Aortic root changes after percutaneous atrial septal defect closure; Insights towards understanding the mechanism and predictors of device erosion and aortic valve dysfunction.

Published: 25-10-2016
Last updated: 16-04-2024

The primary objective is to investigate the determinants of aortic root deformation occurring >= 3 months after successful ASO implantation in adult patients with an atrial septal defect.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON43366

Source
ToetsingOnline

Brief title
ARCADE

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Cardiac therapeutic procedures

Synonym
Slight damage to intracardial structures adjacent to the closure device

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial septal defect, Cardiac perforation, Device erosion, Percutaneous device closure

Outcome measures

Primary outcome

• Assessment of the device shape and relation to adjacent atrial/ aortic walls;

o Device size, device/defect ratio, device/ septal ratio

o Aortic-end shape (flare vs. closed)

o Relation to adjacent structures (aorta/atria): non-touch, touch or pressure

• Retrospective assessment of periprocedural echocardiography before device deployment;

o Total septal length(s)/area (3D)

o Septal mobility (redundancy)

o Septal eccentricity/mal-alignment

o Defect size and shape (3D)

o Defect expansibility (dynamicity)

o Adequacy and consistency of rims

• Retrospective assessment of periprocedural echocardiography before and after device deployment;

o Aortic annular diameters (AP, ML) and eccentricity (systolic and diastolic)

o SOV diameters (AP, ML) and eccentricity (systolic and diastolic)

o STJ diameters (AP, ML) (systolic and diastolic)

Secondary outcome

• Aortic valve dimensions and function at long-term follow-up (>= 3 months)

after successful ASO implantation.

o Planimetered AVA (systolic)

o Leaflet *effective height* (systolic)

o Aortic annular motion (STE)

o Aortic regurgitation (CFM; jet width, VC width and area)

Study description

Background summary

Device erosion is a rare fatal complication of percutaneous atrial septal defect (ASD) closure using the Amplatzer Septal Occluder (ASO) and the risk of erosion continues up to years after device implantation. The absolute risk of erosion after ASO implantation has been estimated to range from 0.043% to 0.5%.1-8 Erosion of ASD closure devices has been linked to different (sometimes confusing and/or contradicting) risk factors (principally, deficient aortic/posterior rim). This discrepancy in the number of supposedly susceptible patients and the actual rate of device erosion precludes a simple direct causal relationship. The extent of interaction between the implanted device and the aorta may be described as post-implantation aortic root deformation and may be detected by transoesophageal echocardiography. Post-implantation aortic root deformation by the ASO has been reported to be more likely in those with deficient aortic rim and may be associated with the occurrence of device erosion. Aortic root deformation could, thus, serve as a surrogate risk marker for device erosion and exploring its predictors is more practical than exploring the direct predictors of device erosion.

Study objective

The primary objective is to investigate the determinants of aortic root deformation occurring >= 3 months after successful ASO implantation in adult

patients with an atrial septal defect.

Study design

Observational cohort study. Patients eligible for the study will undergo a single transesophageal echocardiogram (TEE) from which aortic root deformation will be assessed (i.e. by measuring device size/ shape, aortic annular diameters and eccentricity, among others). Patients* baseline echocardiographic parameters will be retrospectively studied for predictors of aortic root deformation (i.e. device/ defect ratio, defect dynamicity and aortic rim among others).

Study burden and risks

No study-specific benefits and risks are anticipated for the subjects in the study population.

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 (> 18 years)
- Secundum atrial septal defect successfully percutaneously closed in the Academic Medical Center using a single/multiple septal occluder.
- Baseline, procedural and echocardiographic (pre- and intra-procedural) data available.

Exclusion criteria

- Contraindications to transesophageal echocardiography (TEE).
- Inability to record a good-quality 3D echocardiographic images.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	25-10-2016

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL57822.018.16