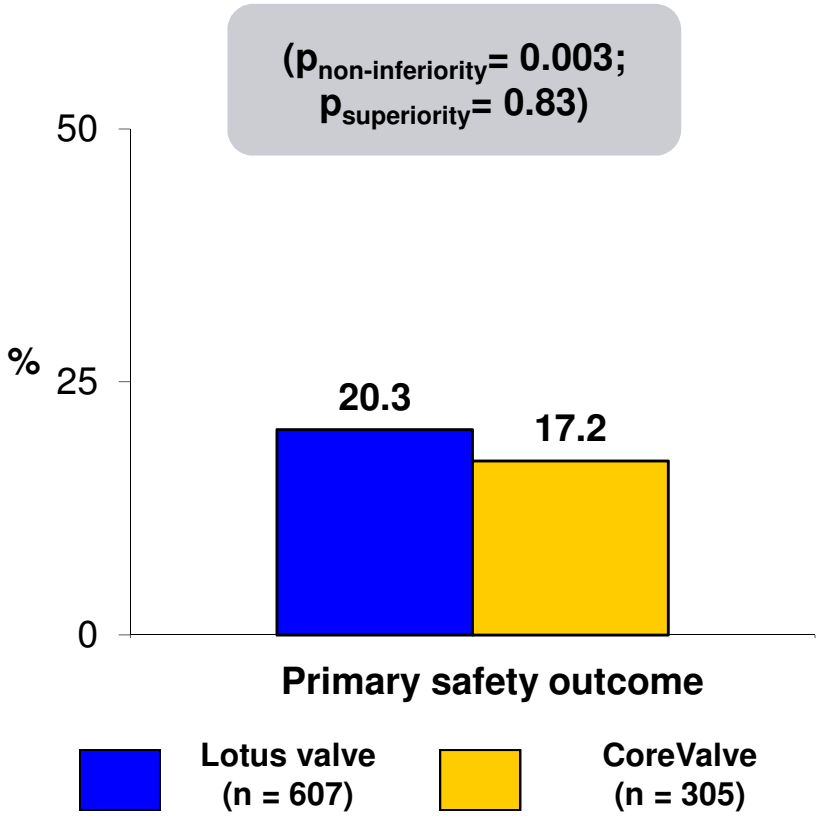
REPRISE III

Trial design: High- or extreme-risk patients with severe symptomatic aortic stenosis (AS) undergoing TAVR were randomized in a 2:1 fashion to either TAVR with the Lotus valve or the CoreValve. Patients were followed for 12 months.



Results

- Primary safety outcome: mortality/stroke/bleeding/ acute kidney injury/major vascular complications at 30 days, for Lotus vs. CoreValve: 20.3% vs. 17.2%, $p_{non\text{-}inferiority}$ = 0.003, $p_{superiority}$ = 0.83
- Primary efficacy outcome: mortality/stroke/ paravalvular leak (PVL) at 1 year: 15.4% vs. 25.5%, $p < 0.001$; moderate to severe PVL: 0.9% vs. 6.9%, $p < 0.001$
- Permanent pacemaker: 34.2% vs. 18.5%, $p < 0.05$

Conclusions

- Mechanically expanding Lotus valve was noninferior to self-expanding CoreValve for the safety and efficacy endpoints at 1 year among high- and extreme-risk AS patients undergoing TAVR
- Rates of moderate to severe PVL with Lotus were significantly lower, while pacemaker implantation rates were significantly higher

Feldman TE, et al. JAMA 2018;319:27-37