Optical Coherence Tomography in Arteriovenous Fistula Management: a proof of principle study

Published: 20-04-2023
Last updated: 11-07-2024

This proof of principle study aims to provide the safety and feasibility of OCT in patients with primary shunt failure requiring re-intervention. Safety is defined as conducting the OCT measurement without complications caused by the OCT measurement...

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

Summary

ID

NL-OMON53327

Source
ToetsingOnline

Brief title
OCT-shunt

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriovenous shunt, dialysis shunt

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Wordt aangevraagd;nog niet definitief

Intervention

Keyword: AVF, dialysis, OCT, shunt

Outcome measures

Primary outcome

This proof of principle study aims to provide the safety and feasibility of OCT in patients with primary shunt failure requiring re-intervention. Safety is defined as conducting the OCT measurement without complications caused by the OCT measurement. Feasibility is defined as successfully completing the OCT measurement before and after PTA.

The main question to be answered is: *Is OCT safe to use during PTA of AVF in patients with failure of the AVF in the Zuyderland Medical Center?*

Secondary outcome

Secondary outcome parameters:

- The difference measured in millimeters between the estimated DSA-based and objective OCT-measured diameters of the vessel, including the stenosis.
- Whether the surgeon would have selected the same type and size balloon based on the DSA images versus the OCT images.
- Whether the OCT-measurement would have caused the surgeon to decide to carry on the procedure to reach a better outcome.
- Whether OCT can capture the different effects of different types of balloons on the vessel wall

Study description

Background summary

The life expectancy of patients with established kidney failure is considerably shortened with worsening quality of life. With renal replacement therapy, such as hemodialysis and peritoneal dialysis, the quality of life and survival of advanced renal disease patients can be markedly improved. The efficiency of hemodialysis treatment relies on the functional status of vascular access. There are three main methods of providing vascular access, which include an arteriovenous fistula (AVF), central venous catheter (CVC) or an arteriovenous graft (AVG). CVCs are used temporarily to ensure vascular access for hemodialysis patients awaiting the creation or maturation of an AVF or AVG. CVCs can also be used permanently if there are no other vascular access options [1].

An AVF is created by connecting a native artery and vein while an AVG is created by using a synthetic graft to make the connection between the artery and vein. An AVF is considered to provide the best long-term functional vascular access with the lowest mortality rate and lowest rate of re-intervention as well as being the most cost-effective. An AVF also has the longest secondary patency rates, defined as the time interval between AVF creation and abandonment with or without surgical or endovascular intervention [2, 3]. The most common site for AVF creation is the forearm using the radial artery and cephalic vein. The AVF could also be placed on the upper arm using the brachial artery and cephalic vein or using the brachial artery and basilic vein [4].
AVF primary failure or failure to mature can occur early due to thrombosis, which can be triggered by a hematoma, low flow rates resulting from low blood pressure or by a hypercoagulable state [5]. Progressive intimal hyperplasia in the venous outflow system can lead to stenosis, resulting in a reduction in the flow rate which can cause late thrombosis of an AVF [5, 6].

The development of a stenosis is the primary cause of fistula failure. The formation of stenosis is initiated by endothelial cell injury, leading to smooth muscle proliferation and neointimal hyperplasia [1, 7]. The endothelium is the largest organ in the body consisting of endothelial cells lining every blood vessel [1, 8]. In healthy subjects, the vascular endothelium has many functions, including identifying hormonal stimuli such as vasoactive substances, as well as mechanical stimuli such as pressure and shear stress. They regulate inflammation, cell proliferation, vascular tone and coagulation due to their output of compounded substances [1, 9]. Endothelial dysfunction occurs when there is an imbalance between vasoconstricting and vasodilating products [1, 10]. Endothelial dysfunction is exhibited by patients with chronic kidney failure, resulting in a higher risk of fistula failure. Fistula failure can occur in the early phase, mainly due to thrombosis which is triggered by

hematoma, low flow rates resulting from low blood pressure or by a hypercoagulable state [1, 11]. Furthermore, late fistula failure can be caused by progressive neointimal hyperplasia in the venous outflow system or at the anastomosis causing a stenosis [1]. The most common site of stenosis is juxta-anastomotic, followed by the body of the fistula, the peripheral draining veins and lastly the feeding artery [12]. The occurrence of late fistula failure can be caused by turbulent flow, high intraluminal pressure and regular needle insertion during hemodialysis. These factors can cause endothelial damage leading to hemostatic activation in the AVF resulting in occlusion. These mechanical stimuli can additionally result in thrombosis and consequently dysfunction of the AVF [13]. However, the exact pathophysiological mechanism remains a point of discussion [14].

Treatment of dysfunctional AVF consists primarily of percutaneous transluminal angioplasty (PTA), which is preferred over open surgery due to its associated short and long term benefits [15]. There is a variety of balloons that can be used to perform PTA of an AVF, including plain old balloons, high-pressure balloons, cutting balloons, scoring balloons and drug-eluting balloons. The choice of balloon depends on the expertise of the surgeon and characteristics of the stenosis, however the most commonly used balloon is a noncompliant high-pressure balloon [15, 16]. Although efficacious on short-term, PTA frequently requires reintervention after the initial procedure, either due to regrowing of occlusive intimal hyperplasia and/or fibrotic scarring of the AVF wall. This is due to the fact that PTA does cause significant injury to the vessel due to stretching of the vein and compression of the intima causing shear mechanical stress, which is additionally one of the triggers for intimal overgrowth [1, 14].

Currently, Digital Subtraction Angiography (DSA) is used during PTA to assess the stenosis in the AVF. However, DSA has its limitations. Firstly, DSA does not allow objective measurement of the vessel diameter. This means that the surgeon must estimate the vessel diameter causing interobserver variability and difficulties in selecting the correct balloon size. Secondly, DSA does not give the surgeon sufficient information on the morphology and shape of the stenosis in the vessel [17]. This information could change intraoperative decision-making as it might influence the size and type of the balloon that is to be used, as well as decision to carry on the procedure after PTA. Past studies have investigated the use of intravascular ultrasound (IVUS), indicating that its use could be beneficial in PTA of AVF. However, IVUS has its limitations as it poorly differentiates between the different vascular layers and has a low resolution resulting in poorer image quality [18].

Optical Coherence Tomography (OCT) is an intravascular imaging modality that is able to provide objective information regarding the morphology of the vessel wall and quality of the vessel. It visualizes the morphology of the stenosis and diameter of the vessel [17]. Using a catheter that is positioned within the affected blood vessel, OCT visualizes the vessel wall by emitting near-infrared

light to provide a high definition, cross-sectional and three dimensional image of the vessel microstructure. The tip of the catheter is placed distal to the stenosis and, while administering a bolus of iodine contrast agent, the tip of the catheter is pulled back while making images to capture the structures of the vessel wall and stenosis. While this is performed, a simultaneous image is made using DSA [19]. Compared to IVUS, OCT has a 10-fold greater spatial resolution. This allows for better visualization of the morphology and shape of the stenosis, preferring OCT over IVUS [20]. OCT is often used within the field of Cardiology and its advantages have improved patient outcomes in percutaneous coronary intervention (PCI) procedures, where it is part of the standard practice in both acute and chronic myocardial ischemia [21]. PTA has comparable limitations to PCI using merely DSA. However, this has not been studied outside of the coronary arteries thus far. This proof of principle study aims to prove the first insight of the usability and safety of OCT in AVF using a small population of patients undergoing PTA due to AVF stenosis.

Study objective

This proof of principle study aims to provide the safety and feasibility of OCT in patients with primary shunt failure requiring re-intervention. Safety is defined as conducting the OCT measurement without complications caused by the OCT measurement. Feasibility is defined as successfully completing the OCT measurement before and after PTA.

Study design

This study will be a proof of principle study. It will be a one-armed trial where patients are their own control, thus the measurements as described do not necessitate a control group to provide the information required to achieve the stated objectives. The study will be conducted between April 1, 2023, and April 1, 2024, in the Zuyderland Medical Center. 10 patients who will undergo a PTA of their AVF will be included. Images using OCT will be made before and after PTA. After the procedure, the surgeon will be asked to assess the OCT-images and discuss whether the intraoperative decision-making would have been altered knowing the information supplied by OCT. As per the standard protocol of the Zuyderland MC, there is no follow-up after the PTA. As this is the first prospective study using OCT in AVF, a validation in a small group is necessary as a step-up to larger studies.

Study burden and risks

There are no additional risks for participating subjects. Subjects undergo a PTA, which they undergo regardless of participation in the study. During this procedure, a catheter is inserted intra-arterially as standard. The OCT measurement is done with the help of this catheter. This means that only an extra measurement is done through this catheter, which does not entail any

additional risks for the test subject. No radiation is used. Contrast fluid is used, but the main risk associated with its use is renal insufficiency. This patient population already has end stage renal insufficiency and the amount of contrast medium used is so minimal that it does not entail any additional risk. The OCT system uses iodinated contrast agent during measurements, the same substance that is already used during PTA to create DSA images. OCT uses 4ml/sec during measurement. The total volume of contrast depends on the length of the stenosis, the maximum amount of contrast administered is equal to what is used with a regular PTA. The contrast is injected into the blood vessel at the site of the stenosis at the level of the arteriovenous fistula. Although it is known that there is a risk of acute renal failure with the use of iodinated contrast media, there is no additional risk in this patient population as they already have end-stage renal disease. Also, the amount used for the OCT measurement is minimal compared to the amount used for DSA. Its use is therefore justified.

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
- Patients undergoing a PTA of an AVF
- Terminal kidney failure defined as an eGFR <15 ml/min
- Patients undergoing hemodialysis
- Patients who are able to provide informed consent

Exclusion criteria

- Revascularization in the same AVF 30 days prior to the index procedure
- Non-maturated AVF
- Patients who have an AVG
- Known allergy to iodine contrast
- Pregnant patients
- PTA performed by a surgeon or interventional radiologist who is not trained to use the OCT equipment

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2023
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	OPTIS Integrated Next-imaging system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-04-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	08-07-2024
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	NL83717.096.23