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Largest CTO PCI Registry to Date Confirms Feasibility, in Expert Hands

To hush the critics, future research should be powered for quality-of-life outcomes, which may come from the ongoing SHINE-CTO study, experts say.

By **Yael L. Maxwell** *April 26, 2018*

SAN DIEGO, CA– Results from the largest registry to date of international patients undergoing PCI for chronic total occlusion (CTO) lesions confirms a high rate of procedural success and low rate of complications over the last 5 years.

"In experienced, high-volume CTO centers, the overall technical and procedural success rate is around 85%-90%, and our result was completely in line with the previous findings," lead study author Peter Tajti, MD (Minneapolis Heart Institute, MN), told TCTMD. Since the creation of the PROGRESS CTO registry in 2012, he added, "we were able to maintain exactly the same

results, same success rate, [and] same complication rate in various international sites and patient populations. So this can serve as an important benchmark for patient communication and also for discussing the benefits and risks of CTO PCI with other providers."

The results, presented today at the Society for Cardiovascular Angiography and Interventions 2018 Scientific Sessions and simultaneously published in JACC: Cardiovascular Interventions, showed overall technical and procedural success rates of 87% and 85%, respectively, among 3,122 CTO interventions performed at 20 dedicated centers in the United States, Europe, and Russia between 2012 and 2017. The rate of in-hospital MACE, including death, acute MI, stroke, emergency CABG, urgent repeat PCI, and pericardial tamponade, was 3.04%.

CTO PCI has certainly had its critics, who most often point to a lack of randomized trial data showing significant improvement in patient quality of life. Yet Thomas Tsai, MD, MSc (Denver VA Medical Center, CO), told TCTMD he thinks the general perception of the procedure has changed over time.

"In the past we used to always think of CTO PCI as having a complication rate that is similar to a regular PCI procedure," said Tsai, who was not involved in the study. "That was because in the past people would bail or they would stop doing the CTO earlier once the initial strategy failed. I think that what this study has shown is, as you are tackling more difficult lesions–it's taking longer, more radiation, more contrast–that invariably you're going to have a higher complication rate as you are doing more and more difficult things. And this confirmed that, where previous [studies] didn't necessarily show that. So the harder you try, the more strategies you employ, the longer it takes, the higher the risks of complications."

'Contemporary Practice'

Patients who had successful CTO PCI were younger, generally healthier at baseline, and tended to be female. Most patients (88.56%) were symptomatic, having at minimum class II angina as defined by the Canadian Cardiovascular Society. Most CTO lesions were in the right coronary artery (55.22%), with the remainder in the left anterior descending (23.81%) and left circumflex (19.91%) coronary arteries.

The initial access approach was successful in 55% of patients. For the 41% who underwent further attempts, technical success was achieved in 79% of patients. Antegrade wire escalation was the most common first-choice approach, especially in less complex CTOs, and antegrade dissection reentry and the retrograde approach were used for more complex lesions ($P < 0.0001$).

Radial access was used in 37% of patients overall and decreased with increasing lesion complexity ($P = 0.003$ for trend). Fewer stents were used in less complex lesions ($P < 0.0001$).

In-hospital MACE increased with lesion complexity, and the rate was higher in failed procedures (7.54% vs 2.37%; $P < 0.0001$) and with more complex crossing techniques (antegrade wire escalation 1.09% vs antegrade dissection reentry 2.96% vs retrograde 5.61%; $P < 0.0001$). Patients with in-hospital MACE had a longer median hospital stay than those without (6 vs 1 day; $P < 0.001$).

Procedural success was more likely at higher-volume CTO centers in both univariate and multivariate analyses, but in-hospital MACE was not affected by hospital experience.

“This paper really describes the contemporary practice,” Tsai said. “For most of us who do CTO PCI, we can feel pretty confident that as long as we're doing a reasonable volume of these that we should be able to get the results that you see in this trial. I think most contemporary operators now have really adopted the hybrid algorithm as their approach, and in doing so, we see a lot of the findings that they see here.”

Patient Selection, Expert Care

Gregg Stone, MD (NewYork-Presbyterian/Columbia University Irving Medical Center, New York, NY), who wrote an editorial accompanying the study, called the new report the “magnum opus” of CTO technique. Now, he said, the focus needs to shift to appropriate patient selection and demonstration of clinical use, as well as to ensuring that most patients with CTOs who can benefit are provided access to expert care.

Tajti stressed that “it's really important to understand right now that we are not doing CTOs for only improving ejection fraction but [also for] improving patient symptoms and quality of life—that should be the main goal.” Additionally, he said the planning stage before any CTO PCI is important, especially when it comes to developing a detailed risk/benefit analysis and

making sure patients at high risk for complications are treated at high-volume centers. “It's also really important to understand whether the patient truly will benefit from this,” Tajti advised.

There are numerous questions the present study cannot answer, Tsai told TCTMD. For example, if CTO PCI is “reducing symptoms, to what degree does it reduce symptoms? And how does it do against optimal medical therapy? Does it really improve longevity? Do patients really live longer? . . . Does it make the heart squeeze better—the LV function—does it really improve that? These are relevant, important endpoints that this study doesn't address.”

The ideal future multicenter randomized trial to answer those questions, Stone says, would “enroll only highly symptomatic patients with at least moderate inducible ischemia or wall motion abnormalities (with viability), without prior (or planned) PCI of non-CTO lesions within 1 year, with one or more CTO lesions involving a large myocardial territory (preferably the left anterior descending coronary artery in a high proportion).” It also should be sham-controlled and involve guideline-directed therapy for patients in both study arms, he suggests, adding that crossovers should be kept to a minimum (<5%). Rather than being powered for MACE, Stone says, the study needs to be powered for quality of life and mortality at 1 year or later.

The currently enrolling, sham-controlled SHINE-CTO study will enable researchers to “clearly able to see if CTO PCI is beneficial or not,” Tajti said.

However, “to throw in the idea of a sham procedure is potentially a new standard in clinical trials that I don't think is realistic,” he cautioned. “I would stop short of that and just request a large randomized clinical trial in symptomatic patients who clearly have medically refractory symptoms and quality of life impairment—that we randomize those patients to a true CTO PCI using the hybrid algorithm versus optimal medical therapy.”

Completing a study that will give relevant information on the quality-of-life endpoint will be difficult, but “should be feasible,” Stone writes. Yet, “until such a definitive trial is performed, a growing choir of increasingly vocal critics doubting the use and cost-effectiveness of CTO PCI should be anticipated.”

Training to ‘Bridge the Gap’

The last component to ensuring the success of CTO PCI in the future is making sure enough operators are proficiently trained in the procedure, all of the experts interviewed for this story said.

“There's at least a 15-20% difference in success rates among high- and low-volume centers,” Tajti estimated. The best way “to bridge this gap,” he suggested, is through proctoring and education.

Tsai also said that “the training piece is instrumental in getting to the type of success or these outcomes that these people are getting here.” His institution employs multiple operators who are able to share expertise and also has dedicated CTO days where they are “not distracted by other clinical duties. . . . It makes the procedure much more rewarding and enjoyable when you're doing it in a protected setting.”

Proctoring “has to be part of it,” Tsai added. “You can't go at this alone by just reading a textbook. You need instruction in order to get comfortable.”

Sources

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Disclosures

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Stone reports serving as a consultant to Matrizyme.

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