The role of left atrial fibrosis in mitral valve repair surgery

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To assess the effects of (reduced) volume overload on the left atrial wall texture (presence, amount and location of atrial fibrosis) and associated geometry and function in patients with MVI, prior to and after elective mitral valve repair surgery...

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

Summary

ID

NL-OMON50111

Source
ToetsingOnline

Brief title
The role of LA fibrosis in MVP surgery

Condition

- Cardiac valve disorders

Synonym
Mitral valve insufficiency, mitral valve regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D CMR, 4D Flow, Left Atrial Fibrosis, Mitral Valve Repair

Outcome measures

Primary outcome

The main study parameters are:

1. Severity of MVI prior to and after surgery (defined as regurgitation volume in ml)

2. Left atrial remodelling prior to and after surgery

3. Presence and distribution patterns of LA fibrosis

4. Blood flow patterns in the left atrium (4D flow)

Secondary outcome

Secondary study parameters are:

-Biomarkers derived from blood samples (NT-proBNP, TNF-β, Angiotensin II, cytokines)

-Heart failure symptoms monitoring derived from questionnaire preoperative and at postoperative follow-up

Study description

Background summary

Patients with mitral valve insufficiency (MVI) frequently suffer from left atrial (LA) remodeling, caused by volume overload and subsequent atrial dilatation.

The associated myocardial stretch and increased wall tension, trigger a cascade of pathways leading to the occurrence of atrial fibrosis as part of the remodeling process. The clinical relevance of this atrial fibrosis, is that its presence is associated with an increased risk of atrial fibrillation (AF),

heart failure (HF), pulmonary hypertension (PH), a reduced quality of life and eventually a shorter life expectancy. In addition, in patients suffering from atrial fibrillation (AF), the presence and amount of LA fibrosis was found to be a strong predictor for ablation efficacy and long-term outcome.

In daily clinical practice, MVI is managed either by medical or surgical therapy. However, since medical therapy is often not sufficient for patients with severe primary MVI, surgical intervention remains the ultimate treatment option for these patients. In general, valve repair is the preferred type of surgery, since it has better clinical results compared to valve replacement. Currently, the indication and timing for valve surgery is mainly based on the severity of MVI and the presence of symptoms and/or severity of left ventricular dysfunction.

For clinical decision making and patient stratification for mitral valve surgery, the presence of atrial fibrosis is currently not taken in account, despite its well-recognized clinical implications.

Detection of atrial fibrosis patterns in patients with severe MVI, however, may be potentially valuable for the indication and timing of mitral valve repair surgery to improve clinical outcomes. Improved insight into atrial fibrosis patterns and changes after mitral valve repair due to reverse remodeling, may help clinicians in their decision and timing for surgery.

Today, quantification of atrial fibrosis can be routinely performed using cardiac magnetic resonance imaging (CMR) techniques and advanced post-processing techniques, offering non-invasive tissue characterization in the thin-walled structures.

Unfortunately, MVI patients suffering from LA remodeling have hardly been studied using these new imaging techniques. Therefore, in this study, we want to combine advanced cardiac MRI and post-processing techniques prior to and after mitral valve repair surgery to gain insight on the clinical role and meaning of atrial fibrosis in this patient population.

In addition, we aim to assess the effects of (reduced) volume overload on atrial wall texture, geometry and function.

It is hypothesized that the atrial fibrosis surface area paradoxically will increase after mitral valve surgery because of global shrinkage of the LA caused by the reversed remodeling process. As a consequence, more frequently atrial fibrosis related events including (paroxysmal) AF, will be observed in these patients.

With this insight, CMR can become clinical valuable for the indication and timing of surgical intervention in these patients. Surgical therapy might be renounced for example when a substantial increase of fibrosis surface is

expected post-surgically causing a higher risk for AF, HF, PH and a reduced quality of life. On the contrary, surgical therapy might be considered in an earlier stage of disease when the fibrosis surface is still acceptable regarding its expected post-surgical development.

Study objective

To assess the effects of (reduced) volume overload on the left atrial wall texture (presence, amount and location of atrial fibrosis) and associated geometry and function in patients with MVI, prior to and after elective mitral valve repair surgery.

Study design

This study is designed as a single center pilot study.

Study subjects that will be included are MVI patients who meet the criteria for mitral valve repair surgery and are on the waiting list for elective surgery. Furthermore, the study subjects are not allowed to meet any exclusion criteria (AF, history of cardiac surgery, comorbidities, MRI contra-indications). These study subjects will be recruited from the Amsterdam UMC surgical waiting list.

The study subjects will visit the AmsterdamUMC hospital (Location VUmc) two weeks prior to mitral valve repair surgery for a CMR scan. This visit will start with checking in- and exclusion criteria using questionnaires regarding medical history and MRI safety. The total duration of the visit - including the CMR scan - will be approximately two hours.

Two weeks later the subjects will undergo the indicated mitral valve repair surgery (Location AMC). During anesthesia, a Swan-Ganz catheter will be used for hemodynamic monitoring. This is all part of standard care and is not influenced by our study.

In the follow-up phase, subjects will visit the AmsterdamUMC hospital (Location VUmc) three months after surgery again for evaluation of the hemodynamic physiology and tissue development (fibrosis).

Study burden and risks

This is an MRI study with use of contrast media (Gadolinium). Gadolinium is a safe contrast agent, which is frequently used in clinical practice. Intravenous gadolinium administration may cause minimal injection site reactions (e.g. pain, cold or burning sensation). As with other contrast-agents, anaphylactic-like reactions can occur. However, due to the design of modern day contrast agents, allergic-type reactions to gadolinium are very rare and unusual. Therefore, there is no associated risk expected for participating

patients

There are no direct benefits for individuals participating to our study.

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

Mitral valve insufficiency patients who meet the criteria for mitral valve repair surgery and are on the waiting list for elective surgery.

Exclusion criteria

Atrial fibrillation,
History of cardiac surgery
Comorbidities
MRI contra-indications (see protocol for specification)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	14-12-2021
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	NL78497.018.21