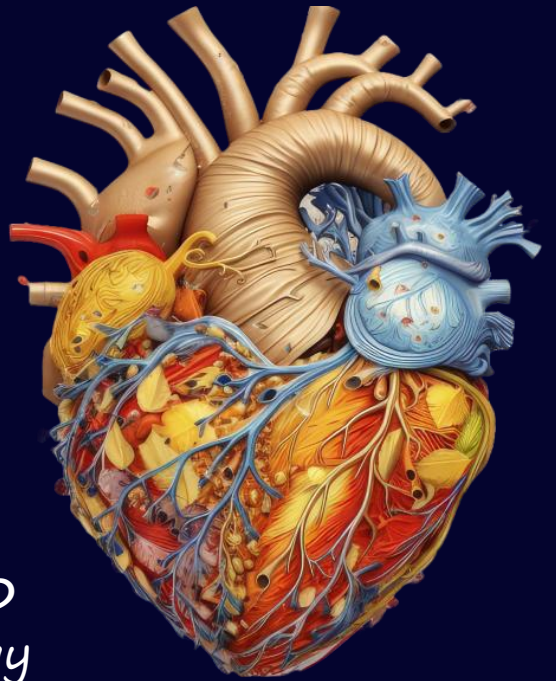
STRUCTURAL HEART INNOVATION
16th October 2024 | Madrid

Myval OCTACOR TRANSCATHETER HEART VALVE



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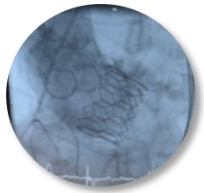
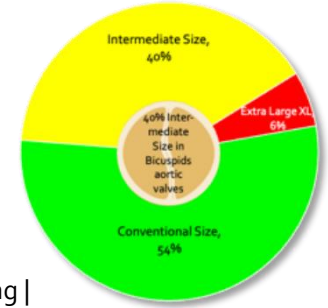
Hospital Clínico Universitario de Valladolid
Instituto de Ciencias del Corazón (ICICOR)

Myval THV Series

20,000+ Implants Globally	95+ Publications	3,500+ Patients Studied	Available Across 85+ Countries	46% Sizes (Int. + XL) Implanted are Unique





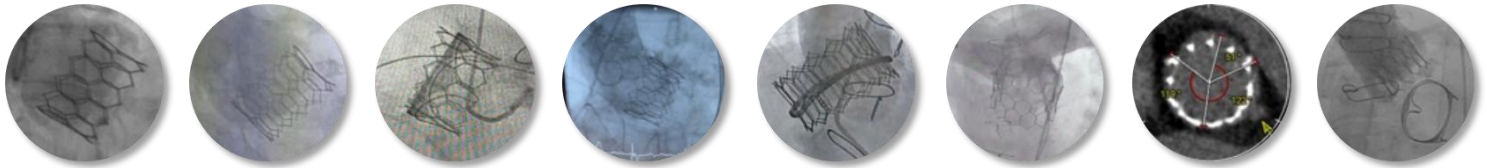
Consistent Performance Across Clinical Indications & Surgical Risk Categories

Low Event Rates

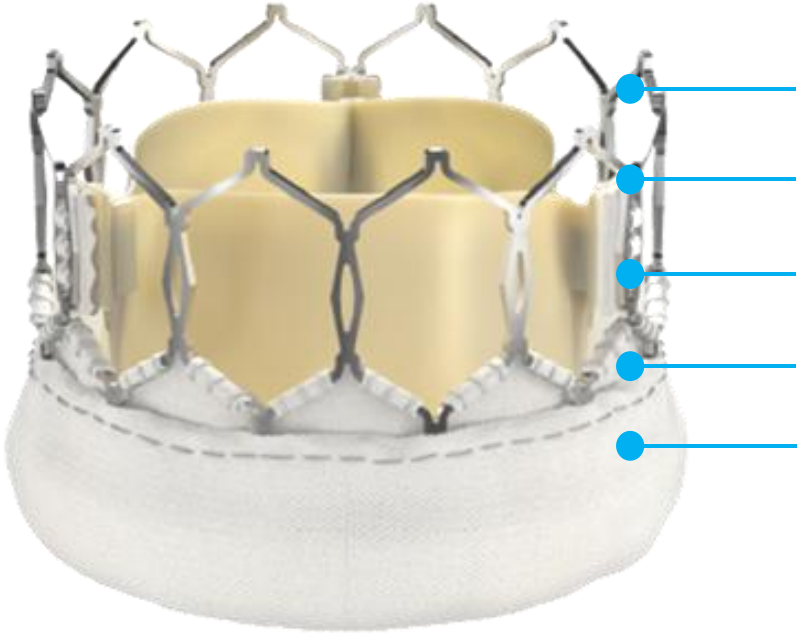
All Cause Mortality | All Stroke | Acute Kidney Injury | Life Threatening Bleeding | Major Vascular Complications | Paravalvular Leak | New Permanent Pacemakers

TAVR operators use Myval Octacor THV in a spectrum of clinical settings

Bicuspid Aortic Valve	Pure Aortic Regurgitation	Valve-in-Valve Interventions	Extra-Large Aortic Valve	Mitral Valve-in-Valve/Ring	Pulmonary Valve Replacement	Commissural Alignment	Paravalvular Leak (PVL)



Myval Octacor THV



Cobalt alloy frame
Radial strength & radiopacity

AntiCa treated bovine pericardium tri-leaflet valve

Naturally incorporated rhombus body for **columnar strength**

Internal PET sealing skirt for **minimizing aortic regurgitation**

Higher external PET skirt to plug micro-channels & further reduce paravalvular leak

Myval Octacor THV

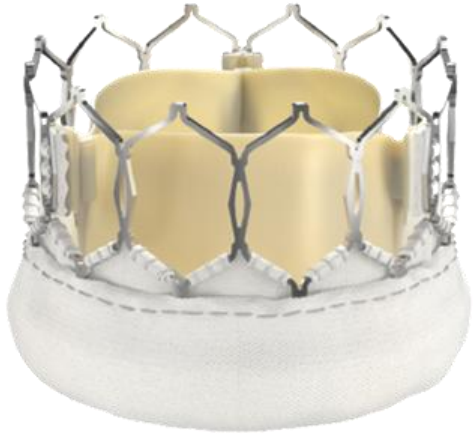
2-Row Hybrid Interlaced Octagons

Identical frame geometry to facilitate uniformity of expansion & to ensure stability during THV deployment

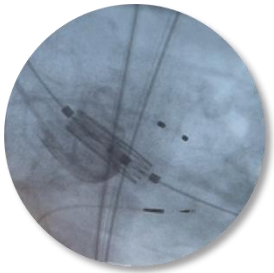
Open cells at outflow zone to **preserve coronary flow** ≈ 50%

Closed cells at inflow zone to **minimize aortic regurgitation** ≈ 50%

Short frame height 17-21 mm



Myval Octacor THV is directly crimped over Navigator Inception THV Balloon Delivery System



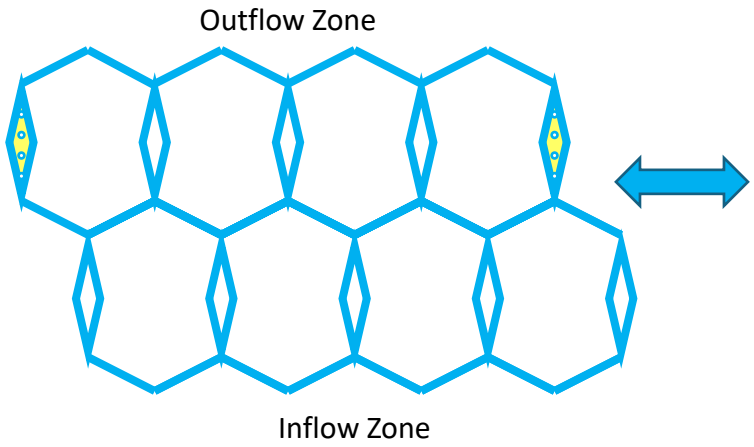
Landing zone marker on Navigator Inception THV Balloon for precise positioning

14Fr Python Introducer Sheath
Compatible with ∅ 20– 32 mm

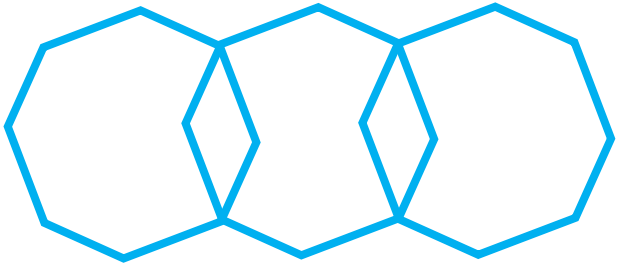
Myval Octacor THV

Novel Myval Octacor THV Design Concept

2-row Hybrid Interlacing Octagonal Cell Design

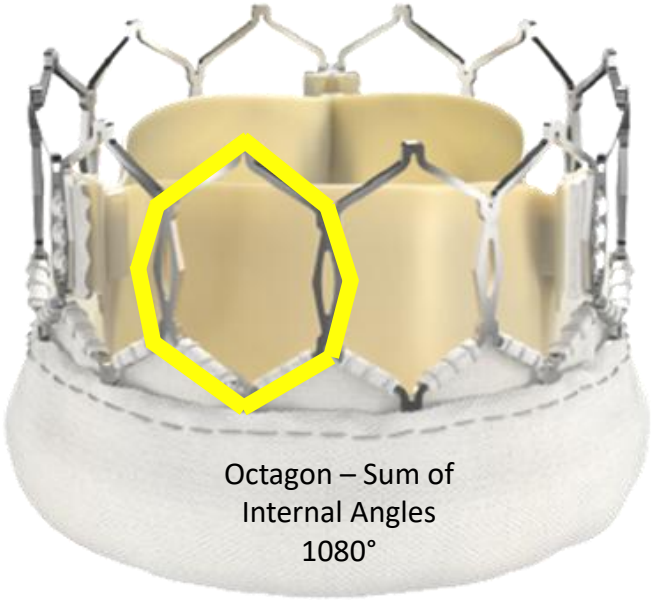


Interlaced Octagons & Rhombus Body



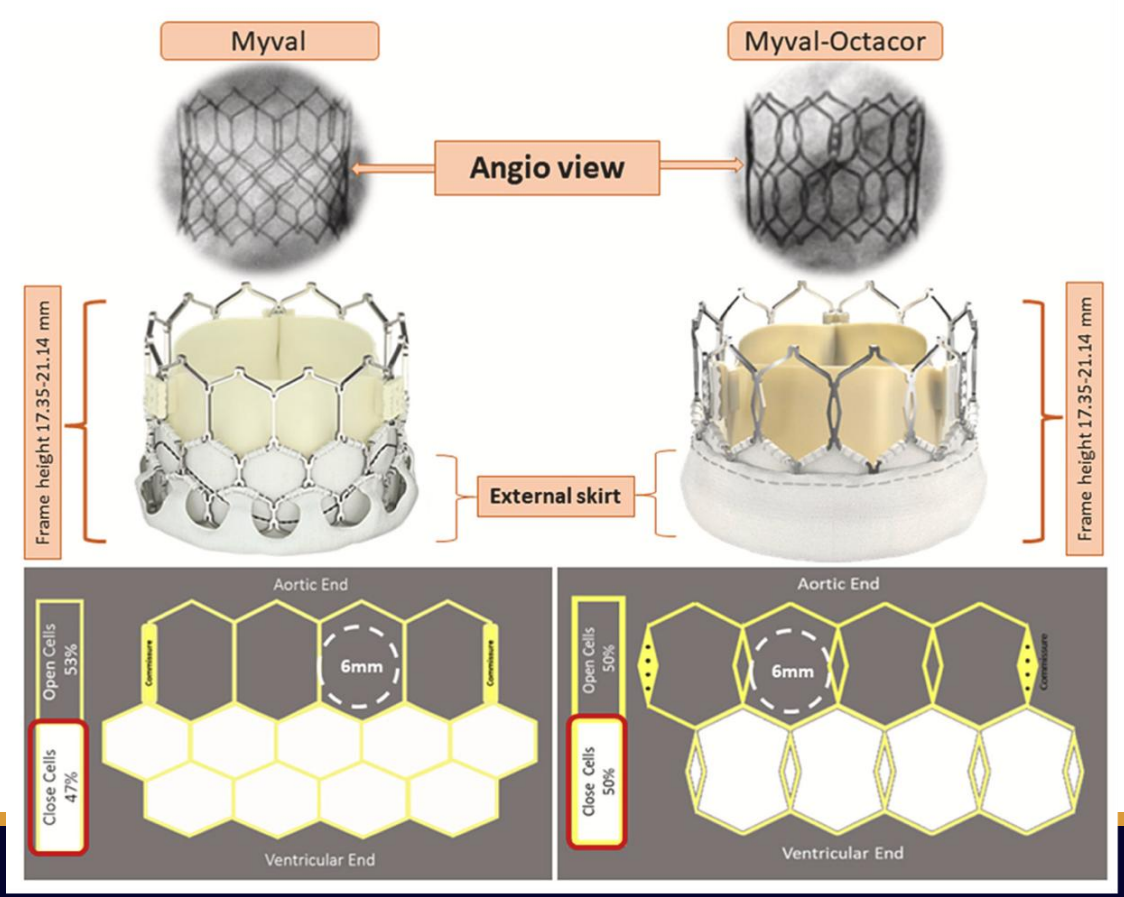
Myval Octacor THV

Myval Octacor THV
Foreshortening 19 – 20%



Octagon – Sum of Internal Angles 1080°

Myval Octacor THV



Myval Octacor THV

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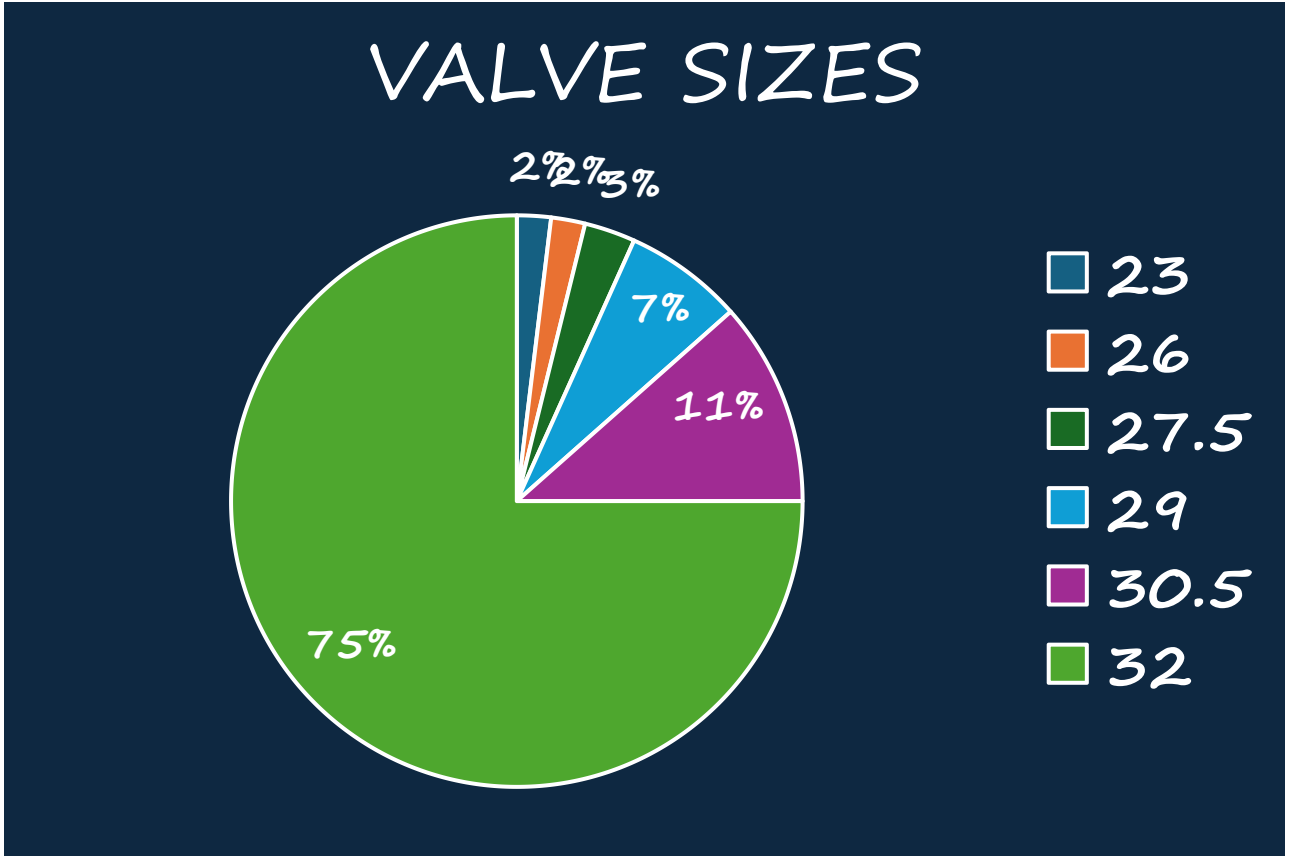
Myval Size Matrix & Technical Specs.	Area 314 mm²  20 mm	Area 363 mm²  21.5 mm	Area 415 mm²  23 mm	Area 471 mm²  24.5 mm	Area 531 mm²  26 mm	Area 594 mm²  27.5 mm	Area 661 mm²  29 mm	Area 731 mm²  30.5 mm	Area 804 mm²  32 mm
Perimeter	62.83 mm	67.54 mm	72.26 mm	76.97 mm	81.68 mm	86.39 mm	91.11 mm	95.82 mm	100.53 mm
Python Expandable *Introducer* Sheath	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr
Native Annulus Area (CT Derived)	270 – 330 mm²	314 – 380 mm²	360 – 440 mm²	410 – 500 mm²	460 – 560 mm²	510 – 630 mm²	570 – 700 mm²	630 – 770 mm²	700 – 840 mm²
Area-derived diameter	18.5 – 20.5 mm	20.0 – 22.0 mm	21.4 – 23.7 mm	22.8 – 25.2 mm	24.2 – 26.7 mm	25.5 – 28.3 mm	26.9 – 29.9 mm	28.3 – 31.3 mm	29.9 – 32.7 mm
Native Annulus Size by TEE	16 – 19 mm	17.5 – 20.5 mm	18 – 22 mm	19.5 – 23.5 mm	21 – 25 mm	22.5 – 26.5 mm	24 – 28 mm	25.5 – 29.5 mm	27 – 31 mm

Sizing of Myval Octacor THV should be in correlation with cross-sectional CT images/measurement of AAo | STJ | SOV | Annulus | LVOT | Coronary ostia heights | Valve anatomy (tricuspid/bicuspid) | Ca^{2+} score & dispersion across the root complex during the heart team meeting prior to procedure.

PURE AORTIC REGURGITATION

- *Need for XL Size Implants in TAVR is NOT TRIVIAL, Requirement is up to 10% in real world scenario*
- Globally, TAVR in very large annuli is an under-served clinical situation due to hitherto non-availability of true XL size TAVR implants
- *Myval Octacor THV = 804 mm² to 840 mm²*

Ø 32.0 mm

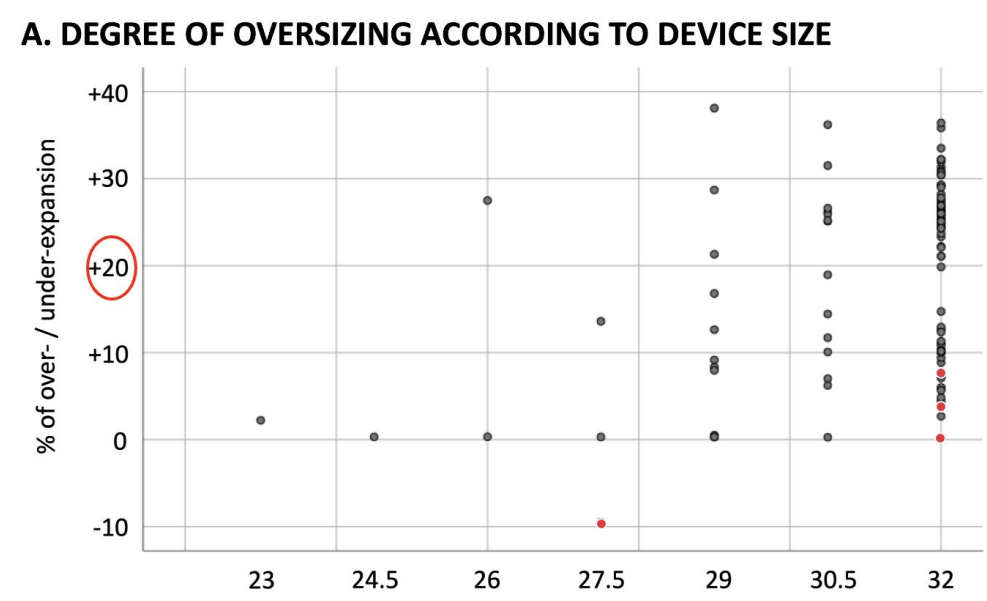


PURE STUDY

Amat-Santos et al. Eurointervention 20

PURE AORTIC REGURGITATION

RANGE OF EXTRA-CC: 0 – 9 cc



Nominal	26 (24.5)
+1 cc	14 (13.2)
+2 cc	15 (14.2)
+3 cc	21 (19.8)
+4 cc	8 (7.5)
+5 cc	4 (3.8)
+6 cc	7 (6.6)
+7 cc	1 (0.9)
+8 cc	9 (8.5)
+9 cc	1 (0.9)

IJ Amat Santos et al. Eurointervention 2023

PURE STUDY

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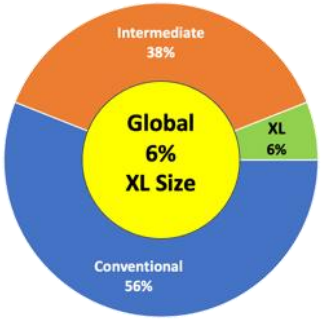
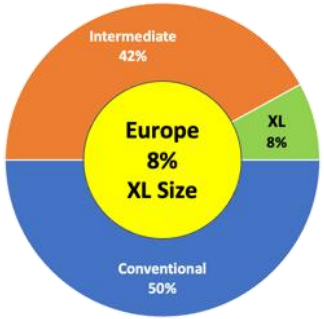
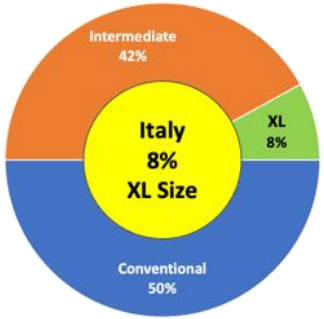
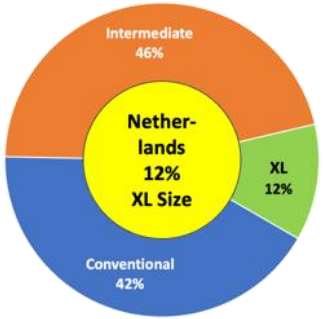
Myval Octacor THV



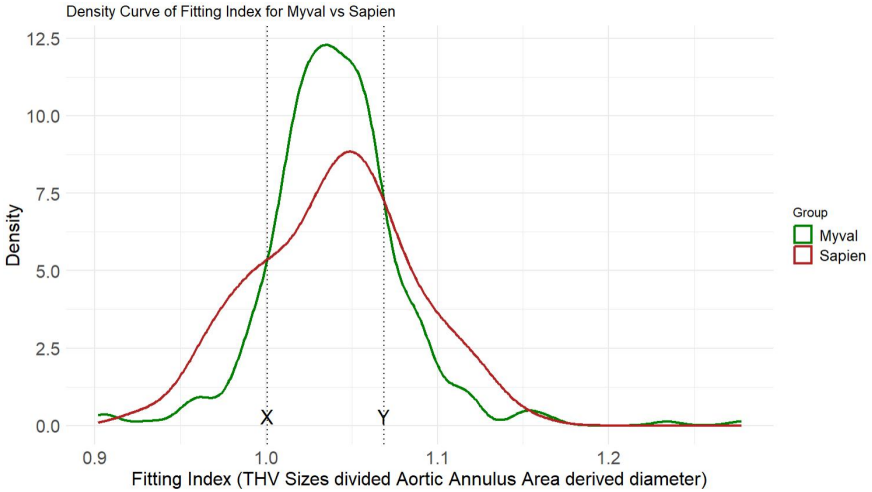


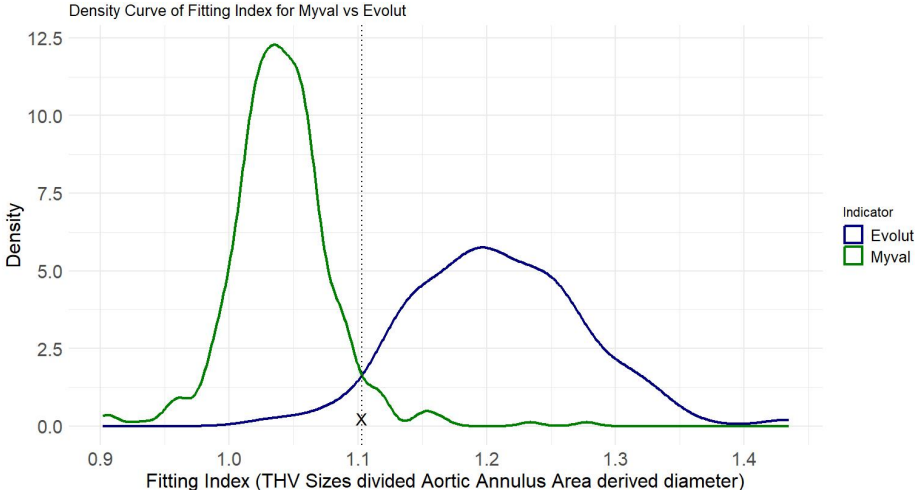




*"The availability of the intermediate-size THVs could mitigate the hazardous selection of grossly undersized or oversized valve, thereby reducing PVR, conduction disturbances as well as life-threatening aortic annular rupture."**

''FITTING INDEX''





PACEMAKER

RATE

	Global population n=1131	Myval n=135	Sapien 3 n=290	p	Evolut n=298	p	Acurate n=180	p	Portico n=125	p	Allegra n=103	p
PPI	176 (15.9)	10 (7.4)	39 (13.4)	0.069	53 (18.5)	0.003	16 (9.1)	0.585	36 (29.5)	<0.001	22 (22)	0.001

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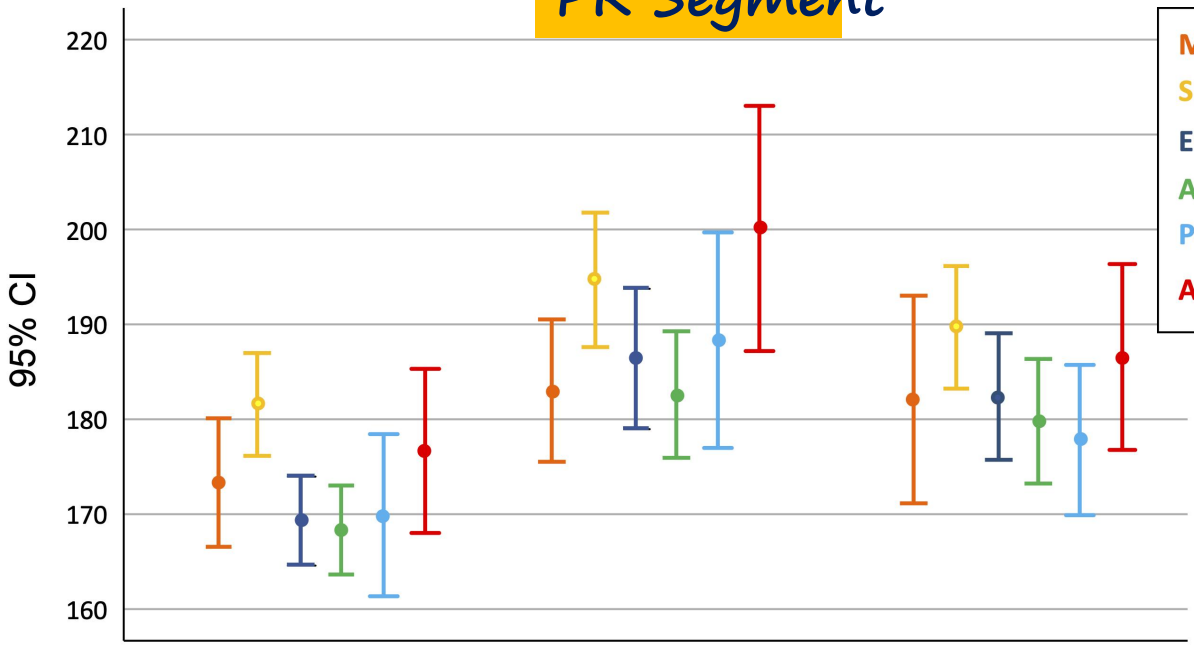
PR Segment



	PR PRE	PR POST	PR DISCHARGE
Myval - Sapien	0.097	0.051	0.226
Myval - Evolut	0.342	0.504	0.967
Myval - Acurate	0.227	0.929	0.715
Myval - Portico	0.525	0.414	0.525
Myval - Allegra	0.554	**0.024**	0.556

Table shows the p-values of the PR comparison between valve types in each time period.

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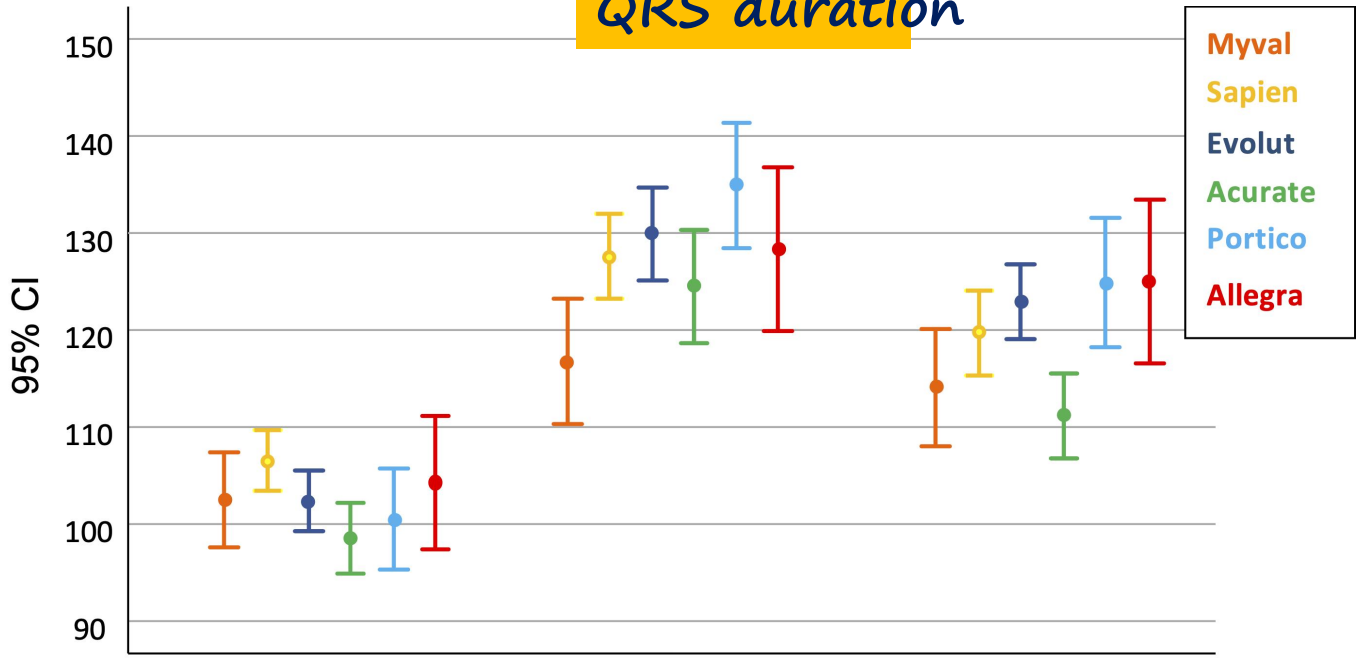
QRS duration

N=1131



	QRS PRE	QRS POST	QRS DISCHARGE
Myval - Sapien	0.200	**0.006**	0.153
Myval - Evolut	0.929	**0.001**	**0.015**
Myval - Acurate	0.177	0.075	0.435
Myval - Portico	0.569	**<0.001**	**0.019**
Myval - Allegra	0.695	**0.030**	**0.040**

Table shows the p-values of the QRS comparison between valve types in each time period.

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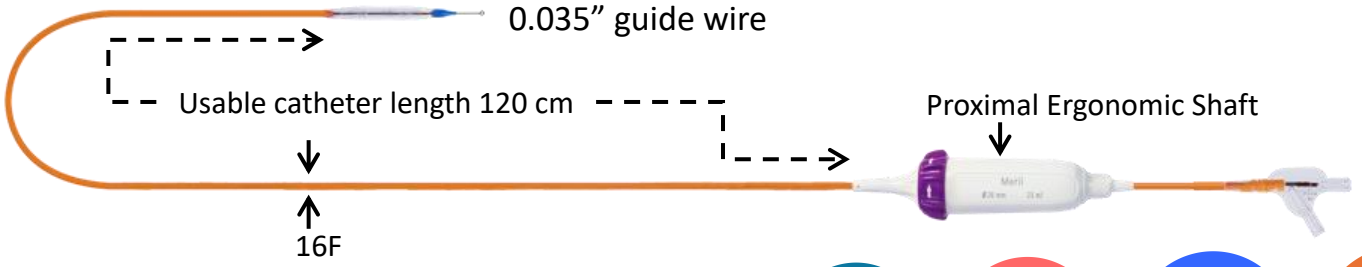
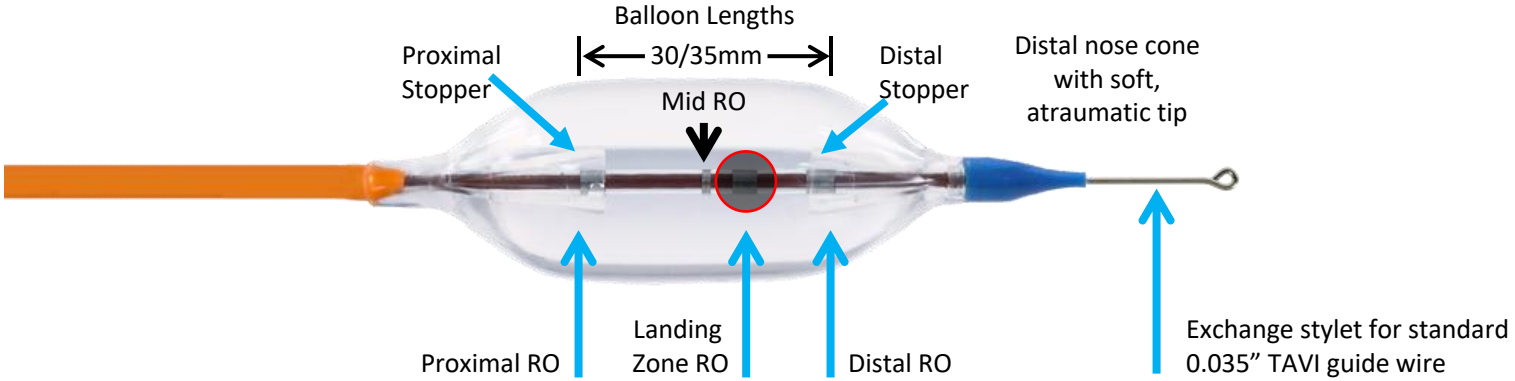
Navigator Inception THV Delivery System



Navigator Balloon Ø	20 mm	21.5 mm	23 mm	24.5 mm	26 mm	27.5 mm	29 mm	30.5 mm	32 mm
Balloon Length	30 mm					35 mm			
Balloon RBP	6 atm								
Ratio of 75:25 Saline : Contrast to achieve stated balloon Ø	13 mL	16 mL	19 mL	21 mL	24 mL	29 mL	33 mL	37 mL	41 mL

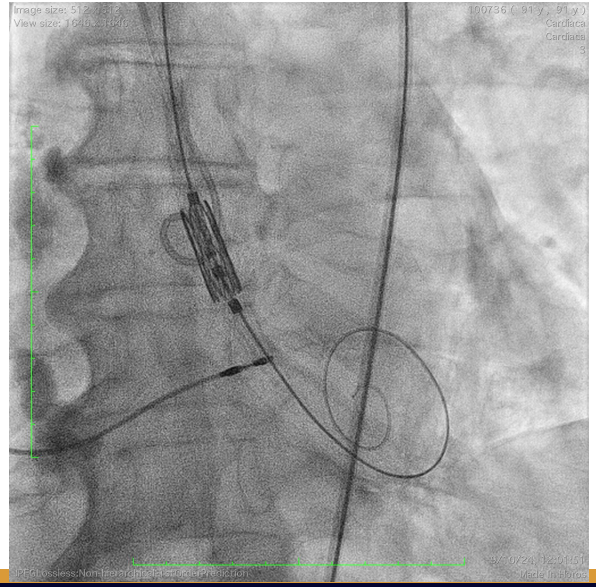
Navigator Inception THV Balloon

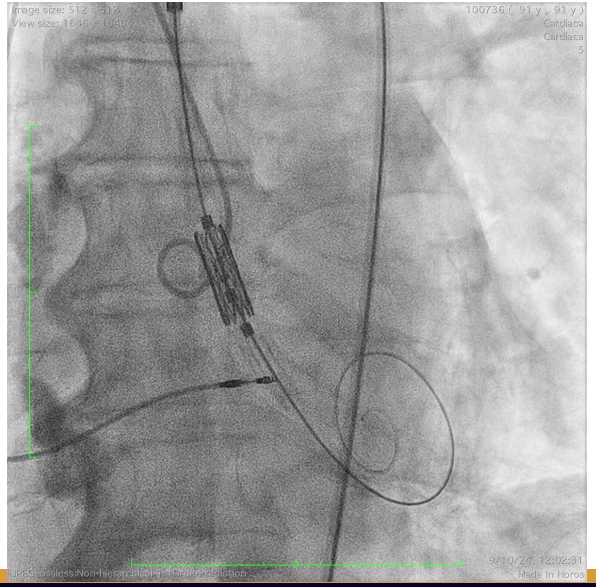


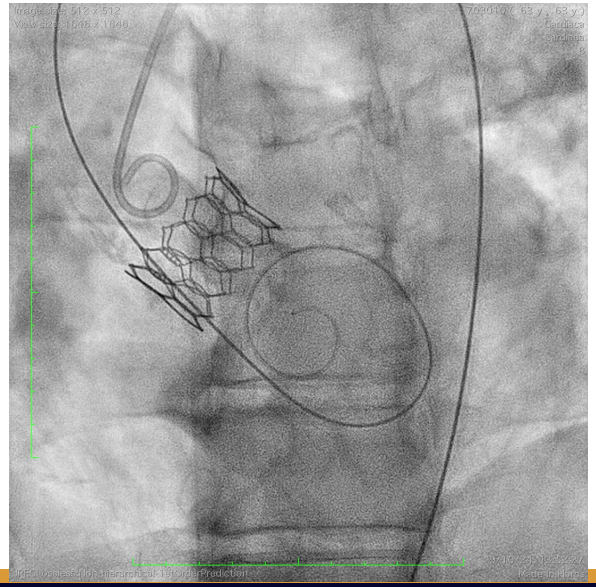
- Landing zone marker is 70 (Aorta) : 30 (Ventricle)
- Proximal=Distal=Landing zone markers = 3m length
- Mid-marker is 50% of balloon length and 1mm length

Navigator Inception THV Balloon Expansion

- Dual expansion ports at each end → rapid, simultaneous, controlled expansion of distal and proximal ends
- Bone pattern of inflation → precision annular position and deployment without any risk of valve migration
- Rapid balloon inflation using a large volume inflation device is possible with controlled palm thrust
- Rapid balloon deflation 3-5 sec ensures procedural safety and compliance







Python 14 Fr Introducer Sheath

Two separate, calibrated loading tubes ensure temporary opening of hemostatic valves in proximal port allowing smooth passage of crimped Myval Octacor THV System

Sheath expands momentarily (like a python swallowing prey) to allow passage of Crimped Myval Octacor THV System

14 Fr entry profile allows atraumatic percutaneous access

RO distal tip

Seamless transition from dilator to distal tip

Lubricious, hydrophilic shaft coating

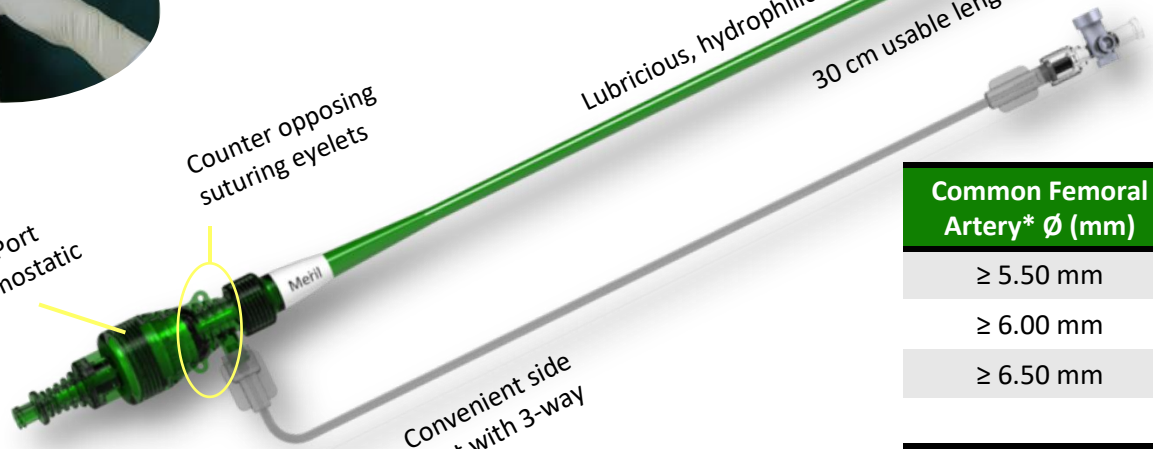
30 cm usable length

Counter opposing suturing eyelets

Proximal Port with Hemostatic valves

Dilator with locking threads

Convenient side port with 3-way



Common Femoral Artery* Ø (mm)	Myval Octacor THV Ø (mm)
≥ 5.50 mm	20 mm, 21.5 mm, 23 mm, 24.5 mm
≥ 6.00 mm	26 mm, 27.5 mm, 29 mm
≥ 6.50 mm	30.5 mm, 32 mm

Python 14 Fr Introducer Sheath comes with additional 18 Fr Dilator

CrocoDial Compass THV Crimping Tool

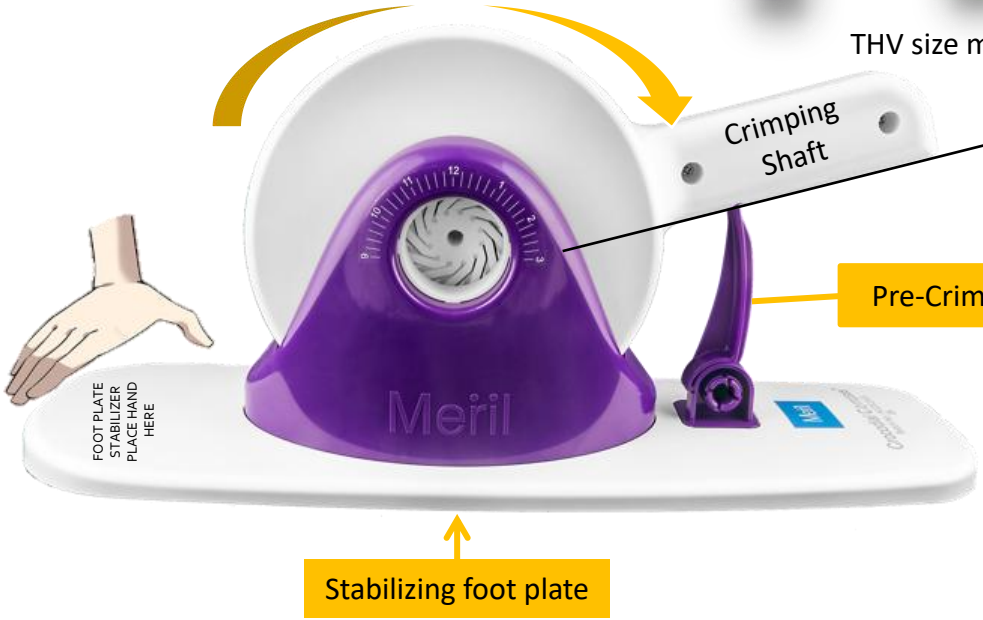
Effort free sliding mechanism

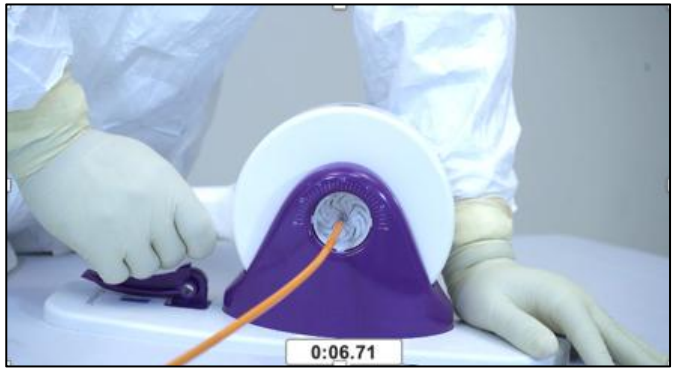
20-21.5 mm

23-27.5 mm

29-32 mm

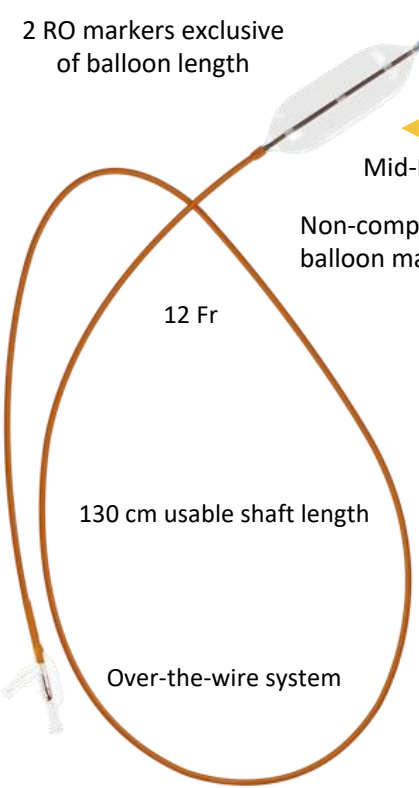
THV size matched anchors



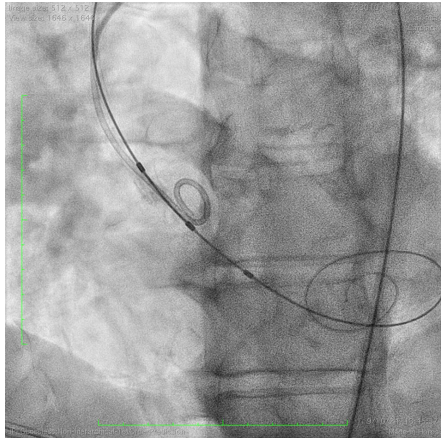


Free hand may be used to stabilize the crimper during final crimping.

Mammoth Balloon Dilatation Catheter

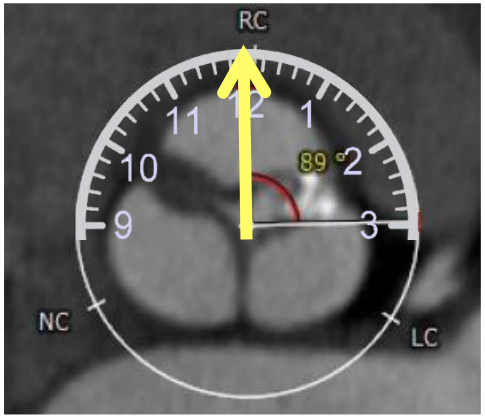


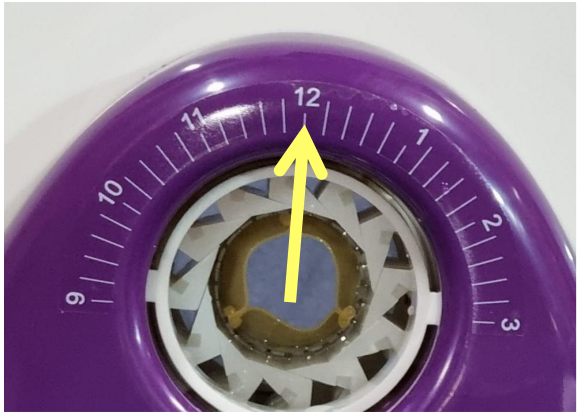
Control balloon depth within LV and minimize iatrogenic damage to conduction system during pre-dilatation.

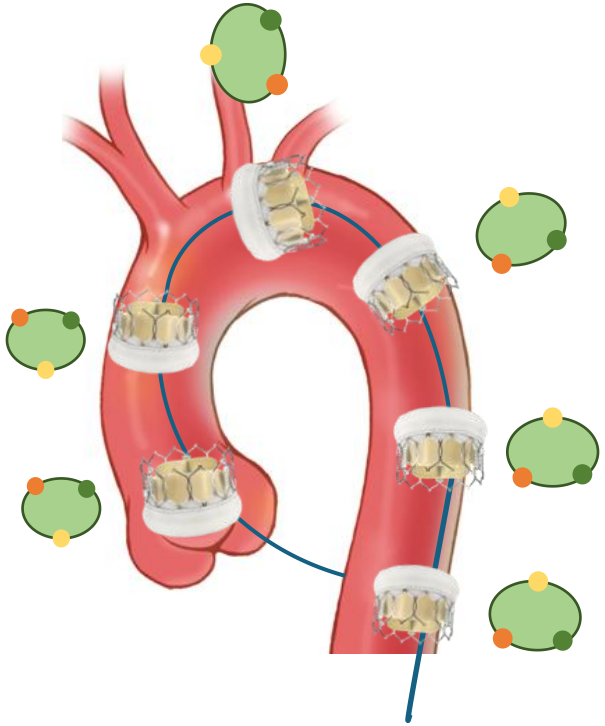


Mammoth Balloon Ø	14 mm	16 mm	18 mm	20 mm	23 mm	25 mm	28 mm	30 mm
Balloon length	← 40 mm →							
Balloon RBP	8 atm	← 6 atm →						
Volume of 75:25 saline:contrast to achieve stated diameter	8 mL	10 mL	13 mL	16 mL	23 mL	25 mL	34 mL	42 mL

OctaAlign Technique







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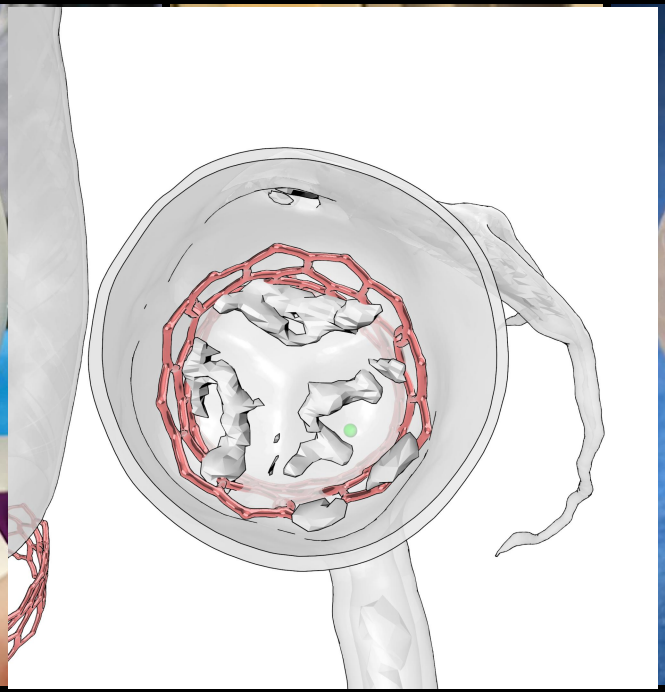
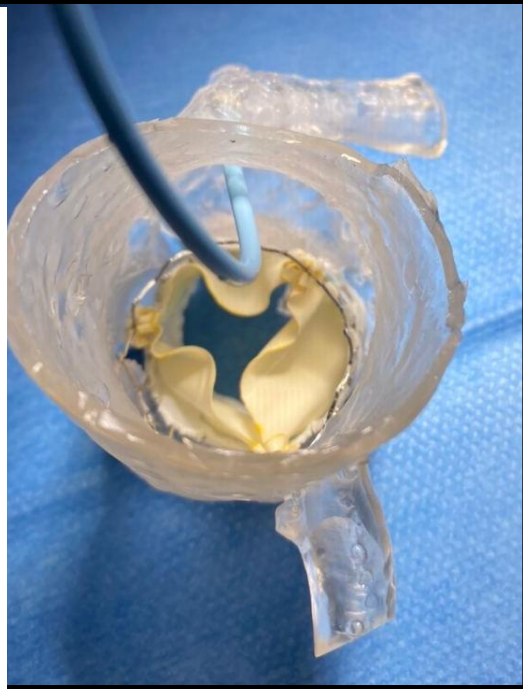




Solftware Patent Number: P20203

ACA PROJECT – Myval

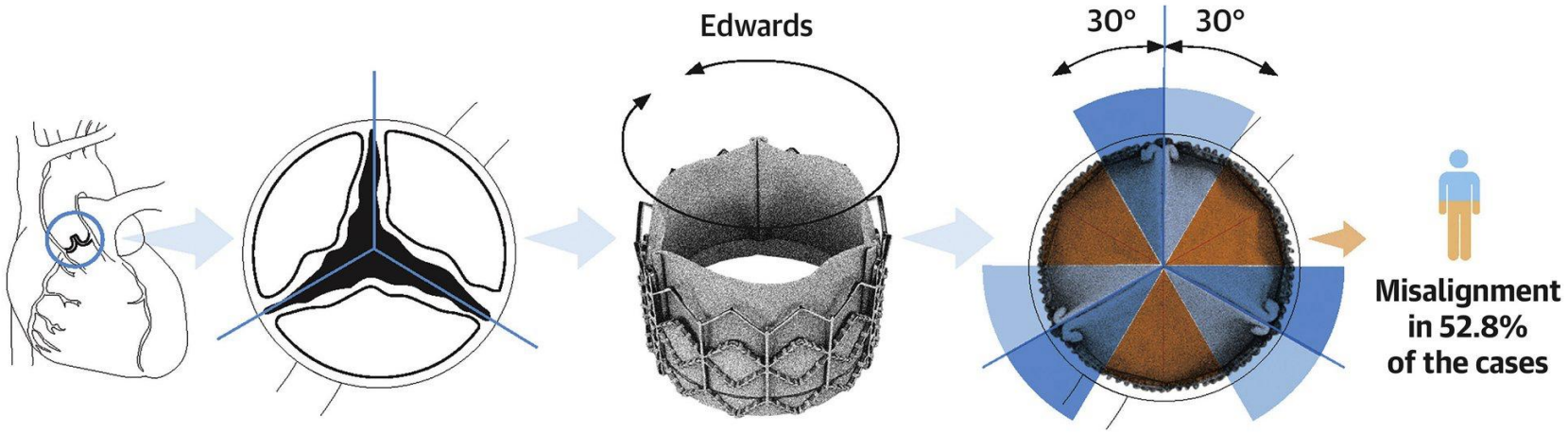
	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7	Case 8	Case 9	Case 10
In silico simulation	9.4	4.1	5.8	9.0	8.8	4.4	11.5	4.3	0.3	3.7
In vivo	11.0	22.8	7.9	10.0	7.9	23.6	18.3	24.0	11.7	30.3

6 PATIENTS NO MISALIGNMENT
4 PATIENTS MILD MISALIGNMENT

NO CASES OF MODERATE-SEVERE MISALIGNMENT

Amat-Santos et al. REC 2

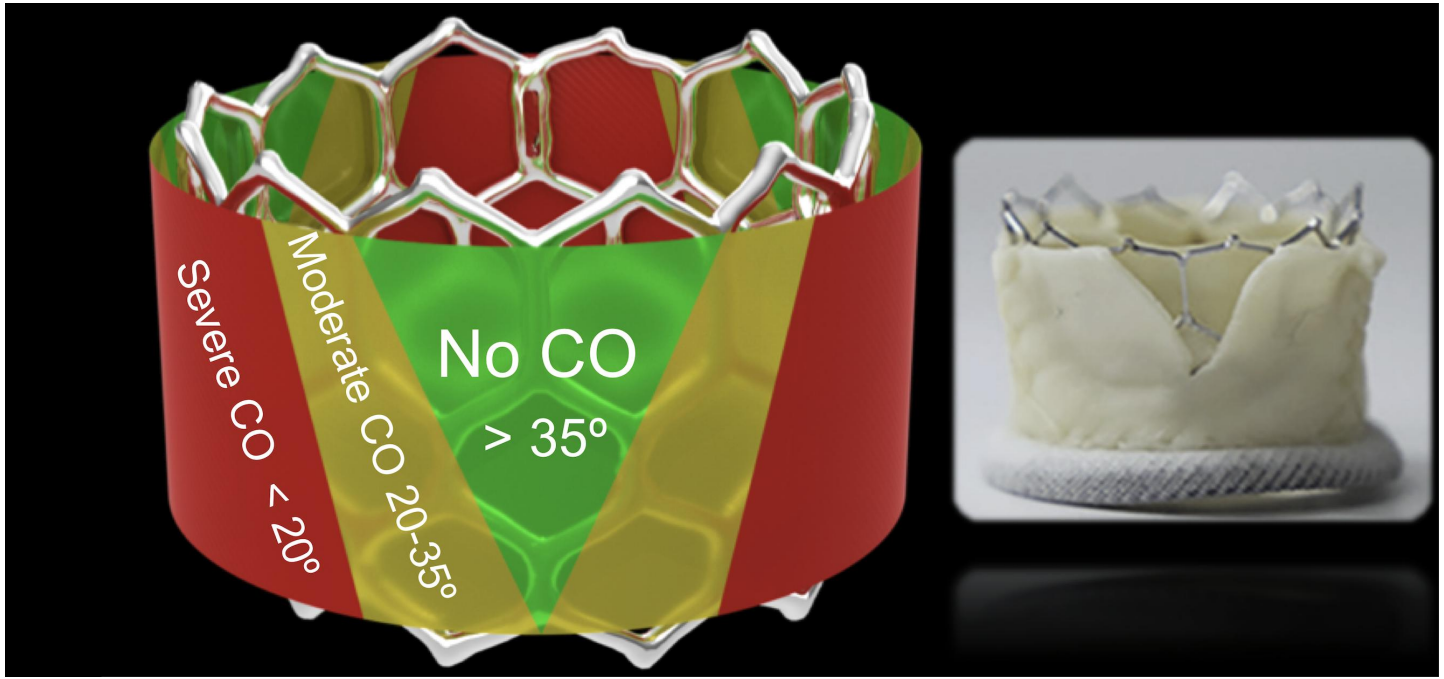
CENTRAL ILLUSTRATION: Main Outcomes of Aligned Versus Misaligned Balloon-Expandable Transcatheter Aortic Valve Replacement (N = 324)



Outcome	Aligned (n = 153)	Misaligned (n = 171)	Odds Ratio [95% CI]
VARC-2 Early Safety	98.5%	94.3%	0.27 [0.04-1.10]
Aortic regurgitation > mild	3.6%	5.7%	1.55 [0.44-6.36]
Residual gradient (>20 mm Hg)	7.2%	7.4%	1.02 [0.37-2.86]
Relative AV gradient increase	8.3%	17.6%	2.35 [1.05-5.69]

Raschpichler M, et al. J Am Coll Cardiol Intv. 2022;15(11):1126-1136.

UN-EFFECTIVE BASILICA??



OCTACOR India study

Table 1
Baseline and demographic characteristics.

Characteristics	n = 123
Age, years, mean ± SD	70.07 ± 8.33
Gender, n (%)	
Male	77 (62.60)
Female	46 (37.40)
Body mass index, kg/m^2, mean ± SD	25.4 ± 4.68
Body surface area, m^2, mean ± SD	1.70 ± 0.18
STS score, %, median (IQR)	3.20 (1.80–5.05)
Type of valve treated	
Native tricuspid aortic valve	74 (60.16)
Native bicuspid aortic valve	49 (39.84)
Type 0 (no raphe)	18 (14.63)
Type 1 (one raphe)	26 (21.14)
Type 1a	22 (17.89)
Type 1b	4 (3.25)
Type 2 (two raphes)	5 (4.07)
Medical history, n (%)	
Coronary artery disease	53 (43.09)
Chronic kidney disease	14 (11.38)
Cerebrovascular disease	3 (2.44)
Mitral valve replacement	7 (5.69)
Mitral valvotomy/mitral valvuloplasty	2 (1.63)
Tricuspid valve repair/annuloplasty	2 (1.63)
Coronary artery bypass graft	11 (8.94)
Hypertension	75 (60.98)
Diabetes mellitus	60 (48.78)
Hemodialysis	1 (0.81)
Chronic obstructive pulmonary disease	19 (15.45)
Peripheral vascular disease	4 (3.25)
Active or past cancer	2 (1.63)
Myocardial infarction	6 (4.88)
Pacemaker	6 (4.88)
Smoking	8 (6.50)

Table 4
Procedural characteristics.

Procedural characteristics	n (%)
Implanted Myval Octacor THV size, mm (n = 123)	
20	10 (8.13)
21.5	21 (17.07)
23	29 (23.58)
24.5	24 (19.51)
26	18 (14.63)
27.5	11 (8.94)
29	9 (7.32)
30.5	1 (0.81)
Intermediate-size Myval Octacor THV, (n = 123)	56 (45.53)
Intermediate-size Myval Octacor THV in bicuspid anatomy, (n = 49)	19 (38.8)
Intermediate-size Myval Octacor THV in tricuspid anatomy, (n = 74)	37 (50.0)
Pre-dilatation, (n = 123)	69 (56.09)
Native bicuspid aortic valve (n = 49)	32 (65.3 %)
Native tricuspid aortic valve (n = 74)	37 (50 %)
Post-dilatation, (n = 123)	17 (13.82)

OCTACOR India study

Table 5
Cumulative clinical outcomes of Myval Octacor THV at 30-days follow-up.

Events, n (%)	Post-procedure (*n* = 123)	30 Days Follow-up (n = 123)
All-cause mortality	1 (0.8)	2 (1.6)
Cardiovascular	1 (0.8)	2 (1.6)[@]
Valve-related	0	0
Non-cardiovascular	0	0
All stroke	0	0
Acute kidney injury	2 (1.6)[@,$]	2 (1.6)
Stage 1	0	0
Stage 2	0	0
Stage 3	0	0
Stage 4	2 (1.6)	2 (1.6)
New permanent pacemaker implant (PPI)	13 (10.6)[^]	13 (10.6)
Bleeding complications (types 3 and 4)	0	0
Major vascular complications	0	0
Paravalvular leakage	2 (1.6)	2 (1.6)
Moderate	2 (1.6)	2 (1.6)
Severe	0	0
Procedure-related or valve-related hospitalization	0	0
Cardiac structural complications	0	0
Conversion to open surgery	0	0
Implantation of multiple (>1) transcatheter valves during index hospitalization	0	0
Valve malposition	0	0
Myocardial Infarction	0	0
Bioprosthetic valve dysfunction	0	0
Technical success*	123 (100)	–
Device success[#] (30 days)	–	121 (98.4)
Freedom from surgery or intervention related to the device (excluding PPI) (through 30 days)	123 (100)	123 (100)

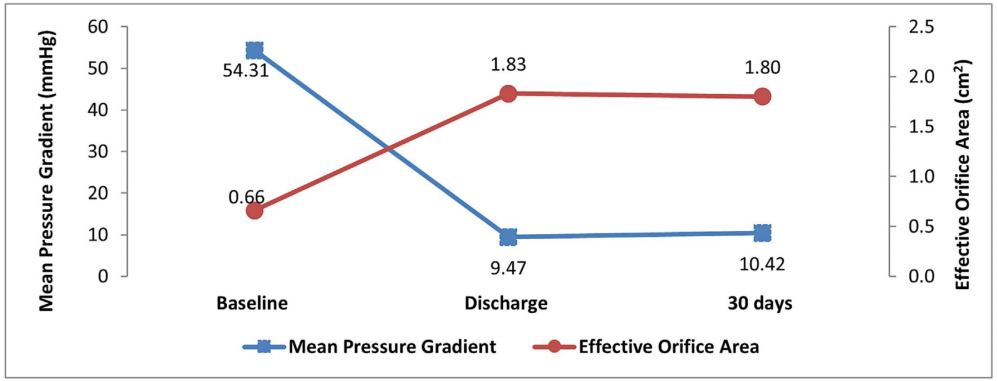
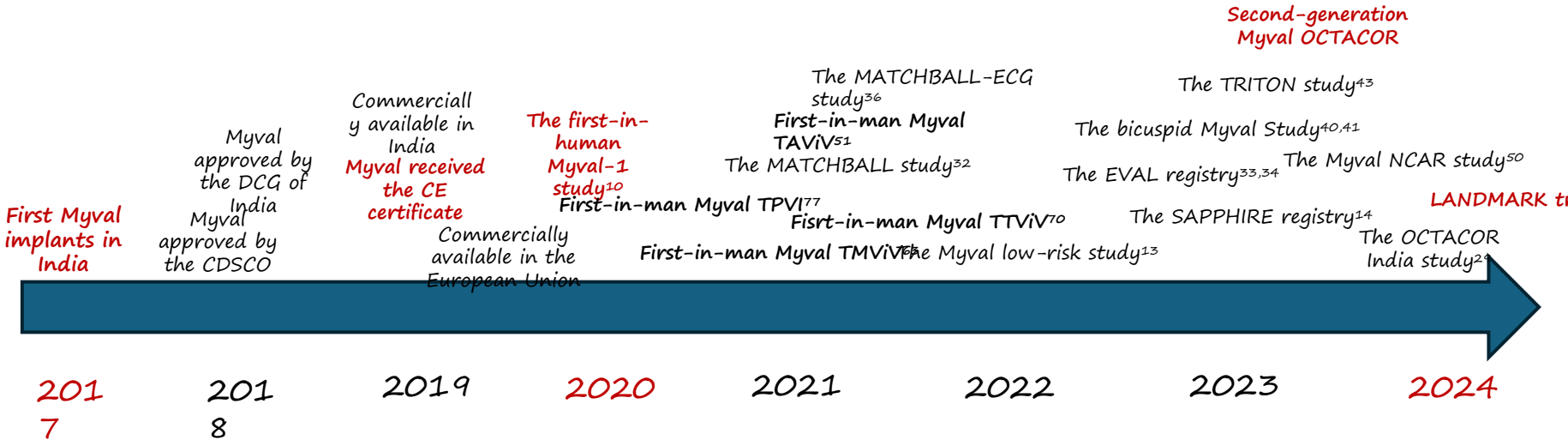
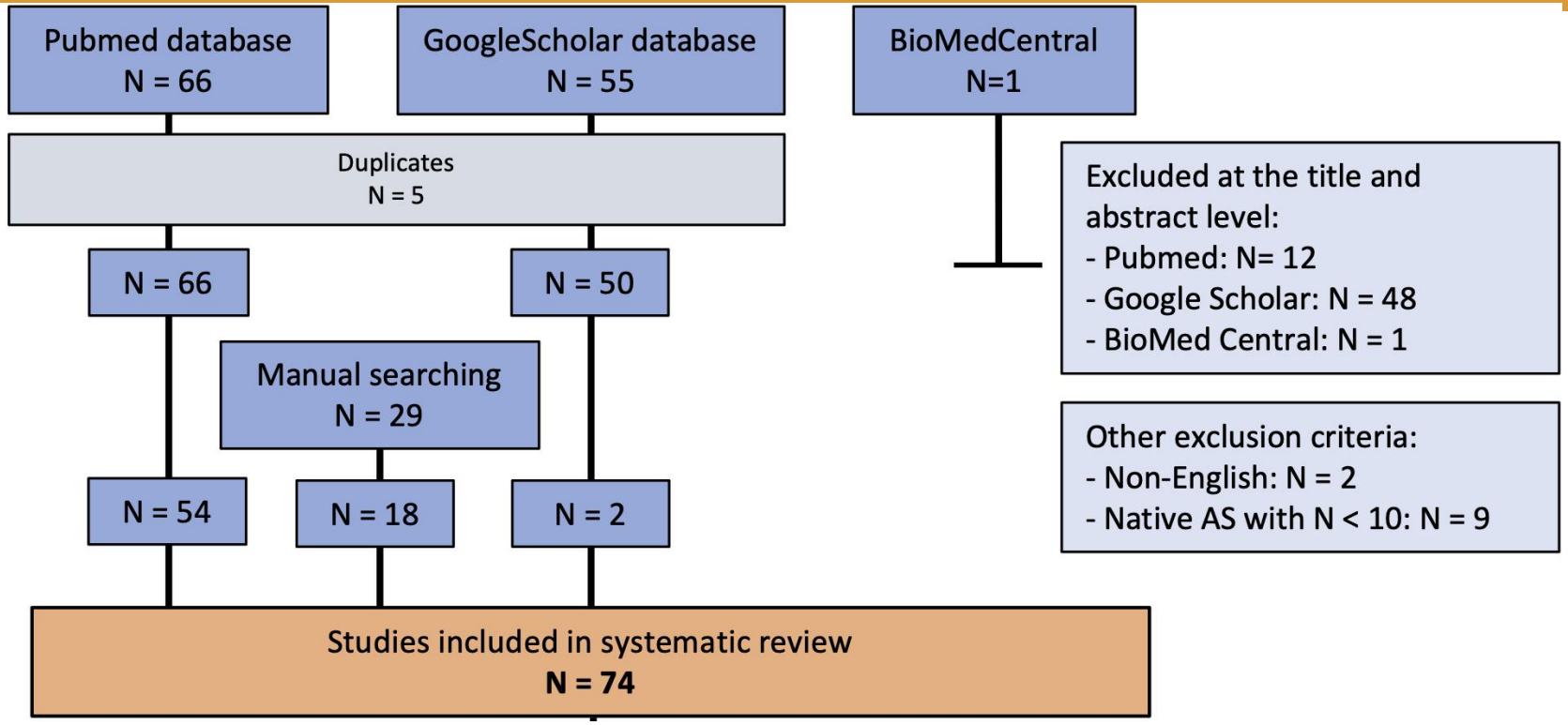
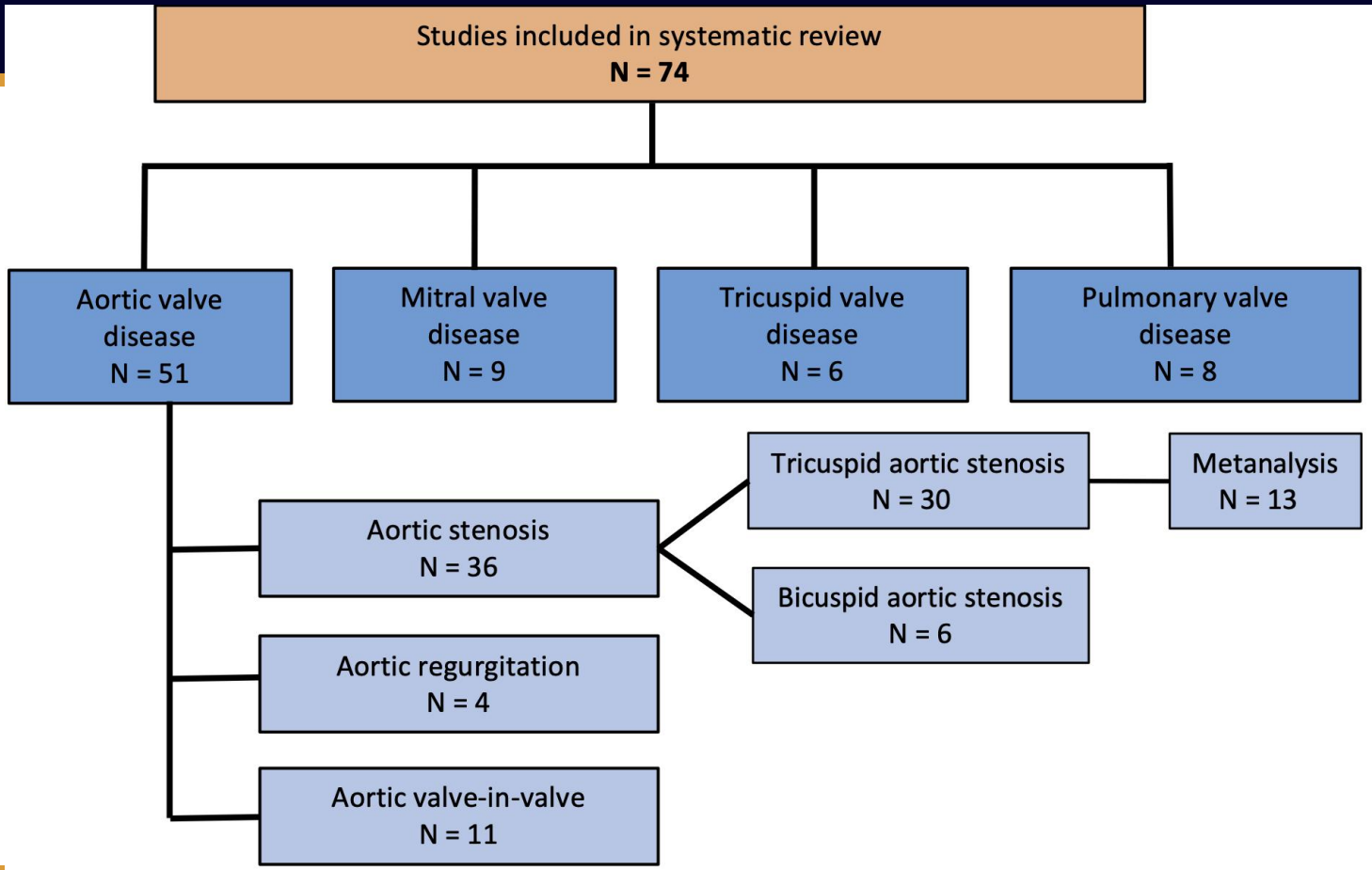


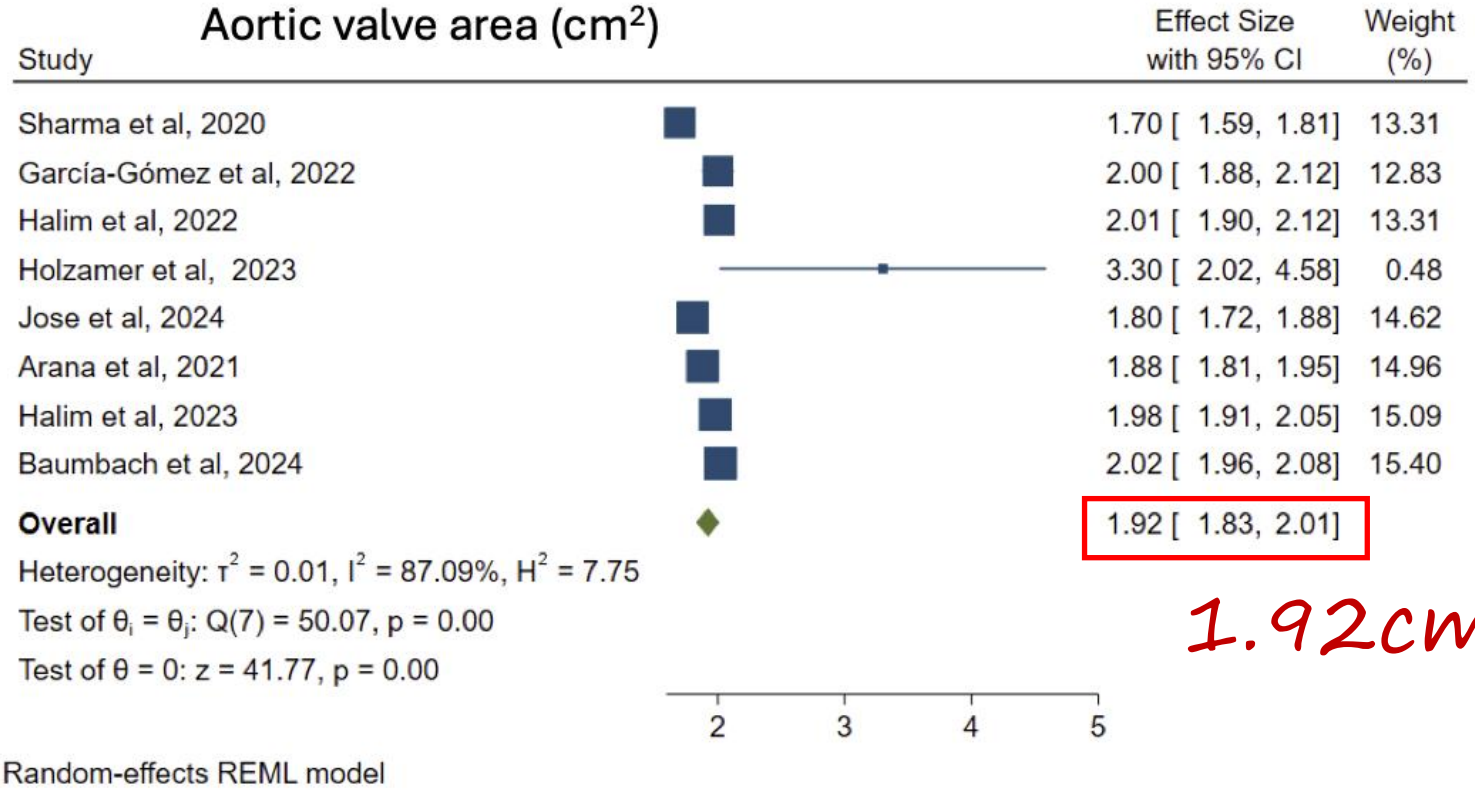
Fig. 2. Comparison of hemodynamic parameters of the matched population (n = 31) up to 30 days follow-up.


First Myval implants in India
Myval approved by the CDSCO
Myval approved by the DCG of India
Commerciall y available in India
Myval received the CE certificate
Commercially available in the European Union
The first-in-human Myval-1 study[10]
First-in-man Myval TPVI[77]
First-in-man Myval TMViV[75]
The MATCHBALL-ECG study[36]
First-in-man Myval TAViV[51]
The MATCHBALL study[32]
Fisrt-in-man Myval TTViV[70]
The Myval low-risk study[13]
Second-generation Myval OCTACOR
The TRITON study[43]
The bicuspid Myval Study[40,41]
The EVAL registry[33,34]
The Myval NCAR study[50]
LANDMARK trial[3
The SAPPHIRE registry[14]
The OCTACOR India study[2
2017
2018
2019
2020
2021
2022
2023
2024


Pubmed database
N = 66
GoogleScholar database
N = 55
BioMedCentral
N=1
Duplicates
N = 5
Excluded at the title and abstract level:
- Pubmed: N= 12
- Google Scholar: N = 48
- BioMed Central: N = 1
N = 66
N = 50
Manual searching
N = 29
Other exclusion criteria:
- Non-English: N = 2
- Native AS with N < 10: N = 9
N = 54
N = 18
N = 2
Studies included in systematic review
N = 74


Studies included in systematic review
N = 74
Aortic valve disease
N = 51
Mitral valve disease
N = 9
Tricuspid valve disease
N = 6
Pulmonary valve disease
N = 8
Aortic stenosis
N = 36
Tricuspid aortic stenosis
N = 30
Metanalysis
N = 13
Bicuspid aortic stenosis
N = 6
Aortic regurgitation
N = 4
Aortic valve-in-valve
N = 11

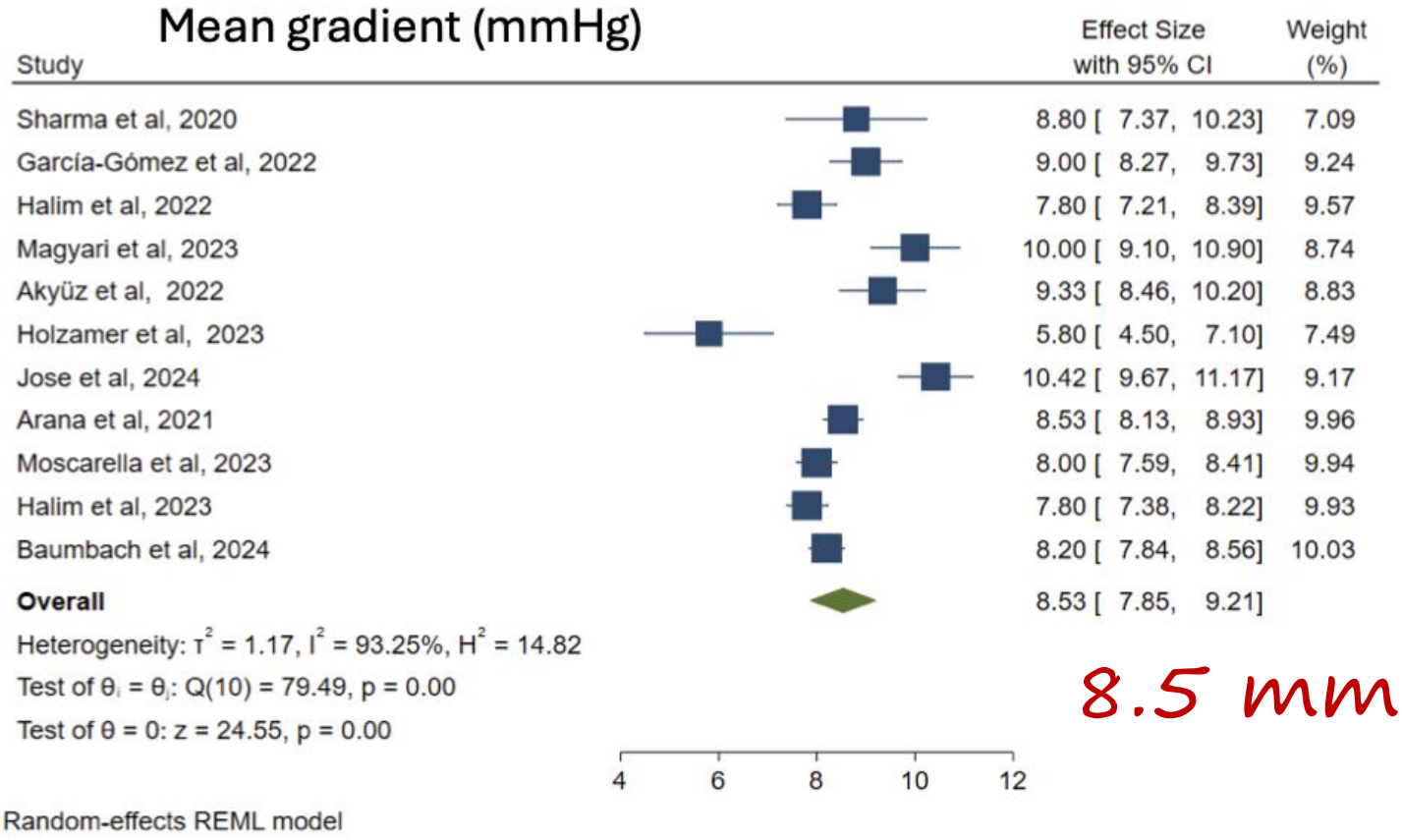
a


Aortic valve area (cm²)
Study
Effect Size with 95% CI
Weight (%)
Sharma et al, 2020
1.70 [1.59, 1.81] 13.31
García-Gómez et al, 2022
2.00 [1.88, 2.12] 12.83
Halim et al, 2022
2.01 [1.90, 2.12] 13.31
Holzamer et al, 2023
3.30 [2.02, 4.58] 0.48
Jose et al, 2024
1.80 [1.72, 1.88] 14.62
Arana et al, 2021
1.88 [1.81, 1.95] 14.96
Halim et al, 2023
1.98 [1.91, 2.05] 15.09
Baumbach et al, 2024
2.02 [1.96, 2.08] 15.40
Overall
1.92 [1.83, 2.01]
Heterogeneity: τ² = 0.01, I² = 87.09%, H² = 7.75
Test of θi = θj: Q(7) = 50.07, p = 0.00
Test of θ = 0: z = 41.77, p = 0.00
2
3
4
5
Random-effects REML model

1.92cm²

b

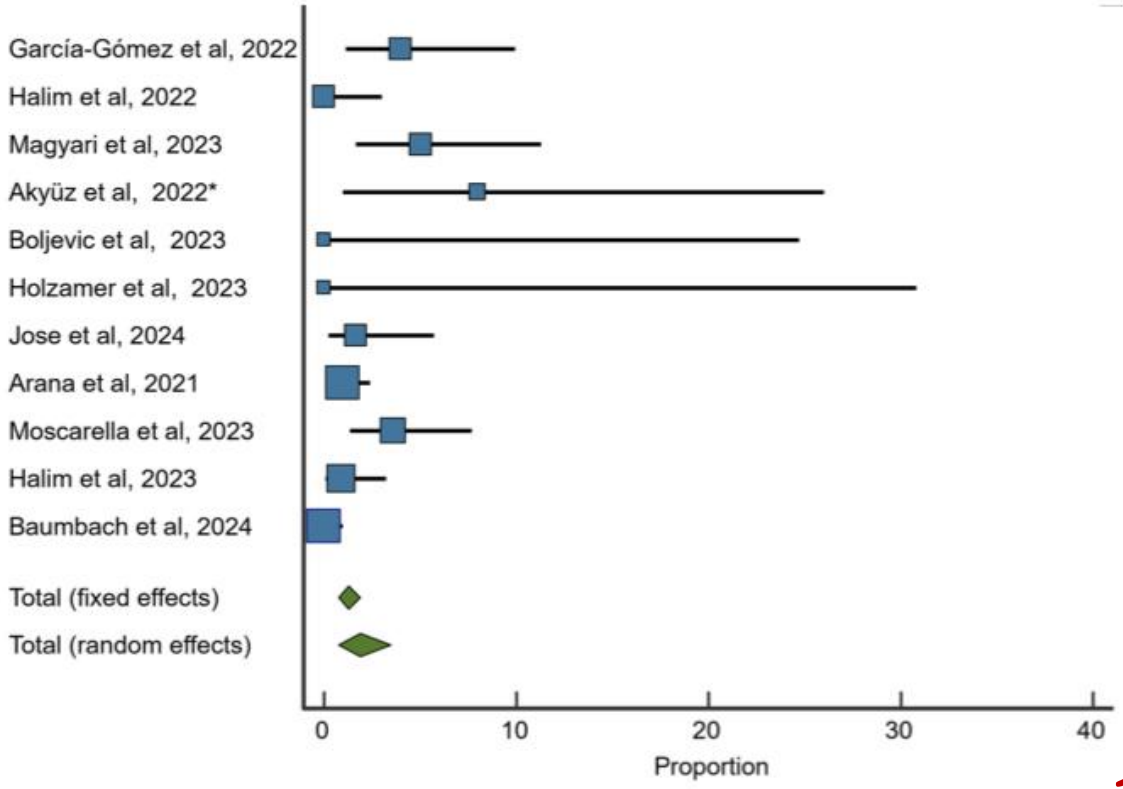
Mean gradient (mmHg)



8.5 mmHg

C

≥ Moderate PVR 1 month (%)



Sample size	N PVR	Proportion (%)	95% CI
100	4	4.00	1.10 to 9.93
120	0	0.00	0.00 to 3.03
100	5	5.00	1.64 to 11.28
25	2	8.00	0.98 to 26.03
13	0	0.00	0.00 to 24.71
10	0	0.00	0.00 to 30.85
123	2	1.63	0.20 to 5.75
416	4	0.96	0.26 to 2.44
166	6	3.61	1.34 to 7.70
223	2	0.90	0.11 to 3.20
384	0	0.00	0.00 to 0.96
1680	25	1.26	0.78 to 1.91
1680	25	1.87	0.77 to 3.45

Heterogeneity: Q=12.36; DF=12; P=0.417; I^2=2.93%

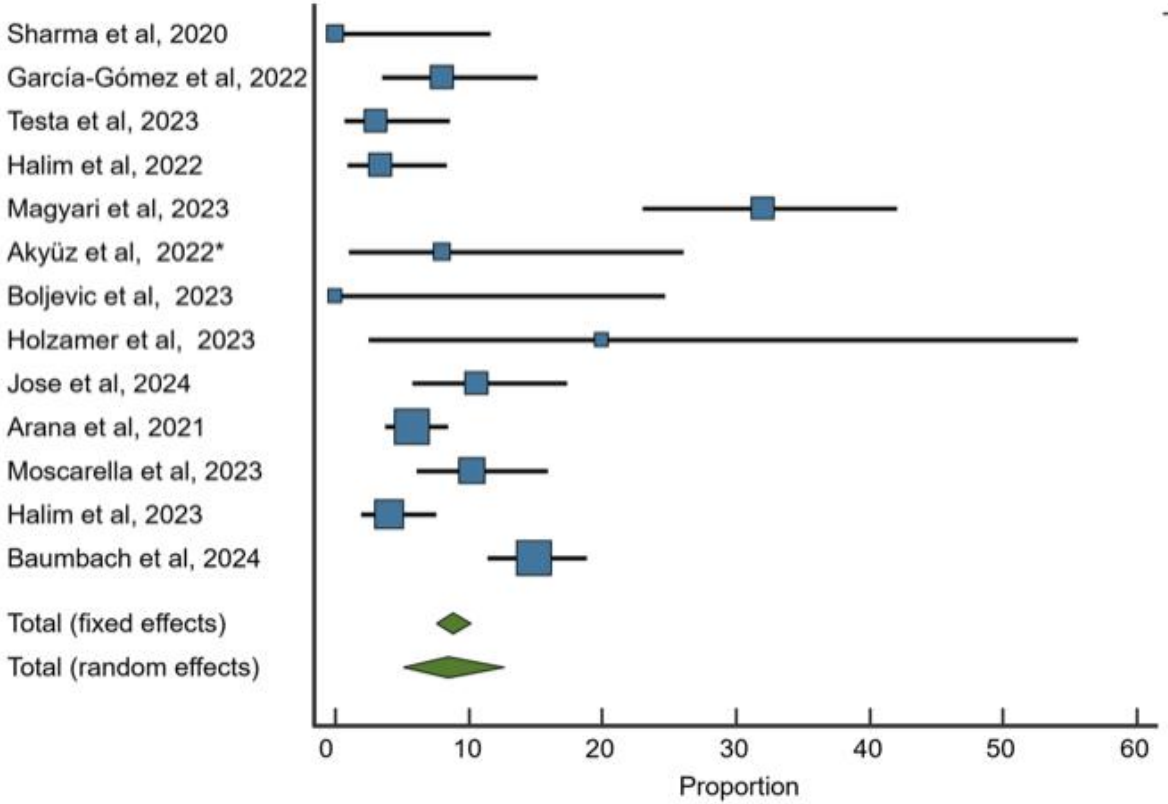
*3 Month Follow-up

1.26%

Amat-Santos et al. REC 20

d

New PPI 1 month (%)



Sample size	N New PPI	Proportion (%)	95% CI
30	0	0.00	0.00 to 11.57
100	8	8.00	3.52 to 15.16
100	3	3.00	0.62 to 8.52
120	4	3.33	0.92 to 8.32
100	32	32.00	23.02 to 42.08
25	2	8.00	0.98 to 26.03
13	0	0.00	0.00 to 24.71
10	2	20.00	2.52 to 55.61
123	13	10.57	5.75 to 17.40
416	24	5.77	3.73 to 8.46
166	17	10.24	6.08 to 15.89
223	9	4.04	1.86 to 7.52
384	57	14.84	11.44 to 18.80
1810	171	8.81	7.55 to 10.20
1810	171	8.49	5.11 to 12.63

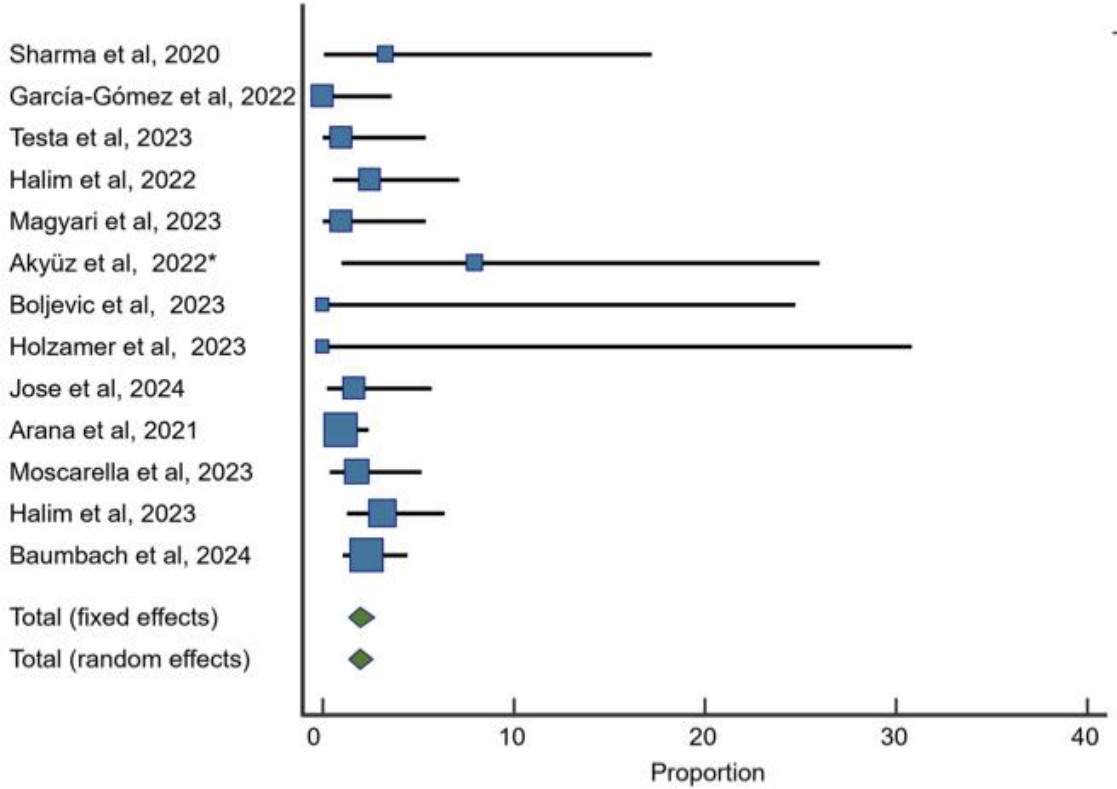
Heterogeneity: Q=84.87; DF=12; P=<0.001; I^2=86%

Month Follow-up

8.1%

e

All cause mortality 1 month (%)



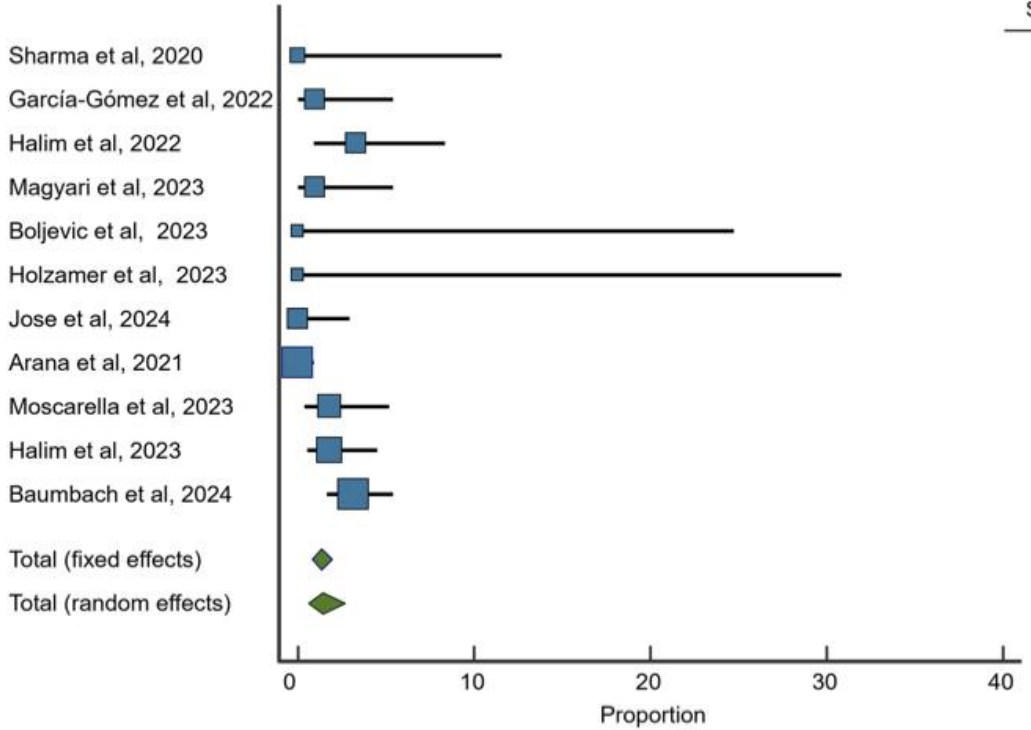
Sample size	N Mortality	Proportion (%)	95% CI
30	1	3.33	0.08 to 17.22
100	0	0.00	0.00 to 3.62
100	1	1.00	0.03 to 5.45
120	3	2.50	0.52 to 7,13
100	1	1.00	0.03 to 5.45
25	2	8.00	0.98 to 26.03
13	0	0.00	0.00 to 24.71
10	0	0.00	0.00 to 30.85
123	2	1.63	0.20 to 5.75
416	4	0.96	0.26 to 2.44
166	3	1.81	0.37 to 5.19
223	7	3.14	1.27 to 6.36
384	9	2.34	1.08 to 4.40
1810	33	1.95	1.37 to 2.70
1810	33	1.96	1.36 to 2.67

Heterogeneity: Q=12.36; DF=12; P=0.417; I^2=2.93%
*3 Month Follow-up

1.95%

f

Stroke 1 month (%)

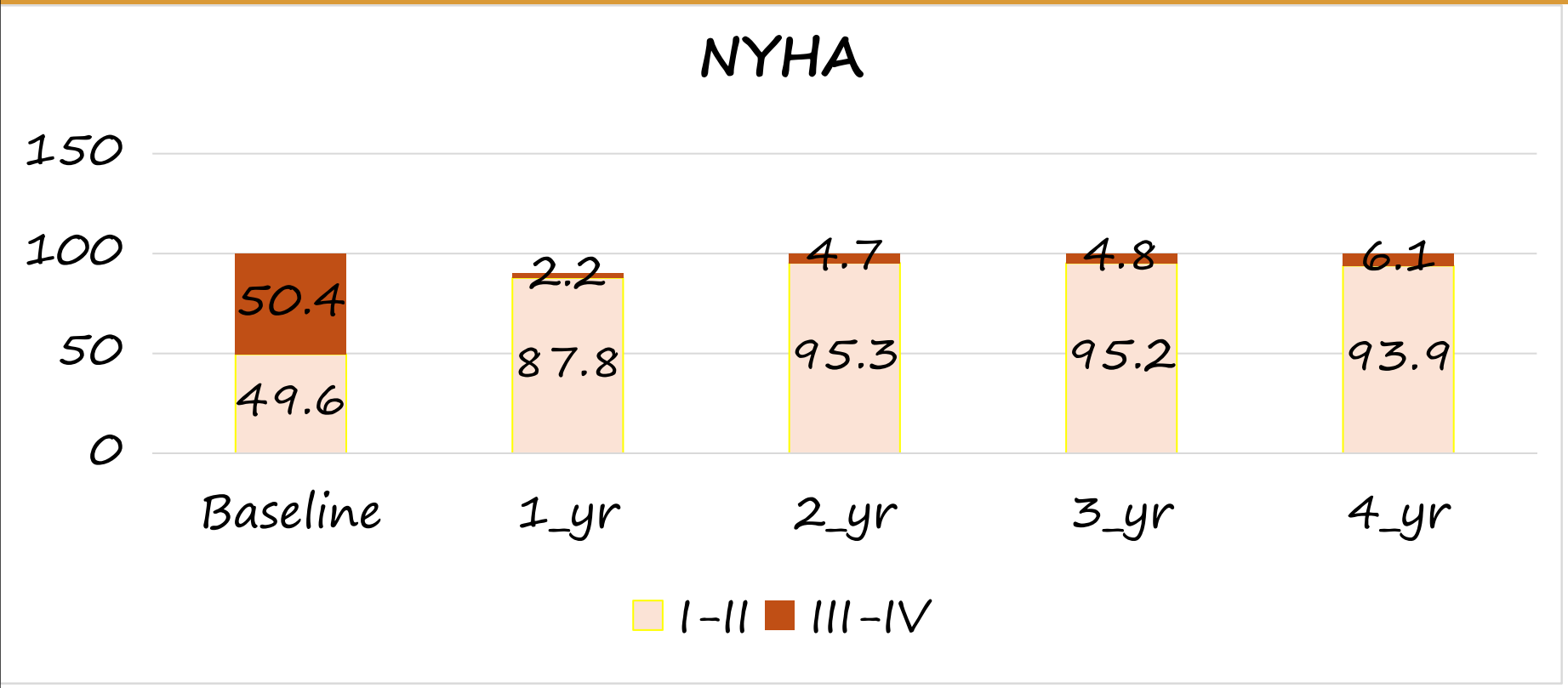


Study	Sample size	N Stroke	Proportion (%)	95% CI
Sharma et al, 2020	30	0	0.00	0.00 to 11.57
García-Gómez et al, 2022	100	1	1.00	0.03 to 5.45
Halim et al, 2022	120	4	3.33	0.92 to 8.32
Magyari et al, 2023	100	1	1.00	0.03 to 5.45
Boljevic et al, 2023	13	0	0.00	0.00 to 24.71
Holzamer et al, 2023	10	0	0.00	0.00 to 30.85
Jose et al, 2024	123	0	0.00	0.00 to 2.96
Arana et al, 2021	416	0	0.00	0.00 to 0.88
Moscarella et al, 2023	166	3	1.81	0.37 to 5.19
Halim et al, 2023	223	4	1.79	0.49 to 4.53
Baumbach et al, 2024	384	12	3.13	1.63 to 5.40
Total (fixed effects)	1685	25	1.33	0.84 to 1.99
Total (random effects)	1685	25	1.44	0.57 to 2.68

Heterogeneity: Q=27.27; DF=10; P=0.0024; I^2=63%

1.3%

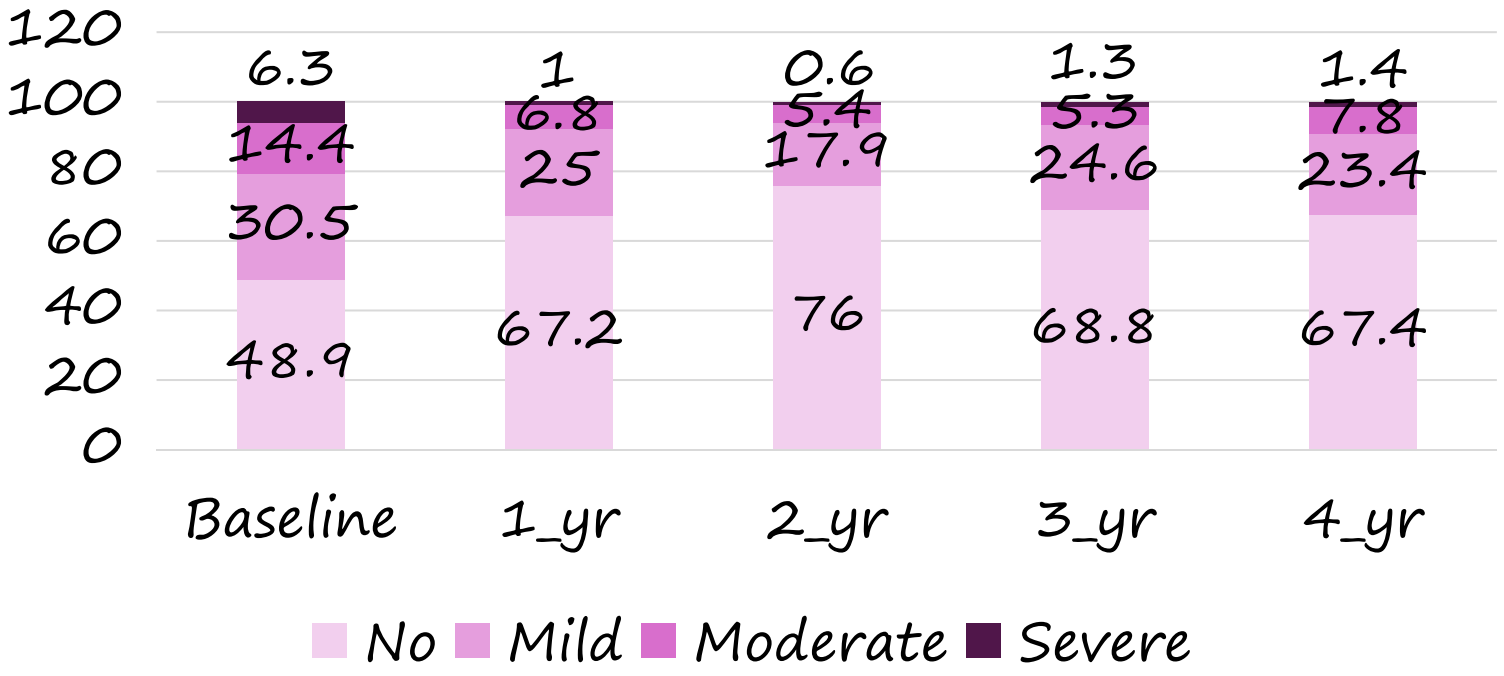
DURABILITY



Work in progress

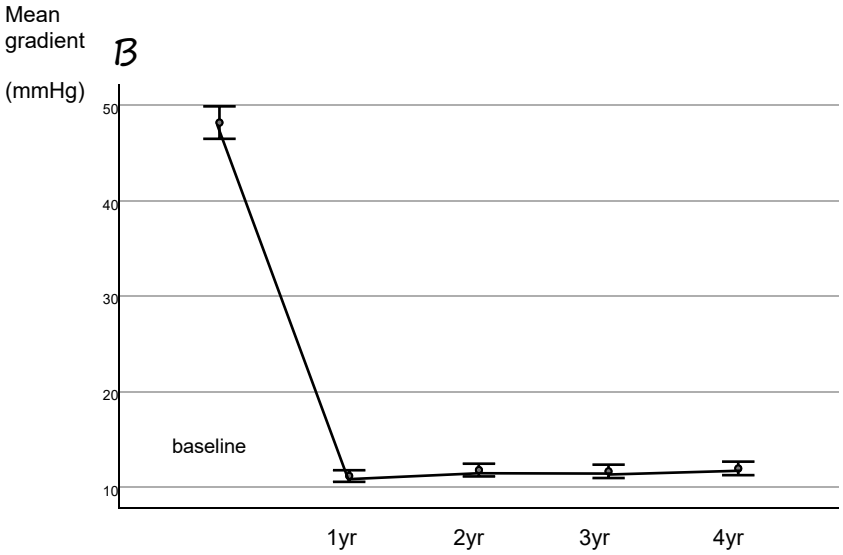
DURABILITY

Ao Regurgitation

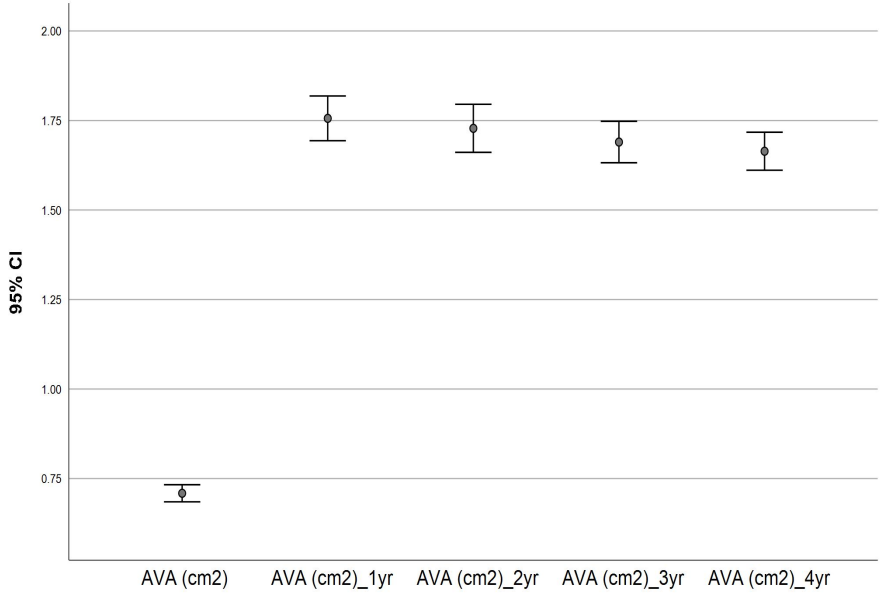


DURABILITY

Mean Gradient



AVA (cm2)



CONCLUSIONS

COMPETITIVE BALLOON-EXPANDABLE TAVR DEVICE

SIMPLE: DIRECTLY CRIMPED ON BALLOON, EASY POSITIONIN

DIFFERENTIAL VALUE: EXTRA-LARGE & INTERMEDIATE SIZE

COMPETITIVE AT SHORT TERM WITH GOLD STANDARD: LANDMA

PRELIMINARY GOOD OUTCOMES AT 4-YEAR FOLLOW UP


5 years ago...
Balloon Expandable THV
Design Philosophy
Python
INTRODUCER SET
THANK YOU!