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ACURATE *neo*™
Aortic Valve System

PROGRESS PVL Registry

The PRospective Observation of aortic reGuRgitation aftEr TAVI and progreSS over time (PROGRESS) PVL registry
Kim, WK, Presented PCR e-Course June 25-27, 2020

Study Design

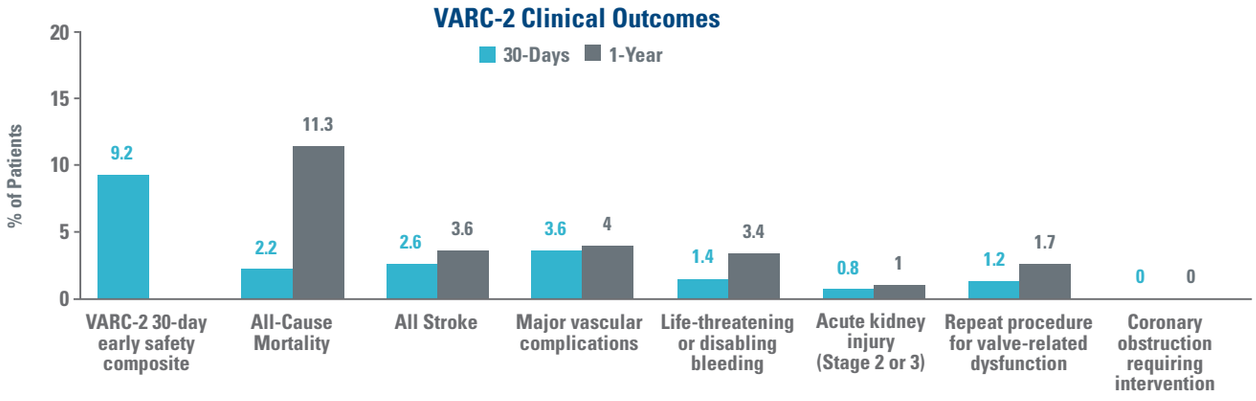
PROGRESS PVL is an open-label, single arm study of 500 patients enrolled at 22 centers in Germany, Canada, the United Kingdom, and Italy between January 2017 and July 2018. The patient population can be assessed as representative for real-world practice, high age, with intermediate surgical risk (STS score 6.0%). No specific inclusion or exclusion criteria were mandated by protocol.

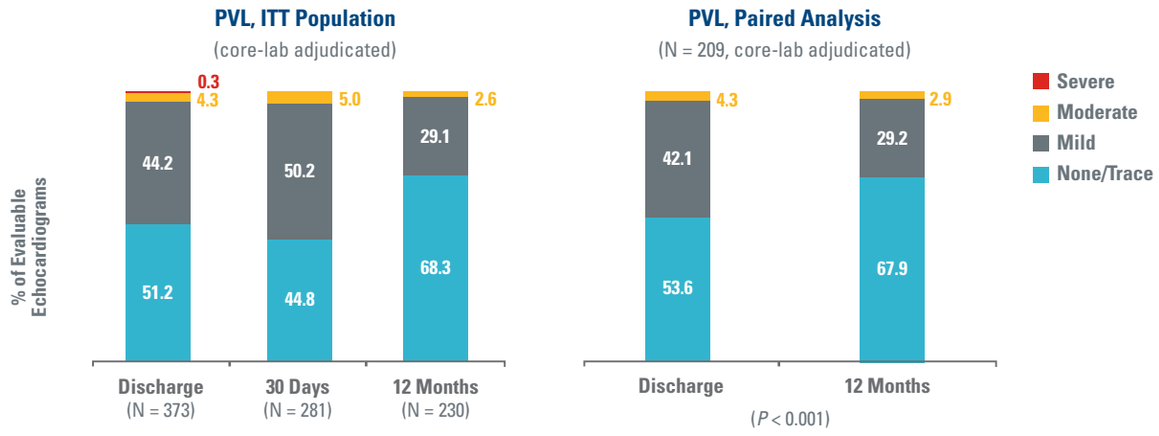
Endpoints Selection

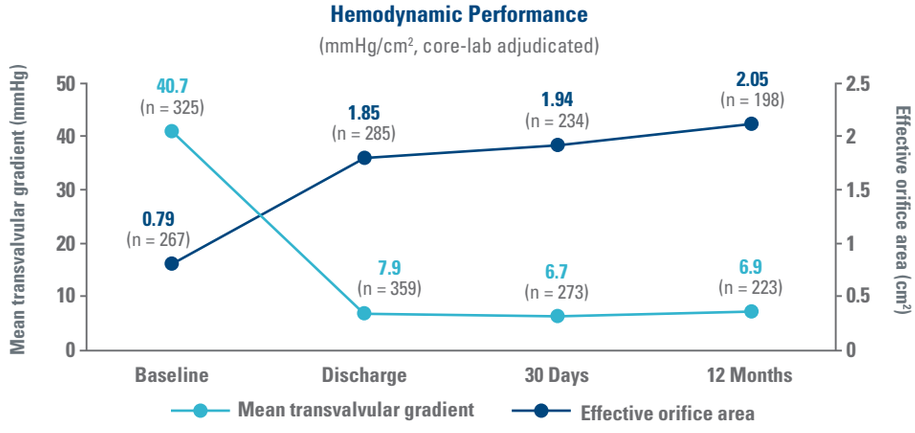
The primary endpoint (per protocol analysis) includes the rate of total aortic regurgitation over time, as determined by an independent echocardiography core laboratory. Key secondary endpoints (intention to treat analysis) include core-lab adjudicated mortality and stroke, VARC-2 early safety composite at 30 days, and hemodynamic function, as well as NYHA functional improvement.

Study Outcomes

Low overall VARC-2 complication rates, PVL improvement over time, and excellent hemodynamic performance







Conclusion

Reconfirming the positive clinical and procedural outcomes seen with ACURATE *neo* in other studies and registries

One-year results from the PROGRESS PVL registry support the sustained safety and performance of TAVI with the ACURATE *neo* Aortic Valve System in patients with severe aortic stenosis.

Core laboratory adjudicated paravalvular leakage (PVL) rates were low (4.3% ≥moderate at discharge, 2.9% at 1-year) and showed a significant overall improvement between discharge and 1-year in a paired analysis (P<0.001).

These positive outcomes of the PROGRESS PVL registry, compared to outcomes seen in SCOPE I, may be attributable to the implanters' experience using ACURATE *neo* and, most importantly, tailoring of device therapy to the individual patient characteristics.

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