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## EMBARGOED FOR RELEASE, Thursday, October 24, 6.30 p.m. EST

# Lancet Study Shows Interventional Neuroradiology Safer than Surgery to Treat Ruptured Brain Aneurysms

### Interim Results Conclusive, International Multicenter Trial Recruitment Halted

Fairfax, VA (October 24, 2002) -- A new study published in the October 26 issue of The *Lancet* shows that using an interventional neuroradiology technique (endovascular coil embolization) to treat cerebral hemorrhage from a ruptured aneurysm substantially reduces the relative and absolute risk of subsequent severe disability or death compared to surgical repair in those patients judged to be equally treatable by surgery or coil embolization. The study showed a 22.6 percent reduction in the relative risk of severe permanent disability or death, and an absolute risk reduction of 6.9 percent for the interventional neuroradiology technique compared to the neurosurgical technique. Using x-ray guided-imaging, the neurointerventionalist guides a catheter through the femoral artery in the groin until it reaches the ruptured aneurysm in the brain, then releases a tiny coil at the site to block the aneurysm. The catheter is withdrawn and the coil remains to provide mechanical occlusion. When a brain aneurysm ruptures, the blood usually goes into the space that closely surrounds the brain, known as the subarachnoid space. Rupture of a brain aneurysm causing subarachnoid hemorrhage occurs in six to eight people out of 100,000 in most western populations. A subarachnoid bleed is a medical emergency which can have serious consequences such as stroke or death.

"This is a highly significant study that proves what we intuitively knew to be correct: the least invasive interventional approach is safer than surgery in this group of patients," says Jacques E. Dion, MD, immediate past president of the American Society of Interventional and Therapeutic Neuroradiology (ASITN). "Interventional radiology is really the new frontier of medicine in the 21<sup>st</sup> century. Many more medical conditions that could only be treated surgically will be treated non-surgically by interventional radiologists in the future," says Michael Darcy, MD, president, Society of Interventional Radiology.

## About Cerebral Hemorrhage Treatments

The International Subarachnoid Aneurysm Trial (ISAT) is the first multicenter, prospective randomized study comparing endovascular coiling, the interventional neuroradiology technique, with surgical clipping for patients with a ruptured cerebral aneurysm causing acute subarachnoid hemorrhage (SAH), a condition that can lead to death or dependency. Although there have been advances in neurosurgery, relatively few patients return to a normal lifestyle after SAH surgery, and many have persistent and disabling neurological or cognitive defects. Surgery had been the primary treatment available until the platinum coil device was introduced into investigational clinical use in 1990 and approved by the FDA in 1995. The coil occludes the aneurysm and was thought to reduce the risk of further rupture without the need for craniotomy, a surgical procedure. There was an urgent need for a large, multicenter trial to determine the safety and efficacy of the interventional neuroradiology technique compared to the surgical technique and to determine which treatment provides the best outcomes for patients.

## ISAT Study Results

ISAT is a multicenter, randomized clinical trial to compare neurosurgical clipping to the interventional treatment of detachable platinum coils in patients with ruptured intracranial aneurysms considered suitable for either treatment. A total of 2143 patients with ruptured intracranial aneurysms were enrolled and randomized to neurosurgical clipping (n=1070) or interventional treatment by detachable platinum coils (n=1073). The primary outcome was the proportion of patients with a modified Rankin scale score of 3-6 (dependency or death) at 1 year. One hundred ninety of 801 (23.7%) of patients assigned to the interventional treatment were dependent or dead at 1 year compared with 243 or 793 (30.6%) of patients allocated to the neurosurgical treatment. The relative and absolute risk reductions in dependency or death after allocation to an interventional neuroradiology versus neurosurgical treatment were 22.6% and 6.9% respectively. The risk of rebleeding from the ruptured aneurysm after one year was two in 1276 patient-years for the interventional treatment and zero per 1081 patient-years for the neurosurgical treatment.

"The study shows that survival free of disability at one year is significantly better with the interventional procedure than with surgery," says Andrew J. Molyneux, MD, ISAT principal investigator and president of the British Society of Neuroradiologists.

An interim analysis of the results was planned at the outset, but the interim results were so compelling that further recruitment into the trial was stopped immediately for ethical reasons, because there is a clear advantage for patients receiving the interventional treatment. Patients already enrolled in the trial will continue to be followed to assess other outcomes of the trial. In addition to the interim data, ISAT is designed to assess the differences between interventional treatment and neurosurgery in prevention of rebleeding, quality of life at one year, the frequency of epilepsy, cost-effectiveness, and neuropsychological outcomes (a substudy conducted in seven UK centers). In addition, ISAT will determine the long-term outcome of treatment, over at least five years, with a particular assessment of the frequency of further hemorrhage, and assess the long-term significance of angiographic results.

### About the American Society of Interventional & Therapeutic Neuroradiology

The American Society of Interventional & Therapeutic Neuroradiology represents interventional neuroradiologists – physicians who specialize in minimally invasive, targeted neurological treatments performed using imaging guidance. Interventional neuroradiology advances include, among others, the treatment of cerebral aneurysms, carotid stents, intracranial stents, stroke treatment, intracranial angioplasty, and vertebroplasty. More information about ASITN can be found on our Web site at www.asitn.org.

#### About the Society of Interventional Radiology

The Society of Interventional Radiology represents interventional radiologists — physicians who specialize in minimally invasive, targeted treatments performed using imaging guidance. Interventional radiology procedures are a major advance in medicine that do not require large incisions – only a nick in the skin – and offer less risk, less pain and shorter recovery times compared to surgery. Interventional radiology advances include the pioneering of angioplasty, the peripheral stenting technique, and the invention of the first catheter- delivered stent — state of the art treatments that are common place in medicine today. More information about SIR can be found on our Web site at <u>www.sirweb.org</u>.

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