Physiology and Imaging Pre- and Post Stenting

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Objectives of this study1. In what percentage of lesions do OCT and/or FFR post-PCI change post-stenting treatment (additional post-dilatation, ic/iv 2B3A treatment) compared to a regular post-stenting assessment based on angiography?2. Do OCT and/...

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

Summary

ID

NL-OMON38867

Source
ToetsingOnline

Brief title
PIPPS

Condition

- Coronary artery disorders

Synonym
atherosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: BIOSENSORS,industrie

Intervention

Keyword: Fractional Flow Reserve, Optimal Coherence Tomography, PCI, Stenting

Outcome measures

Primary outcome

Endpoints

Primary endpoint

Percentage of lesions with treatment change (post-dilatation, extra stent, 2B3A etc.) based on OCT/FFR post-PCI versus based on angiography.

Statistical analysis

- Primary endpoint: Estimated % of lesions treated additionally after stenting based on angiography: <5%. Estimated % of lesions treated additionally after stenting based on OCT/FFR: 10-20%. An absolute difference of 15% between post-angiography and post-OCT/FFR additional treatment will be defined as clinically relevant. An estimated 40 patients is needed in order to detect a clinically relevant difference.

Secondary outcome

Secondary endpoints

Percentage of lesions with change in stent length and/or diameter pre-PCI,

based on OCT/FFR pre-PCI versus based on angiography.

Study description

Background summary

Background

With the availability of drug-eluting stents for percutaneous coronary intervention (PCI), the incidence of in-stent restenosis has importantly decreased as compared with bare-metal stents. (1) However, the issue of (late) stent thrombosis with drug-eluting stents (DES) is still under debate. (2) One of the possible explanations for late stent thrombosis with DES is underexpansion of the stent at the index procedure. (3) Newer, innovated types of DES (like the Biomatrix* Flex biolimus eluting stent (BES) (Biosensors)) can potentially lower major adverse cardiac event rates as compared to *older* generation DES. However, correct selection of lesions to be stented still remains important because even the newer generation drug-eluting stents carry an intrinsic risk of stent-placement related periprocedural myocardial infarction, in-stent restenosis and (late) stent thrombosis. By using fractional flow reserve (FFR) to select ischemic lesions for stenting and select non-ischemic lesions for medical therapy, outcome of PCI can be improved, as shown by the FAME study. (4) PCI results might even be further improved by the routine assessment of stent implantation results by intracoronary imaging techniques like optical coherence tomography (OCT) and intravascular ultrasound (IVUS). (5) Such techniques are able to assess stent implantation results and reveal problems with potential clinical impact like stent-edge dissection or stent underexpansion.
FFR is used in most PCI cases in our cath lab, based on results from large, randomized trials like DEFER and FAME and the recently published European Society of Cardiology guidelines on revascularization, in which FFR now has a class I recommendation for lesion analysis pre-PCI. (6) OCT and IVUS are also already integrated in daily practice in our cath labs. Both imaging modalities are used to determine stent size or diameter pre-PCI in complex cases and stenting results after PCI, but in general only when the operator doubts the angiographic result.
The development of OCT provides new opportunities for the evaluation of coronary stents. Having a much higher spatial resolution than IVUS, OCT is currently used for long-term assessment of stent implantation. In the immediate future, however, it is quite likely that OCT will be used to optimize stent deployment, with an added value in contexts like ambiguous images presenting after stenting, or in complex PCI procedures like bifurcation stenting.
In the literature not much is known about the combined use of FFR and OCT pre- and post-stenting. There seems to be a potential complementary role of

physiological and anatomical assessment to guide decision making in complex clinical scenarios.
Combining these two modalities might even further improve PCI results. FFR has shown to significantly decrease major adverse cardiac event (MACE)-rates when used to determine which lesions are to be stented and which are not. OCT is promising in the assessment of stent implantation, however little is known about the impact of OCT on the frequency of treatment strategy change (like postdilatation of a stent) after stent implantation and subsequent impact on outcome.
The primary goal of the PIPPS study (a prospective, non-randomized study) is to detect in what percentage of lesions OCT and/or FFR post-PCI change post-stenting treatment (additional post-dilatation, ic/iv 2B3A treatment) compared to a regular post-stenting assessment based on angiography? If the PIPPS study detects a clinically relevant difference between both strategies, it creates a basis for future randomized trial(s) comparing both PCI-strategies (PCI with versus without intravascular imaging) with respect to clinical outcome.
In order to avoid potential bias in the PIPPS study due to usage of different types of second generation DES, a single, frequently used in our cath lab, type of second generation DES is used in this study (in casu: Biomatrix* Flex biolimus eluting stent (BES) (Biosensors)).

Study objective

Objectives of this study

1. In what percentage of lesions do OCT and/or FFR post-PCI change post-stenting treatment (additional post-dilatation, ic/iv 2B3A treatment) compared to a regular post-stenting assessment based on angiography?

2. Do OCT and/or FFR (in what percentage of lesions) change the choice of stent-size (diameter and length) pre-PCI, compared to a regular sizing stragegy based on angiography?

3. Sub-objectives:
- In what percentage of lesions that receive additional treatment, based on OCT, does the OCT images improve after additional treatment (disappearing of in stent dissection or protrusion or malapposition after post-dilatation etc.)?

Study design

Design of the study
Stepwise:
1 - Signed informed consent?
2 - Angiography

2 - Still fulfilling in- exclusion criteria?
3 - What would stent length/diameter choice be based on angiogram? Length and diameter fulfilled in file with time registration.
4 - FFR (+pullback) and OCT pre-PCI. What would stent length/diameter choice be based after these measurements?
Length and diameter fulfilled in file with time registration. OCT file and FFR curve file recorded for off-line analysis.
6 - Actual chosen (by operator) length and diameter fulfillled in file with time registration.
7 - PCI according to local, routine practice.
8 - Angiography post-PCI.
9 - What is the opinion of the operator about the stenting-result based on the angiogram? Any signs of dissection, trombus, malapposition etc? Additional treatment needed? If so, what treatment, based on the angiogram? These items are fulfilled in file with time registration.
10 - FFR (+pullback) and OCT post-PCI. Any signs of dissection, trombus, malapposition etc by OCT? Additional treatment needed? If so, what treatment, based on the FFR/OCT tracings? These items are fulfilled in file with time registration.
OCT file and FFR curve file recorded for off-line analysis.
1 1- Registration of any additional treatment (post-dilatation, 2B3A etc) and registration of any lesion-related event.
12 - Recommended to perform FFR (+pullback) and OCT after each additional treatment.
13 - Repeat steps 2-12 for additional lesions.
14 * Post-PCI in-hospital cardiac enzymes according to local routine practice.
Registration of in-hospital patient-related events.

Study burden and risks

NA

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

- Patients 18 years or older
- Signed informed consent
- Stable angina or medically stabilized unstable angina, scheduled for PCI of 1- or 2-vessel disease
- Vessel reference diameter of at least 2.5mm

Exclusion criteria

- Severely tortuous and/or heavily calcified coronary arteries
- Chronically occluded coronary arteries
- Participation in other study
- Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-08-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2013
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
CCMO	NL44357.060.13