Assessment of paravalvular leak after transcatheter aortic valve implantation by hemodynamic measurements and cardiac MRI

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To assess procedural hemodynamic indices of paravalvular leakage and to relate these to cardiac MRI at 1 month and clinical follow-up over 5 years.To diagnose angiodysplasia en determine the effect of TAVI on these angiodysplastic lesions.

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

Summary

ID

NL-OMON50145

Source
ToetsingOnline

Brief title
Appose trial

Condition

- Cardiac valve disorders
- Gastrointestinal vascular conditions

Synonym
Aortic Valve Stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hemodynamic measurements, MRI, Paravalvular leak, Transcatheter Aortic Valve Implantation

Outcome measures

Primary outcome

The primary endpoint is defined as PVL regurgitation fraction as measured by

cardiac MRI.

Secondary outcome

The secondary endpoint will comprise a composite of device success, early

safety and clinical efficacy as defined by the Valve Academic Research

Consortium-2 (VARC-2)(1) and will comprise death, vascular complications,

stroke/ TIA, life threatening bleeding requiring transfusion, and acute kidney

injury requiring dialysis.

Other secondary endpoint is the effect of TAVI on angiodysplasia. The effect is

expressed in difference between hemoglobin level before TAVI and 6 months after

TAVI. The difference between blood transfusion and/or iron infusion

requirements before and 6 months after TAVI will also be determined.

Study description

Background summary

During a TAVI, a new heart valve is placed in the native (calcified) heart valve. Hereby the old valve blades are pushed aside by the new valve. It is possible that the edges of the new heart valve do not fit nicely with the edges of the native valve. This can cause leakage from the aorta (the large body artery) to the left heart chamber. It is known that a serious leakage can have a negative influence on the prognosis in the longer term. When an important leak is seen, the placed valve can be pressed with a balloon so that it better fits the surrounding tissue and the leak can be reduced.

The extent of PVL is currently determined during a TAVI by echocardiography. However, it has been found that this often underestimates the extent of PVL and is poorly reproducible. With a MRI (Magnetic Resonance Imaging) scan the amount of PVL can be determined in a reliable and reproducible manner. However, making an MRI scan takes some time, which means that echocardiography remains the standard during TAVI.

During the TAVI procedure, standard pressures in the heart and the large body artery (aorta) are also measured. With these pressures, particular attention is paid to the pressures needed for the left heart chamber to get the blood into the aorta. However, there are also indications that the degree of PVL could be derived from these pressures. To be able to investigate this, the blood pressure measurements will be compared to the amount of PVL as measured by means of MRI.

In patients with severe aortic stenosis, anemia is common. The anemia is most frequently caused by angiodysplasia. Angiodysplasia are vascular anomalies in the gastrointestinal tract, which tend to bleed easily. This can lead to blood loss from the gastrointestinal tract, which can cause anemia. Symptoms can be paleness and tiredness. In case of coexistence of angiodysplasia and aortic stenosis, this is called Heyde syndrome.

Little is known about Heyde syndrome. Therefore, it is still unknown what the best treatment is. Previous studies showed a beneficial effect of the TAVI procedure on angiodysplasia. However, the duration of this beneficial effect is unknown. To enhance our knowledge about Heyde syndrome, we want to perform a videocapsule endoscopy (VCE). This capsule moves throughout the gastrointestinal tract and visualises the mucosal layer. The VCE will be excreted by the body in a natural way.

Study objective

To assess procedural hemodynamic indices of paravalvular leakage and to relate these to cardiac MRI at 1 month and clinical follow-up over 5 years.

To diagnose angiodysplasia en determine the effect of TAVI on these angiodysplastic lesions.

Study design

This is a prospective, single center clinical trial. Patients will receive a TAVI. After implantation different hemodynamic indices of PVL will be assessed. Within 4-8 weeks after TAVI, a cardiac MRI will be performed to quantify the amount of PVL. Standardized clinical follow-up will take place at discharge, 30 days, 3 months, 6 months and yearly up to 5 years.
The 3- and 6-months visits will only consist of lab analysis.

Patients participating in the substudy 'Heyde syndrome' will undergo a videocapsule endoscopy (VCE) in the period before TAVI.
The VCE will be repeated 6 months after TAVI.

Study burden and risks

The hemodynamic indices can be assessed in a standard fashion using a fluid filled pigtail catheter that is placed in the left ventricle as part of the routine protocol. Following TAVI, enrolled patients will undergo cardiac MRI to assess PVL. The risk of cardiac MRI after TAVI implantation is negligible. Extra blood samples will be taken. After one year, patients will be followed by telephonic follow- up. Risk/benefit: The expected benefit is a structured clinical follow-up at 1,2,3,4 and 5 years, at the cost of an extra visit to undergo cardiac MRI.

Videocapule endoscopy (VCE) is a frequently performed diagnostic procedure. The risk of complications is low. This is described in detail in the 'PIF'.

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

1. Patients must be >18 years old.
2. Written informed consent is obtained from all patients.
3. Severe aortic valve stenosis is defined as: jet velocity greater than 4.0m/s or Doppler Velocity index <0.25 or an initial aortic valve area (AVA) of <= 1.0cm² (indexed EOA<=06cm²/m²) as measured by trans thoracic echocardiography <6months prior to inclusion
4. Patients have symptomatic aortic stenosis, as demonstrated by NYHA functional class 2 or greater or other symptoms of aortic stenosis (e.g. syncope or angina in the absence of coronary artery disease).
5. Surgical risk is deemed high or intermediate by STS score or by documented Heart-team agreement due to frailty or co-morbidities.
6. The aortic annulus diameter as measured by ECG-triggered CT-scanning < 6months prior to inclusion meets the ranges indicated in the instructions for use
7. The access artery diameters (femoral or subclavian) as measured by CT-scanning < 6 months prior to inclusion meet the ranges indicated in the instruction for use
8. There are no contra-indications for and patient is willing to undergo cardiac MRI at discharge to 30 days after TAVI.

Exclusion criteria

1. Patient is unwilling or unable to comply with study-required follow-up evaluations
2. There is evidence of a myocardial infarction within 30 days to index procedure
3. The presence of severe mitral regurgitation or stenosis

4. The presence of pre-existing prosthetic cardiac device, valve or prosthetic ring in any position
5. Left ventricular ejection fraction (LVEF) less than 30%
6. Untreated significant coronary artery disease requiring revascularization
7. Echocardiographic evidence of intra-cardiac mass, thrombus or vegetation suggesting active endocarditis
8. The patient is hemodynamically unstable, requiring inotropic or vasopressive and / or mechanical support
9. The presence of pulmonary edema or intra venous diuretics to stabilize heart failure at index procedure
10. Renal insufficiency, defined as a serum creatinin greater than 250umol/l or end-stage renal disease requiring dialysis
11. Morbid obesity, defined as a BMI >=40
12. A life expectancy of less than one year.

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):	02-10-2019
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	18-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70413.091.19