

Drug-eluting stents confirmed safe, effective for long-term use

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Researchers at the Rabin Medical Center in Israel have determined that the use of drug-eluting stents (DES) improves the long-term clinical outcome for patients undergoing percutaneous coronary intervention (PCI), commonly known as angioplasty. Results of this study appear in the September issue of *Catheterization and Cardiovascular Interventions*, a journal published by Wiley-Blackwell on behalf of The Society for Cardiovascular Angiography and Interventions.

PCI is used to treat <u>coronary artery disease</u> and is one of the most common medical procedures. Expert reports indicate there were 1,313,000 PCI/angioplasties conducted in the U.S. in 2006. Randomized clinical trials indicate DES decreases in-stent restenosis and the frequency of repeat revascularization procedures in patients undergoing PCI, yet questions remain about the long-term safety and/or effectiveness of DES in routine clinical practice among large unselected population cohorts.

In the current study, the Israeli team examined the benefits and longterm risks of DES by evaluating the established pattern of DES versus bare-metal stent (BMS) use in routine clinical practice in Israel. Israeli guidelines established by the Israel Heart Society and the Ministry of Health require DES be used preferentially in proximal main vessels, diabetic patients, and in long lesions to reduce restenosis.

The study population comprised all consecutive cases of PCI with stent implantation over a 4-year period at the two hospitals of the Rabin



Medical Center. The entire cohort consisted of 6,583 patients, 2,633 (40%) patients with a DES and 3,950 (60%) patients with BMS. The minimal follow-up time was 6 months, and the maximal follow-up time was 5.2 years, with a mean follow-up time of 3 years. Propensity score matching and stratified analysis was used to define the clinical effectiveness and safety profile of DES versus BMS among "all comers" patients treated at the Center, using carefully validated long-term follow-up mortality and morbidity endpoints. Propensity score matching was performed using an algorithm to match each DES patient with a BMS patient with the closest propensity score. Each pair was used once and unpaired cases were not used in further analysis. The propensity matched group consisted of 4,398 patients (2,199 matched pairs).

The usage pattern set by the Israel Ministry of Health directives was generally followed, with 40% of the procedures including a DES. Patients who received DES were slightly younger and more likely to be diabetic. Their index intervention was less likely to be emergent. The main features associated with the DES group were the use of longer or more stents per lesion, treatment of more territories, more sites per territory and of more proximal main vessels. Of the patients with DES, 66% had a DES only, whereas 34% had a combination of a DES and a BMS.

Results show that use of DES compared with BMS reduced the occurrence of myocardial infarction (MI) (5.17% vs. 5.83%) and the need for clinically driven target vessel revascularization (TVR) (9.76% vs. 12.28%). Mortality was significantly lower in the DES group, showing a persistent benefit of DES over time (23.38% for DES vs. 26.07% in BMS).

Study leader Dr. Tamir Bental concludes, "The main effect of DES is reduced restenosis, which is evident in our analysis. This outcome was sustained over time and could certainly be a major factor contributing to



the survival benefit of DES. We suggest that a possible additional factor contributing to our results could be the pattern of use of the DES in our practice—treatment of more territories and more sites per territory, probably leading to a more complete revascularization. Another salient feature was the preferential treatment of more proximal main vessel. Therefore, treatment of proximal lesions could contribute to a better outcome."

More information: "A Comparative Analysis of Major Clinical Outcomes Using Drug-Eluting Stents Versus Bare-Metal Stents in a Large Consecutive Patient Cohort." Tamir Bental, Abid Assali, Hana Vaknin-Assa, MD, Eli I. Lev, David Brosh, Shmuel Fuchs, Alexander Battler, and Ran Kornowski. Catheterization and Cardiovascular Interventions; Published Online: February 23, 2010. <u>DOI:</u> <u>10.1002/ccd.22507</u>

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