Is echocardiographic Doppler measurement of mitral inflow and venous pulmonary flow more reliably reflects actual left atrial pressures than PAOP measurements in the presence of impaired myocardial function or myocardial hypertrophy?

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON33638

Source
ToetsingOnline

Brief title
Doppler echocardiographic assesment of left atrial filling pressures

Condition

- Heart failures
- Cardiac therapeutic procedures

Synonym

coronary artery bypass grafting

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiac surgery, echo Doppler echocardiography, left atrial pressure

Outcome measures

Primary outcome

Comparison of left atrium pressure measurement with pulmonary artery occlusion pressure and echo-Doppler derived variables (pulsed wave Doppler of mitral inflow, tissue Doppler imaging of the mitral annulus, pulsed wave Doppler of pulmonary vein flow en colour M-mode of mitral inflow).

Secondary outcome

not applicable

Study description

Background summary

The clinical gold standard for estimation of mean left atrial pressure (LAP) is the pulmonary artery occlusion pressure (PAOP) which is used as an indirect indicator of left ventricular filling pressures. This method requires cannulation of the pulmonary artery and may be associated with the occurrence of adverse events. Several recent studies have demonstrated that LAP can reliably be estimated in a less invasive way using pulsed-wave Doppler echocardiograpy.
Until now research on this subject was performed in groups of patients with good left ventricular function undergoing cardiac surgery. Correct estimation of left ventricular filling pressures is especially important in patients with an impaired left ventricular function. However, to date, there is no evidence

that the use of the Doppler-derived variables for estimation of left ventricular filling pressure is also reliable in the presence of impaired myocardial function or in the presence of myocardial hypertrophy.

Study objective

We hypothesize that also in patients with diminished left ventricular ejection fraction or left ventricular hypertrophy, echocardiographic Doppler measurement of mitral inflow and venous pulmonary flow more reliably reflects actual left atrial pressures than the PAOP measurement.

Study design

The study is designed as a prospective observational study.

Study burden and risks

Induction of anesthesia, monitoring and surgery will be performed according to the institutional protocol.
Measurements will be obtained after pericardiotomy and after insertion of a fluid filled catheter in the left atrium. This canulation site will hereafter be used for canulation of the left ventricular vent according to standard surgical protocol and will be accompanied by a minimal risk of bleeding which imediatelly will be intercepted by the cardiac surgeon.

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

1) Patients scheduled to undergo elective aortic valve replacement due to significant aortic valve stenosis, defined by an aortic valve area of <1 cm^2, and concordingly left ventricular hypertrophy, defined by an interventricular septum thickness > 11 mm on echocardiography.
2) Patients undergoing coronary artery bypass surgery suffering from compromised left ventricular function, defined by a left ventricular ejection fraction of < 45% on preoperative echocardiography
3) written informed consent

Exclusion criteria

Preoperative exclusion criteria include: intracardiac shunts, more than trivial regurge of the mitral valve or tricuspid valve and patients with any degree of mitral valve stenosis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-12-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO 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	NL25344.018.08