

An Operation for Stress Incontinence

Tension Free Vaginal Tape - TVT (Retropubic tape)

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 (TVT BSUG F2)

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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.

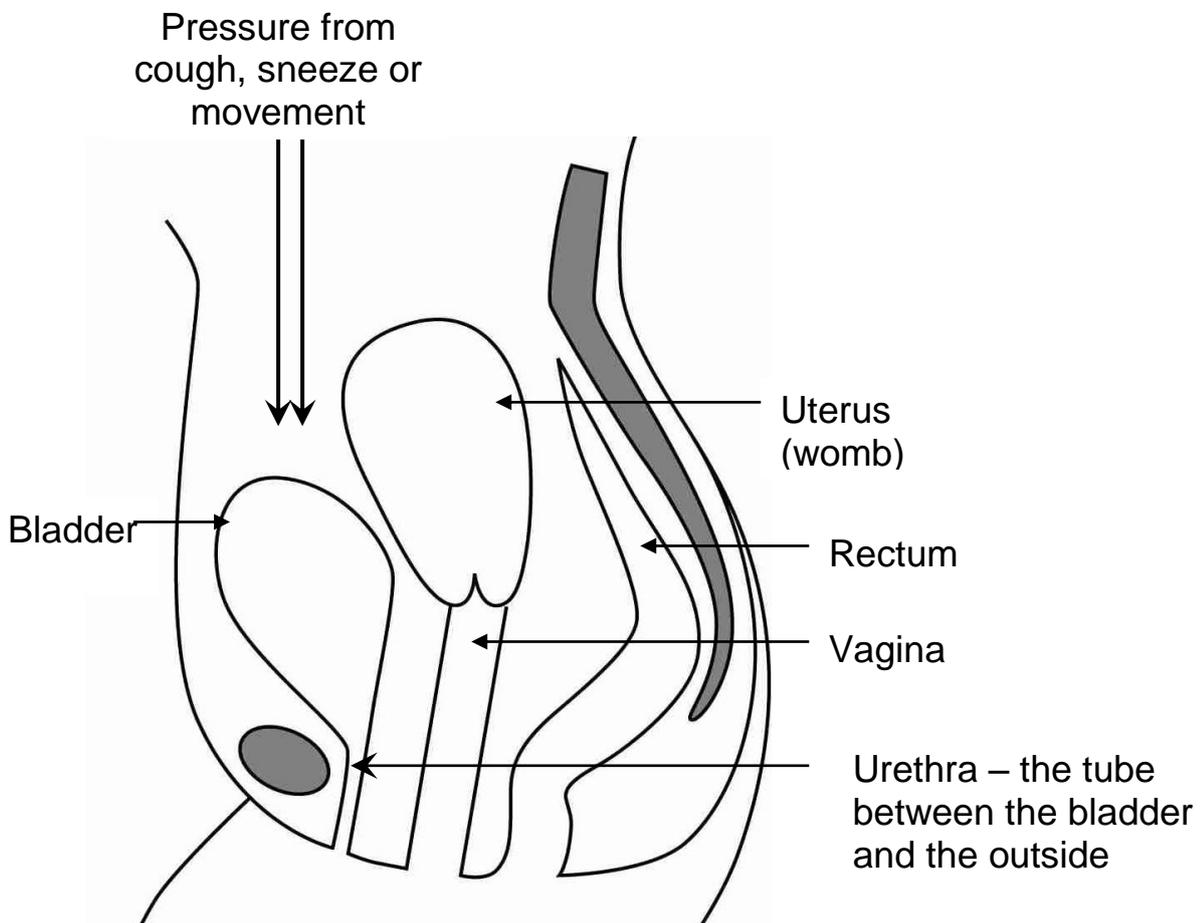
What is Stress Incontinence?

- Stress incontinence is the leakage of urine usually caused by an increase in pressure in the abdomen (tummy) when there is a weakness in the bladder neck.
- This weakness is usually caused by childbirth in the first instance 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 or even bends, turns or jumps and results in urine leakage. This can cause a lot of distress and limit ones 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 bladder neck. Many urinary symptoms seen in clinic are not caused by a weakness in the bladder neck.

Figure 1. Anatomy of a woman in the upright position showing pressure above the bladder with a weak bladder neck



When women 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 minimal and 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, vagina, bladder and rectum). 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 therefore give more support to the pelvic organs. These exercises may not get rid of the prolapse but they make you more comfortable. 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 being more comfortable.
- **Devices** - There are numerous devices (none on the NHS) which essentially aim to block the urethra. The devices are inserted into either the vagina or the urethra. They are not a cure but their aim is to keep you dry whilst in use, e.g. during 'keep fit' etc. A booklet is available if you require further information.

The Benefits of Stress Incontinence Surgery

- 85 - 90% women are substantially improved
- This means you may get back to:
 - Physical activity – running, dancing, gym etc
 - Horse riding
 - Gardening
 - Resume sexual relations if hindered beforehand
- 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, in the car etc
 - You do not have to worry about unpleasant odours

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.
- **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:** 10% (1/10 to 1/100 i.e. common) of women do not gain benefit from the operation, although the operation 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 tapes 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 need to change position to satisfactorily void.
- **Bladder overactivity:** (12% - 1/1 to 1/10 i.e. very common): 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).
- **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 excising. This may result in a return to theatre and may result in the operation being ineffective. Alternatively an attempt to re-cover the tape can be made. Very rarely the tape might erode into the urethra (urine pipe) or the bladder which would require a further operation as well. The risk of exposure is increased by smoking and with certain diseases.
- **Pain on intercourse:** This may arise from scar tissue in the vagina as a result of the incision. It is unusual but unpredictable.
- **Visceral trauma:** During the sub-urethral sling operations the needle used may traumatise an abdominal organ such as the bladder, bowel or urethra (urine pipe). This is rare but if occurs and is noticed at the time of surgery, it may require an abdominal incision (open tummy operation) to repair the damaged organ. If it is noticed after return from theatre to the ward it may necessitate going back to theatre for a general anaesthetic and an abdominal incision to repair the damaged organ.

The Operation - Tension-free Vaginal Tape procedure (TVT)

Facts and Figures

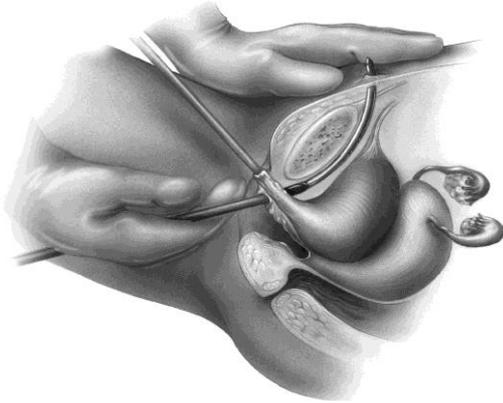
- This operation was invented in 1996 and more than 1 million procedures have been performed worldwide.
- 90% of women are substantially better after the operation. Some of these women will still leak from time to time e.g. with a bad cold in the winter (sneezing).
- It seems to be as effective as the traditional Colposuspension operation for up to 17 years after the operation.
- We don't know whether it will have complications in the long term.

How is the operation performed

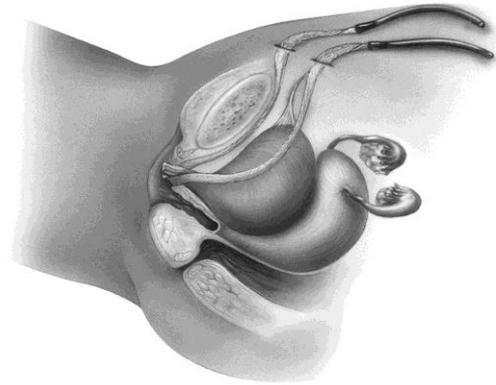
- If done under local anaesthetic, the relevant areas (vaginal wall under the urethra and abdominal wall) are injected with a fine needle and allowed to go numb with local anaesthetic. This will remove any sharp sensation but a pressure sensation will still be felt. Most women will also have a sedative into the veins and this will make you feel very sleepy. In these circumstances most women cannot remember the operation.
- A 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.
- A 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. How the tape is placed in position. (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

After the operation (Post Operative Care)

- 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. 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 will feel tired and it is important to rest. It is also important not to take to your bed. Mobilization is very important. 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.
- It is advisable to have showers rather than baths for three weeks and to keep puncture wounds clean and dry. They heal in about five days.

Avoiding constipation

- Drink plenty of water / juice (prune)
- Eat fruit and green vegetables esp broccoli
- Plenty of roughage e.g. bran / oats
- Do not use tampons, have intercourse or swim for 6 weeks otherwise you put yourself at 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 are also stitches in the tummy. These will dissolve too.
- 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. Leave a very heavy or busy job until 6 weeks.
- 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.

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.ics.org. (International Continence Society)

Things I need to know before I have my operation

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

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Please describe what your expectations are from surgery

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