



CLINICAL TRIAL HIGHLIGHTS

There were no significant differences in safety outcomes between the two groups, and there were no signals of cancer (HR, 0.99; 95% CI, 0.87 to 1.13; log-rank 2-sided p=0.89).

Adherence to the eze/simv regimen was maintained by about two thirds of patients. The study investigators calculated that full adherence with eze/simv would reduce the risk of the primary outcome by 25%, avoiding 30 to 40 events for every 1000 patients treated over 5 years.

Dr. Giugliano noted that the results of the IMPROVE-IT study [NCT00202878], expected to be available in late 2014, should provide further evidence about the benefits of adding ezetimibe to a statin. The study is comparing eze/simv 10/40 mg and simvastatin 40 mg in patients with recent acute coronary syndrome.

First Caribbean Experience: Abbott's Experimental Bioresorbable Stent

Written by John Otrompke

The first Caribbean studies to examine the performance of Abbott's experimental bioresorbable vascular scaffold (BVS) indicate that the device is feasible to be used in clinical practice, according to a presentation by Ingrid Valdez, MD, Los Centros de Diagnóstico y Medicina Avanzada y de Conferencias Médicas y Telemedicina (CEDIMAT), Santo Domingo, Dominican Republic.

As of July 2013, eight patients in the Dominican Republic, who are the first in the Caribbean to receive the device for use, have been treated with the bioresorbable stents. Dr. Valdez presented data from the first five patients for whom 30-day follow-up is available.

Bioresorbable stents are absorbed by the vessel wall over time and evidence of the coronary stent disappears. Thus, it is possible that the normal vascular functions of the vessel can be restored once the stent is absent. The results presented demonstrated the use of the experimental device in four men and one woman. The patients were aged between 39 and 75 years, and all had multivessel coronary artery disease. Dyslipidemia was the most frequent risk factor and was found in 80% of the patients. Hypertension was present in 60% of the patients, and 20% of the patients had diabetes. Ongoing tobacco abuse was present in 20%. Additional angiographic characteristics are outline in Table 1.

For most patients, it was necessary to use more than one device of varying diameters to cover the entire lesion (Figure 1). In one patient, there was one complication: a perforation caused by the guidewire during the predilation phase. In that case, Dr. Valdez noted, physicians performed a double coil implantation, and then successfully performed the remainder of the stenting procedure.

Table 1. Angiographic Characteristics

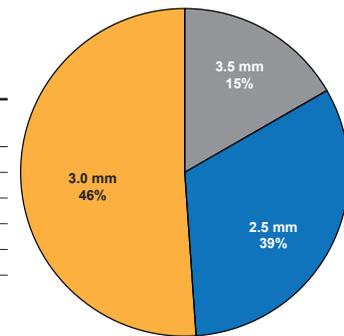
5/5 MVD	3/5 PCI <6 months
3/5 Severe calcification	2/5 Previous AMI
5/5 Diffuse LAD disease	3/5 Guided by IVUS
4/5 SYNTAX score >23	5 Bifurcations
1/5 SYNTAX score >33*	100% Device success
5/5 LAD was treated	100% Procedure success

AMI=acute myocardial infarction; IVUS=intravascular ultrasound; LAD=left anterior descending; MVD=microvascular disease; PCI=percutaneous coronary intervention.

*Discussed by the heart team and rejected for bypass, because of bad beds.

Figure 1. Number of BVSs Used

Case Number	Total Number of BVS	Diameters of BVS		
		2.5 mm	3.0 mm	3.5 mm
1	2	1	1	0
2	3	0	3	0
3	3	2	1	0
4	2	1	0	1
5	3	1	1	1



BVS=bioresorbable vascular scaffold.

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Like the XIENCE V which is a drug-eluting stent using a traditional scaffold, the Abbott BVS serves as a vehicle for everolimus. The efficacy of everolimus with stenting for reducing restenosis has demonstrated in trials of the XIENCE V stent. The delivery platform of the Abbot BVS is the same as the XIENCE V. Although the bioresorbable scaffold is not yet approved by the United States Food and Drug Administration, 12-month data from the Spirit I, II, and III trials in more than 2000 patients have demonstrated bioresorbable stents to be noninferior to the Xience V (MACCE at 12 months) [Serruys PW et al. *Eurointervention* 2005, 2006; Stone GW et al. *JAMA* 2008].

Initial experience with the Abbott BVS demonstrate that implantation is possible even in some complex cases. Thus, these results from the first-ever trials of the device in the Caribbean are consistent with prior studies that have found use of the bioresorbable devices to be feasible. Further studies are needed to better understand the long-term clinical outcomes in patients treated with bioresorbable stents.