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Changing the paradigm of CLI treatment with OBLs

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"The independence that the OBL model offers allowed for more efficient scheduling, same day intervention for critical cases, improved patient satisfaction and better overall coordination and care."

In an interview with Dr. Laiq Raja, we explored his philosophy and protocols for treating critical limb ischemia (CLI) patients in his office-based lab (OBL) setting.

When Dr. Raja joined El Paso Cardiology Associates in El Paso, Texas in 2001, he realized there were limited treatment options for PAD, particularly CLI, which has high rates of amputations. Knowing the mortality rate in patients with amputations is very high, he knew the status quo was no longer acceptable. Thus, began his passion and dedication for finding a better solution for treating CLI and preventing unnecessary amputations. Today, the practice has evolved to include eight physicians, a dedicated team of nurse practitioners and a CLI patient navigator, with a rapidly growing CLI program.

Dr. Raja began working with The Hospitals of Providence – Memorial Campus, to develop an in-patient CLI program and a center of excellence for CLI treatment. The success of this patient-centric model led to immediate reduction in major amputations, leading to the lowest amputation rate in the city. As the CLI program grew, Dr. Raja realized certain limitations impacted patients' outcomes and that this could be resolved by adding an outpatient component. Having an office-based lab (OBL) allowed him to further extend the benefits of the CLI program to provide more individualized patient centered care and optimized outcomes. The independence that the OBL model offers, allowed for more efficient scheduling, same day intervention for critical cases, improved patient satisfaction and better overall coordination and care.

"PVI in an OBL setting can be performed as safely as in the hospital setting with favorable outcomes through 1 year post procedure".[1]

Philips: What types of procedures did you start doing when you first opened your OBL?
Dr. Raja: Patient selection is the most crucial starting point. As an interventionalist you need to become comfortable and confident with procedures to yield good outcomes. Your staff also needs a level of confidence as well, because nothing can derail your intervention more than a postoperative complication. We first started with diagnostic angiograms and then moved to cases we knew we could do safely. As our experience increased, we started doing more complex cases in the OBL, now frequently including the most severe limb-salvage cases, including CLI. In fact, our data was included in a recent publication, LIBERTY 360 trial, that demonstrated "PVI in an OBL setting can be performed as safely as in the hospital setting with favorable outcomes through 1 year post procedure".[1] This included CLI patients.

Philips: How did you start a CLI program in your OBL?
Dr. Raja: CLI is a complex disease, which requires a collaborative team approach in order to achieve the best outcomes for the patient. You must have a group of dedicated physicians in an interdisciplinary model, who work together to provide coordinated care that addresses all aspects of wound healing.

We started our CLI program by working closely in collaboration with the physicians who were already referring vascular patients to our practice. These physicians seemed committed to limb salvage and optimal outcomes, so incorporating them into this type of team network was an easy transition. We had many educational dinners and events to introduce a new way of management for these difficult patients; in essence a paradigm shift in how we treat patients with PAD and CLI. As we interacted and created close channels of communication, we would take each opportunity to share new information and data with our partners.

All this was streamlined by introducing a point person, or navigator, to help keep everyone on the same page. Lorie Henderson is our navigator and she makes sure that the team knows the treatment plan and is in close communication for disseminating results and next steps, as well as assists in coordinating procedures, appointments, follow ups and surgical plans so the patient's care is optimized. Having our own OBL has made this process much easier, as we can add patients to our office schedule and cath lab schedule when needed and there is very little bureaucracy involved. If a physician calls the navigator with an urgent issue, a patient can be seen the same day and triaged quickly. This allows us to manage the care and make quick decisions for the best treatment plan for each patient. We can quickly assess whether a patient can be managed through outpatient procedures or whether they need to be admitted, in which case we direct admit our patients with the help of a hospitalist partner, who assists us in the inpatient management. The hospitalist ensures that our plan is followed and all the care is optimized with the proper disciplines and referrals.

Philips: What are the benefits to patients of this OBL treatment setting?
Dr. Raja: There is much more convenience to the patient, by eliminating the hospital admission process, which could take several hours. Additionally, patients receive personalized care by a member of our staff. There is also the avoidance of acquiring a hospital-related infection with the benefit of a same day discharge, all while providing the same level of care regardless of setting.

Philips: How about economics? Is there a difference in cost to patients or the healthcare system?
Dr. Raja: There is a significant cost savings associated with treating CLI patients in the office-based lab setting. The potential for inpatient cost is extensive when you factor in a 4-5 day hospitalization, as well as all the ancillary cost associated with inpatient care. The lack of continuity and coordination often times leads to additional days and the potential for further hospital-acquired complications.

In the office-based lab setting co-pays could be more manageable and payment arrangements made available for the convenience of the patient. In turn, the continuity of care is more personalized, while providing the same quality of care with significant cost savings to the patient and healthcare system. Most issues can be managed outpatient using home-health nurses and partnering with podiatrist, infectious disease specialists and primary care physicians, to coordinate the necessary care. This translates into further savings when factoring the decrease in ER visits and readmissions that a coordinated CLI program can provide.

Philips: Technology changes constantly. As a privately owned OBL, do you have access to these innovations for your patients?
Dr. Raja: It is my personal belief that patients deserve the best possible outcome, regardless of setting. As the medical industry evolves and better devices are made available that enhance outcomes, we trial and test them both in the hospital and in the OBL. If we feel collectively as a team that they produce a better outcome for the patient, then we adopt them.

Additionally, we have an outstanding working relationship with our industry partners, and are fortunate enough to have devices tested and trialed here in our OBL. Being a standalone operation reduces the bureaucracy and having a dedicated research team to collect and transmit our data makes our OBL an ideal location for clinical trials. Thus again, enhancing the outcomes for our patients.

Philips: What kind of treatment techniques do you perform in your OBL?
Dr. Raja: We begin by doing our diagnostic angiogram via a radial artery approach, which helps to prevent bleeding complications. Similar to our belief in technology, our treatment algorithm does not change in the OBL either. We know through clinical research, that patients with CLI will present with multi-segmental occlusions that many times require multiple access points. We usually begin our interventions in the standard antegrade fashion. As we encounter these difficult and challenging CTOs, we quickly change our strategy, and switch to a retrograde option, usually from a distal tibial vessel accessed under ultrasound.

This strategy helps reduce the case time, the amount of contrast used and operator fatigue. Through this combined approach, antegrade and retrograde, we have elevated our CTO crossing rate well above 90%. Once in recovery, our nurses and techs are well trained on how to obtain hemostasis on femoral, radial and tibial punctures, avoiding any post procedure complications.

Philips: Why is CLI education so important?
Dr. Raja: CLI education is crucial, as we must increase awareness of CLI treatment options both to patients and providers alike. Podiatrist, ED, wound care and primary care physicians may not be aware of what options are available for treating patients with such advanced disease. The first option often offered to patients with CLI (RCC 5/6) is major amputation. This is where we must focus educational efforts to prevent amputation. These physicians are often at the front lines, so the more rapidly they can identify and refer these patients for appropriate treatment, the better the outcomes are likely to be. I am committed to ongoing education in our community to advance the treatment of CLI and provide better care for our patients. I provide training in many ways to include one-on-one training, through proctoring courses held monthly in our OBL and routinely presenting at local, national and international medical conferences. I have trained over 300 physicians nationwide and am actively involved in many clinical trials to advance the treatment of CLI. This has led to greater credibility and has made us a preferred site for ongoing research in the field of CLI treatment.

"Cultivate a network of physician specialists in your community who share your passion for saving limbs and lives."

Philips: What advice would you share with physicians who may be considering implementing an OBL?
Dr. Raja: Several key things:

- Look for a good partner to handle your back-office functions suh as contracting, reimbursement, payroll and staffing so that you can focus on providing exceptional and innovative patient care. We opened our OBL in collaboration with a leading lab management organization, then as our practice grew and matured, we were able to take on those operational functions internally.
- Proper patient selection is fundamental. I would encourage physicians to first focus on safer, simpler cases where positive outcomes are likely, then move to more complex cases as experience and confidence grows.
- Cultivate a network of physician specialists in your community who share your passion for saving limbs and lives. These are the individuals who will champion patients within the hospital as well as work to connect them with your practice where they can get the care they need.
- Maintain a strong working relationship with your hospital, by becoming a thought-leader and CLI expert within your hospital network. This will ensure patients requiring in-patient care have the best continuity and optimal outcomes. This is also an important factor in keeping the hospital engaged in your success and providing a relationship that is mutually beneficial. There are situations where patients are too complex and present critically ill, requiring in-patient care. The hospital is an essential partner in managing these patients.
- Assemble an outstanding clinical team to support the physicians in the OBL. Create a dedicated team of specialized nurse practitioners as well as a patient navigator, who can streamline the patient care and ensures excellent follow-up and coordinated care.
- Educate and create a "circle of care" with specialists in the community who share your passion and commitment. The best care comes out of collaboration.

1. Carr, J et al. Procedural and 1-year outcomes of peripheral vascular interventions performed in office-based labs: LIBERTY 360 subanalysis, presented at OEIS 2018.

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Dr. Laiq M. Raja is the Medical Director of the Cardiology and Critical Limb Ischemia Departments at The Hospitals of Providence, Memorial Campus and Medical Director of PULSE Amputation Prevention Centers. He is also a Clinical Assistant Professor at Texas Tech University Health Sciences Center, El Paso, TX.

Dr. Raja has been in clinical practice for 19 years and is dedicated to the treatment of patients with critical limb ischemia. He is a passionate educator, dedicated to creating awareness of critical limb ischemia treatment and limb salvage. He has participated in multiple national and international clinical trials including Illuminate ATK, Illuminate BTK, Excite, Liberty 360, PRIME registry, Connect I and Connect II and Safe DCB. He conducts CTO training courses emphasizing crossing techniques via alternative access strategies including tibial, popliteal, antegrade and retrograde approaches, as well as the utilization of IVUS and atherectomy to treat patients with severe disease.

Dr. Raja and his team at the Hospitals of Providence have instituted CLI inpatient protocols and algorithms. They have also created protocols for acute limb ischemia to elevate patients with symptoms to the same priority as chest pain/ STEMI, preventing delay in treatment which could lead to unnecessary limb amputation.

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