Aims and expectations of a prospective multicenter study on aortic valve surgery (E-AVR registry)

Francesco Nicolini, Filippo Benassi, Riccardo Gherli, Francesco Musumeci, Giovanni Mariscalco, Aamer Ahmed, Gavin J. Murphy, Evaldas Girdauskas, Hermann Reichenspurner, Eduardo Quintana, Manuel Castellà, Francesco Santini, Antonio Salsano, Marisa De Feo, Alessandro Della Corte, Ciro Bancone, Sandro Sponga, Ugolino Livi, Piergiorgio Tozzi, Andrea Perrotti, Sidney Chocron, Vito Ruggieri, Hervè Corbineau, Jean-Philippe Verhoye, Giuseppe Santarpino, Theodor Fischlein, Mauro Rinaldi, Stefano Salizzoni, Enrico Ferrari, Pietro Bajona, Issam Abouliatim, Giuseppe Faggian, Tiziano Gherli, Alessandra Francica, Carla Lucarelli, Francesco Onorati

Angaben zur Veröffentlichung / Publication details:

Nicolini, Francesco, Filippo Benassi, Riccardo Gherli, Francesco Musumeci, Giovanni Mariscalco, Aamer Ahmed, Gavin J. Murphy, et al. 2018. "Aims and expectations of a prospective multicenter study on aortic valve surgery (E-AVR registry)." *Journal of Visualized Surgery* 4: 172–72. https://doi.org/10.21037/jovs.2018.07.10.

Aims and expectations of a prospective multicenter study on aortic valve surgery: (E-AVR registry)

Francesco Nicolini[1], Filippo Benassi[1], Riccardo Gherli[2], Francesco Musumeci[2], Giovanni Mariscalco[3], Aamer Ahmed[3], Gavin J. Murphy[3], Evaldas Girdauskas[4], Hermann Reichenspurner[4], Eduardo Quintana[5], Manuel Castellà[5], Francesco Santini[6], Antonio Salsano[6], Marisa De Feo[7], Alessandro Della Corte[7], Ciro Bancone[7], Sandro Sponga[8], Ugolino Livi[8], Piergiorgio Tozzi[9], Andrea Perrotti[10], Sidney Chocron[10], Vito Ruggieri[11], Hervè Corbineau[11], Jean-Philippe Verhoye[11], Giuseppe Santarpino[12], Theodor Fischlein[12], Mauro Rinaldi[13], Stefano Salizzoni[13], Enrico Ferrari[14], Pietro Bajona[15], Issam Abouliatim[16], Giuseppe Faggian[17], Tiziano Gherli[1], Alessandra Francica[17], Carla Lucarelli[17], Francesco Onorati[17]

[1]Division of Cardiac Surgery, University of Parma, Parma, Italy; [2]Division of Cardiac Surgery, Department of Cardiosciences, Hospital S. Camillo-Forlanini, Rome, Italy; [3]Department of Cardiovascular Surgery and Anesthesia and Critical Care of Glenfield Hospital, University Hospitals of Leicester NHS Trust, Leicester, UK; [4]Department of Cardiovascular Surgery, University Heart Center Hamburg, Hamburg, Germany; [5]Cardiovascular Surgery, University Hospital Clinic, Barcelona, Cataluna, Spain; [6]Cardiac Surgery Unit, University of Genova, Genoa, Italy; [7]Division of Cardiac Surgery, Department of Cardiothoracic Sciences, Second University of Naples, Naples, Italy; [8]Cardiothoracic Department, University Hospital of Udine, Udine, Italy; [9]Cardiac Surgery Unit, Centre Hopitalier Universitaire Vaudois, Lausanne, Switzerland; [10]Department of Thoracic and Cardio-Vascular Surgery, University Hospital Jean Minjoz, Besançon, France; [11]Chirurgie Thoracique et Cardio-Vasculaire, Pole TCVN, Hopital Robert Debrè, Reims, France; [12]Cardiovascular Center, Klinikum Nürnberg, Paracelsus Medical University, Nuremberg, Germany; [13]Department of Cardiac Surgery, Torino University Hospitals, Turin, Italy; [14]Cardiac Surgery, Cardiocentro Ticino, Lugano, Switzerland; [15]Cardiac Surgery, Southwestern University of Texas, Dallas, Texas, USA; [16]Cardiac Surgery, Clinique Pasteur, Paris, France; [17]Division of Cardiac Surgery, University of Verona Medical School, Verona, Italy

Contributions: (I) Conception and design: F Nicolini, F Onorati; (II) Administrative support: None; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Francesco Nicolini, MD, PhD. Division of Cardiac Surgery, Department of Medicine and Surgery, University of Parma, Via A. Gramsci 14, Parma, Italy. Email: francesco.nicolini@unipr.it.

Background: Treatment of severe aortic valve stenosis (SAVS) is a hot topic due to improved life expectancy of general population, improvement of diagnostic tools, and consequent increased number of patients requiring aortic valve surgery. Traditional aortic valve replacement and recent transcatheter aortic prosthesis implantation have reported comparable or non-inferior mortality in randomised controlled trials (RCTs). However, RCTs have the limitation of the predefined inclusion/exclusion criteria, and cannot completely reflect the 'real clinical world'. Recently sutureless prostheses, often implanted via minimally invasive approaches, have been reported as an alternative strategy. However, their definitive impact on clinical results is not yet completely evaluated because of the limited sample size of patients population of most of published studies, based on monocentric patients series.

Methods: The aim of this prospective multicentre registry including all patients referred for aortic valve surgery and treated with all available techniques is to obtain a 'real-world' scenario of the clinical results arising from current surgical options.

Results: The research protocol enrollment phase is ongoing. Therefore we have not yet results to publish. When available, the research findings deriving from E-AVR registry will be presented in the scientific community in international congresses and published in peer review international journals in the fields of cardiac surgery and cardiology.

Conclusions: This multicenter, prospective, European registry has been designed with the aim to cast light on a lot of controversial issues, particularly those regarding the impact of patient baseline risk factors as well

as treatment methods for SAVR, with or without coronary artery bypass grafting (CABG), on the prognosis after treatment. We believe that the information derived from this registry can provide deep knowledge on the causes that lead to adverse outcomes after SAVR, to avoid them, and finally to identify the best treatment option for SAVS for each patient.

Keywords: Aortic stenosis; cardiac surgery; transcatheter aortic valve implantation (TAVI); aortic valve replacement

Received: 11 June 2018; Accepted: 18 July 2018; Published: 14 August 2018.
doi: 10.21037/jovs.2018.07.10
View this article at: http://dx.doi.org/10.21037/jovs.2018.07.10

Introduction

The prevalence of aortic valve stenosis (AS) can be correlated with the increase of life expectancy (1,2). Surgical aortic valve replacement (SAVR) has recognized the gold standard for AS, based on scientific evidence of published studies reporting improvement in symptoms and survival (3,4). This kind of surgery is performed with low morbidity, and is associated with durable efficacy results in the long-term follow-up (1,2).

For many years, the only available options in AS patients with prohibitive operative risk were maximized medical therapy or balloon valvuloplasty. However, the efficacy of these conservative therapies was limited to short-lasting symptomatic improvement, and balloon valvuloplasty is burdened from early failure with high need for repeat procedure conditioning poor short-term outcome.

Recent technological advances allowed transcatheter aortic valve replacement (TAVR) which proved to be an effective, alternative treatment modality to traditional SAVR in high-risk patients (5,6). Similarly, surgical TAVR have been reported good outcome-results in high-risk AS not amenable to interventional TAVR (5,7). Therefore, both traditional SAVR and surgical TAVR represent nowadays the surgical armamentarium for aortic valve replacement.

In the PARTNER trial cohort A, enrolling patients at high surgical risk, outcomes after TAVR and SAVR were similar up to 5 years in terms of overall mortality, cardiovascular-related mortality, stroke, or repeat hospital admission (7). Moderate or severe aortic regurgitation caused by paravalvular regurgitation was more common in patients who underwent TAVR and led to lower survival in the follow-up (8). The COREVALVE US trial reported results of TAVR in patients at increased surgical risk, demonstrating higher early and 2-year survival rates with self-expanding TAVR implantation compared with traditional surgery (9). Recently, the PARTNER 2 Investigators Trial reported that intermediate-risk patients with severe symptomatic AS had similar results in terms of death or stroke at 2 years, independently from the fact to have received TAVR or SAVR. Moreover, both procedures resulted in a similar degree of improvement of cardiac symptoms (10). Another Italian nationwide prospective registry demonstrated comparable outcome between TAVR and SAVR in intermediate-risk patients (11), but superiority of SAVR *vs.* TAVR in 2- and 3-year mortality in an exploratory subanalysis of low-risk patients (12).

Since TAVR is still burdened from periprocedural paravalvular leakage, due to the calcified native valve left in place, alternative approaches with the use of sutureless valves have been proposed after the earliest experiences. A number of sutureless valve prostheses have been developed to reduce cross-clamp times and are currently in clinical use (13-15). These sutureless valve prostheses may benefit of the conventional surgical approach allowing complete access to the aortic valve, in order to obtain complete decalcification of the annulus, and to create a pliable annulus. These findings may prevent paravalvular leakage, permit an appropriate sizing of the prosthesis into the annulus with shortened myocardial ischemia time. Implantation of sutureless valves has demonstrated safety and efficacy also through minimally invasive approaches, in order to improve inflammatory events and post-operative morbidity related to prolonged extracorporeal circulation (16,17). Several studies compared the outcomes of sutureless valves with TAVR (in patients classified as moderate- to high-risk), and reported benefits with sutureless prostheses (18,19).

However, the long-term results after implantation of TAVR or sutureless prostheses remain still unknown. This issue is of particular interest because a lot of studies reported improved long-term excellent results of recent

biological valve models (20,21), also in patients with an age younger than 65 (22), that is the threshold recommended by the recent European Association for Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC) guidelines (23). Therefore, data on the efficacy, safety and durability of these alternative biological prostheses are key-issues to extended the use of these less invasive procedure to low-risk and younger patients with AS.

Finally, it is well known that many patients with severe AS have concomitant significant coronary artery disease (CAD). Although the most consolidated strategy for these patients is contemporary SAVR and coronary artery bypass grafting (CABG), the introduction of TAVR has considerably shifted the potential optimal treatment options in this subset of patients, leaving some questions on the efficacy and late outcome unanswered. Moreover, the best interventional treatment choice for this scenario has yet to be verified, given the fact that some authors are favorable to combined PCI + TAVR, others to staged PCI and then TAVR, and finally other authors recommend reversed timing first with TAVR and then PCI (24,25).

Thus, robust medium- and long-term efficacy, and quality of life (QoL) data of TAVR compared with standard and innovative SAVR remain an important issue to further refine the clinical selection process of TAVR candidates. It seems reasonable that benefits and risks of TAVR compared with SAVR must be assessed under real world conditions. Therefore, data from a multicentre, real-world registry may provide information to support future recommendations on the use of these innovative devices.

Aim and design of the study

The results obtained by cardiac surgery can be improved with the implementation of present surgical methods and the development of new techniques based on the knowledge derived from large clinical datasets (26).

The main strengths of prospective clinical registries include a high objective scientific meaning because collected data are drawn from the standard clinical practice. Moreover, prospective clinical registries allow large sample size of patient population and then a better estimation of event rates. Thus, the researchers can investigate hard endpoints and outcomes studying general patient populations from different institutions with reduced exclusion criteria. Importantly, clinical registries can collect and analyze data on long-term outcome generally exceeding the study period of a prospective randomized trial (26). They are more practical than randomized controlled trials, require less resources, and have less rigid inclusion and exclusion criteria for patient enrollment (thus resembling better the so-called "real world" practice). Finally, results derived from registries have more scientific significance when study populations derive from different geographic areas and heterogeneous baseline clinical characteristics and undergo different perioperative treatment strategies.

The rationale of this E-AVR registry is to collect prospectively data on baseline characteristics, perioperative variables and postoperative outcome of patients undergoing SAVR, isolated or with concomitant CAD, in several European centers of cardiac surgery. Patients will be followed-up for at least 5 years after treatment.

The main aims of this study are the following:

- A comparative analysis of the early and late outcome with different surgical aortic valve prostheses;
- A specific focus on the comparison between sutureless biologic valve prostheses and conventional biological valve prostheses (either stented and stentless);
- Comparison of third generation stented biologic valve prostheses with second generation TAVR;
- Comparison of sutureless biologic valve prostheses with second generation TAVR;
- Evaluation of results with different approaches for SAVR, i.e., standard full sternotomy, minithoracotomy, ministernotomy, trans-apical and -aortic TAVR;
- Evaluation of limits and benefits of combined SAVR and CABG *vs.* SAVR and staged PCI or TAVR and staged/reversed stage/combined PCI;
- Identification of indication criteria for SAVR based on baseline characteristics;
- In case of future merging with other ongoing prospective registries of interventional TAVR, comparative analyses between interventional TAVR and surgical SAVR and/or TAVR will be accomplished.

This study has been registered in Clinicaltrials.gov. NCT03143361.

Methods

The E-AVR is an observational registry study designed to collect prospectively data on patients undergoing aortic valve surgery from 17 heart surgery centers belonging to University or community hospitals, and located in seven

countries (France, Germany, Italy, Spain, Switzerland, UK, and USA).

Inclusion criteria

Patients aged more than 18 years undergoing isolated primary or re-do SAVR, with or without associated CABG, and regardless of the etiology of the aortic valve disease, are eligible for inclusion in this prospective registry.

Exclusion criteria

Patients receiving concomitant mitral, tricuspid or aortic surgery, or other associated cardiac surgical procedures other than CABG will be excluded from this registry.

Patients will be enrolled in each institution, and their data collected in a dedicated database. The enrollment period will be 24 months. Patients will be followed-up 30 days, 6 months, 1 year, and then every year up to 5 years after surgery.

Data management and monitoring

Data will be stored in a dedicated CRF with predefined variables. Analysis and periodic auditing of data will be accomplished by an independent Central Core Laboratory. Auditing of quality of data will be performed every 6 months by checking 10% of patients. The merged and checked dataset will be available to all E-AVR investigators for scientific analyses.

Statistical methods

An independent central statistical Core Lab will accomplish all the statistical analyses derived from this registry.

Continuous variables will be reported as mean ± SD, or median and interquartile range. Dichotomous and nominal variables will be reported as counts and percentages. Missing data will not be replaced. Univariate analysis will be performed using the Mann-Whitney U test, Student's *t*-test, Kruskall-Wallis test, Wilcoxon test, Fisher exact test, Chi-square test and Kaplan-Meier test, when indicated. Multivariable analyses will be performed using logistic, linear and ordinal regression methods as well as the Cox-proportional hazards method. Propensity score as covariate or one-to-one propensity score matching will be adopted to adjust significant differences between study groups. Matching will be performed using a caliper width of 0.2 of the standard deviation of logit of the propensity score. Multiple propensity score adjusted analysis will be performed in case of multiple study groups. A Bayesian hierarchical approach will be used in case of significant between-centers variability.

Early and late endpoints

Endpoints will be defined according to current guidelines, and in particular according to Valve Academic Research Consortium (VARC)-2 (27) and mortality and morbidity after cardiac valve procedures guidelines (28). More in detail the following outcome variables will be collected:

- Early endpoints of the E-AVR registry:
  - (I) in-hospital mortality and 30-day mortality;
  - (II) post-operative stroke;
  - (III) postoperative need for inotropes;
  - (IV) postoperative need of intra-aortic balloon pump (IABP) or extracorporeal mechanical oxygenation (ECMO);
  - (V) sternal/thoracic wound infection;
  - (VI) blood losses and use of blood products;
  - (VII) nadir hematocrit;
  - (VIII) nadir hemoglobin;
  - (IX) resternotomy for bleeding;
  - (X) atrial fibrillation;
  - (XI) complete atrioventricular block;
  - (XII) need for new pacemaker (PM) implantation;
  - (XIII) acute kidney injury;
  - (XIV) acute myocardial infarction;
  - (XV) early repeat surgery;
  - (XVI) pericardial effusion requiring surgical revision;
  - (XVII) length of stay in the intensive care unit (ICU);
  - (XVIII) in-hospital length of stay;
  - (XIX) echocardiographic data of prosthesis performance;
- Late endpoints:
  - (I) overall mortality;
  - (II) cardiac-related mortality;
  - (III) stroke;
  - (IV) myocardial infarction;
  - (V) reintervention on the aortic prosthesis;
  - (VI) repeat revascularization [with percutaneous coronary intervention (PCI) or CABG];

(VII) thromboembolic events;
(VIII) bleeding events;
(IX) structural valve deterioration;
(X) paravalvular leakage;
(XI) prosthetic endocarditis;
(XII) implantable cardioverter-defibrillator/pacemaker;
(XIII) major adverse cardiac and cerebrovascular events (MACCE), defined as the composite endpoint including any of the following adverse events: overall death, stroke, myocardial infarction, PCI, and CABG;
(XIV) QoL defined according to: (preoperative, discharge, 6 months, 1 year, 5 years SF-8 questionnaire). QoL will be assessed during follow-up visits at outpatient clinics or, at least, by telephone interview;
(XV) echocardiographic data of prosthesis performance.

Echocardiographic data of prosthesis performance are defined according to the VARC-2 definitions (27).

Dissemination policy

The research findings deriving from E-AVR registry will be presented in the scientific community in international congresses and published in peer review international journals in the fields of cardiac surgery and cardiology.

Steering committee

It is constituted by a principal investigator and a representing member from each of the participating centers. The members of the steering committee have the responsibility for the quality of data through local and periodic audit. The steering committee will evaluate each study proposal and accept/reject it by voting after having evaluated the study design and discussed on its feasibility. Investigators will be eligible for authorship if they contributed substantially to study planning, data collection, data analysis and interpretation, writing and critical revision of the manuscripts. The principal investigator will finalize the database and will guarantee that each steering committee member will have a copy of the overall database. Analyses will be performed or monitored by an independent Central Core Statistic Laboratory.

Ethical issues

The study has been approved by the local Institutional Review Board/Ethical Committee of each participating centre, according to local or national guidelines for approval of registry studies. Patient's informed consent will be mandatory.

Results

The research protocol enrollment phase is ongoing. Therefore we have not yet results to publish. When available, the research findings deriving from E-AVR registry will be presented in the scientific community in international congresses and published in peer review international journals in the fields of cardiac surgery and cardiology.

Conclusions

This multicenter, prospective, European registry has been designed with the aim to cast light on a lot of controversial issues, particularly those regarding the impact of patient baseline risk factors as well as treatment methods for SAVR, with or without CABG, on the prognosis after treatment. We believe that the information derived from this registry can provide deep knowledge on the causes that lead to adverse outcomes after SAVR, to avoid them, and finally to identify the best treatment option for severe aortic valve stenosis (SAVS) for each patient.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study has been approved by the local Institutional Review Board/Ethical Committee of each participating centre (No. 10891), according to local or national guidelines for approval of registry studies. Patient's informed consent will be mandatory.

References

1. Iung B, Baron G, Butchart EG, et al. A prospective survey

of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. Eur Heart J 2003;24:1231-43.
2. Vahanian A, Baumgartner H, Bax J, et al. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J 2007;28:230-68.
3. Filsoufi F, Rahmanian PB, Castillo JG, et al. Excellent early and late outcomes of aortic valve replacement in people aged 80 and older. J Am Geriatr Soc 2008;56:255-61.
4. Grossi EA, Schwartz CF, Yu PJ, et al. High-risk aortic valve replacement: are the outcomes as bad as predicted? Ann Thorac Surg 2008;85:102-6; discussion 107.
5. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011;364:2187-98.
6. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597-607.
7. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet 2015;385:2477-84.
8. Van Belle E, Juthier F, Susen S, et al. Postprocedural aortic regurgitation in balloon-expandable and self-expandable transcatheter aortic valve replacement procedures: analysis of predictors and impact on long-term mortality: insights from the FRANCE2 Registry. Circulation 2014;129:1415-27.
9. Reardon MJ, Adams DH, Kleiman NS, et al. 2-Year Outcomes in Patients Undergoing Surgical or Self-Expanding Transcatheter Aortic Valve Replacement. J Am Coll Cardiol 2015;66:113-21.
10. Leon MB, Smith CR, Mack MJ, et al, for the PARTNER 2 Investigators. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med 2016;374:1609-20.
11. Tamburino C, Barbanti M, D'Errigo P, et al. 1-Year Outcomes After Transfemoral Transcatheter or Surgical Aortic Valve Replacement: Results From the Italian OBSERVANT Study. J Am Coll Cardiol 2015;66:804-12.
12. Rosato S, Santini F, Barbanti M, et al. Transcatheter Aortic Valve Implantation Compared With Surgical Aortic Valve Replacement in Low-Risk Patients. Circ Cardiovasc Interv 2016;9:e003326.
13. Shrestha M, Folliguet T, Meuris B, et al. Sutureless Perceval S aortic valve replacement: a multicenter prospective pilot trial. J Heart Valve Dis 2009;18:698-702.
14. Martens S, Sadowski J, Eckstein FS, et al. Clinical experience with the ATS 3f Enable Sutureless Bioprosthesis. Eur J Cardiothorac Surg 2011;40:749-55.
15. Kocher AA, Laufer G, Haverich A, et al. One year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the Edwards Intuity Valve System. J Thorac Cardiovasc Surg 2013;145:110-5.
16. Dalén M, Biancari F, Rubino AS, et al. Aortic valve replacement through full sternotomy with a stented bioprosthesis versus minimally invasive sternotomy with a sutureless bioprosthesis. Eur J Cardiothorac Surg 2016;49:220-7.
17. Dalén M, Biancari F, Rubino AS, et al. Ministernotomy versus full sternotomy aortic valve replacement with a sutureless bioprosthesis: a multicenter study. Ann Thorac Surg 2015;99:524-30.
18. Biancari F, Barbanti M, Santarpino G, et al. Immediate outcome after sutureless versus transcatheter aortic valve replacement. Heart Vessels 2016;31:427-33.
19. Santarpino G, Pfeiffer S, Jessl J, et al. Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: a propensity-matched analysis of 2 strategies in high-risk patients. J Thorac Cardiovasc Surg 2014;147:561-7.
20. McClure RS, McGurk S, Cevasco M, et al. Late outcomes comparison of non elderly patients with stented bioprosthetic and mechanical valves in the aortic position: a propensity matched analysis. J Thorac Cardiovasc Surg 2014;148:1931-9.
21. Bourguignon T, Bouquiaux-Stablo AL, Candolfi P, et al. Very long-term outcomes of the Carpentier-Edwards Perimount valve in aortic position. Ann Thorac Surg 2015;99:831-7.
22. Bourguignon T, Lhommet P, El Khoury R, et al. Very long-term outcomes of the Carpentier-Edwards Perimount aortic valve in patients aged 50–65 years. Eur J Cardiothorac Surg 2016;49:1462-8.
23. Vahanian A, Alfieri O, Andreotti F, et al. Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC), European Association for Cardio-Thoracic Surgery

(EACTS), Guidelines on the management of valvular heart disease (version 2012). Eur J Cardiothorac Surg 2012;42:S1-44.
24. O'Sullivan CJ, Stefanini GG, Stortecky S, et al. Coronary revascularization and TAVI: before, during, after or never? Minerva Med 2014;105:475-85.
25. Virk SA, Tian DH, Liou K, et al. Systematic review of percutaneous coronary intervention and transcatheter aortic valve implantation for concomitant aortic stenosis and coronary artery disease. Int J Cardiol 2015;187:453-5.
26. Hickey GL, Grant SW, Cosgriff R, et al. Clinical registries: governance, management, analysis and applications. Eur J Cardiothorac Surg 2013;44:605-14.
27. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. Eur J Cardiothorac Surg 2012;42:S45-60.
28. Akins CW, Miller DC, Turina MI, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. Eur J Cardiothorac Surg 2008;33:523-8.

doi: 10.21037/jovs.2018.07.10
Cite this article as: Nicolini F, Benassi F, Gherli R, Musumeci F, Mariscalco G, Ahmed A, Murphy GJ, Girdauskas E, Reichenspurner H, Quintana E, Castellà M, Santini F, Salsano A, De Feo M, Della Corte A, Bancone C, Sponga S, Livi U, Tozzi P, Perrotti A, Chocron S, Ruggieri V, Corbineau H, Verhoye JP, Santarpino G, Fischlein T, Rinaldi M, Salizzoni S, Ferrari E, Bajona P, Abouliatim I, Faggian G, Gherli T, Francica A, Lucarelli C, Onorati F. Aims and expectations of a prospective multicenter study on aortic valve surgery: (E-AVR registry). J Vis Surg 2018;4:172.

