Professor Thomas Zeller, MD

The Director of the Department of Angiology at Universitaets-Herzzentrum talks data on renal denervation, drug-eluting balloons, and other recent trials.

When assessing renal and access arteries in consideration for renal denervation (RDN), what anatomical conditions do you classify as treatable versus not treatable?

The minimal vessel diameter should be ≥ 4 mm, even if single side branches originate early from the main trunk. Vessel diameters < 4 mm impose a significant risk for severe, very painful spasm. Diffuse atherosclerosis and aneurysm disease is an exclusion criterion.

Outside of hypertension reduction, what other utilities are being considered for RDN?

Currently, blood pressure control is the only indication for RDN outside of dedicated study protocols. Within study protocols, we are investigating the effect of RDN therapy on heart failure, the recurrence of atrial fibrillation after conversion into sinus rhythm, and the impact on renal function and blood pressure control when performing RDN in patients who are in a progressive stage of renal failure. The effect of RDN on obstructive sleep apnea syndrome and hyperglycemic control is currently not in the scope of relevant studies.

What is the significance of reduction in ambulatory blood pressure after RDN, versus the standard monitoring of office blood pressure?

To the best of my knowledge, there is no uniform definition for a significant decrease in ambulatory blood pressure measurement (ABPM). Some authors consider a drop of > 5 mm Hg systolic blood pressure already as significant, and I personally would consider a drop of mean blood pressure > 5 mm Hg as a significant effect.

Pseudoresistant hypertension is characterized by normal ABPM values despite significantly increased office-based blood pressure values. Thus, ABPM is the screening tool for pseudoresistant hypertension. According to current knowledge, those patients should not be treated with RDN even if pseudoresistance is associated with an increased sympathetic tone.

What level of evidence do you believe the field will need to see to justify the cost of drug-eluting balloons in lower limb procedures? Are the data collected so far supporting that direction?

For above-the-knee use, I believe that the data collected so far, supplemented by the data of the IN.PACT SFA trial (Medtronic, Inc., Minneapolis, MN) and the LEVANT 2 trial (Bard Peripheral Vascular, Tempe, AZ) (both of which will be released very soon), will be sufficient to justify the current premium costs for drug-eluting balloons. The cost will go down significantly as soon as use of those devices is more widespread. For below-the-knee application, the data quality is not yet sufficient to justify the additional costs.

In what way, if any, do the challenges with reimbursement in Europe affect your day-to-day practice?

In Germany, we have an appropriate reimbursement situation for drug-eluting balloons that covers their additional costs. Thus, drug-eluting balloon angioplasty with provisional bare-metal stenting has become the first-line strategy in femoropopliteal lesions and in challenging below-the-knee lesions.

At the present time, the only technology that is not adequately reimbursed in Germany is drug-eluting stents, which currently receive the same reimbursement as bare-metal stents. Additionally, combining different technologies—eg, atherectomy plus stenting—is not sufficiently covered by the reimbursement system.

What are your impressions from the early DEFINITIVE AR data presented at VIVA 13? What must we see in the follow-up to determine if directional atherectomy plus drug-eluting balloon angioplasty is a viable and practical strategy?

The data I presented match with the expectations regarding an improved acute technical outcome. Unfortunately, due to limited funding, the study is not sufficiently powered to show a significant benefit from the dual-treatment approach. To support the debulking-first approach, the study would need to end at least with a beneficial technical 1-year outcome in terms of an increased patency rate as compared to drug-eluting balloon angioplasty alone. We can't expect a better clinical outcome with this small sample size.

Are there any updates to the ETAP (Endovascular Treatment of Popliteal Artery-Balloon Angioplasty Versus Primary Stenting) trial results that you first presented at TCT last year?

We just received the statistics regarding the 2-year outcome. However, we did not yet analyze the dataset.

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How does dual-antiplatelet therapy fit into your postinterventional strategy? How does it compare to mono-antiplatelet therapy?

In our institution, every patient is preloaded with aspirin and clopidogrel, regardless of what kind of interventional procedure will be performed and regardless of the fact that no evidence has been published yet that supports this strategy. The postinterventional duration depends on the treatment strategy. It is at least 4 weeks, except for when treated with Zilver PTX (Cook Medical, Bloomington, IN) (2 months), drug-eluting balloon and provisional stent or drug-eluting balloon treatment of in-stent restenosis (3 months), and drug-eluting stent placement below the knee (6 months).

Can you tell us a little about the technology behind the BioMimics 3D stent (Veryan Medical Ltd., Horsham, UK)? Theoretically, why is a 3D helical stent beneficial? What is the latest on the MIMICS study, which you presented at VIVA 13?

Two design aspects of the stent could be beneficial: (1) The 3D helical design results in a better absorption of particular axial compression forces typically exposed to the stent during leg bending, thus resulting in a significantly higher fracture resistance as shown in bench tests; (2) The helical design translates a laminar flow into a "swirling flow" that increases shear stress, which is linked to a suppression of neointima hyperproliferation, as confirmed in animal tests. ■

Professor Thomas Zeller, MD, is Director of the Department of Angiology at Universitaets-Herzzentrum, Freiburg-Bad Krozingen, in Bad Krozingen, Germany. He has disclosed that he has received honoraria from Abbott Vascular, Angioslide, Bard Peripheral Vascular, BioMimics, Biotronik, Boston Scientific Corporation, Cook Medical, Cordis Corporation, Covidien, ev3 Inc., Gore & Associates, Lutonix, Medrad, Medtronic, Spectranetics, Straub Medical, TriReme, Veryan/Novate, VIVA Physicians, Gore & Associates; consulted for Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corporation, Cook Medical, ev3 Inc., Gore & Associates, Idev Technologies, Inc., Medtronic, Spectranetics, Gore & Associates; and his institution received research, clinical trial, or drug study funds from 480 Biomedical, Angioslide, Bard Peripheral Vascular, BioMimics, Biotronik, Cook Medical, Cordis Corporation, Covidien, ev3 Inc., Gore & Associates, Idev Technologies, Inc., Medrad, Medtronic, Spectranetics, Terumo, TriReme, Volcano, Gore & Associates. Prof. Zeller may be reached at thomas.zeller@herzzentrum.de.