MEETING HIGHLIGHTS

Highlights of the 2004 Transcatheter Cardiovascular Therapeutics (TCT) Annual Meeting: Clinical Implications

Ehtisham Mahmud, MD, FACC, Babek Pezeshki, MD, Ali Salami, MD, FACC, Shahin Keramati, MD, FACC
San Diego, California

In its 16th year, the Transcatheter Cardiovascular Therapeutics (TCT) annual meeting remains one of the largest meetings in interventional cardiology. Live case demonstrations of interventional procedures remain a hallmark of this meeting, where results of several clinical studies and reviews of topics of interest for practicing interventional cardiologists were also presented. This meeting continues to provide a venue for extensive industry exhibits, and the role of devices used in interventions was prominent. We present the results of key studies presented at this year’s meeting and discuss their clinical implications in addition to summarizing the new techniques and topics presented.

DRUG-ELUTING STENTS

Because of their superiority in reducing restenosis, drug-eluting stents (DES) have replaced the use of bare-metal stents (BMS). Multiple studies involving DES including longer-term follow-ups of previously reported trials and results of DES use for higher-risk lesion and patient subsets were presented at this meeting.

TAXUS-IV (two-year results): The Pivotal, Prospective, Randomized Trial of the Slow-rate Release Polymer-based Paclitaxel-eluting TAXUS Stent—Greg Stone, MD. This study evaluated the efficacy of a paclitaxel-eluting stent (PES) in reducing restenosis versus a BMS (1). The investigators randomized 1,314 patients undergoing elective stenting, with single de novo lesions 10 to 28 mm in length, treatable with one stent in vessels 2.5 to 3.75 mm in diameter. Patients were randomized to a 1-mg/mm² slow-release paclitaxel-eluting Taxus stent (Boston Scientific, Natick, Massachusetts) or a BMS and received clopidogrel for six months. The primary end point was the nine-month rate of ischemia-driven target vessel revascularization (TVR). The two groups were matched, and nine-month TVR and target lesion revascularization (TLR) rates were 12.0% and 11.3% with the BMS and 4.7% and 3.0% with the Taxus stent (risk ratio [RR] = 0.39 and RR = 0.27, both p < 0.0001), respectively. There was no difference between the two groups in cardiac death, MI, or stent thrombosis at two years, whereas relative risk reductions of 60% to 70% in TLR were seen with the Taxus stent in most patient and lesion subgroups, except insulin-requiring diabetics, whom the difference did not reach statistical significance. Of importance, although stent thrombosis rates were low in both groups (1.1% Taxus stent and 0.8% BMS, p = 0.77), three patients in the Taxus stent group (none in BMS group) had stent thrombosis between one and two years after Taxus stent implantation.

TAXUS-II (two-year results): Follow-up Angiography and Intravascular Ultrasound (IVUS) Results of the Slow-release and Moderate-release Polymer-based Paclitaxel-eluting Stent with a Bare Metal Stent—Antonio Colombo, MD. The Taxus-II trial was among a series of preliminary clinical trials investigating the utility of PES in reducing restenosis. In this trial, the investigators randomized 536 patients with single de novo lesions of 10.5 mm length in a reference vessel of 2.75 mm diameter to a slow-release (n = 131) or moderate-release (n = 135) polymer-based PES and its bare-metal counterpart (n = 270). Six-month results have been presented previously and revealed TLR reduction of 76% in both the currently approved slow-release and non-commercially available moderate-release PES formulations versus their respective controls.

To demonstrate long-term safety and efficacy, two-year clinical, angiographic, and IVUS results of this study were presented at this meeting. Target lesion revascularization was reduced from 15.5% (BMS) to 5.5% (slow-release PES, p = 0.0047) and 3.9% (moderate-release PES, p = 0.0006) at two years. The TLR rates between six months and two years in all three groups remained unchanged (13.3% vs. 15.5% BMS, 4.6% vs. 5.5% slow-release PES, 3.1% vs. 3.9%...
moderate-release PES, respectively, \( p = \text{NS for all} \). There was no difference in the three groups with respect to cardiac death, MI, or stent thrombosis at two years. However, five patients were felt to have late stent thrombosis between six months and two years, of whom two patients were in the slow-release and three patients in the moderate-release PES formulation. Angiographic substudy results revealed that minimum luminal diameter between six months and two years in the BMS group increased from 1.96 \( \pm 0.47 \) mm to 2.12 \( \pm 0.44 \) mm (\( p < 0.0001 \)), whereas it remained unchanged in the slow-release (2.32 \( \pm 0.39 \) mm vs. 2.32 \( \pm 0.45 \) mm, \( p = \text{NS} \)) and moderate-release (2.34 \( \pm 0.38 \) mm vs. 2.35 \( \pm 0.37 \) mm, \( p = \text{NS} \)) PES formulations. No coronary artery aneurysm formation was noted at two years with either of the paclitaxel formulation–treated patients. The IVUS evaluation at two years revealed in-stent volume by quantitative coronary angiography was reduced by 82% by 76% (33% BMS vs. 7.7% Cypher stent, \( p < 0.0001 \)) with late-stent thrombosis. The IVUS data would suggest that no late restenosis catch-up or late coronary artery aneurysm formation has been noted with PES. The initial inherent in this ARTS II cohort, 30-day MACE rate was 2.8% compared with 5.3% for the ARTS I-CABG and 9.2% for the ARTS I-PCI groups. Six-month MACE rates were 6.4%, 9.0%, and 20.0%, in the three groups, respectively (\( p = \text{NS for all comparisons} \)).

**DIABETES: A Prospective Randomized Controlled Trial of the Polymer-based Sirolimus-eluting Stent Versus a Bare Metal Stent in Patients with Diabetes Mellitus—Manel Sabate, MD.** Diabetic patients have higher restenosis rates after coronary stenting. In this multicenter trial, the investigators randomized 160 patients (221 lesions) with diabetes mellitus (oral hypoglycemic or insulin-treated) and de novo native coronary artery lesions to the sirolimus-eluting Cypher stent (Cordis, Miami, Florida) versus its BMS counterpart. The two groups were matched for baseline clinical and angiographic characteristics, and one-third of the patients were insulin-treated in both groups. The primary end point of in-stent and in-segment (5 mm proximal and distal to stent edge) late loss in minimum luminal diameter at nine months by quantitative coronary angiography was reduced by 82% (0.44 mm BMS vs. 0.08 mm Cypher stent, \( p < 0.0001 \)), and the secondary end point of in-segment restenosis was reduced by 76% (33% BMS vs. 7.7% Cypher stent, \( p < 0.0001 \)) with the Cypher stent. These angiographic findings correlated with comparative reductions in TLR and major adverse cardiac event (MACE) (cardiac death, MI, and TLR) rates at nine months (BMS: TLR 31.3%, MACE 36.3%; Cypher stent: TLR 7.5%, MACE 11.3%, \( p < 0.0001 \) for both). Comparative relative risk reductions were noted in both insulin-requiring and oral hypoglycemic–treated diabetics.

**Arterial Revascularization Therapies Study (ARTS) II—Patrick Serruys, MD.** ARTS I was a large, randomized, multicenter trial, which evaluated complete arterial revascularization with coronary artery bypass graft surgery (CABG) versus multivessel stenting (with BMS) in 1,205 patients with multivessel coronary artery disease (CAD). No significant difference in death, stroke, or MI between the two groups was noted, although there was a 17% reduction in 12-month repeat revascularization with CABG but at a higher cost than multivessel PCI (2). In ARTS II, 607 patients with multivessel CAD were enrolled in a registry and treated with the sirolimus-eluting Cypher stent. This study was designed to compare one-year major adverse cardiac and cerebrovascular event rates between Cypher stent treated patients against the historical control CABG group (\( n = 600 \)) from ARTS I. The patients enrolled in ARTS II had a higher prevalence of diabetes, hypertension, and hypercholesterolemia than patients in ARTS I. Periprocedural use of glycoprotein (GP) IIb/IIIa inhibitors, lesion complexity, and frequency of three-vehicle stenting, the number of lesions treated/patient (ARTS II: 3.2, ARTS I-CABG: 2.6, ARTS I-percutaneous coronary intervention [PCI]: 2.5) and stent length (ARTS II: 73 mm; ARTS I-PCI: 48 mm) were all greater in ARTS II. Despite the greater risk and complexity inherent in this ARTS II cohort, 30-day MACE rate was 2.8% compared with 5.3% for the ARTS I-CABG and 9.2% for the ARTS I-PCI groups. Six-month MACE rates were 6.4%, 9.0%, and 20.0%, in the three groups, respectively (\( p = \text{NS for all comparisons} \)).

**IMPLICATIONS.** One year ago the results of the Taxus-IV trial were reported and the benefit of PES in all lesion subtypes and patient populations, including diabetics, was found to be clinically significant and consistent. However, longer-term safety and efficacy data were lacking. Two-year results of both the Taxus-II and -IV trials are reassuring in that no late restenosis catch-up or late coronary artery aneurysm formation has been noted with PES. The initial benefit in lower TLR rates remains at two years after the index procedure, resulting in lower MACE rates at two years and confirming the efficacy of PCI with PES as a long-term revascularization strategy. On a cautionary note, among the PES-treated patients in both trials, eight patients (0.9%) were felt to have late stent thrombosis between six months and two years, whereas no BMS-treated patients had late-stent thrombosis in either trial. Although this rate of late-stent thrombosis is low and deemed to be not statistically significant by the investigators, it is extremely concerning, as this is an underappreciated phenomenon. A recent report by McFadden et al. (3) describes late-stent thrombosis in patients treated with both Taxus and Cypher stents and further raises questions regarding long-term safety of both of these DES especially with discontinuation of antiplatelet therapy. These data suggest that longer-term dual antiplatelet therapy with aspirin and clopidogrel than the currently recommended three to six months after DES implantation may be required. The reasons behind late-stent thrombosis with DES remain unclear and need further investigation. As the phenomenon has been reported with both of the currently available DES, and the duration of drug elution is significantly different between the two stents, it is unlikely that the duration of drug elution is associated with late-stent thrombosis. The IVUS data would suggest...
that poor stent strut apposition with DES is also not responsible for this problem, so an inflammatory response to the underlying polymer (4) or withdrawal of antiplatelet therapy may be the underlying mechanism. Regardless, an intensive after-marketing surveillance of DES should be performed by clinicians, industry, and regulatory bodies to ensure that the restenosis benefit is not counteracted by life-threatening late-stent thrombosis.

Both the sirolimus-eluting Cypher and paclitaxel-eluting Taxus stents are superior to BMS in reducing restenosis and TLR (1,5). The Diabetes trial presented at this meeting demonstrates that Cypher stents are clearly beneficial in reducing neoimtinal proliferation in diabetics, and data from the Taxus-IV trial (1) support that the same holds true for Taxus stents. Although these are not comparative data between these two stents, it is reassuring that in a subset of patients with the highest restenosis rate (diabetics), both commercially available DES offer low restenosis rates. Abstracts presented at this and other recent meetings confirm low restenosis rates with Cypher and Taxus stents in patients with long lesions, calcified lesions, chronic total occlusions, bifurcation lesions, and in-stent restenotic lesions. Data from ARTS II demonstrate that in the contemporary treatment of patients with multivessel CAD, stenting with Cypher stents offers six-month clinical outcomes comparable to CABG. Data with DES are accumulating in high-risk restenosis lesions, but as comparative data between various DES are limited, it appears that stent choice continues to be based on cost and stent deliverability. Studies utilizing ABT-578 and everolimus-eluting stents continue to appear promising, demonstrating low late-loss indices and restenosis rates.

**ACUTE MYOCARDIAL INFARCTION**

Primary PCI is the preferred revascularization modality for patients suffering an acute ST-segment elevation MI (STEMI) and this has resulted in lower mortality rates and infarct sizes for these patients (6). Recently multiple studies have been designed and completed to evaluate various techniques for myocardial preservation during PCI for STEMI patients. Systemic hypothermia, intracoronary hyperpaequeous oxygen, mechanical thrombectomy with the X-sizer catheter (ev3, Plymouth, Minnesota), and distal microvascular protection with the GuardWire (Medtronic, Minneapolis, Minnesota) all proved to be futile in the treatment of patients with STEMI when tested in a randomized clinical trial (7,8). Studies presented at this year’s TCT meeting addressed an additional adjunctive therapy for treating STEMI patients.

**AIME: Angioplasty Rheolytic Thrombectomy in Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction—Arshad Ali, MD.** This trial used Angioplasty Rheolytic Thrombectomy (Possis, Minneapolis, Minnesota) prior to PCI for patients suffering from large STEMs to test whether thrombus extraction prior to PCI leads to reduction in final infarct size. The investigators randomized 480 STEMI patients with anterior or large inferior myocardial infarcts of <12 h duration to primary PCI or Angiojet Thrombectomy followed by PCI. Patients with left ventricular dysfunction (ejection fraction <35%), cardiogenic shock, previous CABG, uncontrolled hypertension, major surgery within 6 weeks, stroke within 30 days or GP IIb/IIIa inhibitor contraindication were excluded from the trial. The two groups were matched in baseline clinical characteristics, target vessel revascularized, time to PCI, use of stents and GP IIb/IIIa inhibitors, baseline thrombus burden, and Thrombolysis In Myocardial Infarction (TIMI) flow grade in culprit vessel. However, in the thrombectomy group, total procedural time was prolonged (76 vs. 60 min, \( p < 0.0001 \)) and temporary transvenous pacemaker use was greater (58% vs. 16%, \( p < 0.0001 \)). Analysis revealed that final TIMI flow grade 3 was achieved in only 92% of patients in the thrombectomy group and in 97% of patients in the standard PCI group (\( p < 0.02 \)), with no difference in myocardial blush score, corrected TIMI frame counts, or ST-segment resolution with either strategy. Periprocedural clinical and angiographic complications were comparable in both groups. The primary end point of final infarct size at 14 to 28 days after MI by Tc-99m sestamibi SPECT imaging was higher in the thrombectomy group (12.5 ± 12.1% thrombectomy vs. 9.8 ± 10.9% control, \( p < 0.02 \)), and this difference was most pronounced in inferior infarcts (10.2 ± 11.1% thrombectomy vs. 6.5 ± 8.9% control, \( p < 0.005 \)), whereas it was not different in anterior infarcts (16.5 ± 13.1% thrombectomy vs. 15.3 ± 12.0% control, \( p = 0.58 \)). Secondary end point of 30-day MACE (death, Q-wave MI, stroke, urgent CABG, and TLR) was 6.7% in the thrombectomy group and 1.7% in the control group (\( p < 0.01 \)), whereas the secondary end point of ejection fraction at 14 to 28 days was the same in both groups (51 ± 12% thrombectomy vs. 52 ± 11% control, \( p = 0.38 \)). Most importantly, the thrombectomy group had higher 30-day mortality (4.6% thrombectomy vs. 0.8% control, \( p < 0.02 \)).

**IMPLICATIONS.** Recent trials addressing the treatment of patients with STEMI should serve as reminders of the critical need for randomized clinical trials when new devices or therapies are introduced for clinical use. Although intuitively thrombus extraction before PCI in STEMI patients should be effective, the results of the currently reported AIMI trial not only question the routine use of the Angiojet Thrombectomy device for these patients, but question its safety. The increased time to treatment, requirement of adjunctive temporary pacemaker, higher mortality, and larger infarct size in patients treated with this device should lead to the avoidance of this device. With these data in hand, even in the presence of large intracoronary thrombus burden, the X-sizer thrombectomy device or Pronto extraction catheter (Vascular Solutions, Minneapolis, Minnesota) are safer devices to use. In fact, preliminary data from a randomized clinical trial utilizing the Pronto extraction catheter in STEMI patients were presented at TCT
and indicated the efficacy of this device without compromising in patient safety (9). Further analyses from previously reported trials were also presented, and it appears that in selected subgroups of patients both hyperaqueous oxygen and cooling to a body temperature of <32°F may lead to infarct size reduction. This appears promising and requires further investigation.

**CAROTID STENTING**

As symptomatic patients with >50% internal carotid artery stenosis or asymptomatic patients with >80% stenosis have lower stroke and death rates with carotid endarterectomy (CEA) than medical therapy (10–12), most current studies designed to test the safety and efficacy of carotid stenting are enrolling such patients. On the basis of the results of a randomized trial (13), carotid stenting has been shown to be non-inferior to CEA for patients with high-risk surgical characteristics for CEA. The results of this and other studies have led to the Food and Drug Administration approval of carotid stenting for the treatment of obstructive carotid artery stenosis, and the treatment paradigm is rapidly shifting from CEA to percutaneous stenting. Numerous randomized and registry studies with newer stent and distal protection devices for the treatment of carotid artery stenosis are ongoing, and the results of two such studies were presented at TCT.

**CABERNET: Carotid Artery Revascularization Using the Boston Scientific FilterWire and the EndoTex NexStent—L. Nelson Hopkins, MD.** In this multicenter prospective registry, the investigators enrolled 480 patients with carotid artery stenosis who were high-risk surgical candidates for CEA to carotid stenting with the nitinol self-expanding EndoTex NexStent (Boston Scientific) in conjunction with the FilterWire (Boston Scientific) distal embolic protection. Symptomatic patients with an internal carotid artery stenosis >50%, or asymptomatic patients with >80% (ultrasound)/60% (angiography) stenosis and having at least one high-risk comorbidity for CEA were enrolled. The study population was elderly with a mean age of 72.5 ± 8.6 years, 65.2% men, with 79.8% de novo lesions in a majority of asymptomatic patients (75.6%). Procedural success with stent and distal embolic protection was achieved in 96.9% of the patients with stenosis reduction from 83.6% to 6.5%. The primary end point of 30-day major adverse event (MAE) (death: 0.5%, MI: 0.2%, and any stroke: 3.4%) rate was reported to be 3.8%. Major stroke rate was 1.4%, whereas minor stroke rate was 2.0%.

**MAVERICK II (30-day results): Evaluation of the Medtronic AVE Self-expanding Carotid Stent System in the Treatment of Carotid Stenosis—Stephen R. Ramee, MD.** In this prospective multicenter registry, 399 patients with carotid artery stenosis who were at high risk for CEA were enrolled. They were treated with a self-expanding stent Exponent (Medtronic, Minneapolis, Minnesota) and the GuardWire (Medtronic) distal embolic protection system. Although the one-year MAE (death, MI, ipsilateral stroke) rate is the primary end point and these data are still being collected, secondary end points of the study included acute procedural success and 30-day MAE rate. Acute procedural success defined as the successful placement of the stent (with distal embolic protection) with a final residual stenosis of <30% in the absence of in-hospital MAE, was reported to be 90.1%. Thirty-day MAE rate was 5.3% (death: 1.0%, MI: 2.0%, ipsilateral stroke: 3.3%).

**IMPLICATIONS.** Patients who are deemed to be at high risk for surgical complications during CEA include elderly patients (>80 years old), patients with significant cardiac or pulmonary disease, patients with contralateral carotid occlusion or contralateral laryngeal nerve palsy, previous radical neck surgery or radiation therapy, and restenosis after CEA. Patients with any one of these high-risk characteristics for CEA were enrolled in a randomized clinical trial comparing CEA to carotid stenting, and results of this trial demonstrate that these patients can be successfully treated with percutaneous carotid stenting with results that are not non-inferior to CEA (13). Data from two different registries presented at this meeting add to the fund of knowledge regarding the safety and short-term efficacy of carotid stenting with newer stents and distal embolic protection devices for high-risk CEA patients. The Carotid Revascularization Endarterectomy versus Stent Trial (CREST) is a National Institutes of Health/National Heart, Lung, and Blood Institute-funded study in which the investigators are randomizing 2,500 patients at low risk for surgical complications during CEA to carotid stenting versus CEA to evaluate both strategies for carotid revascularization in low-risk patients. As distal embolic protection devices are further improved, anticoagulation regimens optimized and plaque characterization improved, further lowering in procedural complication rates and improvement in both short-term and long-term outcomes can be expected with carotid stenting for all patients.

**SAPHENOUS VEIN GRAFT (SVG) INTERVENTIONS**

Patients with degenerated SVGs who require percutaneous revascularization are a difficult subset of patients to treat. This is primarily owing to high restenosis rates in SVG lesions and distal embolization of macro- and micro-particles material during interventional treatment of SVGs, resulting in a 30-day MACE (death, MI, emergency CABG, or TLR) rate of 16.5% without distal embolic protection and 9.6% to 11.6% with distal embolic protection (14,15). Studies addressing SVG interventions with newer distal embolic protection devices and polytetrafluoroethylene (PTFE)-covered stents were presented at this meeting.
PRIDE: A Multicenter, Randomized Trial of Protection During Saphenous Vein Graft Intervention to Prevent Distal Embolization—Joseph P. Carrozza, Jr., MD. This study was initiated with the intention to prove the superiority of the TriActiv (Kensey Nash Corp., Exton, Pennsylvania) distal occlusion and extraction system in reducing MACE over standard SVG intervention without distal embolic protection. After the initial 62 patients were randomized in this trial, results of two randomized trials confirmed the utility of distal embolic protection during SVG interventions (14,15) resulting in the routine use of distal embolic protection during SVG interventions. This resulted in a change in the study design to a non-inferiority study and the control arm became distal embolic protection with either the GuardWire (Medtronic) or FilterWire (Boston Scientific). The investigators then randomized 631 patients with lesions of any length in SVGs (3 to 5 mm diameter) to either the TriActiv system (n = 313) or GuardWire (n = 236)/Filterwire (n = 83) systems. The two groups were matched with respect to clinical and angiographic characteristics and target vessel revascularized. Procedural success (89.4% TriActiv; 90.5% control, p = 0.64) was comparable between the two groups and the primary end point of 30-day MACE (death, MI, emergent CABG, or TVR) (11.2% TriActiv; 10.1% control, Δ = 1.1%, one-sided confidence interval on the difference = 5.2%) met the prespecified criteria for non-inferiority. A secondary efficacy end point of final TIMI flow grade 3 was achieved in 99.1% of TriActiv patients and 97.8% of the control group (p = 0.20). Several secondary safety end points of MI, in-hospital MACE, and stroke were reported to be comparable between the two groups. However, the TriActiv group of patients had higher vascular and hemorrhagic complications (11.8% vs. 6.6% control, p = 0.02), primarily when 8-F sheaths were used.

CAPTIVE: Cardioshield Application Protects During Transluminal Intervention of Vein Grafts by Reducing Emboli—David R. Holmes, Jr., MD. This was another prospective, multicenter, randomized trial initially designed to prove the superiority of the Cardioshield (Abbott Laboratories, Abbott Park, Illinois) distal embolic protection filter in reducing MACE over standard SVG intervention without distal embolic protection. After 197 patients were enrolled in this trial, based on the results of the Saphenous Vein Angioplasty Free of Emboli Randomized (SAFER) trial (14), distal embolic protection became to be utilized routinely for SVG interventions. Therefore, this trial design was modified to a non-inferiority study design of the Cardioshield versus GuardWire (Medtronic) distal embolic protection and another 652 patients were enrolled in the non-inferiority arm of the trial. Data analysis of the initial superiority cohort (n = 197 patients) revealed that the primary end point of 30-day MACE (death, MI, TLR, and emergency CABG) rate was the same in both groups (10.4% Cardioshield vs. 11.9% no distal embolic protection, p = 0.82).

For the larger cohort of patients enrolled in the non-inferiority arm of the trial (n = 652), baseline clinical and angiographic characteristics and procedural success did not differ between the two groups. However, 30-day MACE rates were higher in the Cardioshield group (11.4% vs. 9.1% GuardWire, p = 0.057). This did not meet the predefined criteria for non-inferiority of the Cardioshield distal embolic protection system.

SYMBIOT III: A Prospective Randomized Trial of a PTFE Self-expanding Stent Graft During SVG Intervention—Late Results—Maurice Buchbinder, MD. Both distal embolization during PCI and restenosis after the index procedure affect success of SVG interventions. The PTFE-covered stents have the potential to reduce distal embolization and may also serve as a barrier for smooth muscle cell proliferation. To investigate this hypothesis, the investigators randomized 400 patients with lesions up to 41 mm in length, in SVGs of 3.5 to 5.5 mm, to any BMS against a PTFE-covered nitonol stent (Symbiot, Boston Scientific). The two groups were matched in baseline clinical and angiographic characteristics, and target vessel revascularized but total stent length was longer in the Symbiot stent group (32.5 ± 14.9 mm vs. 26.2 ± 13.6 mm, p < 0.0001). Eight-month MACE (death, MI, clinically driven TVR, and TLR) rates (26.6% BMS vs. 30.6% Symbiot stent, p = 0.43) and stent thrombosis rates (2.5% BMS vs. 3.5% Symbiot stent, p = 0.16) were comparable between the two groups. The primary end point of the study, eight-month angiographic stenosis, was higher in the analysis segment for the Symbiot stent group (40.1 ± 29.8% Symbiot stent vs. 34.8 ± 26.3% BMS, p = 0.12), though this did not reach statistical significance. Binary restenosis was higher in the Symbiot stent group (34.9% Symbiot stent vs. 23.3% BMS, p = 0.04) and this led to a higher rate of TLR requiring percutaneous revascularization in the Symbiot stent group (17.9% Symbiot stent vs. 10.4% BMS, p = 0.04).

IMPLICATIONS. Distal embolic protection during SVG interventions is the current standard for successful outcomes after percutaneous revascularization for SVG disease. Interestingly, two trials with newer generation devices were presented at this meeting in which a filter device (Cardioshield) did not prove to be non-inferior to the distal occlusion and aspiration device GuardWire while another occlusion and extraction system TriActiv proved to be non-inferior. The fundamental difference in these two newer systems is that one completely occludes the culprit vessel (TriActiv), whereas the other allows blood flow but can capture debris (Cardioshield). Intuitively, the occlusion and aspiration systems should prove to be superior but practically, a number of patients do not tolerate these devices. Generally, the filter devices are better tolerated by patients, as prolonged ischemic time is not associated with them. Unfortunately, the Cardioshield device failed the non-inferiority test against the GuardWire but, as pointed out in the presentation, this difference could be accounted
for by a single clinical event. Nevertheless, with the currently available data it may be hard for this device to be approved for routine clinical use. Both the GuardWire and the FilterWire are commercially available, and the TriActiv system appears to be a reasonable alternative. The results of the SYMBIOT III trial verify the futility of PTFE-coated stents for reducing restenosis and distal embolization. In fact, the higher restenosis rate seen with the Symbiot stent over a BMS should lead to greater vigilance in detecting restenosis after PTFE-covered stent placement for coronary perforations, currently the only accepted indication for the use of a PTFE-covered stent.

**SUMMARY**

The results of several new studies relevant to interventional cardiovascular medicine were presented at this meeting. The field of interventional cardiology has morphed into that of interventional cardiovascular medicine and this was clearly evident at this year’s TCT meeting. Though live case demonstrations of routine coronary interventional procedures were becoming redundant at this meeting, demonstrations of new techniques and concepts for complex coronary, peripheral vascular, and carotid interventions at the meeting this year were educational and relevant. Drug-eluting stents, only recently discovered, are now routinely used for most coronary interventions. Data presented at this meeting confirmed the short- and long-term efficacy of DES for complex lesion and patient subsets. On a surprising note, most recent adjunctive therapies for acute MI patients have been unsuccessful, and further investigative efforts are required in this area to limit myocardial damage during STEMI and possibly regenerate myocardium.

Many clinical trials are either ongoing or in the late stages of organization to better define the indications and therapies for peripheral vascular interventions. The utility of drug-eluting stents for peripheral vascular indications will be a major focus of investigation over the next few years. Furthermore, percutaneous treatments for patients with structural heart disease including patent foramen ovale closure, mitral annuloplasty, aortic valve replacement, and left atrial obliteration for atrial fibrillation are currently in clinical trials.

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**REFERENCES**


