severely calcified lesions. It utilizes centrifugal sanding action, and Dr Chambers specifically highlighted its simplicity of use.

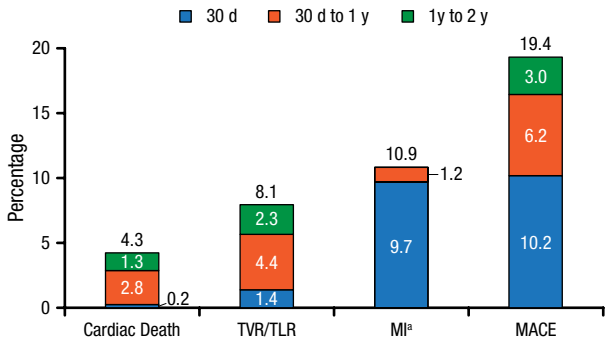
ORBIT II [Généreux P et al. *Am J Cardiol*. 2015] was a prospective, multicenter, nonblinded, single-arm study that evaluated the long-term safety and efficacy of coronary OAS in patients with severely calcified coronary lesions who underwent percutaneous coronary intervention. The objective of the study was to determine whether OAS successfully facilitated stent deployment and was safe in this patient population. The major inclusion criteria were evidence of severe calcification and the target vessel reference diameter between 2.5 mm and 4.0 mm, with the lesion length ≤ 40 mm.

The study enrolled 443 patients (64.6% men; mean age 71.4 years), with 97.7% of patients obtaining successful stent delivery that resulted in 98.6% of patients having < 50% residual stenosis [Chambers JW et al. *JACC Cardiovasc Interv*. 2014]. The adjudicated safety analysis showed that at 2-year follow-up, cardiac death occurred in 4.3% of patients, target vessel revascularization (TVR)/ target lesion revascularization (TLR) in 8.1% (TLR, 6.2%; TVR, 2.9%), myocardial infarction in 10.9%, and the composite end point of major adverse cardiac events in 19.4% (Figure 1). The subanalysis of the diabetic population revealed that coronary OAS produced similar outcomes in patients with diabetes (n = 160) vs those without (n = 283) at 2-year follow-up, with major adverse cardiac events occurring in 20.6% vs 18.7%, respectively.

The economic analysis compared OAS in elderly patients in the ORBIT II study (> 64 years; n = 297) with standard treatment in Medicare patients (n = 308) from hospitals reporting more than 10% of stent patients with calcification during the same time period. The baseline characteristics were comparable between these patient populations. The cost-model framework analysis revealed that the average projected cost offsets in the first year would fully cover the cost of OAS at $3795 and possibly extend to an additional $1118 in savings, yielding a total of $4913 in potential cost offset at 1 year. The incremental cost-effectiveness ratio (ICER) analysis demonstrated that OAS offered good value, with an ICER of $11 895 per life-year gained, which was substantially below the "high value" threshold of $50 000 per quality-adjusted life-year.

Dr Chambers concluded that the ORBIT II study showed that coronary OAS is a safe and effective treatment option in complex patients with calcified coronary lesions that is also cost-effective and potentially cost saving.

Figure 1. ORBIT II Safety Outcomes at 2-Year Follow-up



CEC, Clinical Events Classification; MACE, major adverse cardiac event; MI, myocardial infarction; TVR/TLR, target vessel revascularization/target lesion revascularization.

[a]Not per protocol analysis. Clinically driven evaluation based on CEC adjudication of MI.

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MILLION Study: Aggressive Medical Regimens Can Reduce BP and Lipids

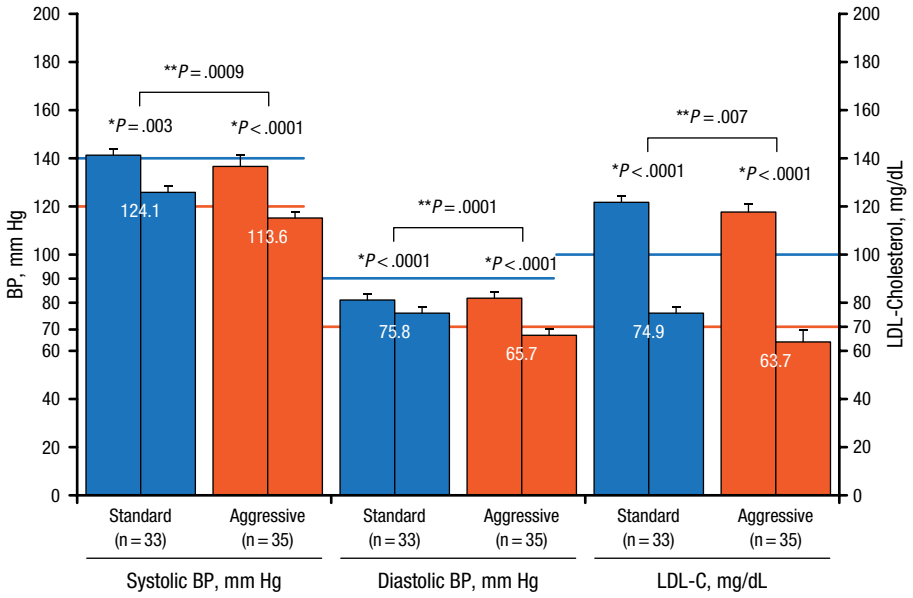
Written by Emma Hitt Nichols, PhD

An aggressive, simultaneous amlodipine- and statin-based regimen significantly decreased blood pressure (BP) and low-density lipoprotein cholesterol (LDL-C) compared with a standard-intensity regimen in a Japanese population with coronary artery disease (CAD). Masa-aki Kawashiri, MD, Kanazawa University, Kanazawa, Japan, presented these unpublished data from the MILLION study.

Intensive statin therapy for lowering LDL-C had been demonstrated to reduce the risk of major adverse cardiovascular events compared with moderate-intensity statin therapy. In addition, lowering BP with an amlodipine-based regimen also reduced major adverse cardiovascular events in patients with hypertension compared with a β-blocker or angiotensin-converting enzyme inhibitor–based regimen. However, the combination of both LDL-C and BP lowering did not affect outcomes compared with standard therapy [Kohro T et al. *Circ J*. 2011]. The purpose of the MILLION trial was to evaluate the change in plaque volume using intravascular ultrasonography, BP, and lipids in a Japanese population with CAD.

In the open-label, multicenter MILLION study, 100 patients with CAD who underwent percutaneous coronary intervention were randomly assigned to receive standard therapy with amlodipine 2.5 mg and atorvastatin 5 mg and other agents as necessary to reduce BP to < 140/90 mm Hg and LDL-C to < 100 mg/dL, or aggressive treatment with amlodipine 5 mg and atorvastatin 10 mg and other agents to decrease BP to < 120/70 mm Hg

Figure 1. Effect of Aggressive Therapy for BP and LDL-C Lowering



BP, blood pressure; LDL-C, low-density lipoprotein cholesterol.

*Paired t-test.

**Unpaired t-test.

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and LDL-C to <70 mg/dL [Kawashiri MA et al. *Heart Vessels*. 2014]. Patients were excluded if the percutaneous coronary intervention was unsuccessful, they had type 1 diabetes or poorly controlled diabetes, they were receiving insulin therapy, had secondary hypertension, were using dihydropyridine calcium channel antagonist for >6 months, used an intensive lipid-lowering statin agent, had familial hypercholesterolemia, or were aged ≥80 years. Baseline characteristics were similar between the 2 arms.

Among the 68 patients who completed the study, the primary end point of this study, the percent change in coronary plaque volume, decreased in the standard treatment arm (n = 33; $P = .006$) and the aggressive treatment arm (n = 35; $P = .008$), but there were no differences between the 2 therapies. In addition, BP and LDL-C were significantly reduced in both arms, with a greater reduction in the aggressive treatment arm compared with the standard treatment arm (BP, $P = .0009$; LDL-C, $P = .007$; Figure 1). There was no significant difference in percent change in lumen and vessel volume between the 2 arms.

Dr Kawashiri concluded that the data from the MILLION trial suggest that both standard and aggressive BP and lipid-lowering regimens were effective; however, a greater decrease in BP and LDL-C was evident in the aggressive treatment group compared with standard therapy.

OUTSIDE START: Successful MACE-Free Cilostazol Bridging to Surgery in Patients With DES

Written by Toni Rizzo

Dual antiplatelet therapy (DAPT) with a $P2Y_{12}$ inhibitor plus aspirin decreases drug-eluting stent (DES) thrombosis [Mauri L et al. *N Engl J Med.* 2014]. Each year, approximately 5% to 10% of patients with a DES must interrupt DAPT to reduce perioperative bleeding. Premature discontinuation of DAPT, especially during the first postoperative year, results in stent thrombosis rates of 10% to 35%, inversely related to duration after stent placement [Moussa ID, Colombo A. *Catheter Cardiovasc Interv.* 2009; van Kuijk JP et al. *Am J Cardiol.* 2009]. The highest stent thrombosis rates have been observed in patients with a paclitaxel-eluting stent (PES) during DAPT discontinuation, leading to increased major adverse cardiac events (MACEs) for prolonged durations, up to 30 months post-stenting [Garratt KN et al. *Circulation.* 2015].

Currently, there is no consensus on the best bridging strategy for patients with a DES discontinuing DAPT preoperatively [Kern MJ et al. *Catheter Cardiovasc Interv.* 2014]. DES bridging has been attempted with aspirin, heparin, glycoprotein IIb/IIIa inhibitors, low molecular weight