Association between electrocardiographic strain, angina, and systolic longitudinal left ventricular (LV) function in patients with severe aortic valve stenosis (AS).

Gepubliceerd: 13-09-2012 Laatst bijgewerkt: 18-08-2022

The optimal timing of aortic valve replacement in patients with severe AS to prevent sudden death, is controversial (reference 1,2). Subendocardial ischemia is a known risk factor for sudden death (3,4). Electrocardiographic ST-segment depression,...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26907

Bron
Nationaal Trial Register

Verkorte titel
Association study AS

Aandoening

diagnostic research, retrospective, aortic stenosis

Ondersteuning

Primaire sponsor: Erasmus MC
Dept. cardio-thoracic Surgery
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the potential association between electrocardiographic stain, angina, and systolic left ventricular longitudinal function.

Toelichting onderzoek

Achtergrond van het onderzoek

Objectives:

To assess the potential association between electrocardiographic stain, angina, and systolic left ventricular longitudinal function.

Background:

The optimal timing of aortic valve replacement in patients with severe AS to prevent sudden death, is controversial (reference 1,2). Subendocardial ischemia is a known risk factor for sudden death (3,4). Electrocardiographic ST-segment depression, so called strain pattern, is thought to reflect subendocardiale ischemia; particularly in patients without coronary artery disease and left ventricular conduction abnormalities (5-7). Therefore, some have advocated the use of strain pattern in the timing of AVR (8). However, the exact association between electrocardiographic strain and subendocardiale ischemia remains unclear.

Methods & Statistics:

Study population consist of consecutive patients who were diagnosed with severe AS, defined by an aortic valve area ≤ 1.0 cm2 or a peak aortic velocity ≥ 4.0 m/s, in the wider Rotterdam area between 2003 and 2009, and were aged ≥ 18 years, were in sinus rhythm, had a LV ejection fraction ≥50% without known coronary artery disease or left bundle branch block. Patient selection is retrospective through 1) the echocardiographic departmental database of the Cardiology Department of the Erasmus University Medical Center or 2) the AVARIJN study database (MEC-2006-066) which consisted of patients with severe AS diagnosed in 7 hospitals (but single center coordinated) in the Rotterdam area (the main aim of the AVARIJN study was to gain more insight in the number of patients with AS, the (timing of) treatment,

and their life course).
Retrospective assessment of electrocardiography and echocardiography will be performed according to the current clinical guidelines by the supervising cardiologist and principal investigator. Extracting data about medical history of the patients from the hospital medical records and the AVARIJN study database will be done by the principal investigator. Continuous variables are expressed as median with interquartile ranges (IQR) and categorical variables are presented as proportions. The Kolmogorov-Smirnov test with Lilliefors correction is used for testing normality of the distribution of continuous variables. Variables are compared using the Mann-Whitney test for two categories or a Kruskal-Wallis test for multiple groups.

Univariate linear regression analysis is used to assess the association between relevant variables and systolic longitudinal LV shortening parameters. Significant variables from the univariate regression model are selected and entered into a multivariable linear regression model using the enter method. All tests were two sided with an significance-level of 0.05. Statistical analysis was performed using Statistical Package for Social Sciences 17.0 for Windows (SPSS, Chicago, IL, USA).

Time schedule:

Overall 5 month time schedule, 1 month for collecting data from the hospital records; 2 month for analysis of the data; 2 month for writing and submitting.

Administrative aspects and publication
Confidentiality & Handling and storage of data and documents.

Each patient will be assigned a study number known only by the investigator. Using these coded study numbers, data will be stored using Microsoft Excel and SAS. Data will be stored on an Erasmus MC personal computer and a back-up is made on a secured mobile memory stick. Stored data regarding patients and personnel included in this study can only be accessed by the investigators, the Erasmus MC ethics committee and any person or agency required by law like the “Inspectie voor de Gezondheidszorg”. All data will be treated according to the “Wet Bescherming Persoonsgegevens” and the Erasmus MC privacy regulations. Any information from this study, if published in scientific journals or presented at scientific meetings, will not reveal patient identity. Data will be stored for a maximum of 15 years after ending the study. Collected data will be secured against unauthorised access and will be stored and secured by the department of Cardio-Thoracic Surgery.

Doel van het onderzoek

The optimal timing of aortic valve replacement in patients with severe AS to prevent sudden death, is controversial (reference 1,2). Subendocardial ischemia is a known risk factor for sudden death (3,4). Electrocardiographic ST-segment depression, so called strain pattern, is

thought to reflect subendocardiale ischemia; particularly in patients without coronary artery disease and left ventricular conduction abnormalities (5-7). Therefore, some have advocated the use of strain pattern in the timing of AVR (8). However, the exact association between electrocardiographic strain and subendocardiale ischemia remains unclear.

Onderzoeksopzet

Overall 5 month time schedule:

1. 1 month for collecting data from the hospital records;

2. 2 month for analysis of the data;

3. 2 month for writing and submitting.

Onderzoeksproduct en/of interventie

None, retrospective.

Study population consist of consecutive patients who were diagnosed with severe AS, defined by an aortic valve area ≤ 1.0 cm2 or a peak aortic velocity ≥ 4.0 m/s, in the wider Rotterdam area between 2003 and 2009, and were aged ≥ 18 years, were in sinus rhythm, had a LV ejection fraction ≥50% without known coronary artery disease or left bundle branch block.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients > = 18 years;

2. Severe AS;

3. Sinus rhythm;

4. LVE fraction > 50%;

5. Absence of coronary artery disease;

6. Absence of left bundle branch block.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients without severe AS;

2. Aged < 18 years;

3. Absence of sinus rhythm;

4. LV ejection fraction <50%;

5. Presence of coronary artery disease;

6. Presence of left bundle branch block.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-09-2012
Aantal proefpersonen:	122
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3460
NTR-old	NTR3612
Ander register	MEC ErasmusMC : 2012-402
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A