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ONE YEAR RESULTS OF A PROSPECTIVE RANDOMIZED EVALUATOR BLINDED MULTICENTER STUDY COMPARING TVT AND TVT-SECUR

Hypothesis / aims of study
To compare TVT-Secur with TVT in terms of efficacy and safety in a prospective, randomized, multicentric setting.

Study design, materials and methods
We set out to enrol 280 stress incontinent women. ~~A~~According to the power analysis, the study was designed to detect a 10 % difference in cure rate at an estimated 85% level of cure and aimed to include 280 patients, with an additional 28 patients to compensate for an estimated 10% drop out. An interim analysis of cure and complications was planned after 140 included patients, or earlier if serious adverse events occurred.
Patients with primary stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) with predominant SUI symptoms were approached for the study. All women underwent a standardized preoperative investigation including a two-day voiding diary, the King's Health questionnaire, a VAS scale regarding bother due to incontinence, a demographic and a contraceptive history and a detailed incontinence history. Furthermore a gynecological investigation, measurement of residual urine, a cystoscopy, a stress-test in upright position and a standardized short term pad-test were performed
Due to three severe adverse events with the TVT-Secur, enrolment was prematurely stopped. A total of 133 randomized women were randomized (TVT *n*= 69, TVT-Secur *n*= 64) by either of four gynecology departments in southern Sweden. Of these women, four were excluded due to protocol violations and another four declined surgery after randomization due to personal reason, 125 were operated and 121 (TVT *n*=61, TVT-Secur *n*=60) were available for follow-up one year after surgery.

Results
No significant differences were found between groups regarding demographics or grade of incontinence. One year after surgery, both subjective and objective cure rates were significantly lower for TVT-Secur than for TVT (subjective cure: TVT 98 %, TVT-Secur 80%, *p*= 0.03; objective cure: TVT 94%, TVT-Secur 71% for cough test, *p*= 0.01, TVT 76%, TVT-Secur 58% for pad test, *p*= 0.05). Three major complications occurred in the TVT-Secur group: a tape erosion into the urethra, a tape inadvertently placed into the bladder and an immediate postoperative bleeding from the Corona Mortis. No major complications occurred in the TVT group. No significant differences were found between groups regarding perioperative bleeding, hospital stay, urge symptoms, residual urinary volume, subjective bladder emptying problems, postoperative urinary tract infections or minor complications. The TVT-Secur group used more anticholinergics after surgery than the TVT group (*p*= 0.03). Median time for surgery was 13 and 22 minutes for TVT-Secur and TVT respectively (*p*< 0.0001).

Interpretation of results
In our series, the subjective and objective cure of stress incontinence was significantly inferior following TVT-Secur than TVT when evaluated one year after surgery. This association might have even been stronger with a completed enrolment as originally planned. However, due to the interim analysis of cure and the occurrence of three serious adverse events we felt compelled to stop the study prematurely.We do not believe that the difference in cure rate, in particular the proportion of uncured and early recurrencies patients in the TVT-Secur group, can be explained by an insufficient surgical technique as the basics of both procedures are similar. Most uncured women in the TVT-Secur group reported either a very short, or no postoperative effect on their incontinence symptoms, suggesting an insufficient anchoring of the sling. Moreover, our results correspond with previous both randomized and non-randomized publications evaluating the efficacy of TVT-Secur. Most of them report lower cure rates for TVT-Secur than for TVT, with rates between 67-80%

Concluding message
The TVT-Secur procedure had significantly inferior subjective and objective cure rates compared with the TVT procedure. Three serious adverse events occurred in the TVT-Secur group. We therefore discourage from further use of the TVT-Secur.

Table: Subjective and objective cure of stress incontinence symptoms at long term follow-up in patients randomized to TVT or TVT-Secur (χ2 test)

Subjective outcome	TVT *n* (%)	TVT-Secur *n* (%)	
Cured	47 (77)	28 (47)	*p*= 0.03¤
Improved	13 (21)	20 (33)	
Slightly improved	0 (0)	5 (8)	
Unchanged	0 (0)	1 (2)	

Worsened	0 (0)	1 (2)	
Early recurrence	1 (2)	3 (5)	
Objective outcome *n*			
No leakage at cough-synchronous test *n*=59 *	56 (94)	40 (71)	*p*=0.01
No leakage at standardized pad-test *n*=56 §	43 (76)	53 (58)	*p*=0.05

¤ Cured + improved compared to all others
* Missing information on four patients
§ Missing information on six patients

Disclosures
Funding: This study has been performed with economical support from Gynecare Scandinavia. Gynecare has had no influence on study design, data interpretation or content of the article. **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Lunds University Ethics Comitee **Helsinki:** Yes **Informed Consent:** Yes