

30-Day outcomes following transcatheter aortic valve implantation with a supra-annular self-expanding valve with pericardial wrap: Primary results from the FORWARD PRO study

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I do not have any potential conflict of interest

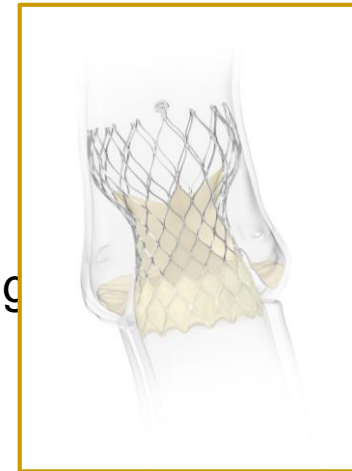
**X I have the following potential conflicts of interest to report:**

Speaker Bureau/Advisory Board: Boston Scientific, Medtronic, LivaNova, Highlife Medical, Jena Valve, CardioMech, Mitral Technology

Equity Interest: InSeal Medical, Cardiovalve, Shockwave, Valve Medical, Pie-Cardia, Imperative Medical, Ancora, MTEch

Medtronic personnel performed all statistical analyses and verified the accuracy of the data, and assisted in the graphical display of the data presented.

- Transcatheter heart valve (THV) technological iterations aim to affect clinical and echocardiographic outcomes.
- The Evolut PRO valve is based on the Evolut R THV, but with the addition of an outer pericardial wrap to help minimise residual AR and to facilitate tissue ingrowth.
- Evolut PRO valve
  - Supra-annular porcine pericardium
  - Self-expanding Nitinol frame
  - Repositionable to assist with accurate positioning
  - 23, 26 and 29 mm sizes



## INCLUSION

- High or greater risk for surgical aortic valve replacement **OR**  $\geq 75$  years and at intermediate risk (STS  $\geq 4\%$ ) per Heart Team
- Symptomatic native aortic valve stenosis or surgical bioprosthetic valve failure
- Acceptable candidate for treatment with the Evolut PRO System in conformity with local regulations

## EXCLUSION

- Contraindication to aspirin, heparin, bivalirudin, ticlopidine, clopidogrel, Nitinol, contrast media
- Mechanical heart valve in aortic position
- Sepsis, including active endocarditis
- Anatomically unsuitable for the Evolut PRO system
- Estimated life expectancy  $< 1$  year
- Participating in another trial that may influence the outcome of this trial
- Need for emergency surgery for any reason

## OBJECTIVE

To evaluate the clinical performance and safety of the Evolut PRO System in patients with symptomatic native aortic stenosis or failed bioprosthesis in routine practice

## DESIGN

Prospective, single arm, multicentre, observational study

## PATIENTS

High or greater risk for surgical aortic valve replacement **OR**  $\geq 75$  years and at intermediate risk (STS  $\geq 4\%$ ) per Heart Team

PRIMARY  
ENDPOINT

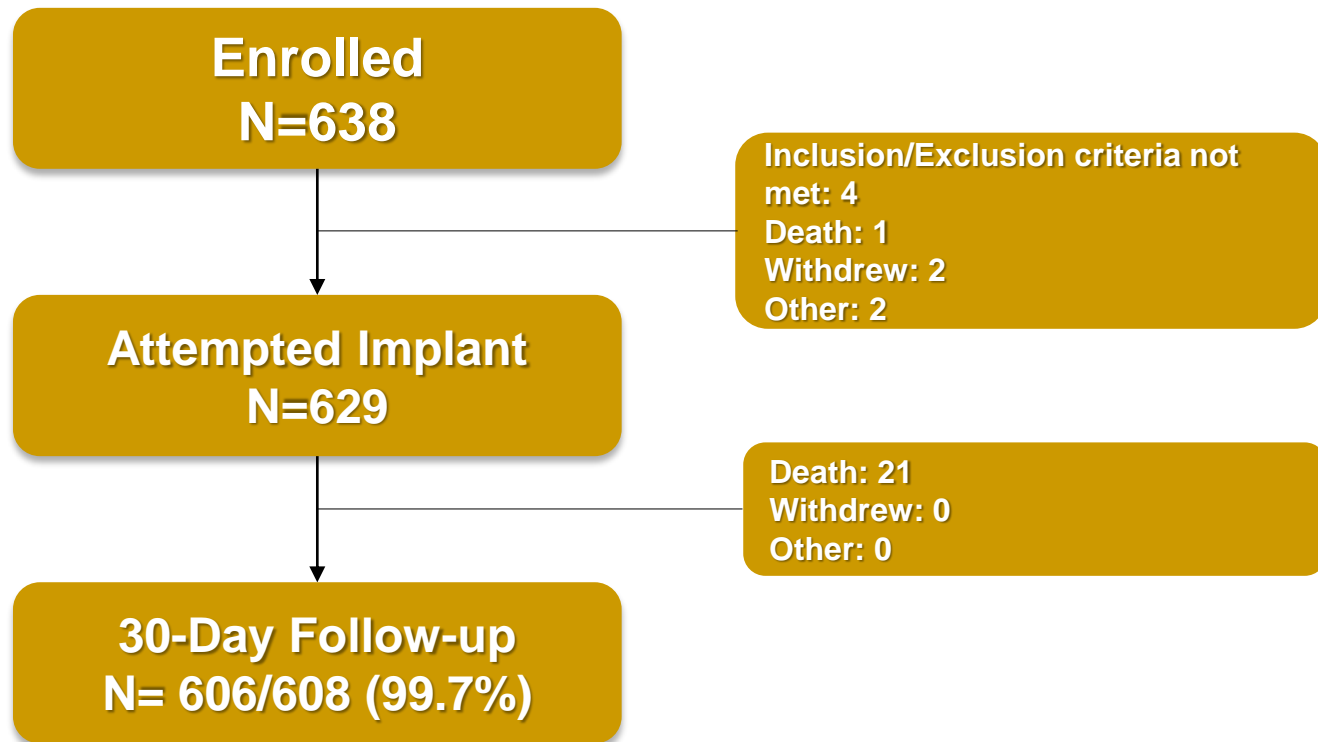
All-cause mortality at 30 days  $< 5.5\%$  (performance goal)

## CORE LAB

Protocol specified echo acquisition with Mayo Clinic oversight

## OVERSIGHT

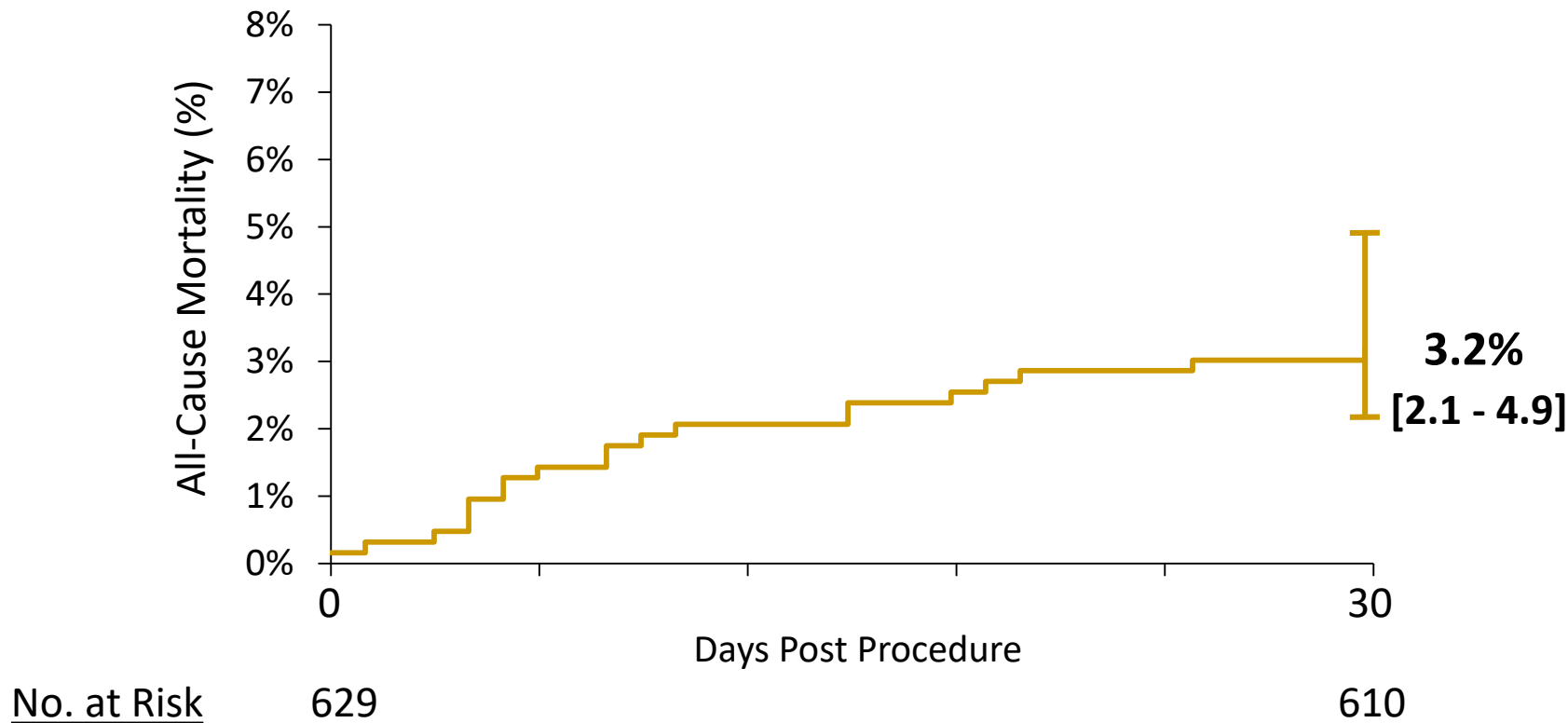
100% monitoring of patient consent, primary and secondary-related endpoints and study-specific adverse events. An independent CEC adjudicated deaths and safety endpoint-related events.



Mean $\pm$ standard deviation or %	N=629
Age, years	81.7 $\pm$ 6.1
Female sex	62.2
STS-PROM, %	4.7 $\pm$ 3.4
New York Heart Association class III/IV	64.3
Diabetes mellitus	34.0
Serum creatinine >2 mg/dL	4.9
Chronic lung disease/chronic obstructive pulmonary disease	26.0
Prior cerebrovascular accident	12.5
Frailty	33.4
Assisted living	14.9
Pacemaker or implanted cardioverter defibrillator	10.5
Moderate or severe LVOT calcification	20.1

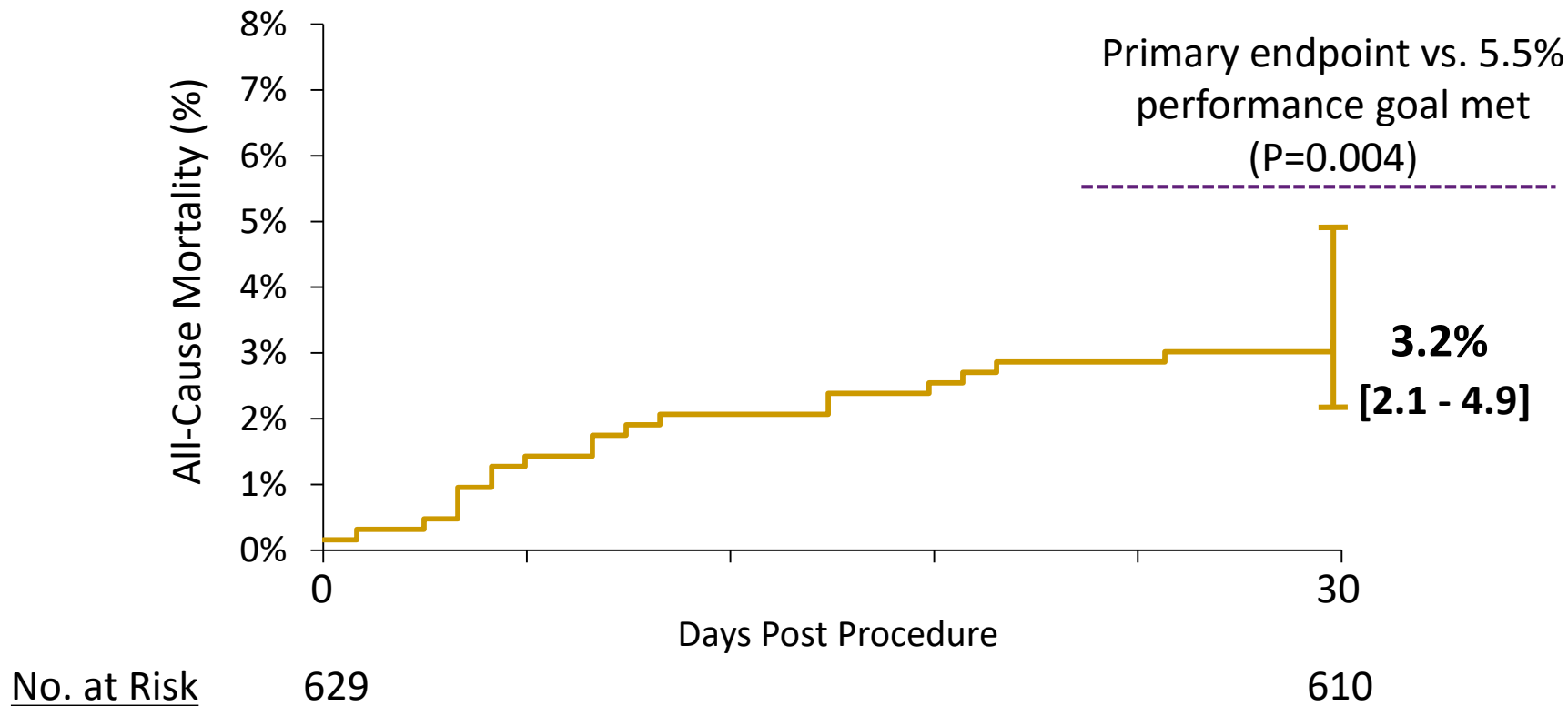
%	N=629
Local anaesthesia	80.1
Iliofemoral access route	97.0
Embolic protection device used	9.1
Implanted valve size	
23 mm	3.9
26 mm	31.6
29 mm	64.5
Pre-TAVI balloon dilation	34.0
Post-implant dilation	31.1
Patients with resheathing or recapture	29.3
Concomitant PCI	3.8
Multiple valves ( $\geq 2$ implanted)	0.8

# FORWARD PRO Study Primary endpoint of all-cause mortality



# FORWARD PRO Study

## Primary endpoint of all-cause mortality

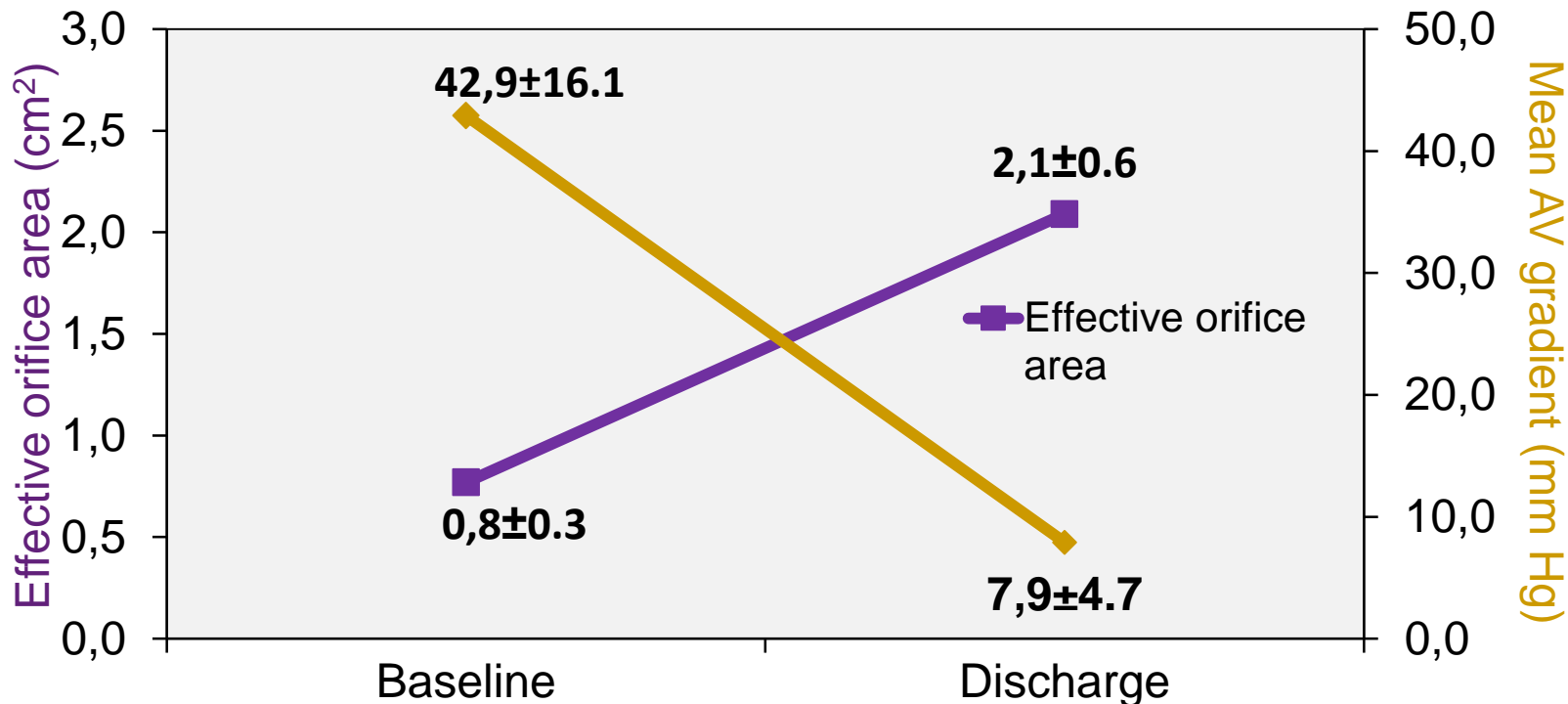


Kaplan-Meier rates as %	N=629
All-cause mortality	3.2
All stroke	3.5
Disabling stroke	2.1
Life threatening or disabling bleed	2.9
Major vascular complication	1.9
Acute kidney injury stage 2 or 3	0.8
Pop outs*	0.6
Pacemaker implanted	18.6
Coronary artery obstruction	0.2
Valve related dysfunction requiring repeat procedure	0.0
Valve thrombosis	0.0
Valve endocarditis	0.0

\*VARC 2-defined intraprocedural embolization or migration.

Kaplan-Meier rates as %		N=629
All-cause mortality		3.2
All stroke		3.5
Disabling stroke		2.1
Life threatening or disabling bleed	<b>VARC 2 Composite Safety</b> Endpoint = 8.1%	2.9
Major vascular complication		1.9
Acute kidney injury stage 2 or 3		0.8
Pop outs*		0.6
Pacemaker implanted		18.6
Coronary artery obstruction		0.2
Valve related dysfunction requiring repeat procedure		0.0
Valve thrombosis		0.0
Valve endocarditis		0.0

\*VARC 2-defined intraprocedural embolization or migration.



Gradient

577

551

Effective orifice area

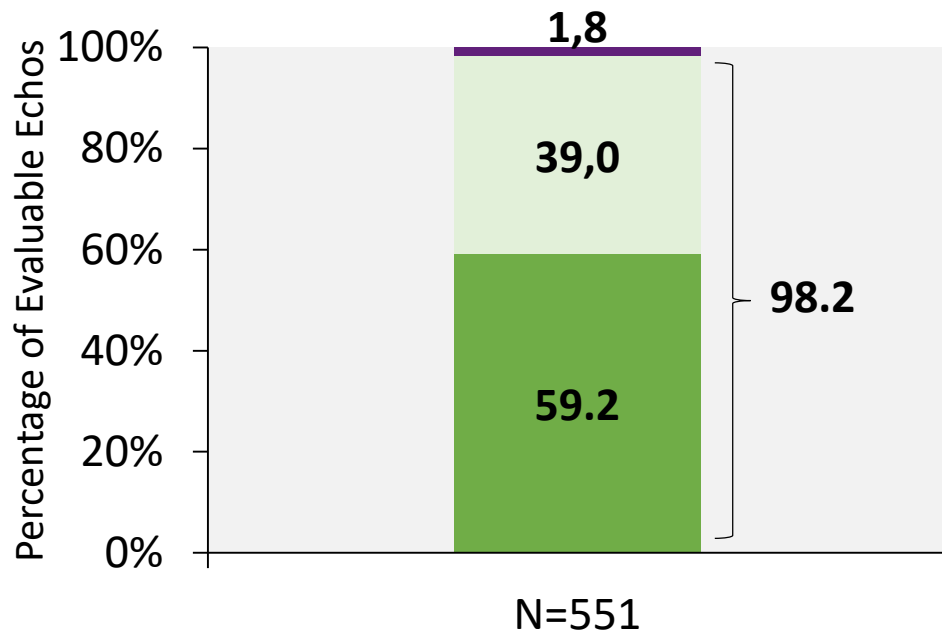
472

394

Per independent core laboratory assessment. Values reported as mean ± standard deviation.

# FORWARD PRO Study

## Secondary endpoint of total AR at discharge

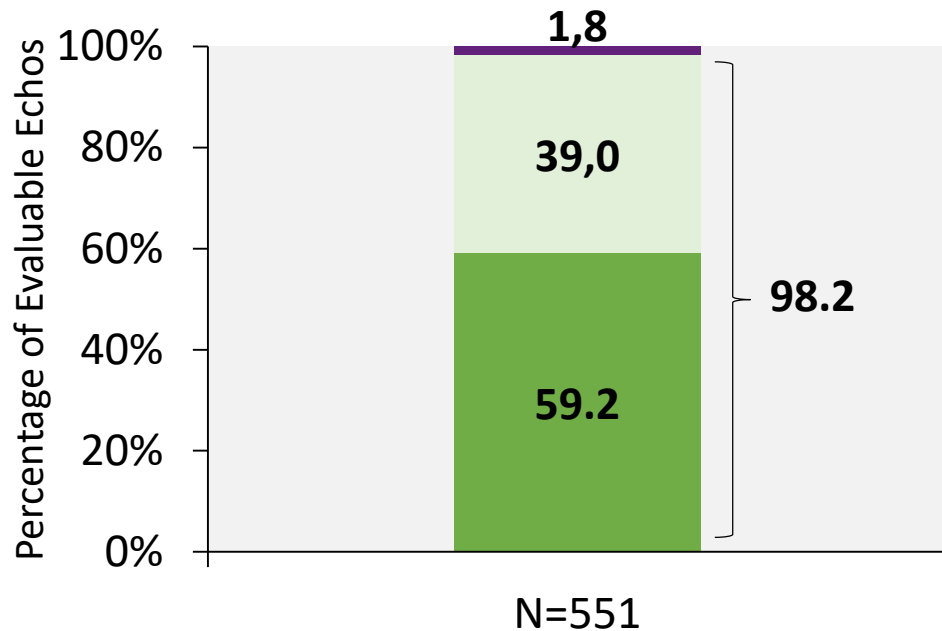


98.2% of patients had none, trace or mild AR.

■ None/Trace    ■ Mild    ■ Moderate/Severe

# FORWARD PRO Study

## Secondary endpoint of total AR at discharge

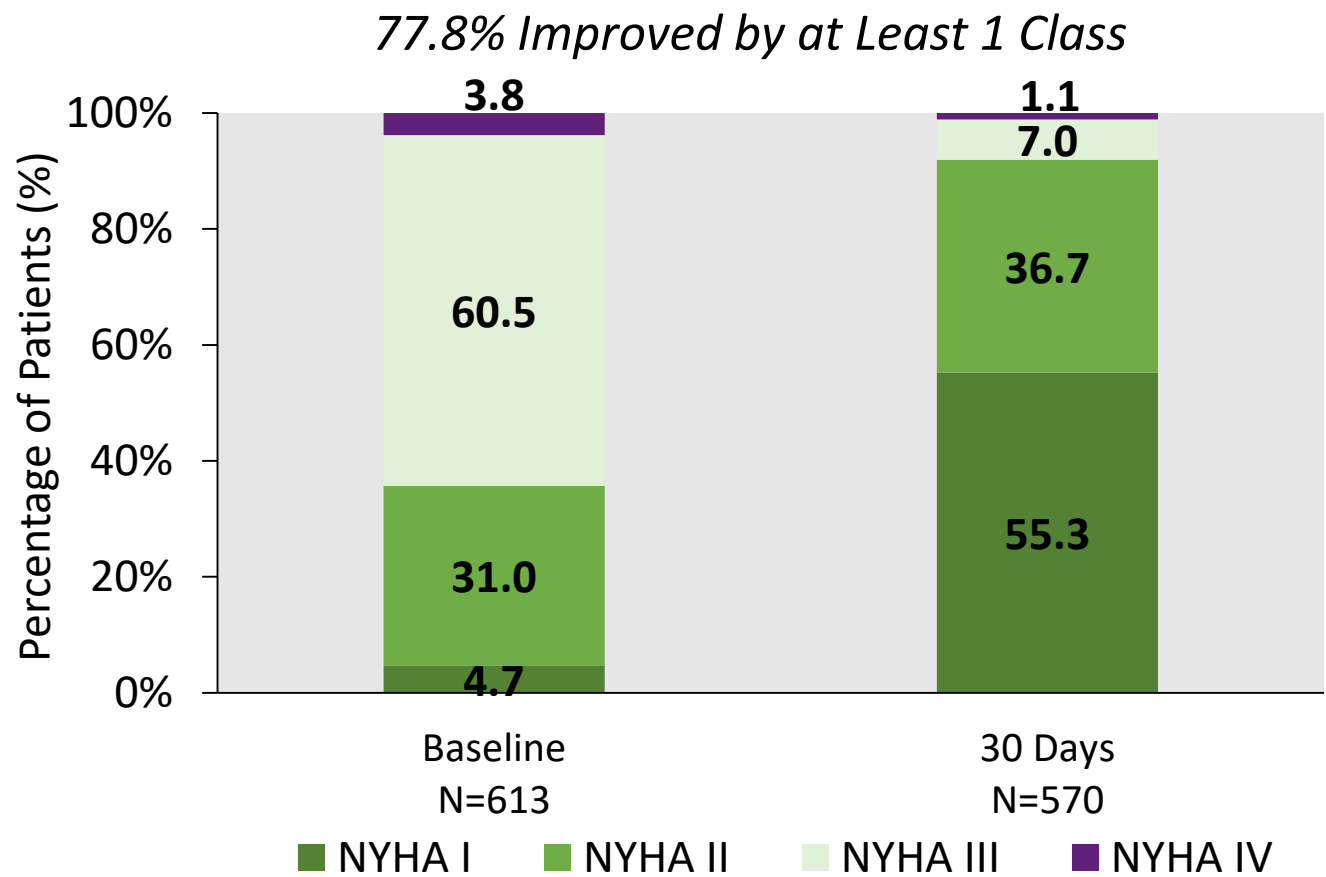


98.2% of patients had none, trace or mild AR.

The prespecified performance goal of none or trace total AR > 67.1% was not met.

■ None/Trace    ■ Mild    ■ Moderate/Severe

# FORWARD PRO Study New York Heart Association at 30 days



- Early results from the FORWARD PRO Study:
  - 30-Day mortality of 3.2% met primary endpoint
  - Procedural safety of 8.1% VARC 2 endpoint
  - Excellent forward flow hemodynamics at discharge
  - 98.2% none, trace, mild AR – 1.8% moderate/severe
  - Low vascular complications/bleeding rates with Evolut PRO