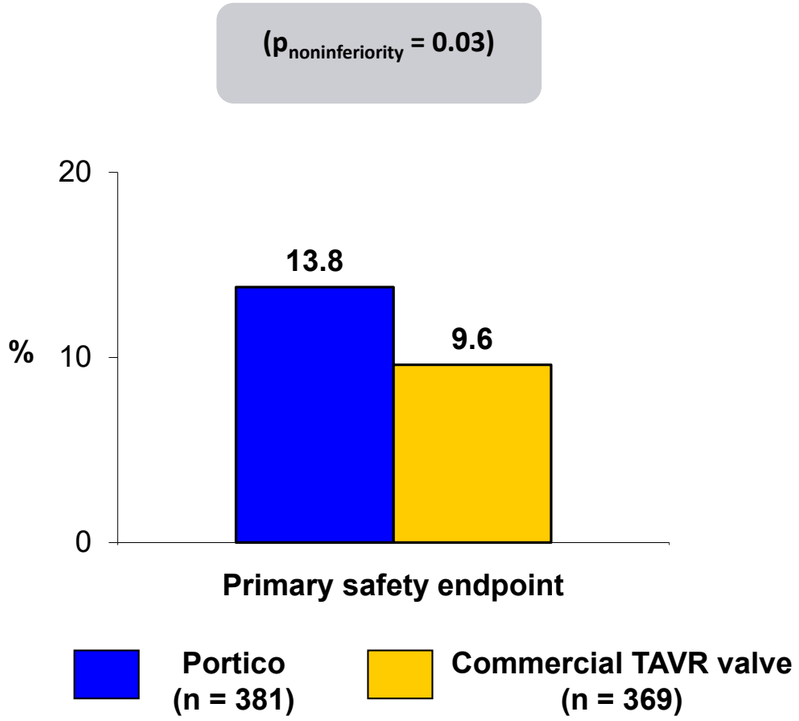
PORTICO IDE

#TCT2019

AMERICAN COLLEGE of CARDIOLOGY

Trial Description: Extreme or high-risk patients with severe aortic stenosis were randomized in a 1:1 fashion to TAVR with either Portico or TAVR with a commercially available valve. They were followed for 1 year.



RESULTS

- Primary safety endpoint (mortality/stroke/life-threatening bleeding/dialysis/major vascular complications) at 30 days for Portico vs. commercial TAVR valve: 13.8% vs. 9.6% (p = 0.03 for noninferiority)
- Primary efficacy endpoint, all-cause mortality or disabling stroke at 1 year for Portico vs. commercial valve: 14.9% vs. 13.4% (p = 0.006 for noninferiority)
- New pacemaker: 27.7% vs. 11.6%, moderate to severe paravalvular leak (PVL): 6.3% vs. 2.1%, major vascular complications: 9.6% vs. 6.3%

CONCLUSIONS

- TAVR with the self-expanding Portico valve met criteria for noninferiority for safety and efficacy compared with commercially available TAVR valves (balloon-expandable Sapien, self-expanding CoreValve)
- Pacemaker rates, moderate to severe PVL, and major vascular complications were higher with Portico, while transvalvular gradients were lower

Presented by Dr. Gregory P. Fontana at TCT 2019