

Fact Sheet Female Stress Urinary Incontinence Treatment Comparison of TOA / TVA (A.M.I.) versus TVT / TVT-O (Gynecare)

Results Summary Negative Stress Test

	number of patients	Average follow-up	Negative stress test		
			Totally continent	Greatly Improved	Treatment failure
TVA (A.M.I.)	64	40 months	94 %	3 %	3 %
TVT (Gynecare)	228	3 months	86 %		14 %
TOA (A.M.I.)	77	24 months	90 %	6 %	4 %
TVT-O (Gynecare)	219	3 months	83 %		17 %

Significantly better results were obtained in the TOA / TVA study (A.M.I.): less patients were leaking urine at stress test.

No single patient in TOA / TVA study (A.M.I.) was obstructed.
Data on obstruction was not reported in the Gynecare study.

Gynecare TVT / TVT-O study excludes patients with urge incontinence.

Gynecare TVT / TVT-O study shows same results as other publications on TVT (average 85% continence).

Comparison of completely dry-rate (including urge) was made between TOA / TVA study (A.M.I.) and literature findings:

Study	Completely-dry-rate
TOA (A.M.I.)	54 %
TVA (A.M.I.)	57 %
Ward & Hilton, TVT 2004	36 %
Munir et al., TVT 2005	20 %
Kobashi & Govier, SPARK 2005	36,6 %

TOA / TVA

A.M.I. Agency for Medical Innovations

Professor Romero, Alicante, Spain
Data Presented at AAVIS Conference in
Venice, Sept. 2008

<u>TVT Continence</u>	
Ulmsten (1995)	78%
Dietz et al. (2000)	85%
Tsivian et al. (2004)	78.9%
Morey et al. (2006)	86%
Sanz Perez et al. (2004)	93%
Hualde et al. (2006)	86%

publications about continence after TVT (Gynecare)

set-up of own study:

<u>70 TVA patients</u>	
64 patients with follow-up period of 40±13 (12-60) months	
<u>98 pacientes TOA</u>	
77 TOA patients with follow-up period of 24.7±10.3 (12-52) months	

	<u>TVA</u>	<u>TOA</u>
Severe incontinence	63%	50%
Moderate or mild	37%	50%
Stress incontinence	60%	25%
Mixed Urinary incont.	40%	75%
Q. Max.	26±15	27±10
TVA	53%	94%
TVA + prolapse	47%	6%

<u>Evaluation in the immediate post-op period.</u>		
	<u>TVA</u>	<u>TOA</u>
Continent	48 (75%)	51 (66%)
Incontinent	16 (25%)	23 (34%)
Obstructed	10 (15.6%)	8 (10%)
<u>At time of discharge:</u> All patients continent and without residue. Q. Max.:TVA 15±5. TOA 17±4 No self-catheterizations needed.		

<u>TVA – Quality of Life</u>		
	<u>Pre-operative</u>	<u>Post-operative</u>
I-QoL	31±24 (6-86)	86±19 (26-100)
ICIQ-SF (Impact)	8±2 (4-10)	1±2 (0-8)
ICIQ-SF (Global)	17±3 (12-20)	5±4 (2-16)
PGI-I	Very much better: 67%	Much better: 27% Same: 3% Worse: 1%

<u>Complications</u>
We have had no cases of intestinal, neurological, or vascular lesions
We have had no cases of infection.
We have had no cases of urethral erosions.
We have had one TOA case of vaginal erosion

<u>Objective evaluation at last revision</u>		
Physical exploration, full bladder 250 c.c.		
	<u>TVA</u>	<u>TOA</u>
Totally continent	94%	90%
Greatly improved	3%	6%
Treatment failure	3%	4%
Q. Max.:	22±10	21.3±7
No residue		



The patients' perception of "cure" may not necessarily imply complete cure of incontinence and may rather reflect the degree of impact the change of symptoms has on the individual's lifestyle

Q. When do you leak urine? (ICIQ-SF)

	TVA	TOA
Never	54%	49%
Upon coughing and/or physical exercise	13%	11%
Before reaching the toilet	27%	35%
Both situations	6%	5%

Completely dry rate patients

Ward & Hilton (TVT 2004)	36%
Munir et al. (TVT 2005)	20%
Kobashi & Govier (SPARK 2005)	36.6%
TVA	57%
TOA	54%



Conclusions

Our results:

Show that tension free tapes are not exactly as such, rather they are of adequate tension.

Show that TVA and TOA adjustable tapes permit post-operative adjustment of tension without adding any surgical complications.

Suggest that these tapes ostensibly improve the results of surgery.

TVT / TVT-O Gynecare

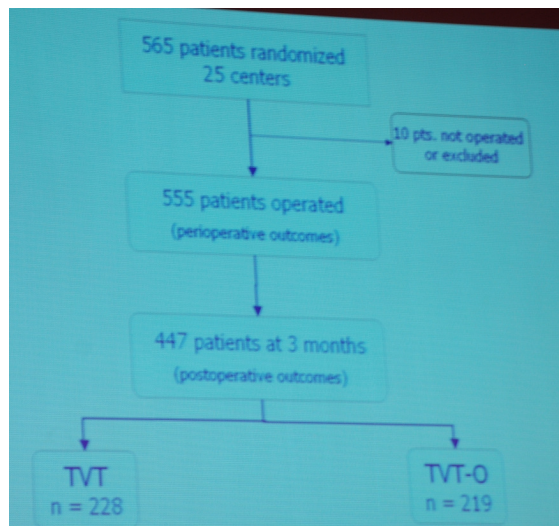
Dr. Tammaa, Vienna, Austria
Data Presented at AAVIS Conference in
Venice, Sept. 2008

Retropubic vs. Transobturator TVT for Primary Stress Incontinence: A Randomized Study

Austrian Urogynecology Working Group (AUG)

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- ### Methods
- Prospective RCT: TVT vs TVT-O
 - Hypothesis: TVT-O not inferior to TVT
 - Sample size >500
 - Randomization: AGO Office Innsbruck (Fax)
 - CONSORT guidelines
 - ClinicalTrials.gov ID NCT00441454
 - No industrial support



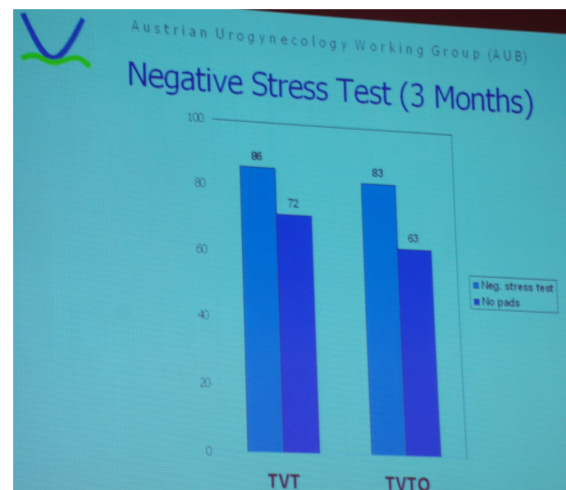
- ### Inclusion/Exclusion Criteria
- Austrian Urogynecology Working Group (AUG)
- + Consent
 - + No previous incontinence surgery (except ant repair)
 - + No concomitant HE or prolapse surgery
 - Urge dominant symptom
 - Residual >100 ml
 - neurolog. disease

Perioperative Outcomes

	TVT (n=288)	TVT-O (n=267)
Bladder perforation	11 (3.8%)*	0
Bowel perforation	1	0
Increased bleeding	3	3
Days until residual <100 ml	1 (0-12)	1 (0-9)
Clinical hematoma	9	0
Reoperation	3	1
Transfusion	0	0
Death	0	0

*P<0.04

- ### 4 Reoperations
- Austrian Urogynecology Working Group (AUG)
- Laparotomy for acute abdomen 2d after TVT: perforation of transverse colon
 - Cutaneous wound infection after TVT
 - 2 tape loosening (TVT, TVT-O)



- ### Conclusions
- Austrian Urogynecology Working Group (AUG)
- TVT-O not inferior to TVT
 - Largest study to date
 - External validity

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