



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



Enrico Cerrato^{a,b,1}, Luis Nombela-Franco^{a,*,1}, Tamim M. Nazif^c, Helene Eltchaninoff^d, Lars Søndergaard^e, Henrique B Ribeiro^f, Marco Barbanti^g, Fabian Nietlispach^h, Peter De Jaegereⁱ, Pierfrancesco Agostoni^j, Ramiro Trillo^k, Pilar Jimenez-Quevedo^a, Fabrizio D'Ascenzo^l, Olaf Wendler^m, Gabriel Maluendaⁿ, Mao Chen^o, Corrado Tamburino^g, Carlos Macaya^a, Martin B. Leon^c, Josep Rodes-Cabau^{p,**}

^a Cardiovascular Institute, Hospital Clínico San Carlos, Madrid, Spain

^b Unified Interventional Cardiology Unit, San Luigi Gonzaga Orbassano University Hospital, Rivoli Infermi Hospital, Turin, Italy

^c Columbia University Medical Center, NewYork-Presbyterian Hospital, the Cardiovascular Research Foundation, NY, New York, USA

^d Cardiology department, Charles Nicolle Hospital, University of Rouen, Rouen, France

^e The Heart Center, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark

^f Heart Institute (InCor), São Paulo University Medical School (USP), São Paulo, Brazil

^g Ferrarotto Hospital, University of Catania, Catania, Italy

^h University Heart Center, Hospital Zurich, Zurich, Switzerland

ⁱ Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands

^j St. Antonius Hospital, Nieuwegein, Netherlands

^k Hospital Clínico Universitario de Santiago de Compostela, Santiago de Compostela, Spain

^l University of Turin, Città della Salute e della Scienza Hospital, Turin, Italy

^m King's College Hospital, London, UK

ⁿ Clinica Alemana, Santiago, Chile

^o West China Hospital, Sichuan University, China

^p Quebec Heart and Lung Institute, Laval University, Quebec City, Quebec, Canada

ARTICLE INFO

Article history:

Received 7 August 2016

Accepted 6 November 2016

Available online 9 November 2016

Keywords:

TAVI

TAVR

Real world assessment valvular stenosis

Web-based survey

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 59 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 h 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.

© 2016 Elsevier Ireland Ltd. All rights reserved.

* Correspondence to: L. Nombela-Franco, Hospital Clínico Universitario San Carlos, Madrid, Spain.

** Correspondence to: J. Rodés-Cabau, Quebec Heart and Lung Institute, Laval University, Quebec City, Quebec, Canada.

E-mail addresses: luisnombela@yahoo.com (L. Nombela-Franco), josep.rodés@criucpq.ulaval.ca (J. Rodés-Cabau).

¹ equally contributed to this work.

1. 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.

2. Methods

2.1. 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) 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.

2.2. 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 (from 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.

2.3. 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 χ^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).

3. 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. These 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 Fig. 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.

3.1. 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 (Fig. 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 (Fig. 2B). Moderate or low risk patients (defined as STS score < 8) represented up to 22% of the current TAVI candidates (Fig. 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 at 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 administered before TAVI in most centers

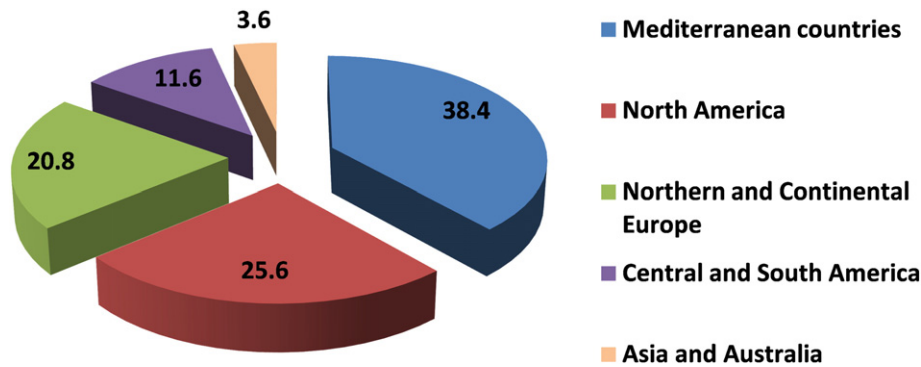


Fig. 1. Geographic worldwide distribution of participating centers. Numbers are percentages.

(91.4%), but high variability was observed in the dose regimen (Table 2).

3.2. 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) (Fig. 3A). Conversely, the operators relied first on TEE (46.7%) in case of discrepancies, followed by aortography (25.2%) and hemodynamic assessment (18.4%) (Fig. 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.

3.3. Post-procedural management

Continuous ECG monitoring following TAVI was maintained during ≤ 24 , ≤ 48 or ≥ 72 h 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) (Fig. 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, $p = 0.064$) (Fig. 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 ($p = 0.828$) (Fig. 4C). Further investigations of new LBBB with either electrophysiological study or transcatheter 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 (Fig. 5A). High variability in antithrombotic regimes between centers was observed in patients with AF: warfarin alone, warfarin + aspirin, warfarin + clopidogrel

Table 1
General characteristics of participating TAVI centers.

Total number of TAVI procedures in 250 centers	68,936 (18,309 in the last year)		Answered question
	n or median	% or IQR or range	
When was the first transcatheter valve implanted in your institution? (year)	2010	2005–2015 (range)	241
How many TAVI procedures have been performed in your institution to date?	161	64–400 (IQR) 10–2300 (range)	238
How many TAVI procedures were performed in your Institution last year? (number):	46	21–100 (IQR) 10–600 (range)	239
Does your local or central health care system place an annual limit on the number of TAVI you can perform			250
Yes	82	32.8 (%)	
No	168	67.2 (%)	
If yes, specify numbers per year	38	20–65 (IQR)	
How long is your average patient waiting time to receive a TAVI? (months)	1	1–2 (IQR)	245

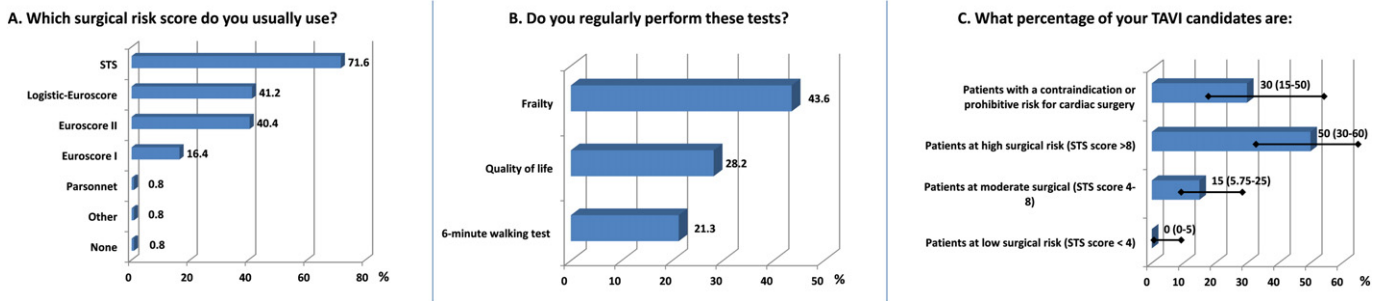


Fig. 2. Clinical evaluation before transcatheter aortic valve implantation.

and triple therapy were used in 27.9%, 38.9%, 25.9% and 4.5% of the centers, respectively (Fig. 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.

4. Discussion

We have reported the results of the first large-scale worldwide survey to describe the current practices in the 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.

4.1. 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

Table 2
Procedural TAVI management.

Approach and procedural management	Centers
Approaches available (n = 250)	
Transfemoral	248 (99.2)
Transapical	174 (69.6)
Transaortic	143 (57.2)
Subclavian	97 (38.8)
Transcarotid	27 (10.8)
Other	15 (6.0)
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)
Accurate 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)
> 50% general anesthesia	149 (60.1)
≥ 50% local anesthesia	99 (39.9)
100% local anesthesia	26 (10.5)
Antibiotic prophylaxis (n = 244)	
None	21 (8.6)
Only 1 dose before TAVI	113 (46.3)
1 dose before and 1 dose after	3 (1.2)
1 dose before and 2 doses after	106 (43.4)
1 dose before and 3 doses after	1 (0.4)

Values are n (%) or median, (IQR).

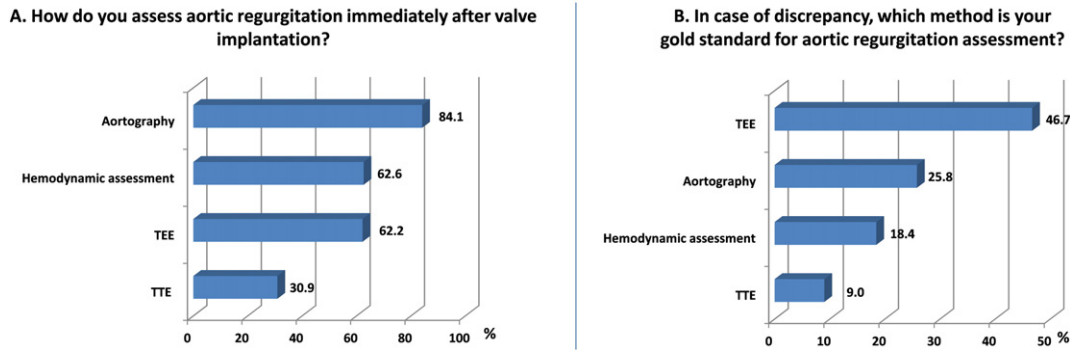


Fig. 3. Procedural assessment of aortic regurgitation.

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].

4.2. 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.

4.3. 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

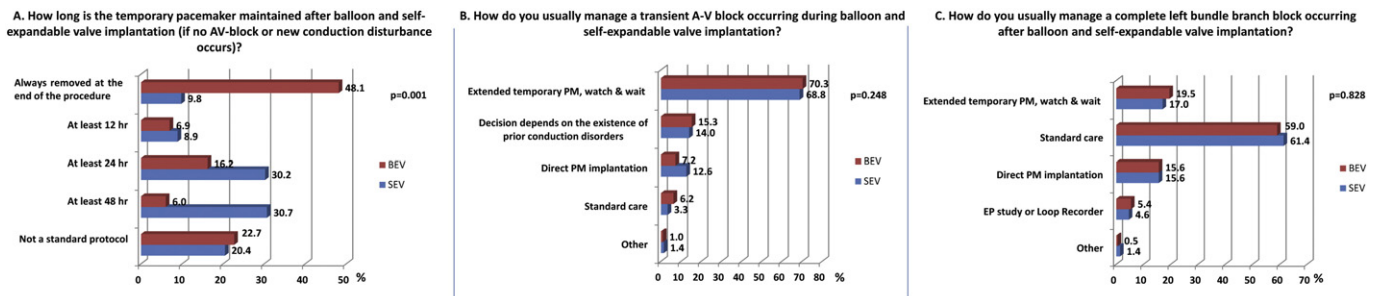


Fig. 4. Temporary pacemaker monitoring and conduction abnormalities management after transcatheter aortic valve implantation according to valve type. BEV: Balloon Expandable Valve; EP: electrophysiology; SEV: Self-Expandable Valve;

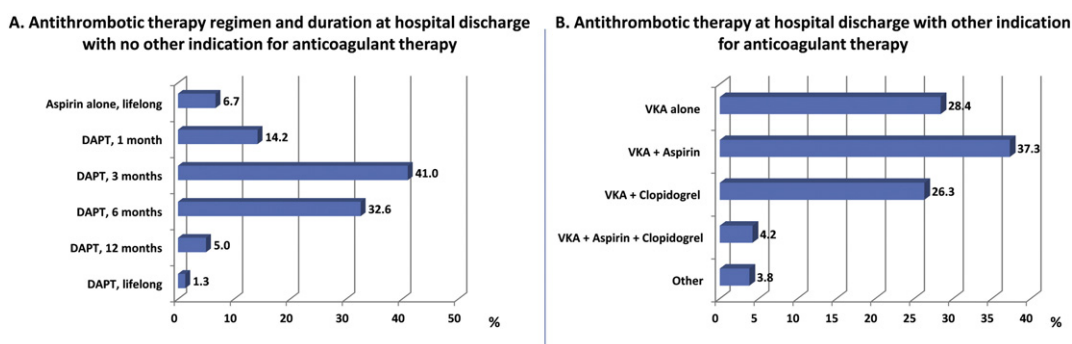


Fig. 5. Antithrombotic therapy at hospital discharge after transcatheter aortic valve implantation. DAPT: dual antiplatelet therapy; VKA: vitamin K antagonist.

after 24 h. Up to 72 h 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 h, 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 SEV (38–57% and 11–39%, respectively) compared to BEV valves (16–28% and 4–13%, respectively) [9,33]. Interestingly, whereas the survey revealed significant differences in the maintenance of a temporary PM 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 those patients with 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 [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.

4.4. 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.

5. 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.

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.

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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.ijcard.2016.11.104>.

References

- M.B. Leon, C.R. Smith, M. Mack, et al., Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery, *N. Engl. J. Med.* 363 (2010) 1597–1607.
- C.R. Smith, M.B. Leon, M.J. Mack, et al., PARTNER Trial Investigators, Transcatheter versus surgical aortic-valve replacement in high-risk patients, *N. Engl. J. Med.* 364 (2011) 2187–2198.
- D.H. Adams, J.J. Popma, M.J. Reardon, et al., Transcatheter aortic-valve replacement with a self-expanding prosthesis, *N. Engl. J. Med.* 370 (2014) 1790–1798.
- T. Walther, C.W. Hamm, G. Schuler, et al., Perioperative results and complications in 15,964 transcatheter aortic valve replacements: prospective data from the GARY registry, *J. Am. Coll. Cardiol.* 65 (2015) 2173–2180.
- D.R. Holmes Jr., R.A. Nishimura, F.L. Grover, et al., Annual outcomes with transcatheter valve therapy: from the STS/ACC TVT registry, *J. Am. Coll. Cardiol.* 66 (2015) 2813–2823.
- H.G. Thyregod, D.A. Steinbrüchel, N. Ihlemann, et al., Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: 1-year results from the all-comers NOTION randomized clinical trial, *J. Am. Coll. Cardiol.* 65 (2015) 2184–2194.
- M.B. Leon, C.R. Smith, M.J. Mack, et al., Transcatheter or surgical aortic-valve replacement in intermediate-risk patients, *N. Engl. J. Med.* 374 (2016) 1609–1620.
- J.J. Bax, V. Delgado, V. Bapat, et al., Open issues in transcatheter aortic valve implantation. Part 1: patient selection and treatment strategy for transcatheter aortic valve implantation, *Eur. Heart J.* 35 (2014) 2627–2638.
- J.J. Bax, V. Delgado, V. Bapat, et al., Open issues in transcatheter aortic valve implantation. Part 2: procedural issues and outcomes after transcatheter aortic valve implantation, *Eur. Heart J.* 35 (2014) 2639–2654.
- S.V. Arnold, M.R. Reynolds, Y. Lei, et al., Predictors of poor outcomes after transcatheter aortic valve replacement: results from the PARTNER (placement of aortic transcatheter valve) trial, *Circulation* 129 (2014) 2682–2690.
- J. Rodés-Cabau, J.G. Webb, A. Cheung, et al., Long-term outcomes after transcatheter aortic valve implantation: insights on prognostic factors and valve durability from the Canadian multicenter experience, *J. Am. Coll. Cardiol.* 60 (2012) 1864–1875.
- M. Barbanti, A.S. Petronio, F. Ettori, et al., 5-year outcomes after transcatheter aortic valve implantation with CoreValve prosthesis, *JACC Cardiovasc. Interv.* 8 (2015) 1084–1091.
- R. Puri, B. Lung, D.J. Cohen, J. Rodés-Cabau, TAVI or No TAVI: identifying patients unlikely to benefit from transcatheter aortic valve implantation, *Eur. Heart J.* 37 (2016) 2217–2225.
- R.A. Nishimura, C.M. Otto, R.O. Bonow, et al., 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, *J. Am. Coll. Cardiol.* 63 (2014) 2438–2488.
- A.P. Kappetein, S.J. Head, P. Genereux, et al., Valve academic research consortium (VARC)-2. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the valve academic research consortium-2 consensus document, *J. Am. Coll. Cardiol.* 60 (2012) 1438–1454.
- N. Beohar, B. Whisenant, A.J. Kirtane, et al., The relative performance characteristics of the logistic European system for cardiac operative risk evaluation score and the Society of Thoracic Surgeons score in the placement of aortic transcatheter valves trial, *J. Thorac. Cardiovasc. Surg.* 148 (2014) 2830–2837.
- S. Stortecky, A.W. Schoenenberger, A. Moser, et al., Evaluation of multidimensional geriatric assessment as a predictor of mortality and cardiovascular events after transcatheter aortic valve implantation, *JACC Cardiovasc. Interv.* 5 (2012) 489–496.
- M. Mok, L. Nombela-Franco, M. Urena, et al., Prognostic value of exercise capacity as evaluated by the 6-minute walk test in patients undergoing transcatheter aortic valve implantation, *J. Am. Coll. Cardiol.* 61 (2013) 897–898.
- P. Green, D.J. Cohen, P. Généreux, et al., Relation between six-minute walk test performance and outcomes after transcatheter aortic valve implantation (from the PARTNER trial), *Am. J. Cardiol.* 112 (2013) 700–706.
- M. Puls, B. Sobisiak, A. Bleckmann, et al., Impact of frailty on short- and long-term morbidity and mortality after transcatheter aortic valve implantation: risk assessment by Katz index of activities of daily living, *EuroIntervention* 10 (2014) 609–619.
- J. Alfredsson, A. Stebbins, J.M. Brennan, et al., Gait speed predicts 30-day mortality following transcatheter aortic valve replacement: results from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry™, *Circulation* 133 (2016) 1351–1359.
- P. Green, S.V. Arnold, D.J. Cohen, et al., Relation of frailty to outcomes after transcatheter aortic valve replacement (from the PARTNER Trial), *Am. J. Cardiol.* 116 (2015) 264–269.
- B.R. Lindman, J.G. Breyley, J.D. Schilling, et al., Prognostic utility of novel biomarkers of cardiovascular stress in patients with aortic stenosis undergoing valve replacement, *Heart* 101 (2015) 1382–1388.
- A. Csordas, F. Nietlispach, P. Schuetz, et al., Midregional Proadrenomedullin improves risk stratification beyond surgical risk scores in patients undergoing transcatheter aortic valve replacement, *PLoS One* 10 (12) (2015 Dec 2), e0143761.
- E.H. Maas, B.M. Pieters, M. Van de Velde, S. Rex, General or local anesthesia for TAVI? A systematic review of the literature and meta-analysis, *Curr. Pharm. Des.* 22 (2016) 1868–1878.
- V.H. Thourani, S. Kodali, R.R. Makkar, et al., Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis, *Lancet* 387 (2016) 2218–2225.
- I.T. Meredith, D.L. Walters, N. Dumonteil, et al., 1-year outcomes with the fully repositionable and retrievable lotus transcatheter aortic replacement valve in 120 high-risk surgical patients with severe aortic stenosis: results of the REPRISE II study, *JACC Cardiovasc. Interv.* 9 (2016) 376–384.
- T. Lefèvre, A. Colombo, D. Tchéhché, et al., Prospective multicenter evaluation of the direct flow medical transcatheter aortic valve system: 12-month outcomes of the evaluation of the direct flow medical percutaneous aortic valve 18F system for the treatment of patients with severe aortic stenosis (DISCOVER) study, *JACC Cardiovasc. Interv.* 9 (2016) 68–75.
- J.M. Sinning, C. Hammerstingl, M. Vasa-Nicotera, et al., Aortic regurgitation index defines severity of peri-prosthetic regurgitation and predicts outcome in patients after transcatheter aortic valve implantation, *J. Am. Coll. Cardiol.* 59 (2012) 1134–1141.
- I.J. Amat-Santos, J. Rodés-Cabau, M. Urena, et al., Incidence, predictive factors, and prognostic value of new-onset atrial fibrillation following transcatheter aortic valve implantation, *J. Am. Coll. Cardiol.* 59 (2012) 178–188.
- A. Sannino, G. Gargiulo, G.G. Schiattarella, et al., A meta-analysis of the impact of pre-existing and new-onset atrial fibrillation on clinical outcomes in patients undergoing transcatheter aortic valve implantation, *EuroIntervention* 12 (2016) e1047–e1056.
- R. Chopard, E. Teiger, N. Meneveau, et al., Baseline characteristics and prognostic implications of pre-existing and new-onset atrial fibrillation After Transcatheter aortic valve implantation: results from the FRANCE-2 registry, *JACC Cardiovasc. Interv.* 8 (2015) 1346–1355.
- M. Abdel-Wahab, J. Mehilli, C. Frerker, et al., Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial, *JAMA* 311 (2014) 1503–1514.
- J.M. Rubin, P. Avanzas, R. del Valle, et al., Atrioventricular conduction disturbance characterization in transcatheter aortic valve implantation with the CoreValve prosthesis, *Circ. Cardiovasc. Interv.* 4 (2011) 280–286.
- C. Ramazzina, S. Knecht, R. Jeger, et al., Pacemaker implantation and need for ventricular pacing during follow-up after transcatheter aortic valve implantation, *Pacing Clin. Electrophysiol.* 37 (2014) 1592–1601.
- M. Urena, J.G. Webb, A. Cheema, et al., Impact of new-onset persistent left bundle branch block on late clinical outcomes in patients undergoing transcatheter aortic valve implantation with a balloon-expandable valve, *JACC Cardiovasc. Interv.* 7 (2014) 128–136.
- A. Regueiro, O. Abdul-Jawad Altisent, M. Del Trigo, et al., Impact of new-onset left bundle branch block and periprocedural permanent pacemaker implantation on clinical outcomes in patients undergoing transcatheter aortic valve replacement: a systematic review and meta-analysis, 2016. *Circ. Cardiovasc. Interv.* 9 (5), <http://dx.doi.org/10.1161/CIRCINTERVENTIONS.115.003635>.
- M. Urena, J.G. Webb, H. Eltchaninoff, et al., Late cardiac death in patients undergoing transcatheter aortic valve replacement: incidence and predictors of advanced heart failure and sudden cardiac death, *J. Am. Coll. Cardiol.* 65 (2015) 437–448.
- J. Rodés-Cabau, H.L. Dauerman, M.G. Cohen, et al., Antithrombotic treatment in transcatheter aortic valve implantation: insights for cerebrovascular and bleeding events, *J. Am. Coll. Cardiol.* 62 (2013) 2349–2359.
- P. Généreux, D.J. Cohen, M. Mack, et al., Incidence, predictors, and prognostic impact of late bleeding complications after transcatheter aortic valve replacement, *J. Am. Coll. Cardiol.* 64 (2014) 2605–2615.
- R. Puri, O.A. Altisent, F. Campelo-Parada, M. Del Trigo, A. Regueiro, J. Rodés-Cabau, Balancing the risks of thrombosis and bleeding following transcatheter aortic

- valve implantation: current state-of-evidence, *Curr. Pharm. Des.* 22 (2016) 1904–1910.
- [42] G.P. Ussia, M. Scarabelli, M. Mulè, et al., Dual antiplatelet therapy versus aspirin alone in patients undergoing transcatheter aortic valve implantation, *Am. J. Cardiol.* 108 (2011) 1772–1776.
- [43] L. Nombela-Franco, M. del Trigo, G. Morrison-Polo, et al., Incidence, causes, and predictors of early (≤ 30 days) and late unplanned hospital readmissions after transcatheter aortic valve replacement, *JACC Cardiovasc. Interv.* 8 (2015) 1748–1757.
- [44] D.R. Holmes Jr., J.M. Brennan, J.S. Rumsfeld, et al., Clinical outcomes at 1 year following transcatheter aortic valve replacement, *JAMA* 313 (2015) 1019–1028.