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HEART OF THE MATTER

Drug-Eluting Stents and the Real World

servations reported at the meeting of the European Society of Cardiology in Stockholm provide insights into the real-world use of drug-eluting stents.

Much of our knowledge of DESs has come from carefully controlled clinical trials using highly selected patients and conducted in academic institutions. What happens after the device is approved and introduced for use in everyday medical practice is often very different.

Human nature drives interventional cardiologists to use the latest new toy, regardless of price,

while patients are educated by the media to demand state-of-the-art stents.

At the same time, cardiologists tend to expand the indications for use of the device or drug beyond the patient inclusion criteria used to established efficacy and safety. In addition, information about the application of new therapies after the FDA has approved them is scarce. In some cases, drugs have been used in patients who differed from those in the seminal clinical trial, resulting in increased major adverse clinical events (MACE).

Gregory J. Mishkel, M.D., described

n this issue of Cardiology News, ob- how he and his associates observed treat stenosis, then the cost of DES imthat in more than 3,000 patients in a general cardiology practice, most of those who received DESs did not fit the criteria used in the trials that estab-

lished the benefits of the stents. (See page 23.) As the patients' characteristics were expanded beyond the initial inclusion criteria, the incidence of MACE increased. The more risk factors the patients had, the more likely was the occurrence of MACE. In the context of patients demanding the latest procedure to get the best results, the investigators found that the pa-

tients were, in fact, being shortchanged.

The investigators suggest that enthusiasm for DESs also led to stenting when coronary bypass surgery might have been a better choice, but they did not provide data to support that possibility.

Another result of the overuse of DESs has been the impact on health care costs. The actual cost of stents varies from institution to institution. Current estimates suggest that a baremetal stent (BMS) costs about \$1,000, whereas a DES costs about three times that. If one considers that it usually takes at least two stents to completely

plantation, compared with that of BMS implantation, begins to mount up.

In the Basel Stent Cost Effectiveness Trial (BASKET, page 1), researchers compared the costs and efficacy of the implantation of the paclitaxel-eluting Taxus and sirolimus-eluting Cypher stents with the Vision stent, a cobaltchromium-based BMS. Although the DESs resulted in an improved target vessel revascularization, they also tacked on almost \$90,000 per year of quality-adjusted life-year gained by the DES.

These reports provide an unusual glimpse into how new devices are actually being used in clinical medicine, as well as how drugs and devices are applied to the general populations based on data from narrowly defined patient samples in clinical trials. Patients in enrolled in clinical trials are recruited to answer specific questions, which results in the exclusion of many in the general population with complicating illnesses. Unfortunately, those complicating illnesses that exclude patients from clinical trials are the problems that the physician deals with every day.

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