International long-term follow-up study of patients implanted with a PORTICO* valve

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The purpose of this clinical investigation is to further assess the performance and safety profile of the commercially available Portico Valve implanted, using the Delivery System and the Loading System, in patients with severe symptomatic aortic...

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

Summary

ID

NL-OMON43837

Source
ToetsingOnline

Brief title
Portico I

Condition

- Cardiac valve disorders

Synonym
Aorta Stenosis - aorta valve calcification

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St. Jude Medical

Intervention

Keyword: 5 years follow-up, Aorta Stenosis, Heart Valve, Transcatheter

Outcome measures

Primary outcome

The primary endpoint is all-cause mortality at 1 year post implant (according to VARC-2)

Secondary outcome

Evaluation of the VARC-2 defined event rates at 30 days, 1 year and annually through 5 years post implant.

o All-Cause Mortality

o Cardiovascular Mortality

o Myocardial Infarction

o Stroke (disabling and non-disabling)

o New or worsened conduction disturbances and cardiac arrhythmias (including pacemaker implantation rate at 30 days and new-onset atrial fibrillation (AF)

Evaluation of the VARC-2 defined event rates at 30 days from the index procedure.

o Vascular access site complication (major and minor)

o Bleeding (life-threatening, major and minor)

o Acute kidney injury

Prosthetic valve function at 30 days, 1 year and annually through 5 years post implant. (Includes prosthetic valve stenosis and prosthetic valve

regurgitation).

Clinical benefit endpoints at 30 days, 1 year and annually through 5 years post implant (if available)

o NYHA functional classification

o 6 Minute Walk Test (6MWT)

o Quality of life measured with EQ-5D questionnaire through 1 year post-implant

Evaluation of the TAVI-related resource utilization through hospital discharge (e.g. index procedural hospital/physician resources)

Interim reporting at 30 days and 1-year all-cause mortality data may be performed on a subset of patients and compared with an appropriate external comparator. The results will be presented to appropriate agencies in France and in other countries where it will be deemed necessary for reimbursement purposes.

Study description

Background summary

Calcific aortic valve stenosis is a common cardiovascular disease, with an increasing incidence in an aging population. In cases of severe aortic stenosis, patients develop symptoms and functional limitation unavoidably followed by physical deterioration, heart failure and poor prognosis.

For many decades, surgical aortic valve replacement has been an effective treatment improving symptoms and survival, but more than one-third of patients with symptomatic severe aortic stenosis do not undergo surgery because of a

high surgical risk; these patients are not referred, are refused or are declined surgery.

Transcatheter aortic valve implantation (TAVI), first performed in 2002, has permitted the treatment of patients with excessive surgical risk. Since the first TAVI case in 2002, 50.000 transcatheter aortic valve procedures have been performed worldwide comparing favorably with surgery in selected cohorts of patients; TAVI being the only intervention for inoperable aortic stenosis that demonstrated to prolong life in a randomized study. Several studies have also reported symptomatic improvement in the short term and midterm after TAVI. However, nearly 20% of patients experienced no symptomatic improvement highlighting Aortic Regurgitation (AR) as the most frequent complication and one of the main factors affecting symptoms and survival. Although significant transvalvular AR is rare after TAVI, paravalvular regurgitation is more common, mainly due to incomplete annular sealing. Paravalvular leaks may occur due to device undersizing, a mismatch between the prosthesis size and the annulus or incomplete expansion also depending on the anatomical characteristics of the patient*s annulus and ascending aorta. Paravalvular regurgitation can be caused also by a non-optimal implantation site where the device is positioned too high or too low within the valve annulus. While severe paravalvular regurgitation may result in severe hemodynamic consequences, moderate and even mild leaks are associated with less favorable late survival rates than no regurgitation. Although moderate and severe AR after surgical aortic valve replacement or balloon valvuloplasty has only been reported anecdotally, the prevalence of moderate and severe AR after TAVI has ranged from 6% to 21%. Recently, the impact of moderate and severe AR on survival and symptoms after TAVI has been highlighted. Significant AR is a main contributor to in-hospital death and an independent predictor of 1-year mortality and poor treatment response. In the absence of approved therapies, strategies for the prevention of significant AR seem to be warranted. Prevention and treatment of AR are of particular importance because there is an increase in the use of TAVI. Moderate AR ultimately induces a change from Left Ventricle pressure overload to volume overload in a situation where the backward volume increases the already elevated end-diastolic pressure resulting in a considerable proportion of patients having either no symptomatic benefit or dying within the first months.

Regarding valve durability, mid-term reports of commercially available devices up to 5 years are showing a rare occurrence of leaflet failure and in vitro accelerated wear testing is comparable with surgical prostheses. However, more studies and more time will be needed to demonstrate whether transcatheter bioprosthesis durability will equal that of surgical bioprosthesis.
Another risk of TAVI is related to rhythm disturbances such as partial or complete heart block due to the position of the atrioventricular conduction system that passes superficially through the interventricular septum immediately below the aortic valve. Risk factors are demonstrated to be advanced age, right bundle branch block, atrioventricular delay, prosthesis oversizing and ventricular positioning. Published studies report a different

number of new pacemaker implants according to the device used ranging from 4.5% at 1 year to 3-fold increase with other devices.

The Portico transcatheter aortic valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered at high surgical risk. It has been designed to minimize the incidence of paravalvular leakage and damage to the conduction system. Durability is aimed to be comparable to that of currently available TAVI bioprostheses. The self-expanding stent is designed to be fully resheathable and repositionable at the implant site and retrievable if needed. Additionally the low leaflet/cuff within the stent design allows for sealing without the valve extending deep into the LVOT, potentially reducing the risk of damage to the AV node or His bundle and subsequent need for permanent pacemaker implantation. Large stent cells in the annulus section of the stent allows for tissue to conform around calcific nodules potentially minimizing paravalvular leaks. Bovine leaflets and porcine cuff are treated with Linx* Anti-calcification Technology.

The aim of this study is to evaluate the Portico transcatheter aortic Valve up to five years, according to the VARC 2 criteria.

Study objective

The purpose of this clinical investigation is to further assess the performance and safety profile of the commercially available Portico Valve implanted, using the Delivery System and the Loading System, in patients with severe symptomatic aortic stenosis.

The primary objective of this clinical investigation is to assess the 1 year all-cause mortality of patients, with severe symptomatic aortic stenosis, implanted with a Portico Valve as per current guidelines.

The secondary objective of this clinical investigation is to assess the peri-procedural and long-term performance and safety profile of the Portico Valve implanted, using Delivery System and the Loading System, in patients with severe symptomatic aortic stenosis.

Study design

This is an international multicenter, prospective, non-randomized, interventional clinical investigation without concurrent or matched control, designed to assess the 1 year all-cause mortality rate of patients implanted with a Portico Valve. In addition, performance and safety profile data of the Portico Valve will be evaluated at 30 days, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years.

Intervention

Not applicable, no additional intervention.

Study burden and risks

There is no additional risk voor the patient.

De patient can benefit from the study due to the regular and extensive follow-up for a period of 5 years.

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. Patient has signed the Patient Informed Consent prior to participating in the clinical

investigation.
2. Patient has been referred for a Portico Valve implant as per Heart Team decision.
3. Patient has senile degenerative aortic valve stenosis confirmed by echocardiographically derived criteria
4. Patient has a life expectancy of more than (>) 12 months.

Exclusion criteria

1. Any case in which the Portico Valve would not be indicated for the patient as per current IFU (i.e. any *off-label* use).
2. Patient has any other aortic valve than tricuspid one.
3. Patient has a prosthetic valve or ring in the aortic position.
4. Patient needs a concomitant structural heart procedure.
5. Patient is unwilling or unable to comply with all clinical investigation-required follow-up evaluations.
6. Patient is pregnant

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2014
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Portico Transcatheter Aorta Valve Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-04-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	25-11-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	17-03-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	21-07-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	07-03-2016
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	02-11-2016
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
ClinicalTrials.gov	NCT01802788
CCMO	NL43748.099.13