News & Views in ...

Interventional Cardiology

News & Views

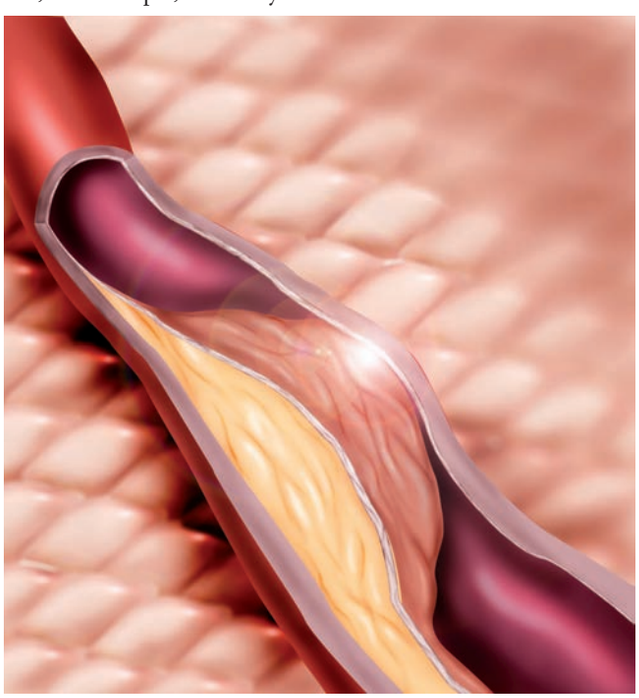
Crossing chronic total occlusions is "safe, efficient and effective": promising results of a new catheter

A novel catheter that utilizes optical coherence tomography (OCT) has been described as hugely successful at crossing chronic total occlusions (CTOs) of the superficial femoral artery (SFA) in a recent study published in *EuroIntervention*. The study, headed by Arne Schwindt of the St Franziskus-Hospital in Münster (Germany), aimed to determine the safety, efficacy and feasibility of the new Ocelot catheter (Avinger Inc., CA, USA) in instances of previous guidewire failure.

With its OCT capabilities, the Ocelot catheter allows for real-time CTO guidance at image resolutions that allow for effective differentiation between healthy and diseased arterial walls and structures. More specifically, an image resolution of 10 µm and 1024 A-lines per image arguably make this method a more beneficial surveillance technique than, for example, intravascular ultrasound (IVUS), a common and well-established medical imaging methodology.

In order to investigate the capabilities of the Ocelot catheter, 33 patients with confirmed CTO of the SFA underwent treatment at three different institutes over a period of 4 months. A successful crossing rate of 94% was reported, without any major adverse safety events. The unsuccessful 6% was identified as being a result of severe calcification of the entire SFA in the affected patients. In addition to this, the authors reported a statistically significant decrease in procedural time and contrast dose when compared with the results of the Wildcat catheter (Avinger Inc.), a similar non-OCT-guided device.

Furthermore, the physicians who performed the procedure were asked to rate the catheter across seven categories and the OCT feedback across five categories, on a scale of 1–5, where 1 = poor and 5 = excellent. In total, 87% of 33 physicians deemed the catheter to be 'good' or 'excellent', while 86% of 32 physicians determined that the OCT feedback was likewise good or excellent. Although the ratings across the seven catheter categories were relatively consistent (ranging from 73 to 100% good/excellent rating), the visualization of vessel wall nonlayered structures was identified as a



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weak point of the OCT feedback, with a good/excellent rating of only 54%.

Such promising feedback would therefore seem to justify the authors' conclusions that Ocelot is "safe, efficient and effective."

However, the small sample size coupled with patient selection bias means that this study is far from conclusive and additional, independent, more extensive studies will certainly be required before an informed decision can be reached regarding the value and further potential of the Ocelot catheter. The upcoming CONNECT II study will hopefully provide a more comprehensive review of Ocelot and will allow for a more definitive conclusion as to its potential, but for now the outlook for the future of this device is most definitely an optimistic one.

Source: Schwindt A, Reimers B, Scheinert D et al. *Crossing chronic total occlusions with the Ocelot system: the initial European experience.* EuroIntervention *pii:20120416-04 (2013) (Epub ahead of print).*

Intravascular ultrasound-guided percutaneous coronary intervention: a success story?

"The major obstacle to successful recanalization of a CTO is difficulty in passing the guidewire through the occlusion," states a new study by a Japanese research team from The Fraternity Memorial Hospital and Nippon Medical School (Toyko, Japan). In the study, which was recently published in *The Journal of Invasive Cardiology*, the team has attempted to tackle this issue, in the first reported successful use of transvenous IVUS-guided percutaneous coronary intervention (PCI).

Two case reports are examined in which the authors elected to use an IVUS-guided approach owing to the absence of usable collateral channels for a standard retrograde approach. During the procedure, a guidewire was passed through the CTO lesion under fluoroscopic guidance and an IVUS catheter was then inserted into the cardiac vein parallel to the target artery – for example, the left circumflex artery in case one and the left anterior descending artery in case two. Not only were the operations successful, but no complications were observed and there was no restenosis in either patient at an 8-month follow-up.

> *"...this technique could be used to a greater extent in order to increase the success rate of treatments for these types of chronic total occlusions."*

The authors describe the procedure as very easy and explain that it does not require any special equipment. The images provided by the IVUS catheter are described as accurate, allowing for visualization of the catheter to ensure that it is in the artery and not the subintimal space. This is essential for a safe and successful operation.

However, there are several limitations to this procedure that need to be taken into consideration. In cases of severe calcification, it may not be possible to insert an IVUS catheter and, even if successful, the obtained images may not be particularly accurate. The main limitation is arguably that transvenous IVUS-guided PCI cannot be used for CTO lesions that are not parallel to the cardiac vein. Despite this, the authors remain confident that this technique could be used to a greater extent in order to increase the success rate of treatments for these types of CTOs.

Larger studies and an increase in successful case reports will be necessary before the significance, if any, of transvenous IVUS-guided PCI can be fully elucidated or for it to ever become common practice for problematic CTOs of this type.

Source: Takahashi Y, Okazaki H, Mizuno K. Transvenous IVUS-guided percutaneous coronary intervention for chronic total occlusion: a novel strategy. J. Invasive Cardiol. *25(7), E143–E146 (2013).*

International chronic total occlusion workshop addresses use of angioplasty

The use of angioplasty for the treatment of CTOs is currently not a widespread practice owing to both its complexity and the need for specialized tools and equipment that may not be standard in most hospitals. Therefore, practitioners will, in general, opt to perform bypass surgery as an alternative. The key exception to this rule is Japanese interventionalists.

In Japan, angioplasty is often the only viable method for CTO treatment owing to the prevalent belief among the Japanese population that the soul may depart the body if the chest is opened. Angioplasty has hence become somewhat of a specialty in Japan. Renowned Japanese cardiologist Masahisa Yamane, from Sekishinkai Sayama Hospital (Saitama,

Japan), was therefore invited to speak at an international CTO workshop organized by Apollo Hospitals (Ayanambakkam, India), in order to share his experiences.

At the workshop, Yamane emphasized the idea that even 100% blockages can be treated with angioplasty. Drawing upon his knowledge and past successes, he was able to advise attendees of the most effective angioplasty techniques using the technology that is currently available outside of Japan. Furthermore, he performed three live demonstrations in order to better explain some of the techniques. The overall aim is to increase the success rate of this type of procedure in Indian hospitals, which Yamane described as "a matter of skill and practice." An additional benefit is that postoperational healing time is generally much shorter for angioplasty compared with open heart surgery. "I hope the techniques discussed in this workshop encourage people in India to consider angioplasty as a viable alternative to surgery," concluded Dr Yamane, also adding that he looked forward to participating in future collaborative efforts.

Dr Anand Gnanaraj, Senior Consultant Interventional Cardiologist at the Apollo Hospitals, said that they were "privileged" that Dr Yamane had shared his expertise and knowledge and that it "will definitely open up new avenues for treatments of patients at Apollo."

Sources: The New Indian Express news article: http://newindianexpress.com/cities/chennai/You-dont-always-need-surgery-to-bypass-a-heart-block/2013/08/05/article1718171.ece; Apollo Hospitals: www.apollohospitals.com/index.php

Japanese study disputes the point of percutaneous coronary intervention for chronic total occlusion

A research team from Kyoto University Graduate School of Medicine (Kyoto, Japan) has recently been assessing the long-term outcomes after CTO PCI. "The clinical benefit of recanalization of CTO is still a matter of debate," state the authors in their review of 1524 patients who received CTO PCI in the CREDO-Kyoto Registry Cohort-2. Of these 1524 procedures, 1192 were described as successful whereas 332 were determined to have been unsuccessful. The team found that the cumulative incidence of all-cause death was not significantly different between the successful and failed CTO PCI groups over a 3-year period, although there was a trend towards decreased cardiac deaths.

> "*The clinical benefit of recanalization of chronic total occlusion is still a matter of debate…*"

This has raised questions over the significance of these findings and has led to discussions regarding the purpose of CTO PCI. It has been stressed by other experts in the field that the absence of a difference in mortality rate between the two populations does not mean that the procedure is not beneficial. Distinct differences were observed in postoperative presentations of acute myocardial infarction, shock, multivessel disease, moderate-to-severe mitral regurgitation and aptness to undergo dialysis, all of which had a higher prevalence in patients whose surgeries had been unsuccessful. In addition, and perhaps most noteworthy, there was a decreased need for coronary artery bypass graft or any other revascularization after instances of successful CTO PCI.

Post hoc subgroup analysis further revealed that the rate of cardiac deaths was markedly decreased in those who had single-vessel disease, no history of heart failure, left anterior descending lesions and in those who did not have diabetes.

A number of short-comings in the study have been highlighted by those who are skeptical of the conclusions. Points have been made about the limited sample size and potential statistical limitation of the all-death subset of patients, the 3-year follow-up period, which is arguably too short for any definitive conclusions to be drawn and the debatable definition of what qualifies as a CTO. One researcher went as far as to describe the conclusion that CTO PCI does not impact mortality rates as ridiculous.

Factors such as symptomatic relief and quality of life were not addressed by the study. Again, this raises questions about what exactly the purpose of CTO PCI actually is. It may be necessary for cardiologists to assess the various factors and decide for themselves whether or not the outcomes of CTO PCI justify performing the procedure in the first place.

> "*…prospective randomized trials … are absolutely required to define the indication of chronic total occlusion percutaneous coronary intervention.*"

The authors themselves are aware of the need for more extensive assessments, concluding that "prospective randomized trials comparing PCI plus medical therapy with medical therapy alone in patients with CTO, adequately powered for evaluating long-term mortality, are absolutely required to define the indication of CTO PCI."

Source: Yamamoto E, Natsuaki M, Morimoto T et al. *Long-term outcomes after percutaneous coronary intervention for chronic total occlusion (from the CREDO-Kyoto Registry Cohort-2).* Am. J. Cardiol. *112(6), 767–774 (2013)*

Training conference held for innovative new procedure

Earlier this year, PeaceHealth Sacred Heart Medical Center at Riverbend (OR, USA) was host to a national 2-day training session for what it described as an innovative new procedure for the treatment of CTOs.

PeaceHealth Sacred Heart is the only hospital in Oregon to perform the minimally invasive hybrid CTO approach, in which a small incision is made in the femoral artery near the groin, allowing for a catheter to gain access to the occlusion and reroute the blood flow around it. With the right technology and expertise, the blockages can be approached from either the front or back, via collateral vessels that develop over time. In patients who have had blockages treated with the hybrid approach in the cardiac catheterization laboratory, outcomes have been particularly inspiring with a reported success rate of 95%.

As well as hearing lectures about the procedure, seven live cases were performed at the hospital and presented to the 20 attending physicians from around the country via a video link. In addition, the cases were streamed live, in real-time, on the internet so that additional registrants who were unable to attend could still watch them remotely.

The attendance of such 2-day training events is a mandatory undertaking for physicians who are interested in performing the hybrid CTO approach themselves. In addition, they are required to perform several procedures at their own hospital in the presence of a suitably experienced and qualified proctor. Stephen Cook, a cardiologist at PeaceHealth St Joseph Medical Center (WA, USA) and one of the leaders of the training conference, is one such proctor and consequently travels across the country, visiting two hospitals a month in order to serve in this capacity.

The success of this training conference resulted in the scheduling of a second conference in September at Oregon Heart and Vascular Institute at PeaceHealth Sacred Heart Medical Center (OR, USA). These training opportunities are highly valuable in interventional cardiology, providing cardiologists with an increasing array of surgical options and allowing for them to make better and more informed decisions as to the most beneficial treatment option for patients on a case-by-case basis.

Source: PeaceHealth news article: www.peacehealth.org/sacred-heart-riverbend/Pages/Sacred-Heart-cardiologist-leads-training.aspx

Re-entry devices investigated for iliac artery chronic total occlusion

New data, from a study regarding the use of use of re-entry devices for CTOs, have been presented at the recent Society of Vascular Surgery Vascular Annual Meeting in San Francisco (CA, USA).

Re-entry devices are attachments that can be used during subintimal angioplasty to obtain true lumen re-entry and can be used with or without IVUS technology. "Sufficient data investigating re-entry device use with or without IVUS guidance in iliac subintimal angioplasty is still lacking," stated Tareq Massini of the Eastern Virginia Medical School (VA, USA) who presented the data at the meeting.

The study retrospectively investigated iliac subintimal angioplasty interventions between 2003 and 2012 in order to determine technical success, safety and patency of re-entry devices for CTOs. In order to determine this, re-entry devices were compared with non-re-entry devices, further subcategorized as IVUS re-entry devices, non-IVUS re-entry devices and non-re-entry devices.

Technical success, hemodynamic change and patency rates were used as primary end points whereas retrograde dissection, iliac rupture and major adverse events were secondary.

For the statistical analysis, 214 instances of iliac CTO and subintimal angioplasty were used; of which 72 used re-entry devices and 142 did not. IVUS was used in approximately half of the re-entry procedures.

Results demonstrated no difference in technical success between re-entry and non-re-entry devices but for the re-entry group there was a strong trend towards an increased patency rate and a significant improvement in hemodynamics ($p = 0.004$), as determined by ankle brachial index. Furthermore, the IVUS re-entry device group demonstrated lower rates of retrograde proximal dissection and major adverse events in comparison to the other two groups. Retrograde dissections requiring proximal treatment were described as being an independent negative factor on primary patency.

"IVUS-guided re-entry device significantly reduced retrograde dissections and overall major adverse events, and showed a trend towards improved primary patency," concluded Massini. However, it has been argued that a formal randomized trial will be necessary before any conclusions can be drawn regarding the differences between the two techniques.

Sources: VascularNews news article: www.cxvascular.com/vn-latest-news/

vascular-news---latest-news/re-entry-devices-improve-haemodynamic-results-in-iliac-arteries-chronic-total-occlusion; Vascular Surgery Vascular Annual Meeting, San Francisco, CA, USA, 30 May–1 June 2013: www.vascularweb.org/educationandmeetings/2013-Vascular-Annual-Meeting/Pages/2013-Vascular-Annual-Meeting.aspx

Launch of new catheter sizes to increase versatility of Turbo Elite® laser

The launch of two new catheter sizes for the Turbo Elite® .035 line (Spectranetics, CO, USA) has just been announced by manufacturer, The Spectranetics Corporation. The new 2.3 and 2.5 mm diameter catheters are compatible with a .035 guidewire and are hence intended to enhance the versatility of the Turbo Elite laser.

The Turbo Elite laser atherectomy catheter was designed specifically for the treatment of peripheral artery disease; however, the introduction of the new catheters will allow it to be used to treat CTOs above and below the knee, requiring less time than bypass surgery and providing an alternative option to amputation.

In attempting to cross an occlusion by using a .035 guidewire, experts have said that the new catheter sizes will eliminate the need to change wires to perform a laser atherectomy procedure once the lesion has been crossed. It will also, in theory, enable clinicians to cross 'uncrossable' lesions, which often arise in complex CTOs, without using a wire. These lesion types are frequently encountered in complex CTOs, which are reported in up to 40% of patients with peripheral lesions caused by peripheral artery disease. The need for more CTO crossing tools has been expressed by many interventionalists.

"The Turbo Elite .035 offers a crossing device with true atherectomy and better guidewire support, ensuring effective treatment within the affected lumen of the vessel," stated Giancarlo Biamino of the Heart Centre Leipzing (Leipzing, Germany). Biamino participated in early physician training on the Turbo Elite .035 and is considered to be a pioneer in the use of laser technology for debulking diseased vessels, introducing the step-by-step technique.

It is reported that Spectranetics will continue to offer extensive physician training events and opportunities throughout 2013 for the new catheters and for other recently introduced crossing tools in order to enhance procedural success.

Source: NASDAQ press release: www.nasdaq.com/press-release/spectranetics-broadens-laser-catheter-portfolio-to-treat-complex-lesions-and-chronic-total-occlusions-ctos-20130819-00688

– All stories written by Emma Sinclair

About the News and Views

The News and Views highlights some of the most important events and research in the field of interventional cardiology.
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