

Feasibility and variability of 2D Speckle Tracking Imaging for measuring left ventricular twist and untwisting on healthy subjects and congenital aortic valve stenosis patients

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Speckle Tracking Imaging is a relatively new echocardiographic technique to quantify the left ventricular twist and untwisting movement. Several populations like healthy adults and patients with hypertension, myocardial infarction or valvular...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32426

Source

ToetsingOnline

Brief title

2DSTILV

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym

Congenital valvular aortic stenosis;

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Congenital valvular aortic stenosis, Left Ventricle Twist, Left Ventricle Untwisting, Speckle Tracking Imaging

Outcome measures

Primary outcome

Peak systolic twist (degree per cm)

Time to peak systolic twist (msec)

Peak negative twist velocity (degree per second)

Time to peak negative twist velocity (msec)

% Untwisting at 20% of diastole (%)

Secondary outcome

Interobserver variability

Intraobserver variability

Study description

Background summary

Young adults with congenital valvular aortic stenosis have a diminished prognosis compared to age-matched healthy subjects despite optimal medical therapy, follow-up by a specialistic and dedicated team and even despite an aortic valve replacement. The cause of this difference in prognosis is not well understood. One explanation is the occurrence of heart failure which often develops at middle age and apparently is not avoided by intervention like aortic valve replacement. Possibly intervention is too long postponed because current diagnostic tests like 2D echocardiography do not show the need for early intervention, because subtle changes in myocardial dysfunction as marker

for future heart failure is missed.

Study objective

Speckle Tracking Imaging is a relatively new echocardiographic technique to quantify the left ventricular twist and untwisting movement. Several populations like healthy adults and patients with hypertension, myocardial infarction or valvular disease have been studied and data seem promising. It is not clear whether congenital valvular aortic stenosis can be studied the same way. If possible, inter- and intraobserver variability and the relationship between conventional and Speckle Tracking Imaging parameters in relation with degree of valvular stenosis have to be explored.

Study design

50 healthy volunteers (no stenosis) and 25 patients with congenital valvular aortic stenosis (mild and moderate to severe stenosis) will be compared. Both groups will be investigated by a conventional 2D echocardiographic examination followed by additional imaging suitable for offline analysis with dedicated software to determine left ventricular twist and untwisting by Speckle Tracking Imaging. No invasive measurements will be performed. No blood samples will be taken. No echo contrast agent will be used. The total examination time will last 30 minutes.

Study burden and risks

Not applicable

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 and < 40 years old

Congenital aortic valve stenosis with AVA <1.0 cm², 1.0-1.5 cm² or 1.5-2.0 cm²

LVEF >= 55%

Exclusion criteria

LVEF < 55%

Non-valvular aortic stenosis

Hypertrophic Obstructive CardioMyopathy

Residual coarctation aorta

Moderate or severe aortic regurgitation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-10-2009
Enrollment: 75
Type: Actual

Ethics review

Approved WMO
Date: 09-02-2009
Application type: First submission
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	NL24818.091.08