AN INTERVIEW WITH...

Kazushi Urasawa, MD, PhD, FJCC

The Sapporo-based interventional cardiologist shares the unique approach to challenging lower limb interventions in Japan.

Japan's Pharmaceutical and Medical Devices Agency (PMDA) has been working to update its regulatory pathways in recent years. How do you foresee changes in the regulatory landscape affecting device availability in Japan in the future?

In the last several years, the Japanese PMDA has tried to accelerate its reviewing process, which includes the replacement of several regulatory laws with regard to new medical devices. There are numerous positive outcomes already from such acts. One example is the Zilver PTX drug-eluting, self-expanding nitinol stent (Cook Medical) for femoropopliteal disease, which was released in Japan before the United States after the collaborative clinical trial. Accumulated device lag to date is, however, extremely vast. I am hoping for further acceleration of the PMDA's reviewing process to fulfill the already existing device lag between the United States and Japan.

What are some key differences in approaches to lower limb intervention in Japan? What is your first-line therapy in below-the-knee lesions?

As previously mentioned, the biggest differences between the United States and Japan is the accessibility to newly developed medical devices, such as chronic total occlusion (CTO) crossing devices, reentry devices, drug-coated balloons, drug-eluting stents, debulking devices, and so on. The restricted access to new devices has been the major driving force for us to develop various wiring techniques in order to improve the initial success rate of our endovascular procedures. So far, I have introduced transcollateral wiring and many different types of distal punctures. By now, many Japanese physicians are regularly using these techniques in their daily practices.

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Another unique feature of Japanese patients with peripheral artery disease is their lesion morphology. There are more than 300,000 patients in end-stage renal failure who depend on hemodialysis in Japan, and these patients are the major source of critical limb ischemia (CLI). Because of that, the target lesions we have to deal with are usually heavily calcified occlusive diseases, which make endovascular treatment quite difficult and complex. In Japan, roughly 90% of patients with CLI are treated by endovascular procedures to establish revascularization for their ischemic limbs. Interventional cardiologists perform more than 80% of those endovascular procedures, with the remaining 20% performed by vascular surgeons and interventional radiologists.

In the last 10 years, we have focused on improving our interventional techniques. At the same time, Japanese medical device companies have actively developed numerous devices for peripheral intervention, especially CTO guidewires and microcatheters. A synergistic effect of these two efforts is that we now achieve nearly 100% initial success in all kinds of peripheral interventions. Now we are facing a much more fundamental problem—how to improve long-term outcomes of our endovascular treatment. The good news is that, within

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a couple of years, we will finally have several new devices, including two self-expandable nitinol stents, directional atherectomy, laser atherectomy, Jetstream atherectomy (Boston Scientific Corporation), and three drug-coated balloons. I do hope these devices ameliorate long-term outcomes of very challenging endovascular therapy in Japan.

In your opinion, what is the best way to approach heavily calcified lesions?

The Crosser system (Bard Peripheral Vascular, Inc.) is my first-line therapy for heavily calcified lesions. Before the introduction of the Crosser system, I sometimes experienced an unfortunate situation where I could not cross any interventional devices through the target lesion, even after the successful crossing of a CTO guidewire. Frequency of such events is considerably reduced these days owing to the flossing power of the Crosser system.

What has been one of the most compelling pieces of literature you have read in the last few months that you would recommend to your peers to read, and what about it interested you?

Recently, Dr. Nakama and his colleagues published "Clinical Implications of Additional Pedal Artery Angioplasty in Critical Limb Ischemia Patients With Infrapopliteal and Pedal Artery Disease" in the *Journal of Endovascular Therapy* (2016;23:83–91). Below-the-ankle (BTA) intervention emerged as a last resort for CLI treatment, especially in patients with severely damaged BTA arteries, although the clinical meaning of such aggressiveness has not been clinically tested. Dr. Nakama showed that aggressive catheter-based recanalization of BTA arteries could significantly improve wound-healing rates and also reduce the time to complete wound healing. ■

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