Operations for Stress Incontinence

Mid-Urethral Tapes (Retropubic and Obturator)

Patient Information Leaflet

BSUG Patient Information Sheet Disclaimer

This patient information sheet was put together by members of the BSUG Governance Committee paying particular reference to any relevant NICE Guidance. It is a resource for you to edit to yours and your trusts particular needs. Some may choose to use the document as it stands, others may choose to edit or use part of it. The BSUGs Governance Committee and the Executive Committee cannot be held responsible for errors or any consequences arising from the use of the information contained in it. The placing of this information sheet on the BSUGs website does not constitute an endorsement by BSUGs.

We will endeavour to update the information sheets at least every two years.

Version 2 (MUT BSUG F2)

Contents

About this leaflet

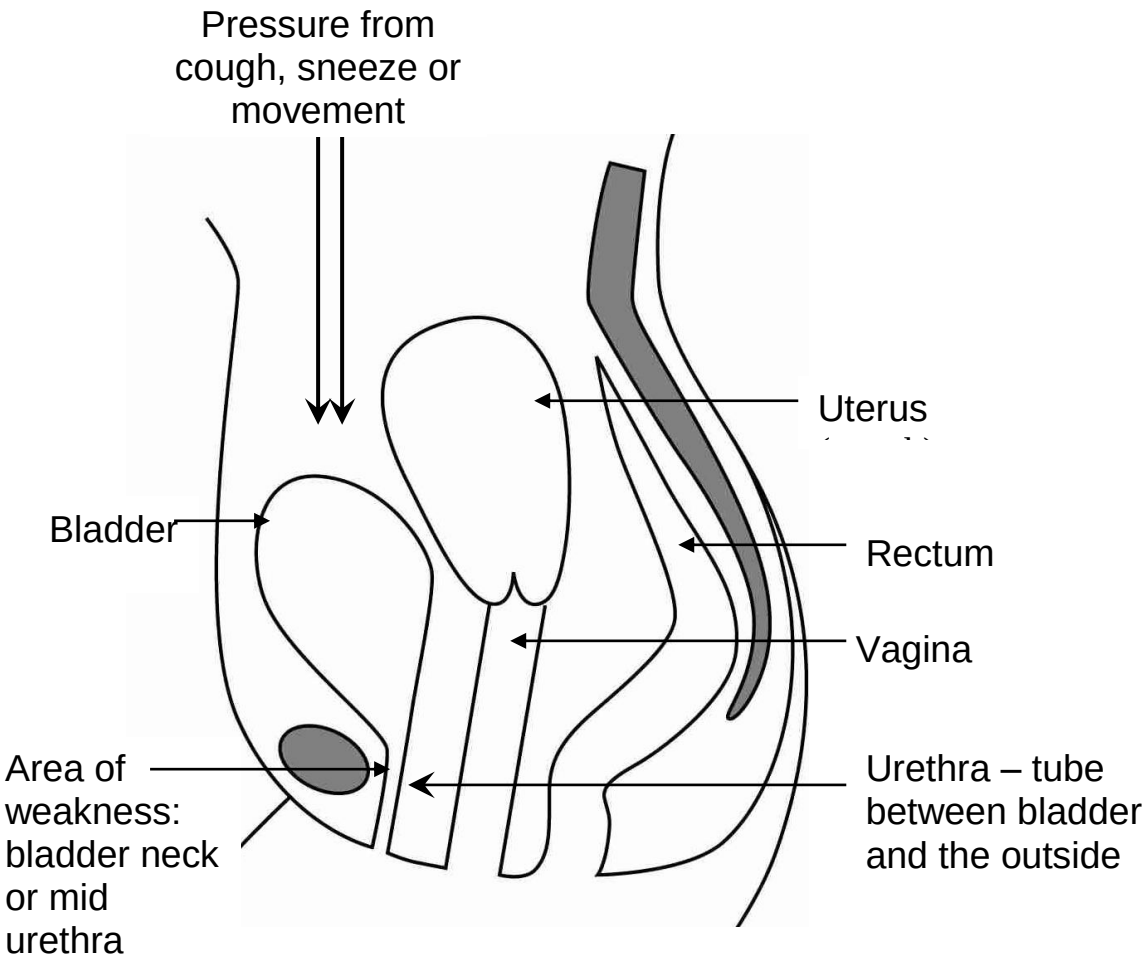
We advise you to take your time to read this leaflet, any questions you have please write them down on the sheet provided (towards the back) and we can discuss them with you at our next meeting. It is your right to know about the operations being proposed, why they are being proposed, what alternatives there are and what the risks are. These should be covered in this leaflet.

This leaflet firstly describes what Stress Incontinence is, it then goes on to describe what alternatives are available within our trust, the risks involved in surgery and finally what operation we can offer.

What is Stress Incontinence?

- Stress Incontinence is the leakage of urine usually caused by an increase in pressure in the abdomen (tummy) e.g. coughing or sneezing (figure 1) due to a weakness in the support of the urethra (urine pipe), and bladder neck.
- This weakness is usually caused by childbirth, heavy lifting and constipation, when the pelvic floor muscles are damaged. Further weakening occurs during the menopause because the quality of the supporting tissues deteriorates.
- The pressure in the abdomen rises when one coughs, sneezes, bends down, etc and results in urine leakage. This can cause distress and limit your quality of life.
- It must be understood that these operations will not cure all urinary symptoms. They will only cure urinary symptoms caused by a weakness in the urethra (urine pipe) and bladder neck. Many urinary symptoms we see in clinic have other causes.

Figure 1: Your anatomy - side view of a woman in an upright position showing pressure above the bladder and a weak bladder neck.



When you cough, sneeze, bend, jump or even laugh the pressure in the abdomen is increased and this may result in leakage of urine

Alternatives to surgery

- **Do nothing** – if the leakage is only very minimal and is not distressing then treatment is not necessarily needed.
- **Pelvic floor exercises (PFE).** The pelvic floor muscles run from the coccyx at the back to the pubic bone at the front and off to the sides. These muscles support your pelvic organs (uterus and bladder) and your bowel. Any muscle in the body

needs exercise to keep it strong so that it functions properly. This is more important if that muscle has been damaged. PFE can strengthen the pelvic floor and correct or reduce stress incontinence. PFE are best taught by an expert who is usually a Physiotherapist. These exercises have little or no risk and even if surgery is required at a later date, they will help your overall chance of becoming continent.

- **Devices.** There are numerous devices (none on the NHS) which aim to support the urethra. The devices are inserted either into the vagina or the urethra. They are not a cure but their aim is to keep you dry whilst in use, for example during 'keep fit' etc.
- **Urethral Bulking Agents -** This involves injecting a substance into the neck of the bladder to make it tighter. Different substances can be used and can be performed whilst you are awake, under local anaesthetic and sedation. The results of the injections are variable and the chance of curing your leaks is less than an operation. About half of the women who have an injection will have been cured of their leaks straight after their injection. However, the effects can wear off over time.

The Benefits of Stress Incontinence Surgery

- 80-90% women are substantially improved.
- This means you may get back to:-
    - Physical activity – running, dancing, gym etc
    - Horse riding
    - Gardening
    - Sexual relations

- This also means you may have renewed confidence so that:-
    - You can e.g. go shopping etc without fear of leaking
    - You do not have to worry about damp patches on clothing, etc
    - You do not have to worry about unpleasant odours.

- There are two types of sub-urethral tapes. The first is a retropubic tape (TVT), this operation has been performed since 1996 and the second is an obturator tape (TOT) which has been performed since 2003. Less long term data is

available for the obturator approach, but information so far suggests that the outcome following TOT is similar to TVT.

- Both tapes are a synthetic mesh material designed to allow the tissues to grow into it and hold the tape firmly in place, preventing the urethra (urine pipe) moving down when the tummy pressure increases for example with a cough, sneeze or exercise.

General Risks of Surgery

- **Anaesthetic risk.** This is very small unless you have specific medical problems. This will be discussed with you.
- **Haemorrhage.** There is a risk of bleeding with any operation. The risk from blood loss is reduced by knowing your blood group beforehand and then having blood available to give you if needed. It is rare that we have to transfuse patients after their operation. Please let your doctor know if you are taking an anti-clotting drug such as warfarin or aspirin.
- **Infection.** There is a risk of infection at any of the wound sites. A significant infection is rare. The risk of infection is reduced by our policy of routinely giving antibiotics with major surgery.
- **Deep Vein Thrombosis (DVT).** This is a clot in the deep veins of the leg. The overall risk is at most 4-5% although the majority of these are without symptoms (1/10 to 1/100 i.e. common). Occasionally this clot can migrate to the lungs which can be very serious and in rare circumstances it can be fatal (less than 1% of those who get a clot). DVT can occur more often with major operations around the pelvis and the risk increases with obesity, gross varicose veins, infection, immobility and other medical problems. The risk is significantly reduced by using special stockings and injections to thin the blood (heparin).

Specific Risks of this Surgery

The table below is designed to help you understand the risks associated with this type of surgery (based on the RCOG Clinical Governance Advice, Presenting Information on Risk)

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10 000	A person in small town
Very rare	Less than 1/10 000	A person in large town

- **Failure:** Approximately 10% of women (1/10 to 1/100 i.e. common) do not gain benefit from the operation. The operation however can be repeated.
- **Voiding difficulty:** Approximately 10% of women will have some difficulty in emptying their bladder in the short term and if this happens, we may send you home with a catheter for up to a week (1/10 to 1/100 i.e. common). If you still have difficulty emptying your bladder after 10 days (3%), then the options will be either learning how to catheterise yourself (you may need to do that few times a day after passing urine to get rid of any urine left behind in your bladder), or going back to theatre to have the tape cut. Once the tape is cut, you may re-develop incontinence but there is an option of having another tape at a later date.

  Some women may need to change position to satisfactorily empty their bladder.
- **Bladder overactivity:** Any operation around the bladder has the potential for making the bladder overactive leading to symptoms such as urgency (needing to rush to the toilet) and frequency (needing to visit the toilet more often than normal). This happens in around 12% of patients (1/1 to 1/10 i.e. very common).
- **Tape exposure and extrusion** (5% - 1/10 to 1/100 i.e. common): The vaginal area over the tape may not heal properly or get infected and therefore part of the tape may need re covering or excising. This will need a return to theatre and may result in the operation being ineffective if the exposed area has to be excised. Very rarely the tape might erode into the urethra (urine pipe) or the bladder which would require an operation as well. The risk of exposure is increased by smoking and with certain diseases. This usually presents with increased vaginal discharge or possibly pain with intercourse for your partner as it acts like a miniature cheese grater.

- **Pain on intercourse:** This may arise from scar tissue in the vagina as a result of the incision. It is unusual but unpredictable. A vaginal exposure may cause discomfort for your partner, see previous point.
- **Visceral trauma:** During the sub-urethral sling operations the needle used may damage other structures such as the bladder, urethra (urine pipe), bowel or blood vessels. This is rare but if it occurs and is noticed at the time of surgery, it may require an abdominal incision (open tummy operation) to repair the damage. If it is noticed after return from theatre to the ward it may mean going back to theatre for a general anaesthetic and an open operation to repair the damage.
- **Leg or groin pain:** occasionally some patients describe pain in the groin or down the legs especially after the obturator approach (<1% - 1/100 to 1/1000 i.e. uncommon). This is usually short lived but can go on for weeks or months rarely.

The Operation: Retropubic tapes - Tension Free Vaginal Tape (TVT)

Facts and Figures

- This operation was invented in 1996 and more than one million procedures have been performed worldwide.
- 90% of women are substantially better after the operation. Some of these women will still leak from time to time e.g. with a bad cold or cough

- It seems to be as effective as the traditional Colposuspension operation for up to 11 years after the operation
- This operation may be performed as day case surgery.
- We don't know whether it will have any complications in the long term.

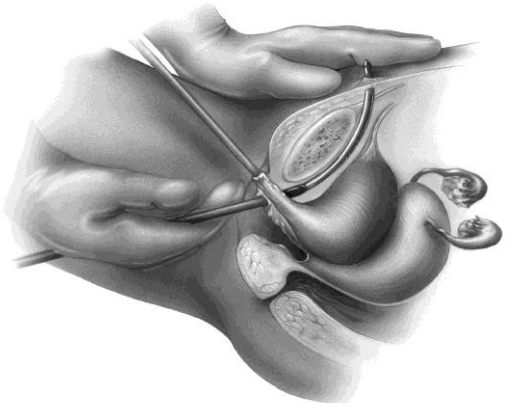
How is the operation performed

- *Local anaesthetic*; the relevant areas (vaginal wall under the urethra and abdominal wall) are injected with a fine needle and

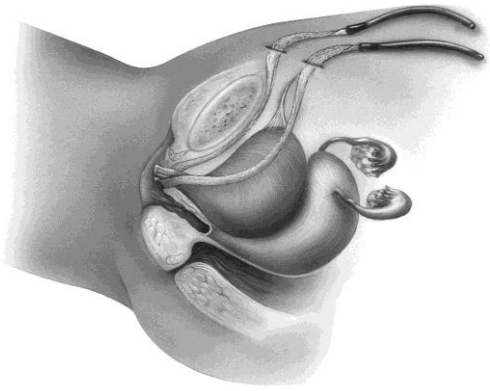
allowed to go numb with local anaesthetic. This will remove any sharp sensation but a pressure sensation will still be felt. Most women will also have a sedative into the veins and this will make you feel very sleepy. In these circumstances most women cannot remember the operation.

- *Spinal anaesthetic;* involves an injection in the lower back, similar to what we use when women are in labour or for a caesarean section. The spinal anaesthetic numbs you from the waist down. This removes any sharp sensation but a pressure sensation will still be felt.
- *General anaesthetic*; will mean you will be asleep (unconscious) during the entire procedure.
- The legs are placed in stirrups (supported in the air).
- A catheter is placed into the bladder through the urethra.
- A small cut is made in the vagina.
- Two small cuts are made in the lower abdominal wall above the pubic bone about 4cm (2") apart.
- The tape introducer (special needle) is pushed through the tissues on each side of the urethra as shown in the diagram. We then look inside the bladder using a cystoscope (bladder telescope) to see whether the bladder has been punctured. If this has occurred, the tape introducer is removed.
- The tape introducers are then pushed through the abdominal wall incisions on both sides so that the tape lies underneath and supports the urethra.

Figure 2. The TVT needles are introduced each side of the urethra, and around the pubic bone. (Images courtesy of Ethicon)



The tape introducer being pushed either side of the bladder neck, through the abdominal wall



The position of the tape having been placed either side of the bladder neck

The Operation: Trans-Obturator Tape (TOT or TVT-O)

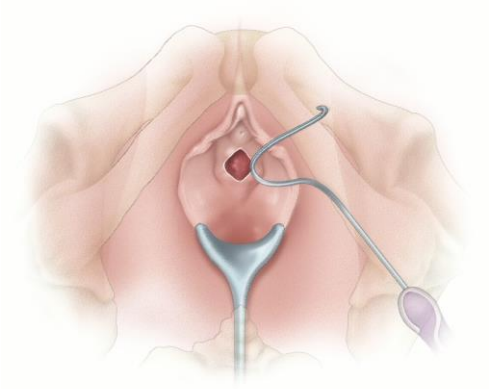
Facts and Figures

- This is a more recently developed operation and therefore less operations overall have been performed.
- The main advantage however is that the procedure is performed through a less risky operative field.
- The short-term results seem comparable to operations like the TVT, but the long-term results are unknown.
- The tape material used is similar to TVT.
- These operations may be performed as day case surgery.

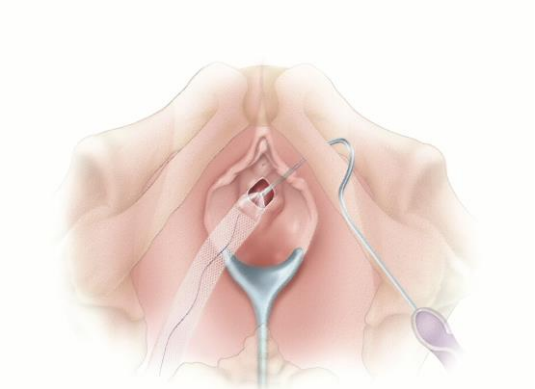
How is the operation performed

- The operation can be performed under local anaesthetic or sedation, spinal or general anaesthetic.
- Special needles are used. The entrance point for these needles is in each groin (see figure 2 and 3)
- A 1cm wide synthetic tape is inserted under the mid-urethra to support it.
- There will therefore be a small incision in each groin as well as the incision in the vagina. These incisions will be closed by an absorbable suture or glue after the operation.

Figure 3: Insertion of Trans Obturator Tape (TOT) (Images courtesy of American Medical Systems, Inc)

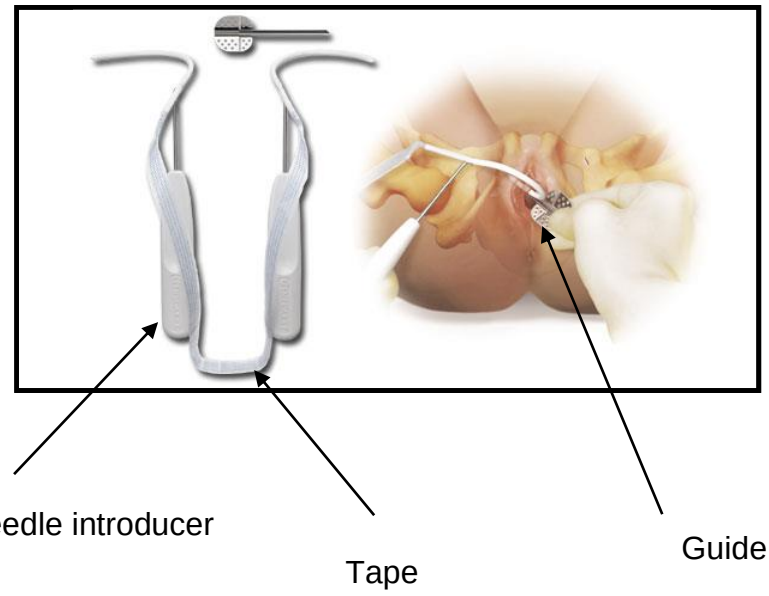


The needle is pushed through the groin incision and around the pubic bone into the vagina



The needle collects the tape which is pulled through the vagina to lie under the mid-urethra

Figure 4: Insertion of Trans-Obturator Tape (TVT-O) (Images courtesy Ethicon)



The needle is inserted from inside the vagina out through the groin carrying the tape with it. The same procedure is followed on the other side, The dotted line outlines the final position of the tape

After the operation (Post Operative Care) - both types of sub-urethral tape

- After the operation you will be taken back to the ward, where the nurses will check your blood pressure, pulse and wound.

- You may eat and drink immediately on return from theatre. A mild pain killer may be required.

- Most women do not have a catheter and can go home once they have urinated satisfactorily and been checked by a bladder scan that the bladder is empty.

- Some women will return from theatre with a urethral catheter to drain the bladder especially if an additional procedure such as a vaginal repair has been performed at the same time. Once this is removed and they have emptied their bladder satisfactorily they can go home.

- You may be given injections to keep your blood thin and reduce the risk of blood clots normally once a day until you go home or longer in some cases.

- The wound is not normally very painful but sometimes you may require tablets or injections for pain relief.

- There will be slight vaginal bleeding like the end of a period after the operation. This may last for a few weeks.

At home after the operation

- It is important to avoid straining particularly in the first weeks after surgery. Therefore, avoid constipation and heavy lifting.

- After any operation you may feel tired and it is important to rest, but not to take to your bed. It important to be up and about. Simply pottering around the house will use your leg muscles and reduce the risk of clots in the back of the legs (DVT) which can be very dangerous. Activity will also help to get air into your lungs and reduce infections.

- You can do pelvic floor exercises but build these up very gently. If you do too much it will be uncomfortable.

- You can have a shower the next day but it is advisable to keep puncture wounds clean and dry. They heal in about five days.

Avoiding constipation

- Drink plenty of water / juice
- Eat fruit and green vegetables especially broccoli
- Plenty of roughage e.g. bran/oats

- Do not use tampons, have intercourse or swim for 6 weeks as there is a risk of the tape eroding into the vagina

- There are stitches in the skin wound in the vagina. The surface knots of the stitches may appear on your underwear or pads after about two weeks, this is quite normal. There may be little bleeding again after about two weeks when the surface knots fall off, this is nothing to worry about. There may be stitches in the groins.

- At 2 weeks gradually build up your level of activity.

- After 4-6 weeks, you should be able to return completely to your usual level of activity.

- You should be able to return to a light job after about 3-4 weeks, and a busy job in 6 weeks. It is important to always avoid unnecessary heavy lifting.

- You can drive as soon as you can make an emergency stop without discomfort, generally after 2 weeks, but you must check this with your insurance company, as some of them insist that you should wait for six weeks.

- Follow up after the operation is usually six weeks to six months. This maybe at the hospital **(**doctor or nurse), with your GP or by telephone. Sometimes follow up is not required.

What the Medicines and Healthcare Products Regulatory Agency suggest?

In response to reported adverse events and concerns about mesh products the Medicines and Healthcare Products Regulatory Agency (MHRA), on behalf of the Department of Health (DOH), commissioned a review of evidence related to most frequent adverse events. The risks quoted in this leaflet are based on the MHRA report. It is now mandatory that any complications related to mesh are reported to the MHRA. In addition the MHRA have published a list of questions patients should discuss with their surgeon before proceeding with the surgery and these are listed below.

- Why have you chosen the use of surgical tape or a traditional non-tape repair in my particular case?
- What are the alternatives?
- What are the chances of success with the use of tape versus use of other procedures such as traditional surgery?
- What are the pros and cons of using tape including associated side-effects and what are the pros and cons of alternative procedures?
- What sexual problems may be encountered with use of tape and traditional surgery and/or other procedures?
- If tape is to be used, what experience have you had with implanting these devices?
- What have been the outcomes from the people whom you have treated?
- What has been your experience in dealing with any complications that might occur?
- What if the tape does not correct my problems?
- What other treatments are available?
- What can I expect to feel after surgery and for how long?
- If I have a complication related to the tape, can the tape be removed and what are the consequences associated with this?

References

You may find the address and websites useful to obtain more information. We can however bear no responsibility for the information they provide.

Bladder & Bowel Foundation
SATRA Innovation Park, Rockingham Road
Kettering, Northants, NN16 9JH

Nurse helpline for medical advice: 0845 345 0165
Counsellor helpline: 0870 770 3246
General enquiries: 01536 533255
Fax: 01536 533240

mailto:info@bladderandbowelfoundation.org
http://www.bladderandbowelfoundation.org/

http://www.nice.org.uk/nicemedia/pdf/word/CG40publicinfo.doc
www.continet.org.sg (International Continence Society)

http://incontinet.com (Resource on Continence)

Things I need to know before I have my operation.

Please list below any questions you may have, having read this leaflet.

1)……

2)……

3)……

4)……

5)……

6)……

7)……

8)……

9)……

Please describe what your expectations are from surgery.

1)……

2)……

3)……

4)……

5)……

6)……

7)……

8)……

9)……