POLESTAR Trial

Project to look for early discharge in patients undergoing TAVI with ACURATE

30-day results of an international early discharge program

By Joris Ooms, MD. On behalf of the POLESTAR investigators

Potential conflicts of interest

Speaker's name : Joris Ooms, MD

☑ I have the following potential conflicts of interest to declare:

Receipt of grants / research support: Institutional grant from Boston Scientific

Why this study?

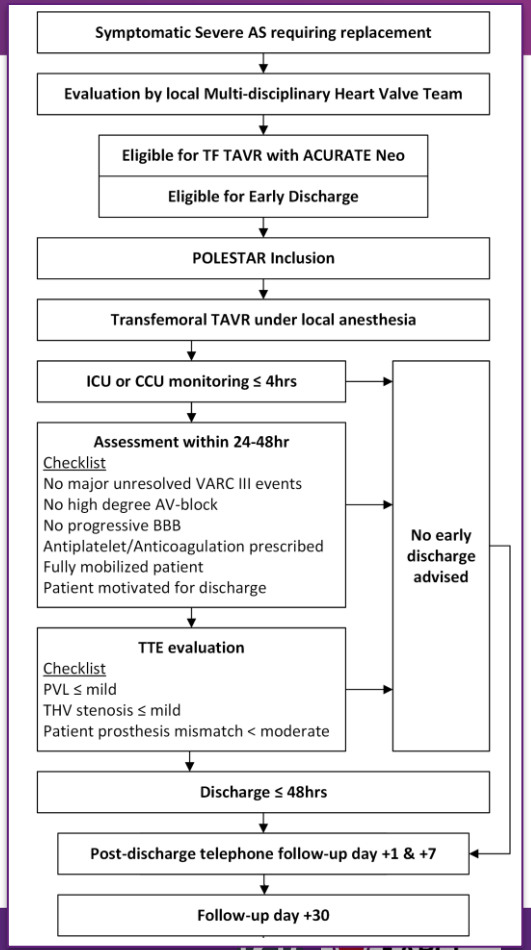
- TAVI in severe aortic stenosis (AS) has matured
- Potential for early discharge (ED) is evident
- Prospective patient selection with use of risk factors for non-ED could improve ED-pathways
- Not all valve platforms are equally represented in ED studies

What did we study?

- **Aim**: evaluation of the safety and feasibility of ED in patients selected pre-TAVI using the ACURATE NEO valve
- International prospective observational single-arm study (NCT03910751)
- **ED**: discharge to patients home environment ≤48hrs
- Main outcomes are VARC III defined safety and efficacy endpoints
- Other outcomes include reasons for non-ED, clinical outcomes, rehospitalizations, QoL

How was the study executed?

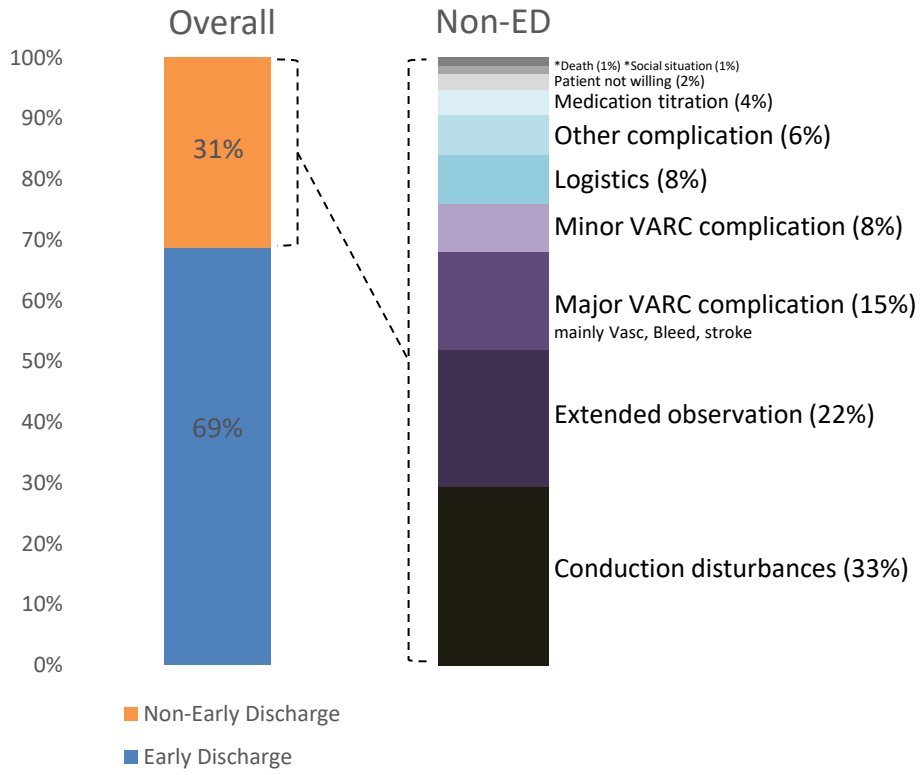
- Conducted in Netherlands, Belgium, Canada, United Kingdom
- Pre-TAVI identification of AS patients suitable for ED
- Inclusion: *≥18yrs, severe AS, eligible for TF-TAVI with ACURATE*
- Exclusion: *LVEF<35%, severe MR, PHT, complex CAD, high degree AV-block/RBBB, BMI>35, COPD>II, eGFR<35, frailty, walking aid dependent, inappropriate support, severe peripheral art. disease, intended non-TF TAVI*



What are the essential results? – Baseline & Discharge

Baseline	Overall n = 252	ED n= 173	Non-ED n = 79	p-value
Age - yrs	82 [78-85]	82 [78-84]	82 [76-85]	0.40
Female	133 (53)	89 (51)	44 (56)	0.53
BMI – kg/m²	27 ± 3.9	27 ± 3.9	26 ± 3.8	**<0.01**
Hypertension	148 (59)	104 (60)	44 (56)	0.48
DM	54 (21)	41 (24)	13 (17)	0.19
GFR < 60ml/min	90 (36)	64 (37)	26 (33)	0.53
Stroke	33 (13)	18 (10)	15 (19)	**0.06**
Periph. Art. disease	15 (6)	13 (8)	2 (3)	0.16
Myocardial infarction	21 (8)	14 (8)	7 (9)	0.84
PCI	62 (25)	40 (23)	22 (28)	0.42
CABG	23 (9)	19 (11)	4 (5)	0.16
Pacemaker/ICD	19 (8)	14 (8)	5 (6)	0.64
NYHA class* I II III IV	 14 (6) 122 (49) 113 (45) -	 8 (5) 82 (48) 80 (47) -	 6 (8) 40 (51) 33 (42) -	0.65
STS-score	2.2 [1.6-3.3]	2.3 [1.7-3.3]	2.2 [1.4-3.3]	0.64
LVEF - %	60 [55-62]	60 [55-63]	60 [55-62]	0.78
Mean gradient - mmHg	43 ± 13	43 ± 14	43 ± 12	0.86
AVA – cm²	0.79 [0.64-0.90]	0.76 [0.61-0.90]	0.80 [0.70-0.90]	0.57

Numbers are displayed with (%), median with [25th-75th percentile], mean ± SD



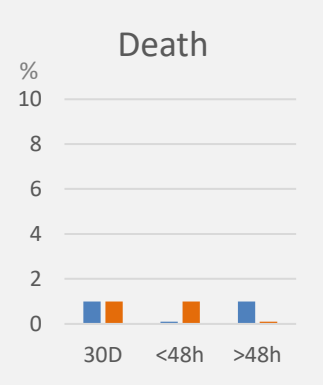
What are the essential results? – Primary Outcomes

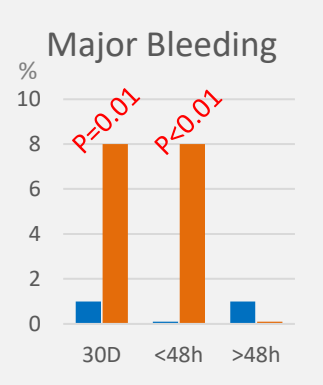
Clinical outcomes	Overall 30 days N = 251	Landmark 2 days N = 250	Landmark >48hr until 30-days		
			Non early discharge	Early discharge	p-value
Safety[1]	34 (13.5)	19 (7.6)	7 (9.0) -	12 (7.0) OR 0.84 [0.31-2.26]	0.73
Efficacy[2]	39 (15.5)	37 (14.9)	12 (15.4) -	25 (14.5) OR 0.97 [0.46-2.06]	0.94
Numbers are displayed with (%) or Odds Ratio with [95%-CI]					

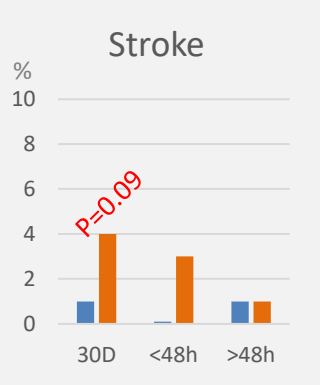
- No difference in primary endpoints between ED and non-ED groups
- Increasing year of procedure was associated with improved safety outcome: OR 0.64 [0.41-0.99], p=0.04

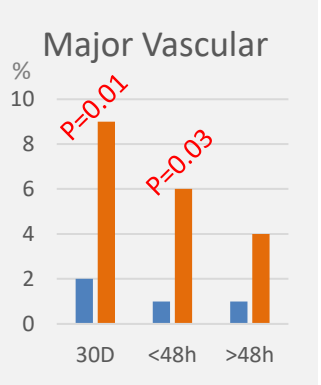
1. Safety: all-cause death, stroke, VARC 2-4 bleeding, AKI stage 3-4, major vascular, major access related, major cardiac structural, moderate or severe AR, new PPM, surgery or intervention related to valve
2. Efficacy: all-cause death, stroke, rehospitalization for procedure-valve related cause, KCCQ Oss <45 or decline >10points

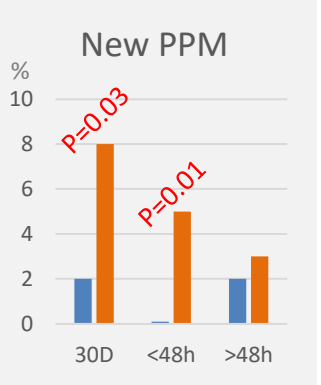
What are the essential results? – Clinical Outcomes

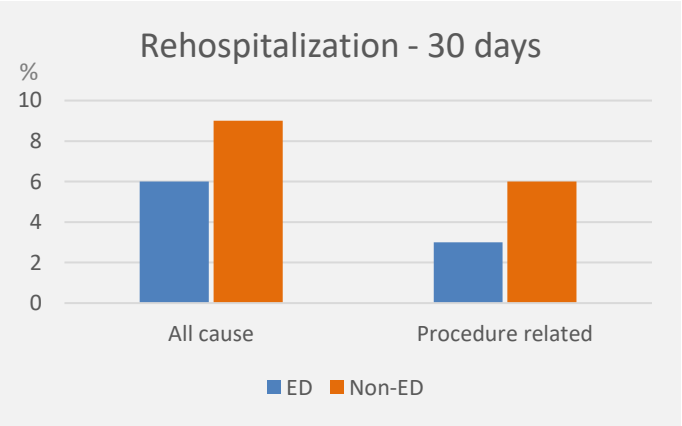




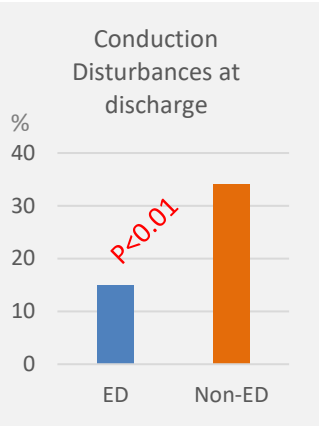






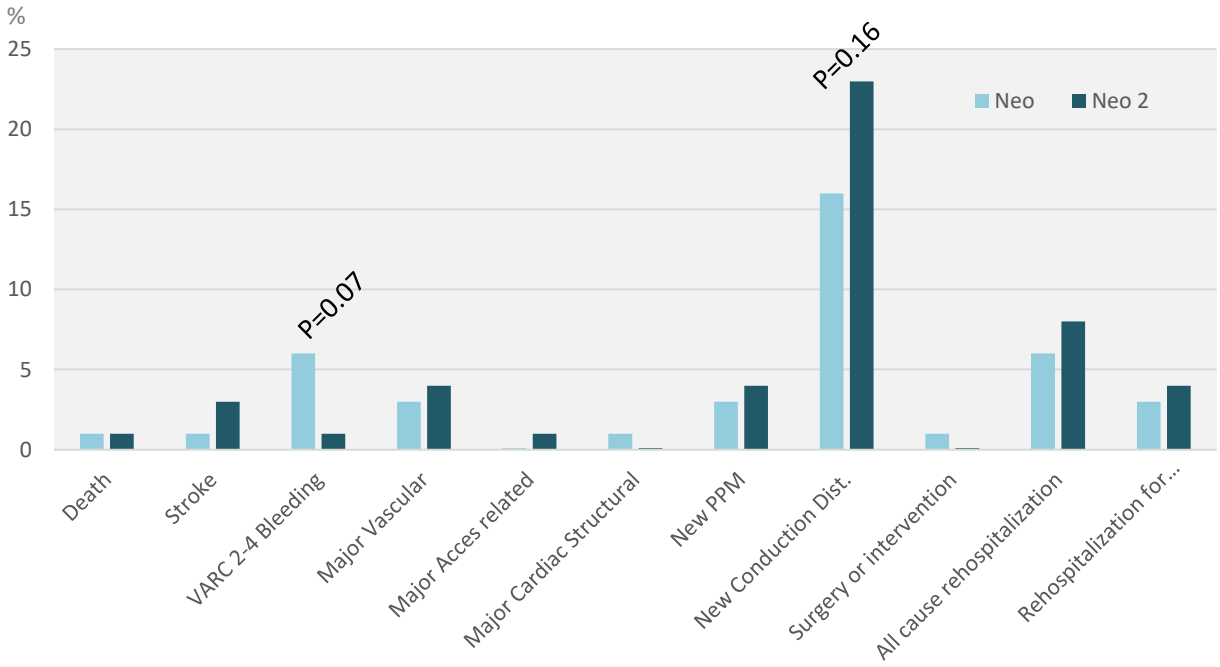


- Overeall PPM rate 4%
- All patients who received PPM in ED group → after discharge
- All patients who received PPM in non-ED group → index hospitalization
- Of patients not discharged due to conduction disturbance 23% received PM

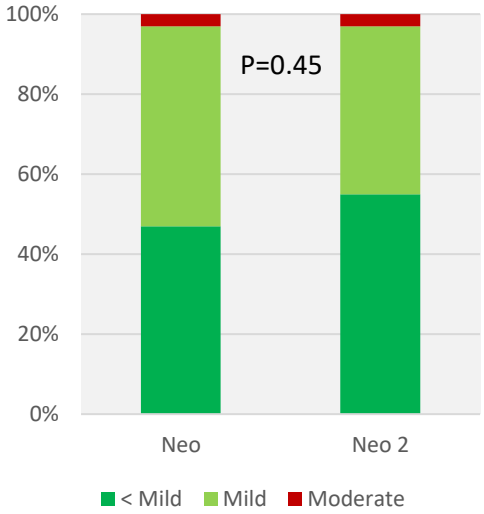


What are the essential results? – Neo and Neo 2

Clinical Outcomes – 30 Days



TTE: Aortic regurgitation post TAVI



Why is this important?

- One third was discharged after 48hrs with low readmission rates
- No penalty in composite endpoints between discharge groups
- Low PM rates, conduction remains important factor in decision for ED
- **POLESTAR** identifies targets for length of stay reduction

- Limitations: Selection bias, Covid policies, no core lab

- **POLESTAR** shows safety and feasibility of early discharge in a selected population

The essentials to remember

- Early discharge < 48 hours after TAVI with ACURATE Neo platform is safe & feasible in selected patients
- Refined selection criteria for early discharge after TAVI in elderly patients requires further research

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