CRF

tct2014 daily

TRANSCATHETER CARDIOVASCULAR THERAPEUTICS DAILY

Washington, D.C.

Monday, September 15, 2014

INSIDE THIS ISSUE

ABSORB II: Similar Clinical Outcomes, Less Angina with Bioresorbable Scaffold vs. EES

LATE-BREAKING TRIAL


Patrick W. Serruys, MD, PhD

In the first randomized trial pitting an everolimus-eluting bioresorbable scaffold against a metallic stent that releases the same drug, researchers found similar safety and efficacy at 1 year in patients with up to two de novo lesions. Results of the ABSORB II trial, presented in a late-breaking trial session at TCT 2014 and simultaneously published in the *Lancet*, suggest that operators may have not been aggressive enough in dilating the newer device and that practice corrections going forward may improve outcomes.

Patrick W. Serruys, MD, PhD, of Erasmus Medical Center, Rotterdam, the Netherlands, and colleagues randomized 501 patients with evidence of myocardial ischemia and no more than two de novo lesions

*(**ABSORB II,** continued on page 33)*

FFR Guidance in Bifurcations: No Impact on MACE

LATE-BREAKING TRIAL

Guidance of provisional side branch stenting of true coronary bifurcation lesions with fractional flow reserve (FFR) instead of angiography results in a similar 1-year MACE rate with less attempted stenting, according to late-breaking clinical trial results presented at TCT 2014.

Shao-Liang Chen, MD, of Nanjing Medical Center, Jiangsu, China, reported findings from the DKCRUSH-VI trial, which was conducted at 8 centers and included patients with medina 1,1,1 or 0,1,1 bifurcation lesions with a side branch diameter ≥2.5 mm who were randomly assigned to angiographic (n=160) or FFR (n=160) guidance. Baseline clinical and angiographic characteristics

*(**FFR Guidance,** continued on page 33)*

RIBS IV: EES Superior to DEB in Patients with In-Stent Restenosis

LATE-BREAKING TRIAL


Fernando Alfonso, MD, PhD

Everolimus-eluting stents (EES) provide superior late angiographic and clinical results compared with drug-eluting balloons (DEBs) in patients with coronary in-stent restenosis of drug-eluting stents (DES).

Fernando Alfonso, MD, PhD, from Hospital Universitario de la Princesa, Madrid, Spain, presented findings from the RIBS IV trial at TCT 2014. In all, 309 patients with DES in-stent restenosis were randomly assigned

*(**RIBS,** continued on page 33)*

Today's Highlights

Plenary Session:
TCT 2014 Thomas J. Linnemeier Spirit of Interventional Cardiology Young Investigator Award
Main Arena, Level 3, Ballroom;
10:55 a.m. to 11:10 a.m.

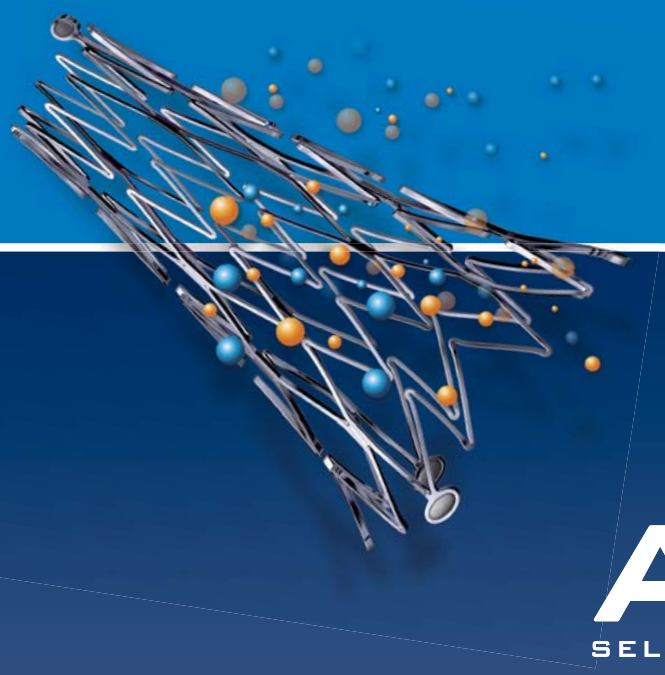
Plenary Session:
Late-Breaking Clinical Trials 3
Main Arena, Level 3, Ballroom;
11:10 a.m. to 12:06 p.m.

Plenary Session:
TCT 2014 Innovation Award
Main Arena, Level 3, Ballroom;
12:36 p.m. to 12:46 p.m.

Special Session:
The Impact of Healthcare Reform on the Future of Cardiovascular Medicine
Level 2, Room 204A/B/C;
12:15 p.m. to 1:45 p.m.

FDA Town Hall Meeting, Day I:
The FDA Year in Review; Clinical Research in the United States; The Revitalization of Early Human Studies in the United States; Regulation and Reimbursement
Level 2, Room 206;
2 p.m. to 6 p.m.

BIOSENSORS
INTERNATIONAL™



AXXESS™
SELF-EXPANDING BIFURCATION DES

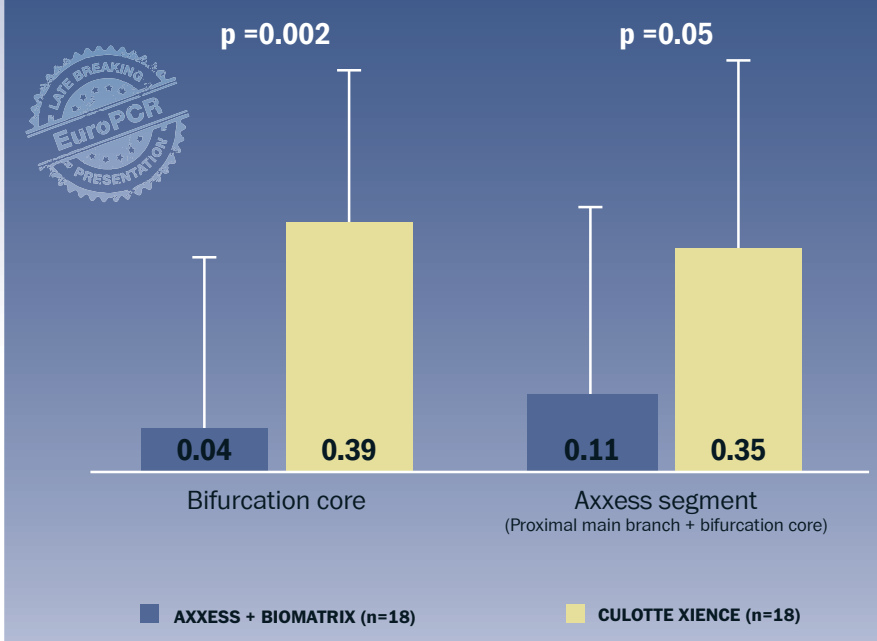
Late loss in bifurcations:
Axxess™ beats Xience™

COBRA
PHYSICIAN INITIATED RANDOMIZED TRIAL

Significant lower late loss for Axxess vs. Xience in bifurcations

In-stent late lumen loss (mm) QCA at 9 months

Compared with culotte, Axxess stenting resulted in significantly lower late lumen loss in both the bifurcation core and the Axxess segment.



Raising the Standard

For display purposes only.
Not approved for use in the United States

Dubois C., University Hospital Leuven (Belgium), "Complex Coronary Bifurcation Lesions: Randomized Comparison of a Strategy using a Dedicated Self-Expanding Biolimus A9-eluting Stent vs. a Culotte Strategy using Everolimus-eluting Stents: Primary Results of the Multicenter COBRA trial", oral presentation,EuroPCR 2014.

www.biosensors.com

11380-00-EN - Rev.01

OCT STEMI: Imaging-Guided PCI Shows Promise

Using optical coherence tomography (OCT) to guide PCI yields comparable MACE rates and fewer uncovered struts than primary PCI alone in patients with STEMI, according to data presented at TCT 2014.

Pavel Červinka, MD, PhD, of Faculty Hospital Hradec Králové in the Czech Republic, and colleagues pretreated 201 patients with aspirin, heparin and clopidogrel. Following angiography, the researchers randomly assigned 96 patients to primary PCI alone and 105 patients to primary PCI guided by OCT. Patients were treated with Promus (Boston Scientific) or Biomatrix (Biosensors) stents. Both groups had similar baseline demographic and procedural characteristics.

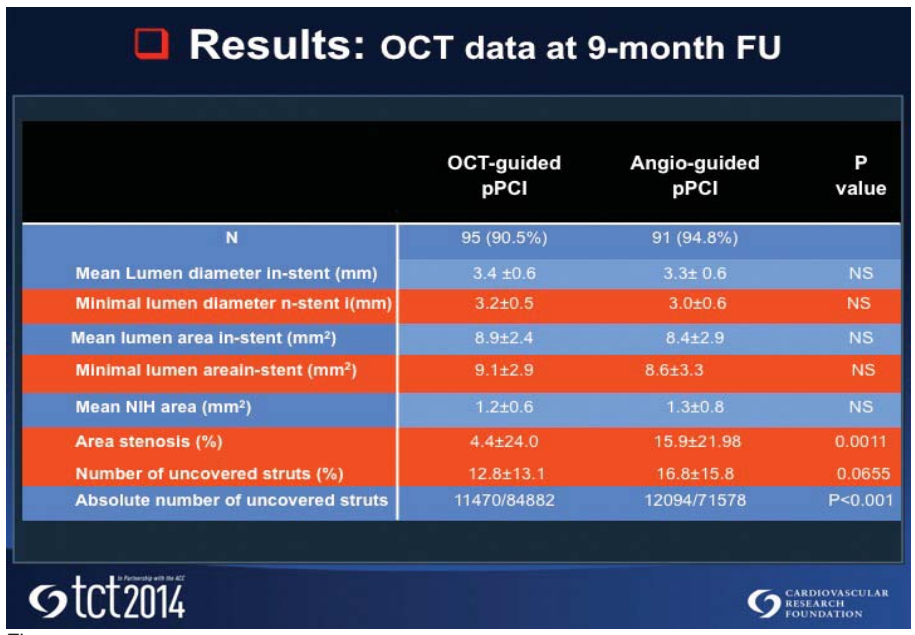

Pavel Červinka, MD, PhD

At 9 months, there were no differences between the two groups in the rate of MACE (composite of death, MI and ischemia-driven target vessel revascularization), nor for the individual components of this outcome, or for stent thrombosis.

"There were two stent thromboses that we considered early and definite," Červinka said. "There were no differences overall at 9-month follow-up, but the cohort of patients was small."

Binary in-stent restenosis was 2% in the OCT group and 3% in the PCI-only group (*P*=NS). Other angiographic results indicated no difference between the two groups in terms of late lumen loss in-stent and in-segment, minimal in-stent and in-segment diameter and minimal lumen area and diameter.

"There were no statistically significant differences between the groups," Červinka said of the majority of the 9-month angiographic outcomes. "However, there was some trend in favor of OCT-guided primary PCI regarding both late lumen loss in-stent and in-segment."



Figure

He added that there was a smaller area of stenosis and trend toward fewer uncovered struts in the OCT-guided group at 9 months (see Table).

"When we looked at the absolute number of uncovered struts, the difference reached statistical significance," Červinka said.

Baseline demographic and procedural characteristics were well balanced in both groups. More stents were used in the OCT group, which he suggested was likely based on the intraprocedural OCT findings. OCT was also associated with longer fluoroscopy times, and more than one-third of those in the OCT-guided group had a suboptimal result, Červinka said.

OCT STEMI is the first prospective, randomized, multicenter study to examine the utility of routine OCT guidance in primary PCI. This study was part of the ROBUST trial.

Disclosures:

- Červinka reports no relevant financial disclosures.

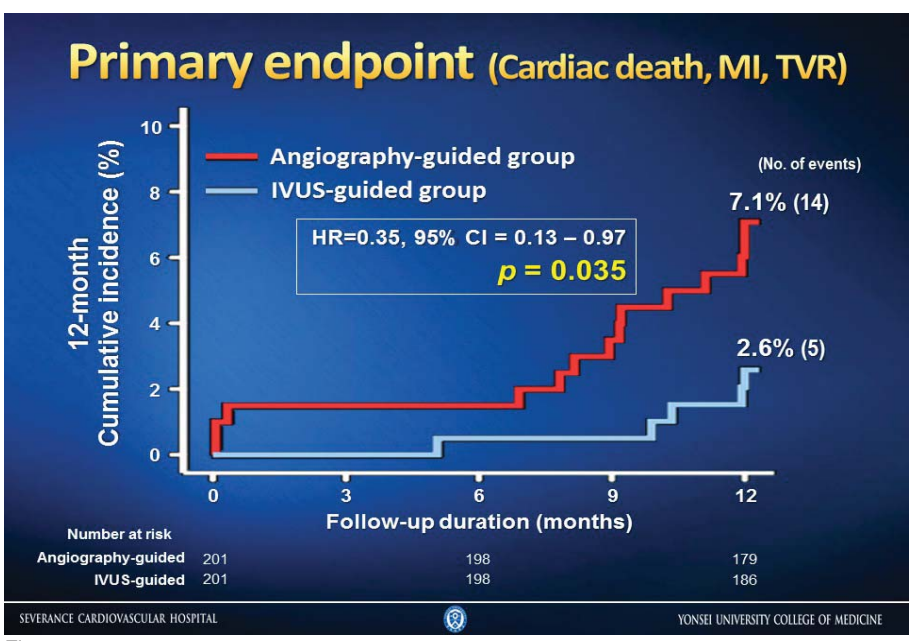
CTO-IVUS Trial Supports IVUS Guidance for CTO PCI


Yangsoo Jang, MD, PhD

In the first randomized trial of its kind in the era of new-generation drug-eluting stents (DES), stenting under IVUS guidance provided clinical benefit at 12 months compared with conventional angiographic guidance in patients with chronic total occlusions (CTOs).

After successful guidewire crossing, **Yangsoo Jang, MD, PhD,** of Yonsei University College of Medicine in Seoul, South Korea, and colleagues randomly assigned 402 patients with CTOs at 20 Korean centers to IVUS guidance (n=201) or angiographic guidance (n=201). In addition, IVUS-guided patients were randomized to implantation with Resolute zotarolimus-eluting stents (Medtronic) or Nobori biolimus-eluting stents (Terumo Medical).

At 12-month follow-up, the cumulative incidence of combined cardiac death, MI and target vessel revascularization (TVR; primary endpoint) was almost three-fold lower in the IVUS-guided group than the angiography-guided group (see Figure).



Figure

The rate of cardiac death or MI also was lower with IVUS (0% vs. 2%; *P*=.045), while TVR rates were equivalent between the groups (2.6% vs. 5.2%; *P*=.186).

Similarly, in a per-protocol analysis taking into account five patients (2.5%) who crossed over from IVUS to angiographic guidance and 35 (17.4%) who switched from angiographic to IVUS guidance, the primary endpoint was almost four-fold lower in the IVUS arm compared with the angiography arm (2.2% vs. 8.4%; *P*=.005). Again, both cardiac death or MI and TVR were reduced (0% vs. 2.3%; *P*=.019 and 2.2% vs. 6.1%; *P*=.049, respectively). The main reason for the crossover from IVUS was the failure of IVUS catheter passage.

IVUS was also favored for the primary endpoint in multiple clinical and angiographic subgroups.

Lesion characteristics and post-dilatation differ

CTOs were defined as lesions with TIMI flow grade 0 and an estimated occlusion duration of at least 3 months. The reference vessel diameter ranged from 2.5 mm to 4 mm by operator assessment, and the total CTO length was no longer than 80 mm (average about 26.5 mm) with implantation of no more than four stents.

Baseline patient and CTO lesion characteristics were similar between the groups. Procedural success was nearly complete in both arms, with no differences in the total number of stents used, mean stent diameter or total stented length. However, the IVUS-guided group were more likely to receive high-pressure dilatation after stenting (51.2% vs. 41.3%; *P*=.045), with a higher maximum balloon pressure (14.6 ± 3.7 atm vs. 13.8 ± 3.8 atm; *P*=.04). Stenting resulted in a larger minimum luminal diameter in the IVUS group compared with the angiography group (2.64 ± 0.35 mm vs. 2.56 ± 0.41 mm; *P*=.025).

Despite limitations, a "great first step"

Jang acknowledged that the 12-month duration of follow-up is too short. In addition, he observed, although IVUS is also helpful in guidewire crossing, it was not used for that purpose in the trial because it is highly dependent on operator skill.

At a press conference, **David G. Rizik, MD,** of Scottsdale Healthcare Heart Group in Scottsdale, Ariz., commented: "One of the Achilles' heels of CTO is the tendency to undersize the stent. This is a great first step in rolling IVUS into the routine algorithm for CTOs, and [these] results are very compelling."

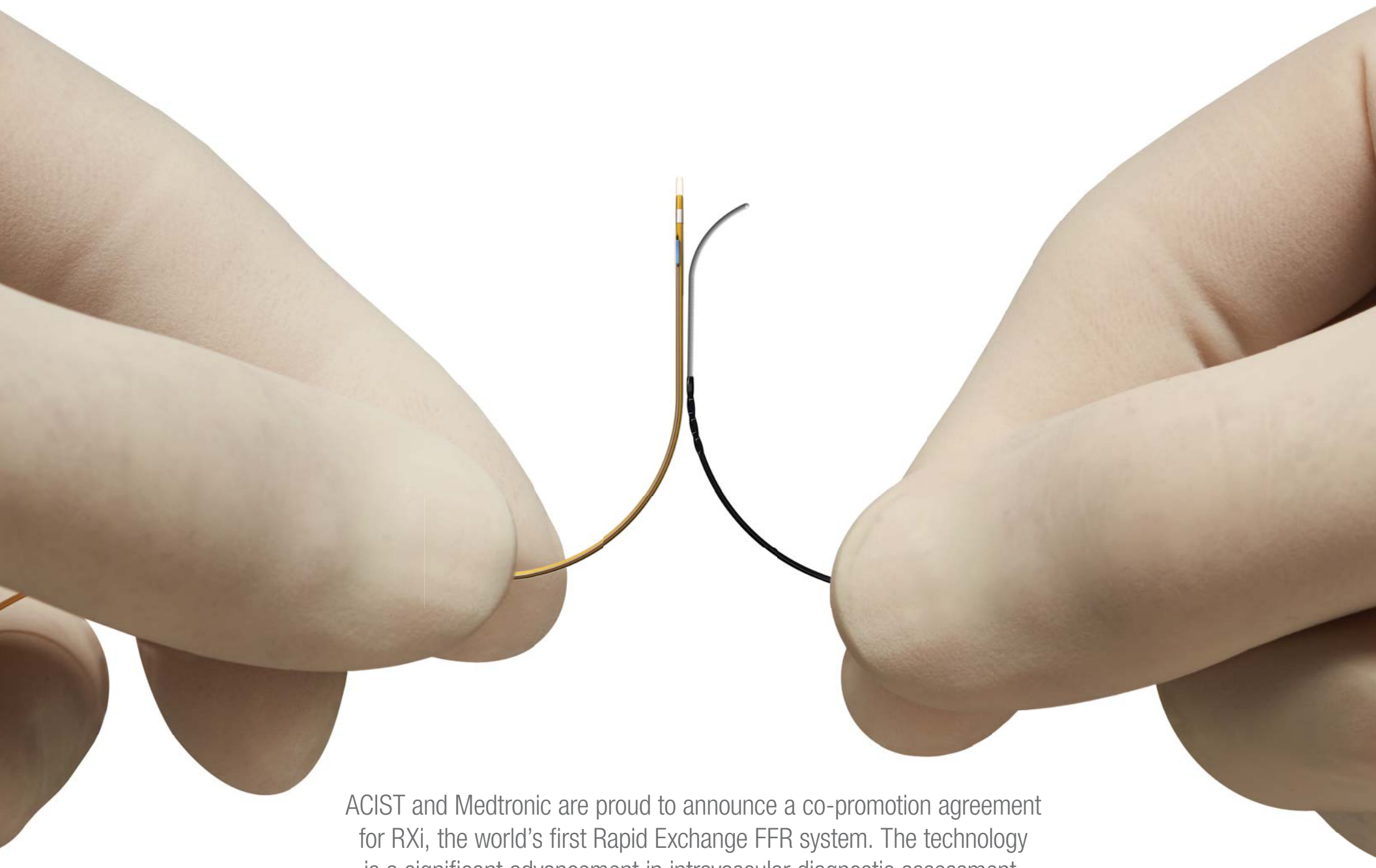
Disclosures:

- Jang and Rizik report no relevant conflicts of interest.

ACIST® the power to

Medtronic

Delivering more solutions.



ACIST and Medtronic are proud to announce a co-promotion agreement for RXi, the world's first Rapid Exchange FFR system. The technology is a significant advancement in intravascular diagnostic assessment, benefitting both clinicians and patients.

Rapid FFR:

- Use your guidewire of choice
- Simple plug-and-play system
- Maintain wire position
- Fiber-optic accuracy

ACIST Booth 1452

Medtronic Booth 1442

To find out more about the RXi collaboration, **visit our booths**

For more information from ACIST Medical Systems, Inc., visit our website: **www.acist.com**

UC201502165EN

Bracco Group

Registry Data Show Promise of Valve-in-Valve TAVR in High-Risk Patients

Transcatheter aortic valve replacement (TAVR) appears to be a viable therapeutic alternative to repeat surgery in high-risk patients with a failed surgical heart valve, according to 1-year results of the PARTNER II Valve-in-Valve Registry.


Rakesh M. Suri, MD, DPhil

Data showing early procedural success, acceptable mortality, and low risk of coronary obstruction or new pacemaker implantation were reported at the American College of Cardiology Scientific Session in 2014, said **Rakesh M. Suri, MD, DPhil,** of the Mayo Clinic, Rochester, Minn.

For the current analysis, Suri and colleagues sought to assess the 1-year safety and efficacy of the Sapien XT valve (Edwards Lifesciences) in a cohort of 97 patients enrolled across 24 sites between June 2012 and April 2013. Patients had symptomatic, severe stenosis or regurgitation of a surgical aortic tissue valve and faced a surgical mortality or major morbidity of 50% or more. All were suitable for a 23-mm or 26-mm TAVR device.

During his presentation at TCT 2014, Suri reported 1-year rates of both all-cause and cardiac mortality (see Figure). All-cause mortality was 18.8% for transfemoral and 21.6% for transapical TAVR. All-cause death stratified by mode of surgical heart valve failure was 19.5% for patients with predominate aortic stenosis, 18.4% for those with predominate aortic regurgitation and 25.0% for those with both. Other clinical outcomes included stroke/transient ischemic attack (4.5%), rehospitalization (17.2%) and permanent pacemaker implantation (1.1%).

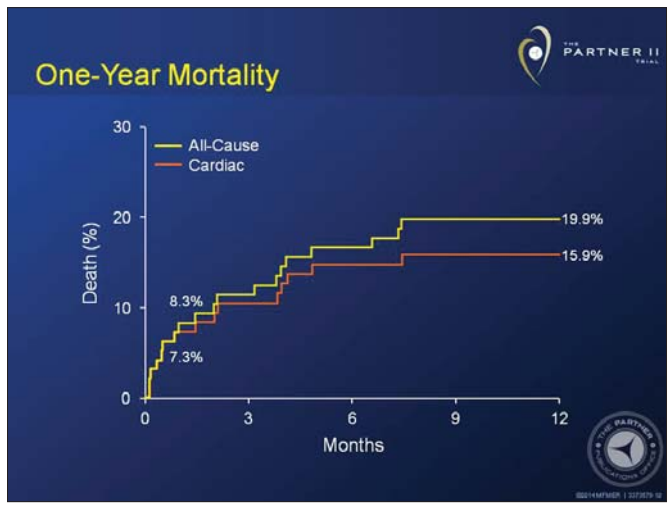
Left ventricular mass index regressed from 141.17 g/m^2 at baseline to 119.16 g/m^2 at 1 year (*P*<.0001). Among surviving patients, 84% were NYHA functional class I and II by 1 year (*P*<.0001 vs. baseline). KCCQ quality of life (QoL) assessment improved from an overall summary score of 39.97 at baseline to 74.74 at 1 year (*P*<.0001). In addition, 33.3% of patients had moderate-to-severe mitral regurgitation at baseline compared with 16% at 1 year (*P*=.04), and the prevalence of moderate-to-severe tricuspid regurgitation decreased from 48% at baseline to 27.5% at 1 year (*P*=.0004).

"Retrospective registries to date have shown valve-in-valve TAVR [to be] an alternative to reoperation for patients with failing surgical heart valves," Suri said. "Patients gained significant benefit from this therapy with improvements in functional class and QOL. However, the current analysis is small, and further study is needed to determine whether these midterm benefits improve long-term outcomes."

Mean age was 80.1 years, and 55.7% of patients were men. Most patients (95.9%) were classified with NYHA class III or IV, and 37.1% were deemed frail.

Disclosure:

- Suri reports no relevant conflict of interests.
- The study was funded by Edwards Lifesciences, the Sorin Group and St. Jude Medical.



Figure

TCT Course Director Outlines Current TAVR Controversies

In a didactic session on Saturday at TCT, **Martin B. Leon, MD,** outlined five major controversies in transcatheter aortic valve replacement (TAVR) facing clinicians in 2014.

Inclusion of low-risk patients

Leon, of Columbia University Medical Center, New York, and TCT course director, highlighted data from the PARTNER and CoreValve studies, along with findings from the STS/ACC Transcatheter Valve Therapy (TVT) Registry indicating that lower-risk patients are being included more frequently in trials as well as in clinical practice. Outcomes are also improving in this patient group, according to Leon. "There is clearly no evidence that TAVR is performing less well than surgery in lower-risk patients," he said.

Leon added that the question of whether the evolution of TAVR use is uncontrolled or ill advised — or a thoughtful consequence of better case selection — is valid. It may be beneficial to wait until results of the PARTNER II and SURTAVI studies emerge before indications are adjusted, he added, and raised the question of when a true low-risk study should be considered.

Device vs. device comparisons

Leon noted that while 95% of TAVR patients around the world have been treated with the Sapien (Edwards Lifesciences) or the CoreValve (Medtronic) devices, clinical trials are not helping to elucidate whether one is preferable over the other. "In the absence of definitive randomized trials and no obvious differences in major clinical endpoints, such as death and stroke, the debate often deteriorates into a subjective diatribe claiming technology advantages, deferring to user preferences, and focusing on softer secondary endpoints," he said, citing a small sample size and indefinite endpoints in the CHOICE study.


Martin B. Leon, MD

The solution may come in the form of new TAVR systems that broaden the device landscape. Self-expanding systems such as the Portico (St. Jude), the Engager and Evolut R (Medtronic) and the Acurate (Symetis) are forthcoming, as are non-expanding systems such as Direct Flow (Direct Flow Medical), Lotus Valve System (Boston Scientific), JenaValve (JenaValve Technology) and Sapien 3 (Edwards Lifesciences).

Paravalvular regurgitation and strokes

Leon also cited recent data from a meta-analysis demonstrating a nearly two-fold mortality increase with mild aortic regurgitation. "There is no question in my mind that this is not a good thing," he added.

While the causes of paravalvular regurgitation after TAVR are multifactorial, Leon suggested that screening techniques such as valve-sizing algorithms based on multislice CT may be helpful, but he noted that 3D measurements can be confusing.

"The striking variability in both the assessment techniques of post-procedure paravalvular regurgitation and the application of post-dilatation thresholds remains unresolved," he observed. "But maybe all of this will just go away [with the advent of] new devices."

> **"The striking variability in both the assessment techniques of post-procedure paravalvular regurgitation and the application of post-dilatation thresholds remains unresolved."**
>
> **- Martin B. Leon, MD**

Leon stressed that strokes remain the one complication that the clinical community needs to work to resolve, noting that they increase mortality by a factor of anywhere from three to five.

However, findings from PARTNER suggest that stroke-related mortality has been decreasing. "Over time, it appeared that stroke frequency after TAVR was declining with improved case selection, device and procedural refinements, and increased operator experience," he said. "So are strokes still a vexing dilemma after TAVR or is the problem stabilized and acceptable?"

Procedural considerations

Finally, Leon suggested that transfemoral access has become the default approach for TAVR, and that many European clinicians are moving to simplify the procedure. "However, overly aggressive transfemoral first-and-only access may be exposing patients to unnecessary vascular complications," he said.

Lower profile and safer transapical systems may be the answer.

The minimalist approach, including the virtual elimination of procedural TEE, may yield suboptimal results in some patients, according to Leon. "Combined procedures also clearly require further careful evaluation," he said. "I would argue that in some cases IVUS is a good thing." However, he added that the management of patients with aortic stenosis, CAD and other CV conditions remains unresolved.

Disclosures:

- Leon reports relationships with multiple pharmaceutical and device companies.

PERIPHERAL

REDEFINING »» MINIMALLY INVASIVE.

Introducing the Diamondback 360® Peripheral Orbital Atherectomy System creating additional access solutions with its low, 4 Fr. profile.

Take a spin online now at conquercalcium.com.

DIAMONDBACK 360®
PERIPHERAL ORBITAL ATHERECTOMY SYSTEM

Caution: Federal law (USA) restricts this device to sale by, or on the order of, a physician. The CSI Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. Contraindications for the system include use in coronary arteries, bypass grafts, stents, or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

REVOLUTIONIZING PAD TREATMENT IN TIBIOPERONEAL VESSELS

Join the Diamondback® Revolution.
BOOTH #1729

CSI® CARDIOVASCULAR SYSTEMS, INC.
651 Campus Drive
St. Paul, MN 55112
T: 877.CSI.0360
www.csi360.com
www.conquercalcium.com

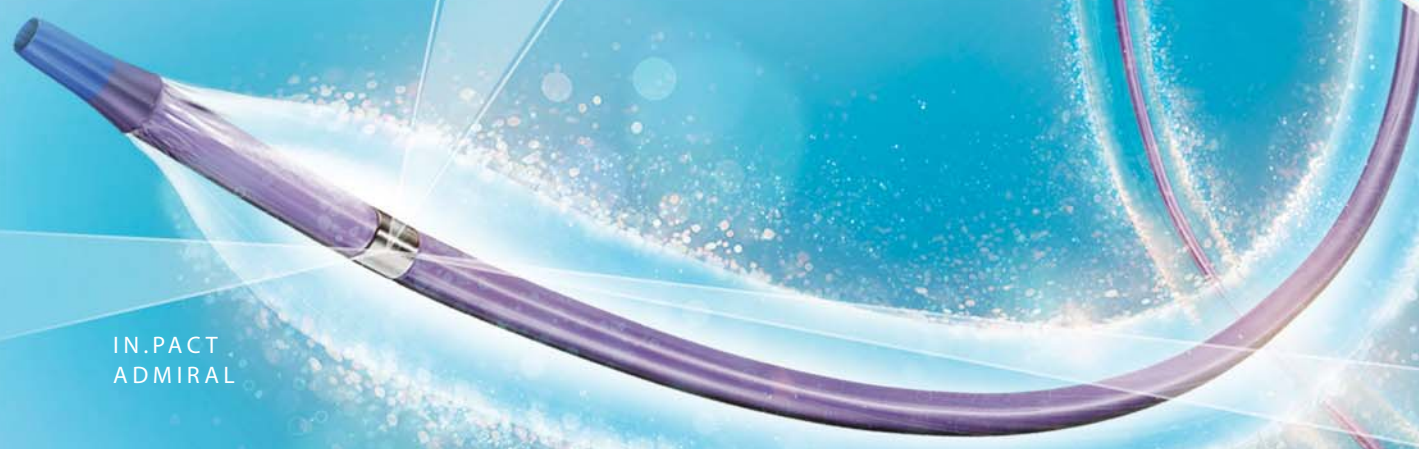
EN-1966.A 0814

Medtronic

IN.PACT™

DRUG ELUTING BALLOONS

CD-TLR*
2.4%
IN.PACT SFA
*12 MONTH OUTCOMES; PP KAPLAN-MEIER DAY 360
89.8%
PRIMARY PATENCY*



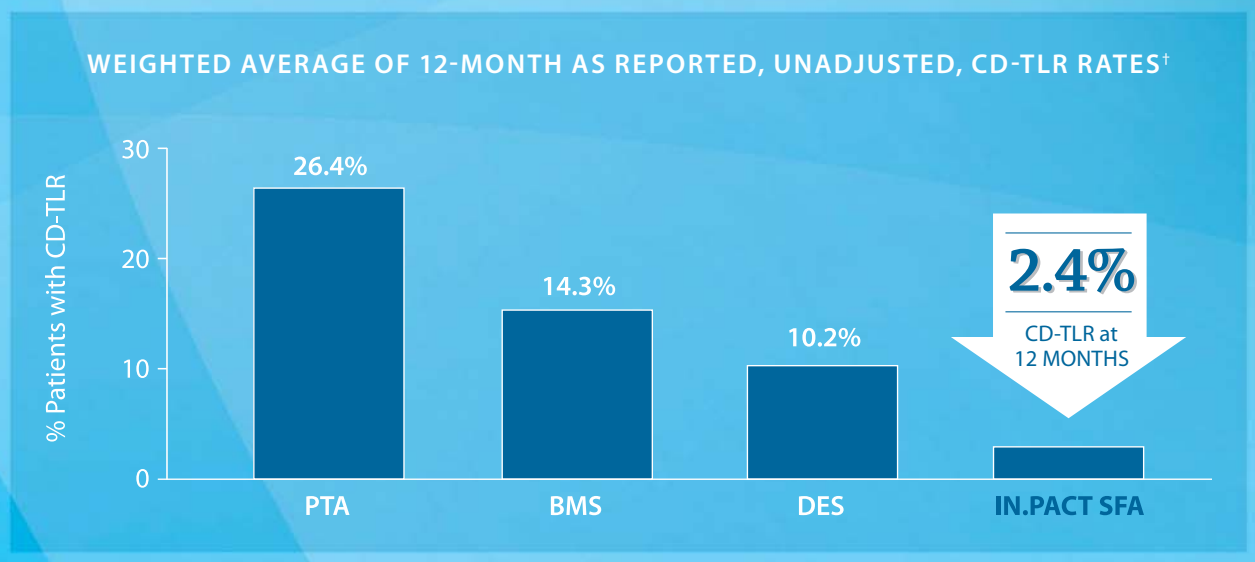
IN.PACT
ADMIRAL

IN.PACT
PACIFIC

Finally, an SFA Standard.

A PROVEN PRIMARY THERAPY FOR THE TREATMENT OF SFA DISEASE

Incomparable Clinical Outcomes in the SFA



†Comprehensive list of cited publications on file with Medtronic.

For further information on Medtronic Endovascular products, visit **peripheral.medtronicendovascular.com**

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use. Not available for sale in the United States.

Innovating for life.

Extend your reach.

With greater ease, precision, and control.

Concerto™

Detachable Coil System

The Concerto™ detachable coil system is designed to deliver high performance at every stage of peripheral vasculature coil embolization.

EASY **DELIVERY**

Soft fibered coils travel smoothly through the microcatheter—enabling navigation of tortuous anatomy and access to distal locations for targeted focal embolization.

PRECISE **DEPLOYMENT**

Superb distal performance provides easier loop formation for accurate coil deployment and secure positioning.

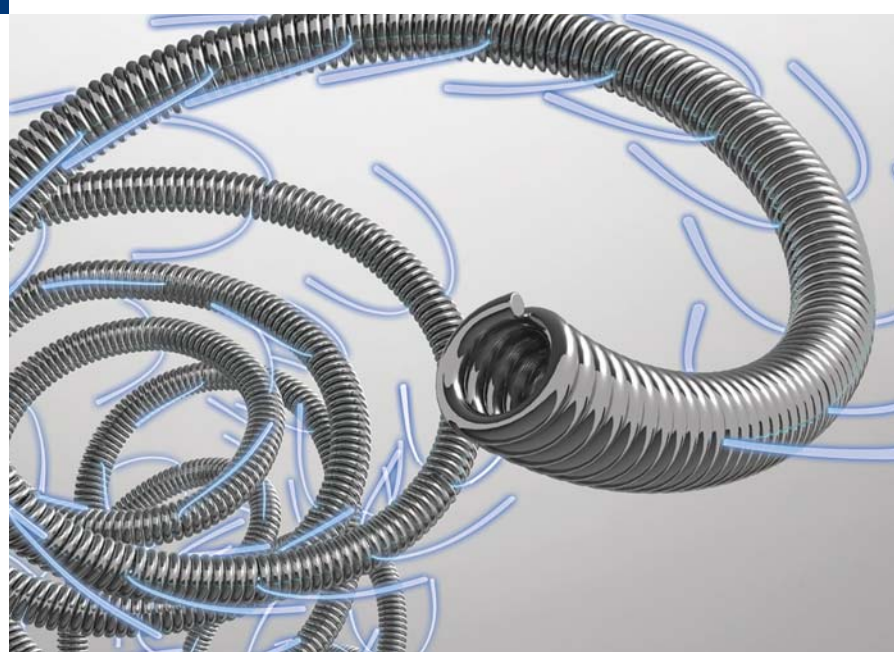
CONTROLLED **DETACHMENT**

Unique articulation zone enables instant detachment and retrievability—and repositioning of the coil before release, if needed.

[Peripheral Embolization]

COVIDIEN

Visit Covidien at Booth 1329.

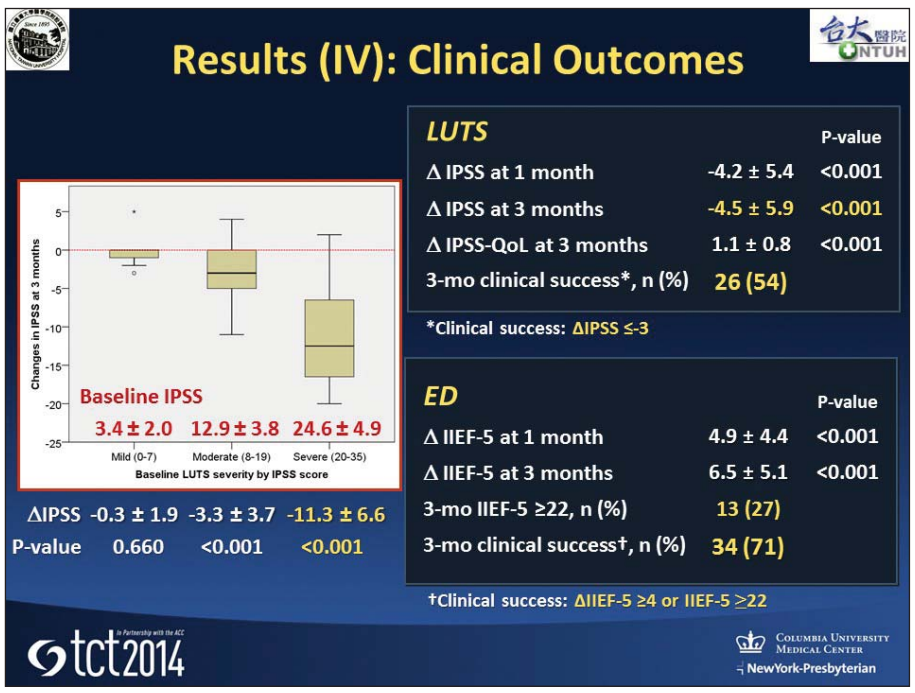


PERFECT-LUTS: Endovascular Revascularization Shows Promise for Patients with ED, Lower Urinary Tract Symptoms

In patients with erectile dysfunction (ED) and lower urinary tract symptoms (LUTS), endovascular revascularization of obstructive pelvic arterial lesions may improve symptoms, according to research presented at TCT 2014.

For PERFECT-LUTS, **Tzung-Dau Wang, MD, PhD,** of the National Taiwan University Hospital, Taipei City, Taiwan, and colleagues examined 48 patients with both ED and LUTS who underwent angioplasty of pelvic arterial lesions between July 2013 and March 2014.

Primary feasibility endpoints were changes in the International Prostate Symptom Score (IPSS) and its quality-of-life component and the International Index of Erectile Function-5 (IIEF-5) through 3 months. The primary safety endpoint was any major adverse events within 1 month, and clinical success was defined as a change of IPSS and IIEF-5 from baseline by at least three and four points, respectively, or IIEF-5 of 22 points or greater, indicating no dysfunction.



Figure

Patients had an average of two lesions each. Most were located in either the penile (39%), distal internal pudendal (28%) or proximal internal pudendal (15%) arteries. Three-month outcomes demonstrated improvements in both ED and LUTS in the overall cohort (see Figure).

While patients with lesions in the proximal internal pudendal artery or higher had marked improvement in LUTS, those with lesions in the distal internal pudendal artery or lower did not (*P*<.001 for interaction). No differential effects based on lesion location were noted for ED.

Limitations of the study, Wang noted, were small sample size, no control arm, no assessment of objective urinary flow and absence of complete CT angiography follow-up results.

"Our finding suggests that, in addition to benign prostatic hyperplasia, bladder ischemia is another important, treatable but under-recognized cause for LUTS," he concluded.

After the session, **Deepak L. Bhatt, MD, MPH,** of Brigham and Women's Hospital, Boston, inquired whether the researchers thought to use nocturnal penile tumescence testing in order to provide a more objective evaluation of the therapy's effect. Wang said although they did not perform this test, they did collect Doppler ultrasound data, but the correlation between the ultrasound and the angiographic flow status is currently only about 60%.


Tzung-Dau Wang, MD, PhD

A randomized trial would be the next step in testing endovascular revascularization for these lesions and symptoms, Wang observed, but the best strategy for long-term durability — stenting, drug-eluting balloon or balloon angioplasty — remains unclear.

Average patient age was 62.3 years, and average IPSS, IPSS-QoL and IIEF-5 scores were 13.4, 3.3 and 8.9, respectively. The majority of patients (65%) had CAD.

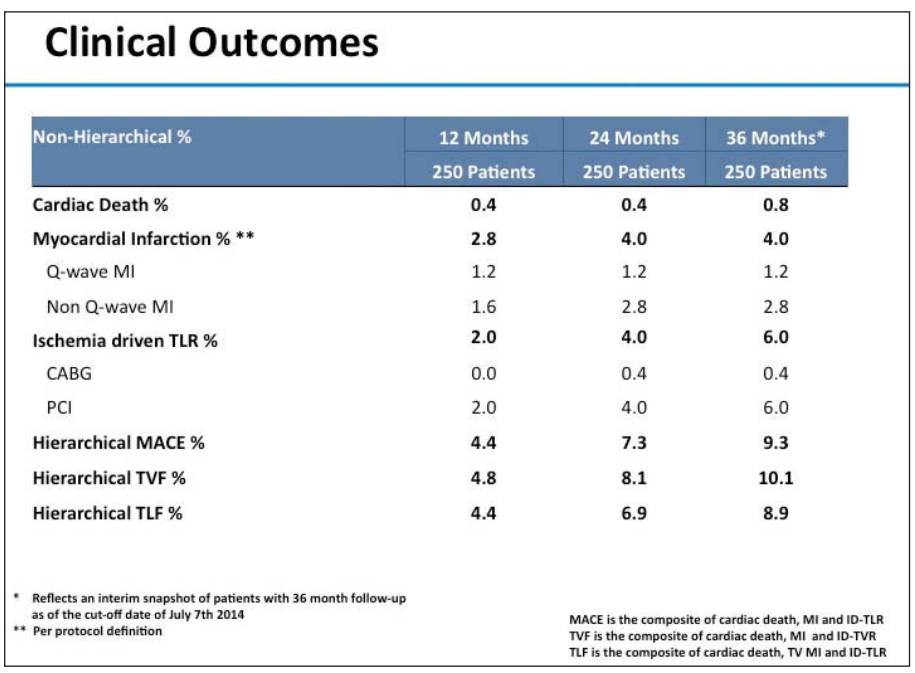
Disclosures:

- Wang reports off-label use of coronary stents in the internal pudendal arteries.

ABSORB EXTEND: BVS Safe Out to 3 Years

A bioresorbable vascular scaffold (BVS) yields low rates of MACE, repeat revascularization and scaffold thrombosis through 36 months, according to an interim analysis of the ABSORB EXTEND trial. The device elutes everolimus and absorbs into the body, leaving no permanent scaffold.

Previous 2-year results demonstrated a MACE rate of 6.7% and definite/probable scaffold thrombosis rate of 1.1% in the first 450 patients treated with the Absorb BVS (Abbott Vascular). Additionally, 3-year angiographic results from Cohort B demonstrated in-scaffold late loss of 0.29 mm.



Figure

The new analysis, presented at TCT 2014 by **Pieter C. Smits, MD, PhD,** of Maasstad Ziekenhuis, Rotterdam, the Netherlands, provides 36-month follow-up on the first 250 patients treated with the BVS. Overall, the analysis showed low rates of MACE, cardiac death, ischemia-driven target lesion revascularization (TLR) and other clinical outcomes (see Figure).

There were no instances of acute (0-1 day) or sub-acute (2-30 days) definite scaffold thrombosis; there was one case of late (31 days to 1 year) definite scaffold thrombosis, as well as one case of sub-acute probable thrombosis and one case of very late (>1 year) probable thrombosis. Overall, the rate of definite/probable scaffold thrombosis at 3 years was 1.2%.

Using propensity matching, the researchers compared 174 patients from ABSORB EXTEND with 290 patients in other trials who were treated with the everolimus-eluting Xience V stent (Abbott Vascular). There were no statistically significant differences between the BVS and Xience V at 36 months for MACE (HR 0.73; 95% CI 0.38-1.41), definite/probable scaffold thrombosis (HR 0.83; 95% CI 0.08-9.15), or MI (HR 1.06; 95% CI 0.41-2.73).

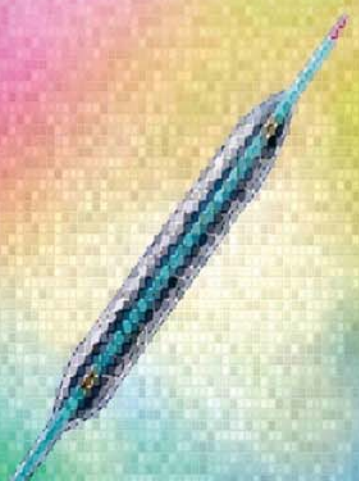
However, there was a hint of difference for target vessel failure (TVF) at 36 months, with rates of 14.2% in the XIENCE V group and 8.1% in the ABSORB EXTEND group (*P*=.0488), which Smits said requires further study. Furthermore, the analysis also found a significantly greater rate of angina in Xience V-treated patients in the SPIRIT IV trial compared with BVS-treated patients in ABSORB EXTEND, he added.

"Clinical data from the first 250 patients enrolled in ABSORB EXTEND demonstrate that the low rates of MACE, repeat revascularization and scaffold thrombosis seen at 12 and 24 months are sustained through 36 months," Smits said.

Patients in ABSORB EXTEND could have up to two de novo lesions treated, located in separate native epicardial vessels; most patients (94%) had one target lesion. Device success was 98.5% and the clinical procedure success rate was 97.2%. Of the 250 patients (mean age 62 years), 74% were male; 29% had previous MI; 35% had unstable angina; and 25% had diabetes.

Disclosures:

- Smits reports receiving lecture fees from Abbott Vascular and institutional grants from Abbott Vascular, Terumo Medical Corporation and St. Jude Medical.



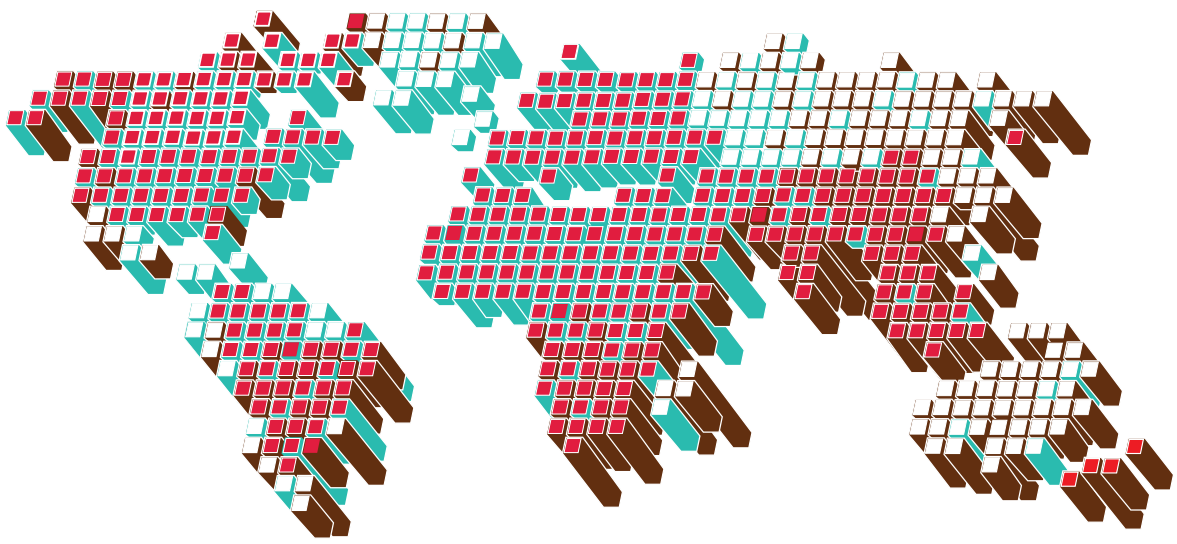
MOZEC™

Rx PTCA Balloon Dilatation Catheter

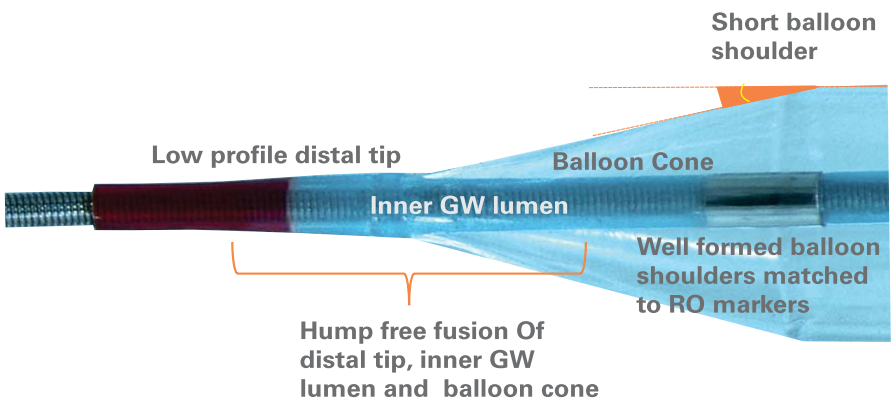
Handicraft for *Angiocraft*.

VISIT US AT BOOTH #1733

Cleared for sale in USA, Canada, Korea, China, Latin America, South East Asia, Middle East & Africa and CE mark countries.



Mozec combines the competitive features of an ideal work-horse balloon dilatation catheter



- Semi-compliant balloon material allowing for flat compliance.
- Hydrophilic coating from distal balloon tip up to Rx port.
- PTFE coated proximal shaft for enhanced navigability.
- Elongated 5 mm tip for Ø – 1.25*, 1.50 & 2.00 mm for distal stability & guide wire support.
- Transparent ergonomic hub displaying balloon dimensions.
- Available size matrix Ø - 1.25*, 1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50 mm. ℓ - 6, 9, 12, 14, 15, 17, 20, 25, 33, 38, 41 mm.

Join us for "Kaleidoscope of Novel Interventional Technologies"

Monday, 15th September 2014, 1 to 2 pm at Presentation Theater 4

Meril

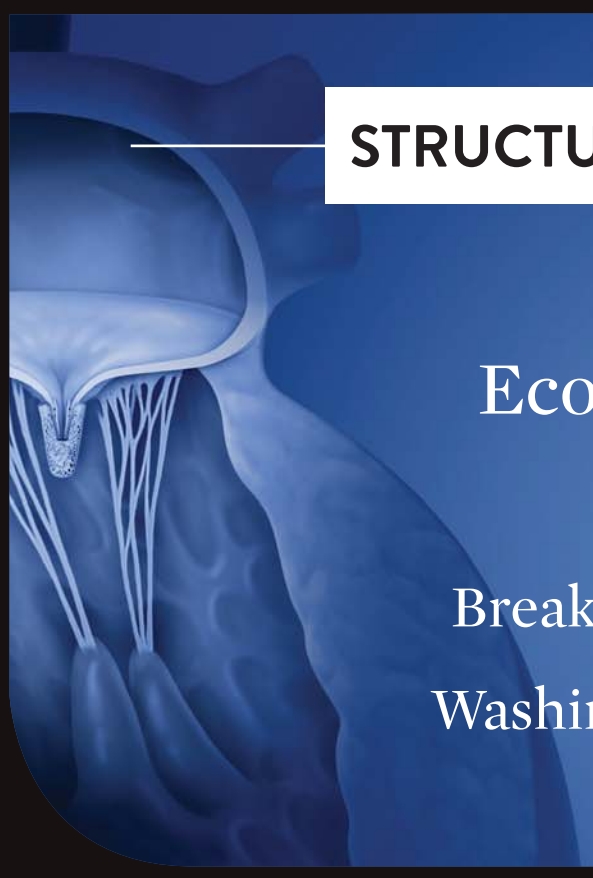
Meril Life Sciences Pvt. Ltd.
Survey No. 135/139,
Bilakhia House,
Muktanand Marg, Chala,
Vapi 396191. Gujarat. India.
T +91 260 3052 100
F +91 260 3052 125

Meril GmbH.
Bornheimer Strasse 135-137,
D-53119 Bonn.
Germany.
T +49 228 7100 4000
F +49 228 7100 4001
E askinfo@merillife.com

Meril South America
Doc Med LTDA
Al. dos Tupiniquins,
1079 – Cep: 04077-003 – Moema
Sao Paulo. Brazil.
T +55 11 3624 5935
F +55 11 3624 5936

Meril Tibbi Cihazlar Imalat Ve Ticaret A. S.
6, Mimar sinan Mah.,
Çavusbasi Cad. Özde Sok.
Aydin Eksi Is Merkezi Kat:1
Cekmekoy/Istanbul, Turkey
T +90 53 2272 5172

International Headquarters - Meril Life Sciences Pvt. Ltd.
612-B, Bonanza, Sahar Plaza, J.B. Nagar, Andheri (E), Mumbai - 400 059, India. T +91 22 3935 0700 F +91 22 3935 0777
E askinfo@merillife.com W www.merillife.com



STRUCTURAL HEART BREAKFAST SYMPOSIUM

Beyond Valve Repair:
Economic Impact of MitraClip®

Tuesday, September 16

Breakfast: 6:30am | Program: 7:00-8:00am

Washington Convention Center, Room 144B

℞ ONLY MitraClip Clip Delivery System

INDICATION FOR USE
The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

CONTRAINDICATIONS
The MitraClip Clip Delivery System is contraindicated in DMR patients with the following conditions:
- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease • Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS
- DO NOT use MitraClip outside of the labeled indication. Treatment of non-prohibitive risk DMR patients should be conducted
  in accordance with standard hospital practices for surgical repair and replacement.
- MitraClip is intended to reduce mitral regurgitation. The MitraClip procedure is recommended to be performed when an experienced heart
  team has determined that reduction of MR to ≤2+ is reasonably expected following the MitraClip. If MR reduction to ≤2+ is not achieved, the benefits of reduced symptoms and hospitalizations, improved quality of life, and reverse LV remodeling expected from MitraClip may not occur.
- The MitraClip Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip System to avoid user injury.
- Use of the MitraClip should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death.
- Inspect all product prior to use. DO NOT use if the package is opened or damaged.

PRECAUTIONS
- Patient Selection:
  - ■ Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:
    - ◆ 30-day STS predicted operative mortality risk score of
      - ✦ ≥8% for patients deemed likely to undergo mitral valve replacement or
      - ✦ ≥6% for patients deemed likely to undergo mitral valve repair
    - ◆ Porcelain aorta or extensively calcified ascending aorta.
    - ◆ Frailty (assessed by in-person cardiac surgeon consultation)
    - ◆ Hostile chest
    - ◆ Severe liver disease / cirrhosis (MELD Score >12)
    - ◆ Severe pulmonary hypertension (systolic pulmonary artery pressure >2/3 systemic pressure)
  - ■ Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery (IMA) at high risk of injury, etc.
  - ■ Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60mm. MitraClip should be used only when criteria for clip suitability for DMR have been met.
- The major clinical benefits of MitraClip are reduction of MR to ≤2+ resulting in reduced hospitalizations, improved quality of life, reverse LV remodeling and symptomatic relief in patients who have no other therapeutic option. No mortality benefit following MitraClip therapy has been demonstrated.
- The heart team should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and may also include appropriate physicians to assess the adequacy of heart failure treatment and valvular anatomy.
- The heart team may determine an in-person surgical consult is needed to complete the assessment of prohibitive risk. The experienced mitral valve surgeon and heart team should take into account the outcome of this surgical consult when making the final determination of patient risk status.
- For reasonable assurance of device effectiveness, pre-procedural evaluation of the mitral valve and underlying pathologic anatomy and procedural echocardiographic assessment are essential.
- The inside of the outer pouch is not a sterile barrier. The inner pouch within the outer pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.
- Note the "Use by" date specified on the package.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS
The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip procedure. Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Aneurysm or pseudo-aneurysm; Arrhythmias; Atrial fibrillation; Atrial septal defect requiring intervention; Arterio-venous fistula; Bleeding; Cardiac arrest; Cardiac perforation; Cardiac tamponade/Pericardial Effusion; Chordal entanglement/rupture; Coagulopathy; Conversion to standard valve surgery; Death; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Dizziness; Drug reaction to anti-platelet/anticoagulation agents/contrast media; Dyskinesia; Dyspnea; Edema; Emboli (air, thrombus, MitraClip Device); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip to the intended site; Failure to retrieve MitraClip System components; Fever or hyperthermia; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Hemorrhage requiring transfusion; Hypotension/hypertension; Infection; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; MitraClip erosion, migration or malposition; MitraClip Device thrombosis; MitraClip System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea/vomiting; Pain; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure/atelectasis/pneumonia; Septicemia; Shock, Anaphylactic or Cardiogenic; Single leaflet device attachment (SLDA); Skin injury or tissue changes due to exposure to ionizing radiation; Stroke or transient ischemic attack (TIA); Urinary tract infection; Vascular trauma, dissection or occlusion; Vessel spasm; Vessel perforation or laceration; Worsening heart failure; Worsening mitral regurgitation; Wound dehiscence.

℞ ONLY Steerable Guide Catheter

INDICATION FOR USE
The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

CONTRAINDICATIONS
- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

WARNINGS
- Read all instructions carefully. Failure to follow these instructions, warning and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps to avoid user injury.
- Use the Steerable Guide Catheter with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- The Steerable Guide Catheter is designed for single use only. Cleaning,
  re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death. • Patients with the following considerations in whom the Steerable Guide Catheter is used may have an increased risk of having a serious adverse event which may be avoided with preoperative evaluation and proper device usage.
  - ■ Previous interatrial septal patch or prosthetic atrial septal defect (ASD) closure device which could result in significant difficulty in visualization or technical challenges during transseptal puncture and/or introducing the SGC
    into the left atrium.
  - ■ Known or suspected unstable angina or myocardial infarction within the last 12 weeks could increase the procedural morbidity and mortality, due to increased hemodynamic stress secondary to general anesthesia.
  - ■ Patients with active infection have an increased risk of developing an intraoperative and/or postoperative infection, such as sepsis or soft tissue abscess.
  - ■ Known or suspected left atrial myxoma could result in thromboembolism and tissue injury due to difficulty with device positioning.
  - ■ Recent cerebrovascular event (CVA) may increase the procedural morbidity associated with a transcatheter intervention, such as recurrent stroke.

PRECAUTIONS
NOTE the "Use by" date specified on the package. Inspect all product prior to use. Do not use if package is opened or damaged. The inside of the outer pouch is not a sterile barrier. The inner pouch within the outer pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

Prior to use, please reference the Instructions for Use at www.abbottvascular.com/ifu for more information on indications, contraindications, warnings, precautions, and adverse events.

Abbott Vascular 3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.AbbottVascular.com

Abbott

Now Available
2.0–6.0mm x 100mm and
4.0–6.0mm x 200mm Sizes

AngioScore®
A Spectranetics Company

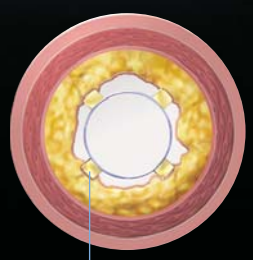
Go Long. Score Big.

AngioSculpt® XL
PTA Scoring Balloon Catheter

Designed specifically to address long, diffuse lesions commonly found in infrainguinal arteries, the AngioSculpt® XL is now available in even longer 100mm and 200mm balloon lengths.

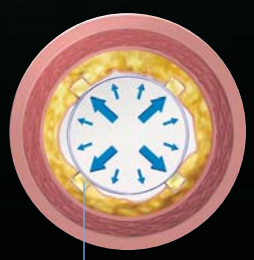
Proven Benefits

Precision



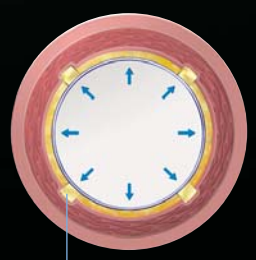
Edges lock in

Predictable Power



~15–25x scoring force

Safety



~1x force post scoring

Visit us at TCT Booth 1224

SUMMARY OF SAFETY AND EFFECTIVENESS—PTA CATHETER

CE Mark Granted for Peripheral Applications

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

INDICATIONS

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

CONTRAINDICATIONS

None known for percutaneous transluminal angioplasty (PTA) procedures.

WARNINGS

This device is intended for single (one) patient use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination. The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device-specific information. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Proceed cautiously when using the AngioSculpt catheter in a freshly deployed bare metal or drug-eluting stent. The AngioSculpt catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the AngioSculpt catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter). Use the catheter prior to the "Use Before" (expiration) date specified on the package.

PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product. Any use for procedures other than those indicated in these instructions is not recommended. The device is not recommended for use in lesions that may require inflation pressures higher than those recommended for this catheter. Do not use if package is opened or damaged. Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used. During and after the procedure, appropriate anticoagulants, antiplatelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries. Pass the AngioSculpt catheter through the recommended introducer sheath size or minimum size guiding catheter indicated on the product label.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, total occlusion of the treated artery, arterial dissection or perforation, arterial spasm, pseudoaneurysm, restenosis of the dilated artery, embolism, thrombus, retained device components, hemorrhage or hematoma, arteriovenous fistula.

AR-1128 Rev B 08/14

TCT Keynote: Global Vision for Prevention in Children and Adults Could Change CVD Landscape

Strategies modeled on Sesame Street and Alcoholics Anonymous are yielding real results around the world.

This years' keynote address focused on eradicating CVD using innovative, globally applicable approaches. **Valentin Fuster, MD, PhD,** of Mount Sinai Hospital, New York, N.Y., spoke about achieving a healthier population by targeting young children as well as their parents for education on healthy behaviors as well as refocusing physicians' efforts.


Valentin Fuster, MD, PhD

Fuster pointed out that over the past 20 years, professional societies have released more than 30 documents and statements on cardiovascular health and strategies for improvement. "This raises the question of whether we are a field of talkers rather than doers," Fuster said. A 2011 Institute of Medicine report on promoting CV health in the developing world, however, has already yielded solid, repeatable results, providing hope that the field can do a lot for heart health before trying to translate the results over to government programs, he added.

Focus on children

In recent years, several preventive programs have been initiated to focus separately on children, middle-aged adults and the elderly. The first was a study of more than 1,000 children in Bogota, Colombia. Utilizing some of the methods from the television show Sesame Street, a program was created to teach healthy habits, describe how the body works, encourage exercise and even provide help with emotional habits to avoid addictions. The program offered new books aimed at varying age groups, including some for parents. "After 6 months and 70 hours of teaching health, the [childen's] knowledge, attitudes, and habits were significantly better than children in a control group," Fuster said.

Three-year results of that study were published in 2013, and they showed significant improvements in mean knowledge, attitude and habit scores from baseline ($P<.001$ for all). There were more tangible results as well: the program yielded a 13% improvement in the number of children at a healthy weight (62% to 75%). As a result, Fuster said, the government of Colombia has since expanded the program to 25,000 children. Spain also has begun participating in the program and a similar effort has been launched in Harlem, N.Y., Fuster noted.

Simple adult interventions

There is ample opportunity to improve CV health in adults around the world as well. In Kenya, Africa, for example, Fuster said a lack of refrigeration leads many people in rural areas to store food using salt, which leads to high rates of hypertension. Through a new program, citizens are taught to check their own and their neighbors' BP using simple methods and to record the results in mobile phones. Fuster said the program thus far has been extremely well received.

Another adult intervention, also in Spain, was based upon the model of Alcoholics Anonymous. The program enrolled subjects with risk factors for CVD, including smoking, obesity, sedentary lifestyle, and hypertension and had groups of 10 to 14 people meet every other week to help each other improve those factors. At 6 months, Fuster reported, 95% had managed to eliminate at least one of their risk factors.

Adherence in the elderly

Finally, a program in elderly patients focused on adherence to medications could be a crucial piece of improving CV health. A study in several countries in Europe and South America found very low rates of adherence (ranging from 17% to about 50%) to evidence-based medications after MI. Non-adherence was influenced by factors including age, depression and degree of social support.

Improving adherence rates, possibly through a polypill strategy, could make an enormous difference based on results from another study of 14,119 patients in an Aetna database. "The people who have the poorest adherence have the largest number of events," Fuster said. "Adherence really has a significant impact."

Disclosures:

- Fuster reports no relevant conflicts of interest.

Experts Look to Big Data to Identify New Therapeutic Targets for CVD

Recent technological advancements — including portable ECGs, wearable health monitors and printable tattoo biosensors — have made complex data more available than ever, according to **Eric Schadt, PhD,** of the Icahn School of Medicine at Mount Sinai, New York, N.Y. These data, he said, will be instrumental in the development of molecular profiling technologies to create a more holistic view of the health of individuals

During a keynote address at TCT 2014, Schadt discussed the challenges of using integrated data to improve health at both the individual and population level.

"We are living in a big data universe," Schadt said. "Can we leverage the digital universe of information that can be generated about individuals and populations of individuals to make better predictions about how we can diagnose and treat patients?"

According to Schadt, it can be done by integrating data on components like DNA, RNA, metabolites and proteins to better understand the networks they comprise. These networks, Schadt said, drive biological processes that cause disease; if we better understand these complex networks, we will better understand the best treatment approach.

Application in research

To give the audience an idea of how this is possible, Schadt cited a 2012 paper published in *Nature* in which he and colleagues analyzed 163 genetic loci for inflammatory bowel disease (IBD) in the context of molecular networks. By projecting these loci onto the network, the researchers were able to identify biological processes in sub-networks and determine the role of specific genes in the course of disease. Once sub-networks are identified, computer simulations can then be performed to better understand which specific genes are important. At times, "key modulators" — genes that change the network to a disease state or healthy state — are identified, he explained.

From there, therapeutic targets can be explored, Schadt said; they can be used to map marketed drugs, natural products or environmental interventions like diet and exercise in order to identify appropriate treatment approaches. In the *Nature* article, he and colleagues determined the antiseizure drug topiramate is as effective as prednisolone for the treatment of IBD in rats.

Potential in CVD

Schadt is currently working with **Valentin Fuster, MD,** also of Mount Sinai, to apply this integrative approach to CVD using the STARNET Biobank. The group has access to tissue samples — including artery wall, atherosclerotic lesion, subcutaneous fat, liver and skeletal muscle — obtained from over 1,000 patients undergoing open thoracic cardiac surgery. Roughly half of these patients had CVD, and the other half underwent the procedure for other reasons, creating a control group from the CVD standpoint, Schadt said. Like the study in IBD, researchers can now integrate these data into workflows to identify molecular networks in an effort to better understand CVD. Thus far, Schadt and colleagues have identified networks consisting of genes that have been shown to increase the risk for CVD, including PCSK9 and ABCG5. Pipelines are also in place to perform higher throughput validation of these networks, he said.

"At the end of the day, what we're hoping to do is use this information — the networks that we form here — and start mapping individuals through the perturbations in their DNA [and] the perturbations in their environment, and start locking onto which sub-networks in the vast network of the complexity of life are underlying their particular form of disease, their particular form of CVD," Schadt said. "Once we know those molecular mechanisms at play, we can map those to therapeutics or behavior modifications. … That ultimately is the goal of this work in the future: We can guide one's health course by better monitoring the health of the individual both at the molecular and physiological level to achieve this kind of benefit."


Eric Schadt, PhD

Disclosures:

- Schadt reports serving on the science advisory board for Ayasdi, Berg Pharmaceuticals, Ingenuity, NuMedii, Pacific Biosciences and Whole Biome. He also reports research collaborations with Eli Lilly and Janssen Pharmaceuticals.

From the publishers of **CARDIOLOGY TODAY**
In association with the Cardiovascular Research Foundation

TECHNIQUE AND TECHNOLOGY
for the interventional cardiologist

In This Issue:

See our photo feature, **"A Close-Up on CLI Intervention,"** with Mehdi H. Shishehbor, DO, MPH, PhD, and his team at the Cleveland Clinic.

Mehdi H. Shishehbor

Don't miss **"5 Questions with Dr. Bhatt."** This issue Dr. Bhatt interviews Ph. Gabriel Steg, MD.

Deepak L. Bhatt

Ph. Gabriel Steg

Check out the **CTO Corner**, as Emmanouil S. Brilakis, MD, PhD, shares the top 10 reasons to perform CTO interventions.

Emmanouil S. Brilakis

Coming Soon:
Expert insight from TCT

Don't miss an issue!

Healio.com/Intervention

Your Daily Source for Intervention News.

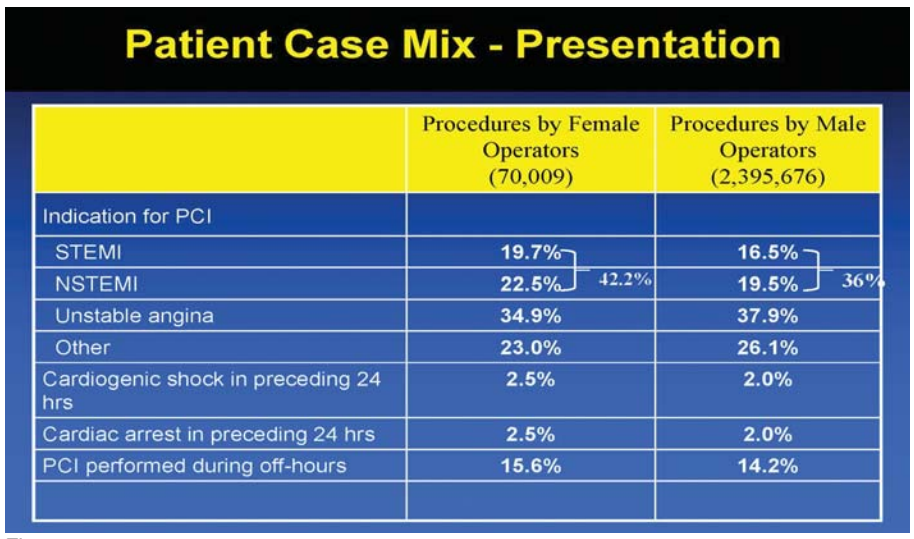
Register for the weekly Intervention email News Wire.

Practice Patterns of Female Interventionalists Show High Volume of Complex Cases

While the number of women working as interventional cardiologists remains low — with operators often isolated professionally from female colleagues — there are positive signs of change. In particular, according to registry findings presented at TCT 2014, female interventionalists are more likely to tackle high-risk cases, such as STEMI, cardiac arrest and cardiogenic shock.

To learn more about practice patterns of female interventional cardiologists, **Cindy L. Grines, MD,** of Detroit Medical Center in Detroit, Mich., and current chair of the SCAI-Women in Innovations (WIN) initiative, and colleagues analyzed data from the NCDR CathPCI Registry on 2,465,685 PCI procedures performed at 1,431 U.S. hospitals between July 1, 2009, and June 30, 2013.

Women accounted for only 4.5% of all interventionalists. In addition, 41% of female interventionalists operated at a hospital with no other women in the same profession, and female operators performed a mere 2.8% of all PCI procedures.



Figure

Patterns of practice

The researchers observed that female interventionalists tended to practice in academic (57%) and urban (62%) hospitals. Compared with male operators, female operators were slightly less likely to treat white patients and more likely to treat uninsured patients. Male and female interventionalists were equally likely to treat female patients.

In addition, female operators were found to be as or more likely to take on high-risk cases as their male counterparts (see Figure).

"From the analysis, it appears that women were more likely to perform procedures off-hours and performed procedures on a higher percentage of STEMI and non-STEMI patients," Grines said, highlighting that approximately 42.2% of cases done by women were in patients with acute MI. "This is significant," she stressed, "because despite handling a smaller volume of cases, and being somewhat isolated, female interventionalists are working with a relatively high-risk population."

Women performing well irrespective of volume

Female operators reported conducting a median of 48 procedures per year. Because women in the field were found to often be low-volume operators, Grines and colleagues decided to specifically examine differences based on volume. After adjustment for variables in the CathPCI mortality risk model, there was no disparity between high- and low-volume female operators in post-PCI mortality risk (OR 1.03; 95% CI 0.84-1.27).

"Even though females are not doing as many cases as males, females are handling a higher proportion of very sick cases, and it appears that women are doing a very adequate job with high-risk interventions," said Grines, noting that the study was not able to ascertain other operator characteristics, such as years in practice, or measure longitudinal outcomes after PCI.

"The good news," she added, "is that we are gradually increasing the number of procedures performed by females. [However], this analysis also illustrates that there is a significant gap, and Women in Innovations is trying to address this and encourage/support more women who may want to go into interventional cardiology."

Disclosures:

- Grines reports serving as a consultant to or on the advisory board of multiple pharmaceutical and device companies and as editor-in-chief of the *Journal of Interventional Cardiology.*

Post-PCI STEMI Infarct Size Strong Predictor of Mortality, Rehospitalization

Measuring infarct size with MRI or single-proton emission computed tomography (SPECT) within 30 days of STEMI after primary PCI can predict subsequent all-cause mortality and rehospitalization for HF and may be a useful surrogate of clinical events in STEMI trials.

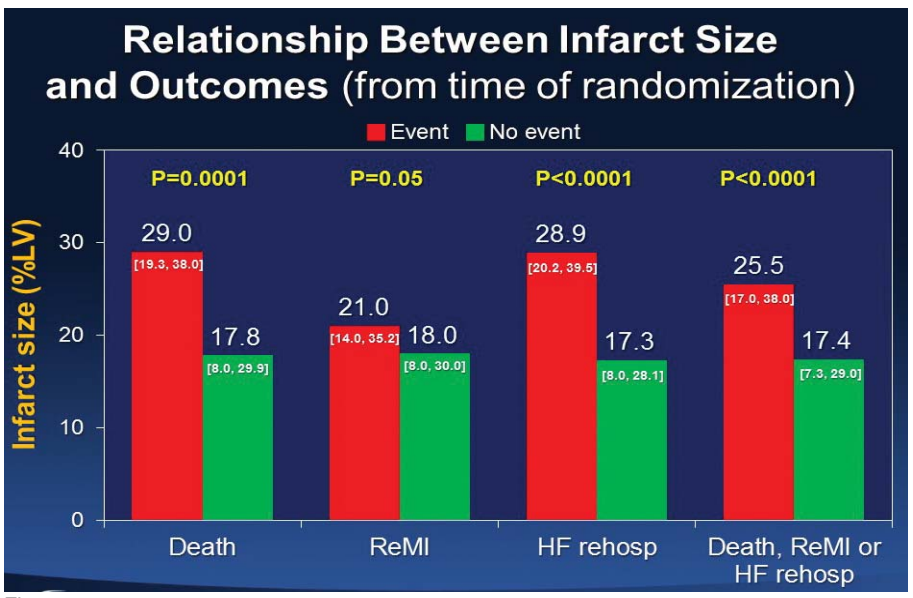
TCT Course Director **Gregg W. Stone, MD,** of Columbia University Medical Center, New York, N.Y., presented a collaborative pooled patient-level analysis of 10 trials (n=2,376) of primary PCI in STEMI in which infarct size was measured via cardiac MRI or tc-99m-sestamibi SPECT.

Strong correlation

Overall, patients averaged 5 days to testing, and median infarct size was 18% of the left ventricular mass. In those monitored with SPECT (n=744), average time to testing was 13 days and median infarct size was 14% of LV mass. MRI monitoring was performed in 1,632 patients at an average of 4 days after the procedure, and the median infarct size was 19.1% of LV mass.

At 1 year, the rate of death was 2%; reinfarction was 2.5%; rehospitalization for HF was 2.7%; and total events was 6.2%.

"There were strong correlations between larger infarct sizes and mortality," Stone said. "There was a borderline relationship between infarct size and reinfarction, but a very strong relationship between infarct size and heart failure rehospitalization, so when you look at the composite, there's also a very strong relationship" (see Figure).



Figure

Influence of infarct size

Analysis of infarct size revealed that higher quartiles were more likely to experience death and rehospitalization due to HF. Quartile 1 (0% to 8% of LV mass), for example, had a rate of death of 0.7% compared with 3.8% for quartile 4 (>30% of LV mass; *P*=.002). Similarly, quartile 1 had a 0.4% rate of rehospitalization due to HF compared with 6.3% for quartile 4 (*P*<.0001), and for all three events the rates were 2.3% and 11.5%, respectively (*P*<.0001).

"There's a graded increase in mortality according to every infarct size quartile," Stone said. "The relationship between infarct size and mortality … was independent of age, gender, diabetes, smoking status, hypertension, hyperlipidemia, importantly LAD vs. non-LAD, symptom-to-balloon time, baseline TIMI flow and post-TIMI flow."

In addition, there was no difference between subgroups for HF rehospitalization or composite endpoints, showing that infarct size was an independent predictor of those outcomes. Similarly, there was no difference between MRI and SPECT measurements.


Gregg W. Stone, MD

During a panel discussion, Stone said MRI should remain the gold standard, as it offers higher resolution and, therefore, the ability to see smaller subendocardial infarcts and other parameters.

"Infarct size was highly predictive of mortality [and] heart failure rehospitalization, but was not predictive of reinfarction, and was predictive of the composite endpoint," Stone said. "The optimal cutoff to predict these events — that is balancing sensitivity and specificity — is approximately 20% of the left ventricle."

Disclosures:

- Stone reports receiving consulting fees/honoraria from TherOx and Velomedix.

AGENDA

6:00 PM Registration and Dinner

6:30 PM Introduction
Deepak Bhatt, MD, MPH (Chair)

6:35 PM Contemporary Management of ACS with Oral Antiplatelet Therapies:

Insights on Clopidogrel
Deepak Bhatt, MD, MPH

Insights on Prasugrel
Philippe Gabriel Steg, MD

Insights on Ticagrelor
Robert Harrington, MD

7:05 PM Antiplatelet Therapy: Long-Term Management Post-ACS
Marc Sabatine, MD, MPH

7:15 PM Case Studies

Case #1
Ajay Kirtane, MD, SM

Case #2
Paul Gurbel, MD

Case #3
Manesh Patel, MD

7:45 PM Question-and-Answer

8:00 PM Program Conclusion

FACULTY

Deepak Bhatt, MD, MPH (Chair)

Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Paul Gurbel, MD

Professor of Medicine
Johns Hopkins University School of Medicine
Baltimore, Maryland

Robert Harrington, MD

Arthur L. Bloomfield Professor of Medicine
Stanford University School of Medicine
Stanford, California

Ajay Kirtane, MD, SM

Associate Professor of Medicine
Columbia University Medical Center
New York, New York

Manesh Patel, MD

Associate Professor of Medicine
Duke University School of Medicine
Durham, North Carolina

Marc Sabatine, MD, MPH

Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Philippe Gabriel Steg, MD

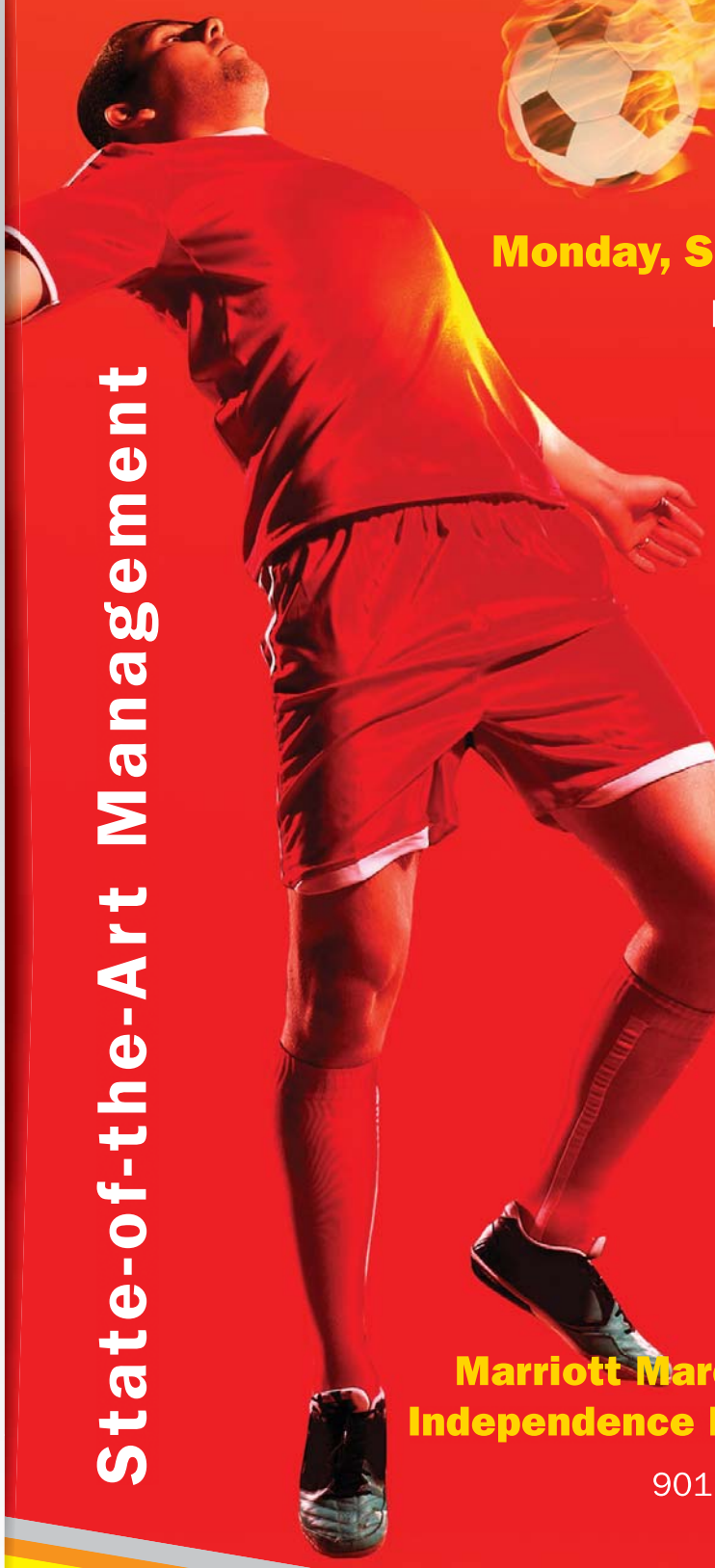
Professor of Cardiology
Université Paris–Diderot
Département de Cardiologie
Hôpital Bichat
Paris, France

REGISTER ONLINE AT: WWW.SYMPOSIAREG.COM/TCT

CME CERTIFIED 1.5 EARN CREDIT

Oral Antiplatelet Therapies for Acute Coronary Syndromes

State-of-the-Art Management



Monday, September 15, 2014

Registration and Dinner
6:00 PM – 6:30 PM

Symposium
6:30 PM – 8:00 PM

Marriott Marquis Washington, DC
Independence Ballroom, Salons A-E

901 Massachusetts Avenue NW
Washington, DC

Scan this code to register

An Evening Program at tct2014

This program is sponsored by VOX media

This activity is supported by an educational grant from AstraZeneca Pharmaceuticals LP.

COMPARE II: STEMI Patients See Strong Results with Both BES and EES

TOP 50 ABSTRACT

A biodegradable polymer-coated, biolimus-eluting stent (BES) is as safe as durable polymer-coated, everolimus-eluting stents (EES) at 3 years in STEMI patients, according to a subanalysis of the all-comers COMPARE II trial presented at TCT 2014.

Georgios Vlachojannis, MD, PhD, of Maasstad Hospital in Rotterdam, the Netherlands, and colleagues compared outcomes of the 569 STEMI patients — 21% of the total COMPARE II cohort — who underwent primary PCI with either EES (n=197; Xience, Abbott Vascular or Promus, Boston Scientific) or BES (n=372; Nobori, Terumo) at 12 European centers.

The groups were similar with regard to rates of the prespecified primary endpoint of MACE (cardiac death or nonfatal MI) along with clinically indicated TVR and TLR and definite/probable stent thrombosis (see Table).

Because of the low event rates, Vlachojannis told *TCT Daily* that the results "have to be regarded as hypothesis generating and remain to be confirmed by properly powered studies."

Biodegradable stents were designed to reduce late adverse events such as the stent thrombosis seen with first-generation DES; newer-generation, permanent-polymer DES, however, also have very low rates of late events, Vlachojannis noted. He added that in the STEMI subgroup of COMPARE II, both EES and BES had definite/probable stent thrombosis rates that were less than half those reported in the HORIZONS-AMI trial with first-generation DES.

"It appears that the opportunity to demonstrate safety benefits — ie, lower stent thrombosis rates — in COMPARE II by biodegradable polymer BES is challenged by the excellent safety performance of the durable polymer EES," Vlachojannis said.

He added that longer follow-up beyond 3 years is still needed to draw more definitive conclusions about any possible benefits of the biodegradable stent and that further studies dedicated to STEMI patients are also warranted.

Table. COMPARE II: Three-Year Outcomes in the STEMI Subgroup

	EES (n=197)	BES (n=372)	RR (95% CI)	*P* Value
MACE	7.1%	8.3%	1.17 (0.64-2.15)	.61
Clinically indicated TVR	2.0%	4.6%	2.25 (0.77-6.60)	.13
Clinically indicated TLR	1.5%	4.0%	2.65 (0.77-9.03)	.10
All-cause death	3.6%	4.3%	1.21 (0.51-2.89)	.67
Definite/probable stent thrombosis	1.5%	1.9%	1.24 (0.32-4.73)	.76

Disclosures:

- Vlachojannis reports no relevant conflicts of interest.

PARTNER: Post-TAVR Survival Higher in Overweight, Obese Patients

TOP 50 ABSTRACT

Overweight and obese patients undergoing transcatheter aortic valve replacement (TAVR) have lower mortality risks compared with normal and underweight patients, according to an analysis of data from the PARTNER trial released this week at TCT 2014. The findings, which embody the so-called obesity paradox, were confirmed even after adjustment for possible confounders.

Danny Dvir, MD, of St. Paul's Hospital in Vancouver, Canada, and colleagues evaluated a total of 2,519 patients from the PARTNER trial who underwent TAVR procedures. They stratified the patients by BMI and found that while heavier patients tended to be younger and have lower baseline STS scores and 6-minute walking test results, they had better survival compared with lower-weight patients (see Table).

Propensity matching that adjusted for imbalances between the obese and normal-weight patients confirmed the results for 1-year mortality (18.7% vs. 29.4%; *P*=.002). On multivariate analysis, obesity was an independent predictor of 1-year survival after TAVR compared with both normal weight (OR 1.37; 95% CI 1.05-1.78; *P*=.02) and underweight (OR 2.13; 95% CI 1.4-3.22; *P*<.001) patients.

Dvir told *TCT Daily* that the results of propensity matching negate the common claim that the obesity paradox is caused by differences in baseline characteristics.

"The mechanism in which non-morbid obesity is associated with improved outcomes is controversial," he continued, adding that one theory suggests normal-weight patients have a higher rate of non-purposeful weight loss and lower muscle strength. "Some consider patients with normal weight living in Western society as actually having a signal for cachexia."

Though this paradox has been studied extensively in other conditions and procedures, this is the first large evaluation of valvular heart disease patients treated with standard therapy, Dvir said. Although the paradox has yet to be fully explained, he noted, there are still a number of clinical implications of the findings, especially related to patient screening.

"We have learned that underweight patients … have poor outcomes after [surgical aortic valve replacement] or TAVR. Valve implantation in some underweight patients may be futile," he said, adding that morbidly obese patients have poor perioperative results but excellent longer-term survival. "Hence, the immense importance of excellent procedural and periprocedural care in morbidly obese patients," Dvir concluded.

Table. Baseline Characteristics and Post-TAVR Mortality by Weight[a]

	Underweight (n=109)	Normal Weight (n=1,029)	Overweight (n=800)	Obese (n=484)	Morbidly Obese (n=97)
Age, years	85.9	86.5	84.9	80.7	76.8
Baseline STS score	12.9 ± 3.9%	11.9 ± 4.5%	11.1 ± 3.6%	10.8 ± 3.7%	10.8 ± 3.9%
Baseline 6-minute walk test, meters	96	116	110	86	58
Mortality					
30 days	9.2%	7.7%	4.6%	4.1%	9.3%
1 year	33.2%	25.6%	21%	17.1%	17.6%

[a]*P* value for trend <.0001 for all but 30-day mortality, which had a value of .007.

Disclosures:

- Dvir reports no relevant conflicts of interest.

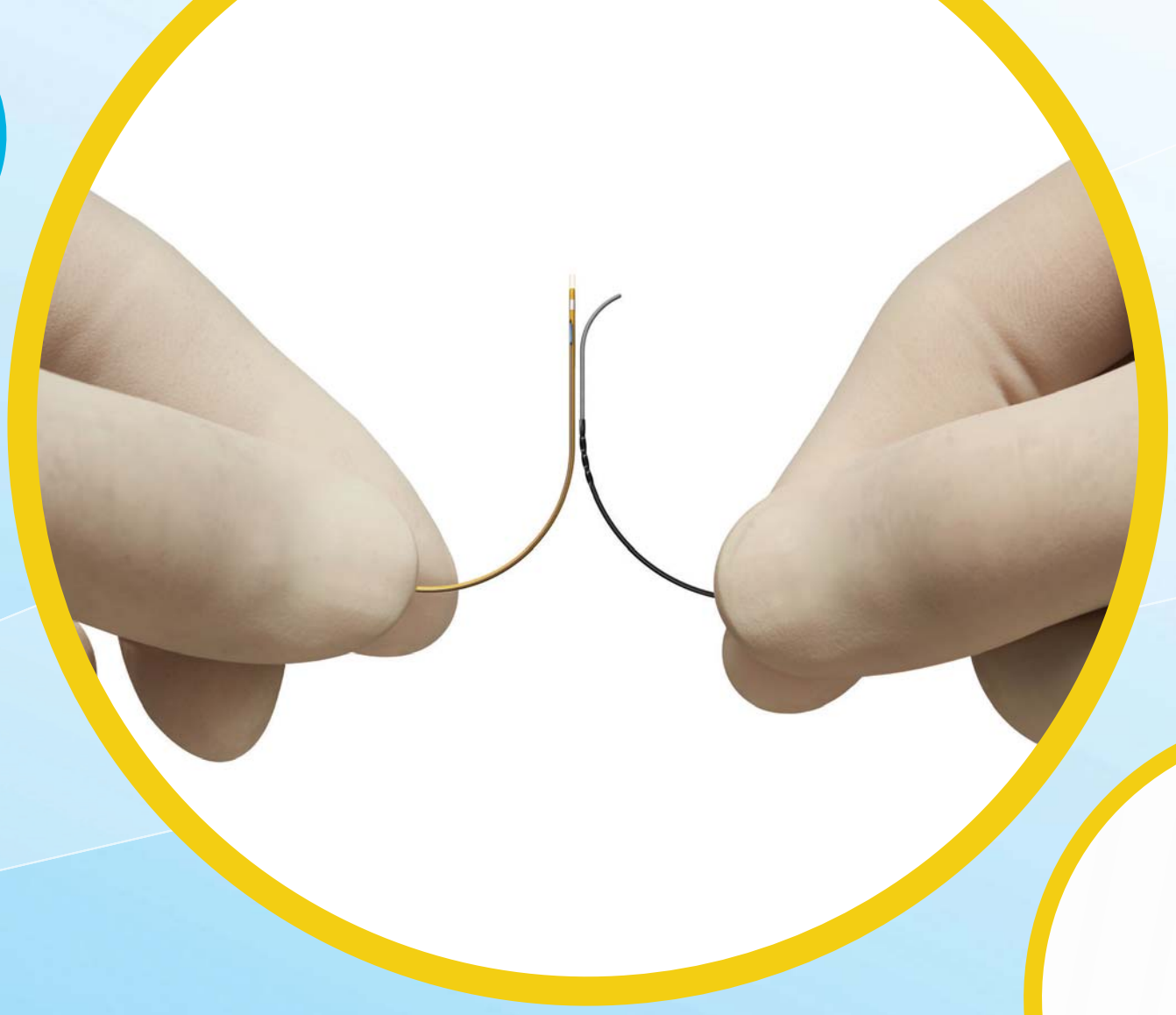
Medtronic

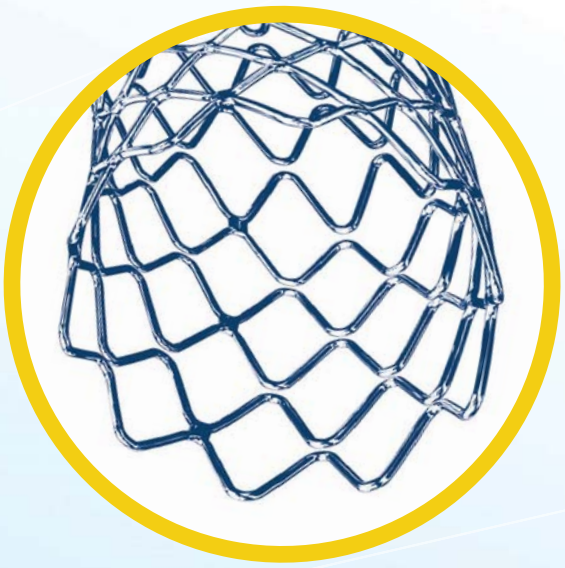
Interventional Portfolio

Delivering more *SOLUTIONS.*

Medtronic and ACIST Enter into US Co-Promotion

INNOVATION / EVIDENCE / SOLUTIONS





ACIST® Navvus™

RAPID EXCHANGE FFR MICROCATHETER

*Working together, we are bringing you the **RXi**™ system, the world's first rapid exchange FFR featuring the Navvus™ MicroCatheter:*

- *Use your guidewire of choice*
- *Maintain wire position*
- *Simple plug-and-play system*
- *Fiber-optic accuracy*

Innovating for life.

LAA Closure Edges Out Medical Therapy for Cost-effectiveness in AF

TOP 50 ABSTRACT

Transcatheter left atrial appendage (LAA) occlusion is more cost-effective than numerous pharmacologic strategies for stroke prevention in patients with nonvalvular atrial fibrillation (AF), according to a modeling study presented at TCT 2014.

Vivian W. Lee, BSc, PharmD, of the Chinese University of Hong Kong, and colleagues used a Markov model to compare LAA closure with seven different medical therapy strategies. The model simulated a cohort of 65-year-old patients with nonvalvular AF moving between different health statuses in cycles of 1 year.

Cost-effectiveness in terms of incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) favored LAA closure over almost all pharmacological strategies (see Table).

Additionally, LAA closure emerged as the preferred therapy in a one-way sensitivity analysis varied by HAS-BLED score and time horizons of 5, 10, 15 and 20 years.

The health states in the model included AF without event, with previous event and with ischemic cerebrovascular events, hemorrhage, MI and vascular or nonvascular events. Data on efficacy were derived from several previously published clinical trials, including ACTIVE, RE-LY, PROTECT AF and PREVAIL.

According to Lee, the better cost-effectiveness of LAA closure compared with medical therapy is not surprising because anticoagulant use can be accompanied by issues like overdosing and noncompliance that may lead to costly complications. "As a clinical pharmacist, I see patients struggling with drug-related problems every day," she said in an interview with *TCT Daily.* "LAA [occlusion] will have fewer issues since patients will only require daily aspirin therapy after the 45 days of warfarin therapy." She added that patients with high thrombotic and bleeding risks in particular would be ideal candidates for closure.

Lee also noted that while some may cite a lack of long-term data as a limitation of LAA closure, PROTECT AF demonstrated superiority at 4 years for closure compared with warfarin. In that trial, the Watchman device (Boston Scientific) yielded a nearly 40% RR reduction in the primary composite endpoint of stroke, systemic embolism and cardiovascular or unexplained death.

Disclosures:

- Lee reports support from Boehringer Ingelheim.

Table. LAA Closure vs. Medical Therapy

	Cost per QALY	ICER per QALY Gained with LAA Closure
Aspirin alone	$2,104	$5,115
Clopidogrel + aspirin	$4,179	$2,447
Warfarin	$2,972	$6,298
Dabigatran 110 mg	$4,876	Dominant[a]
Dabigatran 150 mg	$4,883	Dominant
Apixaban	$5,179	Dominant
Rivaroxaban	$5,672	Dominant

[a] Less costly and more effective.

SMILE: One-Stage PCI Superior for Non-STEMI and Multivessel CAD

In patients with multivessel CAD who experience non-STEMI, achieving complete revascularization in one-stage PCI produces better outcomes than does a multi-stage process, according to findings presented at TCT 2014.

For the SMILE trial, researchers led by **Gennaro Sardella, MD,** of Policlinico Umberto I, University of Rome in Italy, enrolled 500 non-STEMI patients slated to an early invasive strategy who had angiographic evidence of >70% diameter stenosis in multiple vessels. Patients were randomized to single-stage (n=253) or multistage PCI (n=247).

At 12 months, the rate of MACCE (primary outcome; all-cause death, reinfarction, rehospitalization for ACS, repeat revascularization or stroke) was lower in patients treated with one-stage PCI, as were rates of all-cause death, target vessel revascularization and bleeding (see Figure).

Bleeding differences early on

Early in the study period, the only significant difference between the two groups was bleeding, Sardella said. There were seven bleeding events in the multistage group (2.82%) vs. one in the one-stage group (0.39%; *P*=.01) during hospitalization but no additional bleeding events through 30 days.

All incidences of bleeding were minor to minimal, Sardella said, adding that a hypothesis for the increased bleeding in the multistage group is that the second procedure was more likely to be performed via transfemoral access rather than transradial access.

At 6 months, bleeding rates remained higher in the multistage group compared with the one-stage group (3.22% vs. 0.39%; *P*=.01), while the multistage group also had higher rates of MACCE (10.93% vs. 5.13%; *P*=.02) and all-cause death (7.69% vs. 3.16%; *P*=.02) compared with the one-stage group.

There were also differences between the groups in levels of myocardial enzymes after PCI. At baseline, patients had similar levels of troponin and myoglobin. Patients in the one-stage group had lower levels of troponin compared with those in the multistage group after their first procedure (0.54 ± 0.96 vs. 0.95 ± 1.28; *P*<.0001), though myoglobin levels did not differ. The one-stage group had higher levels of myoglobin compared with patients in the multistage group after their second procedure (79.31 ± 129.73 vs. 59.81 ± 34.88; *P*=.0230) but similar troponin level. CK-MB levels were equivalent between the two strategies both at baseline and after PCI.

12 months Clinical Events

SMILE TRIAL

Characteristics	SINGLE Staged (tot. =253)	MULTI Staged (tot. =247)	P value
MACCE – no. (%)	33 (13.04)	57 (23.07)	0.0036
Death – no. (%)	14 (5.53)	28 (11.33%)	0.02
Cardiac Death – no. (%)	9 (3.55)	13 (5.26%)	0.38
Stroke – no.(%)	1 (0.39)	0	1
Myocardial Infarction	7 (2.76)	9 (3.64)	0.61
Q – no. (%)	2 (0.78)	3 (1.21)	0.68
non-Q – no. (%)	5 (1.98)	6 (2.42)	0.76
UA needing Hospitalization	11 (4.34)	13 (5.26)	0.67
TVR – no. (%)	22 (8.69)	36 (14.57%)	0.05
Definite Stent thrombosis	1 (0.39)	1 (0.40)	1.00
Bleedings – no. (%)	4 (1.56)	12(4.85)	0.03

Figure

Noncardiac death drove results

In SMILE, "the superiority of one-staged complete coronary revascularization in terms of major events is mainly due to the unexplained higher incidence of noncardiac death," Sardella noted, adding that trial investigators do not yet have a hypothesis to explain the disparity.

Gennaro Sardella, MD

Sardella said that he and his colleagues undertook the current study because there is little to no guidance from U.S. and European professional societies on whether patients with non-STEMI and multivessel CAD should have all vessels treated simultaneously, or whether non-culprit lesions should be treated on an ad hoc basis.

Disclosures:

- Sardella reports receiving consultant fees/honoraria from Alvimedica, AstraZeneca, Biosensors, Boston Scientific and Terumo Medical.

Elixir®
MEDICAL CORPORATION

INNOVATION FOR LIFE®

A NEW ERA
IN VASCULAR RESTORATION

VISIT BOOTH #1354

DESyne® BD
Novolimus Eluting
Coronary Stent System

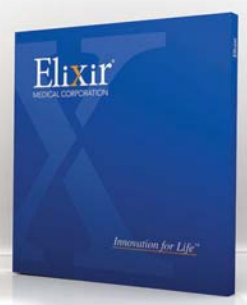
BIODEGRADEABLE COATING

DESolve®

DESolve 100
has gained
CE mark as
THE FIRST
BRS to achieve
100 µm strut
thickness.

DESyne®

New five-year
data demonstrating
superior safety and
efficacy to control.*



Elixir Medical Corporation specializes in developing products that combine state-of-the-art medical devices with advanced pharmaceuticals to provide innovative treatment solutions to patients worldwide.

www.ELIXIRMEDICAL.com

*Iqbal J et.al DESyne Novolimus Eluting Coronary Stent is Superior to Endeavor Zotarolimus Eluting Coronary Stent at 5-year follow-up: Final Results of the Multicentre EXCELLA-II Randomized Controlled Trial. EuroPCR 2014.

As powerful as
the organ
it's helping save.

Impella® The world's smallest heart pump. Supported by five clinical guidelines.*

Not only is Impella the smallest active flow heart pump, it's also the most powerful. That's because it directly unloads the left ventricle and delivers forward flow to the aorta. And since it uses standard guidewires and catheters, it's easy to insert, taking only minutes.

Learn more about the heart pump that has already redefined heart treatment for over 20,000 patients. For more information, go to **abiomed.com** or contact your local Abiomed sales representative.

ABIOMED®

Recovering hearts. Saving lives.

---

* 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Journal of American College of Cardiology 2013*
- "Bridge to Recovery "or "Bridge to Decision" for patients with acute, profound hemodynamic compromise: Class IIa

2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support. *The Journal of Heart and Lung Transplantation, 2013*
- Temporary mechanical support for patients with multi-organ failure: Class I

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. *Circulation 2012*
- STEMI and Cardiogenic Shock Class IIb
- STEMI and urgent CABG Class IIa

2012 Use of Mechanical Circulatory Support: American Heart Association. *Circulation 2012*
- Acutely decompensated heart failure patients: Class IIa

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. *Journal of American College of Cardiology 2011*
- High risk patients (section 5.6) Class IIb
- PCI and Cardiogenic Shock (section 5.2.3) Class I

HCS-EM00740 rA

20 Years Dedicated to Improving Patients' Lives

CORONARY

BIO ACTIVE STENT
3RD GENERATION

BIO ACTIVE STENT

Co-Cr BARE METAL STENT

BIO ACTIVE TECHNOLOGY

PTCA SC CATHETER

PTCA NC CATHETER

ASPIRATION CATHETER

DRUG ELUTING BALLOON

PERIPHERAL

SELF-EXPANDING STENT
SFA

BALLOON EXPANDABLE STENT
ILIAC/RENAL

PTA SC CATHETER

ASPIRATION CATHETER

HEXACATH

PIONEER IN BIO ACTIVE COATING

For any additional information, please contact Hexacath at
4 Passage Saint Antoine - 92500 Rueil-Malmaison - France - Tel.: +33 (0)1 41 39 01 92 - Fax.:+33 (0)1 41 39 01 99
www.hexacath.com

CANARY: Lipid Plaque Burden May Indicate Risk for Periprocedural Myonecrosis

Lipid plaque burden as assessed by near-infrared spectroscopy (NIRS) is moderately associated with periprocedural myonecrosis after percutaneous coronary intervention (PCI), reported researchers on Saturday at TCT 2014. Yet distal protection did not reduce the risk of periprocedural MI.

For the CANARY trial, **Gregg W. Stone, MD,** of Columbia University Medical Center, New York, and colleagues used the TVC Imaging system (Infraredx), which employs both NIRS and IVUS, to prospectively assess lipid core burden (graded 0-1,000) in 85 patients undergoing PCI in a single native coronary artery lesion at nine U.S. sites.

Gregg W. Stone, MD

Data showed a marked reduction in lipid content after PCI. The lipid core burden index for all lesions was a median of 143.2 (interquartile range [IQR] 74.3-236.4) before PCI and 17.9 (IQR 0.0-61.9) after (*P*<.0001). Similarly, the maximum lipid core burden index in any 4-mm long axial segment (maxLCBI4 mm) decreased from 448.4 (IQR 274.8-654.4) to 156 (IQR 75.6-312.6; *P*<.0001).

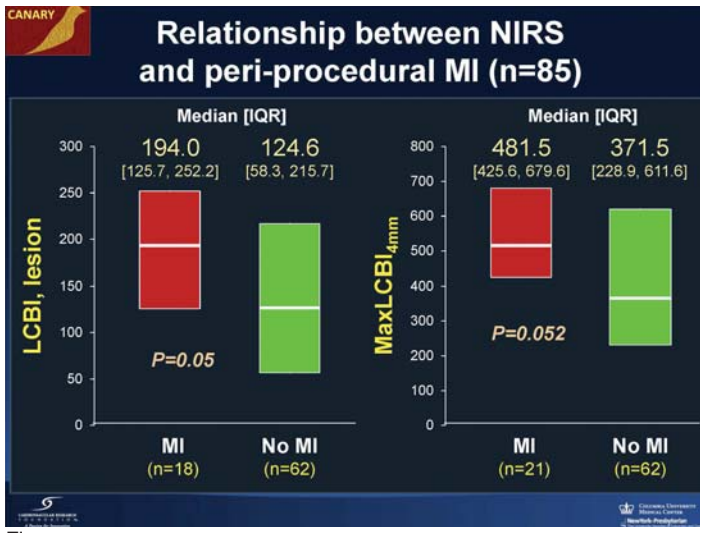
Twenty-one patients (24.7%) developed periprocedural MI, defined as peak cardiac troponin T, cardiac troponin I or CK-MB at least three times the upper limit of normal. Patients who experienced periprocedural MI tended to have higher lipid core burden than those who did not, though the difference did not reach statistical significance (see Figure).

Additional analyses indicated that, for all lesions, the area under the curve (AUC) was 0.64 (IQR 0.5-0.78), with an optimal cutoff for lipid core burden index to predict periprocedural MI of 144. In $maxLCBL_{4mm}$, the AUC was 0.63 (IQR 0.5-0.77) with a cutoff of 388.

Failure to reduce periprocedural MI

In a second comparison, the 31 patients in the cohort with a $maxLCBI_{4mm}$ ≥600 were randomized to PCI plus distal protection with the FilterWire EZ (Boston Scientific; n=14) or PCI alone (n=17).

Four patients assigned to PCI alone (23.5%) developed MI after intervention, compared with five patients assigned PCI plus distal protection (35.7%), indicating that the adjunctive treatment did not reduce the risk of post-procedural MI (RR 1.52; 95% CI 0.50-4.60).



Figure

Stone noted that the lack of an association between distal protection and periprocedural myonecrosis persisted regardless of the threshold used for biomarker levels.

"This was a small study, so it had limited power to detect differences in large MI or major procedural complications, and the chemograms were unblinded so we can't exclude a bias in the treatment of lipidic vs. non-lipidic appearing lesions," Stone said. "Nonetheless, a moderate relationship was demonstrated between the automated NIRS lipid parameters lipid core burden index and $maxLCBL_{4mm}$ and periprocedural myonecrosis. The relationship may be further strengthened by taking segmental lipid plaque burden into account."

Disclosures:

- Stone reports no relevant conflicts of interest.

EUROMAX Substudy: Bivalirudin Noninferior to Heparin Plus GPI for Myocardial Reperfusion

Results of a prespecified subanalysis of the EUROMAX trial presented Saturday at TCT 2014 show bivalirudin matches heparin plus glycoprotein IIb/IIIa inhibitor (GPI) use with regard to residual ST-segment deviation.

The findings reflect "comparable myocardial tissue reperfusion with the two strategies," said investigator **Jurrien M. ten Berg, MD,** of St. Antonius Hospital in Nieuwegein, the Netherlands.

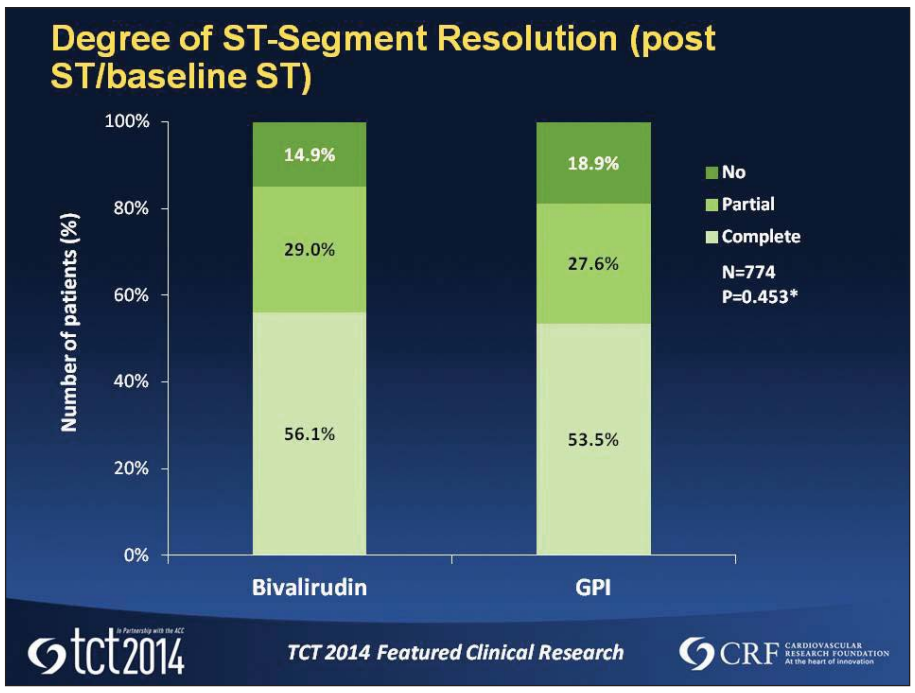
In the main EUROMAX trial, researchers at 65 European centers randomized 2,218 STEMI patients who were being transported for primary PCI to bivalirudin (0.75 mg/kg bolus followed by 1.75 mg/kg/h infusion) or to unfractionated heparin or enoxaparin (standard practice) with optional GPI use. They found that the bivalirudin strategy reduced short-term death and major non-CABG bleeding.

For the current analysis, ten Berg and colleagues looked at myocardial perfusion rates in the two study arms. Only patients from the nine hospitals that routinely used prehospital GPIs were included in the substudy.

Mean values for the primary endpoint of cumulative residual ST-segment elevation as measured by ECG at 1 hour post-procedure were 3.8 ± 4.9 mm in the bivalirudin group and 3.9 ± 5.2 mm in the heparin plus GPI group (*P*=.0019).

No differences in the degree of ST-segment resolution — whether none, partial or complete — were seen between the two groups (see Figure).

At 30 days, the combined rate of death and non-CABG major bleeding was lower for bivalirudin than for heparin plus GPI (3.5% vs. 6.3%; RR 0.55; 95% CI 0.30-1.01; *P*=.05). Protocol major non-CABG-related bleeding was 1.9% with bivalirudin and 5.2% with heparin plus GPI (RR 0.36; 95% CI 0.16-0.79; *P*=.008). Acute stent thrombosis rates were 8% and 2%, respectively (RR 4.10; 95% CI 0.88-19.21; *P*=.06). "We all know that primary PCI is the cause of reperfusion in patients with STEMI, but despite the success of primary PCI, there is microvascular damage in about one-third of these patients. Both antiplatelets and anticoagulants play a crucial role in preventing microvascular damage and improving myocardial tissue reperfusion," ten Berg said.



Figure

In support of his data, ten Berg recounted the double-blind ON-TIME 2 study, published in 2008 in the *Lancet*, which showed better ST-segment resolution 1 hour after PCI in patients who were pretreated with high-dose tirofiban in the ambulance.

"This translated to better outcomes at 1 year and [the advantage] was especially true for patients who presented early. However, this trial was not powered to detect a difference in clinical outcome," he said.

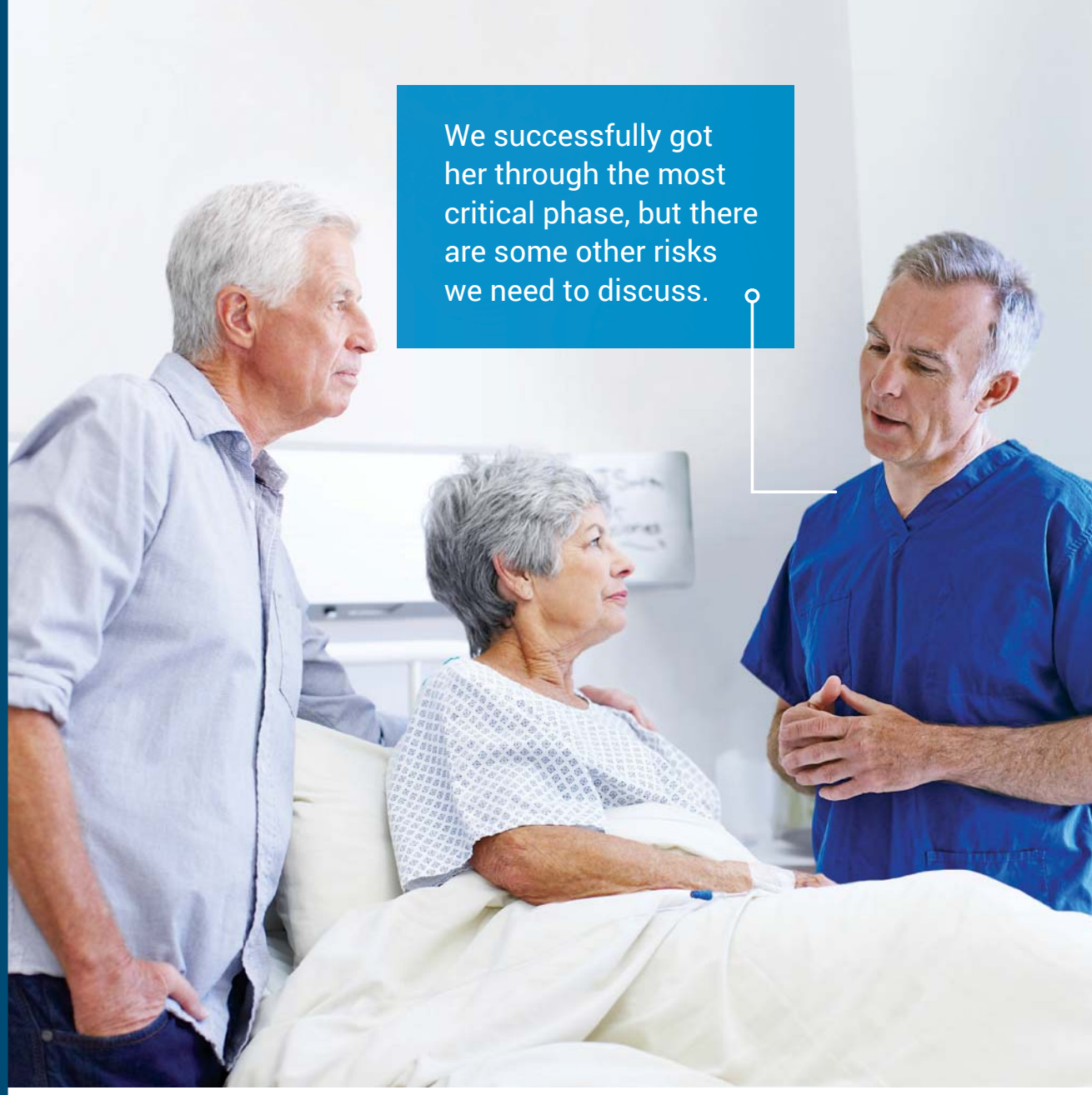
Disclosures:

- The EUROMAX trial was funded by The Medicines Company.
- ten Berg reports receiving speaker honoraria from The Medicines Company.

SUDDEN CARDIAC DEATH
post-PCI and post-MI

Assess It.
Discuss It.
Prevent It.

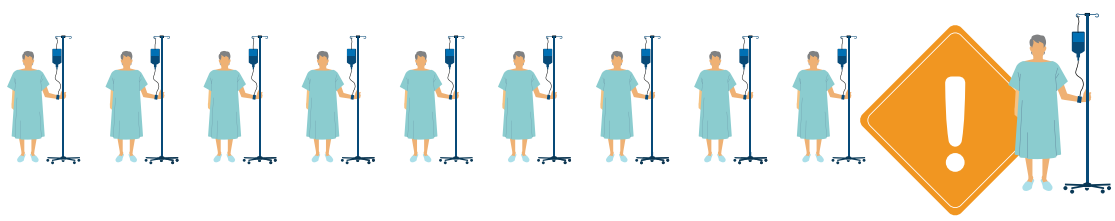
ZOLL®



High-risk post-PCI patients experience significant mortality during recovery from revascularization.

BOTTOM LINE

1 in 10 high-risk post-PCI patients **die in the first 3 months,**



with about

60% of this mortality due to

SUDDEN CARDIAC DEATH.[1,2]

SOURCES: **1.** Halkin A et al. Prediction of Mortality After Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction: CADILLAC Risk Score. *JACC* 2005;45:1397–1405. **2.** Stone G et al. Prevention of Sudden Cardiac Arrest Post PTCA in High-Risk Patients. http://www.theheart.org/article/1202823.do (April 2011).

20C0313 Rev FI

NAC, Sodium Bicarbonate Combo Fails to Improve Renal Protection in High-Risk Patients

The combination of N-acetylcysteine (NAC) and sodium bicarbonate is no more effective than either agent alone in reducing the incidence of contrast-induced nephropathy (CIN) in patients with pre-existing renal impairment undergoing cardiac catheterization.

However, results of the randomized CONTRAST study, presented at TCT 2014, showed a strong trend toward reduced CIN in patients who received prehydration plus oral NAC compared with IV sodium bicarbonate alone.

For the multicenter trial, **Huay Cheem Tan, MBBS,** of National University Heart Centre in Singapore, and colleagues analyzed 453 patients with a glomerular filtration rate of 15 to 60 mL/min/1.73m^2 who were randomly assigned to one of three renoprotective regimens:

- Saline plus high-dose oral NAC (1.2 g twice daily for 3 days, beginning 1 day prior to the procedure [n=153]).
- IV sodium bicarbonate (3 mL/kg/h for 1 hour before and 1 mL/kg/h during and for 6 hours following the procedure [n=149]).
- The same dose of sodium bicarbonate plus oral NAC 1.2 g twice daily for 3 days (n=151).

At 2 to 3 days after the procedure, there was no difference between the combined-regimen and either the NAC or sodium bicarbonate arms in rates of CIN — defined as ≥25% increase over baseline serum creatinine concentration or a ≥44 µmol/L increase in serum creatinine concentration within 48 hours of contrast exposure. The incidence was lowest among patients who received NAC alone (see Figure). Overall, 45 patients developed CIN, but the condition persisted through 30 days in only six patients (13.6%; two in each group).

Maximum rise in serum creatinine and peak creatinine level were similar among all groups both within 48 hours and at 30 days, and there was no difference in rates of mortality or need for dialysis.

Logistic regression analysis showed that contrast volume (OR 2.11; 95% CI 1.40-3.16) and female sex (OR 2.51; 95% CI 1.25-5.05) were independent predictors of CIN.

The treatment groups were similar in terms of baseline mean serum creatinine, ethnicity (most patients were Chinese or Malay), type of procedure (cath with or without PCI) and mean contrast volume.

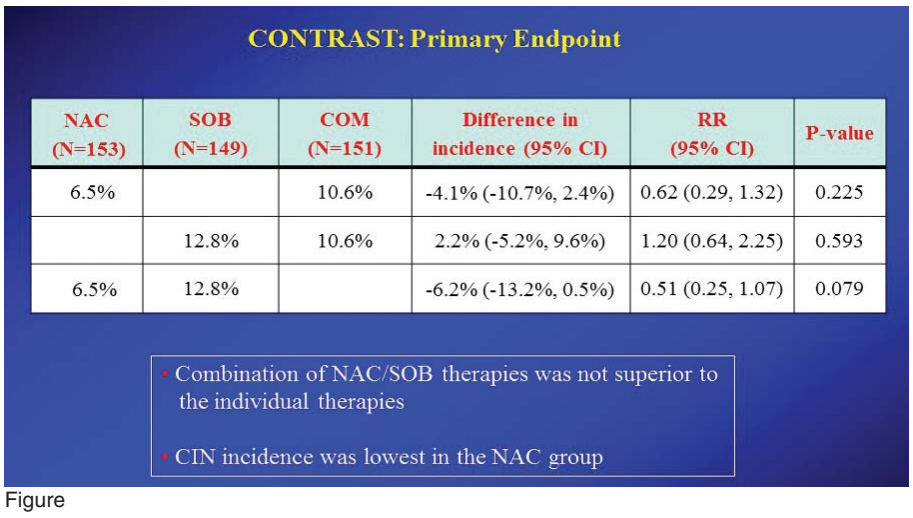
Among the study limitations was the difference in fluid volume supplementation in the abbreviated sodium bicarbonate regimen compared with the oral NAC with sustained saline arm. Tan also noted that due to slow enrollment, the study did not reach its target of 660 patients and thus was underpowered to demonstrate the hypothesized effect of the combined regimen.

In response to one discussant's comment that the combination has been commonly used without much evidence, Tan said, "If you look at the REMEDIAL trial, the combination … was very impressive. They're looking at a 1.9% CIN rate, which is incredible in a real-world population. That's why we were interested in this combination therapy."

Given the current results, however, Tan concluded that prehydration plus NAC may be the preferred real-world renoprotective regimen due to its ease of administration and low cost.

Disclosures:

- Tan reports no relevant conflicts of interest.



Figure

Pooled Trial Data Show No Stent Thrombosis Reduction with Biodegradable Stent

At 1 year, rates of stent thrombosis are similar between patients who received a biodegradable polymer-coated biolimus-eluting stent (BES) and those given a durable-polymer everolimus-eluting stent (EES), according to data presented Saturday at TCT 2014.

Pieter C. Smits, MD, PhD, of Maasstad Hospital in Rotterdam, the Netherlands, and colleagues pooled data on 5,942 patients from the all-comers COMPARE II and NEXT trials to investigate the stent thrombosis rates of BES (Nobori, Terumo Medical Corporation) compared with EES (Xience, Abbott Vascular or Promus, Boston Scientific).

Clinical outcomes of BES vs. EES

Rates of Academic Research Consortium-defined definite stent thrombosis were equivalent between the BES and EES at 1 year both overall and when separated into early and late events (see Table). Rates of definite/probable stent thrombosis also did not differ.

In addition, clinical outcomes including mortality, MI, target lesion revascularization and target vessel revascularization were similar between the BES- and EES-treated patients (see Figure).

"Both stents showed an equivalent safety and efficacy profile up to 1 year in a large all-comers pooled population from a variety of geographic areas and clinical practice," Smits said. On multivariate analysis, he added, use of BES vs. EES failed to predict any difference in stent thrombosis, whether definite (OR 2.52; 95% CI 0.92-6.89; *P*=.07) or definite/probable (OR 1.25; 95% CI 0.57-2.72; *P*=.58).

The advantage of using a biodegradable polymer-coated BES over a durable polymer EES is still unclear, Smits said. He added that a longer follow-up study is required to demonstrate the potential advantage of biodegradable polymer-coated BES in clinical practice.

Table. Definite Stent Thrombosis Rates in COMPARE, NEXT Pooled Data

	BES (n=3,412)	EES (n=2,530)	RR (95% CI)	*P* Value
Overall at 1 Year	0.50%	0.20%	2.52 (0.93-6.83)	.07
Early	0.38%	0.16%	2.41 (0.79-7.38)	.14
Late	0.12%	0.04%	2.97 (0.33-26.53)	.40

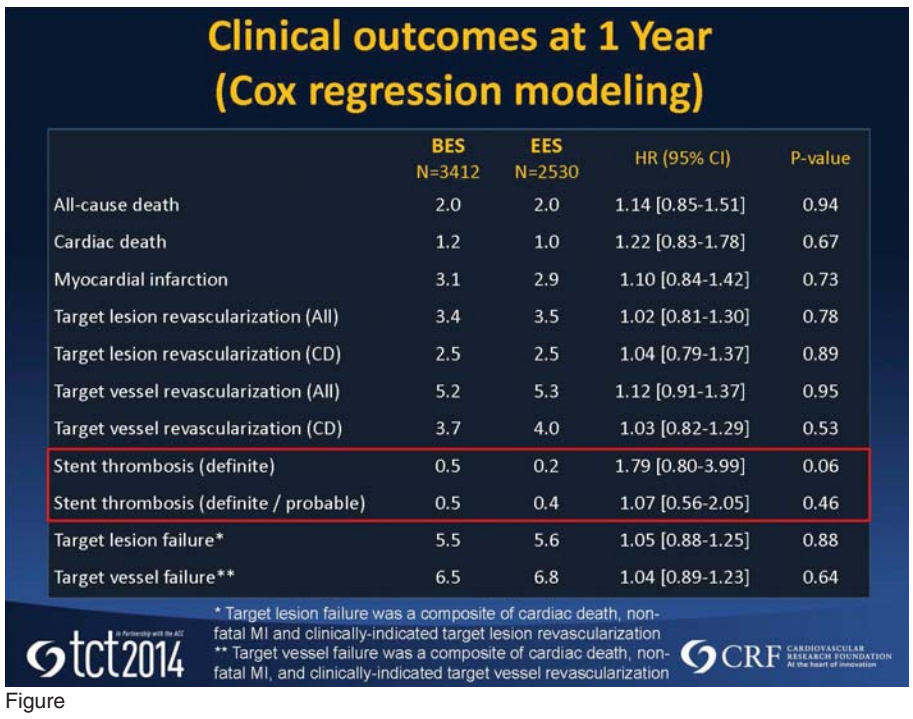
COMPARE II, NEXT trials

COMPARE II and NEXT were both open label, randomized controlled studies that evaluated the safety and efficacy of BES compared with EES. Though the trials had indicated similar outcomes between the two devices, they "were not powered to detect differences in low-frequency events such as stent thrombosis," Smits said.

Smits noted several study limitations. For example, only 26% of potential trial participants undergoing PCI were ultimately enrolled in the COMPARE II trial, so selection bias cannot be ruled out. The power of the COMPARE II and NEXT trials also was attenuated by low rates of the events used for sample-size calculation. In addition, both trials were designed as noninferiority studies at 12 months. Any further analysis of the data would be "posthoc," he said.

Disclosures:

- Smits reports receiving consultant fees/honoraria from Abbott Vascular and institutional grants from Abbott Vascular, St. Jude Medical and Terumo Medical Corporation.



Figure

LOVEYOURLIMBS.COM

FIGHT PAD WITH A SINGLE STENT STRATEGY.

LOVE YOUR LIMBS.COM

LIFESTENT® SOLO™
Vascular Stent System

LIFESTENT® 200MM TRIAL*
LifeStent® Solo™ Delivery System Study

- **91 mm** Mean Lesion Length
- **81.5%** Primary Patency at 12 Months
- **91.2%** Freedom from TLR at 12 Months
- **1.6%** Fracture Rate at 12 Months

*PMA Supplement P070014/S022

BARD | PERIPHERAL VASCULAR

SPOTLIGHT ON

TCT Live Case Transmission Sites

Live case transmission sites span 21 locations around the globe and are broadcast in high-definition to the Main Arena, Coronary Theater and Structural/Endovascular Theater at TCT 2014. In a continuing series, we talk with **Stefan Verheye, MD, PhD,** of ZNA Middelheim Hospital (Antwerp, Belgium).

TCT Daily: Tell us about your institution and any interesting location facts.

Stefan Verheye, MD, PhD

Dr. Verheye:

The Antwerp Cardiovascular Center at ZNA Middelheim is one of Belgium's largest cardiology departments. We offer a wide range of interventional procedures in coronary artery disease, structural heart disease, electrophysiology and heart failure, and we have developed a large cardiac rehabilitation program.

Antwerp is the capital of the Antwerp province of Belgium. The city's population is more than 500,000, making it the country's second most populous. It has one of the largest seaports in Europe and is well known as a mainstay of the diamond trade.

TCT Daily: On what types of procedures do you focus? How does your team approach unique and/or complex cases?

Dr. Verheye:

Working at a tertiary referral center we are faced with a huge spectrum of cardiovascular diseases, which makes for a range of simple to very complex cases. We have always been very focused on various interventional strategies for complex coronary artery disease, such as left main and bifurcation lesions. Over the past 5 to 7 years, we have redirected our focus towards structural heart disease (ie, percutaneous treatment of valvular disease, closure of atrial septal defect, ventricular septal defect, left atrial appendage [LAA], patent foramen ovale and use of partitioning devices for heart failure).

Unique and complex cases are generally discussed by a group of experienced interventional cardiologists. In addition, valvular cases are discussed within a dedicated heart team of interventional cardiologists and cardiac surgeons.

TCT Daily: On what types of research does your group focus? Have there been any significant publications from your site over the past 5 years?

Dr. Verheye:

Our group has focused on performing device-oriented, first-in-man studies in interventional cardiology. We have been fortunate to participate in many of these studies introducing innovative technologies in humans, which has enabled us to be at the forefront of progress in interventional cardiology. This ranges from use of the latest drug-eluting stents to implementation of innovative bioresorbable scaffold technology, percutaneous treatment of refractory angina by an hourglass-shaped stent in the coronary sinus, LAA closure, novel closure devices, debulking strategies in aortic valve disease and new percutaneous aortic and mitral valves. We have also evaluated innovative technologies and performed mechanistic studies on the preclinical side.

TCT Daily: Where do you see the future of interventional cardiology headed? How do you see the next 5 years of your institution?

Dr. Verheye:

I believe that we will see an even larger evolution of bioresorbable scaffold technology, which will be progressively implemented in practice, eventually replacing current metal stent technology.

In addition, I anticipate further penetration of second- and third-generation percutaneous aortic valves and the emergence of percutaneous mitral repair/replacement possibilities. I strongly believe that we will be dealing with more and more complex lesions and that a strong interactive team including cardiovascular surgeons needs to be established. More and more hybrid procedures will occur, and that is something for which a tertiary center needs to be prepared.

TCT Daily: What are you most looking forward to at TCT 2014?

Dr. Verheye:

As usual, the sessions presenting the late-breaking trials, the first report investigations and live cases constitute the highlights of TCT. As with every year, I am very much looking forward to innovative technology. TCT is a very important event, not only in refreshing and expanding our scientific knowledge but also in establishing or maintaining our professional and social networks.

Art from the Heart Exhibition Returns to TCT

Akiva Huber, formerly chief radiographer in the intensive cardiology division at Rambam Medical Center in Haifa, Israel, is an artist whose love for sculpture and science converges in the stunning wood and bronze works that he displays at galleries and exhibitions around the world.

Huber and TCT began their collaboration with Huber's first *Art from the Heart* exhibition at TCT 2001. In addition to being exhibited at the conference, Huber's work also forms part of TCT's Career Achievement Award. Each year since 2004, winners have been presented with a sculpture by Huber. Titled *The Heart of the Matter-2,* it merges art and science and is the perfect representation of career and academic excellence in interventional cardiology. An extension of Huber's original sculpture *The Heart of the Matter-1,* which represents a lovers' embrace, *The Heart of the Matter-2* also depicts a man and woman embracing, creating the outline of a human heart. The space within resembles an apple.

Huber will host his Art from the Heart exhibition, featuring dozens of limited-edition sculptures for viewing and purchase, on the L Street Bridge just outside the Exhibit Hall Saturday through Tuesday from 9 a.m. to 6 p.m.

VISIT US AT
TCT BOOTH
1342

CorPath
Precision Vascular Robotics

ROBOTIC PCI:
PRECISION AND PROTECTION FROM OCCUPATIONAL HAZARDS

A CORPATH® BREAKFAST SYMPOSIUM AT TCT | TUESDAY, SEPTEMBER 16, 2014

BREAKFAST: 6:30 AM | **PROGRAM:** 7:00 AM – 8:00 AM

LOCATION: Walter E. Washington Convention Center, Room 144A

CHAIRS: Ehtisham Mahmud, MD | Giora Weisz, MD

SYMPOSIUM AGENDA:

7:00 AM	Opening Remarks	
7:05 AM	PCI: A Personal Perspective	Spencer B. King III, MD
7:15 AM	Robotic Angioplasty: Precision and Protection	Giora Weisz, MD
7:25 AM	Improve Clinical Outcomes with Robotic Assistance	Paul Campbell, MD
7:35 AM	Case Review: Complex Robotic-assisted PCI	Ehtisham Mahmud, MD
7:50 AM	Discussion and Q&A	
8:00 AM	Adjourn	

SEATING IS LIMITED. RESERVE YOUR SEAT AT
WWW.TCTCONFERENCE.COM/SATELLITEPROGRAMS

If you wish to register by email, please email TCTReg@cmrus.com
with your name, contact information, and the title of the symposium.

SPONSORED BY:
Corindus Vascular Robotics

A Breakfast Meeting at
tct2014

PN 162-02993 Rev A

Lively Debate on Use of TAVR for Lower-Risk Patients

Based on encouraging data from non-randomized trials on intermediate-risk patients and the usage patterns in lower-risk patients in Europe, **Nicolo Piazza, MD, PhD,** of McGill University Health Center, Montreal, Canada, argued that clinical indications for transcatheter aortic valve replacement (TAVR) in the United States should be expanded to lower-risk cohorts. But during a debate at TCT 2014, **Michael J. Mack, MD,** of Baylor Health Care System, Dallas, Texas, advised caution since the noninferiority of TAVR vs. conventional surgical aortic valve replacement (SAVR) has yet to be proven in randomized trials.

Low-risk patients receiving TAVR

Piazza stated that a lack of universally accepted criteria for surgical risk that clearly distinguishes between risk categories is one of the main obstacles in establishing a TAVR trial for low-risk patients.

Among the data supporting use of TAVR in lower surgical risk patients is a study that he and colleagues conducted in 3,666 consecutive patients with symptomatic severe aortic stenosis who underwent TAVR (n=782) or surgery (n=2,884) at three European centers. The study, published last year in the *JACC: Cardiovascular Interventions* found similar cumulative all-cause mortality at 30 days and 1 year among propensity-score matched TAVR and SAVR patients at intermediate surgical risk.

> "Appropriate surgical and TAVR risk scores are currently lacking, which may provide physicians with better guidance in the treatment of patients."
>
> - Nicolo Piazza, MD, PhD

Furthermore, Piazza noted that compared with patients at calculated high risk, well-selected patients at intermediate or low risk, as defined by STS score, experience favorable clinical outcomes following TAVR.

Piazza added that there is a systematic fall in surgical risk scores in Europe, where more lower-risk patients are currently being treated than in the United States. "Appropriate surgical and TAVR risk scores are currently lacking, which may provide physicians with better guidance in the treatment of patients," he said. "And, needless to say, we are awaiting the results of the SURTAVI and PARTNER IIA intermediate-risk trials."

Nicolo Piazza, MD, PhD

Michael J. Mack, MD

Into the unknown

In his rebuttal, Mack highlighted data from Messé and colleagues recently published in *Circulation* showing that clinical stroke after SAVR was more common than reported previously, more than double for this same cohort in the STS database (17% vs. 7%). In addition, this study found that silent cerebral infarctions were detected in more than half of stroke-free patients.

Mack said that despite recent studies demonstrating TAVR's superiority to medical therapy in inoperable patients and its noninferiority to SAVR in high-risk patients, without supporting evidence from randomized trials there are too many areas of uncertainty to fully embrace TAVR implementation in this cohort.

In addition to awaiting outcomes of PARTNER IIA and SURTAVI, "we also don't know the long-term durability or the consequences of paravavular leak," he added.

Mack cited data from a study he and colleagues conducted, which showed that among patients undergoing TAVR at U.S. centers in the STS/ACC TVT Registry, device implantation success was 92%, the overall in-hospital mortality rate was 5.5% and the stroke rate was 2%. However, he further emphasized that long-term follow-up is essential to assess continued efficacy and safety.

Mack concluded that TAVR will inevitably "creep" into treatment considerations for intermediate-risk patients, and the outcomes of TAVR will continue to improve with the advent of new devices and ongoing operator experience.

Disclosures:

- Piazza reports serving as a proctor and consultant for Medtronic.
- Mack reports off-label use of MitraClip (Abbott Vascular) and transcatheter aortic valves and serving on the executive committee of the PARTNER trial.

PFO Closure for Stroke: A Call to Revise the Guidelines

An updated guideline issued this year by the American Heart Association and American Stroke Association (AHA/ASA) regarding the closure of patent foramen ovale (PFO) for cryptogenic stroke revised an earlier document to indicate that current data do not support a benefit in this patient population.

At TCT 2014, neurologist **David E. Thaler, MD, PhD,** of Tufts University School of Medicine, Boston, Mass., argued that the new recommendation — class III, level of evidence A — should be upgraded.

The 2014 update in the journal *Stroke* states: "For patients with a cryptogenic ischemic stroke or transient ischemic attack and a PFO without evidence for deep vein thrombosis, available data do not support a benefit for PFO closure (class III, level of evidence A)." The recommendation from the original guideline published in 2011 stated: "There are insufficient data to make a recommendation regarding PFO closure in patients with stroke and PFO (class IIb, level of evidence C)."

"I submit that the recommendation of class III evidence needs to be changed," Thaler said. "The [AHA/ASA] committee erred in interpreting negative trials. I think they should have supported at least a class IIb recommendation, maybe even class IIa, but certainly not class III."

Changes to classification

During his presentation, Thaler discussed the overall classification of guideline recommendations and the changes to the level of evidence from 2011 to 2014. Previously, class III evidence indicated that risk was equal to or greater than the benefit of a procedure or treatment, which therefore should not be performed or administered since it is not helpful and may be harmful. Now, a new division within class III can indicate that a procedure or treatment is either harmful or there is no proven benefit. "The [AHA/ASA] writing committee chose this 'box' to put the PFO closure story into — no proven benefit," Thaler said.

He noted that there is a common fallacy that a superiority trial that is not positive is the same as neutrality or equivalence of treatment. "Failing to prove that two populations are different is not the same as proving that two populations are the same," he said.

A class IIb categorization of PFO closure for cryptogenic stroke would indicate that benefit outweighs risk, according to Thaler. "Nobody has made the argument that [PFO closure] is a particularly risky intervention. The trials did not have a strong suggestion that there was risk," he said.

In the guideline, the committee wrote, "Although the point estimates favored device closure to various degrees in each trial, none of the studies demonstrated a statistically significant finding for their primary endpoint in an intention-to-treat analysis."

Thaler said the committee incorrectly declared neutrality despite the fact that the confidence interval does not rule out potential benefit and point estimates are favorable.

Moving forward

Recently, Thaler, along with **Jeffrey L. Saver, MD, John D. Carroll, MD,** and **Richard W. Smalling, MD, PhD,** submitted a letter to Stroke asking for a correction of the class III recommendation, stating that "it is an extreme violation of the norms of evidence-based medicine to conclude that there is definitely no benefit of an intervention when the best estimate of treatment effect available from randomized controlled trials actually suggests benefit."

During a panel discussion about this issue, **Sanjay Kaul, MD,** from Cedars-Sinai Medical Center, Los Angeles, Calif., said he does not discriminate between class IIIa or class IIb recommendations. "I leave it up to the patient's judgment and preference. I tell them that the evidence is not very strong; it is weak at best. This is an option that is available … off label. But I still do not tell them that this is evidence based," he concluded.

Sanjay Kaul, MD

Disclosures:

- Thaler reports receiving grant/research support from the National Institute of Neurological Disorders and Stroke as well as consultant fees/honoraria from Coherex and St. Jude Medical.
- Kaul reports receiving consultant fees/honoraria/serving on the speaker's bureau for AstraZeneca, the FDA, Merck/Schering Plough and The Medicines Company and having equity in Cordis.

PCI for CTO Ups Survival vs. Medical Therapy, CABG

Treatment of chronic total occlusion (CTO) with PCI improves survival and reduces adverse events at 1 year compared with medical therapy and CABG surgery, according to data presented at TCT 2014.

Salvatore D. Tomasello, MD, of University of Catania, Italy, and colleagues conducted a 12-month prospective, phase 1 study using data from the Italian Registry of Chronic Total Occlusion (IRCTO), which enrolled 1,777 patients with at least one CTO (>3 months duration) in a main coronary artery (>2.5 mm diameter) at 12 Italian centers. Those with prior CABG were excluded.

Patients were divided into three study arms based on their treatment strategy: medical therapy (n=826), PCI (n=776) or CABG (n=175). Those managed by medical therapy were older in comparison with the other groups, and they more frequently had chronic lung disease and severely impaired left ventricular ejection fraction. Patients managed with CABG had higher prevalence of three-vessel disease.

Difference still seen after adjustment

One-year rates of MACCE were 2.6% for PCI, 8.2% for medical therapy and 6.9% for CABG (*P*<.01). Rates of cardiovascular death were 1.4%, 4.7% and 6.3%, respectively (*P*<.001).

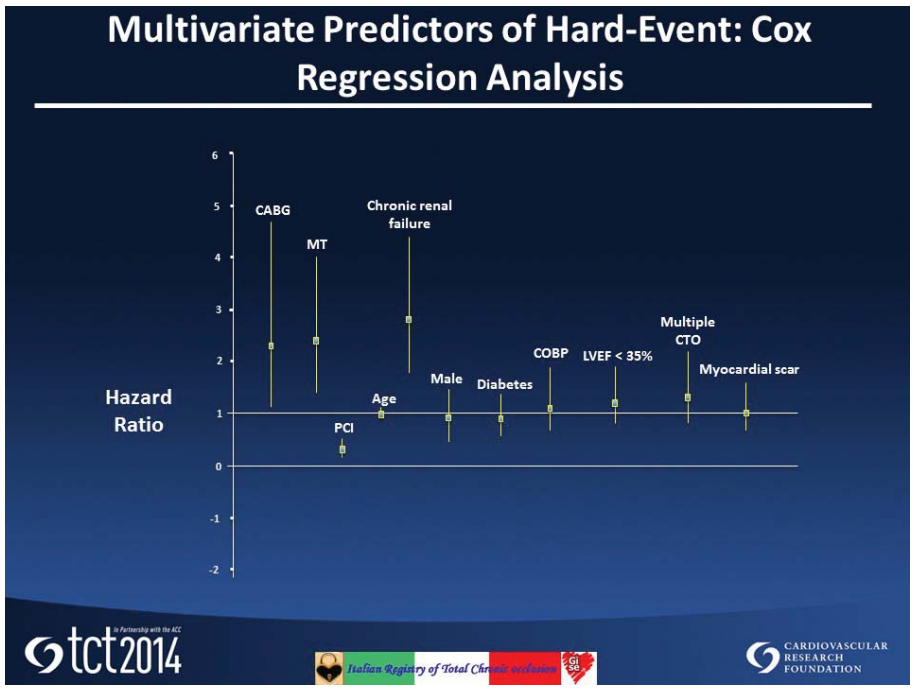
"In the unadjusted results, it seems clear that medical therapy had a higher rate of death, MI and rehospitalization in comparison to patients managed with PCI; surgery had a higher rate of death and stroke in comparison to the other groups," Tomasello said. "PCI was able to achieve a better outcome in comparison to patients managed with medical therapy or compared to surgery. These [results], of course, may be due to the difference in baseline characteristics."

Salvatore D. Tomasello, MD

Yet on multivariate Cox regression analysis, treatment with CABG or medical therapy and chronic renal failure all were identified as independent predictors of MAACE at 1 year (see Figure). In addition, after propensity score matching, patients treated with PCI rather than medical therapy showed lower rates of death (1.5% vs. 4.4%; *P*<.001), acute MI (1.1% vs. 2.9%; *P*=.03) and rehospitalization (2.3% vs. 4.4%; *P*=.04).

Quality of life vs. prognosis

After hearing the data, session moderator **David E. Kandzari, MD,** from the Piedmont Heart Institute, Atlanta, Ga., asked about quality of life, stressing that, by his count, this is approximately the fifteenth study to suggest improved survival in utilizing PCI to treat CTO.



Figure

"While there is a remarkable theme, or consistency, … we also have to be very cognizant of the benefits of CTO revascularization independent of survival, namely with quality-of-life measures," Kandzari said, noting that there may be different standards of success for CTO compared with less severely blocked lesions.

Tomasello agreed and — although he did not present data to support these claims — said that the IRCTO researchers did monitor such issues. "We observed an improvement of the symptoms in all the arms of the study," Tomasello said. However, he emphasized that the goal of CTO treatment should not rest only on improving symptoms, but rather it may be "more important to improve the prognosis of the patient. Maybe we can achieve those results."

Disclosures:

- Tomasello reports no relevant conflict of interests.
- Kandzari reports relationships with multiple device companies.
- Study supported by the Italian Society of Invasive Cardiology.

(ABSORB II, continued from page 1)

in a 2:1 fashion to receive everolimus-eluting bioresorbable scaffolds (Absorb, Abbott Vascular; 335 patients and 364 lesions) or metallic stents (Xience, Abbott Vascular; 166 patients and 182 lesions) at 46 sites in Europe and New Zealand. All patients underwent coronary angiography, IVUS and IVUS-virtual histology before and after device implantation. One-quarter had diabetes, and about 20% presented with unstable angina. All but two lesions in the metallic stent group were predilated.

On quantitative IVUS, both preprocedural vessel area (*P*=.02) and plaque (*P*=.01) were larger in the metallic stent group compared with the bioresorbable scaffold group, but rates of clinical success were similar.

Dilatation pressure was higher (*P*=.01) and balloon diameter at the highest pressure during implantation or postdilatation was larger (*P*=.02) in the metallic stent group. Therefore, the acute gain in minimum lumen diameter and area, as well as the final minimum lumen diameter and area, were larger in the metallic stent group compared with the bioresorbable scaffold group (*P*<.001 for all).

Cumulative angina rates at 1 year were lower with the bioresorbable scaffold than with the metallic stent (22% vs. 30%; *P*=.04), yet results from the Seattle Angina Questionnaire showed no difference between the devices. All clinical secondary outcomes also were similar, although there were trends toward more MI and less revascularization with the bioresorbable scaffold (see Figure). Two instances of scaffold thrombosis were observed in the bioresorbable scaffold group, both within 2 days.

Clinical Outcomes

Cumulative incidence in percentage	Absorb 335 pts	Xience 166 pts	*p* value
Composite of cardiac death, target vessel MI and clinically indicated target lesion revascularization (TLF, DoCE)	**4.8 %**	**3.0 %**	**0.35**
Cardiac death	0 %	0 %	1.00
Target vessel MI	4.2 %	1.2 %	0.07
Clinically indicated TLR	1.2 %	1.8 %	0.69
All TLR	1.2 %	1.8 %	0.69
Composite of all death, all MI and all revascularization (PoCE)	**7.3 %**	**9.1 %**	**0.47**
All death	0 %	0.6 %	0.33
All MI	4.5 %	1.2 %	0.06
All revascularization	3.6 %	7.3 %	0.08

Figure

According to the *Lancet* paper, the "reported reduction of angina through adverse event reporting warrants further clinical and physiological investigation."

Data on the trial's co-primary endpoints — vasomotion and minimum lumen diameter after nitrate administration minus the post-procedure value — will be reported at 3 years. Serruys commented in a press conference that when ABSORB II commenced, common practice was to be "overcautious" with deploying bioresorbable stents because of concern over the fragility of the polymer. Now, he said, "this is something that we have corrected."

Disclosures:

- ABSORB II was funded by Abbott Vascular.
- Serruys reports serving on the advisory board of Abbott Vascular.

(FFR Guidance, continued from page 1)

were well matched.

After stenting of the main vessel, specific criteria were used to determine the need for side branch stenting protocol in both groups. In the FFR group, the trigger was a measurement <0.8, and in the angiography group, the protocol was initiated by an ostial side branch diameter >70%, type B or C dissection and TIMI flow <3. If those criteria were met, kissing balloon inflation was performed. If criteria were still met after kissing balloon inflation, side branch stenting was performed followed by a final kissing balloon inflation.

Shao-Liang Chen, MD

FFR guidance was associated with a reduced rate of attempted side branch stenting (25.9% vs. 38.1%), but also a lower success rate among attempted cases (77.3% vs. 83.6%). At 1 year, rates of composite MACE — including cardiac death, MI and target vessel revascularization — and other clinical outcomes did not differ between the two groups (see Figure).

The main analysis had FFR- and angiography-specific definitions of in-segment restenosis, but in a post hoc analysis defining the complication as diameter stenosis >50% in both groups, in-segment restenosis was greater in the angiography group for the distal main vessel (9.2% vs. 1.7%; *P*=.01) and greater in the FFR group for the side branch (21.2% vs. 11.8%; *P*=.037).

FFR 'simplifies procedure'

Panelist **William F. Fearon, MD,** of Stanford University Medical Center, Calif., said the take-home message is that "a simpler approach is better, meaning that the less we do to the side branch, in general, the better the patient does." FFR guidance resulted in fewer procedures, and although there was more restenosis in the side branch, there was less in the main vessel, which is the main concern, Fearon said.

"It's a specific subset of patients with bifurcation lesions, but [the study] reinforces what we've learned from other studies … that by applying FFR we can simplify our procedure," he said.

Other panelists, however, did not feel the results supported FFR use. **Ron Waksman, MD,** of MedStar Washington Hospital Center, Washington, D.C., questioned the value of taking another measurement when there is no impact on MACE. "Being practical and cosT-effective you can probably avoid this," he said.

Disclosures:

- Chen reports no relevant conflicts of interest.
- Fearon reports receiving grant support/research contracts from Medtronic and St. Jude Medical.
- Waksman reports receiving grant support/research contracts from Biotronik, and consultant fees/honoraria/serving on the speaker's bureau for Abbott Vascular, AstraZeneca and Boston Scientific.

Results (3): One-year clinical outcomes

	Angio group (n=160)	FFR group (n=160)	p
Cardiac death, n(%)	1 (0.6)	2 (1.3)	0.56
MI, n(%)	22 (13.8)	19 (11.9)	0.74
TLR, n(%)	8 (5.0)	5 (3.1)	0.57
CABG, n(%)	0	0	-----
TVR, n(%)	11 (6.9)	9 (5.6)	0.82
MACE, n(%)	29 (18.1)	29 (18.1)	1.00
ST-def/prob, n(%)	2 (1.3)	1 (0.6)	0.56

tct2014

Figure

(RIBS, continued from page 1)

second-generation EES (Xience Prime, Abbott Vascular; n=155) or DEB (SeQuent Please, B. Braun; n=154).

Alfonso and colleagues obtained angiographic success in all cases and late angiographic follow-up in 90% of eligible patients. The primary endpoint, defined as in-segment minimum lumen diameter (MLD) at 9-month follow-up, was larger with EES compared with DEB. Alfonso also reported trends favoring EES in terms of binary restenosis and late lumen loss (see Table).

In addition, cumulative frequency distribution curves for in-segment minimum lumen diameter were larger in the EES group after the procedure (*P*=.04) and through follow-up (*P*=.004). Further analysis of minimal lumen diameter using 10 prespecified clinical and angiographic variables revealed consistent results favoring EES.

The RIBS IV researchers also obtained 360-day clinical follow-up for 100% of the study population. Patients assigned EES had higher rates of freedom from TLR (96% vs. 87%; *P*=.008) and freedom from MACE including cardiac death, MI and TVR (90% vs. 82%; *P*=.044).

Five patients in the DEB group crossed over to stenting, according to Alfonso.

"Treatment of DES in-stent restenosis remains challenging and associated with poorer clinical and angiographic results than treatment of bare-metal stent in-stent restenosis," Alfonso said at a late-breaking clinical trial session. "Further studies including more patients and longer follow-up are still warranted in this adverse setting."

Session moderator and TCT Course Director **Gregg W. Stone, MD,** of Columbia University Medical Center, New York, said DES in-stent restenosis "is a problem that doesn't occur very often, but when it does, [it's] a vexing issue with high rates of recurrence with any of our therapies. These results are somewhat different than RIBS V, [which was conducted in patients with] BMS in-stent restenosis. Here, we get very clearly better angiographic results with EES and clearly better clinical event rates. These are fascinating results."

RIBS IV is the first randomized trial of DEB vs. EES in patients with DES in-stent restenosis. The multicenter trial was conducted at 23 sites in Spain. Baseline characteristics were well balanced between the two groups, Alfonso said. Mean age of enrolled patients was 66 years, and the majority (83%) were men. All patients had DES in-stent restenosis of >50% and angina or silent ischemia. Median time to in-stent restenosis was 547 days.

Disclosures:

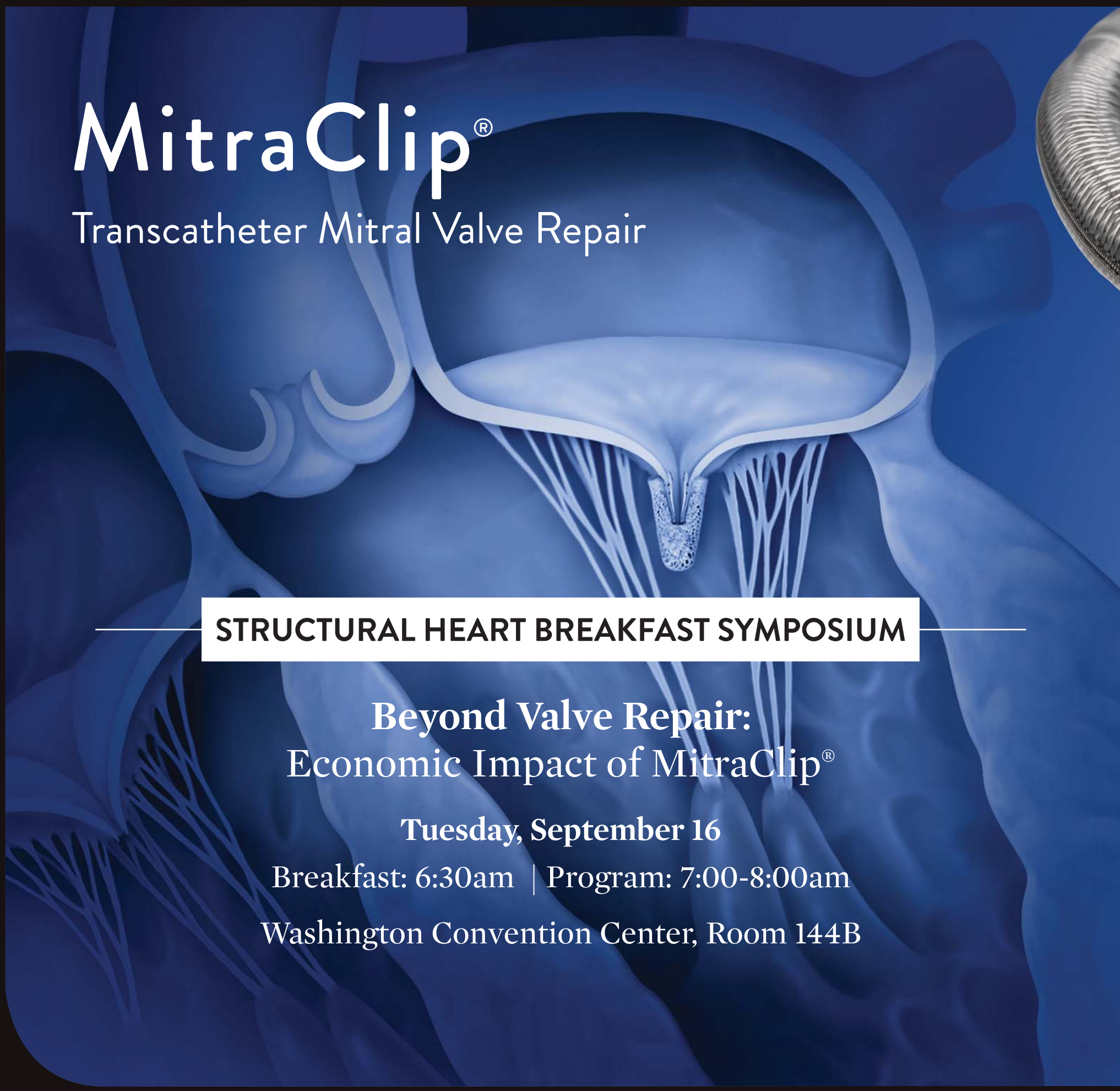
- Alfonso reports no relevant conflicts of interest.
- Stone reports relationships with multiple device companies.

Table. Angiographic Outcomes at 9 Months

	EES (n=133)	DEB (n=139)	*P* Value
In-Segment MLD, mm	2.03	1.80	.004
Binary restenosis	11%	19%	.06
Late lumen loss, mm	0.18 ± 0.6 mm	0.30 ± 0.6 mm	–

MitraClip®

Transcatheter Mitral Valve Repair



STRUCTURAL HEART BREAKFAST SYMPOSIUM

Beyond Valve Repair:
Economic Impact of MitraClip®

Tuesday, September 16

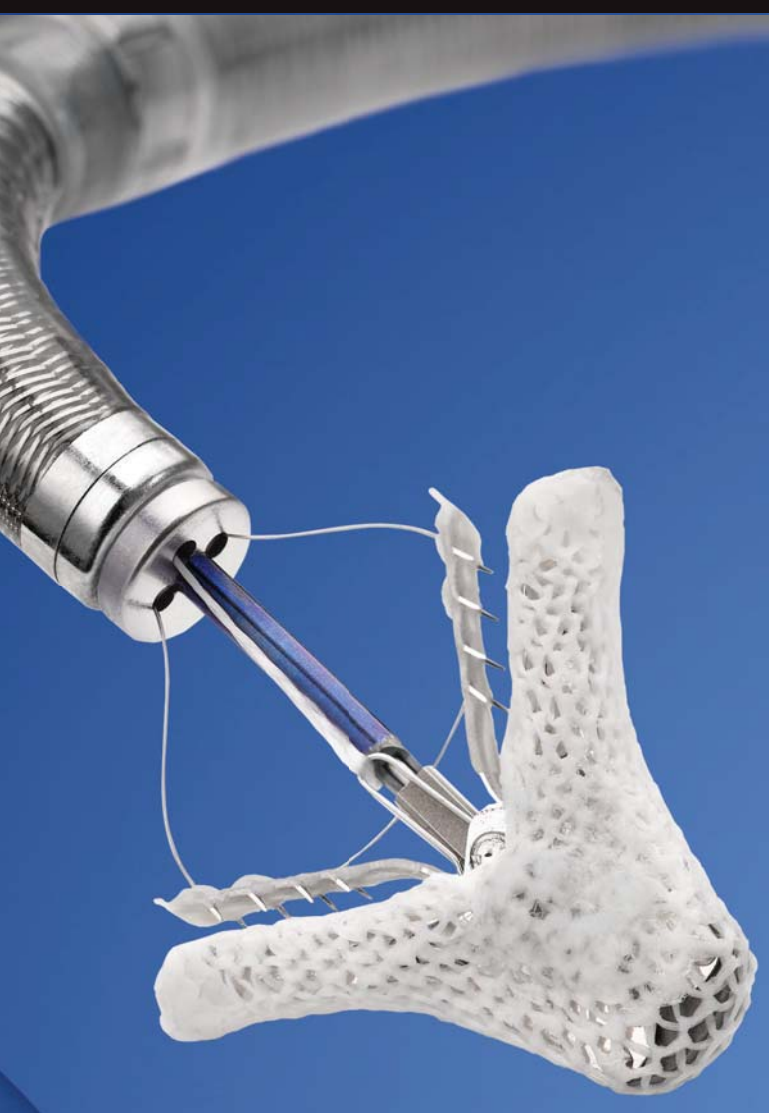
Breakfast: 6:30am | Program: 7:00-8:00am

Washington Convention Center, Room 144B

See page 11 for Important Safety Information.

Abbott Vascular, 3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.AbbottVascular.com



SUSTAINED REDUCTION IN MR SEVERITY

82.5%

OF PATIENTS EXPERIENCED AN MR IMPROVEMENT TO ≤2+ OVER 2 YEARS

*Results following MitraClip® therapy in surviving prohibitive-risk degenerative MR patients (n=40) at 2 year follow-up. Compared to 9.7% of patients ≤2+ at baseline (n=124)

REDEFINING INNOVATION

VISIT US AT BOOTH # 1407

Abbott

Boston Scientific
Advancing science for life™

Advancing Cardiology **Together**

SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System

HEAL with Confidence

The **SYNERGY Stent** is designed to heal. The abluminally-coated stent technology synchronizes the release of drug elution and polymer absorption for optimal healing within the vessel.[1] The polymer is gone when it's no longer needed—shortly after the drug is completely eluted at three months.[2]

In addition, the **SYNERGY Stent's** unique coating design may reduce the risk of thrombosis and the need for prolonged dual-antiplatelet therapy.*

Together, we're advancing cardiology.

1. Eppihimer M, PhD. Impact of Polymer Type and Location on Stent Thrombogenicity and Endothelial Cell Coverage. EuroPCR 2013.
2. Chen YL, PhD, Foss A, PhD, Eppihimer M, PhD, et al. Characterization of In Vivo Poly(DL-lactic-co-glycolic acid) Bioabsorption from a Drug-Eluting Stent. EuroPCR 2012.

* See Directions for Use.

CAUTION: Investigational device. Limited by Federal law to investigational use only. Not For sale in the U.S.

Please visit the Boston Scientific
Booth #1400
for more information on the SYNERGY Stent System