Neurologists Are Urged To Use Stroke Registries

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OLYMPIC VALLEY, CALIF. — Few neurologists have been enrolling patients in any of the three existing stroke registries, in large part because they do not know about them.

Dr. John J. Connors III, medical director of the NeuroVascular Research Foundation, noted that although many neurointerventionists may be aware of these registries, those who are on the front lines of stroke treatment are simply not aware of the registries or are reluctant to participate because of the time and diligence required. There are currently three registries enrolling patients.

'Registries are necessary for proof that neurointerventional procedures work ... and will be mandated by upcoming stroke-treatment training guidelines.'

The first, known as INSTOR (Interventional Stroke Therapy Outcomes Registry), was designed primarily to collect information on intra-arterial lysis for large-vessel occlusion. At first, 159 sites expressed interest in participating, but most have not entered any patients since INSTOR's launch in 2002. Nevertheless, 20 active sites have contributed 278 patients to date, making it the largest database in the world that focuses on this type of stroke treatment.

A second registry, INTRASTOR (Intracranial Angioplasty and Stenting Outcomes Registry), was created to evaluate whether angioplasty and stenting can prevent stroke by treating atherosclerotic disease in the brain. At a poster presented at the annual meeting of the Society of Neurointerventional Surgery, data from 199 patients with 201 lesions indicated that 89% (178) of patients had greater than 70% stenosis. In all, 90 patients were treated with angioplasty alone, 72 by primary stenting, and 29 by angioplasty followed by stenting. (Data were unavailable for the remaining eight patients.)

After treatment, 74% of patients had less than 33% residual stenosis, and 14% of patients had 34%-50% residual stenosis. Symptomatic complications included 10 patients with permanent neurologic deficits, 26 with minor complications that fully resolved, and 3 patients who died.

A third registry that was recently launched, known as INSTOR II, is designed to collect more complete information on the use of mechanical and combination interventions that are used to treat acute ischemic stroke. These interventions include mechanical retrievers and a device that delivers intracranial ultrasound-aided lysis.

"We need neurologists on board," Dr. Connors said. "Although randomized control trial data are always preferable, any data are better than none. The INSTOR registries include [data on] patient selection, usually with [CT angiography] to choose patients with large-vessel occlusions. To this day, even with our ubiquitous neuroimaging tools, large stroke treatment trials [such as the Interventional Management of Stroke III trial] still use only patient selection no more sophisticated than that used 20 years ago. No oncology trial, for instance, would ever include all grades of breast cancer in a chemotherapy trial."

Although larger numbers of patients are still needed, the registries are already revealing worthwhile information, Dr. Connors noted. For instance, the data from INSTOR I indicate that almost one-fifth of the 278 patient were on Coumadin, but 45 of these 53 patients had international normalized ratio levels lower than 2.0, indicating less-than-effective doses that might have allowed a cardiogenic embolus in a patient who was known to be at risk.

Other data suggest many of the patients were being treated with acetylsalicylic acid but had a presumed cardiogenic embolus and possibly should have been on Coumadin. Their average score on the National Institutes of Health Stroke Scale was 17, and 53% of patients had 3-month Rankin grades of 0-2 (though follow-up was incomplete).

"Registries are necessary for proof that neurointerventional procedures work. They are recommended by the Brain Attack Coalition in Comprehensive Stroke Centers. They are mandated by certain health care agencies, including the state of Florida, [and] by several medical societies, and will be mandated by upcoming stroke-treatment training guidelines. Decisions by [the Centers for Medicare and Medicaid Services] have been based upon registry data," Dr. Connors said. "It is necessary for members of the endovascular societies that treat stroke to participate in this effort."

Although most neurologists, particularly those in leadership, do not believe in these interventions, the data from the registries—if adequate numbers are achieved—should help remove any concerns that endovascular intervention for appropriately selected patients works.

"Collecting these data in the long run is beneficial for the science of endovascular stroke therapy and prevention, but requires the commitment of both individual physicians and medical leadership," Dr. Connors said. In the long run, these data are good not only for the patient, but also for the cerebrovascular/stroke business, he added.

For more information about enrollment instructions, equipment, and obtaining Institutional Review Board support for the registries, visit www.strokeregistry.org. ■

Editor's Note: *Do you refer stroke patients to registries? If not, why not? Do you agree with Dr. Connors' assertion that neurologists "do not believe in" interventions? Please write us at clinicalneurlogynews@elsevier.com.*

POLICY & PRACTICE

Neurologists Rank High in MRI Use

Most magnetic resonance imaging services paid for through Medicare Part B in 2005 were ordered by physicians in four specialties—neurology, internal medicine, orthopedic surgery, and family medicine—according to a report from the Health and Human Services Office of Inspector General. Internists topped the list by ordering 21% of the 2.6 million MRI services, followed by orthopedic surgeons (19%), and family physicians and neurologists (13% each). The "high users" of MRI, defined as those whose allowed charges put them at the 95th percentile or above for all physicians who ordered MRIs, were predominately orthopedic surgeons and neurologists. The study did not evaluate the medical appropriateness or necessity of the services ordered. The full report is available at www.oig.hhs.gov/oei/reports/oei-01-06-00261.pdf.

Imaging Cuts Reduce Costs

Medicare Part B payments for physician-performed imaging services dropped almost 13% between 2006 and 2007 due mainly to caps on physician payments called for under the Deficit Reduction Act (DRA) of 2005, according to an analysis from the Government Accountability Office (GAO). Under the DRA, Medicare fees for certain imaging services provided in the physician's office may not exceed what Medicare pays under the hospital outpatient prospective payment system. The imaging payment cap went into effect on Jan. 1, 2007. As a result, Medicare Part B per-beneficiary expenditures for imaging services fell from $419 in 2006 to $375 in 2007. Expenditures for advanced imaging services such as computer tomography and MRI fell even more. Although per-beneficiary expenditures dropped, utilization of services continued to rise, according to the GAO, which did the analysis at the request of Congress. The GAO concluded that beneficiary access at the national level was not affected by the payment cuts. However, the medical technology trade organization AdvaMed said the report indicated that the payments cuts were deeper than expected and are not in the interest of patients. Requiring accreditation of equipment and personnel in physician offices and developing appropriateness criteria would be a better approach to curb high imaging expenses, according to AdvaMed.

NIH: Environment's Role in PD?

The National Institutes of Health is awarding more than $21 million over 5 years to study how environmental factors contribute to the cause, prevention, and treatment of Parkinson's disease. The recipients of the grants, administered through the National Institute of Environmental Health Sciences (NIEHS), will attempt to develop new biomarkers in the blood that could be used to identify individuals at risk for Parkinson's disease, identify agricultural pesticides that disrupt molecular pathways, and analyze how proteins associated with Parkinson's disease are modified by environmental toxins, Cindy Lawler, Ph.D., NIEHS program administrator, said in a statement.

Cephalon Pays $425 Million

Cephalon Inc. has agreed to pay more than $425 million to settle claims that it inappropriately marketed three drugs for off-label uses, according to the U.S. Justice Department. The settlement will resolve civil and criminal complaints alleging that the company marketed Gabitril (tiagabine), Actiq (oral transmucosal fentanyl), and Provigil (modafinil) for off-label uses. Between 2001 and 2006, Cephalon allegedly promoted Actiq, which is an approved pain treatment in opioid-tolerant cancer patients, as a treatment for migraine, sickle-cell pain, and injuries. The epilepsy treatment Gabitril was allegedly promoted for treatment of anxiety, insomnia, and pain. Provigil, which was originally approved to treat excessive daytime sleepiness associated with narcolepsy, was allegedly promoted off label as a nonstimulant drug for sleepiness, tiredness, decreased activity, and fatigue. Under the settlement, Cephalon has entered into a 5-year Corporate Integrity Agreement with the Heath and Human Services Office of Inspector General. The agreement requires the company to notify physicians of the terms of the settlement and to begin disclosing any payments made to physicians on its Web site by Jan. 31, 2010.

Few Nabbed for Pain Prescribing

Few physicians have been charged or sanctioned for prescribing pain medications improperly, according to a study. From 1998 to 2006, only 725 individual physicians, or about 0.1% of practicing physicians in the United States, had been criminally charged or administratively reviewed for offenses involving the prescribing of opioid analgesics. Nearly 40% of the cases involved family medicine or general practice physicians, and 23.7% involved internists. In contrast, only 3.5% of cases involved pain medicine specialists. The high number of investigations of primary care physicians is not surprising given the shortage of pain specialists, the researchers wrote. "Practicing physicians, including pain medicine specialists, have little objective cause for concern about being prosecuted by law enforcement or disciplined by state medical boards in connection with the prescribing of [controlled substance] pain medications," the researchers wrote (Pain Med. 2008;9:737-47 [Epub doi:10.1111/j.1526-4637.2008.00482.x]). The study was conducted by researchers from the National Association of Attorneys General, the Federation of State Medical Boards, and the Center for Practical Bioethics.

—Mary Ellen Schneider