Effects of Percutaneous Aortic Valve Implantation on Left Ventricular Function And Coronary Hemodynamics

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON33340

Source
ToetsingOnline

Brief title
Effects of PAVI on LVF and coronary hemodynamics

Condition

- Cardiac valve disorders

Synonym
aortic valve narrowing, aortic valve stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Coronary hemodynamics, Left ventricular function, Percutaneous aortic valve implantation

Outcome measures

Primary outcome

The short and long term change in left ventricular function after

(percutaneous) aortic valve implantation, measured invasively by means of

PV-loops and non-invasively with echocardiography and cardiac CT and MRI.

Secondary outcome

The secondary study parameters compared with baseline and, where possible,

compared between the PAVI and SAVR are: invasively measured LV systolic and

diastolic properties, coronary flow characteristics, LV ejection fraction, LV

mass, LV myocardial perfusion, flow properties across the aortic valve,

presence/amount of aortic and mitral regurgitation, right ventricular function,

cardiac conduction, microcirculation, mortality and morbidity, NYHA functional

class and quality of life, Von Willebrand factor activity and blood levels of

NT-pro-BNP and other markers of heart failure.

Study description

Background summary

The precise effects of percutaneous aortic valve implantation (PAVI) on left ventricular function (LVF) and coronary hemodynamics (CH) have not been clarified yet. In the literature an observation has been described that the LVF improves after PAVI and after surgical aortic valve replacement (SAVR). This has been evaluated by echocardiography, but instantaneous assessment of LV dynamic parameters by means of pressure volume loops and cardiac MRI/CT scan immediately after PAVI and on long term has not yet been described. Also the

change in CH after PAVI by means of intracoronary flow assessment has not been described before. This study is conducted as an observational study in which the effects on LVF after PAVI will be compared to the effects on LVF after SAVR. Our hypothesis is that by reducing the aortic pressure gradient after PAVI, the left ventricular dynamics will improve immediately after the procedure and continue to improve on the long term. These are expected to be comparable to those of SAVR.

Study objective

The main objective of the single center, observational study is to assess the immediate and long term effects of PAVI on LVF and coronary flow by means of pressure volume loops, intracoronary flow assessment, echocardiography and cardiac MRI/CT. Where possible these effects will be compared with those of SAVR

Study design

The study is designed as an observational investigation in which the effects on LVF will be investigated in patients undergoing PAVI or SAVR.

Study burden and risks

The extent of burden and risks is related to the assessment of PV loops and simultaneous coronary flow performed periprocedurally directly prior to and after PAVI. Uncomplicated assessment of PV loops has been performed in this institute during percutaneous coronary intervention (PCI) in several studies. Also invasive coronary blood flow measurements have been performed in many studies and as part of the regular patient care. The benefit of this study is a better understanding of mechanisms of LVF improvement after PAVI. The knowledge gained by this study can be passed to other interventional cardiologists to improve future treatment with PAVI of high risk patients. Furthermore if LV and coronary hemodynamic effects of PAVI are shown to be non-inferior compared to those of SAVR, the indications for PAVI could be expanded to patients with a lower surgical risk. Lastly patients may benefit directly from this study because of an improved follow-up.

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

- Severe symptomatic native aortic valve stenosis
- Percutaneous or surgical aortic valve replacement (with biological valve prosthesis)
- Age above 75 years with one or more surgical risk factors

Exclusion criteria

- Previous aortic valve replacement
- Surgical aortic valve replacement combined with CABG or other valve surgery
- Severe left ventricular dysfunction
- Severe infection
- Recent myocardial infarction or stroke
- Enrolled in another investigational study

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):	01-06-2009
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL27918.018.09