

10201 Lee Highway
Suite 500
Fairfax, Virginia
22030
703.691.1805
703.691.1855 fax
www.sirweb.org
info@sirweb.org

FOR IMMEDIATE RELEASE, May 11, 2004

**News Highlights from May's Journal of Vascular and
Interventional Radiology (JVIR)**

***JVIR* Reporting Standards for Carotid Artery Angioplasty and Stenting Also
Publish in the Journal *Stroke* This Month**

**Standards Issued to Achieve Uniformity in Stroke Clinical Trial Design in the
Surgical and Interventional Disciplines; Document Reviews Trials to Date**

The purpose of this document is to standardize reporting of carotid stent trials and recommend trial designs so that carotid stenting and carotid endarterectomy surgery may be fairly compared. Using the same parameters will enable a more meaningful analysis of the data. Currently comparisons of carotid stenting and surgical endarterectomy are difficult because of differences in patient selection, the use of case series rather than randomized controlled trials for stenting, differences in definitions of outcomes and complications, and observer bias. The suggested reporting standards in the surgical literature for carotid endarterectomy have not been uniformly followed for surgical trials and have also not been used in trials of carotid stenting. This has led to confusion in interpretation of these studies and ability to compare the trials in the scientific community. In an effort to standardize this, the Technology Assessment Committees of the American Society of Interventional and Therapeutic Neuroradiology and the Society of Interventional Radiology have authored this consensus document. It is being co-published this month in the Journal *Stroke*, to ensure it also reaches a wide audience outside of the interventional medical specialties.

The document serves to standardize reporting terminology and includes pretreatment assessment, neurological evaluation, imaging evaluation, stenosis (degree of obstruction), assessment and quantification, follow-up imaging studies, and post-treatment neurological and cardiac assessments. It also standardizes patient selection for treatment based on neurological condition at presentation, baseline imaging studies, and use of standardized inclusion and exclusion criteria.

The document includes a summary of the trials to date and also provides background for the previous surgical carotid endarterectomy trials in North America and Europe. In addition, it gives results of the current carotid angioplasty and stenting published studies, discusses limitations of various minimally invasive methods, defines predictors for success, and offers the rationale for the different considerations that might be important during the design of a clinical trial for stent-angioplasty for treatment of carotid artery disease.

Societal Impact

Clinical trial data are important in order to know definitively the best treatment option to offer patients. Cerebrovascular disease is the third leading cause of death in the United States. Approximately 750,000 people have a stroke annually and carotid occlusive disease is responsible for 25% of these strokes.

The Society of Interventional Radiology Publishes Quality Improvement Guidelines for Recording Patient Radiation Dose In the Medical Record

There are no federal regulatory requirements in the United States concerning recording or reporting radiation doses for fluoroscopically-guided interventional procedures, which are minimally invasive procedures performed using X-ray guidance. Although there are recommendations from The U.S. Food and Drug Administration, regulations or guidance at the state level are not uniform, and only a small number of states have addressed this issue. The Society of Interventional Radiology has published these guidelines in an effort to make all professionals using imaging aware of the importance of record keeping, so physicians and regulators can better assess outcomes and patient doses.

Fluoroscopy guided procedures are an essential part of the contemporary practice of medicine. In general, the risk of patient injury as a result of radiation exposure during these procedures is quite low. Radiology and interventional radiology training programs include radiation safety, radiation physics, the biological effects of radiation, and injury prevention to promote patient safety. However, many physicians with no formal training in radiation safety now use fluoroscopy. All physicians using fluoroscopy have an obligation to record in the patient record how much radiation is delivered to the patient. This makes it possible to track any adverse events and to look at cumulative exposure over time, if the patient has future procedures. Physicians may also use these data to evaluate their own performance.

This practice guideline sets parameters for measuring and recording the dose, and calls on hospitals to purchase equipment that has state-of-the-art dose measurement capabilities and update existing equipment with after-market devices to improve dose-measurement capability.

Interventional radiologists, physicians who have specialized training in performing minimally invasive procedures using imaging guidance, are guiding the effort to optimize patient radiation dose from fluoroscopy procedures.

Visit www.jvir.org to view articles.

For media inquiries, contact Diane Shnitzler (703) 460-5582, shnitzler@sirweb.org or Emily Oehler at (703) 460-5572, emily@sirweb.org.