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IAGS 2019 Session 1: Coronary Session 1 – Elective PCI

1.1 CT iFR/FFR Will Make Coronary Angiography Unnecessary

Problem Presenter: George S. Hanzel, MD

Statement of problem or issue

More than 50% of patients undergoing invasive angiography are found to have non-obstructive coronary artery disease (CAD). Stress imaging modalities have sensitivity and specificity of 70%-80%, respectively. Although coronary CT angiography (CTA) has a high sensitivity, the specificity is quite low. Coronary CTA/FFR<sub>CT</sub> provides both anatomical and physiological data and has been shown to be superior to SPECT and PET stress testing for assessment of ischemia. A modest-sized study has demonstrated an impressive 80% reduction in the need for invasive angiography compared with standard care. Importantly, this was coupled with an extremely low rate of major adverse cardiac events (MACE) in those in whom angiography was deferred. Thus, CTA/FFR<sub>CT</sub> is poised to become the new “gate keeper” to the cath lab.

Gaps in knowledge

Despite its excellent diagnostic performance, the adoption of CTA/FFR<sub>CT</sub> has been slow in the United States, as well as most of the rest of the world. Some issues are mundane, such as variable reimbursement policies, and control of CTA by radiology. However, it must be acknowledged that the current data regarding outcomes and the reduction in invasive angiography are based on a small number of modestly-sized trials of stable chest pain patients. Additionally, there is a paucity of data on acute chest pain patients.

Possible solutions and future directions

Additional randomized trials, as well as real-world registries, are required to confirm early studies of stable chest pain patients to verify the reported substantial reduction in rates of invasive angiography by CTA/FFR<sub>CT</sub>. These studies should also assess long-term MACE and the possible subsequent need for invasive angiography and PCI in patients in whom angiography was deferred. Studies also need to be performed in the important subgroup of acute chest pain patients, in whom it may also be important to move beyond just lesion-specific ischemia and incorporate plaque characterization as well as novel CTA indices to evaluate plaque vulnerability. The utility of these adjunctive indices will need to be studied. In those patients who do undergo invasive angiography, CTA/FFR<sub>CT</sub> can be used for PCI planning. Whether PCI planning with “virtual stenting” actually adds value to the PCI procedure will need to be determined. Cost-effectiveness analyses need to be performed. From a practical standpoint, cardiologists will need to partner with radiologists to develop viable CTA/FFR<sub>CT</sub> programs and work with insurance carriers to secure reimbursement in order to bring this technology into mainstream clinical care.
1.2 Elective PCI is Not Dead: How to Take ORBITA Out of Orbit

Problem Presenter: Alfredo Rodriguez, MD

Statement of problem or issue

The ORBITA trial continues to generate interest and controversy. This blinded trial compared two groups of patients with stable angina, a positive exercise treadmill stress test (ETT), and an angiographically severe stenosis in a single coronary artery to either optimal medical therapy (OMT) or percutaneous coronary intervention (PCI). Outcome was assessed by a 6-week ETT. The result was a non-significant improvement in exercise time in both the OMT and PCI groups (11 seconds vs 28 seconds, respectively). The conclusion was that PCI in this setting was a mere placebo. Some commentators called for a change in guidelines and restrictions on PCI in patients like these. The study was hailed by some as a new standard in clinical trials, altering the spectrum of future research. However, a perplexing problem was that in prior studies, OMT patients improved exercise time by 55 seconds while PCI patients improved by about 120 seconds. Why ORBITA patients behaved so differently remains unexplained, as admitted even by the study authors.

Gaps in knowledge

Several major limitations in ORBITA have been identified.

A conservative estimate of the enrolled patients at the 5 participating centers reveals they were less than 1% of the total screened. So, enrollees were a highly selected group.

Careful analysis of the angiograms reveals that many lesions were less than the prespecified requirement of >70% severity. This finding could also explain the fact that 30% of enrolled patients had a normal FFR before the PCI.

Importantly, due to blinding, none of the treated patients were told they had received a stent. However, patients in both groups were told that they had a severe stenosis in a major heart artery, possibly inducing a “nocebo” response. What exactly is a nocebo response? It is the opposite of placebo (favorable response) and has been defined as “negative expectations or threats to the patients in response to the clinical encounter.” This uncertainty about the status of their severe narrowing could very well have led patients in both groups to proceed cautiously and hold back on the 6-week ETT in case their artery was not stented. This might explain the markedly reduced exercise response of both OMT and PCI patients relative to all previous trials.

The same investigators subsequently aimed to answer these questions in a small but eloquently performed trial in similar, ORBITA-like patients, in which they replicated the ORBITA protocol but implanted stents in both study arms and informed all patients that they had received a stent, thus effectively removing any possible nocebo response. These patients exercised for an additional 65 seconds at follow-up. The investigators also used a special pressure sensor to perform an eloquent hemodynamic study pre- and post-PCI, which proved that post-PCI FFR, iFR, coronary perfusion pressure, as well as coronary flow velocity at peak exercise, significantly increased and were normalized relative to the pre-PCI measurements. They concluded “PCI for single-vessel stable coronary artery disease shows clear physiological evidence of meeting all that could be demanded of a therapy for ischemia.” The calls for changing the guidelines became much more subdued after the ORBITA investigators acknowledged the original study limitations.

Possible solutions and future directions

The ORBITA trial was a landmark because it was the first to attempt to study the psychological placebo response to PCI. However, it highlighted the potential pitfalls encountered when studying the complexities of human reactions. Future studies in other fields of percutaneous interventions will undoubtedly become subject to this type of trial but would have to circumvent the obstacles encountered in ORBITA:

1. The placebo response is part of any medical therapy and to test an intervention, it must provide evidence of efficacy above and beyond the placebo effect. Accordingly, all
measures should be taken to increase the placebo response, while at the same time minimizing any possible nocebo effects. This would be done through reassuring and comforting verbal communications.

(2) Psychological tendencies of patients are highly varied, with some more prone to a placebo (positive) response than others who may be more prone to a nocebo (negative) response. Control and assessment of these responses remain quite elusive on subjective tests such as the ETT or Seattle Angina Questionnaire (SAQ). For this reason, all efforts should be made to include objective hard endpoints in these trials.

(3) The ongoing ISCHEMIA trial will shed further light on the issue of PCI in patients with stable angina regarding hard endpoints.

1.3 The Fate of PCI in Diabetics

Problem Presenter: Mauricio G. Cohen, MD

Statement of problem or issue

Diabetes mellitus is a major cardiovascular risk factor, present in approximately 20%-30% of patients who require coronary revascularization. The vascular biology of diabetes is characterized by systemic endothelial dysfunction, platelet abnormalities that result in a prothrombotic milieu, increased systemic inflammation, and accelerated atherosclerosis. Diabetics have smaller caliber coronary vessels and more diffuse and extensive coronary disease. The inception of drug-eluting stents (DES) has decreased restenosis and repeat revascularization in diabetes undergoing percutaneous coronary interventions (PCI). However, among diabetic patients with multivessel disease, coronary artery bypass grafting (CABG) is associated with lower mortality and major adverse cardiovascular and cerebral events compared to PCI.

Gaps in knowledge

There have been multiple advances in PCI for diabetics including new generation stents with thinner stent struts, and polymers with higher biocompatibility. However, restenosis and repeat revascularization rates remain higher in diabetics, and it is not clear whether or not biodegradable polymers are associated with better outcomes. There is a need for the development of agents that interrupt signaling pathways that predispose to restenosis in diabetes.

Even though low ejection fraction, multivessel disease, and diabetes is a classic indication for CABG, there is a paucity of randomized clinical trials or sufficiently powered subgroup analyses examining revascularization outcomes in diabetic patients with systolic left ventricular dysfunction. In trials comparing PCI versus CABG in diabetics, patients with low ejection fraction are significantly underrepresented.

Possible solutions and future directions

New technologies that may have an impact in diabetic patients include new stent platforms, including polymer-free stents, reengineered biodegradable vascular scaffolds, and drug-filled stents. Advances in this area could allow improved vessel healing and endothelial coverage, similar to bare metal stents, with the advantage of preventing restenosis. Intravascular lithotripsy for calcific vessels is a promising technology for PCI optimization in diabetics with diffusely diseased and calcified vessels.

Systematic physiologic assessment of coronary lesions in diabetics with estimation of a “functional SYNTAX score,” instead of a purely anatomic score, allows reclassification of diabetics with multivessel disease into a lower SYNTAX category (≤32). These patients may be treated with optimized PCI strategies. Non-invasive functional assessment of coronary lesions is now possible with FFRCT, which may help guide coronary interventions and identify diabetic patients who would derive similar benefits with PCI compared to CABG. However, this imaging modality has not been widely adopted in clinical practice yet.

Hybrid revascularization strategies using a left internal mammary graft for LAD lesions and DES for non-LAD stenoses is an appealing strategy that deserves further study.
Unfortunately, hybrid revascularization has not been adopted in clinical practice and the NIH-sponsored Hybrid Trial has been stopped for poor enrollment. In addition, revascularization strategies in general need to be better studied in diabetic patients with low systolic left ventricular function.

Regardless of the revascularization strategy selected, diabetics remain at high risk for recurrent events. Wide implementation of multidisciplinary disease management programs to improve therapeutic goals in diabetics is necessary. These goals include use of potent antiplatelet agents, tighter glycemic control, aggressive lipid lowering with high-dose statin therapy and/or use of PSK9 inhibitors. Broader adoption of sodium-glucose contransporter-2 inhibitors (SGLT2i) is warranted in diabetic patients with established atherosclerotic disease, in light of clinical trial data demonstrating reduced risk of cardiovascular events.

IAGS 2019  Session 2: Structural Session 1 - Aortic

2.1 TAVR in Standard Risk Patients: A Runaway Freight Train?

Problem Presenter: Augusto D. Pichard, MD

Statement of the problem or issue

Today there are 602 TAVR approved Centers in the United States. As I travel among centers I have observed that not all patients are getting optimal care. I have seen cases with (a) inadequate indication, (b) inadequate device selection, (c) inadequate procedural steps, and (d) inadequate treatment post procedure. This is probably related to lack of current information, lack of expertise, economic incentives, regional competitive forces, and hospital policies leading to inappropriate decisions in some patients. I have seen it in high volume and low volume TAVR Centers. At the IAGS Meeting I showed several case examples to illustrate each one of these points.

Gaps in knowledge

TAVR is a new procedure that has rapidly expanded in the last decade. A great effort by the leaders in this field has generated strong data, based on randomized clinical trials and carefully conducted registries, leading to approval of the procedure with certain very specific guidelines.

Many gaps in knowledge remain. The next 1-2 decades will bring important information that will modify importantly the TAVR world: who does TAVR, which device is optimal for each patient, which patient gets TAVR and when, which ancillary procedures should be considered, how is the TAVR patient cared for during and after the procedure, etc.

Possible solutions and future directions

New data are continuously being generated in scientific publications, leading to important changes in patient selection, procedural aspects, and post procedural management. The TAVR experts are continuously meeting to try and interpret existing data, to share experiences, to discuss possible best strategies, and to suggest practical recommendations. Implanters need to remain involved in these activities to keep up with progress.

The TVT Registry compiles all cases performed in the US (a requirement for reimbursement) and provides important clinical, procedural and outcomes information with follow-up to one year. The TVT Registry has the ability to pinpoint “outliers” and calls the institution asking for corrections.

CMS has recently proposed a liberalization of requirements to begin a TAVR program in an attempt to facilitate access to care. As long as the Heart Teams remain strong, very well informed, and monitored by national organizations, patients may benefit. The need
for “expertise” on the interventional team remains very strong; this is not a procedure to perform occasionally.

A successful TAVR program also needs to invest in an effective and comprehensive effort for the education of the patient and family before and after the TAVR procedure, to fulfill the main objective of TAVR: enhance the patient’s well-being and long-term outcome.

2.2 Which Valve for Which Patient and Whether and When to do Bioprosthetic Valve Modification

Problem Presenter: Adam B. Greenbaum, MD

Statement of problem or issue

For patients with failing surgical bioprosthetic valves, transcatheter aortic valve replacement (TAVR) has been shown to be a safe and efficacious alternative to repeat surgery for those with significant operative risks. However, a substantial percentage of these patients have a surgical prosthesis of small diameter, often with inadequate sinus widths, placing them at risk for life-threatening coronary obstruction during a valve-in-valve TAVR procedure, as well as patient-prosthesis mismatch, leaflet thrombosis, and premature TAVR-valve deterioration from under-expansion.

Gaps in knowledge

Current commercially available TAVR valves have unique design specifications (ie, skirt length, leaflet location, commissural heights), which may uniquely impact aortic and coronary flow after placement. User-driven, novel, adjunctive techniques have been developed to maximize TAVR valve expansion (such as bioprosthetic valve fracture [BVF]) and maintain flow into the native sinus (bioprosthetic aortic scallop intentional laceration to prevent coronary obstruction [BASILICA]). Small retrospective case series of both, and a recently completed 30-patient, NHLBI-funded, prospective study of BASILICA, showed high technical and clinical success with no signal of safety concern. However, predicting the true risk of coronary obstruction as well as understanding the long-term impact of both higher gradients and optimal flow into the sinus post valve-in-valve TAVR, and therefore the benefit of BVF and BASILICA techniques, remain challenging.

Possible solutions and future directions

Long-term clinical and echocardiographic data from large multicenter trials of transcatheter heart valves, and smaller nested registries specifically investigating their use for valve-in-valve applications, should provide further insight into the implication of residual gradients post TAVR. However, industry is less well suited to help answer questions related to the more novel, and somewhat “off-label” techniques of BVF and BASILICA. One solution could be to capture these data within the Transcatheter Valve Therapies (TVT) registry, in which most centers implanting commercial transcatheter valves in the United States are participating. Yet, this registry may not be nimble enough to incorporate the rapid pace of changes to additional adjunctive procedural techniques, let alone capture their individual nuances, and stakeholders would need to be very proactive to overcome this. Additionally, detailed preprocedural CT imaging results are not captured in the TVT registry. Another solution could be separate, prospective, multicenter registries specifically aimed at techniques such as BVF and BASILICA, which could conceivably also involve core lab analysis of all baseline CT data. But, obstacles to operationalizing these concepts remain. Registries of this nature typically require either institutional review board (IRB) oversight and approval at each center as well as individual patient consent, or agreement to rely on a single IRB and a waiver of patient-consent, both of which can be difficult to obtain. Additionally, questions surrounding benefits to BVF and BASILICA with regard to valve durability and overall survival will likely require large numbers of patients, and long-term follow up. Participation in multiple simultaneous registries can be onerous and costly for often understaffed clinical programs with little institutional gain for participation.
Funding for registries of techniques alone is unlikely to come from outside sources. In the meantime, dedicated equipment to simplify and streamline BASILICA is in development and in the end, answers to questions surrounding novel techniques may require equally “out-of-the-box” thinking in terms of proving their long-term benefit.

2.3 The Bicuspid Valve: Does TAVR Compete with SAVR? Are We Ready for a Randomized Trial, and in Whom?

Problem Presenter: David A. Wood, MD

Statement of problem or issue
Transcatheter aortic valve replacement (TAVR) is an alternative therapy to surgery for patients with calcific aortic stenosis irrespective of surgical risk. However, patients with bicuspid valve anatomy have been excluded from the landmark randomized controlled trials. Procedural concerns that may impact transcatheter heart valve (THV) deployment in bicuspid patients include elliptical annuli, asymmetric and bulky calcium distribution, and lower coronary artery heights. All the above may adversely impact both THV positioning and expansion as well as increase the incidence of paravalvular leak and procedural complications. Despite a lack of evidence from randomized controlled trials, successful implants have been performed in a number of bicuspid aortic valve patients with favorable short-term results. However, the long-term durability remains unknown.

Gaps in knowledge
Current gaps in knowledge include optimal sizing, THV selection, the effect of concomitant aortopathy, and mechanical durability. There is currently considerable variability in THV sizing for bicuspid patients. Some sites use a “supra-annular” approach for sizing; however, there is no standardized or reproducible approach to bicuspid valve sizing. The optimal THV platform for bicuspid patients is also poorly understood. In addition, the implications of a concomitant aortopathy is poorly understood. In some patients with an associated aortopathy and aortic valve stenosis, surgery may be a better option. Finally, it is unclear if the long-term durability of TAVR in bicuspid valve patients will be similar to patients with degenerative trileaflet calcific aortic valve stenosis.

Possible solutions and future directions
As TAVR expands to lower-risk and younger patients, where there is a greater likelihood of bicuspid anatomy, the results of an adequately powered randomized trial will be crucial to help address the existing knowledge gaps. In younger patients, an understanding of factors that may impact durability will help guide THV selection. While THV platforms designed specifically to accommodate the unique challenges of bicuspid valve anatomy are still on the horizon, novel techniques have recently been developed that involve laceration of the bicuspid valve leaflets to facilitate procedural success and mitigate the risk of coronary obstruction. While promising, these techniques are still in their infancy.

IAGS 2019 Session 3: Endovascular Session 1

3.1 Is “Leave Nothing Behind” the Right Approach to the SFA?

Problem Presenter: James P. Zidar, MD

Statement of problem and gaps in our knowledge
Current endovascular strategies for superficial femoral artery (SFA) and popliteal intervention started with “plain old balloon angioplasty” or PTA, often with long balloons. This approach is quick and cheap, but may not provide the optimum outcome, especially with very long lesions, calcified vessels, chronic occlusions (CTOs), or dissected vessels.
Atherectomy provides an alternative to PTA at a higher cost, but may optimize vessel wall preparation for drug-coated balloons. We have the options of rotational and directional atherectomy (CSI, Rotoblator, Jetstream and TurboHawk) and also laser atherectomy. Although longer-term outcome data are quite sparse for these treatments, this strategy extends the lesion types one can approach from an endovascular perspective. Embolic protection is frequently required. Impressive early experience with Shockwave "lithoplasty" has been accumulating for calcified SFA vessels, and without the need for distal protection.

Self-expanding nitinol stents have been available for years and are ideal in the short term to treat severe dissections, but long stents do poorly in the longer term, with high restenosis rates and frequent re-occlusions. Even the Supera woven stent, which can sustain the forces of popliteal flexion, has long-term restenosis issues. Drug-coated nitinol stents (Zilver PTX) are more expensive and have shown modest long-term benefits over PTA, but restenosis within these and other stents is much harder to treat. The first drug-eluting peripheral stent on the US market (Eluvia) outperformed the Zilver PTX in the randomized Imperial trial at 1 year of follow-up.

Drug-eluting balloons (DCBs) with paclitaxel (In.Pact Admiral, Lutonix, Stellarex, and Ranger balloons) are currently the most popular strategy, after several small randomized trials suggested benefit vs PTA at 1 and 2 years of follow-up. However, dissections are often left behind and the cost of this technology is high. In the United States, DCBs are often used after lesion preparation with atherectomy or lithoplasty in calcified lesions. Heparin-coated stent grafts (Viabahn) have been used to treat very long SFA disease or sub-intimal recanalization of CTOs. Restenosis tends to limit itself to the edges of the graft. However, the cost is high and the failure mode is more dramatic, as the collateral circulation has been sacrificed.

Possible solutions and future directions

At the current time, most US peripheral interventionalists use an aggressive lesion preparation strategy followed by DCB for most SFA lesions, in an effort to “leave nothing behind.” However, it is much more difficult to avoid stents for severe adventitial dissections, or CTOs that were recanalized into the subintimal space. Most operators are much more likely to “spot stent” than a decade ago. Unfortunately, a recent meta-analysis from Greece (Katsanos, JAHA, published Dec 2018) suggested late mortality concerns with paclitaxel DCBs. This paper has thrown the clinical world into current confusion as we await further patient level outcomes data. Until these data are presented, the field remains in a state of uncertainty.

3.2 Should the Vascular Use of Paclitaxel be Banned?

Problem Presenter: Doug M. Cavaye, MD

Statement of the problem

A recent meta-analysis of randomized controlled trials (RCT) suggests a possible increased mortality rate after two years in patients treated for atherosclerosis of the femoro-popliteal arteries using paclitaxel-coated balloons and paclitaxel-eluting stents, compared to patients treated with control devices (non-coated balloons or bare metal stents). The specific cause for this observation has not been identified (Katsanos K, et al; JAHA 118 01 1245).

Gaps in knowledge

Of the 28 RCTs analyzed (4663 patients), there were only 3 trials with 5-year follow-up data (863 patients). Each RCT showed higher mortality in patients treated with paclitaxel-coated devices than those treated with uncoated devices (20.1% versus 13.4% for crude risk of death at 5 years). It was noted that there was marked heterogeneity across the trials, and accurate mortality risk estimation was potentially low-powered, as a result of the small amount of longer-term data. Because the 28 original trials were not specifically designed for data pooling and meta-analysis, the value and reliability of the conclusions

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becomes uncertain. There was also no specific cause for the increased mortality identified in the study conclusions. It was also noted that paclitaxel has been used as an intravenous chemotherapy agent for many years, using vastly higher doses than those in the drug-eluting intravascular devices, without any specific unexpected drug-related mortality reported.

**Possible solutions and future directions**

Because there is significant and proven benefit from paclitaxel-coated balloons and stents with regard to patency and restenosis reduction, it was determined that these devices should continue to be used. Discussion of risks and benefits in individual patients is paramount, and should continue to guide treatment options for femoro-popliteal atherosclerosis. It was noted that the FDA has issued correspondence on two occasions, January 17, 2019 and March 15, 2019, and provides specific guidelines for device vigilance and disclosure.

### 3.3 Color Coded Angiography: Real Time Quantitative Imaging

*Problem Presenter: Eric J. Dippel, MD*

**Statement of problem or issue**

The goals for treating critical limb ischemia (CLI) are to maximize arterial inflow to the foot, heal wounds, minimize tissue loss, and prevent major amputations. Endovascular techniques and tools have evolved to the point that percutaneous revascularization below the ankle, including pedal arch reconstruction, has become possible, particularly in centers of excellence for CLI therapy. Typically, in the angio suite, we rely on digital subtraction angiography (DSA) to make decisions on procedural success, completeness of revascularization, and predict wound healing.

**Gaps in knowledge**

DSA has not evolved much since its advent in the 1980s, and it has a number of limitations, including the fact that interpretation is highly subjective and only qualitative in determining arterial flow. The subjective nature of DSA data precludes analyses that potentially might aid with real-time decision making. Additionally, DSA images are acquired in black and white, but we live in a color world. In today’s practice, an endovascular revascularization is performed on a patient with CLI and they are then sent back to the wound clinic with the hope that an adequate revascularization was performed, but without quantitative data that it was. Historically, there is no objective, predictive in-vivo imaging performed in the angio suite to assess the completeness of the revascularization. Traditional non-invasive surrogate assessment of limb perfusion, such as ankle-brachial index (ABI), Sensilace, or Tcom measurements, are done at some later date after the intervention and therefore not available in real-time.

**Possible solutions and future directions**

Parametric angiographic imaging can provide near real-time, objective, quantitative, color-coded assessment of blood flow to the affected limb in-vivo in the angio suite. The DSA images are post-processed via a high bandwidth server and displayed within seconds of acquisition. The parametric imaging software analyzes every pixel of every frame of an acquisition run and produces a time-density contrast curve for each pixel. This time density curve can then be used to define discrete data points, such as: (1) time to arrival, (2) time to peak, (3) area under the curve, (4) peak height, and (5) mean transit time. These data points can then be analyzed objectively and quantitatively, potentially using artificial intelligence, to make decisions on the completeness of revascularization in the angio suite prior to ending the case. They can also be mapped to create a color-coded angiogram (Figure 1).

In order to compare pre- and post-intervention parametric images, there are several technical considerations that are important. There must be no motion artifact during image acquisition. The image detector height, the table height, the field of view, the camera
magnification, and the camera angulation must all be the same for the before and after images. There should be no compensation filter in the field of view. The pre and post angiograms should be obtained from the same injection site, and the contrast flow rate and volume should be the same. If a vasodilator was used, the same dose should be administered with the pre and post images. Finally, the same region of interest (ROI) should be used for analysis.

Parametric imaging is in its infancy regarding potential applications for limb salvage. This has tremendous potential in the treatment of CLI to predict the adequacy of restoration of arterial inflow and correlate to the success or futility of wound healing. There are a number of future directions that need to be addressed. The standardization of image acquisition is paramount to be able to conduct any meaningful large-scale multicenter studies. The size and location of the ideal ROI must be determined. Normal parameter ranges of the contrast time density curve need to be defined. There should be comparative studies with various vasodilators and doses to determine what is optimal, this also raises the question of whether a vasodilator is even necessary before imaging. An automated algorithm for determining the data points from the contrast time intensity curve would be very useful. Ultimately, the goal is to use this exciting imaging modality seamlessly during an intervention to predict wound healing, restenosis, late target lesion/vessel failure, long-term success/outcome, or even comparatively between different devices.

IAGS 2019  Session 4: Coronary Session 2 – STEMI

4.1 Multivessel Disease in STEMI: How COMPLETE Should We Be?
Problem Presenter: David A. Wood, MD

Statement of problem or issue
Many patients with STEMI have multivessel epicardial coronary artery disease. When a STEMI patient undergoes primary PCI with successful revascularization of the culprit lesion, there is uncertainty whether other non-culprit lesions should also be treated. Furthermore, if additional non-culprit lesions are to be treated, it is unclear whether they should be treated during the initial (index) primary PCI, later during the same hospitalization before discharge, or with a staged elective hospitalization at a later date.

Gaps in knowledge
Observational studies and meta-analyses have indicated that complete revascularization is superior to culprit-lesion-only revascularization, with a staged strategy possibly superior to a single-index-procedure strategy. However, the observed reductions were in composite endpoints only, and not in the individual hard endpoints of death or recurrent
MI. Importantly, recurrent MI is difficult or impossible to ascertain in the early period after the index MI, since biomarkers are still high, and repeat revascularization as a short- or long-term endpoint event is extremely suboptimal due to foreknowledge of coronary anatomy and known benefits of medical therapies. Likewise, in studies using FFR-guided decision making for non-culprit lesion treatment, improvements occurred in composite endpoints only and not in individual hard endpoints. This finding has held even when confined to the most severe disease (3-vessel disease with ≥90% stenoses). Finally, all studies to date have been underpowered for long-term death/MI events.

**Possible solutions and future directions**

The COMPLETE trial (NCT01740479) has recently finished enrolling 4042 STEMI patients with multivessel disease at 150 sites in 30 countries. Patients were randomized to either staged complete revascularization (vessel diameter >2.5 mm) or culprit-vessel-only PCI. Results will be presented in August 2019 at ESC with simultaneous publication in NEJM. The COMPLETE trial should provide crucial information on the appropriate strategy for revascularization of STEMI patients with multivessel disease.

**4.2 Reducing Infarct Size and Reperfusion Injury in STEMI**

*Problem Presenter: H. Vernon Anderson, MD*

**Statement of problem or issue**

For the 90% of STEMI patients that do not have cardiogenic shock or cardiac arrest, the main determinant of survival and future clinical status is infarct size. Ischemic time is the main factor governing infarct size, but modern STEMI systems-of-care have brought ischemic times down on average to low values that may not be able to be further reduced. Other therapies besides shorter treatment times must be developed to further reduce infarct size and optimize future clinical status.

**Gaps in knowledge**

Basic science investigations have identified and elaborated in great detail multiple interconnected biochemical and cellular pathways that are involved in ischemia-reperfusion. Yet despite extensive research, no effective pharmacotherapies have emerged. Other strategies must still be discovered to minimize myocardial injury and promote healing in already damaged myocardium, while also protecting adjacent uninjured but at-risk myocardium.

**Possible solutions and future directions**

Two promising approaches with potential benefit have emerged. The first is pre-reperfusion left ventricular (LV) support. Preliminary studies show that initiating LV support (unloading the LV) with an intra-aortic balloon pump (IABP) or Impella prior to reperfusion can reduce infarct size, but not when LV support is initiated after reperfusion. Important questions that arise are whether reperfusion should be deliberately delayed while providing LV support, and what the proper balance might be between delay to reperfusion and infarct size reduction. The preliminary data suggest that 30 minutes of LV support prior to reperfusion may be optimal, while additional delay beyond 30 minutes results in increased infarct size despite the LV support. A small clinical pilot trial of 50 anterior-STEMI patients was encouraging for this approach, no apparent danger signals surfaced with 30 minutes delay in reperfusion, and larger clinical studies are planned.

The second area of interest is hypothermia, also termed ‘targeted temperature management.’ Preliminary animal studies demonstrate a graded, dose-dependent effect of temperature reduction on salvage (protection) of ischemic myocardium. A meta-analysis of patient-level data from randomized clinical trials confirmed this dose relationship, and furthermore indicated that 35°C was the appropriate threshold temperature: cooling to <35°C reduced infarct size by 27% in anterior-STEMI compared to controls ($P<.02$), whereas cooling that remained ≥35°C did not reduce anterior-STEMI infarct size. With
inferior-STEMI, which on average were smaller than anterior-STEMI, cooling to <35°C reduced infarct size by 13% compared to controls ($P=0.34$), which seems substantial but did not reach significance. And like anterior-STEMI, cooling that remained ≥35°C did not change inferior-STEMI infarct size. In a novel pilot study of 60 STEMI patients, regional myocardial hypothermia was achieved by infusion of cold saline through a coronary balloon angioplasty catheter. The solution temperature was 4°C, and distal coronary temperature was monitored via the thermistor-containing guidewire. Infarct size was measured by cardiac MRI on day 7. With anterior-STEMI, infarct size was reduced by 9%-points compared to controls ($P=0.023$), whereas with non-anterior-STEMI, infarct size was reduced by 4%-points ($P=0.054$), which just missed significance. Additional studies using this innovative technique are planned.

4.3 Stem Cell Therapy for Heart Failure Post AMI

**Problem Presenter:** Michael R. Mooney, MD

**Statement of problem or issue**

The heart is the least regenerative organ in the body. With an infarction, injured myocardial tissue has little chance of regenerating, and is replaced by scar. This disturbs the normal mechanical functioning of the heart, and can leave it operating in a reduced capacity, possibly leading to clinical heart failure. Stem cells, which are uncommitted precursor cells, have the theoretic potential to differentiate into myocytes in the injury zones, recovering some or all of the normal mechanical function and preventing development of heart failure. Early clinical trials were positive (BOOST [Lancet 2004;364:141–48]; REPAIR-AMI [N Engl J Med 2006;355:1210–1221]), but more recent trials have been less encouraging (MHIF Pilot Trial [Am Heart J 2010;160:428–34; Late-TIME Trial [JAMA 2012;308:2380–2389]; SWISS-AMI [Circulation 2013;127:1968–1979]). The poor uptake (engraftment) and short retention of the administered stem cells has been a major barrier.

**Gaps in knowledge**

An improved understanding of uncommitted cell types that could differentiate into myocytes, and/or provide appropriate paracrine signals, might advance the therapeutic options. Unraveling the biological pathways of these processes will require more research. Uptake and prolonged residence of any cells in the injured myocardium has been problematic. Providing a stable background matrix for cellular retention in the appropriate myocardial sites is one possibility. Another knowledge gap that must be bridged is the observed arrhythmogenic potential of the stem cell colonies within the myocardium. These new cells do not have the same electrodynamic properties of surrounding myocardium.

**Possible solutions and future directions**

New cell types are undergoing evaluation as potential candidates for therapy. These new cell lines include bone-marrow-derived and adipose-derived mesenchymal stem cells (MSCs), cardiac-derived stem cells (c-kit+), embryonic stem cells, skin-derived or blood-derived induced pluripotent stem cells (iPS), mesoblast cells, and cardiopoietic progenitor cells. In addition, new research is being conducted on the extracellular matrix (ECM) components that can help anchor the stem cells in the desired myocardial sites. Normal ECM is composed of families of fibrous proteins like collagen, fibronectin, laminen, proteoglycans, and others. ECM is degraded in areas of infarction and is replaced by scar, which is mostly composed of heavily cross-linked fibrillary collagen chains that may not be a suitable substrate for stem cells. Various natural and synthetic materials are being investigated as possible surrogate ECM. Alginate, derived from seaweed, is a polysaccharide that has favorable properties. Other substances include engineered collagen- and fibrin-based matrices, as well as decellularized porcine cardiac matrix hydrogels. These new advances in stem cell types and biomaterial-tissue engineering may bring about new synergies in regenerative cardiac stem cell therapy. In summary, while the concept of myocardial regeneration is attractive, the challenges remain considerable. Finally, it is
important to make the distinction regarding stem cell therapy for refractory angina or peripheral arterial disease, where the goal is to improve blood flow. In contrast to myocardial regeneration, these other trials have been quite positive and are already available in selected countries.

IAGS 2019  Session 5: Structural Session 2 – Mitral & Tricuspid

5.1 Transcatheter Mitral Valve Repair Devices: Building the Toolbox, But Do They Compete With Surgery and Can They Deal With MAC?
Problem Presenter: Molly Szerlip, MD

Statement of problem or issue
Mitral valve repair by standard surgical techniques is the gold standard for treatment of patients with primary (degenerative) mitral regurgitation. This is due to the fact that surgical treatment can be curative, durable, and symptom eliminating, as well as being performed using minimally invasive techniques (ie, port access or robotic). They however still require the heart lung machine and multiple days in the hospital with a longer recovery time. Surgical treatments are variable amongst operators/hospitals and consist of multiple different techniques. As technology progresses, patients are demanding less invasive options for these treatments that require shorter recovery and no heart lung machine as well as achieving similar outcomes to surgery.

Gaps in knowledge
Primary mitral regurgitation is a variable disease with multiple etiologies and disease processes. This in turn results in multiple different techniques for repair that may not be standardized across institutions and operators. One device demonstrating benefit does not translate into a class effect. For instance, the mitral clip shows benefit but that doesn’t mean that cardioband will. Furthermore, currently only 1 device can be used at one time whereas in surgery multiple techniques can be used (ie, band with chords). Lastly, these new devices are very expensive, more so than traditional surgery.

Possible solutions and future directions
There are multiple transcatheter/percutaneous devices that are in clinical trials to address this disease process. With these trials, we are learning more about primary mitral regurgitation and as a result learning about secondary mitral regurgitation as well. It is clear that one device may not be enough and that multiple devices may be needed to obtain a surgical result such as a transcatheter band with a leaflet repair device. There are not as many mitral surgeons as there are coronary or aortic valve surgeons, and this often leads to incorrect treatment of the mitral valve. For degenerative disease, many surgeons are still replacing the valve instead of repairing. Since this is not the appropriate treatment option, transcatheter mitral repair would be a more correct option with quicker recovery. There also needs to be more emphasis on the heart team approach like TAVR has used. There needs to be more discussions with the patients by both the surgeons and the cardiologists to make sure the correct treatment is given. There also needs to be a bigger push for education of both the patients and the referring physicians to recognize severe mitral regurgitation, and to know who and where to refer. Cardiologists need to better quantify and describe the type of mitral regurgitation on echo to help with the treatment plan. For functional mitral regurgitation, heart failure doctors need to be involved with the treatment regimen so that patients get optimal goal directed medical therapy. As CoAPT showed us, GDMT actually works, and patients did not need to undergo transcatheter mitral repair therapy. As far as mitral annular calcification, there does not seem to be a role for mitral repair devices; however, there may be a role for mitral valve replacement devices.
5.2 Transcatheter Mitral Valve Replacement: What Have We Learned?

*Problem Presenter: Paul Sorajja, MD*

**Summary of problem or issue**

Transcatheter mitral valve replacement (TMVR) is a rapidly evolving therapy with demonstrated feasibility, and it is now being evaluated in pivotal clinical trials. Most patients who are candidates for TMVR are those with secondary mitral regurgitation (MR). The recently published results of the COAPT study, where transcatheter repair was found to be life-saving in patients with secondary MR, have now made the choice of pursuing transcatheter mitral repair versus replacement much more challenging.

**Gaps in knowledge**

The strategies of transcatheter repair and TMVR result in different degrees of MR relief. It is not known if these differences are clinically important, particularly when weighed against the potential risks associated with TMVR procedures, which are currently more invasive in comparison to repair approaches, as well as complications that may arise from a prosthesis, such as bleeding and leaflet durability.

**Possible solutions and future directions**

It is highly likely that future approaches to choosing either transcatheter repair or replacement will follow current practice for open surgery, in which the likelihood of successful mitral repair based on anatomic evaluation will be a key factor. In other words, a repair approach will be pursued when the likelihood of repair is high (e.g., >90% of grade 0 or 1 residual MR), and replacement will be considered for those with anatomy that would pose significant challenges for complete MR relief with repair. In addition, having technologies that permit both transcatheter repair and replacement in a complementary fashion also would be important. Such permissive therapies would help physicians pursue either repair or replacement freely and sequentially (e.g., annuloplasty followed by replacement), without fear of being unable to treat residual MR.

5.3 Percutaneous Tricuspid Valve Repair

*Problem Presenter: Christopher Meduri, MD*

**Statement of problem or issue**

Tricuspid regurgitation (TR) has historically been overlooked and not often treated due to poor resulting outcomes. We know, however, that untreated tricuspid regurgitation (both moderate and severe) is associated with high mortality, up to 50% at 5 years. Surgical treatment has an extremely high reported mortality, but unfortunately there is a paucity of data on surgical treatment. This is the perfect scenario for a transcatheter treatment option, but the studies to date are all early feasibility studies, and they are slow to enroll. Imaging of the tricuspid valve continues to be a major challenge. Until recently there was only 2D/3D transesophageal echocardiography (TEE), which in the best of hands still results in difficulty in seeing the tricuspid valve clearly. Now we have 3D intracardiac echocardiography (ICE) that may greatly advance the field but is still limited to a minority of programs.

**Gaps in knowledge**

Finding suitable tricuspid regurgitation patients is difficult. There is not a natural referral process mainly due to lack of knowledge about the horrific outcomes of tricuspid regurgitation. Referring physicians generally do not identify this valve as a problem. A second issue is deciding what amount of tricuspid regurgitation is appropriate to treat. Both moderate and severe TR are associated with bad outcomes and we have yet to determine how much we need to reduce the TR. We do not even know how to quantify TR precisely by echo. Often patients feel better symptomatically even with only a modest reduction in TR but we do not know if this improvement translates into a mortality benefit. These
are typically highly functional patients, and treating fluid retention and BP may help them as much as a device. How do we quantify our results? Do we look at quality of life metrics, biomarkers, both? Lastly, how do we customize the treatment options for each patient? How do we know when and in which patients to repair or replace the tricuspid valve, and does right ventricular function matter?

Possible solutions and future directions

There needs to be a paradigm shift in the best way to identify the TR patients that might benefit from treatment. Databases within our own systems need to be mined to collect data and to jumpstart the referral process. This will help educate the referring physicians on who to send, and help all providers learn who to treat and who to leave alone. This has built up some tricuspid programs already, and gives those institutions a robust program for data collection and analysis. Referring physicians need to be educated on the importance of this valve and to notice it in the echo reports. Establishing which are the best medicines to give for symptomatic relief is also important. For example, switching furosemide to torsemide may cause a better diuresis because torsemide works better in patients who have gut edema. It is well known that furosemide orally does not work in patients with gut edema because it is not absorbed as well. Referring physicians need to be shown and educated that transcatheter tricuspid technologies are relatively safe and should be tried in place of doing nothing.

The meaning of “significant reduction” in TR needs to be determined. Though a 50% reduction may make a patient feel better, it is probably not adequate for mortality benefit. Using 2D/3D ICE for the clip procedures for accurate leaflet grasping will most likely become the standard of care with or without TEE guidance. There is a much higher risk for single leaflet detachment than in mitral clip because the leaflets are much more delicate. New and improved technology helps in preventing this. Lastly, this technology needs to stay in high volume centers, at least until these questions above are answered. These TR procedures are difficult and require not only experienced operators but experienced imagers as well. We want to make sure that this technology does not go away just because of low volume and less experienced operators trying to perform procedures without appropriate guidance and training.

IAGS 2019 Session 6: Structural Session 3

6.1 Techniques to Avoid LVOT Obstruction in Valve Interventions

Problem Presenter: Tarek Helmy, MD

Statement of problem or issue

Left ventricular outflow tract (LVOT) obstruction in patients undergoing transcatheter mitral valve replacement (TMVR) typically occurs in a specific group of patients and can result in catastrophic complications. This is related to the aorto-mitral angle, LVOT dimensions, presence of septal hypertrophy, and length of the anterior mitral leaflet (AML). Deliberate laceration of the anterior mitral leaflet using electrified wires (LAMPOON) to prevent LVOT obstruction has previously been described. We present a novel technique to prevent LVOT obstruction during trans-apical retrograde mitral valve replacement, which is performed by penetrating and ballooning the AML, resulting in its laceration or posterior translocation.

Preprocedural planning

Computed tomography (CT) of the chest is obtained to assess the anatomic relationship between the left ventricular (LV) apex, existing coronary grafts, and the chest wall. Dimensions of the LVOT, mitral annulus, thickness of the septum, aorto-mitral-annular
angle, and the distance between the papillary muscle and the mitral annular plane can also be evaluated. Transesophageal echo (TEE) can also assess AML length, aorto-mitral-an-nular angle, septal hypertrophy, and dimensions of the mitral annulus or the existing prosthesis.

**Procedural description**

Patient was intubated, and placed on cardio-pulmonary bypass (as a precaution, to minimize hemodynamic changes). Using fluoroscopy and TEE, the optimal intercostal space for access to the LV apex is determined. The left lung is deflated and the pericardial space is accessed through a mini-left thoracotomy incision. Using TEE guidance, the optimal apical position that allows coaxial alignment with the anterior mitral leaflet is identified. Two purse-string sutures are placed with felt pledgets, and the apex is punctured using a long 18G pericardiocentesis needle.

Cardiopulmonary bypass cannulae are then placed. The pericardiocentesis needle is then advanced through the anterior leaflet into the left atrium using TEE guidance. An accurate puncture site of the AML is a point midway between the base and the tip of the A2 portion. Puncture too close to the base of AML can result in injury to the mitral annulus later during balloon inflation. If the puncture is too close to the tip of the AML, the laceration may not be enough to prevent LVOT obstruction. If the puncture is too close to the tip of the AML, the laceration may not be enough to prevent LVOT obstruction. A 0.035-inch stiff wire is inserted and advanced into the right superior pulmonary vein. The apical access site is enlarged with serial dilators and a delivery sheath is placed. During this time, the prosthetic valve is prepared. The co-planar view of the mitral valve annulus is then established with fluoroscopic guidance using the mitral annular calcification (MAC) or the mitral annular ring as a marker. A 20 mm valvuloplasty balloon is then inserted over a wire, positioned within the anterior leaflet and inflated. Cardiopulmonary bypass allows for minimal flow across the mitral valve during inflation. This can result in one of two scenarios. The first is splitting of the AML. The other possibility is that the balloon causes posterior translocation of the anterior mitral leaflet, by creating a large “hole” in the AML, allowing the transcatheter valve prosthesis to be implanted within the mitral leaflet with further splitting during the deployment of the large valve. Caution should be exercised in cases of a heavily calcified AML tip as inflation of the balloon can be directed towards the annulus with subsequent injury or annular rupture. After balloon inflation, severe MR is anticipated, and the hemodynamic effects are mitigated by using the cardiopulmonary bypass.
The delivery system is then advanced over the guidewire and the balloon-expandable valve is deployed. Balloon dilation with “flaring” of the ventricular portion is performed. The positioning of the transcatheter valve is an optimal ratio of 30%-40% atrial and 60%-70% ventricular. Placing the valve within the anterior mitral leaflet “defect” may also allow for a “sealing” effect to prevent paravalvular leaks.

Discussion
The technique we present here of trans-apical ballooning of the AML, with either splitting or posterior translocation of the AML, allows for a chordal-preserving transcatheter mitral replacement option that offers less complexity, and can obtain excellent results. One of the major limitations to the current case is the trans-apical approach needed for the initial puncture of the AML, but with the growing number of devices designed for trans-apical delivery, this technique will have a role in patients with high risk of LVOT obstruction. Other iterations of the technique can be used for trans-septal approach for TMVR.

6.2 Routine vs Selective Use of Cerebral Protection for TAVR: A Debate

Problem Presenters: Michael J. Rinaldi, MD (Pro) / Augusto D. Pichard, MD (Con)

Statement of the problem
Despite advances in technique and technology, stroke remains a persistent and prevalent complication of TAVR, with major stroke rates between 1%-3% and major plus minor stroke rates 5%-10%, particularly when neurologist adjudicated. MRI and transcranial Doppler studies show embolic events in virtually all patients. Cerebral embolic protection devices offer the potential to capture or deflect emboli and thus reduce stroke rates. Clinical trial evidence suggests significant reduction in emboli and stroke, yet the pivotal Sentinel randomized trial showed a reduction in stroke with the Sentinel cerebral embolic protection (EPD) system that failed to meet statistical significance. The entire body of evidence did lead to FDA approval and commercial availability in the US, but widespread adoption has been limited. Given the significant unreimbursed cost of EPD technology, some operators have adopted a selective strategy by applying EPD only in patients perceived to be at higher risk of stroke. No clinical or anatomic characteristics have been shown that define a population that does not benefit from protection, therefore, this strategy is difficult to justify.

Gaps in knowledge
Despite registry data, post hoc analysis, and meta-analysis of clinical trial data all showing 60%-80% reductions in stroke rates, the single randomized Sentinel trial showed no statistically significant difference in stroke or emboli. For this reason, there remain questions about the efficacy of cerebral EPD within the cardiology community which have limited widespread adoption. Larger randomized trials may provide more definitive evidence and are planned. Additionally, asymptomatic cerebral emboli, which are nearly ubiquitous in TAVR, may be associated with long-term cognitive dysfunction, and routine use of EPD may attenuate this. However, this hypothesis is unproven and requires further study. Finally, EPD technology is associated with additional unreimbursed cost, potentially offset by the cost savings of strokes averted, and so the true cost effectiveness of EPD remains unknown.

Solutions and future directions
A more adequately powered randomized trial of Sentinel and of other EPD devices may provide more compelling data, and if positive, would be expected to lead to widespread adoption. Such trials may define anatomic or clinical characteristics that identify populations with greatest benefit, or may confirm that all patients are at risk and thus derive benefit from EPD. Until such data are available, a selective approach
to a “higher risk” population cannot be justified. Therefore, operators, hospital systems, and patients will need to judge the present body of evidence and decide if it is compelling enough to justify systemic application. If future randomized trials provide more definitive evidence for stroke reduction and protection of cognitive function, it is likely that adoption into routine use will be widespread. Device improvements that provide more complete protection of all cerebral territories and simplify use may encourage adoption. Further data on the cost of stroke related to TAVR, and the cost effectiveness of EPD in TAVR, will further support routine use. Finally, it must be acknowledged that unreimbursed cost is a significant impediment to use, and adequate reimbursement will mitigate this barrier. There have been no signals of harm with Sentinel, and registry data and clinical experience have shown that EPD can be incorporated into clinical practice without loss of procedural efficiency. Until additional efficacy studies are available, individual operators will have to decide if the present body of data suggesting 60%-80% reductions in procedural stroke are compelling enough to justify routine use, or if the absence of definitive evidence is enough to justify a more conservative strategy. Selective use for perceived high-risk population subsets is not based on any currently available evidence and cannot be justified.

6.3 LAA Closure: Best Practices and How Do We Make it Mainstream Therapy?

Problem Presenter: Brian O’Neill, MD

Statement of the problem

The hallmark of stroke prevention in the treatment of atrial fibrillation is anti-coagulation (AC). However, registry studies have demonstrated that there are a substantial proportion of patients who are not offered this therapy. For these patients, particularly with high CHADS<sub>2</sub> VASc scores, the annual stroke rate can be unacceptably high. Left atrial appendage closure (LAAO) is an important alternative to anticoagulation in these patients.

Gaps in knowledge

Real world registries have demonstrated increasing success and decreasing complication rates with the dissemination of LAAO technology. This is despite the introduction of the technology to many operators who have not previously performed LAAO. It is because of this that LAAO has now been incorporated into the most recent guidelines for the treatment of atrial fibrillation as a Class IIB indication for those patients who have contraindications to long-term AC. Currently, it is recommended that patients who undergo LAAO should be anticoagulated for 45 days. Although several registries have suggested the efficacy of dual-antiplatelet therapy (DAPT) in patients with absolute contraindications to AC, larger randomized trials are lacking.

Possible solutions and future directions

Newer devices and trials are currently in development for LAAO which will require DAPT only. The use of cardiac CT to accurately size the LAA is replacing transesophageal echo (TEE) in the preprocedural work-up of these patients. CT has previously been shown to allow more appropriate device sizing of the LAA and to reduce the amount of devices used per case. Implantation success rates are likely to increase as this imaging modality continues to disseminate. LAAO still requires general anesthesia and TEE. Operators are gaining experience with mini TEE probes and intracardiac echo (ICE) to help eliminate the need for general anesthesia. However, these techniques remain in their infancy, and enhanced imaging technology is needed for this practice to become mainstream, particularly for ICE. Device related thrombus occurs in 3.7% of patients who undergo LAAO. Risk factors for this phenomenon have been described, and further study is needed to identify patients pre-procedure who are at risk and may benefit from prolonged AC post LAAO. Finally, further study is needed to assess the efficacy of the LAAO technology with the further adoption of direct oral anticoagulants (DOAC).
IAGS 2019  Session 7: Hemodynamics Session 1

7.1 Hemodynamic Support for AMI With Cardiogenic Shock: Which Device is Best? Are We Ready for Primetime? Do We Need Systems of Care?

Problem Presenter: Srihari S. Naidu, MD

Statement of the problem

Despite major advances in the treatment of acute myocardial infarction (AMI), including primary percutaneous coronary intervention (PPCI), adjunctive pharmacotherapy and judicious use of intra-aortic balloon counterpulsation, the incidence and associated mortality of cardiogenic shock has seen little decline. Indeed, after adjustment for co-morbidities, there has been a two-fold increase in the incidence of cardiogenic shock in AMI, and this is similar for both males and females, and in those over and under the age of 75. Mortality with cardiogenic shock has improved from roughly 45% to 35% in this time span, representing a 25% improvement in survival, but has hit a plateau despite high penetration of PPCI and IABP use (roughly 70% and 50%, respectively) within the United States. Although higher penetration of PPCI may improve survival incrementally, further use of the IABP would be unlikely to improve outcomes based on the randomized IABP-SHOCK II trial.

Gaps in knowledge

Goals for the management of cardiogenic shock would include decreasing both the incidence of shock as well as its associated mortality. While there is good reason to believe that improvements in symptom-onset-to-PCI time will reduce infarct size and reduce both electrical and mechanical complications, this has not yet been proven in prospective fashion. In addition, early recognition of cardiogenic shock, and those patients at risk of developing cardiogenic shock in various clinical settings, remains problematic. Next, although mechanical support has theoretic benefits in this population through ventricular unloading and possible reductions in infarct size, as well as hemodynamic support to prevent and/or reverse end-organ damage, there exists no completed and adequately powered randomized trial with supportive data. In this context, it is difficult to know whether the increasing penetration of these mechanical support devices is helping or hurting this population. Finally, although systems of care and heart teams for identification, triage, and rapid stabilization and transfer of patients in a so-called hub-and-spoke model are emerging, data showing this to improve mortality remain absent.

Possible solutions and future directions

Much discussion among the IAGS delegates revolved around the fact that cardiogenic shock is both a time-based and an anatomy-based modifiable variable. That is, the risk of developing shock from extensive myocardial damage increases based both on the extent of myocardium at risk and the duration from symptom onset to PCI. Indeed, shock typically develops more than 12 hours after infarction begins, and can be as late as 1-2 days, and it may be even exacerbated in some cases by PPCI reperfusion injury. Accordingly, defining cardiogenic shock in all clinical settings becomes paramount to early identification and treatment. To this end, the group discussed the SCAI/HFSA Clinical Expert Consensus Document on Defining Cardiogenic Shock. This document is a multi-society definitions paper to be released during the SCAI 2019 scientific sessions which creates a universal lexicon for the stages of cardiogenic shock. Such a definition is anticipated to aid in rapid identification of shock and its severity, as well as those at risk of shock, whether the stage modifies through time and intervention, and whether the patient should be transferred to another facility and/or escalated in terms of hemodynamic support. The definition and stages can then be prospectively and retrospectively validated as a tool to improve outcomes.
Second, the group supported a systems of care approach to hospitals, where community hospitals (level 3) would identify and stabilize patients but have a system in place for rapid transfer to either level 2 hospitals (those with PPCI and minimally-invasive MCS) or directly to level 1 hospitals (those with ECMO, temporary VAD and heart transplantation) depending on the clinical picture and response to initial intervention. Models of such a hub-and-spoke protocol exist in various regions of the country and outcomes data are needed from these hospitals to validate this approach. In addition, each hospital and system should create heart teams of heart failure, interventional cardiology, critical care, surgical and nursing providers in order help identify these patients and rapidly determine strategy and disposition.

Finally, the group strongly supported the objective that more data are needed to guide choice and escalation of MCS devices in patients with cardiogenic shock. In addition, more algorithm-based management protocols should be developed and validated prospectively. To this end, the national Cardiogenic Shock Initiative (CSI) was discussed. This algorithm which is utilized in multiple hospitals across the United States as an IRB-based research protocol employs a model of MCS (in this case, Abiomed’s Impella CP) prior to PPCI and right heart catheterization to guide escalation of devices and weaning of vasopressors prior to the patient leaving the catheterization laboratory. In preliminary data, survival in patients within CSI appears excellent at >70%, but ranges from 30% to 96% based on biochemical (lactate) and hemodynamic (cardiac power output) variables over the initial 24 hours. Other algorithms are needed, with an aim to prospectively test different algorithms in randomized fashion or between networks. To this data should be added further randomized controlled trials of MCS in shock, such as the DANGER trial currently underway in Europe.

7.2 Hemodynamic Support for High-Risk PCI: In Whom and How to Integrate the Skills Necessary for Best Outcomes
Problem Presenter: Sundeep Mishra, MD

Statement of problem or issue
Over the past 3+ decades we have developed a multitude of devices, from the IABP to ECMO, all designed to support cardiac function. Despite the available options, ventricular support devices are not all the same, with some designed to more indirectly improve cardiac function (IABP) and others designed to primarily impact LV mechanics (Impella), while others support the entire circulation (ECMO). One must understand the differences in order to make an informed decision on the appropriate device for a particular patient. An additional issue with appropriate selection is the data set on which the decision must be based. The need for companies that make the devices to gain expanded approval of their device has driven some of this problem: in the United States, approval can be obtained without rigorous data to support their expanded use (510K process). This has led to expanded approval based on inadequate data on which to make informed clinical decisions. Layered onto all of this are the financial issues with payors (expensive devices), particularly in the United States, with reluctance to reimburse a procedure when there is a lack of firm evidence to support its use in specific populations.

Gaps in knowledge
The evidence base on which to make the decision to support someone undergoing high-risk PCI is incomplete. This is primarily due to the heterogenous patient population that might require support (from MI with cardiogenic shock to unprotected left main), the types of support available, and variable inclusion criteria used to define the population that might benefit from a given technology. Most sites actively involved in intervention in this complex patient group have developed their own algorithms such that the definition of an appropriate patient has been a bit like the definition of pornography: “I know it when I see it,” rather than basing the assessment on more rigorous and consistent criteria for high risk intervention.
Possible solutions and future directions

While one can almost always state that we need more data, this area is ripe for more data to inform our practice. But before we ask for such, a very strict, universal definition of high-risk intervention is needed, too. With that, not only are randomized trials designed better, subsequent meta-analysis will be simpler to perform as well, realizing that large trials in this space are difficult. A universal definition would also allow well-designed registries to be used to inform our practice. The eVAD registry is a start, but the ideal registry doesn’t include just one device, it should include all devices used in patients who meet the registry definition of high-risk PCI. It is unlikely that industry will have an interest in supporting such a registry, but perhaps governments or professional societies could lead that charge and financially support the effort. We must also deal with the question of where these procedures are best performed, since some devices, e.g. Impella, are relatively easy to place. That fact, however, doesn’t argue for these procedures to be performed without adequately trained staff who have frequent exposure to their use and the infrastructure to care for these complex patients.

We must also be willing to randomize patients into trials and treat them as the protocol arm indicates. Despite a number of trials in this space, we clearly still have clinical equipoise in many patients, so we must be willing to submit patients to well-designed trials and not fall into the trap of innately knowing “what is best for my patient” and then refusing to randomize them. These devices, in their current state, have significant potential complications and expense which also begs the question of which device for which patient, or importantly, perhaps no support due to futility. This becomes all the more important in a world of ever-increasing surgical turndowns due to high surgical risk. We must know which device to use and who will benefit from this technology before we apply it. To quote a past surgical mentor of mine “just because you have a technology doesn’t mean you need to apply it.” Sage words that continue to resonate all these years later.

7.3 Interventional and Surgical Therapies for Massive PE: What’s PERTinent?

Problem Presenter: Herbert Aronow, MD

Statement of problem

The number of hospitalizations for acute pulmonary embolism (PE) in the United States continues to climb and PE is now the third leading cause of cardiovascular mortality. Massive (also known as “high-risk”) PE, where there is associated hypotension, comprises only about 5% of all PE presentations but is associated with approximately a 30% mortality rate. Various therapeutic interventions are available, including systemic full-dose fibrinolysis, surgical embolectomy and catheter-directed therapy (CDT), but robust comparative safety and effectiveness data for these approaches are lacking.

Gaps in knowledge

While randomized controlled trials (RCTs) have demonstrated that systemic fibrinolysis reduces the incidence of mortality and recurrent PE, its benefit is offset by the increased risk of major bleeding, including intracranial hemorrhage. Meta-analyses of contemporary surgical embolectomy observational studies suggest that this intervention may be associated with reduced mortality as well. However, surgery is only an option for those with proximal PE and even when feasible, its potential benefits are countered by the attendant risks of surgery; furthermore, RCT data are lacking. More recently, CDT options have become available, two of which have FDA clearance for use in patients with PE. The EKOS Acoustic Pulse Thrombolysis catheter (EKOS, BTG), which is employed for ultrasound-assisted, low-dose catheter-directed fibrinolysis, may have greater potential benefit in the setting of more stable submassive (ie, intermediate-risk) than in massive PE, given that its therapeutic onset may not be immediate. In contrast, the FDA-cleared Flowtether (Inari Medical) yields immediate results, which may make it a more attractive therapeutic option for patients with massive PE. Other non-FDA-cleared devices that are used in
an off-label fashion in patients with massive PE include the Indigo Cat-8 (Penumbra) which is being evaluated in the Evaluating the Safety and Efficacy of the Indigo Aspiration System in Acute Pulmonary Embolism (EXTRACT-PE) study, the Angiovac (Angiodynamics), and the Aspire Max (Control Medical) catheters. Neither randomized studies nor comparative effectiveness data are available for any of these devices. Consequently (and not surprisingly), there is tremendous practice variability in the setting of massive PE.

Possible solutions and future directions

While randomized trials would address many unanswered questions surrounding the management of patients with massive PE, there are many challenges inherent in conducting such studies, including the relatively small number of patients presenting with this condition to any one institution and the array of available therapies, each of which would require separate evaluation. Absent such data, the most practical approach to treating patients with massive PE may be to standardize our treatment algorithms and to simultaneously collect national registry data to inform decision-making. To date, the most successful such initiative has been organized by the Pulmonary Embolism Response Team (PERT) Consortium. In the near future, Consortium leadership anticipates that its registry will include data on approximately 1500 patient episodes from more than 60 participating sites. The PERT Consortium and its leadership have advocated for a multidisciplinary approach to the management of submassive and massive PE that results in consensus-driven treatment recommendations. PERT treatment protocols support the decision-making process and are informed by existing data and expert opinion. Institutional participation in this initiative’s companion registry should be encouraged, as doing so will allow for real-time modification to treatment protocols based on registry safety and effectiveness observations.

IAGS 2019 Session 8: Emerging Therapies Session 1

8.1 Expanding the Frontiers of Acute Stroke Intervention: Viability Imaging and “Facilitating” Devices

Problemi Presenter: Gyula Gal, MD

Statement of problem or issue

Acute ischemic stroke (AIS) is a leading cause of death and disability, especially in older populations. Standard care for AIS consists of routine support, aggressive rehabilitation, and immediate administration of intravenous thrombolysis (IVT) if patients arrive within 6 hours of symptom onset. Beyond 6 hours, infarcted brain tissue is not recoverable. Current care standards improve outcomes, but many patients succumb to their strokes and many others are left with profound disability.

Gaps in knowledge

The effectiveness of intra-arterial thrombectomy (IAT) as an adjunct to medical therapies has only recently been studied in adequately powered randomized trials. New devices for thrombus management have been developed, but their effectiveness is uncertain. Options for care of AIS patients with >6 hours of symptoms are limited.

Possible solutions and future directions

The MR CLEAN randomized clinical trial (Berhemer, et al. NEJM 2015;372:11-20) involved AIS patients with ≤6 hours of symptoms who received IVT or IAT (with or without IVT; the majority had concomitant IVT). This trial showed definitively that use of IAT was associated with better recovery of function than standard care. Based on this trial and other works, interest in IAT has increased. The DAWN randomized clinical trial (Nogueira RG, et al, NEJM 2018;378:11-21) studied AIS patients with >6 hours but <24
hours of symptoms. All patients underwent brain CT or MRI imaging, and patients with more severe clinical disability than expected based on the volume of infarcted brain were randomized to standard care or IAT. The hypothesis was that some brain tissue was ischemic but still viable in these patients, and could be recovered with aggressive treatment. Patients meeting criteria were randomized to standard care or IAT. This trial found superior recovery with IAT for those patients with a “mismatch” between deficit and infarct size. Based on this study and other works, neuro-interventionalists are beginning to use CT or MRI brain imaging to identify patients who may benefit from IAT despite having symptoms for >6 hours.

Several technologies have been developed to accomplish IAT:

1. **Stentriever.** This device uses an 8 Fr occluder balloon positioned at the internal carotid artery (ICA) or the vertebral artery (VA) and an expandable wire mesh to extract thrombus from intra-cranial arterial segments. The mesh is placed by advancing a micro-catheter over a guidewire through the thrombus. The guidewire is removed and replaced by a retrieval mesh, which is expanded within the thrombus. This partially relieves the occlusion and allows initial relief of acute ischemia. The occluder balloon is then inflated and the retrieval mesh with thrombus is withdrawn while continuously aspirating through the occluder balloon.

2. **Proximal aspiration.** A 6 Fr long sheath is inserted to the ICA or VA. A 6 Fr large-bore soft-tipped aspiration catheter is mounted over a micro-catheter. The micro-catheter is advanced to the thrombus over a guidewire. The aspiration catheter is advanced over the micro-catheter and used to aspirate thrombus.

3. **Combined stentriever and proximal aspiration system.** This system aims to capture the benefits of both the stentriever and proximal aspiration methods. An aspiration catheter is advanced to the thrombus as above, and the micro-catheter is advanced through the thrombus. A stentriever device is advanced through the micro-catheter and expanded in the thrombus. The stentriever with thrombus is withdrawn during simultaneous aspiration.

These systems are evolving but they’re having a positive impact on stroke management. The number of neuro-interventionalists worldwide is increasing. Early intervention is still essential, but routine brain imaging with assessment of viability/deficit mismatch is changing the approach to care for AIS patients with >6 hours of symptoms. Comparative studies to assess the relative merits of the various devices, and determine when to select one over another, are needed.

### 8.2 Robotic PCI Remotely?

**Problem Presenter: Amir Lerman, MD**

**Statement of the problem or issue**

It is apparent there is a lack and a gap in the standardization and equalization of access to medical care. This is specifically true for more specialized medical care such as access to various procedures. Examining the access to medical care and the physician shortage throughout the world reveals that there are several major areas, such as in Africa and Asia, where there are fewer than 5 physicians per 10,000 population, in some cases less than 1 per 10,000. This imbalance creates an uneven access to lifesaving procedures worldwide. It is anticipated that by the year 2025, there will be a shortage of 90,000 physicians in the United States, specifically in the area of coronary intervention. A recent study demonstrated that from the year 2001 to 2006, the hospitals capability to perform percutaneous coronary intervention grew by 44%, whereas the access to the procedure grew by only 1%. Thus, the growth to perform PCI was actually in places which already had the facilities and capability, and this growth did not distribute equally and evenly throughout the United States. Thus, the capability to perform primary PCI in a timely manner and reduce even the door-to-balloon time and the distribution gap remains a major challenge. In order to bridge this gap, it has become apparent that if we cannot bring all the patients to the cath lab, we need to think about a creative and novel method to bring facilities and cath labs to the patients.
The idea to be able to perform coronary intervention safely and accurately by using remote robotic procedures is currently being assessed.

**Gaps in knowledge**

In order to build a system that will enable us to safely perform coronary intervention using robotic arms remotely from a distance, several gaps in knowledge need to be filled. The first one is the ability to safely perform PCI using a robotic arm, rather than the traditional method that has been done so far using operator tactile sensation for the procedure. The second gap in knowledge that needs to be filled is the ability to operate this robotic arm safely and with acceptable reaction time. Thirdly, other obstacles need to be overcome such as the training and reimbursement for this procedure.

**Possible solutions and future directions**

Operating robotic arms to perform PCI became available in the past several years. The introduction of the CorPath device from Corindus allows the operator to safely perform interventional procedures situated in a cockpit in the same room where the patient is having the procedure. This ‘robot’ is composed of a bedside unit optimized for radial access, easy and simple setup within the procedure workflow, and during intervention, and with imaging and device handling capability. The operating physician is situated in a protected cockpit in the same procedure room. The rational in building this robotic assist device stems from the growing body of evidence demonstrating health hazards to the operator during coronary intervention. More specifically, accumulated evidence demonstrates increased risk of spine injury, head radiation exposure that may lead to cataracts, as well as several reports of brain and neck tumors among physicians performing interventional procedures. To address the feasibility and safety robotic PCI, several studies were performed demonstrating that the procedure is safe, and there is significant reduction in contrast media volume as well as fluoroscopy time and radiation dose. Other studies have demonstrated the feasibility of robotically assisted PCI in complex lesions and with low levels of adverse events. These were completely robotic procedures in more than 80% of the cases. Robotic procedures also have expanded to the peripheral vascular intervention, with potential for neurovascular procedures very soon. The safety of using a robotic arm to perform PCI is now well established.

The second challenge is with the ability to operate this robotic arm from a distance with acceptable reaction time and safely. There is both increasing interest and data in using robotics in multiple areas, and not only in medicine. NASA is operating a vehicle on Mars more than 50 million kilometers away, however, the reaction time is about 20 minutes, which is unacceptable for coronary procedures. Several years ago, a laparoscopic cholecystectomy was performed between New York and Germany, more than 14,000 kilometers with a reaction time of 155 milliseconds. This reaction time is acceptable and safe.

Recent studies by Dr. Madder et al demonstrated the feasibility of using and operating the robotic arm remotely from a separate operating room. The success of this remotely operated procedure was 95%. We have launched a multi-stage protocol in collaboration with the Helmsley Foundation as well as Corindus Vascular Robotics to assess the feasibility and safety of performing remote robotic procedures. We previously demonstrated the safety of performing this procedure with a reaction time of less than 30 seconds in several animal models. Recently, the first in-man procedures were done in India operating the remote PCI arm 22 miles away in five patients.

There are still challenges coming before the procedure will be clinically available, including safety of the procedure, reduction and stabilization of the reaction time, and other legal issues such as reimbursement and malpractice concerns.

This new technology allows us to integrate the robotics with wireless capability in order to perform procedures remotely, and thus, bridging the gap of the lack of distribution of specialized physicians throughout the world.
8.3 Advanced Multimodality Fusion Imaging

Problem Presenter: Anthony Medigo

Current status and statement of problem
Over the last decade, the complexity of interventional cardiac and vascular cases has been steadily increasing. The need for better diagnostic imaging has been growing in parallel in response to new approaches to treat structural heart disease, coronary chronic total occlusions, aortic abdominal aneurysms using fenestrated grafts for EVAR, and critical limb ischemia. These new and improved imaging tests are essential for diagnosis, but can also be very impactful for therapy planning and correlative image guidance. Fusion of different modalities (CT, MR, PET, US) intraprocedurally could possibly improve precision of device placement; reduce radiation, and reduce contrast volume and procedure time. Even with the amount of imaging that is currently being performed, many challenges remain that inhibit adoption of these image-fusion techniques.

Gaps in knowledge
There are both technical and clinical challenges that impact the adoption of image-fusion guidance, but these can be overcome. Technically, some of the tools are not as robust. Image artifacts, anatomical variabilities, inconsistency between modalities and time variation all prove to be challenges. Accuracy may be sacrificed due to patient positioning, instrumentation of vessels, and motion artifact of certain organs. Additionally, a fair amount of manual manipulation of the image data is still needed, and cross vendor compatibility remains an impediment. Clinically, when first adopting image-fusion techniques there can be discouraging moments. Initially, the process can be time consuming during a case as it requires a dedicated, skilled technologist and/or trained physician. Training opportunities at times can be limited and procedural support for these advanced applications has to be considered. To further complicate the issue, access to these image-fusion applications can be difficult due to a disconnect between the purchasing cycle of hardware and the speed at which software applications are developed. If the applications were not available at the time of purchase, it often becomes financially challenging for institutions to find additional unbudgeted capital to purchase these upgrades.

Therefore, advanced and efficient training, improved automation, and new economic models will be needed to increase adoption of fusion imaging for therapeutic purposes. Lastly, instead of having to fuse the complete multimodality datasets, it would be optimal to isolate the best parts of the imaging dataset of one modality, combine it with best of another, and produce a completely new way of seeing the data. In essence, have 1+1=3.

Possible solutions and future directions
The next generation of fusion imaging will be completely based on artificial intelligence, even well beyond what is performed now. The need for an automated plug-and-play program will be necessary. This will bridge the gap between diagnosis, planning and guidance that “Just Works.” The moment that the patient receives a diagnostic imaging test, these data will be sent to a PACs system, automatically segmented per organ, automated measurements provided, and the data will then appear in the procedure room. These data will be fused and registered without any manipulation or human interaction from the moment of image acquisition. (1) This will further be enhanced by 3D body surface recognition cameras within the diagnostic and procedural rooms. Once the patient’s body surface or avatar is determined in relation to their organs from imaging scans, the ability to locate, register, and guide intervention in an augmented and virtual way becomes possible. (2) This will open up a completely innovative and predictive way to treat different diseases and provide true precision medicine. We are still in the early stages of what is possible for fusion imaging and therapy guidance. As technology and deep learning programs develop, physician satisfaction, and patient safety will ultimately benefit.
References

IAGS 2019 Session 9: Emerging Therapies Session 2

9.1 Renal Denervation for Moderate and Severe Hypertension: Waiting for Godot?
Problem Presenter: Herbert D. Aronow, MD

Statement of problem or issue
According to the ACC/AHA definition, nearly 1 in 2 adults in the United States has hypertension (HTN). Epidemiologic data indicate that higher blood pressures are associated with a greater risk for ischemic heart disease mortality, stroke mortality and other vascular mortality. The SPRINT randomized controlled trial (RCT) demonstrated that when compared with standard treatment to a systolic blood pressure (SBP) goal of <140 mm Hg, intensive treatment to a SBP goal of <120 mm Hg significantly reduced the risk of cardiovascular death, myocardial infarction, other acute coronary syndromes, stroke, and heart failure, as well as the overall incidence of all-cause mortality. Nevertheless, despite these data, blood pressures are at target in only half of US adults with HTN. The reasons for uncontrolled HTN are manifold and range from true treatment failure to poor adherence to lifestyle and pharmacologic prescriptions. Non-adherence to antihypertensive agents commonly results from drug intolerance and/or the desire to avoid additional medications. Recently, device therapies (most commonly renal sympathetic denervation [RSD]) have been proposed as a method to augment if not replace antihypertensive agents. RSD has been accomplished using a variety of methods, including surgery, endovascular delivery of radiofrequency energy, ultrasound, cryotherapy, pharmacologic agents or beta radiation, renal pelvis catheter-based ultrasound delivery and external ultrasound application. The most studied of these modalities is catheter based, endovascular RSD. After promising observational and non-sham controlled RCTs evaluating catheter-based endovascular RSD, the SYMPLICITY HTN-3 RCT compared RSD to sham-therapy in patients with resistant HTN, but found no difference in blood pressure control. A number of confounding issues surrounding patient selection, operator training, device development, and endpoint ascertainment were addressed, and several recent proof-of-concept, sham-controlled pilot RCTs have yielded favorable short-term outcomes, demonstrating that RSD significantly lowers blood pressure. Despite the promising early results summarized above, important questions still remain unanswered.

Gaps in knowledge
Although larger, pivotal trials are ongoing, even if these are positive questions will remain about how to identify the ideal patient, ascertain treatment success at the time of the procedure, determine whether RSD is complementary or competitive with medical therapy, discern whether RSD can improve clinical outcomes beyond its ability to lower blood pressure, and finally, whether RSD is cost-effective.

Possible solutions and future directions
Data from earlier RSD trials have suggested that patients with isolated systolic hypertension respond less favorably than those with more sympathetically-mediated combined systolic-diastolic HTN. Accordingly, ongoing RSD trials are preferentially
enrolling combined hypertensives. The currently recommended ablation approach is also more extensive than in prior trials and involves treatment of both main and accessory renal arteries as well as large sized renal artery branches. Although this modification of treatment approach will likely result in more extensive ablation of renal afferent and efferent sympathetic nerves, operators remain blind to whether the degree of ablation is satisfactory; no real-time bedside test exists to ascertain treatment success. Post-hoc analyses of clinical trial data from ongoing studies may identify technical approaches that are more favorable but a real-time method to assess sympathetic nerve activity pre- and post-ablation is greatly needed and would facilitate more efficient evolution of optimal procedural technique. To date, changes in systolic and diastolic blood pressures resulting from RSD, whether in the office or averaged over 24 hours, have been relatively small. While small changes in blood pressure are associated with large changes in cardiovascular event risk, both in epidemiologic studies and clinical trials, larger studies that are powered to detect clinical outcomes will be needed. Additionally, whether RSD will afford enough blood pressure reduction for patients to discontinue all antihypertensive agents remains to be seen. For some higher-risk patients, such as those with diabetes or atherosclerosis, discontinuation of all agents may not be desirable as many of these agents confer reductions in atherothrombotic risk beyond their ability to lower blood pressure. Finally, if clinical outcome studies demonstrate reductions in hard events with or without attendant improvements in quality of life, well-designed cost-effectiveness studies will need to be conducted from the patient, payer and societal perspectives.

9.2 Developments in Large Bore Closure
Problem Presenter: Robert M. Bersin, MD

Statement of problem
Given the proven clinical advantages of percutaneous large bore (>10 Fr) closure over surgical exposure and repair, shown in the PEVAR trial, and the ever expanding list of interventional procedures employing large bore devices (TAVR, TEVAR, EVAR, and LVADs), there has been explosive growth in the development and application of percutaneous large bore closure devices. The standard percutaneous approach has been with suture-based devices (Perclose and Prostar), which have overall technical success rates of 90%, but fail more frequently when there is anterior wall calcium and/or the patient is obese, and they have major vascular complication rates of 5.5%-8.5%. Device misfires and/or suture breaks are common, requiring use of an additional device to achieve hemostasis in 10%-15% of cases. Given these limitations of the suture-mediated devices, a number of non-suture based large bore closure devices have been developed, mostly based on biodegradable platforms.

Gaps in knowledge
Four bioresorbable large bore closure devices (InSeal Medical InClosure, Vivasure Medical PerQseal, Transluminal Technologies velox LB, Teleflex MANTA) have human implant experience. Of these, only the MANTA device has undergone an IDE trial and received FDA approval. The remainder underwent FIH or CE mark trials. All trials to date have been single-armed and generally demonstrate safety with more rapid times to hemostasis (≤2 min) as compared to suture-mediated closure devices. One other hybrid suture-based plus bioresorbable device (Rex Medical Closer) has also demonstrated a rapid time to hemostasis (2 min) in anticoagulated patients. The MANTA IDE trial (SAFE MANTA) demonstrated the MANTA device has a VARC-2 MAE rate equivalent to the pooled literature MAE rate of the double Perclose technique (5.3% vs 5.5%). However, concern has been raised by some investigators that although the overall MAE rate is the same with MANTA and suture-mediated closure devices, the failure mode may be more catastrophic given the large mass of bioresorbable materials used to effect closure, which, if deployed intravascularly, may be immediately occlusive and result in acute limb ischemia rapidly.
Possible solutions and future directions
More research is needed to determine if bioresorbable VCDs work reliably in patients with anterior wall calcium and/or morbid obesity. We also need to know if bioresorbable VCDs lead to more vessel scarring, and if the failure mode is more catastrophic as a result of the size/mass of the devices when compared to suture-mediated devices. And finally, none of the current devices discussed have been specifically designed to address the unmet need for a large bore closure option for devices left in place post procedure (ie,VADs).

9.3 Lithoplasty: “Disruptive,” But Not Ablative: Is This the Best Way to Deal With Heavily Calcified Lesions?
Problem Presenter: Ayman A. Magd, MD

Statement of problem
Despite advances in current balloon and stent technology, along with operator experience, coronary calcium remains one of the most challenging frontiers during percutaneous interventions. It impedes stent passage of equipment to the lesions, friction that may damage the polymer coating, and it interferes with optimal stent expansion leading to increased stent thrombosis and late restenosis. Indeed, studies have shown that death, myocardial infarction, and target vessel revascularization are markedly increased in calcified relative to non-calcified lesions. The ROTAXUS trial compared the two current strategies of standard balloon angioplasty for predilatation followed by a Taxus stent vs Rotablation predilatation followed by stenting. The results showed no benefit for Rotablation, with longer procedure times, more perforations, and a higher acute gain that was, however, countered by more late loss resulting in higher restenosis rates.

Gaps in knowledge
Historically, it has been recognized that an arc of calcium >270° was a predictor of such events, however, interventionists have noticed a worrying unpredictability of such lesions. Recent data from Mahera & Mintz using OCT have shown that the 3 most predictive criteria of MACE in calcified lesions are: (1) calcium thickness > .5 mm, (2) an arc of calcium > 270°, (3) length of calcium > 5 mm, and that all three must be present to predict MACE, with calcium thickness being most predictive alone. Traditionally, Rotablator has been utilized for heavily calcified lesions, but barriers to use include the need for highly experienced operators, the occurrence of cracks in the superficial calcium only, and the potential increase in late loss and restenosis. These disadvantages have led to a decrease in Rotablator usage with a current utilization rate of about 5% of cases in the United States and 1% in Europe. Meanwhile, orbital atherectomy is currently undergoing clinical trials to determine its impact relative to Rotablator, although preliminary results show no major differences in patient outcomes.

Possible solutions and future directions
Shockwave lithotripsy has been successfully used for many years to treat renal stones, but the concept has just recently been adopted for peripheral vessels with success. It acts by creating controlled sonic pressure waves that disrupt hard tissue with no impact on soft tissues. The equipment consists of three parts: (1) A small and compact generator that delivers the pulses; (2) a connector cable; and (3) a catheter that ends in a small balloon which is inserted like a traditional angioplasty balloon but has 2 emitters that pulse 1/second up to 80 pulses at the calcified vascular segment when the balloon is inflated at low pressure of 4-6 atm. By creating an expanding and collapsing vapor bubble sonic wave that generates an internal pressure similar to a localized 50 atm, cracking both intimal as well as deep calcium with multiple fractures, producing a smooth lumen at low balloon inflation pressure, thus minimizing vessel injury along with the potential for optimal stent deployment and apposition at low pressures. The recent DISRUPT trial for heavily calcified coronary lesions, although conducted in a small number of patients, has shown promising results with a very low complication rate. It is notable that there were no instances of perforations.
or no-reflow, there was 100% stent delivery as well as a low MACE rate at 6 months. This technology has generated considerable optimism among interventionists as a potential breakthrough for these lesions, although future ongoing larger trials must prove its efficacy in calcified lesions relative to Rotablator and orbital atherectomy.

IAGS 2019  Session 10: Coronary Session 3

10.1 Bioerodable Scaffolds: A “Disappearing Act”?

**Problem Presenter:** J. Dawn Abbott, MD

**Statement of problem**

Thin-strut metal alloy drug eluting stents (DES) with either biocompatible durable or bioerodable polymers are the current standard of care in percutaneous coronary intervention (PCI). At 5 years, current generation zotarolimus and everolimus eluting stents both have remarkably low rates of clinically driven restenosis and stent thrombosis. Bioerodable or bioresorbable scaffolds (BRS), however, have potential advantages over durable metal platforms, including earlier and more complete restoration of coronary endothelial and vasomotor function, positive vascular remodeling, ability for reintervention including bypass of the coronary segment, and designs that have potential novel options for antiproliferative drug elution.

The first generation of BRS had several limitations, but early studies showed favorable safety and efficacy profiles, and several received CE mark in Europe. The Absorb BRS, which consisted of a 150-μm-thick bioresorbable poly(l-lactide) (PLLA) scaffold with a 7-μm thick bioresorbable poly(d,l-lactide) coating, and eluted everolimus, was FDA approved in 2016. Issues with first generation PLLA BRS, including Absorb, were lack of radio-opacity and thick struts which were necessary to achieve radial strength due to the tensile modulus of the material. These devices required cold storage, were difficult to deliver, had limited expansion capability, and were prone to fracture. These issues likely contributed to the slow uptake in the US. When large randomized trials reached three-year follow up, BRS were found to be associated with higher rates of adverse outcomes including target lesion failure and device thrombosis compared to metal alloy EES. In September 2017, there was a worldwide halt of sales of Absorb BRS. In Europe, the use of all remaining CE mark devices has been discouraged outside of clinical trials.

**Gaps in knowledge**

Strut fracture and luminal protrusion are postulated to be factors responsible for late adverse events. The process of reabsorption of struts not in contact with the endothelium is altered and embolization into the distal vessel can occur. Additional mechanisms of late BRS failure are unclear but may be related to the vessel remodeling. While expansive remodeling is favorable with respect to an increase in luminal gain, the process could potentially be detrimental over time. DES failure includes stent thrombosis, neointimal hyperplasia and neoatherosclerosis. Whether BRS can reduce the incidence of neointimal hyperplasia through a more functional endothelium is unknown. The fundamental gaps in the field of coronary BRS include determining the optimal time course for absorption, ideal BRS materials including polymers, metals (magnesium), and most recently iron-based scaffolds, bioresorbable polymer and drug dosing, and the optimal adjunctive pharmacology such as dual antiplatelet therapy.

**Possible solutions and future directions**

Several improvements to PLLA BRS are already in development. With advances in polymer science, and ability to manipulate PLLA molecules by stretching, warming, and cooling, scaffolds with thinner struts (~100 μm) that have greater capacity for full expansion with less risk of fracture, are in preclinical and early human trials. New technology
will allow BRS to be constructed in layers rather than by extrusion which leads to novel designs of drug elution. Non-polymer materials are emerging, including a thin strut (~70 μm) iron based, PDLLA coated SES-eluting BRS that is in preclinical trials. This BRS reabsors through corrosion and dissolution into hemosiderin. The possibility to reduce thrombogenicity through inherent properties of metals and bioresorbable polymers also exists. Outside of BRS design, ideal patients and lesions need to be characterized, and vascular response to BRS should be defined over time by intracoronary imaging with optical coherence tomography. Lastly, in order to reduce ischemic events in BRS patients there needs to be a focus on reducing disease progression with high dose statins, and in specific high-risk subsets with alirocumab. While the removal of the first generation PLLA BRS from the market was a setback, there certainly remains momentum in the field that will ultimately yield a commercially available device in future years.

10.2 Left Main Interventions: A NOBLE Effort, But How and In Whom Do We EXCEL?

Problem Presenter: Theodore A. Bass, MD

Statement of problem or issue
The cardiovascular community has debated the optimal role of percutaneous coronary intervention (PCI) in the treatment of patients presenting with left main coronary artery (LMCA) disease for over a decade. Interventional catheter-based treatment of LMCA stenosis was strongly discouraged after initial experience in the era of balloon angioplasty resulted in unfavorable outcomes in several reported cases. However, as technology has advanced, PCI has evolved into a safe and effective treatment option for an expanding population of patients with complex coronary disease. This has renewed interventional interest in unprotected LMCA PCI.

Gaps in knowledge
Many of the technical and procedural challenges involving left main coronary PCI have been well addressed. The optimal use of adjunctive imaging, improved stent technologies and expanding operator experience with LMCA bifurcation lesions has resulted in improved procedural outcomes. Comparing early registry data with subsequent more recent randomized trial clinical outcomes, we see that procedural safety has continually improved. There are, however, gaps in our knowledge that still involve some incompletely resolved issues. The most compelling of these issues has to do with patient selection criteria in patients who are also candidates for possible surgical revascularization. United States and European guidelines have some differences regarding their respective recommendations. These differences mostly involve the quantity and complexity of coronary disease that would favor a stronger evidence-based surgical recommendation. There is a clear and consistent signal that patients with more severe coronary artery disease require more repeat revascularization when treated with a PCI strategy than with a surgical bypass strategy. The latest available NCDR data suggests that unprotected LMCA represents roughly 1% of all PCIs performed in the United States. It is reasonable to assume that a significant percentage of these patients were at high surgical risk and may not have been candidates for coronary artery bypass surgery (CABG).

Possible solutions and future directions
Two interesting randomized clinical trials published in the last several years shed further light on the optimal revascularization strategy for patients with LMCA disease. The EXCEL (Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease) trial concluded that patients with LMCA disease and less complex CAD (low to intermediate SYNTAX scores by site assessment) did as well (non-inferior) when treated by PCI versus CABG, using a 3-year clinical endpoint of death, MI or stroke. Very shortly following this publication, NOBLE (percutaneous coronary angioplasty versus coronary bypass grafting in treatment of unprotected left main stenosis: a prospective randomized,
open label non-inferiority trial) reported that the composite major adverse cerebrovascular and cardiac events (MACCE; death from any cause, non-procedural MI, repeat revascularization, and stroke) at 3-year follow-up favored a surgical revascularization strategy. Why do these two similar RCTs send what appear to be conflicting signal, and how does this affect current interventional practice?

Some baseline differences exist comparing the United States and European EXCEL trial with the exclusively European NOBLE trial. The trials used different coronary stents. In addition, there were some minor baseline differences in the study populations comparing both trials. However, the major reason for the seemingly contradictory signals involves the use of different primary composite endpoints, most notably the inclusion of revascularization in the NOBLE trial but not in the EXCEL trial. Review of individual clinical endpoints, including death, cardiovascular death, spontaneous MI, procedural MI, stroke, and revascularization, demonstrate little outcome differences when comparing both trials. The disadvantage of more subsequent repeat revascularizations noted for patients treated with a PCI strategy versus CABG is well known, and expectedly was a potent driver of the PCI inferiority signal noted in the NOBLE trial.

Why has unprotected LMCA PCI not caught on in the United States and are our current Guidelines still relevant regarding this area? What are the factors influencing physician and patient decision-making involving the choice of a coronary revascularization strategy in this population when both options might be reasonable? Patient preference, quality of life concerns, patient age, and uncertainties about the optimal long-term clinical follow-up strategies may all play a role in this decision-making. Is there a need for further clinical randomized studies or will future practice be best defined by subsequent large registry derived data?

10.3 New Devices and Techniques for Coronary CTOs: Will They Change Our Indications?

Problem Presenter: Emmanouil S. Brilakis, MD, PhD

Statement of problem or issue

The outcomes of coronary chronic total occlusion (CTO) percutaneous coronary intervention (PCI) have significantly improved, with experienced centers currently achieving 85%-90% success with 2%-3% complication rates. However, success rates remain significantly lower (around 60%) at less experienced centers. Moreover, CTO PCI procedures can be long and equipment intensive. The EuroCTO trial demonstrated that CTO-PCI improves symptoms, however DECISION CTO showed no impact on the incidence of major adverse cardiac events, but that trial had multiple limitations. The EXPLORE and REVASC trials did not demonstrate improvement in ejection fraction after CTO-PCI.

Gaps in knowledge

Despite recent studies and advances in equipment, there remain questions about the clinical benefit of CTO-PCI, and uncertainty about how to further optimize the success, efficiency, and safety of the procedure.

Possible solutions and future directions

A large randomized-controlled clinical trial of CTO-PCI vs no CTO-PCI in patients with high ischemic burden and with the primary endpoint defined as the incidence of major adverse events would be ideal, but would require a large sample size. A sham-controlled study could provide more definitive evidence on the symptomatic benefits of CTO-PCI. CTO-PCI studies aiming to improve left ventricular function should enroll patients with baseline left ventricular dysfunction and viable myocardium in the CTO-supplied zone. Standardization of the definitions and the terminology used in CTO-PCI could facilitate performance of future studies and comparisons between studies.

Improving the guidance of CTO-PCI with imaging, such as imaging with computed tomography, could facilitate lesion crossing and thereby improve the safety of
the procedure. Development of novel re-entry devices could also facilitate procedures that involve subintimal guidewire crossing. Evolution of microcatheter and guidewire technology can help overcome anatomic challenges, such as impenetrable proximal caps and collateral vessel tortuosity. Expanding training in CTO-PCI could generate more physicians well prepared to treat such lesions: CTO-PCI and complex PCI in general may be best taught as a subspecialty of interventional cardiology, similar to structural and peripheral interventions.

IAGS 2019  Session 11: Industry Session 1

11.1 How to Harness the Power of Social Media: Physicians, Industry and Innovation

*Problem Presenter: Charles Simonton, MD*

**Statement of problem or issue**

Innovation in interventional cardiology is a complex process of problem solving that encompasses R & D engineers, business executives, academic and non-academic physician experts, and investors. Traditional models of innovation utilize advisory boards, paid surveys, and key opinion leaders (KOLs) which are time consuming, expensive and not comprehensive. The cost, time and uncertainty in the innovation process begs the question if the use of social media can assimilate KOLs, digital opinion leaders (DOLs) and others in the process, to speed the time and efficiency from idea to the practical application of new interventional tools.

**Gaps in knowledge**

From the industry perspective, which is the operational arm of the innovation process, how can they utilize techniques like crowd sourcing, online collaborations, and social media to speed innovation? While there are several successful examples of how social media has advanced other areas of business by putting the power in the hands of end users, this has not yet occurred in medical innovation. Examples in other industries include Kickstarter in venture capital, Apple iTunes in music, Sermo in online collaboration and Udemy and Coursera in education. The validation steps for the medical uses of social media have not been accomplished, and this is a large knowledge gap that will need intensive research and solid solutions.

**Possible solutions and future directions**

The use of programs like Symplur, which catalog and quantify the opinions of medical professionals and physicians in response to certain topics, treatments, or devices, may help industry and their cardiology partners to resist or to sway the course of fledgling innovation and new ideas. The use of crowdsourcing for difficult diagnostic dilemmas may help individual cardiologists and patients to arrive at a correct diagnoses or employ interventional techniques to treat uncommon conditions. Eventually, technology, like the use of social media, could lead to the “democratization of innovation” and the companies and cardiologists that crack this nut first may be on the cutting edge of new, faster and a more trustworthy innovation process.

11.2 What Happens When Cardiovascular Service Lines Become Cost Centers in Value-Based Payment Systems?

*Problem Presenter: Kirk N. Garratt, MSc, MD*

**Statement of the problem or issue**

Acute care procedures are the financial backbone of hospital organizations and many cardiovascular practices. Further movement away from per-procedure (fee for service)
payment models and toward payment for efficient, high quality care, is anticipated and expected. Some form of capitation (set payment to cover the needs of a defined population) may also evolve. Changing reimbursement models threaten to significantly reduce hospital operating margins by reducing payments for the high acuity, high cost treatments common in acute cardiovascular care. Allowing cardiovascular services to become a cost center (consuming more revenue than is generated) would cause collapse of nearly all hospital organizations. The imperative is to prepare for future reimbursement methods and maintain a positive contribution to hospital/practice margin from cardiovascular work.

Gaps in knowledge

No clear direction for payment reform has surfaced beyond the Center for Medicare and Medicaid Services (CMS) pursuit of policies that reward efficient/effective care and penalize inefficient/ineffective care. Private insurance companies are threatened by political changes that could herald a “Medicare For All” environment. Hospitals and practices must decide what changes to make now that are most likely to mitigate revenue losses in the future.

Possible solutions and future directions

CMS remains the best reference point. The following areas are central to new CMS payment models, and are likely good directions to consider:

1. **Pursue population health.** CMS is looking to reward hospitals/practices that engage in population health activities. So, programs or policy changes aimed at improving the health of groups of patients will likely position an organization well to face future changes. For example, rather than looking to increase the number of PCIs done per year, hospital organizations might look to broaden the number of patients that rely on their services, enhance preventive cardiology efforts, and try to keep the number of procedures flat. This is counter-intuitive now, but will be the winning hand in a capitated environment.

2. **Improve channels of communication.** Always key, communication is more valuable now than ever, especially for hospitals with a mix of employed and independent providers. Aligning incentives begins with understanding of the goals and why they’re important.

3. **Aim to minimize CMS penalties/maximize rewards.** We’re used to talking about hematoma rates, guideline-directed medication use, etc., and these things now fold into CMS quality metrics. Rewards and penalties are linked to performance here. Regular (e.g., monthly) reviews with physicians, and special events off hospital grounds to inform independent providers, are high value.

4. **Steer toward care standardization.** By some estimates, variability in care is among the principal drivers of high healthcare costs in America. The best way to cut costs is to avoid waste, and the best way to avoid waste is to have agreed-upon standard care approaches whenever possible. Even small variations (“I like wire A, you like wire B”) can be expensive but some flexibility is necessary in a practice. Big variations (“I like to try 3-vessel stenting in my diabetics before I bring a surgeon into the picture”) should be addressed openly, and care expectations set based on objective measures of optimal outcome.

5. **Focus on patient experience.** The rewards and penalties for good (or bad) patient experience account for 25% of CMS payment holdback. Simple changes can greatly improve patient experience. For example, sitting down with patients and their families during daily in-patient rounds dramatically increases perceptions of the amount of time spent and effectiveness of communication.

6. **Attend to provider wellness.** MDs have twice the suicide rate of other professionals. Signs of burnout affect as many as two-thirds of cardiologists. Listening to what providers need, and doing the best to reduce burdens (especially administrative burdens) leads to a happier, healthier workforce and better care.

7. **Leverage technologies smartly.** IT isn’t the solution for everything, but can be the solution for some (perhaps many) factors that hinder communication, contribute to care variability, and add to provider dissatisfaction.
8. *Get involved in community health.* This is linked to the first listed suggestion. Primary care providers are expected to become stronger gatekeepers of services. Routine clinical care should be the domain of primary care, not specialty care. Specialists need to partner with primary care teams more effectively to deliver optimal, cost-effective primary and secondary preventive cardiovascular care.

### 11.3 Payors as Change Agents for Physician Employment Models

*Problem Presenter: J. Jeffrey Marshall, MD*

**Statement of problem or issue**

Over the last decade, the number of cardiologists in employed models of integrated practice has grown from ~15% to over 50%. Concurrently, the number of cardiologists in private practice has gone down from ~50% to ~20%. Over the same decade, reimbursement for both private practice and integrated cardiologists has increased, although a payment gap of around $150,000/annum, on average, separates these two groups in favor of integrated cardiologists. The source of this gap is external to a cardiologists' actual productivity, and while it has many components, a prominent piece of it is the site-of-service fee (also known as the facility fee) collected by the hospital who employs the cardiologists. Since the facility fees are external to a cardiologists' productivity, and a source of aggravation to insurance companies and payors, these fees could be manipulated by outside forces, including payors, to affect physician employment decisions. Examples of payors attempting to change these fees to alter cardiologists' employment decisions, have been attempted, thus far without much success.

**Gaps in knowledge**

The healthcare landscape is changing rapidly. Traditionally, payors and providers were on opposite sides of a chasm – hospitals and physicians submitted invoices and payors remunerated for services rendered. Now, big data companies like Alphabet, Amazon, Apple and Microsoft are entering the healthcare arena. Additionally, insurance companies have teamed up with other big businesses to create new models of healthcare delivery. Some of these big data and insurance conglomerates are becoming payor-provider entities (i.e., they deliver healthcare services and they pay themselves for the care, controlling all aspects of care delivery and expenditures). Examples include, but are not limited to: Amazon/Berkshire Hathaway/JP Morgan, CVS/Aetna, and many others. Many have well known, indeed luminary, physicians as leaders. These payor-provider entities recognize that about 30% of every dollar spent in healthcare is waste. Eliminating and retrieving this waste would be advantageous to payor-provider entities. This recovered waste could be redirected as profits to companies, savings to patients, and means to motivate providers and their decisions, including their choice of employment models.

**Possible solutions and future directions**

While no one knows with certainty what the future holds in healthcare and cardiovascular care-delivery, the introduction of big data and big business, payor-provider entities is concerning to cardiologists who deliver care, one patient at a time either in private practice or as an employed physician. Current healthcare systems (mostly hospital-based companies) and their cardiology employees have a few options when interacting with payor-provider entities. They can begin to collaborate with new payor-provider entities, ignore them, be consumed by them, or create their own payor-provider entities. The presence of luminary cardiologists and other physicians as executive members of big-data/business, payor-provider entities may signal that the ever-important physician perspective is being considered when decisions are made by these large entities.
IAGS Mission Statement

The International Andreas Gruentzig Society is an international educational society of physicians and scientists interested in the health sciences in the cardiovascular and related fields. Society members cooperate in the advancement of knowledge and education through research, publication, study and teaching in the fields of cardiovascular disease. In addition, the society:

(a) fosters the continuing development of the specialties of health sciences in the cardiovascular and related fields as an art and science;
(b) improves the methods of teaching cardiovascular therapeutic techniques;
(c) stimulates interest in the study of diseases of the vessel wall and research in treating cardiovascular disease;
(d) promotes close fellowship and exchange of ideas amongst specialists in the health sciences in cardiovascular and related fields;
(e) conducts a scientific meeting every other year with high-level clinical investigators specializing in the interventional branches of radiology, cardiology, surgery and neurology in order to provide a platform for presenting problems, offering solutions and debating innovations with the end goal of advancing percutaneous therapies for vascular and structural diseases;
(f) publishes the proceedings from the scientific meeting in a medical journal to disseminate the knowledge and conclusions accomplished during the meeting throughout the medical community.

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