CIJGLOBAL THE OFFICIAL PUBLICATION OF THE CRITICAL LIMB ISCHEMIA GLOBAL SOCIETY

CLI Global Society Members Present at International Symposium on Endovascular Therapy 2020

he Critical Limb Ischemia (CLI) Global Society was established by passionate leaders in 2016 to address the unmet needs of CLI. The patient-centric society is led by an esteemed multi-disciplinary group of board members (interventional radiology, podiatry & wound care, vascular surgery, angiology and interventional cardiology). Membership has grown to over 600 physicians and healthcare providers globally from 40 countries who represent the full spectrum of multi-disciplinary providers who care for complex CLI patients.

The CLI Global Society held a fullday board retreat prior to the ISET meeting. During the meeting, Society President, Dr. Barry Katzen was pleased to announce the addition of Dr. Andrew Holden to the Board. Dr. Holden, from Auckland City Hospital, Auckland, New Zealand, will represent the Asia-Pacific region. The Board reviewed 2019 accomplishments and set goals for 2020.



Figure 1. CLI Global Society Board Members at the ISET Welcome Reception, Drs. Jihad Mustapha, Jos van den Berg, Vickie Driver, Barry Katzen and Richard Neville (left to right).

CRITICAL LIMB ISCHEMIA IS A THREAT TO LIFE AND LIMB

A recent publication on behalf of the CLI Global Society confirmed that CLI is an under-diagnosed and under-treated deadly disease that requires proper diagnostic imaging and increased awareness. Worldwide, 202 million adults have peripheral arterial disease (PAD) which has a higher prevalence that ischemic heart disease, heart failure, Alzheimer's disease/dementia, cancer, HIV/ AIDS and opioid addiction. Among 9 to 20 million adults with PAD in the United States, 11% suffer from CLI. This is widely believed to be an underestimation.

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From WWE to Double Amputee A Professional Wrestler's Fight He Couldn't Feel

Paul Michael, MD



Paul Michael, MD

"If you know the enemy and know yourself, you need not fear the result of a hundred battles. If you know yourself but not the enemy, for every victory gained you will also suffer a defeat. If you know neither the enemy nor yourself, you will succumb in every battle." -Sun Tzu, The Art of War

n the end, I lost both my legs, piece by piece, in six operations." Hearing this will likely create imagery of a brave soldier losing both legs on a bloody battlefield, but this particular story is nothing of the sort. These six tours were spent fighting a disease on a very different kind of battlefield, but also against a ruthless enemy. This disease is slowly picking apart our population piece by piece, openly taking credit for destruction, but rarely held accountable for its actions. To stop this preventable terror, we must educate ourselves and unite as a society against this enemy.

Under Section 802 of the USA PATRIOT Act (Pub. L. No. 107-52) the definition of terrorism was expanded to cover domestic in addition to international terrorism.⁽¹⁾ Although the definition was broadly established, two important types were left out: diabetes and obesity domestic terrorism. These two terrorist groups have organized into one



Paul Michael and James Harris at Harris's home in Mississippi.

Continued on page 8

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Epidemiology of Critical Limb Ischemia (CLI): Changing Patient Characteristics and the Impact of Sex and Race

Mary L. Yost President, The Sage Group



Mary L. Yost

HIGH PREVALENCE OF SERIOUS COMORBIDITIES

Hospitalized CLI patients have a high prevalence of hypertension (75%) and diabetes (57%). Other serious comorbidities include chronic kidney disease (38%), prior amputation (18%), and obesity (15%). Furthermore, these comorbidities have increased and represent an important cause of hospital admissions.¹

Non-CLI causes account for almost half of hospital admissions (46%). These

"More women initially present with CLI than men. This reflects the higher prevalence of asymptomatic disease, underdiagnosis, and lower intervention rates at less severe stages.¹⁵ In addition to presenting with more severe disease, women are older and may be less likely to undergo revascularization than men.¹⁵"

include diabetes, septicemia, procedure complications, cardiovascular events, hypertension complications, respiratory disorders, and kidney disease.¹

CHARACTERISTICS OF CRITICAL LIMB ISCHEMIA INPATIENTS-SICKER AND YOUNGER

During the decade of the 2000s significant changes occurred in the characteristics of CLI patients admitted to the hospital. These changes have implications for morbidity and mortality, as well as treatment patterns.

Critical limb ischemia patients have become sicker with a higher prevalence of severe comorbidities.^{1,2} Furthermore, the number of comorbidities increases with severity of CLI (Rutherford Category), especially diabetes, hypertension, congestive heart failure (CHF), chronic kidney disease (CKD), and anemia.²

CLI patients have become younger (age < 65). Currently, almost 40% of patients with severely ischemic limbs are under age 65.¹

Emergent admissions have grown and now represent 75% of the total.¹

Finally, there has been a shift to uninsured patients, as well as to those insured by Medicaid. Uninsured and Medicaid insurance currently accounts for 12% of

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Advanced Limb Salvage With Failed Infra-Popliteal Bypass Revascularization in a Patient With "No Options" and Planned Major Amputation

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Kumar Madassery, MD

ritical limb ischemia (CLI) is a devastating diagnosis due to the natural course of the disease, which typically coincides with several comorbidities that get exacerbated. The sad truth is that preventative management decades before the diagnosis could help to prevent the scores of associated deaths we witness yearly. However, what we are left with is the ongoing and challenging task of fighting vigorously to save limbs from major amputation, which if it occurs, leaves the patient with an over 50% mortality rate within 4 years. Long ago, surgical revascularization was the only option, if any, to improve perfusion to a patient's distal lower extremities, many times with restricted opportunities due to lack of autologous

The sad truth is that preventative management decades before the diagnosis could help to prevent the scores of associated deaths we witness yearly.

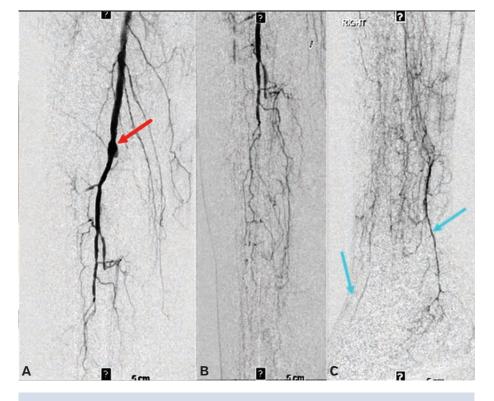


Figure 2. Infra-popliteal angiograms showing (A) proximal hood (red arrow) of the occluded right P3 to posterior tibial artery bypass with occluded anterior tibial, peroneal, and posterior tibial arteries; (B) extensive diminutive collateral network in the mid to distal leg; (C) subtle and diminutive reconstituted short segments of the distal posterior tibial and dorsalis pedis arteries (blue arrows) with no significant outflow in the mid and forefoot.

veins and lack of distal arterial targets. Over the years, increasingly innovative endovascular salvage approaches and techniques have been developed, which in many cases have prevented major amputation for patients at the "terminal arterial cancer" stages.

In this case, we describe a patient facing major amputation after prior surgical bypass and progressive transmetatarsal amputation (TMA) site wounds, with successful endovascular revascularization.

CASE HISTORY

A 67-year-old male with a past medical history of insulin-dependent diabetes, coronary artery disease with prior coronary artery bypass surgery, and peripheral vascular disease with prior right-sided popliteal to distal tibial bypass due to "acute severe lower extremity compromise" approximately 10–15 years prior to presenting to our center. The patient had developed dry gangrenous wounds of the great toe and second digit in the past. These wounds had been managed with wound care, medical management, and surgical debridement, eventually necessitating toe amputations and then TMA.

Continued on page 14



Figure 1. Right non-healing transmetatarsal amputation with areas of necrosis and areas of non-healing.



Figure 3. (A) Retrograde tibial access with micropuncture into the small posterior tibial artery. After successful traversal into the popliteal artery, (B) successful flossing of retrograde wire through the antegrade base angled catheter.



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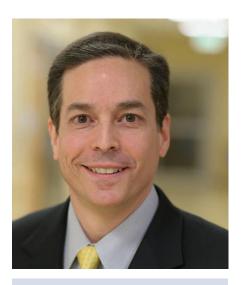




Hypertension and Hyperlipidemia Treatment in CLI Patients

Lawrence Garcia, MD, presented on hypertension and hyperlipidemia treatment in critical limb ischemia (CLI) patients at the 2019 AM-Putation Prevention Symposium in Chicago, Illinois.

Dr. Garcia is Chief of the Section of Interventional Cardiology and Vascular Medicine Programs, St. Elizabeth's Medical Center, at Tufts University School of Medicine in Boston, Massachusetts. His presentation covered hypertensive therapy for CLI patients, as well as the importance of managing CLI patients from a global perspective.



Lawrence Garcia, MD

When should hypertensive therapies be administered to CLI patients?

Hypertension is very critical to treat because it has so many secondary effects, including cerebrovascular, cardiovascular, and vascular effects. All those areas play a huge role in protecting and prolonging lives. However, in the past, many people have thought that lowering blood pressure in patients with CLI would reduce the pressure gradient to the limb and potentially put the limb at risk. In the consensus document in the recent guidelines, there is a stipulation that says there has been no data to suggest that lowering blood pressure puts the limb at risk for patients with CLI.

How do recent updates to blood pressure guidelines affect which patients qualify for treatment?

The guidelines have recently shifted to include more people in the range of hypertension. According to the recent guidelines, approximately half of the U.S. population is hypertensive. This shift has been challenging with regards to treatments, but treating to a more aggressive level allows us to protect a wider swath of the population and reduce the amount of progressive carotid disease, cardiovascular disease, and vascular disease in the current population. The shift in guidelines and more aggressive treatment benefits patients with significant peripheral arterial disease (PAD) in that we now tend to treat early and long term in patients

at most risk for progressive cardiovascular disease.

How do angiotensin-converting enzyme (ACE) inhibitors affect patients with CLI?

ACE inhibitors and angiotensin-receptor blockers (ARBs) have pleiotropic effects that are essentially the same pleiotropic effects seen in statin therapy. These drugs tend to lower the inflammatory state. We used to think that the pathway to atherosclerosis was simple, a result of oxidative stress that grew the plaque burden and ultimately created the stenosis. That pathway remains true, but one of the final common pathways to failure of an artery is through inflammatory markers and cytokines. Guidelines stipulate blood pressure, LDL, and comorbidities. Patients who have risk but no overt disease should be taking a statin, and anyone who is higher risk/has overt cardiovascular disease should already be on a statin. Thus, any patient with coronary disease, PAD, or carotid disease should already be on a high dose statin.

What is the role of revascularization in treating patients with CLI?

Although we have surrogate therapies such as aspirin and dual antiplatelet therapy, returning blood flow is absolutely necessary to maintain the limb. If blood flow is not returned to the limb, statins and ACE inhibitors will not salvage that limb. The risk of limb loss for patients with CLI is probably around 50% at 2

"Patient outcomes improve when we become global physicians and advocates for the patient in terms of surrogate issues such as hypertension, diabetes, statin control, and cholesterol control. Becoming a global physician is a great service to all our patients."

that ARB and ACE inhibitors are beneficial to our patients with atherosclerotic burden because these medications tend to reduce the inflammatory burden as statin medications also do.

What do the guidelines say about who should be treated with statins?

In the old days, we waited for people to have disease before commencing treatment, but then we realized that primary prevention in patients who are most at risk is a far better strategy. We can limit mortality in these patients and help them to be productive members of society for a longer time while treating with primary prevention. To get to this point as a field, we needed to improve our ability to identify high-risk patients. We developed calculators to assess risk based on a number of factors, including race, gender, to 3 years, even with significant revascularization. Patients with CLI need to be treated early, and in some cases often, with revascularization in order to avoid losing the limb. CLI remains a terrible disease.

Are there any areas in which patient care could be improved?

In many respects, we tend to take on the role of being only "the plumber" or the role of being a "technician" who opens up the artery. However, at the end of the day, we need to take ownership of the patient, which means that we need to not only be a plumber or a technician, but also take global care of the patient. We need to ensure that patients have appropriate follow-up, including podiatric care, wound care, and nutritional care. We need to follow patients from a global perspective and take into account all of their cardiovascular risks, as well as hypertension, diabetes, and statin therapy. It takes a village to care for CLI patients, and we in the village need to be in close communication with all stakeholders in their care.

How do medical management and revascularization align?

Medical management and revascularization should go hand in hand. Our role is not limited or exclusive to performing revascularization. We also need to review patient medications and fix medication issues. Sometimes, our role is to revascularize the patient and then transfer care back to the primary vascular specialist. In that scenario, a follow-up phone call with the primary vascular specialist is important. At other times, it may be appropriate for us to hand care back to the primary physician while at the same time proactively scheduling a follow-up appointment for the patient to ensure that everything is proceeding optimally post revascularization. Patients with CLI need a near continuous follow-up.

Any final thoughts?

If we revascularize without considering other aspects of patient care, patients are still going to lose a limb and, ultimately, potentially a life. Patient outcomes improve when we become global physicians and advocates for the patient in terms of surrogate issues such as hypertension, diabetes, statin control, and cholesterol control. Becoming a global physician is a great service to all our patients.

Disclosure: Dr. Garcia reports consulting for Abbott Vascular, Boston Scientific, and Medtronic; grant/research support for Abbott Vascular, Medtronic; being a major stock shareholder of CV Ingenuity, Essential Medical, Syntervention, Orchestra, and Transit Medical.

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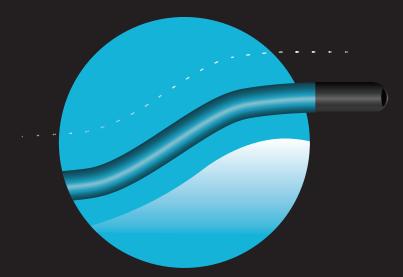
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Paul Michael and James Harris.

"I believe his true achievement derives from wanting to rise up and raise the awareness of a devastating disease by sharing his story to help others."

MICHAEL from cover

group, one we now refer to as diabesity. Not only is it a domestic threat, with 83% of men and 72% of women predicted to be overweight in the United States in the year 2020 (based on the National Health and Nutrition Examination Surveys from 1988 to 2008), but diabesity has become a global pandemic. According to the World Health Organization, the planet Earth has seen the number of people with diabetes rise from 108 million in 1980 to 422 million in 2014, and it is the seventh leading cause of death worldwide. These devastating numbers should certainly be grabbing more headlines as well as the attention of more government bodies, health-care professionals, health-care payers, and, most importantly, the global community. Unfortunately, these astronomical numbers are largely ignored. Aided by the continued transition away from the traditional human lifestyle as well as corporate welfare, subsidies, and heavy government support of the sugar industry, the sedentary sugar-fueled insulin-resistant diabesity lifestyle eventually takes control of almost every physiologic and anatomic operating system of the body like a slow-moving cancer.

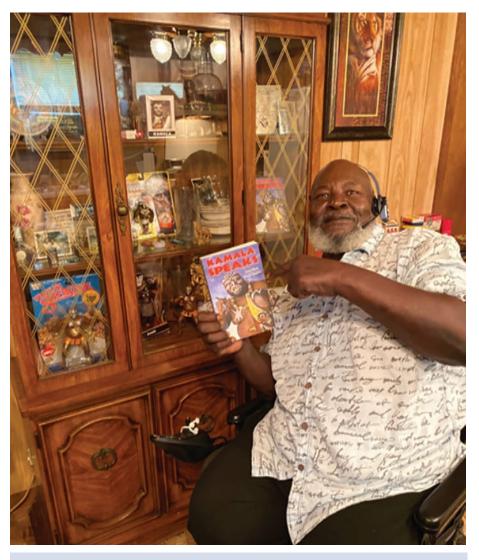
Despite improvements in modern medicine, rates of diabetes-related non-traumatic lower-extremity amputations are on the rise in the young and middle-aged population.^{3,4} The end result is a less

functional, lower quality of life leading to a slow death and usually succumbing to one or more of the many chronic diseases affecting the microvasculature. These effects start to emerge as early as the teenage years, with type 2 diabetes in youth having a higher risk of complication than youth with type 1 diabetes.⁵ With millions affected and few brave enough to speak up, I share with you an incredible story and journey of a man who, piece by piece, went from being a celebrity in sold-out stadiums to losing his professional career along with his body parts, and even his freedom, to this insidious terror.

"What you can't feel can hurt you." — Andrew J.M. Boulton, MD

THE STRUGGLE IS REAL

This is a story of a male African American professional wrestler, though his story is representative of any person, unrelated to sex, age, race, or occupation. Through his vulnerability, we will all share in the possibility that we may also have to fight this disease. If you saw our hero now, sitting in his electric scooter inside his modest home in Senatobia, Mississippi, sidelined by diabetic gangrene and bilateral above knee amputations, you would not envision that his history was that of a professional wrestler who fought against the likes of Hulk Hogan, Andre the Giant, Ultimate Warrior, or the Undertaker in front of 80,000 screaming



James Harris displays his WWE program..

fans at Wembley Stadium in London.

Whether or not you are a wrestling fan, you can appreciate the magnitude of performing in front of a very large crowd in the same stadium where only months earlier the Freddie Mercury Tribute Concert drew an audience of 72,000. In case you were wondering, the Intercontinental Championship Match that year was won by the hometown hero, the British Bulldog, with Lennox Lewis, heavyweight boxing champ of the world, in his corner to beat his brotherin-law, Bret Hart. I grew up entertained by professional wrestling, and now I am sitting with this larger-than-life character at his dining table in a small town in Mississippi. Although he is deserving of the WWE Hall of Fame, I believe his true achievement derives from wanting to rise up and raise the awareness of a devastating disease by sharing his story to help others. This is a story about a preventable terror of a disease called diabetes leading to end-stage peripheral arterial disease (PAD). This disease is distinguished by blockages in the leg arteries, ultimately causing non-healing foot ulcers which lead to amputation. This killer of a disease is better known as critical limb ischemia (CLI), and those dedicated to eradicating it are known as amputation prevention specialists.

"I got 99 Complications, and Amputation is One." – Diabetes

To physicians, nurses, wound care providers, and all those involved in the treatment of patients with chronic complications of diabetes, this story sounds all too familiar. This leads us to the reason why James "Kamala" Harris graciously agreed to do this interview — because "it doesn't have to be like this!" James Harris arrived at the simple conclusion which thousands of years of diabetes research agrees with; that, if well controlled, not ignored, and proactively managed; diabetes could be contained as a threat rather than an attack on his limbs and life. Prior to having his first amputation, Kamala had to go on hemodialysis for kidney failure. He explained, in a soft, now slowed-down. and more distant tone, how he would begin noticing that his friends at the dialysis center developed leg ulcers which would become infected. They would begin to randomly miss sessions until they wouldn't show up again at all. When James would ask about them he would be simply informed that they had passed. Watching this happen over and over again made him realize that there was a predictable slow pattern to what he was observing. Whether through a stealth or "shock-and-awe" attack, diabetes follows the same battle plan over and over again, regardless of its victim, launching a motor, sensory, and autonomic neuropathy attack. This causes its victims to slowly develop foot deformities in feet they can't



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Focus on Technique Tibiopedal Crossing Tips: Remodified Schmidt Technique

Timothy E. Yates, MD and Warren Swee, MD, MPH CLI Vascular Specialists & Palm Vascular Centers of Florida, Miami Beach, Florida



Timothy E. Yates, MD

ATEN SITE ME MEN

Warren Swee, MD, MPH



Figure 1. Left heel ulcer.

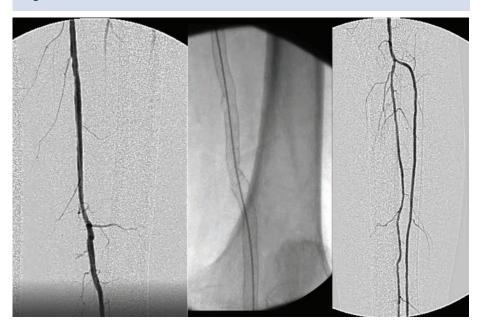


Figure 2. Left SFA stent fractures and in-stent stenosis. SFA = superficial femoral artery.

ndrej Schmidt of the Leipzig group has been credited with forwarding novel techniques for peripheral artery recanalization.1 One such technique employs his name, which involves direct access of a vessel or stent occlusion (Schmidt vs modified Schmidt technique). This approach has increased technical success for crossing superficial femoral artery (SFA) chronic total occlusions, particularly those for stent occlusions. Other operators, such as Walker, Montero-Baker, Mustapha, and Saab, have published their experience²⁻⁴ for tibial access including puncture of occluded tibial arteries, demonstrating both safety and efficacy. In this short technical article, we present this same technique in accessing tibiopedal vessels to increase technical success in pedal plantar loop reconstruction (directability, pushability, and torqueability). Both patient cases involve a combination of ultrasound and fluoroscopic-guided retrograde access (one of the distal plantar (DP) and another of the common plantar arteries), after crossing through the pedal-plantar loop with a 0.014" wire. This approach was chosen because the more proximal

tibial vessels were also occluded and retrograde pushability through the pedalplantar loop was complicated both by the length of passage and opposing force vectors. Both patients had flush occlusions of the affected tibial arteries, such that antegrade recanalization was essentially impossible. Below we present short vignettes and technical tips to maximize lesion crossing for limb preservation.

CASE #1:

A 78-year-old female patient presented to our office with diabetes mellitus type I, coronary stents for prior acute myocardial infarction, chronic kidney injury, deep vein thrombosis on anticoagulation, and bilateral SFA stenting for claudication. She presented with a stage 4 left heel ulcer (Figure 1) and ischemic rest pain, Rutherford class VI. Due to her relative frailty, the family wanted to pursue an endovascular approach over open surgery. Additionally, she had severe venous insufficiency making her saphenous veins poor conduits for distal bypass. Duplex demonstrated a right common femoral artery occlusion, left SFA in-stent stenosis, and tibial disease bilaterally.

Angiography was recommended.



Figure 3. Pedal-plantar loop crossing, angioplasty of the same, retrograde CPA puncture, and traversal. CPA = **[Auth: please define]**

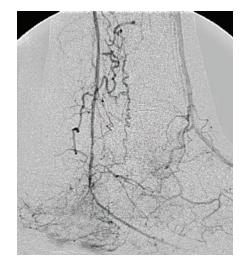




Figure 4. Completion lateral foot angiogram with calcaneal wound blush.



Figure 6. Right AT perforation after failed antegrade crossing.



Figure 7. Right pedal plantar loop crossing and retrograde DP access.

Antegrade left common femoral access was achieved with leg prep. Initial runoff demonstrated left SFA stent fractures and TASC II type D posterior tibial occlusion (Figure 2), with diminutive plantar arteries in the foot.

The AT and DP were crossed into the pedal plantar loop and lateral plantar artery, in which angioplasty was performed. The 0.014" wire crossed into the common plantar and distal posterior tibial, but further pushability was complicated by the tortuosity and angulation of the loop.

The common plantar artery was punctured retrograde (Figure 3). A 0.018" wire was advanced retrograde, and the PT was crossed, treated with orbital atherectomy and angioplasty. The pedal-plantar loop was reconstructed in this fashion (Figure 4) and improved wound blush was achieved.

CASE #2:

A 56-year-old female with diabetes, hypertension, and coronary artery disease presented to our office with right 4th and 5th toe gangrene. She had two recent interventions at a hospital including angioplasty of right SFA in-stent stenosis and recanalization of short common plantar occlusion. Despite this, gangrene had progressed to other toes and now the forefoot (Figure 5). She was told by her vascular specialist that nothing further could be done and presented to our facility for second opinion.

Initial angiogram demonstrated patent femoropopliteal segments, with a TASC II type D AT occlusion, diffusely diseased peroneal, and single vessel outflow via the posterior tibial. The proximal AT occlusion was crossed, but resulted in perforation (Figure 6).

The pedal plantar loop was then crossed via the posterior tibial and retrograde into the DP (Figure 7), but like the last case, crossing the TASC II type D occlusion was complicated by length and tortuosity of the loop. A combination of ultrasound and fluoroscopy were used to puncture the DP occlusion retrograde, on top of the wire. Then a 0.018" wire was used to cross the AT, which was then treated with atherectomy and angioplasty. She subsequently underwent a high forefoot amputation that completely healed after 2.5 months of wound care (Figure 8).

BRIEF TECHNICAL COMMENTARY:

Densely calcified and fibrotic occlusions can be challenging to cross, particularly in the feet of diabetics and renal failure patients. Using a guidewire within an occlusion can serve as a useful target for retrograde puncture of tibiopedal pedal arteries for limb preservation efforts. We call this the remodified Schmidt technique, and it can easily be combined with ultrasound as well for real-time imaging and crossing.

Disclosures: None.

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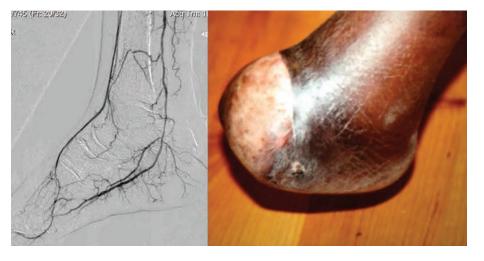


Figure 7. Completion angiogram with intact pedal-plantar loop and complete healing of high forefoot amputation.

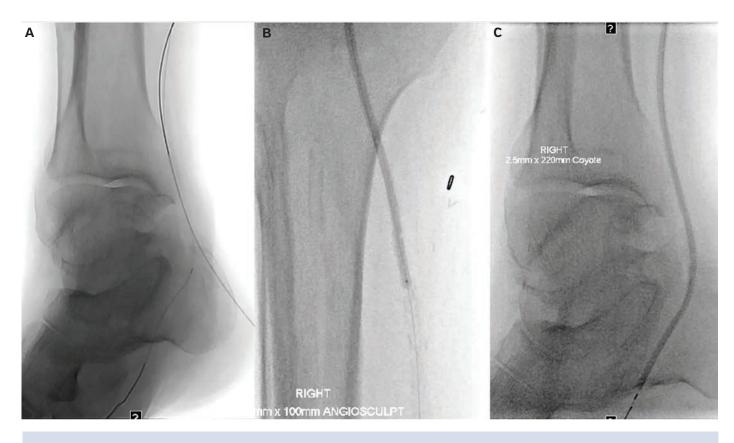


Figure 4. (A) Reversal of the retrograde flossed wire into the distal lateral plantar artery to have a single antegrade wire. (B & C) Serial angioplasty of the entire posterior tibial artery.



Figure 5. (A) Reversal of the retrograde flossed wire into the distal lateral plantar artery to have a single antegrade wire. (B & C) Serial angioplasty of the entire posterior tibial artery.

Over the years, increasingly innovative endovascular salvage approaches and techniques have been developed, which in many cases have prevented major amputation for patients at the "terminal arterial cancer" stages. The patient has been evaluated several times by vascular specialists (surgical and interventional), with the consensus that even after performing angiograms, there were no endovascular or surgical revascularization options, and a major amputation was recommended and planned. The patient was sent to my clinic by his podiatrist, who had known from our prior discussions that advanced peripheral vascular disease and CLI cases do deserve multiple opinions.

The patient and family reported that he was experiencing constant rest pain at the plantar side of the foot and towards the wound, without fever or other symptomatology. His diabetes was being well managed, now with an A1c of 6.2 and glucose levels consistently in the normal range. The TMA wound showed eschar with non-healing areas despite optimal wound care. He had palpable femoral and popliteal arteries. No palpable dorsalis pedis (DP) or posterior tibial (PT) pulses were present, however, barely audible tones were noted. Noninvasive testing showed monophasic waveforms of the PT and DP, and we were unable to discern an ankle brachial index. After discussion with the patient and family, the decision was made to attempt revascularization.

TECHNIQUE

The patient was brought to the interventional radiology (IR) suite and placed under general anesthesia due to his baseline pain intolerance and inability to remain still. Ultrasound-guided access was obtained in the right common femoral artery in the antegrade direction (after review of prior outside hospital angiogram showing no inflow issues). Our initial angiogram showed a patent superficial femoral artery, profunda, and popliteal arteries. The proximal hood of a popliteal origin to distal posterior tibial artery (PT) bypass was noted with no flow. The anterior tibial artery (AT) and peroneal artery were chronically occluded after their origins. The majority of the lower leg was being supplied by a collateralized network, with subtle reconstitution of the most distal aspect of the PT and occlusion of the plantar arteries beyond their origin. A very faint short 2–3 cm segment of the DP artery was noted on delayed imaging.

A braided sheath was advanced into the distal superficial femoral artery. After a failed brief attempt at antegrade PT recanalization, retrograde pedal access was obtained by accessing the distal PT just above the calcaneus under ultrasound guidance. Using a 0.014" guidewire and support catheter, I successfully recanalized the occluded bypass graft and obtained flossing access through the right groin sheath. Sequential balloon angioplasty was performed with long tapered 0.014" balloons as well as scoring balloons. The retrograde wire was reversed, and the lateral plantar artery was successfully recanalized, followed by serial balloon angioplasty. I don't typically use retrograde sheaths in my practice, so I obtained pedal access hemostasis during this angioplasty. The completion angiogram showed widely patent flow through the popliteal to PT bypass and through the plantar arteries.

In order to maximize direct perfusion, a decision was made to revascularize the AT as well. Retrograde access with ultrasound guidance into the DP was obtained. A 0.018" guidewire and support catheter were advanced through the occluded AT. This resulted in a mostly subintimal course in the mid and proximal segments. Advanced techniques to regain luminal entry were attempted, including antegrade balloon assisted subintimal disruption (CART), which ultimately allowed retrograde passage into the popliteal artery true lumen. This was snared and flossed out of the right groin sheath.

In order to protect the luminal integrity of both origins, simultaneous kissing balloon angioplasty was performed of the AT and PT. During intermittent angiograms, it was noted the bypassed PT would not stay patent, despite adequate heparinization, angioplasty, and evaluation by intravascular ultrasound. There did, however, appear to be an area of irregularity and recalcitrant stenosis at the distal bypass anastomotic region. Therefore, a 3 mm coronary drug-eluting stent was deployed across this area. The completion angiogram demonstrated patent two-vessel runoff with direct TMA wound hyperemia. A repeat angiogram was performed after 15 minutes to ensure on-the-table patency.

The patient was discharged home 3 hours later with follow-up scheduled in the IR clinic as well as with his podiatrist. After 3 weeks, during IR follow-up, the



Figure 6. (A) Retrograde access into the small dorsalis pedis artery. (B) Failed subintimal course of antegrade and retrograde recanalization attempts (red arrow). (C) Successful luminal re-entry of the retrograde wire into the popliteal artery after balloon-assisted subintimal disruption (not shown).



Figure 7. (A–C) Completion angiogram after serial angioplasty shows intact two vessel runoff by the anterior and posterior tibial arteries with intact plantar and dorsalis pedis as well as direct wound angiographic blush.

In this case, we describe a patient facing major amputation after prior surgical bypass and progressive transmetatarsal amputation site wounds, with successful endovascular revascularization. patient reported resolution of rest pain, and consensus with the podiatrist confirmed evidence of healing with granulation formation. A noninvasive study showed triphasic PT and biphasic DP waveforms. Our patient will be continually monitored during the months ahead, and close consultation with the podiatrist will be continued.

DISCUSSION

CLI intervention for limb salvage requires many advanced and innovative techniques. Anecdotal experience has shown that failed chronically occluded bypasses can at times be revascularized, and this should be attempted if there are limited options left. This case demonstrates one such example. Also, for limb salvage, as many vessels as possible need to be revascularized to provide the best chances for wound healing. However, repeat interventions may be required at times to counteract the unacceptably high mortality rate that is too common in these patients.

The general awareness of the progressive and devastating nature of CLI is slowly but luckily growing, thanks to the efforts of many operators, societies (including CLI Global), and patient testimonials. However, we are far from achieving an acceptable level of uniform high-level care delivered to patients with limbthreatening wounds and disease. Until that time, it is imperative that CLI be treated as "terminal arterial cancer" and patients be referred for, and approved for, second and third opinions to high-level centers and operators, similar to multidisciplinary cancer centers. We need centers of excellence in CLI so that all patients have access to the best chances of survival.

Disclosure: Speakers bureau for: Cook, Abbott, Penumbra. Consultant for Cardiva. Advisory board for: Philips, Boston Scientific.

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ISET from cover

PROPENSITY SCORE-ADJUSTED COMPARISON OF LONG-TERM OUTCOMES AMONG REVASCULARIZATION STRATEGIES

A recent study by the Society published in the September 2019 issue of Circulation: Cardiovascular Interventions found that among Medicare beneficiaries with CLI who received percutaneous transluminal angioplasty (PTA), stent placement, atherectomy or surgical bypass, minor differences in mortality (ranging from 49.3% to 54.7%) and major amputation (ranging from 6.8% to 10.8%) rates were observed among treatment groups over 4 years. A diagnosis of CLI portends a grave prognosis that is more fatal than most cancers. Few studies have reported long-term comparative outcomes among specific revascularization techniques for CLI patients.

CLI GLOBAL SOCIETY COALITION SUBMITS ICD-10 PROPOSAL FOR 2021 UPDATE

As part of its mission to raise awareness and better define CLI disease, the CLI Global Society is leading a multi-specialty medical society task force (SCAI, SVM, SVS and SIR) to differentiate CLI disease from peripheral arterial diseases in the medical coding and billing nomenclature, beginning with ICD-10 CM Diagnosis codes. The goal is to support the myriad of coding professionals, educators, compliance staff and physicians in identifying and defining CLI. This is necessary in order to properly track and monitor patient treatments and outcomes in the future. The proposal was presented to the CDC ACD-10 CM Coordination and Management Committee for addition to the 2021 update on October 1, 2019. This effort is a first step in building awareness among public and commercial payers of the complexity associated with caring for patients who experience critical limb ischemia. A notification regarding the decision on the final codes in the "Official Addendum" to the FY 2021 Inpatient Payment Rule is expected in June 2020. The task force met during the retreat and, in anticipation of approval, will be working toward an awareness and education campaign directed toward primary care and specialty care coders to prepare them for anticipated changes.

CLI GLOBAL SOCIETY CO-SPONSOR WELCOME RECEPTION AT ISET

The CLI Global Society partnered with the ISET meeting to co-sponsor the opening Welcome Reception on Wednesday, January 22, 2020. The reception allowed attendees to mingle with the CLI Global Society board members and current members. The high volume of traffic at the Society membership table, along with the large number of new members registered, was a



Figure 2. CLI Global Society Members interact with the Board at the ISET Welcome Reception, Drs. Vickie Driver, Jihad Mustapha, Jos van den Berg, Barry Katzen, D. Chris Metzger, Richard Neville, Constanino Peña and Paul Michael (left to right).

strong signal of the growing interest in caring for patients with CLI (Figures 1 and 2). In speaking with a group of attendees who were asking about the CLI Global Society and its goals in attending a meeting like ISET, Dr. Mustapha said, "We are raising awareness and working with other societies to be a beacon of awareness as one society for CLI, all societies against amputation!"

ISET CLI TRACK CO-DEVELOPED IN PARTNERSHIP WITH CLI GLOBAL SOCIETY

The CLI Global Society, in partnership with the ISET course directors, developed a daily CLI Track again this year. Attendance at the track was high, again demonstrating the growing interest in CLI disease and therapy. Board members, Drs. Barry Katzen (Figure 3) and Richard Neville moderated the first CLI session. Dr. Katzen shared that the CLI Global Society is the only organization that is solely dedicated to patients. He spoke about the impact of CLI on the US population and shared findings of the CLI Global Society studies.

The CLI sessions highlighted that CLI and PAD are different diseases with different therapy and management requirements. Claudicants require a different approach than patients who are facing limb loss. With amputation rates increasing, more energy and dedication is required to train those interested in fighting the disease. This means an awareness of the complexities inherent in treating this patient group needs to be emphasized. For example, novel therapies, such as advanced imaging using fiber optic technology, presented by Dr. Katzen, will also increase the need for more adjunctive imaging modalities, since most CLI patients also will have renal disease. This concept was also highlighted by Dr. Paul Michael who presented cases using zero contrast and the need to standardize this protocol for all CLI cases.



Figure 3. Drs. Barry Katzen (right) and Jihad Mustapha (left) engaged in discussion during CLI case presentation at ISET 2020.

"Claudicants require a different approach than patients facing limb loss. With amputation rates increasing, more energy and dedication is required to train those interested in fighting the disease."

Board Member Dr. Vickie Driver, DPM, chair of the CLI Global Society Wound Committee, shared the common reasons for limb loss which included: vascular compromise, symptoms treated but underlying problems not addressed, prober antibiotic regimens not prescribed, failure to properly debride infected ulcers, and no or poor wound care. She shared case-based examples for alternatives to major amputations. She stressed that many providers, patients, and their families have little or no understanding regarding the CLI disease process and how patient and family education plays a crucial role in recovery.

Of the physicians attending ISET, 61% reported that they perform endovascular procedures in an outpatient setting. Founding Board Member Dr. Jihad Mustapha shared his experience developing an outpatient endovascular CLI center. With the support of experienced and well-trained staff who work on CLI cases almost exclusively, he performs the bulk of his CLI work in the outpatient setting, with the exclusion of aorto-iliac CTOs and patients hospitalized due to other comorbidities. Over the past two years, over 1,000 CLI cases have been performed, including long CTOs, AV reversal, pedal loop reconstruction,



Figure 4. Dr. Jihad Mustapha performing a CLI live case from the Cardiac and Vascular Centers for Amputation Prevention in Grand Rapids, MI. Panelists Drs. Robert Lookstein, John Rundback, Fadi Saab, D. Chris Metzger, William Gray (Moderator), Bret Wiechmann, Richard Neville, George Adams and Joseph Lombardi (left to right).

 "Overall," says faculty member, Paul Michael,
"there was something for everyone and
everything for someone interested in CLI." '

TAMI technique, Schmidt procedures



Figure 5. #CLIFighters and Board Members, Drs. Richard Neville (left) and Michael Jaff (right) showing their support in the fight against CLI!

and clinical trial cases. Dr. Mustapha performed 2 live CLI cases at ISET; one was the first ISET live case performed from a self-standing outpatient facility, Advanced Cardiac and Vascular Centers for Amputation Prevention in Grand Rapids, Michigan (Figure 4). This interesting case was a subject in the DES BTK Vascular Stent System vs PTA in Subjects with Critical Limb Ischemia (SAVAL) Trial who was randomized to DES stent treatment.

Board Member, Dr. Jos van den Berg, from Lugano, Switzerland, gave an overview of CLI in Europe. He focused on the significant global variation in the incidence of lower extremity amputation. A significant reduction in the incidence of lower extremity amputations has been shown in specific at-risk populations after the introduction of specialized diabetic foot clinics. Countries that have implemented specialized diabetic podiatry services have seen a significant drop in the rate of diabetes-related major amputations, despite a rise in the prevalence of diabetes. Richard Neville (Figure 5), CLI Global

Society Board member and System Chief of Vascular Services at Inova Health System in Falls Church, Virginia, spoke on the importance of an integrated approach to the CLI patient. With over 7 million chronic wounds treated annually. health care costs of \$20 billion, an explosion of diabetes mellitus (350 million worldwide) and poor outcomes following amputation, CLI should be recognized as a growing concern worldwide. Few disease processes lead to a higher mortality rate. It is repeatedly validated that multidisciplinary limb programs reduce amputation, as shown by studies by Drs. Driver (USA), Larsson (Sweden), Krishnan (UK), and Anichini (Italy). There is evidence for the value of a limb program, especially in patients with diabetes. Dr. Neville shared thoughts on the structure of a limb preservation/ CLI program. He encouraged physicians to bring their specialty to the table and champion such programs at their institutions. He also encouraged consideration of arteriography prior to amputation, as it is shown to be underused and is still important. He encouraged all attendees to watch for a study soon to be published by the CLI Global Society that addresses this issue.

Chair of the CLI Global Society's Membership and Social Media Committee, Dr. Fadi A. Saab, educated the audience on when it is appropriate to start recanalization from a retrograde approach. He gave a case-based and data-driven talk on the tibiopedal arterial minimally invasive retrograde revascularization (TAMI) procedure. "The TAMI approach increases technical success, time savings, and increases in safety. Tibial access is no longer deemed alternative access by those who perform high volume CLI cases and is gaining potential as the standard of care as experience is gained among operators."

CLI Global Society Board Member, Dr. Robert Lookstein discussed the feasibility of long everolimus-eluting stents in infrapopliteal vessels following failed angioplasty. He described in "a real-world cohort with mean lesion length >10 cm, excellent freedom from clinically driven target lesion revascularization was maintained for Rutherford 4 and 5 patients at 83% at 12 months." He noted that proximal edge lesions appear to be a frequent location of failure, so proximal and ostial disease may be best suited for this technology. Of interest to him was that Rutherford 4 and 5 patients maintain the greatest clinical benefit.

Dr. Paul Michael sits on both the CLI Global Society's Wound and Membership & Social Media Committees. He gave an innovative talk on wires used in CLI cases. He has adopted a mnemonic approach to teaching his approach, ABCD (Access, Backup, Crossing, and Delivery). He gave a case-based demonstration on wire selection and function.

Mary Yost, CLI Global Society member and healthcare economist showed her data on amputation and mortality increasing with disease severity. Major amputations increase CLI costs. She discussed how earlier diagnosis, treatment, and reducing amputations could reduce costs.

Dr. William Gray, System Chief of Cardiovascular Services and President of Lankenau Heart Institute in Wynnewood, PA, gave a powerful, critical approach of the Katsanos et al meta-analysis on paclitaxel BTK published in the Journal of Vascular Interventional Radiology. This meta-analysis reported a significant increase in all-cause death and major amputation that was associated with paclitaxel-coated balloons for the treatment of CLI below the knee. It also showed an association with a significant reduction in target lesion revascularization. The study showed no finding of paclitaxel effect on death or major amputation at 6-12

months. It did show a finding of paclitaxel effect on amputation-free survival at 6-12 months. Dr. Gray demonstrated how numbers available were inadequate to construct a study-level meta-analysis with significant risk of Type I error (false positive). The analysis included studies with non-standard follow-up, mixing 6-month to 1 year. He went on to describe the significant inclusion of nonpeer reviewed data (approximately 25%) and how the math was wrong in the IN.PACT Deep analysis. The patients lost to follow-up and withdrawals were not completely and accurately accounted for. Additionally, the dose analysis was highly flawed in his opinion. 'No lesion length, number of balloons used, or adjustment for selection bias or cross-trial differences exist. This is inconsistent with prior methodology." The purported effect was noted at 2 and 5 years, but not at 1 year. "This bring the entire mechanistic explanation, which was already a tortured one, into even further question." Additionally, he noted the PTA group is likely not paclitaxel naïve for the entire analysis. Paclitaxel device approvals in Europe and the US preceded all of the trial data. In summary, he stated, "this 'analysis' is very poorly constructed and conducted, and therefore should have no meaningful impact on this high-risk, in-need CLI population, especially given the marked improvement documented in the same manuscript in patency."

Most importantly, a multidisciplinary approach to CLI therapy was presented in the CLI sessions, with non-biased presentations of the latest and greatest on advanced therapies from distal tibial bypass, hybrid AV reversal, zero contrast, BTK drug-coated scaffolds and beyond. "Overall," says faculty member, Paul Michael, "there was something for everyone and everything for someone interested in CLI."

YOST from page 3

CLI admissions.¹ Since uninsured and Medicaid patients are more likely to present with severe ischemia (CLI rather than IC), this shift has implications for disease severity.³ Medicaid patients are more likely to present with gangrene than private pay patients.^{4,5}

Treatments and outcomes also differ for CLI patients with Medicaid insurance.6 Specifically, Medicaid patients are less likely to undergo a diagnostic angiogram, and they have the highest risk of undergoing primary major amputation (MA).^{7–9} Even after revascularization, Medicaid patients have a higher risk of subsequent MA.³

MEDICARE CRITICAL LIMB ISCHEMIA PATIENTS-LOW SURVIVAL

A recent study found that at 1 year 29% of Medicare CLI patients were either dead or had undergone major amputation. Of those who underwent amputation, over half (51%) had no prior revascularization. Survival was quite poor when compared with age- and sexmatched controls. Median survival for CLI patients was only 3.5 years versus 13.4 years for controls.¹⁰

HALF OF CRITICAL LIMB ISCH-EMIA PATIENTS ARE WOMEN

Approximately 1.7 million of the 3.4 million with CLI are women.¹¹ U.S. data indicates that women represent 50%–54% of those with CLI.^{12,13} A Swedish study found that CLI was even more prevalent in women than men, or 1.9X more common.¹⁴

More women initially present with CLI than men. This reflects the higher prevalence of asymptomatic disease, underdiagnosis, and lower intervention rates at less severe stages.¹⁵ In addition to presenting with more severe disease, women are older and may be less likely to undergo revascularization than men.¹⁵ Although older studies found women had lower rates of revascularization, some of the more recent data suggests that revascularization rates are similar.¹⁵

Emergent admissions are more likely for women with CLI than men.¹⁶ Since emergent admissions are independently associated with greater probability of death and amputation, this has implications for in-hospital outcomes and may explain higher female mortality.⁶

Women have a different lesion distribution and disease morphology with a higher risk for multilevel disease (4X), femoral popliteal disease (2.5X), and chronic total occlusions (3X).¹⁷ Consequently, women are more likely to undergo femoropopliteal procedures and procedures for multilevel disease.¹⁸

Above-the-knee amputation (AKA) occurs more frequently in women.¹⁹ Unfortunately, female gender significantly increases the risk for AKA.²⁰

Female sex is associated with in-hospital

mortality.¹ After revascularization or amputation, mortality is higher in women. Even after adjustment for age and comorbidities, increased female mortality is associated with all procedures and in all disease severities.²¹

CRITICAL LIMB ISCHEMIA MORE PREVALENT IN BLACKS

CLI is more prevalent in blacks, and initial disease presentation is more severe. Approximately 18%–20% of CLI inpatients are black.^{10,22,23} In contrast, only 11% of the U.S. population ages 45 and older is black.²⁴

In Medicare patients, African Americans have a higher risk for CLI, or 2.3X the risk adjusted for age, gender, and diabetes.¹³ Black patients also present with more severe disease, gangrene rather than ulcers and rest pain.^{10,25}

A recent analysis of Nationwide Inpatient Sample (NIS) data showed that comorbidities and sex differ by race.²⁵ A higher percentage of black CLI patients were female, or 53% versus 43% of whites.²⁵ Diabetes and CKD were more prevalent in black CLI patients than in whites. Diabetes was present in 51% of black patients versus 43% of whites, while CKD was found in 10% of blacks versus younger patients an increase in the number of interventional procedures required over the patient's lifetime.

Women and blacks with CLI represent two significant patient groups. Both are underserved in terms of CLI education, awareness, and timely diagnosis, as well as treatment with revascularization rather than amputation. Both women and blacks have different lesion distributions. The morphology of CLI in women is different. The above suggests the potential for educational and interventional strategies and technologies targeted to these specific groups. In addition, earlier diagnosis of disease in women and blacks is needed, which could reduce morbidity and mortality.

Contemporary Medicare data continues to demonstrate that CLI patients have very low survival rates, as well as worse survival than controls. Since cardiovascular disease is the main cause of death, mortality could be reduced through improved management of cardiovascular risk factors. As discussed in "Epidemiology of Critical Limb Ischemia (CLI): Prevalence and Comorbidities," which was published in the December 2019 issue of CLI Global, risk factor management is suboptimal even when compared with patients with intermittent claudication.^{28–30}

"CLI is more prevalent in blacks, and initial disease presentation is more severe. Approximately 18%–20% of CLI in patients are black.^{10,22,23} In contrast, only 11% of the U.S. population ages 45 and older is black.²⁴"

6% of whites. In contrast, coronary heart disease (CHD) and chronic obstructive pulmonary disease (COPD) was more common in white patients.²⁵

Although the prevalence of multilevel disease is similar in blacks and whites, disease distribution is different with more infrapopliteal disease in blacks. For example, in one study 48% of blacks underwent infrapopliteal revascularization compared with 28% of whites.²⁶

White patients are more likely to undergo an attempt at limb salvage with revascularization, while nonwhite patients are more likely to undergo amputations.^{1,13,25} African American race is an independent predictor of amputation.²⁵ The multivariate adjusted risk for MA is 1X–4X in blacks.^{13,27} Furthermore, blacks have a longer time to first revascularization and a shorter time to first MA.¹³

CONCLUSION

The trend to CLI patients becoming sicker, younger, presenting emergently, and being uninsured or insured by Medicaid has implications for morbidity and mortality. It also suggests more complex procedures and in the case of Mary Yost can be reached the Sage Group, Email: yost@thesagegroup.us

Disclosure

Stock Ownership: Abbott, AbbVie, Angiodynamics, Portola Pharmaceuticals 2018 Clients: LimFlow, Bard, CSI, Cagent, Cordis, Pulse Therapeutics (now Euphrates Vascular), Sanofi, Centers for Vein Restoration, Hancock Jaffe, Pluristem

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CLI Society New Ad coming



Figure 4. A tall, lean, athletic James Harris began wrestling under the name "Sugar Bear."

MICHAEL from page xx

feel, which become dry and cracked after losing the ability to sweat properly, leading to callus formation. This repetitive cycle of trauma makes one prone to ulcer formation which can become infected. If one has a lack of blood flow to the area, the risk of losing the limb is always present. He felt that being taken apart limb by limb, piece by piece, like one of the WWE wrestling action figures he showed me in his home, until you "didn't show up for dialysis anymore," could have been prevented. Although mostly housebound now without access to a handicap vehicle, and still with some serious upper body size on him, Kamala remains the gentle giant he was behind his character's painted mask. He was such a nice person throughout his career that the mask and his character's lack of speech were necessary to facilitate the Kamala act. Otherwise, "Sugar Bear" was too nice a guy to be an entertaining wrestler and convince you he could be a savage beast. All his life he had to overcome obstacles and adversity, from growing up on a sharecropping farm in Mississippi during the civil rights movement to being one of the first black profesional wrestlers to tour in wrestling. If, by telling his story, he can help prevent unnecessary amputations, then he feels he is accomplishing something much more positive in his life.

James Harris realized in hindsight that preventable problems required a completely different approach than the one he wasn't given a chance to refuse. Had a friend, nurse, or physician been available to educate and warn our friend James "Kamala" Harris that his diabetes was causing the loss of sensation in his feet while fighting barefoot in the ring as a "Ugandan Giant," he would have made alternative choices which may have spared his limbs. One incredible story he was able to share with me was that he was forced by the WWE, under the threat of fines, to remain barefoot during matches even after he began developing diabetesinduced peripheral neuropathy.

If kids could relate to a childhood hero urging them to understand that processed sugar is their enemy instead of a seemingly harmless and colorful friend, it could turn the tide against the diabetic terror threat by protecting feet, preventing amputation, and saving lives.

I would like to thank James "Kamala" Harris for his courage and humility in sharing his life story to help others who are at risk or are sharing a similar path. The domestic and foreign terrorist threat of diabesity is real, but society, the media, and medicine unfortunately are not doing a good enough job in educating at the children's and people's level. I chose to publish the story in this journal dedicated to CLI and amputation prevention because this publication is supported by the patient-centric CLI Global Society and founded by a call to action to end preventable amputations. As Henry Ford eloquently stated, "Coming together is a beginning, keeping together is progress, and working together is success." Together we need to stand against the world's scariest pandemic of diabesity and join James "Kamala" Harris in saying "No to Amputation."

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Disclosures: none

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Upcoming Meetings and Events

March 28-30, 2020

(ACC.20) American College of Cardiology Location: Chicago, Illinois accscientificsession.acc.org

March 28-April 2, 2020

(SIR 2020) Society of Interventional Radiology Location: Seattle, Washington www.sirmeeting.org

April 16-18, 2020 (DLS 2020) 11th Diabetic Limb Salvage Conference Location: Washington, DC www.dlsconference.com

April 21-24, 2020 (CX 2020) Charing Cross

International Symposium Location: London, UK Venue: Olympia London www.cxsymposium.com

May 13-16, 2020

(SCAI) Society of Cardiovascular Angiography & Intervention Location: Atlanta, Georgia www.SCAI.org

May 13-17, 2020

(SAWC) Spring /WHS Location: San Diego, CA / Henry B. Gonzalez Convention Center www.sawcspring.com

May 19-22, 2020

PCR Peripheral at EuroPCR Location: Paris, France Venue: Palais des Congrés Website: www.europcr.com May 26-29, 2020

New Cardiovascular Horizons

Location: New Orleans, LA Venue: The Roosevelt Hotel www.ncvh.org

June 4-5, 2020

2nd National Interdisciplinary CLI Congress Location: Düsseldorf, Germany www.cli-kongress.de

June 17-20, 2020

Society for Vascular Surgery (SVS) Annual Meeting Location: Toronto, Ontario Website: www.vascular.org

August 12-15, 2020

(AMP) Amputation Prevention Symposium Location: Chicago, Illinois www.amptheclimeeting.com

September 23-27, 2020

(TCT) Transcatheter Cardiovascular Therapeutics Location: Miami, FL www.tctconference.com

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