Perspectives on RESILIENT

John R. Laird Jr, MD, and Barry T. Katzen, MD, the principal investigators of the recently published RESILIENT trial, discuss the current SFA study landscape and explain that although angioplasty alone may be sufficient for short lesions, these data show that there is a place for stenting in this challenging vessel.

What do the results of the RESILIENT trial tell us about the use of stents in superficial femoral artery (SFA) lesions?

Dr. Katzen: This trial has provided very important data to support the use of stents in moderate-length lesions. Interestingly, one of the benefits of the RESILIENT data is that they show that angioplasty is effective for certain types of lesions, particularly those under 5 cm. Based on the trial design and on clinical practice, it makes sense to choose a primary stenting approach in lesions longer than 5 cm and to continue to use angioplasty as a standalone technique in shorter lesions.

Can we extrapolate these data to other self-expanding stents, or are these results limited solely to LifeStent (Bard Peripheral Vascular, Inc., Tempe, AZ)?

Dr. Katzen: One of the things we are lacking in our field is a head-to-head comparison of devices. As such, it is not reasonable to extrapolate data about a stent that was specifically designed for the SFA and compare it to other types of stents. The data may or may not be similar, but you cannot extrapolate to other stents because they have different lengths, geometries, delivery systems, etc. It is difficult to extrapolate even to other studies because, although there are other randomized trials, this is certainly the largest prospective, randomized, multicenter trial. We can compare trial data to other trial data to understand the differences, but it is very difficult to extrapolate these particular data for other stents.

Dr. Laird: There are important differences between some of the stents that are currently being implanted in the SFA or those that were used in the past. Some stents have clearly been associated with higher fracture rates and worse patency. The newer-generation, more flexible nitinol stents are providing improved results. I agree that we cannot extrapolate the results from RESILIENT to these other stents, but I would expect that we will see similarly good results from some of the other stents in the prospective registries that are currently underway or just completed. We will likely soon see some head-to-head comparisons with the LifeStent.

Why is this randomized trial important?

Dr. Katzen: I believe that in the United States, RESILIENT has particular importance because it is the first time a peripheral device manufacturer has provided financial support to create level 1 data about a specific device and a specific application as it relates to peripheral arterial disease. As far as I know, even today, all of the other stents being used in the SFA are done so without a specific SFA indication. This was a landmark event among those who treat peripheral arterial disease.

As interventionists, we should support companies that elect to do studies aiming to provide scientific information of high level—level 1 data, level 1B data, or other types of high-level data. Otherwise, we are not going to get the kind of clinical information that allows us to treat patients most effectively. As a result, if there is a manufacturer that provides data supporting the use of a particular device, we do not extrapolate that data to mean it is good for all devices. This relates to all aspects of what we are doing at my institution, whether it is in the cardiac, surgical, valve, or structural heart arena. It is fundamental that interventionists support those who commit to obtaining level 1 data that help us better treat our patients. That is the only way we can do it: by using the data to select devices.

Dr. Laird: Although there are those who have criticized the trial design in RESILIENT, Edwards Lifesciences (Irvine, CA) and Bard Peripheral Vascular are to be congratulated for completing this randomized trial. We

need more studies such as this to bring a little more data and science to our daily practice of peripheral vascular intervention.

What is the future of randomized trials in the SFA now that the US Food and Drug Administration (FDA) is permitting companies to use objective performance criteria and goals as a reference?

Dr. Laird: As previously mentioned, I am expecting that there will be some head-to-head randomized comparisons of new nitinol stents against the LifeStent because it is currently the only FDA-approved and commercially available bare-nitinol stent. We will also soon be seeing some randomized trials of drug-eluting balloons against plain old balloon angioplasty or stents. It is unlikely that the FDA will require any more randomized trials of bare-nitinol stents against PTA as part of the approval process.

Dr. Katzen: I think it is appropriate to use objective performance criteria for SFA studies; however, it is not fair to the original sponsor who makes the investment to study a particular device because subsequent studies may then get clearance based on similarity to the first study. For this reason, our ability to perform randomized trials may be limited going forward. We will have similar questions in other areas such as carotid stenting with the results of the CREST trial and ACT 1 trial, which are the two principal randomized trials being supported by industry. It will be interesting to see whether the FDA acts similarly in regard to the manufacturer of carotid stents, who made huge investments in these randomized trials. The potential downside is that we may be discouraging companies from undertaking pivotal trials in the future.

Based on this study, is stenting now the gold standard for treating moderate-length SFA lesions?

Dr. Katzen: I am not sure about using the term *gold standard*. In many practices, based on the results of this study, which were originally presented some time ago, stenting has achieved a much higher role in treating moderate-length lesions. In our own intuition, it is the standard of care for moderate-length lesions to be stented primarily. I believe that there are still many physicians who will continue with angioplasty first and then perform provisional stenting. We do not have strong data one way or another regarding the outcomes of that practice. Actually, the RESILIENT trial shows that in the moderate-length lesions, patients treated with a primary stenting protocol have better outcomes.

Dr. Laird: There will still be some argument about the strategy of primary stenting versus a strategy of PTA with provisional stenting if a suboptimal angiographic result is obtained with the balloon. The results from RESILIENT are consistent with the findings of the Schillinger study and would suggest that primary stenting is better than PTA plus provisional stenting, at least for lesions up to 15 cm in length. What we are lacking is any comparative data regarding atherectomy for lesions of this length. It would be great to see a study of atherectomy versus stents for these type lesions—and then there are drug-eluting balloons and drug-eluting stents to consider.

What can we conclude about the performance of the LifeStent in short and long SFA lesions?

Dr. Laird: I believe it is a great stent. That being said, like all of the more flexible stents, care must be taken during deployment to ensure that the stent does not elongate or compress. When type IV fractures occurred during RESILIENT, they seemed to be associated with inappropriate stent elongation during deployment. That was a much bigger issue with the original delivery system. The newer delivery handle has solved most of this problem, but operators still must pay attention to the back of the stent during deployment.

Dr. Katzen: In the RESILIENT trial, we found that the LifeStent is an excellent device for long and short SFA lesions. LifeStent performs well, but angioplasty is usually sufficient for most short lesions. In terms of long SFA lesions, I am not talking about full-metal jackets, meaning from the ostium down. We still need to get more data in that area.

The term *long lesions* within the context of this clinical trial indicated lesion lengths up to 15 cm. Preliminary reports of the VIBRANT trial have raised concerns about stenting in very long segments of disease (longer than 15 cm).

There are still many unanswered questions in the SFA, questions that will require high-level data to sufficiently address. ■

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