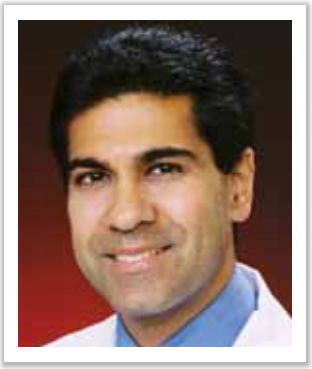
Tony S. Das, MD

Trialist, innovator, and educator, 2011 VIVA President Tony S. Das, MD, shares his opinion on decision making for SFA disease treatment and discusses some of his latest projects.

To what degree does on-label status affect your decision making in terms of superficial femoral artery (SFA) stent choice?

We have previously been more interested in performance than the actual on-label status. The issue is that the companies are now challenged with the inability to promote or discuss any of their devices that are deemed biliary devices unless they do clinical trials. The marketplace is being forced by regulators to do the on-label trials, which I do believe is a good thing. I think on-label status has affected our decision making to an extent, but it is going to affect more of us as reimbursement becomes a bigger issue. Obviously, off-label status is something on everyone's radar, including industry, physicians, industry, regulators, and even patients.



When do you elect to use a covered stent in the SFA as opposed to a bare-metal option?

In the SFA, a covered stent is my go-to device for in-stent restenosis after ablating the plaque, usually with laser. I use covered stents in other areas as well where I am concerned about stent fracture. The Viabahn trial (Gore & Associates, Flagstaff, AZ), VIBRANT, was interesting in that the pattern of restenosis was clearly different for covered versus noncovered stents. The lack of diffuse restenosis by using covered stents was encouraging, but the actual restenosis numbers were not significantly different. Viabahn still makes for a good choice in the SFA because the mechanism of restenosis is much more focal than in a nitinol stent.

Based on your experience using a variety of devices throughout their evolution and your participation in clinical trials, do you believe that technology is continuing to grow nearer to meeting the clinical need posed by SFA disease?

The bottom line is that medical device development continues to evolve to meet the needs of the practicing endovascular specialist. The problem is that device development itself has probably slowed down because a lot of limitations that have occurred through the funding in the capital markets and the changes in the 510(k) US Food and Drug Administration approval process. Innovation itself is probably more expensive and slower in the vascular field due to these challenges, but the devices that have been developed appear quite promising. What we don't know is the long-term success of these devices, including drug-eluting stents and balloons, but we are hopeful in their early results.

Will a vessel that is exposed to the forces seen in the SFA always pose a challenge, regardless of the advances in technology?

The SFA is a challenging artery because it has such high resistance and low flow along with mechanical issues—being compressed, elongated, and shortened—implantable devices in particular, such as stents, are going to have challenges like fractures. Stents that are made of newer materials, such as woven nitinol, will have less chance of fracture and show better patency long term and in difficult anatomy such as the popliteal artery.

What types of devices must you have in the room when approaching a potentially challenging chronic total occlusion?

Challenging chronic total occlusions require experience with wire skills first and foremost. Hydrophilic guidewires and catheters (Glidewire and Glidecath, Terumo Interventional Systems, Somerset, NJ) are my mainstay for most of these cases. Having said that, reentry devices are absolutely imperative to performing successful subintimal recanalization of an occluded SFA. If you do not have a reentry device, your success rate will be lower. My threshold for using a reentry device earlier in a case has come down significantly. A chronic total occlusion case is clearly expedited and more successful with the right tools and knowing when to use them appropriately.

What do you believe the role of drug-eluting balloons will be if approved in the United States?

I believe drug-eluting balloons, in general, if they are effective in long diffuse lesions below and above the

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knee, will be used as first-line devices. Our challenge with nitinol stents has always been the issues of restenosis and fracture especially in longer lesions. If you can get by with balloon angioplasty in these patients for at least the first or second procedure, I think there will be a relatively high adoption rate of these balloons. Of course, price will play a role in the overall adoption rate.

Is angiogenesis proving to be a potential treatment option for patients with unreconstructable peripheral arterial disease? What is the status of angiogenesis study for these patients?

Angiogenesis has always been an interesting research concept. We were involved early on with VEGF (Vascular Endothelial Growth Factor) and the TRAFFIC (Therapeutic Angiogenesis With Recombinant Fibroblast Growth Factor-2 for Intermittent Claudication) trials, which looked at inoperable lesions and lesions that could not be treated with angioplasty. These trials did show improvement in patients, but the benefit to patients with critical limb ischemia is relatively limited. Angiogenesis is for patients with extensive disease who do not have ulcers for the most part, and it still has a long way to go as far as the level of diseases that we can treat.

Are there other entirely new therapeutic approaches on the horizon for peripheral arterial disease treatment?

Several interesting devices are in development that enhance local drug delivery to lesions by pretreatment with atherectomy or focal drug delivery balloons. The approach is a mechanical and biological one combined. Ultimately, we need to address both the mechanical and the biologic problems of vascular atherosclerotic disease to gain a reasonable therapeutic treatment that will remain durable.

Have you performed a case recently that was particularly memorable?

What is becoming more frequent and therefore more memorable are the cases where there appear to be no specific options. Recently, I had to go through the foot anterior tibial vessel directly retrograde. We have shown cases like this in the past, but I think creativity with access is increasing our ability to cross these chronically occluded lower extremity vessels. This is leading toward lower amputation rates and improving limb salvage, which has always been our goal. These are the types of cases that truly stand out.

What will be new at VIVA 2011?

We have a very ambitious educational program this year in Las Vegas at the Wynn from October 18th through 21st. A major focus for VIVA in 2011 is International Education. We are hosting several international physician ambassadors. Our goal is to create an exchange of ideas for vascular disease therapy across disciplines and across continents. We are very interested in learning from each other and from experts across the globe.

What is the status of your medical education project?

I have participated in medical education for many years, and recently, I started an educational company called Cardiovascular Education Group. I am in the process of developing a unified educational slide set that covers everything from access tips to the data on different devices in an attempt to get industry reps and physicians up to speed on this rapidly changing field. I don't think one can obtain this information fast enough by just reading about it and attending meetings such as VIVA. My goal is to create an identifiable one-stop location to get this information out there to educate people in the vascular field. I started disseminating this to industry reps, and I've recently spoken at a couple of national sales meetings. I am trying to level the playing field for those involved in the vascular space to help them understand the techniques, the challenges, the devices, the data, etc., so that we can all make intelligent choices.

What has your involvement been with device development over the years?

My other big project, which is something I've been involved in since 2008, is my partnership with Jihad Mustapha, MD, in a company called TDJM Medical Technologies. We are dedicated to medical device development. We have put together some innovative ideas about the currently available devices, offering new iterations on these, and are tackling some interesting new products as well. We have been working on an exciting aspiration catheter that could really help the field move along. We are in a pretty rapid growth phase and are looking forward to the next stages of development. ■

Tony S. Das, MD, is Director of Peripheral Vascular Interventions at the Presbyterian Heart Institute in Dallas, Texas. He has disclosed no specific conflicts with this interview, however he has disclosed that he is a paid consultant to and receives grant/research funding from Abbott, BSC, Cordis, CSI, Angioslide, Gore, Bard, Spectranetics, Medtronic, and IDEV Dr. Das may be reached at tdas@civadallas.com.