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ORIGINAL ARTICLE

Data standards for transcatheter aortic valve implantation: the European Unified Registries for Heart Care Evaluation and Randomised Trials (EuroHeart)

Suleman Aktaa[1,2,3,*], Gorav Batra[4], Stefan K. James[4], Daniel J. Blackman[1,3], Peter F. Ludman[5], Mamas A. Mamas[6], Mohamed Abdel-Wahab[7], Gianni D. Angelini[8], Martin Czerny[9], Victoria Delgado[10], Giuseppe De Luca[11], Agricola Eustachio[12], Dan Foldager[13], Christian W. Hamm[14,15], Bernard Iung[16], Norman Mangner[17], Julinda Mehilli[18,19,20], Gavin J. Murphy[21], Darren Mylotte[22], Radoslaw Parma[23], Anna Sonia Petronio[24], Bodgan A. Popescu[25], Lars Sondergaard[26], Rui C. Teles[27], Manel Sabaté[28], Christian J. Terkelsen[29], Luca Testa[30], Jianhua Wu[2,31], Aldo P. Maggioni[32], Lars Wallentin[4], Barbara Casadei[33] and Chris P. Gale[1,2,3]

[1]Leeds Institute of Cardiovascular and Metabolic Medicine, University of Leeds, LS2 9JT Leeds, UK; [2]Leeds Institute for Data Analytics, University of Leeds, LS2 9JT Leeds, UK; [3]Department of Cardiology, Leeds Teaching Hospitals NHS Trust, LS1 3EX Leeds, UK; [4]Department of Medical Sciences, Cardiology and Uppsala Clinical Research Center, Uppsala University, 38 751 85 Uppsala, Sweden; [5]Institute of Cardiovascular Sciences, University of Birmingham, B15 2SQ Birmingham, UK; [6]Keele Cardiovascular Research Group, Keele University, ST5 5BG Stoke on Trent, UK; [7]Heart Center Leipzig, University of Leipzig, 04109 Leipzig, Germany; [8]Bristol Heart Institute, Bristol University, BS8 1TH Bristol, UK; [9]Department of Cardiovascular Surgery, Faculty of Medicine, Albert-Ludwigs-University of Freiburg, University Heart Center Freiburg, 79189 Freiburg, Germany; [10]Heart Institute; Department of Cardiology; Cardiovascular Imaging Section; Hospital University Germans Trias i Pujol, 08916 Badalona, Spain; [11]Clinical and Experimental Cardiology Unit, AOU Sassari, 07100 Sassari, Italy; [12]Cardiovascular Imaging Unit, San Raffaele Hospital, Milan, Vita-Salute University, 20132 San Raffaele Milan, Italy; [13]ESC Patient Forum, Denmark.; [14]Medical Clinic I, University of Giessen, 35390 Giessen, Germany; [15]Kerckhoff Heart Center, 61231 Bad Nauheim, Germany; [16]Cardiology Department, Bichat Hospital, APHP and Université Paris-Cité, 75006 Paris, France; [17]Heart Centre Dresden, Department of Internal Medicine and Cardiology, Technische Universitaet, 01069 Dresden, Germany; [18]Department: Medizinische Klinik I, Landshut-Achdorf Hospital, 84036 Landshut, Germany; [19]Klinikum der Universität München, Ludwig-Maximilians-Universität, 80539 Munich, Germany; [20]German Centre for Cardiovascular Research (DZHK), Munich Heart Alliance, 80539 Munich, Germany; [21]NIHR Biomedical Research Unit, University of Leicester, LE1 7RH Leicester, UK; [22]Department of Cardiology, University Hospital and National University of Ireland Galway, H91 YR71 Galway, Ireland; [23]Department of Cardiology and Structural Heart Diseases, Medical University of Silesia, 40-055 Katowice, Poland; [24]Cardiothoracic and Vascular Dpt. University of Pisa, 56126 Pisa, Italy; [25]Department of Cardiology, University of Medicine and Pharmacy "Carol Davila" -Euroecolab, Emergency Institute for Cardiovascular Diseases 050474 Bucharest, Romania; [26]Department of cardiology, Rigshospitalet, Copenhagen University Hospital, 2100 Copenhagen, Denmark; [27]Centro de Documentação, Centro Hospitalar de Lisboa Ocidental, Nova Medical School, Hospital de Santa Cruz, 1169056 Lisbon, Portugal; [28]Department of Interventional Cardiology, Cardiovascular Institute, Hospital Clínic, Institut d'Investigacions Biomèdiques August Pi I Sunyer (IDIBAPS), 08036 Barcelona, Spain; [29]Aarhus University Hospital & The Danish Heart Foundation, 8200 Denmark; [30]IRCCS San Donato Hospital, 20097 Milan, Italy; [31]School of Dentistry, University of Leeds, LS2 9JT Leeds, UK; [32]ANMCO Research Center—Heart Care Foundation, 50121 Florence, Italy; and [33]Division of Cardiovascular Medicine, NIHR Oxford Biomedical Research Centre, University of Oxford, OX1 2JD Oxford, UK

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Aims

Standardized data definitions are necessary for the quantification of quality of care and patient outcomes in observational studies and randomised controlled trials (RCTs). The European Unified Registries for Heart Care Evaluation and Randomised Trials (EuroHeart) project of the European Society of Cardiology (ESC) aims to create pan-European data standards for cardiovascular diseases and interventions, including transcatheter aortic valve implantation (TAVI).

* Corresponding author: Leeds Institute of Cardiovascular and Metabolic Medicine, Faculty of Medicine and Health, University of Leeds, Leeds LS2 9JT, United Kingdom. Tel: +0044 (0)113 343 8916; Email: s.aktaa@leeds.ac.uk; Twitter: @SulemanAktaa

Methods and results We followed the EuroHeart methodology for cardiovascular data standard development. A Working Group of 29 members representing 12 countries was established and included a patient representative, as well as experts in the management of valvular heart disease from the European Association of Percutaneous Cardiovascular Interventions (EAPCI), the European Association of Cardiovascular Imaging (EACVI) and the Working Group on Cardiovascular Surgery. We conducted a systematic review of the literature and used a modified Delphi method to reach consensus on a final set of variables. For each variable, the Working Group provided a definition, permissible values, and categorized the variable as mandatory (Level 1) or additional (Level 2) based on its clinical importance and feasibility. In total, 93 Level 1 and 113 Level 2 variables were selected, with the level 1 variables providing the dataset for registration of patients undergoing TAVI on the EuroHeart IT platform.

Conclusion This document provides details of the EuroHeart data standards for TAVI processes of care and in-hospital outcomes. In the context of EuroHeart, this will facilitate quality improvement, observational research, registry-based RCTs and post-marketing surveillance of devices, and pharmacotherapies.

One-sentence summary The EuroHeart data standards for transcatheter aortic valve implantation (TAVI) are a set of internationally agreed data variables and definitions that once implemented will facilitate improvement of quality of care and outcomes for patients receiving TAVI.

Graphical Abstract EuroHeart = European Unified Registries for Heart Care Evaluation and Randomised Trials, HRQoL = health-related quality of life, TAVI = transcatheter aortic valve implantation.

Keywords Data standards • Variables • Data definitions • TAVI • Quality of care • Registry • EuroHeart • Aortic valve

Introduction

Transcatheter aortic valve implantation (TAVI) has increased in recent years with rates now exceeding those of surgical aortic valve replacement (SAVR).[1,2] Whilst the expanding indications for TAVI are supported by evidence,[3] there are variations in the delivery of TAVI care across the European Society of Cardiology (ESC) member countries, with an overall procedural volume ranging from 0.6 to 200 per million people.[4] National registries have played an important role in exploring the patterns of TAVI care and outcomes.[5–8] However, heterogeneity in design and delivery of TAVI registries limits the robust investigation of the effectiveness and safety of novel TAVI devices and adjunctive medications across countries.[9]

There is a lack of standardized definitions for TAVI registry variables. Even though the Valve Academic Research Consortium (VARC) provides endpoint definitions for heart valvular interventions including TAVI,[10] the definitions of clinical outcomes vary between TAVI studies.[11,12] Besides, VARC harmonizes outcome definitions, but there remains a need to standardize the methods by which the processes of TAVI care delivery are captured. Such a harmonization across TAVI registries, randomised controlled trials (RCTs), and quality improvement initiatives, improves the efficiency of data collection and help generate new knowledge relevant to TAVI. The American College of Cardiology (ACC) and the American Heart Association (AHA) have developed data standards for a range of cardiovascular diseases, but no ACC/AHA data standards exist for TAVI.[13]

The European Unified Registries On Heart Care Evaluation and Randomised Trials (EuroHeart) is an ESC initiative that aims to improve the quality of cardiovascular care through the continuous capture of individual patient data by standardizing the definitions of variables and offering a common IT platform for data collection, analysis, and reporting. To date, EuroHeart has developed data standards for acute coronary syndrome and percutaneous coronary intervention (PCI),[14] heart failure[15] and atrial fibrillation. This docu-

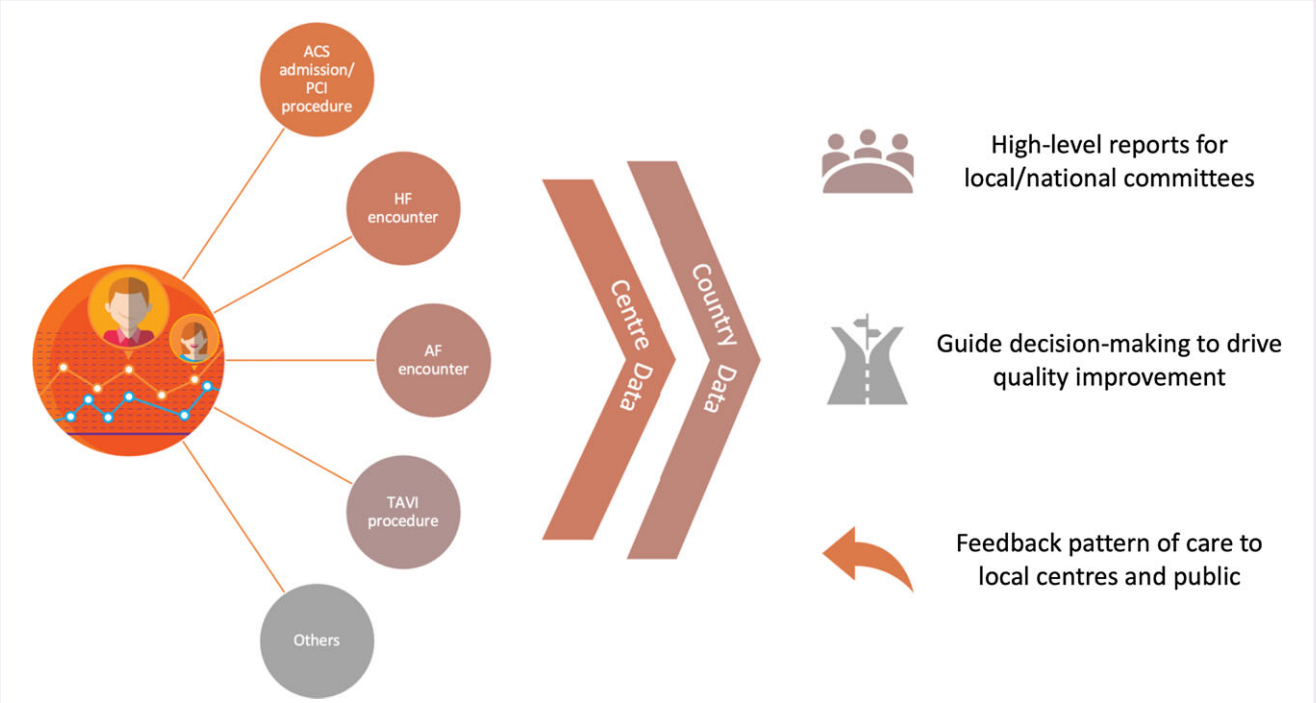

Figure 1 Role of EuroHeart registries in monitoring individual patients care. ACS, acute coronary syndrome; AF, atrial fibrillation; HF, heart failure; PCI, percutaneous coronary intervention; TAVI, transcatheter aortic valve implantation.

ment presents the EuroHeart data standards for TAVI, which have been developed in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI), the European Association of Cardiovascular Imaging (EACVI) and the Working Group on Cardiovascular Surgery of the ESC.

Methods

The Data Science Group of EuroHeart was established in August 2019. It comprises a project chair (C.G.), two medical experts (S.A. and G.B.), a biostatistician (J.W.) and a project manager.

Working group and reference group

The Working Group for the development of the 2022 EuroHeart data standards for TAVI included 29 members from 12 countries. The Group comprised members of the EuroHeart Data Science Group and nominees from the EAPCI, EACVI and the Working Group on Cardiovascular Surgery, as well as leaders of existing TAVI registries and a patient representative. Further 19 experts from 18 countries formed the Reference Group (Acknowledgment) and provided feedback on the selection and definitions of the included variables in the EuroHeart TAVI dataset.

European Unified Registries On Heart Care Evaluation and Randomised Trials data standards methodology

We followed the EuroHeart methodology for cardiovascular data standard development.[16] In brief, this involved: (1) identification of the cardiovascular domain for the development of data standards; (2) conduction of a systematic review of the literature to synthesise a list of 'candidate' variables; (3) selection and prioritisation of variables by domain experts using a modified Delphi method; (4) Reference Group feedback, and (5) programming the final data variables into the EuroHeart IT platform.[16]

Variable level

In EuroHeart, variables are classified as Level 1 variables if they are needed for the assessment of the quality of care (for example, information that would be required for the calculation of quality indicators), risk stratification, case-mix adjustment, or clinical outcomes. The Level 1 variables are defined in the EuroHeart data standard documents and are programmed into the EuroHeart IT platform.

Level 2 variables collect information that may prove useful for quality assessment and observational, or randomised research, but which may not be universally available, routinely used, or a pre-requisite for the evaluation of quality. The Level 2 variables are defined in the EuroHeart data standard documents but are not implemented into the EuroHeart IT platform.

For the countries which adopt the EuroHeart IT platform, a third level of variables can be programmed into the platform to address unique centre- or country-specific requirements.[16] Thus, the Level 3 variables are not defined in the EuroHeart data standard documents. EuroHeart aims to align international data collection activities and therefore countries with existing registries may not choose to implement the EuroHeart IT platform, but harmonize their data standards with the EuroHeart variables.

Scope

The Working Group agreed that the EuroHeart-TAVI registry should capture pre-procedural care processes as well as procedural details, in-hospital events and follow up data. As far as possible, the data definitions were aligned with these collected in other EuroHeart registries including heart failure, acute coronary syndrome, PCI and atrial fibrillation[14,15] allowing re-utilization of existing information and avoiding duplication in different registries. Thereby, the TAVI registry may, especially in the EuroHeart IT-platform, be integrated with these databases to form a unified system for data collection and quality improvement (*Figure 1*).

Systematic literature review

The EuroHeart Data Science Group conducted a systematic review of the literature to identify a list of candidate variables for potential inclusion in the EuroHeart TAVI dataset. The search included two databases (Embase and MEDLINE via OVID®) and captured peer reviewed RCTs and prospective observational studies that provided definitions for at least one variable relevant to TAVI diagnosis, management, or outcomes published between 01 January 2011 and 23 July 2021 (Appendix). Two reviewers (SA and GB) assessed retrieved articles against a pre-specified eligibility criteria and extracted potential variables from included studies. Existing TAVI registries[17] and Clinical Practice Guidelines[3] were also reviewed for potential data variables relevant to TAVI.

Selection of the final set of variables

Using a modified Delphi method, the Working Group voted on the list of candidate variables that were identified from the literature review. In total, two voting rounds and nine virtual meetings were conducted between April 2021 and January 2022, with a large volume of e-mail correspondence between meetings. The EuroHeart criteria for data standard development (importance, evidence base, validity, reliability, feasibility and applicability) were used to guide the selection process.[16] The Working Group members voted on each of the candidate variables with include as Level 1, include as Level 2 or exclude. Variables achieved ≥75% agreement were included whilst those did not were carried to a second voting round and discussed in the subsequent meetings. The final set of variables was presented to the Reference Group for feedback on their validity and feasibility.

Implementation

After arriving at the final set of variables, the Data Science Group collaborated with the Registry Technology groups of the EuroHeart project to programme the Level 1 variables into the EuroHeart IT platform. The variables were structured in a chronological order from the pre-procedural details to the outcomes of TAVI. The platform was designed to improve the data entry consistency and reduce the burden of data entry.

Results

The systematic review retrieved 3225 articles. Of these, 372 met the inclusion criteria and were used to extract candidate variables. Following the modified Delphi method, 93 Level 1 variables (Supplementary material online, *Table S1*) and 113 Level 2 variables (Supplementary material online, *Table S2*) were selected for 10 domains of TAVI care.

The domains of care in the EuroHeart TAVI registry are: (1) Demographics, (2) Patient characteristics and comorbidities, (3) Health-related quality of life, (4) Prior interventions, (5) Presentation details, (6) Pre-procedural tests, (7) Procedural details, (8) Outcomes, (9) Discharge details and (10) Follow up.

Demographics

This domain is purposefully aligned with the EuroHeart registries for acute coronary syndrome-PCI, heart failure and atrial fibrillation.[14,15] This reduces the amount of data that is needed to be entered for patients who are enrolled in more than one EuroHeart registry. The domain captures patient-identifiable information to allow data linkages (Supplementary material online, *Table S1*)[18] and is therefore only stored at the local centre or at country-level in accordance with the each country's data-sharing regulations. De-identified, aggregated data may be shared with the EuroHeart Data Science Centre to create high-level reports following agreements from relevant parties (Supplementary material online, *Table S1*).

Patient characteristics and comorbidities

This domain contains information about the patient's characteristics (e.g. height and weight) at the time of hospital admission for the TAVI procedure. Baseline comorbidities (e.g. heart failure) and prognostic variables (e.g. frailty) are also captured because of the role of such variables in risk adjustment models and risk stratification scores for TAVI outcomes.[3] Although the definitions of the variables are the same as those in the other EuroHeart registries, the domain also records TAVI specific variables such as the assessment of aortic calcification (Supplementary materials online, *Tables S1* and *S2*).[19,20]

Health-related quality of life

Patient health-related quality of life (HRQoL) is important prior to invasive procedures,[21] but its systematic collection in routine clinical practice is difficult. Thus HRQoL has been included as Level 2 variable in the EuroHeart-TAVI data standards (Supplementary material online, *Table S2*).

Prior interventions

This domain captures information about aortic valve or other cardiac interventions (e.g. PCI) prior to the TAVI procedure (Supplementary materials online, *Tables S1* and *S2*). The collection of information about prior SAVR and TAVI procedures contributes to the understanding of the characteristics and outcomes following valve-in-valve procedures given that TAVI in failed surgical bioprosthetic valves is now an established treatment[22] and TAVI-in-TAVI may become an important treatment in the future.

Presentation details

This domain includes information about a patient's clinical status at the time of admission to hospital. It includes the presenting symptoms, New York Heart Association (NYHA) class and some ECG parameters (Supplementary material online, *Tables S1*).[23] The EuroHeart TAVI data standards enables patient risk stratification from the submitted variables and allows the entry of the EuroSCORE II (Supplementary material online, *Table S1*).[3] Data about cardiogenic shock, the Canadian Cardiovascular Society (CCS) grade of angina and the Society of Thoracic Surgeons (STS) score are included as Level 2 variables (Supplementary material online, *Table S2*).

Pre-procedural tests

The ESC guidelines recommend an assessment of coronary artery disease prior to invasive valve intervention.[3] This domain collects information about concomitant coronary artery disease prior to a TAVI procedure, as well as biochemical (e.g. haemoglobin, creatinine) and echocardiographic parameters (e.g. left ventricular ejection fraction, mean aortic valve gradient) prior to the procedure (Supplementary material online, *Table S1*). Information concerning the extent of aortic, leaflet and left ventricular outflow tract calcification are captured in this domain in addition to concomitant valvular (e.g. mitral) disease (Supplementary material online, *Table S1*).[24] A selection of the Level 1 variables is shown in *Figure 2*.

Procedural details

The specifications of the TAVI procedure are captured in this domain including the date of the procedure, type of anaesthesia, access site and valve types used (Supplementary material online, *table S1*). This domain collects information such as the planned concomitant interventions (e.g. PCI) as well as the use of cerebral embolic protection and/or vascular closure devices (Supplementary material online, *Table S1*). Procedural events are included in this domain as Level 1 variables (Supplementary material online, *Table S1*) with additional details (e.g.

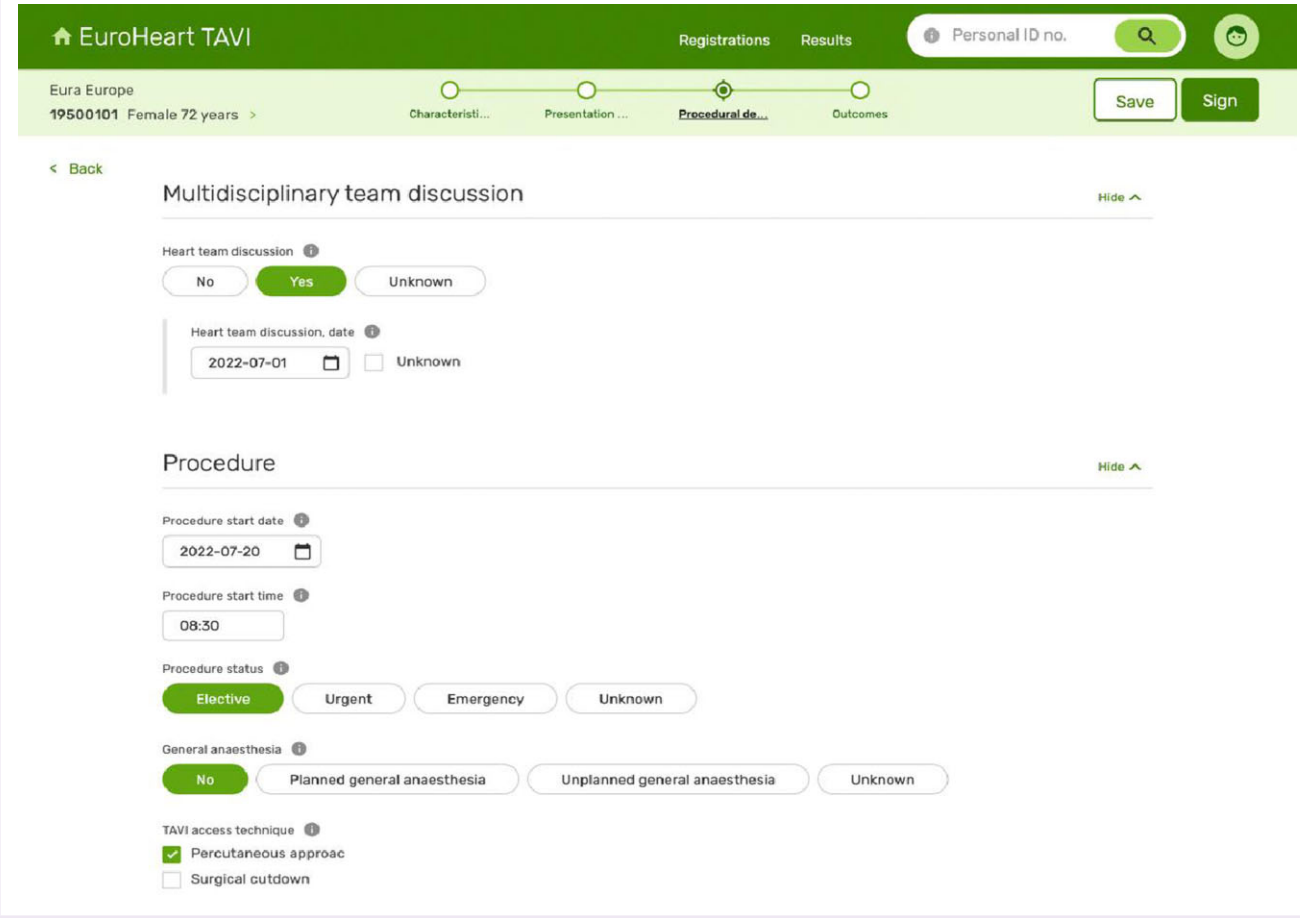

Figure 2 An illustration of the IT platform. AV, aortic valve; LAD, left anterior descending artery; Lcx, left circumflex artery; LMS, left main stem; RCA, right coronary artery.

pacing, circulatory support) as Level 2 (Supplementary material online, *Table S2*).

In-hospital data

This domain captures the findings from echocardiography undertaken after the TAVI procedure and before hospital discharge (Supplementary material online, *Table S1*). In-hospital events that occur after the TAVI procedure are also recorded here. These events include cardiac interventions during the same admission, in-hospital myocardial infarction, stroke, bleeding or death (Supplementary material online, *Table S1*). The definitions of these events are aligned with the VARC-3 criteria.[10]

Discharge details

This domain records information about antithrombotic therapy and some ECG findings at the time of discharge from hospital (Supplementary material online, *Table S1*). Biomarkers (e.g. haemoglobin, creatinine) other medications and referral for cardiac rehabilitation are included as Level 2 variables (Supplementary material online, *Table S2*).

Follow up

All of the variables in this domain are Level 2. This is because concerns were raised about the feasibility of efficiently collecting patient information beyond the hospital stay. The domain defines variables to be collected after hospital discharge and specifies the intervals for their collection (Structured Graphical Abstract).

Discussion

The EuroHeart data standards for TAVI processes of care and in-hospital outcomes comprise 93 mandatory (Level 1) and 113 optional (Level 2) variables across 10 TAVI domains. They set forth an internationally agreed and ESC endorsed standards for the conduct of observational studies and RCTs that are relevant to TAVI, provide a platform for monitoring the effectiveness and safety of new devices and treatment strategies, and align with published EuroHeart data standards for other cardiovascular diseases.[14,15] The standardisation of the definitions of TAVI-related data variables enables the conduction of international comparative analyses and facilitates the development of a comprehensive registry for various forms of valvular heart disease regardless of its treatment strategy.

Despite previous efforts, there remains a need for a harmonised, internationally endorsed and feasible set of data standards for TAVI encompassing both processes of care and key outcomes.[9,11] For instance the ACC and the Society of Thoracic Surgeons (STS) Transcatheter Valve Therapy (TVT) registry comprises 216 variables, 160 of which are mandatory.[25] To reduce the burden of data collection, a recent collaboration between various stakeholders in the US was established to develop a 'Minimum Core Data Elements' for TAVI.[26] However, this dataset defined 132 mandatory variables and

maintained an additional 35 variables as mandatory in the ACC/STS TVT registry increasing the total number to 167.[26] Moreover, the definitions of the variables in the updated ACC/STS TVT registry have not been fully aligned with these in other relevant registries. For example, the definition of cerebrovascular disease varies between the ACC PCI[27] and TVT[28] registries limiting the opportunity to combine data from different resources.

In Europe, national registries had an important role in illustrating the patterns of TAVI care and understanding its outcomes.[5–8] However, the heterogeneity in the data standards between these registries hampers the conduction of pragmatic registry-based RCTs (R-RCT) and the performance of post-marketing surveillance of new TAVI technologies across borders.[9] Furthermore, the lack of harmonisation between national TAVI registries and existing databases for other cardiovascular diseases (e.g. PCI) results in redundancy and unnecessary duplication of healthcare data collection.[29] EuroHeart provides an umbrella under which standardised data definitions are developed and harmonised across various cardiovascular disease domains.[16]

The data standards for TAVI presented in this document have been developed in collaboration with the EAPCI the EACVI and the ESC Working Group on Cardiovascular Surgery and with involvement of a patient representative. Furthermore, the definitions of the selected variables were aligned with the ESC guidelines for valvular heart disease and the VARC endpoints.[3,10] Consequently, these standards were endorsed by the ESC Association of Cardiovascular Nursing and Allied Professions (ACNAP) and the ESC Committee for Young Cardiovascular Professionals, highlighting their potential role in evaluating and addressing the variation in TAVI care and outcomes within and between countries.[4,30]

Developing internationally recognised standards for data collection may not necessarily guarantee their uptake in practice. For instance, the VARC clinical endpoints which aimed to harmonize the methods by which TAVI outcomes are defined have not been adopted in over 40% of TAVI studies.[11,12] This may be explained by the need to integrate process variables with outcomes in a single system, which the VARC lacks.[10] Additionally, the implementation of the developed variables into a web-based interface may facilitate the uptake of the data collection system.[31] The EuroHeart-TAVI data standards comprise key processes and in-hospital outcomes as Level 1 variables which are embedded into an IT platform, with additional variables that capture follow up data as Level 2. We anticipate that the EuroHeart-TAVI registry will provide the means for a wider valvular heart disease registry that capture data relevant to various treatment strategies.

We recognise that countries may be interested in adopting the EuroHeart definitions and not implementing the EuroHeart-IT platform. Those countries can, of course, use the data standards presented in this document and modify their existing registries accordingly. Whilst long-term follow up outcomes are developed as Level 2 variables in the EuroHeart-TAVI dataset, harmonized clinical outcomes will be an integral component of the EuroHeart Data Standards for Clinical Outcome module which is currently under development. Adjudication of the imaging parameters or outcomes can be implemented to serve a future R-RCT that is conducted using the EuroHeart-TAVI IT platform. We acknowledge that the EuroHeart standards are not mapped to an electronic health record coding system that facilitates their syntactic interpretation—presently, this is beyond the remit of EuroHeart.[32] The EuroHeart methodology relies on expert opinion to select the final set of variables and therefore may have been influenced by the participant bias. However, inclusiveness of the Working and Reference Groups, and the use of a modified Delphi method enabled the standardization of the selection process.

Conclusions

The EuroHeart data standards for TAVI processes of care and in-hospital outcomes are an internationally agreed and ESC endorsed set of standards that may be used for the conduct of observational studies, RCTs and TAVI devices surveillance. In total, 93 mandatory Level 1 variables are programmed into the EuroHeart IT platform and provide the core TAVI dataset.

Supplementary material

Supplementary material is available at *European Heart Journal—Quality of Care and Clinical Outcomes* online.

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Data availability

The data underlying this article are available in the article and in its online supplementary material.

Appendix

Databases:

- Ovid MEDLINE(R) ALL
- Embase

Limitations:

- English language
- 01 January 2011—23 July 2021

First phase

1	aorta valve/ab
2	heart valve diseases/or exp aortic valve stenosis/
3	aorta valve stenosis/
4	(aortic* adj stenosis).tw.
5	(aortic adj stenosis).tw.
6	(valv* adj3 disease).tw.
7	((percutan* or transcath*) adj3 (heart* or aortic*) adj3 valve*).tw.
8	((percutan* or transcath*) adj3 valve*).tw.
9	PAVR.tw.
10	TAVR.tw.
11	TAVI.tw.
12	((transap* or transventric* or percutan* or transcath*) adj3 (deliver* or access* or approach* or minimal*)).tw.
13	Clinical Trial/
14	Randomized Controlled Trial/
15	controlled clinical trial/
16	exp RANDOMIZATION/
17	Double Blind Procedure/
18	Crossover Procedure/
19	Placebo/
20	randomi?ed controlled trial$.tw.
21	rct.tw.
22	(random$ adj2 allocat$).tw.
23	double blind$.tw.
24	((treble or triple) adj blind$).tw.
25	placebo$.tw.
26	'exp cohort analysis/or exp longitudinal study/or exp prospective study/or exp follow up/or exp Registries/or cohort$.tw.
27	Case Study/
28	case report.tw.
29	abstract report/or letter/
30	Conference abstract.pt.
31	animals/not humans/
32	or/1–6
33	or/7–12
34	32 and 33
35	or/13–26
36	34 and 35
37	or/27–31
38	36 not 37

Second stage

1	exp common data elements/
2	core data elements/
3	exp nomenclature/
4	(data adj3 (harmoni? * or standard* or defin*)).ti, ab.
5	(data adj3 (element* or field* or variable*)).ti, ab.
6	data aggregation/
7	big data/
8	data base/
9	clinical data repository/
10	data extraction/
11	data consistency/
12	data collection method/
13	exp common data elements/

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