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### **What do you find to be the most challenging and rewarding aspects of peripheral vascular disease management?**

The biggest challenge I have is selecting between the many different mediocre modes of therapy available. As endovascular technologies have evolved, surgeons have steered away from the gold standard of surgical bypass in favor of these less-durable and more expensive industry-driven therapies that really don't compare. We have lowered our expectations of therapy and use the phrase "management of PVD" to obligate us less to definitive procedures from the start. We are all enticed by the quick fix endovascular therapy can provide our patients and are forced to run with the bulls, occasionally getting horned when surgical therapy or no therapy would have been best. Our biggest challenge as vascular specialists will be filtering through all of the technology available and honing in on the therapies that are truly worthwhile to patients, with cost containment as an important part of the mix.

Having a patient tell me that he or she has quit smoking is the most rewarding. I believe that I can make the biggest impact on someone's life by helping him or her quit tobacco use. It's so infrequent, that it is an absolute jewel when it happens. When a patient comes to me and says, "The speech you gave me the other day really hit home, and I've quit smoking since," for me, that is fantastic because I give patients extensive counseling on tobacco use. I know no matter what I do for them surgically, I will have benefitted them more by getting them to quit tobacco. I also explain and teach them how it brought them to my office and what the effects can be thereafter. This is all before I start talking about any form of therapy. It truly is painfully frustrating when most patients can't stop but very satisfying when it occasionally happens.

### **How exactly do you talk to your patients about lifestyle factors that may lead to restenosis?**

I discuss their hypertension, as well as glucose control if they are diabetic; with our nurse practitioners, we try to coordinate care with primary care physicians when statins are used. I discuss cessation of tobacco use. These are very important in terms of restenosis. I also tell patients if they can fine-tune their habits, they can live more fulfilling lives. I often pose to them what it means to be dependent on other people. As you get older, you find that these patients are very dependent on others, secondary to stroke, limb loss, or myocardial infarction etc. The ability to maintain independence is a strong motivator. I don't think patients have that vision of their life in mind. They should consider how dependent they will be in the future; when they must rely on someone else for transportation, meals, bathing,

etc., as well as not able to manage all of their faculties. Discussing their future in terms of dependence gives them a better perspective of what they can do now to avoid or at least put off this scenario. It's a very honest yet scary conversation that is sometimes effective.

### **Does a refusal to modify lifestyle affect your treatment decisions for individual patients?**

Absolutely. Some patients with severe ischemia and tissue loss smoke three packs a day. In this scenario, I counsel them on the hazards of continued tobacco use and tell them that no matter what I do, if they continue to smoke this way, it will result in a bad outcome. But I often take these patients to the operating room and perform some form of revascularization regardless because the severity and urgency of their disease. Then there are the patients who have severe claudication, can't walk more than a block, and also smoke three packs a day—those patients come in looking for a solution. They want to feel better. They will leave my office knowing that they will not undergo a procedure unless they quit tobacco. Intervention in this setting is an abuse of health care dollars and the time of health care professionals, and yet the primary issue is still not remedied. It is, for the most part, a benign disease, and you don't want to put a patient at risk especially if his or her risk factors aren't finely tuned. Risk factor modification is a very important piece of successful vascular outcomes.

### **What are you looking forward to this June at the International Aortic Summit in Venice, Italy?**

This will be our second summit of who's-who in aortic surgery. We invite the thought leaders to come and have in-depth discussions on the treatment of all types of aortic disease, whether aneurysmal disease, aortic dissection, aortic occlusive disease, etc. We have very interesting case presentations brought to us by our selected fellows who submit competitive abstracts to present to the faculty. If it is any thing like last year, the discussions will be lengthy and heated. You wouldn't believe how many different ideas there are about treating the same problems. We tend to assume that people think in parallel about how to treat aortic disease, but that is not true at all. The meeting gives us a lot of perspective and ideas on how to tackle the same problem. ■

*Joseph V. Lombardi, MD, is Chief, Division of Vascular and Endovascular Surgery; Associate Professor of Surgery, Cooper Medical School of Rowan University; and Director, Cooper Aortic Center in Camden, New Jersey. He has disclosed that he receives grant/research funding from Gore & Associates, Cook Medical, and Medtronic, Inc. Dr. Lombardi may be reached at [lombardi-joseph@cooper-health.edu](mailto:lombardi-joseph@cooper-health.edu).*

# Joseph V. Lombardi, MD

*Endovascular Today* talks to vascular surgeon Dr. Lombardi about device decisions, patient management, and the 2012 International Aortic Summit.



**How would you describe the goals of the STABLE trial and any unique design elements it has? How does a challenging population such as this impact the way a trial like this one is designed?**

The goal of the STABLE trial was to look at the feasibility and safety of a composite graft specifically made to treat type B aortic dissection. The design of the trial was to treat patients with complicated type B aortic dissection—in other words, patients who present with impending rupture, malperfusion, early aneurysmal presentation, etc.

The 30-day mortality rate thus far has been very favorable at 5%. We have 2-year follow-up data for more than 40 patients, and the mortality rate continues to be favorable in comparison to other single center series. If you look at most studies to date reflecting 30-day mortality rates for complicated type B aortic dissection, you will see a rate of about 10% or 11%, which demonstrates that this is a very challenging patient population to treat. This is the first prospective study designed to treat complicated type B dissection using a pathology-specific device.

The design of the trial was meant to be inclusive of the variety of presentations a patient with aortic dissection can have. We tried to gear the design of the trial to be inclusive of patients who had an impending disaster. However, we didn't want to broaden the entry criteria so much that the trial was watered down to the point where the data we extracted from it didn't provide us with a true representation of the device's effectiveness. Creating the entry criteria was indeed a challenge. We targeted a complicated group of patients, and as you can see from our initial publication, the results were fairly compelling.

**As fenestrated AAA devices gain approval in the US, including the recent addition of the Zenith fenestrated platform (Cook Medical, Bloomington, IN), how do you think they will affect vascular practices?**

I think that fenestrated devices will have a significant impact on vascular practices. There will be an increased number of patients in whom endovascular therapy will be applicable. However, they won't be available to most

community practices due to the necessary resources involved in performing this type of procedure (ie, catheter skills, hybrid operating rooms, fixed imaging systems, and belonging to a center where a high volume of open aortic surgeries is performed). I think that the institutions that are already doing this, which are few, will continue to do it, and as the rollout continues and people become a little more facile with their endovascular skills, more high-volume centers will adopt this technology and offer it to more patients. Ultimately, you will see some direction of patient referrals going to these medical centers because of the technology, and that's what we have found even with the advent of EVAR; most patients in the community were being referred to the high-volume institutions performing EVAR.

**How far away are drug-eluting balloons from reaching US practices? Will their effectiveness in lower limb procedures justify a potentially higher cost?**

I think they are a few years away. Clinical trials are starting to blossom with respect to drug-eluting balloons. It's hard to know how effective they will be because the mechanism of action is still a bit cloudy. It is also difficult to know what a drug's influence will be on a plaque that you have fractured. You would hope that the drug is just treating the artery wall and not necessarily wasted on the plaque. From my standpoint, the delivery is still questionable in terms of how the drug will interact with the arterial wall. However, in conjunction with atherectomy, there may be significant applications of drug-eluting technology in terms of restenosis prevention. If you have an occluded artery and atherectomize the plaque, you can allow direct delivery of the drug to the arterial wall in the absence of plaque and perhaps see a true biologic effect. Otherwise, I don't think it will be much different from run-of-the-mill balloon angioplasty. I believe drug-coated balloons offer promise as an adjunctive therapy most applicable to atherectomy. As a primary therapy, I fear it will be a costly equivalent to balloon angioplasty.

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