INVAsive, ultraSOUND and MRI assessment of transvalvular gradients after transcatheter aortic valve implantation

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

Summary

ID

NL-OMON56835

Source
ToetsingOnline

Brief title
INVA-SOUND-MRI

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
bioprosthetic heart valve, TAVI

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: De MRI's worden vergoed uit in-kind radiologie en onderwijs.

Intervention

Keyword: Echocardiography, Invasive, MRI, TAVI (Transcatheter Aortic Valve Implantation)

Outcome measures

Primary outcome

The primary study endpoint is the transprosthetic aortic gradient by 4D flow

MRI.

Secondary outcome

Echocardiography derived:

• Mean aortic pressure gradient (PG) (mmHg)

• Peak aortic pressure gradient (PG) (mmHg)

• Peak aortic velocity (m/s)

Invasive:

• Mean aortic pressure gradient (PG) (mmHg)

• Peak aortic pressure gradient (PG) (mmHg)

• Peak aortic velocity (m/s)

4D Flow MRI derived:

• Peak aortic pressure gradient (PG) (mmHg)

• Peak aortic velocity (m/s)

• Wall shear stress (Pa)

• Energy loss (mW)

• Flow eccentricity

• LV ejection fraction (%)

• LV enddiastolic volume (ml)

• LV endsystolic volume (ml)

• LV stroke volume (ml)

• Ascending aortic diameter (mm)

For all included patients, baseline (medical) details will also be obtained from patient records including age, sex, body mass index (BMI), relevant medical history (including chronic obstructive pulmonary disease, asthma, kidney failure, any previous malignancy, hypertension, diabetes mellitus, hypercholesterolemia, cerebrovascular accident or transient ischemic attack, any pre-existing supraventricular or ventricular rhythm disturbances, assessment of valvulopathy, myocardial infarction or coronary artery bypass graft and NYHA class of functional impairment. Kidney (dys)function prior to the intervention will be graded according to the 2005 KDIGO guidelines.

Results of routine laboratory testing prior to the scheduled intervention will be evaluated for all patients, including haemoglobin (mmol L-1), creatinine level (µmol L-1), estimated glomerular filtration rate (e-GFR, ml min-1), high sensitive troponin-T (ng L-1), C-reactive protein (CRP, mg L-1) and leucocyte count (109 L-1).

Study description

Background summary

There is renewed interest in the evaluation of hemodynamic transcatheter aortic valve performance with different imaging modalities. Recent studies suggest that there is a discrepancy in transaortic pressure recordings between invasive and ultrasound techniques. Notably, these discrepancies seem more pronounced with balloon expandable than self-expanding supra-annular functioning transcatheter aortic heart valves. The impact of the pressure recovery phenomenon and intrinsic limitations of the ultrasound derived continuity equation may explain these differences but the scientific underpinning is limited. 4D flow Magnetic Resonance Imaging (MRI) can visualize blood flow patterns and can be used to further elucidate these differences.

Study objective

The INVA-SOUND-MRI (INVAsive, ultraSOUND and MRI assessment of transvalvular gradients after transcatheter aortic valve implantation) study aims to elucidate:

1) The accuracy of transaortic gradient assessment with different modalities (invasive, echocardiography). By comparing invasive and echo gradients to 4D flow MRI-derived gradients, this may enhance the understanding of heart valve performance after transcatheter aortic valve implantation (TAVI); 2) Different patterns of transaortic pressure gradient recordings after TAVI with different commercially available transcatheter heart valve platforms.

The primary objective of this study is to measure the transprosthetic aortic gradient by 4D flow MRI after TAVI with a balloon expandable or self-expanding transcatheter heart valve. These gradient measurements will then be compared to both invasive and echocardiography-derived transvalvular gradient (these are secondary objectives).

Study design

This study concerns a single-center, prospective, observational study which will be conducted by the department of Cardiology and department of Radiology and Nuclear Medicine. The primary objective of this study is to measure the transprosthetic aortic gradient by 4D flow MRI in patients who recently received a TAVI using either a balloon expandable or self-expanding transcatheter heart valve. These gradient measurements will then be compared to both invasive and echocardiography-derived transvalvular gradients. In addition to comparing the gradient with different modalities (MRI, invasive, ultrasound) within the same patient, the above parameters are also compared between 2 groups: the patients with balloon expandable versus the patients with self-expanding transcatheter heart valve. Both groups will consist of 32 patients. After the MRI scan, there is no further follow-up as part of the

study. Acquisition of echocardiography-derived and invasive hemodynamic measurements are standard clinical practice.

Intervention

The intervention involves a 4D flow MRI scan in which intravenous gadolinium contrast is administered (0.2 mmol/kg).

Study burden and risks

Participating in the INVA-SOUND-MRI study does not offer any benefit to the included patient. The risks and burden directly attributable to study participation are considered low. Potential complications are directly attributable to the MRI examination and gadolinium based contrast admission. All invasive measurements during TAVI procedure as well as transthoracic echocardiography exams are considered standard of care.

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

- Adult patient (>18 years)
- Post TAVI procedure
- Successful TAVI with no unresolved procedure related complications (VARC-3 definition)
o Successful access, delivery of the device, and retrieval of the delivery system
o Correct positioning of a single prosthetic heart valve into the proper anatomical location
o Freedom from surgery or intervention related to the device or to a major vascular or access-related, or cardiac structural complication

Exclusion criteria

- Age < 18 years
- Atrial fibrillation or atrial flutter or frequent extrasystole limiting the quality of the cardiac MRI
- ICD or (temporary) pacemaker in situ
- Valve in valve procedure
- Claustrophobia
- Kidney injury (eGFR <30 mL/min per 1.73 m2)
- Gadolinium based contrast allergy
- No (written) informed consent was obtained

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	64
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-06-2024
Application type:	First submission
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	NL86024.078.24