Balloon Expandable vs. Self Expanding Transcatheter Valve for Degenerated Bioprosthesis

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To compare safety and efficacy of EVOLUT R/Pro vs. SAPIEN3 Ultra for the treatment of a failing surgical aortic bioprosthesis

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

Summary

ID

NL-OMON50789

Source
ToetsingOnline

Brief title
BASELINE Trial

Condition

- Cardiac valve disorders

Synonym
degenerative aortic valve bioprosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Balloon Expandable Transcatheter Valve, Degenerated Bioprosthesis, Self Expanding Transcatheter Valve, Transcatheter Aortic Valve Replacement

Outcome measures

Primary outcome

Primary endpoint is device success by VARC-II at 30 days, defined by:

- Absence of procedural mortality AND

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

anatomical location AND

- Intended performance of the prosthetic heart valve (no prosthesis- patient

mismatch and mean aortic valve gradient < 20 mmHg or peak velocity

< 3 m/s, AND no moderate or severe prosthetic valve regurgitation)

- Clinically significant prosthesis patient mismatch is defined by EOAi < 0.85

cm2/m2 (< 0.70 if BMI > 30kg/m2).

Co-primary endpoint is efficacy at 1 year defined by the composite of all-cause

death, disabling stroke and rehospitalization for valve related problems.

Secondary outcome

Clinical endpoints as defined by the most recent VARC document will be

collected in an eCRF (including need for permanent pacemaker).

Cardiovascular rehospitalisation

Coronary obstruction requiring intervention/operation

New conduction disorders

Prosthetic valve function, as measured by trans thoracic echocardiography:

- Left ventricular ejection fraction (%)

- Peak velocity (m/s)

- Mean gradient (mmHg)

- Effective orifice area (cm2)

- Indexed effective orifice area (m2/cm2)

- Prosthetic aortic valve regurgitation

Study description

Background summary

Approximately 80% of surgical aortic valve replacements (SAVR) is performed using a bioprosthesis. Durability of surgical bioprostheses varies based on the patient*s age at the moment of implantation, type and size etc. Redo open-heart surgery for a degenerated aortic bioprosthesis is a relatively high-risk procedure with reported procedural mortality of 4 - 9% and overall high morbidity including stroke, bleeding and conduction disorders. Transcatheter aortic valve replacement (TAVI) has become the preferred treatment for degenerated aortic bioprostheses in elderly patients. The median time since index SAVR and TAVI for bioprosthetic valve degeneration is typically 8 - 10 years. TAVI in this setting has proven to have equally favorable results as in native aortic valves. Furthermore, a US based retrospective analysis from the National Readmission Database claims reported better short term survival and less morbidity with TAVI vs. redo SAVR. Balloon expandable and self-expanding transcatheter heart valves (THV) can be used for TAVI in a degenerated bioprosthesis and each have specific assets and limitations. The Sapien3 Ultra and EVOLUT R/Pro are the 2 most commonly used THV platforms in contemporary clinical practice including treatment of failing surgical aortic bioprostheses.The balloon expandable SAPIEN3 is an intra-annularly functioning THV which is fundamentally different from the supra-annularly functionaning self-expanding Evolut platform. A supra-annular design may offer superior hemodynamic THV performance but may be at higher risk for paravalvular leaks and conduction disorders. Whether other potential hazards related to TAVI in a failing surgical aortic bioprosthesis (e.g. coronary obstruction, aortic rupture) is different for both THV designs is unsettled.

Study objective

To compare safety and efficacy of EVOLUT R/Pro vs. SAPIEN3 Ultra for the treatment of a failing surgical aortic bioprosthesis

Study design

International multi-center randomized study with 1:1 randomization to TAVI with SAPIEN3 Ultra or Evolut R/Pro.

Intervention

Following screening and signing the informed consent form, patients will be randomized in the cathlab or hybrid operating room prior to arterial access:
• SAPIEN3 Ultra
• EVOLUT R/Pro
Patients are admitted prior to the TAVI procedure per local practice. TAVI procedure is executed per local standard (use of ancillary devices (e.g. dedicated large-bore closure devices, cerebral embolic protection devices) and techniques (e.g. valve fracture) are per operator*s discretion.
Antithrombotic regimen is at the operator*s discretion. In addition, the TAVI procedure is preferably performed under local anaesthesia/conscious sedation.
Only transfemoral approach is allowed.
Post procedure care is per local standard.
Clinical assessment at the outpatient clinic will occur per local standard of care 1 month and 1 year post TAVI. A follow up transthoracic echocardiography after TAVI will be performed pre-discharge or at 30 days and at 1 year.

Study burden and risks

This study may prove superiority of one THV design over the other in terms of valve performance, which may translate in improved long-term outcome.
In contrast, patients may be exposed to an inferior THV design in the context of a failing surgical bioprosthesis. Eligibility to participate in the study will be confirmed by the local multi-disciplinary heart valve team.

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

o Age >= 65 years
o Failing surgical aortic bioprosthesis requiring valve replacement and eligible for transfemoral TAVI per heart team consensus based on multi-modality imaging assessment (including echocardiography and multidetector CT).
o Written informed consent

Exclusion criteria

o Not eligible for Transfemoral TAVI with SAPIEN3 and Evolut R/Pro
o Multi-valve defects requiring intervention
o Clinically unstable and/or inotropic/vasopressor /mechanical support.
o Known mural thrombus in the left ventricle
o Presence of a mechanical aortic valve
o History of recent (within 1 month) stroke or TIA

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-11-2021
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Transcatheter Aortic Valve (Sapien 3 Ultra en Evolut Pr/R)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	28-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	13-08-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL76548.078.21