Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

Enrico Cerrato, Luis Nombela-Franco, Tamim M. Nazif, Helene Eltchaninoff, Lars Søndergaard, Henrique B Ribeiro, Marco Barbanti, Fabian Nietlispach, Peter De Jaegere, Pierfrancesco Agostoni, Ramiro Trillo, Pilar Jimenez-Quevedo, Fabrizio D'Ascenzo, Olaf Wendler, Gabriel Maluenda, Mao Chen, Corrado Tamburino, Carlos Macaya, Martin B. Leon, Josep Rodes-Cabau

PII: S0167-5273(16)33561-6
DOI: doi: 10.1016/j.ijcard.2016.11.104
Reference: IJCA 23966

To appear in: International Journal of Cardiology

Received date: 7 August 2016
Accepted date: 6 November 2016


This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.
Evaluation of Current Practices in Transcatheter Aortic Valve Implantation:

The WRITTEN (WoRldwIde TAV ExperieNce) Survey

Enrico Cerrato, MD1,2; Luis Nombela-Franco, MD, PhD3; Tamim M. Nazif MD3; Helene Eltchaninoff, MD3; Lars Søndergaard, MD, DMSc5; Henrique B Ribeiro, MD, PhD6; Marco Barbanti MD7; Fabian Nietlispach, MD, PhD8; Peter De Jaegere, MD9; Pierfrancesco Agostoni, MD10; Ramiro Trillo, MD11; Pilar Jimenez-Quevedo, MD, PhD1; Fabrizio D’Ascenzo, MD12; Olaf Wendler, MD, PhD13; Gabriel Maluenda, MD14; Mao Chen, MD15; Corrado Tamburino, MD7; Carlos Macaya MD1; Martin B. Leon, MD3; Josep Rodes-Cabau, MD16*

1. Cardiovascular Institute, Hospital Clínico San Carlos, Madrid, Spain;  
2. Unified Interventional Cardiology Unit, San Luigi Gonzaga Orbassano University Hospital and Rivoli Infermi Hospital, Turin, Italy;  
3. Columbia University Medical Center/NewYork-Presbyterian Hospital and the Cardiovascular Research Foundation, New York, New York, USA;  
4. Cardiology department, Charles Nicolle Hospital, University of Rouen, Rouen, France;  
5. The heart Center, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark;  
6. Heart Institute (InCor) of São Paulo University Medical School (USP), São Paulo, Brazil  
7. Ferrarotto Hospital, University of Catania, Catania, Italy;  
8. University Heart Center, Hospital Zurich, Zurich, Switzerland;  
9. Thoraxcenter, Erasmus Medical Center, Rotterdam, Rotterdam, Netherlands;  
10. St. Antonius Hospital, Nieuwegein, Netherlands  
11. Hospital Clínico Universitario de Santiago de Compostela, Santiago de Compostela, Spain;  
12. University of Turin - Città della Salute e della Scienza Hospital, Turin, Italy;  
13. King's College Hospital, London, UK;  
14. Clinica Alemana, Santiago, Chile;  
15. West China Hospital, Sichuan University, China;  
16. Quebec Heart and Lung Institute, Laval University, Quebec City, Quebec, Canada

† E.C. and L.N.F. have equally contributed to this work

Statement of authorship: These authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.  
Funding: Fundación de Cardiología from Cardiovascular Institute, Hospital Clínico San Carlos, provided funding for the electronic web platform.  
Conflicts of interest: FN, TMN, FN, OW, and MBL are consultant for Edwards Lifesciences. All others authors have nothing to declare. OW has received research grants from Edwards Lifesciences and St Jude Medical. JR-C has received research grants from Edwards Lifesciences and Medtronic. FN is consultant for Medtronic and St. Jude Medical.

*Address for correspondence:
Josep Rodés-Cabau, MD  
Quebec Heart and Lung Institute, Laval University OR  
Quebec City, Quebec, Canada  
E-mail: josep.rodes@criucpq.ulaval.ca
Luis Nombela-Franco, MD, PhD  
Hospital Clínico Universitario San Carlos  
Madrid, Spain  
E-mail:luisnombela@yahoo.com
ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) has been adopted worldwide as the standard treatment for severe aortic stenosis in symptomatic patients at prohibitive or high surgical risk, but there are still several areas where consensus and evidence are lacking. The purpose was to obtain a global view of current practice related to TAVI with the potential to identify the main areas of consensus and divergence between centers.

Methods: An online questionnaire was distributed in centers performing TAVI including a total of 58 questions concerning pre-procedural evaluation, procedural practices and post-procedural management.

Results: The survey was completed by 250 centers (with a cumulative experience of nearly 70,000 TAVI) from 38 different countries. Heart team meetings and surgical risk scores were routinely performed in most (>95%) centers, but frailty (44%) and quality of life (28%) assessments were less frequently performed. General anesthesia remained the most frequent type of anesthesia (60% of centers), and significant variability was detected in the examinations for residual aortic regurgitation assessment during the procedure and in post-procedural ECG monitoring and temporary pacemaker implementation (from none to ≥72 hrs post-TAVI). Dual antiplatelet therapy duration post-TAVI was highly variable (1, 3, and ≥6 months in 14%, 41% and 32% of centers, respectively) and lack of consensus in antithrombotic regimen was observed in patients with atrial fibrillation requiring anticoagulation therapy (anticoagulation alone, anticoagulation+aspirin, anticoagulation+clopidogrel, and triple therapy in 28%, 37%, 26% and 4% of centers, respectively).

Conclusions The WRITTEN survey provided extensive data on current TAVI-related practice and identified important differences between centers in key aspects of pre-, intra-, and post-operative management. This highlights the urgent need for further studies and evidence-based data to guide multiple aspects of the TAVI field.

Key words: TAVI; TAVR; Real World Assessment Valvular Stenosis; Web-based Survey
INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has been widely adopted as a standard treatment for symptomatic, severe aortic stenosis in patients at high or prohibitive surgical risk [1-3]. Increased operator experience, technological developments and improvements in patient selection have significantly decreased peri-procedural complications and improved procedural success rates and clinical outcomes [2,4,5]. To date, it is estimated that more than 200,000 TAVI procedures have been performed worldwide and these numbers are expected to increase exponentially with anticipated expansion towards treatment of intermediate and low-risk patients [6,7].

There remain, however, multiple areas in the TAVI field where adequate evidence-based data or even expert consensus recommendations are still lacking [8,9]. Thus, several issues around the patient selection process remain unresolved. Similarly, there are important differences in procedural approaches and techniques for TAVI based on local clinical practice. Finally, post-procedural management varies widely by center and transcatheter valve type, particularly with respect to antithrombotic therapies and management of conduction disturbances. Therefore, we designed the WRITTEN survey, an internet-based questionnaire, to investigate current practice in TAVI centers around the world and to better understand contemporary practices related to patient selection, main technical aspects of the procedure, and post-procedural management.

METHODS

Survey design

The survey was designed by a team of interventional cardiologists (E.C., L.N-F.) and independently reviewed by a third physician with research experience in the TAVI field (J.R-C.). It was developed on a dedicated online platform (www.cardiogroup.org/TAVI/) and finally included a total of 59 questions with single (n=43), multiple (n=9) choice and open-ended (n=7) questions (supplementary material, online Table 1). The survey was designed to address five major domains related to TAVI: (i) general information about the TAVI program in each institution, (ii) the patient selection process, (iii) procedural techniques and imaging tools, (iv) post-procedural management, and (v) patient follow-up. The survey engine was built under supervision of one of the investigators (E.C.) using a dedicated web platform, PHP code language and
Oracle MySQL client as appropriate. The software allows monitoring results at all times as well as, and ongoing monitoring for survey accrual and completion was performed. The study was approved by the Ethics Committee of Hospital Clinico San Carlos, Madrid, Spain.

**Survey distribution**

At least one regional TAVI expert from each country or region was contacted and invited to distribute the survey locally. In addition, the survey was promoted through general interventional cardiology mailing lists, announcements by official societies of interventional cardiology, website advertisements (www.TCTMD.com), and personalized emails to TAVI operators. Invitations were distributed in different geographic areas simultaneously over a period of 6 months (March 2015 to September 2015). It was requested that only one individual from each TAVI center complete the survey on behalf of the entire heart team, and only one questionnaire per center was accepted. The name of each participating institution was recorded to avoid duplicate entries but was registered separately in the web engine and blinded during analysis and reporting. Participation was purely voluntary and unpaid, and all responses were kept completely confidential.

**Statistical Analysis**

Categorical variables were expressed as percentages and continuous variables as mean (SD) or median (interquartile [IQR]: 25-75th percentile or range: minimum-maximum) according to variable distribution. Comparison of qualitative variables was performed with the X$^2$ test and quantitative variables were compared with a Student t test or Wilcoxon rank-sum test. All analyses were performed using SPSS 20 (IBM, Armonk, NY, USA) or Prism graph pad version 6.0 (GraphPad Software, Inc. Ca, USA).

**RESULTS**

A total of 296 surveys were retrieved from the website. Of these, 46 (15.5%) were excluded for the following reasons: 32 were completely empty, 12 were significantly incomplete (less than 50% of valid answers) and 2 were duplications. A total of 250 (84.5%) TAVI centers completed the questionnaire adequately and were analyzed. The centers were from 38 different countries distributed in the Mediterranean region (n=96 centers, 38.4%), North America (n=64 centers, 25.6%), Northern and Continental Europe (n=52 centers, 20.8%), Central and South America (n=29 centers, 11.6%), and Asia or Australia (n=9 centers, 3.6%) as
shown in Figure 1. The name, city and country of participating centers are listed in supplementary material (online Table 2). Participating centers accounted for an overall experience of 68,936 TAVI procedures between 2005 and 2015, with a median of 46 procedures (IQR: 21 to 100; range: 10 to 600 procedures) in the year prior to survey completion (Table 1). Centers with a limitation on the annual number of TAVI procedures by their health system (n=82, 32.8%) performed a much lower number of procedures per year than those centers without a limitation (30 procedures/year, IQR: 16-65, versus 60 procedures/year, IQR: 26-128, p<0.001). The average waiting time to receive a TAVI was 1 month, ranging from 1 to 20 months.

Pre-procedural evaluation process

Heart team meetings were regularly scheduled in most (97.0%) centers with a high participation of interventional cardiologists (96.8%), cardiac surgeons (95.6%) and general cardiologists (61.6%), but low involvement of other specialists (anesthesiologists: 38.0%; radiologists: 20.8%; internists/geriatricians: 12.8%). At least one surgical risk score was used for clinical evaluation in almost all centers (99.2%), and 137 (54.8%) centers preferred to combine 2 surgical scores (figure 2A). Frailty tests were systematically performed in less than half of the centers (44.5%) and were very heterogeneous in nature (more than 20 different frailty tests were reported). Quality of life (28.2%) and 6-minute walk (21.3%) tests were rarely performed (figure 2B). Moderate or low risk patients (defined as STS score <8) represented up to 22% of the current TAVI candidates (figure 2C).

Regarding pre-procedural imaging, cardiac computed tomography (CT) was performed in the vast majority of centers (94.0%) and it was considered the gold standard for aortic annulus assessment and valve sizing in the majority (90.3%). Transesophageal echocardiography (TEE) and femoral angiography were routinely performed before the TAVI procedure in 66.4% and 49.2% of the centers, respectively. Systematic coronary angiography was performed pre-procedure in all centers, and concomitant severe coronary artery disease was usually treated before the TAVI procedure (79.6%). Deferring treatment of severe coronary disease prior to TAVI was a marginal strategy (3.6%). Physiological assessment of the severity of coronary artery disease with fractional flow reserve or instantaneous flow ratio was performed in 16.4% of the centers. In patients considered to be high risk for coronary obstruction during TAVI (low coronary artery ostia), the use of a coronary protection wire was the most common strategy (45.7%), followed by the selection of a self-
expandable valve (SEV) system (27.8%). Antibiotic prophylaxis was generally administrated before TAVI in most centers (91.4%), but high variability was observed in the dose regimen (Table 2).

**Procedural Management**

TAVI approaches, the percentage of valve type and transcatheter valve prostheses availability in the participating centers are listed in Table 2. The transfemoral approach was the most frequently used access route (median of 84% of the procedures, IQR: 80-94%) followed by the transapical approach (median: 5.0%, IQR: 0-10%). Patients with adequate transfemoral access were referred for a non-transfemoral approach in only a small minority of centers (6.6%). A fully percutaneous approach was the preferred technique for gaining femoral access in 82.5% of centers, and surgical cut-down was used in 17.5% of centers. In case of a fully percutaneous approach, the two Perclose (Abbott Vascular, Santa Clara, California) pre-closure technique was the most commonly reported for femoral artery hemostasis (57.3%). Most centers (60%) used general anesthesia in >50% of the transfemoral procedures, and local analgesia + conscious sedation was the preferred anesthesia technique in 40% of centers. Regardless, an anesthesiologist assisted with the transfemoral and subclavian approach procedures (irrespective of the type of anesthesia) in the vast majority of centers (94%). Anticoagulation during the procedure was almost universally achieved with heparin (99.6%) and was guided by activated clotting time measurements in most centers (72.4%).

Intra-procedural TEE guidance was systematically used in 46.2% of centers. Aortography, followed by hemodynamic assessment and TEE were the most common examinations used for assessing residual aortic regurgitation (AR) immediately following valve implantation (84.1%, 62.6% and 62.2% of centers, respectively) (Figure 3A). Conversely, the operators relied first on TEE (46.7%) in case of discrepancies, followed by aortography (25.2%) and hemodynamic assessment (18.4%) (Figure 3B). Whereas aortic balloon valvuloplasty was performed in most centers (84.6%) prior to valve implantation, direct implantation without valvuloplasty was routinely performed in 15.4% of the centers. No center used embolic protection devices systematically during the TAVI procedures, but 13.5% of centers reported a selective use of embolic protection devices.

**Post-Procedural Management**

Continuous ECG monitoring following TAVI was maintained during ≤24, ≤48 or ≥72 hours in 21.6%, 38.6% and 39.8% of the centers, respectively. The temporary pacemaker (PM) was removed at the
end of the procedure in the absence of new conduction disturbances in 28.6% of the centers, but major differences were observed according to valve type (48.1% and 9.8% for balloon-expandable and self-expandable valves, p=0.001, respectively) (Figure 4A). If transient atrioventricular (AV) block occurred during the TAVI procedure, a watchful waiting strategy (temporary PM maintenance and observation for a definitive indication for permanent PM implantation) was the most commonly adopted (68.8% for SEV and 70.3% for BEV, p=0.248), but a permanent PM was implanted without further delay in 8.4% of centers (12.6% for SEV and 7.2% for BEV, p=0.064) (Figure 4B). The occurrence of a new left bundle branch block (LBBB) did not alter post-procedural management in the majority of the centers (60%). However, new LBBB was considered an indication for permanent PM implantation in 15.6% of centers and for extending maintenance of the temporary PM in 18% of centers, without differences between BEV and SEV (p=0.828) (figure 4C). Further investigations of new LBBB with either electrophysiological study or transcutaneous loop recorder was reported in only 5% of the centers.

Dual antiplatelet therapy (DAPT) was the most common antithrombotic treatment prescribed at hospital discharge in patients without atrial fibrillation (AF) (89.5% of the centers), but the duration of such antithrombotic therapy varied widely among centers (1, 3, 6, 12 months and indefinitely in 14.3%, 43.8%, 35.5%, 4.6% and 0.5% of centers). A minority of centers (8.8%) reported the systematic use of single antiplatelet therapy with aspirin alone (Figure 5A). High variability in antithrombotic regimes between centers was observed in patients with AF: warfarin alone, warfarin+aspirin, warfarin+clopidogrel and triple therapy were used in 27.9%, 38.9%, 25.9% and 4.5% of the centers, respectively (Figure 5B). Left atrial appendage closure was marginally reported (<0.5%) as an alternative therapy to medical treatment. Post-discharge, patients were followed in a dedicated TAVI clinic in only half (n=137, 56%) of the centers, and the interventional cardiologist was the primary physician responsible in the majority (n=123, 89.8%). In the absence of a TAVI clinic, both interventional (n=59, 56.7%) and general cardiologists (n=44, 42.3%) took care of patients’ follow-up.

DISCUSSION

We have reported the results of the first large-scale worldwide survey to describe the current practices in TAVI field, including patient evaluation and selection, procedural practices and post-procedural
management. Our main findings can be summarized as follows: 1) whereas heart team meetings (involving cardiologists and cardiac surgeons) and surgical risks scores were widely implemented during the patient selection process, the involvement of other specialists and the use of functional and frailty tests were infrequent; 2) with respect to pre-procedural imaging, cardiac CT scan has been nearly universally adopted as the gold standard for annulus assessment and valve sizing; 3) the transfemoral arterial approach was by far the most common access route, and only a small minority of centers treated patients with adequate transfemoral access by any other approach. However, a significant variability among centers was observed in the type of anesthesia (general vs. local), as well as in the used of imaging guidance and evaluation of residual AR during TAVI procedures; 4) substantial variability was also observed among centers regarding the duration of ECG monitoring and temporary pacing post-TAVI, in addition to significant differences according to valve type. However, a higher degree of agreement was observed in the management of conduction disturbances such as peri-procedural transient AV block or new LBBB; and 5) DAPT (aspirin + clopidogrel) was the most common anti-thrombotic treatment post-TAVI, but the duration of such therapy was highly variable (ranging from 1 to 12 months). In patients requiring anticoagulation therapy due to AF, the recommended antithrombotic regimen varied widely between centers.

**Pre-procedural evaluation process**

The pre-procedural evaluation process is essential in the patient selection-process and in determining TAVI eligibility. TAVI candidates usually have several comorbidities that may impact long-term outcomes. In fact, a relatively high proportion of patients fail to experience functional improvement or even die due to non-cardiovascular causes within the months following successful TAVI [10-12], leading to a high proportion of “futile” procedures [13]. The results of this survey showed that heart team meetings have been largely adopted across centers worldwide for the evaluation of TAVI candidates as recommended by guidelines [14] and the Valve Academic Research Consortium-2 (VARC) [15]. Although the true clinical impact of the heart team in the TAVI decision-making process has not been evaluated yet, it is generally accepted that team-based, individualized decision making helps to determine the optimal treatment strategy for each patient. However, the survey revealed that the involvement of other specialists such as imaging experts, anesthesiologists or geriatricians, who might contribute to this process, is highly infrequent. The survey demonstrated that most centers used at least one surgical risk score in the evaluation process, with the
STS score being the most commonly utilized. Despite the well-recognized limitations of surgical risk scores in the TAVI arena [16] and the demonstrated incremental value of functional, frailty and quality-of-life tests [10,17-24], particularly in identifying patients unlikely to benefit from the procedure [13], these additional tests appear to be underused in current clinical practice. The reasons for this are probably multifactorial and may include time constraints and organizational issues, as well as a lack of consensus regarding the best test for evaluating frailty (up to 20 frailty tests were reported by different centers). These findings reflect the importance of further research regarding the composition of the heart team and the optimal risk scores and ancillary evaluations to be used in the TAVI population.

Although this survey was conducted before the publication of any randomized data on the treatment of moderate risk patients, up to one-fourth of the patients receiving TAVI among different centers were considered to be moderate-to-low risk surgical candidates. The shift towards the treatment of lower risk patients has spontaneously occurred together with the increasing experience of operators/centers and improvements in transcatheter valve technology [4,5]. The recent results of the PARTNER-II trial showing the non-inferiority of TAVI vs. SAVR in moderate-risk patients and TAVI superiority for those patients treated through the transfemoral approach provides the basis for formally recommending this treatment in this important group of patients [7].

**Procedural Management**

In recent years, technical developments and the improvement in complication rates have made TAVI a more simplified procedure. Use of the transfemoral approach has increased over the years [5] and this was confirmed in this survey, with up to 85% of the cases treated through this approach around the world. With the expansion of the technique to lower risk candidates with fewer comorbidities, we may expect a further increase in the rate of transfemoral procedures. Likewise, the surgical cut-down access - the standard way to access the femoral artery in the early TAVI era- has been replaced by a fully percutaneous approach in more than 80% of the centers.

There is current controversy about the need for general anesthesia in TAVI procedures [25], and the results of this survey, reporting a large variability between centers in the type of anesthesia, also reflect the lack of consensus on this important aspect of the procedure. Future studies will have to further determine the potential advantages of a minimalist TAVI approach on in-hospital infections, earlier discharge, cost-saving
and patient comfort, without jeopardizing safety. Of note, the vast majority of centers reported the presence of an anesthesiologist on most of the procedures irrespective of the type of anesthesia, and this is also an important logistic aspect of the TAVI procedure that may need further evaluation in case of the full implementation of a minimalist approach. Also, the systematic use of TEE for TAVI guidance (strategy applied by close to half of the centers in this survey) may preclude further expansion of the minimalist approach. Taking into consideration that the rate of peri-procedural complications including significant AR is much lower with the use of newer transcatheter valve platforms [26-28], TEE may be a back-up tool in case of significant AR or hemodynamic instability. Notably, aortography was the most frequent examination used to assess residual AR, probably because of its accessibility and rapidity. However, it has the disadvantages of increasing the total amount of contrast and the impossibility of determining the origin of AR (paravalvular versus central). In fact, AR assessment continues to be challenging, but TEE was the most reliable tool for the evaluation of AR according to the results of this survey. In addition, hemodynamic evaluation has become an important AR-assessment tool used in 60% of the centers and may have incremental added value in case of discrepancies between imaging tests [29]. Overall, significant divergences between centers were observed regarding the evaluation of AR post-TAVI, one of the major factors determining procedural success. This highlights the need for further studies in order to establish evidenced-based recommendations in this important procedural aspect.

Post-Procedural Management

The survey revealed several significant differences across centers in post-procedural management and follow-up. The occurrence of arrhythmias, conduction disturbances and the need for a permanent pacemaker after TAVI remain frequent complications and are a major concern. Whereas the majority of conduction disturbances and arrhythmias occur during the procedure, a significant number may also occur after 24 hours. Up to 72 hours of continuous rhythm monitoring after TAVI is recommended by the VARC-2 consensus document in order to maximize detection of conduction disturbances and arrhythmias [15], which have an important impact on clinical short and long-term outcomes [30-32]. However, almost 60% of the centers reported maintaining continuous ECG monitoring for less than 48 hours, which may result in the under-diagnosis of rhythm disturbances.
It is well established that the rates of both new-onset LBBB and the need for permanent pacemaker implantation are higher with the use of self-expandable (38-57% and 11-39%, respectively) compared to balloon-expandable valves (16-28% and 4-13%, respectively) [9,33]. Interestingly, whereas the survey revealed significant differences in the maintenance of a temporary pacemaker in the absence of new conduction disturbances according to valve type, the management of transient AV block during valve implantation and new persistent LBBB appeared to be similar between self- and balloon-expandable valves. The clinical impact of transient AV block during valve implantation remains unclear. The most commonly adopted strategy was to extend the time with a temporary PM and wait for a definitive indication of a permanent PM implantation. Transient damage of the AV conduction system has been previously reported [34] and direct permanent PM implantation in such patients may lead to a low ventricular pacing rate in the follow-up [35]. However, around 10% of the centers preferred to implant a permanent pacemaker in such patients. Similarly, the management of new LBBB has not been well defined and the survey confirmed the adoption of several different strategies. Although, patients with new LBBB have been shown to have a higher rate of permanent PM implantation during the follow-up [36-37], Ramazzina et al. reported a very low rate of ventricular pacing (<1%) in patients with permanent PM implantation immediately after LBBB occurrence, suggesting a more conservative approach in this scenario [35]. Moreover, the protective effect of PPM implantation after TAVI remains unclear, especially in very wide LBBB [38]. The relatively high proportion of patients with new LBBB, the expansion of future TAVI indications and the potential negative effect of LBBB justify additional investigations and rigorous ECG and clinical follow-up in this setting.

Bleeding and ischemic events following TAVI are common, have significant deleterious clinical impact, and may be modifiable with the optimization of post-procedural pharmacology [39,40]. In the absence of an indication for therapeutic anticoagulation, DAPT with aspirin (indefinitely) and clopidogrel has been empirically recommended by consensus of TAVI experts [16,41]. The survey showed that this recommendation was followed by the vast majority of centers, but that major differences existed in the duration of antithrombotic therapy. Importantly, data on antithrombotic treatment post-TAVI are limited to observational studies and very small randomized studies (aspirin+clopidogrel) [42]. Several larger randomized studies are currently ongoing [41] and should provide evidence-based data with respect to the optimal antithrombotic therapy strategy. In addition, about one-third of patients undergoing TAVI require an
oral anticoagulant, typically warfarin for AF [43,44]. In this setting, the absence of consensus was even more evident and according to the results of this survey, the antithrombotic regimens were highly variable. The clinical impact of ischemic and bleeding events during follow-up highlights the difficult equilibrium in this elderly and high-risk population. Therefore, the optimal pharmacological or mechanical (left atrial appendage occlusion) therapy in patients with concomitant AF undergoing TAVI should also be tested in future randomized trials.

**Limitations**

The voluntary nature of this survey has inherent limitations and may have biased the results. However, this may have been partially compensated for by the large number of centers from different regions that participated in the survey. Also, the survey provided a snapshot of TAVI practices around the world during a brief period of time and therefore does not take into account changes in practice patterns over time.

**CONCLUSIONS**

This TAVI survey provided extensive data on current practice in the TAVI field and identified important differences between centers in some key aspects of pre-, intra- and post-operative management. Whereas a general consensus was observed on the implementation of the heart team for the patient selection process, the involvement of other specialists as well as frailty examinations were largely underused. With respect to the TAVI procedure, modes of anesthesia and the method for evaluating residual AR immediately after valve deployment were highly variable. Further research for obtaining evidence-based data appears important in order to provide consistent recommendations on these important aspects of the TAVI procedure. A major lack of consensus was also observed in the post-procedural management of conduction disturbances and antithrombotic treatment (particularly regarding duration and regimen in AF patients). These differences evidenced the urgent need for well-conducted studies in this field. More than 10 years after the very first TAVI procedure and in an era in which TAVI is expanding towards the treatment of lower risk patients, the current survey evidenced a large number of uncertainties and practice differences in TAVI. To date, major research efforts have focused on showing the safety and efficacy of this procedure compared to medical or surgical treatment. It is now time to obtain further evidence-based data on several peri-procedural aspects of
this important therapy. This should translate into a more uniform practice and may also contribute to improving the results of TAVI.
ACKNOWLEDGMENTS, FUNDING AND CONFLICTS OF INTEREST:

**Funding**: Fundación de Cardiología from Cardiovascular Institute, Hospital Clínico San Carlos, provided funding for the electronic web platform.

**Conflicts of interest**: FN, TMN, FN, OW, and MBL are consultant for Edwards Lifesciences. All others authors have nothing to declare. OW has received research grants from Edwards Lifesciences and St Jude Medical. JR-C has received research grants from Edwards Lifesciences and Medtronic. FN is consultant for Medtronic and St. Jude Medical.
REFERENCES


Figure 1. Geographic worldwide distribution of participating centers.

Numbers are percentages

Figure 2. Clinical evaluation before transcatheter aortic valve implantation.

Figure 3. Procedural assessment of aortic regurgitation.

Figure 4. Temporary pacemaker monitoring and conduction abnormalities management after transcatheter aortic valve implantation according to valve type.

BEV: Balloon Expandable Valve; EP: electrophysiology; SEV: Self-Expandable Valve;

Figure 5. Antithrombotic therapy at hospital discharge after transcatheter aortic valve implantation.

VKA: vitamin K antagonist
### TABLES

**Table 1. General characteristics of participating TAVI centers**

<table>
<thead>
<tr>
<th>Total number of TAVI procedures in 250 centers</th>
<th>68,936 (18,309 in the last year)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n or median</strong></td>
<td><strong>% or IQR</strong></td>
</tr>
<tr>
<td>When was the first transcatheter valve implanted in your institution? (year)</td>
<td>2010</td>
</tr>
<tr>
<td>How many TAVI procedures have been performed in your institution to date?</td>
<td>161</td>
</tr>
<tr>
<td>How many TAVI procedures were performed in your Institution last year? (number):</td>
<td>46</td>
</tr>
<tr>
<td>Does your local or central health care system place an annual limit on the number of TAVI you can perform if yes, specify numbers per year</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>82</td>
</tr>
<tr>
<td>No</td>
<td>168</td>
</tr>
<tr>
<td>How long is your average patient waiting time to receive a TAVI? (months)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 2: Procedural TAVI management**
## Approach and procedural management

### Centers

<table>
<thead>
<tr>
<th>Approaches available (n=250)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfemoral</td>
<td>248 (99.2)</td>
</tr>
<tr>
<td>Transapical</td>
<td>174 (69.6)</td>
</tr>
<tr>
<td>Transaortic</td>
<td>143 (57.2)</td>
</tr>
<tr>
<td>Subclavian</td>
<td>97 (38.8)</td>
</tr>
<tr>
<td>Transcarotid</td>
<td>27 (10.8)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (6.0)</td>
</tr>
</tbody>
</table>

### Approach selection criteria (n=242)

- If ilio-femoral access is adequate, all patients are referred for a transfemoral approach: 226 (93.4)
- Some TAVI candidates are referred for non-transfemoral approach even if ilio-femoral arteries are adequate: 14 (5.8)
- Most TAVI candidates are referred for non-transfemoral approach even if ilio-femoral arteries are adequate: 2 (0.8)

### Percentage of valve type (n=231)

- Balloon-expandable valve: 65 (30-90)
- Self-expandable valve: 40 (15-80)

### Prosthesis available (n=250)

- Edwards valve: 205 (82.0)
- Corevalve system: 199 (79.6)
- Lotus valve: 57 (22.8)
- Direct Flow: 34 (13.6)
- Portico: 28 (11.2)
- Acurate Symetis: 12 (4.8)
- Jena Valve: 11 (4.4)
- Engager: 8 (3.2)
- Others: 5 (2.0)

### Anesthesia Regimen (n=248)

- 100% General Anesthesia: 98 (39.5)
<table>
<thead>
<tr>
<th>Anesthesia Type</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50% General Anesthesia</td>
<td>149 (60.1)</td>
</tr>
<tr>
<td>≥50% Local Anesthesia</td>
<td>99 (39.9)</td>
</tr>
<tr>
<td>100% Local Anesthesia</td>
<td>26 (10.5)</td>
</tr>
</tbody>
</table>

Antibiotic Prophylaxis (n=244)

<table>
<thead>
<tr>
<th>Prophylaxis Type</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>21 (8.6)</td>
</tr>
<tr>
<td>Only 1 dose before TAVI</td>
<td>113 (46.3)</td>
</tr>
<tr>
<td>1 dose before and 1 dose after</td>
<td>3 (1.2)</td>
</tr>
<tr>
<td>1 dose before and 2 doses after</td>
<td>106 (43.4)</td>
</tr>
<tr>
<td>1 dose before and 3 doses after</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

Values are n (%) or median, (IQR).
Figure 2
Figure 3
Figure 4
Figure 5