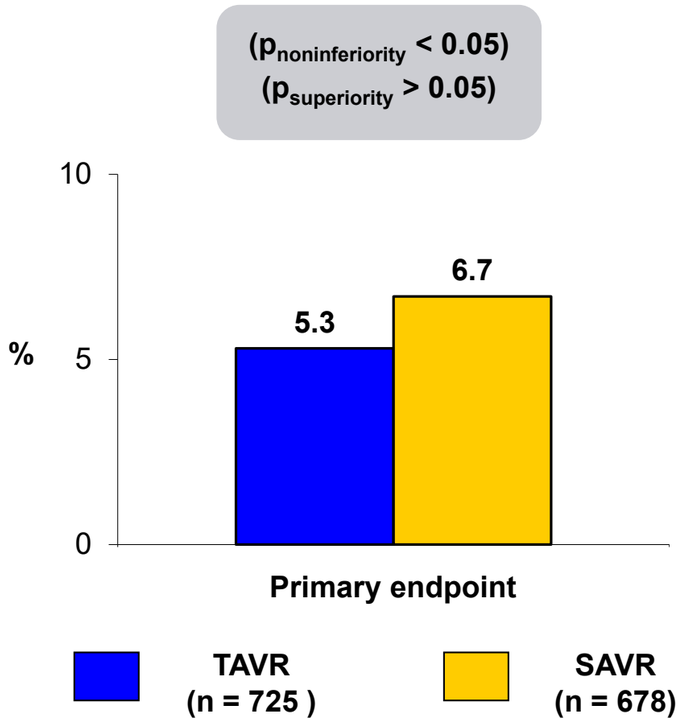
Evolut Low Risk

#ACC19

AMERICAN COLLEGE of CARDIOLOGY

Trial Description: Patients with severe aortic stenosis with low STS PROM score (<3%) were randomized in a 1:1 fashion to either TAVR with CoreValve Evolut or SAVR. They were followed for 24 months.



RESULTS

- Primary endpoint: All-cause mortality/disabling stroke for TAVR vs. SAVR at 24 months: 5.3% vs. 6.7%, $p < 0.05$ for noninferiority, $p > 0.05$ for superiority
- Disabling stroke at 2 years: 1.1% vs. 3.5%, $p < 0.05$; mortality: both 4.5%, $p > 0.05$
- New permanent pacemaker at 30 days: 17.4% vs. 6.1%, $p < 0.05$; moderate-severe paravalvular leak (PVL): 3.5% vs. 0.5%, $p < 0.05$; mean aortic gradient at 1 year: 8.6 vs. 11.2 mm Hg, $p < 0.05$, mean EOA at 1 year: 2.3 vs. 2.0, $p < 0.05$

CONCLUSIONS

- TAVR with the self-expanding CoreValve Evolut valve was noninferior to SAVR for treatment of severe symptomatic aortic stenosis in low-risk patients
- Strokes, atrial fibrillation, and severe bleeding were higher with SAVR; need for permanent pacemaker and moderate-severe PVL was higher with TAVR
- Landmark trial; longer-term results are awaited

Popma JJ, et al. N Engl J Med 2019;Mar 17:[Epub]