Portico Alternative Access; Assessment of the St. Jude Medical Portico Resheathable Aortic Valve System - Alternative Access

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Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON45366

Source
ToetsingOnline

Brief title
Portico ALT EU

Condition

- Cardiac valve disorders

Synonym
Aorta Valve Stenosis, Narrowing of the heart valve

Research involving
Human

Sponsors and support

Primary sponsor: Abbott

Source(s) of monetary or material Support: Abbott

Intervention

Keyword: Delivery system, Subclavian, TAVI, Transaortic

Outcome measures

Primary outcome

The study will have a single primary safety endpoint of major vascular complications through 30 days, as defined by the Valve Academic Research Consortium (VARC-2) for each access arm of the study.

Secondary outcome

Secondary Endpoints for each access arm of the study:

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

• All-cause mortality

• Cardiovascular mortality

• Disabling stroke

• Non-disabling stroke

• Life-threatening bleeding requiring transfusion

• Acute kidney injury requiring dialysis

• Composite of

* - Periprocedural encephalopathy

* - all stroke

* - all TIA

2. The event rates at 1 year of the following:

• All-cause mortality

• Cardiovascular mortality

• Disabling stroke

• Moderate and severe aortic regurgitation

3. Improvement from baseline as compared to 30 days by:

• NYHA Functional Classification

• Six minute walk test

• Effective Orifice Area (EOA)

4. Acute device success defined as:

• 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

* - peak velocity <3 m/s

* - no moderate or severe prosthetic valve regurgitation

In addition successful access, delivery and deployment of the valve and

retrieval of the delivery system will be collected.

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.

The safety and effectiveness of TAVI is now confirmed with the recent published results of the randomized, controlled PARTNER trial, CoreValve IDE which demonstrated the non-inferiority of TAVI as compared to conventional AVR in high risk patients.

Although the TF route is the least invasive, it may not be feasible in every patient. General contraindications to the TF approach include severely calcified or tortuous iliac arteries; an iliac artery diameter of < 6 mm to < 9 mm (depending on the type of device used); previous aortofemoral bypass grafts; severely angulated aorta or atherosclerotic aortic arch; transverse ascending arch (for balloon-expandable devices); and aortic aneurysm with extensive mural thrombus and coarctation of the aorta. In a recent evaluation by Kurra et. al. of 100 patients undergoing TAVR screening, 35% of patients had at least one criterion of unsuitable iliofemoral anatomy, including 27 patients with small minimal luminal diameter (<8 mm), 12 patients with severe circumferential calcification at the iliac bifurcation (>60%), and 4 with severe angulation of the iliac arteries (<90°).
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.

Subclavian/axillary and Transaortic (TAo) access have been introduced as alternative routes in patients with difficult transfemoral access for implantation of a transcatheter heart valve. Compared to the TF approach, subclavian/axillary and TAo access provides a less remote access point to the aortic valve. This shorter distance also reduces bending stress on the delivery system potentially improving steerability and placement control of the transcatheter aortic valve.
The subclavian/axillary approach is preferably performed via the left subclavian artery. Hence, a left internal mammary artery (LIMA) graft is a relative contraindication for TAVR from the left side. In these patients, the right subclavian artery can be used; however, it may be challenging to achieve the correct angulation of the transcatheter aortic valve during positioning. The presence of a permanent pacemaker in the left pectoral region is not an absolute contraindication.
Transaortic (TAo) approach, also known as *direct aortic* access, provides proximate, direct access to the aortic annulus allowing for precise manipulation of both the delivery system and transcatheter heart valve. This is important in cases where the implantation with other approaches (e.g., TF, TA) may be difficult such as cases with a vertical valve orientation, a horizontal ascending aorta, or where the native valve is at the upper limit of the size. TAo approaches are either through a ministernotomy or through a mini-right thoracotomy. A ministernotomy is preferred in obese patients, patients with an

ascending aorta in the mid-line/to the left or a short ascending aorta, and in patients with poor respiratory reserve because the pleura remains intact, and it has less effect on the respiratory dynamics.

The use of each of these alternate access approaches has been demonstrated to be a safe and effective means of delivering transcatheter aortic valves as evidenced by the already approved products and thus increases the number of patients who can be treated successfully and can ultimately benefit from transcatheter aortic valve replacement.

The study will use the CE Marked PorticoTM transcatheter valves available in 23, 25, 27, and 29mm sizes. The devices under investigation are the Portico TF (110cm) Delivery System, used for alternative access routes and the Alternative Access (65cm) Delivery System. The Portico Tf Delivery system is a CE marked device for Transfemoral access route. Both delivery systems come in 18Fr or 19Fr diameter are over-the-wire systems, (0.035*-compatible). The outer diameter of the delivery systems is 18Fr and 19Fr at the distal end and 13Fr at the proximal end.

Study objective

The purpose of this clinical investigation is to expand the indication of the Portico TF Delivery System and obtain approval of the Alternative Access Delivery System to place a Portico transcatheter aortic valve through an alternative access site, specifically subclavian/axillary or transaortic (TAo) in subjects with symptomatic severe native aortic stenosis who are considered high surgical risk.

Study design

This is a multicenter prospective, non-randomized, 2-arm investigational study without concurrent or matched controls, designed to assess the use of the Portico TF or Alternative Access Delivery System to place a transcatheter aortic valve through an alternative access site, specifically subclavian/axillary and TAo.

A minimum of 45 subjects will undergo transcatheter aortic valve replacement (independent of valve size) using the Portico TF or Alternative Access Delivery System in each study access arm (subclavian/axillary and TAo). A minimum of 45 implants will be accessed via the subclavian/axillary access site and a minimum of 45 implants will be accessed via the TAo access site. A maximum of 12 investigational sites with prior alternative access technique experience in Europe will be trained to participate in the study. Enrollment is anticipated to be completed approximately 8 months from the date of first enrollment. Data will be collected at pre-procedure, peri-procedure and at discharge as well as at 30 days, 6 months and 1 year post implantation. All active subjects will be

followed for 1 year.

Data from other prospective Portico clinical trials with ALT access in similar patient populations outside of Europe may be included in the analysis and support the submission for CE Mark. CE Mark will be submitted for each access route after implantation and 30 day follow up are completed.

Intervention

Subclavia/transaxillaire of transaortale (TAo) placement of the Portico transcatheter aortavalve according to a normal TAVI procedure.

Study burden and risks

The inoperable patient population has an 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. Een Transcatheter Heart Valve implantatie provides a less invasive treatment, with similar outcomes to surgery. Via Alternative Access approach patients with difficult transfemoral access can be eligible for implantation of a transcatheter heart valve. Compared to the TF approach, subclavian/axillary and TAo access provides a less remote access point to the aortic valve.

Complications associated with the implantation of TAVI aortic valves are listed at question E9 and are similar to standard TAVI implant.

During the 4 follow up visits during the study the patients will have an echocardiography and ECG at each visit. This is only a time burden for the patient but does not give an additional risk. 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 provided written informed consent prior to uploading CT scan to core lab.
2. Subject is 18 years of age of legal age in the host country.
3. Subject*s aortic annulus diameter meets the range indicated in the Instructions for Use as measured by multislice CT conducted within 180 days prior to the index procedure.
4. Subject has senile degenerative aortic stenosis seen by echocardiography within 90 days of index procedure as measured by one of the following:
; Mean gradient >= 40 mmHg
; Peak velocity >= 4.0 m/s
; Doppler Velocity Index < 0.25
; Aortic valve area (AVA) of < 1.0 cm2 or indexed EOA < 0.6 cm2/m2.
5. Subject has symptomatic aortic stenosis as demonstrated by NYHA Functional Classification of Class II, or greater or other symptoms of aortic stenosis (e.g. syncope).
6. Subject is deemed high operable risk and preferred TAVI delivery route is alternate access (subclavian/axillary or direct aortic) per the medical opinion of the center*s heart team and confirmed by the SSC.
• High risk is defined as an STS mortality > 8% or documented heart team agreement >= high risk for SAVR due to frailty or co-morbidities

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 (less than or equal to 180 days) prior to the index

procedure.
3. Subject has carotid artery disease requiring intervention.
4. Subject has evidence of a myocardial infarction (MI) within 30 days prior to patient index procedure.
5. Subject has a native aortic valve that is congenitally unicuspid, bicuspid, quadricuspid or non-calcified as seen by echocardiography.
6. Subject has severe mitral valvular regurgitation.
7. Subject has severe mitral stenosis.
8. Subject has a pre-existing prosthetic cardiac device, valve, or prosthetic ring in any position.
9. Subject refuses any blood product transfusion.
10. Subject has resting left ventricular ejection fraction (LVEF) less than 20%.
11. Subject has documented, untreated symptomatic coronary artery disease (CAD) requiring revascularization.
12. Subject has had a percutaneous interventional or other invasive cardiovascular or peripheral vascular procedure less than or equal to 14 days prior to index procedure.
13. Subject has severe basal septal hypertrophy that would interfere with transcatheter aortic valve placement.
14. Subject has a history of, or is currently diagnosed with, endocarditis.
15. There is imaging evidence of intracardiac mass, thrombus, or vegetation.
16. Subject is considered hemodynamically unstable (requiring inotropic support or mechanical heart assistance).
17. Subject is in acute pulmonary edema or requiring intravenous diuretic therapy to stabilize heart failure.
18. Subject with severe pulmonary disease as determined by STS score.
19. Subject is on chronic oral steroid therapy.
20. Subject has a documented hypersensitivity or contraindication to anticoagulant or antiplatelet medication.
21. Subject has renal insufficiency as evidenced by a serum creatinine greater than 3.0 mg/dL (265.5 µmol/L) or end-stage renal disease requiring chronic dialysis.
22. Subject has morbid obesity defined as a BMI greater than or equal to 40.
23. Subject has ongoing infection or sepsis.
24. Subject has uncontrolled blood dyscrasias as defined: leukopenia (WBC<3000 mm3), acute anemia (Hb<9 mg/dL), thrombocytopenia (platelet count <50,000 cells/mm3,).
25. Anatomy falling outside the recommended values in the IFU, unless specifically approved by the Subject Selection Committee.
26. Subject has an active peptic ulcer or has had gastrointestinal (GI) bleeding within 90 days prior to the index procedure.
27. Subject is currently participating in another investigational drug or device study, unless approved by the Sponsor.
28. Subject has/had emergency surgery for any reason within 30 days of the index procedure.
29. Subject has a life expectancy less than 1 year.
30. Subject has other medical, social or psychological conditions that, in the opinion of the site Heart Team or the Subject Selection Committee, preclude the subject from study participation.
31. Subject is diagnosed with a state of dementia which would fundamentally complicate

rehabilitation from the procedure or compliance with follow-up visits.
32. Subject has a documented allergy to contrast media that cannot adequately be treated, nitinol alloys, porcine tissue, or bovine tissue.
33. Significant aortic disease including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5cm or greater
34. Subjects with severe pulmonary hypertension and severe RV dysfunction
35. Subjects with hypertrophic cardiomyopathy;Transaortic Subject Cohort Specific Exclusion Criteria
1. Subject has a chest condition (anatomical or otherwise) that prevents TAo access.
2. Subject has pre-existing patent RIMA graft that would preclude access.
3. Subject has a porcelain aorta, defined as an extensive circumferential calcification of the ascending aorta that would complicate TAo access.;Subclavian/Axillary Subject Cohort Specific Exclusion Criteria
1. Subject*s access vessel (subclavian/axillary) diameter will not allow for introduction of the 18/19 Fr delivery system.
2. Subject*s subclavian/axillary arteries have severe calcification and/or tortuosity.
3. Subject has a history of LIMA/RIMA graft that would preclude access

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-03-2017
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	Portico Delivery System 110 and 65 cm
Registration:	No

Ethics review

Approved WMO Date:	09-02-2017
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	06-03-2017
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	10-05-2017
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	09-11-2017
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-06-2024
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
CCMO	NL59517.099.16

Study results

Date completed: 26-03-2020

Results posted: 25-03-2020

First publication
02-03-2020