ACURATE Prime XL Clinical Combined Cohort

30 Day Outcomes

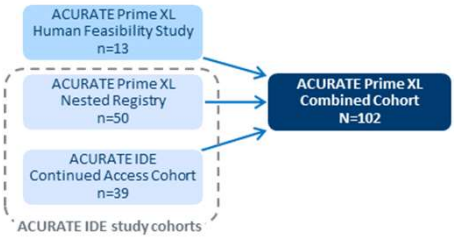
Design: Combined dataset from clinical studies enrolling subjects with symptomatic severe native aortic stenosis indicated for TAVR, who have a native annulus diameter between 26.5 mm and 29 mm (See Analysis Population graphic).

Objective: Evaluate clinical outcomes of the ACURATE Prime XL (29mm).

Positive, 30-Day results demonstrated:

- No deaths and disabling stroke at 30 Days (low non-disabling stroke rate (2%) through 30 Days)
- Favorable hemodynamics: improved aortic valve area and single-digit gradients were sustained through 30 Days
- Zero patients had moderate or greater paravalvular regurgitation 30 Days

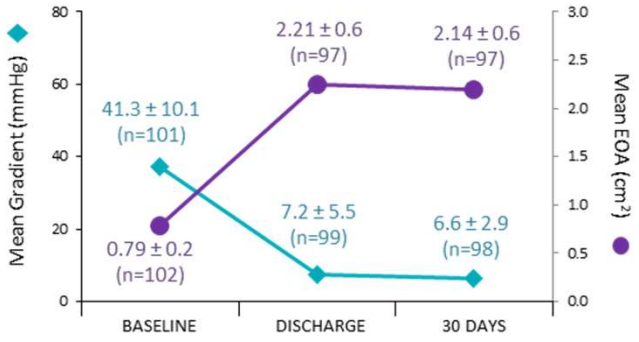
Analysis Population



Safety Outcomes [N=102]	Discharge	30 Days
Death	0.0% (0)	0.0% (0)
Stroke	1.0% (1)	2.0% (2)
Disabling stroke	0.0% (0)	0.0% (0)
Rehospitalization†	0.0% (0)	1.0% (1)
Myocardial infarction	0.0% (0)	0.0% (0)
Bleeding (life-threatening/disabling)	0.0% (0)	0.0% (0)
Acute kidney injury (Stage 2/3)	0.0% (0)	0.0% (0)
Major vascular complication	0.0% (0)	0.0% (0)
Repeat procedure for valve-related dysfunction	0.0% (0)	0.0% (0)
New permanent pacemaker	5.9% (6)	12.7% (13)
Prosthetic valve malposition	0.0% (0)	0.0% (0)
Prosthetic valve thrombosis	0.0% (0)	0.0% (0)
Prosthetic valve endocarditis	0.0% (0)	0.0% (0)

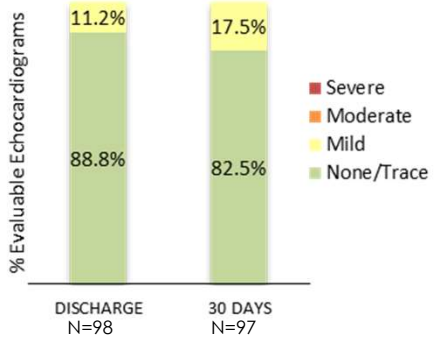
†Hospitalization for valve-related issues or worsening CHF, per VARC-2 definition

Valve Hemodynamics



Baseline echo data are site-reported; discharge & 30d echo data are core laboratory-adjudicated

Paravalvular Regurgitation



Presented by Raj Makkar, MD at PCRLV 2024

CAUTION: The ACURATE Prime Aortic Valve System is CE Marked. In the USA, it is an investigational device. And is restricted under federal law to investigational use only. Not available for sale. CE 0344

Clinical Experience with ACURATE Prime XL

Michael Reardon, MD[1]; Ravi Ramana, DO[2]; Scott Lim, MD[3]; Srinivasa Potluri, MD[4]; Robert Gooley, MBBS (Hons), PhD, MBA[5]; Dale Murdoch, BSc, MBBA[6]; Steven Yakubov, MD[7]; Sanjay Sami, MD[8]; Rodrigo Modolo, MD, PhD[9]; Raj Makkar, MD[10]

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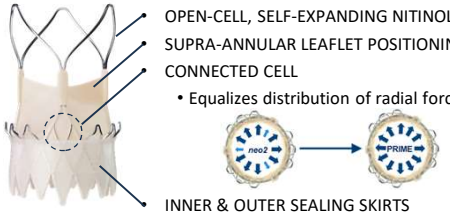
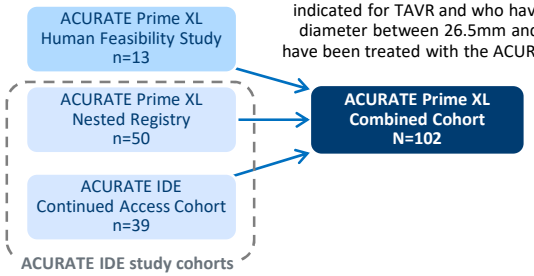
The ACURATE Prime XL Valve

Leverages ACURATE *neo2* design, with adaptations for compatibility with a larger annulus diameter (26.5mm—29mm)



Analysis Population



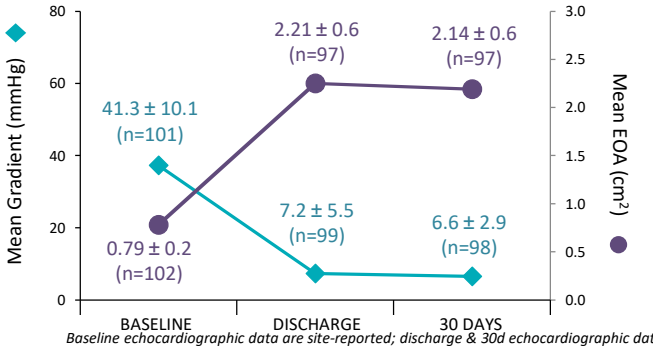
Combined dataset from studies enrolling subjects with symptomatic severe native aortic stenosis indicated for TAVR and who have a native annulus diameter between 26.5mm and 29mm, and who have been treated with the ACURATE Prime XL valve.

Baseline Characteristics

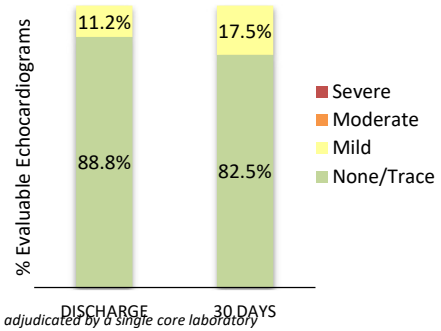
ACURATE Prime XL Combined Cohort (N=102)		
Age (years)	79.6 ± 6.8	
Gender	Male: 94.1%	Female: 5.9%
STS Score (%)	3.4 ± 3.1	
Operative Risk (per Case Review Committee)	High/Extreme: 40.2%	
	Intermediate: 42.2%	
	Low: 17.6%	
Mean AV gradient	41.3±10.1 mmHg	
Aortic valve area	0.79±0.2 cm^2	

Baseline echocardiographic measures are site reported

Valve Hemodynamics



Paravalvular Regurgitation



Baseline echocardiographic data are site-reported; discharge & 30d echocardiographic data are adjudicated by a single core laboratory

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Conclusions: Patients treated with the ACURATE Prime XL valve exhibited good early clinical outcomes at discharge and 30 days post procedure. Although the sample size is small, clinical results in this cohort were in line with those observed in other TAVR studies of patients with extra-large annuli and are encouraging for this new size iteration.

Disclaimer

CAUTION: In Europe, the ACURATE *neo2*™ Aortic Valve System and the ACURATE Prime™ Aortic Valve System are CE-marked. In the USA, the ACURATE *neo2* Aortic Valve System and the ACURATE Prime Aortic Valve System are investigational devices and are restricted under federal law to investigational use only. Not available for sale.

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