BANDELETTES SOUS URETHRALES : SCANDALE SANITAIRE OU FAKE NEWS

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Tension-free Vaginal tape
Fig 19: DISPOSITIF TVT

CONSENSUS

- **TVT is safe**
  - Infection
  - Erosion
  - Biocompatibility
- **Efficient**

- **The concept of mid urethra synthetic sling is validated**

Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence

Carl Gustaf Nilsson, MD, PhD, Christian Falconer, MD, PhD, and Masoumeh Rezapour, MD, PhD

OBJECTIVE: To evaluate the long-term cure rates and late complication rates after treatment of female urinary stress incontinence with the minimally invasive tension-free vaginal tape operation.

METHODS: Prospective observational, 3-center cohort study originally of 90 women requiring surgical treatment for primary urinary stress incontinence. Assessment variables included a 24-hour pad weighing test, a stress test, visual analog scale for assessing the degree of bother, and a questionnaire assessing the subjective perception of the women on their continence status.

RESULTS: The follow-up time was a mean of 91 months (range 78–100 months). Both objective and subjective cure rates were 81.3% for the 80 women available for follow-up. Asymptomatic pelvic organ prolapse was found in 7.8%, de novo urge symptoms in 6.3%, and recurrent urinary tract infection in 7.5% of the women. No other long-term adverse effects of the procedure were detected.

CONCLUSION: The tension-free vaginal tape procedure for treatment of female urinary stress incontinence is effective over a period of 7 years. (Obstet Gynecol 2004;104:1259–62. © 2004 by The American College of Obstetricians and Gynecologists.)

LEVEL OF EVIDENCE: II-3

During the past decade a number of new minimally invasive surgical procedures for treatment of female stress urinary incontinence have been made available for clinical use. This is perhaps a reflection of modern health care, which strives to provide the individual and the society with rapid, resource-saving, and cost-effective treatment. Not only cure in the sense of dryness but also quality of life have become important outcome measures when assessing results of treatment of female urinary incontinence. Quality of life can be defined in many ways, of which one is the absence of short- or long-term complications in association with cure.

Low cure rates and high complication rates have been a concern among those studying many of the minimally invasive procedures. Endoscopic colposuspension, periurethral bulking agents, and needle suspension procedures have been associated with either unacceptable complications or rapidly declining cure rates[1–3]

The tension-free vaginal tape (TVT) procedure for treatment of female stress incontinence has become a widely used new minimally invasive operation probably due to the fact that it has been systematically and prospectively evaluated. Numerous reports reveal high rates of cure in primary cases of stress incontinence,[4–6] in recurrent cases,[7,8] in cases of mixed incontinence,[6,9] and in cases with intrinsic sphincter deficiency.[10] A nationwide survey of the incidence of intraoperative and postoperative complications in connection with the TVT procedure has been performed in Finland. The results of this survey indicate a low rate of complications, even though the learning curve of the performing surgeons was included in the material.[11]

High long-term cure rates enhance the cost-effectiveness of a given treatment. Five-year follow-up results of the TVT procedure have been published.[12] The cure rate of 85% corresponds very well with those of our most effective traditional, but more invasive, surgical incontinence procedures. The aim of the present study was to evaluate the continence status 7 years postoperatively of the women included in one of the earliest prospective clinical trials.

MATERIALS AND METHODS

Ninety consecutive patients suffering from urodynamically proven stress incontinence had a tension-free vaginal tape procedure performed between January 1, 1995, and October 15, 1996. The trial was a prospective 3-center study in 2 Nordic countries. All women were primary

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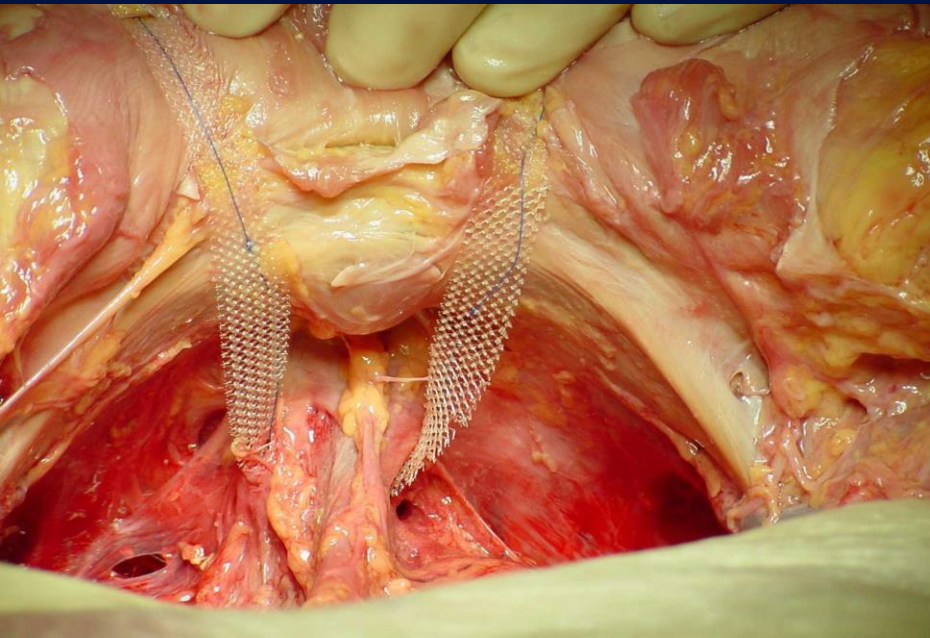
COMPLICATIONS
1455 pts, Kuuva 2002

- Bladder perforation 38/1000
- Blood loss > 200 cc : 19/1000
- Major vessels injury : 0.7/1000
- Nerve injury : 0.7/1000
- Urethral injury : 0.7/1000
- Vaginal defect healing : 7/1000

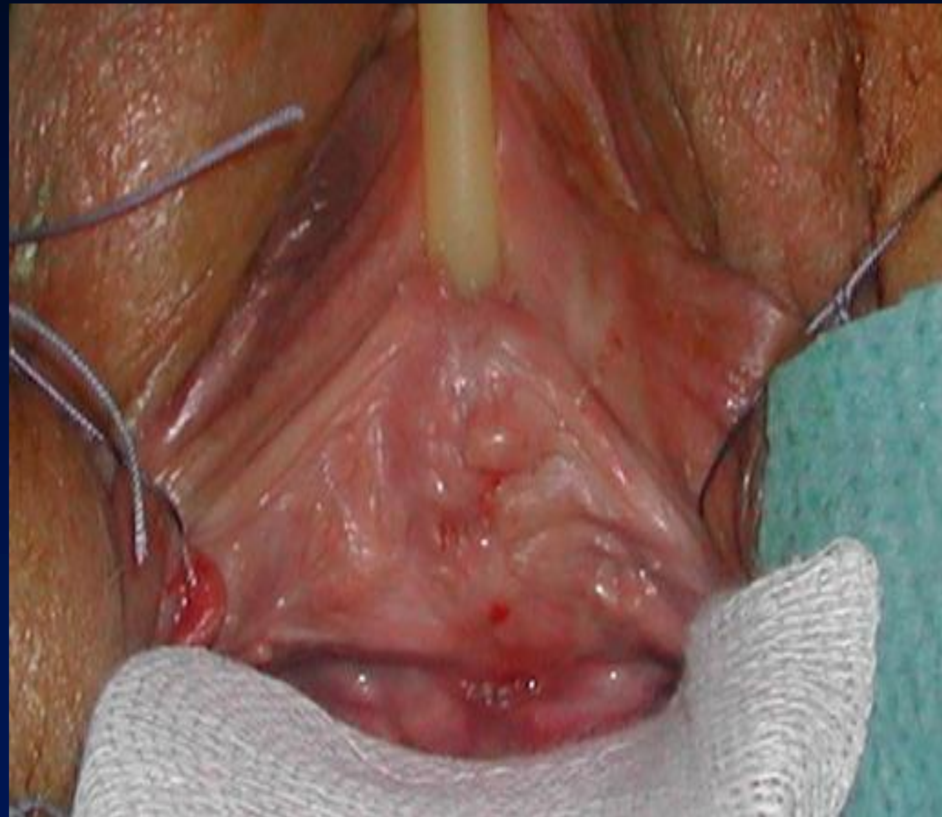
Complications of sub-uretral tapes for stress urinary incontinence / TVT

N	Bladder (%)	Vasc. (%)	Nerve (%)	Bowel (%)	Inf (%)	VD (%)	Er . (%)	De novo Urg. (%)
6832	4	1.7	0.09	0.01	20.9	6.2	0.4	12.4



B.Deval F Haab: TVT:a review 2006

TVT EROSIONS



EROSIONS

- Vaginal erosion
  - 2 / 380 pts
  - 10 / 1455 (0,7%) : scandinavian series
- Symptoms
  - Asymptomatic
  - Sexual pain expressed by the partner
  - Scar palpation > inspection
- Risk factors
  - Atrophy ? (age : 35, 38 y old)
  - Post op infection
  - Rejection of material

NORME AFNOR

French national TVT-O registry

Innocuité de la voie trans obturatrice « inside-out »

dans le traitement de l'incontinence urinaire d'effort

Prospective multicenter study on 994 patientes

Registre TVT-0®

P. Collinet, P. Costa, C. Ciofu, M. Cosson,

B. Deval, P. Grise, F. Haab, B. Jacquetin

Results

- Surgeons :
  - Gynecologists : 48
  - Urologists : 41
- Patient main criteria :
  only with SUI (no associated prolapse cure)
- Population :
  - Gynecology : 556 patients / Urology : 438 patients
  - N = 994
- Mean age : 57,7(27-93) years
- Follow-up : 4-12 weeks

Post-operative pain

- Anbormal: 148 Visual scale = 4,8
  - Bilateral 93
  - Unilateral right: 33
  - Unilateral left: 22

- Pain location

Aine	Cuisse	Fesse	Hanche	Lombaire	Perineale	Sciatique	Autres
16	105	2	3	3	10	4	Abdominale2 Jambes1 Pubienne1

Second procedures

- Bleeding : 1 (D1)
- Inguinal abcess (2 months): 2
- Vaginal extrusion = 2
- Tape section (obstruction) = 2

ETUDE ACADEMIE NATIONALE DE CHIRURGIE

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Recherche séjours comportant l'un des actes CCAM suivants :

JDDA003 Cervicocystopexie par bandelette par abord vaginal et par voie transcutanée, avec guidage endoscopique

JDDB001 Cervicocystopexie par bandelette synthétique infra-urétrale, par voie transvaginale et [par] voie transcutanée, avec guidage endoscopique

JDDB005 Soutènement vésical par bandelette synthétique infra-urétrale, par voie transvaginale et par voie transobturatrice

JDDB007 Soutènement vésical par bandelette synthétique infra-urétrale, par voie transvaginale et par voie transrétropubienne, avec contrôle endoscopique

Résultat : 292 563 séjours avec l'un de ces codes

Mortalité (230 837 opérées)

décès synchrones

n=14

balayage patient par patient

3 par infarctus codé

11 imputables au geste que la complication soit codée ou non (0,4/10000)

décès non synchrones

n=677

balayage patient par patient

12 décès imputables

11 décès avec doute

soit au total 37 décès maximum (sur 691) pour 230837 patientes (1,6/10000)

Morbidité (236 133 DMI)

Repérage des sections de bandelettes :

JRPA001 Section d'une bandelette synthétique infra-urétrale, par abord vaginal

SYNCHRONES n = 969 (0,41%)
A DISTANCE n = 2420 (1%)

Repérage des ablations totales ou partielles

JRGA001 Ablation d'une bandelette synthétique infra-urétrale, par abord vaginal
JRGA002 Ablation partielle d'une bandelette synthétique infra-urétrale, par laparotomie
JRGA003 Ablation totale d'une bandelette synthétique infra-urétrale, par laparotomie et par abord vaginal
JRGA004 Ablation totale d'une bandelette synthétique infra-urétrale, par cœlioscopie et par abord vaginal
JRGC001 Ablation partielle d'une bandelette synthétique infra-urétrale, par cœlioscopie

SYNCHRONES n = 1096 (0,46%)
A DISTANCE n = 3697 (1,6%)

Conclusion

- Les bandelettes sous uréthrales ont transformé la prise en charge de l'incontinence urinaire
- Dispositif SUR et EFFICACE
- Information objective des patientes
- Reste la problématique de l'indication : quelle bandelette pour quelle patiente

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