Stress Aortic Valve Index for normal aortic valves

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The primary objective is to obtain data of invasively measured SAVI in patients with a normal aortic valves undergoing routine, clinically indicated, invasive cardiac catheterization..The secondary objective(s) is/are to investigate the correlation...

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

Summary

ID

NL-OMON54218

Source
ToetsingOnline

Brief title
SAVI-NORM

Condition

- Cardiac valve disorders

Synonym
narrowed aortic valves

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: TopZorg subsidie

Intervention

Keyword: aortic valve, stress aortic valve index

Outcome measures

Primary outcome

The primary outcome will be purely descriptive and will include the calculation of mean, median, range values of the invasively measured SAVI.

Secondary outcome

Correlation will be quantified by determining Peason's correlation coefficient between the different parameters of interest when comparing SAVI physiology and methodology (invasive versus non-invasive, with or without dobutamine). Agreement will be assessed by performing a Bland-Altman analysis. We anticipate that a two-dimensional scatterplot of SAVI (Ao/LV during dobutamine) versus Ao/LV at baseline will show a large and unpredictable heterogeneity of response, as we have already demonstrated for severe and low-gradient aortic stenosis.

Study description

Background summary

Aortic valve physiology is in first instance assessed at rest by a standard transthoracic echocardiogram (TTE). During this assessment the maximal aortic valve velocity (AOV max), mean aortic gradient (MAG), and aortic valve area (AVA) are quantified to grade the presence of aortic valve stenosis (AS). Additionally an indexed AVA (cm2/m2) and velocity ratio (dimensionless index) can be used to adjudicate the severity further. In European and American guidelines the severity of any aortic valve stenosis is typically categorized as none, mild, moderate, or severe. When in doubt of the severity of an aortic stenosis, in particular cases, physicians can consider valvular stress testing using exercise or dobutamine. However, all other measurements are performed at

rest, although patients generally complain of symptoms during exertion. Therefore, the hypothesis has arisen that valvular stress testing might have value beyond current guideline recommendations.

Our AoS-STRESS study already showed that a resting assessment of a stenotic aortic valve could not predict its severity during stress conditions. It also showed that AVA does not provide a valid physiological description of hemodynamics since few valves display a quadratic pressure loss versus flow profile. The limitations of AVA to grade the stenosis of AS or exclude the presence of severe AS have also emerged in other, independent studies, indicating the need for a new metric to quantify stenosis severity. We already designed and validated a new tool to differentiate between AS severity in patients undergoing transcatheter aortic valve implantation (TAVI). This metric, the Stress Aortic Valve Index (SAVI), corresponded better to peak transvalvular flow than resting measurements and gave a better understanding of valve severity during stress conditions. Based on prior work, we reclassified 39% of valves in patients with low-gradient AS. At the moment we are conducting another study (SAVI-AoS) to reclassify the severity of AS in patients with unexplained symptoms and moderate AS, who based on their resting valve quantification not are eligible for any form of intervention.

The goal of the current study is to measure the numeric distribution of SAVI (invasive versus non-invasive) in patients with relatively normal aortic valves. Based on earlier work SAVI <= 0.70 indicates severe AS. Our hypothesis is that SAVI will correlate with classic echocardiographic measures of valve severity and reach values near 1.0 when these traditional metrics are completely normal. We have already validated (or are validating) SAVI in patients with severe AS undergoing TAVI, in patients with moderate symptomatic AS, in patients with normal and reduced left ventricular ejection fraction (LVEF).

Study objective

The primary objective is to obtain data of invasively measured SAVI in patients with a normal aortic valves undergoing routine, clinically indicated, invasive cardiac catheterization..
The secondary objective(s) is/are to investigate the correlation and potential agreement between the SAVI and standard echocardiographic metrics (MAG, AOV max, and AVA).

Study design

This study will enroll an observational cohort of patients undergoing routine cardiac catheterization. The indication for the cardiac catheterization will be determined by the patient*s cardiologist and potential subjects will be identified by local investigators through screening of healthcare databases and

lists for invasive cardiac catheterization. If a potential subject is identified (for example, a patient with an intermediate coronary stenosis on non-invasive referred for invasive study and potential treatment), than he or she will be invited to join the study after review of inclusion/exclusion criteria and providing informed consent as approved by each local MEC/IRB. After informed consent has been given, visits will be planned for the catheterization with invasive SAVI measurements. Stress echocardiography could be performed during this procedure as well. The clinical catheterization will contain additional research SAVI measurements that have been investigated in two previous studies and are safe to use.

Study burden and risks

- adverse events to dobutamine
- standard risk of a cardiac catheterization

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

- Age >= 18 years
- No important aortic stenosis (AVA > 1.5 cm2, MAG < 20 mmHg, AOV max <= 2.5 m/s) (note: high flow, high gradient is permitted if dimensionless index is normal)
- Normal LVEF (>= 50%)
- Ability to undergo (exercise) stress testing
- Ability to understand and the willingness to provide written informed consent

Exclusion criteria

- Any hemodynamic criterion for moderate or greater AS
- Known, unrevascularized, and severe coronary artery disease (for example a 90% diameter stenosis or FFR<0.7 in the proximal left anterior descending artery) (note: concurrent coronary artery percutaneous coronary intervention is permitted)
- Impaired left ventricular function (ejection fraction <50%)
- Unicuspid and bicuspid observed during echocardiography (note that later cusp fusion noted during study-related cardiac imaging will not exclude a subject)
- Severe aortic regurgitation, mitral valve disease, tricuspid regurgitation, or a significant intracardiac shunt
- Co-existing hypertrophic cardiomyopathy or severe septal hypertrophy >15mm
- Persistent atrial fibrillation with uncontrolled ventricular response
- Recent (within 6 weeks) acute coronary syndrome
- Estimated glomerular filtration rate <=30 mL/min or end-stage renal disease on replacement therapy (dialysis)
- Severe COPD GOLD stage 3 or 4, home oxygen dependence, or >=2 pulmonary inhalers (note that well-treated and stable asthma and GOLD stage 1 or 2 COPD is permitted)
- Severe comorbid condition with life expectancy <2 years
- Prior adverse reaction to dobutamine
- Severe iodine contrast allergy (note: well treatable contrast allergy is permitted)
- Pregnancy
- Severe pulmonary hypertension with systolic pulmonary artery pressure greater than 50mmHg or isolated and symptomatic right ventricular failure

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):	11-01-2022
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	20-10-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	25-04-2023
Application type:	Amendment
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	NL78962.100.21