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EDITORIAL

ORBITA-CTO: Liftoff for CTO PCI?

Salman A. Arain

University of Texas Health Sciences Center, Houston, Texas, USA.

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Corresponding Author Email:
salman.a.arain@uth.tmc.edu

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Chronic total occlusion percutaneous coronary intervention (CTO PCI) remains one of the most technically demanding domains in interventional cardiology. Despite high success rates and low complication rates reported in contemporary series, CTO PCI continues to carry a stigma among both interventional and non-interventional practitioners. This perception stems from procedural complexity, prolonged fluoroscopy times, higher contrast use, operator dependence, and variability in outcomes. Although success rates have improved in experienced centers, they are not uniform across practice settings, raising concerns about generalizability and cost-effectiveness[1]. Moreover, many critics perceive a disconnect between technical success and patient-centered outcomes, particularly symptom relief and quality of life.

The Achilles heel of CTO PCI is the relative lack of robust data. Whereas there is a plethora of randomized controlled trials (RCTs) exploring nearly every form of non-CTO PCI, there is comparatively little systematic investigation of CTO PCI. Until recently, most supporting data came from registries and guideline-based consensus, with only a limited number of randomized studies. Existing RCT evidence has been mixed and, at times, controversial. While trials and registries suggest improvements in angina and quality of life, consistent reductions in hard endpoints such as mortality or myocardial infarction have not been demonstrated[2–6]. Studies such as DECISION-CTO raised questions about incremental benefit[2], while others like EURO-CTO suggested symptomatic improvement but were criticized for potential placebo effects inherent to open-label designs[3,4]. The absence until recently of blinded, placebo-controlled data has perpetuated uncertainty regarding the true magnitude of benefit.

The good news is that this landscape may be shifting. The recent presentation of the ORBITA-CTO trial at the 2026 American College of Cardiology Annual Scientific Session in New Orleans has re-ignited discussion around CTO PCI. This multicenter, double-blind, placebo-controlled trial randomized 50 patients with symptomatic single-vessel CTO and no significant bystander disease to CTO PCI or a sham procedure, with rigorous efforts to maintain blinding. The trial demonstrated a statistically significant and sustained improvement in angina frequency and quality of life beyond placebo, with fewer angina episodes and more angina-free days over approximately six months of follow-up[7].

The strength of ORBITA-CTO lies in its thorough design, building on prior work from the ORBITA program[8]. Key features included a placebo-controlled framework with a sham procedure (a remarkable feat in itself), withdrawal of anti-anginal medications prior to randomization to isolate the true effects of PCI, and daily symptom tracking via a smartphone application to reduce recall bias.

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The study also incorporated objective measures of ischemia, including stress echocardiography, exercise testing, and coronary physiology assessments, to better understand the mechanistic basis of symptom improvement. As this was designed to be a pilot study, it enrolled carefully selected patients with less complex anatomy (Japanese CTO score ≤3), and procedures were performed by experienced operators[7].

It is too early to predict the full impact of ORBITA-CTO; however, it has already opened an important dialogue within interventional circles. The insights gained extend beyond understanding the isolated impact of CTO PCI on angina and quality of life. The trial reinforces that symptom relief in patients with CTO is not an "all-or-nothing" phenomenon, as many continue to experience some degree of angina despite successful recanalization[7]. Additional insights from the placebo arm will help clarify the role of medical therapy, the magnitude of the placebo effect, and patient selection for revascularization. Important questions remain, including the role of CTO PCI in patients with multiple occlusions, complex multivessel disease, or refractory angina despite optimal medical therapy.

As populations age and more patients survive coronary artery disease at younger ages, the prevalence of symptom-causing CTOs is expected to rise. The need for CTO PCI will likely increase. Techniques such as hydrodynamic contrast recanalization, intravascular ultrasound-guided wiring, and three-dimensional wiring are already making the procedure more accessible and reliable even in very complex anatomies. However, broader adoption will depend on a solid clinical foundation supported by high-quality data. To that end, ORBITA-CTO represents a threshold: the launch of CTO PCI from a niche procedure into the orbit of contemporary practice[7].

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