Coronary Physiology Peri-Transcatheter Left-sided Valvular interventions in Patients with Severe Aortic Stenosis or Mitral Regurgitation

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To evaluate the immediate impact of TAVI or TMVr on a battery of coronary (non-) hyperemic physiology tests in patient with severe aortic valve stenosis or functional/degenerative mitral regurgitation and at least intermediate coronary artery…

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

Summary

ID

NL-OMON53992

Source
ToetsingOnline

Brief title
POTUS

Condition

- Coronary artery disorders

Synonym
coronary artery disease, valvular heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Abbott Vascular,Abbott Vascular, Santa Clara, Ca, US.

Intervention

Keyword: coronary physiology, fractional flow reserve, transcatheter aortic valve implantation, transcatheter mitral valve repair

Outcome measures

Primary outcome

The change in the FFR value before and after transcatheter left-sided valvular

intervention (i.e. TAVI or TMVR).

Secondary outcome

The change in

• RFR;

• Pd/Pa;

• CFR;

• IMR;

• dPR;

• transvalvular gradient;

• LVEDP;

• Systemic aortic pressure;

• Heart rate;

before and after transcatheter valvular intervention (either TAVI or TMVR).

Differences in changes in the physiology indices mentioned above between the

TAVI cohort and the TMVR cohort.

The number of patients in who the post FFR, RFR, Pd/Pa or dPR value crosses the border of hemodynamic significance as compared to the value pre-valvular intervention.

The number of patients in whom the decision for coronary revascularization is changed when based on the post-procedural FFR value instead of angiographic stenosis severity.

The diagnostic performance of a new physiological index that is corrected for the hemodynamic changes induced by either aortic stenosis or mitral regurgitation.
(i.e. sensitivity, specificity, agreement, positive predictive value, negative predictive value, area under the curve of the receiver operating curve).

The diagnostic performance of vFFR in the setting of valvular heart disease.
The vFFR pre-intervention will be validated against the FFR-value both pre- and post-intervention (i.e. sensitivity, specificity, agreement, positive predictive value, negative predictive value, area under the curve of the receiver operating curve).

Study description

Background summary

Patients who undergo transcatheter aortic valve implantation (TAVI) or transcatheter mitral edge-to-edge valve repair (TMVr) often have concomitant coronary artery disease. Fractional Flow Reserve (FFR) guided percutaneous coronary intervention (PCI) has proven its superiority over angiography-guided PCI in patients with stable angina, but has not been validated in patients with valvular heart disease. Valvular heart disease induces a number of changes in myocardial mass and intracardiac pressures that may affect coronary flow patterns. Coronary physiology in general and epicardial and microvascular flow in the context of left sided valve disease is only partially understood and its clinical applicability is so far unsettled. Previous studies have found contradictory results comparing hyperemic and non-hyperemic pressure ratios pre- and post-TAVI, whereas no studies have been performed to evaluate the effect of TMVr on physiological indices. The purpose of the present study is to provide a comprehensive overview of physiological and hemodynamic changes after transcatheter left-sided valvular treatment and unravel coronary physiology patterns that may help promote the adoption of physiology-guided PCI in patients with valvular heart disease.

Study objective

To evaluate the immediate impact of TAVI or TMVr on a battery of coronary (non-) hyperemic physiology tests in patient with severe aortic valve stenosis or functional/degenerative mitral regurgitation and at least intermediate coronary artery disease.

Study design

Prospective, single-arm, observational study with invasive measurements in two cohorts (TAVI cohort and TMVr cohort). Coronary physiological measurements in the coronary artery of interest directly before and after the valvular intervention. A pressure wire will be advanced distal to the lesion of interest and Pd/Pa, RFR and CFR will be measured under resting circumstances, and FFR, CFR and IMR will be measured during maximal hyperaemia.

Study burden and risks

Coronary physiological measurements are part of the standard practice in our coronary catheterization laboratory. The burden of participation in this study is limited to selective catheterization of the right and/or left coronary artery and the navigation of a pressure wire down to assess coronary physiology under hyperemic and non-hyperemic conditions before and after the valve

intervention. This implies a prolonged procedural time of approximately 15 minutes per procedure. The invasive physiological measurements carry a small additional risk of 0.09% (this includes conduction disturbances, bronchospasm, ventricular arrhythmia, thrombus formation) on top of the standard risks of transcatheter valve treatment. The majority of these cases are relatively easy to solve and almost never have lasting harmful consequences. The induction of maximum hyperaemia might lead to mild complaints (chest discomfort and dyspnea) in up to 30% of patients. These complaints are brief and self-limiting after discontinuation of intravenous adenosine. Of note, patients receiving TMVr will not experience these side-effects because the procedure takes place under general anaesthesia. Benefits for patients participating in this study might include adequate hemodynamic assessment of intermediate coronary lesions which might result in 1) deferral of angiographically severe coronary lesions with post-valvular intervention FFR > 0.80 and 2) revascularization of coronary lesions with diameter stenosis < 70% but post-valvular intervention FFR <= 0.80.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age >= 18.
2. a. TAVI Cohort: severe aortic valve stenosis for which TAVI is scheduled after discussion in the Heart Team.
b. TVMR Cohort: severe functional mitral regurgitation for which TVMR is scheduled after discussion in the Heart Team.
3. At least intermediate coronary artery disease, defined as 50 - 99% DS in a vessel >=2.5 mm.
4. Elective procedure.
5. Written informed consent.

Exclusion criteria

1. TAVI cohort: height coronary ostia < 10 mm.
2. Severe chronic kindey disease, defined as estimated glomerular filtration rate < 30 ml/min.
3. Contra-indication for intravenous adenosine (severe asthma or chronic obstructive pulmonary disease, known allergy to adenosine or precious reported bronchospasm in response to adenosine).
4. Degenerated surgical or transcatheter aortic valve bioprosthesis.
5. Vessels that have collaterals to a chronic total occlusion or that are supplied by an arterial or venous bypass graft will not be interrogated in this study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2021
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Pressure Wire X guidewire
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-02-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-09-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL75310.078.20