TCT 2011: New Findings Shine a Spotlight on Novel Device-Based Therapies for Cardiovascular Disease

Highlights from the 23rd Annual Transcatheter Cardiovascular Therapeutics Scientific Symposium, November 7-11, 2011, San Francisco, CA

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KEY WORDS

Coronary artery disease • Peripheral vascular disease • Structural heart disease • Drug-eluting stent • Transcatheter aortic valve replacement • Percutaneous coronary intervention

The annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium is the world's preeminent forum at which interventional cardiologists, cardiac surgeons, and vascular medicine specialists gather to hear the latest data from key clinical trials and to observe live cases focusing on coronary artery disease (CAD), peripheral vascular disease, and structural heart disease. The conference enables clinicians to incorporate the most advanced minimally invasive techniques for treating cardiovascular (CV) disease into their everyday practices. Here we examine important late-breaking studies and first reports of new data presented at TCT 2011 regarding groundbreaking developments in transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis, current and future drug-eluting stents (DES), and conventional and emerging pharmacologic and catheter-based strategies.

Reviewed by Jason Kahn, MA, Gary S. Mintz, MD, Kim Dalton, MA, Yael L. Maxwell, BA, Laura A. McKeown, BA, Martin B. Leon, MD, Gregg W. Stone, MD; Columbia University Medical Center, and the Cardiovascular Research Foundation, New York, NY.

Transcatheter Aortic Valve Therapy

PARTNER at 2 Years

The groundbreaking results at 1 year from Cohort B of the PARTNER (Placement of Aortic Transcatheter Valves) trial were maintained at 2 years, continuing to support the superiority of TAVR over standard therapy for symptomatic patients with severe aortic stenosis who are not candidates for surgery.

Raj R. Makkar, MD, of Cedars-Sinai Medical Center (Los Angeles, CA), presented the 2-year results of PARTNER, which randomized 358 inoperable patients with severe aortic stenosis and cardiac symptoms to TAVR (n = 179) with the SAPIEN heart valve system (Edwards Lifesciences, Irvine, CA) or standard therapy.[1] The latter consisted of medical therapy, conservative care, and/or balloon aortic valvuloplasty.

From 1 to 2 years, TAVR continued to show an incremental mortality benefit compared with standard therapy (18.2% vs 35.1%; hazard ratio [HR] 0.58; 95% confidence interval [CI], 0.37-0.92; $P = .0194$). This was similar to the benefit seen from 0 to 12 months (30.7% vs 50.7%; HR 0.57; 95% CI, 0.44-0.75; $P < .0001$).

At 2 years, cumulative rates of CV mortality, repeat hospitalizations, and New York Heart Association (NYHA) class III/IV symptoms were all lower with TAVR, whereas stroke rates were higher (Table 1).

TABLE 1

PARTNER, Outcomes at 2 Years

	TAVR (%)	Standard Therapy (%)	*P* Value
CV mortality	31.0	62.4	< .0001
Repeat hospitalizations	35.0	72.5	< .0001
NYHA class III/IV symptoms	16.9	57.5	< .0001
Stroke	13.8	5.5	.009

CV, cardiovascular; NYHA, New York Heart Association; PARTNER, Placement of Aortic Transcatheter Valves; TAVR, transcatheter aortic valve replacement.
Data from Makkar RR.[1]

PARTNER: Placement of Aortic Transcatheter Valves

After 30 days, differences in stroke frequency were largely due to increased hemorrhagic strokes in TAVR patients. Major bleeding was also somewhat more common at 2 years with TAVR (28.9% vs 20.1%; $P = .093$), although there were no differences in the need for new pacemaker implantation between the standard therapy and TAVR groups (8.6% vs 6.4%; $P = .469$). In addition, moderate or severe paravalvular aortic regurgitation did not influence 2-year survival in patients undergoing TAVR.

A subgroup analysis according to surgical risk score suggested that the most pronounced benefit of TAVR is in patients without extreme clinical comorbidities. Dr. Makkar concluded that 2-year data continue to support the role of TAVR as the standard of care for symptomatic patients with aortic stenosis who are not surgical candidates.

PARTNER Quality of Life and Cost Effectiveness

In Cohort A of the PARTNER trial, researchers demonstrated that TAVR was less invasive and noninferior to surgical aortic valve replacement (SAVR) in 699 high-risk patients with severe aortic stenosis. David J. Cohen, MD, MSc, of the Saint Luke's Mid America Heart Institute (Kansas City, MO), presented data from a subanalysis of PARTNER Cohort A focusing on quality-of-life (QOL) measurements stratified according to transfemoral or transapical access in the TAVR group.[2] The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used to assess the primary endpoint, comprising heart-failure-specific QOL as well as symptoms, physical limitations, QOL, and social limitations. In addition, the SF-12® Health Survey (Medical Outcomes Trust, Hanover, NH) was used to evaluate general physical and mental health, and the EQ-5D™ health status measure (EuroQol, Rotterdam, The Netherlands) was used to assess quality-adjusted life years (QALYs). There was a significant relationship between treatment effect and access site for the primary endpoint ($P = .01$) and multiple secondary endpoints.

The transfemoral approach was associated with a 10-point increase in the KCCQ at 1 month ($P < .001$), although at 6 and 12 months the difference decreased and was no longer significant compared with surgery. Early improvements in the transfemoral group were also noted on the SF-12 physical ($P = .04$), SF-12 mental ($P < .001$), and EQ-5D ($P = .008$) measures, though all of these became nonsignificant by 12 months compared with surgery. However, the transapical approach demonstrated a significant 8-point reduction in KCCQ compared with surgery at 6 months ($P = .04$). Regardless of the intergroup comparisons, Dr. Cohen noted that both

SAVR and TAVR resulted in substantial improvement in disease-specific and generic health-related QOL over 1-year follow-up:

- KCCQ Summary Scale ~ 25-30 points
- SF-12 Physical ~ 6 points
- SF-12 Mental ~ 5 points

Matthew R. Reynolds, MD, MSc, of Harvard Medical School (Boston, MA), presented similar access site-specific data from PARTNER Cohort A regarding 12-month cost-effectiveness of TAVR compared with SAVR.[3] In terms of resource use, although there was a shorter procedural time by about 87 minutes in the transfemoral arm and 130 minutes in the transapical arm compared with surgery ($P < .001$ for both comparisons), only the transfemoral approach significantly decreased hospital length of stay (by 6.2 days; $P < .001$).

Meanwhile, major vascular complications were higher with transfemoral TAVR versus surgery (13.2% vs 3.2%; $P < .001$), whereas major bleeding was lower (9.4% vs 22.6%; $P < .001$). Comprising procedure, nonprocedure, and total physician fees, index admission costs were equivalent between the transfemoral TAVR ($71,955) and SAVR ($74,452) groups ($P = .53$).

One-year follow-up costs, consisting of hospitalizations, rehabilitation, skilled nursing facility care, and other outpatient care, were also equivalent between transfemoral and surgical patients ($22,251 vs $21,965; $P = .97$). On cost-effectiveness analysis, transfemoral TAVR provided small but significant gains in 12-month quality-adjusted life expectancy (0.06-0.07 QALYs) compared with surgery. Thus, transfemoral TAVR was declared to be "economically dominant" to SAVR (better outcomes and less expensive).

Procedural costs of transapical TAVR, however, were increased compared with surgery by about $25,000 per patient. Although nonprocedural costs during index admission were higher in the surgical arm, this did not fully offset the difference in procedural costs, such that overall costs were approximately $11,000 per patient higher in the transapical group compared with surgery. Overall, SAVR was deemed to be "economically dominant" to transapical TAVR. Dr. Reynolds concluded that for patients with severe aortic stenosis and high surgical risk, TAVR was an economically attractive strategy compared with SAVR, provided that patients are suitable for the transfemoral approach.

STACCATO

In the STACCATO (Surgical Aortic Valve Replacement [AVR] in Operable Elderly Patients With Aortic Stenosis) trial, data presented by Leif Thuesen, MD, of Aarhus University Hospital (Aarhus, Denmark), focused on a comparison between elderly ($\geq$ 70 years) operable patients with aortic stenosis who were randomized to transapical TAVR or SAVR.[4] Despite a planned enrollment of 200, the trial was stopped early after only 70 patients were randomized after the Data Safety Monitoring Board recommended the trial be halted due to an excess number of adverse events in the TAVR arm.

Specifically, the primary endpoint (composite of all-cause mortality, major stroke, and renal failure at 30 days), occurred in five TAVR patients, comprising two deaths, two major strokes, and one case of renal failure, compared with one stroke in the surgery group ($P = .07$). The two groups were well balanced in terms of baseline characteristics, with an average patient age slightly over 80 years and Society of Thoracic Surgeons scores of 3.1 $\pm$ 1.5 for SAVR patients and 3.4 $\pm$ 1.2 for TAVR patients.

Aortic valve area and peak aortic gradient were significantly improved compared with baseline by both treatments ($P < .0001$), but afterward there was no difference between the TAVR and SAVR groups for these parameters. After 30 days, rates of moderate/severe paravalvular leakage, minimal leakage, and no leakage were 13%, 43%, and 43%, respectively, in the TAVR group, compared with 6% minimal leakage and 94% no leakage in the SAVR group ($P < .001$). NYHA functional class improved in both groups, but to a similar extent ($P = .16$), and there were no differences in rates of myocardial infarction (MI), placement of permanent pacemakers, hospital length of stay, or composite physical or mental function scores.

Dr. Thuesen acknowledged several limitations of the study, including the limited enrollment compared with what had been expected. As a result of the small numbers, the excess events in the TAVR arm may have been due to chance. In addition, he added, preoperative multislice computed tomography, which was not used in the trial, may have helped optimize valve sizing, and only one valve size was available during the trial enrollment period. Several physicians attending the presentation commented that the outcomes with transapical TAVR from this small trial were not representative of those currently being achieved at experienced centers.

Primary Percutaneous Coronary Intervention in STEMI

RIFLE STEACS

For the prospective multicenter RIFLE STEACS (Radial Versus Femoral Randomized Investigation in ST Elevation Acute Coronary

TABLE 2

RIFLE STEACS: 30-Day Outcomes

	Radial (%) (n = 500)	Femoral (%) (n = 501)	PCI
NACE	13.6	21.0	.003
MACCE	7.2	11.4	.029
Bleeding events	7.8	12.2	.026

MACCE, major adverse cardiovascular and cerebrovascular events; NACE, net adverse clinical events; PCI, percutaneous coronary intervention; RIFLE STEACS, Radial Versus Femoral Randomized Investigation in ST Elevation Acute Coronary Syndrome.
Data from Romgnoli E.[5]

Syndrome) trial, Enrico Romagnoli, MD, PhD, of Policlinico Casilino (Rome, Italy), randomized 1001 ST-elevation MI (STEMI) patients to either transradial (n = 500) or transfemoral (n = 501) percutaneous coronary intervention (PCI). There was a 4.7% crossover rate in the radial arm and a 1.4% crossover rate in the femoral arm.[5] For the intent-to-treat analysis, the researchers determined net adverse clinical events (NACE), a composite of cardiac death, MI, target lesion revascularization (TLR), stroke, or non-coronary artery bypass graft (CABG) bleeding at 30 days. NACE, major adverse CV and cerebrovascular events (MACCE; composite of cardiac death, MI, TLR, and stroke), and bleeding events were all lower with transradial PCI (Table 2).

Within bleeding events, non-access-site–related bleeding was equivalent between groups. However, access-site–related bleeding was significantly higher with transfemoral PCI (6.8% vs 2.6%; $P = .002$), and accounted for 47% of all bleeding events in both arms. In terms of individual adverse events, cardiac death was significantly lower with transradial PCI (5.2% vs 9.2%; $P = .02$), but there was no difference between groups in rates of MI, TLR, or stroke. On multivariable analysis, transradial PCI was an independent predictor of reduced 30-day NACE (odds ratio [OR] 0.6; 95% CI, 0.4-0.9; $P = .012$).

Based on the results, Dr. Romagnoli concluded that the radial approach should no longer be considered a valid alternative to transfemoral PCI but become the recommended access site for STEMI patients. Others noted, however, that the absolute reduction in mortality was nearly identical to the reduction in bleeding, thus questioning whether the former was a chance finding. Moreover, bivalirudin was not used in the control arm, and the rate of closure devices was not reported. Thus, additional large-scale studies are required to definitively address this important question.

MUSTELA

For the prospective MUSTELA (Thrombectomy Versus No Thrombectomy in Patients With ST-Segment Elevation Myocardial Infarction and Thrombus-Rich Lesions) trial, Anna Sonia Petronio, MD, of the University of Pisa (Pisa, Italy), presented data on 208 patients with STEMI and high thrombus burden (thrombolysis in myocardial infarction [TIMI] thrombus grade ≥ 3) randomized to primary PCI with (n = 104) or without (n = 104) thrombus aspiration.[6] Thrombectomy patients were split between rheolytic and manual methods.

In terms of procedural results, postprocedural TIMI 3 flow was achieved in 90.4% of thrombectomy patients compared with 81.7% of controls ($P = .07$), whereas TIMI 2 flow was reduced with thrombectomy (6.7% vs 15.4%; $P = .04$). Myocardial blush grade 3 was increased with thrombectomy (68.3% vs 52.9%; $P = .03$), as was ST-segment resolution > 70% at 60 minutes, one of the trial's two co-primary endpoints (57.4% vs 37.3%; $P = .004$).

At 3 months, the other co-primary endpoint, infarct size as assessed by delayed enhanced magnetic resonance imaging (MRI), was similar between the thrombectomy and control groups. Left ventricular ejection fraction was also equivalent, whereas microvascular obstruction was lower, and dyshomogenous scar was increased with thrombectomy (Table 3). At 1 year, freedom from major adverse cardiac events (MACE) was 93.9% in control subjects versus 92.3% in thrombectomy patients ($P = .57$).

In a subanalysis of the thrombectomy patients, angiographic success was more common in those who underwent rheolytic aspiration (n = 54) compared with those who underwent manual aspiration (n = 50; 94.4% vs 78.0%; $P = .02$). There was also a trend for a smaller delayed enhanced MRI area in the rheolytic thrombectomy patients (17.5 ± 8.6% vs 21.3 ± 11.3%; $P = .10$). There were no other significant differences. Both types of thrombectomy catheters achieved successful delivery (98% manual, 100% rheolytic).

Based on the data, Dr. Petronio arrived at a mixed conclusion: that thrombectomy was not associated with significant reduction in infarct size on MRI at 3 months but was associated with a higher rate of complete ST-segment resolution,

TABLE 3

MUSTELA: MRI Results at 30 Days

	Thrombectomy (%) (n = 79)	Control (%) (n = 75)	*P* Value
Delayed enhanced area	20.4 ± 10.5	19.3 ± 10.6	.54
Microvascular obstruction	5.1	19.4	.01
Dyshomogenous scar	35.4	2.7	< .0001
LVEF	56 ± 12	59 ± 11	.10

LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging; MUSTELA, Thrombectomy Versus No Thrombectomy in Patients With ST-Segment Elevation Myocardial Infarction and Thrombus-Rich Lesions. Data from Petronio AS.[6]

although there was no impact on 1-year freedom from MACE.

DEB-AMI

In a small randomized study, a drug-eluting balloon plus a bare-metal stent (BMS) was less effective than either a BMS or a DES alone for primary PCI, putting a damper on the hope that a non-DES strategy might be used to reduce the risk of stent thrombosis.[7]

For the DEB-AMI (Drug Eluting Balloon in Acute Myocardial Infarction) trial, after successful thrombus aspiration (TIMI flow > 1), 149 STEMI patients were randomized to a paclitaxel-eluting balloon (DIOR® II; Eurocor, Bonn, Germany) plus a BMS (n = 50), a BMS alone (n = 50), or a paclitaxel-eluting stent (PES) alone (n = 49). All stent platforms were identical. Patients who received only stents underwent predilatation, whereas 60% of balloon angioplasty patients received predilatation.

According to Pieter R. Stella, MD, PhD, of University Medical Centre Utrecht (Utrecht, the Netherlands), at 6-month angiographic follow-up, the paclitaxel-eluting balloon strategy did not meet the primary endpoint of a 50% reduction in late lumen loss compared with the BMS or DES (0.64 ± 0.56 mm vs 0.78 ± 0.59 mm and 0.21 ± 0.32 mm, respectively; $P = .25$ for drug-eluting balloon vs BMS; *P* value for drug-eluting balloon vs DES not reported). In addition, at 6 months, there was no significant difference in rates of cardiac death, MI, TLR, or MACE (composite of death, MI, and TLR; Table 4) between the drug-eluting balloon and BMS, although the rates were lower for DES (*P* values not provided). Dr. Stella noted that predilatation is mandatory with balloon angioplasty and suggested that further investigation is needed to optimize results.

PCI Pharmacology and Stent Thrombosis

ADAPT-DES

The absolute and relative levels of platelet inhibition to adenosine diphosphate antagonists are powerful independent predictors of ST within 30 days, according to data from the ADAPT-DES (Assessment of Dual Antiplatelet Therapy With Drug Eluting Stents) trial. However, modest sensitivity and specificity suggests little usefulness in individual patients.

The large-scale, prospective, multicenter registry study ADAPT-DES, led by Gregg W. Stone, MD, of Columbia University Medical Center (New York, NY), included 8575 patients presenting with stable CAD (48.3%) or acute coronary syndromes (ACS; 51.7%) treated with DES between 2008 and 2010. Patients were given dual antiplatelet therapy (DAPT) and tested for platelet response using the VerifyNow P2Y12 assay (Accumetrics, San Diego, CA).[8]

Definite or probable stent thrombosis occurred in 39 (0.46%) patients. Prespecified measures P2Y12 reactivity units (PRU) = 208, PRU ≥ 230, and P2Y12 inhibition ≤ 11%, were significantly associated with subsequent stent thrombosis after multivariate analysis (Table 5). Aspirin reactivity was unrelated to subsequent stent thrombosis within 30 days. Sensitivity and specificity thresholds for PRU and aspirin ranged from 57% to 94%.

TABLE 4

Six-Month Clinical Endpoints

	BMS (%) (n = 10)	Paclitaxel-Eluting Balloon (%) (n = 12)	DES (%) (n = 10)	*P* Value (Drug-Eluting Balloon vs BMS)
Cardiac death	3.9	0	0	0.16
MI	0	2.0	0	0.50
TLR	17.6	20.0	2.0	0.76
MACE	23.5	20.0	4.1	0.67

BMS, bare-metal stent; DES, drug-eluting stent; MACE, major adverse cardiovascular events; MI, myocardial infarction; TLR, target lesion revascularization.
Data from Stella PR.[7]

TABLE 5

Platelet Response and Subsequent Stent Thrombosis

Verify Now[a] Test	Definite/ Probable ST (n = 39)	No Definite/ Probable ST (n = 8536)	*P* Value
P2Y12 PRU	249.4 ± 88.5	187.6 ± 96.7	.0001
PRU > 208	74.4%	42.6%	.0002
PRU ≥ 230	64.1%	34.9%	.0003
P2Y12 % inhibition	19.8 ± 23.7	40.1 ± 28.2	< .0001
Inhibition ≤ 11%	51.3%	19.9%	< .0001

[a]Accumetrics, San Diego, CA.
PRU, P2Y12 reactivity units; ST, stent thrombosis.
Data from Stone GW.[8]

Researchers said these results, especially the modest sensitivity and specificity numbers, imply that testing of platelet adenosine diphosphate antagonist responsiveness is unlikely to provide useful information to guide clinical decision making in most individual patients at 30 days. However, this method would still be useful for large clinical trials, especially in patients with ACS. The relationship between platelet responsiveness testing and the occurrence of late and very late stent thrombosis (in patients who have maintained and discontinued DAPT) will be assessed during the 2-year clinical follow-up phase of the ADAPT-DES study.

DESERT

After 7 years, patients implanted with first generation DES continue to be at risk for late stent thrombosis according to results of the DESERT (Drug Eluting Stent Event Registry of Thromboses) trial. In addition, mortality with late stent thrombosis was lower when compared with historically reported acute and subacute stent thrombosis events.

Ron Waksman, MD, of the Cardiovascular Research Institute (Washington, DC), presented data from the largest case-control registry of late and very late stent thrombosis patients treated with DES. To determine the correlates of late stent thrombosis, defined as longer than 30 days after stent implantation, researchers studied data from 956 patients with (n = 478) or without (n = 478) stent thrombosis.[9]

Stent thrombosis after DES was reported to occur from 30 days to beyond 7 years after implantation; 35% of stent thrombosis events in the study arm occurred more than 4 years after stent implantation. Of these patients, 67% presented with STEMI and 22% with non-STEMI or ACS. At the time of stent thrombosis, 29.8% of patients were on DAPT; of those not on DAPT (64.9%), 43.9% stopped therapy within 5 days of the stent thrombosis event. At 1-year follow-up the mortality rate was 1.67% and the MACE rate was 16.54% in patients who were discharged after treatment for their stent thrombosis. Patients in the stent thrombosis group were typically younger ($P < .001$), black ($P = .044$), current smokers ($P < .001$), and had either prior PCI ($P = .002$) or MI ($P = .003$). Thus, researchers concluded that these patients should be reconsidered for DES or for a potent or longer DAPT regimen.

PARIS

The multinational, observational PARIS study is evaluating the modes and clinical consequences of nonadherence to DAPT in more than 5033 "all-comer" patients following stent implantation (82% DES, 16% BMS, 2% both DES and BMS).[10] For the thienopyridine component of dual therapy, which is recommended for at least 30 days for BMS patients and at least 1 year for DES patients, most patients received clopidogrel (92%), whereas the remainder received prasugrel (6%) or ticlopidine (2%).

Thirty-day data, presented by Roxana Mehran, MD, of Mount Sinai Medical Center (New York, NY), showed that only 2.1% of patients were nonadherent. Compared with adherent patients, nonadherent patients had higher rates of multiple ischemic events, including MACE (composite of cardiac death, MI, and clinically driven TLR), all-cause death, MI, and stent thrombosis, as well as several types of bleeding (Table 6).

Modes of any nonadherence (which was distributed equally between aspirin and a thienopyridine) varied: 69% of patients disrupted (including use at lower levels) dual therapy, mostly due to lack of compliance with the regimen or episodes of bleeding; 19% interrupted dual therapy (reinstituted within 14 days), either on their own or on a physician's advice, typically due to need for surgery or a medical procedure; and 12% discontinued dual therapy on the recommendation of their physician.

RAPID GENE

Rapid genotyping of the CYP2C19 gene can help personalize antiplatelet treatment after PCI and improve rates of on-treatment platelet

TABLE 6

Adverse Events at 30 Days

	Adherent (%) (n = 4929)	Nonadherent (%) (n = 104)
MACE	1.4	10.6
Death	0.3	1.9
MI	0.9	7.7
Stent thrombosis	0.5	2.9
Bleeding (BARC ≥ 3)	0.4	11.5

BARC, Bleeding Academic Research Consortium; MACE, major adverse cardiovascular events; MI, myocardial infarction.
Data from Mehran R.[10]

reactivity, according to results from the RAPID GENE (Reassessment of Anti-Platelet Therapy Using an Individualized Strategy Based on Genetic Evaluation) study.[11]

Derek So, MD, of the University of Ottawa Heart Institute (Ottawa, ON, Canada) led the study, which randomized 200 patients undergoing PCI with non-ST ACS or stable CAD to rapid genotyping (n = 102) or standard therapy (n = 98). The rapid genotyping was performed with the Spartan RX CYP2C19 device (Spartan Biosciences, Ottawa, ON, Canada), which employs a one-step insertion from a buccal swab. A unique characteristic of the device is that nurses do not need prior experience and are only required to take a 30-minute instructional course before use. The test identifies heterozygous or homozygous CYP2C19*2 carrier status within 60 minutes. Both groups underwent standard DNA sequencing in order to compare the rapid genotyping results. Patients who were carriers of CYP2C19*2 in the rapid genotyping arm were switched to prasugrel; all other patients in the trial were maintained on clopidogrel.

There were 23 carriers of CYP2C19*2 in both groups; the rapid genotyping was found to have a sensitivity of 100% and a specificity of 99.4%. None of the subjects in the rapid genotyping group had on-treatment platelet reactivity greater than 234 PRU after 7 days of prasugrel (Effient®; Daiichi Sankyo, Parsippany, NJ and Eli Lilly & Co., Indianapolis, IN) treatment. In contrast, 30.4% of the 23 CYP2C19*2 carriers who underwent standard clopidogrel therapy (Plavix®; sanofi-aventis, Bridgewater, NJ, and Bristol-Myers Squibb, New York, NY) without rapid genotyping had high on-treatment platelet reactivity after 7 days ($P = .009$).

The study also examined what happens when the PRU value cutoff is lowered to 208. In the rapid genotyping group, 4.3% of patients exceeded the new cutoff compared with 47.8% of standard therapy patients ($P = .002$). The baseline PRU for both groups was 198.7; PRU and percent platelet inhibition at day 7, as well as change in PRU from baseline to day 7 were all improved in the rapid genotyping group (Table 7). No MACE events occurred in either group at 7 or 30 days, and TIMI bleeding rates were not significantly different between the two groups (although they tended to be higher in the rapid genotyping arm).

TRIGGER-PCI

Although stopped early for futility and low event rates, TRIGGER-PCI (Testing Platelet Reactivity in Patients Undergoing Elective Stent Placement on Clopidogrel to Guide Alternative Therapy With Prasugrel) showed that prasugrel treatment after PCI is associated with a reduction in high on-treatment platelet reactivity versus clopidogrel.[12]

In the study, 423 patients who had an initial PRU of > 208 were randomized to prasugrel or clopidogrel. All patients received DES,

TABLE 7

Platelet Function Measures in CYP2C19*2 Carriers

	Rapid Genotyping (n = 23)	Standard Therapy (n = 23)	*P* Value
PRU at day 7	75.6 ± 57.3	207.3 ± 55.8	< .001
% Platelet inhibition at day 7	73.3 ± 20.3	27.0 ± 13.4	< .001
Change in PRU from day 0-7	123.09 ± 77.2	−8.48 ± 74.0	< .001

PRU, P2Y12 reactivity units.
Data from So D.[11]

with everolimus-eluting stents (Xience V™/Promus™; Abbott Vascular, Abbott Park, IL, and Boston Scientific, Natick, MA) accounting for more than 50% of the total, followed by sirolimus- (Cypher®; Cordis Corporation, Miami, FL) and zotarolimus-eluting stents (Endeavor®; Medtronic, Minneapolis, MN).

After 90 days of treatment, 5.9% of prasugrel patients and 70.4% of clopidogrel patients had a PRU > 208 ($P < .001$). After 176 days, 5.8% of 139 prasugrel patients and 70.8% of 144 clopidogrel patients met the cutoff rate for high on-treatment platelet reactivity ($P < .001$).

The study's primary endpoint was a composite of CV death or MI; overall, there was only one such event—in the clopidogrel group—after a median of 174 days on treatment. Secondary efficacy endpoints included MI, rehospitalization, target vessel revascularization (TVR), definite stent thrombosis, stroke, CV death, and all-cause death (Table 8).

Study author Dietmar Trenk, PhD, of Herz-Zentrum Bad Krozingen (Bad Krozingen, Germany), made comparisons to the EXCELSIOR (Impact of Extent of Clopidogrel-Induced Platelet Inhibition During Elective Stent Implantation on Clinical Event Rate) trial, which indicated strong clinical predictive power of on-treatment platelet reactivity. In TRIGGER-PCI, high on-clopidogrel platelet reactivity was observed less frequently than expected. Given the low event rate in elective PCI patients treated with contemporary stents without periprocedural complications despite being clopidogrel hyporesponsive, a favorable risk–benefit ratio with prasugrel treatment in these patients could not be demonstrated.

BRIDGE

P2Y12 inhibition with the rapid-acting agent cangrelor is a safe management strategy in patients who require continued platelet inhibition following thienopyridine interruption prior to cardiac surgery, according to results of the BRIDGE (Maintenance of Platelet Inhibition with Cangrelor after Discontinuation of Thienopyridines in Patients Undergoing Surgery) trial.[13]

For the prospective, double-blind, multicenter trial, Dominick J. Angiolillo, MD, PhD, of the University of Florida College of Medicine (Jacksonville, FL), and colleagues enrolled 210 patients with ACS treated with a coronary stent (BMS or DES) who discontinued thienopyridine therapy (ticlopidine, clopidogrel, or prasugrel) and were awaiting CABG. After thienopyridine therapy was stopped, patients were randomized to cangrelor (n = 106) or placebo (n = 104) for at least 48 hours, which was then discontinued 1 to 6 hours prior to surgery. Cangrelor was administered in a step-wise fashion at predetermined doses until platelet inhibition was > 60% in 80% of daily samples or until a dose of 2 μg/kg/min was reached.

Using the VerifyNow P2Y12 test, researchers analyzed levels of platelet activity < 240 PRU. A greater proportion of patients treated with intravenous cangrelor had low levels of platelet reactivity throughout the treatment period compared with the placebo arm (PRU < 240: 98.8% vs 19%; OR 353; 95% CI, 45.6-2,728; $P < .0001$).

The primary safety endpoint, excessive CABG-related bleeding, was similar between the cangrelor and placebo groups (11.8% vs 10.4%; $P = .763$), with a total of 22 bleeding events. Results showed no difference between the two groups in individual components of bleeding, such as surgical re-exploration, transfusions, and reoperation for bleeding. After examining preoperative bleeding using the Acute Catheterization and Urgent Intervention Triage

TABLE 8

Primary and Secondary Endpoints After a Median of 174 Days

	Prasugrel (n = 212)	Clopidogrel (n = 211)	*P* Value (HR, 95% CI)
CV, death, MI	0	1	–
MI	0	1	–
Rehospitalization for cardiac ischemic event	2	4	.992 (0.99, 0.14-7.03)
Urgent TVR	2	1	–
Definite ST	0	0	–
Stroke	0	1	–
CV death	0	0	–
All-cause death	0	1	–

CI, confidence interval; CV, cardiovascular; HR, hazard ratio; MI, myocardial infarction; ST, stent thrombosis; TVR, target vessel revascularization.
Data from Trenk D.[12]

TABLE 9

Angiographic Outcomes at 6 Months

In-Stent Values	Promus Element™[a] (n = 98)	SYNERGY™[a] Full Dose (n = 94)	*P* Value	SYNERGY™[a] Half Dose (n = 99)	*P* Value
Late loss, mm	0.15 ± 0.34	0.10 ± 0.25	.19 (< .001 for noninferiority)	0.13 ± 0.26	.56 (< .001 for noninferiority)
MLD (mm)	2.29 ± 0.50	2.41 ± 0.42	.08	2.45 ± 0.44	.02
Binary restenosis	3.2%	0	.25	0	.25

[a]Boston Scientific, Natick, MA.
MLD, minimal lumen diameter.
Data from Meredith IT.[14]

Strategy (ACUITY), Global Use of Strategies to Open Occluded Arteries (GUSTO), and TIMI definitions, there were no significant differences in major bleeds but an increase in minor pre-CABG bleeding with cangrelor.

DES and Drug-Coated Balloons

EVOLVE

The randomized EVOLVE (Evaluation of a Novel Bioabsorbable Polymer-Coated, Everolimus-Eluting Coronary Stent) trial compared the safety and efficacy of a metallic stent using an abluminal bioabsorbable polymer to elute everolimus versus a permanent-polymer everolimus-eluting stent.[14] For the trial, Ian T. Meredith, MBBS, PhD, of Monash Medical Centre Clayton (Melbourne, Australia), assigned 291 patients to receive the Boston Scientific SYNERGY™ Everolimus-Eluting Coronary Stent System at either full (n = 94) or half drug dose (n = 99) or the Promus Element/ Xience V stent.

For the primary angiographic endpoint of in-stent late loss at 6 months, both dose formulations of SYNERGY were noninferior to Promus. Minimum lumen diameter (MLD) and rates of binary restenosis were similar for Promus and SYNERGY, except that the half-dose SYNERGY stent yielded a higher MLD (Table 9).

In addition, both half- and full-dose formulations of SYNERGY showed rates of the primary clinical endpoint of target lesion failure (composite of target vessel-related death, MI, and TLR) at 30 days similar to that of Promus Element (3.1%, 1.1%, and 0%, respectively; $P = .25$ for the half dose vs Promus and $P = .49$ for the full dose vs Promus). The same held true for 6-month follow-up. In addition, at 6 months, no differences were seen among the stent arms for all-cause or cardiac death, MI, TLR, or TVR. No cases of stent thrombosis were observed in any group.

The SYNERGY stent is composed of a thin-strut platinum-chromium platform with a bioabsorbable previously synthesized lactic/glycolic acid polymer applied only to the abluminal surface. The polymer is completely absorbed within 4 months. The hypothesized advantage of a reduced polymer load is that it lessens short-term polymer exposure, thereby potentially reducing the chronic inflammation and impaired healing associated with durable polymer coatings. Large-scale randomized trials will be performed to investigate these potential benefits.

REMEDEE

Data from the prospective, multicenter, first-in-human REMEDEE (Randomized Evaluation of an Abluminal Sirolimus Coated Bioengineered Stent) trial, presented by Michael Haude, MD, of Lukaskrankenhaus Neuss (Neuss, Germany), showed that a novel dual-therapy DES is as safe and effective as a PES at 9 months.[15]

For the study, 183 patients with single de novo coronary lesions were randomized in a 2:1 ratio to the Combo™ Dual Therapy Stent (OrbusNeich, Hong Kong, China; n = 124) or a PES (TAXUS® Liberté®, Boston Scientific; n = 59). The dual therapy stent combines a sirolimus-eluting abluminal biodegradable polymer with a layer of anti-CD34 antibody to capture endothelial progenitor cells, which may accelerate healing.

At 9 months, multivariate analysis showed that the Combo stent was noninferior to the PES for the primary endpoint of in-stent late lumen loss (mean 0.39 ± 0.45 mm vs 0.44 ± 0.56 mm; *P* for noninferiority = .0012). Rates of in-stent

restenosis and minimum lumen diameter were also similar for the two devices (5.5% vs 9.6%; $P = .34$ and 2.31 ± 0.58 mm vs 2.30 ± 0.56 mm; $P = .86$, respectively). In addition, at 9 months no differences were observed in rates of MACE (composite of death, MI, emergent CABG, or TLR; 8.7% for Combo vs 11.0% for TAXUS Liberté; $P = .69$). There were no cases of cardiac death or Academic Research Consortium (ARC)-defined definite or probable stent thrombosis.

NEXT

Compared with a first-generation PES, the new polymer-free, sirolimus-eluting stent Cre8™ (Carbostent and Implantable Devices, Saluggia, Italy) results in less in-stent late lumen loss, according to data from the prospective, multicenter NEXT (International Randomized Comparison Between DES Limus Carbostent and TAXUS Drug-Eluting Stents in the Treatment of De Novo Coronary Lesions) trial.[16] Didier Carrié, MD, PhD, of Hôpital de Rangueil (Toulouse, France), and colleagues randomized patients with ischemic myocardial symptoms related to de novo lesions to Cre8 (n = 162; or TAXUS Liberté, n = 161). Cre8 uses abluminal reservoir technology, which controls and directs drug elution to the vessel wall, as well as a sirolimus/organic acid formulation that enhances drug bioavailability, permeability, and overall safety and efficacy.

Multivariate analysis showed significantly less in-stent late lumen loss at 6 months with Cre8 versus TAXUS Liberté (0.34 ± 0.4 mm vs 0.14 ± 0.36 mm, $P < .0001$). For this endpoint, Cre8 proved to be both noninferior and superior to the TAXUS Liberté stent ($P < .0001$ for both). Six-month angiographic results also showed Cre8 to be associated with significantly less in-segment late lumen loss ($P = .0041$), in-stent minimal lumen diameter ($P = .0006$), in-segment minimal lumen diameter ($P = .0353$), in-stent diameter stenosis ($P < .0001$), and in-segment diameter stenosis ($P = .0022$). Differences in binary restenosis between the two stents were not significant at 1 year. There was a low incidence of cumulative cardiac death, MI, and TLR at 1 year, resulting in an overall Cre8 MACE rate of 6.5%, consistent with lesion complexity. Dr. Carrié recommended future clinical trials to address clinical safety and efficacy.

TWENTE

The TWENTE (The Real-World Endeavor Resolute Versus Xience V Drug-Eluting Stent Study in Twente) trial demonstrated that newer-generation zotarolimus-eluting stents were noninferior to everolimus-eluting stents in terms of safety and efficacy for treating real-world patients with a vast majority of complex lesions and off-label indications for DES.[17] Clemens von Birgelen, MD, PhD, of Thoraxcentrum Twente (Enschede, the Netherlands), presented data on 1391 patients undergoing PCI who were randomized to a zotarolimus-eluting stent (Resolute; Medtronic CardioVascular, Santa Rosa, CA; n = 697) or an everolimus-eluting stent (Xience V; Abbott Vascular; n = 694).

At 1-year follow-up, Resolute met the criteria for noninferiority to Xience V for the primary endpoint of target vessel failure (composite of cardiac death, target vessel MI, and clinically driven TVR). Similarly, there was no difference between groups in the individual components of the primary endpoint at 1 year (Table 10).

In addition, there was no difference between the groups in the patient-oriented endpoint of death, any MI, and any revascularization (11.2% with Resolute vs 10.5% with Xience; $P = .69$). The incidence of ARC-defined definite stent thrombosis was similarly low for both stent groups (0.58% vs 0%; $P = .12$), as was definite/probable stent thrombosis (0.86% vs 1.16%; $P = .59$). These data, in concert with the RESOLUTE All-Comers (A Clinical Evaluation of the Medtronic Resolute Zotarolimus-Eluting Coronary Atent System in the Treatment of De Novo Lesions in Native Coronary Arteries With a Reference Vessel Diameter of 2.25 mm to 4.2 mm) trial, suggest similar patient outcomes with these two stent platforms.

TABLE 10

TWENTE: 1-Year Outcomes

	Resolute[a] (%) (n = 697)	Xience V[b] (%) (n = 694)	Log-Rank *P* Value
Primary endpoint	8.2	8.1	.940
Cardiac death	1.0	1.4	.462
Target vessel MI	4.6	4.6	.983
Clinically driven TVR	3.3	2.7	.534

[a]Medtronic CardioVascular, Santa Rosa, CA.
[b]Abbott Vascular, Abbott Park, IL.
MI, myocardial infarction; TWENTE, The Real-World Endeavor Resolute Versus Xience V Drug-Eluting Stent Study in Twente; TVR, target vessel revascularization.
Data from von Birgelen C.[17]

TABLE 11

Angiographic Results at 6 Months

	Paclitaxel-Coated Balloon	Uncoated Balloon	*P* Value
Late lumen loss (mm)	0.43 ± 0.61	1.03 ± 0.77	< .001
MLD (mm)	1.75 ± 0.70	1.10 ± 0.73	< .001
Binary restenosis (%)	17.2	58.1	< .001

MLD, minimum lumen diameter.
Data from Rittger H et al.[18]

PEPCAD-DES

For the prospective, randomized PEPCAD-DES (Paclitaxel-Eluting PTCA-Balloon Catheter in Coronary Artery Disease Drug-Eluting Stent) trial, 110 patients with restenosis in multiple types of DES were allocated 2:1 to angioplasty with a paclitaxel-coated balloon (n = 72; SeQuent® Please; B. Braun Melsungen Vascular Systems, Berlin, Germany) or an uncoated balloon (n = 38). All patients underwent predilatation at a pressure of 15.1 atm for approximately 40 seconds.[18]

Harald Rittger, MD, of the University of Erlangen (Erlangen, Germany), reported that the paclitaxel-coated balloon significantly reduced the primary endpoint of late lumen loss in the target lesion at 6 months compared with an uncoated balloon. In addition, the target vessel MLD was larger and the incidence of binary restenosis was lower in the paclitaxel-coated balloon group (Table 11). At 6-month follow-up (100% for both groups), the incidence of MACE (composite of cardiac death, target vessel MI, and TLR) favored the paclitaxel-coated balloon group (16.7% vs 50.0%; $P < .01$), driven by a reduced rate of TLR (15.3% vs 36.8%; $P = .005$).

Interventional and Adjunctive Techniques

ROTAXUS

Rotational atherectomy does not increase efficacy of a DES in complex calcified lesions compared with standard balloon dilatation, according to data from the prospective multicenter ROTAXUS (Prospective, Randomized Trial of High-Speed Rotational Atherectomy Prior to Paclitaxel-Eluting Stent Implantation in Complex Calcified Coronary Lesions) trial.[19] In fact, the early angiographic gain is more than offset by late loss. Gert Richardt, MD, PhD, of Herzzentrum Bad Segeberg (Bad Segeberg, Germany), and colleagues randomized 240 patients with moderate to severe calcification in a de novo coronary lesion to high-speed rotablation (n = 120) or standard balloon angioplasty (n = 120) followed by PES implantation.

At 9 months, the control arm had less in-stent late lumen loss (the primary endpoint) than the atherectomy arm (0.31 mm vs 0.44 mm; $P = .01$). Qualitative comparative analysis data showed similar results but no significant difference in MLD, percent diameter stenosis, or binary restenosis between the two arms.

Nine-month rates of death, MI, TVR, TLR, MACE (composite of death, MI, or TVR), and definite stent thrombosis did not differ between the two groups (Table 12). Thus, in most patients, rotational atherectomy prior to DES implantation should be reserved for lesions that cannot be adequately predilated.

ADVISE

A new type of intracoronary resistance measurement that takes advantage of a naturally occurring period of stasis in the arteries results in a drug-free index of stenosis severity comparable with fractional

TABLE 12

ROTAXUS: 9-Month Clinical Outcomes

	Rotablation (%) (n = 120)	Balloon Angioplasty (%) (n = 120)	*P* Value
Death	5.0	5.8	0.78
MI	6.7	5.8	0.79
TVR	16.7	18.3	0.73
TLR	11.7	12.5	0.84
MACE	24.2	28.3	0.46
Definite ST	0.8	0	1.0

MACE, major adverse cardiovascular events; MI, myocardial infarction; ROTAXUS, A Prospective, Randomized Trial of High-Speed Rotational Atherectomy Prior to Paclitaxel-Eluting Stent Implantation in Complex Calcified Coronary Lesions; ST, stent thrombosis; TLR, target lesion revascularization; TVR, target vessel revascularization.
Data from Richardt G.[19]

flow reserve (FFR) measurement.[20] According to Justin Davies, MD, PhD, of Imperial College (London, United Kingdom), recent studies have shown that, at best, FFR is used in approximately 6% of all PCI procedures in the United States. A major reason for this is the need to administer adenosine, which minimizes and stabilizes coronary resistance during the test, but is uncomfortable for patients, as well as time consuming and expensive.

For the nonrandomized, international, multicenter ADVISE (Adenosine Vasodilation Independent Stenosis Evaluation) study, Dr. Davies and colleagues developed a new pressure-based index, the instantaneous wave-free ratio (iFR), based on a wave-free period when intracoronary resistance is naturally constant and minimized. Unlike FFR, iFR calculation does not require adenosine or any other drug to be administered.

In an initial proof-of-concept study, the measurement of stability and magnitude of resistance during the wave-free period was statistically similar to that seen under adenosine hyperemia. In a subsequent validation study in 131 patients (157 stenoses), the resting ratio of the distal-to-proximal pressure with iFR and with FFR were statistically similar ($r = .9$; $P < .001$). When the relationship was examined according to both left and right coronary arteries, the differences were minimal. Overall, diagnostic efficiency was excellent (receiver operating characteristic area under the curve of 93%). Diagnostic accuracy was 88%, whereas specificity, sensitivity, and negative and positive predictive values were 91%, 85%, 85%, and 91%, respectively.

COBRA

Using cryoplasty for postdilation following stent implantation reduces restenosis compared with conventional balloon angioplasty in diabetic patients with superficial femoral artery (SFA) disease. Cryoplasty uses liquid nitrous oxide rather than saline to inflate the angioplasty balloon, cooling its surface temperature to approximately −10° C. Proponents of the technique have suggested that it reduces restenosis by altering plaque response, which reduces elastic recoil and induces apoptosis in smooth muscle cells.

For the COBRA (Cryoplasty or Conventional Balloon Post-Dilation of Nitinol Stents for Revascularization of Peripheral Arterial Segments) trial, researchers led by Subhash Banerjee, MD, of the University of Texas Southwestern Medical Center (Dallas, TX), studied 90 diabetic patients with severe intermittent claudication or critical limb ischemia (≥ Rutherford stage 3) and SFA disease treated with self-expanding nitinol stents.[21] Patients were randomized to postdilation with cryoplasty (PolarCath® Peripheral Dilatation System, Boston Scientific; n = 45) or conventional balloon angioplasty (n = 45).

Procedural success with the cryoplasty system, which consists of a balloon catheter, a nitrous oxide refrigerant cylinder, and a microprocessor-controlled inflation unit, was 100%, with a mean fluoroscopy time of 31.82 ± 20.30 minutes. The primary endpoint of binary restenosis at 12 months was significantly reduced in patients receiving cryoplasty compared with conventional angioplasty (29.3% vs 55.8%; $P = .01$), showing a cumulative HR of 2.39 (95% CI, 1.19-4.78; $P < .01$). On subanalysis, cryoplasty also reduced 12-month restenosis in patients with chronic total occlusion lesions and in those who received bilateral stent implantation, although the difference in the former group just missed statistical significance (Table 13).

Ankle brachial index measurements improved from baseline to 12 months in both groups, but the difference was only significant in cryoplasty patients (0.59 ± 0.21 to 0.77 ± 0.30; $P = .004$). Improvements in walking impairment questionnaire scores, meanwhile, were significant in both the conventional angioplasty ($P = .002$) and cryoplasty ($P = .005$) groups. Adverse events were low in all patients, with just four deaths (3 cryoplasty, 1 conventional balloon), no amputations, no surgical revascularizations, and no cases of MI, stroke, or contrast nephropathy.

PROFI

In patients undergoing carotid artery stenting (CAS), proximal balloon occlusion was associated with fewer new cerebral ischemic lesions than filter protection in the prospective, single-center PROFI (Prevention of Cerebral Embolization by Proximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting) trial presented by Klaudija Bijuklic, MD, of Hamburg

TABLE 13

COBRA Subanalysis: 12-Month Binary Restenosis

Subgroups	Cryoplasty (%)	Balloon Angioplasty (%)	*P* Value
CTO lesions	36.0	70.0	.06
Bilateral SFA stents	26.7	66.7	.03

COBRA, Cryoplasty or Conventional Balloon Post-Dilation of Nitinol Stents for Revascularization of Peripheral Arterial Segments; CTO, chronic total occlusion; SFA, superficial femoral artery.
Data from Banerjee S.[21]

University Cardiovascular Center (Hamburg, Germany).[22]

PROFI randomized 62 patients with symptomatic (≥ 60%) or asymptomatic (≥ 80%) internal carotid artery stenosis undergoing CAS to cerebral protection with either a filter (n = 31) or proximal balloon occlusion (n = 31). Using diffusion-weighted MRI, researchers compared the incidence, number, and volume of new cerebral ischemic lesions. At 30 days, the incidence of new cerebral ischemic lesions was significantly higher in the filter group (87.1% vs 45.2%; $P = .001$). These differences were maintained in the subgroups of symptomatic ($P = .04$) and asymptomatic ($P = .02$) patients. In patients older than 80 years, there was a trend toward a higher rate of new lesions in the filter group, but the difference was not significant.

Patients receiving filter protection also had a higher mean volume (0.59 cm^3 vs 0.16 cm^3; $P = .0001$) and number (3.5 vs 1.0; $P = .0001$) of new ischemic lesions. The incidence of MACCE at 30 days was minimal, with only one minor stroke in the filter arm. However, larger randomized trials are needed to determine whether use of proximal balloon occlusion translates into reduced rates of periprocedural stroke. ■

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