Uses of Drug-Eluting Stents Grow Quickly, Despite Cost

BY MITCHEL L. ZOLER
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Despite their higher cost, and despite recent concerns about late thrombosis, drug-eluting stents now own coronary stenting.

In the final 3 months of 2004, drug-eluting stents were estimated to have been used for 87% of all U.S. interventional coronary procedures, Martin B. Leon, M.D., said last November at the American Heart Association's scientific sessions in New Orleans. Less than 2 years earlier, in the first quarter of 2003, not a single drug-eluting stent had been used outside of a clinical trial. The Food and Drug Administration first approved a drug-eluting stent in April 2003.

'We desperately need more data regarding the safety and efficacy of drug-eluting stents in unapproved and high-risk indications' before use is considered routine.

"There has never been a technology in the world with this kind of rapid penetration over a short period of time," said Dr. Leon, associate director of the Center for Interventional Vascular Therapy at Columbia University in New York.

"We have not yet identified any subsets of patients who don't benefit from receiving drug-eluting stents [by having less restenosis] compared with bare metal stents," said David J. Cohen, M.D., associate director of interventional cardiology at Beth Israel Deaconess Medical Center in Boston. "De facto practice in the United States today is to use drug-eluting stents whenever the available stent lengths and diameters fit. At Beth Israel Deaconess, most of the time when patients [who are undergoing coronary stenting] don't receive drug-eluting stents it's because the vessel is too small or too large to accommodate available stent sizes," he told this newspaper.

In fact, use of drug-eluting stents has become so widespread that medicolegal concerns may now drive their use even more than purely clinical factors. "When the risk of restenosis is low, operators must balance the need for drug-eluting stents with the medicolegal risk of avoiding what has become the de facto standard of care for all patients," said Herbert D. Aronow, M.D., director of the cardiac catheterization laboratories at the Veterans Affairs Medical Center in Philadelphia.

According to one study, in 2003, about a third of all sirolimus-eluting (Cypher) stents used in the United States were for off-label, coronary-artery indications (INTERNAL MEDICINE NEWS, Feb. 15, 2005, p. 16).

As of early this year, no cardiology society had issued formal recommendations on the appropriate uses of drug-eluting stents, although these are expected soon. In the meantime, some experts have given their personal opinions.

One set of standards was laid out by Gregg W. Stone, M.D., in a talk at the AHA scientific session. "In workhorse lesions, in patients undergoing elective coronary interventions with de novo lesions up to 46 mm in length and in vessels with reference diameters of 2.5-3.75 mm without acute coronary syndrome or acute myocardial infarction, in general the safety and efficacy of two drug-eluting stents, Cypher and Taxus, has been proved," said Dr. Stone, an interventional cardiologist at Columbia University in New York. "Using drug-eluting stents over bare metal stents in these lesions is the appropriate thing to do."

But, he added, "we desperately need more data regarding the safety and efficacy of drug-eluting stents in unapproved and high-risk indications before their use should be considered routine. We must be very circumspect about extending drug-eluting stents to more complex patients and lesions. We are in the midst of stent frenzy, where everyone is putting in drug-eluting stents in every single lesion. You need to be aware of the evidence so you know what you are doing."

According to Dr. Stone's assessment last November, there are "pretty good grounds" for using a single drug-eluting stent to treat in-stent restenosis within a bare metal stent.

Use of a drug-eluting stent can "probably be recommended" for the following: treating in-stent restenosis in place of brachytherapy when the existing stent was bare metal; bifurcations when the drug-eluting stent is placed in the main branch with angioplasty only for the side branch; aorto-ostial lesions; chronic, total occlusions; patients with multivessel disease instead of bypass surgery if they have only simple, focal lesions; and saphenous vein grafts.

But because of an "absence of sufficient data to warrant routine use," Dr. Stone cautioned physicians to "think twice" about using drug-eluting stents outside of an investigational setting for these indications: bifurcations when two stents are used; ultralong lesions; unprotected left main disease; in-stent restenosis following failed brachytherapy; and in patients with acute MI. There is even less evidence on using drug-eluting stents for V-stenting of a bifurcation, and it is unclear how cardiologists should manage restenosis within a drug-eluting stent. ■

Type D Personality Signals Stent Risk

BY BRUCE JANCIN
Denver Bureau

MUNICH — Type D personality is an independent risk factor for death or acute MI following coronary stent placement, regardless of whether a bare metal or drug-eluting stent is deployed, Susanne S. Pedersen, Ph.D., reported at the annual congress of the European Society of Cardiology.

Type D personality is the polar opposite of the aggressive and impatient type A personality. The "D" stands for "distressed." Type D is a stable, broad personality trait marked by the combination of a high degree of negative affect coupled with inhibited self-expression in social interactions. The type D individual is reserved, insecure—even timid—anxious, and uneasy interacting with others.

Prior studies have shown that type D personality is a cardiac risk factor and that coronary artery disease patients with type D personality have worse outcomes than patients without this personality structure. Dr. Pedersen presented the first study to evaluate the impact of type D personality on clinical outcomes in the contemporary drug-eluting stent era of percutaneous revascularization.

She reported on 875 consecutive participants in the Rapamycin [sirolimus]-Eluting Stent Evaluated at Rotterdam Cardiology Hospital (RESEARCH) registry who completed the Type D Personality Scale 6 months after undergoing percutaneous intervention with either a bare metal or sirolimus-eluting stent.

The scale is a brief 14-item standardized and validated instrument well suited for use not only in trials but also as a risk-stratification tool in clinical practice, according to Dr. Pedersen of Tilburg (Netherlands) University.

The primary end point in this RESEARCH substudy was the combined rate of death or nonfatal MI during the 9 months following patient completion of the Type D Personality Scale, that is, during months 6-15 post stenting.

Of the 875 patients, 254 (29%) were classified as type D on the basis of their test scores. They were significantly more likely than were non–type D patients to be current smokers (37% vs. 29%, respectively), but the two groups didn't otherwise differ in terms of the standard cardiovascular risk factors.

The rate of the combined study end point in type D subjects was 5%. In a multivariate logistic regression analysis, type D personality was an independent predictor of death or MI, conferring a 5.3-fold increased risk. The only other independent risk factor for these adverse outcomes was a history of prior coronary artery bypass surgery, associated with a 3.0-fold risk.

There was no association between stent type and risk of the combined end point. This finding is in keeping with other studies showing a dramatic reduction in restenosis with drug-eluting stents, compared with bare metal stents, but no significant differences between the two stent types in mortality or MI, the psychologist noted. ■

Hyperbaric Chamber Protects Against Post-CABG Cognitive Decline

BY BRUCE JANCIN
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NEW ORLEANS — Spending a few hours in a hyperbaric chamber before undergoing on-pump coronary artery bypass graft surgery markedly reduces postoperative neurocognitive dysfunction, according to the findings of a randomized double-blind trial.

The trial included 64 patients scheduled for on-pump CABG surgery, who spent three sessions inside a hyperbaric chamber at 24, 12, and 4 hours prior to their surgery. During each session, they were exposed to 60 minutes of 100% oxygen at either 2.4 atm of pressure or normobaric room air. Surgeons, patients, and the neuropsychologist were blinded to which treatment the patient received, Joseph Alex, M.D., said at the annual scientific sessions of the American Heart Association.

Treated patients showed less neurocognitive impairment and significantly less postoperative anxiety and depression symptoms.

A battery of neuropsychological tests was administered 1 week before and again 4 months following CABG surgery. Significant neurocognitive dysfunction—a decline of at least 1 standard deviation on any two tests in the battery—was documented in 55% of control subjects and 30% of patients who underwent hyperbaric oxygenation before surgery, according to Dr. Alex of Castle Hill Hospital, Cottingham, and the University of Hull, England.

The two patient groups in the study were comparable in terms of all key perioperative variables that might have affected neurocognitive function, including time spent on a ventilator, need for and length of ICU stay, blood transfusion, development of renal dysfunction, and cardiac arrhythmias.

The neuropsychologic test battery consisted of the digit-span forward and backward, the grooved peg board, the Rey Auditory-Verbal Learning Test, trail-making A and B, and the adult memory and information processing table A.

Patients who underwent preoperative hyperoxygenation not only had less neurocognitive impairment; they also showed significantly less postoperative anxiety and depression symptoms, Dr. Alex added.

The increased tissue oxygen concentrations achieved in the hyperbaric chamber have been shown to promote healing of refractory leg ulcers and other wounds. ■