Hemodynamic Performance of Sutureless Versus Conventional Bioprostheses for Aortic Valve Replacement: The 1-Year Core-Lab Results of the Randomized PERSIST-AVR Trial

Fischlein T, et al. Front. Cardiovasc. Med., 18 February 2022. https://doi.org/10.3389/fcvm.2022.844876

Sub-group analysis of the PERSIST-AVR trial

Objective: to report the 1-year hemodynamic performance of Perceval (Su-AVR) compared with stented valves (SAVR), assessed by an independent echocardiographic core-lab on a sub-group of patients

Central message: Comparable 1-year hemodynamic performances between Su-AVR and SAVR groups, confirmed by an independent echo core lab

Study background

- PERSIST-AVR[1] was a prospective, randomized trial designed to demonstrate the non-inferiority of Perceval versus stented valves
- 407 Perceval and 412 Stented patients enrolled from March 2016 to September 2018 in 47 International centers
- Main outcomes of the PERSIST-AVR:
  - Perceval was non-inferior to stented valves in term of MACCE (major cardiovascular and cerebral events) at 1-year (primary endpoint)
  - Comparable implant success rates to traditional valves, while allowing for faster procedures in both isolated and combined AVR
  - Comparable good and stable hemodynamic performance and equivalent PVL rates of sutured valves (site-reported echocardiographic data)
- To further confirm the hemodynamic performance a subgroup analysis of the PERSIST AVR trial was planned including a complete independent core-lab echo assessment *(MedStar Health Research Institute, Washington D.C., USA)*
  - The use of core-lab plays a critical role, providing an independent assessment of the site-reported echo data

1.Fischlein T, et al. Sutureless Versus Conventional Bioprostheses for Aortic Valve Replacement in Severe Symptomatic Aortic Valve Stenosis. The Journal of Thoracic and Cardiovascular Surgery (2021), doi: https://doi.org/10.1016/j.jtcvs.2020.11.162.

Study results

Methods

- 71 pts Perceval, 82 pts stented
- For each patient, echo assessment was done at hospital discharge, between 1-3 months and at 1 year:
  - Site reported echo data
  - Complete echocardiographic examination independently assessed by a Core Lab
    - Mean and peak gradients calculated both with the simplified and modified Bernoulli equation*
- The focus of the paper is on 1-year data

Baseline characteristics

- Mean age: 74.7 ± 5.7 years (SuAVR), 74.7.0 ± 4.5 (SAVR)
- Euroscore II: 1.9 ± 1.1 (SuAVR), 1.8 ± 1.1 (SAVR) – low risk patients
- Concomitant cardiac procedures: 43.7% (SuAVR), 42.7% (SAVR)
- Minimally invasive cardiac surgery: 49.3% (SuAVR), 51.2% (SAVR)

No difference in term of preoperative patient profile and operative characteristics

*The modified Bernoulli equation is a more accurate echo methodology for measuring the aortic mean and peak pressure gradients, because it considers not only the delta pressure measured across the valve itself but also the presence of a narrowing of the LVOT. This methodology is used in echo core-lab assessed data, but generally not in site reported echo data.

Study results

1 year hemodynamic «core-lab assessed»

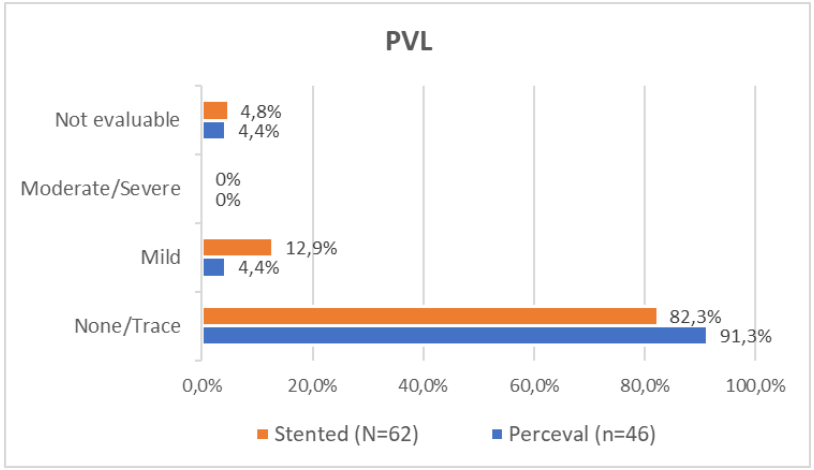
	Su-AVR	SAVR	p-value
Mean Gradient (mmHg) with the modified Bernoulli equation	**10.0±5.3**	**11.1±6.8**	**0.3881**
Peak Gradient (mmHg) with the modified Bernoulli equation	**16.7±8.2**	**19.2±11.8**	**0.2371**
Mean Gradient (mmHg) with the simplified Bernoulli equation	12.8±5.7	13.4±7.7	0.6445
Peak Gradient (mmHg) with the simplified Bernoulli equation	21.5±9.1	23.0±13.0	0.4854
EOA (cm2)	1.3±0.4	1.4±0.4	0.3069
LV mass (g)	198.8±75.9	202.1±74.8	0.8223

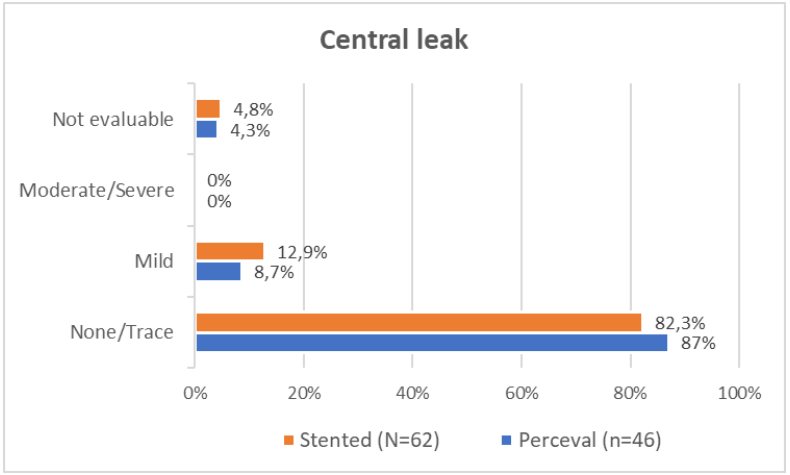
Comparable 1-year hemodynamic results between Perceval and stented, confirmed by an independent echo core lab:

- No difference in terms of gradients, EOA and LV mass at 1-year
- Lower gradients calculated with the modified Bernoulli equation
- Results are valid across all valve sizes *(Data reported in the supplemental material)*

Study results

1 year hemodynamic «core-lab assessed»





- No difference in terms of paravalvular (p=0.84) and central (p=0.31) leaks at 1-year between Perceval and stented valves, confirmed by an independent echo core lab
- The majority of the patients were free from PVL (91.3% in Perceval and 82.3% in stented) or central leak (87% in Perceval and 82.3% in stented)
- Results are valid across all valve sizes *(Data reported in the supplemental material)*

Key take-aways

- Comparable 1-year hemodynamic performances between Perceval and the stented valves, confirmed by an independent echo core lab
- The use of core-lab plays a critical role, providing an independent assessment of the site-reported echo data
- Perceval provides optimal sealing at the annulus level with equivalent risk and even lower incidence of PVL and central leak compared to stented valves
- "Sutureless valves are a reliable and essential technology within the modern therapeutic armamentarium to treat aortic valve disease".
- The Perceval satisfactory hemodynamic performances have been already assessed by other clinical experiences (1-3)

Study limitations:

- The PERSIST- AVR study was not powered for this sub-group analysis
- Limited number of patients were included in the core-lab assessment

1. Fischlein T, et al. J Thorac Cardiovasc Surg (2021) S0022-5223(21)00001-5.
2. Solinas M et al.. Ann Cardiothorac Surg (2020) 9(4):305-313
3. Concistrè G et al.. Ann Thorac Surg (2018) 105(1):40-46

INTENDED USE/INDICATIONS

EUROPE: Perceval/Perceval Plus prosthesis is intended to replace a damaged native aortic heart valve or a malfunctioning aortic prosthesis via open heart surgery. The prosthesis is indicated for use in adult patients suffering from aortic valve stenosis or steno-insufficiency or with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement. Physicians should give careful consideration to the use of this valve in patients less than 65 years of age, as sample size in clinical studies for this patient population is insufficient to demonstrate a clinical benefit.

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

CANADA: The Perceval/Perceval Plus bioprosthesis is intended for use in patients aged ≥ 65 years in which the aortic valve pathology is in an advanced stage to require the replacement of the native or malfunctioning previously implanted prosthesis.

AUSTRALIA: Perceval prosthesis is indicated for the replacement of a diseased native or a malfunctioning prosthetic aortic valve via open heart surgery. The prosthesis is indicated in patients who meet the following criteria: 1) subjects of age ≥ 65 years 2) subjects with aortic valve stenosis or steno-insufficiency.

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, non structural dysfunction, structural valve deterioration, thromboembolism.

MRI conditional

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