Fractional flow reserve calculation from 3D quantitative coronary angiography and TIMI frame count

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Primary Objective: The primary objective is to assess the feasibility of QCA-FFR in our centre. Secondary Objective:To assess the correlation and agreement of QCA-FFR with conventional pressure-wire based FFR. The pressure-wire derived FFR will...

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

Summary

ID

NL-OMON42424

Source
ToetsingOnline

Brief title
FFR calculation from QCA

Condition

- Coronary artery disorders

Synonym
1. Atherosclerosis of the coronary arteries 2. Coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FFR, QCA

Outcome measures

Primary outcome

To assess the feasibility of QCA-FFR in the catheterisation laboratory of the

department of cardiology of the LUMC.

Secondary outcome

To assess the correlation and agreement of QCA-FFR with conventional

pressure-wire FFR.

Study description

Background summary

Assessment of stenosis severity by invasive coronary angiography (ICA) is important regarding the need for coronary revascularisation: percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG). Currently, in patients with stable coronary artery disease (CAD), the guidelines recommend to re-vascularise only in hemodynamic significant lesions. Visual estimation of stenosis severity frequently fails to accurately identify the ischemic potential of a lesion. Fractional flow reserve (FFR) is nowadays the golden standard to assess whether a lesion is hemodynamically significant. FFR is defined as the ratio of maximal blood flow in a stenotic artery to normal maximal flow. It is measured during ICA by mean of a coronary pressure-wire that measures the pressure distal of a stenosis. A FFR value of 0.8 or less is considered hemodynamically significant. FFR-guided revascularisation is associated with favourable clinical outcome. Despite the clinical benefits, the employment of FFR has been slow, possibly due to high cost and extra procedure time of the operation. Recently, a new technique that can accurately and rapidly calculate FFR without the need for an intra-coronary pressure wire has been developed. This technique is based on calculations from 3D quantitative coronary angiography (QCA) and TIMI (thrombolysis in myocardial infarction) frame count. One previous pilot study demonstrated good correlation and agreement of the calculated FFR with conventional pressure-wire FFR. The technique is called QCA-FFR. It provides a facilitation in measuring FFR and has therefore great potential to enlarge the applicability of FFR.

The Leiden University Medical Center (LUMC) measures FFR on daily basis by the judgement of the interventional cardiologist. This project will provide more insight into the feasibility and diagnostic value of QCA-FFR in our center and would certainly position the LUMC as a pioneer center in this technique.

Study objective

Primary Objective:
The primary objective is to assess the feasibility of QCA-FFR in our centre.

Secondary Objective:
To assess the correlation and agreement of QCA-FFR with conventional pressure-wire based FFR. The pressure-wire derived FFR will serve as a reference standard when assessing the value of QCA-FFR.

If the primary and secondary objective appear a success, this pilot-study will serve as a start up for a larger study.

Study design

Study subjects are patients who are referred for diagnostic ICA and in who the interventional cardiologist decides to perform invasive FFR measurement to decide to perform PCI yes or no. The subjects in which no conventional pressure-wire FFR is performed will be excluded. The clinical diagnostic path will not be interfered by this study, because the invasive FFR will be used in the decision making process and the decision to perform FFR measurement is based on clinical grounds.

During regular diagnostic ICA, multiple orientating angiographic projections from different angles are made to assess the patency of all coronary arteries. For QCA-FFR, two angiographic projections with > 25 º between them are needed from the vessel of interest. These projections will be obtained from the clinically indicated orientating projections.
During pressure-wire FFR measurement, first, adenosine is infused (intravenously or intracoronary,140 ug/kg/min) to induce maximal coronary blood flow. When steady-state hyperemia is achieved, the FFR is calculated by mean of a intracoronary pressure-wire distal to the stenosis. For QCA-FFR, during steady-state hyperemia, one extra contrast enhanced projection is needed to obtain the required data to calculate QCA-FFR.

Post-processing of the obtained data will be done with validated software (QAngio XA 3D research edition 1.0, Medis Special BV, Leiden, the Netherlands), which is available in the LUMC. Calculation of the QCA-FFR will be done by an independent observer blinded for the pressure-wire FFR.

Study burden and risks

The subjects will be exposed to a small extra amount of radiation and contrast agent. The additional radioation will be estimated at 0.69 mSv, equal to seven 2-sided chest x-rays. Only subjects with good renal function will be included to minimize the risk for contrast induced nephropathy.

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

Age >=18 years
Clinically indicated invasive coronary angiography and FFR measurement during procedure

Exclusion criteria

The vessel of interest has too much overlap with other vessels on the baseline or hyperemic projections.
Renal insufficiency (eGFR < 60 ml/min)
Insufficient quality of the coronary projections obtainable
Coronary artery bypass graft that supplies the vessel of interest
Known allergy for contrast agent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL52916.058.15