Reflections on the 8th Annual AMPutation Prevention Symposium (AMP)

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AMP was held in August 8-11, 2018 in Chicago, Illinois. This year's AMP meeting had record attendance, with attendees from all 50 states and 17 countries.

Ramon Varcoe, MD, MBBS, MS, PhD, giving the keynote address at AMP.

Thomas Zeller, MD, PhD

J.A. Mustapha, MD

Critical limb ischemia (CLI) is one of the fastest growing diseases. My fear is that one day it will reach epidemic proportions for those patients predisposed to the disease. Hence, my reason for developing the AMPutation Prevention Symposium (AMP), which is the only medical meeting focused exclusively on critical limb ischemia. Every year, we work hard as a team to bring together knowledge, experience, and data from around the globe. We share with our audience what has happened over the last 12 months that could help slow down the growth of CLI, along with all its associated morbidities and mortality. At AMP this year, we learned of significant new devices specifically made for CLI. This is a great victory for our patients, because now we are gaining tools to treat the complex, difficult CLI disease state.

Highlights From Four Days of AMP

The 2nd annual Alan T. Hirsch Memorial Keynote Address, "A True Multidisciplinary Approach to Limb Preservation and Why Is it Important?" was given by Dr. Ramon Varcoe, a vascular surgeon from Sydney's Prince of Wales and Prince of Wales Private Hospitals, where he is supervisor of vascular training and director of the Vascular Institute. Dr. Varcoe's busy clinical practice specializes in the minimally invasive treatment of aortic conditions, carotid disease, and the full gamut of occlusive arterial disease of the lower limb, for which he is internationally renowned.

It was also exciting to see complex CLI cases performed by some of the best CLI operators in the world, who were able to show us extreme, unique approaches to treat complex disease from the groin to the toes. Live cases this year were performed by Drs. Fadi Saab, D. Christopher Metzger, Constantino Peña, and Lawrence Garcia.

Alternative access has been discussed annually for many years at AMP. This year, we took another unique turn and witnessed a live case done by Dr. Fadi Saab from Advanced Cardiac and Vascular Amputation Prevention Centers in Grand Rapids, Michigan. He utilized the radial to peripheral (R2P) approach in his outpatient CLI center, which was an eye-opener for everyone in the audience. Dr. Saab was able to successfully treat very complex superficial femoral artery (SFA)/popliteal disease without having to access the common femoral artery (CFA). The patient was able to leave Dr. Saab's institution within 45 minutes post procedure. We have certainly come along way from the days where we use 7 to 8 French (Fr) up-and-over sheaths to treat SFA, popliteal, and tibial arteries, now utilizing a variable multitude of sheaths with a range of 3 to 5 Fr that essentially allow operators to deliver the majority of needed therapies. With the recent approval of the Slender sheath (Terumo), we are now able to use a 6 Fr sheath to perform therapy with devices that previously required a 7 Fr sheath. This kind of ingenuity gives me comfort that as time passes, we are going to see more and more effective CLI devices that provide alternative options to our suffering patients.

During the course of AMP this year, we experienced phenomenal discussions on imaging modalities of CLI patients with a broad spectrum of options, including noninvasive magnetic resonance imaging (MRI) and computed tomography (CT) scans, all the way to selective digital subtraction angiography (DSA). What is unique about the imaging modalities discussion at AMP is how it is received by the audience and the eye-opening surprise as we consider the discrepancy of approaches in the cascade of CLI therapy diagnostic imaging. AMP strives to continue fueling the discussion and call for additional data so that one day we will reach a consensus on a therapeutic approach for CLI patients.

We also saw some amazing breakthrough technologies presented at AMP this year, including the DEEPER trial, sponsored by Reflow Medical. For the first time in the history of CLI tibial therapy, we were able to see 6-month angiographic patency with no acute recoil or late lumen loss. Who would have thought that this could be possible? As we all know, as of 3 years ago, the data available at that time showed that even when we used the most advanced and aggressive therapies in CLI, acute recoil continued to be the Achilles' heel for much of what we treat. The DEEPER trial data brings light to the end of the tunnel and hope to our patients that there is something on the horizon that will give them a more prolonged perfusion pressure.

We also saw fascinating data presented from the LIBERTY 360° trial. Two-year outcomes demonstrated hope for Rutherford class 6 patients, who some guidelines deem as untreatable and recommend sending for primary amputation without any further evaluation or attempt at revascularization. This trial, with four core labs adjudicating, showed that many Rutherford class 6 CLI patients two years post-revascularization still have their limbs and also, most importantly, are alive and living independently. I have learned the biggest lesson that I can learn from this trial. We should never prejudge what can be done for CLI, despite any form of presentation. Every patient deserves a chance, which starts with a simple physical exam, followed with the necessary non-invasive evaluation, and invasive evaluation and treatment.

Dr. Thomas Davis from the St. John Hospital and Medical Center in St. Clair Shores, Michigan, discussed the FAST trial, sponsored by Cardioflow, a unique first-in-human trial performed in the United States. The trial is investigating a unique atherectomy device that is able to treat severely calcified arteries and severely fibrotic arteries at the same time. Industry is listening and responding to operator requests for innovative devices to treat the heterogeneous composition of disease of the CLI arterial tree.

A special thanks to our colleagues from Asia, who shared with us at AMP this year their unique approach to CLI, along with Professor Zeller and his thought-provoking session "How We Would Have Done It Differently", which allowed everyone in the audience and panel to be involved in the thought processes behind case selection, device

This year at AMP, I listened to faculty describing how each and every CLI patient was treated by different approaches, and despite different approaches, each patient did well. That tells me one thing and one thing only — the common denominator to improve outcomes for our CLI patients is simply to treat them!

Disclosure: Dr. J.A. Mustapha reports that he is a consultant for Abbott Vascular, Boston Scientific, CSI, and Terumo Interventional Systems.

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Fadi Saab, MD, onscreen during a live case, with panel members George Pliagas, MD, Bryan Fisher, Sr., MD, Laiq Raja, MD, and J.A. Mustapha, MD.

selection, and outcome predictions, based off of the friendly discussion that occurs during this advanced CLI session.

We learned from a few presentations at AMP this year that the disease state in the SFA and popliteal are completely different than the disease state in the tibial and pedal arteries. I can't help but believe what I saw — and then quickly think, wow, how can we treat this significant variation in the pathophysiology that changes from one segment to another? I see drug-coated balloons (DCB) and drug-eluting stents (DES) do a phenomenal job in the SFA and popliteal. Yet as we migrate toward the popliteal/tibial segments, we find that the therapeutic options suddenly become scarce and with low yield in terms of patency. However, we have learned to adapt and accommodate available therapies to heal wounds, and save limbs and lives.

Let's Continue the Fight Against CLI

This is where I would like to ask you to continue the revolution of CLI and never give up on those patients that need yet another procedure until the wound is completely healed. I don't believe we will ever see CLI as a disease that will be treated once and we can walk away from it — as can happen now with disease above the knee, where treatment with advanced DCB, stents, and/or surgery is successful, often with only one procedure. We can't say the same for the tibial-pedal arteries. I remain optimistic as we look ahead to the Micro Medical Solutions trial evaluating the MicroStent, led by Dr. Robert Beasley from Mount Sinai Medical Center in Miami, Florida, the pending results of the Lutonix BTK drug-coated balloon trial (Bard), and the recently initiated SAVAL trial of a self-expanding DES (Boston Scientific). I am enthusiastic to see there are multiple ongoing trials attempting to find a more durable therapy for CLI. In my opinion, a new, durable therapy allowing us to achieve longer patency by just 3-6 months will be a huge success. For those of us who see and treat CLI every day, we appreciate the simplest and smallest addition of time for the wound to heal. As we know, wound healing is associated with reinstating a human being to a functional and independent state.

As AMP continues to evolve, we have seen an avalanche of data that supports the outcome of what we do on a daily basis. I, for one, don't expect a one-treatment-fits-all approach, now or ever. This year at AMP, I listened to faculty describing how each and every CLI patient was treated by different approaches, and despite different approaches, each patient did well. That tells me one thing and one thing only — the common denominator to improve outcomes for our CLI patients is simply to treat them!

Reimbursement and Support Are Crucial

A simple and quick message to our governmental bodies:

I hope you can see that CLI is a disease that is killing more patients than many serious cancers. I see operators who spend hours and hours standing on their feet, wearing heavy lead, in radiation, away from their families, trying to save a limb and save a life. Instead of stepping up and asking, "What can we do to help you end this hostile terrain?", we see you putting obstacles in our way. Decreasing reimbursement deters institutions with physicians who are excellent at what they do from treating those patients who are dying from this disease. This leaves patients neglected and deprived, with outcomes that are most likely amputation and death. I urge you to aggressively study critical limb ischemia with us and understand what it takes to treat it. Be our partner in the fight against the epidemic of CLI, as you have done in the fight against many cancers.

> The revolution will continue on so many fronts, here in the U.S. and around the globe. CLI is here to stay, but so are we. Join the revolution. Join the CLI Global Society (www.cliglobalsociety.org) and become a #CLIFighter.

The CLI Global Society: On the Front Lines

A recent study by the CLI Global Society published in the Journal of the American Heart Association[1] showed that CLI patients, despite their presentation, had similar positive outcomes if they received any form of revascularization (surgery or endovascular) versus a significant, higher mortality for those who did not receive any therapy or went straight to primary amputation.

The CLI Global Society is working endlessly to raise awareness of CLI. The CLI Global Society board members understand, in depth, the seriousness of this deadly disease. Their primary focus is raising public, governmental, and healthcare provider awareness. A recent social media movement of CLI Global Society members, tweeting under #CLIFighters, is bringing further attention to this needed revolution. Their endless effort and work to spread awareness through social media and through their everyday practice has created a movement in the right direction. The revolution will continue on so many fronts, here in the U.S. and around the globe. CLI is here to stay, but so are we. Join the revolution. Join the CLI Global Society (www.cliglobalsociety.org) and become a #CLIFighter. ■

Reference

1. Mustapha JA, Katzen BT, Neville RF, Lookstein RA, Zeller T, Miller LE, Jaff MR. Determinants of long-term outcomes and costs in the management of critical limb ischemia: a population-based cohort study. J Am Heart Assoc. 2018 Aug; 7 (16): e009724. https://doi.org/10.1161/JAHA.118.009724