

SATISFACTION AND SAFETY WITH TVT-SECURE: A DISTRICT GENERAL HOSPITAL EXPERIENCE

Hypothesis / aims of study

TVT-Secure, one of the youngest in the tension free vaginal tape family attained popularity in view of the technique of insertion with no exit wounds for the tape. These devices have been in use in our district general hospital since 2006. We reviewed the technique used by our two urogynaecological surgeons and evaluated post-operative patient satisfaction on two different parameters i.e urinary symptoms and sexual function.

Study design, materials and methods

A study population of 28 women who underwent TVT-Secure between May 2006 and October 2008 were chosen. Women who had concurrent major pelvic surgeries were excluded from the study.

The modified International Continence Society sexual satisfaction questionnaire and a post-operative evaluation on subjective improvement of symptoms were sent to all 28 women who underwent this procedure. Patients were asked to score their sexual satisfaction on a visual analogue score card scaled from one to ten. Universal sexual indicators that were questioned included sexual desire, climax, sexual excitement, sexual satisfaction and intensity of orgasm. Individual symptomatic indicators included coital pain, coital incontinence, fear of coital incontinence and negative feelings on sex. Information on the change of urinary symptoms was supplemented by long-term complications that are still being registered with our database.

A retrospective operative notes review was performed on a case by case basis. The aim was to evaluate consistency in technique and compliance with safety standards proposed at our departmental level in keeping with our clinical governance infrastructure.

Results

The two questionnaires yielded a 50% response rate with only half of them (25% of total number of operated patients) being sexually active. This information was supplemented by a thorough search for long-term complications that became apparent during follow-up clinics.

86% of patients reported either a cure or improvement of their incontinence. A third of them reported absolute cure from urgency and one patient developed urgency as a new symptom post-operatively. None of our patients developed hesitancy to suggest a voiding difficulty or outflow obstruction needing self-catheterisation.

Majority of women (>70%) in the small sexually active subgroup reported a remarkable decline in coital incontinence and fear of coital incontinence. There was a slight reduction in the number of women experiencing coital pain postoperatively with no significant difference in their scoring of pain. The average scores for sexual desire, climax, satisfaction and excitement showed no remarkable change postoperatively. The procedure did not have a direct impact on negative perceptions towards sex, neither did it improve the intensity of orgasm.

Our retrospective review of patient characteristics showed a patient population varying between 33 and 77 years of age with a mean of 51.2 and they had an average body mass index of 28.7. 88% of patients had a general anaesthetic for the procedure and hydro-dissection was used by both surgeons in all of them. There were considerable variations in the documentation of technical aspects of the procedure including the technique used (hammock versus 'U' technique), usage of a urethral guide, performance of a check cystoscopy and achievement of neutral tension on the tape. The estimated blood loss was documented to be less than 100mls in 65% of patients. The operating time was documented to be less than 30 minutes in 54% of patients. No bladder perforations were encountered during any of these procedures and no significant haematomas needed a return to theatre. One patient in the entire study group developed post-operative retention and 72% of patients were discharged within eight hours. Our long-term follow-up registry has recorded no tape erosions so far.

Interpretation of Results:

Cure rates from our series of TVT-Secure patients, mirrors the 82-85% cure rates that has been achieved by other mid-urethral sling procedures, with post-operative onset of urinary urgency staying low at 3.5%. There was no direct impact on sexual satisfaction by the procedure per se, but a remarkable decline in coital incontinence and fear of incontinence was noted. Our operative performance review has helped us in maintaining a strict vigil for intra operative complications and in identifying our pitfalls including suboptimal documentation.

Conclusion:

Our small series of women with a decent post-operative follow-up period of 12-24 months have shown equivalent cure rates with other sub-urethral sling procedures with low intra-operative and long term complications. This contrasts with extremes of success

rates from other centres, where the follow-up timescales were three months. Our study highlights the need for further unbiased long-term follow up registries and randomised trials to compare individual devices available for mid-urethral slings.

References

1. Seven year followup of tension free vaginal tape procedure for treatment of urinary incontinence *Obstet Gynaecol* 2004;104:1259-62

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require eithics committee approval because</i>	the case note review or the questionnaire used was not an interventional.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes