Comparative assessment of aortic regurgitation post TAVR in commercially available TVH's

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Background

Paravalvular Leak Assessment After TAVR

Can You Please Ask the Echocardiographer to Get Out of the Catheterization Laboratory?*

Bernard Cosyns, MD, PhD

- **Aortic regurgitation after TAVR negatively impacts patients' prognosis.**
  - ✓ *A meta-analysis comprising over 15,000 patients showed a 2.12-fold increase in mortality for patients with more than mild regurgitation after TAVR*
- **With the rise of the minimalist TAVR era, without general anesthesia, echocardiogram evaluation during the procedure becomes restricted.**
- **Thus, aortogram (re)emerges as a practical and familiar tool for the interventional cardiologist.**

H. Takagi, et. al. Int. J. Cardiol. 2016 (15) 221. 46-51
Tateishi H, Serruys PW, et al. EuroIntervention. 2016 Mar;11(12):1409-1

Quantitative assessment of regurgitation
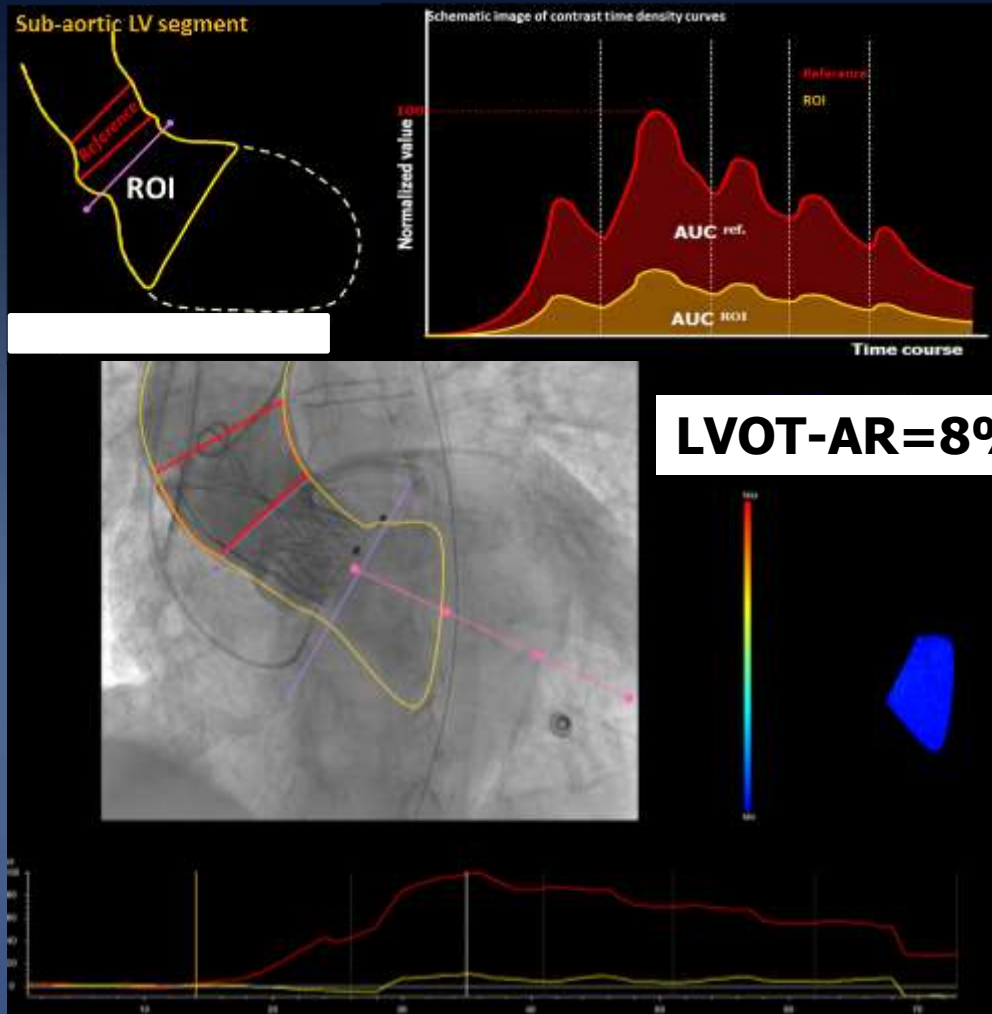
LVOT-AR=8%

- **Performed using single aortogram with videodensitometry technique.**

- **2 time-density curves are obtained in the reference area (aortic root) and in the region of interest (ROI).**

- **The ratio between the 2 area under the time-density curves is translated in percentage of regurgitation.**

Modolo R, Serruys PWet al. EuroIntervention. 2019 Nov 19

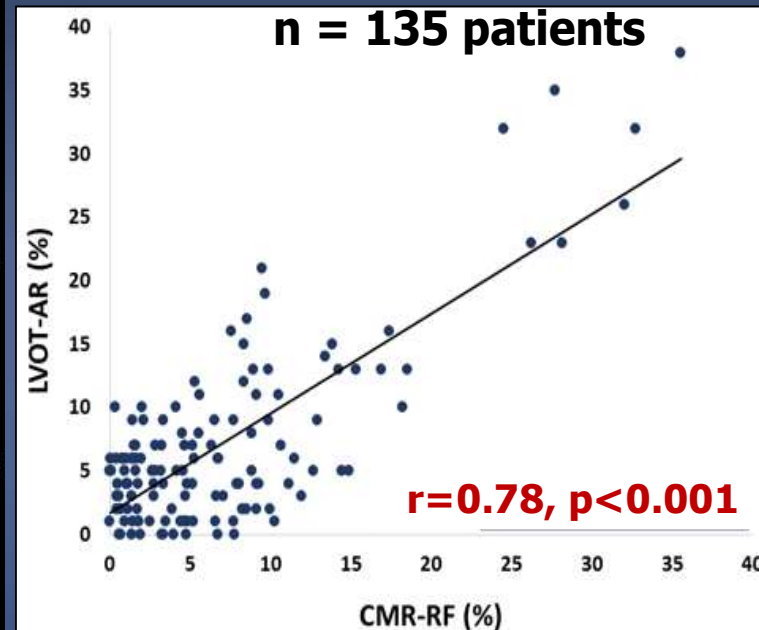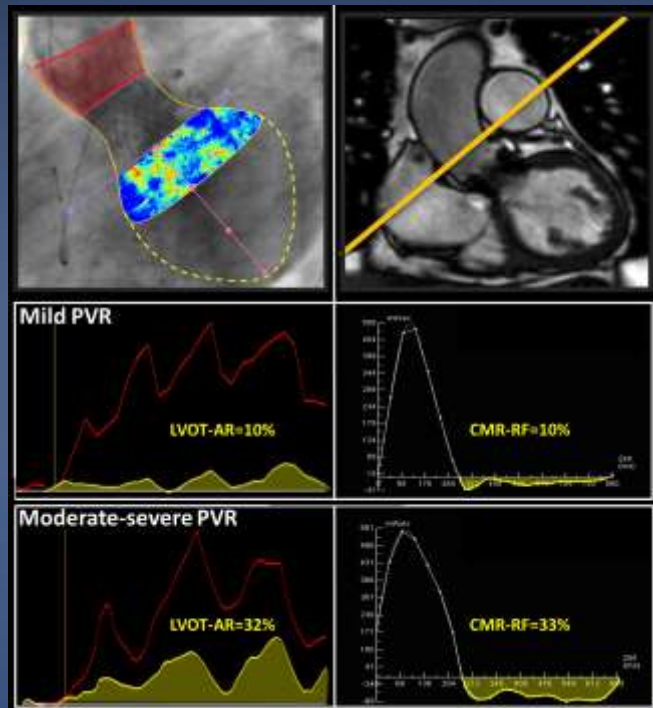# Quantitative assessment of regurgitation

LVOT-AR=18%

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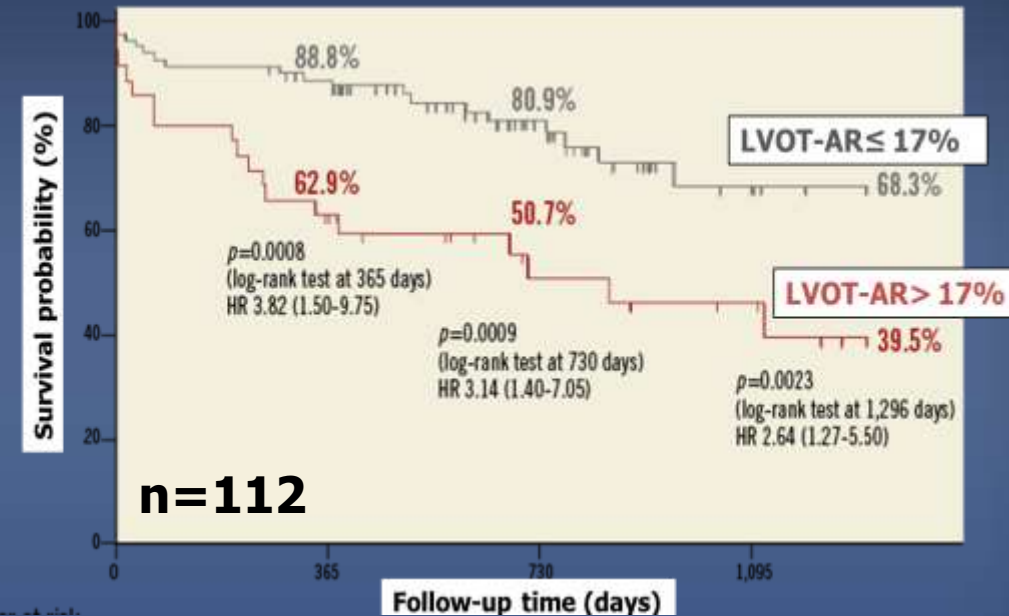
Modolo R, Serruys PWet al. EuroIntervention. 2019 Nov 19

Quantitative assessment of regurgitation

Validated in vitro[1], in animal model[2], with regards to echo[3,4], MRI[5], and has shown to have prognostic value[6]

Videodensitometry versus MRI [5]

n = 135 patients

r=0.78, p<0.001

Mild PVR — LVOT-AR=10%, CMR-RF=10%

Moderate-severe PVR — LVOT-AR=32%, CMR-RF=33%

Prognostic value [6]

88.8%

80.9%

62.9%

50.7%

LVOT-AR≤ 17%

68.3%

p=0.0008
(log-rank test at 365 days)
HR 3.82 (1.50-9.75)

p=0.0009
(log-rank test at 730 days)
HR 3.14 (1.40-7.05)

LVOT-AR> 17%

39.5%

p=0.0023
(log-rank test at 1,296 days)
HR 2.64 (1.27-5.50)

n=112

Up to 3.5 years

1. Miyazaki, et. al. EuroIntervention. 2018 Jan 20;13(13):1527-1535
2. Modolo R, et. al. Catheter Cardiovasc Interv. 2019 Apr 1;93(5):963-970
3. Modolo R, et al. JACC Cardiovasc Interv. 2019 Jan 28;12(2):216-218
4. Tateishi H, et al. Circ J. 2018 Aug 24;82(9):2317-2325
5. Abdel-Wahab M, et al. JACC Cardiovasc Interv. 2018 Feb 12;11(3):287-297
6. Tateishi H, et al. EuroIntervention. 2016 Mar;11(12):1409-1

Objectives

- **To date, little is known about comparative quantitative angiographic assessment of aortic regurgitation in clinical trials comparing transcatheter heart valves (THV).**

- **Thus, we sought to evaluate aortograms from clinical practice in a large multicenter cohort of TAVR patients in order to determine the sealing features amongst multiple commercially available THV platforms.**
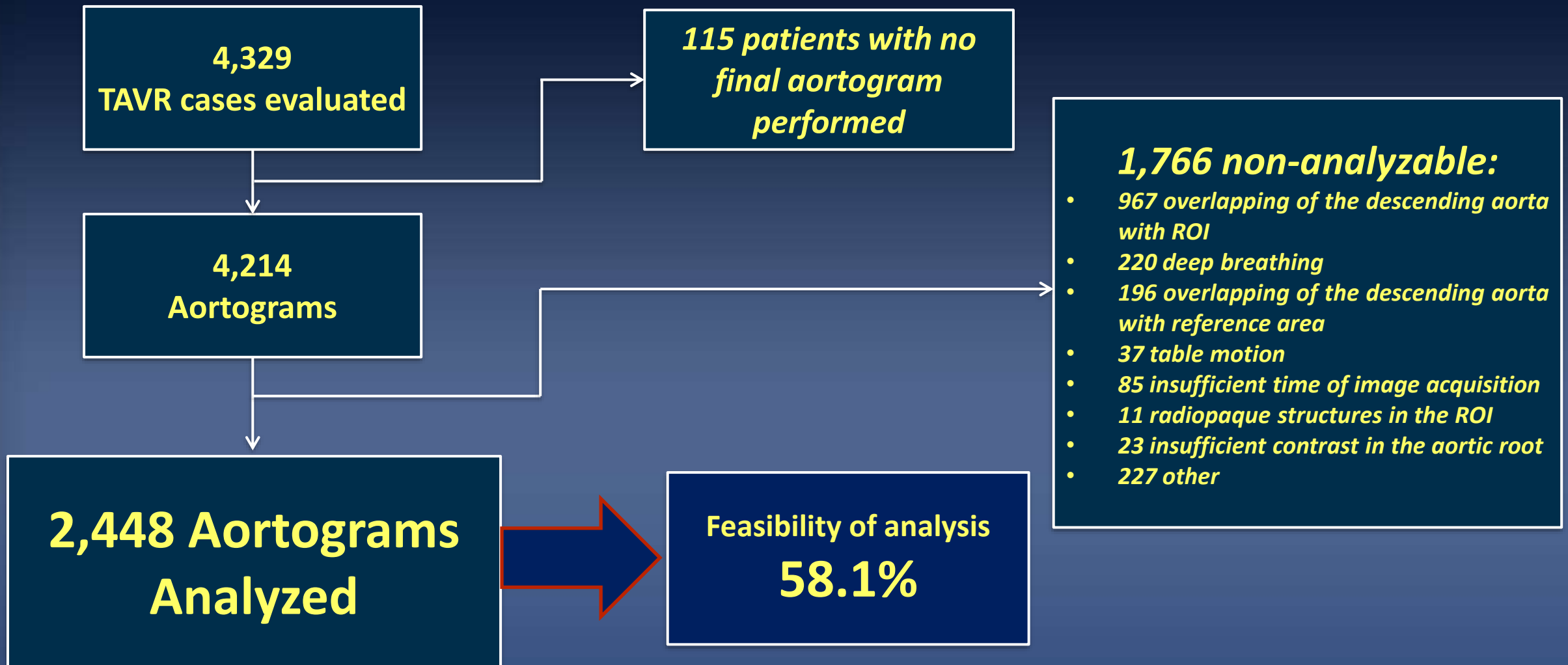
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Methods

- **The present study is a retrospective analysis of aortograms from a multicenter, multicontinental cohort.**

- **Consecutive patients that underwent TAVR following each participating Institution's Heart Team recommendation were included.**

- **Aortograms were analyzed using the videodensitometric technique (CAAS-A Valve, Pie Medical Imaging, Maastricht, The Netherlands) by an independent core lab, not sponsored by the industry.**

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Multicenter cohort

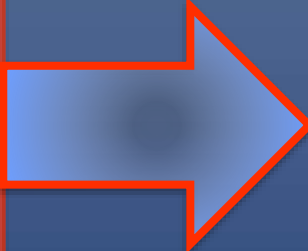*Modolo R, Serruys PW, et al. JACC: Cardiovasc Interv 2020.*

Flowchart of core lab quantitative assessment of regurgitation

4,329
TAVR cases evaluated

115 patients with no final aortogram performed

4,214
Aortograms

1,766 non-analyzable:
- *967 overlapping of the descending aorta with ROI*
- *220 deep breathing*
- *196 overlapping of the descending aorta with reference area*
- *37 table motion*
- *85 insufficient time of image acquisition*
- *11 radiopaque structures in the ROI*
- *23 insufficient contrast in the aortic root*
- *227 other*

2,448 Aortograms Analyzed

Feasibility of analysis
58.1%

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Evaluated Transcatheter Heart Valves

- **Lotus**   **(n=546)**
- **CoreValve**   **(n=532)**
- **Sapien 3**   **(n=397)**
- **Evolut R**   **(n=295)**
- **Sapien XT**   **(n=239)**
- **Acurate**   **(n=115)**
- **Evolut Pro**   **(n=95)**
- **Direct Flow Medical (n=21)**
- **Centera (n=11)**
- **Inovare (n=4)**
- **Lotus Edge (n=3)**

Excluded from the main analysis (n<50)

Modolo R, Serruys PW, et al. JACC: Cardiovasc Interv 2020.

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Evaluated Transcatheter Heart Valves

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Myval   (n=108)
Venus   (n=82)

*Modolo R, Serruys PW, et al. JACC: Cardiovasc Interv 2020.*

Device Features

	Myval		Venus A-valve
Country		India	China
Frame		Nickel-chrome	Nitinol
Leaflets	Bovine pericardium		Porcine pericardium, supra-annular
Expansion	Balloon expandable		Self-expanding
Recapturable	-		No
Valve sizes	20, 21.5, 23, 24.5, 26, 27.5, 29,32 mm.		23, 26, 29, 32 mm
Sheath inner diameter	14 Fr		19 Fr
PVL reduction	Antileak skirt External pericardial wrap		Antileak skirt
CE mark	April 2019		-

Cumulative percentage of different degrees of regurgitation

LVOT-AR > 17%
(moderate or severe regurgitation)

Transcatheter aortic valves
- Lotus, n=546
- Evolut R and Pro, Sapien 3 and XT, Acurate, n=1140
- CoreValve, n=532
- MyVal, n=108
- Venus-A Valve, n=82

Quantitative aortograms cutoffs:
- none/trace: **< 6%**
- Mild: **≥ 6%** and **≤ 17%**
- Moderate / severe: **> 17%**
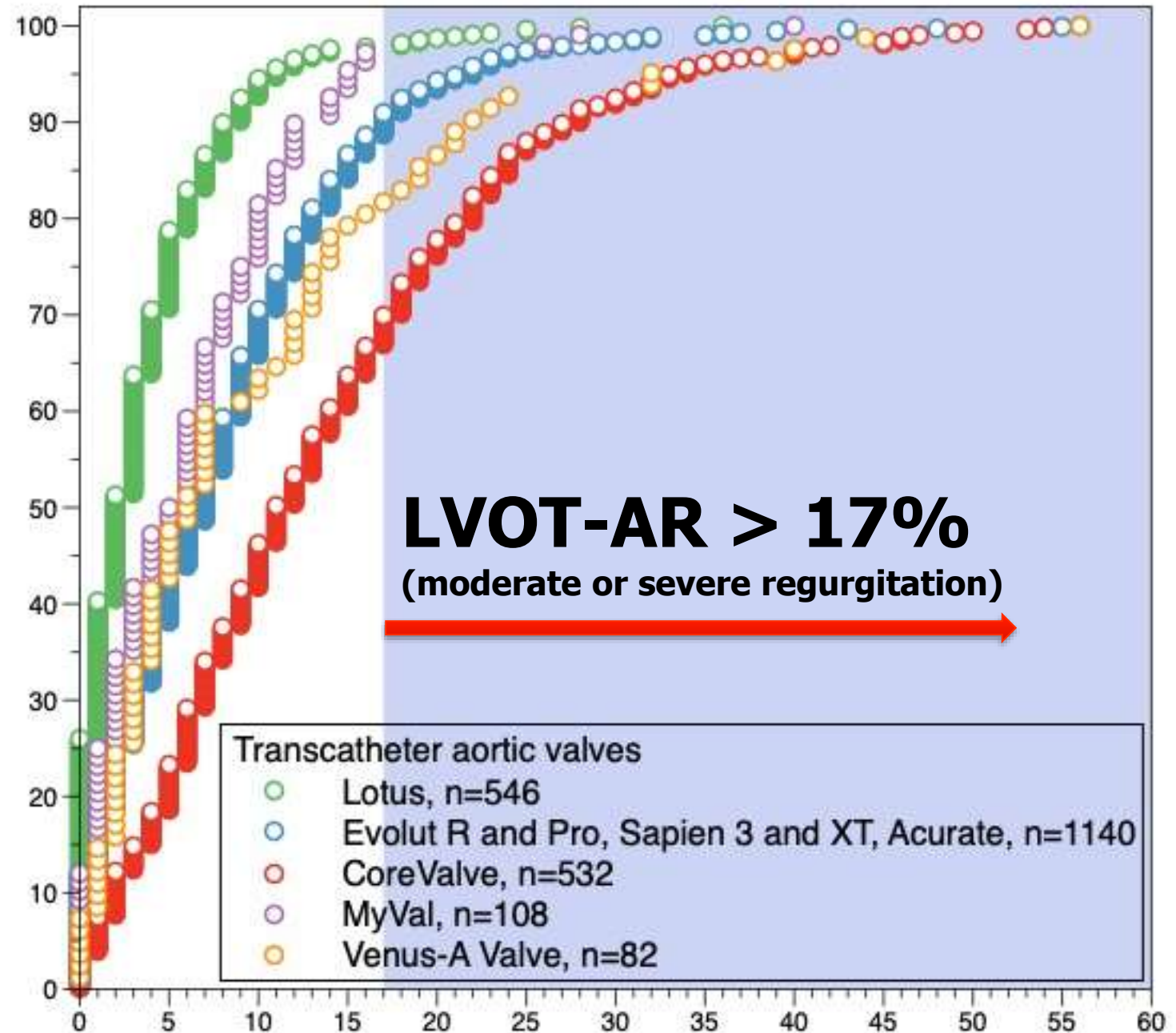
Cumulative percentage of different degrees of regurgitation

Regurgitation:

- 🟥 moderate or severe (LVOT-AR > 17%)
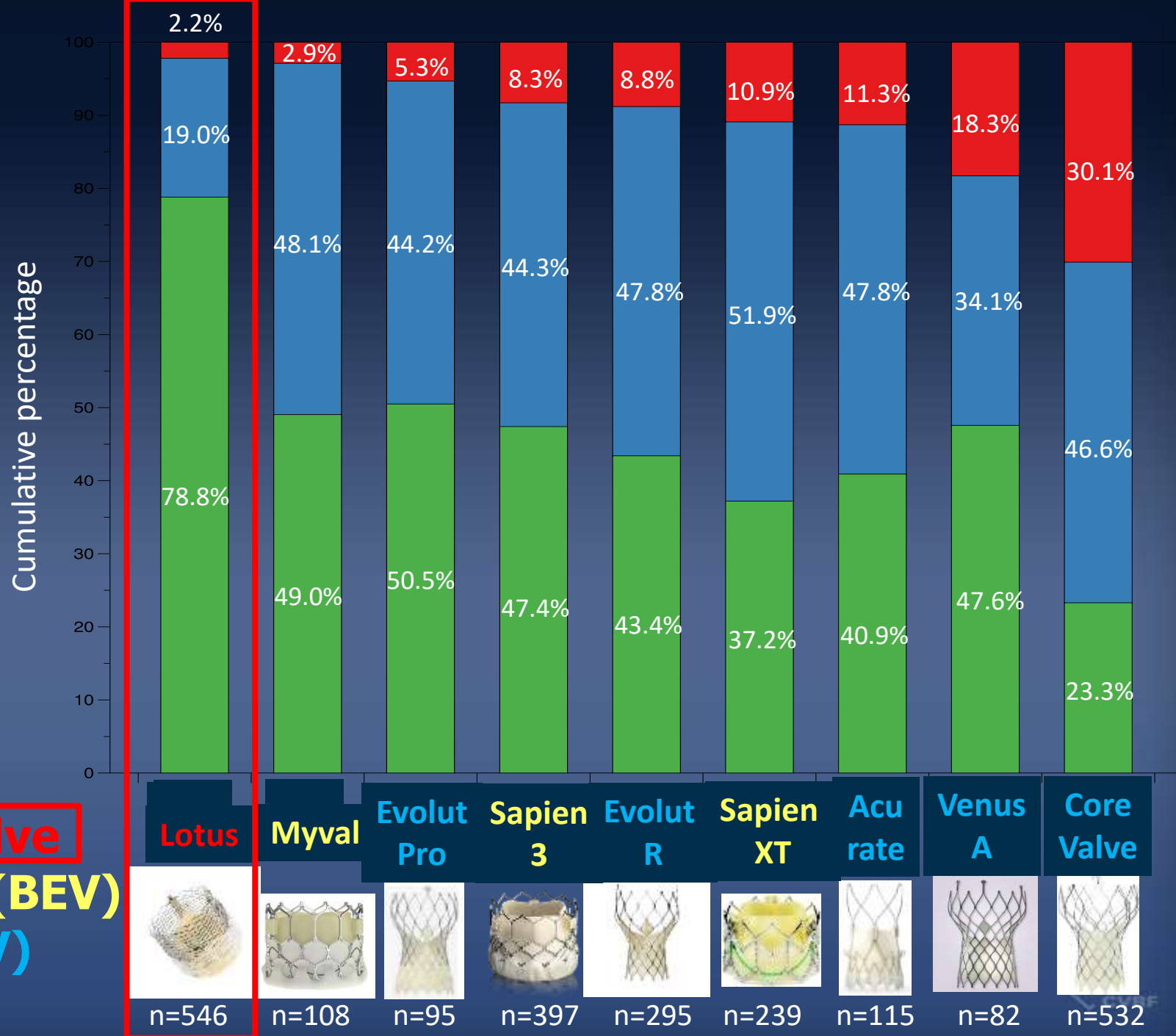- 🟦 Mild (6% ≤ LVOT-AR ≥ 17%)
- 🟩 none or trace (LVOT-AR < 6%)

	Lotus	Myval	Evolut Pro	Sapien 3	Evolut R	Sapien XT	Acu rate	Venus A	Core Valve
moderate/severe	2.2%	2.9%	5.3%	8.3%	8.8%	10.9%	11.3%	18.3%	30.1%
mild	19.0%	48.1%	44.2%	44.3%	47.8%	51.9%	47.8%	34.1%	46.6%
none/trace	78.8%	49.0%	50.5%	47.4%	43.4%	37.2%	40.9%	47.6%	23.3%
n	n=546	n=108	n=95	n=397	n=295	n=239	n=115	n=82	n=532
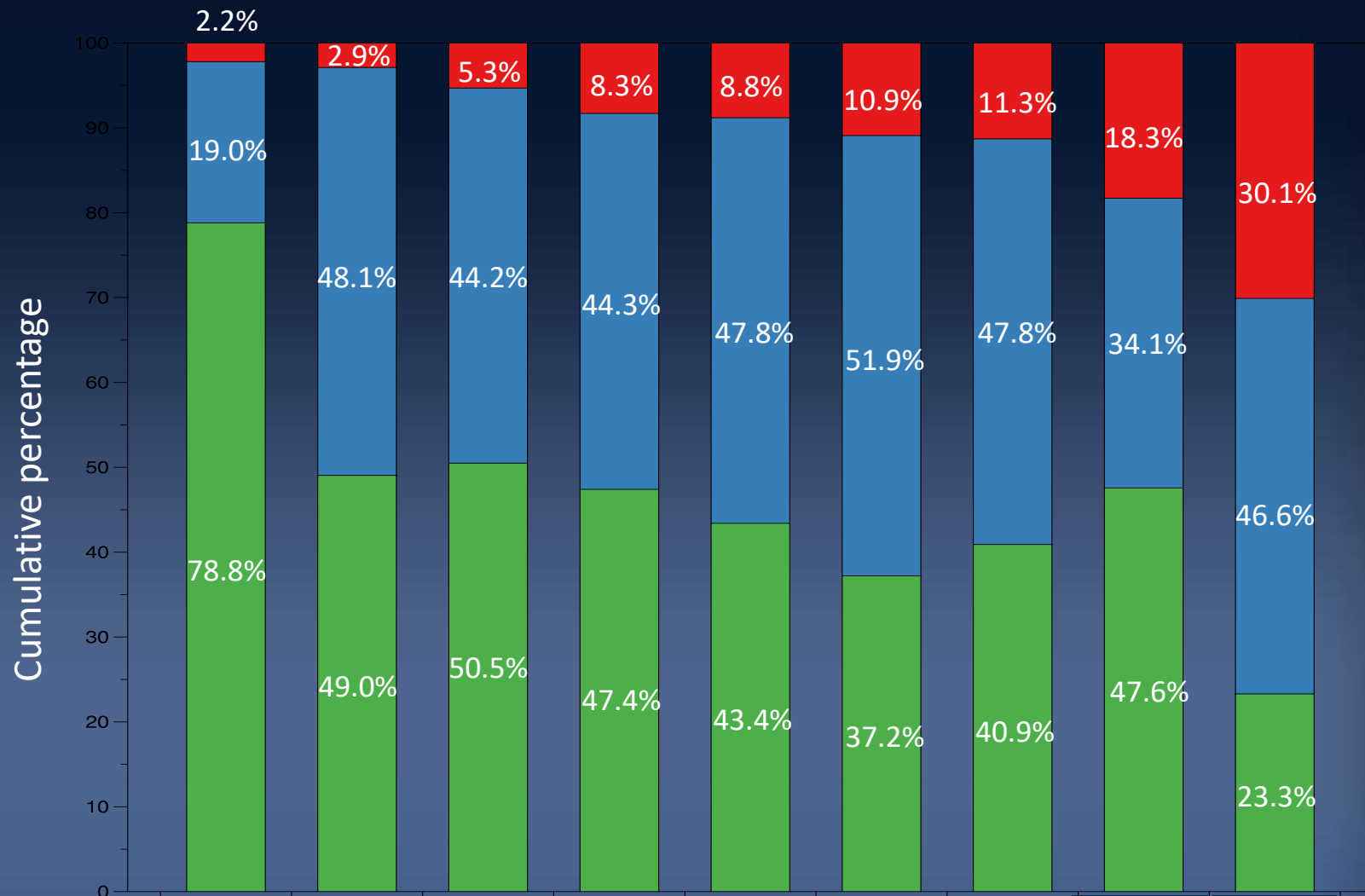
- **Mechanical-expandable valve**
- **Balloon-expandable valve**
- **Self-expandable valve**
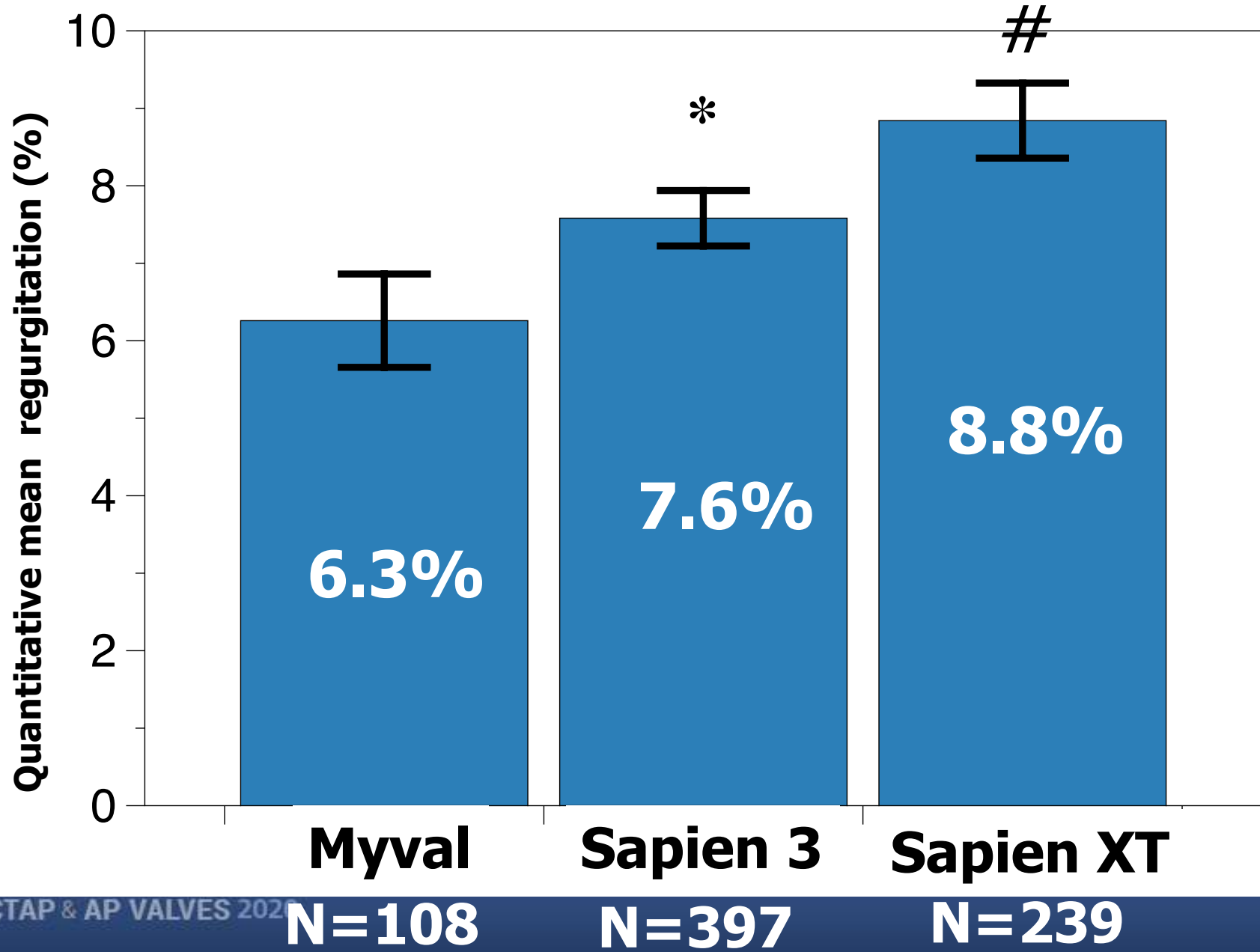
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Cumulative percentage of different degrees of regurgitation

BEV - Quantitative mean regurgitation (%)

- Two by two comparisons with post-hoc Bonferroni test.

- Bars show the mean of regurgitation and standard errors.

- * p=NS vs Myval.

- # p<0.05 vs Myval.
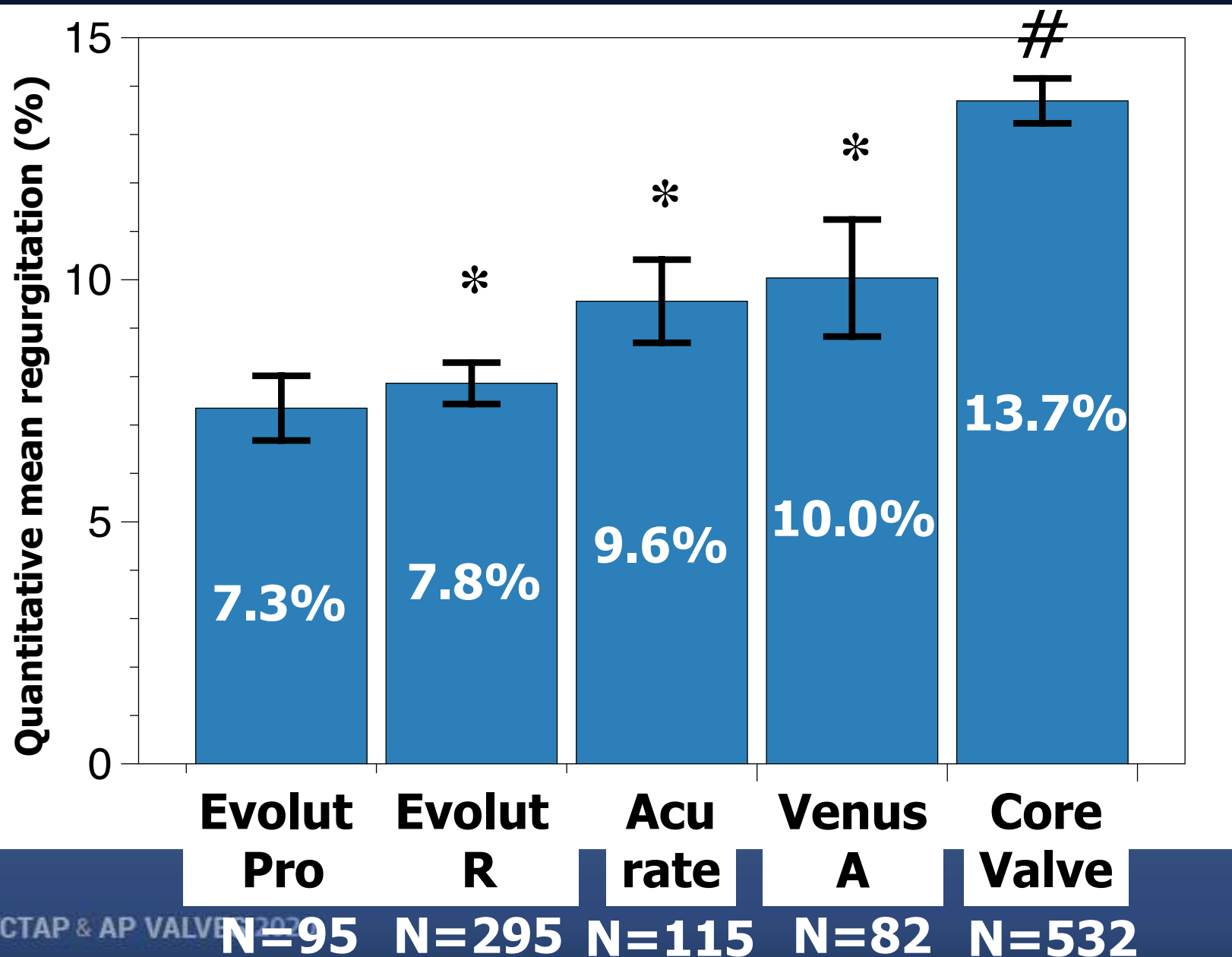
Myval
N=108

Sapien 3
N=397

Sapien XT
N=239

SEV - Quantitative mean regurgitation (%)

- Two by two comparisons with post-hoc Bonferroni test.

- Bars show the mean of regurgitation and standard errors.

- * p=NS vs Evolut Pro.

- # p<0.05 vs Evolut Pro.

Chart values:
- Evolut Pro: 7.3% (N=95)
- Evolut R: 7.8% * (N=295)
- Acu rate: 9.6% * (N=115)
- Venus A: 10.0% * (N=82)
- Core Valve: 13.7% # (N=532)

Y-axis: Quantitative mean regurgitation (%), scale 0 to 15

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Strengths

- "Real-world" data – daily clinical practice.
- Quantitative assessment with a validated and reproducible method (previously shown to be high)[1]
  - ✓ Inter-observer correlation coefficient of 0.95
    - (p<0.001, Bland-Altman: mean difference±SD: 0.01±0.04, p=0.326)
  - ✓ Intraobserver correlation coefficient of 0.97
    - (p<0.001, Bland-Altman: mean difference±SD: 0.01±0.05, p=0.528)
- Analyzed by an independent core lab with no sponsoring by THV industries.

1. Tateishi H, Serruys PW, et al. EuroIntervention 2016;11:1409-18

Limitations

- No randomization was performed for the valve comparison, what may inherently lead to selection bias.

- Since this was retrospective, without an acquisition protocol, the feasibility of analysis was moderate with 41% of the aortograms were not analyzable.

  - *For prospective analysis a simple protocol for acquisition may render the analyzability almost perfect (95.5% in the multicenter ASSESS-REGURGE Registry) [1]*

- Since they were not the purpose of the present report, no information regarding calcification, presence of bicuspid valves, aortic annulus size and shape, THV diameter, technique and depth of implantation were collected.

1. Modolo R, Serruys PW, et al. ASSESS-REGURGE. EuroIntervention 2019;15:420-426

Conclusion and perspectives

- **The Lotus valve had the lowest amount of acute regurgitation post-TAVR and the first generation CoreValve had the highest.**

- **Myval and Venus A-valve demonstrated acceptable amount of aortic regurgitation.**

- **This objective assessment may be of great value for clinical trials of TAVR, comparing different valves, techniques of implantation or clinical scenarios.**

- **These results should be confirmed in prospective cohorts of randomized patients with head-to-head comparisons.**

Acknowledgements

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