Calibration of time-densitometry for the quantification of aortic regurgitation

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Primary objective: To validate the quantification of AR by time-densitometry on contrast aortography with the gold standard of CMRI measurements in order to refine the interpretation and evaluate the accuracy of the qRA method. Secondary objective:...

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

Summary

ID

NL-OMON41724

Source
ToetsingOnline

Brief title
IQ-AR

Condition

- Cardiac valve disorders

Synonym
aortic valve insufficieny, aortic valve leak, aortic valve regurgitation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: aortic valve, aortography, MRI, regurgitation

Outcome measures

Primary outcome

1. Regurgitant volume and regurgitant fraction measured by velocity encoded MRI

2. qRA-index measured on aortography

Secondary outcome

1. Semi-quantitative TTE measurements

a. in patients without TAVI or pre-TAVI:

i. Vena contracta (VC) width (mm)

ii. Pressure half-time (PHT) (ms)

b. only in case of TAVI: Post-TAVI:

i. Circumferential extent of prosthetic valve paravalvular regurgitation

ii. Diastolic flow reversal in the descending aorta

2. Quantitative TTE(pre-) / TOE (post) measurements (only in case of TAVI: pre- and post-TAVI)

a. Effective regurgitant orifice area (EROA) (mm2)

b. Regurgitant Volume (RV) (ml)

3. Sinning index / (AR-index) calculated from haemodynamic pressure measurements

Study description

Background summary

Aortic regurgitation (AR) is common after Transcatheter Aortic Valve Implantation (TAVI) and is associated with increased mortality in the first year after the implantation procedure. In the catheter laboratory contrast aortography (CA) is always performed at the end of each TAVI procedure to evaluate prosthesis position and evaluate procedural success including quantifying paraprosthetic regurgitation if present. Yet the grading of AR on contrast aortography, which was described by Sellers in 1964, is semi-quantitative, based on visual interpretation and therefore open to interpretation. Studies that have calculated native valve aortic regurgitant volumes and fraction based on ventriculography and the indicator dilution technique demonstrated a wide scatter of regurgitant volumes within each visually graded category and also substantial overlap between categories. These studies were done before the widespread use of echocardiography and may have contributed to the ascension of echocardiography for the evaluation of native valve AR. Transoesophageal echocardiography (TEE) is now routine practice during TAVI procedures to ensure optimal valve position and absence of clinically important valve regurgitation. Transthoracic echocardiography (TTE) is preferred for routine clinical follow-up of AR in TAVI patients and in patients with native aortic valve disease.

Yet current guidelines recognize that the quantification of paravalvular AR after TAVI by echocardiography can be problematic for several reasons: There may be multiple regurgitant jets, regurgitation jets may follow a circuitous course around the TAVI prosthesis, dense metal causes acoustic signal attenuation, the regurgitant jets frequently are too eccentric to be aligned with the Doppler beam and it is often not possible to locate the vena contracta. On the other hand carefully performed contrast aortography may in principle overcome several of the above-mentioned difficulties encountered with echocardiography, provided that objective measurement rather than subjective visual scoring of AR were possible.

Computer assisted measurement of radiographic contrast density changes over time allows objective quantification of myocardial blush grade on coronary angiograms. Similar principles may be applied to the evaluation of AR. Recently, a prototype software system was developed (CAAS qRA, Pie Medical Imaging, Maastricht, The Netherlands) based on time-densitometry to measure AR based on the area under the contrast time-density curves (RAUC) in the aortic root and the left ventricle (LV).

In order to understand how to interpret the RAUC and other measurements obtained from contrast aortography time density curve analysis a comparison

with a golden standard volumetric method, i.e. cardiac Magnetic Resonance Imaging (CMRI), is needed. CMRI is able to overcome several of the obstacles discussed above and allows quantification of regurgitant volumes and fraction with a high level of reproducibility. Yet CMRI carries a financial, logistical and time cost and, more importantly, is not available on-site in the catheter laboratory where TAVI is performed. Therefore it is attractive to validate the measurements obtained from time-densitometry of aortograms with CMRI.

Study objective

Primary objective:
To validate the quantification of AR by time-densitometry on contrast aortography with the gold standard of CMRI measurements in order to refine the interpretation and evaluate the accuracy of the qRA method.

Secondary objective:
To validate the quantification of AR by time-densitometry on contrast aortography with echocardiographic measures of AR.

Study design

A pilot study validating the measurement of AR by time-densitometry analysis (qRA) on contrast aortography compared to the gold standard of CMRI.

Multicenter study, recruitment of 15 - 20 patients from each of 3 - 4 sites.

A follow-up study on a larger patient population will be initiated only if the agreement between the investigational method (qRA) is considered to be superior to echocardiography, i.e. :
(1) The average difference in regurgitant volume and fraction measured by velocity encoded MRI and qRA on aortography is less than 10%.
and
(2) The average difference in regurgitant volume and fraction between CMRI and echocardiographic measured AR is higher than (1).

Study burden and risks

Patients undergo following burden / risk:

Aortography: Extra 30ml of contrast injected. Small extra chance of renal toxicity or iodine contrast allergy.
CMRI: procedure can cause a claustrophobic reaction or allergic reaction to gadolinium (MRI contrast).

All subjects will already undergoing invasive evaluation and / or treatment for coronary artery disease, which is not different from the current standard

cardiological practice and the guidelines of the ACC / AHA / ESC. The only difference is that a aortography is carried out. The additional risk associated with the aortography is minimal.
The cardiac MRI (CMRI) is an additional investigation outside the normal standard diagnostic setting. The additional risk associated with this CMRI is estimated as minimal.

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 aged >18y
2. At least mild (grade 1 or more) aortic regurgitation (AR) on contrast aortography or echocardiography
3. Per protocol Contrast aortography

4. Contrast aortography meets all the image quality criteria that allows quantification of AR by qRA
5. Cardiac MRI (CMRI) can be performed within 1 week of aortography
6. Written informed consent

Exclusion criteria

1. Advanced renal impairment that precludes contrast aortography (eGFR<30ml/min)
2. Contra-indication to cardiac MRI
3. Contrast aortography has been performed but does not meet quality criteria
4. CMRI not performed within 1 week of contrast aortography
5. Allergy to radiological iodine- or gadolinium-based contrast agents

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):	01-01-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-06-2015
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	NL50942.078.14