3. Valgimigli M, Campo G, Penzo C, et al. Transradial coronary catheterization and intervention across the whole spectrum of Allen test results. J Am Coll Cardiol 2014;63:1833–41.

4. Valgimigli M, Gagnor A, Calabro P, et al. Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomised multicentre trial. Lancet 2015;385:2465–76.

REPLY: Digital Gangrene Following Transradial Coronary Angiogram

We would like to thank Dr. Santucci and colleagues for their interest in our case report (1) and for raising an important issue regarding the use of Allen's test before cardiac catheterization using the transradial approach (TRA). The importance of the TRA for patient comfort and same-day discharge post-coronary intervention cannot be overemphasized.

Increasingly, the TRA is the default approach, and Allen's test is performed variably to assess the patency of the ulnar artery before the TRA. Importantly, this practice varies among centers and is not commonly performed everywhere. One reason for this variability is that the sensitivity and specificity of Allen's test to assess artery patency are minuscule (2). A variety of noninvasive options, including plethysmography, pulse oximetry, and duplex ultrasonography, are available to supplement Allen's test. Still, there is no consensus on the best test for assessing collateral circulation of the hand, and the choice of test depends on the preference of cardiologist or the availability of equipment. Given the high false positive rate of Allen's test, many patients are wrongly excluded from the TRA for coronary angiography (3). Furthermore, hand ischemia is usually caused by either digital embolization of radial artery thrombus or in situ thrombosis of collateral vessels because of severe vasospasm, which usually occurs in the setting of normal radial, ulnar, and superficial palmar arteries.

There are many strategies for reducing radial artery occlusion, such as patent hemostasis (4), the use of a 5-F system for diagnostic angiography, proper administration of antispasm medications, and the use of at least 50 U/kg unfractionated heparin, all of which are backed by scientific evidence. We agree with Santucci et al. that the presence of a normal result on Allen's test may not reduce ischemic complications, as illustrated by our case presentation. We believe that the TRA should be the default in the majority of patients, especially post-thrombolysis; nonetheless, occasional devastating complications occur, and we as interventional cardiologists need to be cognizant of their existence.

Kuljit Singh, MBBS, PhD
Aun-Yeong Chong, MBBS, BSc (Med), MD
***Derek Y. So, MD**
*University of Ottawa Heart Institute
40 Ruskin Street
Ottawa ON K1Y 4W7
Canada
E-mail: dso@ottawaheart.ca

http://dx.doi.org/10.1016/j.jcin.2016.02.043

Please note: The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Singh K, Abunassar J, So DY. Digital gangrene following transradial coronary angiogram. J Am Coll Cardiol Intv 2016;9:e21–2.

2. Jarvis MA, Jarvis CL, Jones PR, Spyt TJ. Reliability of Allen's test in selection of patients for radial artery harvest. Annals Thorac Surg 2000;70:1362–5.

3. Starnes SL, Wolk SW, Lampman RM, et al. Noninvasive evaluation of hand circulation before radial artery harvest for coronary artery bypass grafting. J Thorac Cardiovasc Surg 1999;117:261–6.

4. Pancholy S, Coppola J, Patel T, Roke-Thomas M. Prevention of Radial Artery Occlusion–Patent Hemostasis Evaluation Trial (PROPHET study): a randomized comparison of traditional versus patency documented hemostasis after transradial catheterization. Cathet Cardiovasc Interv 2008;72:335–40.

Biodegradable-Polymer Sirolimus-Eluting Stents Versus Durable-Polymer Everolimus-Eluting Stents in Patients With Acute ST-Segment Elevation Myocardial Infarction

Insights From the 2-Year Follow-Up of the BIOSCIENCE Trial

Among patients with acute ST-segment elevation myocardial infarction (STEMI), early-generation drug-eluting stents (DES) have been associated with a reduction in target-vessel revascularization compared with bare-metal stents after primary percutaneous coronary intervention. However, this early benefit was offset by an increased risk for very late stent thrombosis (1–3). The development of new-generation DES resulted in improved vascular healing and clinical outcomes. To date, there is a lack

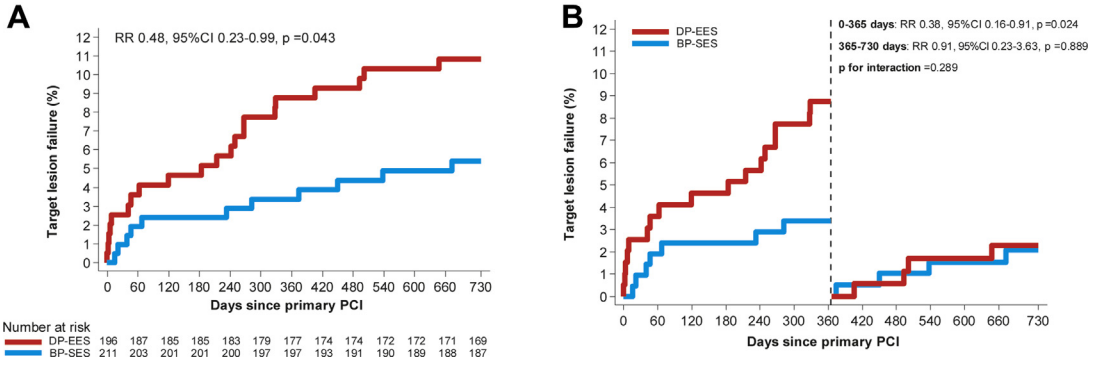
of evidence for the long-term efficacy and safety of newer generation biodegradable-polymer (BP) compared with durable-polymer (DP) DES in the setting of STEMI.

Herein, we report the 2-year outcomes of the STEMI cohort enrolled in the BIOSCIENCE (Biodegradable Polymer Sirolimus-Eluting Stent Versus Durable Polymer Everolimus-Eluting Stent for Percutaneous Coronary Revascularization) trial comparing thin-strut, BP sirolimus-eluting stents (SES; Orsiro, Biotronik AG, Bülach, Switzerland) with DP everolimus-eluting stents (EES; Xience Prime/Xpedition, Abbott Vascular, Abbott Park, Illinois) in an all-comers patient population. Randomization was stratified according to the presence or absence of STEMI. The primary endpoint, target lesion failure (TLF), was a composite of cardiac death, target-vessel myocardial infarction, or clinically indicated target lesion revascularization (4).

A total of 407 participants with STEMI have been enrolled into the BIOSCIENCE trial, of whom 211 patients with 289 lesions were allocated to treatment with BP SES and 196 patients with 267 lesions to treatment with DP EES. There were no significant differences in terms of baseline characteristics or angiographic features between the 2 treatment arms (5). Clinical follow-up at 2 years was available in 393 patients (96.6%). The risk for TLF was significantly reduced in patients treated with BP SES compared with those treated with DP SES (5.4% vs. 10.8%; risk ratio [RR]: 0.48; 95% confidence interval [CI]: 0.23 to 0.99; p = 0.043), with a positive qualitative interaction compared with patients without STEMI (RR: 1.15; 95% CI: 0.86 to 1.53; p = 0.86; p for interaction = 0.026) (Figure 1A). The decrease in the risk for TLF was greater during the first year (RR: 0.38; 95% CI: 0.16 to 0.91; p = 0.024) than subsequently (RR: 0.91; 95% CI: 0.23 to 3.63; p = 0.89; p for interaction = 0.29) (Figure 1B). Of note, the benefit in terms of TLF was driven mainly by numerically lower rates of cardiac death or myocardial infarction in patients randomized to BP SES compared with DP EES (RR: 0.46; 95% CI: 0.21 to 1.02; p = 0.05). Among cardiac death or myocardial infarction events, 5 of 9 (55%) in the BP SES group and 9 of 18 (50%) in the DP EES group were due to definite or probable stent thrombosis. With respect to efficacy endpoints, there was no significant difference in the risk for target lesion (3.0% vs. 4.3%; RR: 0.69; 95% CI: 0.24 to 1.99; p = 0.49) or target-vessel (5.0% vs. 6.5%; RR: 0.77; 95% CI: 0.33 to 1.78; p = 0.54) revascularization throughout 2 years of follow-up. Although the use of BP SES was associated with numerically lower rates of definite or probable stent thrombosis at 2 years (2.5% vs. 5.2%; p = 0.14), very late (>1-year) stent thrombosis occurred only in 2 patients and 1 patient randomized to BP SES and DP EES, respectively (p = 0.62).

Although randomized evidence consistently indicates improved performance of DP EES over bare-metal stents and early-generation DES, the present analysis is the first assessment among 2 newer generation DES in patients with STEMI with extended follow-up. The study lends further support to the maintained efficacy and safety of BP SES in patients undergoing primary percutaneous

FIGURE 1 Kaplan-Meier Curves for the Primary Endpoint: Target Lesion Failure



Kaplan-Meier curves are shown at 2 years **(A)** and for the landmark analysis at 1 year **(B)**. BP-SES = biodegradable-polymer sirolimus-eluting stent; CI = confidence interval; DP-EES = durable-polymer everolimus-eluting stent(s); PCI = percutaneous coronary intervention; RR = risk ratio.

coronary intervention for STEMI at the time when polymer degradation is almost completed (6). Although randomization in the trial was stratified by STEMI, our comparisons were underpowered for many of the clinical outcomes, as reflected by the wide CI for TLF. As to whether the lower strut thickness, which has the potential for less thrombogenicity and thrombus mobilization, and the passive coating with silicon carbide, which eliminates the interaction between stent surface and the surrounding prothrombotic milieu, may be relevant in reducing the risk for failures in treated lesions, these are speculative mechanisms of DP-SES that require further assessment. On the basis of the hypothesis-generating findings of this study, we have planned the BIOSTEMI (A Comparison of an Ultrathin Strut Biodegradable Polymer Sirolimus-Eluting Stent With a Durable Polymer Everolimus-Eluting Stent for Patients With Acute ST-Segment Elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention) trial (NCT02579031), which will test the superiority of BP SES to DP EES among 1,250 patients with STEMI undergoing primary percutaneous coronary intervention.

Raffaele Piccolo, MD
Dik Heg, PhD
Anna Franzone, MD
Marco Roffi, MD
David Tüller, MD
André Vuilliomenet, MD
Olivier Muller, MD
Stéphane Cook, MD
Daniel Weilenmann, MD
Christoph Kaiser, MD
Peiman Jamshidi, MD
Juan F. Iglesias, MD
***Stephan Windecker, MD**
Thomas Pilgrim, MD

*Bern University Hospital
Department of Cardiology
Bern 3010
Switzerland
E-mail: stephan.windecker@insel.ch

http://dx.doi.org/10.1016/j.jcin.2016.02.044

Please note: Dr. Windecker has received research grants to the institution from Biotronik and St. Jude Medical and speaking fees from AstraZeneca, Eli Lilly, Abbott Vascular, Medtronic, and Biotronik. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Kalesan B, Pilgrim T, Heinimann K, et al. Comparison of drug-eluting stents with bare metal stents in patients with ST-segment elevation myocardial infarction. Eur Heart J 2012;33:977–87.

2. Piscione F, Piccolo R, Cassese S, Galasso G, Chiariello M. Clinical impact of sirolimus-eluting stent in ST-segment elevation myocardial infarction: a meta-analysis of randomized clinical trials. Catheter Cardiovasc Interv 2009; 74:323–32.

3. Piccolo R, Cassese S, Galasso G, et al. Long-term clinical outcomes following sirolimus-eluting stent implantation in patients with acute myocardial infarction. A meta-analysis of randomized trials. Clin Res Cardiol 2012;101:885–93.

4. Pilgrim T, Heg D, Roffi M, et al. Ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for percutaneous coronary revascularisation (BIOSCIENCE): a randomised, single-blind, non-inferiority trial. Lancet 2014;384:2111–22.

5. Pilgrim T, Piccolo R, Heg D, et al. Biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents for primary percutaneous coronary revascularisation of acute myocardial infarction. EuroIntervention 2015 Dec 23 [E-pub ahead of print].

Three Cases of Early Lotus Valve Thrombosis

Transcatheter aortic valve replacement (TAVR) is a well-established therapeutic option for the treatment of inoperable/high-risk patients with symptomatic severe aortic stenosis. Before this therapy extends to younger and/or lower-risk populations, appropriate valve performance and durability should be verified.

One of the potential causes of valve dysfunction is valve thrombosis, an entity thought to be rare. Diagnostic criteria for valve thrombosis included a transthoracic echocardiography mean gradient increase from post-procedural value ≥20 mm Hg and mean gradient ≥40 mm Hg with reduced leaflet mobility and/or perileaflet hypodense mass consistent with thrombus by 3D transesophageal echocardiogram or multidetector computed tomography (1).

The incidence with newer second-generation valves is essentially unknown. Recent studies suggest that TAVR thrombosis incidence may be higher than previously reported (2).

The Lotus valve (Boston Scientific, Natick, Massachusetts) is a second-generation transcatheter aortic valve. Lotus is a bovine trileaflet pericardial tissue valve incorporated in a nitinol autoexpandible stent. Device features include a precise release, the potential for repositioning and full recovery after implantation, and the presence of a urethane membrane sealing system to minimize the risk of paravalvular leak. To our knowledge only 1 case of Lotus valve thrombosis has been published. In this case valve thrombosis occurred only a few days after implantation (3).

We present 3 cases of well-documented valve thrombosis in our small series of 10 patients undergoing Lotus valve implantation. A summary of