Improved foam for varicose veins found to be safe in preliminary results from phase II trial

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A small group of patients with a common heart defect who were treated for varicose veins with an injectable microfoam experienced no neurological, visual or cardiac changes as a result of the treatment, according to preliminary results from a phase II trial. The results are being presented today (March 17) in Washington, D.C., at the annual scientific meeting of the Society of Interventional Radiology (SIR).

Injectable foams are usually made by mixing a sclerosant, an irritant that causes damage to the vein wall and subsequent scarring, with room air. Sclerosant foams have been a standard treatment since 1997 for spider veins and small varicose veins. Varisolve®, a foam made with carbon dioxide, is relatively painless compared to other sclerosants, which can cause burning, said John D. Regan, M.D., clinical director of the Interventional Section in the Department of Radiology at Wake Forest University Baptist Medical Center.

Veins in the leg have valves that are designed to prevent blood from flowing backward as it returns to the heart. Varicose veins are caused by weakened valves (commonly in the great saphenous vein, the large vein running up the inner side of the leg) which allow blood to flow backward and pool in the veins in the leg. The resulting high pressure causes veins to expand like balloons and become tortuous or twisted. The latest treatments involve blocking the great saphenous vein (GSV) to prevent the backflow, called reflux. The Varisolve foam injection procedure is a less invasive alternative to surgical techniques and intravenous techniques that close the vein with radiofrequency ablation or laser

energy.

Although any air-based foam carries a theoretical risk to the patient because of the insolubility of air in the blood, the risk is small, said Regan, the presenting author of the phase II trial's preliminary results. "We believe that the carbon-dioxide-based foam used in Varisolve will be totally safe due to the small size of the bubbles, the consistency of the foam and the solubility of carbon dioxide."

However, patients with a right-to-left shunt in their hearts – a common, usually asymptomatic heart defect in about one-fourth of the population – are at increased risk of foam bubbles crossing the shunt and going to the brain or heart without being filtered in the lungs, according to Regan. These patients, the subjects of the study, are continuously monitored by transcranial Doppler ultrasound of the brain before, during and after the procedure. They also undergo magnetic resonance imaging (MRI) of the brain, visual testing, neurological examinations and examinations for changes in cardiac markers in the blood.

During the procedure, a small catheter is placed in the malfunctioning GSV, and the Varisolve foam is injected into the vein. The GSV is compressed in the groin to trap the foam in the leg and additional foam is injected. The patient's leg is then put in a compression dressing and stocking, and the patient is able to get up and walk immediately.

In more than 90 percent of the 28 patients studied so far (13 at Wake Forest Baptist) at six research sites across the country, tiny bubbles have been detected in the blood during the procedure. However, no neurological, visual or cardiac changes were observed in the monitoring. The study will continue until a total of 50 patients have been treated and monitored.

Source: Wake Forest University