Medtronic

Avalus™ bioprosthesis

Proof in Practice: Avalus™ valve delivers when surgery gets complex.

Cardiac surgery is becoming more complex – and that makes real-world data more valuable than ever. Beyond clinical trials, surgeons need to know how a valve performs in everyday SAVR, across varied anatomies, risk profiles, and procedural combinations.

The ACE prospective multicentre registry, led by UZ Leuven and primary investigators Prof. Bart Meuris and Prof. Tom Verbelen, delivers exactly that: robust, real-world evidence from 26 leading centres, capturing Avalus™ valve performance across diverse and complex SAVR patients – including those undergoing combined procedures.

Led by:

Prof. Meuris

Prof. Verbelen

The result?

- **A clear, trustworthy picture of how Avalus™ valve performs** where it matters most: your daily practice.
- Avalus™ valve provides **real-world safety, industry leading hemodynamics,** and **remarkably low PPM** – delivering reliable results even when surgery gets challenging.

Who is it for?

- Surgeons who want **predictable surgical performance, strong hemodynamics,** and **low PPM** – not just in isolated AVR, but in **combined** and **complex** cases.[1]

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With every beat, expect more.

Key study outcomes

1

Avalus™ valve **performs where it matters most** – your everyday, high variability surgical practice.

Real-world 1,000 patient data of ACE from 26 centres shows:

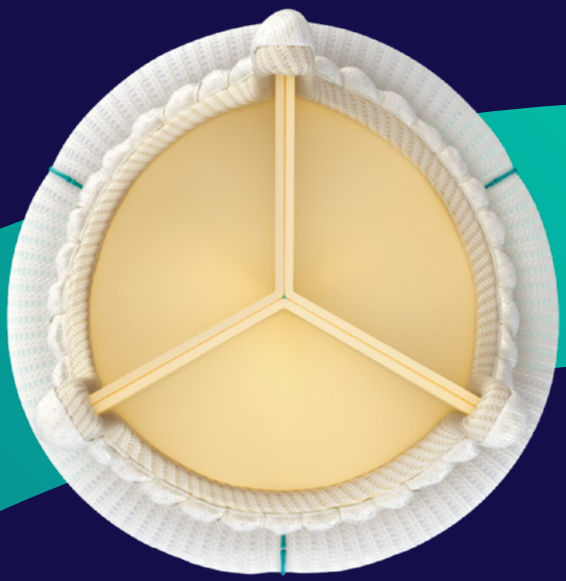
1.7%
early mortality
in a cohort with mean EuroSCORE II of 3.4%

3.3%
mortality
at one year

Stroke rate
only 1.6%
at one year

Why it matters:

This is real-world evidence, not ideal trial conditions, proving reliable outcomes even in complex cases.



2

Avalus™ valve offers **industry leading hemodynamics** you can trust from day one – even in the complex patients.

Mean gradient
11.6 mmHg
at discharge

Effective orifice area nearly
2.0 cm^2
at discharge

Hemodynamic stability
maintained
over the first year

Why it matters:

Excellent hemodynamics aren't just numbers – they directly shape patient recovery, long-term function, and your surgical success.

Key study outcomes

3

Avalus™ valve has **exceptionally low PPM rates** – helping you protect patients from long-term complications.

74%
no PPM,
only 5% severe PPM at discharge

PPM rates far lower than reported for other bioprosthesis
(moderate PPM up to 64%, severe up to 34% in published data)

Why it matters:

PPM is one of the strongest predictors of poor long-term outcomes – and Avalus™ valve helps you avoid it.

4

Avalus™ valve performs **reliably in complex, real-world surgical conditions** – not just isolated AVR.

Only

42%

were isolated AVR

Remaining

58%

had concomitant procedures

(CABG, mitral/tricuspid work, aortic aneurysm repair)

Why it matters:

Not every valve performs when cases get complex. Avalus™ valve delivers predictable, reliable results – even in real-world, high complexity SAVR.

Key study outcomes

5

Avalus™ valve delivers **proven durability,** confirmed in real-world practice and aligned with long-term PERIGON data.

One-year outcomes show **stable gradients, sustained EOA,** and strong functional recovery (**74% NYHA class I**)

Reinforced by

7 year PERIGON

data demonstrating durable performance in >1,100 patients

Why it matters:

Long-term valve durability is essential for patient outcomes and future interventions. Avalus™ valve provides early stability backed by robust long-term evidence – giving surgeons confidence that today's implant will continue to perform for years to come.

Background and study objective

As cardiac surgery becomes increasingly complex, real-world data is essential to evaluate bioprosthetic valve performance beyond controlled trials. The Avalus™ Clinical confidencE (ACE) registry provides real-world insights into the safety and effectiveness of the Avalus™ valve across diverse patient populations.

Methods

Prospective, single arm registry using secure REDCap server. Monitoring of completeness-of-data done by coordinating study centre:

- All-comers population providing real-world data: only exclusions are < 18y and salvage surgery. Enrolment 2021-2024

26 sites across Europe in 9 countries (Belgium, Denmark, Finland, France, Germany, Italy, Israel, Spain, and the Netherlands)

End-points: mortality, stroke, bleeding complications, pacemaker need, ICU/hospital stay, prosthetic valve function, reintervention

- Data at discharge (complete) and 1y follow-up (ongoing)
- Extended follow-up is planned

Patient-prosthesis mismatch (PPM) was classified according to VARC-3 criteria, including adjustments for obesity (BMI ≥ 30 kg/m^2)[2]

PPM	None	Moderate	Severe
BMI < 30	> 0.85 cm^2/m^2	0.85 – 0.66 cm^2/m^2	≤ 0.65 cm^2/m^2
BMI ≥ 30	> 0.70 cm^2/m^2	0.70 – 0.56 cm^2/m^2	≤ 0.55 cm^2/m^2

Table 1: Baseline characteristics

Characteristic	Patients (N=1000)
Age (yr)	71.5±6.6
Age range	42–90
<65y (no.(%))	124 (12.4)
>75y (no.(%))	272 (27.2)
Female sex (no.(%))	233 (23.5)
BMI (kg/m^2)	27.44±4.45
BSA (m^2)	1.95±0.21
Renal impairment (no.(%))	
Normal	467/994 (46.9)
Moderate	432/994 (43.5)
Severe	95/994 (9.6)
NYHA class (no./total no.(%))	
I	152/989 (15.4)
II	565/989 (57.2)
III	250/989 (25.3)
IV	21/989 (2.1)
EuroSCORE II (%)	3.4±5.3
Median	1.88 (IQR 1.14–3.71)
EuroSCORE II range	0.52–77.4
Clinical history (no./total no.(%))	
Diabetes: Insulin treated	62/997 (6.2)
Previous cardiac surgery	52/989 (5.3)
Severe impairment of mobility	22/982 (2.2)
Chronic lung disease	68/981 (6.9)
Pulmonary hypertension	
Moderate	198/979 (20.2)
Severe	26/979 (2.7)
Endocarditis	43/981 (4.4)
Critical preop state	12/992 (1.2)
Extra-cardiac arteriopathy	85/993 (8.6)
Recent myocardial infarction	28/991 (2.8)
Rhythm (no./total no.(%))	
Sinus rhythm	820/993 (82.6)
Atrial fibrillation	138/993 (13.9)
Pacemaker	29/993 (2.9)
CCS class 4 angina	26/993 (2.6)
Echocardiographic findings	
Left ventricular ejection fraction (%)	57.2±10.1
Aortic valve area (cm^2)	0.93±0.6
Mean aortic valve gradient (mmHg)	42.0±20.2
Peak aortic valve gradient (mmHg)	63.2±30.6
Aortic regurgitation (no./total no.(%))	
Mild	331/988 (33.5)
Moderate	176/988 (17.8)
Severe	216/988 (21.8)

Table 2: Procedural characteristics

Characteristic	Patients (N=1000)
Prosthesis size (no/total no.(%))	
19	36/998 (3.6)
21	157/998 (15.7)
23	304/998 (30.5)
25	328/998 (32.9)
27	155/998 (15.5)
29	18/998 (1.8)
Urgency (no./total no.(%))	
Elective	879/997 (88.2)
Urgent	111/997 (11.0)
Emergent	7/997 (0.7)
Native valve (no/total no.(%))	
Unicuspid	1/994 (0.1)
Bicuspid	256/994 (25.7)
Tricuspid	710/994 (71.4)
Prosthetic	27/994 (2.7)
Single AVR (no./total no.(%))	417/1000 (41.7)
Concomitant procedures (no./total no.(%))	
CABG	271/1000 (27.1)
Number of grafts	1.77±0.9
Graft range	0–5
Mitral valve repair/replacement	83/1000 (8.3)
Tricuspid valve repair/ replacement	35/1000 (3.5)
Ascending aorta aneurysm	156/1000 (15.6)
Ablation treatment	57/1000 (5.7)
Other	141/1000 (14.1)
Aortic cross-clamp time (minutes)	89.0±32.1
Isolated AVR	66.0 (IQR 55.0–80.0)
Combined procedures	97.0 (IQR 78.0–118.0)
Second clamp needed (no./total no.(%))	
Paravalvular leak	4/999 (D.4)
Bleeding	5/999 (0.5)
CPB time (minutes)	117.2±45.2
Isolated AVR	88.0 (IQR 73.0–105.0)
Combined procedures	126.0 (IQR 104.0–159.0)
Access (no./total no.(%))	
Full stemotomy	829/996 (83.2)
Mini stemotomy	137/996 (13.8)
Arterior thoracotomy	19/996 (1.9)
Use of automatic suturing device (no/total no.(%))	4/133 (3.0)

AVR, Aortic Valve Replacement; CABG, Coronary Artery Bypass Graft; CPB, CardioPulmonary Bypass; IDR, Interquartile Range

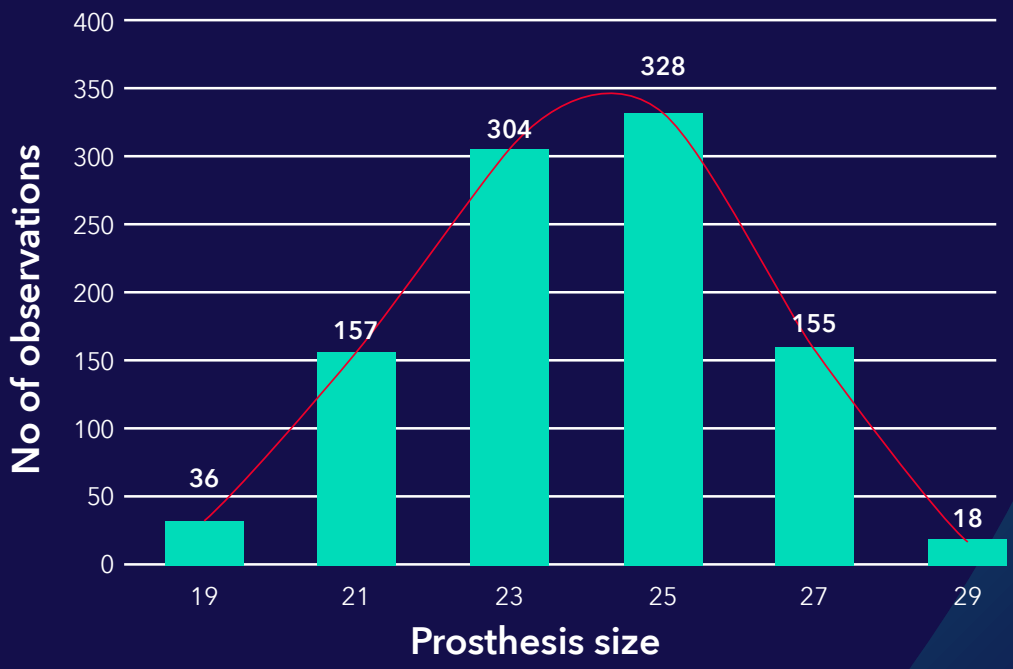
Table 3: Status at discharge

Characteristic	Patients (N=1000)
Mortality (no./total no.(%))	17/1000 (1.7)
Cardiac cause	7/17 (41.2)
Procedure-related	1/17 (5.9)
Sudden or unwitnessed death	2/17 (11.8)
Other	7/17 (41.2)
Stroke (no./total no.(%))	24/989 (2.4)
TIA	9/24 (37.5)
Ischemic	4/9 (44,4)
Haemorrhagic	0/9 (0.0)
Undetermined	3/9 (33.3)
CVA	15/24 (62.5)
Ischemic	10/15 (66.7)
Haemorrhagic	2/15 (13.3)
Undetermined	3/15 (20.0)
Periprocedural myocardial infarction (no./total no.(%))	4/991 (0.4)
Cardiac reoperation (no./total no.(%))	50/992 (5.0)
Bleeding	34/50 (78.0)
Other	16/50 (32.0)
Bleeding (no./total no.(%))	87/986 (8.8)
Minor bleeding	32/87 (36.7)
Major bleeding	44/87 (50.6)
Life-threatening	14/87 (16.1)
Postoperative pacemaker implantation (no./total no.(%))	38/985 (3.9)
Acute kidney injury (no./total no.(%))	
Stage 1	69/981 (7.0)
Stage 2	23/981 (2.3)
Stage 3	23/981 (2.3)
Need for dialysis (no./total no.(%))	23/991 (2.3)
Prolonged ventilation (no./total no.(%))	56/985 (5.7)

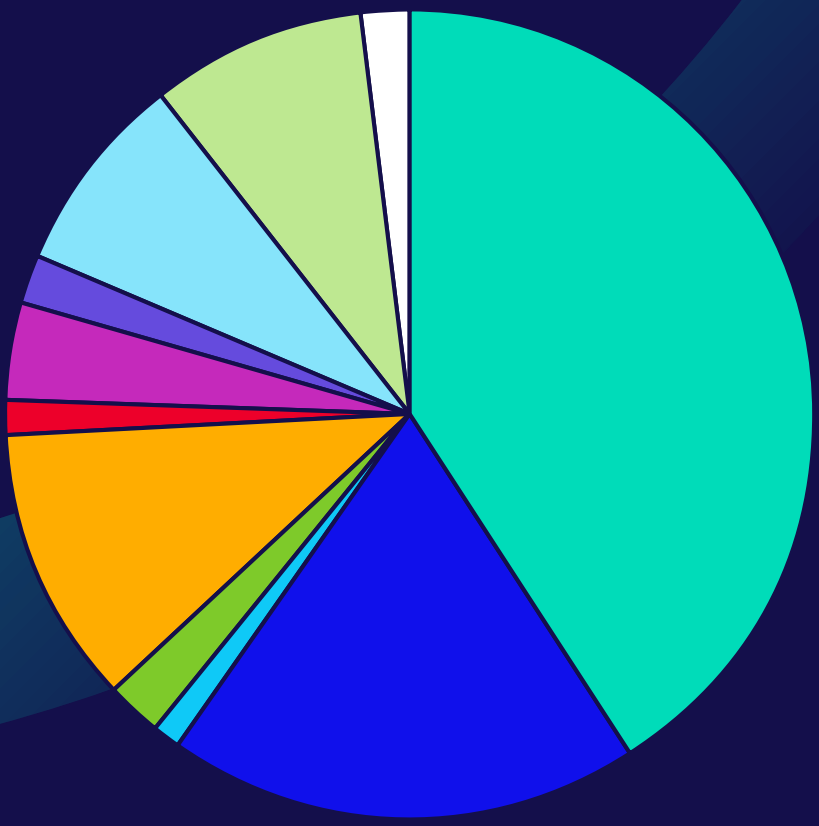
Characteristic	Patients (N=1000)
Need for mechanical support (no./total no.(%))	
ECMO	4/981 (0.4)
IABP	5/981 (0.5)
ICU duration (days)	3.1±5.9
Hospital duration (days)	10.7±9.6
Echocardiographic data	
Left ventricular ejection traction (%)	55.0±10.0
Aortic valve area (cm^2)	1.98±0.61
Mean aortic valve gradient (mmHg)	11.6±5.3
Peak aortic valve gradient (mmHg)	20.7±8.8
Aortic regurgitation (no./total no.(%))	63/952 (6.6)
Intravalvular	36/952 (3.7)
Mild	36/36 (100.0)
Paravalvular	26/952 (2.7)
Mild	25/26 (96.2)
Moderate	1/26 (3.8)
PPM	
No PPM	327/442 (73.9)
Mild PPM	93/442 (21.0)
Severe PPM	22/442 (5.0)
Oral anticoagulants	362/980 (36.9)
Novel oral anticoagulants	161/970 (16.6)
Antiplatelet medication	669/972 (68.8)
Rhythm (no./total no.(%))	
Sinus rhythm	756/984 (76.8)
Atrial fibrillation	165/984 (16.8)
Pacemaker	49/984 (5.0)

Figure 1

A. Valve size: Mean implanted valve size 24 mm



B.



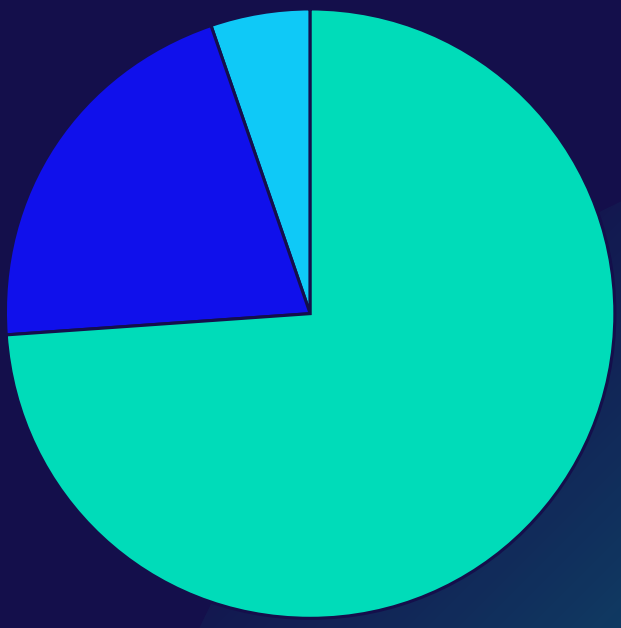
- **41.7%** Single AVR
- **19.8%** CABG
- **1.2%** CABG + Aorta aneurysm
- **2.2%** CABG + other
- **11.3%** Aortic aneurysm
- **1.3%** Aorta aneurysm + other
- **3.8%** Mitral
- **2.0%** Ablation
- **6.1%** Other
- **8.9%** Various combinations
- **1.7%** Unknown

Table 4: Status at 1 year follow-up

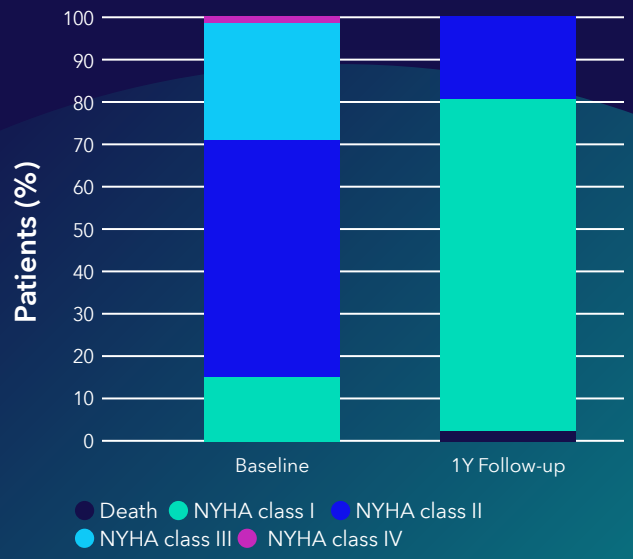
Characteristic	Patients (N=703)
Mortality (no/total no.(%))	23/703 (3.3)
Cardiac cause	4/23 (17.4)
Rhythm (no./total no.(%))	
Sinus rhythm	540/654 (82.6)
Atrial fibrillation	76/654 (11.6)
Pacemaker	26/654 (4.0)
NYHA class (no./total no.(%))	
I	513/650 (78.9)
II	120/650 (18.5)
III	13/650 (2.0)
IV	2/650 (D.03)
Cardiac reoperation (no./total no.(%))	19/680 (2.8)
Aortic valve	7/680 (1.0)
Non aortic valve	12/680 (1.8)
Endocarditis (no./total no.(%))	19/677 (2.8)
Stroke (no./total no.(%))	11/677 (1.6)
TIA	3/11 (27.3)
CVA	8/11 (72.7)
Pacemaker implantation (no./total no.(%))	20/674 (2.9)
Rehospitalization for valve related symptoms (no./total no.(%))	23/674 (3.4)

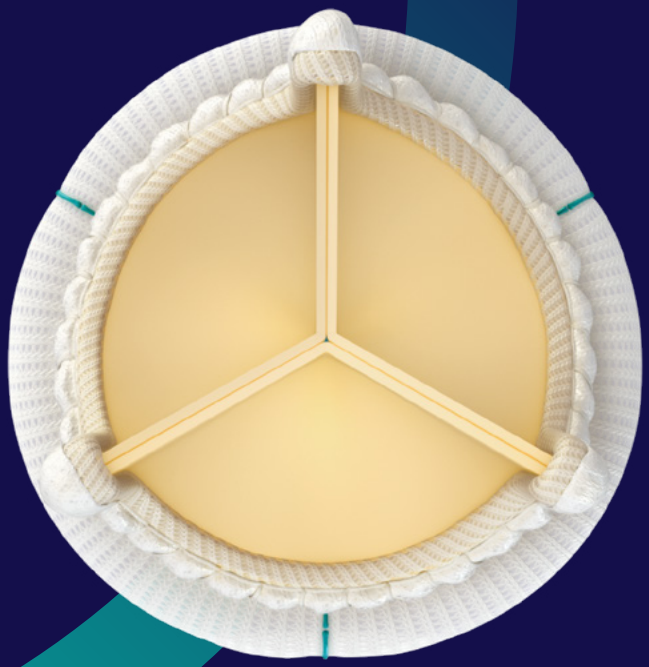
Characteristic	Patients (N=703)
Echocardiographic data	
Left ventricular ejection traction (%)	58.6±8.7
Aortic valve area (cm^2)	1.82±0.5
Mean aortic valve gradient (mmHg)	12.2±4.9
Peak aortic valve gradient (mmHg)	20.6±8.4
Aortic regurgitation (no./total no.(%))	38/606 (6.3)
Intravalvular	25/38 (65.8)
Mild	25/25 (100)
Paravalvular	13/38 (34.2)
Mild	13/13 (100)
PPM	
No PPM	172/265 (64.9)
Mild PPM	75/265 (28.3)
Severe PPM	18/265 (6.8)
Oral anticoagulants	108/669 (16.1)
Novel oral anticoagulants	181/670 (27.0)
Antiplatelet medication	362/667 (57.2)

Rates of patient-prosthesis-mismatch



73.9% No PPM
21.0% Moderate PPM
5.0% Severe PPM





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