

WOMEN'S HEALTH PARTNERS, LLC

DIPLOMATES AMERICAN BOARD OF OBSTETRICS & GYNECOLOGY

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PROCEDURE EDUCATION LITERATURE

We recommend that you read this handout carefully in order to prepare yourself or family members for the proposed procedure. In doing so, you will benefit both the outcome and safety of the procedure. *If you still have any questions or concerns, we strongly encourage you to contact our office prior to your procedure so that we may clarify any pertinent issues. "An educated patient is the best patient."*

SURGERY FOR STRESS URINARY INCONTINENCE

Definition

Urinary incontinence, the involuntary loss of urine, is a symptom that affects millions of women. While urinary incontinence is more common in women over 60 years of age, *it is not a normal consequence of aging*. There are a variety of very effective treatments for urinary incontinence, including behavioral remedies, medicines, and surgeries.

Your doctor has made the diagnosis of stress (exertional) urinary incontinence and you have been scheduled for surgical treatment. **Stress urinary incontinence** is the symptom of urine loss occurring with activity such as walking, exercise, or coughing and sneezing, where increased pressure on the urinary bladder causes urine to leak. Another type of urinary incontinence is urge incontinence. **Urge urinary incontinence** occurs when you have a sudden, involuntary loss of urine associated with a strong urge to void. Many women with symptoms of involuntary urine loss are found to have a combination of these two types of urinary incontinence.

Risk factors for urinary incontinence include:

-) Female gender
-) Advancing age
-) Childbirth
-) Menopause
-) Smoking
-) Obesity

Treatment of urinary incontinence can involve non-surgical/minimally invasive management, pharmacologic (medicinal) treatment and surgical treatment. Non-surgical treatments, such as fluid management, bladder training/retraining, and pelvic floor exercises can lead to improvement in properly motivated patients. This approach to urinary incontinence can take several months before improvement is seen. Behavioral changes need to be incorporated into your lifestyle for lasting results. Medicinal treatment of urinary incontinence has been most effective in treating urge-type incontinence, although medicines such as pseudoephedrine and imipramine are used in the treatment of stress-type incontinence. There are new medicines in development that will add to options for treatment of stress-type incontinence. When minimally invasive and medicinal approaches to treatment do not help or incontinence is severe, surgical treatment is a very effective option.

Surgical treatment of stress urinary incontinence can be performed both abdominally and vaginally. Often these procedures are combined with other surgeries to treat uterine or vaginal prolapse (bulging from loss of normal support). The "Burch" procedure is an operation with good long-term results. It is performed abdominally (through the abdominal wall) and involves connecting the tissues around the urethra (tube carrying urine from the bladder to outside) to the pubic bone for support. This surgery is most often performed when other abdominal surgeries are also being performed. Anterior repair (Kelly placation) is an operation performed entirely through the vagina. Often it is used as a treatment for cystocele (dropped bladder) and urinary incontinence. While it has good long-term result for the treatment of cystocele, it is not an effective treatment for urinary incontinence. Injection of collagen (an inelastic protein from animal tissue) can be performed in your doctor's office to add bulk to the urethra.

This can be effective in some women with a specific type of stress incontinence known as intrinsic sphincter deficiency.

The most common surgery for stress urinary incontinence is the sling procedure. This procedure involves placing a "sling" beneath the urethra. The sling then acts as a firm surface for the urethra to close against. The sling can be made from a variety of materials including the patient's own fascia (strong connective tissue), specially treated human cadaver fascia, animal tissue, or a synthetic material. Sling procedures are approached through the vagina, but also require small incisions on either the abdomen (retropubic) or groin (trans-obturator) for correct placement or attachment of the sling.

The type of material used, and the surgical approach will depend on any prior surgeries you might have had, your anatomy, your surgeon's preference, and input from you after you understand the pros and cons of each type. In your surgical consultation, we will have discussed the type to be used in your procedure.

Prior to your surgery, we may have already performed a *urodynamic test* (UDT). This is a minor office procedure used to specifically evaluate problems of urinary incontinence or other problems with urination. Often, other possible conditions causing incontinence need to be excluded prior to recommending surgery for urinary incontinence. Occasionally, the diagnosis (based on your symptoms and physical examination) is straightforward, and a UDT is therefore unnecessary.

Preparation

Preoperative clearance may be required before your surgery, in which case you will be asked to see your family doctor/internist one to three weeks before your scheduled surgery. Blood work, EKG, chest x-ray, and consultation with the anesthesiologist may also be necessary.

As with all procedures in which regional or general anesthesia is administered, you will be asked not to eat or drink anything after a certain time, usually midnight, on the evening prior to your surgery. You may brush your teeth in the morning but should not swallow the water. If you are on medications that must be taken, you will have discussed this with us and/or the anesthesiologist and instructions will have been given to you. The procedure will not be performed if you are currently taking or have recently taken any medication that may interfere with your ability to clot your blood ("blood thinners, aspirin, anti-inflammatory medicines, etc..."). The most common of these medications are aspirin and all related pain relievers or anti-inflammatory compounds (whether prescription or over the counter). ***Please refer to the attached list and tell us if you took any of these within the past 10 days.*** If your new medication is not on the list, alert us immediately so that we may ensure optimal procedure safety. We will have reviewed all of your current medications with you during the pre-operative/pre-procedure consultation. You are obligated to inform us if anything has changed (medication or otherwise) since your previous visit.

"It is probably to your advantage not to strain to have a bowel movement in the week after the procedure. We therefore recommend that for the entire week before the procedure, you avoid constipating foods such as rice, bananas, and red meat. You should be eating lots of fruits and vegetables as well as oatmeal and cereals. If you have a known problem of constipation, you should administer an enema 1 hour before bed the night before your procedure.

Procedure

The procedure takes as little as 30 minutes, but usually one to two hours depending on an individual's anatomy, other operations being performed at the same time, any previous operation in this area, and which anti-incontinence procedure is to be performed. A suprapubic tube (small catheter placed through the lower abdomen and into the bladder) may be inserted. This temporary tube would be used in the immediate post-operative period to empty your bladder and possibly measure residual urine volume (the amount of urine left in the bladder after you urinate). Many patients and certain techniques do not require placement of this tube. In some patients, a tube is left in the urethra only for a few days or longer. In some patients, no tubes are left at all.

Vaginal Approach: Depending on your surgeon's preference, the surgery may be done completely through one or two incisions in the vagina; or through a combination of a vaginal incision and small lower abdominal or groin incisions. The vaginal incision is made for placement of the sling material around the bottom of the urethra. The very low abdominal incision may be for placement of the tiny bone screws into the pubic bone, to anchor the sutures in another fashion, or to bring the sling material through the proper location behind the pubic bone. A small abdominal incision may also be made when using your own body tissue as the sling material. Small incisions in the groin are made in place of abdominal incisions if a trans-obturator approach to sling placement is taken. When the procedure is done only through the vagina, the tiny screws may be placed into the underside of the pubic bone instead of the upper margin of the bone. If used, the screws are attached to a very strong suture material that secures the sling in proper position. During the procedure we may perform a cystoscopy (placing a small telescope into the bladder to visualize the inside) to check for normal emptying of urine into the bladder from each ureter (tubular structures that carry urine from the kidneys to the urinary bladder) and to verify proper placement of the sling. The incision sites are then closed, and your procedure is completed.

Abdominal Approach: Abdominal surgery for stress urinary incontinence can be done using traditional "open" surgery or with laparoscopy, a technique that uses "telescopic" visualization and miniaturized instruments to accomplish surgery through small incisions. The tissues around the urethra are exposed and using permanent suture (surgical thread) are attached to the strong supporting tissue along the pubic bone. During the procedure we may perform a cystoscopy (placing a small telescope into the bladder to visualize the inside) to check for normal emptying of urine into the bladder from each ureter (tubular structures that carry urine from the kidneys to the urinary bladder) and to verify proper placement of the suture. The incision sites are then closed, and your procedure is completed.

Post Procedure

You will be in the recovery room for a short time before being sent to your hospital bed. Although often an ambulatory procedure, some patients usually will stay overnight in the hospital. There may be some discomfort around the incision sites within the vagina and on the lower abdomen/groin. Most patients have some sense of urgency (the feeling of a need to urinate). There will be a dressing over the abdominal or groin incisions, which are to remain until your follow up visit unless otherwise directed.

The Suprapubic Tube (SPT): If used, you may be discharged home with a SPT. It will remain for a week or so until you are urinating well and adequately emptying your bladder. You will be instructed on how to easily open and close the drainage switch. The tube may serve two purposes:

1. You will attempt to urinate when you go home. If you are unsuccessful, you can simply open the tube and drain the urine from your bladder. When you are completely empty (no more draining from the tube), you will close the switch and allow your

bladder to fill again over the next several hours (time will vary according to how much fluid you are drinking). When you get another sensation to urinate, you will go to the bathroom and attempt to go. Again, if you cannot, you will open the tube, empty the bladder, close the tube, and try again later.

2. If you do urinate, you will open the tube when you believe that you are done urinating. The reason for doing so is to determine whether you are emptying your bladder fully. If there is urine remaining in the bladder, you will record how many ounces were left. You will do this each time you urinate so that you and your surgeon know if you are effectively emptying your bladder and thus ready to have the tube removed.
3. Urethral Catheter: Sometimes a catheter is left in the urethra and removed a few days or week later to see if you can urinate on your own. If you cannot, it can be replaced, or you can learn self-catheterization.
4. Self-Catheterization: You may be instructed on how to catheterize yourself. The indications to do so may be the same. In other words, you would do it if you cannot urinate yet. You may also be asked to catheterize to measure what is left in the bladder after urinating.

There may be small blood staining on the wound dressing. If the dressing becomes soaked, or you see active blood oozing, please contact us immediately. You may shower the day after surgery, but no bathing or swimming (unless otherwise instructed). Some surgeons may ask you to take warm baths a couple of times a day a few days after your surgery. We ask that you refrain from any strenuous activity or heavy lifting until your follow up office visit. Every patient has some degree of swelling and bruising, and it is not possible to predict in whom this might be minimal or significant. It is very important that you intermittently apply ice to the abdominal area as soon as you return home for 24 hours as instructed.

We strongly encourage you to take at least one week off from work and perhaps more if your occupation requires strenuous activity or heavy lifting. In the first 48 hours, it is to your advantage to minimize activity and too often rest in a lying down position. Periodic walking is encouraged. Some patients have almost no discomfort while others are somewhat uncomfortable for a few days to weeks. Severe pain is unlikely but possible. We may provide you with a prescription for pain medication to alleviate most of the discomfort. Take this medication as prescribed and as needed. An antibiotic prescription may also be given and should be taken until completion. If any side effects occur, contact our office immediately.

**You must refrain from any strenuous activity or heavy lifting until we tell you otherwise. Sexual activity of any sort is absolutely prohibited (usually four to six weeks) until we tell you that you may resume.*

Expectations of Outcome

The Burch procedure and sling procedures are very effective modalities for treating stress urinary incontinence but require careful consideration for selection of the proper procedure. The majority of women will have surgical correction of other uterine and vaginal prolapse performed in conjunction with incontinence surgery. Between 80 to 90% of women will report cure or improvement of incontinence following surgery. The goal of all treatments for incontinence, non-surgical and surgical, is improved quality of life.

“Normal Voiding” may be delayed for many weeks due to swelling and operative manipulations. Improvement is usually gradual and not immediate.

*There is an entity termed "bladder instability" that should be understood. It is actually not a complication of the surgery because we expect some degree of its presentation in anywhere from 30 to 40% of patients following repair of urethral hypermobility. Because the bladder neck support has been restored, you may develop urinary frequency and/or urgency (a sensation to urinate urgently). When severe, this rarely can be associated with urge-type incontinence (strong urge to void with an uncontrolled loss of some urine). The symptoms are usually mild and resolve with time. In some patients, medications could be necessary to relax the bladder. Very rarely are other treatments necessary

Possible Complications of the Procedure

All surgical procedures, regardless of complexity or time, can be associated with unforeseen problems. They may be immediate or even quite delayed in presentation. While we have discussed these and possibly others in your consultation, we would like you to have a list so that you may ask questions if you are still concerned. Aside from anesthesia complications, it is important that every patient be made aware of all possible outcomes, which may include, but are not limited to:

-)] **Urinary Tract infection or Sepsis:** Although we may give you antibiotics prior to and after the operation, it is possible for you to get an infection. The most common type is a simple bladder infection (after the catheter is removed) that presents with symptoms of burning urination, urinary frequency and a strong urge to urinate. This will usually resolve with a few days of antibiotics. If the infection enters the bloodstream, you might feel very ill. This type of infection can present with both urinary symptoms and any combination of the following: fevers, shaking chills, weakness or dizziness, nausea, and vomiting. You may require a short hospitalization for intravenous antibiotics, fluids, and observation. This problem is more common in diabetics, patients on long-term steroids, or in patients with disorders of the immune system.
 -)] **Wound Infection:** The incision sites can become infected. While it typically resolves with antibiotics and local wound care, occasionally, part or all of the incision may open and require revision and or catheter replacement.
- *If you have symptoms suggesting any of the above after your discharge from the hospital, you must contact us immediately or go to the nearest emergency room.***
-)] **Treatment failure:** Although usually associated with a high success rate, the procedure can fail in the immediately, or months to years later. In this regard, stress-type or total incontinence may persist or resume.
 -)] **Urinary Retention:** Retention is the inability to urinate and occurs in fewer than 5% of cases. Usually, a patient is able to urinate normally within two to three weeks following the procedure. However, if retention is prolonged, a catheter may be necessary. If you

had an SPT placed, it may remain in for a while longer. Otherwise, you could learn to self-catheterize or simply have a urethral catheter placed back in for a few days at a time. It would periodically be removed to test whether you are able to urinate. It is important to be patient, because urinary retention usually resolves with time and observation. In rare instances of prolonged retention, a corrective procedure may be required. Factors which may delay the rapid return of voiding include: excessive sling tension, poor bladder function before the surgery, and multiple repaired organs (i.e. a dropped bladder, a dropped uterus, or a prolapsed rectum) during the same surgery Urodynamic testing may need to be performed for further assessment.

- J) Painful Intercourse and Vaginal Shortening: After anti-incontinence surgery (especially in combination with other vaginal surgery) the shape of the vaginal can change. In certain cases, the size or angle of the vagina may be changed. While usually not a problem, some women may complain of pain or difficulty with intercourse. Sometimes it is temporary, but it can also be permanent.
- J) Blood Loss/Transfusion: The vaginal region is quite vascular. Usually blood loss in this procedure is minimal to moderate. In 1 to 2% of cases, blood loss can be significant enough to necessitate transfusion.
- J) Deep Vein Thrombosis (DVT)/Pulmonary Embolus (PE): In any operation (especially longer operations), you can develop a clot in a vein of your leg (DVT). Typically, this presents two to seven days (or longer) after the procedure as pain, swelling, and tenderness to touch in the lower leg (calf). Your ankle and foot can become swollen. ***If you notice these signs, you should go directly to an emergency room and also call our office.*** Although less likely, this blood clot can move through the veins and block off part of the lung (PE). This would present as shortness of breath and possibly chest pain. We may sometimes ask the medical doctors to be involved with the management of either of these problems.
- J) Sling Erosion: It is possible for the sling material to erode through the tissue that surrounds it. If the vaginal tissue breaks down, the sling can often be removed with a minimal procedure. Often, the patient is still continent because scar tissue from the surgery will continue to support the urethra. On the contrary, if the sling erodes into the urethra the surgical removal is more involved, and the rates of incontinence afterward are higher.
- J) Bleeding/Hematoma: When a small blood vessel continues to ooze or bleed after the procedure is over, the area of collected blood is referred to as a hematoma. The body normally re-absorbs this collection over a short period of time, and surgical drainage is rarely necessary.
- J) Lower Extremity Weakness/Numbness: This, too, is a rare event which may arise due to your position on the operating table. It is possible in procedures in which you are in the lithotomy (legs up in the air) for a long period. The problem is usually self-limited, with a return to baseline expected.
- J) Injury from Suprapubic Tube: If a suprapubic tube is being placed, it can rarely puncture a structure adjacent to the bladder. Although rare in any instance, the small intestine is the most commonly involved organ. When recognized, a general surgeon may be consulted to repair the intestine or other organ.
- J) Chronic Pain: As with any procedure, a patient can develop chronic pain in an area that has undergone surgery. Typically, the pain disappears over time, although some feeling of numbness may persist. If persistent, further evaluation may be necessary.
- J) Transferred viral infection: With the use of human cadaveric material, transferred virus is theoretically possible. The processing of this material is quite extensive. *With use in tens of thousands of patients, we are not aware of a single published case of transferred viral infection.*

Patient Signature

Date

Account #

Patient Name (Print)

Physician

Date

Witness

Date

The information contained in this Medical Informed Consent Form ("Consent Form") is intended to solely inform and educate and should not be used as a substitute for medical evaluation, advice, diagnosis or treatment by a physician or other healthcare professional. Please call your doctor if you have any questions.