

**The Colposuspension Procedure (Open and Laparoscopic) for the surgical treatment of stress urinary incontinence**

**Information Leaflet and Consent Form**

**Obstetrics & Gynaecology**

**Queen Elizabeth University Hospital**

**1345 Govan Road,**

**Glasgow,**

**G51 4TF**

**☎ 0141 201 1100 Ask for Gynaecology Ward.**

**About this leaflet**

This leaflet gives you information about the surgery being offered and also other options. It includes advice from Scottish consensus panels, the relevant national organisations and other evidence-based sources, for example the Cochrane Collaboration and National Institute of Health and Clinical Excellence. The information is made up of the best practice in the UK. The information aims to supplement any advice you may already have been given by your family doctor (GP) or surgeon.

Please take your time to read it carefully. Then, write down any questions and what you hope the surgery will do for you to discuss with your surgeon before you sign the information checklist.

***Acknowledgement:***

This leaflet contains information based on original developed by the Scottish Government Working Group with input from:

* British Association of Urological Surgeons (BAUS);
* Royal College of Obstetricians and Gynaecologists (RCOG),
* Pelvic, Obstetric and Gynaecological Physiotherapy Professional Network of Chartered Society of Physiotherapy; and
* Patient Support Groups, with reference to national guidance.

***Disclaimer:***

The authors cannot be held responsible for errors or any consequences arising from the use of the information contained. As current evidence is incomplete and further evidence will be available in due course, the West of Scotland Regional Planning Group will review and consider updating this leaflet every two years. Please make sure you are reading the up-to-date document.

**What the terms in this leaflet mean:**

|  |  |
| --- | --- |
| ***Bladder Neck*** | Where your bladder and water-pipe meet |
| ***Catheter*** | A flexible tube to drain urine from the bladder after surgery which is put in for a short time |
| ***Catheterise*** | To put in a catheter to drain urine from the bladder after surgery |
| ***Cystoscopy*** | Keyhole surgery to the bladder |
| ***Fascia*** | A sheet of supporting fibrous tissue that holds body organs in their correct positions |
| ***Laparoscopy*** | Keyhole surgery to the abdomen (tummy) |
| ***Pessary*** | A removable device placed inside the vagina to support the pelvic organs |
| ***Retropubic Space*** | This is the space behind the pubic bone and in front of the bladder. This is where the suspension stitches are placed using your own tissues during the surgery. |
| ***Urethra*** | The water-pipe from the bladder to the outside |
| ***Open Surgery*** | A lower bikini-line cut is made on your abdomen (tummy) |
| ***Laparoscopic (keyhole) surgery*** | One small cut is made in the belly-button and two to three smaller cuts are made in the lower abdomen. |

**What is stress urinary incontinence?**

Your bladder and urethra are supported by your pelvic floor muscles and ligaments (tissue that connects bones to other bones). If this support is weakened (for example, after childbirth and, or menopause), it can lead to urine leakage when coughing, sneezing, laughing or when lifting and exercising.

**What is the colposuspension procedure?**

This is an abdominal (tummy) procedure which involves placing two or three stitches in the vagina on each side of the bladder neck to support it.

IMAGE TO BE INSERTED

**What are the benefits?**

* The main benefit of the colposuspension procedure is to cure or improve your stressurinary incontinence.
* Studies have shown similar success results to those obtained by vaginal mesh tape and the sling procedures that use your own tissues.
* The procedure will not improve symptoms of an overactive bladder (urinary frequency, urgency, urgency incontinence or waking up at night to pass urine). This is a different condition that can sometimes improve after this type of surgery but can sometimes get worse.

**During the procedure**

* This is an abdominal surgery and you normally spend two to three nights in hospital. We will give you a general and, or spinal anaesthetic. Your anaesthetist or surgeon will talk to you about the type of anaesthesia you need and this depends on the kind of surgery you are having, your health as well as your wishes.
* **Open colposuspension:** A lower bikini-line cut is made on your abdomen (tummy) to access the retropubic space (where the bladder lies just behind the pubic bone). Two or three stitches are placed in part of the vagina on each side of the bladder neck. These are then tied to the ligament behind the pubic bone to provide support to the bladder neck. These stitches may be permanent or may dissolve after sometime. Permanent stitches remain inside your body for life. Dissolvable stitches remain inside until your own tissues take over the support. You may have an abdominal drain after the procedure to remove any excess blood.
* **Laparoscopic colposuspension:** Some hospitals in Scotland can offer this. Instead of abikini-line cut, one smaller cut is made in the belly-button and two to three smaller cuts are made in the lower abdomen.
* You may have a cystoscopy (telescopic examination of the bladder) during the procedure and you will have a urinary catheter inserted after the procedure.

**After the procedure**

* We will take you back to the ward, where the nurses will look after you. We can give you painkillers to help with any pain and you may eat and drink shortly after your surgery.
* We may give you elastic stockings and injections to keep your blood thin and reduce the risk of blood clots. You will normally get this injection once a day until you go home, or longer in some cases.
* We will remove your catheter, usually after 24 to 48 hours and check that you are emptying your bladder. We use a bladder ultrasound scan and once staff are happy that your bladder empties well, you can usually go home two or three days following the procedure.

If there is any concern with your bladder emptying, we will offer you intermittent self catheterisation (ISC) or we will leave a catheter inside your bladder for three to seven days. (Intermittent self catheterisation involves passing a small catheter in and out of your bladder yourself 4-5 times a day, through your urethra, to empty your bladder). We will ask you to come back to the hospital to make your bladder is emptying well.

**The first few days and weeks:**

* Recovery time is around six weeks; however, you may go back to your everyday activities after four weeks.
* Care for your abdominal wound is similar to that after a caesarean section or open hysterectomy.
* You can drive as soon as you can make an emergency stop without discomfort. This is about three weeks after but you must check this with your insurance company as some of them insist that you should wait for six weeks.
* There is no restriction, if you feel able to do so, on doing light activities in a few days, and normal activities after a few weeks. You should wait for six weeks before doing more difficult tasks and heavy lifting.
* To let your wound heal comfortably, you should refrain from sexual intercourse and inserting any creams or devices for six weeks after your procedure, unless your doctor tells you.
* Make sure you drink plenty of fluid and eat fruit and vegetables to stop you becoming constipated. You may need laxatives may be needed to help your bowels work better.
* Your return to work will depend on the type of work you do. Please ask your doctor for their opinion and also if you require a ‘Fitness for work’ certificate.
* We would advise you to continue with the physiotherapy advice you were given beforeyour procedure\*.
* You will have a follow-up appointment usually 2-6 months after your procedure (in clinic or by phone).

\*For more information on physiotherapy following your procedure, please ask your doctor or visit the following web link: http://www.csp.org.uk/sites/files/csp/secure/pogp-ffsurgery1.pdf

**Other Options:**

There are several non-surgical and surgical treatment options for women with stress urinary incontinence. Non-surgical treatment options:

Your doctor should talk to you about these options before considering surgery.

* Pelvic floor muscle exercises are the most effective non-surgical treatment. Many women who have undergone training supervised by a physiotherapist may not need surgery.
* Weight loss is an effective treatment option for overweight women with stress urinary incontinence. Please talk to your GP about this.
* Drug treatment (Duloxetine tablets) may also be a suitable option for some women.
* Continence devices: These are placed inside the vagina or urethra and may occasionally be useful for managing urine leakage such as during physical exercise.
* Absorbent products such as incontinence pants or pads may offer extra ways of managing urinary problems for some women.
* Do nothing: If the leakage is not troublesome, no treatment is an option.

**Surgical treatment options\*:**

If non-surgical treatment options have not been successful or are not appropriate or suitable, you may want to discuss the following surgical procedures with your doctor:

* **Mesh Tape:** Vaginal surgery to place a polypropylene mesh tape underneath the water-pipe.
* **Autologous Fascial Sling:** Combined abdominal - vaginal surgery to lift the urethra using a natural sling (hammock-like) from your own body tissue.
* **Urethral bulking agents:** Vaginal surgery where a synthetic ‘bulking’ material (absorbable or permanent) is injected in or around the water-pipe to improve the seal.

Please ask your doctor for leaflets which tell you more about these options. There is more information about the pros and cons of these on the following website:

www.nhs.uk/Conditions/Incontinence-urinary/Pages/treatmentoptions.aspx

\*Please note your surgeon may not provide all of these procedures and we may refer you to another surgeon or hospital.

**Possible Risks of Surgery\*:**

The tables below are to help you understand the risks associated with surgical procedures. The terms used to show the degree of risk in the main table are explained here:

|  |  |  |
| --- | --- | --- |
| **Term** | **Rate** | **Example** |
| Very common | Up to 1 in 10 | A person in a family |
| Common | Up to 1 in 100 | A person in the street |
| Uncommon | Up to 1 in 1000 | A person in a village |
| Rare | Up to 1 in 10000 | A person in a small town |
| Very rare | Less than 1 in 10000 | A person in a large town |

\*Based on the RCOG Clinical Governance Advice, Presenting Information on Risk

**General Risks of Surgery**

Any surgical procedure has risks and potential problems. Listed below 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 talk to you about this.
* **Bleeding:** You should expect some vaginal bleeding after the surgery. The risk of major bleeding, which is severe enough to need a blood transfusion, is common but it can happen with any surgery.
* **Infection**: The risk of infection with any surgery is common, and we will give you antibiotics in theatre to reduce this risk. Even though we will give you routine antibiotics, urine or wound infection is common. Serious hospital-acquired infections (for example, 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, most go unnoticed and mend on their own. It is rare for a clot to travel to the lungs and cause serious problem. However, there have been deaths following such clots and, therefore we will give you special stockings and, or injections to thin the blood.

**Specific Complications and Risks of the Autologous Fascial Sling procedure\***

|  |  |
| --- | --- |
| ***Complication*** | ***Risk*** |
| Recognised damage to the bladder during the procedure | Common and may require surgical repair. No long-term problems have been found following this complication |
| Failure of the procedure to stop stress urinary incontinence | Common - Stress urinary incontinence can return after some time. This can happen years after the procedure even if it cured your symptoms to begin with. You may need further surgery for stress urinary 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 (urgency) may worsen or develop after surgery. These are managed with bladder retraining, physiotherapy and, or drug treatment. |
| Short-term problems with emptying bladder fully | Common - May require catheterisation (indwelling or intermittent self-catheterisation) for a few days or weeks. If needed, we will offer you training on how to carry out intermittent self-catheterisation. |
| Short-term pain in the wound, pelvic area or during sexual intercourse....  | Common - Often mends on its own or with painkillers |
| Feeling of a bulge coming down due to pelvic organ prolapse | Very Common - Often in the back wall of the vagina and may require treatment. |
| Long-term pain in the pelvic area, at the site of the stitch or during sexual intercourse | Uncommon - Could be due to closeness of stitch to the bone. Inflammation of the bone (osteitis) may require removal of the stitch. |
| Continued problems emptying bladder fully with regular urine infections | Uncommon - May require intermittent self-catheterisation (ISC) or further abdominal surgery to release, cut or remove the stitch. Stress urinary incontinence may return, and you may need further surgery |
| Long-term problems emptying bladder fully | Uncommon - May require long-term intermittent self-catheterisation for months or years. |
| Stitch moves into the bladder | Rare and can happen years after surgery. May need further surgery to remove the stitch (see further notes below). |
| Injury to other organs such as ureter, urethra, bowel and major blood vessels | Very rare - A second abdominal surgery may be needed to fix the problem. |
| Death | Very rare |

\*The risk levels quoted are those reported in medical literature and confirmed and approved 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. As current evidence is incomplete and further evidence will be available in due course, this booklet will be updated every two years. Please make sure you are reading the up-to-date version.

**Further notes on risks:**

* **Risks if the permanent stitch requires removal:**

A permanent stitch can be completely removed during cystoscopy (keyhole surgery to the bladder) or through the same tummy cut(s) you had initially. Complete removal of the permanent stitch may result in the surgery no longer working. You may then wish to consider further surgery for incontinence.

* **Your individual risk:**

The risks of any surgical procedure are increased above the average risks if you have any significant medical conditions (such as diabetes), if you smoke, are over-weight or if you have had previous abdominal surgery or had surgery for a similar problem. Please talk to your surgeon about your own individual risks.

* **Pregnancy and Childbirth:**

We highly recommend you do not consider this procedure until your family is complete. While it will not affect your ability to become pregnant, there is an increased risk the colposuspension procedure will not work after pregnancy and childbirth. A Caesarean section may be recommended to reduce this risk. Such recommendation applies to women following all types of surgery for stress urinary incontinence. Please talk to your GP and surgeon if you intend to have more children.

**Risks of not having this procedure (Doctor to document in space provided)**

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**Is there any research being carried out in this area?**

There may be national and local research studies in these areas and we may ask you to participate.

Useful Resources

* The British Association of Urological Surgeons – Colposuspension Procedure www.baus.org.uk/\_userfiles/pages/files/Patients/Leaflets/Colposuspension.pdf

http://www.baus.org.uk/search/?q=sling%20female%20synthetic

* The British Society of Urogynaecology – Colposuspension Procedure

http://bsug.org.uk/userfiles/file/patient-info/Colposuspension%20for%20Stress%20Incontinence-%20COLP%20BSUG%20F1.pdf

* Bladder and Bowel Foundation www.bladderandbowelfoundation.org
* The Pelvic, Obstetric and Gynaecological Physiotherapy Professional Network of the Chartered Society of Physiotherapy www.pogp.csp.org.uk
* NHS Inform Website:
https://www.nhsinform.scot/illnesses-and-conditions/kidneys-bladder-and-prostate/urinary-incontinence#surgery-and-procedures-for-urinary-incontinence

Note: If you do not have access to Internet, please ask your GP or Surgeon for paper copies of these leaflets.

***Disclaimer: Apart from NHS Inform, NHS Scotland is not responsible for the content and does not necessarily approve the information published in the above websites.***

**Questions to my Surgeon**

Having read the leaflet, please write down any questions you may have to ask your surgeon.

**Example questions:**

* Is this type of treatment right for me?
* What are the pros and cons of the different procedures available?
* Is my own individual risk different from those mentioned in the leaflet?
* Are you adequately trained to do this procedure?
* Are your success and complications rates comparable to national figures?
* What happens if surgery does not work?
* What would happen if I had a complication?
* Is there anything I can do myself to help make my surgery more successful?

**What I hope to get out of the surgery?**

What do you expect the surgery to do to you?

What activity do you expect to be able to do again after surgery?

**Example expectations:**

* Have less urinary leakage and use less protection (for example, pads).
* Be able to exercise or do sport regularly.
* Be dry and stop using pads and protection.
* Be more socially confident.
* Enjoy sexual life in general.

**Contact Telephone Numbers:**

**Queen Elizabeth University Hospital –**

* Ward 49 - 0141 201 2282
* Pre-assessment – 0141 201 2286
* Same-day Admission Unit – 0141 201 1488

**Notes**

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**Information Checklist\***

Please read the following points and write your initials in the boxes next to each statement.

I confirm that I have read and understood, to the best of my ability, all the information in the booklet including:

* The details of the procedure proposed and the desired outcome
* All available alternatives of this procedure and their advantages and disadvantages
* All information on possible risks including my own
* All my questions were answered

**Signatures**

Signed (Patient):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Patient(Print):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed (Health professional) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*This is not a consent form .This information checklist ensures your understanding of all the important information regarding this procedure. Your surgeon will then ask for your consent to undergo the procedure by signing a separate document.

**Consent Form**

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The Colposuspension Procedure (open and laparoscopic) for the Surgical Treatment of Stress Urinary Incontinence in Women.**

**A . Statement of health professional (details of treatment, risks and benefits)**

I confirm I am a health professional with an appropriate knowledge of the proposed procedure, as specified in the hospital’s consent policy.

I have explained the procedure to the patient. In particular, I have explained:

* The above intended benefits of the procedure as follows: To cure or improve stress urinary incontinence. This is not intended to improve symptoms of an overactive bladder (urinary frequency, urgency or waking up at night to pass urine).
* The possible risks involved as discussed above in details (including those specific to the patient).
* The benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of the patient.

**Any additional procedure(s) that might become necessary during surgery such as:**

**Any competing interests I may have regarding the material used in this procedure:**

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**This procedure will involve: (tick all that apply)**

* General and, or regional anaesthesia
* Local anaesthesia
* Sedation

**Consultant or other responsible health professional**

Signed (health professional):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time (24 hour): \_\_\_\_\_\_\_\_\_\_\_

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_GMC number: \_\_\_\_\_\_\_\_\_\_\_

**Consent Form**

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The Colposuspension Procedure(open and laparoscopic) for the Surgical Treatment of Stress Urinary Incontinence in Women**

**B . Consent of patient or person with parental responsibility**

I confirm that all information has been discussed with me and my questions have been answered to my satisfaction and understanding.

**I acknowledge that the doctor has explained:**

* The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
* My expected outcome and the risks of not having the procedure.
* That no guarantee has been made that the procedure will improve my condition even though it has been performed with due professional care.
* Other relevant procedure or treatment options and their associated risks.
* That a qualified doctor undergoing training may perform the procedure under the supervision of my consultant.
* I agree £
* I disagree
* The right to change my mind at any time, including after I have signed this form.

**On the basis of the above statements:**

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood all the patient information in the booklet about this procedure.

I understand all the possible risks and I agree to the procedure.

Signed (Patient): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Patient (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Confirmation of consent (where the procedure has been discussed in advance).**

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wishes the procedure to go ahead.

Signed (health professional): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Time (24 hour): \_\_\_\_\_\_\_\_\_\_

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