The Data Behind Atherectomy and Drug-Coated Balloons

Dr. Lawrence A. Garcia shares his thoughts on what is needed most from future trials and reflects on his key learnings in this space.



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He has disclosed that he does research for and is a noncompensated consultant for Abbott Vascular and Medtronic; is a noncompensated consultant for Bard Peripheral Vascular, Cook Medical, TriVascular, and Boston Scientific Corporation; is a compensated consultant for St. Jude Medical; and has equity in CV Ingenuity, Primacea, Spirox, Tissue Gen, Arsenal, Syntervention, Essential Medical, and Scion Cardiovascular.

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EVT: What type of trial data do you want to see moving forward in the atherectomy and drug-coated balloon (DCB) space, and why? What type of "real world" questions might the data help to answer?

Dr. Garcia: What we really need now is head-to-head comparisons. At the end of the day, everybody is going to be looking for superiority trials.

I suspect that for a superficial femoral artery (SFA) or an infrapopliteal segment, which is so inhospitable for everything we do endovascularly, that as long as you get a primary patency and the pattern of restenosis is less aggressive than what you first started with, then the therapy for that is a lot cheaper. What you spend up front becomes absolutely critical to the health care dollar downstream, and that's where I think we're going to win or lose on a lot of these head-to-head trials.

The combination therapy of atherectomy and DCB has a large cost, but if the downstream side is that you have a 91% primary patency, and of those 9% that fail, they fail in focal ways, then the downstream reintervention for any patient who needs it is a balloon. [This is more cost efficient] as opposed to having a similar up front cost [with a stent] and having a failure that may become an occlusion, which may then require more

expensive reintervention, so your health care dollar just got wasted. I think that is where we're going with ACO models and primary payers—we're going to have to focus a lot on the health care economics.

EVT: You have been intimately involved in both atherectomy and DCB trials. What have you learned in your experience that you're applying to your practice today about both of those?

Dr. Garcia: We've championed atherectomy for a lot of years, and I still believe that the technology, in and of itself, particularly for the SFA, is a very viable and valuable commodity for how we treat our patients when it comes to treatment for claudication. The DCB world, I think, is the holy grail. A lot of us in the United States have seen other parts of the world, particularly Europe and Asia, get DCBs for so many years, and we felt left out. However, once DCBs got here, I think many of us have gravitated to using them in these anatomic locations, particularly the SFA.

In my particular practice, I have found that the combination of therapy, both with atherectomy as well as with DCB is very useful. My hope is that our anecdotal experience translates scientifically when testing combination therapy versus DCBs alone, or against what should be considered the standard right now, which is Zilver PTX's (Cook Medical) 5-year data. Eventually, we have to go against other therapies, and if the endoprosthesis wins, then it will save a lot of time, but we should prove it. If it fails, and atherectomy is proven to be best with the combination therapy, then we should gravitate toward that.

In my particular practice, I've always been somebody who likes to leave nothing behind, and it's interesting to see the worldwide consensus come back to the folks who used to stent a ton and now say that they are leaving nothing behind. I think we've all learned that once you put a stent in there, it's in there forever, and you have to deal with it in some way, shape, or form in the future.