The Correlation between Mechanical Alternans measured by Pressure-Volume (PV) Loop catheter and the Occurrence of Microvolt T wave Alternans (MTWA) in Transcatheter Aortic Valve Implantation (TAVI) patients.

Published: 07-01-2013
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The main objective is to investigate mechanical alternans and MTWA in TAVI patients to demonstrate a possible correlation between these two phenomena.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON36934

Source
ToetsingOnline

Brief title
Mechanical and electrical alternans in TAVI patients

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
aortic valve disease, ventricular arrhythmia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Mechanische alternans, MTWA, TAVI

Outcome measures

Primary outcome

Presence or absence of mechanical alternans and MTWA.

Secondary outcome

NA

Study description

Background summary

In patients with severe heart failure and aortic valve disease, mechanical alternans or pulsus alternans (a condition in which there is a beat-to-beat oscillation in the strength of cardiac muscle at a constant heart rate) and electrical alternans is observed. The mechanisms linking mechanical to electrophysiological dysfunction in heart failure are still under investigation, but impaired calcium cycling is the most striking abnormality of failing myocytes, and is most responsible for contractile dysfunction. Yet it remains unclear how this influences susceptibility to arrhythmias. The MTWA is suggested as a risk marker to identify high risk patients for potential VTEs but the underlying mechanism is not completely understood. The aim of this study is to investigate this in a clinical setting by measuring LV parameters using a PV loop conductance catheter and generate TWA recording simultaneously to demonstrate a possible correlation between these two phenomena in patients with TAVI and find out if MTWA could turn into a more valuable risk stratifier. Our hypothesis is that alternating changes in LV filling explain the electrocardiogenesis of TWA by changing the position of the heart relative to the body surface electrodes in an alternating way.

Study objective

The main objective is to investigate mechanical alternans and MTWA in TAVI

patients to demonstrate a possible correlation between these two phenomena.

Study design

Observational study of 50 patients.

Study burden and risks

Positioning the condunctance catheter requires up to maximum 1 minute extra fluoroscopy time. According to the advice of the radiation commitee, this causes minor risk. The high resolution electrodes could cause skin reactions such as irritation and itching. The standard procedure will be extended by 20 minutes maximally.

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 will be included if they are over 18 years and able to give informed consent. Patients are admitted for TAVI.

Exclusion criteria

• Age < 18 years
• Hemodynamically unstable patients

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-01-2013
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	NL41610.018.12