

SHOULD WE FEEL 'SECUR' USING SINGLE INCISION TAPE FOR URODYNAMIC STRESS INCONTINENCE?

Hypothesis / aims of study

TVT SECUR is a new short midurethral tape with a novel securing mechanism. It is a macroporous (Type1) polypropylene mesh similar to that used in the TVT, and similarly uses a bottom up approach. However, it is minimally invasive, can be inserted under LA, and has a decreased risk of perioperative complications such as bladder, vascular or bowel injury. Post operative pain should also be reduced. But is it as revolutionary as it looks? We studied its effectiveness.

Study design, materials and methods

The procedure was introduced in our Trust subject to audit and clinical governance.

All patients were fully informed about the technique and alternatives. Informed written consent was obtained. Patients were informed of the limited experience with the tape, and of the lack of long term data concerning its efficacy.

All patients had undergone conservative therapies preoperatively. All had a urodynamic diagnosis of USI or mixed incontinence.

All operations were performed or supervised by the lead consultant who had undergone formal training. All operators were consultants.

Patients were also assessed preoperatively using a three day bladder diary, a one hour pad test and a QOL questionnaire.

Short term results were recorded at a six week follow up visit, whilst medium term results were collected using a postal questionnaire.

Results

16 women aged between 41 and 87 years underwent a TVT SECUR procedure from December 2006. Their mean parity was 3. Symptomatology varied amongst patients, but all had symptoms of stress incontinence.

Nine patients had no previous pelvic surgery, three had a TAH+BSO, one had LSCS, one had a laparotomy and ovarian cystectomy, one had an anterior colporrhaphy. Two patients had already had a primary continence procedure; one had a Burch colposuspension and one had a TVT.

Ten patients had urodynamic stress incontinence, and six had mixed incontinence.

All patients underwent a TVT SECUR procedure only.

Fifteen patients had GA, and one patient had spinal anaesthesia.

All patients went home on the first post operative day.

No intraoperative complications were recorded.

One patient developed a urinary tract infection which was treated with antibiotics. One patient developed partial tape erosion, which was initially treated with topical oestrogens, but subsequently required local excision.

No patient required clean intermittent self catheterisation.

At six weeks follow up, four patients reported being dry all the time, six patients reported a marked improvement in their symptoms, whilst six patients reported no improvement.

Of the 'wet' group, two had developed detrusor overactivity and were managed on anticholinergics. The other four patients underwent a TOT or TVT-O procedure.

At twelve to eighteen months follow-up, two further failures were reported. One patient did not respond.

Interpretation of results

TVT SECURE is a quick, safe and minimally invasive procedure. However its efficacy is questionable.

The results show a failure rate of 25% at six weeks follow up and 37.5% at twelve months. This is a significantly higher failure rate than that obtained with the more conventional TVT procedure (1), in a similar patient population. It is unclear what is the main factor for this, however, it may be due to the lack of a securing mechanism to hold the tape in place immediately postoperatively.

Concluding message

There is a need for formal randomised controlled trials with large patient numbers to evaluate this technique and compare it with the standard incontinence procedures for urodynamic stress incontinence, both in the short, and especially in the long term.

References

1. Nilsson CG, Falconer C, Rezapour M. 7-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. ACOG. 2004; Vol. 104; No. 6: 1259-1262

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Southport and Ormskirk Hospitals NHS Trust Ethics Committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes