Surgical Replacement and Transcatheter Aortic Valve Implantation Trial 10 Year Follow-up

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The objective of this trial is to characterize annually the safety and durability data through 10 years in a subset of subjects randomized in the SURTAVI trial.

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

Summary

ID

NL-OMON45149

Source
ToetsingOnline

Brief title
SURTAVI Trial 10 Year Follow-up

Condition

- Cardiac valve disorders

Synonym
severe aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic Inc.

Intervention

Keyword: Aortic Valve Bioprosthesis

Outcome measures

Primary outcome

The primary objective of the 10 Year follow-up study is prospectively evaluate all-cause mortality or disabling stroke annually up to 10 years between TAVI (Transcatheter Aortic Valve Implantation) and SAVR (Surgical Aortic Valve Replacement).

Secondary outcome

The following secondary endpoints will be compared between MCS TAVI and SAVR subject cohorts:

1. MACCE event rates annually up to 10 years

2. Individual MACCE components annually up to 10 years

3. MAE event rates annually up to 10 years

4. Conduction disturbance requiring permanent pacemaker implantation annually up to 10 years

5. Change in NYHA class from baseline annually up to 5 years, 7 and 10 years

6. Echocardiographic assessment of prosthetic valve performance annually up to

5 years, 7 and 10 years using the following measures:

• Transvalvular mean gradient

• Effective orifice area

• Degree of prosthetic aortic valve regurgitation (transvalvular and

paravalvular)

7. Aortic valve disease related hospitalizations annually up to 10 years

8. Cardiovascular deaths and valve-related deaths annually up to 10 years

9. Strokes and TIAs

10. Evidence of prosthetic valve dysfunction annually up to 10 years

Study description

Background summary

Aortic valve stenosis (AS) is the most prevalent valve disorder in the adult population in developed countries affecting approximately 2% to 4% of people over 65 years of age. This corresponds to approximately 3 million people with AS in Europe and approximately 1.5 million in the United States. One in five will eventually progress to symptomatic AS representing more than 900,000 patients in these two greographies.
Patients with severe AS face a grim prognosis once they become symptomatic. The landmark paper on symptomatic AS by Ross and Braunwald in 1968 highlighted this premise: median survival averages only 2, 3 and 5 years after symptom onset of angina, syncope and heart failure respectively. Furthermore mortality is already substantial in the months following the first symptoms. The dismal prognosis of patients with untreated severe, symptomatic aortic stenosis has been recently corroborated in the conservative treatment arm of the PARTNER B cohort. Both, the ESC and ACC/AHA cardiology societies have endorsed guidelines

on valvular heart disease emphasizing the need for surgical aortic valve replacement (SAVR) once symptoms develop or in case of impaired LV function (Level of evidence grade 1).

Physicians'preferences for lesser invasive strategies have fuelled the ongoing interest in developing minimally invasive transcatheter therapies. Alain Cribier pioneered the transcatheter aortic valve implantation (TAVI) technology and reported the first in man experience of TAVI in a patient with symptomatic AS who was deemed inoperable in 2002. Subsequent feasibility studies validated the proof of concept. The Edwards-SAPIEN valve (Edwards Lifesciences, Irvine, CA, USA) and the Medtronic-CoreValve system (Medtronic Corporation, Minneapolis, MN, USA) were the first two TAVI platforms with CE mark approval, followed by the Symetis Acurate (Semetis, Ecublens, Switzerland) and JenaValve (JenaValve, Munich, Germany). Numerous single-center and multi-center observational registries followed suggesting the safety and performance of the TAVI technology. The TAVI technology comes with its own specific complications, not necessarily overlapping with those of SAVR: vascular injury; stroke, cardiac injury such as heart block, coronary obstruction, and cardiac perforation; paravalvular leak; and valve misplacement. The non-uniformity in presenting respective data makes a comparison of results from different centers challenging. The Valvular Academic Research Consortium (VARC), a FDA-endorsed collaboration between academic research organizations and professional societies in the United States and Europe is an initiative to generate a consensus statement on TAVI related definitions aiming to create order and uniformity making data more prone to analysis and comparison.

Technical refinements and commercial entrepreneurship have made the technology accessible to many centers worldwide. This might pose future implications since few randomized trials with TAVI have been performed.

There are three types of medical practices. The first is the institution with on-site interventional cardiologic and cardiothoracic surgical acivity and with close inter-disciplinary collaboration where interventional cardiologists and cardiothoracic surgeons reach a consensus on which patients to select for a specific surgical or interventional treatment strategy. These centers would reasonably respect and adhere to CE mark labelling indications. Second there are centers where interventional cardiologists and cardiothoracic surgeons do not often convene and usually work as two separate departments. Finally there are practices with an interventional cardiology program but without on-site cardiothoracic surgery, estimated to make up 37% of all PCI centers in the European Union. Expectedly, these kinds of organizations without intimate collaboration between cardiothoracic surgeons and interventional cardiologists will look to broaden their interventional activities with an attractive innovation like TAVI. A worldwide practice that is less controlled would potentially cloud the safety and efficacy profile of the procedure. This criticism by the medical community and health authorities could jeopardize future reimbursement policies. The advent of randomized trial data is crucial

and this next step in establishing a new treatment strategy should not be taken for granted as governmental authorities entitled to grant premarket approval to cardiovascular devices are under increased scrutiny and quality control.

After nearly a decade of worldwide mounting TAVI experience, the Cohort -B arm of the much anticipated PARTNER (Placement of AoRTic TraNscathetER Valve Trial) trial representing the first randomized data set, reported a dramatic 20% absolute reduction in mortality in favor of TAVI compared to medical therapy in patients who, as determined by surgeons could not undergo conventinal surgical valve replacement.

In the Cohort-A of the PARTNER trial, patients for whom a surgeon and cardiologist concurred that the predicted risk of operative mortality was 15% and/or with a minimum STS score of 10, were randomized to TAVI or SAVR. The trial completed its randomization in early 2009 and first data were presented at ACC in April 2011 reporting successful achievement of the primary endpoint (TAVR was non-inferior to SAVR for all-cause mortality at 1 year).

At the PCR London Valves meeting in October 2010, it was reported that over 22000 patients had been treated with TAVI worldwide. To date over 25000 Medtronic CoreValve Systems have been implanted worldwide (data on file provided by Medtronic). Inevitably, with increased operator experience and access to the device, physicians will shift their attention to younger patients with a less pronounced operative risk due to the decreased invasiveness of the TAVI procedure as compared with SAVR, coupled with the safety and performance observed in the PARTNER trial and other literature reports in the extreme and high risk populations. Similar to the coronary revascularization arena, the blending of surgical and interventional expertise has created unique interdisciplinary dynamics paving the way for a randomized trial comparing TAVI with SAVR in a surgical intermediate risk patient population.

It is in this spirit that the SURTAVI trial (SURgical and Transcatheter Aortic Valve Implantation) was conceived. The interdisciplinary approach and consensus of the Heart Team (the cardiothoracic surgeon, interventional cardiologist and other treating physicians if necessary) is crucial. This aspect of decision making cannot be over-emphasized and is essential for the quality of current medical practice in general and any planned randomized trial of TAVI versus SAVR in particular. The VARC publication on TAVI definitions and the accumulating TAVI expertise in Europe has created a unique momentum for such a randomized initiative complementary to the US pivotal IDE randomized trial in AS patients with high operative risk.

For a new technology to be accepted as a new asset for treating symptomatic AS several essential questions need to be answered: is the technology effective? Which patients are likely to benefit (patient selection)? How does this new strategy compare with the alternatives? And what is the cost of the intervention relative to alternatives? The proof of concept has been validated.

The innovative and less invasive transcatheter approach should be at least as effective and safe as conventional SAVR or have proof of superiority for both safety and efficacy compared to medical therapy.

The theoretical benefits seem evident of this transcatheter approach by avoiding the need of musculoskeletal incisions, cardioplegic arrest, aortic cross clamping, aortotomy, full cardiopulmonary bypass. Ultimately the cost-effectiveness will determine whether the new treatme

Study objective

The objective of this trial is to characterize annually the safety and durability data through 10 years in a subset of subjects randomized in the SURTAVI trial.

Study design

This is a longitudinal observational clinical trial with long-term follow up of subjects who were randomized in the SURTAVI Trial.

Intervention

General Procedural Considerations (TAVI)

Transcatheter Aortic Valve Implantation (TAVI) requires meticulous preparation and typically a multi-disciplinary team approach involving among others, interventional cardiologists, cardiac imaging specialists, cardio-thoracic surgeons and anesthesiologists.
In case of significant coronary artery disease that requires revascularization, the heart team will assess the feasibility of performing PCI simultaneously with the TAVI procedure based on the coronary lesion characteristics. When it is anticipated PCI can be performed in timely fashion with only a limited amount of additional contrast medium it is encouraged to perform PCI concomitant with the TAVI. When PCI is deemed challenging requiring relatively more time and contrast medium, staged PCI is recommended: TAVI will then be performed at least 7 days after PCI.
The implantation procedure itself takes place either in a catheterization laboratory with adequate hygiene precautions or ideally in a hybrid operating room equipped for state-of-the-art transcatheter and/or surgical procedures.
The execution of the TAVI involves an operating team typically consisting of 1 or 2 operators, an anesthesia team and at least 2 nurses/technicians.
Both the dedicated *valve team* and the operators should have the expertise to select the appropriate access route and device size on a patient-per-patient basis.
All patients undergoing TAVI should be treated using the ilio-femoral access route by default (first treatment strategy). Additional non-ilio-femoral access

routes will only be used in case ilio-femoral access is not feasible.
The use of an embolic protection device during the TAVI procedure is not permitted.

Minimum standards for surgical aortic valve replacement:
Subjects randomized to SAVR should be treated according to the surgeon and hospital*s standard practices. The surgeon or co-surgeon performing the SAVR must be a trial investigator for the site. The choice of surgical valve is left to the discretion of the investigator. However, the use of a bioprosthetic valve is required.

Surgical Considerations:
Surgical aortic valve replacement is typically performed with cardio-pulmonary bypass (CPB) on an arrested heart with a clamped aorta. Local practice and surgical standards should govern type of cardioplegia and the temperature/flow/pressure perfusion strategy as well as the activated clotting time used at either institution for safe CPB. Typically a minimum of 2 liters/m^2/minute with a systemic arterial blood pressure of 60mmHg during CPB should be maintained and possibly increased in the elderly patients. Cannulation for isolated SAVR CPB should be ascending aorta for arterial return unless there is ascending aortic arteriosclerosis or dilatation (>4 cm in diameter), and right atrial for venous drainage. Embilic devices are not routinely used in SAVR.

Study burden and risks

Echocardiography
Physical exam inclusive NYHA classification evaluation

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 subjects currently enrolled in the randomized cohort of the SURTAVI trial are eligible to consent to 10 year follow-up.

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-07-2012
Enrollment:	160

Type:	Actual

Medical products/devices used

Generic name:	CoreValve System
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	01-05-2012
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	25-10-2012
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	11-06-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	23-07-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	11-02-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	11-03-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek

	(Leeuwarden)
Approved WMO Date:	13-10-2016
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	14-11-2017
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	NL38566.099.12