

MASTER THE COMPLEX™

THE EVOLUTION OF PCI: **Treating Complex and Higher-Risk Indicated Patients Today**

A Roundtable Discussion With:

- Dimitri Karpaliotis, MD
- Ajay Kirtane, MD
- Bill Lombardi, MD
- Jeffrey Moses, MD
- William Nicholson, MD
- Manish Parikh, MD

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Treating Complex and Higher-Risk Indicated Patients Today

INTRODUCTION: Top interventional cardiology thought leaders gathered to discuss the evolution of Complex PCI as it relates to treating complex, higher-risk indicated patients. The panel included: Dr. Dimitri Karpaliotis, Dr. Bill Lombardi, Dr. Jeffrey Moses, Dr. William Nicholson, and Dr. Manish Parikh, moderated by Dr. Ajay Kirtane.



Dimitri Karpaliotis, MD

is an internationally recognized expert on the evaluation and treatment of chronic total occlusions (CTOs). He currently serves as the Director of the CTO Service and Director of the Complex High-Risk Angioplasty Program at NY-Presbyterian / Columbia University Medical Center (CUMC) and, to date, has performed more than 1,200 CTO PCIs. He also has an appointment as Assistant Professor of Medicine at Columbia University School of Medicine.

Q: Ajay Kirtane, MD

Dr. Jeffrey Moses is somebody who's founded his career basically on the principle of treating complex patients. Tell us how that happened historically. How did you get into treating these patients? How did you get away from the more "mundane" cases, if you will, in terms of your practice?

Jeffrey Moses, MD: It's actually quite interesting because when I started doing PCI in New York City, there was a gentleman named Si Stertz who was also doing PCI, and he was the first operator to do it in the United States. Being a junior operator in New York City, no patient who had options was going to go to the guy who did 40 PCIs when the guy down the block did 400. What I cut my teeth on was a surgical colleague coming to us and saying, "Here's a case we don't want to do." It was re-do's, complex cases. That was really the substrate of what I started when I started the program at Cornell. It was just a handful of electives, so you worked very closely and collaboratively with the surgeons. You had to do a lot of very discriminatory work in terms of deciding whom to treat and not to treat. **We of course didn't have anything like the tools we have today which is why today is so much more gratifying.**

Ajay Kirtane, MD:

In terms of the recovery of these complex patients' lives and function, it's one of those subsets maybe outside the acute MI subset where as a physician one can really dramatically benefit these patients. It's interesting that conventional wisdom now is that much of the benefit that we give these patients is in symptom relief alone.

Q: Ajay Kirtane, MD

Dr. Nicholson, you treat a lot of these patients – how profound is the sense of benefit that you can get from treating a complex patient versus somebody who comes in asymptomatic with a positive stress test and some of the lesions that we don't even really treat with revascularization much anymore?

William Nicholson, MD:

Symptoms are, by far, my biggest driver for doing complex PCI and CTO work on patients. These patients tend to get profound and dramatic effects, and I think more so than any of your general, run of the mill, standard PCI patients. It'll translate to a lot of dyspnea relief as a result, and an increased return of functional capacity that they're able to have than there'd previously been. **Many times patients don't know how profoundly affected they were until after you've fixed them. They're typically the most satisfied, thankful patients that you take care of because they really do notice a substantial difference.** I think symptoms are the number one most impressive variable that you see after treatment of a patient.

Ajay Kirtane, MD: It's an interesting observation that among the quality of life folks, somebody like Dr. John Spertus, for instance, he's a believer in treating this type of patient because for him it's all about the treatment/risk paradox. If you have somebody that's very, very symptomatic with complex disease, we sometimes, incorrectly, find ourselves trying not to treat those patients because maybe the procedures are perceived to be inherently more risky.

Q: Ajay Kirtane, MD

Dr. Lombardi, how do you manage the expectations of the patients and the referring physicians in terms of the risk and benefit of what you're doing?

Bill Lombardi, MD: Well, I think, as you said, you have to have a very honest discussion with patients. The number one reason a lot of these people are getting it done is symptoms. There is potentially multi-vessel disease and other factors like depressed LV function and survival benefits, but the number one thing you're going to look at is symptoms. You're going to talk about the improvement in quality of life. These are not the same as PCI, so you can't have the same discussion about complications that you might have with a Type A right lesion. The first is these patients tend to have a bigger reward in that they're usually much more debilitated and limited, mostly because of lack of information. We don't understand a lot about chronic ischemia. **Many people have had these issues for many years. A lot of them are without hope. They've been told repetitively that they can't be treated, so you have a very motivated patient population. They've got more symptoms than they realize and have been told a lot of times that it can't be treated. Now it can.**

For all these people, either surgery is not an option, it's a high-risk surgery, or they get nothing. The important thing is that we give them the equivalent outcome that they would have gotten from a surgical therapy. **It's the clinical paradox where the patient is referred for a high-risk surgery. When that is turned down, they get medical therapy and that doesn't make any physiological or clinical consistent construct. Either you believe in revascularization or you don't. Methodology may be related to ability to achieve completeness.**

Ajay Kirtane, MD: I think that's a really important point, that **this is about revascularization as a whole, rather than PCI alone.** That is really critical to stress with all treatment providers, the patient and his/her family, in order to come up with the best way in order to do it.



Ajay Kirtane, MD currently serves as the Director of the Cardiac Cath Lab at NY-Presbyterian Hospital/ Columbia University Medical Center (CUMC) and an Associate Professor of Medicine at CUMC. He is a Co-director of the Cardiovascular Research Foundation's Transcatheter Cardiovascular Therapeutics meeting. He is a Principal Investigator for several multicenter trials of interventional devices and serves on the steering committees of several large-scale clinical trials in interventional cardiovascular medicine.



Bill Lombardi, MD

practices at University of Washington in Seattle, Washington. He is an internationally recognized leader of contemporary CTO treatment in the U.S. He gives this issue significant importance. He has participated in numerous clinical trials and is a leader for the FAST-CTOs trial. He serves as a global proctor on CTO cases.

Q: Ajay Kirtane, MD

Dr. Karpaliotis, you're responsible for training some of the next generation, not only within the construct of a fellowship program, but outside of those formal pathways. Many people come to you for advice and you proctor people in many complex procedures. What sort of skills do people need to be able to take this forward? Is it primarily technical? Or cognitive? What areas do people really need to excel in?

Dimitri Karpaliotis, MD:

I think it's a combination. **You need to have both technical and cognitive skills so that you have a good fit for a complex PCI or CTO program. The first thing I would say is that it's not just about the operator, this should be viewed in the context of a program.** You first start with getting your administration to back you up, your colleagues, and then you go through a process.

You don't need to start from scratch. I was fortunate enough to learn from Bill Lombardi and Craig Thompson and people that actually learned it themselves. They made it even easier for younger operators but it will never be easy. This is not something that can be taken lightly. Once the decision is made that there's a need within a specific hospital or healthcare setting, then there's a process that you should go through. First off, to get the cognitive and technical skills to get there, and you can start by going to workshops, either regional or national meetings, CTO-specific meetings like the CTO Summit. There are excellent websites too, like CTOFundamentals.org. People can come to our labs. We do live cases, it's very interactive and informal. Then we can go to their labs and actually proctor them in cases.

The educational process is pretty much well-standardized right now, and it's teachable and reproducible. There's nothing magic about it but you need to put in the time and take it seriously.

Q: Ajay Kirtane, MD

It seems to go beyond just the technical components. Dr. Moses, you started off by saying you didn't have the tools when you started. Now we have so many tools but do you find that there's a lapse in terms of the cognitive understanding of hemodynamics and/or patient complexity? Can spectacular technical skill alone be overemphasized?

Jeffrey Moses, MD:

If you have the tools, the question becomes when do you apply them, in what order do you apply them, how do you minimize the risk for the patient? I mean, we don't put hemodynamic support in everybody; do you perform a bifurcating rotablation first in a person with bad LV function or do you open the CTO first? It's different for each patient. **It's not just being able to master the ability to put the device through an obstruction, it's really how you integrate all of these techniques along with a good understanding of what the net benefit is going to be.**

Bill Lombardi, MD:

It's not just patient selection and skill, but there's the cognitive piece within the procedures themselves. When do I need to rotablate? When do I need hemodynamic support? When do I need to switch to a different device? It's become interventional cardiology made easy.

Right? It's a wire, balloon, and a stent, and really now as we do more complex stuff it's really coming back to atherectomy, CTOs, bifurcations, and much more complex stuff. It's about completeness of revascularization, and those are challenging lesion sets to achieve that.

Q: Ajay Kirtane, MD

Take us through what completeness of revascularization means. How do we decide what's important for the patient?

William Nicholson, MD:

It's a complex question, and I think you do have to have some tangible quantitative ischemic measurements to help guide you. **I think the completeness of revascularization is the endpoint. How we get there is less important because in today's day and age, interventionally, in the right hands there's virtually nothing that can't be revascularized,** but the surgical option is always a reasonable option in my opinion. We're blessed at our center of having a very talented hybrid robotic LIMA to the LAD surgeon. We do a lot of hybrid revascularizations where he'll do a robotic LIMA and we'll do other diseased vessels. We'll save the patients a lot of morbidity and accelerate their time to discharge to get out of the hospital quicker.

For me, ischemia is a big factor. Whether you want to show that with non-invasive testing or physiologic testing with FFR in the cath lab, both are reasonable options. With intermediate lesions in the LAD or something along those lines, I will typically treat the chronically occluded segment first. One, because I know my success rate's going to be very high with getting it open, but you often times may not need to treat the intermediate LAD lesion because you relieve the dual supply burden. If they're left with the LAD being physiologically still significant, it can be treated after re-evaluating with FFR after the CTO vessel has been fixed. **You shouldn't be walking away from a case just because of the complexity. Whether you choose an interventional strategy, a surgical strategy, or a hybrid approach, complete revascularization of the ischemic territories is the important final result.**

Ajay Kirtane, MD:

What's actually very interesting in this scenario, a totally occluded right with a working wall, is in some cases we see operators try with a workhorse wire and stop after being unable to wire the right and then stopping to send the patient for bypass surgery because they have LAD disease and the right is occluded. Whereas the same operator, if he/she got the right open, then would medically manage the left. That means that they're functionally sending the patient for bypass surgery for the right coronary alone which is not really what they're thinking.

Bill Lombardi, MD:

The converse is true, too. You'll see operators go down and treat the LAD diagonal lesion and leave the patient with a sub-totally occluded right, or they'll send them to surgery. What it gets back to is **we have a fundamental care variability issue that goes on in that our field doesn't have a consistent approach to what we do and why we do it because so much of it is dependent upon operator skill set, operator experience,** and their decision and interpretation of the literature.



Jeffrey Moses, MD

is an internationally recognized cardiologist who has performed more than 15,000 interventional procedures and served as national or international principal investigator for numerous clinical trials. Dr. Moses is an associate course director for TCT and also serves on the board of Cardiovascular Research Foundation (CRF). He currently serves as Professor of Medicine at Columbia University Medical Center (CUMC) and Director of Advanced Cardiac Interventions at St. Francis Hospital & Heart Center in Roslyn, NY.



William J. Nicholson, MD

is an Interventional Cardiologist with Wellspan Cardiology at York Hospital in York, PA. He is Director of the Interventional Cardiac Catheterization Lab at York Hospital as well as Director of the Complex PCI Programs and the Structural Heart Programs for Wellspan Health. He also serves as the Director of the Cardiac Catheterization Labs at Gettysburg Hospital and Hanover Hospital. Dr. Nicholson is an expert CTO operator and, as such, is an invited guest operator and lecturer at numerous national and international conferences and hospitals. To date, he has performed more than 1,100 CTO procedures.

Jeffrey Moses, MD: **I think the knowledge gap is that primary caregivers, clinical cardiologists, and the internists don't really understand the contemporary capabilities. I think if they did they would demand it for their patients. If they can't give the service themselves, they'll explain to patients that there are centers where these services are available.** I've read about it. I know about it. We can talk about this in our interventional journals, but this has to be part of the general knowledge and understanding. Every internist knows what a CABG can do, but they don't know what *we* can do.

Q: Ajay Kirtane, MD

Dr. Parikh, talk about how you start deploying people to treat these complex patients. Is this something that every interventionalist should do? Is this something where people should just know some of the skills and once they are aware of what can be done they can practice within their own limitations and then appropriately refer?

Manish Parikh, MD: Clearly this is not for every interventionalist, and most interventionalists are very accepting of that. **The bottom line is educating the referring docs and interventional cardiologists about what can be done and when it's appropriate to refer and when it's appropriate to revascularize.** I think there is only one segment where I wouldn't revascularize which is an asymptomatic patient, which I still don't believe exists. **I must tell you that having now seen it and lived it the last couple of years, almost every patient does much, much better when they're revascularized. If I can't do it, that's why we have a team.** That's the beauty of having a place like this where we work together and get it done.

I think what the CTO field has done, is make a lot of operators better at complex PCI. They may not be able to do a retrograde reverse CART, but they will use the skill sets they've learned to get a complex right done that they otherwise would have walked away from or sent to bypass surgery. Skill sets are what this is all about.

Q: Ajay Kirtane, MD

One of the things that I find really interesting, Dr. Karmapaliotis, is that ever since you started doing CTOs, you've kept a record of every single patient that you've either treated or been involved with and how they've done. This is the start of some data in addition to expanding on registries like Progress CTO and Open CTOs. How does that help you?

Dimitri Karmapaliotis, MD: We are getting fascinated by acrobatics in the coronaries and fancy techniques, but at the end of the day, we're not going to win this battle unless we are able to convince general cardiologists, internists, our EP colleagues, and heart failure colleagues that what we do has a significant impact not only on symptoms, but also a month-to-month survival benefit. I'm not aware of any survival data for PCI in chronic stable

angina, but when it comes to CTO-PCI, they demand from us that we prove a survival benefit. That's a little bit of a discordance there.

I'm excited because now we are in the position that we have the techniques, the capabilities, and the structure to use this data. You don't want to do a study to examine somebody's learning curve. **You want a mature technology and a mature technique that can be applied in a wide range of settings by several operators. I think that we are at this point right now where we can accumulate data from multiple centers and have very good quality data.**

Q: William Lombardi, MD

I have a question for Dr. Moses, just from a historical perspective but also looking forward. There's a lot of healthcare information that comes out of the lay press, and historically most of that press for PCI has been less than helpful. What are your thoughts as we move forward trying to get that to change?

Jeffrey Moses, MD: Yeah, that's something I've struggled with for a long time because, as you know, we see presentations amongst our colleagues where we talk about the hard endpoints of death and MI. There are data sets, meta-analyses, and clinical trials that do show clear benefits in terms of symptoms, maybe MI, maybe into survival. They're published in Circulation and in JACC and respectable journals, but somehow when the plenary lectures are given in the ACC, these studies are just not mentioned. I am encouraged a little bit, by some recent press activity. The New York Times is a great newspaper, but they have a very skewed view of where we're coming from. They had a phenomenal article actually on TAVR, it was so phenomenal that when I told my father, who had one by the way, that there was a positive article about one of our techniques, he was in stark disbelief. The reason is that we had data. I don't think we have to rule the world, but I think once we get past that point where this is not just a symptomatic benefit, that's still the rule in the lay press.

Q: William Lombardi, MD

Dr. Kirtane, as you develop this data, do you think we need to stop competing with surgery and start really looking at patients rather than the mode of revascularization?

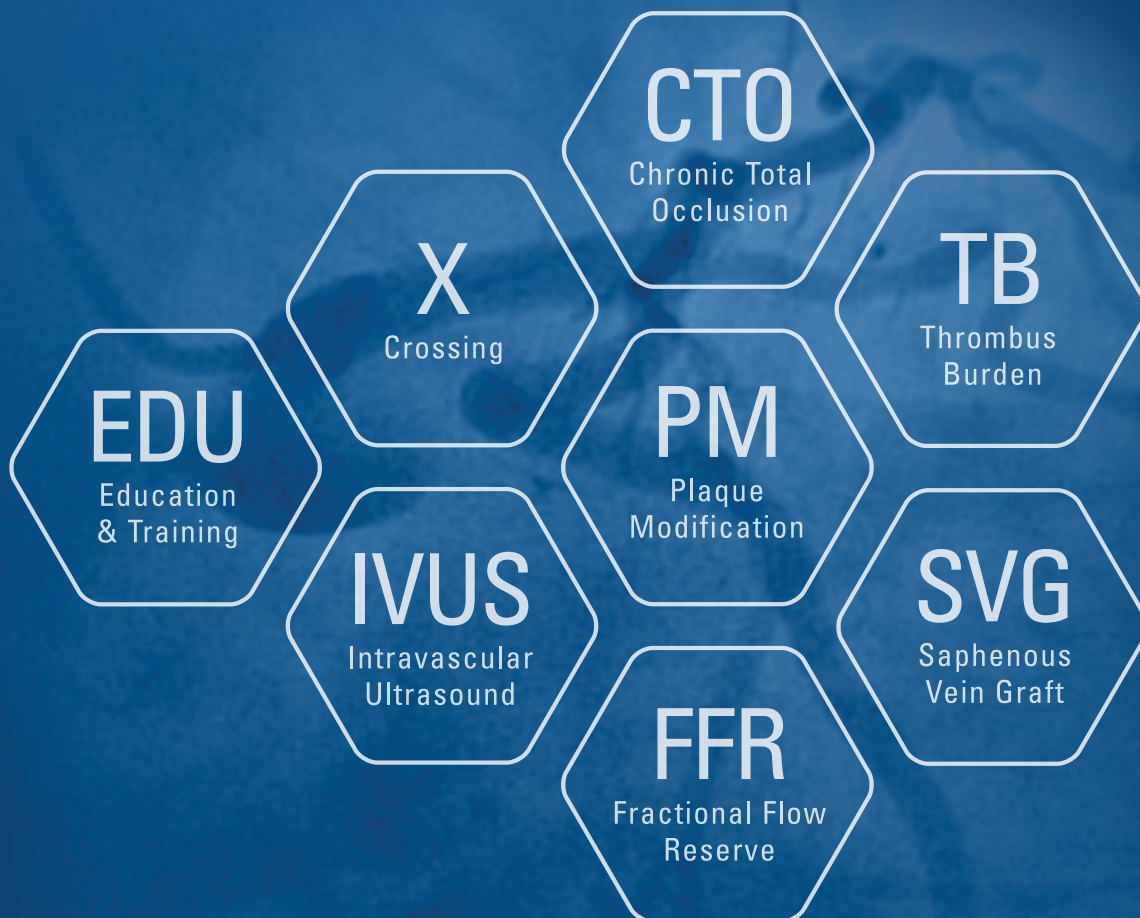
Ajay Kirtane, MD: Yes, I agree. I actually think there was a lot more competition between PCI and surgery that went away once the TAVR programs and the heart team approach (of interventionalists and surgeons working collaboratively) started getting established. **Nobody wants to send somebody for a surgery or PCI if that patient doesn't need revascularization. On the other hand, if the person needs it, to deprive that patient of the opportunity to even be seen by somebody who might be able to do it safely, I think, is a disservice to our patients.** I think it's about revascularization as a whole, and it's really about finding the most appropriate patients to revascularize.



Manish Parikh, MD

serves as the Associate Director of the Cardiac Catheterization Laboratory, Director of Business Development for the Center for Interventional Vascular Therapeutics, Associate Professor of Clinical Medicine and is an attending physician in Interventional Cardiology at The New York Presbyterian Hospital-Columbia Medical Center.

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