

**Guidance on
the use of
tension-free
vaginal tape
(Gynecare TVT) for
stress incontinence**

Technology Appraisal No. 56

Guidance on the use of tension-free vaginal tape (Gynecare TVT) for stress incontinence

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This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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**Guidance on
the use of
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vaginal tape
(Gynecare TVT)
for stress
incontinence**

1 Guidance

- 1.1 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.
- 1.2 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, set against the disadvantage of the 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.
- 1.3 The TVT 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.

This section (Section 1) constitutes the Institute's guidance on the use of tension-free vaginal tape (Gynecare TVT) for stress incontinence. The remainder of the document is structured in the following way:

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- 2.1 Urinary incontinence is defined as the complaint of any involuntary leakage of urine. There are several types of urinary incontinence and, in women, the most widespread form is stress urinary incontinence. This is the involuntary loss of small amounts of urine due to increases in abdominal pressure resulting from activities such as coughing, laughing, lifting and positional changes. When the condition has been confirmed by urodynamic investigations (studies of pressure and flow of urine within the urinary tract) it is termed urodynamic stress incontinence.
- 2.2 Several surveys have estimated the overall rates of urinary incontinence to be 10–52% in adult women. This wide range may be accounted for by variations in the definition of incontinence, the populations sampled, and the survey methods used. Under-reporting is suspected because of the reluctance of many sufferers to seek help for this condition.
- 2.3 People with incontinence are often distressed and socially disabled by their condition. Some can cope reasonably well with only small modifications to their usual lifestyle, while others curtail their activities considerably.
- 2.4 The initial treatment of urinary incontinence usually involves conservative techniques. These include specific exercises to strengthen the pelvic floor muscles with or without the aid of devices, such as weighted vaginal cones, visual or tactile biofeedback devices, or electrical stimulation. Surgery is usually considered only when conservative management has failed or is unsuitable.
- 2.5 The effectiveness of treatments for urinary incontinence is primarily evaluated by the proportion of women achieving **subjective** or **objective** cure or improvement. Subjective outcomes are typically based on responses to questionnaires evaluating symptoms. Objective outcomes are generally based on measurements of urine loss, such as pad tests, and urodynamic studies.
- 2.6 Various surgical techniques are available for the treatment of stress incontinence. The most commonly used procedure is colposuspension, where the bladder neck is surgically elevated. This technique has been shown to be effective in stress urinary incontinence, with subjective cure rates in the region of 82–95% at 1 year. These high cure rates appear to be maintained in the long term. There are several traditional suburethral ‘sling’ procedures available, where a hammock of biological or synthetic material is used to support the bladder neck and proximal urethra. These procedures have also been shown to be effective, with short-term cure rates similar to those for colposuspension. Other surgical procedures include needle suspensions and anterior repairs, although these techniques have been found to be less effective than colposuspension in the treatment of stress incontinence. However, anterior repair is a primary procedure for the

treatment of cystourethrocele (prolapse of the bladder and urethra into the vagina).

2.7 Injection of bulking materials into the wall of the urethra is another treatment option for stress incontinence. The aim is to exert pressure on the urethra to improve its ability to resist increased abdominal pressure. This is usually performed under local anaesthetic, and the bulking material is injected transurethrally or periurethrally. Materials used for this procedure include silicone, collagen, polytetrafluoroethylene, and autologous fat. In systematic reviews of effectiveness, subjective cure rates for injectable bulking agents have varied widely. For example, one review suggested a subjective cure rate beyond 12 months of 33% for autologous fat while another reported a cure rate of 63%. Cure rates of 60–70% have been reported for silicone, 40–78% for collagen, and 34–70% for polytetrafluoroethylene.

3

The technology

3.1 The tension-free vaginal tape (TVT) procedure is a form of low-tension urethropexy. The Gynecare TVT device (Ethicon) consists of a polypropylene mesh tape 40 cm long and 1 cm wide covered by a plastic sheath, which is attached to two needles. A non-disposable applicator handle is used in the placement of the tape. The tape forms a U-shaped sling around the middle third of the urethra, with the tape lying flat against the posterior surface of the urethra. The plastic sheath is removed and the ends of the tape are left unfixed. There is no bladder neck elevation. TVT placement is a minimal-access technique that can be performed under local, regional or general anaesthesia.

3.2 The rationale for the technology is grounded in a controversial idea called the ‘integral theory of female urinary incontinence’. This theory proposes that the cause of stress incontinence is connective tissue laxity in the vagina itself, or in its anterior and/or posterior supporting ligaments. The pelvic floor muscles are unable to compensate for the laxity of the connective tissues sufficiently to maintain closure of the urethra. It is thought that the tape simulates the support mechanism of the pubourethral ligament. According to the integral theory, the role of the pubourethral ligament – and hence the tape – is to provide a firm anchoring point for the three muscles associated with urethral closure.

3.3 The TVT procedure is associated with a range of potential complications. In particular, bladder perforation appears to occur more frequently with this procedure than with other standard surgical procedures for stress incontinence. This complication can be successfully managed by bladder drainage and catheterisation, provided that it is detected by cystoscopy during TVT placement. Managed in this way, this complication does not usually have long-term sequelae. Other traumatic injuries and postoperative bleeding complications have also been reported.

- 3.4 There are few data on longer-term complications following TVT placement. Problems that have been reported include the development of urinary retention and difficulties with micturition following surgery, and this may require the tape to be cut or removed. Erosion of the tape material into the bladder, urethra or vagina is a potential problem with synthetic sling devices. Limited data from case series suggest that this occurs at a rate of about 1%, but further long-term follow-up data are required. New-onset symptoms of urgency and detrusor overactivity have also been reported following the TVT procedure.
- 3.5 The Gynecare TVT device costs £425 for a single device or £1185 for a pack of three, excluding VAT. The additional costs of materials used in the TVT procedure relative to some of the other surgical techniques are offset by a shorter operating time and/or hospital stay.

The Appraisal Committee considered evidence from a number of sources (see Appendix B).

4.1 Clinical effectiveness

- 4.1.1 The evidence considered in this appraisal relates to the Gynecare TVT device made by Ethicon.
- 4.1.2 The TVT procedure has been evaluated in randomised and non-randomised studies, and case series reporting cure rates have been published. The most important piece of evidence is a randomised controlled trial conducted by Ward and Hilton that compared the Gynecare TVT device with open colposuspension. In this study, 344 women with stress incontinence were randomised to receive either TVT or open colposuspension. The TVT procedure was performed under local anaesthesia with sedation in all but a few cases, while colposuspension was performed under general anaesthesia in all but one case.
- 4.1.3 The primary endpoint for this study was objective cure, defined as a negative pad test (less than 1 g change in weight in an absorbent pad worn for 1 hour during exercise) **and** a negative urodynamic stress test (an objective demonstration of urine loss associated with increased abdominal pressure). This is a particularly stringent definition of cure. The study also investigated subjective measures of incontinence and quality-of-life using standard questionnaires. Unfortunately, this study was weakened by the fact that a large number of patients dropped out of the trial after randomisation. In all, 23 patients withdrew from the colposuspension group before surgery, compared with only five from the TVT group. At later stages in the study the numbers of patients withdrawing from the trial were similar in both groups. Additionally, the trial was smaller than planned, so it lacked the statistical power to exclude a potential

difference in cure rates between the procedures as large as 10%.

- 4.1.4 According to the intention-to-treat analysis in the published report of the study, at 6 months after surgery 66% (115 of 175) of patients randomised to the TVT procedure were objectively cured, compared with 57% (97 of 169) of patients randomised to colposuspension. This difference was not statistically significant. However, this analysis contains an inherent assumption that patients who dropped out of the study after randomisation, or who did not return for follow-up investigations, would not have been successfully treated. Since more patients dropped out of the colposuspension group at this stage, this assumption favours the TVT intervention. An alternative analysis, including only patients who received treatment and returned for reassessment, gives objective cure rates of 72% in both groups (115 of 159 patients in the TVT group and 97 of 134 in the colposuspension group).
- 4.1.5 In the same study, subjective cure rates were reported according to the patients' answers to the relevant questions on the Bristol female lower urinary tract symptoms (BFLUTS) questionnaire. In the intention-to-treat analysis – with the assumption that treatment was unsuccessful in patients with missing data – the proportion of patients reporting cure of stress leakage at 6 months was 59% (103 of 175) in the TVT group and 53% (90 of 169) in the colposuspension group. Using the alternative analysis, which ignores patients for whom there were no data, the proportions of patients reporting no stress leakage were 65% (103 of 159) in the TVT group and 66% (90 of 137) in the colposuspension group.
- 4.1.6 Quality of life was assessed using three different questionnaires: two generic measures – the SF-36 and the EQ-5D questionnaires; and one disease-specific measure – the BFLUTS questionnaire. There was no significant difference in the BFLUTS scores between the two treatment groups. The SF-36 measures quality of life in eight domains: role limitation due to emotional problems, role limitation due to physical problems, physical functioning, social functioning, mental health, pain, energy/vitality, and general health. In this study, patients undergoing TVT placement had significantly greater improvements for role limitation due to emotional problems, social functioning, physical functioning, and energy/vitality than the colposuspension group at 6 weeks. By 6 months the improvements in role limitation due to emotional problems, social functioning, and energy/vitality were still significantly greater in the TVT group than the colposuspension group. Mental health improvement was

also significantly greater in the TVT group at 6 months. The EQ-5D results were not included in the published report of this study, although these results were presented in the economic analysis submitted by the manufacturer.

- 4.1.7 Subjective cure rates reported in other randomised and non-randomised comparative studies of TVT and published case series varied between 74% and 97%. These results are consistent with those from the large randomised study by Ward and Hilton.
- 4.1.8 Data on the effectiveness of the procedure in selected populations – such as those undergoing a second surgical procedure after previous failed surgery, those with mixed incontinence (coexistent stress and urge incontinence) and those with coexistent vaginal prolapse – are very limited. These types of patient were excluded from the Ward and Hilton study. However, the limited data suggest that there is little reason to suspect that the procedure performs less well in these patients than in the general population of women with stress incontinence. There are no adequate data on TVT placement performed in conjunction with other procedures, such as repair of prolapse or hysterectomy.
- 4.1.9 The most commonly reported operative complication in comparative studies and case series of the TVT procedure was bladder perforation. This may occur as a result of inadvertent insertion of the applicator. Current data suggest that this complication occurs in about 1 in 25 TVT procedures, although some of the smaller comparative studies have reported much higher rates. Other traumatic injuries have been reported with the TVT procedure – including obturator nerve injuries, which occur at an incidence of around 0.2%. Bowel perforations and vascular injuries have also been reported, but are rare.
- 4.1.10 Data on later postoperative adverse events are sparse but suggest that complications, such as infection and tape erosion, occur only rarely.
- 4.1.11 In comparative studies, the length of hospital stay after TVT placement was 1–3 days. Data from published case series were consistent with these findings. This compares with mean stays of 3.4–6.5 days for open colposuspension and 2–3.5 days for laparoscopic colposuspension. Traditional sling procedures involve a similar length of stay to colposuspension (mean of 5.6 days in one comparative study). It is likely that the TVT procedure is associated with a more rapid return to usual activities than colposuspension.

4.1.12 In summary, the TVT procedure appears have similar effectiveness to the main alternative therapies in the surgical management of stress urinary incontinence. It is associated with a shorter hospital stay than standard methods, such as open colposuspension or traditional sling procedures.

4.2 Cost effectiveness

4.2.1 The Appraisal Committee considered two estimates of the cost effectiveness of TVT; one was performed by the Assessment Group, and the other was commissioned by the manufacturer and submitted for this appraisal. Both evaluations expressed the benefits of treatment in terms of quality-adjusted life-years (QALYs). The values of the QALYs were derived from the EQ-5D questionnaire results of the Ward and Hilton study. Both economic analyses took an NHS perspective. No evaluations of cost effectiveness were found in the published literature.

4.2.2 The Assessment Group's economic evaluation used an estimate of effectiveness based on a meta-analysis of two published controlled trials. The costs were derived from the manufacturer's submission, which was considered to be the best source of information. It was assumed that patients who were not cured would be offered colposuspension as a secondary procedure, and that this would be less effective than colposuspension as a primary procedure.

4.2.3 According to the Assessment Group's model, TVT results in slightly fewer QALYs than colposuspension in the short term, but at a lower cost. Using colposuspension rather than TVT would cost £88,450 per additional QALY at 1 year. By 5 years TVT dominates – that is, it results in more QALYs at a lower cost than the alternative procedure.

4.2.4 The Assessment Group also performed a probabilistic analysis. According to this analysis, TVT is likely to be considered cost effective relative to colposuspension across a broad range of acceptable amounts to pay for an additional QALY.

4.2.5 Using the assumptions that traditional sling procedures have the same effectiveness as open colposuspension and are more costly, that laparoscopic colposuspension is similarly or slightly less effective than open colposuspension, and that periurethral injections are less effective than TVT but cost more, the TVT procedure appears cost effective relative to these procedures.

4.2.6 The manufacturer's economic evaluation was conducted alongside the Ward and Hilton trial (see

4.1.1 to 4.1.5), and reported costs and utilities over the 6-month duration of the study. The analysis was well conducted and showed a probabilistic assessment that suggested that TVT was likely to be cost effective across a broad range of acceptable amounts to pay for an additional QALY.

4.2.7 In summary, although the cost of the materials used in the TVT procedure is higher than for colposuspension, the overall cost is lower because of the shorter associated hospital stay. The TVT procedure appears to be cost effective relative to colposuspension.

4.3 Consideration of the evidence

4.3.1 The Appraisal Committee considered that there was evidence to confirm the effectiveness of the TVT procedure in women with uncomplicated urodynamic stress incontinence, although the duration of follow-up was limited. The procedure also appeared to be cost effective relative to the main alternative procedures. Colposuspension is the most commonly used of these alternatives in England and Wales. There is good evidence that colposuspension is effective; it has been in use for many years, and long-term data on effectiveness and complications are available.

4.3.2 The Committee noted that the TVT procedure has several advantages over colposuspension. These are primarily associated with minimal access, use of local or regional (rather than general) anaesthesia, and a short hospital stay (it can be performed as a day-case procedure). However, there are few data on its continued effectiveness and complication rate beyond the first few years. 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 outcome is better established. This consideration may be particularly important in younger women. The relative risks and benefits of TVT versus colposuspension should be fully discussed with the patient so that she can make an informed choice of treatment.

4.3.3 The Committee noted that surgical procedures are normally considered only for those women whose symptoms have not been alleviated by conservative management, such as pelvic floor muscle training. The Committee saw no reason why this criterion should not be applied to the TVT procedure. TVT should be used only after conservative management has failed.

4.3.4 TVT is sometimes used in conjunction with other urogynaecological procedures, such as repair of prolapse or vaginal hysterectomy. The effectiveness of TVT

when used in this way is not known. In these circumstances the advantages associated with the use of local or regional anaesthesia do not apply. It is particularly important to discuss the relative merits of TVT combined with repair of prolapse compared with colposuspension with those patients who require both prolapse repair and treatment of stress incontinence.

4.3.5 The Appraisal Committee accepted the view that surgical procedures for stress incontinence, including TVT, are not considered appropriate for women who may go on to have children. TVT should therefore be reserved for women who have completed their families.

4.3.6 The Committee noted that this procedure requires that surgeons be adequately trained. The amount of training required by each individual surgeon varies according to his or her experience in urogynaecological surgery. Expertise in identifying patients for whom the procedure is appropriate is also necessary.

5

Implications for the NHS

5.1 Further information on the long-term effectiveness and complication rate of the TVT procedure is required. It is recommended that observational data on effectiveness and safety of the procedure is collected over a period of 10 years or more. Preferably this should be nationally coordinated in the form of a registry of audit data to include both the numbers of procedures carried out and measures of outcome and adverse events.

6

Further research

6.1 The extent to which this guidance might change current practice in the NHS depends on two factors. Firstly, the extent to which TVT is chosen over colposuspension in patients for whom either procedure is suitable, and secondly, the extent to which the availability of a less invasive procedure results in an expansion of the number of patients considered eligible for surgery. For example, some patients who are too frail or unfit to undergo colposuspension might be able to undergo the TVT procedure.

6.2 The number of TVT procedures performed in England has risen from 214 in the year 1998–1999 to 2706 in the year 2000–2001. About one-third of operations for urinary incontinence in women in the year 2000–2001 in England were TVT placements. A similarly rapid rise in the number of TVT procedures has also been seen in Wales, the number of TVT procedures having increased from 13 in the year 1998–1999 to 108 in the year 2000–2001. In Wales, TVT placement accounted for 25% of surgical procedures performed for incontinence in women in the year 2000–2001.

6.3 If the number of operations for stress incontinence remains stable, but the number TVT procedures as a proportion of these continues to rise, then this would result in savings to the NHS. This is mostly as a result of the shorter hospital stay

associated with TVT placement compared with colposuspension. The operating time is also shorter: an experienced surgeon can perform three TVT procedures in the time it takes to perform two open colposuspensions. If the availability of TVT results in an increase in the number of surgical procedures for stress incontinence then, depending on the extent of this increase, there may be a modest increase in NHS expenditure, although this is difficult to quantify.

7

Implementation and audit

- 7.1 NHS Trusts and consultants treating women with stress incontinence should review policies and practices regarding the surgical treatment of uncomplicated urodynamic stress incontinence to take account of the guidance set out in Section 1.
- 7.2 Local guidelines or care pathways on the care of women with stress incontinence should incorporate the guidance in Section 1.
- 7.3 To measure compliance locally with the guidance, the following criteria can be used. Further details on suggestions for audit are presented in Appendix C.
 - 7.3.1 The TVT procedure is a surgical treatment option for a woman with uncomplicated urodynamic stress incontinence in whom conservative management has failed.
 - 7.3.2 For a woman who is undergoing the TVT procedure, the informed consent refers specifically to the patient being made aware of the advantages and drawbacks of the procedure.
 - 7.3.3 The TVT procedure is performed only by a surgeon who has received appropriate training in the technique, and who regularly carries out surgery for stress incontinence in women.

8

Related guidance

- 8.1 There is no related guidance for this technology.

9

Review of guidance

- 9.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider any new evidence on the technology, in the form of an updated Assessment Report, and decide whether the technology should be referred to the Appraisal Committee for review.
- 9.2 The guidance on this technology will be reviewed in February 2006.

Andrew Dillon
Chief Executive

February 2003

APPENDIX A

Appraisal Committee members

NOTE The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month except in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declaration of interests, are posted on the NICE website.

Professor R. L. Akehurst

Dean, School of Health Related Research, University of Sheffield

Dr Tom Aslan

General Practitioner, The Surgery, Stockwell, London

Professor David Barnett (Chair)

Professor of Clinical Pharmacology, University of Leicester

Dr Sheila Bird

MRC Biostatistics Unit, Cambridge

Professor Rosamund Bryar

Professor of Community & Primary Care Nursing, St Bartholomew's School of Nursing & Midwifery

Professor Martin Buxton

Director of Health Economics Research Group, Brunel University

Dr Karl Claxton

Health Economist, University of York

Dr Richard Cookson

Senior Lecturer, Health Economics, School of Health Policy and Practice, University of East Anglia

Professor Sarah Cowley

Professor of Community Practice Development, King's College, London

Professor Terry Feest

Clinical Director & Consultant Nephrologist, Richard Bright Renal Unit, & Chairman of the UK Renal Registry

Professor Gary A Ford

Professor of Pharmacology of Old Age/Consultant Physician, Newcastle upon Tyne Hospitals NHS Trust

Mrs Sue Gallagher

Former Chief Executive, Merton, Sutton and Wandsworth Health Authority

Ms Bethan George

Interface Liaison Pharmacist, Tower Hamlets Primary Care Trust and St. Bartholomew's & The Royal London Hospital

Dr Trevor Gibbs

Head, Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline

Mr John Goulston

Director of Finance, Barts & the London NHS Trust

Professor Philip Home

Professor of Diabetes Medicine, University of Newcastle upon Tyne

Dr Terry John
General Practitioner, The Firs, London

Mr Muntzer Mughal
Consultant Surgeon, Lancashire
Teaching Hospitals NHS Trust

Mr James Partridge
Lay Representative, Chief Executive,
Changing Faces

Mrs Kathryn Roberts
Nurse Practitioner, Hattersley Health
Centre, Hyde, Cheshire

Professor Philip Routledge
Professor of Clinical Pharmacology,
University of Wales

Ms Anne Smith
Lay Representative; Trustee, Long Term
Medical Conditions Alliance

**Professor Andrew Stevens
(Vice-Chair)**
Professor of Public Health, University
of Birmingham

Dr Cathryn Thomas
General Practitioner & Senior Lecturer,
Department of Primary Care and
General Practice, University of
Birmingham

Dr Norman Vetter
Reader, Department of Epidemiology,
Statistics and Public Health, University
of Wales College of Medicine

Dr David Winfield
Consultant Haematologist, Royal
Hallamshire Hospital, University of
Wales College of Medicine

APPENDIX B

Sources of evidence considered by the Committee

The following The following documentation and opinions were made available to the Committee:

- A. Assessment report** Report prepared by Institute of Applied Health Sciences, University of Aberdeen:
Systematic review of the clinical effectiveness and cost effectiveness of tension-free vaginal tape (TVT) for the treatment of urinary stress incontinence, August 2002
- B. Manufacturer/sponsor submissions :**
- Ethicon
- C. Professional/specialist group submissions :**
- Health Technology Board for Scotland
 - The Royal College of Obstetricians and Gynaecologists, the British Association of Urological Surgeons and the British Society of Urogynaecology.
 - The Research Institute for the Care of the Elderly.
 - The Royal College of Nursing
 - The Royal College of Physicians and the British Geriatrics Society
 - The Chartered Society of Physiotherapy in consultation with the Association of Chartered Physiotherapists in Women's Health
- D. Patient/carer group submissions:**
- The Continence Foundation
 - Incontact
- E. Expert perspectives:**
- Professor Linda Cardozo, Professor of Urogynaecology, King's College Hospital, London
 - Mr David Richmond, Consultant Gynaecologist, Liverpool Women's Hospital
 - Mr Jolyon Rose, Executive Director, Incontact
 - Dr Judith Wardle, Director, Continence Foundation
- F. National Collaborating Centre for Women and Children's Health perspective**
- Dr Jane Thomas, Co-Director, National Collaborating Centre for Women and Children's Health

APPENDIX C

Information for the public

Tension-free vaginal tape (Gynecare TVT) for stress incontinence

The information in this appendix has been designed to support the production of your own information leaflets. You can download it from our website at www.nice.org.uk where it is available in English and Welsh. If you would like printed copies of the leaflets please ring the NHS Response Line on 0870 1555 455 and quote reference number N0192 for the English version and N0193 for the Welsh and English version.

What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance for both the NHS and patients on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures and under what circumstances they should be used.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance. Each appraisal takes about 12 months to complete.

NICE was asked to look at the available evidence on the use of a surgical method of treating stress incontinence in women called tension-free vaginal tape (Gynecare TVT) and to provide guidance to help the NHS in England and Wales decide when it should be used.

What is stress incontinence?

Stress incontinence is the accidental leakage of urine during normal everyday activities. This condition mainly affects women. People with this condition may leak urine when laughing, sneezing or coughing, or when exercising or changing position. People with stress incontinence are often embarrassed by their condition, and may avoid activity and social events.

Stress incontinence in women can be caused by weakness of the pelvic floor muscles, which support the bladder and the urethra (the tube leading from the bladder to the outside of the body). When there is increased pressure in the abdomen, for example when coughing, the muscles can't keep the urethra closed and urine can leak out. Treatments for stress incontinence in women include non-surgical methods such as exercises to help to strengthen the muscles in the pelvic floor; if the non-surgical methods don't work, surgery may be considered.

What is tension-free vaginal tape?

Tension-free vaginal tape is one way of treating stress incontinence in women, using surgery. The evidence considered for the NICE appraisal was for the Gynecare TVT device made by Ethicon.

The tape is put around part of the urethra, creating a supportive sling. The tape supports the urethra, allowing it to keep closed and stop urine leaking out when there is a sudden increase in pressure in the abdomen. The tape provides support only when needed, without any unneeded tension on the urethra (this is why it is called tension-free).

A short operation is needed to fit the tension-free vaginal tape. It can be carried out under a general or local anaesthetic and is carried out without opening up the abdomen. The surgeon inserts the tape through the wall of the vagina, and then passes it either side of the urethra. The surgeon pulls the ends of the tape up through two cuts in the skin's surface just above the pubic area. At the end of the operation, the surgeon snips the tape, just under the skin's surface, and closes the cuts.

What has NICE recommended?

NICE has recommended tension-free vaginal tape as one option for the surgical treatment of women with stress incontinence where non-surgical treatments (such as pelvic floor exercises) have not worked.

The operation should only be carried out by a surgeon who has been specially trained in this operation and who regularly carries out surgery for stress incontinence in women.

Women who are considering having surgery for urinary stress incontinence should be given full information about the advantages and drawbacks of the options available. The issues that need to be considered include:

- the advantages of an operation that requires only small cuts to be made and for which a local or regional (rather than general) anaesthetic may be used
- the data available on how well the treatment works in the long term – not much is known about how effective tension-free vaginal tape is, or whether there are likely to be any problems, after the first few years
- whether the woman may become pregnant – surgical procedures for stress incontinence, including tension-free vaginal tape, are generally not suitable for women who may go on to have children
- whether the surgery for stress incontinence will be carried out at the same time as other surgery such as a 'vaginal hysterectomy' (removal of the womb through the vagina).

What should I do?

If you or someone you care for has stress incontinence, you should discuss this guidance with your doctor. All surgery has some risk. You should discuss this with your doctor or surgeon.

Will NICE review its guidance?

Yes. The guidance will be reviewed in February 2006.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on stress incontinence that has been issued to the NHS. The guidance can also be requested from the NHS Response Line by phoning 0870 1555 455 and quoting reference N0190.

If you have access to the Internet, you can find more information about stress incontinence on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 08 45 46 47.

Appendix D

Detail on criteria for audit of the use of tension-free vaginal tape for stress incontinence

Possible objectives for an audit

An audit on the use of tension-free vaginal tape (TVT) for stress incontinence could be carried out to ensure the following objectives are met.

- The TVT procedure is considered as a surgical option for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed.
- The informed consent signed by women undergoing the TVT procedure includes information about the advantages and drawbacks of the procedure.
- 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.

In addition, because of the need to gather clinical data on the effectiveness of this technology in the long term, follow-up data may be collected and submitted to any registries set up in selected centres.

Possible patients to be included in an audit and time period for selection

An audit on the first objective above could be carried out on all women referred to a urologist or to a gynaecologist for treatment of uncomplicated urodynamic stress incontinence in whom conservative management has failed in a reasonable time period, for example 3-6 months

An audit on the second and third objectives could be carried out on all women who have the TVT procedure.

Measures that can be used as a basis for an audit

The measure that can be used in an audit to confirm that the TVT procedure is being considered for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed is as follows.

Criterion	Standard
1. The TVT procedure is considered as a surgical option for a woman with uncomplicated urodynamic stress incontinence in whom conservative management has failed	100% of women with uncomplicated urodynamic stress incontinence in whom conservative management has failed

The measures that can be used in an audit to confirm that the use of the TVT procedure is being carried out the correctly are as follows.

Criterion	Standard
1. The patient's informed consent refers specifically to the patient being made aware of the advantages and drawbacks of the procedure	100% of women having the TVT procedure
2. The TVT procedure is performed by a surgeon who: <ul style="list-style-type: none"> a) has received training specifically in the technique b) regularly carries out surgery for stress incontinence in women 	100% of women having the TVT procedure

Calculation of compliance with the measures

Compliance (%) with each measure described in the tables above is calculated as follows.

$$\frac{\text{Number of patients whose care is consistent with the criterion plus number of patients who meet any exception that might be agreed locally}}{\text{Number of patients to whom the measure applies}} \times 100$$

Clinicians should review the findings of the audit, identify whether practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.

Exception	Definition of Terms
A. The woman intends to have more children	Clinicians should agree locally on how to record that the TVT procedure has been considered for each eligible patient, and how failure of conservative management is to be defined and recorded for audit purposes.

Exception	Definition of Terms
A. None	Clinicians should agree locally on information that will be provided to the patient as part of the consent process, including the following: the advantages of a minimal-access technique, the disadvantage of the absence of data on long-term effectiveness, consideration of whether the woman is likely to have children subsequently, if the procedure will be used in conjunction with another procedure such as vaginal hysterectomy or repair of prolapse.
A. None	Surgeons should agree on what constitutes appropriate training in the use of the TVT technique and regular carrying-out of surgery for stress incontinence in women



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