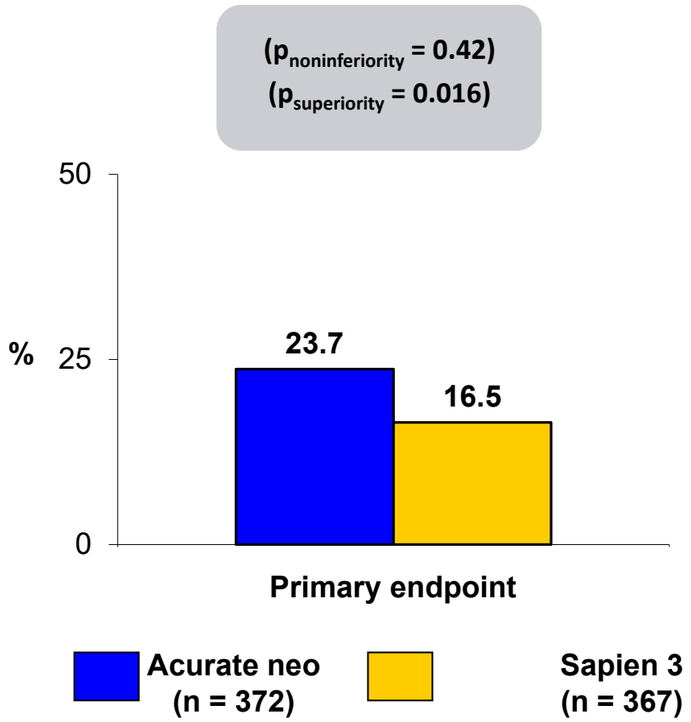
SCOPE I

#TCT2019

AMERICAN COLLEGE of CARDIOLOGY

Trial Description: Patients with severe aortic stenosis undergoing transfemoral TAVR were randomized in a 1:1 fashion to Acurate neo or Sapien 3 TAVR valves. They were followed for 30 days.



RESULTS

- Primary endpoint (death/stroke/bleeding/vascular complications/coronary obstruction/AKI/rehospitalization/repeat intervention/valve dysfunction): Acurate neo vs. Sapien 3: 23.7% vs. 16.5% ($p_{noninferiority}$ = 0.42; $p_{superiority}$ = 0.016)
- All-cause mortality: 2.5% vs. 0.8% (p = 0.09)
- Valve-related dysfunction: 9.7% vs. 4.7% (p = 0.0084); need for multiple valves during implant: 3% vs. 1% (p = 0.012); new pacemaker implantation: 11.5% vs. 10.3% (p = 0.68) 30-day PVL ≥ moderate: 9.4% vs. 2.8% (p < 0.0001)

CONCLUSIONS

- TAVR with the self-expanding Acurate neo valve did not meet criteria for noninferiority compared with balloon-expandable Sapien 3 valve among patients undergoing transfemoral TAVR. TAVR with Sapien 3 was superior for the composite 30-day endpoint, driven primarily by lower rates of AKI, paravalvular regurgitation, and vascular complications

Presented by Dr. Jonas Lanz at TCT 2019