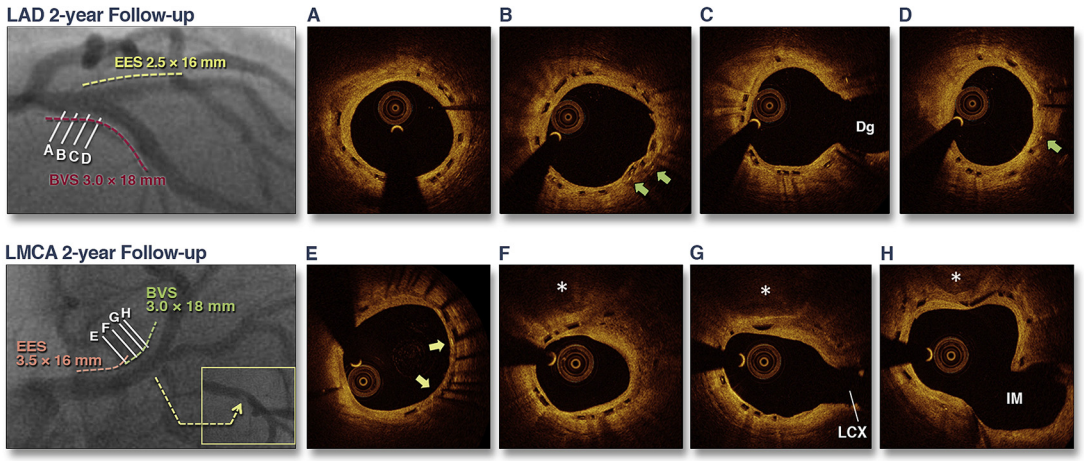
JACC: CARDIOVASCULAR IMAGING, VOL. 8, NO. 5, 2015
MAY 2015:616–22

FIGURE 1 Angiographic and OCT Images of LAD-Dg and LMCA Bifurcations



Follow-up angiograms show excellent results in the LAD-Dg bifurcation lesion treated with a bioresorbable vascular scaffold (BVS) **(red dotted line)** in the LAD and an everolimus-eluting stent (EES) **(yellow dotted line)** in the diagonal ostium with the mini-crush technique. **(A)** Optical coherence tomography (OCT) image at 2-year follow-up shows good expansion of the BVS with homogeneous neointima. Proximal **(A and B)** and distal **(D)** to the bifurcation, BVS struts seen on top of crushed EES struts **(B and D)** have been completely covered with neointima **(yellow arrows)**. **(C)** BVS struts previously jailing the Dg have completely disappeared. In the LMCA trifurcation lesion, a follow-up angiogram shows restenosis in the distal LMCA **(yellow arrow, yellow box)**. The **yellow box** shows a left anterior oblique cranial view of the distal LMCA. **(E)** At 2-year follow-up, EES struts on top of BVS struts are covered with thin neointima **(yellow arrows)**. **(F)** OCT image reveals homogeneous pattern of neointimal hyperplasia and late recoil of BVS (minimal scaffold area [MSA] 6.29 mm^2). According to the IVUS findings, MSA was 6.11 mm^2 (follow-up) versus 7.72 mm^2 (after index procedure). **(G and H)** BVS struts previously jailing the left circumflex artery (LCX) and intermediate (IM) branches have completely disappeared. OCT reveals the deformation of BVS struts superimposed on the calcified plaque **(F to H, *)**.

Follow-up OCT images clearly revealed the mechanism of in-scaffold restenosis (combination of neointimal hyperplasia and late scaffold recoil) and provided further insight in the treatment of bifurcation lesions with the single crossover technique. Disappearance of BVS struts jailing the side branch ostia may reduce very late restenosis in this location and facilitate very late side branch access should new disease develop in the jailed vessel. This case also demonstrates the importance of meticulous lesion preparation with rotational atherectomy or scoring balloon in case of BVS implantation for calcified lesions.

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http://dx.doi.org/10.1016/j.jcmg.2014.07.025

Please note: Dr. Latib has served on advisory boards for Medtronic and has received a research grant from Angioscore. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Accurate Conductance-Based Post-Dilation Balloon Catheter Sizing

Balloon underexpansion during percutaneous coronary intervention is a major reason for stent underdeployment, which occurs in part because the predicted relationship between balloon pressure and diameter is not always realized in vivo (1). We herein describe a new device that accurately measures balloon cross-sectional area (CSA) during inflation.

The CB catheter provides an accurate, real-time digital display of the balloon CSA based on continuous electrical conductance recordings made inside the balloon. Within each balloon, there are 4 radiopaque platinum-iridium electrodes mounted on the catheter body. The 2 outer electrodes inject a small and alternating electrical current (136 μA_{pp},

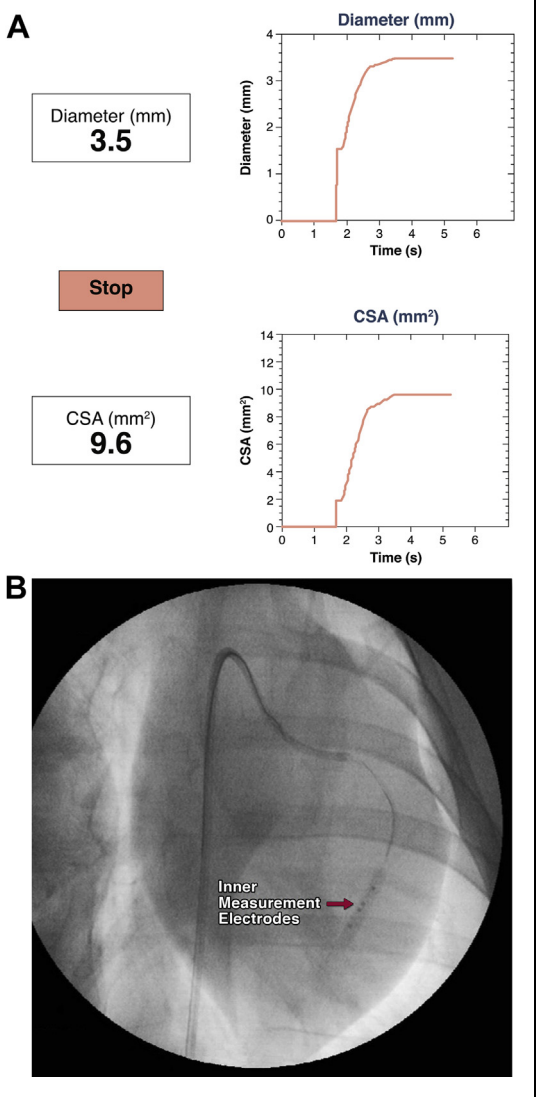
10 kHz) during inflation/deflation, and the 2 inner electrodes make continuous voltage measurements related to the local balloon size across an approximate 3-mm cross-section at the center of the balloon (i.e., a focal measurement is made at the balloon center and is not averaged across the entire balloon). When the CB catheter is connected to a computer console, the local balloon CSA is calculated and displayed in real time (Figure 1A) based on Ohm's law ($CSA = I \times L/[\sigma \times V]$), which states that the 3-mm focal central balloon CSA across the inner electrodes is equal to the known constant current (I) times the known length between the electrodes (L) divided by the known constant of the fluid conductivity (σ) and the continuously measured voltage (V).

Validation of the CB catheter was first completed on the bench using randomized, repeat measurements made in uniform plastic cylindrical phantoms of known dimensions. The average CSA difference between the CB catheter measurements and the true phantom dimension was -0.1 ± 0.2 mm^2 with an error of 2.6%. The average CSA difference on the bench between the repeat CB catheter measurements was 0.0 ± 0.1 mm^2 with an error of 1.6%.

Validation in vivo was completed in 5 domestic swine (approximately 70 kg each). The CB catheter studies were performed in 7 coronary vessels having previous mild fibrotic coronary injuries (CSA stenosis approximately 25%) and in 3 normal coronary vessels. Manual measurement of the vessel area by intravascular ultrasound (IVUS) (Eagle Eye coronary catheter, Volcano Corporation, San Diego, California) was used to determine the vessel size before stent deployment (8.2 ± 3.8 mm^2). Bare-metal (Veriflex, Boston Scientific, Natick, Massachusetts) or drug-eluting stents (Xience, Abbott Vascular, Abbott Park, Illinois) were deployed at the manufacturer-specified pressure (4.0 to 16.0 atm; 9.1 atm average) and diameter (2.8 to 4.5 mm; 3.4 mm average), with an IVUS-measured CSA of 7.8 ± 2.9 mm^2 versus an expected stent CSA of 9.4 ± 4.1 mm^2. A high-pressure CB catheter (polyethylene terephthalate/nylon; fully inflated $>$ 1 atm) larger than the deployed stent diameter determined by IVUS was selected and placed within the stent at the same location as the IVUS, and at least 4 repeat inflations/measurements (Figure 1B) were completed (no difference between the first and last CB measurements). As expected for these noncompliant balloons, the in vivo stent/vessel recoil (0.32 mm) was almost identical to what is described in published reports (0.28 mm) (1). The CB catheter had an average CSA of 10.9 ± 3.4 mm^2 versus a predicted stent CSA of 9.4 ± 4.1 mm^2 and a post-deployment IVUS CSA of 10.6 ± 3.4 mm^2 when recoil was accounted for (1). The in vivo CSA measurement accuracy bias (difference) versus post-procedural IVUS when recoil was accounted for was 0.3 ± 0.9 mm^2 with an error of 8.5%. There were no observed arrhythmias or deaths during any of the CB measurement procedures.

The overall excellent CB catheter accuracy and repeatability can be attributed to the fundamental

FIGURE 1 CB Measurement Display and Balloon Usage In Vivo



(A) Numerical and running graphical display (x-axis is time) of the size measurement for a 3.5-mm CB catheter on the console and the corresponding **(B)** cine image in vivo in a swine left circumflex artery. CSA = cross-sectional area.

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electrophysical law governing the catheter design and the insulative nature of the balloon that gives accurate results regardless of the electrical properties of the surrounding environment. The CB catheter offers accurate, real-time sizing capabilities completely independent of subjective user input and allows the user to adjust the inflation instantaneously. The CB sizing electrodes easily integrate into existing standard coronary balloons and hence do not significantly alter clinical procedures. The CB catheter functionality is flexible and could easily be integrated into other devices, such as stent delivery balloons, drug-eluting balloons, and valvuloplasty balloons. Future work will include a first-in-man validation and the use of multiple sets of measurement electrodes inside the balloon to provide a balloon profile showing variation in the CSA dimension along the balloon length.

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http://dx.doi.org/10.1016/j.jcmg.2014.07.021

Please note: This study was supported by National Institutes of Health grant R43-HL120517. Drs. Svendsen and Berwick are employed by 3DT Holdings, LLC. Dr. Sinha has a speaking relationship with Boston Scientific; and has received a research grant from Edward Life Sciences. Dr. Bhatt has received research grants from Amarin Corporation, AstraZeneca, Bristol-Myers Squibb, Eisai, Ethicon, Medtronic, Roche, Sanofi-Aventis, and The Medicines Company; and has participated in unfunded research for FlowCo, PLx Pharma, and Takeda. Dr. Kassab is the founder of 3DT Holdings, LLC. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Physical Examination Is Still Necessary and Important

Handheld ultrasound (HHU) is very useful in clinical diagnosis of suspected cardiac condition, but there are limitations. How can one diagnose Heberden's angina by HHU? It is necessary to take an adequate history for diagnosis of angina.

Heart failure is a common and potentially lethal condition. Admittedly, HHU can distinguish between heart failure with reduced ejection fraction and heart failure with preserved ejection fraction. However, the prognosis of these patients is related to the severity of heart failure. New York Heart Association (NYHA) functional classification is an accepted method to assess the severity of heart failure. I do not believe that HHU can diagnose NYHA functional class.

I believe that bedside clinical examination is less expensive than transthoracic echocardiography (TTE) or even the HHU device. It can be repeated as frequently as necessary, and it is less expensive than repeated TTE or HHU examination.

I can provide many more examples of limitations and usefulness of both physical examination and imaging studies.

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http://dx.doi.org/10.1016/j.jcmg.2014.10.018

Please note: Dr. Chatterjee passed away between final acceptance and publication of this letter.

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REPLY: Physical Examination Is Still Necessary and Important

We agree with Dr. Chatterjee that history is key to making a diagnosis. In our paper (1), we did not suggest a substitution of history by handheld ultrasound (HHU), but the substitution of the stethoscope. In regard to heart failure, again it is a clinical diagnosis, as Dr. Chatterjee rightly states, but HHU can differentiate patients with reduced left ventricular (LV) systolic function from those with "normal" LV function. It can