

# **Uterine Artery Embolization**

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#### **Uterine Artery Embolization (UAE):**

An alternative to surgery for patients with uterine fibroids

It ibroids are benign tumors of the uterus that are a common cause of heavy menstrual bleeding and pelvic pain and pressure in women. Fibroids often fail to respond to medical therapies and either myomectomy (surgical removal of the fibroids) or hysterectomy is then recommended.

In recent years, there has been considerable research aimed at developing less invasive alternatives to surgery. One such therapy, **uterine artery embolization (UAE)**, shows great promise in controlling symptoms caused by fibroids. This site is intended to inform patients and physicians about uterine fibroids, their current treatment, about uterine artery embolization and the research Georgetown University is conducting on this therapy.

Contact us regarding any aspect of uterine artery embolization:

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Dept. of Educational Media.

#### What are Fibroids?

What causes them? Who gets them? What symptoms do they cause and why? Review this page for a detailed background discussion of uterine fibroids.



#### **Current Treatment Options**

There are a number of different treatments for fibroids. The choice of therapies depends on a number of factors. What are the options and how does one decide on a given therapy?



#### Uterine Artery Emb. Procedure

This is a fundamentally different approach to treating fibroids. What is this therapy? How does it work? What are the side effects? How well does it work?

See also: Embolic Agents Pregnancy after UAE



#### Patient's Guide to UAE at Georgetown

Interested in uterine artery embolization at Georgetown University? Find out about our pre-procedure evaluation, treatment plan, and follow-up protocols. Also provided are the results of patients treated at Georgetown and other research we have completed on UAE.



#### FIBROID Registry

Georgetown University Hospital is one of the first core site participants in the FIBROID Registry, a national data registry intended to determine the long term outcome of uterine embolization for fibroids. Learn about this large study of this fibroid therapy and the participating sites at www.fibroidregistry.org/about.htm.



#### Finding a Physician

Patients from all over the country have been treated with UAE at Georgetown University, but there are many other centers that have extensive experience with this procedure. This page provides links and guidelines on how to best select a program.



#### Physicians' Resource

This section provides information for physicians on current scientific literature on uterine artery embolization, patient eligibility criteria, and referral information.

See also: UAE for Physicians Georgetown Univ. Experience Published Georgetown Research Literature Review

Patient Protocol and Referral



#### Adenomyosis

Adenomyosis is a condition in which endometrial tissue occurs deep within the muscular wall of the uterus. This can cause heavy menstrual bleeding and severe cramps. Hysterectomy is the most commonly used therapy. This section discusses the role of UAE as a possible alternative treatment for adenomyosis.



**Meet Our Staff**Read more about our care team at Georgetown.



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#### What are Fibroids?

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Fibroids are benign tumors of smooth muscle, which is the type of muscle that makes up the uterus. They are also called leiomyomas or myomas. Fibroids may arise in different parts of the uterus, as shown in the figure.

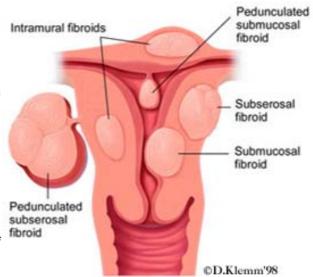
Fibroids are named according to their position within the uterus; **submucosal, intramural, and subserosal.** A submucosal fibroid lies just under the inner lining of the uterus, which is called the **endometrium**. Some of these fibroids grow on a stalk. These are referred to as "**pedunculated**". An intramural fibroid that lies completely within the muscular wall of the uterus ("intra" means within and "mural" means wall). A serosal or subserosal fibroid lies on the outer part of the uterus, just under the covering of the outside of the uterus, which is called the serosa. Subserosal fibroids may also grow on a stalk and be called pedunculated.

Abnormal bleeding is usually caused by submucosal or intramural fibroids. Intramural and subserosal fibroids are the usual cause of pelvic pain, back pain, and the generalized pressure that many patients experience.

#### Who gets fibroids?

All women are at risk of getting fibroids. Uterine fibroids are the most common tumors of the female genital tract. They occur in 20 to 25 % of women of childbearing age. The presence of fibroids is the most common reason for a woman to have a hysterectomy in this country, totaling approximately 200,000 each year. In addition, many patients suffer symptoms from fibroids but never undergo a hysterectomy.

African-Americans are as much as 3.2 times as likely to develop fibroids as Caucasians. There is some variation among other racial groups. The reason for this increased risk is not known, although genetic variability is presumed to be a significant factor. While fibroids may appear in patients in their twenties, most patients do not have any symptoms until their late thirties or forties.



#### What causes fibroids?

The cause for fibroid development is not known. Leiomyomas arise after menarche (beginning of menstruation in adolescence) and regress after menopause, which suggests that the development of fibroids is dependent on the presence of hormones (primarily estrogen). But the triggering event for the development of the fibroid is not known and the interaction of the various hormones and growth factors likely to be involved is not well understood.

Once fibroids appear, their growth rate is also dependent on estrogen, progesterone and possibly other hormones. Growth rates vary greatly among women and the exact cause for this variability is not known, making the prediction of the behavior of fibroids very difficult.

#### **Symptoms**

Most leiomyomas do not cause symptoms. While 25% of women develop fibroids during their lives, only 10 to 20% of these women have symptoms. Therefore, only a minority of women ever require treatment.

#### **Heavy Menstrual Bleeding**

The most common symptom associated with fibroids is abnormal bleeding, which typically presents as heavy menstrual bleeding, often with clot formation. Anemia (low blood count) is a common side effect. The medical term for heavy menstrual bleeding is **menorrhagia** (pronounced men-o-ray-ja). As the bleeding severity increases, clot passage with the menstrual period commonly occurs. The clots form because the blood stays in the uterus long enough to clot prior to being expelled into the vagina. As these clots pass, they may cause severe menstrual cramping.

How fibroids cause abnormal bleeding is not known. Fibroids are believed to alter muscular contraction of the uterus, which may prevent the uterus from controlling the degree of bleeding during a patient's period. In addition, it has been shown that fibroids compress veins in the wall of the uterus. This results in dilation of the veins of the uterine lining. As the pressure in these veins increases, the the lining of the uterus becomes engorged. This may result in heavy bleeding during a menstrual period. It may also contribute to abnormal bleeding.

Heavy menstrual bleeding is usually caused by fibroids deep within the wall of the uterus (intramural) or those just under the inner lining of the uterus (submucosal). Very small fibroids in the wall of the uterus or fibroids in the outer part of the uterus (subserosal) usually do not cause abnormal bleeding.

There are many other potential causes of heavy menstrual bleeding and so a careful gynecologic history and physical examination is an important part of the evaluation of a patient with heavy bleeding. Just because a patient has fibroids, it does not mean that the fibroids are the cause of abnormal bleeding. Other causes include endometrial hyperplasia (an abnormal thickening of the uterine lining), endometrial polyps, adenomyosis, and even uterine cancer. The likelihood of these causes can often be determined based on a gynecologic history and physical examination, but on occasion additional tests may be needed.

#### **Pelvic Pain and Pressure**

Another symptom is pelvic pain. On rare occasions, a fibroid may suddenly degenerate (spontaneously shrink and scar due to decrease in blood supply). This is a painful process that may last several days or weeks. This type of severe pain is unusual. Severe or burning pain during a menstrual cycle is perhaps more commonly caused by other conditions, such as endometriosis. However, because of the broad range of presenting symptoms of fibroids, gynecologic evaluation is needed to confirm the diagnosis.

If fibroids cause symptoms related to the pressure they exert on other structures, they most commonly cause a sensation of pressure or discomfort in the pelvis. This may feel like heaviness, bloating, a dull ache, or mild tenderness of the fibroids themselves. The discomfort may be greater with exercise, while bending over or during sexual intercourse. As fibroids grow, they may compress nerves that supply the pelvis and the legs, causing pain in the back, flank, or legs. Patients also report increasingly severe menstrual cramps with the growth of their fibroids.

#### **Urinary Symptoms and Other Symptoms**

Pressure on the urinary system also may be caused by fibroids. Typically, this results in urinary frequency (increased frequency of urination, including the need to get up at night to urinate). Fibroids may also contribute to incontinence (urine leakage) or rarely, they may partially block the outflow of the bladder, making it difficult to empty the bladder. Occasionally, an enlarged uterus may press on other urinary structures resulting in partial blockage of the urine flow from the kidneys. On occasion, fibroids may also cause rectal pain or pressure.

Many of these symptoms may be cyclic, worse in the days leading up to the menstrual period and during the period. If the fibroids get large enough, the pressure and discomfort they cause may occur at any time.

#### Fibroids and Fertility

It has often been suggested that infertility and/or repeated miscarriage can be caused by fibroids. However, the statistical evidence for infertility is lacking and other factors are more likely to cause infertility in fibroid patients. Some researchers have suggested that the presence of fibroids may predispose a patient to miscarriage, but again firm statistical evidence to support this possibility is not yet available. There have been studies in infertile women in whom the only identifiable cause is the presence of fibroids. After myomectomy (surgical removal of the fibroids, leaving the uterus in place), these studies have shown that 40 to 60 % of these women have been able to become pregnant. However, because large studies have not been completed and infertility may have many causes, it is imprudent to assume that fibroids are the cause without a careful evaluation for other problems.

#### Fibroids and the Risk of a Malignant Tumor

A common question is whether a large mass in the uterus, presumed to be a benign fibroid, could be a malignant tumor. The answer is yes, although these tumors, called leiomyosarcomas, are very rare. They occur in about 1 in 1000 cases. Based on recent genetic studies, it does not appear that these malignant tumors result from a preexisting benign tumor. It appears that they arise separately from any existing fibroids.

The problem is that it can be impossible to tell a benign fibroid from a malignant tumor without surgery. No imaging test, such as ultrasound or MRI, can reliably distinguish these tumors. There is no blood test that can detect them. By history, they are often suspected when a presumed fibroid grows very rapidly. However, the majority of rapidly growing "fibroids" are just that, benign fibroids.

Biopsy also cannot reliably distinguish benign from malignant tumors of the uterus, because the sample may be taken from a relatively benign appearing portion of the mass.

Unfortunately, the reliable means of detecting malignant solid tumors of the uterus is surgery. This would either be by removal of the fibroids alone (myomectomy) or hysterectomy. Hysterectomy, with surgical removal of lymph nodes near the uterus is the primary treatment for leiomyosarcoma.

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### **Treatment Options**

Uterine fibroids that are not causing symptoms do not require specific therapy, other than periodic examinations by a gynecologist. Usually the diagnosis is made by physical examination confirmed by either ultrasound examination or MRI. Once diagnosed, the growth of fibroids may be monitored by physical examination.

#### **Medical Management**

Once symptoms develop, medical management is usually the first therapy. This might include treatment with non-steroidal anti-inflammatory agents (such as Motrin or Naprosyn), birth control pills, or progesterone agents. If these fail to control the symptoms, the decision for further medical management depends on the patient's age, the size of the fibroids, the desire for future pregnancy, and the severity of symptoms.

Another medication that may be used in certain circumstances is a Gonadotropin Releasing Hormone (GnRH) agonist. This group of medications block the production of hormones, particularly estrogen, by the ovary. The most commonly used GnRH agonist in this country is Lupron, which is given by injection either once a month or every three months depending on the dose. Because these medications decrease estrogen levels and because fibroid growth depends on estrogen, fibroids usually shrink when treated with Lupron or other GnRH agonists. These drugs may cause hot flashes and mood changes in some patients, similar to those experienced with menopause. These symptoms may be controlled with small doses of supplemental estrogen. A potentially more serious side effect of these medications is a decrease in the density of bones, which can lead to osteoporosis if used long term. For this reason, the use of these medications is usually limited to 6 months. Unfortunately, fibroids usually regrow after GnRH agonists are stopped. There is ongoing research studying the intermittent use of Lupron and similar drugs, or use in combination with other medications, to determine if symptoms are controlled long-term while avoiding bone loss.



#### Hysteroscopy

If the fibroids are submucous (inside the uterus, just below the lining) and projecting into the uterine cavity, a hysteroscopic resection may be possible. Hysteroscopy is a procedure in which a fiber-optic scope is advanced into the uterus through the vagina and cervix. It is commonly used in conjunction with a dilatation and currettage (D and C) to diagnose abnormal bleeding.

A hysteroscope may also be used to remove polyps or submucosal fibroids. Larger submucosal fibroids can sometimes be removed or partially removed with a hysteroscopic device that shaves off pieces of tissue. These methods may be combined with techniques to ablate or remove the lining of the uterus to control bleeding. Endometrial ablation is the intentional destruction of the uterine lining and is intended to permanently stop menstrual bleeding. If successful, it will prevent future pregnancy.

In the hands of a skilled operator, hysteroscopic procedures are safe and effective. They are usually performed in the operating room under general anesthesia, but a patient is typically discharged on the same day as surgery and may return to normal activities within a few days.

Hysteroscopic removal of fibroids is usually only done after a GnRH agonist is given for three to six months. This causes the fibroid to shrink and decreases its blood supply, which reduces bleeding at the time of the surgery and improves the chance for success.

#### Surgical procedures

The two conventional surgical choices are myomectomy and hysterectomy. Myomectomy is an operation in which the fibroid or fibroids are removed leaving the rest of the uterus in place. This is most commonly used in younger women who wish to maintain their ability to have a child. While bleeding and other complications are somewhat higher than with hysterectomy, myomectomy appears to be successful in controlling symptoms in about 80% of women. Fibroids may regrow after myomectomy, with recurrence rates of between 10% and 30% by 3 to 5 years after treatment. The procedure may cause extensive pelvic scarring which may make future surgery very difficult and may contribute to future fertility problems. Long-term studies of myomectomy patients attempting to become pregnant have shown pregnancy rates between 40 and 60%. In recent years, there has been the development of less-invasive techniques, such as laparoscopy, for performing myomectomy and these may represent alternatives to conventional surgery in some patients.

Hysterectomy is effective in essentially all cases in which bleeding is the primary symptom and usually it resolves the pain or urinary symptoms which women may have as well. It is a safe procedure, with a very low complication rate in experienced hands. It is the standard therapy for fibroids that fail to respond medical therapy in women who do not wish to have further children. While it is a major surgical procedure, with a four to six week recovery, studies have shown that the patient's quality of life after hysterectomy is normal for most patients within 2 months of the surgery. Recent large studies have confirmed that hysterectomy is effective and safe, with a very low complication rate.

One common question about hysterectomy is whether it will have any effect on sexual functioning. A recent study addressed this question and found that for the large majority of patients, sexual functioning is actually improved after hysterectomy. The reason is the symptoms caused by fibroids are often severe enough to significantly impact sexual interest and enjoyment. Once the symptoms are gone, sexual interest and enjoyment increase.

There are patients who will have depression and other psychological effects from hysterectomy and others whose sex lives will be worse after the surgery. Since it is major surgery, there can be complications and it takes several weeks to recover. For these and many other reasons patients have long sought an alternative to surgery for control of symptoms caused by fibroids.

#### **Uterine Artery Embolization (UAE)**

Uterine artery embolization is a treatment for fibroids that has developed over the past decade. It was originally performed in France and first reported in the medical literature in 1995. Since that time, numerous centers in the United States have begun uterine embolization programs.

Embolization is a medical term for a procedure in which a physician injects small particles through a catheter placed in the uterine artery. The particles block the blood supply to the fibroids, resulting in the death of the fibroid tissue. This leads to shrinkage of the fibroids and relief of symptoms for most patients, without the need for surgery or removal of the uterus. For additional information on this procedure, please review the **page on UAE**.



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### **Uterine Artery Embolization Procedure**

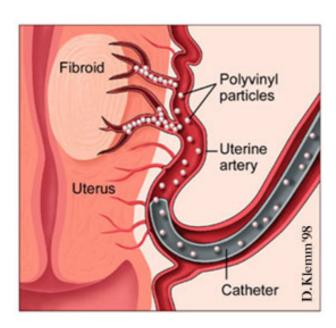
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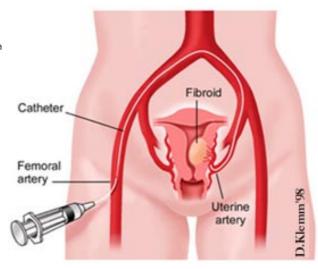
#### Introduction

Uterine artery embolization represents a fundamentally new approach to the treatment of fibroids. Embolization is a minimally invasive means of blocking the arteries that supply blood to the fibroids. It is a procedure that uses angiographic techniques (similar to those used in heart catheterization) to place a catheter into the uterine arteries. Small particles are injected into the arteries, which results in their blockage. This technique is essentially the same as that used to control bleeding that occurs after childbirth or pelvic fracture, or bleeding caused by malignant tumors. The procedure was first used in fibroid patients in France as a means of decreasing the blood loss that occurs during myomectomy. It was discovered that after the embolization, while awaiting surgery, many patient's symptoms went away and surgery was no longer needed. The blockage of the blood supply caused shrinkage of the fibroids resulting in resolution of their symptoms. This has led to the use of this technique as a stand-alone treatment for symptomatic fibroids.

#### The Procedure

The procedure is usually done in the hospital with an overnight stay post-procedure. The patient is sedated and very sleepy during the procedure. The uterine arteries are most easily accessed from the femoral artery, which is at the crease at the top of the leg (figure at right). Initially, a needle is used to enter the artery to provide access for the catheter. Local anesthesia is used, so the needle puncture is not painful. The catheter is advanced over the branch of the aorta and into the uterine artery on the side opposite the puncture.





Before the embolization is started, an arteriogram (an injection of contrast material while X-rays are performed) is performed to provide a road map of the blood supply to the uterus and fibroids. After the arteriogram, particles of polyvinyl alcohol (PVA) are injected slowly with X-ray guidance (see figure at left). These particles are about the size of grains of sand. Because fibroids are very vascular, the particles flow to the fibroids first. The particles wedge in the vessels and cannot travel to any other parts of the body. Over several minutes the arteries are slowly blocked. The embolization is continued until there is complete blockage of flow to the fibroids.

Both uterine arteries are embolized to ensure the entire blood supply to the fibroids is blocked. After the embolization, another arteriogram is performed to confirm the completion of the procedure. Arterial flow will still be present to some extent to the normal portions of the uterus, but flow to the fibroids is blocked. The procedure takes approximately 1 to 1 1/2 hours.

There is variability in the technique used at different centers that are performing UAE. At Georgetown, a second arterial catheter is placed from the opposite femoral artery to the other uterine artery and the embolization of the fibroids is done from both sides simultaneously. At other centers, a single catheter technique is used with one side treated then the other. In any case, all physicians who are performing UAE treat both uterine arteries.

There are other variations in technique, including the use of different types and sizes of particles to block the arteries. Many patients have questions about the particles and their fate. For a more detailed discussion of the various substances used to block the arteries, please review the page on embolic agents.

#### Complications

Serious complications are rare after UAE, occurring in less than 4% of patients. These include injuries to the arteries through which the catheters are passed, infection or injury to the uterus, blood clot formation, and injury to the overy.

The most severe complications to date have been 4 deaths reported after UAE, 3 in Europe and 1 in the United States. In England, a patient developed a very serious infection in the uterus 10 days after the procedure. Despite a hysterectomy, the patient developed septicemia (blood stream infection) and died 2 weeks later. Another patient recently died in the Netherlands from a similarly severe infection. There have been 2 deaths from pulmonary embolus, which is the passage of a blood clot from the veins in the legs or the pelvis to the lungs. Pulmonary embolus may occur after any of a number of different surgical procedures, including most gynecologic surgeries. It does not appear that a patient treated with UAE is at any greater (or lesser) risk for pulmonary embolus than surgery patients. While pulmonary embolus usually does not result in permanent injury, it can cause death in rare instances. These very serious complications are the only deaths that have occurred in the 20,000 to 25,000 patients treated worldwide thus far.

About 1% of the time, a patient might have an injury to the uterus or infection in the uterus that might necessitate a hysterectomy. Injuries to other pelvic organs is possible but has

not yet been reported. There have been a few patients that have had a nerve injury, either in the pelvis or at the puncture site, although happens in less than 1 in 200 patients. An injury to the puncture site, such as clot formation or bleeding, is also similarly rare.

The most likely problem to develop in the first several months after the procedure is the passage of fibroid tissue. This is only likely to happen with submucosal or intramural fibroids that touch the lining of the uterus. In our experience, this occurs in about 2 or 3 % of cases. While the fibroids may pass on their own, a D and C may be needed to remove the tissue. While the passage of tissue may be beneficial in the long run, it may be associated with infection or bleeding and this may be severe enough to require hospitaliation. For this reason, it is important to monitor this process carefully to avoid more serious problems.

X-rays are used to guide the procedure and this raises a concern about potential long-term effects. There have now been several studies of X-ray exposure during uterine embolization, and in most of these, exposure was found to be below the level that would be anticipated to have any health effect to the patient herself or to future children. It is always possible that very prolonged exposure could cause an injury, and there has been one patient reported (not at Georgetown) that developed a skin burn after uterine embolization. Most interventionalists limit the duration of X ray exposure in any procedure and will stop the procedure if it cannot be completed within a safe interval.

Another unresolved question is the effect, if any, of this procedure on the menstrual cycle. The overwhelming majority of women who have had embolization of fibroids have had decreased bleeding with normal menstrual cycles. There have been a few women (most of whom are near the age when menopause would be expected) who have lost their menstrual periods after uterine embolization. The most likely cause is decrease in blood supply to the ovaries as a result of the embolization. Most researchers have noted a 2 to 6% chance of losing menstrual periods and the onset of menopause as a result of UAE. There has been one study that noted a higher rate of menopause after the procedure (15% of patients treated) but the reason for this higher rate is not clear. We have completed a study on ovarian function after uterine embolization. In women under the age of 45, there was no permanent change in FSH, a hormone often used to estimate ovarian reserve. That report is discussed in the section on Research at Georgetown University.

About 1% of the time, a patient might have an injury to or infection in the uterus that might necessitate a hysterectomy. Injuries to other pelvic organs is possible but has not yet been reported and the chance of other significant complications is less than 4%. We have recently reviewed our experience in the first 230 patients treated at Georgetown and we have summarized our complications. You may review that experience on the page describing our experience at Georgetown.

#### **Expected result**

As of this time, 20.000 to 25,000 patients have had this procedure world-wide. Our initial results, along with those that have been published or presented at scientific meetings, suggest that symptoms will be improve in 85-90% of patients with the large majority of patients markedly improved. The improvement rate is similar for heavy menstrual bleeding and for pressure and pain symptoms. Most patients have rated this procedure as very tolerable and in almost all cases hospitalization is necessary for only one night. In some centers, the patients are treated and discharged the same day.

The quality of life of patients also improves significantly. Again in research completed here at Georgetown, with either a quality of life questionnaire specific for fibroids or a more general questionnaire, statistically significant improvement is evident in all areas.

The expected average reduction in the volume of the fibroids is 40-50% in three months, with reduction in the overall uterine volume of about 30-40%. Over time, the fibroids continue to shrink. With several years follow-up now available, it does not appear that fibroids successfully treated regrow. It is not known whether patients may develop new fibroids.

This section was written to provide patients with an overview of uterine artery embolization. If you are interested in a more detailed discussion of the reported scientific results, we encourage you to read our **Literature Review**.

If you would like to consider this procedure or would like more information about uterine artery embolization at Georgetown University, please review our **Patient's Guide**. Also our patient's guide gives a detailed discussion of what the patient can expect before, during, and after UAE.

#### Pregnancy after UAE

While UAE has not been used as a fertility procedure, there have been many pregnancies after uterine artery embolization. For a detailed review, please consult the section on **Pregnancy after UAE**.

#### For more information

You may call James B. Spies M.D. of Georgetown Interventional Radiology at (202) 784-5478 to make an appointment. You may also contact us via email at info@fibroidoptions.com.

If your gynecologist is interested in information on this procedure or if you are interested in more technical detail about UAE, additional information is available at our **Physician's Resource** page. They may also call us; we would be happy to discuss this procedure with them.

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## **Embolic Agents:**

## Choice of particles for uterine artery embolization for leiomyomata

With the emergence of uterine embolization for fibroids, there has been renewed interest in the properties of embolic material (particles) used to block the arteries. This page will review the theory behind the use of embolic particles in UAE and describe the materials currently in use.

#### **FDA Approval Status**

When reviewing this material, it is important to realize that while both PVA and Emboshperes® are approved for general embolization by the FDA, neither is specifically approved by the FDA for the treatment of uterine fibroids. To obtain this approval, multi-center studies are underway with both products. The standard for this type of approval is high. Not only must the material be shown to be safe and effective for treating fibroids, but uterine embolization must be shown to be safe and effective when compared to surgical treatment. So each study must compare the results of UAE with surgery. The PVA study is using myomectomy as the comparison; the Embospheres® study is comparing UAE to hysterectomy.

#### Embolization: how much blockage of the artery is enough?

When UAE was first performed, it was assumed that the artery had to be completely blocked to successfully treat the fibroids. This has become the common practice during uterine

Some experts in this field have theorized that the artery may not need to blocked entirely, but only the vessels going to the fibroids. This theory has been supported by research into a new particle, called Embospheres® Microspheres. This particle is a clear acrylic flexible sphere. Studies have shown that it is more likely than other types of particles to block the fibroid vessels without closing the entire uterine arteries. The particles appear to be equally effective to others in use. It is not yet clear whether Emboshperes® are safer than other agents, but their introduction has caused many interventionalists to reassess the extent of embolization and many now attempt to leave the main uterine artery open and try only to occlude the fibroid feeding vessels.

Both Emboshperes® and PVA can be used in a similar way, leaving at least partial flow in the uterine arteries. It is not yet known if one particle type is superior to the other for UAE. At Georgetown, we are just beginning a study to compare these 2 products, asking patients to allow us to randomly assign to one or the other particle and then measuring the outcome. This will allow us to determine is there is an advantage of one product over the other.

#### Polyvinyl Alcohol Particles (PVA)

PVA is ground from blocks of foam and then separated into different size groupings. The commonest sizes used for uterine embolization are 355 to 500 micron and 500 to 710 micron. A micron is one thousandth of a meter and so these particles are about the size of grains of coarse sand.

PVA has a number of desirable characteristics. It is a particulate material capable of penetrating the fibroid blood supply and blocking it. PVA is relatively inexpensive and easy to deliver. Most interventional radiologists have extensive experience in its use and both animal studies and the published experience in patients suggest that it is safe without any known long-term side effects.

There are some potential downsides. The particles swell after they mix with saline or contrast. Once wet, they tend to aggregate and may clump within vessels after injection. As a result, PVA may completely block the uterine artery. As discussed above, there is not yet agreement among experts in this area as to the extent to which the artery ought to be blocked. It is fair to say that the majority of interventionalists completely block the artery and that does effectively treat the fibroids. However, there is an ongoing debate as to whether complete blockage of the artery is needed and whether it might be safer to just block the blood supply to the fibroids. At this time, PVA is in common use for embolization.

#### Gelfoam (gelatin sponge)

Gellfoam or gelatin sponge is a dissolvable sponge-like material that has been used for many years in surgery. It comes in small flat rectangular blocks about the size of a matchbook. In this form, it can be applied to a minor area of bleeding during an operation and helps a clot form. It has also been used for embolization of fiboids as well, although the reported experience is very limited. For embolization the sponge is compressed flat and then cut into tiny squares (called pledgets) with a sterile scissors. Prior to injection, many operators will load these pledgets into syringes and mix them until they break down into a slurry. Whether used as a slurry or as cut pledgets, gelatin sponge usually results in complete occlusion of the uterine artery at the end of the embolization. Because it generally behaves as a temporary agent in other vascular beds, it has been assumed that the gelfoam will dissolve and the artery will reopen in several days to a few weeks. This reopening of the uterine artery has not been documented in any study to date and therefore it is unclear whether this actually occurs. Its use has been suggested for patients that may want to preserve their fertility because of the perception that the artery will reopen, but further study is needed to determine the long-term rate of reopening (called recanalization) of the uterine arteries. To provide some perspective, reopening of the main uterine arteries has been reported in over 80% of patients after PVA embolization. This research by Dr. Razavi at Stanford suggests that permanent occlusion of the uterine arteries is uncommon after a PVA embolization.

#### **Embosphere® Microspheres**

Embosphere® Microspheres are clear acrylic microspheres that were previously used as a micro-carrier for cell culture, which helped confirm their biocompatibility. They received FDA approval in May of 2000 for general use for embolization. There are some attractive characteristics of this material. The spheres are compressible and this allows easy passage through a micro-catheter with a lumenal diameter smaller than that of the spheres. Studies by Derdelyn and Pelage have shown that these spheres are more uniform in size and the particle sizes do not changed in liquids. They have little tendency to clump after injection and animal studies indicate that they have less tissue reaction than is typically seen with PVA.

In September of 2001, we reported the initial US results with Embospheres from a three center study. The initial clinical experience with Embospheres® is very promising. The symptom change following UAE was substantial, resulting in a dramatic decrease in the impact of symptoms both during menstrual periods and between periods. MRI 3 months after treatment showed no evidence of injury to the normal uterine tissue and fibroid reductions similar to those seen after PVA embolization. This study confirmed that blockage of the main uterine artery is not necessary to achieve successful treatment of the fibroids.

#### Summary

At this time there is not clear evidence if one of the embolic agents in use is superior to others. Currently, most physicians choose the material to fit the individual patient circumstances and their preference. It is hoped that with additional study, the use of products will be able to be tailored to the anatomy of a patient to optimize the results.

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EMBOLIC AGENTS | PREGNANCY AFTER UAE

### **Pregnancy after Uterine Embolization**

The long-term effect that UAE may have on a woman's ability to have a child is not known. It may reduce chances of becoming pregnant for some women, but in others it may be just as likely that the chances will increase.

There are a number of ways that pregnancies may be affected by UAE. During the procedure, some of the flow in the uterine arteries is decreased at least temporarily. It is uncertain what effect this will have on the ability to become pregnant or to carry a pregnancy to term. It appears that in most patients, the arteries reopen to the normal parts of the uterus and it is rare for there to be a permanent injury to the uterus. As the fibroids die and begin to shrink, in some cases this may weaken the wall of the uterus. This would appear to be most likely with large fibroids that span the entire wall of the uterus. However, fibroids compress the normal uterine tissue adjacent to them and as they shrink, we have seen the normal tissue restored to a more normal configuration. For any individual, it is difficult to predict whether the uterus will be weakened to the point where there might be a problem during delivery of a baby. For our patients that have become pregnant, we recommend that a sonogram be performed to assess the site of implantation and the overall integrity of the uterine wall.

Another potential effect of this procedure is the loss of menstrual cycles, with the onset of menopause. The overwhelming majority of women who have had embolization of fibroids have had decreased bleeding with normal menstrual cycles. There have been a few women (most of whom are near the age when menopause would be expected) who have lost their menstrual periods after uterine embolization. The cause is most likely decrease in blood supply to the ovaries as a result of the embolization. Most researchers have noted a 2 to 6% chance of losing menstrual periods and the onset of menopause as a result of UAE (1-4). There has been one study that noted a higher rate of menopause after the procedure (15% of patients treated) but the reason for this higher rate is not clear (5). It is very rare for a woman under the age of 45 to lose menstrual periods.

To further evaluate ovarian function after UAE, at Georgetown, we have completed a study on ovarian function after uterine embolization (6). Among the 35 women in the study under the age of 45, there was no permanent change in FSH, a hormone often used to estimate the likelihood of pregnancy. None of the women in that study had cessation of menstrual periods.

#### **Published Data**

Thus far, over 100 patients have become pregnant after this procedure worldwide. There have been two papers summarizing pregnancy after UAE (7, 8). In Ravina's study, among 184 women who had uterine embolization, 12 unexpected pregnancies occurred during the follow-up period. The average age of this group of patients was 36. There were 5 miscarriages (in 3 women) among the 12 pregnancies. There were 7 deliveries, 4 by cesarean. There was 1 twin pregnancy. There was one baby that died during delivery from an infection. The mother in this case had AIDS and had a serious streptococcal infection at the time of the delivery. The other 7 babies were all normal. In McLuca's study, there were 52 women under the age of 40 who stated an interest in pregnancy. Of these there were 17 pregnancies in 14 patients, for a 33% pregnancy rate. There were 10 term pregnancies, 5 miscarriages, and 2 ongoing pregnancies at the time of publication.

Both of the above studies are small and are not of sufficient size to determine overall fertility rates. However, there are other sources of data on pregnancies after uterine embolization. For example, it is also known that patients who have had this procedure for other reasons, such as bleeding after childbirth, have successfully carried pregnancies (9).

At this time there is insufficient information to predict the percentage of women who will be able to become pregnant after UAE. It is very likely that the chance of pregnancy will depend on the extent of the fibroids. Those patients with very extensive fibroids are probably less likely to become pregnant whether they have UAE, myomectomy or even if they have no therapy at all.

It is hoped that the FIBROID registry will answer the question about subsequent pregnancies after UAE. Until that data is available, each patient's treatment will need to be carefully considered and UAE recommended in those patients in whom other more established therapies have failed or are likely to reduce fertility further.

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**Uterine Artery Embolization** 

DISCHARGE INSTRUCTIONS

### Patient's Guide

#### Uterine Artery Embolization at Georgetown University

In July 1997, the Vascular and Interventional Radiology Section of Georgetown University Medical Center began a protocol to study uterine artery embolization as a treatment for fibroids. Our initial focus was on the safety, effectiveness, and durability of the procedure in controlling symptoms. For a summary of our initial patient outcomes, please review the section of Georgetown Experience. In recent years, uterine embolization has become an accepted part of the management of fibroids in our practice. We believe that our own initial results and those published by others have established the safety and effectiveness of this treatment. It is important for us to determine whether uterine embolization permanently relieves symptoms, whether the fibroids can grow back, and whether there are any other long-term effects. We continue to follow the first 200 patients we have treated to obtain detailed information on the long-term outcome of this procedure. We also continue to research specific questions about the technique of uterine embolization and we continue to study and refine outcome measures for therapies for fibroids. In addition we are one of the leading sites contributing data to the national uterine FIBROID Registry, which will help

#### Georgetown University Pre-Procedure Evaluation

Potential candidates for uterine embolization include those patients with symptomatic fibroids. Whether UAE is the best option for an individual patient can only be determined after a preliminary evaluation is completed.

#### Pre-Procedure Gynecologic Evaluation:

- 1. Each patient should have a pelvic examination by her gynecologist within six months of the procedure. We will need a copy of the records for the most recent gynecology office visit.
- 2. We also need the results of the most recent Pap smear, which must be within the last year and should be normal.
- 3. For patients with abnormal uterine bleeding (periods lasting longer than 10 days or periods more frequently than every 21 days), an endometrial biopsy should be done, preferably within the preceding 3 to 6 months. This is to be certain that endometrial carcinoma or hyperplasia is not present. We usually decide if an endometrial biopsy is needed at the time of the interventonal radiology consultation.
- 4. If the patient has a history of pelvic infection within 2 years, cultures for Gonorrhea and Chlamydia should be obtained.

This evaluation may be done by your gynecologist: you do not need to be seen by a Georgetown Gynecologist.

#### Pre-Procedure Radiology Evaluation:

- 1. All patients will be required to have a pre-procedure evaluation by the interventional radiology staff at Georgetown. This allows us to obtain a gynecologic and general medical history, perform a brief physical examination, review the imaging findings and to discuss the procedure with the patient.
- 2. The patient must not be pregnant. We will confirm this with a pregnancy test the day of the procedure.
- 3. A blood count and follicle stimulating hormone blood test will be obtained on the day of the procedure. If the patient has a history of kidney disease or coagulation defect, further laboratory testing may be required.
- 4. An MRI of the pelvis must be obtained. We prefer that this be done at Georgetown to ensure uniformity of imaging. We have instituted a reduced charge for this study. If the MRI is done at another site, the study must be done with and without contrast and include length, width, and depth of the uterus and the dimensions of the identifiable dominant fibroids. The study must also be of sufficient quality to allow adequate detail of the fibroids and the lining of the uterus. If these are not done, the study will have to be repeated.

#### Preparing for the Procedure

On the day of your procedure, you should not have anything to eat or drink by mouth (unless we have given you special instructions to the contrary). This will allow us to give medication to sedate you during the procedure. You may take any prescription medications by mouth with a sip of water.

We will give you a specific time to arrive, usually 2 hours before your procedure is to start. This will allow time for you to register and to be changed into a hospital gown. We will need time to start an intravenous line, to obtain blood and urine tests, and to answer any last minute questions you may have.

We usually obtain a blood sample to check your blood count on the day of the procedure. In special circumstances, we might obtain other blood tests. If you are more than 10 days from the start of your last period, we will need to confirm you are not pregnant with a urine pregnancy test.

We also need to place a catheter in your bladder, so that the bladder will remain empty during the procedure. Since the bladder is directly in front of the uterus, it is important that it does not fill during the procedure or it would obscure our view

#### The Procedure

The procedure is usually done in the hospital with an overnight stay post-procedure. The patient is sedated and very sleepy during the procedure. Initially, a needle is used to enter the artery to provide access for the catheter. Local anesthesia is used, so the needle puncture is not painful. The catheter is advanced over the branch of the aorta and into the uterine artery on the side opposite the puncture. At Georgetown, a second arterial catheter is placed from the opposite femoral artery to the other uterine artery and the embolization of the fibroids is done from both sides simultaneously.

We routinely use polyvinyl alcohol particles or Embospheres to block the fibroid arteries. In recent months, we have begun to favor Embospheres as they allow for a more controlled embolization and it is easier to preserve flow to the normal parts of the uterus. We have used gelfoam for uterine embolization in only one patient and it was in a patient with primary adenomyosis. While others have used it more frequently, there is not yet any data that confirms that the uterine artery is likely to open up after embolization. For a more detailed discussion of the various substances used to block the arteries, please review the page on embolic agents.

After the embolization is complete, a final arteriogram is performed to be sure the fibroid flow is blocked. Usually we will obtain images of the ovarian arteries in addition to be sure there is no contribution of blood flow to the fibroids.

When the procedure is finished, the catheters are removed and the puncture sites are compressed for 15 to 20 minutes. The patient must remain at bedrest for 6 hours after the procedure in order to prevent bleeding from the puncture sites. As an alternative to compression and bed rest, we are now on some occasions using a closure device to seal the puncture sites. If these devices are used, no compression is needed and the patient is able to get up 2 hours after the procedure.

#### Post-Procedure: What to expect

#### Pain

Most patients will experience several hours of moderate to severe pain after the procedure. It is believed that this pain is due to the death (infarction) of the fibroids, similar to a heart attack. Temporary decrease in the blood supply to the normal portions of the uterus may also contribute to the pain.

The severity of pain is quite variable. Approximately 20% of patients have little or no pain after the procedure. About 20% of patients will have severe pain that may last for several hours. Most patients have pain some where in between the two extremes. We have completed a study at Georgetown to determine the severity of the pain after UAE and whether its severity can be predicted. Unfortunately, the severity of pain is not predictable based on the size of the uterus or the size of the fibroids. Some patients with very large fibroids have minimal pain and some with small fibroids have severe pain. The pain usually begins to diminish after 4 to 6 hours. Parenthetically, the severity of the pain also does not predict outcome. Severe pain does not correlate with a better outcome.

Since pain does not have any value in predicting outcome, it should be treated aggressively to ensure that the patient has a tolerable procedure. Most centers use a combination of anti-inflammatory medicines (such as Motrin) and narcotics (such as morphine) to control the pain. The most common means of providing the narcotics is via a PCA pump, which is a device attached to the patient's intravenous line. PCA stands for patient controlled analgesia. If pain occurs, the patient is able to press a button and administer a dose of pain medication. Many studies have demonstrated that PCA pumps are more reliable in controlling pain than nurse administered doses. The large majority of patients at Georgetown and elsewhere are managed with PCA pumps after the procedure. This is not to say that there are not effective alternatives. There has been research on the effectiveness of using an "all oral" medication regimen, without any injected drugs.

Some centers, including Georgetown, offer the alternative of epidural pain control. With epidural pain control, a tiny tube is placed in the spinal canal outside the sac where the nerves lie. This is usually done by an anesthesiologist. It is the same procedure that is commonly used during labor, but the legs are not numbed. After the procedure, pain medications are given via the epidural catheter. Although the use of an epidural catheter is more invasive than an intravenous line, the pain control may be better. As of yet a study has not been completed comparing the two methods of pain management.

Nausea and Vomiting

Another frequent side effect of uterine embolization is nausea and vomiting. This may be caused by the death of the fibroid tissue or as a result of the pain control medications. The nausea can usually be controlled by medications and most physicians performing uterine embolization provide standing orders for nausea medicine if needed.

Because the severity of the symptoms from uterine embolization is very variable, many centers routinely observe patients in the hospital overnight. Under most insurance plans, this is still considered an outpatient procedure, because the length of stay is less than 24 hours.

#### After discharge from the hospital: What to expect

Most patients will have recurrent cramping pelvic pain over several days after discharge. Usually this pain feels like menstrual cramps. On occasion, the pain may become severe. At Georgetown, patients are given an anti-inflammatory medicine to take continuously for four days. This is supplemented by oral narcotics as needed.

Nausea may also recur and medication is also provided for this. Fever is common and is a side effect of the death of the fibroid tissue. Most patients feel as if they have the flu for several days. All these symptoms begin to improve after 4 to 5 days and most patients are ready to return to work 7 to 10 days after the procedure.

For a more detailed discussion of the post-procedure recovery, review our post-discharge instructions.

#### Georgetown University Follow-up Protocol

We call the patient the day after discharge to be sure that there are no unusual problems and to answer any questions the patient may have. We will also arrange for a follow-up visit I week after the procedure. At that visit we will check the puncture sites and intravenous site to be sure they have healed and we will review the progress of your recovery. At that time we usually release a patient to return to full activity. We will call the patient 30 days after the procedure to be sure that no problems or gynecologic procedures have been

To follow the progress of the symptoms, we will send questionnaire 3 months post-procedure. Follow-up imaging with MRI is at 3 months. If symptom improvement has occurred and the images shows the fibroids have died and are shrinking, then further follow-up is on an as needed basis. For many of our research protocols, we have longer and more detailed follow-up.

We ask that all the patients we treat allow us to anonymously submit baseline and procedure data to the national FIBROID registry. A fibroid-specific symptom and quality of life questionnaire and a short questionnaire will be sent to a randomly selected group of patients at 6 months, 12 months and 24 months after the procedure. We hope to obtain federal funding to continue follow-up for up to five years in this registry

We consider this procedure and the MRI before and 3 months after the procedure to be standard medical care and therefore bills will be submitted to the patient's insurance as usual. Any additional imaging that is done for research purposes will be provided at no charge to the patient.

#### For more information

If you would like to consider this procedure or would like more information, you may call James B. Spies M.D. of Georgetown Interventional Radiology at (202) 784-5478 to make an appointment. You may also contact him via email spiesj@gunet.georgetown.edu. We would also be happy to discuss uterine embolization with your gynecologist.

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## **Uterine Artery Embolization**

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#### **Patient's Guide**

## **Discharge Instructions**

Note: The following represents the written instructions that we provide for our patients upon discharge at Georgetown University. This is provided on this website for patients to understand the recovery process. The instructions you receive from your physicians where you are treated may vary from these and we recommend that you follow the instructions you are given. If you experience difficulties in your recovery, you should contact your own physicians who know your situation best.

In order to ensure a rapid and worry-free recovery from your procedure, we have put together this set of instructions to answer the most common questions that patients have. We are always happy to have you call with your questions, but it will be easier and quicker for you to refer to these instructions first: the answers you seek will often be here.

#### The recovery process

Over the next several days you are likely to have cramps that come and go as well as feeling as if you have the flu, with low energy, intermittent nausea, and possibly fever. These are all normal side effects of the procedure as your body reacts to the death of the fibroid tissue. Usually these symptoms are most pronounced in the first 2 or 3 days and by the fourth or fifth day after the procedure you will start to feel better. It is unusual for these symptoms to last longer than 7 days. The cramps may continue for a few days longer. Because of the flu-like symptoms, most patients will need about 1 week off from work. While you will progressively feel better over several days, you should anticipate a generalized lack of energy and should gauge you activity accordingly. We do not recommend travel plans for two weeks (except for those patients from out of the Washington area who are returning home) and would not recommend overseas travel for 1 month or until you feel completely recovered. With this overview, we discuss specific problems below.

#### Follow-up Care

We will call you the day after your discharge to check your progress and to answer any questions. At that time, we will schedule a follow-up visit for the following week. We will call you 30 days after the procedure to be sure that there have not been any problems.

At 3 months post-procedure, we will send you a brief questionnaire and a prescription for an MRI. We would encourage you to have a brief follow-up visit at that time to review the films and your symptom status.

You should continue your normal gynecologic well-woman care with your gynecologist. This includes monthly self-breast exams and yearly pelvic exams with Pap smear as suggested by your gynecologist.

#### **Puncture Sites**

Arterial punctures were performed at the top of both legs and Band-Aids are in place over those puncture sites. You may shower today and each day. For the next two days after each shower remove the wet Band-Aids and replace them with dry, clean Band-Aids. This will promote healing. If you notice any swelling or active bleeding from the puncture sites, you should use direct pressure by placing your fingers and a clean cloth or paper towel over the site. Immediately call for assistance and report to the nearest emergency room for evaluation. This is extremely rare and occurs in less than 1 in 500 patients.

There may be some bruising at the puncture sites and this is normal. This bruising may spread out over several days. This is the normal way in which a small amount of blood under the skin is reabsorbed. This should not be of concern.

You may notice small knots under the skin at the puncture sites, usually about the size of a large pea. These are part of the healing process and will usually fade away within a few months.

Infrequently, patients will notice continuing pain at the puncture sites or in the upper thigh. This is usually due to irritation of the nerve branch that passes by the puncture site. If this is bothersome, you may continue to take Motrin or Advil, which will usually reduce the discomfort. While it is possible for this discomfort to continue for several weeks or longer, this is very rare. Should this occur, please contact us.

#### **Diet and Activity**

Resume your normal diet and medications. You should slowly increase your activity over the next three to four days. You may have unrestricted activity, including sexual activity and exercise, 7 days after the procedure. Do not drive until you are no longer taking the prescription pain medications (Percocet or Dilaudid). These medications may make you sleepy. Because of this, do not operate any machinery or kitchen appliances while you are taking them.

#### Medications

You have been given a number of prescriptions to help manage pain and nausea that may occur in the first several days post-procedure. For convenience, we have provided the following table of the generic and trade names of the prescription drugs we usually use.

ACTION	GENERIC NAME	BRAND NAME
Anti-inflammatory	Ibuprofin	Motrin
Pain relief	Oxycodone	Percocet
Pain relief severe	Hydromorphone	Dilaudid

Anti-Nausea Ondansetron HCI Zofran

#### Post-procedural Pelvic Pain and/or Cramps

You should expect to have pelvic pain and cramping over the next several days to two weeks. Usually this lasts for 3 to 4 days. It is most intense the day after the procedure and decreases each day thereafter. You have been given Motrin (Ibuprofen) which is an anti-inflammatory medication. You will take one pill (800 mg) every 6 hours for 4 days. In addition, you have been given narcotic pain medications to assist with pain control. Percocet (Oxycodone) is a narcotic pain reliever and generally provides substantial relief for most patients. You may take one or two tablets every four hours as needed for pain. You have also been given a stronger narcotic pain reliever called Dilaudid (Hydromorphone). If you do not receive any relief from the Percocet, you may use Dilaudid instead of the Percocet. Take the Dilaudid, one tablet every four hours as needed for pain.

#### Nausea

It is not unusual to experience nausea after the procedure. You have been given a prescription for an anti-nausea medication. This is either Phenergan (promethazine) or Zofran (ondansetron hydrochloride). You may take this medication according to the label directions every four to six hours as needed for nausea. If the medication you have been given does not relieve the nausea, call us and we can prescribe an alternate.

#### **Heartburn and Constipation**

While taking the Motrin it is important to protect your stomach from irritation. Try and eat some food before taking the medication and to take it with a full glass of water. It is best to remain in an upright sitting position for at least 30 minutes after taking the Motrin.

A common side effect of the prescription pain medicine is constipation. Feel free to use Milk of Magnesia or warm a glass of prune juice prior to drinking your morning coffee. Also, remember to drink at least 8 glasses of water a day.

#### Fever

A mildly elevated temperature is a common side effect of the uterine artery embolization and occurs in approximately 20-25% of patients. The fever is a side effect of the fibroids dying and does not indicate infection in most cases. This should be treated with regular Tylenol. You may take 2 tablets every 4 hours while the fever is present. Motrin will also relieve fever.

High temperatures (greater than 102°), a fever that persists for more than 3 days, or a fever arises more than a week after the procedure might indicate infection and you should call the Interventional Radiology Service as described in the bottom of this instruction set. In general, infections that might develop would be much more likely to develop in a week to several weeks after the procedure.

#### Menstrual Periods, Vaginal Discharge or Spotting

A brown or reddish brown vaginal discharge or spotting after the embolization is considered normal and may continue for a few weeks or until your first period. You may use a sanitary napkin until it resolves. We would prefer you not use a tampon for the first week after the procedure.

Occasionally, patients will have a clear watery discharge for several weeks or months post-procedure. This does not indicate infection. Of greater concern is a thick or foul smelling discharge, particularly if it is accompanied by fever or pelvic pain. This may indicate an infection and you need to contact us.

On occasion, the procedure causes you to start a menstrual cycle early or you may skip a period or two. If heavy bleeding was one of the symptoms caused by your fibroids, often your periods will be better right away. However, some patients will not improve for 2 or 3 cycles, so don't be discouraged if there is no immediate improvement. Regardless of whether bleeding or pressure and pain were symptoms, most patients will have improvement by the 3rd month after the procedure.

The first and possibly the second menstrual periods may be more uncomfortable than typical. Some patients tend to have increased cramps during these periods. This should resolve as the fibroids shrink. The fibroids take several months to significantly shrink and therefore short-term improvement in the size of the uterus should not be expected.

#### **Hormonal Changes**

Some patients may experience symptoms as a result of changes in their hormonal balance after the procedure. Fibroids are estrogen driven. As the fibroids die, there may be a sudden change in hormones. Some women experienced mild depression, which subsides within a few days. Others experienced "hot flashes" and/or night sweats and these may persist for a few weeks. In our experience here at Georgetown, we found these symptoms to be self-limiting and resolved without treatment.

#### Signs of Potential Problems

Symptoms that might indicate problems include swelling or active bleeding form the puncture sites, pain that arises several days or weeks after the initial pain resolved, a temperature several days to weeks after the initial procedure or an irregular vaginal discharge (particularly if foul smelling or copious). This might indicate either an infection or partial passage of a portion of the fibroid and may require gynecologic evaluation. If any of these symptoms occur, please contact the Interventional Radiology service to assess the symptoms and to make further treatment recommendations.

#### Research Protocols

As you are aware, we have an active research program on Uterine Embolization here at Georgetown University Hospital. You may have agreed to participate in one or another of the studies that are ongoing. We ask that you assist in that effort by promptly completely the follow-up questionnaires and imaging studies as required. In order to answer the key questions regarding the outcome of this procedure, we need high quality and complete data. You are the source of that data and, without you, we will not be able to answer those questions for our future patients

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### **FIBROID Registry**

The FIBROID Registry is a national data registry formed to assess the long-term outcome of uterine artery embolization, its durability, impact on fertility and quality-of-life, and to obtain data which will allow researchers to compare UAE to other fibroid therapies. Georgetown University Hospital is one of the first core site participants in the FIBROID Registry.

Learn about this large study and the participating sites at

www.fibroidregistry.org/about.htm.

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## Finding a Physician who Performs UAE

While we here at Georgetown University Hospital in Washington DC have treated patients from all over the country (and the world), there are uterine embolization programs in many parts of the US and we encourage patients to seek out physicians in their region that are experienced in this procedure.

The best approach is to contact a program that is a core site in the fibroid registry and they can be located at the website www.fibroidregistry.org. The core sites were chosen because they have considerable experience in the procedure. Another source is the physician locator at the website www.scvir.org/fibroid. Again participants in the fibroid registry are identified there and they may be more likely experienced than others, although there are some high volume practices that do not participate.

When choosing a physician and hospital for treatment, we suggest that you ask about the program's protocol for pain management, patient care, and follow-up. The SCVIR, the national interventional radiology specialty society, recommends that every program create a standard treatment approach, with mechanisms in place for appropriate patient care and follow-up. This type of organized approach is one indicator of a program that is striving for quality care.

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## **Uterine Artery Embolization**

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### **Adenomyosis**

#### Introduction

Adenomyosis has long been an underdiagnosed condition of the uterus (1). With the advent of uterine embolization of fibroids, interest in adenomyosis has increased. How often is it mistaken for fibroids? Can it be treated by embolization? Is it a cause for failure of embolization? With modern imaging techniques, adenomyosis can be diagnosed without surgery and thus we are able to begin to understand the natural history of the condition and to test the effectiveness of non-surgical therapies.

#### **Pathology**

Adenomyosis is the presence of uterine lining tissue deep within the myometrium or muscular wall of the uterus (1) (see **Figure 1**). When diffuse, the uterus becomes enlarged, although rarely larger than a pregnancy of 12 weeks size. The adenomyosis tissue can extend throughout the lining of the uterus or in just one spot (focal). When focal, a localized collection of adenomyosis tissue may form a mass-like adenomyoma.

Adenomyosis most commonly occurs in women who have had children, raising questions as to a possible role that pregnancy may have in its development (2). Uterine trauma during childbirth and post-partum infection have been suggested as possible causes of adenomyosis. No definitive cause has been identified and certainly adenomyosis can occur in women who have never been pregnant.

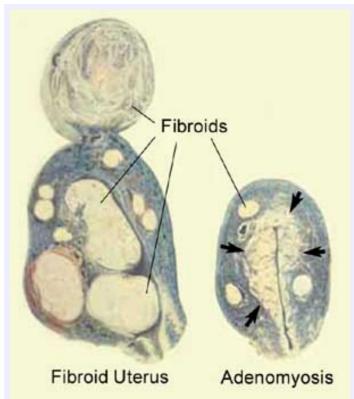


Figure 1: Surgical specimens after hysterectomy. On the left is a uterus with several large fibroids, some of which are indicated. On the lower right, the specimen has 3 small fibroids, but also extensive adenomyosis (arrows), which appears as a thickening of the inner portion of the muscle wall of the uterus, which is called the junctional zone.

#### **Clinical Presentation**

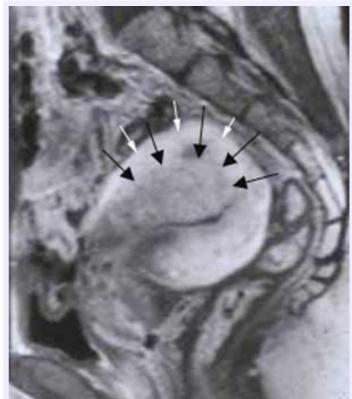
The most common symptom of adenomyosis is abnormally heavy menstrual bleeding. Severe cramps are a frequent accompaniment when the adneomyosis exceeds 80% or more of the uterus (2). There is usually globular enlargement in the uterus on pelvic examination and the uterus may be somewhat boggy if the adenomyosis is advanced. The posterior wall of the uterus is more commonly involved than the anterior.

Adenomyosis and particularly adenomyomas are commonly misdiagnosed as fibroids, because the symptoms are similar. The uterus is often enlarged, and ultrasound imaging often fails to distinguish the two conditions. This can be a particular problem if myomectomy is undertaken. Adenomyosis has a poorly defined border and is not "shelled out" as leiomyomas may be. An attempted myomcetomy for "fibroids" on a patient with adenomyosis can result in extensive bleeding and may result in the need for hysterectomy.

#### **Imaging**

Modern imaging methods have been a great aid in accurately diagnosing adenomyosis (3). With modern ultrasonography, the diagnosis can frequently be made, although the changes can be subtle. The findings may include myometrial thickening with increased or decreased echogenicity of the myometrium, a poorly defined area of heterogeneous myometrium, or cysts. The sensitivity of transvaginal sonography ranges from 53-89% and specificity of 50 to 89%.

MR imaging increases both sensitivity (88-93%) and specificity (66-91%) of the diagnosis of adenomyosis. The signal intensity is similar to that of the junctional zone and usually is perceived as a thickened junctional zone to greater than 12 millimeters. Usually there is focal thickening of the junctional zone as well. On T2 weighted images, foci of increased signal are seen, representing islands of endometrium within the hypertrophied myometrium. Variable enhancement patterns are seen depending on the present of cystic areas. A common and useful finding is the relatively mild distortion of the endometrial cavity that occurs with even advanced adenomyosis (see Figure 2) It exerts much less mass effect than fibroids and this is a helpful finding differentiating when adenomyosis from fibroids.



**Figure 2:** MRI scan from the side showing a uterus with extensive adnomyosis (black arrows), which appears as a darker shade of gray on this scan when compared to the normal portions of the uterine wall (white arrows).

#### **Current Therapies**

The definitive therapy of adenomyosis is hysterectomy and commonly the diagnosis is not confirmed or even suspected until examination of the removed uterus. Surgical resection of the adenomyosis alone is not technically feasible in most cases. Until recently, even when the diagnosis has been suggested pre-operatively, hysterectomy was the only option to offer.

In recent years there have been investigations of various less invasive therapies for adenomyosis. In Europe, a levonorgestrel-releasing intrauterine device has been shown to be effective in controlling menorrhagia caused by adenomyosis (4). While the treatment is effective in the short term, the symptom control rapidly dissipates once the therapy is terminated. Endometrial ablation has been attempted, and with very superficial adenomyosis, endometrial ablation can be effective. However, if the penetration exceeds 2 millimeters, ablation usually fails to control bleeding (5).

#### **UAE** for Adenomyosis

It is not yet clear what embolotherapy may have to offer in controlling the symptoms from adenomyosis. There were three recent reports of experience with embolization in patients with adenomyosis. Two small studies demonstrated that in patients with fibroids and adenomyosis, embolization had similar rates of symptomatic improvement. In a small group (N=13) at Georgetown, 92% had symptomatic improvement in both menorrhagia and pelvic pain and pressure. In this series, there was reduction in the fibroid volume and uterine volume. There was not a significant change in the internal appearance of the adenomyosis, although in some cases there was regression of the adenomyosis extent (6). At Albany Medical School, Siskin treated 14 patients with focal adenomyomas or diffuse adenomyosis (7). In 90% of the patients, there was improvement in symptoms. Regression in uterine volume, focal adenomyoma volume, and thickness of the junctional zone was noted in all cases,

Ahn and his associates from Korea presented a much larger series (N=65) at the SCVIR 2000 (8). Twenty-nine percent of the group had both myomas and adenomyomas, with the balance having adenomyosis alone. Among all patients, 93.8% reported improvement in symptoms. The authors used varying sizes of polyvinyl alcohol particles, and commented that coagulation necrosis only occurred when particles of 355-500 micron size or smaller. They suggested that this finding is necessary to assure clinical improvement. The group at Georgetown used 500-710 micron size particles and did not see infarction of the adenomyosis, but had similar rates of symptomatic improvement.

Certainly additional study is needed to determine the role that UAE will play in the treatment of adenomyosis, but these initial reports are very encouraging. The optimal method for embolization has yet to be determined and validated outcome measures have yet to be used in assessing embolotherapy.

#### Summary

Adenomyosis is a difficult condition to both diagnose and manage, with hysterectomy the most commonly used definitive therapy. With the more extensive use of MRI as a gynecologic imaging tool, the diagnosis of adenomyosis will become more accurate and the testing of new therapies, including uterine embolization, will be greatly facilitated. With the initial positive reports of uterine embolization as a possible therapy, there is hope that alternatives to surgery may soon be available.

#### **UAE for Adenomyosis at Georgetown University**

Last year we began a protocol to determine whether patients with predominant adenomyosis (with few or no fibroids) could be successfully treated with uterine embolization. While the initial results are encouraging, the number of patients treated thus far has been small and the follow-up duration is relatively short. We are continuing to enroll patients in this study and would be happy to evaluate patients for inclusion. There are no research funds available to provide the treatment. The study uses validated measures of heavy bleeding and quality of life questionnaires to assess symptom status before and after treatment. MRI's are obtained at baseline and at 3 months after treatment.

For additional information, please call us at (202)784-5478 or email us at info@fibroidoptions.com.

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### **Physician's Resource:**

#### **Uterine Artery Embolization of Fibroids**

A brief summary for physicians

#### **Georgetown University Experience**

In 1997 we began performing UAE at Georgetown. Since then we have treated nearly 600 patients. We present the results of our experience to date, including the details of our published experience in our first 200 patients (Obstetrics and Gynecology 2001; 98:29-34.).

#### **Published Georgetown University Research on UAE**

This section summarizes some of the research on UAE that we have completed at Georgetown and that has been published in the medical literature.

#### **Literature Review**

A comprehensive review of the published data and a selected review of important scientific presentations.

#### Physician's Guide for Patient Protocol

Review the details of our protocol at Georgetown, including pre-procedure gynecolgic and radiologic evaluation and referral information.

## **Uterine Artery Embolization of Fibroids:** A Brief Summary for Physicians

#### Introduction

Uterine artery embolization is a minimally-invasive therapy for symptomatic fibroids that is an alternative to hysterectomy and myomectomy. This method uses angiographic techniques and fluoroscopic guidance to embolize the uterine arteries, similar to the methods used to control post-partum hemorrhage. The embolization occludes the blood supply to the fibroids, which results in their ischemic infarction and subsequent degeneration. This leads to a reduction in the fibroid's size and a decrease or resolution in the symptoms they cause.

#### The Procedure

The procedure is done as an outpatient, with a 23 hour overnight admission. It is performed with conscious sedation and local anesthesia. The common femoral arteries are the access sites and, at Georgetown University, both are used. The uterine arteries are most easily accessed from the contralateral femoral artery. After selective catheterization of the uterine arteries, an arteriogram is performed. A typical example is shown in the figure below, left (**Pre-embolization Angiogram**) with large abnormal fibroids vessels indicated with arrows.

#### Pre-embolization angiogram



#### Post-embolization angiogram



Next, particles of polyvinyl alcohol (Contour, Boston Scientific, Natick, MA) or tris-acryl microspheres (Embospheres, Biosphere Medical, Rockland, MA) are injected slowly with fluoroscopic guidance. These particles wedge in the fibroid vessels and occlude them. Both uterine arteries are occluded. After the entire study, another arteriogram is performed. After embolization, all the fibroid vessels are gone with only very sluggish flow present in the uterine arteries (black arrows in the figure on right -- Post-Embolization Angiogram). Normal myometrial branches are spared (white arrows). The procedure takes approximately 1-2 hours.

#### **Side Effects**

Most patients will experience 4 to 5 days of symptoms after the procedure. This includes pelvic pain, nausea, and possibly fever. After an initial period of bed rest for six hours, patients are hospitalized overnight to control pain. The pain after the procedure usually lasts 6 to 8 hours and is moderately severe and usually requires intravenous narcotics. In nearly all cases, the pain is gone or minimal the day after the procedure. Rarely, a second night of hospital care is needed for pain control.

Cramping pain, fatigue, and possibly fever are common side effects during the subsequent few days, but most symptoms resolve within 4 to 5 days and a patient might anticipate returning to work 7 days after the procedure.

Major procedural complications (<30 days) have been reported in less than 4% of patients. An ischemic injury to the uterus of such severity that a hysterectomy is required is possible but occurs in only .05% of patients. Pyometrium has also been reported, which may necessitate a hysterectomy. Less severe infections have been reported and treated with intravenous antibiotics. Injuries to other pelvic organs have not occurred. Another rare, but potentially severe complication, is pulmonary embolus, which has been noted in 1 in 500 patients. To date, there have been 4 deaths reported after uterine embolization in the world's experience, 2 from sepsis (1 in England, 1 in the Netherlands) and the others from pulmonary embolus (1 in Milan, Italy, 1 in Alabama, USA).

Another potential side effect is diminished ovarian function. A 1-5% of patients have been reported to have lost their menstrual periods after this procedure. Nearly all have been at the age at which menopause typically occurs. In our experience, 5 patients of the first 400 treated became menopausal as a result of UAE. We have completed a study of basal FSH levels pre and post-procedure to determine if is there is a change in ovarian function in the majority of patients or whether any effects are limited to those who already peri-menopausal. There were changes in basal FSH in 15% of patients over the age of 45. Additional details are given in the section on Research on UAE at Georgetown University.

#### **Expected Results**

After the embolization, the fibroids infarct and degenerate over a period of weeks and months. Average fibroid volume reduction is approximately 43% at three months and 65% at one year. Uterine volume decreases by approximately 34% in three months. Two cases are shown in the accompanying figures.

The first case shows MRI's before and three months after embolization in a patient with multiple fibroids. The patient presented with severe menorrhagia, back pain and painful periods. Three months after embolization, the fibroids are infarcted and by measurement, the uterine volume decreased by 66% and the two dominant fibroids decreased by 86 and 91%. Her symptoms resolved.

The second case shows a large single submucosal fibroid in a patient with severe menorrhagia. At three months after embolization, her symptoms had resolved and the fibroid had decreased 61% in volume. At one year, it had decreased 88% in volume. At two years, only a tiny scar remains of the fibroid. Her menstrual periods have remained normal in the 4.5 years since treatment.

The studies that have been published to date suggest that symptoms will be significantly improved or will resolve in 80-90% of patients. The patients in these series rated the procedure as very tolerable. An evidence table has been included at the end of the Literature Review, detailing the reported results. The long-term outcome is not known, although mid-term results from several centers show that the fibroids successfully treated do not recur, with MRI evidence of hemorrhagic infarction. Post-procedure fertility and the ability to carry a pregnancy to term is not known. Some of the patients in published series have successfully carried pregnancies but most patients have not sought to become pregnant and therefore the percentage that will be able to become pregnant is not known. For more detailed discussion of the published and presented data, we invite you to review the Literature Review

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## **Uterine Artery Embolization**

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#### Physician's Resource

## **Georgetown Experience**

At Georgetown University, we have treated nearly 600 patients with uterine embolization for fibroids. Beginning as a research protocol, embolization is now established as an accepted alternative to surgical management of fibroids. We have completed a number of studies on this procedure. Perhaps the most important is our recent report of our experience in 200 consecutive patients treated and followed for a minimum of 12 months. In this section, we will discuss those results in some depth.

#### **Uterine Artery Embolization for Leiomyomata**

Authors: Spies JB, Ascher SA, Roth AR, Kim J, Levy EB, Gomez-Jorge J. Obstetrics and Gynecology 2001;98:29-34.

A total of 200 patients were treated between July 1997 and December 1999. The procedure was technically successful on both uterine arteries in 99% (n=198) of patients.

The large majority of patients (93%) had an overnight (23 hour) admission to the hospital. An additional 4% were discharged the day of the procedure. Admission for more than one night was required in 3% of patients. The average days until return to normal activity was 8, including weekend days.

The mean duration of study participation was 21 months and ranged from 12 to 36 months. Follow-up questionnaires were obtained from 91% of patients at three months, 82% at six months, 92% at one year and 69% at two years. Each patient in the study had a minimum of 12 months interval from the procedure.

Table 1 provides a summary of the symptom outcome from therapy. The majority of patients had improvement in symptoms by three months post-procedure and the symptom control persisted in most patients for up to two years of follow-up. Patient satisfaction paralleled the symptom change.

Table 1
Summary of symptom change

#### **Heavy Menstrual Bleeding**

	3 months	6 months	1 year
	n=181	n=158	n=167
Improved	87	89	90
Unchanged	10	5	8
Worse	3	5	2

#### **Bulk Symptoms (%)**

	3 months	6 months	1 year
Improved	93	92	91
Unchanged	4	5	7
Worse	3	3	2

#### Satisfaction with symptom change (%)

	3 months	6 months	1 year
Improved Unchanged Worse	93 4 3	93 2 5	92 2 6
Questionaire Response Rate	95.5%	85%	90.5%

The imaging follow-up was obtained in 174 patients at 3 months and 116 at 12 months after treatment. The mean uterine volume reduced by 27% (std. dev. 29) 3 months post-treatment and further reduced by a mean of 38% (std. dev. 31) by 12 months after treatment. The mean dominant fibroid volume reduced by 44% (std. dev. 27) after 3 months and 58% (std. dev. 29) after 12 months. The data revealed a progressive reduction in both uterine and dominant leiomyoma mean volume from baseline to one year after treatment. There was a significant time effect for the percent reduction in uterine volume (F=26.26, df = 1, p<0.001).

There were 13 minor complications (6.5%), all treated with nominal therapy. The majority of these complications were for additional pain management (N=7). One major complication occurred. A patient developed a pulmonary embolus within 36 hours of the procedure. Her pulmonary embolus was diagnosed 2 days after discharge, prompting readmission for 4 days for anticoagulation.

Eleven patients were amenorrheic 3 months after embolization. The majority of these resumed normal menses within the subsequent 3 months, with only 4 patients made permanently amenorrheic by the procedure.

Subsequent gynecologic interventions or readmission occurred in 10.5% of patients. Most gynecologic procedures occurred months after the procedure. In our experience dilatation and curettage or hysteroscopic resection were the most common interventions for acute gynecologic problems related to the treated leiomyomata. During follow-up, 5 of the subsequent interventions were for endometrial infection, fibroid tissue passage, or severe bleeding; 2.5% of the study group.

Nine hysterectomies were performed, none for complications of the procedure. Seven patients underwent hysterectomy for failure of symptoms to improve sufficiently. Two patients had incidental hysterectomies for other conditions

The conclusion from this study is that uterine embolization is safe, with remarkably few complications. It also appears to be effective in the large majority of patients, with approximately 90% improved.

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#### Physician's Resource

#### **UAE Research at Georgetown University** Published Papers

Since we began to perform uterine embolization in July of 1997, we have actively studied the results of this therapy. We have always completed our research studies using protocols reviewed and approved by the institutional review board of Georgetown University Medical Center. While the goals of research efforts have varied with the particular questions under study, we are continuously gathering data to present at scientific meetings or published in medical journals. We have summarized our published research papers below, along with the references for finding the original articles in the medical literature.

#### Transcervical expulsion of a fibroid as a result of uterine artery embolization for leiomyomata.

Authors: Abbara S, Spies JB, Scialli AR, Jha RC, Lage JM, Nikolic B.

Journal Reference: JVIR 1999; 10:409-411.

This case report was one of the first to document that submucosal fibroids (those just under the inner lining of the uterus) can be expelled through the cervix into the vagina as a result of uterine embolization. Usually this occurs spontaneously and, as with the patient reported here, it is a relatively benign event with removal of the fibroid by either a simple pelvic examination or with a minor surgical procedure, such as a D and C or hysteroscopy. The particular patient reported here has done very well in the two years since the fibroid passed.

#### Ovarian artery supply of uterine fibroids as a cause of treatment failure after uterine artery embolization: a case report.

Authors: Nikolic B, Spies JB, Abbara S, Goodwin SC. Journal Reference: JVIR 1999;10:1167-1170.

This was the first report of failure of uterine embolization due to supplemental blood supply from the ovarian arteries. This represents an unusual variation in blood supply to the uterus, but may account for up to 5% of patients. The patient reported here had been treated six months earlier at another center and although she had had initial improvement, her symptoms recurred. An arteriogram revealed very large ovarian arteries that supplied the upper portion of the uterus. This blood supply prevented the fibroids from dying and

#### Initial results from uterine fibroid embolization for symptomatic leiomyomata.

Authors: Spies JB, Scialli, AR, Jha RC, Imaoka I, Ascher S, Fraga VM, Barth, KH Journal Reference: JVIR 1999;10:1149-1157.

This was the initial report of the results of the patients treated at Georgetown University. Sixty-one patients were treated, with the procedure completed successfully in sixty. Menstrual bleeding was improved in 89% and pelvic pain and pressure improved in 79%. At three months post-procedure the medican uterine volume had decreased 34% and the medican dominant fibroid volume decreased 50%. There were few complications and patient satisfaction was very high.

#### Measurement of health-related quality of life before and after uterine fibroid embolization for symptomatic leiomyomata.

Authors: Spies JB, Warren E, Mathias S, Walsh SM, Pentecost MJ. Journal Reference: JVIR 1999:10:1293-1303.

The most common method of determining the results of uterine embolization is the use of simple questionnaires that ask questions about the improvement in symptoms after the procedures. This study used a broader measure of outcome, a health-related quality of life (HRQoL) questionnnaire. Not only was symptom status evaluated, but broader measures of health as well, such as general health, energy, vitality, self-image, bodily pain, physical functioning, sexual functioning, and comparative health. The use of these measures is important to ensure that the patient's overall health is improved, not just the symptoms associated with the fibroids.

This study showed a very substantial improvement in all of the symptoms and the broader health indices measured. The general health perception changed from below normal to above normal. This study provides the first evidence using a validated questionnaire that UAE is effective in improving the overall health of patients treated.

#### Patient radiation dose associated with uterine artery embolization for leiomyomas.

Authors: Nikolic B, Spies JB, Lundsten M Journal Reference: Radiology 2000;214:121-125.

This is the first study reporting the amount of X-rays needed to complete UAE. That amount is significantly more than X-rays used for diagnosis of a variety of abdominal conditions, but substantially less than the amount needed to treat cancer. The amount of X-rays needed is well below that expected to cause harm to the ovaries, future children, or the patient's own long term health.

#### Symptomatic fibroleiomyomata: MR imaging of the uterus before and after uterine arteral embolization.

Authors: Jha RC, Ascher SM, Imaoka I, Spies JB. Journal Reference: Radiology 2000;217:228-235.

This study reviews the characteristics of fibroids in the uterus before and after embolization. It is the first major review of the findings associated with successful embolization. In particular, the study shows that MRI can determine whether the fibroid has infarcted (died). This is important in cases where the fibroid has had only minor size reduction. In those cases, the MRI reassures us that the procedure was technically successful and, with time, additional shrinkage should occur,

Influence of technique and equipment on absorbed ovarian dose associated with uterine embolization.

Authors: Nikolic B, Abbara S, Levy EB, Lundsten M, Spies JB Journal Reference: J Vasc Intervent Radiol 2000;11:1173-1178.

This is a technical study to determine the relative contributions of various technical factors in the X-ray dose that occurs during UAE. The findings of this study indicate that fluoroscopy is the major contributor to the X-ray dose and that various measures can be used to reduce the dose. These include the use of pulsed fluoroscopy, minimization of the use of oblique and magnification fluoroscopy, and collimation.

### Pain After Uterine Artery Embolization for Leiomyomata: can its severity be predicted and does the severity predict outcome?

Authors: Roth, AR, Spies JB. Walsh SM, Wood, BJ., Gomez-Jorge J, Levy, EB. Journal Reference: J Vasc Interv Radiol 2000; 11:1047-1052.

This study was intended to determine whether the pain that occurs in the first 24 hours after UAE can be predicted pre-procedure. There was not any relationship with either the size of the fibroids or the uterus pre-procedure. In addition, the severity of the pain does not predict how much the uterus or fibroids will shrink after UAE nor does it predict symptom improvement.

## Patient radiation dose associated with uterine artery embolization for leiomyomata: reduced dose using a refined technique.

Authors: Nikolic B, Spies JB, Campbell L, Walsh SM, Abbara S, Lundsten MJ. Journal Reference: J Vasc Interv Radiol 2001;12:39-44.

This paper demonstrated that by using technical advances in performing UAE that were pioneered at Georgetown, the X-ray dose associated with this procedure can be reduced 60% on average over conventional techniques. While the amount of X-rays used in the procedure are unlikely to have any health effects, our goal is to have the lowest possible use of X-rays for any patient.

#### Ovarian function after uterine artery embolization: assessment using serum follicle-stimulating hormone assay.

Authors: Spies JB, Roth, AR, Gonsalves, SM, Murphy-Skrzyniarz, KM. Journal Reference: J Vasc Interv Radiol 2001;12:437-442.

This is the first study published assessing the effect of uterine embolization on ovarian function. It demonstrates that among women under the age of 45, there was no evidence of any change in ovarian function. This finding is important for women who wish to have children in the future. In 15% of women over the age of 45, a change in ovarian function can be detected by hormone testing. The onset of menopause as a result of UAE is rare.

#### Uterine Artery Embolization for leiomyomata: resource use and cost estimation.

Authors: Subramanian S, Spies JB.

Journal Reference: J Vasc Interv Radiol 2001;12:571-574.

This is the first economic study of the cost of UAE. The average hospital cost of UAE was approximately \$3100, considerably less than the reported cost of hysterectomy or myomectomy. The difference in cost was primarily due to the shorter length of stay for UAE (1 day versus 3 to 4 days)

#### Uterine Artery Embolization for Leiomyomata.

Authors: Spies JB, Ascher SA, Roth AR, Kim J, Levy EB, Gomez-Jorge J. Journal Reference: Obstetrics and Gynecology 2001;98:29-34.

This paper reports on the results of UAE in the first 200 patients treated at Georgetown, with a minimum of 12 months and 21 months average follow-up. Ninety percent of patients had symptomatic improvement after treatment and the effects are durable for most patients. It is the first paper to report on symptom outcome, complications and subsequent treatments on a large group of patients with long-term follow-up. It demonstrates that UAE is both safe and effective and that the results are durable.

#### Initial US experience with Embospheres™ Microspheres for uterine leiomyomata

Authors: Spies JB, Benenati, JF, Worthington-Kirsch, RL. Journal Reference: J Vasc Intervent Rad 2001;12:1059-1063

This is the first report of the use of Embospheres for UAE. These are a new embolic agent that may offer certain advantages over traditional embolics for uterine embolization. This study, which was a Phase I FDA approved multi-center study, demonstrated the effectiveness of Embospheres in embolization of uterine fibroids, with control of symptoms in the large majority of patients.

#### Initial experience with intra-arterial lidocaine in controlling pain after uterine artery embolization for leiomyomata.

Authors: Keyoung JA, Levy EB, Roth AR, Gomez-Jorge J, Chang TC, Spies JB. Journal Reference: J Vasc Intervent Rad 2001;12:1065-1069.

This technical study was intended to determine if the pain after uterine embolization could be reduced by the intra-arterial lidocaine, which has been effective in other types of embolization procedures. This study was a randomized blinded study and demonstrated that the lidocaine causes severe spasm of the uterine arteries. This unexpected result suggests that the use of intra-arterial lidocaine may hinder successful completion of the embolization and therefore its use is not recommended

#### Uterine artery embolization for leiomyomata: factors associated with successful symptomatic and imaging outcome.

Authors: Spies JB, Roth, AR, Jha RC, Gomez-Jorge J, Levy EB, Chang TC, Ascher SA Journal Reference: Radiology: in Press.

This extensive statistical analysis of the results of treatment in the first 200 patients to determine if baseline factors could be identified that would predict outcome from treatment. This analysis showed that smaller fibroids shrink more rapidly than larger fibroids and those deeper in the in the uterus shrink more rapidly than those on the outside of the uterus. However, though bleeding improvement improves more rapidly in deep fibroids and smaller fibroids, by one year after treatment there is no difference in symptom improvement based on any of these factors.

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## Uterine Artery Embolization

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## Physician's Resource Literature Review

**By James B. Spies M.D.** Associate Professor of Radiology Georgetown University Hospital Sept 1, 2001

Published Data

#### **Early Reports**

Uterine artery embolization as a primary therapy for fibroids was reported by Ravina in 1995 (1). In that initial report, 16 patients were treated. Polyvinyl alcohol particles were used as the embolic agent, injected through catheters placed selectively in the uterine arteries. With a mean follow-up of 20 months, symptoms resolved in 11 of 16. 3 patients had partial improvement, and the residual heavy bleeding subsequently controlled with progestins. There were 2 failures, one of which required hysterectomy 6 weeks after the procedure and another requiring myomectomy 6 months after the procedure.

Goodwin at UCLA subsequently reported on the results of this treatment in 11 patients (2). The embolization procedure used by Goodwin was very similar to that of Ravina, although he used a larger size polyvinyl alcohol particle (500-700 micron). They were successful in bilateral embolization in 10 patients and unilateral in one. One patient developed endometritis and pyometrium within 3 weeks of the procedure that required hysterectomy. In the 10 other patients, the dominant symptom was noticeably improved in 8. One patient was lost to follow-up and another had no improvement. The mean decrease in uterine volume was 40% and dominant fibroid volume decreased 60-65% at three-month follow-up

Ravina's group reported a larger group of patients in February of 1997(3). 88 women underwent attempted embolization. Of these, the procedure was not successfully completed in five and three others were lost to follow-up or required LH-RH analogue for other reasons. This paper reports on the results of the remaining 80 women. 89% (60 of 67 patients) had resolution of their menorrhagia. There were 7 failures. Fibroid volume was reduced by 55% at 2 months and 69% at 6 months. One patient required a hysterectomy for severe ischemic injury.

Bradley and Reidy reported the results of this therapy in 8 patients with large fibroids (4). Menorrhagia was controlled in 4 of 5 patients presenting with that symptom, while bulk related symptoms improved in all patients. These authors reported that most of their patients experienced an intermittent non-purulent vaginal discharge, presumed to be necrotic fibroid tissue debris. One patient did spontaneously pass a substantial portion of a submucosal fibroid 6 weeks after the procedure. In addition, these authors did have one patient, aged 41, who became amenorrheic following the procedure. Serum follicle stimulating hormone was measured at 59.8 IU/L.

A brief report of two patients in Melbourne, Australia details the experience of two patients treated with UFE (5). One patient did not have adequate control of symptoms and underwent supracervical hysterectomy 26 weeks after her embolization procedure. The pathologic specimen revealed aseptic necrosis of two of the fibroids, with hyaline change of the others.

Burn and McCall also have published their results in 14 patients treated at the Chelsea and Westminster Hospital in London (6). No complications were encountered and in follow-up in 6 patients, all were significantly improved. There was a mean fibroid volume reduction of 43%.

#### Larger Case Series

Worthington-Kirsch reported the results in 53 patients treated with technically successful procedures in 52 (7). Follow-up at three months indicated marked improvement in 88% in menstrual bleeding patterns. For the 31 patients with bulk-related symptoms, 29 (94%) experienced marked improvement. The mean reduction in fibroid volume was 46% in the 32 patients in whom follow-up ultrasound was performed. Complications included extensive infarction requiring in hysterectomy 12 days post-procedure in one patient. Two patients required re-hospitalization for post-embolization syndrome. Another patient developed a self-limited episode of upper gastrointestinal hemorrhage secondary to vomiting.

A large series was recently published by Hutchins and Worthington-Kirsch (8). Three hundred five patients were treated, with follow-up at 3 months, 6 months and 12 months post-therapy. Menorrhagia was controlled in 86% of patients at 3 months, 85% at 6 months, and 92% at 12 months. Pelvic pressure due to the bulk of the fibroids was controlled in 64% of patients at 3 months, 77% at 6 months and 92% at 12 months. The patients reported in this series include those reported previously by Worthington-Kirsch (7). No additional complications were reported other than those mentioned earlier.

The initial results at Georgetown University have been published by Spies et al (9). Of 61 patients reported, all procedures but one were technically successful. Mean clinical follow-up was 8.7 months. Minor complications occurred in five patients during the follow-up period. All were treated without permanent sequelae. One patient (age 49) became amenorrheic post treatment.

Menstrual bleeding was improved in 89%, with 81% of patients moderately to markedly improved. Pelvic pain and pressure was improved in 96% of patients, with moderate to marked improvement in 79%. At initial imaging follow-up (mean 4.4 months post-procedure), median uterine volume decreased 34% and the median dominant fibroid volume decreased 50 %. Imaging at one-year (mean 12.3 months) post-procedure showed continued reduction with a median uterine volume reduction of 48% and median dominant fibroid volume decrease of 78%

Goodwin has reported mid-term results on his initial group of 60 patients (10). With a mean of 16.3 months follow-up, 81% had continued control of symptoms. Mean reduction of uterine volume was 42.8%. Dominant fibroid volume decreased 48.8%. Seven patients have undergone hysterectomy in the follow-up, one for a complication (mentioned above) and six in patients who did not improve after embolization. One patient became amenorrheic after treatment and four patients expelled significant portions of their fibroids in the follow-up period.

Siskin at Albany Medical College (11) used an outpatient management protocol in 49 patients. In addition to showing the potential feasibility of an all oral pain management protocol, his patient series showed a similar outcome with 88.5% of patients at three months follow-up reporting improvement of symptoms. Dominant uterine volume reduction was 47.5%.

Pelage has most recently reported on the results of 80 consecutive patients treated for menorrhagia caused by fibroids at the Hotel Lariboisiere in Paris (12). This group of patients had a minimum of 2 years follow-up. Menorrhagia was controlled in 90% of patients. Hysterectomy was required in one patient for infection while portions of fibroids were expelled in four patients in the first month post-procedure. Four patients experienced permanent amenorrhea after the procedure. Three full term pregnancies were reported among this group.

Brunneau, also from Paris, has published the results on 58 patients with a mean duration of follow-up of 12 months (13). As in the other series, a high percentage of patients had improved bleeding ((90% at 3 months, and 93% at 12 months. These authors reported similar reductions in uterine volume, with reduction of the dominant fibroid of 51% at 12 months. While there were not hysterectomies required for complications, there was one patient sho suffered an external iliac artery dissection.

McLucas et al from Los Angeles reported on the results in 167 patients with a mean of 6 months follow-up (14). At 6 months after treatment, menorrhagia was improved in 82% of patients with 52% mean reduction in dominant fibroid. These fibroid passage in 5% of patients and a hysterectomy was required in one for infection.

From Anderson's group, there was a recent report of 62 patients with 96% of patients noting improved menstrual bleeding and 70% improved bulk symptoms (15). These authors report 2 episodes of fibroid expulsion and one case of endometritis in follow-up.

The Georgetown group has recently reported on results, including subsequent gynecologic interventions in 200 patients (including the 61 noted above) (16). This patient group had a mean follow-up of 21 months, with a range of 12 to 37 months. Menorrhagia was improved in 87 % at 3 months and 90% at 12 months. Similarly, bulk symptoms were improved in 93% at 3 months and 91% of patients at 12 months. During the course of follow-up, subsequent gynecologic interventions or re-hospitalizations occurred in 21 patients (10.5%). Of these, approximately half were for failure to improve or recurrence of fibroids, while the others were for acute gynecologic problems, such as fibroid tissue passage, endometritis or recurrent heavy bleeding. It is interesting to note that the cause for recurrent bleeding was often a polyp or hyperplasia, rather than recurrent fibroids.

An evidence table (Table 1 [PDF file]) has been appended to this review which focuses on the results of treatment in the larger series (those with 40 or more patients, excluding duplicate reports).

#### **Additional Studies**

Early in the experience with UAE, two papers report a total of 4 cases of fibroid expulsion as a consequence of UFE. One of these patients had the fibroid removed during a simple pelvic examination and had no sequelae (17). The other three patients had clinical evidence of infection that responded to oral antibiotics (18). Fibroid passage is now recognized to occur in 2 to 5% of patients after uterine embolization.

The causes of failure of UAE have not yet been completely explored, but two case reports shed some light on potential causes. Nikolic and Spies (19) have reported a case of ovarian artery supply to the uterus and fibroids, which prevented successful infarction of the fibroids. Another patient, reported by Smith (20), failed to respond to embolization as a result of coincident adenomyosis. These are single cases, but they point to areas that would benefit from further research.

There was a recent report from England of a death that occurred after UFE (21). The patient developed a uterine infection 7 to 10 days post-embolization and presented to the emergency room with septicemia. Despite antibiotic therapy, emergency hysterectomy and supportive care, she developed multi-system organ failure and died 15 days later. This is the onlycase report of a death published in the literature thus far. There has been another death reported at the 1999 SMIT meeting (22). There have been two additional anectdotal reports of fatal complications, one from sepsis and another from pulmonary embolus (23). To date, approximately 20,000 women have been treated world-wide.

Spies has published results of a study of health-related quality of life before and after uterine embolization (24). Fifty consecutive women were enrolled in the study and completed the baseline assessment. Health-related quality of life scores improved in all instances at follow-up. Mean change scores were statistically significant for all domains between baseline and month 3 (p<0.01) and between baseline and month 6 (p<0.05), except backache (p=0.12). The study authors concluded that patients undergoing UFE report significant improvements in health-related quality of life and fibroid-specific symptoms.

In a related subject, Nikolic and Spies (25) reported on the radiation dose associated with UAE. In 20 patients, the mean estimated ovarian dose was 22.34 cGy and the mean skin dose was 162.32 cGy. This is an order of magnitude (10 to 30 times) larger than typical diagnostic radiographic studies, but is 10 to 30 times less than radiotherapy for Hodgkin's Disease of the pelvis. Studies on Hodgkin's patients have not shown any increase in infertility or genetic defects and thus an effect from UAE is extremely unlikely. Further, in follow-up studies, the group at Georgetown demonstrated that the large majority (93%) of the radiation dose was during fluoroscopy . By combining pulsed fluoroscopy, dose reduction methods and bilateral femoral access for simultaneous embolization of both uterine arteries, the dose was reduced by 60% with a mean absorbed ovarian dose of 9.8 cGY (26)

In each of the major published series, there have been cases of amenorrhea that have occurred after embolization. In most reports this has occurred in between 2 and 7% of patients (8, 10, 12, 14, 27, 28). However, Chrisman et al noted a much higher rate of amenorhea, including 43% of patients over the age of 45 and 15% of all patients treated (29). The group at Georgetown University also reported on the initial results of a study of ovarian function before and after uterine embolization (28). Basal FSH levels were obtained in 61 patients before and after embolization. Although the study is not complete, no patient under the age 45 had any permanent change in FSH after embolization. Four of 25 (15%) of patients over the age of 45 did have change in FSH from less than 20 to over 20 IU/L. None of these four had cessation of menses, although 2 developed symptoms suggesting the entry into peri-menopause.

#### Scientific Abstract Presentations

A number of investigators have presented results of their experience, but these findings have not yet been published. Because it details the use of gelfoam, one of these is reviewed below.

At the Society of Cardiovascular and Interventional Radiology Meeting in San Francisco, CA in March of 1998, Katz presented the preliminary results of a randomized comparison of polyvinyl alcohol particles with gelfoam pledgets (30). Although the study size was small (n=17), the initial symptomatic control was similar both groups, raising the possibility that temporary occlusive agents may be effective in treating fibroids. Amenorrhea occurred in two of the patients in this study, both treated with polyvinyl alcohol particles. These patients were aged 52 and 47.

#### Conclusion

The results from the published series and those presented at scientific meetings are similar. It appears from this initial experience that this treatment controls both menorrhagia and symptoms caused by the bulk of these fibroids in 85 to 90% of patients. Patients have tolerated the procedure well and patient satisfaction is high. While severe ischemic injury to the uterus has been feared, it appears that this occurs in only 1 to 2 % of patients. Late infection of the endometrium or myometrium may be the most common serious complication and the report of a death post-treatment from sepsis related to uterine infection is a reminder of the potential for catastrophic outcome after any medical intervention. Other reported complications have included spontaneous passage of fibroid tissue and amenorrhea, which has also been reported by several investigators. This is more likely in peri-menopausal women with the incidence probably 5% or less. The true incidence of all these complications requires the completion and publication of larger studies.

Pregnancies have been reported in a number of patients, but the pregnancy rate is not known. The large majority of patients treated to date do not wish additional children. Further, the number of patients seeking pregnancy is not known and there are currently no reports of pregnancy rates in the literature. It is likely that a registry or large multi-center study will be needed to answer this question.

The accumulating reported experience with the procedure suggests that it is effective and generally safe in the short term and midterm results suggest that it is a durable alternative to surgical therapy for this very common medical condition.

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#### **Physician's Guide for Patient Protocol**

#### Georgetown UFE Protocol and Patient Referral Information

Candidates include those patients over 18 who have one of the following symptoms:

- 1. Menorrhagia (with or without anemia)
- 2. Chronic pelvic, back, or leg pain or discomfort that can be attributed to the fibroids
- 3. Ureteral compression causing dilated renal collecting structures or urinary symptoms referable to compression of the bladder.

#### Pre-Procedure Gynecologic Evaluation

- 1. Each patient should have a pelvic examination by her gynecologist within six months of the procedure. We will need a copy of the records for the last two gynecology office visits.
- 2. We also need the results of the most recent Pap smear, which must be within the last year and should be normal.
- 3. For patients with abnormal uterine bleeding (periods lasting longer than 10 days or periods more frequently than every 21 days), an endometrial biopsy should be done, preferably within the preceding 3 to 6 months. This is to be certain that endometrial carcinoma or hyperplasia is not present. We usually decide if an endometrial biopsy is needed at the time of the interventonal radiology consultation.
- 4. If the patient has a history of pelvic infection, cultures for Gonorrhea and Chlamydia should be obtained.

Patients do not need to be seen by a Georgetown Gynecologist.

#### **Pre-Procedure Radiology Evaluation:**

- 1. All patients will be required to have a pre-procedure evaluation by the interventional radiology staff at Georgetown. This allows us to obtain a gynecologic and general medical history, a brief physical examination, and to review the imaging findings and to discuss the procedure with the patient.
- 2. The patient must not be pregnant and we will confirm this with a pregnancy test if the procedure is done more than 14 days after the beginning of the patient's most recent menstrual cycle.
- 3. A blood count and FSH will be obtained on the day of the procedure. If the patient has a history of renal disease or coagulation defect, further laboratory testing may be required.
- 4. An MRI of the pelvis must be obtained. We prefer that this be done at Georgetown to ensure uniformity of imaging. We have instituted a reduced charge for this study. If the MRI is done at another site, the study must be done with and without contrast and include length, width, and depth of the uterus and the dimensions of the identifiable dominant fibroids. The study must also be of sufficient quality to allow adequate detail of the fibroids and the lining of the uterus. If these are not done, the study will have to be repeated.

#### Follow-Up Protocol

After the procedure, follow-up visits occurs at 1 week and at 3 months, which will include completing a follow-up MRI and questionnaire. Patients are instructed to continue all their normal gynecologic care with their referring gynecologist. Each gynecologist will be sent a letter at 3 months to update them on the patient's imaging and symptom status.

#### For more information

If you would like to refer a patient or would like more information, you may call **James B. Spies M.D.** of **Georgetown Interventional Radiology** at **Phone: (202) 784-3420** to make an appointment. You may also contact him via email at spiesj@gunet.georgetown.edu.

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#### Meet Our Staff

Georgetown University Interventional Radiology Care Team

#### James B. Spies, MD

Dr. Spies is an Associate Professor of Interventional Radiology. He attended medical school at Georgetown, completed residency in Diagnostic Radiology at the University of California at San Francisco and fellowship in Interventional Radiology at New York University. He served in the Air Force as chief of Interventional Radiology at Wilford Hall USAF Medical Center from 1985 to 1989. Subsequently, he was in private practice in interventional radiology until January of 1997, when he joined the faculty at Georgetown. He leads the Georgetown Uterine Embolization Program and serves as Vice Chairman of Radiology. His particular research interests include the outcome of uterine fibroid embolization and measuring health outcomes in interventional radiology.



#### Pamela Flick, MD

Dr. Pamela Flick joined the faculty of Georgetown University Hospital in September 2001 as Chief of Interventional Radiology. She attended Jefferson Medical College in 1984. After a surgical internship at the Graduate Hospital in Philadelphia, she completed a diagnostic radiology residency at Hahneman University Hospital. She then completed a fellowship in Vascular and Interventional Radiology in 1991. She then joined the faculty of the University of Tennessee, Memphis where she practiced until 1998. She then went into private practice at the Washington Hospital Center in Washington, DC prior to joining us at Georgetown. She has broad interests in interventional radiology, including peripheral vascular disease, thrombolytic therapy and uterine embolization.



#### Michelle French CNP

Michelle French graduated from Edinboro University in Edinboro, Pennsylvania in 1994 and has had extensive experience as a nurse practicing in both medical and surgical units. She completed a Maters of Nursing in Adult/Women's Health Nurse Practitioner at the University of Pittsburgh, in Pittsburgh, Pennsylvania. She worked at Genetics and IVF Institute for 2 years as a nurse practitioner in their infertility program. She joined the Uterine Embolization program at Georgetown University Hospital in September of 2001. She actively participates in initial patient evaluation and manages patient follow-up.



#### Monique Harrison

Monique Harrison is our practice coordinator and is responsible for our overall practice administration. She has many years experience in medical office practice, has served as a medical assistant and as a supervisor of registration here at Georgetown. Her primary mission is to ensure that the administrative details of our patient's care are correct. She helps coordinate procedure scheduling and insurance pre-certification and is our point of contact for insurance-related problems for UAE patients.



#### Corie McGhee

Corie McGhee is our receptionist and is the primary contact for office visit appointments and also schedules many of our procedures. Hers is likely the first voice you'll hear when contacting us and her cheerful and helpful manner is appreciated by our patients. After several years experience in reception positions, she joined our practice in 2000.

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Table 1. Evidence table of case series on uterine artery embolization\*.

Reference	# of Patients	Duration of Follow-up	Menorrhagia % improved (mean)	Pressure / Pain % improved	Mean Fibroid Volume Reduction	Reported Complications (number)
Hutchins F J Am Assoc of Gynecol Laparosc 1999;6:279-84	305	12 months	86% @ 3 months 85% @ 6 months 92% @ 12 months	64% @ 3 months 77%@ 6 months 92% @ 12 months	-	Puncture site hematoma 4 Hysterectomy 1 Readmission for Pain 2
Goodwin SC J Vasc Intervent Rad 1999;10:1159-65	60	16.3 months	81%	93%	48.8%	Hysterectomy for infection 1
Walker WJ Min Invas Ther & Allied Technol 1999;8:449-454	111	5 months	79%	-	69% at 1 year	Hysterectomies 2 (1 for uterine perforation, 1 for susp. infection) Hysteroscopy for infection 1
Ravina JH Min Invas Ther & Allied Technol 1999;8:441-447	188	29 months	90%	-	50-100 % in 87% of patients at 6 months	Fibroid expulsion 6 Hysterectomy 1 for uterine necrosis and bowel obstruction
Siskin GP JVIR 2000;11:305-11	49	-	88.5%	-	47.5% @ 6 months	Hysterectomy for prolonged pain 1 Prolonged fever 6 wks, resolved 1
Pelage JP Radiology 2000;215: 428-31	76	-	94%	-	20% @ 2 months 52% @ 6 months	Hysterectomy for infection 1 Amenorrhea 4 Fibroid passage 4
Brunneau Am J of Roentgenol 2000:175:1267-72	58	12 months	90% @ 3 months 92% a@ 6 months 93% @ 1 year	-	23% @ 3 months 43% @ 6 months 51% @ 1 year	External iliac artery dissection 1 Hysterectomies 0
McLucas, B J Am Coll Surg 2001;192:95-105	167	6 months	82% @ 6 months	-	49% @ 6 months 52% @ 12 months	Fibroid passage 5% Hysterectomy for infection 1
Andersen Acta Radiol 2001;42:234-8	62	6 months	96%	70%	68% @ 6 months	Fibroid expulsion 2 Endometritis 1 Hysterectomy 0
Spies J, Obstetrics and Gynecology 2001:98-29-34.	200	21 months	86% @ 3 months 88% @ 6 months 90% @ 1 year	93% @ 3 months 93% @ 6 months 91% @ 1 year	42% @ 3 months 60% @ 1 year	Hysterectomies 0 Endometrial infection 2 Fibroid expulsion 1 Pulmonary embolus 1, DVT 1

<sup>\*</sup> Inclusion Crtieria: Case series of at least 40 patients excluding duplicate reports.



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# Uterine Fibroids Symptoms and Diagnosis

This brochure was created by the Society of Cardiovascular & Interventional Radiology (SCVIR) to answer frequently asked questions about uterine fibroids. The brochure contains general information about this common condition, as well as details about a treatment option performed by interventional radiologists to treat uterine fibroids.

For more information on interventional radiology, please contact the Society of Cardiovascular & Interventional Radiology at 1-877-35-SCVIR.



### **Questions and Answers about Uterine Fibroid Tumors**

What are uterine fibroids?

What are typical symptoms?

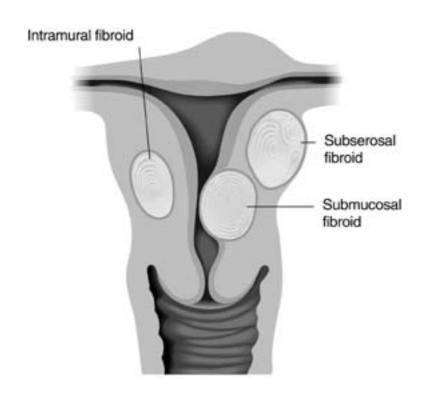
Who is most likely to have uterine fibroids?

How are uterine fibroids diagnosed?

#### Q. What are uterine fibroids?

A. Fibroid tumors are noncancerous (benign) growths that develop in the muscular wall of the uterus. While fibroids do not always cause symptoms, their size and location can lead to problems for some women, including pain and heavy bleeding. They typically improve after menopause when the level of estrogen, the female hormone that circulates in the blood, decreases dramatically. However, menopausal women who are taking supplemental estrogen (hormone replacement therapy) may not experience relief of symptoms.

Fibroids range in size from very tiny to the size of a cantaloupe or larger. In some cases they can cause the uterus to grow to the size of a five-month pregnancy or more. Fibroids may be located in various parts of the uterus. There are three primary types of uterine fibroids:



#### Intramural fibroids.

which develop within the uterine wall and expand, making the uterus feel larger than normal. These are the most common fibroids. This can result in heavier menstrual flows and pelvic pain or pressure.

#### Subserosal fibroids,

which develop under the outside covering of the uterus and expand outward through the wall. They typically do not affect a woman's menstrual flow, but can become uncomfortable because of their size and the pressure they cause.

#### Submucosal fibroids

are deep within the uterus, just under the lining of the uterine cavity. These are the least common fibroids, but they often cause symptoms, including very heavy and prolonged periods.

You might hear fibroids referred to by other names, including myoma, leiomyoma, leiomyomata and fibromyoma.

#### Q. What are typical symptoms?

A. Depending on location, size and number of fibroids, they may cause:

- Heavy, prolonged menstrual periods and unusual monthly bleeding, sometimes with clots. This often leads to anemia.
- Pelvic pain
- Pelvic pressure or heaviness
- Pain in the back or legs
- Pain during sexual intercourse
- Bladder pressure leading to a constant urge to urinate
- Pressure on the bowel, leading to constipation and bloating
- Abnormally enlarged abdomen

#### Q. Who is most likely to have uterine fibroids?

A. Uterine fibroids are very common, although often they are very small and cause no problems. From 20 to 40 percent of women age 35 and older have uterine fibroids of a significant size. African-American women are at higher risk for fibroids: as many as 50 percent have fibroids of a significant size.

#### Q. How are uterine fibroids diagnosed?

Fibroids are usually diagnosed during a gynecologic internal examination. Your doctor will conduct a pelvic exam to feel if your uterus is enlarged.

The presence of fibroids is most often confirmed by an abdominal ultrasound. Fibroids also can be confirmed using magnetic resonance (MR) and computed tomography (CT) imaging techniques. Ultrasound, MR and CT are painless diagnostic tests. Appropriate treatment depends on the size and location of the fibroids, as well as the severity of symptoms.



NEXT >

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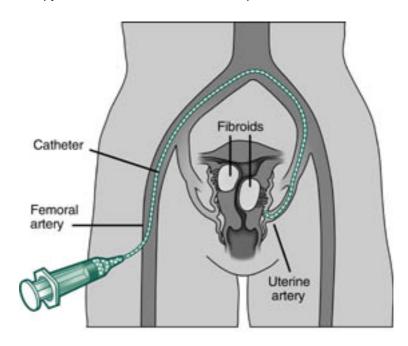
# Uterine Fibroids Treatment Options

#### Q. How are uterine fibroids treated?

A. Most fibroids do not cause symptoms and are not treated. When they do cause symptoms, drug therapy often is the first step in the treatment. This might include a prescription for birth-control pills or other hormonal therapy, or the use of non-steroidal anti-inflammatory drugs, such as ibuprofen or naproxen sodium. In many patients, symptoms are controlled with these treatments and no other therapy is required. Some hormone therapies do have side effects and other risks when used long-term so they are generally used temporarily. Fibroids often grow back after therapy is discontinued.

The next step is to try more invasive therapy. The most common treatment options include:

**Uterine artery (or fibroid)** embolization. This minimally invasive procedure will be explored further later in this brochure. Briefly, an interventional radiologist makes a tinv incision in the groin and passes a small tube called a catheter through the artery. When the catheter reaches the uterine artery, the interventional radiologist slowly releases tiny plastic particles the size of grains of sand into the vessels. The particles flow to the fibroids first and wedge into the vessels and cannot travel to other parts of the body. This blocks the blood flow to the tumor, causing it to shrink.



**Myomectomy.** Myomectomy is a surgical procedure that removes visible fibroids from the uterine wall. Myomectomy, like UFE, leaves the uterus in place and may, therefore, preserve the woman's ability to have children. There are several ways to perform myomectomy, including hysteroscopic myomectomy, laparoscopic myomectomy and abdominal myomectomy:

Hysteroscopic Myomectomy: Hysteroscopic myomectomy is used only for fibroids that are just under the lining of the uterus and that protrude into the uterine cavity. There is no need for a surgical incision. The doctor inserts a flexible scope (hysteroscope) into the uterus through the vagina and cervix and removes the fibroids using special surgical tools fitted to the scope. Usually this is an outpatient procedure performed while the patient is under anesthesia and not conscious.

Laparoscopic Myomectomy. Laparoscopic myomectomy may be used if the fibroid is on the outside of the uterus. Small incisions are made so the doctor can insert a probe with a tiny camera attached and another probe fitted with surgical instruments inside the abdominal cavity and remove the tumors. It is performed while the patient is under general anesthesia and not conscious. The average recovery time is about two weeks.

Abdominal Myomectomy: This is a surgical procedure in which an incision is made in the abdomen to access the uterus, and another incision is made in the uterus to remove the tumor. Once the fibroids

are removed, the uterus is stitched closed. The patient is given general anesthesia and is not conscious for this procedure, which requires a several-day hospital stay.

While myomectomy is frequently successful in controlling symptoms, the more fibroids there are in a patient's uterus, generally, the less successful the surgery. In addition, fibroids may grow back several years after myomectomy.

**Hysterectomy**. Approximately one-third of the more than half-million hysterectomies performed in the United States each year are due to fibroids.

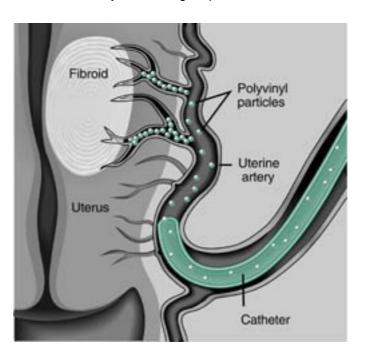
In a hysterectomy, the uterus is removed in an open surgical procedure. This operation is considered major surgery and is performed while the patient is under general anesthesia. It requires three to four days of hospitalization and the average recovery period is about six weeks. Some women are candidates for a newer, laparoscopic procedure. The recovery time for this procedure is considerably shorter.

Hysterectomy is the most common current therapy for women who have fibroids. It is typically performed in women who have completed their childbearing years or who understand that after the procedure, they cannot become pregnant.

#### Q. What is fibroid embolization?

A. It is a minimally invasive procedure, which means it requires only a tiny nick in the skin. It is performed while the patient is conscious but sedated —drowsy and feeling no pain.

Fibroid embolization is performed by an interventional radiologist, a physician who is specially trained to perform this and other minimally invasive procedures. The interventional radiologist makes a small nick in the skin (less than 1D4 of an inch) in the groin and inserts a catheter into an artery. The catheter is guided through the artery to the uterus while the interventional radiologist watches the progress of the procedure using a moving X-ray (fluoroscopy). The interventional radiologist injects tiny plastic particles the size of grains of sand into the artery that is supplying blood to the fibroid tumor. This cuts off the blood flow and causes the tumor (or tumors) to shrink. The artery on the other side of the uterus is then treated



Fibroid embolization usually requires a hospital stay of one night. Pain-killing medications and drugs that control swelling typically are prescribed following the procedure to treat cramping and pain, which are common side effects. Fever is an occasional side effect, and is usually treated with acetaminophen. Many women resume light activities in a few days and the majority of women are able to return to normal activities within one week.

While embolization to treat uterine fibroids has been performed since 1995, embolization of the uterus is not new. It has been used successfully by interventional radiologists for 20 years to treat heavy bleeding after childbirth. The procedure is now available at hospitals and medical centers across the country. To find a site near you, visit the SCVIR Web site, www.scvir.org or call toll-free 1-877-357-2847.

#### Q. How successful is the fibroid embolization procedure?

A. Studies show that 78 to 94 percent of women who have the procedure experience significant or total relief of heavy bleeding, pain and other symptoms. The procedure also is effective for multiple fibroids. Recurrence of treated fibroids is very rare. In one study in which patients were followed for six years, no fibroid that had been embolized regrew.

#### Q. Are there risks associated with the treatment of fibroid tumors?

A. Fibroid embolization is considered to be very safe, however, there are some associated risks, as there are with almost any medical procedure. Most women experience moderate to severe pain and cramping in the first several hours following the procedure. Some experience nausea and fever. These symptoms can be controlled with appropriate medications. A small number of patients have experienced infection, which usually can be controlled with antibiotics. It also has been reported that there is a 1 percent chance of injury to the uterus, potentially leading to hysterectomy. A small number of patients have entered into menopause after embolization. This is more likely to occur if the woman is in her mid-forties or older, and is already nearing menopause.

Myomectomy and hysterectomy also carry risks, including infection and bleeding leading to transfusion. Patients who undergo myomectomy may develop adhesions causing tissue and organs in the abdomen to fuse together, which can lead to infertility. In addition, the recovery time is much longer for abdominal myomectomy, generally one to two months.

You should talk with your doctor about possible side effects of any procedure you may choose.

#### Q. Will my fertility be affected?

A. A recent study comparing the fertility of women who had uterine fibroid embolization with those who had myomectomy showed similar numbers of successful pregnancies for both groups. However, this study has not yet been confirmed by other investigators and the long-term effects of uterine fibroid embolization (UFE) on the ability of a woman to have children have not been fully determined.

#### Q. Will my insurance pay for the fibroid embolization procedure?

A. Most insurance companies pay for fibroid embolization. You will want to talk with your interventional radiologist about this before your procedure.

#### Q. Is fibroid embolization an FDA-approved procedure?

A. The FDA does not regulate the practice of medicine, but it does approve devices and medications. All devices, equipment and medications used for fibroid embolization are approved by the FDA for use in people.

Many women wonder about the safety of leaving plastic particles in the body. It is reassuring to know that the particles most commonly used in UFE have been available with FDA approval for over 20 years. During that time, they have been used in thousands of patients without long-term complications.

#### Q. What is an interventional radiologist?

A. Interventional radiologists are physicians who are specially trained to diagnose and treat conditions using tiny, miniaturized tools, while watching their progress on X-ray or other imaging equipment. Typically, the interventional radiologist performs procedures through a very small nick in the skin, about the size of a pencil tip. Interventional radiology treatments are generally easier for the patient than surgery because they involve no surgical incisions, less pain and shorter hospital stays. Your interventional radiologist will work closely with your primary care physician or gynecologist to be sure you receive the best possible care.

For more in-depth information on fibroids and their treatment and to locate an interventional radiologist in your area, visit the SCVIR Web site at www.scvir.org, or call toll-free 1-877-357-2847.





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# Real Stories From Women Who Have Had Fibroid Embolization



Joan, Age 42. Symptoms: Two years of breakthrough and heavy bleeding and pain that intensified in the second year. Periods that lasted as long as 14 days. Bleeding that would soak through tampons and pads, and her clothing. Anemia.

"....Something inside me said, don't have a hysterectomy. I just couldn't envision surgery, so I wanted to look further."

Sandy, Age 52. Symptoms: Progressively heavier periods over more than six years. Severe clotting and bleeding that continued for four months. Anemia.

"I couldn't believe my first period [after the procedure]....No more clotting, no more cramping and no heavy bleeding."

Dona, Age 37. Symptoms: Six years of heavy, prolonged bleeding (as much as two weeks at a time) and severe cramping. Pressure on the bowel and bladder and constant urination. Anemia.

"I think the most important thing is for women to know their options and make their own, best choice."

Kristie, Age 44. Symptoms: Diagnosed with fibroids 10 years earlier but no symptoms until one of the fibroids started rapidly growing, causing very heavy bleeding and anemia.

"When it's time for my regular exam I'm going back to my gynecologist and I want to be sure he knows more about [uterine fibroid embolization]. My interventional radiologist is going to send him some more information."

Betsy, Age 46. Symptoms: Extremely heavy bleeding every month to the point of having to change double super tampons and a pad every five to 10 minutes. Anemia. Problem progressively worsened over five years.

"I'd never heard of the embolization procedure before but I was interested because it was so non-invasive....They explained to me that this is a new procedure for fibroids but that doctors have been doing this procedure in the uterus for years for a different hemorrhaging problem."

Eddie, Age 48. Symptoms: Diagnosed with multiple fibroids at the age of 22. Symptoms included excessive bleeding, pain, bloating and anemia that grew progressively worse with age. Periods lasted up to two weeks. Underwent several myomectomy procedures to remove the fibroids, but they always returned.

"It's been three years and I am still absolutely free of symptoms. I know even before I go for my checkups that the fibroids haven't come back, because my stomach is flat....I thought I would never be free of this and now I'm like a new person."

Victoria, Age 44. Symptoms: History of heavy menstrual bleeding that became especially severe after age 35. Gushing, heavy clotting, severe cramps and swollen abdomen. Anemia.

"With the doctors who wanted me to have a hysterectomy, there was this feeling of 'them and me.' I was trying to keep the parts I was born with and they were trying to take them out. With the embolization procedure, that wasn't the attitude at all. It was, let's fix this, let's work together. It was very comforting."

Vicki, Age: 44. Symptoms: Diagnosed with fibroids at the age of 38. Extremely heavy bleeding and severe pain with menstrual cycles that lasted as long as two weeks or more. Uterus the size of a five-month pregnancy. Had to wear both tampons and pads and change them every 20 minutes to half hour.

"It's a big relief — I was so tired of looking pregnant when I'm not. I would recommend this [fibroid embolization] to any woman who has felt the dilemma of what to do about fibroids."

#### Conversations With Women Who Have Had Fibroid Embolization

#### A Conversation With Joan...

Age: 42

Symptoms: Two years of breakthrough and heavy bleeding and pain that intensified in the second year. Periods that lasted as long as 14 days. Bleeding that would soak through tampons and pads, and her clothing. Anemia.

"I didn't know I had fibroids. I went to my OB/GYN and he did some tests but didn't know what was causing the bleeding. Then he retired and I got copies of my records and I found an entry from 12 years earlier that said I had fibroids. No one ever told me.

"I started looking for a new gynecologist but I wasn't happy with the doctors I talked to. One woman doctor was very rude, very matter of fact about the whole thing. She said I should have a hysterectomy—'You don't want any more children—we'll just give you a hysterectomy.' She made it sound so simple but I know there is a hormone change when you have one and it's not just so easy. Something inside me said, don't have a hysterectomy. I just couldn't envision surgery so I wanted to look further.

"I wasn't the only one I knew with the problem, either. Five women in my office had the same thing going on. So, we checked the Internet to see what we could find out and we found information on the fibroid embolization procedure and some of the doctors who were doing it. A friend suggested I see a gynecologist she knew and he knew about the embolization procedure. He examined me and said I was a good candidate for it —he didn't give me any argument. He referred me to the doctor who does the procedure and within a month and a half I was scheduled for it.

"When I got to the hospital they wheeled me up to radiology and the doctor and nurses told me all about the procedure so I wouldn't be going in cold. They were very comforting and told me if I needed something for pain or anything they would give it to me. The doctor asked if I wanted to see what was going on and I did, so he turned the TV screen around. He showed me the two different 'road maps' they would follow —the blood vessels that went to my uterus —and he talked me through the whole thing. They gave me Valium to calm me but I didn't have to have anything else. They did say that I was the first patient who didn't need something stronger. They were going to send me home but my doctor wanted them to keep me overnight, so they did.

"After the procedure, I had some mild cramping, but it was mild compared to what I had before. They said I should take Tylenol or Motrin or whatever and this was quite doable. Then two days later, I had pain that just wouldn't quit, but I had a prescription for pain and it knocked it out. I took the prescription drugs for two days and then went back to the over-the-counter stuff. I was back to work in a week and feeling like myself again by my first menstrual cycle. My period was like normal —the pain was much less and the blood flow was much less. Now it's a year later and I'm on a normal cycle with normal blood flow and manageable pain maybe for one day during my period. I'm very happy with the results.

"If I had one thing to say to other women having this problem it would be, don't be afraid. This will make the quality of your life much better."

#### A Conversation With Sandy...

Age: 52

Symptoms: Progressively heavier periods over a period of more than 6 years. Severe clotting and bleeding that continued for four months. Anemia.

"This gradually got worse and worse over a period of years and no one seemed to be able to do anything to help. I went in for regular exams to my family practitioner and he told me he could feel the fibroids, but he didn't know what to do about it. So, he referred me to a gynecologist in October 1997. She said I was losing blood from somewhere and wanted me to have a colonoscopy. I kept trying to tell her about my heavy periods but she wouldn't listen to me. At one point she said she wanted to do a hysterectomy before she would do any other tests. Finally, she did an ultrasound and said I had a big fibroid and the only thing I could do was to have a hysterectomy. She scared the pants off me. So I quit going to her and went to another gynecologist —this was in June 1998. At this point I had been bleeding for more than three months and on the heaviest days, I couldn't even go out of the house. I would wear two pads at a time and would go through five and six bags of pads for one period. She did a D&C on me and the next day the bleeding came back again. She did a hysteroscopy and took a piece of the tissue of my uterus and told me the only thing I could do was have a hysterectomy. I was so depressed, I didn't want a hysterectomy because of the long recovery time and, to be honest, doctors frighten me.

"That very night, there was a news program with a doctor talking about this new procedure for fibroids that was just starting to be done in the Chicago area. I called his office the next day and he saved me! He was the first person to really listen to me. He told me I would have to see a gynecologist first to be sure I was a good candidate for this procedure. I did and the gynecologist felt the fibroids and said I would be a good candidate. I had to go back a second time to the gynecologist for some tests —simple tests —and they scheduled me right away. I had it done July 6, 1998.

"It was pretty simple. I was awake but I didn't feel anything. I didn't even feel the little incision they made in the groin. I didn't even know it was happening. They had a TV screen up there and I could see the whole thing —the fibroid and the little balls going in there. The doctor made me feel so comfortable —he talked to me the whole time and told me what was going on. He'd say, 'Oh, good shot. Good shot." and we'd laugh. I'm just terrified of hospitals and they were so great that it was fine. It took an hour and a half but it didn't seem that long. It was uncomfortable afterwards and the worst part was that I had to lay still for six hours. They checked my incision every 10 minutes for a while and then we had a little meeting and they explained what I could expect. I was uncomfortable but I really wasn't in any pain and I was fine with just Advil, which I took for about a week. I also was nauseated and that lasted for about five days. And I got tired out pretty easily that first week. I had the procedure on a Monday and I was signed up to do crafts at our church Sunday school the following Sunday and I did it. It did take a couple weeks until I felt completely normal again.

"I couldn't believe my first period. I only used one pack of pads compared to the five or six I would use before. I did have some unusual cramps that first time but that was the last time. It's been seven months now and I've only had three periods since then and I love it. We don't know if I'm having so few periods because of hormones or what but I'm happy. No more clotting, no more cramping and no heavy bleeding.

"I've talked to two women who were thinking of having the procedure because I told the doctor he could give out my name to other women. I've told them my experience and told them I was all for this. And I think my doctor was the greatest —I just love him!"

#### A Conversation With Dona...

#### Age: 37

Symptoms: Six years of heavy, prolonged bleeding (as much as two weeks at a time) and severe cramping. Pressure on the bowel and bladder and constant urination. Anemia.

"I've had fibroids since I was 30. I loved my gynecologist but she totally missed the point on this. I was bleeding two weeks at a time so she took me off 'the Pill' and my periods got somewhat better —at least they went down to one week. But I also had horrible cramping and lots of pressure, constant urination. She gave me a prescription to deal with the pain and I had a couple of D&Cs, but that made only my next period better. I saw a doctor on television once who talked about a laser myomectomy but I couldn't find anyone who knew how to perform that procedure. I saw one doctor who wanted to do a hysterectomy and, even though I don't plan on having more children, I didn't want to go through that. The hormonal issues are tremendous and I want to keep my parts —all of them. You don't cut off your hand to fix a broken fingernail.

"Then my fiancé saw a small item in the newspaper about a lecture that these two doctors were giving on the fibroid embolization procedure. I went to hear it and it was amazing to me. This was more like what I wanted to do.

"I didn't sleep much the night before the procedure, so whatever they gave me to make me relax put me right to sleep. I didn't have general anesthesia but I still slept through the whole thing. The thing I didn't expect was to wake up in such pain and I have a low threshold for pain. I was not prepared for that. But they gave me a pain medication and that knocked me right out. They tell me that my recovery period took longer than many women. At one point my cramping got really intense and then I passed the tumor and I think that made it more painful. When I passed that tumor I felt like I came face to face with my tormentor! Altogether, I was on prescription drugs for a month. Then I got my period and it was a breeze —it was the best one I ever had in my life. I'm down to two regular tampons a day and no cramping, and it's been like this for six months. Even my PMS symptoms are better, like breast sensitivity and bloating.

"The whole point of this isn't about the recovery, though. I think if they had told me I was going to have pain for a month or three months I would have taken that over having a hysterectomy. I'm glad to talk to other women about this because anything I can do for public education is important to me. I'm a pretty aggressive patient. I ask questions and when I want to know more about something I go straight to the library and look it up. If I was not this type of person, I would have thought hysterectomy was my only option. I think the most important thing is for women to know their options and make their own, best choice."

#### A Conversation With Betsy...

#### Age: 46

Symptoms: Extremely heavy bleeding every month to the point of having to change double super tampons and a pad every five to 10 minutes. Anemia. Problem progressively worsened over five years.

"I lived with this for years before I saw a doctor about it because so many other women I know had the same problem. You talk with your friends and it just seems that this must be part of something that happens at our age —everyone has it.

"When I finally went to a doctor, she put me on Provera [the female hormone progesterone] but that didn't work. She said I would just have to face it, that I should have a hysterectomy, and I said, no way. Nothing was wrong with my uterus —nothing. I don't think you should take everything out that makes me a woman and then put me on a bunch of drugs that make me a woman again. She didn't offer any other alternatives and I knew I didn't want to do this so I started to do some research to see what I could find out. Then one day, my friend saw a doctor on television who was talking about a new procedure for fibroids. She called me and I called him right away.

"I'd never heard of the embolization procedure before but I was interested because it was so non-invasive. I figured even if it didn't work, it was better than having my uterus taken out. They explained to me that this is a new procedure for fibroids but that doctors have been doing this procedure in the uterus for years for a different hemorrhaging problem. I'm not afraid of new procedures. I previously did an experimental procedure for my back and it worked great and I avoided having back surgery.

"I don't remember much about having the actual procedure. You're awake but not really. Nothing hurt or anything and then it was done. I had really bad cramps for two days or so and I took prescription drugs for three days. And that was it. I was back to work on the third day because I had to be. If I had a choice, I probably would have taken a week off work but I didn't have a choice. I 'm a single mother with three kids and I need to work. I'm a jogger and I was back to that in maybe a week and a half. I think I recovered so fast because I am in good shape —I work out and jog a lot. The only bad part was that I had to go to a gynecologist for a diagnostic test before I had the procedure and that hurt. That doctor didn't tell me beforehand that it was going to hurt so much and I think they should have.

"When I had my next period, it was amazing. I didn't have to use super tampons again and I never have to use pads. It is just like when I was young. Another benefit was that when I had the fibroids, my stomach was kind of big —like I was four months

pregnant. Just a couple months later my stomach was way down.

"It's been 10 months and I have been normal for long enough that I really feel secure that it worked. I've already talked to a friend about it and she's had it done, too. I'll tell anybody because I think this is a really great option and too few women know about it."

#### A Conversation With Kristie...

Age: 44

Symptoms: Diagnosed with fibroids 10 years earlier but no symptoms until one of the fibroids started rapidly growing causing very heavy bleeding and anemia.

"After about three months of very heavy bleeding I went to see my gynecologist —this was January 1998. He did an examination and said, 'You should rid your body of this.' He wanted to do a hysterectomy, take out the ovaries and, while he was at it, take out my appendix. When I told him I didn't want a hysterectomy he said that at my age he would definitely recommend it since I just didn't need it anymore. I had done some reading on this and didn't want to lose my uterus. It supports all of the other organs in there and some women have problems with their other organs dropping when it's not there. I just didn't see it as necessary. Fibroids don't turn cancerous, so why do this. I told my doctor I wanted a second opinion.

"The second gynecologist told me the same thing. I felt like this really was my only option so I was scheduled for the hysterectomy. My blood count was so low they couldn't do it, and while I was waiting, I saw a program on television about a procedure they were doing for fibroids in California called uterine artery embolization. I told my doctor about it and he said he wasn't familiar with it but was willing to do some research. Then I saw a local doctor talk about doing it right here, called his office and went in to talk with him. It seemed like I would be a good candidate for the procedure but I had to see another gynecologist who works with him to have some tests. They did an ultrasound and they took a biopsy of the tissue in my uterus to be sure there were no cancer cells and I was scheduled for the embolization. I called my gynecologist to tell him what I was going to do and he wasn't really for it. He said it was an experimental procedure and they didn't know enough about it, but I decided to go ahead.

"I had the procedure in August 1998. I went in early in the morning and they put in a catheter and an IV and brought me up to the room. They gave me one of those 'twilight' drugs so I was awake but I kept dozing on and off, and I don't remember a lot. There was a TV screen there, though, and I could see what was going on on the screen. It was not painful at all. When I came out of it, I went to a room and had to stay there flat on my back for about six hours. I had a lot of cramping -- it felt like back labor pains -- but I wasn't nauseated or anything. Once they let me get up, they took the catheter out and I was able to move around and walk, I was fine. I went home the next day with a prescription for ibuprofen and another pain killer and I didn't even need them all. I had cramps for two days and on the third day I went up to Wisconsin and went on a boat ride.

"It's six months later and I'm due to have an ultrasound to see how much the fibroid has shrunk. I know it has some. I used to be able to feel it when I would lay flat on my back. Now I can't feel it anymore. I haven't had any problems since the procedure. I haven't had my period yet, which is great as far as I'm concerned. I haven't had any menopausal symptoms so I don't really care if I never have another one again. When it's time for my regular exam I'm going back to my gynecologist and I want to be sure he knows more about this. My interventional radiologist is going to send him some information and that will be good."

#### A Conversation with Eddie...

Age: 48

Symptoms: Diagnosed with multiple fibroids at the age of 22. Symptoms included excessive bleeding, pain, bloating and anemia that grew progressively worse with age. Periods lasted up to two weeks. Underwent several myomectomy procedures to remove the fibroids, but they always returned.

I was diagnosed with fibroids for the first time in 1972. I was very young and didn't want to lose my uterus, so my gynecologist performed a myomectomy, an open surgical procedure that took six to eight weeks to recover from and left me with a scar. It was the first of many, because my fibroids kept recurring. I always knew when they grew back because my stomach would get bloated. I was having a myomectomy every two to three years. In 1978 my gynecologist told me I should have a hysterectomy. That's when I learned my mom had a history of fibroids, too. She'd had a hysterectomy —but after she'd had children. I was only 27 years old and I was scared to death. I was living in the Midwest at the time. Then I moved to California and a female gynecologist said she would try again to remove my fibroids with myomectomy, but they came back again. She introduced me to my current gynecologist, who she thought might be able to help me. That was back in 1992. The new gynecologist performed a laparoscopic myomectomy and removed 13 fibroids. It was a rough surgery; I was hospitalized for eight days. Still, the fibroids came back and, a year later, I had the surgery again. By this time I was desperate —nothing seemed to work and my symptoms were growing worse. In 1996, I woke up one morning and I couldn't walk, I was in such excruciating pain. I went to see my gynecologist and he said, "Do you want to keep your uterus?" When I said yes, he said I was a good candidate for the fibroid embolization procedure and referred me to an interventional radiologist. I was so grateful to that gynecologist that he knew about this procedure and didn't just pressure me into having a hysterectomy. The doctors wanted to be certain that it was fibroids that were causing my pain, so my gynecologist looked inside with a laparoscope. He found terrible adhesions and scarring from my previous surgeries —that was what was causing my pain. The interventional radiologist had given me a lot of information about uterine fibroid embolization and I was really interested when he told me how noninvasive it was. I'd been through so many surgeries and I didn't want to go through another one. What really sticks in my mind was that, although I was sedated, I was awake for the procedure. They didn't have to give me general anesthesia like they did for the surgeries. My gynecologist was there with the interventional radiologist and I could hear them talking about the procedure. I don't remember much else; there was some cramping, but nothing unbearable. Afterward, I had to lie still for 8 hours and then I went home. I had some nausea, but it didn't last long. I couldn't believe that a week later I was up and about and walking about two miles a day. This was incredible to me —after my surgeries it took as long as six or eight weeks to recover. And my symptoms were gone. I had so much energy; when the fibroids were bad and I was anemic, I'd try to exercise, but I'd

just peter out. Three weeks after the embolization procedure, I was up to five miles of walking at a stretch—it was great. It's been three years and I am still absolutely free of symptoms. I know even before I go for my checkups that the fibroids haven't come back, because my stomach is flat, I don't have any bloating. I thought I would never be free of this and now I'm like a new person. It's so wonderful to have my life back; it's like a miracle. I'm so grateful to the gynecologist who referred me to the interventional radiologist. It makes me almost want to cry whenever I see him.

#### A Conversation with Victoria...

Age: 44

Symptoms: History of heavy menstrual bleeding that became especially severe after age 35. Gushing, heavy clotting, severe cramps and swollen abdomen. Anemia.

"I was first diagnosed with fibroids when I was 38. The doctor said I had four or five fibroids and also some endometriosis. My stomach was so swollen, people asked me if I was pregnant. The bleeding and gushing were horrible —I'd wear two overnight super pads at a time, which I'd have to change hourly. I'd still have accidents if I found myself in a situation where I couldn't access a bathroom quickly -- say, on my drive into work. Usually when I got out of the car blood would be running down my legs before I could get from the parking lot into the building to a bathroom. I didn't want a hysterectomy, so the first thing I tried was myomectomy. I hated everything about it. There was a pretty big incision and I was in pain for a long time. I couldn't walk up and down stairs for four or five weeks afterward; I couldn't drive a car. What I really hated was it didn't ease my symptoms. My periods continued to be terrible; I had bad cramping and I would just gush blood. I was really upset; I went through the pain of a procedure and paid all that money and still had the same symptoms. I went back to my primary care doctor and my gynecologist. Their attitude was, "What's your problem? Why don't you just have a hysterectomy and be done with it?" But I didn't want to lose my uterus. I have a friend who had a hysterectomy because she had cancer and she helped me put it in perspective. She said, "Do you have cancer?" Of course, I said no, so she suggested that before I agreed to have my uterus removed I should do some research. I got on the Internet and learned about the uterine embolization procedure. I heard about a woman in Canada who'd had it done, so I called her and she told me it had worked for her. She gave me the name of her doctor, who put me in touch with interventional radiologists in the United States. They were wonderful. They sent me case histories and gave me a lot of information. My gynecologist was totally opposed, even though he knew nothing about the procedure. I resented not so much that he was uninformed, but that his attitude about taking out a part of my body was so casual. He acted like I was crazy because I didn't want a hysterectomy, like I was trying to hold onto my youth or something. I made the decision to try the embolization procedure after an incident that happened when I was applying for a new job in my company. I was sitting in the lunch area with my new supervisor, and when I stood up, I could feel this gush of blood running down my leg. I just froze. I excused myself and ran to the bathroom, I could feel stuff gushing out with each step. It was such a mess, I said, "This is it; I'm not putting up with this anymore." My gynecologist refused to refer me for the embolization procedure, which I needed for my insurance. So I went to another female doctor who had heard of the procedure and she referred me. It went very smoothly. I had a local anesthetic, so I was conscious, but I didn't feel anything. The doctor talked to me the whole time, asked me how I was doing, and told me what was going on. The whole thing was like teamwork; I was involved. There's no comparison between this and my myomectomy. With fibroid embolization, there was no pain and it worked instantly. Afterward, I took off a few days from work and I was fine. There was a little cramping, but nothing so bad as what I was used to during my periods. When my next period came, I couldn't believe it. I never remember having such a decent period. Since then, all of my periods have been manageable. People notice that my abdomen has shrunk —the doctor confirms that my uterus is smaller. I also used to suffer a lot of pain and cramping during my periods. All of these have magically disappeared. But the biggest difference was in the attitude of the doctors. With the doctors who wanted me to have a hysterectomy, there was this feeling of "them and me." I was trying to keep the parts I was born with and they were trying to take them out. With the embolization procedure, that wasn't the attitude at all. It was, let's fix this, let's work together. It was very comforting.

#### A Conversation with Vicki....

Age: 44

Symptoms: Diagnosed with fibroids at the age of 38. Extremely heavy bleeding and severe pain with menstrual cycles that lasted as long as two weeks or more. Uterus the size of a five-month pregnancy. Had to wear both tampons and pads and change them every 20 minutes to half hour.

I was diagnosed six years ago with fibroids after my periods became extremely painful with heavy bleeding, especially during the first few days. I'm self-employed and the bleeding got so bad, I'd just stay home on the worst days, it was so messy and inconvenient. I didn't want a hysterectomy; I'd heard horror stories about possible complications and I didn't want to give up the option of some day having children. Myomectomy was also not an attractive option — I'd heard that the chances were good that the fibroids would grow back. I kept thinking, there has to be something else. Then I saw an article in a magazine about the fibroid embolization procedure and I went to the Internet for more information. I found a list of interventional radiologists who did the procedure and one of them was in Atlanta where I live, so I called him. He talked to me at length, explaining the procedure and giving me a lot of information. He was very helpful. The procedure definitely sounded like something worth trying, so I went to my gynecologist who had been recommending a hysterectomy. She didn't know about the embolization procedure, but she called another doctor who'd heard of it. He said the basic procedure was done all the time to control other types of bleeding. I thought it was definitely worth a try and my gynecologist agreed. First, I had an endometrial biopsy to test for uterine cancer. When the test came back negative, I had the embolization procedure in September 1998. I reported to the hospital at 6 a.m., the procedure was performed at 9 a.m. and I went home that evening. The doctors' main concern was being certain that I wouldn't bleed from the tiny incision they made in my groin, so they kept me in the hospital for several hours with my leg completely straight. Then they got me up to walk around and make sure everything was alright. There was no pain from the procedure —the only discomfort I felt was indigestion that I got from eating too big a meal afterward. After I went home, they told me to take it easy and have someone with me for 18 hours, which I did. I took it easy for another two or three days and that was it. The first month after the procedure when I got my period, it was a major change. I could hardly believe it, but for the first time in years my period was normal. It lasted only two to three days, the heavy bleeding was gone and there

was very little pain. Since then, the bleeding is lighter. I am absolutely pleased with the results. I used to take 800 milligrams of Motrin when my period started and it still didn't take the pain away. Now, at the most I need a couple of Tylenol for minor cramps right before my period starts, and that's it. I went in for an ultrasound a month after the procedure to see how everything was looking. There wasn't a noticeable change, but since then my abdomen has begun to shrink and I can see a difference. The doctor indicated that there should be a 65 percent reduction in the first three to six months. It's a big relief — I was so tired of looking pregnant when I'm not. I would recommend this to any woman who has felt the dilemma of what to do about fibroids.



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