Sutureless aortic valve replacement: 15-year experience in 1136 patients

Lamberigts M. et al.,
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15-year results from single center, retrospective, real-world study
1136 patients implanted with Perceval between 2007 and June 2022

15 yrs

KEY OUTCOMES

Very low SVD	Very low endocarditis	Very low reintervention	Excellent hemodynamics
0.74% patient-year	**0.50%** patient-year	**0.48%** patient-year	Stable over time

"Sutureless AVR can be used in various settings, as it is suitable for both minimally invasive single AVR and in difficult combined procedures, where it saves valuable cross-clamp time. Our study shows favorable early and late outcomes with low rates of endocarditis, severe SVD, and need for reintervention."

Sutureless aortic valve replacement: 15-year experience in 1136 patients

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Objective: To analyze the 15 years of continued use of the Perceval sutureless valves in all-comers patients.

Central message: In this large real-world study, Perceval valve showed to be suitable for both minimally invasive single AVR and in difficult combined procedures, with favorable early and late outcomes and low rates of endocarditis, severe SVD, and need for reintervention.

15yrs

Study design

Methods

- Retrospective, single-center, non-randomized, real-world study
- **1136 patients from 2007 to 2022**
- Inclusion criteria: any sutureless AVR, regardless of combined procedures (CABG and/or multiple valves)

Follow-up

- Clinical outcomes and echocardiographic data collected until June 2022
- Cumulative follow-up **3775.7 patient-years**
- Competing risk analysis using cumulative incidences was used for the long-term endpoints

Structural valve deterioration (SVD) definition

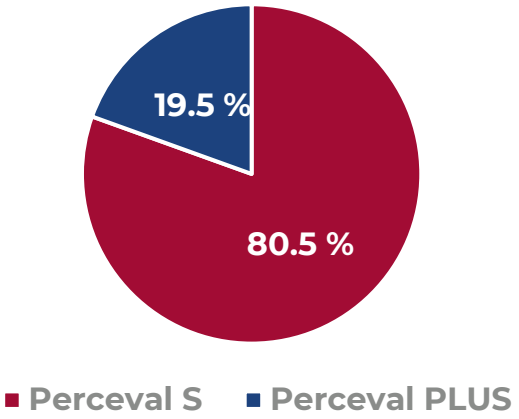
Severe SVD defined as presence of central valve insufficiency of >2 out of 4, an increase in mean gradient > 20mmHg or a mean gradient >40 mmHg, in accordance to standardized definitions.[1]

1. Capodanno et al. Eur Heart J. 2017; 38(45):3382–3390.

Study results

Baseline and operative characteristics

- Age (median): 79 years (IQR: 75-82)
- Male: 50.2%
- Median EuroSCORE II: 4.2 (interquartile range: 2.4-7.7%)
- Single AVR: 44.5%
- AVR with CABG: 27.1%
- Multiple concomitant procedures: 28.3%
- Surgical access:
  - Full sternotomy 66.1%
  - Mini-sternotomy 31.7%
  - Right anterior thoracotomy 2.2%
- Cardio-pulmonary bypass time (median): 81 min (60-120)
- Cross-clamp time (median): 51 min (36-82)



Study results

Early outcomes

Postoperative events	N = 1136
Reoperation for bleeding	48 (4.2%)
Stroke	20 (1.8%)
New dialysis	16 (1.4%)
Pacemaker rate at 30 days	92 (8.1%)
In hospital mortality	39 (3.4%)
ICU length of stay (days)	3 (2-5)
Fast-tracked (no ICU stay)[a]	237 (20.9%)
Hospital length of stay (days)	10 (7-14)

Low rates of 30-day mortality, stroke, and reoperation for bleeding

20% of the patients were not transferred to ICU and fast-tracked to the ward

Hemodynamic results at discharge:

Median mean gradient: 13 (IQR 10-17) mmHg

Median EOA 1.6 cm^2 (IQR 1.3-2.0).

Very low rate of >1/4 para-valvular (1.8%) and central (0.8%) leak

Study results

Focus on permanent pacemaker implant (PPI) rate

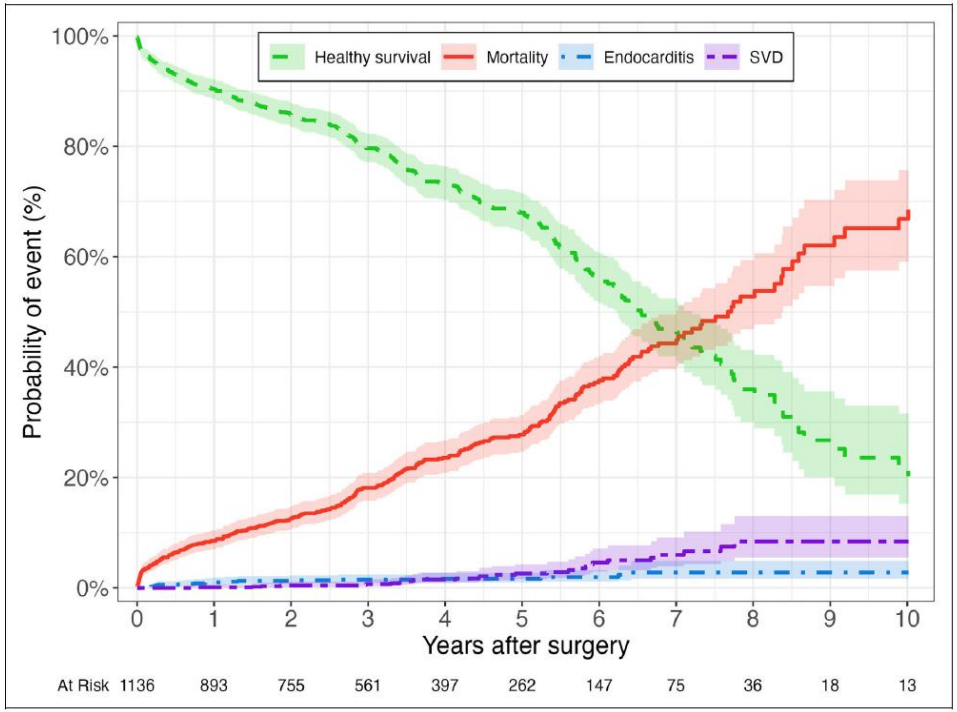
PERCEVAL	NEW SIZING	PERCEVAL PLUS
2007-2017	2017	2020
Perceval launch (438 pts)	Changed sizing strategy to avoid oversizing and prevent PPI (476 pts)	*FREE Treatment* and reduced valve ventricular protrusion in XL valve (222 pts)

PPI rate 11% → **PPI rate 6.8%**

Pacemaker rate decreased significantly throughout time due to the changes in sizing shift, with simultaneously improving transprosthetic gradients

Study results

Late outcomes

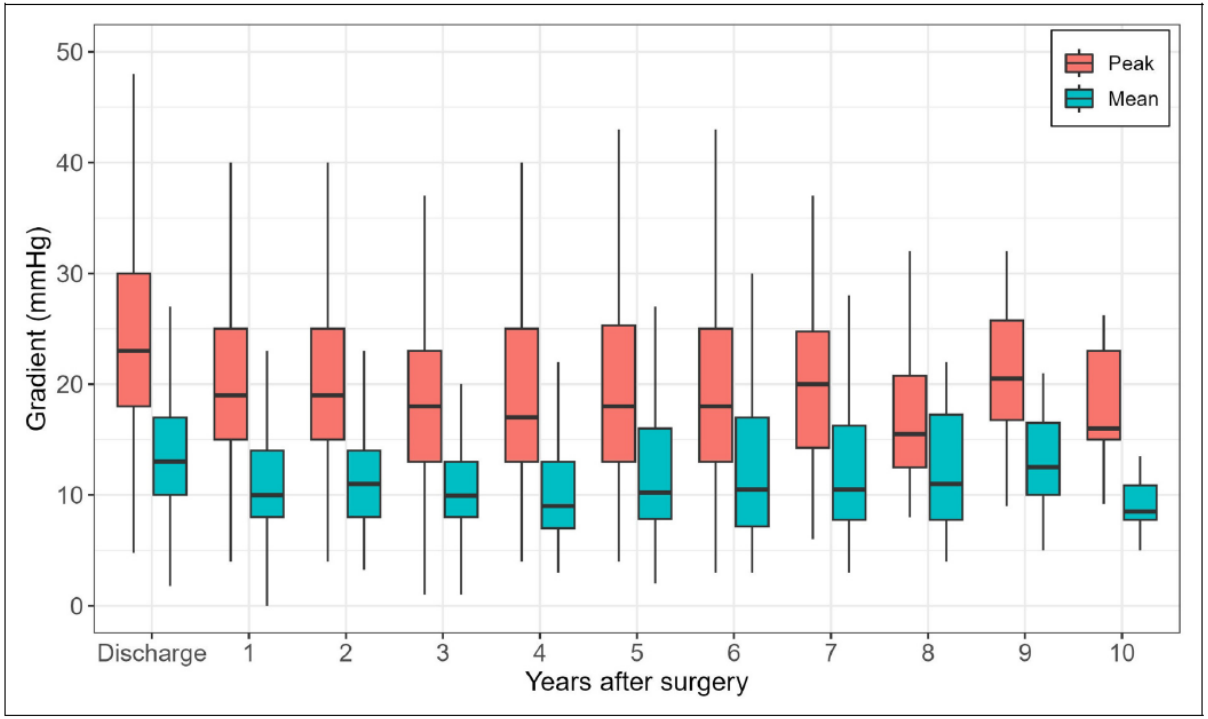


- Median survival time: 7.2 years
- Freedom from reoperation:
  - 97.8% at 5 years
  - 95.3% at 10 years
- **SVD incidence: 0.74%/pt-yrs**
  - Reintervention with ViV in 10 pts
  - Mean time to ViV 5.4 ± 1.2 yrs
- **Endocarditis incidence: 0.50%/pt-yrs**
- Reintervention due to endocarditis: 0.37%/pt-yrs

Low rate of SVD, endocarditis and reintervention, similar to other bioprostheses.

Study results

Hemodynamic outcomes



Excellent and stable hemodynamic outcomes

Key take-aways

- Longest available experience with Perceval sutureless valves
- Sutureless AVR can be used in various settings:
    - very suitable for MICS single AVR
    - decrease procedure time during more difficult combined procedures
- Highly favorable early and long-term outcome, with low rates of endocarditis, severe SVD and reinterventions
- Optimal for TAVR valve-in-valve if needed

"Long-term results show stable results with low rates of endocarditis, severe SVD, and reinterventions. Additionally, sutureless AVR can be used in various settings, as it is suitable for both minimally invasive single AVR and as an option to limit procedure time during more difficult combined and redo procedures."

Study limitations:

Retrospective design, lack of a control group, absence of established criteria for valve failure , longterm adverse events such as reintervention can also potentially be influenced by older age of the study population and lower rate of survival at 10 years. The follow-up period for most patients remains limited.

INTENDED USE/INDICATIONS

EUROPE: The Perceval Plus prosthesis is intended to replace a damaged native aortic heart valve or a malfunctioning aortic prosthesis via open- heart surgery in adult patients:

- suffering from aortic valve stenosis or steno-insufficiency;
- with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement.

US, CANADA and AUSTRALIA: The Perceval Plus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves

KEY CONTRAINDICATIONS

Aneurysmal dilation or dissection of the ascending aortic wall; known hypersensitivity to nickel or cobalt alloys; ratio between the sinotubular junction and the annulus diameter greater than 1.3.

KEY WARNINGS

Do not under or oversize the prosthesis. This could result, in possible migration, excessive compression/rupture of the aorta, suboptimal expansion or valve folding that may lead to fatal arrhythmia or hemorrhage, regurgitation or altered hemodynamics. Severe LVOT hypertrophy may prevent optimal expansion of the inflow portion of the stent.

TOP POTENTIAL SIDE EFFECTS

Potential adverse events associated with cardiac valve replacement with a bioprosthesis and the related surgical procedure include: bleeding, cardiac conduction disorders, endocarditis, heart failure, neurological events, nonstructural dysfunction, structural valve deterioration, thromboembolism.

MRI conditional

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