A US Perspective:

SFA CTO Crossing: Is Perfection Possible?

A formal credentialing criteria for femoropopliteal chronic total occlusions.

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ndovascular treatment for femoropopliteal (FP) artery stenosis is now considered by many a first-line therapeutic option for patients with symptomatic peripheral artery disease. Chronic total occlusions (CTOs) of the FP arterial segment are part of a more complex lesion subset. These lesions are often underrepresented in clinical trials, despite being frequently encountered in real-world interventions. An example of this is demonstrated in the randomized clinical trial of the Zilver PTX drug-eluting peripheral stent (Cook Medical), in which 30% of treated lesions were CTOs. However, at our institution, we observed a CTO rate of > 60% in a registry of our Zilver PTX population.¹

CTO CROSSING TECHNOLOGY, EXPERIENCE, AND COSTS

The ability to consistently cross a CTO takes years of experience and intimate knowledge of the multitude of wires, support catheters, and dedicated CTO crossing devices that are now available. Certainly, with these advances in CTO crossing technology, coupled with safe alternative access sites and more experienced vascular interventionalists performing these procedures, our ability to successfully cross these lesions has increased over the last several years. However, as with any endeavor in which repetition breeds success, there are interventionalists who often attempt complex reconstruction of CTOs but have low success rates. These operators offer less valued care and may place their patients at an increased risk while adding further costs to the already strained United States health care system.

Despite the fact that high-volume, experienced physicians often suggest that these advances in CTO crossing technology now allow for a much higher successful crossing rate that is upwards of 90%; we must not forget that most of these experts are just that, experts. They have hundreds, if not thousands, of these cases in their portfolios and have learned from their previous mis-

adventures in the FP space. In reality, however, there is a paucity of data regarding actual FP crossing rates in the United States, and not every institution has access to these CTO crossing devices or physicians with the proper skill set and experience to cross these lesions. It is also highly probable that across the United States, many unsuccessful attempts are being made to recanalize FP CTOs without any detriment to the patient and little thought of squandered health care dollars.

The inability to cross a CTO is tantamount not only to a failed procedure with misspent health care dollars, but it also leads to unintended retreatment for the patient. Failed procedures generate no benefit to patients, as they still have claudication symptoms or critical limb ischemia to address. The physician, after spending 1 or 2 hours "renting" the catheterization suite, often generates little in billing, while consuming both valuable lab time and equipment that has not led to a successful therapeutic intervention. This ultimately taxes the insurer with nonvalued added expenses that someone is responsible for reimbursing. However, the greatest travesty is that the patient is no better off and perhaps worse than they were before the case started. The objective of the procedure was not completed during the first attempt, and the patient will now need a second procedure, whether it is performed by a more experienced endovascular operator with even more expensive, single-use equipment (eg, a dedicated crossing device) or a surgical bypass. The latter will certainly lead to at least an overnight admission in the hospital, further increasing the cost to the health care system.

RETHINKING THE APPROACH

In a day and age when bundled payments for expensive procedures are being implemented by insurance providers, coupled with a movement toward value-based health care, perhaps we need to rethink our approach to CTOs. As the population ages and the prevalence of periph-

eral artery disease increases, many with Trans-Atlantic Inter-Society Consensus (TASC) C and D lesions, should we consider implementing a credentialing requirement for this lesion subset?^{2,3} Should we require those who attempt FP or any peripheral CTO endovascular recanalization to have success rates of 80% or perhaps even > 90%? Should we have centers of excellence in a health system or region that drive patients to these institutions for advanced levels of care, or should we merely require the delivery of this level of success wherever it is completed? Practically speaking, the outcomes of physicians with low success rates in treating CTOs are equivalent to those who continue to use plain old balloon angioplasty, which necessitate repeat procedures and lack cost efficiency.

These questions are particularly germane in light of the presumed changes in reimbursement (ie, the very palpable paradigm shift from a volume-based health care model to one of value and quality). It is a matter of when these changes occur, not if. This new method of reimbursement will ultimately shift risk from the payer to the institution and then from the institution to its physicians. Therefore, it behooves those of us who perform these procedures to become more proactive and less reactive. By actively seeking ways to curtail expenses and reduce the number of failed procedures, we can achieve our ultimate goal of improving patient care while reducing costs. The health care system that I am a part of has begun experimenting with these ideas, with the physicians leading the way.

CRITERIA FOR QUALITY: THE OHIOHEALTH APPROACH

The OhioHealth health care system is focused on delivering value-based, high-quality vascular care via the OhioHealth Vascular Institute (OHVI). Created in 2014, the OHVI supports collaboration among its 11 hospitals, 42 care site locations, and more than 45 clinicians who provide vascular care throughout much of the state. Its mission is to provide the highest-quality vascular care while sharing knowledge and resources and developing best practice guidelines for the membership. As a voluntary membership, we created quality-based criteria that are meant to drive the quality mantra. One of the unique parts of these membership criteria is the creation of a CTO credential. With the goal of creating a valued care environment in mind, the membership agreed to an 80% success rate for this treatment. In order to be inclusive and facilitate the membership, CTO training was offered as well as on-site proctoring by highly successful members.

In an attempt to benchmark and improve the quality of the vascular procedures performed by members of

the OHVI, we collect and analyze our vascular procedure data using the Vascular Quality Initiative (VQI), which is governed by the Society for Vascular Surgery Patient Safety Organization. The VQI has several registries for vascular procedures that require discrete data points to be captured in a longitudinal fashion during the many phases of a patient's procedure. Our operations committee has operationalized several registries within the VQI, one of which is the peripheral vascular intervention registry. While we collect the required data for the VQI, we also track success rates for CTO interventions. Tracking these rates will allow the OHVI to provide additional training to those who fail to meet the 80% benchmark while also potentially restricting CTO treatment for consistent underperformers. With these efforts, we as an institution are well on our way to developing a sustainable model for high-quality care in the vascular interventional space. We believe that enterprises like these will help position OhioHealth to be successful in this new era of health care delivery and may become a model for others to follow.

CONCLUSION

By taking a page from the coronary arena, in which CTO crossing algorithms have been created and validated with improved success rates, oftentimes > 90%, we believe that we can accomplish this in the peripheral CTO arena, not just for the FP segment, but also for other TASC C and D lesions in the iliac and tibial regions. Developing validated algorithms with escalation of equipment in a proven, cost-effective manner, leading to highly successful CTO crossing, will be important for the field.

Ultimately, the challenge is for our profession to take on this charge and demand high-quality, value-based care before it is taken out of our hands. Underperformers will need to improve or potentially face restriction in patients they are allowed to treat.

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