AN INTERVIEW WITH…

Luis Mariano Palena, MD

Dr. Palena discusses the necessary skills for tackling challenging CLI cases, his ongoing research of new technology in this area, and his educational work around the world, particularly as Course Director of the CLIC meeting series.

In a 2017 *Endovascular Today* article,[1] you mentioned that your institution was establishing a fellowship program for advanced and complex techniques for critical limb ischemia (CLI). How is the program going so far, and what specific skills are included in the curriculum?

The fellowship program at the Interventional Radiologist Unit, Policlinico Abano Terme started in October 2017. Our program is actually a mini-fellowship program (1–3 months) and is focused on CLI. This not only covers complex techniques for superficial femoral artery (SFA) and popliteal artery interventions, but also includes endovascular therapy in the tibials and pedal arteries. Enrollment in the program has a been huge success so far—in fact, we have added 11 physicians from all over the world (eg, Argentina, Mexico, Venezuela, Colombia, Canada, United Kingdom, Sweden, Kuwait, Ukraine, and Spain) from November 2017 to July 2018. Our intent is to provide a practical fellowship program, and for this reason, we have two spots available per month, so that we can offer the opportunity to be involved in our cath lab to all the participants. The program has gained lot of interest among our colleagues who wish to focus on CLI care, and we actually do not have any available spots until next year.

The curriculum includes all of the specific skills needed for the endovascular therapy of CLI: from access to closure, all of the crossing strategies including retrograde access and the most challenging technical strategies (above the knee, below the knee, and below the ankle), and all of the therapeutic options (balloon angioplasty, drug-coated balloons, bare-metal and mimetic stents, drug-eluting stents, atherectomy, and other emergency technologies). For next year, the next step in the fellowship program is to start to promote research and investigation, asking the participants to provide a research project to be completed during the program, with the idea to stimulate scientific activities.

You have also stated that there are currently no strict or specific guidelines for the skills that an operator must obtain before tackling complex SFA chronic total occlusion cases. What would you propose for these requirements?

For these specific requirements, I believe we need more trials and scientific data. For example, a learning curve study to determine the average case volume per operator necessary for independence could help. Specifically, knowing the average length of time or number of complex cases performed under supported supervision to achieve good results while learning to manage complications would be a good starting point.

Can you share any updates about your analysis of the use of automated carbon dioxide (CO_2) angiography in diabetic CLI patients? Do you see any potential barriers to widespread adoption of this technique?

We have been conducting a large study of our experience with CO_2 over the last few years. Our preliminary data, published in 2016,[2] were very enthusiastic in diabetics with CLI who are affected by chronic renal failure. This is cohort of patients who cannot undergo imaging with traditional iodinated contrast media. These data showed that CO_2 has the potential to be an alternative contrast media for these CLI patients. Since then, we've studied diffuse use of CO_2 in all our patients affected by CLI, and the experience showed little difference compared to the original data.

The automatic injection of gas allows us to manage the volume and pressure of contrast during the procedure, but from the technical perspective, there were no steps forward with the injector or software for digital subtraction angiography. So, we are more or less at the same place as we were 3 years ago (ie, we can obtain acceptable images, but they are not the same quality compared with iodine). From a clinical perspective, the pain sensation for patients who underwent CO_2 is high-

(Continued on page 104)

(Continued from page 106)
er, but still acceptable, and the amputation-free survival rate was similar in both groups. We also performed a test with a manual injector system, and the results were comparable between automatic and manual injection.

This year, during Critical Limb Ischemia Course (CLIC) 2018, I presented the latest data about the CO_2 experience in our clinic, which was more based in cost analysis. When we compared patients treated only with iodinated contrast media or with both iodinated contrast media and CO_2, we discovered a > 50% reduction in iodinated contrast media use, which seems to translate to an initial cost benefit. When we analyzed the finding further, taking into account the price of the automatic injector and the single-use connectors, the use of CO_2 was not more beneficial in terms of cost and provided inferior imaging quality.

I would be interested in a head-to-head comparison between automatic and manual CO_2 injection to have more robust data about the cost-benefit situation. We are also awaiting new developments in software improvements for CO_2 digital subtraction angiography.

Can you tell us about the SUPERSUB II trial and its current status?

The SUPERSUB II trial (NCT03452293) is an ongoing trial evaluating the safety and efficacy of subintimal stenting in complex de novo or reocclusive chronic total occlusions (TASC C/D lesions) in patients with CLI. This will be multicenter study with primary patency evaluated at 24 months, which differs from the previous phase 1 trial, as it was performed at a single center with outcomes to 1 year. SUPERSUB II will be enrolling patients at eight to 10 centers in Italy, one in the United Kingdom, one in the United States, and one center in Argentina.

Despite the time for initiation (ethics committee approval, etc) and thanks to the huge support of EndoCore Lab Srl, enrollment has begun in six centers in Italy and in one center in Argentina, which amounts to 15% of the target sample size. We expect to continue

this good trend in enrollment after the summer holidays have ended.

How have your experiences living in various parts of the world shaped your approach to medicine?

My professional experience has been in Italy, and I've had other experiences all around the world as a proctor. But, even when I'm there to teach, I always learn, probably more than I teach. I could talk for hours about the Latin American experience (Argentina, Chile, Colombia, Costa Rica, and Mexico), because it is always nice to be back home, speaking Spanish and working in an atmosphere that I know very well. On the other hand, it is always a very challenging situation, because not all of the devices are available and the procedures can incur costs related to additional setup, because most of the patients come from poor economic conditions. From the technical perspective, the patients are similar to those in Europe, and I would treat them in the same way, or at least try, depending on device availability.

Another good experience I had this year was in Southeast Asia (Thailand, Malaysia, and Singapore). What I always observe in my proctor and preceptorship activities is the high interest for endovascular treatment of CLI, as well as the skills gaps and how these are reduced, step by step, in the centers I frequently visit.

As a Course Director for CLIC, can you explain how this meeting initially came about? What was the original intent and has that changed at all now that you are planning the third iteration?

CLIC was born in 2017 with the goal of creating a space for young doctors to discuss all topics related to CLI. From the beginning, the format was and continues to be based on live cases. Our idea was to share live interventions from the beginning through completion to offer everyone the chance to see, learn, and discuss.

We discovered some gaps in the first meeting, as well as in the second, which has allowed us to improve the next edition. These include improvements to technical aspects and the operators involved in the live cases, as well as some adjustments to the presentations and debates. However, the original intent still remains the same; we provide a place for interaction, innovation, and discussion in which everyone learns and everyone teaches. Our final interest is to remain small and focused on CLI.

Fortunately, the meeting has been growing and achieving more success and interest, and now we are expanding to other locations, the first of which is CLIC Central/East Europe (November 9–10, 2018) in Warsaw, Poland.

Can you share any of the preliminary details about the 2019 courses?

First, we have CLIC 2019 (March 21–22, 2019) in Padua, Italy, which is the third edition and includes more live cases, interaction, and international participants. After CLIC, we will have CLIC Latam (June 6–7, 2019) in Rosario, Argentina, the Spanish-speaking version of CLIC, with the same format, live cases, interaction, and discussion. We also anticipate CLIC Italia, with its webinar and face-to-face meeting, and the last and not completely confirmed will be CLIC Mexico and Central America, with the same format as CLIC Italia, similar to a master class on CLI, combining a webinar and local meeting. ■

1. Palena LM, Jabalera EG, Manzi M. A European perspective: valued care and the potential for CTO credentialing. Endovasc Today. 2017;9:46, 48-49, 53-54.
2. Palena LM, Diaz-Sandoval LJ, Candeo A, et al. Automated carbon dioxide angiography for the evaluation and endovascular treatment of diabetic patients with critical limb ischemia. J Endovasc Ther. 2016;23:40-48.

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