

ACURATE TF™ Clinical experience

TF First-in-man

TF First-in-Man (FIM) (n=20)

- Symetis conducted a first-in-man (FIM) trial across four sites in Brazil and Germany between May 2012 and July 2012 consisting of 20 patients with severe aortic stenosis
 - 4 different operators
 - 4 different centres
 - 3 valve sizes implanted (21mm – 27mm)
- The ACURATE TF system exhibited results in the FIM trial mirroring the ease of use of the commercially available ACURATE TA

Baseline Patient Characteristics

| | TF 20 |
|---|-------------|
| n= | 20 |
| Age [years] | 85.3 ± 3.7 |
| Logistic EuroSCORE [%] | 26.5 ± 8.0 |
| STS Score [%] | 7.0 ± 5.2 |
| NYHA Class III/IV [%] | 100 |
| Female [%] | 85.0 |
| Mean aortic gradient [mmHg] | 42.7 ± 12.6 |
| Mean aortic valve area [cm ²] | 0.7 ± 0.2 |

Procedure Success

| | |
|------------------------------------|-----------|
| Implant procedures [n] | 20 |
| Procedural success [n/%] | 19 / 95.0 |
| • 1 VnV (too low placement) | |
| New pacemaker required by DC [n/%] | 2 / 10.0 |

30-day Outcomes

| | |
|---------------------------------|-----------|
| Death [n/%] | 0 / 0.0 |
| Stroke [n/%] | 1 / 5.0* |
| MI [n/%] | 0 / 0.0 |
| Reintervention post-DC ** [n/%] | 1 / 5.0 |
| PVL grade 2 = 2 [n/%] | 1 / 5.6 |
| PVL > 2 [n/%] | 0 / 0.0 |
| Mean aortic gradient [mmHg] | 6.9 ± 3.0 |
| Mean EOA [cm ²] | 1.8 ± 0.4 |

* VnV patient (14 days post-implant)

** Conversion to SAVR for VSD (17 days post-implant)