Marc Sapoval, MD, PhD

The Paris-based interventional radiologist discusses renal denervation applications, device regulation, as well as how to best involve interventional radiology in trauma cases.

At ISET 2013, you discussed several of the key factors influencing the uptake of procedures such as renal denervation, highlighting in particular how closely European national volumes relate to reimbursement. How do you foresee the reimbursement landscape developing in the next several years?

Reimbursement will obviously be linked to clinical evidence. All countries in Europe have to contain their health care expenses and are concerned about the development of new technologies that have little or no clinical evidence at this point. Clinical evidence is still preliminarily based only on one randomized trial with a little more than 100 patients. The SIMPLICITY HTN-3 trials will have results soon, and the DENER-HTN (the so-called STIC trial) in France will soon be completed.

A central theme of your presentation was that it is still relatively early in the lifespan of renal denervation and that its potential could be adversely affected by overapplication in the near term. What is your opinion on how this procedure should currently be used?

All country-specific and European consensus statements command for controlled use of renal denervation today. Patients treated with this approach should have clearly demonstrated primary resistant hypertension and be treated in the setting of a multidisciplinary hypertension team with a dedicated hypertension specialist and dedicated interventionist.

Which specific population is appropriate, and which patients should not yet be treated?

The appropriate population is patients with resistant primary hypertension. Patients who have not been fully examined for the potential secondary cause of hypertension and those in whom medical treatment has not been attempted according to the international guidelines should not be treated.

What data do you most anticipate in the renal denervation arena in the coming months or years ahead?

Many trials are ongoing and registered worldwide. As far as I know, the HTN-3 trial is in the process to complete inclusion, as well as the French DENER-HTN (STIC) trial.

Beyond resistant hypertension, in which applications do you feel renal denervation has potential benefit?

Many different applications of renal denervation are being studied these days outside of treating resistant hypertension patients. The first is cardiac failure. There is animal evidence and probably preliminary human data showing that denervation can be efficient; more data are anticipated. This could be a very important application of the technique. Renal failure and proteinuria in diabetic patients, which is currently being studied in the DERENEDIAB randomized trial in France and other trials worldwide, will also be an important challenge.

Results on glucose tolerance and atrial fibrillation have been reported, but these are all very preliminary and without solid evidence. More work is needed in this area.

Another intriguing presentation you recently gave was part of the SIR 2013 scientific sessions, during which you engaged in a creative and light-hearted debate with Anne Roberts, MD, on the merits of FDA and CE Mark regulatory methods. Which regulatory practice do you feel is better for both patient care and the advancement of the field?

I think that both sides of the Atlantic have advantages and drawbacks. In the United States, access to very new technology of high clinical risk and implication is very well controlled; the FDA has significant power to ask for level-one clinical evidence. On the other hand,

(Continued on page 113)

(Continued from page 114)
510(k) clearance can lead to acceptance of technologies that are not proven and sometimes go to market without enough evidence.

On the contrary, in Europe, the CE Mark controls access to all new technology relatively well, but the level of clinical demonstration is not defined enough. In some cases, medical technologies are adopted too early, before negative or positive results on their use have been demonstrated by appropriate randomized control trials. In any case, CE Mark does not imply direct access to the market because reimbursement is acquired on a country-by-country basis.

In what ways do you feel each regulatory format could realistically be improved?

I think that in Europe, the CE Mark can be improved by more appropriately defining what clinical evidence is needed before going to market. Transparency and control of notified bodies should also be improved. The European Commission is currently working on new regulations. In the United States, 510(k) clearance should be refined, and the FDA should allow access to technologies earlier—at least when evidence has been proven in other countries, then in the United States.

One of your presentations at GEST 2013 involves the role of embolization in trauma cases. How can interventional radiologists prepare for cases that are at once both unique and emergent? What kind of training is needed?

Interventional radiologists (IRs) can prepare by training in embolization techniques and performing cases outside of emergent situations so in case of emergency, they can react rapidly. The angio lab should have a high level of reanimation capabilities and the ability to implant all devices, including stent grafts, which can be percutaneously implanted through a catheter at the inguinal level. Teaching IRs should be based on clinical training and diagnostic radiology first and followed by interventional radiology specifics, including catheter skills and material knowledge.

At a minimum, which devices and materials must be on hand in order to offer this service?

Have diagnostic catheters and microcatheters in different sorts of curves, pushable catheters, 0.035- and 0.018-inch diameters; gelfoam; glue; particles; plugs; and stent grafts, including a large aortic stent graft for transaortic rupture. Imaging and basic reanimation capabilities should be available in the angio suite.

> Both sides of the Atlantic have advantages and drawbacks. In the US, access to new technology is well controlled … In Europe, CE Mark controls access relatively well, but the level of clinical demonstration is not defined enough.

How would you describe the interdepartmental communication and networking that must be in place in order to ensure that, for example, the emergency department knows the embolization capabilities of the interventional radiology department?

It is clear that communication has to be well organized between the emergency department and all clinical specialties involved in the care of trauma cases, including surgeons of different subspecialties, diagnostic radiologists, IRs, and reanimators. Physicians in the emergency department sometimes don't know what interventional radiology can do for trauma patients. In some places, trauma cases are not frequent, so those who arrive in the hospital may be poorly managed because IRs are not present.

What advice would you offer an IR entering the first year of practice?

When entering the first year of practice, the clinical implication of this specialty must be understood. Young IRs must learn the basics of diagnostic radiologists, of course, but also how to manage the patients in clinics and the main clinical features of the diseases that we treat.

Overall, the specialty has a brilliant future. A lot of dedicated IRs are needed worldwide. There is a lack of IRs in most countries, so young IRs have a very bright future in front of them. ■

Marc Sapoval, MD, PhD, is Head of the Interventional Radiology Department, Hôpital Européen Georges Pompidou, Assistance Publique–Hôpitaux de Paris and Université Paris Descartes, Sorbonne Paris Cité, Faculté de Médecine in Paris, France. He has disclosed that he is a consultant for Cordis, ReCor, and Boston Scientific Corporation, and receives research grants from Boston Scientific Corporation, St. Jude Medical, and Medtronic. Prof. Sapoval may be reached at marc.sapoval2@egp.aphp.fr.