The impact of coronary chronic total occlusion percutaneous coronary intervention on culprit vessel physiology

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON48075

Source
ToetsingOnline

Brief title
IMPACT-CTO II Study

Condition

- Coronary artery disorders

Synonym
Chronic Total Occlusions (CTO)

Research involving
Human

Sponsors and support

Primary sponsor: Basildon and Thurrock University Hospitals
Source(s) of monetary or material Support: Abbott,er is geen extra financiering. Er is enkel verstrekking van een drukdraad en OCT katheter door Abbott. We krijgen geen geld.

Intervention

Keyword: Chronic total occlusion, follow-up, Fractional flow reserve, percutaneous coronary intervention

Outcome measures

Primary outcome

Primary endpoints

- To identify changes in absolute coronary flow, fractional flow reserve,

pressure and microvascular resistance (physiological measures) between index

and three months follow-up after successful PCI of chronic total coronary

occlusion.

Secondary outcome

Secondary endpoints

- To a identify changes in vessel diameter (anatomical measures) between index

and three months after successful PCI of chronic total coronary occlusion.

- To identify a relation between anatomical changes and physiological

measurements between index and three months.

- To identify a relation between intra plaque and sub-intimal recanalization

techniques and changes in anatomical/physiological measures between index and

three months follow-up after successful PCI of chronic total coronary occlusion.

- To identify a relation between anatomical/physiological measurements and

quality of life

Study description

Background summary

Background
Coronary chronic total occlusions (CTOs) are defined as an occluded coronary vessel with (TIMI) grade flow 0 and a definite or an estimated duration of at least 3 months . They are frequently encountered in patients undergoing coronary angiography, and contemporary registries have demonstrated a prevalence of approximately 25% in patients with obstructive coronary artery disease .

Percutaneous recanalization of a CTO is challenging due to factors as the chronicity of the occlusion, the length of the occluded segment and the difficult visualisation distally to the occluded segment. For the above reasons in the past, interventional cardiologists were reluctant to tackle CTOs. It is characteristic that in the landmark SYNTAX trial , the incidence of a CTO was double in the subjects with incomplete revascularisation in the PCI arm compared to the ones with complete revascularisation . Furthermore when attempted the procedural success was low compared to non-CTO PCI .

However, contemporary techniques and equipment lead to a high procedural success and low adverse events rates in experienced centres. The hybrid algorithm has incorporated dissection re-entry techniques (antegrade or retrograde) as planned steps of the procedure that sometimes can be the first/preferred choice. Using these methods, success rates of at least 80% are now common when undertaking CTO PCI and complication rates resemble standard PCI 9.

Rationale
Although, procedural success rate in expert centres is approaching the one of non-CTO PCI long-term outcomes are not as good as with conventional angioplasty. For example, contemporary registries showed increased rates of TVR at one year and there have been no reproducible data supporting a reduction in MACE. Thus, the focus has shifted in optimising long-term term outcomes and ways to achieve that should be identified. The use of IVUS/OCT has been shown to improve long-term outcomes in conventional angioplasty procedures . However, recovery of blood flow and restoration of vasomotor tone will lead to vessel remodeling with significant lumen and vessel enlargement weeks or months after the index procedure. Studies using OCT at short term follow up in conventional angioplasty have shown high rates of stent strut mal-apposition and incomplete stent strut coverage . This highlights the unique challenges associated with stent implantation in CTO vessels.

Fractional Flow Reserve is a validated tool to assess physiological severity of coronary artery disease and the need for subsequent percutaneous revascularisation. Recent studies have shown that FFR measurements have a prognostic role even after PCI. A cut-off point of 0.90-0.93 has been suggested to correlate with better outcomes.

The aim of the study is to document changes in CTO vessels physiology post PCI

and at 3 months follow up. We intend to look for correlations between anatomical features identified with intravascular imaging and physiological parameters, how these develop at follow up and how they relate to the revascularization technique. These observations will help us to plan methods of optimising CTO procedures and design randomised studies to test hypotheses generated from our study observations.

Study objective

The aim of the study is to document changes in CTO vessels physiology post PCI and at 3 months follow up. We intend to look for correlations between anatomical features identified with intravascular imaging and physiological parameters, how these develop at follow up and how they relate to the revascularization technique. These observations will help us to plan methods of optimising CTO procedures and design randomised studies to test hypotheses generated from our study observations.

Study outcome measures
1. To identify changes in coronary physiology (flow, pressure and resistance) between index procedure and follow up.
2. To identify changes in anatomy between index procedure and follow up
3. To identify a relationship between anatomical/physiological measurements and exercise indices
4. To identify a relationship between anatomical/physiological measurements and quality of life

Study design

Prospective observational study

Study burden and risks

Risks of procedure
Patients will undergo the CTO PCI procedure in line with standard practice and international guidelines. After successful stenting, research measurements of anatomy and physiology. Follow up angiography will take place as a research procedure (complication rate of 1/1000), unless this is clinically indicated by the operator at the time of PCI.

Pressure wire risks
The measurement of physiological parameters requires passing a small pressure measuring wire into the stented vessel with a complication rate of 1/1000.

Use of adenosine
The risk of using adenosine is usually very small. It is short acting and pharmacological effect continues for 3-5 seconds after discontinuation of the

infusion. The effects of adenosine include bradycardia and hypotension. As these patients will be stable elective patients, there should be very few instances where adenosine use is contraindicated. In these cases, it will not be given.

Use of additional contrast
FD-OCT measurements will require the use of a small volume additional contrast. As patients with a significant burden of renal impairment would not be enrolled, the risk of this additional contrast is unlikely to result in contrast nephropathy.

Additional radiation exposure
Consultant Cardiologists involved in the study are acting as Radiation Practitioners under the Ionising Radiation Medical Exposure Regulations (IRMER 2000).

Additional fluoroscopic time to place the pressure wire at the end of the case is small/negligible and unlikely to make any measurable change in radiation exposure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* > 18 years of age
* Willing to participate and able to understand, read and sign the informed consent document before the planned procedure.
* Presence of a coronary CTO scheduled for elective PCI
* Evidence of viability in the CTO territory
* Presence of additional coronary lesions (other than the CTO vessel) in need of FFR/PCI in a second session.

Exclusion criteria

* < 18 year of age
* Unable to give informed consent
* Known severe chronic kidney disease (creatinine clearance *30 mL/min), unless the patient is on dialysis
* Unable to receive antiplatelets or periprocedural anticoagulation
* Any study lesion characteristic resulting in the expected inability to deliver FD-OCT catheter at the distal vessel post CTO PCI (e.g. moderate or severe vessel calcification or tortuosity)
* Pregnancy or planning pregnancy during study period

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Rayflow catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-07-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03830853
CCMO	NL69739.100.19