SIMS

Standard vs. Mini-Slings

PATIENT INFORMATION LEAFLET

The purpose of this study is to compare the effectiveness of Mini-Slings Versus Standard Slings in the Surgical Management of Stress Urinary Incontinence in Women

Web address: https://w3.abdn.ac.uk/hsru/sims/

INVITATION TO TAKE PART

We would like to invite you to take part in a research study comparing two surgical treatments for stress urinary incontinence. Before you decide if you would like to do so, it is important for you to understand why the research is being done and what it will involve.

Please take your time to read the following information carefully, discuss it with your family, friends, or G.P. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information.

SIMS is funded by the National Institute for Health Research Health Technology Assessment Programme (NIHR HTA)

NHS
National Institute for Health Research

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BACKGROUND

Stress urinary incontinence is the involuntary leakage of urine during effort, exercise, or simply coughing/ laughing etc. It may be caused by weakness in the supporting structures of the bladder and the bladder outlet (urethra).

One of the current standard surgical treatments for stress incontinence is the mid-urethral sling (MUS). MUS involves insertion of a special sling (mesh tape) underneath the bladder outlet, to provide support to help prevent urinary leakage. The mesh tape is made of non-soluble polypropylene mesh, which is designed to be permanent after insertion. The procedure involves passing the mesh tape from the vagina to either the inner thigh or just behind the pubic bone to secure the mesh tape position. This usually requires the patient to have a general anaesthetic (i.e. put to sleep).

A new procedure, SIMS (Single Incision Mini-Slings), which is a mini version of the standard mesh tape has been developed. It uses less volume of the same type of mesh material as the standard mesh tape, and is less invasive to insert. SIMS is a recent development which is in routine clinical practice in a small number of hospitals in the UK. Other hospitals have offered the SIMS procedure to their patients within the context of research.

WHAT IS THE PURPOSE OF THE STUDY

Doctors and patient groups agree that a large study is needed to compare the new minimally invasive procedure (SIMS) to the standard mesh tape procedures. The study will inform surgeons, patients and decision makers about the effective and safe surgical treatments for stress urinary incontinence in women.

This UK-wide study will collect information from 650 women over 3 years following their surgery to see if the two procedures have similar results. This will be done by evaluating the questionnaires completed by participating women over 3 years following surgery. The questionnaires will ask women relevant questions about their everyday experiences associated with bladder and sexual function.

The results of this study will enable us to decide a) the most effective surgical treatment for stress urinary incontinence; b) the procedure with fewest associated risks and c) assist the NHS to decide which surgical procedure makes best use of the NHS and patient resources.

WHY HAVE I BEEN INVITED TO TAKE PART?

We are inviting you to take part in this study because you have been diagnosed with stress urinary incontinence and both you and your consultant have decided to proceed with surgical treatment in the form of a mesh tape procedure.

DO I HAVE TO TAKE PART?

It is entirely up to you whether or not you take part. Once you have read this information leaflet, ask your doctor (GP or hospital doctor) as many questions as you like, and also the research nurse who will be helping you at every stage of the study (if you decide to go ahead).

Whether or not you decide to take part in the SIMS study, you will receive the normal high standard of NHS care. You are also free to withdraw from the study at any time without giving a reason.

WHAT WILL HAPPEN IF I TAKE PART?

- Information and Consent:

The consultant in charge of your treatment or the local research team will give you full information about the study either in person or by sending you the information by post. If appropriate, a member of the local research team will discuss the study with you at the clinic or contact you by telephone to give you more information and answer any queries you may have.

After taking your time to consider the study and if you decide to take part, you will be asked to sign a consent form.

- Before Surgery:

The local research team will provide you with a baseline questionnaire which can be completed in the hospital or in the convenience of your home and returned in the pre-paid enveloped provided.

You will also be asked to do 2 simple tests, at your home, called the “pad test” and “home continence stress test” (you will receive an information sheet that explains these simple tests within the pack). You will not undergo any invasive examinations/ tests in this study.

If you agree, we will send you a text message reminder 48 hours before surgery to undertake these tests.

- Type of Surgery:

You have already decided, with your consultant, to undergo an MUS (mesh tape) procedure for treating your stress urinary incontinence.

The particular treatment given to each woman in the study will be decided at random by computer. There is an equal chance of being placed into either group: the standard surgery group or the SIMS group. The surgeons participating in this national study are well trained in both of these procedures.

If you are in the SIMS group: we recommend that the procedure will be done under local anaesthesia (with possible sedation) to obtain the full benefit. You will be accompanied by a nurse at all times for support. However, if you wish to have general anaesthesia, your wishes will be fully respected and you can still participate in the study. If so please make your choice clear to your hospital doctor or the research nurse.

- After Surgery:

In the first 2 weeks: We will ask you to record your pain score every day on a paper diary provided to you. If you agree, we will text you to ask that you send us these scores by free text messages as well as via the diary. We are aiming to find out if text messaging can replace paper pain diaries in future.

At 4 weeks after the operation you will complete the last section of your paper diary and send the completed diary by pre-paid post to the Study Office in Aberdeen.

At 3 months, 1 year, 2 years and 3 years: you will be sent a questionnaire similar to the one you completed at baseline. You will also be asked to repeat the “pad test” and “continence stress test” at home at 1, 2 and 3 years.

At approximately 20 months: we will send you a questionnaire to explore any personal expenses you may have incurred (e.g. hospital and/or GP visits.)

On return of your 3 month and yearly questionnaires: we will send you a token of appreciation for your time spent on completing the questionnaires. Please let us know, on the consent form, if you don't wish to receive such a token.

Towards the end of the study: we will send you a questionnaire to explore your views on the treatment you received.

Summary: The above information is summarised in the boxes below.

Before Surgery

- You will be asked to complete a questionnaire about the problems caused by your incontinence and how it affects your life
- You will be asked to complete 2 simple tests at home "pad test" and "continence stress test"
- You will return the completed forms to the local research team on the day of the operation or by post to the Study Office using pre-paid post.

After Surgery

- At days 1-14, you will complete a diary recording any pain you have had.
- At 4 weeks, you will complete a short questionnaire about your recovery period and satisfaction with your operation.
- You will then return the diary and questionnaire booklet to the Study Office using pre-paid post.

Later

- We will send you questionnaires by post at approximately 3, 12, 24 and 36 months after the operation to find out how you are progressing, how successful the operation has been and the impact it had on your quality of life.
- You will also be asked to repeat the “pad test” and “continence stress test” at home at 1, 2 and 3 years.
- We will also send you a questionnaire at 20 months to explore how much it cost you if you had to attend any hospital and/or GP visits.
- You will send us the completed forms by pre-paid post.
- On return of your 3m and yearly questionnaires we will send you a token of appreciation for your time spent completing the questionnaires.
- Towards the end of the study we will send you a questionnaire to explore your views on the treatment you received.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You may or may not benefit personally from taking part. By taking part, however, you will be directly helping us to inform the treatment of future patients with Stress Urinary Incontinence. The results of the study will help plan effective services offered by the NHS in the future.

WHAT ARE THE POSSIBLE ADVANTAGES AND DISADVANTAGES OF TAKING PART?

The MHRA published a report stating: “MHRA’s current position is that, for the majority of women, the use of vaginal mesh implants is safe and effective.”(MHRA report Nov 2014).

With the new types of SIMS procedures, small studies that followed up patients for relatively short periods (1-2 years) have shown the following results:

- It is well tolerated under local anesthesia, which may make the operation potentially safer for patients.
- It results in earlier recovery, return to work and normal activities.
- It can be less painful during and after the operation compared to trans-obturator mesh tape procedures.
- None of the studies have raised safety concerns specific to SIMS procedures.
- May achieve equal success rate to the standard mesh tapes. Possibly associated with higher chance of repeat surgery for stress urinary incontinence compared to standard MUS (mesh tapes).

However robust evidence is lacking especially on long-term effectiveness of this new procedure hence the need for this study.

We do not think that there are any possible disadvantages or additional risks to you taking part in the study. Whichever group you are allocated to, your operation will be performed by a competent and appropriately trained surgeon. There are always risks associated with all operations and anaesthetics as explained in detail below and in the surgical leaflet about the different operations. Every effort is made to ensure that these risks are minimised.

Late in 2015, the independent review groups in Scotland and England, set-up to evaluate the use of mesh in the treatment of prolapse and stress urinary incontinence, published interim reports. You can read the full reports and their recommendations here: http://www.gov.scot/Publications/2015/10/8485 *and* *https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf*

In-addition, the European commissioned review has published its final report (December 2015); you can read its summary and recommendations at this link: http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_27_en.htm

To make it easier, you can also access any of the above links on the public documents section of the study website (https://w3.abdn.ac.uk/hsru/sims/). In-addition, if you require a printed copy of the information please contact the SIMS study office (contact details are on the last page of this leaflet).

Full descriptions of the surgical procedures are detailed in the SIMS study surgical leaflet (appendix). More information can be found in the local surgical leaflet provided by your hospital; or national leaflets such as those provided by British Society of Urogynaecology (http://bsug.org.uk/patient-information.php) and the Scottish Government leaflet on “synthetic vaginal mesh mid-urethral tape procedures” (http://www.gov.scot/Resource/0045/00453999.pdf)**.**

The following information on possible risks (pages 13 to 17) is reproduced from the Scottish Government June 2014 publication: Synthetic Vaginal Mesh Mid-urethral Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women – Patient Information and Consent Booklet. These possible risks also apply to the SIMS surgical procedure. (This document is also available on the Scottish Government Website: www.scotland.gov.uk).

POSSIBLE RISKS OF THIS PROCEDURE

The tables below are designed to help you understand the risks associated with this type of surgery based on the RCOG Clinical Governance Advice, Presenting Information on Risk). The terms used to denote the degrees of risk in the main table are explained here:

Term	Equivalent numerical ratio	Equivalent environment
Very common	1/1 to 1/10	One person in a **family**
Common	1/10 to 1/100	One person in a **street**
Uncommon	1/100 to 1/1000	One person in a **village**
Rare	1/1000 to 1/10,000	One person in a **small town**
Very rare	Less than 1/10,000	One person in a **large town**

GENERAL RISKS OF SURGERY

Any surgical procedure has its risks and potential problems. The following are possible problems that you may experience:

- **Anaesthetic risks:** This is rare unless you have specific medical problems. Death is very rare. Your anaesthetist will discuss with you in detail.

- **Bleeding:** You should expect some vaginal bleeding after the operation. The risk of major bleeding, which is severe enough to need a blood transfusion, is small but it can happen with any operation.
- **Infection:** The risk of infection at any of the wound sites is common, and you will receive antibiotics in theatre to reduce such risk. One in ten women will need a course of antibiotic to treat a urine infection. Serious hospital-acquired infections (e.g. MRSA and Clostridium Difficile) are rare.
- **Deep Vein Thrombosis (DVT):** A clot in the deep veins of the leg. While the overall risk is common (4-5%), the majority pass unnoticed and resolve spontaneously. It is rare for a clot to migrate to the lungs and cause serious problem following day-surgery (less than 1% of those who get a clot). However, there have been deaths following such clots and, therefore, special stockings and/or injection to thin the blood are provided to all patients.

SPECIFIC COMPLICATIONS AND RISKS*

Complication	Risk
Mesh exposure (erosion) into the vagina	**Common**. The vaginal skin over the sling may not heal properly or get infected. Could also be due to inflammation, foreign body reaction or unusual immune response. It can happen years after surgery. Further surgery may be required to cover the sling or to partly remove it (please see below).*
Recognised damage to the bladder or urethra during the procedure	**Common**, especially with the retropubic approach. When discovered during the procedure, the sling is removed and replaced correctly. Long term problems

Complication	Risk
	following this complication are unlikely.
Failure of the procedure to stop urine leakage	**Common**. Persistence or recurrence of urinary leakage after some time. This can happen years after the sling has been inserted even if it cured your symptoms originally. You may need further surgery for incontinence and success rates may be lower.
Problems with the need to pass water more often than normal or having trouble getting to the toilet in time	**Common**. Overactive bladder symptoms are managed with physiotherapy and/or drug treatment.
Temporary problems emptying bladder fully	**Common**. May require short-term home catheterisation (indwelling or intermittent) for few days or weeks.
Temporary pain in the pelvic area or at the site of the sling insertion (the groin area or inner thigh in transobturator procedure) or during sexual intercourse	**Common**. Often resolves spontaneously or with painkillers.
Chronic pain in the pelvic area, at the site of the sling insertion or during sexual intercourse (due to vaginal scarring)	**Common** with transobturator tape, affecting the groin area and/or inner thigh. Could be due to nerve damage/irritation. **Uncommon** with retropubic tape. Repeat procedures to remove the sling may be necessary (see below).*

Complication	Risk
Persistent problems emptying bladder fully with recurrent urinary tract infections	**Uncommon**. May require further surgery to release, cut or remove the sling.* Urine leakage may return and you may need further surgery.
Mesh extrusion (erosion) into the urethra or the bladder	**Rare**. This may lead to fistula formation and can occur years after surgery. Could be due to spontaneous sling displacement or unrecognised damage to the bladder or urethra during the procedure. Requires further surgery to remove the sling (see below).
Injury to other organs such as bowel and major blood vessels	**Rare**. An abdominal operation may be necessary to resolve the problem.
Chronic problems emptying bladder fully	**Rare**. May require long-term self-catheterisation for months/years.
Death	**Very rare**.

*The risk levels quoted are those reported in medical literature and confirmed/endorsed by the National Institute of Health and Clinical Excellence. Data from large relevant registries are not yet available at the time of writing this leaflet.

*RISKS IF THE MESH TAPE IS TO BE REMOVED

Repeat procedures may be necessary and complete sling removal may not be possible to do safely. Referral to a different hospital (with a mesh removal team) may be required and, even after complete removal, symptoms may persist. Partial or complete removal of the mesh sling may result in the operation no longer working so you may need further surgery for incontinence.

FURTHER INFORMATION ON RISKS

- The risks of any surgical procedure are increased above the average risks if you have any significant medical conditions, if you are over-weight or if you have previously had surgery for a similar problem.
- The National Institute for Health and Clinical Excellence has produced further information regarding the risks of vaginal slings in August 2013. You are able to access this using the following link: http://publications.nice.org.uk/urinary-incontinence-cg171/recommendations
- The Medicines and Healthcare products Regulatory Agency (MHRA) produced further information regarding the risks of vaginal slings in November 2012. You are able to access this using the following link: http://www.mhra.gov.uk – go to search box and type 'synthetic vaginal slings'.
- The sling is a synthetic **mesh permanent** implant and **it is strongly recommended you consider this procedure only after your family is complete**. There is an anticipated increased risk of failure following pregnancy and childbirth. Please discuss with your GP and surgeon if you intend to have more children.

(End of information from Scottish Government publication)

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

If the study is stopped earlier than expected for any reason, you will be informed and your continuing care will be arranged as per the standard clinical care from the NHS.

Once the study is completed, the results will be analysed and will inform the NHS on the best clinically effective and cost-effective procedure to be offered as primary surgical treatment for stress urinary incontinence in women.

WHAT IF THERE IS A PROBLEM?

We do not expect any harm to come to you by taking part in this study. All procedures performed in this study are already being used in the NHS to treat patients with stress urinary incontinence.

However, if you believe that you have been harmed, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen. Sponsor contact details are available through the research team.

Taking part in this study does not affect your legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS, which include professional indemnity insurance for negligence. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the usual National Health Service complaints procedures would be available to you.

If you become unable (for any reason such as severe un-related illness) or unwilling to continue in the study, we would withdraw you from further participation. A member of the research team will contact you by mail/telephone and complete a “change of status form”, which includes your instructions on which parts, or whole, of the study you may wish to withdraw from. We will keep the relevant information already collected about you up to that point, for the study results. This information will remain confidential and will not be used for any other purpose.

If you have private medical insurance you should check with the company before agreeing to take part in the study. We do not know of a reason, however, why participation might affect your medical insurance.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the Patient information leaflet (PIL) may be updated.

This has already happened with the new information from the MHRA report and the Scottish, English and European expert review groups' publications which are included in this updated version of the PIL. The SIMS Study Office staff may contact you to let you know about the new information and any action that needs to be taken. We will also use the study website to keep you updated.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. All information collected about you during the course of the research, including information you provide in your questionnaires, will be kept strictly confidential, and will only be seen by those who have a "need to know" i.e. the relevant personnel in the research team. Your clinical team and your local doctor (GP/Consultant) will not normally have access to this information. It will be held securely in accordance with the Data Protection Act 1998.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for example, to send you the questionnaires.
We will inform your GP that you are taking part, but only with your permission.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with Stress Urinary Incontinence. We shall publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The research is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme i.e. NHS funded. This study is being co-ordinated by the Centre for Healthcare Randomised Trials (CHaRT); a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED AND APPROVED THE STUDY?

This study has been approved by the North of Scotland Research Ethics Committee.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsors and the Research & Development Department of your local hospital, whose roles are to check this research is properly conducted and the interests of those taking part in this study are protected.

Other researchers may wish to access data from this study in the future. However, your confidentiality will be maintained as data will not include personal details.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the SIMS study. Please ask us if you have questions or would like more information about the study.

INDEPENDENT CONTACT

If you would like further information on the study from an independent contact, the SIMS study office can put you in touch with the Chair of the Independent Steering Committee.

APPENDIX – SURGICAL LEAFLET

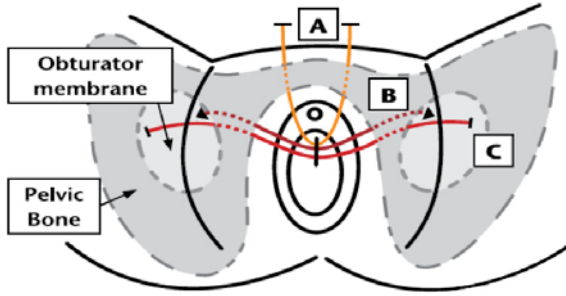
Mid-urethral slings (tension-free vaginal tapes)

for the treatment of

Female Stress Urinary Incontinence

(TVT/TOT/TVT-O/SIMS)

Surgical Information for patients



Figures: A TVT — Retropubic TVT

B SIMS — Single Incision Slings

C TVT-O /TVT — Transobturator Tapes

You have decided with your consultant to undergo a mid-urethral sling (MUS – tension free vaginal tape) procedure for treating stress urinary incontinence as per best NHS practice in your local hospital. You would have discussed, with your consultant, all other options for treatment of stress urinary incontinence (SUI) including non-surgical treatment (physiotherapy) and other surgical operations.

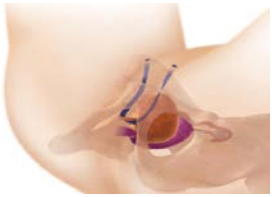
This leaflet aims to provide information about the mid-urethral tension-free vaginal mesh tape operations to treat stress urinary incontinence in women and the likely plan of care after the operation. It should be read in conjunction with the local information leaflet provided by your hospital or national leaflets such as British Society of Urogynaecology or the Scottish Government leaflet.

WHAT DO THESE OPERATIONS INVOLVE?

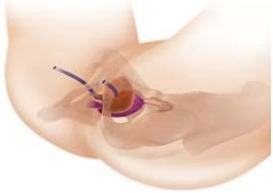
These are minimally invasive procedures, which take about 15 - 30 minutes in the operating theatre. A synthetic polypropylene mesh in the form of a tape is placed via a small cut in the vagina to create a "hammock" under the urethra (the tube coming out of your bladder). The tape eventually becomes integrated into your body and forms an extra ligament that supports the urethra and is intended to prevent leakage at times of effort, coughing, sneezing, etc. This tape is intended to be permanent.

There are usually three cuts associated with these procedures. The stitches will dissolve and don't need to be removed.

For the **Retropubic vaginal mesh tape (TVT™)** procedure, one cut is in the vagina and the other two cuts are just above your pubic bone.



For the **Transobturator vaginal mesh tape (TVT-O™ and TOT)** procedures, one cut is in the vagina and the other two cuts are in the groin on either side.



There are different brands and makes of the devices used in these procedures. They all aim to produce the same end result.

These procedures can be done in the day surgery unit, or as inpatients depending on the medical conditions and social circumstances of the patient. They are most commonly done under general anaesthesia, unless spinal anaesthesia is advised due to certain medical conditions. In some settings the retropubic TVT™ procedure can be done under local anaesthesia and intravenous sedation.

SINGLE INCISION MINI-SLINGS (SIMS)

Recently, a new and modified way of inserting a shorter vaginal mesh tape has been described using a single cut in the vagina and no cuts on the skin (i.e. one cut only instead of three – Figure B).

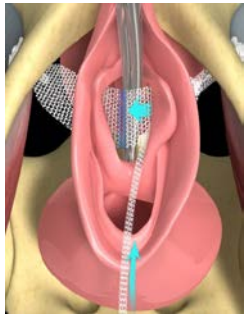


Figure B

This new procedure is designed to create the same hammock under the urethra (tube coming out of the bladder) as in the standard tape procedures described above, however using a shorter version of the same tape material. SIMS is usually attached using a special anchor to the obturator internus muscle and membrane (side-wall of the pelvis).

However, the SIMS procedure avoids passing through the groin muscles and therefore reduces the risk of the groin pain associated with the transobturator TVT-O™ procedure. It

WHAT IS THE SUCCESS RATE OF THESE PROCEDURES?

85 - 90% of patients will have their stress incontinence either cured or significantly improved by these procedures at one-year follow-up. The success rate depends on a number of factors that are assessed before the operation. Please discuss these with your surgeon.

The **retropubic TVT™ procedure** has the longest follow-up data. Recent research showed that the success rate is around 75% with up to 10-15 years follow-up.

The **TVT-O™ & TOT procedures** have shown similar medium-term success rates to the TVT™ procedure, with 70-75% with up to five years follow-up. One large study showed the patient-reported success rate of 71% at 9-years. Longer follow-up of the transobturator tapes is yet to be assessed.

Women with previous unsuccessful continence procedures have considerably lower success rates depending on the reason why the first operation failed. The treatment of urinary incontinence in women with previous failed continence surgery should only be performed by specialists in continence surgery and is outside the scope of this leaflet.

Research in the UK, USA and Europe has shown that:

- **SIMS procedures** are associated with a good safety profile, comparable to the standard tape procedures (TVT/TOT/TVT-O).

- Women reported significantly lower pain scores during and after the operation, enabling it to be done under local anaesthesia for the majority of women, which may be safer.

- Women undergoing SIMS procedures were able to leave the hospital, return back to their normal activities and to work in a significantly shorter time in comparison with the standard tape procedures.

- 80% of women reported successful outcome following SIMS procedure at 1-year follow-up. This is comparable to the success rate of women undergoing the standard TVT-O procedures in the same study.

- However, there is currently little data on the long-term outcome of this relatively new procedure. Therefore, this procedure is mainly offered within research projects or for selected patients, depending on their associated medical conditions.

WILL THIS OPERATION CURE THE SENSATION OF "URGENCY"?

It is important to know that although "urgency" (the overwhelming sensation of needing to pass urine) might improve in 50-60% of patients after surgery, it may persist in 30-40% or get worse in 10-15% of patients after the operation. New onset urgency is reported in 10-20% of cases.

WHAT ARE THE POTENTIAL COMPLICATIONS OF THE SURGERY?

These procedures are generally safe with minimal hospital stay (average of one day). However, potential complications include:

- **Injury to the bladder (1-10%) or urethra (1-2%)** i.e. the introducing needle creating a small hole. This risk is higher in the retropubic TVT approach. It is usually recognised at the time of surgery and in most cases does not require stitches. A catheter is left in the bladder for up to 10 days after the operation (depending on the injury). There is usually no long-term effect of this complication and you do not have to stay in hospital during that period.

- **Incomplete emptying of the bladder (10-15%)** of patients, but usually resolves within few days. The risk is higher with the retropubic TVT approach. You may have to go home with a catheter for a few days (5-7) to allow the bladder to rest and then come back for catheter removal. You may need to be taught clean intermittent self-catheterisation (CISC) for a short period (3-6 months) after the operation. Occasionally this may persist for more than six months and/or lead to recurrent infection in the lower urinary tract (recurrent cystitis)

- **Groin pain**: This risk is higher in the transobturator approach. It is generally mild and transient for 2-4 weeks and occurs in 10-26% of patients. However, some (4%) of women describe it as marked pain. It is more common with TVT-O™.

- **Mesh extrusion/ Exposure (5%):** the vagina does not heal properly leading to exposure of the mesh. This usually occurs within the first 6 months after the operation, however may occur several years later. Patients usually present with vaginal discharge and or pain during intercourse; this may require an extra procedure to remove the eroded part of the mesh and re-approximate the vaginal walls – can be done under local anaesthesia. Multiple procedures may be required, though this is uncommon.

- **Mesh Erosion (≤1%):** This represents true erosion of the mesh into a nearby organ such as the urinary bladder, or the urethra (tube that carries the urine from the bladder to the outside). This is a serious complication as it requires major and difficult operation(s) to fix the erosion and reconstruction of nearby organs. In some cases permanent damage has occurred.

- **Mesh Erosion/ Extrusion** may be higher in women with previous unsuccessful continence procedures, in women with increased bodyweight, in smokers and those undergoing other surgery at the same time, such as repair of a prolapse.

- **Bleeding:** Rarely insertion of the tape can cause an injury to one of the big blood vessels in the pelvis leading to severe bleeding that may require extra procedures to stop bleeding and blood transfusion (<1%). This is more common in the retropubic TVT.

- **Chronic Pain (Hip / Thigh / Vagina or Pelvic pain):** The risk is (1-5%) being higher in the transobturator approach. In some cases it can be difficult to treat and may require long-term pain killers or surgical removal of the mesh tape.

- **Nerve Damage:** this is an uncommon complication that can accompany any of the mesh tape procedures (and indeed any type of surgery for stress urinary incontinence) due to accidental injury of nerves during the procedure. This can lead to long-term pain and/or muscle weakness depending on the inured nerve.

- **Removal of mesh** can be difficult and it may be impossible to be removed completely. This may require long hospitalisation and can lead to long-term complications and permanent scarring.

HOSPITAL CARE AFTER THE OPERATION

The nursing staff will assess your ability to pass urine normally. Each time you void (empty) your bladder we will measure how much urine is voided. The amount of urine remaining in your bladder will be assessed, usually using a portable simple ultrasound machine. Once you are voiding satisfactorily and the amount of urine left in your bladder after voiding is small, you may be allowed home, if all else is well.

As mentioned above, 80% of patients achieve satisfactory voiding within a few hours after these procedures. In some cases, it might take 48 hours or up to a week to achieve this, during which you may be sent home with a catheter for a few days. In few patients this voiding

difficulty may persist for a few months, possibly requiring surgical slackening of the tape or self-catheterization (CISC). If your operation was under spinal anaesthesia, you will routinely have a catheter for an average of six hours after the operation.

INSTRUCTIONS AND ADVICE WHEN YOU GO HOME

Depending on the type of procedure performed, most women will feel back to normal within a few days to 1-2 weeks after the operation. You can go back to work/day-to-day activities (not including heavy lifting) as early as you feel appropriate – usually 2 weeks.

You may feel sore for 1-2 weeks after your operation, but you will be given painkillers which you may take when you feel they are needed. You should avoid constipation, lifting anything heavy such as heavy laundry or children, or strenuous exercise / work for 4-6 weeks. You are encouraged to be mobile at home and you can start doing light ordinary household duties and light exercise (not including heavy lifting) when you feel you are ready.

To minimise the risk of infection, you will be asked to avoid sexual intercourse, bathing, swimming and using tampons for 2 weeks. You can shower as many times as you wish.

You should delay driving until you are fully mobile and able to do an emergency stop. You should also check with your insurer before driving.

You are encouraged to do pelvic floor exercises within 1-2 weeks after the operation. For more information on recovery, please visit the following web link: https://www.rcog.org.uk/en/patients/patient-leaflets/mid-urethal-sling-operation-for-stress-urinary-incontinence/

FURTHER RECOMMENDATIONS

- "Bracing" of the pelvic floor whenever there is any raise in intra-abdominal pressure (cough, sneeze, lift, shout etc.).

- Healthy fluid habits.
  - Avoid caffeine and fizzy drinks
  - Drink three pints of water and simple juice per day.

If you get a sensation of incomplete emptying, try regular "double voiding," i.e. every time you go to the toilet empty your bladder twice with 10 minutes apart; do not push to empty your bladder.

Get out of the habit of going to the toilet "just in case".

PREGNANCY AND MID-URETHRAL SLINGS (MESH TAPES)

This procedure is recommended only for those who have completed their family, as any future pregnancy *might* negate the effect of this type of surgery.

WHAT HAPPENS IF I FEEL UNWELL AFTER I GO HOME?

You may expect some minor bleeding, especially some old, brownish blood for two weeks. If you experience fresh bleeding or unusual vaginal discharge, or if you have any other concerns, you should contact your GP.

Thank you for your time in reading this leaflet.
If you have any queries, please discuss with your surgeon before the operation.

This leaflet has been produced by Dr. Abdel-fattah (Sub-specialist Urogynaecologist) and peer reviewed by four urogynaecologists (two of whom are independent of the SIMS trial) and the two SIMS trial Patient Public Involvement (PPI) representatives. Further information on the peer reviewers can be obtained by contacting the trial office on 01224 438180 or sims@abdn.ac.uk.

FURTHER INFORMATION AND CONTACT DETAILS

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