However, patients who underwent CABG plus valve repair required greater rates of aortic cross clamp, cardiopulmonary bypass, and intensive care unit stay time versus those who underwent CABG only. In addition, postoperative low-output syndrome occurred more frequently in patients who received mitral valve repair. Other SAEs that occurred more frequently in patients who underwent CABG plus valve repair included neurologic events and supraventricular arrhythmia ($P = .03$ for both). At the end of the study, quality of life, NYHA functional class, and rate of death were similar between arms.

In conclusion, Dr Michler stated that data from this trial suggest no clinical advantage to performing a mitral valve repair in patients with moderate ischemic MR who are undergoing CABG. However, long-term follow-up is ongoing. In addition, Dr Michler commented that a limitation of this study was that the primary end point was not a clinical end point. However, the more appropriate end point of mortality would require a much larger study population and a longer follow-up time, he stated.

BASKET-PROVE II: BP-DES Noninferior to DP-DES

Written by Brian Hoyle

Christoph A. Kaiser, MD, University Hospital Basel, Basel, Switzerland, discussed the main results of the randomized BASKET Prospective Validation Examination II trial [BASKET-PROVE II; Kaiser C et al. *Circulation*. 2014], which compared the long-term outcome of biodegradable-polymer drug-eluting stents (BP-DEs) to both durable-polymer drug-eluting stents (DP-DESs) and bare metal stents (BMSs).

In BASKET-PROVE II, 2291 patients requiring ≥3.0-mm stents were randomized between April 2010 to May 2012 in a 1:1:1 fashion to either a biolimus-eluting BP-DES (Nobori; n = 765), an everolimus-eluting DP-DES (Xience-PRIME; n = 765), or a thin-strut coated cobalt-chromium BMS (Prokinetik; n = 761). Patients with shock, in-stent restenosis, stent thrombosis (ST), unprotected left main or saphenous vein graft, planned surgery within 12 months, increased bleeding risk due to oral anticoagulant, and history of stroke or transient ischemic attack and who required stents > 4 mm in diameter were excluded.

The noninferiority margin for the BP-DES versus DP-DES comparison was 3.8%, based on prior findings [Kaiser C et al. *N Engl J Med.* 2010]. The primary efficacy end point during the 2-year follow-up after stent implantation was the occurrence of major adverse cardiac events (defined as cardiovascular [CV] death, myocardial infarction [MI], or target vessel revascularization). A superiority analysis was planned between the BP-DES and BMS using a secondary safety end point of CV death, MI, or definite/probable ST.

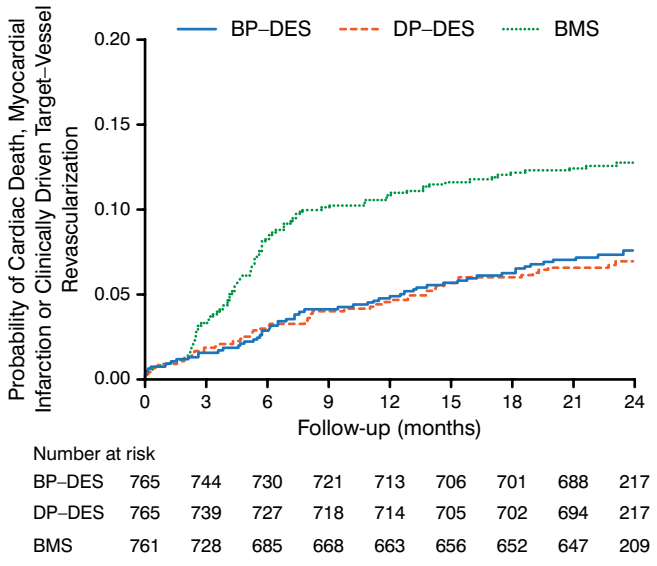
Baseline characteristics were comparable in the 3 trial arms. At 2-year follow-up, 98.5% of patients were alive and 97.7% of patients remained in follow-up. The primary end point was comparable in patients receiving BP-DES and those receiving DP-DES (2-year rate, 7.6% vs 6.8%; absolute risk difference, 0.75%; 95% CI, –1.93% to 3.50%; $P_{\text{Noninferiority}} = .04$; HR, 1.11; 95% CI, 0.77 to 1.62; $P = .58$; Figure 1).

The results were consistent in the per-protocol population although it did not meet the prespecified noninferiority margin (absolute risk difference, 1.41%; 95% CI, 1.33% to 4.15%; $P_{\text{Noninferiority}} = .09$). Both DES platforms had lower occurrence of target vessel revascularization as compared with BMS.

The secondary safety end point was similar for BP-DES as compared with BMS (3.7% vs 5.0%; HR, 0.72; 95% CI, 0.44 to 1.18; $P = .20$; left panel of Figure 2). A landmark analysis at 1 year revealed no difference in late safety between the 2 stents (right panel of Figure 2).

In summary, BP-DES were noninferior to DP-DES after 2 years in patients requiring large-vessel stents. Both were

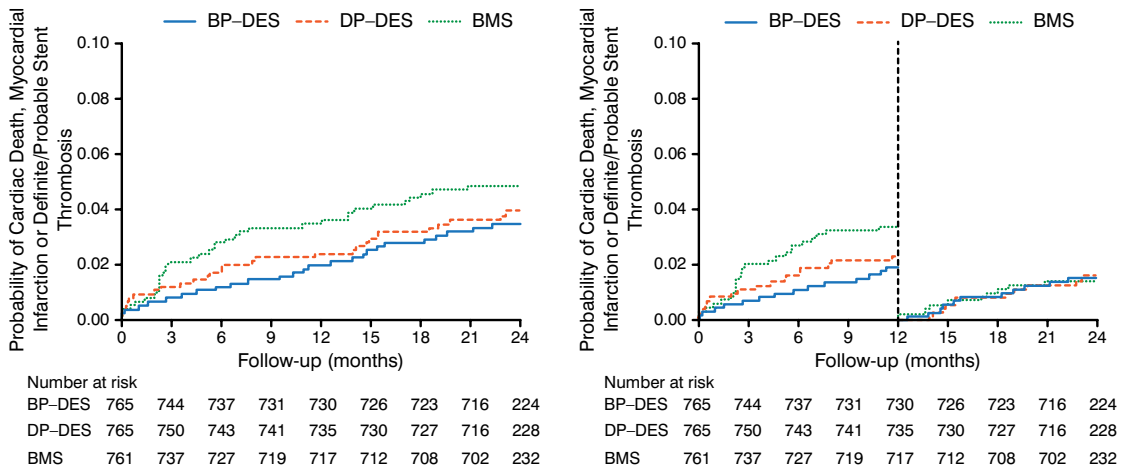
Figure 1. Primary End Point Between Drug-Eluting Stents



BMS, bare metal stent; BP-DES, biodegradable-polymer drug-eluting stent; DP-DES, durable-polymer drug-eluting stent.

Adapted from Kaiser C et al. Long-Term Efficacy and Safety of Biodegradable-Polymer Biolimus-Eluting Stents Main Results of the Basel Stent Kosten-Effektivitäts Trial-PROspective Validation Examination II (BASKET-PROVE II), A Randomized, Controlled Noninferiority 2-Year Outcome Trial. *Circulation*. E-pub ahead of print. DOI: 10.1161/CIRCULATIONAHA.114.013520. Accessed December 10, 2014. With permission from American Heart Association, Inc.

Figure 2. Key Safety Secondary End Point Between BP-DES and BMS



BMS, bare metal stent; BP-DES, biodegradable-polymer drug-eluting stent; DP-DES, durable-polymer drug-eluting stent.

Adapted from Kaiser C et al. Long-Term Efficacy and Safety of Biodegradable-Polymer Biolimus-Eluting Stents Main Results of the Basel Stent Kosten-Effektivitäts Trial- PROspective Validation Examination II (BASKET-PROVE II), A Randomized, Controlled Noninferiority 2-Year Outcome Trial. *Circulation*. E-pub ahead of print. DOI: 10.1161/CIRCULATIONAHA.114.013520. Accessed December 10, 2014. With permission from American Heart Association, Inc.

superior to BMS in efficacy. There was no evidence of superior safety of BP-DES beyond 1 year. The findings do not support the idea that polymers are key in the perceived association of DP-DES with very late ST, although the trial was not powered to definitively assess this.

SYNERGY Everolimus-Eluting Stent Noninferior to PROMUS Element Plus: Results From EVOLVE II Randomized Clinical Trial

Written by Brian Hoyle

Dean J. Kereiakes, MD, Christ Hospital Heart and Vascular Center, Cincinnati, Ohio, USA, reported on the primary outcomes of the prospective, randomized, single-blind, multicenter EVOLVE II Clinical Trial to Assess the SYNERGY Stent System for the Treatment of Atherosclerotic Lesion(s) [EVOLVE II; NCT01665053], which assessed the safety and effectiveness of 2 different everolimus-eluting stents, the second-generation SYNERGY stent and the PROMUS Element Plus durable-polymer drug-eluting stent (DP-DES).

The polymer in a DES acts as a drug reservoir and allows for the programmed release of the drug. Once drug release is complete, the polymer has no function and, if it becomes physically damaged, may be detrimental, leading to late/very late stent thrombosis (ST), chronic inflammation, late restenosis, or hypersensitivity. The SYNERGY stent features a platinum chromium platform coated with poly (lactic-co-glycolic acid). Everolimus is subsequently applied to the surface of the biodegradable coating.

Drug release occurs fairly constantly and in parallel with polymer degradation. The potential value of the design has been indicated in a porcine model and in the 30-day EVOLVE trial involving 291 patients [Meredith IT et al. *J Am Coll Cardiol.* 2012]. These data prompted the EVOLVE II trial, in which 1684 patients were randomized to treatment with the DP-DES (n = 842) or the SYNERGY stent (n = 842). Exclusion criteria were left main disease, chronic total occlusion, saphenous vein graft, in-stent restenosis, and recent STEMI.

Patients received acetylsalicylic acid plus clopidogrel, ticlopidine, prasugrel, or ticagrelor for at least 6 months. The primary end point in the intention-to-treat and per-protocol populations was target lesion failure at 12 months (defined as a composite of cardiac death, myocardial infarction [MI], or ischemia-driven revascularization). Secondary end points included the individual components of target lesion failure, definite or probable ST (Academic Research Consortium definition), technical and clinical success of stenting, and longitudinal deformation of the stent.

Baseline characteristics in the 2 groups were similar for a number of demographic and clinical features. Procedural and postprocedural characteristics and outcomes were also comparable between groups. Antiplatelet medication use was similar at 6 and 12 months.

At 1 year, complete follow-up was available in 806 (96.2%) patients in the DP-DES group and 831 (98.2%) patients in the SYNERGY group. The primary end point