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EDITORIAL COMMENT

Primary CTO Crossing Device Strategy Provides Superior Midterm Clinical Outcomes Following Peripheral Endovascular Procedures at a Reasonable Additional Cost*

Stavros Spiliopoulos, MD, PhD,[a] Panagiotis Kitrou, MD, PhD[b]

The number of patients with symptomatic peripheral arterial disease (PAD) requiring treatment is continuously rising (1). Mounting experience and development of highly effective endovascular devices has led to an increase in the range of the disease that vascular specialists are attempting to treat using percutaneous approaches, with continuously improving clinical outcomes. After more than a decade of experience with the bolia subintimal technique for CTO crossing, in modern, everyday clinical practice, an endovascular-first approach is preferred in patients with severe lifestyle-limiting claudication or critical limb ischemia due to long, TASC (TransAtlantic Inter-Society Consensus Document) II C or D chronic total occlusions (CTO), especially those with comorbidities, unfit for surgery or in the absence of an appropriate venous conduit for bypass. Notably, TASC-II classification was recently updated to recommend endovascular treatment options in more complex disease morphology (2). Currently, endovascular therapeutic modalities can be performed using a variety of new devices, which aim to broaden the spectrum of indications, as well as improve the feasibility and clinical efficiency. However, in this new era of paclitaxel-coated balloons and drug-eluting stents for the treatment of infrainguinal arterial disease, a major concern is raised on the actual cost benefit between traditional methods and contemporary, but more expensive, new devices (3). With most studies focusing on results produced by the newly proposed treatments, immediate lumen gain produced, primary patency and vessel preparation, and clinical results (survival, amputations, or major cardiovascular events), little attention has been paid so far to the actual cost benefit and technical success of the initial and most important part of the procedure, which is lesion crossing. Apart from the traditional wire-catheter approach, a plethora of devices and techniques have been implemented in the last few years for intraluminal or subintimal crossing of CTOs, including the Bolia Curve Glidewire (Terumo Interventional Systems, Piscataway, New Jersey) for subintimal approach, various dedicated CTO wires and catheters, subintimal re-entry devices such as the Outback (Cordis Corporation, Bridgewater, New Jersey) and newly implemented, more sophisticated re-entry devices using not only fluoroscopy for guidance but also intravascular ultrasound and optical coherence tomography technologies enabling endovascular imaging for more accurate and targeted true-lumen re-entry (4). As the use of the previously mentioned technologies becomes necessary and more and more popular in PAD patients, cost-effectiveness analysis becomes essential as the trend for modern minimally invasive vascular procedures is to decrease overall treatment budget while remaining equally effective to open surgical options (5).

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From the [a]2nd Department of Radiology, Interventional Radiology Unit, Attiko University Hospital, Athens, Greece; and the [b]Interventional Radiology Department, Patras University Hospital, Rio, Greece. Both authors have reported that they have no relationships relevant to the contents of this paper to disclose.

In this issue of *JACC: Cardiovascular Interventions*, Banerjee et al. (6) report cost analysis and midterm outcomes following peripheral artery CTO endovascular treatment. The authors retrospectively analyzed the large data set of the prospective, multicenter, XLPAD (Excellence in Peripheral Artery Disease intervention) registry (1,006 patients with 1,362 CTOs in 11 U.S. centers) to compare cost, 30-day, and 12-month outcomes of wire-catheter versus dedicated crossing device strategies for the management of infrainguinal CTO (6). The authors divided crossing procedures into 3 categories; wire catheter first, crossing device first, and wire catheter first bail-out crossing device. Crossing was mainly performed with a wire catheter approach (82% vs. 18% for CTO devices; $p < 0.0001$). Successful lesion crossing rate was significantly lower with the primary wire catheter approach compared with the primary crossing device approach (65% vs. 74%; $p < 0.0001$). Despite the

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similar procedural success rates between the 2 treatment strategies, the primary wire catheter approach resulted in a significantly lower 12-month patency rate. As a result, although mean procedural cost was significantly higher in the crossing device group ($7,800.09 vs. $4,973.24; $p < 0.0001$), 12-month repeat revascularization (11.3% vs. 17.2%; $p = 0.02$), and amputation rates (2.8% vs. 8.5%; $p = 0.002$) were significantly lower in the CTO crossing device arm. One could speculate that less traumatic lesion crossing and targeted lumen re-entry, respecting collateral arterial network and normal vessel segments could represent factors contributing to superior angiographic and long-term clinical outcomes. As a result, according to the logistic computational model per primary strategy, net additional cost for the crossing device group decreased from $2,122.4 per procedure at 30-day follow up to only $423.80 per procedure at 12 months. Further sensitivity analysis of alternative models not including lesion length demonstrated a net cost of primary CTO crossing device strategy compared with wire catheter around $168 at 12 months. Interestingly, procedural costs were significantly lower when the bail-out option was used compared with directly using crossing device. This might be explained by operator preference, as more challenging, difficult, and therefore more cost-demanding lesions could have been directly negotiated with a crossing device. Another interesting finding was that 40% of procedural cost in the crossing device arm was the actual price of the crossing device whereas atherectomy cost was higher for the wire catheter arm (22.68% vs. 12.61%). This cost-benefit analysis took into consideration procedural microcosts giving an accurate figure of the cost for each procedure. However, there was not sufficient accuracy regarding overall hospitalization and follow-up costs, while the study is also subjected to selection bias and the drawbacks of its retrospective design. Nevertheless, good-quality data were acquired by a prospective multicenter registry, which included a large number of patients.

Conclusively, according to these initial data, using dedicated CTO devices as a primary strategy for peripheral endovascular revascularization procedures results in significantly lower repeat intervention and amputation rates, at an additional but not very high cost. This cost could be minimized in case of future device price reduction, which might occur due to a widespread use of CTO devices. These results justify the design of prospective trials with long-term clinical endpoints to further investigate the role of CTO devices in the endovascular treatment of PAD.

REPRINT REQUESTS AND CORRESPONDENCE: Dr. Stavros Spiliopoulos, ATTIKO University Hospital, 2nd Radiology Department, Interventional Radiology Unit, 1st Rimini Street, Chaidari, Athens 12461, Greece. E-mail: stavspiliop@med.uoa.gr.

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KEY WORDS cost-effectiveness, CTO devices, re-entry devices, PAD