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ABSTRACT

Background: Transcatheter aortic valve replacement (TAVR) is now an established treatment strategy for elderly patients with symptomatic aortic stenosis (AS) across the entire operative risk spectrum. Streamlined TAVR protocols along with reduced procedure time and expedited ambulation promote early hospital discharge. Selection of patients suitable for safe early discharge after TAVR might improve healthcare efficiency.
Study design: The POLESTAR trial is an international, multi-center, prospective, observational study which aims to evaluate the safety of early discharge in selected patients who undergo TAVR with the supra-annular functioning self-expanding ACURATE Neo transcatheter heart valve (THV). A total of 250 patients will be included based on a set of baseline criteria indicating potential early discharge (within 48 h post-TAVR). Primary study endpoints include Valve Academic Research Consortium (VARC)-3 defined safety at 30 days and VARC-3 defined efficacy at 30 days and 1 year. Endpoints will be compared between early discharge and non-early discharge cohorts with a distinct landmark analysis at 48 h post-TAVR. Secondary endpoints include quality of life assessed using EQ5D-5L and Kansas City Cardiomyopathy Questionnaire (KCCQ) questionnaires and resource costs compared between discharge groups.
Summary: The POLESTAR trial prospectively evaluates safety and feasibility of an early discharge protocol for TAVR using the ACURATE Neo THV.

1. Background and rationale

Transcatheter aortic valve replacement (TAVR) serves a growing spectrum of patients with symptomatic severe aortic stenosis (AS). Updated guidelines on valvular heart disease recommend transfemoral TAVR in elderly patients ≥75 years with symptomatic severe AS [1,2]. With respect to individual clinical, anatomical and procedural parameters, patients with fewer comorbidities and overall low-to-moderate operative risk are now also considered for TAVR [3–6]. In selected centers and geographies TAVR has transitioned to a streamlined and simplified procedure under local anesthesia/conscious sedation mitigating procedure related complications, hospital acquired infections and delirium and thereby catalyzing early ambulation and reduced length of hospital stay [7,8]. An early discharge policy may increase hospital turnover, expand TAVR capacity and reduce healthcare costs [7].

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Early discharge requires proper screening of candidates with recognition of important risk factors for procedure related complications, assuring smooth recovery, early ambulation and appropriate social support for safe and comfortable recovery in an individual's home environment [9–12]. Prior studies established the feasibility and safety of early discharge protocols using selected transcatheter heart valve (THV) platforms [9,13,14]. Transcatheter heart valve selection and its complication profile may determine early discharge opportunities. Notably, new conduction disorders may require prolonged in-hospital rhythm monitoring and new permanent pacemaker (PPM) implantation. The ACURATE Neo THV (Boston Scientific, Marlborough, MA) is a self-expanding supra-annular functioning bioprosthesis with low rates of new conduction disorders and may be suitable for an early discharge policy [15,16]. So far, the ACURATE THV has been underrepresented in previous early discharge studies [9,17]. The Project to look for early discharge in patients undergoing TAVR with ACURATE (POLESTAR) Trial is a prospective observational multicenter study to evaluate the safety and feasibility of early discharge in selected patients who undergo TAVR with the ACURATE THV.

2. Methods

2.1. Study design

The POLESTAR Trial (NCT03910751) is an international multicenter, prospective, observational single-arm study in which TAVR patients, eligible for early discharge within 48 h, are enrolled pre-TAVR and evaluation of early discharge feasibility, procedural safety and efficacy is performed at 30 days and 1 year of follow-up. Study sites are located in Europe and Canada.

2.2. Study objectives

The primary objective of this observational study is to address safety and feasibility of a predetermined plan for early discharge to the patient's home environment within 48 h after TAVR with ACURATE Neo. Clinical endpoints are recorded per VARC III definitions at hospital discharge, 30 days and 1 year follow up [18].

2.3. Patient selection and study workflow

The multidisciplinary heart team determines patient eligibility for: 1) TAVR with the ACURATE Neo (including CE-marked iterations) platform and 2) early discharge within 48 h post procedure in accordance with a set of in- and exclusion criteria (Table 1). Assessment of patient eligibility for early discharge follows local standard of care that includes a multi-disciplinary heart team decision based on the assessment of electrocardiography (to anticipate conduction issues) [19], echocardiography (to assess LV function, AS severity and concomitant valve disease), multi-slice computed tomography (to assess aortic valve dimensions and feasibility for transfemoral TAVR with ACURATE Neo2), patient comorbidities and proper social support at home. After confirmation of POLESTAR study eligibility by the multidisciplinary heart team, patients are informed about the early discharge strategy. The patient needs to agree to this strategy, confirm appropriate social/familial support and sign informed consent prior to study enrollment.

2.4. Rationale for patient selection criteria

Study specific selection criteria relate to the anatomical requirements for the selected ACURATE transcatheter heart valve platform and patient-specific factors.

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
Age ≥ 18 years
Eligible for transfemoral Transcatheter Aortic Valve Implantation with the ACURATE Neo platform
Able to provide written informed consent
Exclusion criteria
Cardiac
Left ventricular ejection fraction <35 %
More than moderate mitral regurgitation
Severe pulmonary hypertension (sPAP >60 mmHg)
Unresolved complex coronary artery disease
Defined as: multivessel disease, left main lesions, bifurcation lesions
Untreated high degree atrioventricular block or right bundle branch block
Other comorbidities/conditions
Body mass index >35 kg/m^2
Pregnancy
Chronic obstructive pulmonary disease class > II
Chronic kidney dysfunction (eGFR <35 ml/min)
Frailty per multi-disciplinary heart team evaluation
Walking aid dependent for mobilization
Inappropriate social support and/or familial care
TAVR strategy
Severe peripheral artery disease (history)
Defined as: claudication within < 200 m, previous thromboendarterectomy, plastic patch in situ of common femoral artery, uni-/bilateral lower extremity amputation
Severe peripheral artery disease (Computed Tomography)
Defined as: protrusion of calcium into the arterial lumen and/or circumferential distribution at the level of intended access site
Non-transfemoral access TAVR
Follow-up
Inability to adhere to planned follow-up of one year

CE: Conformité Européene, eGFR: estimated glomerular filtration rate, sPAP: systolic pulmonary artery pressure.

2.5. Cardiac factors

2.5.1. Left ventricular ejection fraction

Patients suffering from heart failure with reduced ejection fraction (HFrEF) are considered to be at risk post-procedure morbidity and prolonged hospitalization [2,20]. Registry data of patients with low-flow low-gradient AS who underwent TAVR showed a median admission time of 6 days [21]. Furthermore, a large registry assessing predictors for length of stay identified depressed LV EF as a predictor for delayed discharge [10].

2.5.2. Mitral regurgitation

Moderate or severe concomitant mitral valve disease at baseline could negatively influence short-term mortality post TAVR [22,23]. Additionally, baseline ≥moderate MR is associated with an increase in 30-day readmission rates [24] which could impact the safety of an early discharge strategy.

2.5.3. Severe pulmonary hypertension

In patients with severe AS, severe pulmonary artery pressure (PAP) (>60 mmHg) is associated with increased early, mid and late-term mortality rates post TAVR as well as readmission for heart failure [25,26].

2.5.4. Unresolved complex coronary artery disease

Simultaneous TAVR and PCI is considered feasible [27]. However, for patient subgroups with complex coronary lesions (i.e. high syntax score) at the time of TAVR, risk of mortality is increased [28,29]. Multivessel coronary artery disease, left main stem disease and bifurcation lesions are relative exclusion criteria for POLESTAR.

2.5.5. Untreated high-degree atrioventricular block or right bundle branch block

Conduction disturbances progressing to a need for definite pacemaker are major contributors for prolonged admission times [9,12]. Conversely, prior PPM implantation is a predictor of early discharge [10]. Preexisting right bundle branch block (RBBB) and high degree atrioventricular (AV) block (Mobitz I and II) are strong independent predictors of PPM after TAVR [19,30].

2.6. Oher comorbidities

High Body Mass Index is a risk factor for cardiovascular disease [31] and may affect access site management and post procedural mobilization. TAVR using an alternative non-femoral access may preclude an early discharge pathway [32]. Severe chronic Obstructive Pulmonary Disease and the use of home oxygen are associated with delayed discharge [10]. Similarly, severe chronic kidney dysfunction at baseline is a limiting factor for early discharge post-TAVR and is associated with increased short-term mortality and rehospitalization rates [10,33].

2.6.1. Frailty

Advanced frailty at baseline increases procedural risk, delirium frequency and may coincide with additional care in nursing facilities [34]. In POLESTAR, frailty is determined by a multi-parametric assessment and separately discussed in the multi-disciplinary heart team that may involve geriatricians.

2.6.2. Inappropriate social support and/or familial care

Absence of proper social support may preclude early discharge to a patient's home environment. Involvement of family, friends and local caregivers should be ascertained (by heart team members such as nurse practitioners, physician assistants and geriatricians)and discussed with the patient, and is essential for early discharge.

2.7. TAVR strategy

Severe peripheral artery disease is a well-known risk factor for TAVR periprocedural complications and with it delayed discharge [10]. For POLESTAR we defined presence of peripheral artery disease by both clinical and computed tomography (CT) parameters as those are considered of high risk for vascular complications and therefore not suitable for an early discharge pathway (Table 1) [35].

2.7.1. Non-transfemoral access TAVR

Alternative access TAVR predominantly occurs under general anesthesia which is associated with longer length of stay [36]. An exception is transaxillary TAVR, which can be performed using a simplified approach. However, these patients often have an increased risk profile (i.e. vascular comorbidities) leading to vascular complications and prohibiting early discharge [37].

2.7.1.1. Transcatheter aortic valve replacement. Transfemoral TAVR with ACURATE Neo follows local practice and fits within an early discharge policy. Local anesthesia/conscious sedation, ultrasound guided femoral artery access, pacing on the LV wire techniques, restricted use of urinary catheters, limited use of intensive care resources and logistics for predischarge transthoracic echocardiographic (TTE) evaluation are recommended. Use of cerebral embolic protection is left to the operator's discretion. Concomitant percutaneous coronary intervention of significant non-complex coronary artery disease is allowed. The ACURATE Neo prosthesis consists of a self-expanding nitinol frame characterized by axial self-aligning stabilization arches that extend into the ascending aorta, an upper crown for supra-annular anchoring and a lower crown with a pericardial skirt for intra-annular seating. Porcine pericardium valve leaflets are sutured in a supra-annular position. The ACURATE Neo received CE-mark in 2014 [38]. The ACURATE Neo2 is a THV iteration with CE mark in 2020 featuring an integrated and augmented inner and outer porcine pericardial sealing skirt to further reduce PVL (Fig. 1).

2.7.1.2. Post-procedural workflow. The treating physician determines optimal timing for home discharge based on clinical factors and shared decision making with the individual patient. The physician ascertains 1) absence of unresolved procedure related complications and high-degree AV/progressive intraventricular conduction disorders, 2) proper ambulation, 3) appropriate antithrombotic regimen, 4) predischarge TTE without moderate or severe paravalvular leak or aortic stenosis and 5) social support (Fig. 2, Supplementary Table 1). Telemetric rhythm monitoring and daily ECG are recommended throughout the hospital stay. Patients with pre-existing or new intraventricular conduction delay, i.e. QRS >120 msec and/or prolonged AV conduction times are only eligible for early discharge when the QRS and AV intervals have plateaued or shorten again [19,39].

2.7.1.3. Discharge. The POLESTAR trial specifically registers duration of in-hospital stay defined by the time the patient leaves the catheterization laboratory after the TAVR procedure until discharge home. Target is a post TAVR hospital stay ≤48 h. Of note, patients should be discharged to his/her home environment and not to a referring hospital. Reasons for discharge >48 h after TAVR will be recorded.

2.7.1.4. Follow-up. A TAVR team member (e.g. a dedicated nurse or nurse practitioner) contacts the patient by telephone on day one and seven after discharge to assure patient comfort and safety. An in-person follow-up visit occurs per local standard of care 4 to 6 weeks and one year after TAVR. Table 2 and Fig. 2 summarize the study specific follow-up proceedings including mandatory quality of life and TTE assessments.

2.8. Study endpoints

The number of patients who were discharged to their home environment within 48 h after TAVR will be recorded as a proportion of the overall study population. *The safety endpoint is* a composite of all-cause death, any stroke, VARC type 2–4 bleeding, acute kidney injury stage 3–4, major vascular, major access related, major cardiac structural

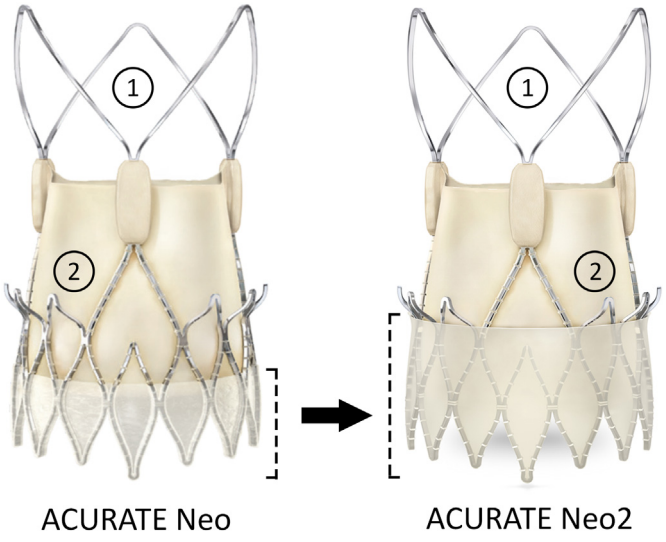

Fig. 1. ACURATE Neo and Neo2
First and second generation ACURATE valve. The device has a self-expanding nitinol frame with stabilization arches (1) and an upper crown (2). Note the extended inner/outer porcine pericardial sealing skirt in the Neo2 (black arrow).

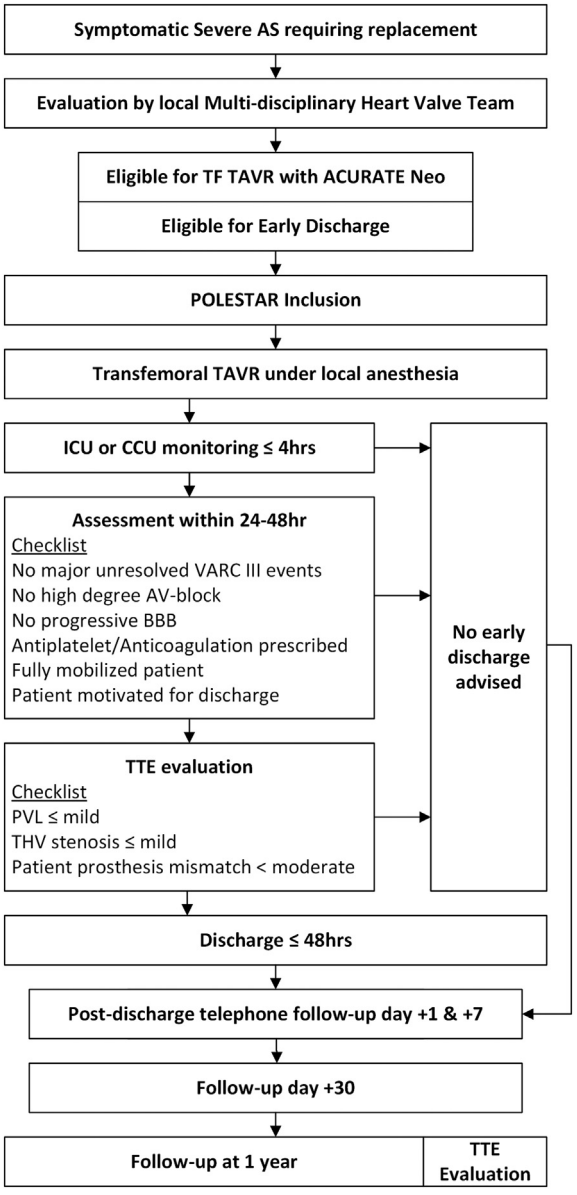

Fig. 2. POLESTAR Trial workflow
AS: Aortic Stenosis, AV: Atrioventricular, BBB: Bundle Branch Block, CCU: Coronary Care Unit, ICU: Intensive Care Unit, PVL: Paravalvular Leakage, TAVR: Transcatheter Aortic Valve Replacement, TF: Transfemoral, THV: Transcatheter Heart Valve, TTE: Transthoracic Echocardiogram, VARC: Valve Academic Research Consortium.

complication, moderate or severe aortic regurgitation, new PPM implantation, surgery or intervention related to the transcatheter heart valve at 30 days. The *efficacy endpoint features* a composite of all-cause death, all stroke, rehospitalization for procedure- or valve-related causes, KCCQ Overall Summary Score < 45 or decline from baseline >10 points at 30 days and 1 year after TAVR.

Secondary endpoints are the individual components of the composite primary endpoints, new conduction abnormalities and need for PPM and prosthetic valve performance (including: mean gradient, effective orifice area, presence of (paravalvular) aortic regurgitation). Additionally, reasons for failure to achieve early discharge will be captured. Quality of life (QoL) will be assessed at baseline and at 30-days and one year of follow-up. The EQ-5D-5L index/utility score assesses health status based on 5 levels and a visual analogue scale [40]. The Kansas City Cardiomyopathy Questionnaire (KCCQ) evaluates symptoms, physical and social limitations, and QoL in heart failure patients. KCCQ has been validated in TAVR trials and serves as a performance measure for quantification of the quality of life [41].

Early discharge may have relevant financial implications. Resource use will be assessed in each participating center. All costs will be assessed from the Dutch Healthcare system perspective and reported in euros in the latest year for which resource data will be available at the time of analysis. Procedural costs will be assessed through a micro-costing approach of the TAVR procedure in at least one catheterization laboratory that participates in the study. This includes costs of the transcatheter heart valve and delivery system, disposables, catheterization laboratory use, overhead, depreciation of the catheterization laboratory and will be adjusted for actual procedure duration. In hospital costs include the ICU length-of-stay, general ward admission length, additional tests and additional procedures during the index hospitalization. Follow-up costs include expenses for re-hospitalization and emergency room visits not resulting in hospitalization.

2.9. Statistical considerations

The primary analysis is based on the intention-to-treat cohort. Normality of continuous variables will be tested using the Shapiro-Wilk. Accordingly, continuous variables will be described as mean with standard deviation, or as median with 25th and 75th percentile. Categorical variables will be expressed as percentages and counts.

The safety and efficacy endpoint at 30 days will be described as proportions. A landmark analysis of the efficacy and safety endpoints set at 48 h post-TAVR with follow-up up to 30 days will be performed using logistic regression with the discharge group as the independent variable.

The efficacy endpoint at one year follow-up will be described using the Kaplan-Meier method. Patients are followed from day of index procedure up to 1 year of follow-up. Subsequently, in a separate analysis, patients are followed from 48 h post-TAVR (landmarked) to 1 year of follow-up. Patients are censored if lost to follow-up before reaching the one year follow-up mark. Values will be presented in numbers with estimated Kaplan-Meier incidence in percentage (with 95 % confidence interval). Stratification based on geographical clustering and time of enrollment in the study will be performed. Discharge groups will be compared using log-rank tests to evaluate differences in event-free survival. Additionally, primary endpoints at one year will be evaluated using Cox proportional hazard models to adjust for confounders such as country and time of enrollment.

Overall EQ5D-5L index/utility score and KCCQ scores at the different follow-up visits will be compared with baseline values using paired *t*-tests analysis. Differences of baseline, 30-day and 1 year scores will be evaluated between groups using linear mixed effects models taking into account the clustering of data. All tests will be 2-tailed, and a *p*-value of <0.05 will be considered statistically significant. Comparisons of the individual components of the composite endpoints are hypothesis generating and therefore no adjustment for multiple testing will be made.

2.10. Planned sample size

Prospective data on safety and feasibility of early discharge protocols related to TAVR are scarce and involve other THV platforms than the ACURATE THV [38,42]. The POLESTAR study is a feasibility study with no formal power calculation regarding clinical endpoints. The chosen sample size is based on the following reasoning. A large registry reported a 30-day readmission rate of 16 % in hospitals with a relatively high number of direct-home discharges post TAVR [43]. Taking into account the reports on early discharge known at the time of protocol conception, a 10 % readmission rate was considered feasible [11,12,42]. In order to confirm this readmission rate with an accuracy of ±5 % and with 95 % confidence, a total of 150 early discharge patients (with 15 readmissions) are needed. In view of the pre-selection made and in view of studies mentioned previously, we expect that 60 % of

Table 2
POLESTAR Trial study outline.

Event	Baseline pre-screening	Screening procedures	Procedure	Pre-discharge	1 day	1 week	30 days	1 year
Clinical inclusion/exclusion criteria	X							
- Medical history	X							
- Physical examination	X			X			X	X
- 12-lead electrocardiogram	X			X			X	X
- Laboratory tests	X	X		X			X	X
- NYHA heart failure class	X						X	X
- CT of heart and vasculature	X							
- Eligibility for early discharge	X	X	X	X				
Local heart team indication for TAVR		X						
Eligibility for ACURATE aortic valve		X	X					
Informed consent		X						
Follow-up by phone call					X	X		
Follow-up face-to-face							X	X
Transthoracic echocardiogram	X			X				X
Quality of life assessment	X						X	X
Adverse event monitoring			X	X	X	X	X	X

CT: Computed Tomography, NYHA: New York Heart Association, TAVR: Transcatheter Aortic Valve Replacement.

our patients will be discharged early. Therefore, the total sample size is set at 150/0.6 = 250 patients.

3. Ethical conduct and study oversight

This study complies with the ISO 14155 principles (Clinical investigation of medical devices for human subjects — Good Clinical Practice, GCP), the Declaration of Helsinki and applicable local regulatory requirements. The trial is registered at clinicaltrail.gov (NCT03910751).

National and local ethical committees review the POLESTAR study protocol and all major amendments. Subject data will be collected in a dedicated electronic Case Report Form (eCRF) in a pseudo-anonymized fashion. An independent clinical research organization (AVANIA BV, Bilthoven, The Netherlands) is responsible for on-site study monitoring outside of the Netherlands/Belgium, in particular informed consent process confirmation in all subjects and source data verification of a minimum of 25 % of key data points (incl. primary endpoints). For the Netherlands and Belgium monitoring is directly organized by the study sponsor. An independent clinical events committee, including three independent medical doctors, adjudicates all death and stroke events and the indications for new PPM implantation.

4. Sources of funding

The POLESTAR trial is an investigator-initiated study conducted by the Erasmus University Medical Center. An unrestricted research grant is provided by Boston Scientific (Marlborough, MA) that is not involved with study related activities, data acquisition, analysis or reporting.

5. Study progress

A total of 11 sites in Europe and Canada are recruiting patients. The global Covid-19 pandemic affected local TAVR referrals and practices. Overall, TAVR volumes declined and on-site clinical follow-up visits and TTE studies were restricted. Also, national regulatory processes of the ACURATE Neo THV platform were delayed. As a result, POLESTAR study enrollment did not meet initial expectations and time for enrollment was prolonged from the Q4 2020 to Q2 2022. Enrollment completion is projected in 2022.

6. Discussion

The POLESTAR trial is the first prospective multicenter study to evaluate safety and feasibility of an early discharge protocol in patients who undergo transfemoral TAVR with the ACURATE THV. Limited data on early discharge after TAVR exist but are restricted to a balloon expandable THV platform. The 3 M study selected patients based on a set of inclusion/exclusion criteria including expected life expectancy of >3 years to early discharge within 24 h of TAVR [17]. The FAST-TAVI study aimed to determine specific criteria following transfemoral TAVR with a balloon expandable THV for safe discharge within 72 h of the procedure to home or a referring hospital or nursing care facility [9]. Conversely, POLESTAR evaluates an early (defined as ≤48 h after the procedure) discharge policy to the subject's home environment based on patient selection prior to TAVR with a self-expanding THV.

The ACURATE Neo platform has consistently shown low PPM rates. A lower hazard for clinically relevant conduction disorders seems an asset for a THV platform in the context of early discharge. Randomized trials failed to demonstrate non-inferiority of the ACURATE Neo THV with a balloon expandable (SCOPE 1) [44] or different self-expanding THV (SCOPE 2) [45]. Yet, these findings need to be interpreted with caution and do not impair further research. In SCOPE 1 important selection bias (only 14 % of screened patients were enrolled) may have affected the final trial results and the trial was powered only for its primary endpoint at 30 days of follow up. Notably, clinical outcomes were similar with the ACURATE and balloon expandable THV at 1 year, but warrant further investigation [46]. In SCOPE 2, patient screening was unclear and there was an imbalance in operators' experience in favor of the self-expanding Evolut (Medtronic Inc., Minneapolis, MN) over the ACURATE THV [45]. Furthermore, it is important to note that in the per-protocol analysis, non-inferiority was reached, which contrasted with the intention-to-treat analysis [47]. Also, a next generation EVOLUT platform with a sealing wrap was allowed in SCOPE 2 whereas the first generation ACURATE THV did not have this feature in the study. Paravalvular leakage was consistently more frequent after ACURATE Neo TAVR than with other platforms. In SCOPE 1 and 2, >mild PVL with ACURATE Neo was reported in 9.6 % (as-treated) and 10 % (per-protocol) of patients respectively. The latest generation ACURATE Neo2 is equipped with a sealing skirt to mitigate paravalvular leak. Of note, a recent prospective study confirmed favorable clinical outcome with the ACURATE Neo2 THV at 1 year with more than mild PVL in 2.5 % of patients as assessed by an independent echocardiography core laboratory [48].

7. Summary

The international multi-center prospective observational POLESTAR trial evaluates safety and feasibility of early discharge in selected patients with symptomatic severe aortic stenosis after ACURATE Neo TAVR.

CRediT authorship contribution statement

Joris F. Ooms: Conceptualization, Methodology, Investigation, Resources, Writing – original draft, Writing – review & editing,

Visualization, Project administration. **Kristoff Cornelis:** Investigation, Resources, Writing – review & editing, Project administration. **Pieter R. Stella:** Conceptualization, Investigation, Resources, Writing – review & editing. **Benno J. Rensing:** Investigation, Resources, Writing – review & editing. **Jan Van Der Heyden:** Investigation, Resources, Writing – review & editing. **Albert W. Chan:** Investigation, Resources, Writing – review & editing. **Joanna J. Wykrzykowska:** Investigation, Resources, Writing – review & editing. **Liesbeth Rosseel:** Investigation, Resources, Writing – review & editing. **Bert Vandeloo:** Investigation, Resources, Writing – review & editing. **Mattie J. Lenzen:** Conceptualization, Methodology, Writing – original draft, Writing – review & editing. **Michael S. Cunnington:** Investigation, Resources, Writing – review & editing. **David Hildick-Smith:** Investigation, Resources, Writing – review & editing, Project administration. **Harindra C. Wijeysundera:** Investigation, Resources, Writing – review & editing. **Nicolas M. Van Mieghem:** Conceptualization, Methodology, Investigation, Resources, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

Dr. Cornelis serves as a proctor for Boston Scientific. Dr. Cunnington has received fees for speaking at educational meetings from Medtronic and Abbott Vascular. Dr. Hildick-Smith is a proctor and advisor of Edwards Lifesciences, Medtronic, Abbott Vascular and Boston Scientific. Prof. Dr. Van Mieghem is a member of the advisory board of Abbot Vascular, Boston Scientific, Medtronic and a member of the scientific board of PulseCath B.V.

The other authors have no conflict of interest to declare. Individual files with the ICMJE forms will be provided separately.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2022.06.009.

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