

VA Research Currents

Study questions benefits of coronary repairs in preparation for vascular surgery

multisite VA study published in the Dec. 30 New England Journal of Medicine may help physicians decide how to manage patients with blocked coronary arteries who are awaiting surgery for noncardiac vascular problems, such as clogged leg arteries.

Conventional medical wisdom calls for many of these patients to delay their elective vascular surgery until their coronary arteries can be fixed, usually through bypass surgery or balloon angioplasty and stenting. This is thought to lower the risk of heart attack after vascular surgery. But the new study says preventively clearing the coronary arteries is unlikely to improve the outcomes of vascular surgery.

"The technological advances in coronary catheritization and revascularization have made us more comfortable doing more procedures. But it's not translating into a survival advantage for these patients," said study leader Edward O. McFalls, MD, PhD, a cardiologist at the Minneapolis VA Medical Center and University of Minnesota.

The study, conducted at 18 VA medical centers, included more than 500 older men who were scheduled for operations to fix either blocked leg arteries or abdominal aneurysms—a condition in which part of the abdominal aorta, a main artery, bulges and sometimes bursts. All the veterans had angiograms showing at least 70-percent blockage in one or more coronary arteries. Half the men were assigned to undergo coronary revascularization before their vascular procedure. The others underwent vascular surgery as planned, with no

see **HEART** on page 2

Fiber may help GERD

In a VA study of 371 volunteers, those with diets higher in fiber and lower in fat were less likely to suffer serious heartburn. Though fiber has long been praised for its role in heart and colon health, the VA study is among the first to suggest it may provide further digestive benefits. The findings appear in the January issue of the journal *Gut*.

"To our knowledge, this is the first study of its kind to suggest a protective effect for dietary fiber on gastroesophageal reflux disease," said lead author Hashem B. El-Serag, MD, MPH, of the Michael E. DeBakey VA Medical Center and Baylor College of Medicine in Houston.

Gastroesophageal reflux disease, or GERD, refers to chronic heartburn and regurgitation of

see GERD on page 2

Update from the Office of Research and Development...

Despite budget cuts, VA research should continue to shine in FY '05

By Stephan D. Fihn, MD, MPH, acting chief research and development officer

The advent of a new year is occasion to review the accomplishments of the year past and the challenges ahead. For VA Research, the past year has been one of transition. Although the transition is incomplete, we have had important successes, some not so visible and others readily apparent. Among the less visible activities, major progress has been made to address the March 2004 recommendations from the Office of the Inspector General. The progress includes a major reorganization of CO

personnel and a complete overhaul in the mechanism for funding jointly sponsored cooperative studies. We have started to institute financial systems that provide greater accountability. The QUERI redesign is complete, and we are making progress on streamlining the IRB approval process for multi-center studies.

We have also made strides in improving support for field

see UPDATE on page 3

HEART (continued from page 1) revascularization of the blocked coronary arteries.

After the vascular operations, the results for both groups were virtually the same: Within a month after surgery, 3 percent of patients in either group died. During the five-year follow-up period, 22 percent of the revascularization group and 23 percent of the no-revascularization group died. The rate of heart attack within a month after surgery was slightly higher for the no-revascularization patients—14 versus 12 percent—but the difference was not statistically significant.

Both vascular surgery and orthopedic surgery involve heart risks for older patients, particularly those with coronary artery disease. But vascular surgery can be especially risky. The procedure entails fluctuations in blood pressure and heart rate, and can trigger immune responses that harm the coronary arteries.

Most of the VA patients in the study were on a strict regimen of heart-protecting medications. According to McFalls, the results show that drug therapy alone—without costly, time-consuming and invasive revascularization procedures—may be enough to safeguard patients with coronary artery disease who must undergo vascular surgery.

"Beta blockers, statins, aspirin,

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ACE-inhibitors—all these medicines have the potential to protect patients so adequately that even someone with blocked arteries of the heart can withstand the stress of the vascular operation as well as someone just like them who has gone through revascularization," he said.

McFalls pointed out that the arteries fixed by revascularization—those showing at least 70-percent blockage—are often not the arteries responsible for heart attack. Research has shown that arteries narrowed by only 20 or 30 percent may worsen and cause heart attack.

The blockages fixed by stents or bypass surgery do play a role in angina, however. "We fix arteries that cause symptoms like chest pain and shortness of breath, because that will improve people's quality of life," said McFalls. "But that says nothing about protection from heart attacks."

The study was funded by VA's Cooperative Studies Program.

HSR&D national meeting

The 2005 national meeting of VA's Health Services Research and Development Service will be held Feb. 16 – 18 at the Wyndham Inner Harbor Hotel in Baltimore, MD. This year's meeting theme is "Improving Care for Veterans with Chronic Illnesses."

The meeting will include a presentation on chronic illness from a patient's perspective; a keynote address by Edward Wagner, MD, MPH, an expert on care coordination issues; and plenary paper sessions, exhibits, workshops, and a poster session.

Registration and other meeting information is available on the HSR&D web site at: http://www.hsrd.research.va.gov/about/national_meeting/2005/registration.cfm.

GERD (continued from page 1)

food. The disorder affects as many as one in five Americans. While millions of Americans suffer occasional heartburn, doctors diagnose GERD when the heartburn is frequent and persistent.

Previous studies have implicated fatty foods—along with many other culinary factors, including the size and timing of meals—as a GERD trigger. But the new VA study is one of the broadest analyses yet of how diet affects GERD. Study volunteers answered extensive questions about their diet over the previous year, and reported any symptoms of heartburn and regurgitation. Doctors performed endoscopies on 164 of the study participants to check for erosion and inflammation of the esophagus.

Those who ate the most fiber on a regular basis had about a 20-percent lower risk of GERD, regardless of body weight. No other nutrient or food group appeared to lower the risk for the disorder.

On the other hand, study volunteers who ate the most fat—particularly saturated fat—were a third more likely to have GERD than those who ate the least fat. Those with fattier diets were also more likely to have erosive inflammation of their esophagus, as determined by endoscopy. This condition was also linked to higher meat intake.

The researchers say that since participants who ate the most fatty foods were more likely to be overweight or obese, it is unclear whether their increased GERD risk resulted from a fatty diet or extra body weight. "There is probably an independent role for dietary fat, especially in obese individuals whose body mass index exceeds 30," said El-Serag. "On the other hand, obesity seems to be a risk factor irrespective of dietary intake."

Recent publications and presentations

Due to space constraints, only VA authors and affiliations are noted in this sampling of recent publications.

"Accounting for Apparent 'Reverse' Racial Disparities in Department of Veterans Affairs-Based Medical Care: Influence of Out-of-VA Care." Andrea D. Gurmankin, PhD, MBe; Daniel Polsky, PhD; Kevin G. Volpp, MD, PhD. Philadelphia. American Journal of Public Health, Dec. 2004.

"Accumulated Lead Exposure and Risk of Age-Related Cataract in Men." David Sparrow, DSc. **Boston.** *Journal of the American Medical Association*, Dec. 8, 2004.

"Actin Critical Concentration in Presence of Profiling and Capping Protein." Evguenia S. Klimenko; Elena G. Yarmola, PhD; Michael R. Bubb, MD. **Gainesville**. The American Society for Cell Biology 44th Annual Meeting, Washington, DC, Dec. 2004. "Alcohol-Related Advice for VA Primary Care Patients: Who Gets It, Who Gives It?" Daniel Kivlahan, PhD; Xiao H. Zhou, PhD; Mary B. McDonell, MS; Stephan D. Fihn, MD, MPH; Katharine A. Bradley, MD, MPH. **Puget Sound.** *Journal of Studies on Alcohol*, Sept. 2004.

"Are Racial Disparities in Health Conditional on Socioeconomic Status?" Melissa M. Farmer, PhD. **Sepulveda.** *Social Science & Medicine*, Jan. 2005.

"Burden of General Medical Conditions Among Individuals with Bipolar Disorder." Amy M. Kilbourne, PhD, MPH; Jack R. Cornelius, MD, MPH; Xiaoyan Han, MS; Mujeeb Shad, MD; Ihsan Salloum, MD, MPH; Joseph Conigliaro, MD, MPH; Gretchen L. Haas, PhD. **Pittsburgh**. *Bipolar Disorders*, Oct. 2004.

"Feasibility of Combining Multi-Channel Functional Neuromuscular Stimulation with Weight-Supported Treadmill Training." Janis J. Daly, PhD, MS; Robert L. Ruff, MD, PhD. Cleveland. Journal of Neurological Sciences, Oct. 2004. "Food Frequency Questionnaire Results Correlate with Metabolic Control in Insulin-Treated Veterans with Type 2 Diabetes: The Diabetes Outcomes in Veterans Study." Glen Murata, MD; Jayendra H. Shah, MD; William C. Duckworth, MD; Christopher S. Wendel, MS; M. Jane Mohler, MPH, PhD; Richard M. Hoffman, MD, MPH. **Southern Arizona, New Mexico.** Journal of the American Dietetic Association, Dec. 2004.

"High-Risk Alcohol Consumption and Late-Life Drinking Problems." Rudolf Moos, PhD; Penny L. Brennan, PhD; Kathleen K. Schutte, PhD. **Palo Alto**. *American Journal of Public Health*, Nov. 2004.

"Is There a Standard of Care for Eccentric Viewing Training?" Joan A. Stelmack, OD, MPH. **Hines**. *Journal of Rehabilitation Research & Development*, Sept./Oct. 2004.

"A Taxpayer-Funded Clinical Trials Registry and Results Database." Erick H. Turner, MD. **Portland**. *PLoS Medicine*, Dec. 2004.

UPDATE (continued from page 1)

investigators. Initiated under the leadership of Dr. Perlin, the Field Research Advisory Committee formalizes input from researchers. Also, we have embarked on an upgrade of the PROMISE system, which by all accounts is severely deficient, to tide us over us over until we design and implement a completely new system. We are examining the merit review application process to minimize bottlenecks. And, ORD has also reestablished partnerships with colleagues and partners in academia and government.

In the midst of administrative change, VA investigators have continued to perform outstanding research and 2004 was a good year for VA Research. Just one indication of this has been four major reports of cooperative studies within the past nine months.

The outlook for 2005 is favorable, although there are some difficult obstacles ahead. Foremost among these is

the FY05 budget, which is about \$3 million, or six percent, below our FY04 appropriation. After accounting for mandated pay increases and inflation, this represents a substantially greater decrease in real terms that nearly all VA investigators will experience in relation to funding lines and award amounts. Nonetheless, VA research should continue to shine. And shine we must, for in the final analysis, it will be the quality of our research and its relevance to veterans that will ultimately determine our future funding.

From a personal standpoint, I would like to express my sincerest gratitude to everyone who has supported VA Research during the past year, including VHA leadership, the dedicated staff in ORD and the investigators and staff in the field. Your loyalty and devotion to the mission of unearthing knowledge to improve the care and the lives of patients are awe-inspiring. Thanks and happy New Year.

New handbook covers VA policy on financial conflicts of interest in research

A newly published VA handbook will help medical centers develop comprehensive programs to deal with financial conflicts of interest in research, and guide investigators in complying with all VA and other federal and state regulations in this area. VHA Handbook 1200.13, available on the VA research website at http://www.va.gov/resdev/resources/policies/default.cfm, summarizes the steps VA is taking to address an issue of growing significance in the medical research world.

According to a review study by a team at Yale University School of Medicine, published in 2003 in the *Journal of the American Medical Association:* "Financial relationships among industry, scientific investigators, and academic institutions are widespread. Conflicts of interest arising from these ties can influence biomedical research in important ways."

One of the main procedures outlined in the new VA handbook is that all research proposals submitted to VA for review must contain a Financial Conflict of Interest Statement and Certification form, identifying conflicts of interest for each principal investigator, co-principal investigator and investigator, as well as for certain collaborators. For example, the form asks research personnel to identify whether they or their family members hold copyrights, receive royalties or outside salaries, or own stock related to the proposed research project.

The new policy, which medical centers must implement by June 1, 2005, also sets forth responsibilities for Central Office staff, medical center directors, and the various local committees involved in research oversight: the Financial Conflict of Interest Committee, Institutional Review Board, Institutional Animal Care and Use Committee, and R&D Committee.

John Fotiades, health services researcher, 39

John Fotiades, MD, MPH, a VA physician and health services researcher, died on New Year's Day as the result of a fire in his Queens, NY, home. He was 39.

Fotiades earned his BA in 1987 from New York University, and completed his MD in 1991 at Mount Sinai School of Medicine. He completed his residency in internal medicine at NYU School of Medicine in 1994, and went on to earn a master's of public health degree from Columbia University. Since 1998, Fotiades had worked as a primary-care physician and researcher at the Bronx VA Medical Center and assistant professor at Mount Sinai School of Medicine. He was principal investigator for a \$1.4-million multisite study to develop and evaluate patient education materials on bioterrorism. He also served as an investigator for two other multisite VA studies.

Fotiades was particularly interested in improving care for older veterans and those with serious mental illness, and served on two national VA committees in these areas.

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help prevent GERD

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