Optical Coherence Tomography (OCT) guided Percutaneous Transluminal Angiography (PTA) in lesions below the knee: a proof of concept study

Published: 24-11-2022
Last updated: 07-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON51664

Source
ToetsingOnline

Brief title
OCT-guided PTA concept

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
'peripheral arterial disease' en 'intermittent claudication'

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Abbott,Zie G2a

Intervention

Keyword: BTK, Concept, OCT, PTA

Outcome measures

Primary outcome

The main question to be answered is: *Is OCT safe to use in PTA procedures in patients with critical limb ischemia in below the knee arteries in the Zuyderland Medical Center, and what is the effect of OCT on intraoperative decision-making?*

Secondary outcome

For the secondary objectives, the following questions will be answered.

- What is the difference in millimeters between the measured diameter of the vessel using OCT and the estimation of the surgeon based on DSA?

- In what percentage of cases would intraoperative decision making have been altered knowing the OCT measurement in terms of balloon and stent sizing, stent placing and the surgical endpoint?

Study description

Background summary

The golden standard imaging modality for Percutaneous Transluminal Angioplasty (PTA) is Digital Subtraction Angiography (DSA) using an iodine contrast agent. This imaging modality is able to visualize the approximate diameter of the vessel where the contrast agent is injected, thus enabling the surgeon to estimate the size of the stenosis in the vessel wall. This technique however has its shortcomings. Firstly, DSA does not allow objective measurement of the vessel diameter. This means the surgeon must estimate the vessel diameter, causing interobserver variability and difficulties in selecting the correct

balloon size or stent. Secondly, DSA does not give the surgeon sufficient information on the morphology and shape of the plaque or stenosis in the vessel. This information could change operative decision making it might influence the decision to use or not use a stent, and the type of stent that might have to be used. DSA uses iodinated contrast to visualize the vessels, making it hazardous to use in patients with kidney failure with an eGFR below 29 ml/min/1.73m2 , as the risk of inducing acute kidney failure is increased in these patients.

Optical Coherence Tomography (OCT) is an intravascular imaging modality that is able to provide objective information, visualizing the quality of the vessel wall, the morphology of the stenosis and the diameter of the vessel. Using a catheter that is positioned within the affected blood vessel, OCT visualizes the vessel wall by emitting near-infrared light to provide high-definition, cross-sectional and three-dimensional image of the vessel microstructure. The tip of the catheter is placed distal of the stenosis and, while administering a bolus of iodine contrast agent, the tip of the catheter will be pulled back while making images to visualize the structures of the vessel wall and stenosis. While this is performed, a simultaneous image is made using DSA. This enables the surgeon to assess the quality of the vessel wall and the morphology and stability of the plaque while correlating the image made with the DSA to the OCT images. Furthermore, it allows for objective measurement of the diameter of the vessel, thus allowing the surgeon to select the correct balloon size without guessing as the vessel wall can objectively be measured. If a stent needs to be placed in the vessel, OCT provides information on the correct size and can be used to ensure correct placement of this stent. OCT does not require the use of additional contrast agent, enabling it to be used in patients with reduced kidney function. Intravascular ultrasonography has also been proposed to this end; however, OCT has a 10-fold greater spatial resolution compared to intravascular ultrasonography. OCT is already being used in the field of Cardiology, and this study aims to make the first steps with this technique in the field of Vascular Surgery.

The advantages of OCT have improved patient outcomes in PCI procedures, where it is part of the standard practice in both acute and chronic myocardial infarction. PTA has comparable limitations to PCI using merely DSA. However, this has not been studied outside of the coronary arteries thus far. The first steps need to be taken to study the safety and efficacy of OCT within the peripheral vascular system. This study will be the first step, using OCT in a small population of patients undergoing PTA to provide the first proof of its viability and its effectiveness in the peripheral vessels. This study will focus on below the knee (BTK) arteries, as these are most comparable of all peripheral vessels compared to coronary vessels.

Study objective

This proof-of-concept study aims to prove the safety and usability of OCT in

BTK lesions. Furthermore, it aims to provide information on the discrepancy between objective measurement of the vessel diameter using OCT versus the estimated vessel diameter based on DSA, as well as the effect this extra information has on intraoperative decision-making regarding the surgical endpoint.

Study design

This will be a proof of principle study. It will be a one-armed trial wherein patients will be their own control, thus the measurements as described will not need a control group to provide the information required to achieve the stated objectives. This study will be conducted between January 1, 2023, and January 1, 2025, in the Zuyderland MC. 20 patients will undergo PTA guided by DSA. When the surgeon has located the stenosis within the blood vessel, OCT will e utilized to measure the vessel diameter. After the procedure, the surgeon will assess the OCT measurements and discuss whether their intraoperative decision-making would have been altered knowing these measurements. Patients will be followed until 6 weeks after the procedure, which is adequate to detect adverse events caused by the procedure. This is also the current standard clinical practice. As this is the first prospective study using OCT in BTK arteries, a validation in a small patient group is necessary as a step-up to larger studies.

Study burden and risks

The OCT system uses iodinated contrast during measurements, the same substance as is already being used during PTA in order to make DSA images. OCT uses 4ml/sec during the measurement. The amount of contrast fluid is determined by the length of the lesion. The contrast is injected in the vessel at the site of interest. Although iodinated contrast is known to cause risk of acute kidney failure, the amount used for the OCT measurement is minimal compared to the amount used for DSA. The use of the agent is therefore justified. There are no additional risks for participating subjects. Subjects undergo a PTA, which they would undergo regardless of study participation. During this procedure, a catheter is inserted into the artery. The additional OCT measurement is performed using this catheter. This means that merely an extra measurement is made using this catheter, which has no additional risks for the test subject.
No radiation is used.

Contacts

Public
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL
Scientific
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients of any race or sex, and any age above 18 years, who electively undergo a single-lesion PTA of the anterior or posterior tibial artery
- The lesion is no longer than 3 cm
- Critical limb ischemia defined as Fontaine class 3 or 4
- Patients provide informed consent
- Kidney function with eGFR > 30 ml/min, allowing contrast iodine to be used unless patient is dependent on dialysis without residual diuresis

Exclusion criteria

- Acute limb ischemia
- Revascularization involving the same limb within 30 days prior to the index procedure
- Known allergy to iodine contrast
- Previous implanted stent at the index site
- Previous major amputation in the same limb as the index site

- Pregnant patients

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2023
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-11-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date:	29-02-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL82909.096.22