WOMEN'S HEALTH PARTNERS, LLC

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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 UTERO-VAGINAL PROLAPSE

Definition
Surgery = the treatment of disease, injury or deformity by an operation Utero -= relating to the uterus (womb)
Vaginal = relating to the vagina (birth canal)
Prolapse = a sinking or downward movement of an organ

Uterovaginal prolapse, a sinking or downward movement of the uterus and or vagina, is a common condition that impacts large numbers of women. The degree of prolapse varies widely and although a small number of women with mild changes to their pelvic supports will be bothered by symptoms, by age 80 up to 11% o of the overall female population will undergo major surgery for prolapse or incontinence.

The uterus and vagina are supported in the pelvis by a complex interaction of ligaments and connective tissue attached from the cervix and top of the vagina to the muscles and bones of the pelvis. When ligaments stretch or break, changes in support can lead to movement of the uterus and vagina from its "normal" position, and development of symptoms of pelvic pressure, vaginal fullness, bulging, and backache. Uterine and vaginal prolapse may cause symptoms of pelvic pain and painful or difficult intercourse in some, but not most women.

Factors contributing to loss of normal support of the uterus and vagina include any one or a combination of:

- Pregnancy and vaginal childbirth, especially multiple deliveries and those associated with large babies or prolonged, difficult labor
- Menopause (both natural and as a result of surgical removal of ovaries)
- Aging
- Chronic coughing
- Obesity
- Years of strenuous activity or heavy lifting

Procedures to treat prolapse can be divided into those that are obliterative (surgical elimination of the vagina) or reconstructive. The goals of obliterative surgery are to provide the least invasive and brief operation that will relieve symptoms, while the goals of reconstructive prolapse surgery are the return to a normal quality of life including sexual function and the relief of symptoms through restoration of normal support.

Surgery to correct or restore uterine and vaginal support can be approached through incisions in the vagina or abdomen. Abdominal surgery can be either a traditional "open" surgery or laparoscopic surgery. Of extreme importance, regardless of the surgical approach, is re-establishment of support to the "top" of the vagina. Sometimes it is necessary to add strength to the repair using a graft. The graft can be made from a variety of materials including specially treated human cadaver fascia, animal tissue or a synthetic material. Over the past century, several procedures to restore normal support have been developed and modified. No single procedure has yet been proven superior and success rates are quite variable.

Before proceeding with prolapse repair, your doctor may suggest you use a pessary (a rubber instrument, fit into the vagina, to keep the uterus in place). This can act as a test to see if your symptoms improve with changing the position of the uterus, as well as being a possible substitute for surgery. Surgical repair of prolapse does not necessarily include surgical removal of the uterus (hysterectomy). In any case, these symptoms and this condition, as bothersome as they are, do not require treatment.

The type of approach taken will depend on your anatomy, whether prolapse repair is being done in conjunction with another surgery (such as treatment of incontinence, cystocele, or rectocele), your prior surgical history, and the preference of your surgeon. The pros and cons of each will be discussed with you in your consultation.

Because uterovaginal prolapse is often accompanied by urinary incontinence, we may recommend evaluation prior to prolapse repair. Urodynamic testing (UDT) is a diagnostic procedure used to specifically evaluate problems of urinary incontinence or other problems with

urination. Occasionally, the diagnosis (based on your symptoms and physical examination) is straightforward, and a UDT is therefore unnecessary.

Preparation

As with all procedures in which 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.

Procedure

Vaginal Approach: You will be lying on your back with your knees bent and heels in stirrups, much like you would for a pelvic examination. The procedure usually takes approximately one to three hours, depending on your anatomy, which procedure is planned, and any other procedures being performed at the same time.

Obliterative surgery is performed by first removing a layer of skin from the prolapsed vagina. With successive "purse-string" sutures through the vagina, the uterus is returned to a pelvic location. The opening of the vagina is made small to help prevent a repeat of prolapse. Vaginal intercourse is not possible following obliterative surgery.

Vaginal reconstructive surgery involves elevating the uterus and cervix using strong supporting structures within the pelvis. These include the uterosacral and sacrospinous ligaments and the connective tissue around the cervix and upper vagina. The ligaments are located, in some operations surgically shortened, and then attached to the cervix or vagina. In this manner the uterus and/or vagina are supported in a position approximating that which is normal. The incisions are then closed. Sometimes a gauze packing is placed in the vagina overnight.

During the procedure, we may perform cystoscopy (placing a small telescope through the urethra to visualize the inside of the bladder) 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). A suprapubic tube may have been placed or you may have a catheter placed in the bladder through the urethra.

Abdominal Approach: You will be lying on your back with your legs extended. The procedure takes between one to three hours, depending on your anatomy, which procedure is planned, and any other procedures being performed at the same time.

The reconstructive surgery is performed through incisions made on the abdomen. If vaginal reconstructive operations (such as rectocele repair or perineal repair) are to be performed in the same setting, they will require additional incisions within the vagina. Some uterovaginal prolapse repair procedures can be performed using laparoscopy, a technique that uses "telescopic" visualization and miniaturized instruments to accomplish surgery through small incisions.

Just as vaginal prolapse repair involves elevating the uterus and cervix using strong supporting structures within the pelvis, so do abdominal procedures. These include the uterosacral ligaments and the connective tissue around the cervix and upper vagina. Additionally, strong ligaments of the bony sacrum (base of the spine) are accessible with abdominal surgery and may be used as an attachment site for graft material. The pelvic ligaments are located, in some operations surgically shortened, and then attached to the cervix or vaginal cuff. Some operations use graft material to substitute for the ligaments and to add strength to uterine or vaginal support. In this manner the vagina is supported in a position approximating that which is normal. The incisions are then closed, and dressings applied. Sometimes, a gauze packing is placed in the vagina overnight (when vaginal surgery is combined).

During the procedure, we may perform cystoscopy (placing a small telescope through the urethra to visualize the inside of the bladder) 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). A suprapubic tube may have been placed or you may have a catheter placed in the bladder through the urethra.

Please see Procedure *Education Literature for Rectocele Repair, Cystocele Repair, or Urinary Incontinence* if any of these procedures are anticipated or planned.

Post Procedure

You will be in the recovery room for a short time before being sent to your hospital bed. Most patients usually will stay one or two nights in the hospital, although it is possible to have a prolapse surgery as an ambulatory procedure. There may be some discomfort around the incision sites, within the vagina, or on the lower abdomen depending on the procedure you had performed. There will be a small dressing over the abdominal incision site (if one was made) which is to remain until your follow up visit unless otherwise instructed. Sometimes a catheter is left in the urethra and removed the afternoon or morning after surgery, when you are better able to walk to the toilet. If you also had treatment for urinary incontinence, the catheter may remain for a longer period of time.

There may be small blood staining on the wound dressing or menstrual pad. If the dressing or pad becomes soaked, or you see active blood oozing, please contact us immediately. You may shower one to two days after surgery, but no bathing or swimming (unless otherwise instructed). It is normal to have some bloody discharge from the vagina for a day or two. If you have significant bleeding, you should call our office. 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.

We strongly encourage you to take at least four weeks off from work and ask that you "take it easy" for 12 weeks after surgery. You may need more scheduled time off 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, six to eight weeks) until we tell you that you may resume.*

Expectations of Outcome

Several different procedures can be performed to correct loss of normal uterine and vaginal support and alleviate the accompanying symptoms. Prolapse can lead to symptoms of pelvic pressure, vaginal fullness, vaginal bulging, backache, pelvic pain and painful or difficult intercourse in some, but not most women.

Procedures to treat prolapse can be divided into those that are:

1. Obliterative: provide the least invasive and shortest operation that will relieve symptoms.
2. Reconstructive: return to a normal quality of life including sexual function and the relief of symptoms through restoration of normal support.

Surgical correction of prolapse can be approached both through the vagina and abdomen. There is no clear answer to what procedure is superior for which patient. When appropriate support structures are used, the rate of improvement is very good, although no procedure is successful 100% of the time. Failure will occur in approximately 5 to 15% of women. It remains difficult to estimate the rate of long-term recurrence.

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.
- 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.
- Ureteral Injury/Ureteral Kinking: Operations to correct uterine and vaginal prolapse often utilize ligamentous structures within the pelvis that are near or adjacent to the ureters (tubular structures that carry urine from the kidneys to the urinary, bladder). When tension is placed on these ligaments the ureters can be drawn along with the ligaments, away from their normal position becoming partially or completely blocked by kinking. It is also possible to inadvertently injure the ureter by placing an instrument across it, a suture around it or cutting it with surgical instruments. Ureteral injury can be quite serious and requires prompt attention

  ****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.***
- Blood Loss/Transfusion: Significant blood loss is rare most with prolapse repair procedures. Uncommonly, small or even large blood vessels can be injured during the surgical procedure. Minor to moderate bleeding can usually be controlled without additional incisions, while more severe bleeding may require additional or larger incisions. If severe bleeding occurs, transfusion could be necessary.
- Organ Injury: During any part of the surgical procedure, any organ in the abdomen or pelvis (liver, spleen, colon, intestine, bladder, stomach, ureter, etc.) can be inadvertently injured. Often the injury is minor and can be treated with relative ease. In other instances, when the injury is major, or the repair is complicated, more extensive surgery may be necessary. Treatment depends on the particular organ injured and the severity of the injury. These are described in your primary surgical pamphlet.
- Treatment Failure: Most pelvic prolapse surgeries have been shown to give very good results, although no procedure is successful 100% of the time. Results vary according to each procedure, with success rates ranging between 85 to 95%. In this sense, treatment can fail.
- Recurrent prolapse/Need for Cesarean Deliver: Should you choose to carry a pregnancy after your operation, it is possible that the stretching of the uterus and uterine support during pregnancy will be sufficient to undo the corrections made during your surgery. A recommendation for cesarean delivery will likely be made to help prevent post-delivery prolapse but cannot insure against it. Cesarean delivery involves risk to mother and baby.

- Dyspareunia and Vaginal Shortening: After prolapse repair surgery, the shape of the vaginal vault can change. In certain cases, the 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.
- 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.
- Mesh Erosion/Graft Rejection: It is possible for the mesh material to erode through the tissue that surrounds it. If the vaginal tissue breaks down, the mesh can sometimes be removed with a minimal procedure. If the mesh is removed it is possible that prolapse and its associated symptoms will return. If this occurs, another surgery may be necessary to relieve symptoms.
- 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.
- Lower Extremity Weakness/Numbness: This, too, is a rare event that 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.
- 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.
- 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.
- Unintentional dissemination of an unrecognized uterine malignancy through the use of morcellation technique: Uterine morcellation is commonly performed intracorporeally to remove the uterus through small incisions. Most commonly, morcellation is performed to reduce the size of an enlarged uterus so that it may be removed through small laparoscopic incisions or through the vagina, thus minimizing the morbidity of a larger "open" incision. Less than one out of 1000 women who undergo hysterectomy for fibroids (leiomyomas) will have an underlying malignancy. Currently there is no reliable method to differentiate between benign fibroids from malignant fibroids (leiomyosarcomas or endometrial stromal sarcomas) before they are removed. These tumors have a very poor prognosis even if they are removed intact. The risk of spreading an unknown occult uterine malignancy through morcellation is thought to be very low at approximately 0.1%-0.25%.

_____ _____ _____

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.