Assessment of the St. Jude Medical Portico (TM) Re-sheathable Transapical Aortic Valve System (PORTICO TA EU)

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The purpose of this study is to assess the safety and performance of the SJM Portico Transcatheter Heart Valve and the SJM TAVI Transapical Transcatheter delivery system in subjects with severe symptomatic aortic stenosis (AS).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON42009

Source
ToetsingOnline

Brief title
PORTICO TA EU

Condition

- Cardiac valve disorders

Synonym
Aorta Valve Stenosis, Narrowing of the heart valve

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Delivery system, Safety, TAVI, Transapical

Outcome measures

Primary outcome

The primary endpoint is all cause mortality at 30 days.

Secondary outcome

1. The event rates at 30 days of the following:

* Cardiovascular mortality

* Myocardial Infarction (MI)

* Disabling stroke (Major Stroke)

* Non-disabling stroke (Minor Stroke)

* Acute kidney injury (AKI)

* Vascular access site and access-related complications

* Bleeding

* Composite of:

periprocedural encephalopathy

all stroke

all TIA

2. Functional improvement from baseline as compared to 30 days by:

* NYHA Functional Classification

* Six Minute Walk Test

* Effective Orifice Area (EOA)

3. Acute device success defined as:

* Ability of the Portico TA Delivery System to successfully deliver, deploy,

and resheath (if necessary) a transcatheter aortic valve

* Absence of procedural mortality

* Correct positioning of a single prosthetic heart valve into the proper

anatomical location

* Intended performance of the prosthetic heart valve (mean aortic valve

gradient <20 mmHg or peak velocity <3 m/s, and no moderate

or severe prosthetic valve regurgitation)

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 for 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, more than 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. The randomized, controlled PARTNER trial, which demonstrates the non-inferiority of TAVI as compared to conventional aortavalve replacement (AVR) in high risk patient .

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.
The results of recent multicenter trials using either the Edwards SAPIEN valve or CoreValve Revalving System have shown that the procedure is safe and effective. Moreover, in the majority of series, the two technologies were associated with success rates >90% and 30-day procedural mortality rates <10% even though the trials involved high-risk patients.

As summarized above in the cited literature, high risk patients are often unable to tolerate a full surgical valve replacement due to comorbidities or frailty. TAVI is a viable option due to quicker recovery times as compared to surgical aortic valve replacement. The Portico Transcatheter Heart Valve is the only valve that allows for resheathability, which helps achieve optimal placement.

Transfemoral, transapical, transaxillary, and, subclavian delivery approaches have been explored35-42 for percutaneous aortic valve implantation, taking into consideration the anatomy and condition of the patient*s vessels prior to the implant. The transfemoral, transaxillary, and subclavian approaches involve a retrograde delivery of the valve, whereas the transapical route involves an antegrade approach. More recently, the transaortic route also has been introduced, allowing a direct aortic access to the native valve.

The transfemoral approach is usually the preferred strategy and is performed whenever feasible. As opposed to the transfemoral approach, the transapical approach is reserved for patients with inappropriately sized iliofemoral vessels, or with excessive tortuosity, calcification and atheroma in the aorto-ilio-femoral arterial tree. The decision of using one delivery approach versus another is typically based upon a multidisciplinary team*s consensus, comprising the expertise of interventional cardiologists, imaging cardiologists, cardiac surgeons, and cardiac anesthetists - following a careful evaluation of the patient

For a transapical approach a special delivery and loading system is used to place the transcatheter aortavalve via the transapical approach in the heart.

Study objective

The purpose of this study is to assess the safety and performance of the SJM Portico Transcatheter Heart Valve and the SJM TAVI Transapical Transcatheter delivery system in subjects with severe symptomatic aortic stenosis (AS).

Study design

This is a multicenter, prospective, non-randomized, investigational study

Intervention

Transapical inplantation of the SJM Portico Transcatheter Aorta Valve.

Study burden and risks

Although conformance to all relevant production standards minimizes the probability of migration, tissue tears, or undesirable leaflet functional characteristics, they can potentially still occur. Complications associated with the implantation of TAVI aortic valves are listed at question E9. Nevertheless, the benefit of using a TAVI device in high-risk and/or inoperable patients outweighs the residual risk of these.

The inoperable patient population is at increased risk of death despite maximal medical therapy. In clinical practice, at least 30% of the high risk patient population with severe aortic stenosis do not undergo surgery, so a Portico Transcatheter Heart Valve provides a less invasive treatment, with similar outcomes to surgery. An additional advantage of the Portico TAVI valve can be the option to reposition the valve in case of suboptimal valve placement.

During the 4 follow up visits during the study the patients will have an echocardiography and ECG at each visit. This is a time burden but does not give an additional risk for the patients. During these 4 visits also blood will be drawn, which gives a minor risk of bruises, or hematomas at the puncture site. Finally the patients will have to do a 6 minute walk test during the follow up visits and fill out a quality of life questionnaire. This is also a time burden.

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. Subject has given written study Informed Consent.
2. Subject is 65 years of age or older at the time of index procedure, and/or has comorbidities that, in the opinion of the Principle Investigator or the Subject Selection Committee, preclude surgical valve replacement.
3. Subject*s aortic annulus diameter meets the range indicated in the Instructions for Use as measured by multi-slice CT conducted within the past 120 days prior to the index procedure.
4. Subject has senile degenerative aortic stenosis with echocardiography within 30 days of index procedure defined by at least 1 of the following:
derived mean gradient >40mmHg OR
jet velocity greater than 4.0 m/s OR
aorta valve area of *1.0 cm2 OR
aortic valve area index * 0.6 cm2/m2).
5. Subject has symptomatic aortic stenosis as demonstrated by NYHA Functional Classification of II, III or IV.
6. Subject is deemed high operable risk and delivery route is suitable for TAVI per the medical opinion of the Subject Selection Committee.
7. Subject*s predicted operative mortality or serious, irreversible morbidity risk is less than 50% at 30 days post index procedure

Exclusion criteria

1. Subject is unwilling or unable to comply with all study-required follow-up evaluations
2. Subject has a documented history of a cerebral vascular accident (CVA) or transient ischemic attack (TIA) within 6 months (*180 days) prior to the index procedure.
3. Subject has hostile chest or other condition that complicates transapical access
4. Subject has carotid artery disease requiring intervention.
5. Evidence of a myocardial infarction (MI) within 180 days prior to patient providing consent

(defined as: ST Segment elevation as evidenced on 12 Lead ECG) .
6. Subject has a native aortic valve that is congenitally unicuspid, bicuspid, quadricuspid or non-calcified as seen by echocardiography.
7. Subject has mitral valvular regurgitation greater than grade III)
8. Subject has moderate to severe mitral stenosis.
9. Subject has aortic root angulation greater than (>)70 degrees (horizontal aorta).
10. Distance from the left ventricular apex tothe aortic annulus is less than 45mm (4.5cm).
11. Subjetcs has pre-existing prosthetic valve or prosthetic ring in any position.
12. Subject refuses blood transfusion
13. Subject refuses surgical valve replacement.
14. Subject has resting left ventricular ejection fraction (LVEF) less than 20%.
15. The subject has documented, untreated symptomatic coronary artery disease (CAD) requiring revascularization.
16. Subject has had a percutaneous interventional or other invasive cardiac or peripheral procedure * 14 days of the index procedure.
17. Subject has severe basal septal hypertrophy that would interfere with transcatheter valve placement.
18. Subject has a history of or has active endocarditis.
19. There is imaging evidence of intracardiac mass, thrombus, or vegetation.
20. Subject is considered hemodynamic unstable (requiring inotropic support or mechanical heart assistance).
21. Subject is in acute pulmonary edema or requiring intravenous diuretic therapy to stabilize heart failure.
22. Subject with significant pulmonary disease as determined and documented by the Investigator.
23. Subject has significant chronic steroid use as determined and documented by the Investigator.
24. Subject has a documented hypersensitivity or contraindication to anticoagulant or antiplatelet medication.
25. Subject has renal insufficiency as evidenced by a serum creatinine > 3.0mg/dL (265.5 *mol/L) or end-stage renal disease requiring chronic dialysis.
26. Subject has morbid obesity defined as BMI * 40.
27. Subject has ongoing infection or sepsis.
28. Subject has blood dyscrasias (leukopenia, acute anemia, thrombocytopenia, bleeding diathesis, or coagulopathy).
29. Subject has a current autoimmune disease that, in the opinion of the Principal Investigator or Subject Selection Committee, precludes the subject from study participation.
30 Significant ascending aortic disease documented by diameter greater than 40mm.
31. Subject has an active peptic ulcer or has had gastrointestinal (GI) bleeding within 90 days prior to the index procedure.
32. Subject is currently participating in another investigational drug or device study.
33. Subject requires emergency surgery for any reason within 30 days of the index procedure.
34. Subject has a life expectancy < 12 months.
35. Subject has other medical, social or psychological conditions that, in the opinion of the Subject Selection Committee, preclude the subject from study participation.
36. Subject is suffering from dementia or is admitted to a chronic care facility which would

fundamentally complicate rehabilitation from the procedure or compliance with follow-up visits.
37. Subject has a known allergy to contrast media, nitinol alloys, porcine tissue, or bovine tissue

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Transcatheter Aortic Valve and transapical delivery system
Registration:	No

Ethics review

Approved WMO

Date:	22-07-2015
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
ClinicalTrials.gov	NCT01742598
CCMO	NL52186.018.15