

Effects of Percutaneous MitraClip Implantation On Atrial Septum and Mitral Inflow Patterns During Exercise

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To evaluate the effects of MitraClip implantation on:* mitral inflow patterns during exercise* the atrial septum, moreover the persistence of the iatrogenic atrial septal defect and the consequential risk of right atrial and ventricular dilatation...

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

Summary

ID

NL-OMON37635

Source

ToetsingOnline

Brief title

Exercise echocardiography after MitraClip implantation

Condition

- Cardiac valve disorders

Synonym

mitral stenosis and atrial septal defect; stenosis of mitral valve and defect of the interatrial septum

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Exercise echocardiography, Iatrogenic Atrial Septal Defect, MitraClip, Safety

Outcome measures

Primary outcome

The effect of MitraClip implantation on mitral inflow patterns during exercise and the prevalence of persisting iASD, measured by resting and stress echocardiography.

Secondary outcome

The amount of contrast crossover (bubbles) into the left ventricle, within 3 heartbeats, after visibility of contrast in the right ventricle.

Presence of right atrial or right ventricular dilatation, caused by the increased left to right shunt across the iASD.

Study description

Background summary

Due to the implantation of one or more MitraClips in patients with mitral valve regurgitation (MR), a decrease in mitral valve area (MVA) is created, which has not been shown to result in clinically significant mitral stenosis. However, mitral inflow patterns were only measured in these patients during resting conditions. Mitral inflow patterns were measured during exercise in patients treated by the surgical double-orifice technique of Alfieri and increased significantly during exercise but stayed within the upper reference limits. Therefore, we would like to investigate the effect of MitraClip implantation on mitral inflow patterns after exercise.

Over the last decades, there has been renewed interest in the use of the transseptal (TS) approach during treatment of heart diseases. As the number of TS procedures grows and the diameter of puncture devices increases, there is concern for an increased prevalence of persistent iatrogenic atrial septal defects (iASDs). The iASD has been reported as a complication of TS puncture performed in different types of cardiological procedures. Paradoxical embolism

resulting in a transient ischemic attack (TIA), acquired cyanotic heart disease and right ventricular failure has been reported in patients with an iASD. In a previous study iASD has been shown to persist beyond 9 months in 30% of patients undergoing pulmonary vein isolation⁴. Current studies assessing the incidence of iASDs after TS catheterization suggest that the majority of iASDs close by 6 months. However, these data were largely obtained after TS puncture using 8F sheaths.

The sheath used with MitraClip implantation is one of the largest TS puncture devices, with a diameter of 24F. Until now the persistence and possible risk of an iASD created during MitraClip implantation is not known. Therefore we would like to investigate the prevalence, persistence and risk factors associated with the iASD in MitraClip patients.

Study objective

To evaluate the effects of MitraClip implantation on:

- * mitral inflow patterns during exercise
- * the atrial septum, moreover the persistence of the iatrogenic atrial septal defect and the consequential risk of right atrial and ventricular dilatation and paradoxal embolism.

Study design

In this single center study we would like to include at least 30 patients who underwent MitraClip implantation with placement of one or more clips in our institution between May 2009 and February 2012. As this is an exploratory study, no formal sample size calculation can be made.

Study burden and risks

Participants will have no direct benefit from the study itself, although the echocardiography by high-level investigators may reveal potential valve- or atrial septum related problems which may be corrected at an early stage. The benefit of this study consists of the knowledge the investigators can gain from this study about the effects on mitral inflow patterns and the atrial septum after MitraClip implantation. The possible risks that participants are exposed to are minor; an intravenous cannula is needed for contrast for ASD measurements.

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

Patients who underwent a MitraClip implantation in the Academic Medical Center Amsterdam between May 2009 and February 2012.

Exclusion criteria

Unable to give informed consent.

Unable to undergo an exercise echocardiography.

Inadequate windows on echocardiography.

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): 26-01-2012

Enrollment: 30

Type: Actual

Ethics review

Approved WMO

Date: 17-01-2012

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	NL39025.018.11