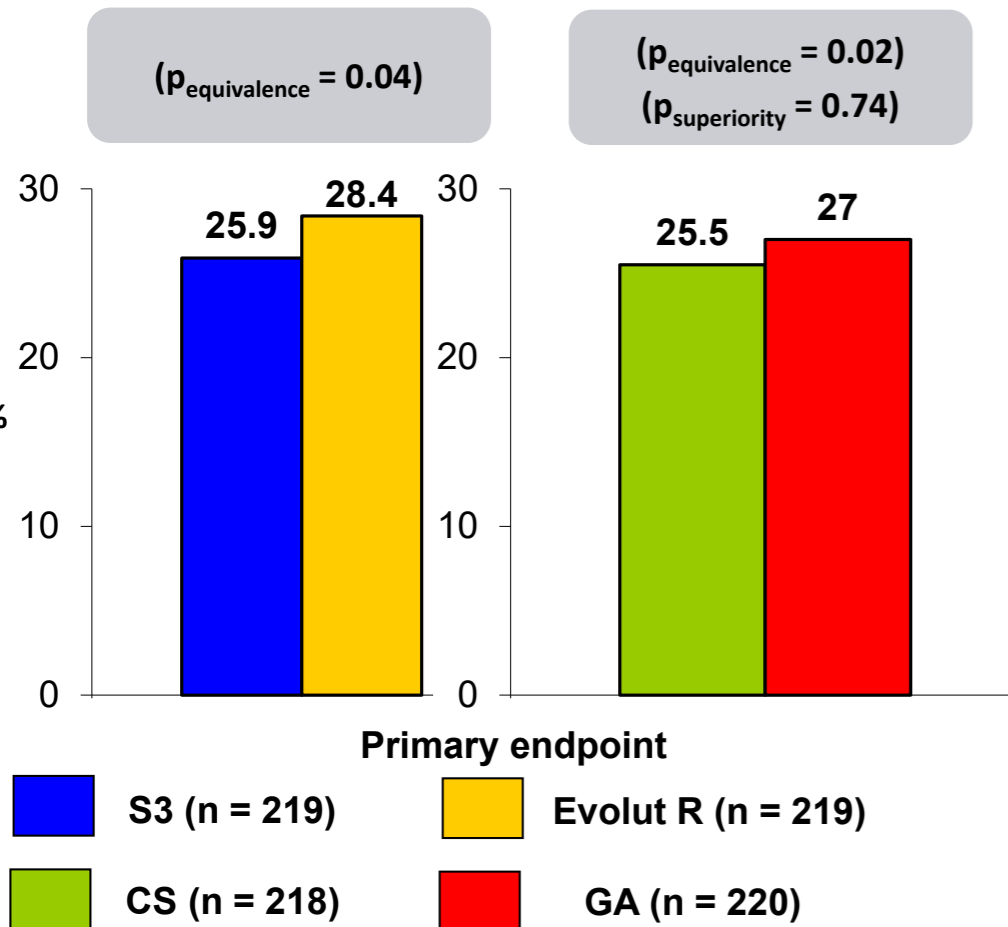# SOLVE-TAVI

Trial description: In a 2x2 factorial design, patients undergoing TAVR were randomized to either: a) TAVR with the Edwards Sapien S3 valve or the Medtronic CoreValve Evolut R, or b) conscious sedation (CS) with local anesthesia vs. general anesthesia (GA). Patients were followed for 30 days.

$(p_{equivalence} = 0.04)$

$(p_{equivalence} = 0.02)$
$(p_{superiority} = 0.74)$

25.9 | 28.4 | 25.5 | 27

Primary endpoint

- S3 (n = 219)
- Evolut R (n = 219)
- CS (n = 218)
- GA (n = 220)

RESULTS
- Sapien S3 vs. Evolut R: Primary endpoint: 25.9% vs. 28.4%, $p_{equivalence} = 0.04$, stroke: 4.7% vs. 0.5%, $p_{equivalence} = 0.03$
- CS vs. GA: Primary endpoint: 25.5% vs. 27.0%, $p_{equivalence} = 0.02$, $p_{superiority} = 0.74$; moderate/severe PVL: 1.9% vs. 1.4%, p = 0.72

CONCLUSIONS
- Both the Sapien S3 valve and CoreValve Evolut R have equivalent outcomes at 30 days. Stroke rates numerically higher with Sapien S3; moderate to severe PVL with Evolut R
- CS is equivalent to GA for TAVR, with no differences in moderate to severe PVL, with a lower need for inotropic agents

Thiele H, et al. Eur Heart J 2020;Feb 12:[Epub]