



Tiny Ultrasound Dissolves Clots Faster, More Effectively

MIAMI BEACH, January 23, 2006 – A new ultrasound device small enough to snake through blood vessels is being used to dissolve dangerous clots faster, more easily and more safely than conventional methods, according to data being presented at the 18th Annual International Symposium on Endovascular Therapy (ISET).

The ultrasound-enhanced drug delivery system – composed of tiny transducers smaller than grains of rice situated on a hair-thin wire – significantly reduces the time it takes to dissolve clots in the legs and pelvis and is far less likely to cause major bleeding, according to research on 99 patients being presented at ISET. Blood clots that form in the legs or pelvis may necessitate amputation of the feet or legs, or lead to death if not treated. The ultrasound device also is showing early promise as a therapy to more quickly dissolve stroke-causing blood clots in the brain.

Currently, clot-busting drugs are infused at the site of the clot, whether in the leg or pelvic arteries (known as a peripheral arterial occlusion, or PAO) or thigh veins (known as deep vein thrombosis, or DVT). The new device may revolutionize the way severe DVT is treated. The current infusion process can take up to 48 hours, particularly if the clot is large. The longer the infusion, the greater the risk of limb- or life-threatening bleeding elsewhere in the body, particularly the brain. Also, patients are immobilized and must be treated in monitored care beds, which are costly.

Blood clots are made of fibrin, the protein that allows the blood to clot. Under a microscope, the strings of fibrin in a clot look like tangled yarn. The ultrasound device emits sound waves that loosen the fibrin and push conventional clot-busting drugs into the clot, encouraging it to dissolve faster.

“This is a big step forward,” said Thomas McNamara, M.D., chief of vascular and interventional radiology at UCLA Medical Center, Westwood, Calif., who is presenting data on the device at ISET. “USing this device we may be able to begin doing infusions without the patient having to stay overnight. When you don’t have overnight infusion, you almost never have bleeding.”

Data from a 13-center ongoing observational study is being presented at the meeting, involving clots in 99 patients, 66 with PAOs and 33 with DVTs.

In the PAO group, 1.3 percent of patients experienced major bleeding after treatment with the ultrasound-enhanced delivery system. The bleeding caused bruising but was not

fatal. After 17.5 hours of treatment with the new system, clots were completely dissolved in 58 patients of the 66 (88 percent). Comparatively, a study found 68 percent of patients' clots were completely dissolved 24.4 hours after conventional treatment, and the major bleeding rate was 12.5 percent.

Overall, ultrasound-enhanced delivery resulted in a 28 percent improvement in dissolution of clots and a 92 percent reduction in bleeding complications compared to conventional treatment.

Data on 33 DVT patients also is being presented at ISET, with 5 percent suffering non-fatal major bleeding that caused bruising. After 23.3 hours, clots were completely dissolved in 23 of the patients (70 percent). In DVT studies of conventional clot-busting therapy, 31 percent to 38 percent of clots were completely dissolved after 36.8 to 53.4 hours and 11.4 percent had major bleeding. Ultrasound-enhanced delivery more than doubled the number of patients whose clots were completely dissolved and resulted in a 56 percent reduction in bleeding complications compared to conventional treatment.

“This device is exciting because it enhances the ability to dissolve clots and may lead to a procedure with fewer complications,” said James F. Benenati, M.D., medical director of the peripheral vascular laboratory Baptist Cardiac & Vascular Institute, Miami, one of the sites in the on-going study. “It also may have the advantage of allowing the procedure to be done much more quickly, which will save physicians and hospitals time, and lower the cost of the procedure.”

In the conventional clot-busting procedure, a thin tube called a catheter is advanced through the blood vessels through a small cut in the groin and situated at the site of a clot. Clot-busting drugs are infused through numerous holes at the end of the catheter, much like a soaker hose.

The new device delivers drugs in the same manner as the conventional catheter system, with the addition of a central wire that has tiny ultrasound transducers situated one-half-inch apart on the wire. Each device has from six to 30 transducers, depending on the size of the clot. When the drug is delivered, the transducers emit high-frequency, low-energy ultrasound waves to both loosen up the fibers and force the drug throughout the clot. The more fibrin the drug touches, the better and faster the clot dissolves.

PAO are a result of a build-up of fatty tissue, or plaque (atherosclerosis), and can cut off blood supply to the legs and feet, which can necessitate amputation.

A DVT can form in the thigh vein as a result of a number of conditions, including a lengthy period of inactivity (such as after surgery or during a transcontinental airplane ride), pregnancy and obesity. If untreated, a portion of the clot can break off, travel to the lungs and cause a blockage called pulmonary embolism, which can be deadly. Untreated DVT also can cause permanent damage to the valves in the leg veins and lead to lifelong problems, including the risk of developing more clots.

Long used as an imaging technique, ultrasound is now appearing elsewhere in the medical world. At a very high energy level (focused ultrasound), it can burn tissue and is being used to zap breast, prostate and bone cancer tumors. At a low energy level, it's used to break up kidney stones.

The ultrasound used in the new device does not cause temperature changes nor does it damage tissue, said Dr. McNamara.

Considered to be the premier meeting on endovascular therapy, the International Symposium on Endovascular Therapy (ISET) is attended by more than 2,000 physicians, scientists and industry professionals from around the world. The meeting is well known for its multidisciplinary approach to and live case demonstrations of procedures and devices for the diagnosis, treatment and prevention of cardiac and vascular disease. ISET is presented by the Baptist Cardiac & Vascular Institute, Miami.