Left Bundle Branch Block after Transcatheter Aortic Valve Implantation (TAVI)

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1. to compare the extent of reversal of left ventricular remodelling at 3 months and 1 year after a TAVI procedure between patients with a TAVI-induced LBBB and patients without a LBBB; 2. comparison of strain patterns in TAVI-induced LBBB (as being...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON34321

Source
ToetsingOnline

Brief title
LBBB-TAVI

Condition

- Heart failures

Synonym
conduction disorder of het heart, left bundle branch block

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Stichting Vrienden van het Hart

Intervention

Keyword: dyssynchrony, left bundle branch block, strain, transcatheter aortic valve implantation

Outcome measures

Primary outcome

1. To compare the extent of reversal of left ventricular remodelling at 3 months and 1 year after a TAVI procedure between patients with a TAVI-induced LBBB and TAVI patients without LBBB. Left ventricular remodelling will be defined using echocardiographic parameters (left ventricular endsystolic diameter, left ventricular ejection fraction, left ventricular mass, global longitudinal and circumferential 2D-strain).

2. To evaluate and compare the immediate and long-term effects of a TAVI-induced and non-TAVI-induced LBBB on the ECG, regional and global 2D-strain profile of the left ventricle in a circumferential and longitudinal direction. 2D-Strain will be measured by post-processing of B-mode echocardiographic images (speckle tracking).

Secondary outcome

1. To compare the TAVI-induced LBBB ECG profile and 2D-strain pattern to that of patients with spontaneous LBBB in order to discriminate a proximal from distal LBBB.

2. To correlate the ECG profile and 2D-strain of TAVI-induced LBBB with that of CRT patients with LBBB and indicate whether a dyssynchrony caused by TAVI-induced LBBB is likely to respond to CRT.

3. To evaluate the feasibility of 3D-TOE in guiding placement of the aortic

tissue valve during TAVI procedure

Study description

Background summary

The introduction of the transcatheter aortic valve implantation (TAVI) has proven to be a valuable alternative to surgical valve replacement in the older, co-morbid patient with a high operative mortality risk. However, as a consequence of the properties of the self-expanding stent, there is a high incidence of newly-acquired left bundle branch block (LBBB) after TAVI presumably caused by localised pressure of the stent on the ventricular septum. The clinical consequence of this new-onset LBBB is not known , however in general cardiology it is well appreciated that LBBB is an independent predictor of cardiovascular disease and LBBB has been shown to induce dilatation of the LV cavity and hypertrophy.
Secondly, the TAVI-induced LBBB is a proximal block of which the onset is exactly known. These unique characteristics offer possibilities to study the changes of left ventricular mechanical properties caused by LBBB in time. Although extensively studied in animals, so far it has not been possible to do so in patients with LBBB simply because the onset of the bundle branch block is unknown. This knowledge can contribute to better understanding of LBBB in general and the application of cardiac resynchronization therapy (CRT).
Thirdly, there is evidence that the depth of prosthesis implantation is a risk factor for the development of TAVI-induced LBBB. Three-dimensional transoesophagal echocardiography could be of additional value in defining correct size and guiding placement of the aortic tissue valve.

Study objective

1. to compare the extent of reversal of left ventricular remodelling at 3 months and 1 year after a TAVI procedure between patients with a TAVI-induced LBBB and patients without a LBBB; 2. comparison of strain patterns in TAVI-induced LBBB (as being a clear example of proximal LBBB) with that in a group of CRT patients.

Study design

a single-centre, prospective, nonrandomized study.

Study burden and risks

both the TAVI intervention and the clinical and echocardiographic assessment are part of routine clinical practice concerning the percutaneous aortic valve

replacement. The transesophagal echocardiography is also a standard procedure during TAVI intervention. 3-Dimensional images are additionally recorded without additional burden for the patient. Only the echocardiographic examination performed within 1 week after the TAVI procedure is supplemental. However, this examination will be performed during hospital stay and is in general not considered as a burden by patients.

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 planned/accepted for transcatheter aortic valve implantation

Exclusion criteria

inability to give informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-09-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	02-09-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL33070.060.10