HEART OF THE MATTER

The Risks of Drug-Eluting Stents

There are few if any medical therapies that are without any risks. No matter what the treatment, there have always been some risks associated with therapeutic intervention.

Drug-eluting stents (DES) appeared to be an exception to the rule once they were shown to have excellent short-term patency, compared with the bare-metal stents (BMS). DES are now widely used for the treatment of stenotic coronary arteries even in conditions for which there are few data to support a clinical benefit. In the last few years the indication for implantation of stents, and particularly DES, has slipped to a state where clinical judgment has given way to an unfettered response to the "oculostenotic reflex" of the angiographer.

BY SIDNEY GOLDSTEIN, M.D.

The fact is that the only proven clinical benefit of percutaneous coronary intervention for chronic coronary artery disease is to improve the symptoms of angina. There is nothing to support a mortality or morbidity benefit for the treatment of angina pectoris with PCI. There is also abundant information to indicate that the next acute coronary event usually involves a site in the coronary artery that has little or no preexisting disease. Despite this, PCI with stenting, particularly with the seemingly safe DES, is applied to many asymptomatic patients with anatomic abnormalities alone, to prevent future acute ischemic events.

It now appears that drug-eluting stents, like many previous therapeutic interventions, are not quite as safe as it may seem. Recent press reports indicate that Boston Scientific recently appraised the Food and Drug Administration of its concerns about the long-term morbidity and mortality of the paclitaxel-eluting (Taxus) stent when compared with BMS in regard to the development of thromboses. This follows the reports at the recent meeting of the European Society of Cardiology that Swiss investigators found a significant increase in myocardial infarctions and death in patients receiving DES compared with the BMS in patients followed out to 3 years (see p. 1). In that study, adverse events occurred to a greater degree in the sirolimus-eluting (Sirius) stent than in the Taxus stent.

A proposed mechanism for this late thrombosis is the lack of endothelialization in the DES and the inconsistent use of chronic antiplatelet agents. It was also noted that there was a unique increase in noncardiac deaths, including cancer and infection, suggesting that the antimitotic drug coating of the stents could lead to adverse systemic effects.

All of these reports are preliminary and require further examination. However, if true it could have far reaching effects on the millions of patients who have received DES. It is an even greater paradox for the many asymptomatic patients who received these stents to prevent the morbidity and mortality of coronary artery disease. They now have developed a new disease, the nature and duration of which is uncertain.

Unfortunately, we do not have adequate monitoring systems to fully understand the magnitude of events following implantation of DES. Nevertheless, these very preliminary observations should infuse into the interventional cardiology world caution before implanting DES into asymptomatic patients and in symptomatic patients only after failure with drug therapy. ■

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Diabetes Status Didn't Alter BP Benefits in ASCOT

COPENHAGEN — Nondiabetic and diabetic patients benefit equally from the hypertension-lowering effects of an amlodipine/perindopril regimen, according to a subanalysis of a large trial reported at the annual meeting of the European Association for the Study of Diabetes.

The Anglo-Scandinavian Cardiac Outcomes Trial–Blood Pressure Lowering Arm (ASCOT-BPLA) was stopped early because of the distinct advantages of the calcium channel blocker/ACE inhibitor combination over a traditional β-blocker (atenolol)/thiazide diuretic (bendroflumethiazide) combination in reducing stroke, cardiovascular (CV) events and procedures, and all-cause mortality. In the ASCOT-BPLA cohort of more than 19,000 hypertensive patients, the amlodipine-based regimen also resulted in a significant reduction in new-onset diabetes.

The current analysis included a subset of 5,137 trial participants who had preexisting diabetes and found similar benefits for the amlodipine-based therapy, reported Dr. Jan Östergren from Karolinska University Hospital in Stockholm.

At the end of 5 years, total CV events and procedures were reduced by 14% in the amlodipine-treated group compared with the atenolol-treated group. Specifically, the incidence of fatal and nonfatal stroke was 25% lower, peripheral arterial disease was 48% lower, and noncoronary revascularization procedures were 57% lower, said Dr. Östergren.

—Kate Johnson

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