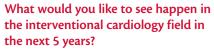
Issam D. Moussa, MD

Dr. Moussa shares what he believes is the way to generate and transfer new knowledge in the interventional cardiology community and explains why decision-making workshops such as CICT are important.

Are you currently participating in any clinical trials or other research projects at Weill Cornell Medical Center?

The Weill Cornell Medical Center catheterization laboratory is busy (more than 5,000 procedures—diagnostic and interventional—per year) including coronary, struc-

tural, and peripheral interventions. So, we are naturally involved in most of the ongoing pivotal clinical trials. However, we are particularly excited about being part of the PARTNERS (Placement of Aortic Transcatheter Valves) trial, which is evaluating transcatheter versus surgical aortic valve replacement, because of the transformational potential of this technology.



Without a doubt, interventional cardiology has witnessed tremendous progress during the last 2 decades on numerous fronts that are well known to everyone. However, we are now at a crossroads where the "traditional" approach of generating new knowledge to guide clinical decision making is no longer adequate.

There are three fundamental problems in that regard. First, the majority of past clinical trials were actually designed to gain device/drug approval rather than to generate information that assists patients and their physicians in decision making in day-to-day clinical care. Why is that the case? Because it is much easier to do. To that end, we have oversimplified the clinical questions we are asking to be able to answer them. We need a radical departure from past practices by designing clinical trials that address the complex clinical questions that we face every day. The recent SYNTAX trial, which compared coronary artery bypass surgery to drug-eluting stents (DES) in patients with left main and/or multivessel disease, is a good example of what we need to do in the future except, of course, for the imprudent choice of the primary endpoint that equated death, myocardial infarction, and stroke with repeat revascularization.

Second, the operative interpretation of the phrase

"evidence-based medicine" has taken a form that can be described as *counter scientific*. Specifically, this phrase has come to embody "absolute and certain knowledge" that we all must abide by even though the premise of the scientific theory is the ability to prove it wrong. This overarching interpretation has led the way to generat-

ing guidelines and performance measures that are typically based on less-than-optimal evidence and are occasionally outdated, yet the regulatory agencies find it convenient to restrict individual physician judgment and patient preferences. Evidence-based medicine should embody the use of individual clinical judgment that uses high quality and clinically relevant evidence to guide decision making.

Last, what has been strikingly absent from the debate and the generation of

medical knowledge is the opinion of the consumer, ie, the patient. What has followed is that we manufactured primary endpoints for the clinical trials that facilitate the conduct of these trials but does not necessarily reflect patient choices or priorities. A case in point is the wellknown primary endpoint for the majority of clinical trials in interventional cardiology: major adverse cardiac events (MACE), which typically include death, myocardial infarction, stroke, and repeat revascularization, for which each are assigned equal weight. Everyone agrees that repeat revascularization cannot and should not be equated with irreversible end points. This does not make sense from a medical perspective, as well as from patient perspective. In the future, primary endpoints should be tailored to the clinical question we are asking, and more focus should be placed on quality-of-life issues and on the patient's perception of what is being done.

Based on your experience with various medical journals, do you believe that the cardiology community is effectively disseminating information about new technologies and data?

There is no question that there is a plethora of cardiovascular journals that publish a tremendous

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amount of information. This forum is not the place to discuss any details about the merits and limitations of specific journals. However, knowledge dissemination cannot be measured by the number of journals, the number of articles in these journals, or the frequency with which these articles get referenced (the impact factor). What really counts is the quality of the manuscripts, the relevance to clinical practice, and the quality of the critique that accompanies the manuscript. On that front, much remains to be accomplished. No longer is a publication necessarily a guarantee of the quality of the study. There are numerous examples of publications in the New England Journal of Medicine and other high-impact-factor journals that are poorly designed with erroneous conclusions. Knowledge dissemination cannot happen in isolation from individual physician education as to how to interpret studies. An ideal guideline for the interpretation of most studies is to skip the conclusion, read the methods and results, and formulate one's own conclusions. It would then be instructive to match one's own conclusions to that of the authors. Often, they are not the same.

We understand that you are holding an annual interventional meeting (Tips & Tricks in Complex Interventional Cardiovascular Therapy [CICT]). What is the need for an additional meeting with the already numerous meetings available?

Excellent question. I think this question should be viewed in continuity with your previous question regarding whether medical journals are disseminating knowledge effectively. I think various meetings serve various purposes. For example, TCT, the i2 Summit, and the SCAI annual sessions are large meetings that cover a wide spectrum of topics and are focused on presentations of ground-breaking clinical trials and introduction of new technology. The sheer size of these meetings limits the ability to have a large number of faculty in one room discussing patient-centered decision-making.

My colleague, Dr. Joseph De Gregorio of Hackensack Medical Center, and I started CICT 3 years ago as a product of the Antonio Colombo Alumni Association (ACAA). Our vision was to put on a small meeting with a sole focus on the complexities of patient-centered decision making. We accomplished this by building a 2-day program where expert faculty present complex coronary, structural, and peripheral cases followed by a one-on-one discussion on how to integrate the available knowledge from clinical trials into the decision-making process for an individual patient. The presence

and active participation of approximately 25 senior faculty in the same room lends itself to a tremendous educational experience for the faculty and attendees alike.

Is there any one rule or treatment paradigm that you follow for your DES patients?

I usual avoid using the word "rules" when it comes to decision making. I would use the following general guidelines: (1) If the patient is at moderate to high risk for restenosis, I use a DES unless the patient has a contraindication to prolonged antiplatelet therapy; (2) If the patient is at low risk for restenosis, I would further evaluate his/her risk versus benefit from DES and involve the patient in the decision-making.

We are beginning to hear more about biodegradable polymers on DES. What do you believe needs to be achieved to ensure that they successfully prevent late stent thrombosis (ST)?

There will be no magic bullet for the prevention of ST because it is a multifactorial event involving patient predisposition, operator technique, and of course, the implantable device (stent). Stent-related factors involve inflammation and the lack of healing, which may be attributable to the durable polymer, as well as to the drug itself. Although some data point to the advantages of biodegradable polymers in reducing the incidence of late ST, it will take very large clinical trials to demonstrate the superiority of these stents. A particularly exciting technology in that regard is the biodegradable stents, which are still under development.

How much crossover is there in the techniques you use in cardiac versus peripheral procedure? Do you apply what you learned in your cardiac cases to the periphery—or the other way around—or is it always both?

This is an important and relevant issue. There is no question that technology and techniques are transferable between the coronary and peripheral circulation (putting aside the labeling issues). For example, the skills and equipment necessary to racanalize coronary chronic total occlusions and infrapopliteal occlusions are transferable with few modifications. I encourage all interventional cardiology trainees to gain qualifications in peripheral intervention during their fellowship because that will foster their skills in both areas. Of course, this is easier said than done because most training programs do not have dedicated funding for an extra year of peripheral intervention training. Other alternatives would be to attend industry-sponsored courses and/or work with someone who is well established in the field.