

## Why Treat Chronic Total Occlusion without Stents? - A Short Comment

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### Abstract

The treatment of chronic total occlusions is complex and associated with several risks and problems. Among therapeutic options including bypass surgery and medical therapy PCI represents an important strategy. PCI with stents, however, has limitations in such lesions due to characteristics like lesion length, unknown reference diameter and delayed stent coverage. Drug coated balloons have shown promising properties to overcome some of those limitations: They promote positive vessel remodeling and have a minimal thrombosis rate. In a first multicenter study it has been shown that drug coated balloons in proper indications and applied with appropriate technique might become a new treatment option for patients with chronic total occlusions.

### Commentary

Chronic total occlusions (CTO) of coronary arteries have been a focus point of research in interventional cardiology for several years. Recanalization, balloon dilatation and implantation of drug eluting stents (DES) are recognized treatment options for patients with symptomatic CTO. Recanalization of CTO ranks among the most complicated percutaneous coronary interventions (PCI) and the procedures are to be performed by well-equipped and experienced centers. During the last decades the procedural success rates increased due to improved technical equipment and increasing operator experience [1,2].

It is still uncertain whether PCI is the optimal treatment method for CTO and it competes with coronary artery bypass grafts (CABG) and medical treatment. Large retrospective registries have shown a reduction of adverse events and a clinical improvement after successful CTO PCI [3,4]. The only recently conducted DECISION-CTO trial [5] was the first large randomized controlled trial (RCT) to compare different treatment modalities for CTO. It failed to show a significant difference between PCI and optimal medical therapy. In general CTO PCI should only be considered for symptomatic patients with viable myocardium and no contraindications for PCI.

Further research and new strategies might improve CTO PCI in the future, amongst them bioresorbable vascular scaffolds and drug coated balloons (DCB). CTO vessels usually have long lesions to be treated [6], have often an unknown vascular diameter and might have a number of side branches, often not readily recognizable beforehand.

Thus, there are several characteristics of CTO that call for a stent free PCI approach. In the attempt of covering the lesion completely frequently more than 5 cm of the affected vessel have to be stented during CTO PCI. DES of such lengths has shown an increased risk of diffuse restenosis and other stent-linked complications [7]. The selection of a proper stent size can be difficult due to the lack of a reference diameter. An inappropriate stent size however can lead to

either extensive vessel damage or to secondary malapposition. Also side branches might be occluded.

In addition, even in comparison with similar long non-CTO lesions a delayed coverage of stent struts has been observed in CTO after DES implantation [8] which increases the risk of (late) stent thrombosis (ST). In order to avoid such complications associated with DES a stent free approach might be a reasonable alternative for CTO PCI.

DCB are devices for local drug delivery after thorough lesion preparation. Paclitaxel - a lipophilic compound - has to be used in conjunction with an excipient to allow rapid delivery of the drug into the vessel wall. Iopromide or urea is examples of such drug carriers [9]. Paclitaxel accumulates in crystalline form in the vessel wall and is detected there for several weeks [9]. In native coronary artery lesions and in-stent restenosis (ISR) this approach leads to an extremely low restenosis and an almost zero percent thrombosis rate [10-12], thus obviating the need for prolonged dual antiplatelet therapy (DAPT). Four weeks of DAPT is sufficient after DCB [13] compared to six to twelve months after DES [14]. Also, a DCB approach without foreign body implantation gives the vessel the opportunity to remodel positively. Positive remodeling with late lumen gain has been described by us and others, contributing largely to the lack of restenosis with this approach [15-17].

While positive remodeling is favorable after DCB it is unfavorable after stenting, leading to secondary stent malapposition and thrombosis.

We explored a novel approach for CTO PCI using drug-coated balloons only (DCB) and avoiding stents [18]. In a multicenter approach we investigated CTO recanalization results in 34 patients. Overall results were at least comparable with DES treatment. In the larger subgroup of patients treated according to the German consensus recommendations [13,19] we found unexpected low restenosis and reocclusion rates exceeding the results described with DES. Improvement of angina was impressive as well. Certainly this rather

small study cannot set the claim to treat most CTO lesions with DCB only. However, it opens a new possibility heading at natural vessel restoration instead of full metal jacket.

Current recommendations state that a DCB approach should only be used after proper preparation and predilatation of the lesion, meaning no significant residual stenosis and no major dissection [13,19]. If such a result is achieved a DCB might be a good alternative for certain lesion types, such as ISR, bifurcations and small vessels [19], and for patients with an increased bleeding risk as assessed e.g. by the HAS-BLED score. CTO lesions might show similar benefit.

After DCB treatment almost no cases of vessel thrombosis have been reported even with a DAPT duration of 4 weeks or even less, if necessary. This is one of the main reasons why this novel approach seems an attractive alternative for interventional cardiologists and is of special interest in lesions that are more prone to ST than others, such as CTO.

It is also important to keep in mind other treatment options for CTO patients besides PCI. A surgical approach by CABG might be preferred in patients with high Syntax scores [20]. Also, CTO is often associated with multivessel coronary artery disease [3,21]. CABG might be necessary during progression of coronary disease later on and a DCB-only approach can facilitate subsequent bypass surgery.

Medical therapy for patients with small ischemic areas, with only mild angina or with unproven myocardial viability has also to be considered.

In conclusion, aside from stenting, CABG and medical therapy, the DCB-only approach as treatment for CTO is a promising opportunity to further improve CTO PCI. A first step to show its feasibility and efficacy has been taken and larger, randomized and controlled trials are needed to further evaluate this technique and to compare it to the other treatment modalities.

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