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## **Non-Surgical Embolization Treats Male Infertility and Pain, and Chronic Pelvic Pain in Women Caused by Enlarged Veins**

### ***Addition of Newly Available Foam Improves Interventional Radiology Technique***

TORONTO, Ontario (March 31, 2006) – Research presented today at the Society of Interventional Radiology's 31<sup>st</sup> Annual Scientific Meeting shows that the addition of foam allows the smallest varicose veins to be treated, improving this non-surgical treatment for men and women. In men, enlarged varicose veins in the scrotum, known as varicoceles, may cause pain, testicular atrophy, or fertility problems. In women, enlarged varicose veins in the pelvis can cause disabling chronic pelvic pain, known as pelvic congestion syndrome. The embolization procedure closes off the faulty veins so they can no longer enlarge with blood, alleviating the symptoms in both men and women. In this research out of Yale University, foam was added to the technique, which closes off the small collateral vessels in the faulty veins that were previously unreachable. The new foam agent, Sotradecol, has only recently become available in the United States. All the men and the women were successfully treated, and the majority continues to have symptom relief up to the time of this report.

“This simple and elegant embolization technique allows us to treat testicular atrophy in young boys, reverse infertility in some men, and relieve debilitating pain in women – all non-surgically,” said Robert White, Jr., M.D., interventional radiologist, study author and co-inventor of original non-surgical treatment for varicoceles in the United States.

In the standard embolization procedure, an interventional radiologist makes a nick in the skin to access the femoral vein, then uses X-rays to guide a catheter up the femoral vein and into the faulty vein. Then small coils are released to block the vein. The coils have Dacron filaments that allow clots to form on the coil, helping to seal shut the faulty vein in addition to the mechanical occlusion. In this technique, the coils could only be deployed in larger areas of the faulty vein. The addition of the foaming liquid agent allows physicians to block even the smallest collateral veins which otherwise cannot be blocked.

### **Varicoceles In Men**

The standard embolization treatment for varicoceles is already highly effective, with equivalent results to surgery, but is much less invasive and has a much shorter recovery time. The surgical technique and the U.S. standard embolization technique both have

about a 90 percent success rate. In the study, 100 percent of the varicoceles were successfully treated with symptom relief, and 12 months out, there are no clinically significant recurrences. “We expect the addition of foam will improve the embolization technique making it even more effective. The combination of foam and coils create a more complete blockage of the faulty veins which should help prevent a recurrence,” says White, who co-invented the original varicocele treatment with urologist Patrick Walsh, M.D., in 1978 in the U.S.

“Varicocele embolization is a standard interventional radiology treatment that is widely available across the country. No incision is made. No general anesthesia is used. No scars are left behind. When we are done, the patient leaves with only a band-aid,” says White.

There is an average of one to two days for complete recovery with embolization, including physical activity. Surgery has a two to three weeks recovery time, with another two to three weeks until the patient can return to full exercise, such as jogging. The interventional radiology treatment is much less painful and does not have the risks associated with general anesthesia. As many as 80,000 men in America may undergo surgical correction of a varicocele annually. “Surgery is still the most common treatment in the U.S. because patients aren’t aware that they have choices,” says White.

A varicocele is a varicose vein of the testicle and scrotum that may cause pain, testicular atrophy (shrinkage), or fertility problems. Veins contain one-way valves that work to allow blood to flow against gravity from the testicles and scrotum back to the heart. When these valves fail, the blood pools and enlarges the veins around the testicle in the scrotum to cause a varicocele. Approximately 10 percent of all men have varicoceles. Among infertile couples, the incidence of varicoceles increases to 30-40 percent, and fertility studies show that after correction that one-third of couples will conceive.

### **Pelvic Congestion Syndrome in Women**

It is estimated that one-third of all women will experience chronic pelvic pain in their lifetime. Although there are many causes of pelvic pain, in about 30 percent of the women with pelvic pain, it is due to hard-to-detect varicose veins in the pelvis, known as pelvic congestion syndrome. In pelvic congestion syndrome, the pain occurs randomly throughout the month and increases in intensity as the day progresses. The pain is often so severe that heavy narcotics are required, and the pain is alleviated by lying down, because it allows the pressure to subside and blood to flow out of the affected veins.

Because they are often incapacitated several days a month, many of these women are unable to hold down jobs. They are also unable to engage in basic activities, such as cooking or caring for their children on days they are symptomatic. Unable to find a cause or treatment after seeing multiple specialists, many of these women are sent to psychiatrists.

Diagnosis of pelvic congestion syndrome requires an MRI to rule out other causes of pelvic pain such as uterine fibroids, endometriosis and adenomyomatosis, as well as a complete history. The enlarged pelvic varicose veins can be difficult to detect during a

pelvic exam because women lie down. This relieves pressure from the ovarian veins, so that the veins no longer bulge with blood as they do while a woman is standing.

“Most women I have treated have spent years looking for a solution to their chronic pelvic pain—suffering needlessly because they aren’t aware interventional radiologists have a treatment. We are vascular experts that can help determine the cause of chronic pelvic pain, and treat it if it has a vascular origin,” says White. The condition is difficult to detect and is more common in women who have had children and have varicose veins in the leg.

This is an outpatient, non-surgical procedure that does not require general anesthesia, and has a recovery time of only a few days. Embolization is a standard technique to treat many vascular conditions that all interventional radiologists are taught in their specialty training.

## **Prevalence**

- Up to 15 percent of women, generally between the ages of 20 and 50, have varicose veins in the pelvis, although not all experience symptoms.
- Chronic pelvic pain accounts for 15 percent of outpatient gynecologic visits
- Studies show 30 percent of patients with chronic pelvic pain have PCS as the sole cause of their pain and an additional 15 percent have PCS along with another pelvic pathology

## **About The Study**

This study reports interim results in 24 patients. To date 16 men and eight women have been treated in this ongoing study. Embolization has been successful in all 24 patients. All the men’s varicoceles were gone at one month. Using foam with coils was found to be safe for the management of varicoceles and pelvic congestion syndrome, and the addition of foam may result in fewer recurrences, but additional follow-up is necessary. Although the study is ongoing and follow-up will continue, 5 out of 8 of the women are symptom free at two-years.

Embolization for varicoceles is an established treatment with a known long-term efficacy rate. The treatment for pelvic congestion is much newer and fewer women are referred for treatment.

Abstract 23 is available at [www.SIRmeeting.org](http://www.SIRmeeting.org).

## **Interventional Radiologists**

Interventional radiologists are board-certified physicians who specialize in minimally invasive, targeted treatments. They use X-rays, MRI and other imaging to advance a catheter in the body, usually in an artery, to treat at the source of the disease non-surgically. They are certified in both Diagnostic Radiology and Vascular & Interventional Radiology. As the inventors of angioplasty and the catheter-delivered stent, interventional radiologists pioneered minimally invasive modern medicine, and

provide treatments that offer less risk, less pain and less recovery time compared to open surgery. More information can be found at [www.SIRweb.org](http://www.SIRweb.org).

***Local interviews, medical illustrations and broadcast quality video footage are available by contacting SIR's Communications Department at [Emily@SIRweb.org](mailto:Emily@SIRweb.org) or (703) 691-1805.***