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ORIGINAL ARTICLE

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Procedural and clinical outcomes of patients undergoing a TAVI in TAVI procedure: Rationale and design of the multicentre, prospective, observational ReTAVI registry

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[Correction added on 21 June 2024, after first online publication: The author Hector Alfonso Alvarez-Covarrubias was added in the author byline].

Abstract

Background: Transcatheter aortic valve implantation (TAVI) is increasingly being used in younger patients and those with lower peri-procedural risk, meaning more patients will live long enough to experience structural valve deterioration (SVD) of the bioprosthesis, indicating repeated TAVI. Experience of repeated TAVI—transcatheter heart valve (THV) implantation into an index THV is limited. This registry aims to assess the peri-procedural and short-term safety, efficacy and durability of repeated TAVI.

Methods: The ReTAVI Prospective observational registry is an investigator-initiated, multicentre, international, prospective registry of patients undergoing repeated TAVI using balloon-expandable SAPIEN prosthesis to evaluate procedural and short-term safety, efficacy and durability as well as anatomical and procedural factors associated with optimal results. The registry will enrol at least 150 patients across 60 high-volume centres. Patients must be ≥18 years old, have had procedural success with their first TAVI, have index THV device failure, intend to undergo repeated TAVI and be considered suitable candidates by their local Heart Team. All patients will undergo a 30-day and 12-month follow-up. The estimated study completion is 2025.

Conclusions: The registry will collect pre-, peri-, postoperative and 12-months data on patients undergoing repeated TAVI procedures with THVs for failure of the index THV and determine VARC-3-defined efficacy and safety at 30 days and functional outcome at 12 months. The registry will expand existing data

For affiliations refer to page 7.

sets and identify patient characteristics/indicators related to complications and clinical benefits for patients with symptomatic severe calcific degenerative aortic stenosis.

KEYWORDS
aortic stenosis, redo-, ReTAVI registry, TAVI, transcatheter aortic valve implantation

1 | BACKGROUND

The most common indication for aortic valve replacement (AVR) is aortic stenosis (AS), associated with decreased systemic and coronary blood flow and impaired valvular and ventricular function. With growing life expectancy, an increasing number of patients require AVR or the less invasive transcatheter aortic valve implantation (TAVI) procedure (for review, see[1]). Furthermore, younger patients and lower-risk patient groups are also increasingly undergoing TAVI procedures, which introduces challenges with valve durability.[2,3]

It is estimated that 1.4%–2.8% of all patients undergoing transcatheter heart valve (THV) implantation will require a second THV implanted into the index THV because of clinically significant prosthesis degeneration.[4–6] More than 70% of THV-in-THV implants are expected to be successful.[7]

Repeated TAVI may be a promising approach for degenerated THVs, but there is insufficient knowledge about which strategy and valve design may result in the best outcomes.[6] Unlike first-time TAVI, there are fewer valve options for repeated TAVI, with the SAPIEN 3/Ultra THVs currently being the only registered medical devices for this use.[7] The expanded use of THV for treating lower-risk patients with severe AS means that the estimated number of patients requiring re-treatment for THV failure will likely rise over the coming years.

Current evidence to support repeated TAVI is based on case reports and small case series, and there is no documentation from prospective, multicentre studies or registries. Furthermore, existing retrospective registries are biased by initial decision to perform TAVI (older and sicker patients) and do not capture the decision-making not to choose THV. It is therefore timely to set up a prospective observational study in which a standardised, stepwise approach is applied,[7] and in which critical procedural parameters and post procedural short-term outcomes will be documented. Furthermore, data on the post procedural haemodynamic performance of repeated TAVI procedures will be collected, improving the registry's value to demonstrate the clinical benefits of the procedure. As a result, the findings from this registry will help gain contemporary knowledge on TAVI-in-TAVI, modify and fine-tune procedural flow, pre-screening and post-operative care and help identify unmet needs of future TAVI technology.

2 | METHODS/DESIGN

2.1 | Registry design

The ReTAVI registry is an investigator-initiated, observational, multicentre, international, prospective registry conducted in more than 60 high-volume sites with consecutive patient enrolment. Each centre will recruit 3–5 patients over 12 months, resulting in a maximum of 250 patients. If recruitment is <5 patients per centre, this forecasted inclusion rate will result in a buffer of 100 patients to arrive at a minimum of 150 evaluable patients. The local Heart Team at each centre will be required to familiarise itself with the registry protocol, requirements and procedures. Overall, the study sponsor (IPPMed-Institute for Pharmacology and Preventive Medicine) will randomly select and monitor 20% of all sites and source data verification (SDV) will be performed for all patients.

The registry will be performed in accordance with the Declaration of Helsinki recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland 1964 and later versions. The registry will also be conducted in accordance with the valid European Medical Device Regulation and ISO 14155:2020. Furthermore, the study will comply with country-specific regulations and each site will comply with local institutional review board (IRB)/independent ethics committee (IEC) regulations.

The registry has been registered at www.clinicaltrials.gov (NCT05601453) and in the Clinical Trials Information System (CTIS). The estimated study completion date is 2025.

2.2 | Patients

Consecutive patients fulfilling the inclusion and exclusion criteria will be enrolled in the registry (refer Table 1). All patients being in accordance with the

TABLE 1 Inclusion and exclusion criteria.

Inclusion	Exclusion
• Consenting patients ≥18 years • Procedural success of the first TAVI irrespective of SVD severity • TAVI device deficiency of index THV irrespective of SVD severity • Intention to treat the patient with a redo-TAVI procedure (SAPIEN family THV) • The Local Heart Team and Case Review Board considers the patient suitable and indicated for elective redo-TAVI procedure • Patient is scheduled to undergo a 30 Day and 12 Months follow-up (both visits taking place in hospital)	• Patients without signed informed consent / data protection statement (according to requirements of local IRB/IEC) • Life expectancy below 12 months • Patients with largely incomplete data with respect to the aims of the project • Pregnant women at the time of the redo-TAVI

Abbreviations: IEC, independent ethics committee; IRB, institutional review board; SVD, structural valve deterioration; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve.

stated inclusion and exclusion criteria and receiving a balloon-expandable transcatheter aortic valve will be included in the extended documentation. The site Investigator and local Heart Team will screen patients for operative risk and fundamental enrolment criteria. The Case Review Board will recommend procedurals suggestions based on the provided data and planned procedural details. Eligibility will not be assessed—only risk assessment will be performed based on operative risk, valve size and positioning, proper vascular access, valve morphology and any relevant clinical factors impacting treatment planning for all screened patients. Due to the non-interventional character of the registry the treatment decision however remains fully at the discretion of the local Heart Team.

2.3 | Study objectives

The ReTAVI registry has the following objectives to prospectively evaluate safety and efficacy of redo-TAVI performed due to index THV structural valve deterioration (SVD) using the balloon-expandable SAPIEN THV platform; to explore anatomic and procedural factors associated with optimal results (e.g. valve sizing, implantation depth, commissural alignment, coronary position, primary valve type, valve to coronary [VTC] distance, valve to aorta [VTA] distance); to assess peri-procedural and short-term (up to 1 year) redo-TAVI durability; to identify early and late THV failure predictors (after TAVI and redo-TAVI procedures); to explore CT findings related to THV failure; validate VARC-3[1] applicability[8] in repeated TAVI setting; and to validate and assess adherence to recommended procedural strategy using SAPIEN family THVs in a published expert consensus.[7] A summary of study outcomes and their associated definitions is provided in Table 2.

2.4 | Procedural recommendations

A consensus on procedural recommendations for redo-TAVI has been published.[7] Centres will be informed about this consensus manuscript, and although it is not required to be used, it will be documented how closely the recommendations are followed. Use of anticoagulation/antiplatelet therapy will be based on current recommendations and their approach will be documented in the electronic case report form (eCRF).

2.5 | Data collection

Clinical outcome data collection will be based on the local site's standard of care for TAVI and the current European Society of Cardiology guidelines. A log book will be used to capture the number of patients treated for failure of the first implanted valved and the proportion of repeated TAVI, surgical corrections and conservatively treated patients noted. Examinations may include, but are not limited to, physical assessments, electrocardiograms (ECGs), laboratory results, X-rays, angiograms, computed tomography (CT) scans and transthoracic or transoesophageal echocardiography (TTE and TEE). Table 3 presents specific time points for data collection to assess short term outcomes. Further, based on the 12 months results from the registry, a discretionary 3-and 5-year follow-up will be conducted to assess the long-term outcomes after informing ethical committee.

Based on the observational study design, any echocardiography and CT examinations performed by the local Heart Team to diagnose heart failure symptoms suggestive of SVD after repeated TAVI will be recorded.

The physician or study nurse will capture pseudonymised patient data in an eCRF located in a secure, password-protected, web-based electronic database. The eCRF database will be based on the s4trials software (www.s4trials.com) and stored on a dedicated server in a professional environment in Nürnberg, Germany (www.hetzner.de). The eCRF is designed to allow for automatic checks for plausibility and completeness. Manual queries will be generated for the sites to check and correct data points, if applicable. All data sets will be checked for accuracy and completeness, and submit

TABLE 2 Study outcomes and definitions.

Outcome	Definition
Efficacy	Determine VARC-3 defined device success at 30 days • Technical success • Freedom from mortality • Freedom from surgery or intervention related to the device or a major vascular access-related or cardiac structural complication • Intended performance of the valve (mean gradient <20 mmHg, peak velocity <3 m/s, Doppler velocity index ≥0.25, and less than moderate aortic regurgitation) (Different definitions, in addition to the predefined such as the consideration of higher gradients than 20 mmHg, will be explored) These events will be adjudicated.
Technical success	Technical success (at exit from procedure room) • Freedom from mortality • Successful access, delivery of the device, and retrieval of the delivery system • Correct positioning of a single prosthetic heart valve into the proper anatomical location • Freedom from surgery or intervention related to the device (excluding pacemaker) or to a major vascular or access-related, or cardiac structural complication
Safety	Determine VARC-3 defined early safety at 30 days • Freedom from all-cause mortality • Freedom from all stroke • Freedom from all VARC type 2–4 bleeding • Freedom from all major vascular, access-related, or cardiac structural complication • Freedom from all acute kidney injury stage III/IV • Freedom from all moderate/severe aortic regurgitation • Freedom from all new permanent pacemaker implantations due to procedure-related conduction abnormalities • Freedom from all surgery/intervention related to the device These events will be adjudicated.
Procedural outcomes	Determine Procedural outcomes (30 days) • Clinical and anatomical predictors of technical success (type of SVD [stenosis vs. regurgitation], valve size, implant depth, redo-TAVI balloon dilation, CT and echo-derived variables, etc.) • Rate of central and paravalvular regurgitation at 30 days • Valve performance, including residual mean gradient at 30 days • Risk and predictors of coronary obstruction at 30 days
Durability	Determine the durability of the second aortic THV • Subclinical transcatheter heart valve thrombosis at 30 days and at 12 months (when it becomes apparent, but no systematic screening) • Clinical transcatheter heart valve thrombosis defined as clinical sequelae of a thromboembolic event [e.g. stroke, TIA, retinal occlusion, other evidence of systemic thromboembolism] or worsening valve stenosis/regurgitation [e.g. signs of heart failure, syncope] and haemodynamic valve deterioration Stage 2 or 3 or confirmatory imaging (CT evidence of HALT or TEE findings) or in the absence of clinical sequelae, both haemodynamic valve deterioration Stage 3 and confirmatory imaging (CT evidence of HALT or TEE findings) at 3 (if data obtained) and 12 months • All-cause mortality, stroke, myocardial infarction, and cardiovascular hospitalisation at 12 months • Stage II or III structural valve degeneration according to VARC-3 definitions at 12 months (stage I may be documented) • Endocarditis Discretionary longer-term follow-up • Subclinical transcatheter heart valve thrombosis • Clinically symptomatic transcatheter heart valve thrombosis • All-cause mortality, stroke and cardiovascular hospitalisation
Compliance	It will be assessed if centres followed the published recommendation (itemised, compliance being voluntary) and whether alterations to the protocol may impact procedural outcomes

TABLE 2 (Continued)

Outcome	Definition
Exploratory objectives	Further, not predefined research questions will be explored based on the dataset, such as • Haemodynamic outcome of the intervention • Applicability of VARC-3 criteria for the redo-TAVI situation • Coronary artery obstruction due to valve implantation • Coronary artery cannulation (in particular in case of risk plane above ostia) • Early and late THV failure predictors (after TAVI and redo-TAVI procedures) • CT findings related to THV failure (SVD)

Abbreviations: CT, computed tomography; HALT, hypo-attenuating leaflet thickening; SVD, structural valve deterioration; TAVI, transcatheter aortic valve implantation; TEE, transoesophageal echocardiography; THV, transcatheter heart valve; TIA, transient ischaemic attack.

TABLE 3 Time points for data collection.

	Echo	CT	Fluoroscopy	Events
Baseline: Patient characteristics	X	X		
Intervention: Procedural details			X	x
Discharge: Post-procedure—hospitalisation				x
FU data 30 days ±6 days	X			x
FU data 3 months ±14 days (optional)	(X)			x
FU data 6 months ±1 month (optional)				x
FU data 12 months ±2 months	X	(X)		x

Note: (X), Echo or CT will be assessed when they become available (i.e. not enforced at a certain time point).

Abbreviations: CT, computed tomography; Echo, echocardiography; FU, follow-up.

them for biostatistical analysis. The pseudonymised data will be stored in the database for 15 years and then be anonymised.

2.6 | Quality assurance

Anonymised echocardiograms will be uploaded onto a central server at a predefined echocardiogram CoreLab (www.s4trials.com). An assessment of echocardiograms, including an evaluation of their quality, will be performed following a standardised protocol. Data from the echocardiogram CoreLab will be entered into the eCRF. A similar process will be followed for all CT scans and fluoroscopy data. The CoreLab will be responsible for assessing SVD at the relevant time points.

The components of the 30-day efficacy and safety outcomes and the hard endpoints (all-cause mortality, stroke and cardiovascular hospitalisation) will be centrally adjudicated (Figure 1).

2.7 | Statistical analysis

In this prospective registry, a sample size of 150 patients will be feasible to recruit within a reasonable time frame (12 months). Approx. Sixty international high-volume centres will participate in this registry (Table S1). For this purpose, up to 70 centres will be approached. Noticeably, about 60 centres each recruiting 3–5 patients in 12 months will results in maximal 250 patients. This will result in a buffer of 100 patients if actual recruitment is <5 per centre to arrive at a minimum of 150 evaluable patients.

Statistical analysis will be performed for the total study population and defined subgroups where applicable. Continuous variables will be presented as mean ± standard deviation (SD) or as median with interquartile range (IQR), and categorical variables (e.g. sex) will be reported as frequencies and percentages. The Kolmogorov–Smirnov test may be used to test for normal distribution. For comparison, the $\chi 2$ test or Fisher's exact test may be used for categorical variables, and the *t*-test or Mann–Whitney *U* test for continuous variables. Linearised rates and actuarial probability statistics may be used where appropriate for adverse event reporting. Kaplan–Meier analysis may be performed for survival outcomes and safety outcomes. Cox proportional hazards will be derived to account for confounding variables. All statistical analyses will be performed using IBM SPSS Statistics version 29 (IBM, Armonk, New York) or R Core Team (https://www.R-project.org/).

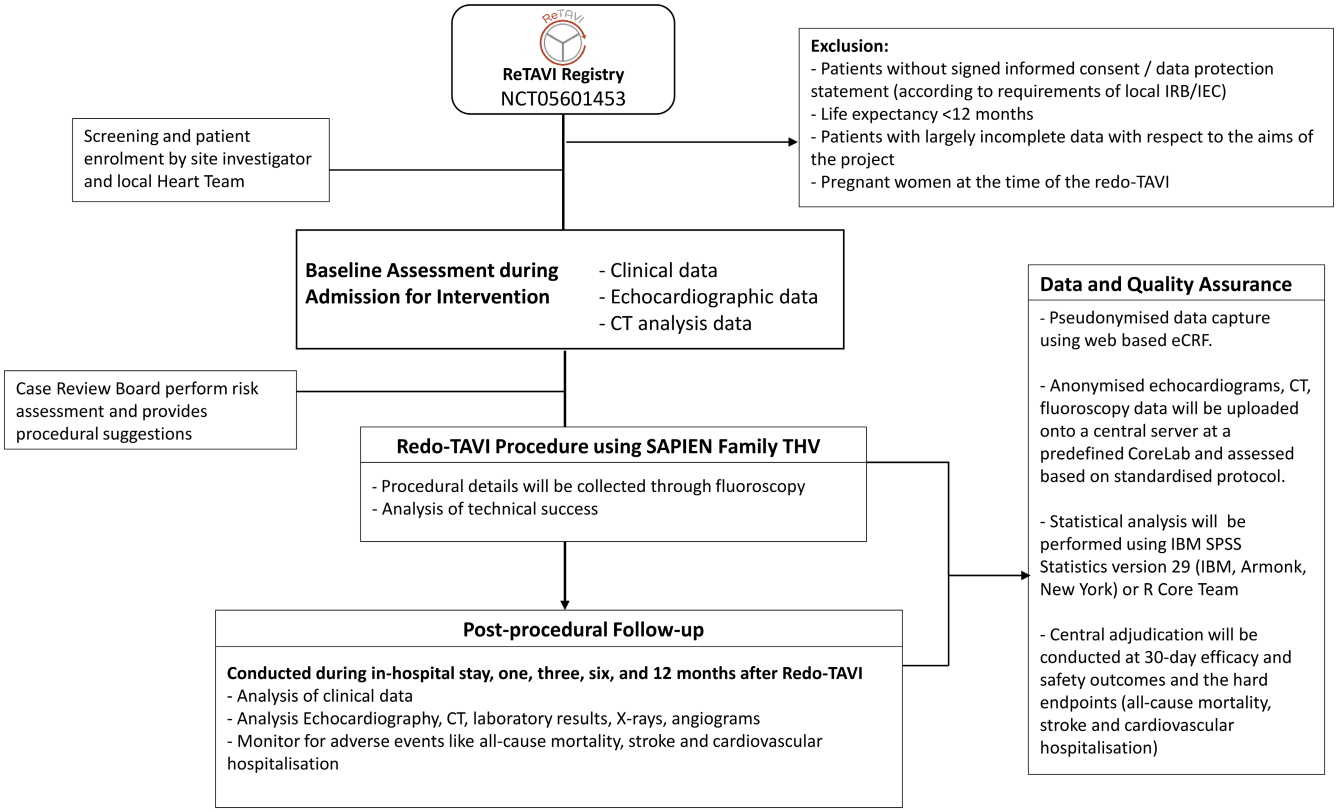

FIGURE 1 ReTAVI registry flow diagram of the process through phases of the study. CT, computed tomography; eCRF, electronic case report form; IEC, independent ethics committee; IRB, institutional review board; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve.

3 | DISCUSSION

The ReTAVI registry aims to evaluate the peri-procedural and short-term safety, efficacy and durability of redo-TAVI due to index THV SVD (Figure 1). In addition, the registry will provide information on anatomic and valve-related factors (such as size, implantation depth, commissural alignment, coronary position and primary valve type amongst other factors) associated with treatment success and predictors of early and late THV failure.

The VARC initiative was driven by the fast emergence of TAVI therapies for treating severe AS, with the first consensus manuscript published in 2011.[9] This initiative has since been updated, clarifying specific definitions and increasing understanding of patient risk stratification and case selection for TAVI.[8,10] VARC criteria are used in over half of TAVI-related studies.[11] With the increasing use of repeated TAVI, it is crucial to establish the validity of VARC-3 criteria in this setting and the gathered data from this registry will provide this information. It is also essential to understand if the procedural recommendations for repeated TAVI are helpful in clinical practice.[7]

The use of TAVI in increasingly younger patients means that patient life-expectancy is likely to exceed that of higher-risk, older, multimorbid TAVI candidates and that these younger patients will outlive their THVs.[7] As a result, the valve durability has become a more pressing concern. Its assessment from the published literature is more challenging due to the heterogeneity of SVD criteria before their standardisation in 2017 and 2018.[12,13] Studies have reported good outcomes for TAVIs performed with balloon and self-expanding transcatheter aortic valves.[14,15] However, SVD can occur and is related to various aetiologies, including TAVI procedure-related factors (leaflet injury, pinwheeling, abnormal flow patterns and incomplete or asymmetric stent deployment), patient-related factors (age, sex, comorbidities such as dyslipidaemia, diabetes, inflammatory diseases or immune rejection) and bio prosthesis-related factors (absence of anti-mineralisation treatment, prosthesis-patient mismatch and small prosthesis size).[14]

The repeated TAVI is a reliable and promising treatment option for patients with degenerated index THVs who have already undergone a TAVI procedure. Available data to support this approach's use is based on case reports and small case series. While they present valuable insights, such as the faster dissemination of new information, techniques and approaches, cannot be used for causal inference or generalisations and may be biased by

reporting the treatment successes against treatment failures.[16] Subsequently, as TAVI procedures are increasingly performed in younger and lower-risk patients, there is an urgent need for more robust data. The use of registries improves transparency and provides a wealth of information that can be used to answer specific questions, such as how patient- or procedure-related variables impact treatment outcomes. The ReTAVI registry aims to provide this much-needed information on the peri-procedural and short-term safety, efficacy and durability of redo-TAVI procedures, as well as information on anatomical and procedural factors associated with optimal results, predictors of early/late THV failure and the applicability of VARC-3 definitions.

3.1 | Limitations

There is insufficient knowledge about which strategy and valve design result in the best repeated TAVI outcomes. However, SAPIEN 3/Ultra THV is the only medical device registered for redo-TAVI in the European Union, which may not suit all patients with SVD of the index THV.

4 | CONCLUSIONS

The ReTAVI registry is designed to provide robust, large-scale information to support the current case studies and case series on the use of redo-TAVI in patients with SVD in their index THV, including anatomic and procedural factors associated with treatment success and the identification of early and late THV failure predictors. This information may also help shape treatment strategies and recommendations for future redo-TAVI procedures.

AUTHOR CONTRIBUTIONS

RP, EvB, GT, and PB were involved in the conception and design of the study. The idea was discussed and refined by the group of authors. RP, GT, EvB, LnF, UL, JlZ, MJ, ME, FC, and JnS contributed significantly to the study design and also to the study execution, acquisition of data, analysis and interpretation together with FS, TC, JR, VD, JK, TM. PB drafted the first version of the manuscript, which subsequently underwent critical revision by RP, GT, FS, and MJ for important intellectual content. PB and DG took part in drafting, revising or critically reviewing the article based on the author's comments and submitted the manuscript. All authors reviewed the final manuscript version and approved the submission (RP, MJ, FS, TC, VD, JR, TM, EvB, LnF, UL, MB, JlZ, ME, FC, JnS, JK, DG, PB, GT).

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CONFLICT OF INTEREST STATEMENT

RP is a proctor for Edwards Lifesciences and received speaker honoraria. FS is a proctor for Edwards Lifesciences and received speaker honoraria from Edwards, Medtronic, Abbott, Boston Scientific. JK is an employee of Edwards Lifesciences. DG and PB received research support from Edwards Lifesciences for their institution. All other authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

All relevant data within this clinical study design manuscript will be shared upon reasonable request to the corresponding author.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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