Erectile Dysfunction Is a Window on CAD Risk

BY JANE SALODOF MACNEIL
Southwest Bureau

PARIS — Erectile dysfunction may be an independent risk factor for heart disease, according to investigators from two studies who gave poster presentations at the annual meeting of the European Association of Urology.

Dr. Francis Dubosq reported that myocardial scintography revealed coronary artery disease in 9 (29%) of 31 men who sought treatment for erectile dysfunction (ED) from urologists at Hôpital Foch in Suresnes, France. The investigators excluded patients with known coronary artery disease (CAD) or two or more cardiovascular risk factors from the population referred to cardiology for screening.

Dr. Arthur Bohnen reported that ED was an independent risk factor for acute myocardial infarction and stroke in a longitudinal, population-based study that followed 1,248 men for an average of 6.5 years in Krimpen, Netherlands.

His group found that older men with severe ED were 2.5 times more likely to have a cardiovascular event than men with no ED; the odds were 1.5 times higher for those with moderate ED.

Both investigators said the results from the ongoing studies were preliminary. Although they stopped short of drawing definitive conclusions, each saw immediate implications for physicians.

Dr. Dubosq, a urologist at Hôpital Foch, said physicians should view men with ED as being at high risk for coronary artery disease. "You have to be very careful because these patients are going to be candidates for artery involvements," he said, emphasizing that the patients screened had no symptoms of coronary artery disease.

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DR. DUBOSQ

Dr. Bohnen, a general practitioner at Erasmus Medical Center, Rotterdam, Netherlands, said physicians should consider ED when estimating a patient's cardiovascular risk. "They should ask a question about ED and not only ask about smoking," he said. "It shows here [ED] is an independent risk factor, independent of the other risk factors."

The French study looked at a younger population, aged 45-70 years, chosen from 153 men seeking treatment for ED. The 20% sample selected for cardiology screening had a median age of 58 years. Scores on the International Index of Erectile Dysfunction showed that 2 of the men had severe ED, 10 had moderate ED, and 19 had mild ED.

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DR. BOHNEN

Blood tests showed no evidence of diabetes, dyslipidemia, or androgen deficiency, and Doppler ultrasound did not detect peripheral artery disease in any of the subjects screened for heart disease in the French study. Using Laurier scores, described as "an estimation adapted to [the] European population of the 10-year risk for 'hard' CAD," the investigators found that the median score was significantly different from "the ideal index of people the same age without CAD risk factors": 6.84 for the ED population vs. 5.32.

The Dutch study enrolled men aged 50-78 years at baseline without regard to whether they presented with ED. Patients with a radical prostatectomy, prostate or bladder cancer, or neurogenic disease were excluded.

Of 1,248 men enrolled, 856 had no erectile disfunction, 284 had moderate ED, and 108 had severe ED based on responses to the International Continence Society male sex questionnaire. During the follow-up period, 4.6% of the men had cardiovascular events. Within the population of men who had a cardiovascular event, 20% had severe ED and 31% had moderate ED.

The investigators defined cardiovascular disease as "acute myocardial infarction, stroke, or sudden death determined by an expert panel based on general practitioner data and hospital discharge letters."

Risk associated with ED was independent of cardiovascular risk factors such as cholesterol, blood pressure, body mass index, Framingham risk scores, family history, and smoking status. ■

Carotid Procedure Registry May Shore Up Evidence Base

BY CHRISTINE KILGORE
Contributing Writer

With a new carotid registry on both carotid artery stenting and endarterectomy about to open, the American College of Cardiology is at the forefront of an intensifying national focus on the use of patient registries for measuring effectiveness of new treatments.

Officials at the Agency for Healthcare Research and Quality (AHRQ), the National Committee for Quality Assurance (NCQA), the Centers for Medicare and Medicaid Services (CMS), and other organizations increasingly view patient registries as a key component of outcomes research, benchmarking, and payment policy, including future pay-for-performance initiatives.

They also view carotid artery stenting (CAS) as a perfect example of a complex, high-risk procedure involving different specialists that must be systematically studied and analyzed after it has been unveiled in clinical practice—and one for which registries may be an ideal tool.

The collection of outcomes data on high-risk patients who undergo CAS is now a requirement for Medicare payment. When CMS expanded coverage of CAS a year ago to high-risk, symptomatic patients with carotid artery stenosis of at least 70% (treated outside the context of clinical trials), it stipulated that facilities must be certified by CMS to perform carotid stenting and that facilities must also collect data on all CAS procedures.

Data must be analyzed at least every 6 months and made available to CMS "upon request" and as part of the CMS process of recredentialing facilities. According to the CMS Web site, more than 800 hospitals are now certified and collecting data.

The ACC's carotid registry is expected to open officially this month or next. The Society for Vascular Surgery (SVS) has already opened a similar registry. Both registries will make it easier for facilities and physicians of all specialties to comply with CMS's payment requirements for CAS, leaders at the organizations say.

The registries also will allow them to collect long-term outcomes data on both CAS and carotid artery endarterectomy (CAE) and to benchmark their outcomes against those of other institutions.

The ACC's CAS registry has been in the works for some time, but the decision to include CAE was a more recent consideration, after it became evident that including it would make the registry an attractive option for surgeons as well as interventional cardiologists, said Dr. Kenneth Rosenfield, who led development of the registry.

Having a registry that is as multispecialty as possible has always been a goal of the ACC, Dr. Rosenfield said. "We're talking about optimizing patient safety across the board. We owe it to patients to collaborate."

The ACC and SVS registries have their origins in a broader "Clinical Competence Statement on Carotid Stenting" that was published jointly by vascular surgery and interventional cardiology organizations last year.

The statement endorsed the creation of a national multispecialty carotid registry "for reporting of outcomes and assessment of institutional and individual operator competence." It was issued by SVS, the Society for Cardiovascular Angiography and Interventions (SCAI), and the Society for Vascular Medicine and Biology, and endorsed by the ACC.

Officials at ACC and SVS said that despite efforts to welcome all specialties, the two organizations decided to develop separate registries. However, officials at both organizations have also said in interviews that they are fully committed to sharing data elements and definitions.

"Both of our societies are committed to a process that will enable us to compare apples with apples," said Dr. Rosenfield, director of the cardiac and vascular invasive service at Massachusetts General Hospital, Boston.

Officials at NCQA and AHRQ, in the meantime, are trying to anticipate and prepare for challenges in coordinating and analyzing data on carotid procedures from multiple patient registries.

The issue was discussed at a conference held late last year by NCQA and SCAI with funding from AHRQ, when experts discussed registries as evaluation tools and focused on CAS as a case study.

CMS, which anticipated and has supported the development of more than one carotid registry, also has told societies there should be as many common data elements as possible among the registries, that they should have "full transparency," and that the registries should be accessible to the public.

ACC is adding the carotid registry to its larger Web-based National Cardiovascular Data Registry (NCDR), which houses two other registries—the CathPCI Registry, used by about 750 hospitals, and the ICD [implantable cardioverter defibrillator] Registry, which, starting this month, is the required registry for hospitals to receive Medicare coverage for the use of implantable cardioverter defibrillators for primary prevention of sudden cardiac death. (CMS contracted last fall with the ACC's NCDR to collect data on ICDs used for this indication. By this month, all hospitals must have transferred their current ICD data reporting activities to the ICD Registry.)

For carotid procedures, registry-level data are not enough, and randomized trials of CAS and CAE "need to be completed," said Dr. Steve Phurrough, director of the Coverage and Analysis Group at CMS, in an interview. "With ICDs, we had lots of good-quality, high-volume data—with CAS we don't."

Still, he said, registries are an important part of it all, especially because "comparing [and] risk-adjusting are better done in larger databases."

The collection of data as a condition of coverage "will become more and more prevalent, especially [in light of recent cases in which] the risks of drugs and devices weren't known until a few years out," he said.

Dr. Rosenfield said he believed the ACC registry is "a bit more robust" than the SVS registry, particularly with respect to preprocedural history, including neurologic history, and neurologic end points.

Dr. Ralph G. Brindis, chairman and chief medical officer of the ACC-NCDR, said the new registry would benefit from the NCDR's multifaceted strategy for auditing registry data to ensure it is complete and accurate.

"The biggest Achilles' heel [for registries] is the ability of [outsiders] to feel comfortable with the validity of the data," he said. ■