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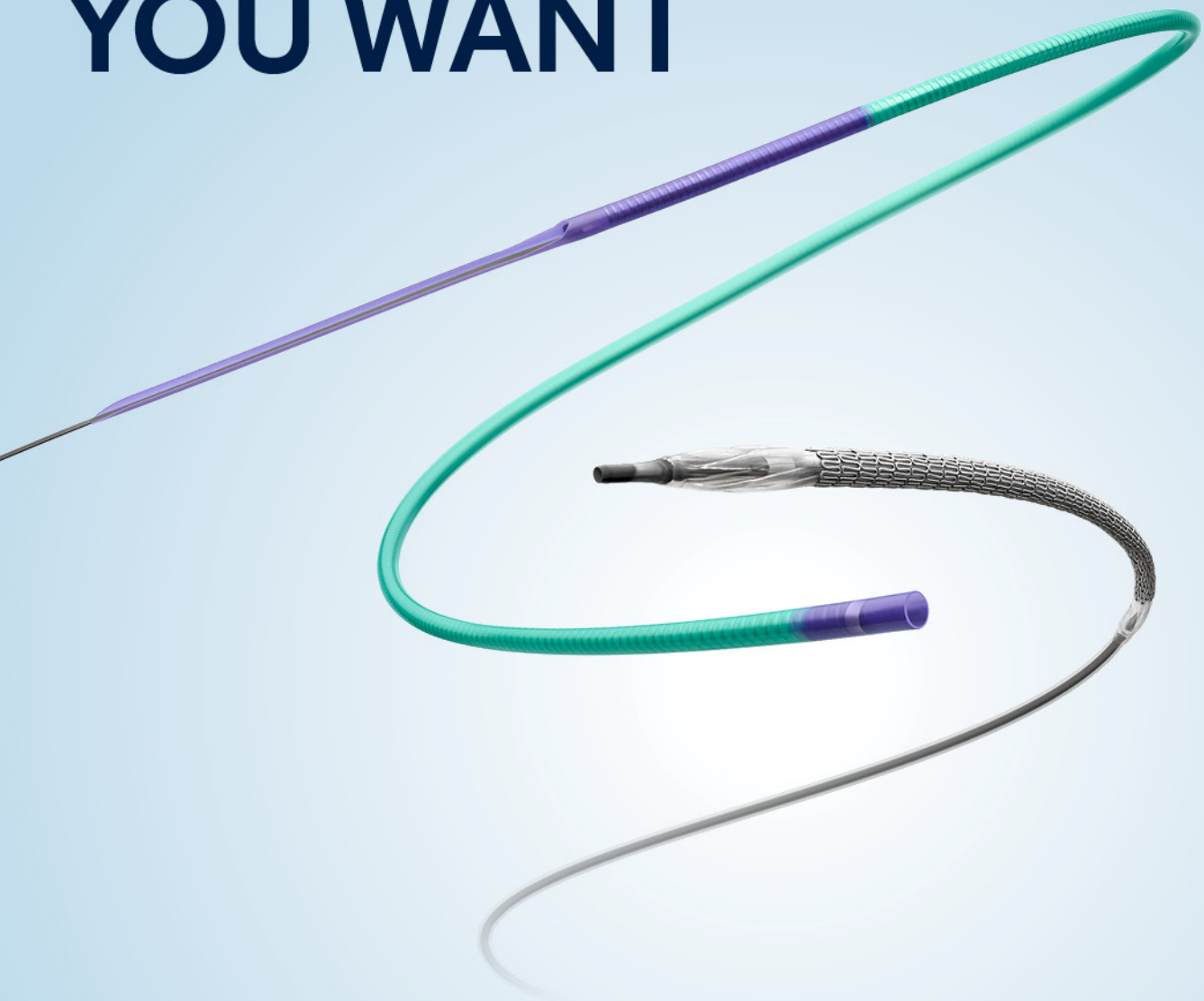

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CORE CURRICULUM

Training in high-risk coronary procedures and interventions: Recommendations for core competencies

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1 | INTRODUCTION

With rapid advancement within the field of interventional cardiology, we are now able to treat a wide spectrum of coronary artery disease (CAD) percutaneously. During an accredited general interventional ACGME training year, a fellow may be exposed to a variety of percutaneous interventional cases in order to obtain a basic understanding and comfort with an assortment of procedures. These procedures can include diagnostic cardiac catheterization, interventional procedures, in addition to the assessment and treatment of patients with valvular, myocardial, and basic adult congenital heart diseases.[1] However, there still remains a large population of patients who may be declined for revascularization due to increased risk.[2] These patients, despite having an appropriate indication, are often not offered revascularization because of their comorbidities, surgical ineligibility, complexity of coronary anatomy, or adverse hemodynamics.[2] Additionally, these patients often have the most to gain in terms of symptom relief and/or prognosis, consistent with a risk-treatment paradox in which the highest-risk patients frequently have the greatest potential benefit but are the least likely to be offered treatment.

As risk increases, more advanced skillsets are required to achieve high technical and procedural success rates. The clinical and technical abilities of operators leaving fellowship may be varied due to differences within training institutions. In a single year of post-fellowship training, it may be difficult to master the technical skills that may be learned during a dedicated year of High-Risk PCI training including atherectomy, CTO-PCI, proficiency with management and placement of mechanical circulatory support devices including large bore access, especially as some centers may lack the case volume necessary to adequately train fellows with these skills.

Specifically, complete revascularization has shown to be associated with reduced adverse outcomes, and thus if deemed to be safe, is considered strongly in appropriately selected patients presenting with High-Risk coronary artery disease. Often, in order to achieve complete revascularization however, percutaneous intervention of a technically challenging lesion may be necessary. Advanced training to increase comfort with High-Risk lesions and patients may help an interventionalist achieve complete revascularization despite challenging anatomic or hemodynamic circumstances.[3,4]

Dedicated training in conjunction with high volume, experienced operators can facilitate development of an advanced skillset that would allow an interventionalist to comfortably approach high-risk scenarios including left main disease, CTOs and patients with cardiogenic shock. Some have argued against additional advanced training secondary to lack of volume, lack of time for proctoring/mentoring, and lack of support from hospital administration. However, in order to safely and appropriately manage this population, additional training to master high-risk techniques and become facile with management of these patients can be very advantageous.[3,4]

These recommendations have been written by several internationally recognized leaders in the field of High-Risk Interventions, in addition to several of their past and current fellows. Our goal of this document was to describe expectations to achieve minimal competency in High-Risk PCI (Table 1). In this construct, an additional year of training to be completed after 1 year of an ACGME-accredited interventional fellowship is proposed. We have developed a curriculum to train a generation of High-Risk operators (Figure 1) that will be equipped to safely treat an underserved patient population and advance the growing field of PCI. We have focused this document on the minimum competencies to managing high-risk patients and lesions including left main coronary artery stenosis, coronary bifurcations, coronary artery calcification, underexpanded stents, chronic total occlusions (CTO), and cardiogenic shock both inside and outside of the catheterization laboratory. The goal of this manuscript is to standardize training and minimize the variability of therapy in patients at increased procedural risk.

TABLE 1 High-risk PCI fellowship technical competencies and proposed procedural volumes

Procedure	Recommended minimum procedural volume
• Unprotected left main PCI	20 patients
• Intravascular imaging	100 patients
• Chronic total occlusions ○ Retrograde CTO PCI technique ○ ADR techniques (stingray and subintimal tracking and reentry [STAR])	150 successful retrograde and antegrade CTO PCI
• Placement of hemodynamic support ○ V-A ECMO ○ Percutaneous RV support devices ○ Percutaneous LV support devices, including Impella and TandemHeart	10 patients
• Management of cardiogenic shock including transition to durable forms of long-term support (LVAD, TAH, transplant, etc.)	Co-training with MCS/heart failure 6–8 weeks
• Hemodynamic support assisted PCI	15 patients
• Large bore vascular access management ○ Crossover/up and over techniques ○ Dry closure ○ Covered stent	5 patients
• Complication management ○ Perforation ○ Dissection ○ Device entrapment ○ Embolization (coils, beads, fat, thrombin, etc.) ○ Snaring	5 pericardiocentesis 5 coil embolization 5 fat embolization 10 snaring procedures

Abbreviations: ADR, antegrade dissection re-entry; CTO, chronic total occlusion; LV, left ventricle; LVAD, left ventricular assist device; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention; RV, right ventricle; STAR, subintimal tracking and re-entry; TAH, total artificial heart; V-A ECMO, veno-arterial extracorporeal membrane oxygenation.

2 | ANATOMIC SUBSETS

2.1 | Unprotected left main PCI

Left main PCI may be categorized as "High-Risk" PCI as it often requires careful hemodynamic management, more complex decision making, and technical expertise. Several studies have supported the role of percutaneous left main coronary intervention.[5] Moreover, familiarity with intravascular imaging and routine use during left main PCI is critical to optimize outcomes. Data have suggested that increased experience in performing left main PCI is associated with improved outcomes. In a recent study that evaluated unprotected left main PCI (ULM PCI) in the National Cardiovascular Data Registry in the US, the mean annual ULM PCI volume was 0.5 procedures per operator.[4] Approximately 16.5% of operators performed an average of 1 or more ULM PCI annually.[4] While real world patients had more comorbidities, adverse events occurred more frequently in this study compared to ULM PCI trials.[4] In a separate study by Xu et al., an experienced, high-volume ULM PCI operator was defined as one who performed at least 15 ULM PCIs per year for at least 3 consecutive years, and reported a significant reduction in mortality at 30 days and 3 years when ULM PCI was performed by an experienced operator.[6] In the DKCRUSHV trial, operators who were selected to participate in the trial to evaluate ULM PCI or distal left main coronary artery bifurcation lesions were required to have performed ≥300 PCIs/year for 5 years with at least 20 ULM PCIs per year.[7] Thus, while clinical trials show promise of excellent outcomes after left main PCI, this is not always achieved by operators with less experience, and data support the need for significant experience in left main interventions. We thus recommend that High-Risk training programs support minimum volumes of ULM PCI with intravascular imaging in 20 patients to develop proficiency.

2.2 | Calcific coronary disease, bifurcations, stent underexpansion, restenosis, etc

The High-Risk operator must also be comfortable with management of a variety of other lesion characteristics that may pose additional technical challenges including calcific coronary artery disease, bifurcations, stent underexpansion, and restenosis. Many, but not all trainees, will develop some proficiency with these during their first year of interventional training. The second year of advanced interventional training will serve to solidify expertise in these procedures.

Moderate to severe coronary calcification is prevalent in approximately 20–30% of patients and is an important predictor of incomplete revascularization.[8-10] Coronary artery calcium is associated with higher rates of periprocedural MI, underexpanded stents, stent thrombosis, and stent restenosis.[10-13] A recent study demonstrated that atherectomy was utilized in 3% of PCI cases.[14]

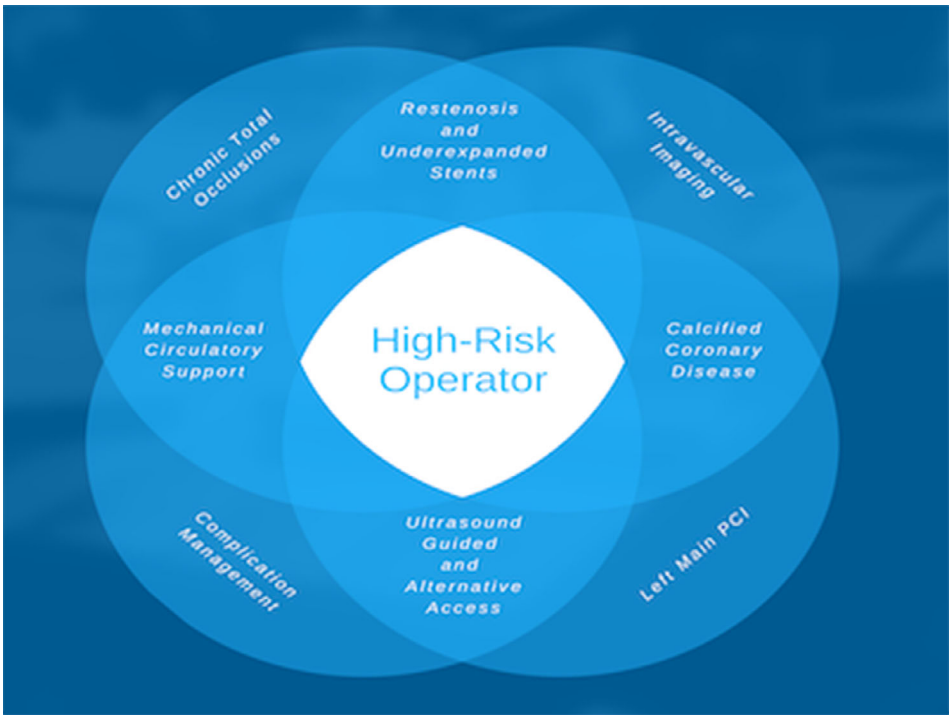

FIGURE 1 A high-risk operator competently treats patients with calcified coronary disease, severe left main lesions, in-stent restenosis, underexpanded stents, and chronic total occlusions. Additionally, they should be proficient with use of intravascular imaging, ultrasound guided and alternative access, management of complications and placement of mechanical circulatory support [Color figure can be viewed at wileyonlinelibrary.com]

During an additional year of dedicated High-Risk training, trainees should become proficient in the use of orbital/rotational atherectomy and lithotripsy, and be comfortable managing complications associated with this technology. We suggest a minimum procedural volume of 30 such cases to demonstrate competence in treatment of coronary calcium.

Managing stent underexpansion/restenosis is important in developing the High-Risk skill set, as many patients may present with severe underexpansion refractory to balloon inflation. Operators must have an algorithmic treatment approach to managing underexpanded stents which should include laser atherectomy (in addition to possible rotational and orbital atherectomy), lithotripsy, and brachytherapy as needed, and use of intravascular imaging. We recommend a minimum of five cases of stent underexpansion/restenosis.

The presence of bifurcation lesions is another predictor of incomplete revascularization.[8,9] Competence should ideally be achieved during general interventional fellowship but this is not always the situation. While often simple one-stent strategies are sufficient, High-Risk operators must be comfortable performing two stent strategies either as bailout or as an initial strategy when treating high-risk bifurcations with large subtended myocardial territories.

2.3 | Chronic total occlusions

The prevalence of unattempted CTOs remains quite high, and this has been cited to be secondary to inherent technical challenges. Angina is the indication to proceed with routine PCI, and the same is true for CTO-PCI. In patients with persistent angina despite optimal medical therapy, consideration of CTO-PCI is important to alleviate symptoms. Additionally, successful CTO PCI revascularization is critical to achieving complete revascularization, which has been associated with improved outcomes. Successful CTO-PCI can be technically challenging, and thus chronic total occlusions may remain unattempted despite continued symptoms.

Historically, CTO-PCI success rates were around 60%,[3,15] however recent registries from high-volume CTO-PCI centers with highly skilled, experienced operators demonstrate success rates of 85–90%.[15-24] While CTO-PCI proctoring has been shown to increase success rates, case complexity and volume during an advanced training year allows this skillset to be learned systematically despite a condensed time period.[25] The hybrid algorithm stresses the importance of flexibility and having multiple approaches to achieve revascularization.[26] As lesion complexity increases, more technically challenging approaches such as ADR (Antegrade Dissection/Reentry) and retrograde CTO-PCI may be required to achieve high procedural/technical success rates.[18,20,27] Each of these techniques pose unique challenges and a series of steps that must be thoroughly explained including prevention of donor vessel thrombosis, donor vessel guide dissection, gear entrapment, protection of collateral vessels, and snare management. As lesion complexity increases, and ADR and/or a retrograde approach is used more frequently, the complication rate may increase as well, which requires an additional skillset to appropriately and safely manage.[3]

In addition to a thorough understanding of technical approaches to successfully treat a CTO, it is important for the trainee to be familiar with the CTO toolbox which includes the variety of wires and microcatheters. Trainees must graduate with a thorough understanding of the structure and composition of these tools to optimize the selection of their equipment during a case and to optimize their results. This education should be provided both via didactics in a one-on-one setting with their senior operator, but also during cases.

We recommend that High-Risk PCI training programs support a minimum of 150 CTO-PCIs during advanced training. We recommend using retrograde techniques in at least 50–75 patients and ADR techniques in at least 50–75 patients each to develop proficiency.

2.4 | Intravascular imaging

Intravascular imaging is important for all percutaneous coronary revascularization but is even more critical in the treatment of High-Risk coronary disease. The use of imaging can help optimize stent results and provide durable outcomes.[27,28] Routine imaging may help identify calcium and allow for adequate lesion preparation, appropriate stent sizing and expansion.[27,28]

Imaging can also identify a subintimal course during a CTO intervention, aid in stent placement, identify hematomas or dissections, in addition to facilitate cap puncture.[27,28] Therefore, it is important that High-Risk operators are comfortable with the use of intravascular imaging to help guide decision making when treating this patient population. We recommend a minimum of 100 cases in which intravascular imaging is used.

2.5 | Hemodynamic support and cardiogenic shock management

Hemodynamic support may be used in a variety of cases including but not limited to PCI of a last remaining conduit, reduced ejection fraction with adverse hemodynamics, and acute myocardial infarction complicated by cardiogenic shock.[29-31] As this field of High-Risk PCI evolves and more robust data continue to become available, we hope to better understand patient selection, hemodynamics, timing of implantation, and utility of mechanical support in improving patient outcomes in this population.

In addition to being facile with implantation of devices such as the Impella CP, Impella RP, and Protek Duo, High-Risk PCI, operators should also be comfortable with transseptal punctures and implantation of TandemHeart for hemodynamic support, and extracorporeal membrane oxygen (ECMO) cannulation. TandemHeart may be useful in specific scenarios such as in patients with prior mechanical aortic valve, LV thrombus, or when more robust support is needed.

While technical proficiency in inserting devices is important, a thorough understanding of hemodynamics including measures such as cardiac power output (CPO) and pulmonary artery pulsatility index (PAPi) is necessary to appropriately choose the correct mechanical support device and optimally manage these patients in the intensive care unit.

We recommend that training programs support a minimum volume of hemodynamic support in 15 patients to develop this necessary skillset. Additionally, we recommend that the trainee spend time managing patients in the intensive care who require mechanical circulatory support.

2.6 | Access, alternative access, and closure

Significant peripheral arterial disease and large bore access may contribute to increased risk of vascular complications when performing High-Risk PCI. Data has suggested that the use of ultrasound to perform arterial access was associated with reduced vascular complications.[32] If possible, radial artery access should be utilized. However, there are several issues which may arise during a procedure that may prohibit the use of the radial artery including spasm or tortuosity.[33] Additionally, large-bore access may be necessary depending on the indicated procedure thus use of the femoral artery may be required.

Ultrasound should be used routinely in all High-Risk procedures and trainees should be comfortable with large bore ultrasound guided access, having performed at least 100 ultrasound guided femoral punctures. Additionally, trainees should be comfortable with at least two different closure devices, have a thorough understanding of pitfalls of each device, and be able to manage device failures and complications associated with both access and closure.

Especially in the higher risk population where significant peripheral vascular disease is common, alternative access may need to be considered in patients that require hemodynamic support. Use of alternative access is an important skillset to allow safer revascularization in these patients.

We recommend that High-Risk PCI training programs support minimum volumes, of their trainees, to five cases of alternative access site (transaxillary, transcaval, etc.) to develop proficiency.

2.7 | Complication management

High-risk PCI is associated with a higher complication rates compared to conventional PCI which varies by subset and method of revascularization employed. Complications that occur in this patient population may be associated with worse long-term health status outcomes.[33] It is imperative that fellows training in High-Risk procedures develop proficiency in complication management. Complications can be broadly categorized into cardiac (coronary and noncoronary) and extracardiac (vascular, thromboembolic, etc.). Coronary complications include no-reflow, dissection, and perforations. Operators must be competent in pharmacologic management, reentry (wire-based and device-based), and perforation management (fat, coils, beads, etc.). Noncoronary complications include aortic dissection and cardiac tamponade. While competence should be developed during interventional fellowship, High-Risk PCI trainees should perform a minimum of five pericardiocentesis procedures. Trainees should be equipped to manage large-bore access site complications such as balloon tamponade and bail-out use of covered stents. We suggest a minimum volume of five bailout procedures (balloon tamponade, covered stenting, etc).

While the frequency of complications may be limited in an individual operator, High-Risk trainees should develop an algorithmic approach to management of complications through both their own experiences but also through other educational initiatives including conferences and the use of simulators.

3 | NON-TECHNICAL SKILLSETS

In addition to time spent in the laboratory training in technical proficiency, we also recommend that special attention be given to ensuring competence in other important skills including clinical decision

making, complication management both inside and outside the laboratory, and research.

3.1 | Clinical decision making

Training in clinical decision making should be pursued through outpatient clinics or in the hospital setting outside of the cardiac catheterization laboratory in which trainees will evaluate patients with High-Risk coronary anatomy and assist in shared decision making. The trainee should be comfortable discussing risks and benefits of High-Risk PCI and participating in heart team discussions with cardiovascular surgeons, the patient's primary cardiologist, and the patient to reach a shared decision as to whether to proceed with PCI or CABG. We recommend at least two clinics per month in addition to time spent consulting on inpatients referred for High-Risk PCI. Additionally, we recommend dedicated time spent rounding in the cardiac intensive care unit to ensure a thorough understanding of hemodynamic support and its clinical management.

3.2 | Research

We also recommend that trainees participate in research and database management through their year of additional training. These individuals will continue to shape the future of High-Risk PCI and exposure to research endeavors and an understanding of database management will be important to continue to contribute to registries and trials that will help advance the field of High-Risk PCI.

3.3 | Didactic training

Lastly, we recommend formal didactic training and conference participation. Didactic training should include thorough understanding of algorithmic approach to various complications that may occur during High-Risk PCI. First-hand experience of these complications is impossible during a single year of training, but use of these didactics will help teach an algorithmic approach to complications. Didactic training should also include a standardized lecture on the "CTO toolbox" to ensure that the trainee is familiar with the use of various tools. Lastly, trainees should attend a formal hemodynamic tutorial early in their training to solidify their understanding of hemodynamic support.

High-Risk PCI trainees should also attend at least two conferences focused on High-Risk PCI, that will not only help further develop their approach to management of High-Risk cases and associated complications, but also allow exposure to new technology and innovation, provide networking opportunities to encourage collaboration and teamwork while becoming a part of a larger community.

In defining these non-technical skillsets we hope that we will encourage innovation and teamwork amongst our trainees. These individuals are expected to move the field of High-Risk PCI forward as they innovate and adopt new technologies. They should be early adopters, and be able to assess promising ideas, techniques and devices by the end of their training. Additionally, they should be team players that can work with others to both care for their patients and advance the field forward.

4 | CONCLUSIONS

The need for standardized advanced coronary training has emerged as a result of limitations in general interventional cardiology training and continued advancement in the field of High-Risk coronary interventions. Formal training to safely and adeptly manage High-Risk patients both inside and outside of the cardiac catheterization laboratory is important. As this field continues to evolve with increasing technologic advances and new data, it becomes more important to standardize minimum competencies for trainees to achieve to safely and skillfully treating High-Risk coronary disease. We have aimed to define minimal procedural volumes in various key High-Risk procedures while also defining nontechnical skills necessary including shared decision making, clinical management of High-Risk patients and adverse hemodynamics, innovation, and research. We believe these skills are necessary to produce the next generation of technically skilled, clinically astute, and innovative operators who can collaborate with each other to continue moving the field of High-Risk PCI forward.

CONFLICT OF INTEREST

Khaldoon Alaswad Consultant and speaker for Boston Scientific, Abbott Cardiovascular, Teleflex, and CSI; **Dimitrios Karmpaliotis** Honoraria: Abbott Vascular, Boston Scientific, Abiomed Equity: Saranas, Soundbite, Traverse Vascular; **Robert Riley** Speaking honoraria from Boston Scientific, Medtronic, and Asahi Intec.; **James McCabe** CSI, Teleflex, Boston Scientific; **Ajay Kirtane** Institutional funding to Columbia University and/or Cardiovascular Research Foundation from Medtronic, Boston Scientific, Abbott Vascular, Abiomed, CSI, CathWorks, Siemens, Philips, ReCor Medical. In addition to research grants, institutional funding includes fees paid to Columbia University and/or Cardiovascular Research Foundation for speaking engagements and/or consulting. Personal: Travel Expenses/Meals from Medtronic, Boston Scientific, Abbott Vascular, Abiomed, CSI, CathWorks, Siemens, Philips, ReCor Medical, Chiesi, OpSens, Zoll, and Regeneron.

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