iäkkäät potilaat, hoitojaksot, laitoshoito)
- Kirurgisen hoidon kokonaiskustannukset pienet (obs. QALY)

Käypä Hoito – suositus: Virtsankarkailu (naiset), 2017

Teoriat (kontinenssi mekanismit)







1961 Enhöring

- painetrans-missioteoria

Urethro – vesicaalisen junktion tukeminen / nostaminen

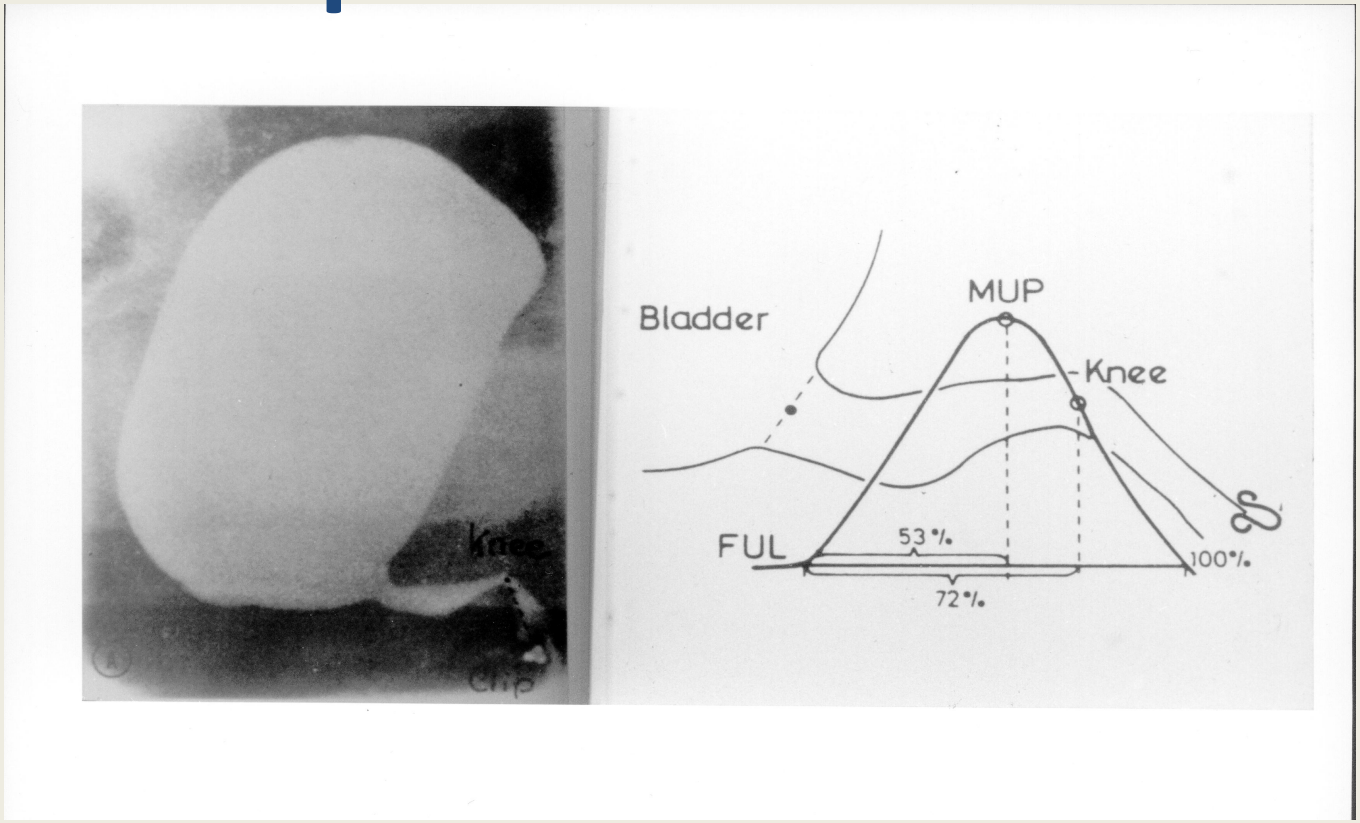
1991 Ulmsten ja Petros

- integraaliteoria

mid-urethra concept

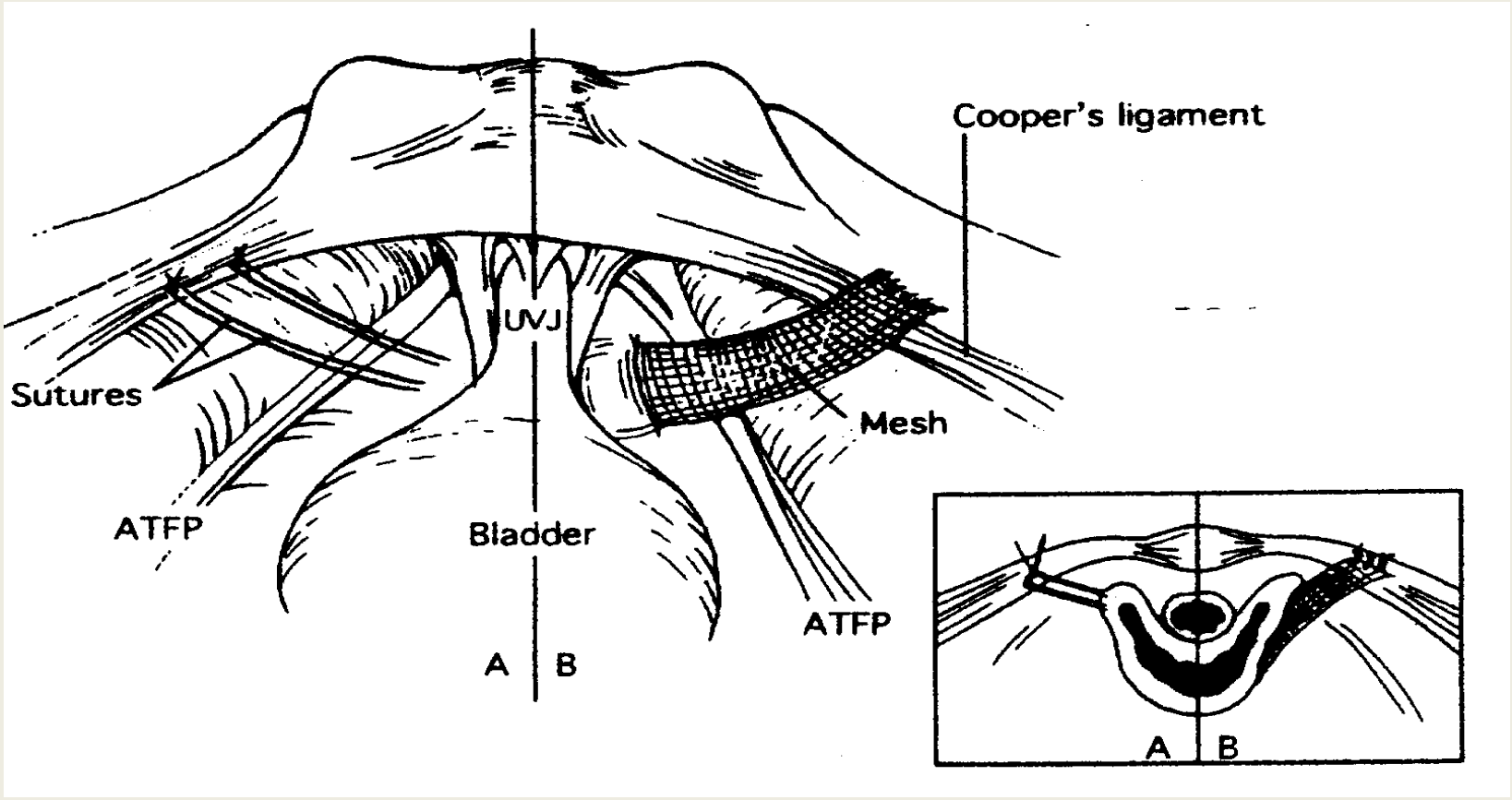
keskiuretran tukeminen

The Mid-Urethra Concept



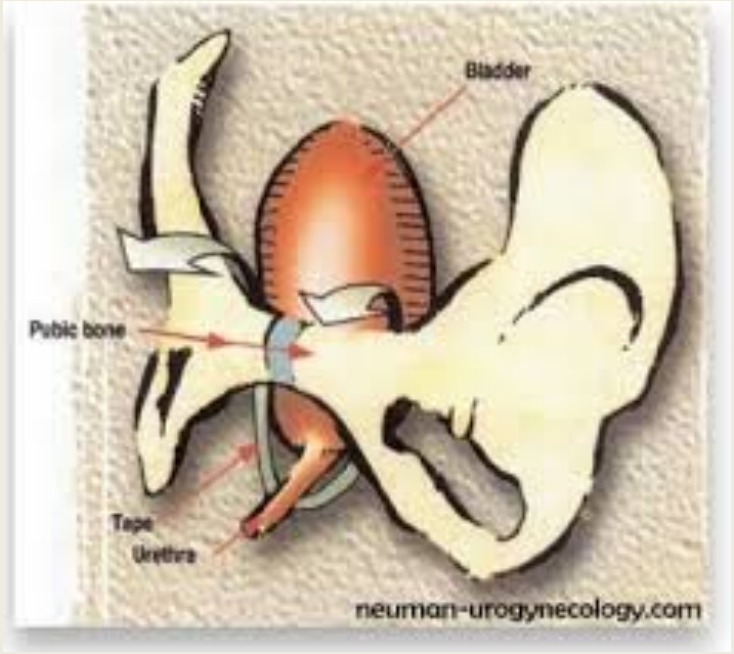
Westby, Asmussen and Ulmsten Am J Obstet Gynecol 1982

Burch colposuspension



Burch 1961

Tension-free Vaginal Tape - TVT

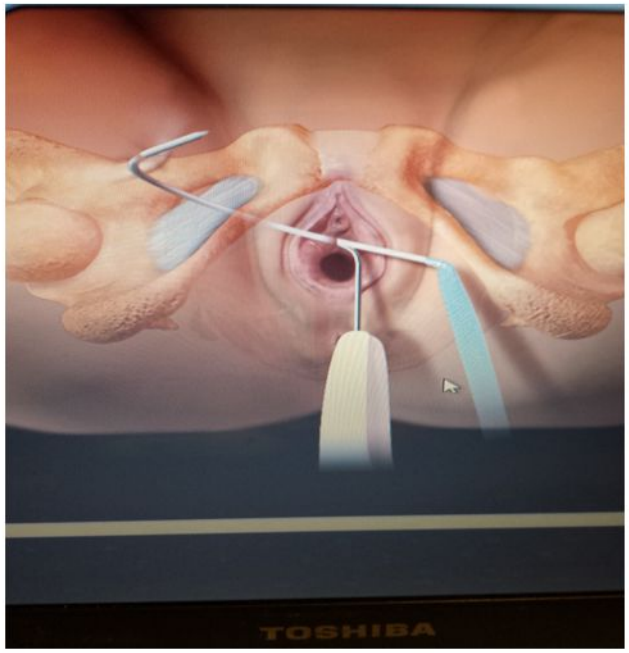


Ulmsten et al. 1996

TVT-O / TOT (transobturatorinen)

Tension Free Vaginal Tape

Side to side (TVT-O, TOT)



Delorme 2001: TOT, de Laval 2003: TVT-O

Leikkausten kokonaismäärät

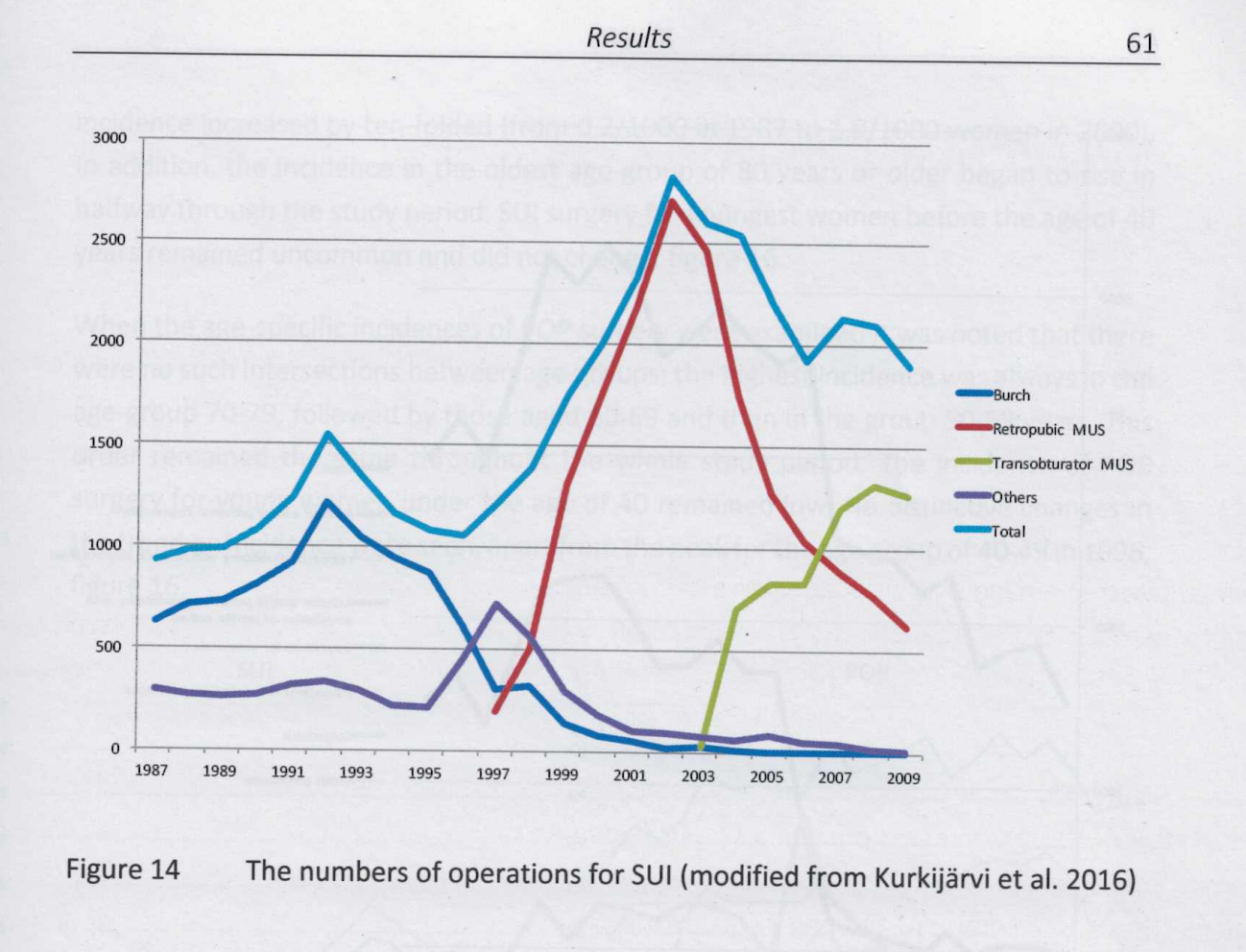


Figure 14 The numbers of operations for SUI (modified from Kurkijärvi et al. 2016)

THL /Hilmo 1987 – 2009
- inkontinenssi leikkaus
N=38 500

Kurkijärvi K. Surgery for stress urinary incontinence and pelvic organ prolapse in Finnish women. Doctoral Thesis, Univ.of Turku, 2017

’ It is not about anatomy – but restoring function… ’

’Tutte’ Nilsson

TVT:n systemaattinen kehitystyö ja koulutus

- 2 vuosikymmentä perustutkimusta (urodynamiikka, kuvantaminen, eri kudoskomponentit) – **Mid Urethra Concept**
- Em. teoriaan perustuen aloitettiin mini-invasiivisen leikkaustekniikan kehitys – tuloksena nykyinen TVT Classic

- Ensimmäinen kliininen tutkimus aloitettiin 1995 – tarkat kriteerit (genuine stress incontinence)
  - N=131, seuranta 1 vuosi: obj cure 91 %, complic. n. 3%

    Ulmsten et al 1998
- Kliinisempi aineisto (aik. leikkauksia, mixed, ISD)
  - N=161 , seuranta 16 kk: obj. cure 87%, complic. n. 8%

    Nilsson CG, Kuuva N 2001

British Journal of Obstetrics and Gynaecology
April 2001, Vol. 108, pp. 414–419

The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence

Carl Gustaf Nilsson*, Nina Kuuva

Table 5. Percentage and number of women completely cured, significantly improved, failed or lost to follow up in different categories of incontinence. Values are given as *n/n* (%).

Incontinence category	Completely cured	Significantly improved	Failed	Lost to follow up
Primary	88/100 88.0	6/100 6.0	4/100 4.0	2/100 2.0
Recurrent	38/45 84.4	4/45 8.9	2/45 4.4	0/45 0.0
Mixed	48/59 81.4	6/59 10.2	5/59 8.5	0/59 0.0
Low UCP*	12/18 77.8	2/18 11.1	2/18 11.1	0/18 0.0
Total	140/161 87.0	11/161 6.8	8/161 5.0	2/161 1.2

Acta Obstet Gynecol Scand 2002; 81: 72–77
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Acta Obstetricia et Gynecologica Scandinavica
ISSN 0001-6349

ORIGINAL ARTICLE

A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure

NINA KUUVA AND CARL GUSTAF NILSSON

From the Department of Obstetrics and Gynaecology, Helsinki University Central Hospital, Helsinki, Finland

- kansallinen systemaattinen koulutus ja sertifiointi Suomessa
- 38 sairaalaa: 4 yliopisto klinikkaa, 13 keskussairaalaa ja 21 aluesairaalaa

TVT leikkauksiin liittyvät komplikaatiot

Table 2 Published safety outcomes associated with the tension-free vaginal tape procedure in the treatment of female urinary incontinence

Complications	Kuuva and Nilsson [2] *n* (%)	Meschia et al. [8] *n* (%)	Hong et al [9] *n* (%)	Karram et al. [10] *n* (%)	Present series *n* (%)
Perioperative complications					
Bladder perforation	56 (3.8)	24 (6.0)	35 (9.3)	17 (4.9)	13 (4.7)
Excessive bleeding[a]	27 (1.9)	2 (0.5)	-	4 (1.1)	-
Major vessel injuries	1 (0.1)	-	1 (0.0)	-	-
Nerve injuries	1 (0.1)	1 (0.2)	-	3 (0.9)	-
Other perioperative complications	2 (0.2	-	-	-	-
Postoperative complications					
Urinary retention[b]	34 (2.3)	-	32 (8.5)	-	38 (13.9)
Other voiding problems	124 (8.5)	17 (4.0)	47 (12.5)	59 (16.9)	57 (20.8)
Retropubic hematomas	27 (1.9)	6 (1.5)	4 (1.1)	6 (1.7)	-
Urinary tract infection	59 (4.1)	-	5 (1.3)	38 (10.9)	1 (0.4)
Wound infection	12 (0.8)	-	3 (0.1)	-	1 (0.4)
Defect of the vaginal incision	10 (0.7)	2 (0.5)	-	3 (0.9)	-
Other postoperative complications	14 (1.0)	-	16 (4.3)		
Total	1455	404	375	350	

[a]Excessive bleeding was defined as blood loss > 200 ml in Kuuva and Nilsson [2], blood loss > 500 ml in Meschia et al. [6], and subjective assessment of the amount of bleeding in Karram et al. [10]
[b]Urinary retention was defined as complete urinary retention in Kuuva and Nilsson [2], the need for intermittent catheterization for at least 3 days after the procedure in Hong et al. [9], and residual urine volume of > 100 ml twice consecutively or failing to void in the present series

Paick JS, Ku JH, Shin JW et al. Complications associated with the tension-free vaginal tape procedure: the Korean experience. Int Urogynecol J (2005) 16: 215-219

TVT leikkauksiin liittyvät komplikaatiot

Complication	Kuuva and Nilsson *n* (%)	Meschia *n* (%)	Hong et al *n* (%)	Karram et al *n (%)*	Paick et al *n (%)*
Bladder perforation	56 (3.8)	24 (6.0)	35 (9.3)	17 (4.9)	13 (4.7)
Exessive bleeding	27 (1.9) > 200 ml	2 (0.5) > 500 ml	-	4 (1.1)	-
Urinary retention	34 (2.3) - totaali	-	32 (8.5)	-	38 (13.9)
Other voiding problems	124 (8.5)	17 (4.0)	47 (12.5)	59 (16.9)	57 (20.8)
Number of patients	1455	404	375	350	276

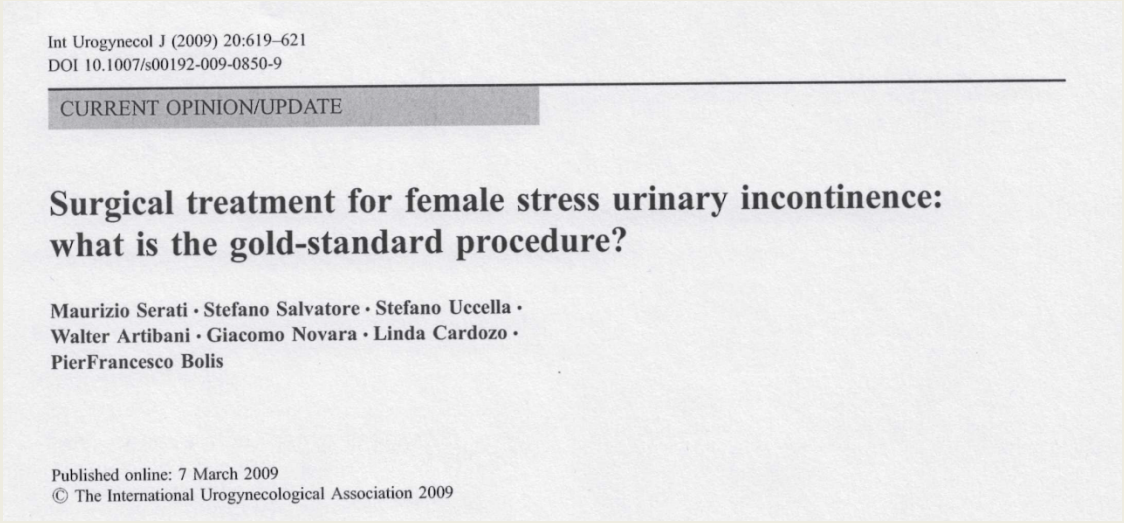
Paick JS, Ku JH, Shin JW et al. Complications associated with the tension-free vaginal tape procedure: the Korean experience. Int Urogynecol J (2005) 16: 215-219

Pitkäaikaistulokset - TVT

	Follow up	N	Obj. cure	Subj.cure	Reoper.	Urge /OAB	Obs.
Svenningsen et al. 2013 (registry)	10 y	483/603	89,9 %	76,1 %	2,3 %	14,9 %	- 0,8 % exposure
Nilsson et al. 2013	17 y	58/90	90,0 %	87,1 %			- one erosion, no shrinkage
Braga et al. 2018	17 y	46/52	91,4 %	89,1 %		32,6 %	- no other complications
Bakas et al. 2018	17 y	56/61	83,9 %	78,6 %	0 %	30,3 %	- 1,7 % erosion

Gold – standard ?

- Burch – historiaa
- TVT – nykyinen
- Haastaja: TOT / TVT-O



Int Urogynecol J (2009) 20:619–621
DOI 10.1007/s00192-009-0850-9

CURRENT OPINION/UPDATE

Surgical treatment for female stress urinary incontinence: what is the gold-standard procedure?

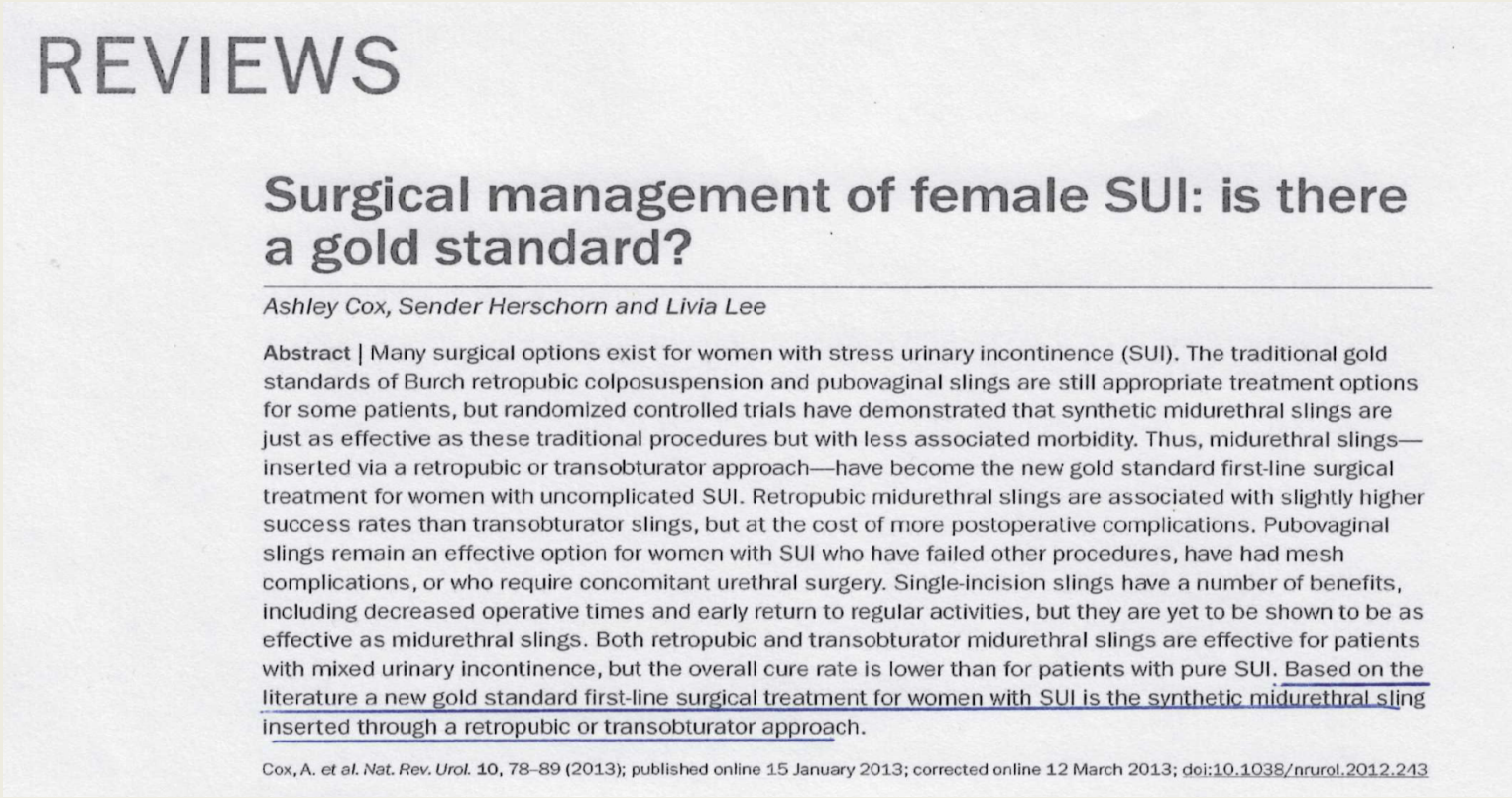
Maurizio Serati · Stefano Salvatore · Stefano Uccella · Walter Artibani · Giacomo Novara · Linda Cardozo · PierFrancesco Bolis

Published online: 7 March 2009

TVT vs. TOT / TVT-O (RCT)

	Follow up	N		Obj.cure	Subj.cure	Urge/OAB	Obs
Laurikainen et al. 2014	5 y	273	95 %	84,7% vs. 86,2%	94,2% vs. 91,7%	- preop 28,0% - postop 4,7% - de novo: 1,9%	- TVT-O: 1 extrusio, 1 retentio - katkaisu
Kenton et al. 2015 (randomized equivalence trial)	5 y	597	68 %	- *success 7,9% greater in TVT group*	79% vs. 85% (satisfaction)		- erosio: 3 vs. 4
Zhang et al. 2016	7 y	140	86 %	79,3% vs. 69,4%	74,3 % vs. 62,9%		- tape exposure 3,4 % vs 8,1% - ei eroa komplikaatioissa pidemmän aikavälin seurannassa

Gold –standard ? - MUS



REVIEWS

Surgical management of female SUI: is there a gold standard?

Ashley Cox, Sender Herschorn and Livia Lee

Abstract | Many surgical options exist for women with stress urinary incontinence (SUI). The traditional gold standards of Burch retropubic colposuspension and pubovaginal slings are still appropriate treatment options for some patients, but randomized controlled trials have demonstrated that synthetic midurethral slings are just as effective as these traditional procedures but with less associated morbidity. Thus, midurethral slings—inserted via a retropubic or transobturator approach—have become the new gold standard first-line surgical treatment for women with uncomplicated SUI. Retropubic midurethral slings are associated with slightly higher success rates than transobturator slings, but at the cost of more postoperative complications. Pubovaginal slings remain an effective option for women with SUI who have failed other procedures, have had mesh complications, or who require concomitant urethral surgery. Single-incision slings have a number of benefits, including decreased operative times and early return to regular activities, but they are yet to be shown to be as effective as midurethral slings. Both retropubic and transobturator midurethral slings are effective for patients with mixed urinary incontinence, but the overall cure rate is lower than for patients with pure SUI. Based on the literature a new gold standard first-line surgical treatment for women with SUI is the synthetic midurethral sling inserted through a retropubic or transobturator approach.

Cox, A. *et al. Nat. Rev. Urol.* **10**, 78–89 (2013); published online 15 January 2013; corrected online 12 March 2013; doi:10.1038/nrurol.2012.243

’ Based on the litterature a new gold standard first-line surgical treatment for women with SUI is the synthetic midurethral sling inserted through a retropubic or transobturator approach.’

2 systemaattista katsausta ja meta-analyysia

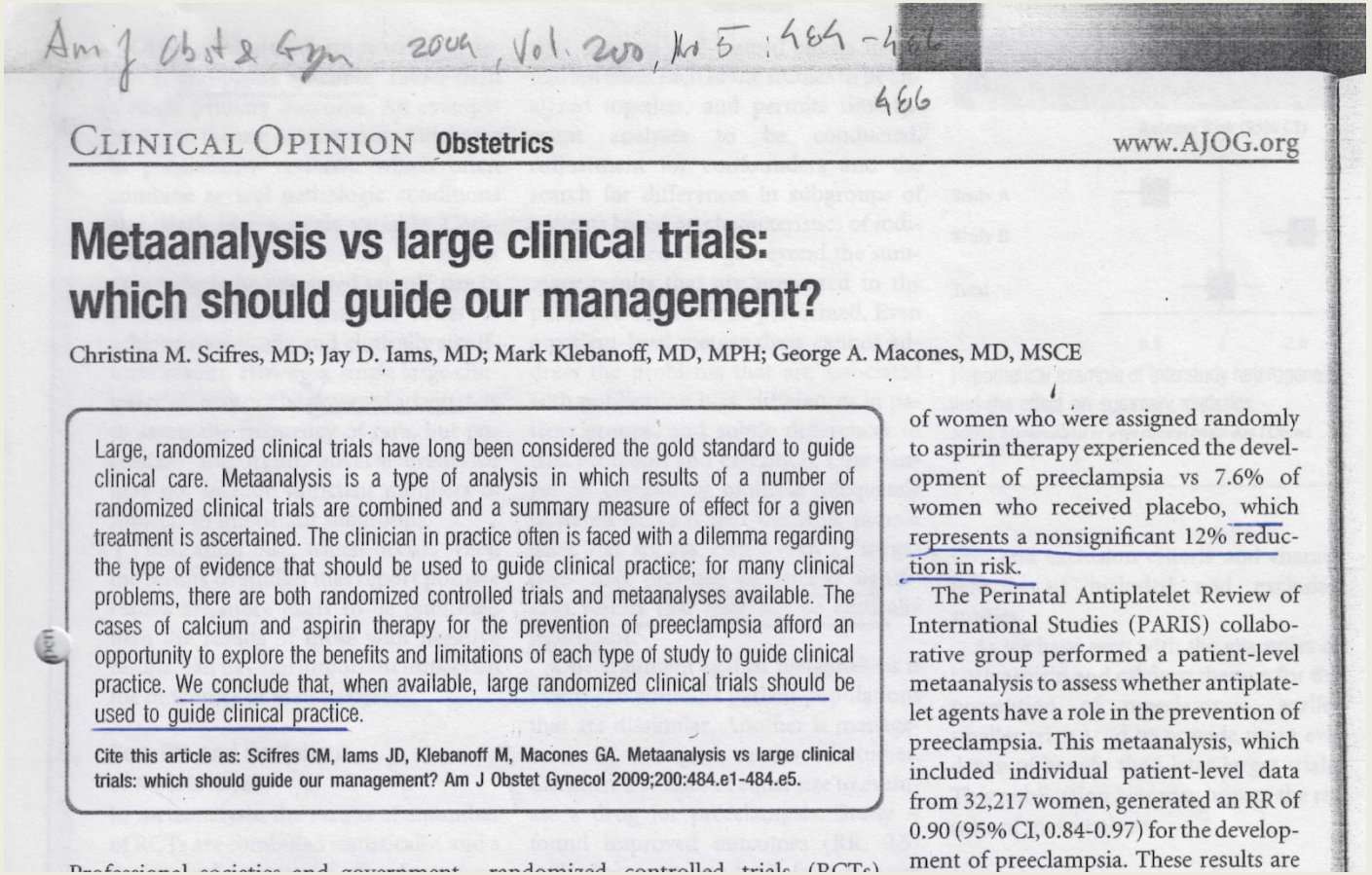
Fusco F, Abdel-Fattah M et al Eur Urol 2017 72(4): 567-591

- N=28 RCTs, 15 855 potilasta
- '… **retropubic tapes** are followed with slightly higher continence rates as compared to **transobturator tapes**, but are associated with higher risk of intra- and postoperative complications…'
- '… efficacy of inside-out and out-side in techniques of TOT was **similar**, altough the risk of vaginal perforation was lower in the inside-out technique (TVT-O)

Maggiore ULR, Agro EF et al Int Urogynecol J 2017 28:1119-1130

- N=11 RCTs, N=5 non-RCTs, seuranta-aika > 5 vuotta
- '… TVT and TOT are associated with **similar** long-term cure rates (obj. and subj.)
- '… no differenc between TOT technique regarding cure rates…'
- '… no significant difference in the complication rates for all comparisons…'

Mitä tässä nyt tulisi uskoa ?



Am J Obst & Gyn 2004, Vol. 200, No 5 : 484 - 486

Metaanalysis vs large clinical trials: which should guide our management?

Christina M. Scifres, MD; Jay D. Iams, MD; Mark Klebanoff, MD, MPH; George A. Macones, MD, MSCE

Large, randomized clinical trials have long been considered the gold standard to guide clinical care. Metaanalysis is a type of analysis in which results of a number of randomized clinical trials are combined and a summary measure of effect for a given treatment is ascertained. The clinician in practice often is faced with a dilemma regarding the type of evidence that should be used to guide clinical practice; for many clinical problems, there are both randomized controlled trials and metaanalyses available. The cases of calcium and aspirin therapy for the prevention of preeclampsia afford an opportunity to explore the benefits and limitations of each type of study to guide clinical practice. We conclude that, when available, large randomized clinical trials should be used to guide clinical practice.

Cite this article as: Scifres CM, Iams JD, Klebanoff M, Macones GA. Metaanalysis vs large clinical trials: which should guide our management? Am J Obstet Gynecol 2009;200:484.e1-484.e5.

of women who were assigned randomly to aspirin therapy experienced the development of preeclampsia vs 7.6% of women who received placebo, which represents a nonsignificant 12% reduction in risk.

The Perinatal Antiplatelet Review of International Studies (PARIS) collaborative group performed a patient-level metaanalysis to assess whether antiplatelet agents have a role in the prevention of preeclampsia. This metaanalysis, which included individual patient-level data from 32,217 women, generated an RR of 0.90 (95% CI, 0.84-0.97) for the development of preeclampsia. These results are

Professional societies and government ... randomized controlled trials (RCTs)

Sitten tuli Gunnar ja Niels…

Int Urogynecol J (2017) 28:1113–1114
DOI 10.1007/s00192-017-3403-7

CrossMark

EDITORIAL

Retropubic versus transobturator MUS: time to revisit?

Gunnar Lose[1] · Niels Klarskov[1]

Received: 30 May 2017 / Accepted: 14 June 2017 / Published online: 4 July 2017

Uusintaleikkausriski

- Tanskalainen rekisteri tutkimus (kohortti)
  - N=8 671, seuranta 10v : 2x riski uusinta leikkaukselle TOT:n jälkeen

    Hansen MF, Lose G et al 2016

- National Health Service Data (Scotland)
  - N=9478, ’…beyond 12 months there is a substantially greater need for repeat SUI-surgery following the transobturator approach…’ Retropubista leikkausta suositellaan.

    The Scottish Government 2017

- 2 Cochrane katsausta
  - ISD: > 5 vuotta 14x riski
  - long-term: 9x riski (limited data; low quality evidence)

    Ford AA, Ogah JA 2016,

    Ford AA, Rogerson L et al 2017

Survival ilman uusintaleikkausta

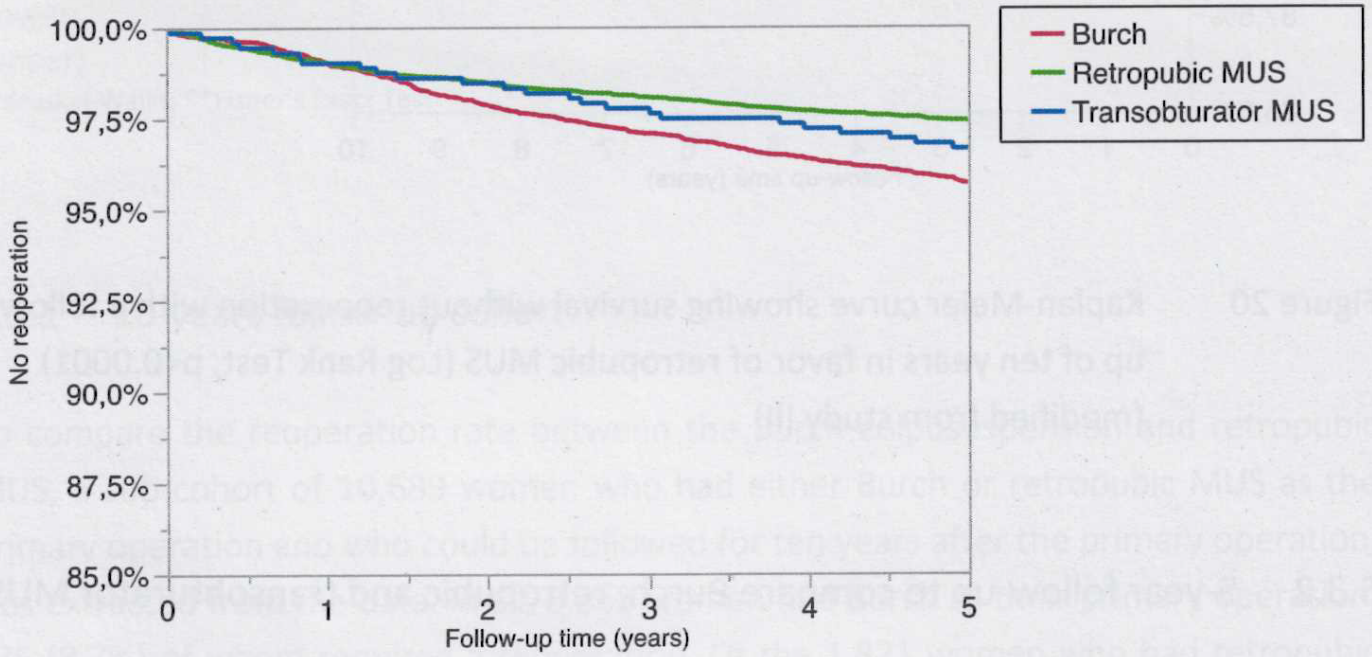


Figure 21 Kaplan-Meier curve of survival without reoperation with a follow-up of five years, showing statistical significance between the curves ($p<0.0001$, Log Rank Test) (modified from study III)

Kurkijärvi K. Surgery for stress urinary incontinence and pelvic organ prolapse in Finnish women. Doctoral Thesis, Univ.of Turku, 2017

Mutta…

- ’ … the retropubic procedure should as a rule of thumb be considered the primary choice…’
  Lose et al 2017

- Komplikaatioprofiili erilainen
  - rakkovaurio 4,5 % vs. 0,6 %,
  - virtsaamisvaikeudet vähäisempiä TOT tekniikoilla
  - nivuskipu 1,3% vs. 6,4 %

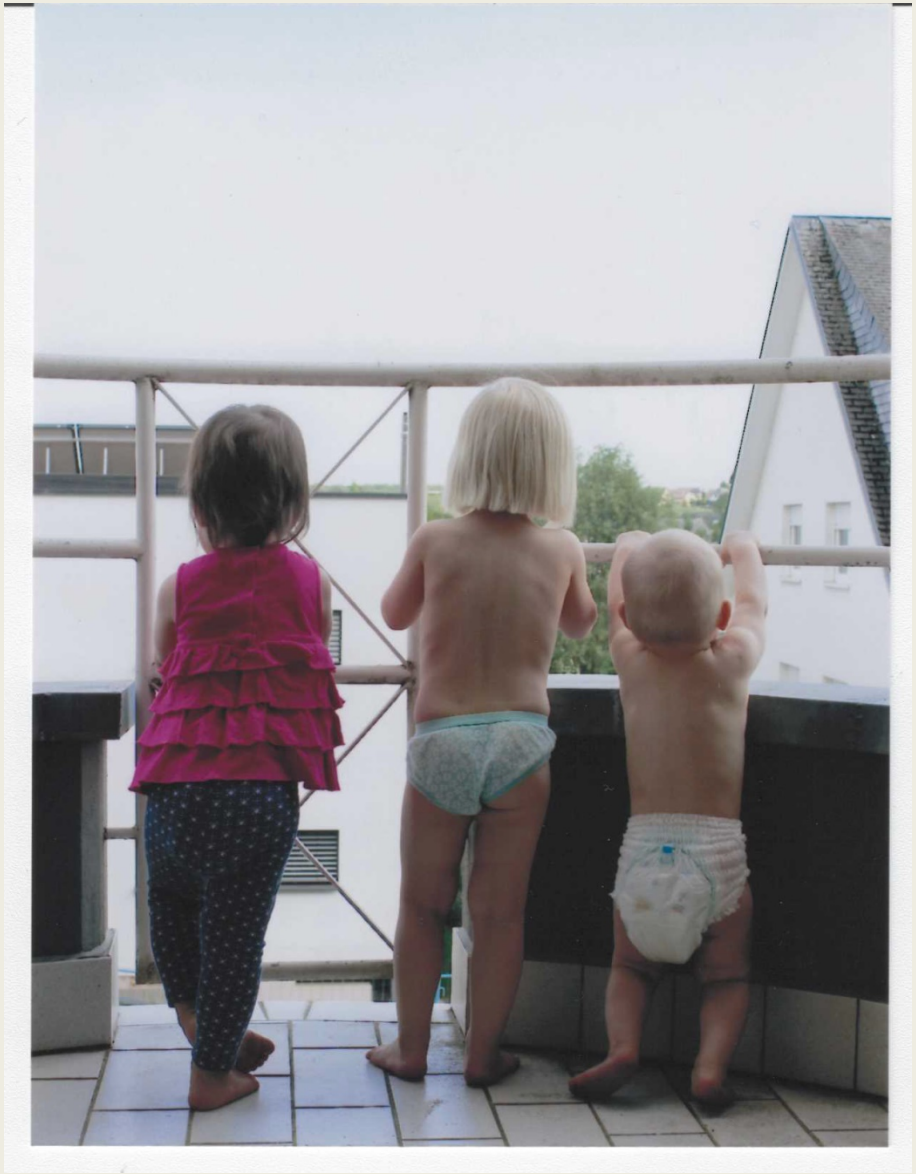
- Jos anamneesissa esim. useita abdominaalisia leikkauksia tai muita syitä – TOT tekniikat ?

TVT – edelleen ” The Gold Standard ”

Suomi 2017

	N
TVT (LEG 10)	310 (29,9%)
TOT (LEG 12)	505 (48,7%)
TVT-O (LEG 13)	220 (21,2%)
Yht.	1035

Lähde: THL



Kiitollinen – kyllä

Ps. Illalla juhlitaan …