HV Electrophysiology Study In Transcatheter Aortic Valve Implantation Patients

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Primary Objective: 1. To investigate the anatomical location of a TAVI-induced LBBB. Secondary Objectives: 1. To investigate during which phase of the TAVI-procedure the conduction disorder develops.2. To investigate predictors for the occurrence of...

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

Summary

ID

NL-OMON43555

Source
ToetsingOnline

Brief title
HESITATE study

Condition

- Cardiac arrhythmias

Synonym
Cardiac conduction disease, Left Bundle Branch Block

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electrophyiology study, Left Bundle Branch Block (LBBB), Transcatheter Aortic Valve Implantation (TAVI)

Outcome measures

Primary outcome

Occurrence of a new LBBB.

Secondary outcome

-Symptomatic or asymptomatic high degree atrioventricular conduction disorder,

defined as: asystole >5 seconds, second degree Mobitz-II block or third degree

atrioventricular block.

-Pacemaker implantation.

Study description

Background summary

Aortic valve stenosis is the most frequent type of valvular heart disease in Western countries. Although the recommended treatment for severe and symptomatic aortic valve stenosis is surgical valve replacement, the operative risk can be very high in older patients with comorbidities, which impedes the decision to perform surgery. Transcatheter aortic valve implantation (TAVI) has proven to be an elegant alternative for patients with high risk for classic surgical aortic valve replacement.

The TAVI procedure is frequently complicated by the development of a new left bundle branch block (LBBB) with an incidence varying from 7% to 65%, with an average of 28.5%, depending on the type and size of prosthesis being used. The TAVI-induced LBBB, however, is associated with poorer outcome, as there is an increased risk of developing high-degree atrioventricular conduction disorders possibly leading to bradyarrhythmia and death.

Until present, new LBBB has been diagnosed from ECG acquired at the post-procedural department. However, our experience has shown that there is a group of patients who develop a short term LBBB which has disappeared within 60 minutes, which often is before the first ECG post-procedural.

The common belief has been that the *damage* in a LBBB is located in the left bundle branch. However, a LBBB can also be located in the His-bundle, the common bundle preceding the Left and Right Bundle Branch. The left bundle and the His bundle are both located near the location in the outflow tract of the left ventricle where the new valve is placed during the TAVI procedure.

If a TAVI-induced LBBB progression to a high-degree atrioventricular conduction disorder can be predicted, bradyarrhythmic death can be prevented by implantation of a pacemaker. On the other hand also an unnecessary pacemaker implantation could be prevented.

Preliminary electrophysiology studies have shown that in patients with new-LBBB after TAVI, a post-procedural HV interval of * 65ms is predictive of AV block in the follow-up. These studies, however, are retrospectively analysed from prospective acquired data, do not look at the anatomical location of the block, do not take persistency and timing of the new LBBB into consideration and have a limited follow-up.

Elucidation of the anatomical location of the conduction pathology of a LBBB could impact valve design and placement and thereby reduce the number of new LBBB induced by TAVI. Furthermore, finding predictors for progression to a high degree AV block in the follow-up (and thus an indication for permanent pacemaker) could improve management of post-operative conduction abnormalities and prevent the risk of brady-arrhythmic death.

Study objective

Primary Objective:
1. To investigate the anatomical location of a TAVI-induced LBBB.

Secondary Objectives:
1. To investigate during which phase of the TAVI-procedure the conduction disorder develops.
2. To investigate predictors for the occurrence of TAVI-induced LBBB.
3. To investigate predictors for the persistency of the TAVI-induced LBBB.
4. Pilot study for the power calculation of a future study to investigate electrophysiological predictors for progression of new LBBB to a high degree AV-block in the follow-up period (and thus pacemaker indication).

Study design

A prospective, single center, non-randomized pilot study in which patients will undergo an electrophysiology (EP) study during the TAVI procedure.

Study burden and risks

Patients need to undergo one extra femoral vein puncture, in addition to the other standard arterial and venous femoral punctures used with TAVI, to insert a HIS-catheter, a standard electrophysiological catheter to measure the HV-duration during the entire procedure. This procedure carries a very low complication risk limited to local hemorrhage in the groin and will prolong the operation with only a few minutes. There will be no direct benefits for the patients participating in the 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

All patients undergoing a TAVI procedure.

Exclusion criteria

-Pre-existent LBBB
-Pre-existent sick sinus syndrome
-Pre-existing high-degree atrioventricular block
-Pre-existent permanent pacemaker
-Patients unable to provide written informed consent

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):	21-01-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	04-11-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	03-02-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	gaat bij aanvang studie geregistreerd worden
CCMO	NL54488.068.15