of renal artery ablation in an Afro-Caribbean population and to determine whether medication use could be reduced as a result of the procedure. In addition to being of Afro-Caribbean descent, subjects were required to have hypertension that was resistant to 4 classes of hypertensive drugs, including aldosterone blocking agents, and to be between 18 and 75 years old, with no renal artery stenosis > 5 mm, no calcification or accessory arteries, no secondary hypertension, and an estimated glomerular filtration rate > 45 mL/min. All patients had left ventricular hypertrophy diagnosed by echocardiography and evidence of microalbuminuria, putting them at high risk for cardiovascular problems.

Of the 10 patients who met the study criteria, 6 were selected for participation and flown to the Netherlands for the ablations. Participants had a mean body mass index (BMI) of 42.73 kg/m^2 and were a mean age of 60 years. Four patients had type 2 diabetes; 5, dyslipidemia; 1, paroxysmal atrial fibrillation; and 1, asthma.

All patients had renal nerve stimulation done before and following denervation with the electrophysiology stimulation catheter for evaluation of position and to obtain the results of denervation. The EnligHTN Renal Denervation System (St. Jude Medical, Inc.) was used for renal denervation through right femoral access and under sedation. The system delivers radiofrequency energy from an ablation catheter to create lesions along the renal nerves with the hypothesis that it may lower blood pressure.

There was no change in day or night blood pressure, BMI, or HbA1C 6 months after ablation. A positive response was defined as a 50% lowering of medication dose. For the majority of antihypertensive drugs that the patients were taking, patients either stopped taking them altogether or reduced their dose or frequency. Four of the 6 patients had a positive response. Table 1 shows the percentage drop in medication use after ablation for each patient in the study.

Table 1. Percentage Drop in Medication Use After Renal Denervation.

Patient	%
1	83.5
2	52.0
3	16.6
4	25.0
5	50.0
6	62.5

There were no complications. Dose reductions were required for 2 patients immediately after the intervention and for 1 patient within 48 hours of intervention due to hypotension. Neither of the patients (patients 3 and 4) with a BMI > 50 had a positive response.

Dr. Liqui Lung concluded that the pilot results suggest that renal denervation with the EnligHTN catheter may be safe and allow a reduction in antihypertensive medication in patients of Afro-Caribbean decent with drug-resistant hypertension who have a BMI < 50 kg/m^2, dyslipidemia, and diabetes. The promising results of this pilot study will require verification in well-powered, placebo-controlled trials. Results of the blinded controlled SYMPLICITY HTN-3 trial, which showed no difference in blood pressure after renal denervation, provide cautionary data stressing the importance of controlled assessments of renal denervation strategies before wider adoption.

Outcomes of Unprotected LMCA Stenting

Written by Maria Vinall

Approximately 7% of patients who undergo cardiac angiography have left main coronary disease (LMCD). Guidelines as recent as 2012 have recommended surgical revascularization or coronary artery bypass grafting (CABG) over percutaneous coronary intervention (PCI) [Patel MR et al. *J Am Coll Cardiol* 2012]. Some studies evaluating elective PCI with drug-eluting stent (DES) implantation as compared to CABG in unprotected left main coronary artery (LMCA) lesions, however, have reported short- and midterm outcomes that are similar [Chieffo A et al. *JACC Cardiovasc Interv* 2010; Lee MS et al. *J Am Coll Cardiol* 2006].

Antonio Vellegas, MD, Medicina Cardiovascular Asociada, Santo Domingo, Dominican Republic, presented the results of a study that evaluated clinical and demographic characteristics and the outcomes of unprotected LMCA stenting. This was a retrospective, observational case series of 49 patients selected from the Interventional Cardiovascular Department database who received PCI between 2009 and 2013. Outcomes included in-hospital complications, cardiovascular deaths, total deaths, and total days of admission.

The majority of patients were men (69%) with a mean age of 70.3 ± 3.9 years and a body mass index (BMI) of 26.9 ± 11.1 kg/m^2. Participants were 85% Hispanic and 15% Caucasian. Most patients (86%) presented with hypertension. Diabetes mellitus was seen in 37% of patients, hypercholesterolemia in 27%, and chronic kidney disease in 6%; 16% were smokers. The following

diagnoses were made at admission: stable coronary disease (n = 19), unstable angina (n = 16), myocardial infarction (n = 10), heart failure (n = 3), and cardiogenic shock (n = 1). Radial or femoral vascular access was obtained in all cases. Angiographic assessment denoted isolated left main (LM) disease (11 patients), LM disease plus single-vessel coronary vessel disease (11 patients), and LM disease plus 2 diseased coronary vessels (27 patients). In 81.7% (n = 40) of patients, intravascular ultrasound was used to guide placement of bare metal (n = 2) and sirolimus- (n = 3), everolimus- (n = 21), and/or zotarolimus (n = 23) eluting stents.

The mean days of in-hospital observation following PCI was 3.3 ± 2.2 (range, 2 to 7 days). Few patients (6%) experienced in-hospital complications. Major bleeding from the access site, coronary artery dissection and abrupt vessel closure, and coronary artery dissection/abrupt vessel closure/acute kidney failure/death was noted in 1 patient for each event.

Dr. Villegas noted that this was a retrospective case series with only in-hospital follow-up. In this series, stenting of unprotected LMCA was associated with a high procedural success and low in-hospital complication rate. He stressed that patient selection for both techniques is fundamental to success and directly affects clinical outcomes.

Results at 1 Year With CoreValve TAVR in Patients With Symptomatic Aortic Stenosis

Written by Phil Vinall

Transcatheter aortic valve replacement (TAVR) has become a treatment option for patients with severe aortic stenosis who either are not surgical candidates or are at high risk for surgical complications. The results from the US CoreValve pivotal trials support the safety and efficacy of the CoreValve prosthesis in these patient populations. In high- and extreme-risk patients with aortic stenosis, TAVR, using a self-expanding transcatheter aortic valve bioprosthesis, results in significantly higher rates of 1-year survival compared with surgical aortic valve replacement (SAVR). TAVR performed better than a prespecified objective performance goal (OPG) set prior to the study [Adams DH et al. *N Engl J Med* 2014; Popma JJ et al. *J Am Coll Cardiol* 2014]. One-year outcomes from the CoreValve ADVANCE study confirmed these findings [Linke A et al. *Eur Heart J* 2014].

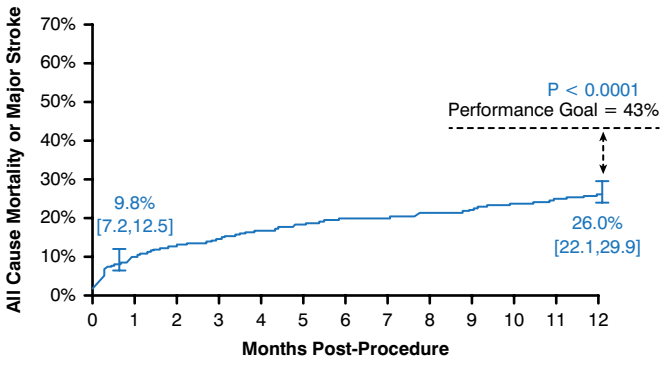
Juan Gaspar, MD, Director of Training and Medical Education of Medtronic Cardiovascular in Latin America, presented detailed data from the CoreValve trials. In the extreme-risk trial, 489 patients who were not candidates for SAVR underwent TAVR. This cohort was elderly (mean age, 83.2 ± 8.7 years) and had a high predicted surgical risk on the basis of the Society of Thoracic Surgeons risk score (mean predicted mortality, 10.3 ± 5.5%), and a high proportion had New York Heart Association (NYHA) functional class III or IV heart failure (91.8%). These patients also had high scores on tests for frailty and disability. At 1 year, the rate of all-cause mortality or major stroke was 9.8% at 1 month and 26 in patients treated with TAVR. The results at 1 year were superior to the prespecified OPG of 43% (p < .0001; Figure 1); thus, the trial was considered to have met its primary end point.

All-cause and cardiovascular mortality were 24.3% and 18.3%, respectively, at 1 year. There were low rates of major stroke at 1 month (2.3%) and 1 year (4.3%). Life-threatening or disabling bleeding was 17.6%, and major bleeding was 28.5% at 1 year. Echocardiographic findings showed mean gradients of 9.55 mm Hg at discharge and 8.86 mm Hg at 1 year, and a more than doubling in orifice size. Severe cases of paravalvular regurgitation (PVR) were infrequent (1.6% at discharge and 0% at 1 year). There was no association between mild or moderate paravalvular leak and late mortality (Figure 2).

The results from the US CoreValve study in extreme risk patients support the safety and efficacy of TAVR therapy in patients deemed not candidates for SAVR.

The second CoreValve US pivotal trial compared TAVR and SAVR in symptomatic patients with severe aortic

Figure 1. All-Cause Mortality or Major Stroke Following TAVR in Extreme-Risk Patients



TAVR=transcatheter aortic valve replacement.

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