

GYNAECOLOGY

Clinical audit of the use of tension-free vaginal tape as a surgical treatment for urinary stress incontinence, set against NICE guidelines

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Summary

Urinary incontinence affects a large proportion of adult women and is associated with considerable distress and social disability. In February 2003 the UK National Institute for Clinical Excellence (NICE) published new clinical guidelines on the use of tension free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Against these guidelines we have conducted a retrospective audit of patient care by the Oxford Radcliffe NHS Trust over three years, using the BFLUTS questionnaire in conjunction with patient records. This is believed to be the first such audit.

Our results show overall performance to be satisfactory with no major problems. For all women the type of incontinence was confirmed by urodynamic investigation and in 92% of cases conservative management was tried and had failed before surgery was considered. For the TVT operation patients reported a high subjective cure rate, with 95% either fully cured or showing substantial improvement in their condition. Incidences of the main complications of TVT were found within statistical limits to be low (bladder /urethral perforation 4%; haemorrhage 1%; long term voiding dysfunction 2%; tape rejection 0%; defective healing 0%; de novo urine retention 12%). These levels are similar to those reported elsewhere in the literature.

However, a quarter of patients either did not receive full information about the TVT procedure in order to make an informed choice, or this was not documented. To improve care we recommend that local agreement should be reached between clinicians on information that will be provided to the patient as part of the consent process.

Introduction

History of TVT

Tension-free vaginal tape (TVT) is a relatively new procedure for the treatment of urinary stress incontinence. The use of an intravaginal sling plasty was first described by Papa Petros and Ulmsten³ of Sweden in 1993 as a method of restoring the posterior pubourethral ligament. The TVT operation for urinary stress incontinence was subsequently introduced into clinical practice in 1994-5. Approximately 200,000 operations have been performed worldwide since then. The number of TVT procedures performed in England has risen from 214 in 1998-89 to 2706 in 2000-01¹.

Pros and Cons

This technique claims to have several advantages compared with the most commonly used alternative operative treatment, colposuspension, including minimal surgical trauma, shorter hospital stay and the use of local or regional anaesthetics. A further advantage of TVT is that of generally lower cost than for colposuspension because of shorter hospital stay and shorter operating time.

However, TVT is associated with a range of potential complications. In particular, bladder perforation appears to occur more frequently than with other standard surgical procedures for stress incontinence. Nevertheless, this complication can be managed successfully by bladder drainage and catheterisation and does not usually have long-term consequences^{1,3}.

There are few published data on longer-term complications following TVT placement. Problems that have been reported include the development of urinary retention and difficulties with micturation following surgery. Erosion of the tape material into the bladder, urethra or vagina is a potential problem with synthetic tape devices. Limited data from case series suggests that this occurs at a rate of less than 1%¹. New onset symptoms of urgency and detrusor overactivity have also been reported following use of TVT.

Success Rate

The TVT procedure has been evaluated in both randomised and non-randomised studies. The most important piece of evidence is a randomised controlled trial by Ward and Hilton⁴ that compared TVT with colposuspension. The results of this work showed an objective cure rate of 72% in both groups six months after the surgery.

NICE Guidelines

In the UK the National Institute of Clinical Excellence (NICE) has recently, in March 2003, issued the following new guidelines for the use of TVT for stress incontinence in its Technology Appraisal Guidance booklet No. 56¹:

1. "The tension free vaginal tape (TVT) procedure is recommended as one of a range of surgical options for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed.
2. In making the decision to use TVT, the patient should be fully informed of the advantages and drawbacks of the relevant surgical procedures. The considerations should include:
 - the advantages of a minimal access technique, seta against the disadvantage of absence of data on long term effectiveness;
 - whether the woman is likely to have children subsequently;
 - whether the procedure will be used in conjunction with another procedure, such as vaginal hysterectomy or repair of prolapse.
3. The procedure should be performed only by surgeons who have received appropriate training in the technique, and who regularly carry out surgery for stress incontinence in women".

The Oxford Radcliffe Hospitals NHS Trust had been using the TVT procedure for the past three years, since January 2000. During this time its performance of this procedure was not monitored. The ORH Trust therefore considered it appropriate to undertake a first audit of its performance of the TVT procedure, in order to determine whether its patient care is fully compliant with the new NICE guidelines for TVT. This audit was carried out between April and June 2003 and is believed to be the first to check such compliance.

Methodology

Aims of the Audit

A first audit of TVT treatment by the Oxford Radcliffe NHS Trust of patients for stress incontinence was carried out during second quarter of 2003. The overall aims of this audit were:

- to evaluate the extent of compliance by the Oxford Radcliffe NHS Trust with the new NICE guidelines on the use of TVT for stress incontinence;
- to evaluate the clinical effectiveness of TVT treatment of patients by the Oxford Radcliffe NHS Trust;
- to measure the outcomes of TVT treatment of patients by the Oxford Radcliffe NHS Trust and to compare them with the results of recognised controlled trials;
- to assess the prevalence of intra- and post-operative complications on TVT treatment of patients by the Oxford Radcliffe NHS Trust. These included bleeding; bladder or urethral perforation; post operative urinary retention; long term voiding dysfunction; de novo detrusor instability; aggravation of pre-existing urge incontinence; rejection of the tape or defective healing.

Sample

The audit comprised a retrospective analysis of all tension free vaginal tape operations for stress incontinence performed by the Oxford Radcliffe NHS Trust, England, between January 2000 and December 2002.

Data Collection

The medical records of 95 women with a mean age of 59 years (range 33–90 years) were examined and the following types of information collected from patient records:

- whether the type of incontinence had been confirmed by objective urodynamic investigation;
- whether conservative treatment had been tried prior to surgery;
- what information had been provided to the patient prior to obtaining consent;
- the type of anaesthetic used;
- any other surgical procedure carried out concurrently with the TVT;
- any complications during and immediately after the operation;
- the number of previous operations for urinary stress incontinence;
- the level and experience of the surgeon carrying out the TVT procedure;
- the patient's length of stay in hospital;
- the time elapsed since the operation.

A carefully designed postal questionnaire (based on the Bristol Female Lower Urinary Tract Symptoms questionnaire described on page 5 of the NICE Technology Appraisal Guide No. 56) was then sent to each patient in order to determine further information about the patient's present urinary condition. Questions were designed to ascertain whether the patient is now continent (ie subjective cure); the extent of subjective improvement in the patient's condition; the level of the patient's satisfaction with the TVT treatment and whether she would recommend it to her friends.

Out of the 95 questionnaires sent out to the patients, 89 completed questionnaires were received back. This excellent response rate of 93.7% gives some confidence that meaningful results can be obtained from their analysis.

On average the period of time that had elapsed since the operation was 20.1 months, with a range of 6 to 40 months.

Cure was defined as absence of urinary leakage during episodes of increased intra-abdominal pressure (eg coughing, laughing, lifting, physical activity), and was assessed subjectively by the patient.

Results

General

All 95 TVT patients included in this study had undergone urodynamic investigations before surgery and were found to have genuine stress incontinence.

Conservative management (physiotherapy) was tried and had failed in 80 women (84.2%) prior to surgery. Of the 15 patients who did not receive physiotherapy, 7 had complete genital prolapse and 5 had declined physiotherapy. In 3 cases no reason was recorded.

In all patients the TVT operation was carried out using polypropylene tape (Ethicon) and using the technique described by Ulmsten et al¹⁰.

TVT was carried out as the primary surgical procedure for urinary stress incontinence in 55 patients (57.9% of total cases). In 40 patients (41.6%) the TVT procedure was undertaken to treat relapses following previous incontinence surgery.

TVT was combined with pelvic floor repair of a concomitant genital prolapse in 25 cases (26.3%), with vaginal hysterectomy in 2 cases (2.1%), and with both vaginal hysterectomy and pelvic floor repair in 7 cases (7.4%). In a further 61 patients (64.2%) TVT was carried out alone.

TVT was performed under different types of anaesthetics. For TVT-only operations spinal anaesthesia was greatly preferred, being used in 80.3% of cases. General anaesthetics (13.6%) and local anaesthetics (6.6%) were used for the remainder.

The average hospital stay for patients undergoing only the TVT procedure was 2.69 days (range 1 - 6 days, including the day of surgery).

Surgeons

Out of the total of 95 TVT procedures, 79 were performed by consultants and 16 by specialist registrars working under the close supervision of a consultant.

One surgeon (A) was responsible for conducting over three quarters (73 or 76.8%) of all procedures, with the remaining one quarter (23.2%) being shared between three other surgeons (B, C and D), each conducting 5-12 procedures over the three year period (Table 1).

Consultant	Number of TVT cases			
	2000	2001	2002	Totals
Surgeon A	19	20	34	73
Surgeon B	6	3	3	12
Surgeon C	0	0	5	5
Surgeon D	5	0	0	0

Table 1: Number of TVT operations per surgeon per year

Informed Consents

Altogether, 68 patients (71.6%) were provided with full information about the main advantages and disadvantages of the TVT operation prior to signing their consent form. This information was often written on the consent form or a record was made in the patient's medical notes. The main points that were often omitted from the counselling were absence of long term data in 24 cases (25.2%); risk of bladder perforation in 23 cases (23.2%); risk of new onset of urinary urgency in 11 cases (11.6 %).

Complications

Perioperative bladder perforation occurred in just four cases (4.2%). This was recognised immediately during intra-operative cystoscopy and the needle was reinserted. In none of these four cases was significant bleeding reported and the surgical procedure was completed. Following bladder perforation, treatment was by indwelling catheter for three days and no long-term complications were encountered. There were no cases of urethral damage. In one case a post-operative retropubic haematoma occurred, which was managed conservatively.

All patients underwent measurement of residual urine 24 hours post operatively. Failure to void (defined as residual urine volume greater than 100mls after two consecutive voids 24 hours post operatively) was registered in 26 women (27.4%). Patients with failure to void were treated with an indwelling catheter and their ability to void was checked again after 2-3 days and once more at 7-10 days. In two cases failure to void persisted after 7-10 days and required intermittent self-catheterisation managed by the patient. In both cases voiding disfunction resolved after 6 weeks without further intervention.

Twelve women (12.6%), who had no symptoms of urinary urgency before surgery, developed them after the operation. They varied in degree from mild symptoms of urgency to occasional urge incontinence.

There were no cases of erosion or rejection of the tape.

Cure Rate and Patient Satisfaction

Improvement in urinary condition was evaluated by analysing the responses in the BFLUTS questionnaires completed by the patients.

The number of women subjectively reporting themselves completely cured of stress leakage was 66, representing 74.2% of total returned questionnaires (Fig 1). Nineteen (21.3%) women reported significant improvement, as measured by no more than occasional leakage on severe coughing. Three patients (3.4%) experienced no change and one (1.1%) felt that her symptoms had got worse.

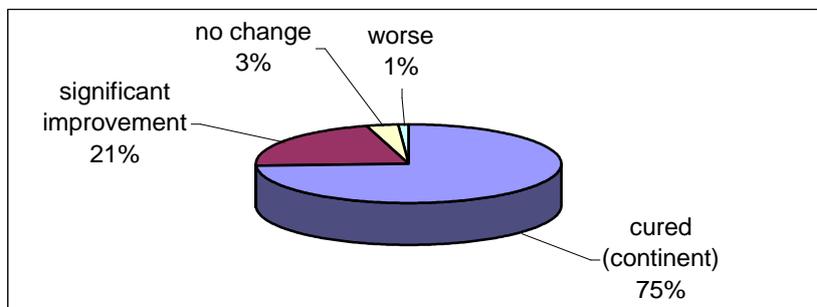


Fig. 1: Subjective Cure Rate

The patients' level of satisfaction was closely in accordance with the subjective cure rate. Almost 76% of patients declare themselves to be very happy or mostly satisfied with the treatment. Fourteen (15.7%) patients had "mixed feelings", 5 (5.6%) patients were "mostly dissatisfied" and no (0%) patients were "very unhappy".

In response to a final question, 82 women, representing 92.1% of those returning questionnaires, stated that they would recommend TVT treatment to their friends.

Conclusions

The overall picture of findings from the audit is generally satisfactory and reassuring, with no major problem areas identified (Table 2).

For all women the type of incontinence was confirmed by urodynamic investigation. In the great majority (92%) of cases, conservative management was also tried and had failed before surgery was considered. This represents adequate compliance with these NICE guidelines.

On the other hand, only 71% of women received full information about the TVT operation before signing their consent to it. Compliance with this NICE guideline is considered inadequate, especially when taking into account the importance for the patient to be fully aware of the advantages and drawbacks of the procedure in order to be able to make an informed consent. However, it is possible that such information was given orally in many cases but was not recorded.

Compliance with the NICE guideline, “that the TVT procedure should only be carried out by surgeons who have received appropriate training in the technique and who regularly carry out surgery for stress incontinence in women”, was less easy to determine. Over three quarters of the Trust’s TVT operations were carried out by one specialist surgeon, with three other surgeons undertaking the remaining operations in small numbers and relatively infrequently. However, there appears to be no clear definition for “adequate training” and “regularity” in the NICE guidebook on TVT. Because of this it is recommended that surgeons at the Trust agree what constitutes “appropriate training” and “regular surgery” before considering further action.

High success rates for the tension free vaginal tape operation have been reported in the literature^{7,9}. Our (subjective) results, with 74% of women completely cured and an additional 21% showing significant improvement, are fully in accordance with these reports.

The incidences of the main complications of the TVT operation (ie. bladder/urethral perforation, haemorrhage, long term voiding dysfunction, tape rejection, defective healing, de novo detrusor instability) were found within statistical limits to be low and of very similar levels to those reported in the literature (see Table 3). This is both satisfactory and reassuring. However, the incidence of failure to void post operatively was registered at 27%, an unexpectedly high level compared with other reports (10-20%)^{3,5,6,7}. This may possibly be because of differences in the definition of residual urine and how it is measured. Also, combination with surgery for cystocele in some women might contribute towards this.

The extent of compliance with each of the audit criteria developed from the NICE guidelines for TVT is summarised in Table 2 below.

Audit Criterion	Standard	Exception	Compliance
1 Type of incontinence is confirmed by urodynamic investigations before surgery	100% of women having the TVT procedure	None	100%
2 The TVT procedure is considered as a surgical option for women with stress incontinence only when conservative management has failed or is unsuitable.	100% of women with urodynamic stress incontinence in whom conservative management has failed	The woman is considered unsuitable for physiotherapy (eg complete genital prolapse)	92%
3 The informed consent signed by women undergoing TVT procedure includes information about the advantages and drawbacks of the procedure	100% of women having the TVT procedure	None	78%
4 The TVT procedure is performed only by a surgeon who is trained specifically in this technique and who regularly carries out surgery for stress incontinence in women	100% of women having the TVT procedure	None	77-89% (further consideration needed)
5 The treatment for urinary stress incontinence, evaluated by the proportion of women achieving subjective cure, is effective	74-94% subjective cure rate (reported in other randomised and non-randomised trials)	Women not returning a completed BFLUTS questionnaire	100%

Table 2: Summary of Compliances

Objective		Literature Standard²	Audit Result
The prevalence of intra- and post-operative complications with TVT is comparable with that achieved by current best practice reported in the literature ²	1 Perioperative bladder / urethral perforation	5%	4%
	2 Bleeding	1%	1%
	3 Failure to void urine post operatively	10-20%.	27%
	4 Long term voiding dysfunction	1%	2%
	5 Tape rejection	0.1%	0%
	6 Defective healing	0.1%	0%
	7 De novo urinary urgency	10%	12%

Table 3: Summary of Complications Found

Recommendations

Two areas in need of improvement have been highlighted by this audit:

Firstly, in every case the relative risks and benefits of the TVT operation should be fully discussed with the patient, so that she can make an informed choice of treatment.

Documentation can always be improved but particular attention should be paid to recording information given to the patient. The NICE Guidebook on TVT recommends that clinicians should agree locally on information about the TVT operation that should be provided to the patient as part of the consent process. Information to be considered should include the advantages for TVT of a high cure rate, a minimal access technique, use of regional anaesthesia and a short hospital stay. These should be set against the disadvantage for TVT of lack of information on long-term effectiveness and level of complications. For some individuals, this lack of long-term data may tip the balance in favour of a procedure, such as colposuspension, where the long term-outcomes are better established. This consideration may be particularly important in younger women.

Secondly, as mentioned earlier, the NICE Guidebook on TVT does not give any clear definitions of the “appropriate training” which the surgeon should receive in the technique, or the “regularity” with which the surgery should be performed.

On these two important points the most appropriate solution would be local agreement by surgeons.

References

This clinical audit was assisted by information and guidance from the following sources:

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