ESC European Society of Cardiology

European Heart Journal - Cardiovascular Imaging (2020) **21**, 85–92
doi:10.1093/ehjci/jez066

Intra-procedural monitoring protocol using routine transthoracic echocardiography with backup trans-oesophageal probe in transcatheter aortic valve replacement: a single centre experience

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Received 29 September 2018; editorial decision 15 March 2019; accepted 25 March 2019; online publish-ahead-of-print 11 April 2019

Aim The aim of this study is to describe our 9-year experience in transcatheter aortic valve replacement (TAVR) using transthoracic echocardiography (TTE) as a routine intra-procedural imaging modality with trans-oesophageal echocardiography (TEE) as a backup.

Methods and results From January 2008 to December 2017, 1218 patients underwent transfemoral TAVR at our Institution. Except the first 20 cases, all procedures have been performed under conscious sedation, with fluoroscopic guidance and TTE imaging monitoring. Once the TTE resulted suboptimal for final result assessment or a complication was either suspected or identified on TTE, TEE evaluation was promptly performed under general anaesthesia. Only 24 (1.9%) cases required a switch to TEE: 6 cases for suboptimal TTE prosthetic valve leak (PVL) quantification; 12 cases for haemodynamic instability; 2 cases for pericardial effusion without haemodynamic instability; 4 cases for urgent TAVR. The 30-days and 1-year all-cause mortality were 2.1% and 10.2%, respectively. Cardiac mortality at 30-days and 1-year follow-up were 0.6% and 4.1%, respectively. Intra-procedural and pre-discharge TT evaluation showed good agreement for PVL quantification (k agreement: 0.827, $P = 0.005$).

Conclusion TTE monitoring seems a reasonable imaging tool for TAVR intra-procedural monitoring without delay in diagnosis of complications and a reliable paravalvular leak assessment. However, TEE is undoubtedly essential in identifying the exact mechanism in most of the complications.

Keywords transcatheter aortic valve implantation • echocardiography • fluoroscopy • intra-procedural monitoring

Introduction

Transcatheter aortic valve replacement (TAVR) has been established as a valid alternative to open heart surgery in high and intermediate risk or inoperable patients with symptomatic aortic stenosis (AS).[1,2]

Intra-procedural imaging in TAVR relies on fluoroscopic guidance, with echocardiographic imaging used as a fundamental supportive imaging modality. Indeed, intra-procedural trans-oesophageal echocardiography (TEE) offers real-time imaging throughout the procedure and may contribute to improve procedural results by ensuring guidance, prompt complications detection, and leak evaluation.[3–8]

Intra-operative TEE can be valuable for valve positioning and provides rapid and accurate information for detection of potentially lethal complications. Prompt diagnosis and subsequent treatment

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improve outcomes.[3] Although some centres choose not to use this imaging tool during TAVR,[9] other sites have advocated using TEE as the primary imaging tool,[10] reporting a significant reduction in contrast media use with no reduction in safety. As a consequence, some European and American centres adopt a so-called 'minimalist' approach with exclusively fluoroscopic and angiographic guidance under conscious sedation, without echocardiographic monitoring or with intermittent transthoracic echocardiographic assessment, demonstrating the feasibility and safety of this simplified transfemoral TAVR procedure.[9,11,12] However, despite some evidences validating the minimalist/on-demand TEE approach which may provide advantages in terms of cost/effectiveness in TAVR monitoring, there are still reluctances to endorse this strategy. Indeed, it is not recommended by current guidelines, which on the contrary, establish 2D- and 3D-TEE as the standard approach for peri-interventional guidance of TAVR.[13–15] However, recently the latest ACC Expert Consensus seems to recognize that as the volume of cases performed without general anaesthesia increases, there may be an expanding role for peri-procedural transthoracic echocardiography (TTE).[16]

Thus, in this study, we report our 9-year experience in TAVR imaging monitoring using TTE as a routine intra-procedural imaging modality with TEE as a backup.

Methods

This retrospective, single centre, observational study includes 1218 consecutive patients that underwent transfemoral TAVR at our institution between January 2008 and December 2017. All patients were evaluated by our multidisciplinary Heart Team for severe AS ($n = 1152$, 94.5%) or severe degenerated aortic bioprosthetic valve ($n = 66$, 5.4%). The pre-procedural planning included multi-slice computed tomography (MSCT), TTE, and TEE. Patients included in the study were treated with different TAVI devices: Sapien (25.3%) (Edwards Lifesciences, Irvine, CA, USA), Sapien XT (13.5%) (Edwards Lifesciences, Irvine, CA, USA), Sapien 3 (7.3%) (Edwards Lifesciences, Irvine, CA, USA), CoreValve (25.1%) (Medtronic, Fridley, MN, USA), CoreValve Evolut R (10.8%) (Medtronic, Fridley, MN, USA), CoreValve Evolut Pro (0.8%) (Medtronic, Fridley, MN, USA), Direct Flow Medical valve (7.6%) (Direct Flow Medical, Inc., Santa Rosa, CA, USA), Lotus (5.9%) (Boston Scientific, Natick, MA, USA), and Portico valve (3.2%) (St. Jude Medical, Saint Paul, MN, USA).

All procedures were performed under conscious sedation with exception of the first 20 cases (between 2008 and 2009), which were performed under general anaesthesia. Conscious sedation consisted of intravenous administration of Remifentanyl (0.025 mcg/kg/min) at the beginning of the procedure. If necessary, general anaesthesia was performed using Propofol (1–2 mg/kg) and subsequent endotracheal intubation.

Device success was defined according to the VARC (Valve Academy Research Consortium) criteria as follows[17,18]: successful vascular access, delivery, and deployment of the device, successful retrieval of the delivery system with correct position and function of transcatheter heart valve (THV).

All patients provided informed consent for both the procedure and subsequent data collection and analysis.

Intra-procedural imaging monitoring

Intra-procedural imaging monitoring relied on fluoroscopic guidance using TTE and TEE as a routine supportive imaging modality. The echocardiographic exams were performed with Vivid E9 (GE Healthcare) equipped with transthoracic MS5 and trans-oesophageal 6VT probes, iE33 (Philips, Best, The Netherlands) using X5-1 transthoracic and X7-2T trans-oesophageal probes, and Epiq 7 (Philips, Best, The Netherlands) equipped with X5-1 transthoracic probe and X7-2T trans-oesophageal probes.

With the exception of the first 20 cases, in which TEE was routinely performed, TTE was used as a routine supportive imaging modality.

The echocardiographic protocol consisted in TTE evaluation after valvuloplasty and THV deployment for final result assessment or, if a complication was suspected during procedure, by temporary interrupting fluoroscopic guidance and starting TTE examination. To assure prompt detection of complications, the echocardiographist was present in the cath-lab since the first attempt to cross the valve with the stiff wire. Once the TTE evaluation resulted suboptimal for final result assessment or a complication was either suspected or identified on TTE, TEE evaluation was promptly started under general anaesthesia (*Figure 1*).

TTE/TEE imaging protocol

After THV deployment, TTE/TEE imaging was performed for a rapid and accurate assessment of valve position, valve shape, leaflet motion, transvalvular gradients, and ventricular functions. In addition, the aetiologies of haemodynamic compromise were rapidly identified and classified as follows: acute valvular dysfunction (aortic or mitral regurgitation), tamponade physiology (chamber perforation or annular rupture), ventricular dysfunction (acute coronary obstruction or ischaemic dysfunction), aortic root catastrophe (aortic dissection or rupture), and systolic anterior motion, major bleeding and fistula.[19]

For both TTE and TEE evaluation of prosthetic valve leak (PVL), colour-Doppler images were obtained in multiple views and multiple planes to ensure complete visualization of the paravalvular regions and proper detection and assessment of all PVL jets. With TTE, the parasternal short-axis, parasternal long-axis, apical five-chamber, and apical three-chamber views were acquired. A multi-parametric approach was used for PVL evaluation by colour Doppler, taking into account the total circumferential extent of the jets, width of the jets at their origin, number of jets, path of the jet, and presence of proximal flow convergence.[19,20] The circumferential extent of the jet was measured using the short-axis plane where the vena contracta of the jet is the smallest. The circumferential extent was expressed as a percentage and, according to the 2009 ASE guidelines,[21] a value between 10% and 20% would correspond to moderate PVL, and a value >20% to severe PVL. After Valve Academic Research Consortium 2 recommendations in the 2012,[18] we used the revised cut-point values as follows: an extent between 10% and 30% corresponds to moderate PVL, and >30% to severe PVL.

Finally, a multimodality, multi-parametric, integrative approach including Doppler echocardiography, cineangiography, and haemodynamic assessment, was used to accurately define the severity of PVL and the underlying aetiology. According to the unified grading scheme, five classes of grading were used (mild, mild to moderate, moderate, moderate to severe, and severe), which allows to unify different grading scales (cineangiography—qualitative; invasive haemodynamics—qualitative; Doppler parameters—qualitative or semi-quantitative).[20]

In case of discordant PVL quantification with different modalities, final assessment of PVL grade was based on echo results.

Statistical analysis

Continuous variables were reported as mean ± standard deviation (SD) or median and categorical variables as percentage. Kappa Cohen and McNemar's statistical test were used for matched-pair data to verify if the intra-operative PVL quantification agreed with the pre-discharge

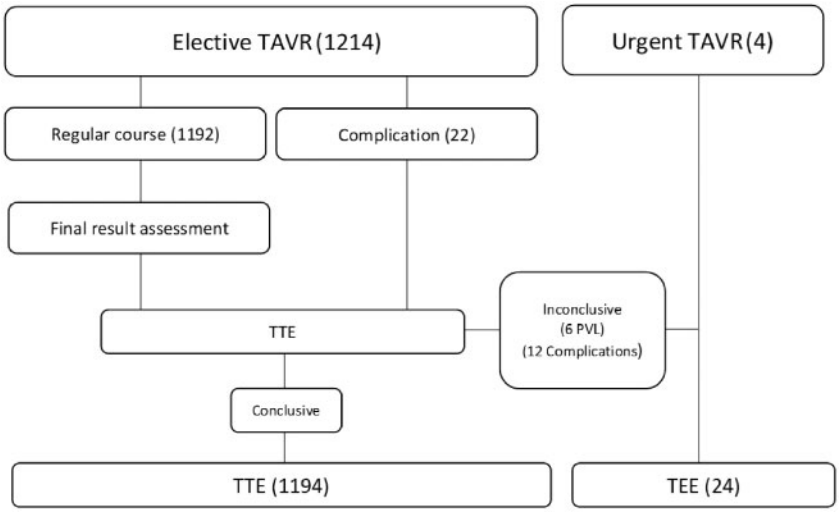

Figure 1 Study flow chart.

Table 1 Baseline population characteristics

	Mean ± SD
Age (years)	83.6 ± 8.1
Weight (kg)	69.3 ± 13.5
Height (m)	1.64 ± 0.08
BSA (m^2)	1.88 ± 0.15
STS	5.25 ± 3.01
STS MM	23.99 ± 9.18
Euroscore II	9.25 ± 3.83
Log. Euroscore	15.55 ± 10.6
NYHA class	2.4 ± 0.7
CCS	0.4 ± 0.9

BSA, body surface area; CCS, Canadian Cardiovascular Society grading of angina; NYHA, New York Heart Association class; STS, Society of Thoracic Surgeons risk score; STS MM, Society of Thoracic Surgeons risk score Morbidity or Mortality.

Table 2 Causes of switching to trans-oesophageal echocardiography

Cause	*N* tot. 24
Inconclusive PVL evaluation due to suboptimal transthoracic window	6 (0.5%)
Complications	
Haemodynamic instability	12 (1.0%)
Pericardial effusion without haemodynamic instability	2 (0.2%)
Emergent TAVR (no previous MSCT)	4 (0.4%)

MSCT, multi-slice computed tomography; PVL, paravalvular leak; TAVR, transcatheter aortic valve replacement.

evaluation. Significance level was accepted at $P < 0.05$. Statistical analysis was performed using SPSS 23 (SPSS, Inc., Chicago, IL, USA).

Results

During the index period transfemoral TAVR was performed in 1218 patients (mean age 83.6 ± 8.1 years), of whom 49% were female. Detailed characteristics of the population are provided in *Table 1*.

According to VARC criteria, 1198 patients (98.5%) underwent a successful prosthetic valve implantation. Twenty-nine (2.3%) patients had a valve embolization and underwent multiple (≥2) transcatheter valve implantations. Overall, we reported 22 (1.8%) complications: two cases of aortic rupture, two cases of aortic dissection, four cases of cardiac tamponade, two cases of pericardial effusion, two cases of severe aortic regurgitation, one case of valve dislocation in the left ventricle, one case of severe mitral regurgitation, two cases of severe left ventricular outflow tract (LVOT) obstruction, one case of intracardiac fistula, four cases of myocardial ischaemia, and one cases of cardiac arrest (occurred while crimped THV crossed extremely stenotic aortic valve). In seven cases of the previous reported complications, cardiac arrest was the initial presentation. Urgent cardiac/vascular surgery was required in 10 patients (0.8%). Three (0.2%) patients died during the procedure (one due to aortic annular rupture, two for aortic wall rupture).

The 30 days all-cause mortality and cardiac mortality after the procedure were 2.1% and 0.6%, respectively. At 1-year follow-up the incidence of all-cause and cardiac mortality were 10.2% and 4.1%, respectively; stroke and myocardial infarct were reported in 1.2% and 0.8% of patients.

The switch to TEE was needed in 24 (1.9%) patients (*Table 2*). In six cases (0.5%) TEE was performed because TTE was inconclusive for PVL quantification due to suboptimal transthoracic window. In four cases of urgent TAVR without previous MSCT evaluation, 3D-TEE was performed in cath-lab to evaluate aortic root measurements

for prosthesis sizing. In 14 cases (64% of complicated procedures) TEE was demanded to confirm or identify the underlying causes of complication (*Table 3*), and in all cases TEE was conclusive for the diagnosis. Of them, 12 cases showed haemodynamic instability: three cases for cardiac tamponade (one case of aortic annular rupture, two cases of right ventricle perforation by temporary pace-maker lead), one case for severe acute mitral regurgitation due to papillary muscle rupture (repaired by urgent MitraClip implantation, *Figure 2*), one case for ventricular septal perforation due to guidewire injury (repaired by the placement of an occluder device), two cases for ascending aorta dissections (both bicuspid aortic valves), two case for ascending aorta rupture, three cases for severe acute PVL (one case due to valve dislocation in the left ventricle). In this case, a retrieval of the valve was partially obtained by using a gooseneck catheter and a second valve implantation was needed (*Figure 3*). Finally, in two cases of haemodynamic instability in which TTE evaluation was apparently normal, TEE showed a stable peri-aortic haematoma in one of them (*Figure 4*); in the other no structural abnormality was evident, and the hypotension was probably due to vagal response. Moreover, TEE was also performed in two cases of complications without haemodynamic instability and in both cases showed pericardial effusion due to right ventricle wall lesion by temporary pacemaker lead.

To notice, TTE alone provided a definitive diagnosis of complication in eight cases (36% of all complicated cases): two cases of haemodynamic instability due to myocardial ischaemia, two cases of myocardial ischaemia without haemodynamic deterioration, one case of left ventricle anterior wall lesion leading to cardiac tamponade, two cases of left ventricle outflow tract dynamic obstruction (*Figure 5*), one case of severe aortic insufficiency due to guidewire

Table 3 Procedural TAVR complications

	Echocardiographic/ angiographic assessment
Hemodynamic instability	
Acute hypotension	Severe paravavular leak
	Valve dislocation in the LV
Severe mitral regurgitation	Papillary muscle rupture
Cardiac tamponade	Aortic rupture/dissection
	RV perforation by TPM lead
Ventricular dysfunction	Coronary occlusion
Fistula	IVS perforation by guidewire
Pericardial effusion	RV wall lesioned by TPM lead
	Aortic annular rupture
Major bleeding	Vascular accesses lesion

IVS, interventricular septum; LV, left ventricle; PVL, paravalvular leak; RV, right ventricle; TPM, temporary pace-maker.

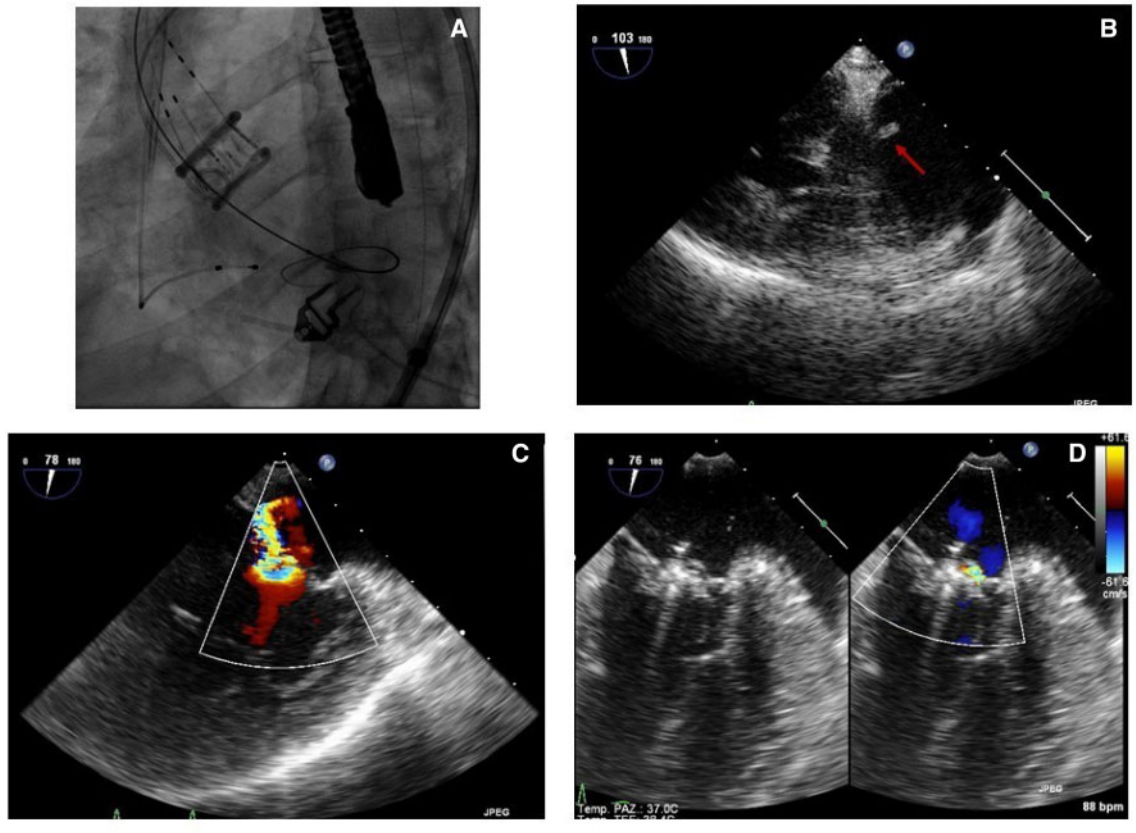

Figure 2 (*A*) Fluoroscopic imaging of Direct Flow valve implantation. (*B*) TEE transgastric view showing papillary muscle rupture. (*C*) Colour-Doppler mid-oesophageal view showing severe mitral regurgitation. (*D*) Mild residual mitral regurgitation after urgent Mitraclip implantation.

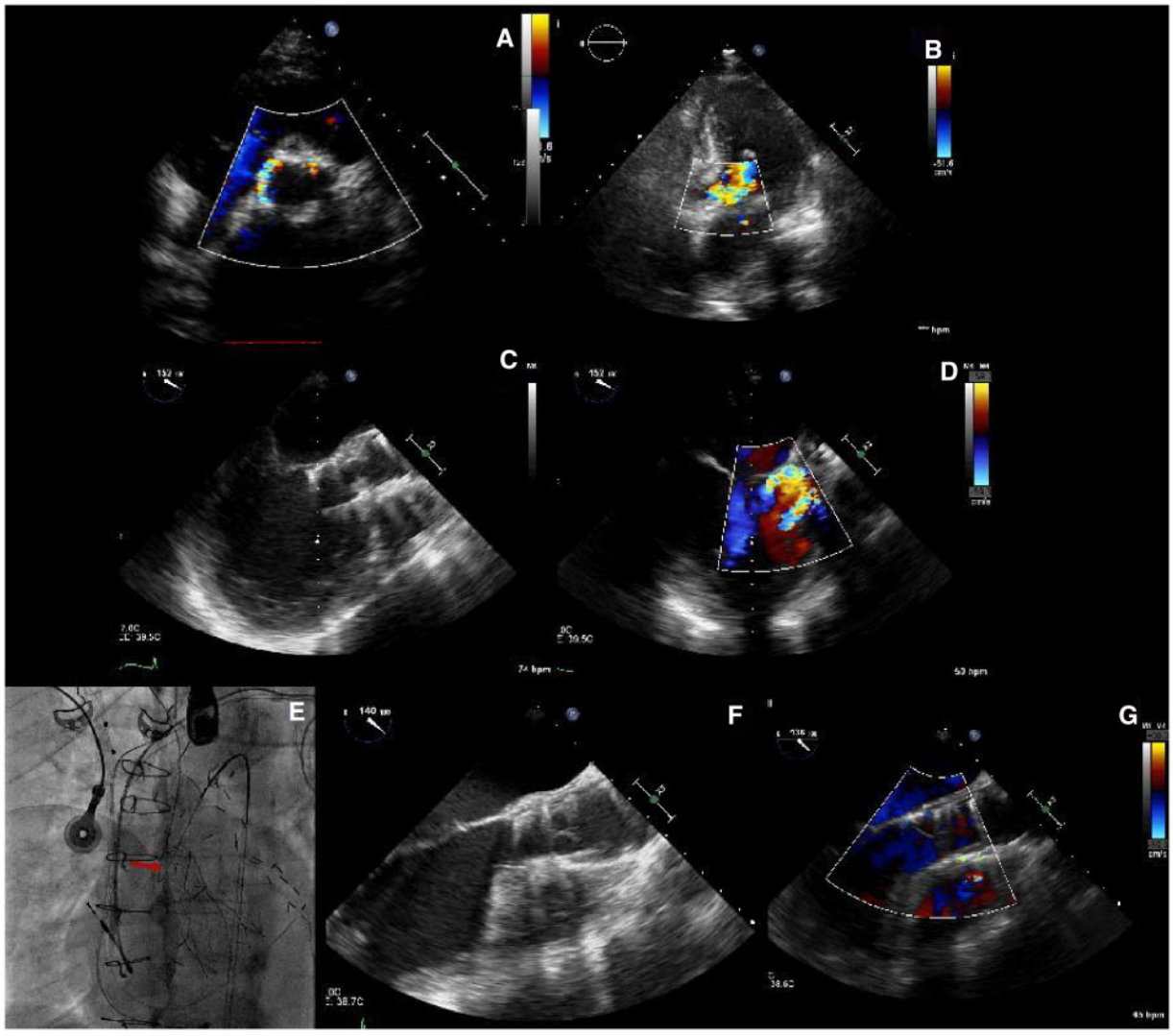

Figure 3 (*A*) TTE colour-Doppler parasternal short-axis view and apical five-chamber view (*B*) showing severe PVL. (*C*) TEE mid-oesophageal long-axis view confirming severe PVL (*D*), due to THV dislocation in LVOT. (*E*) Fluoroscopic view showing valve retrieval by the goose neck catheter. (*F*, *G*) TEE mid-oesophageal long-axis view shows the correct reposition of THV with the absence of PVL.

interference with aortic cusps and in four cases of cardiac arrest with rapid return of spontaneous circulation without mechanical complications or coronary artery occlusion.

Final result assessment

According to the integrative approach, a greater than or equal to moderate residual PVL was observed in 13% of cases. Balloon post-dilation or/and second valve implantation were used in 257 (21%) and 17 patients (1.3%), respectively, to treat PVL with effective results in most of them. At the end of the procedure only in 1.3% of cases showed more than moderate aortic regurgitation.

At intra-procedural evaluation, 39% of patients did not show any PVL, 47% presented mild PVL, 11% moderate PVL, 0.9% moderate to severe, 0.3% severe PVL; eventually, at pre-discharge TTE evaluation, 32% of patients did not show any PVL, 57% presented mild PVL, 7% moderate PVL, 2% moderate to severe, 0.1% severe PVL (K agreement 0.827 ± 0.05, 95% CI 0.703-0.912, $P = 0.005$). Finally, 86% and 89% of patients presented less than moderate PVL at intra-procedural and pre-discharge TTE evaluation, respectively (McNemar paired χ^2 test did not show a significant difference between intra-operative and pre-discharge TTE evaluation, $P = 0.24$).

Discussion

The main findings of this study are: (i) on-demand TEE approach for TAVR is feasible and not inferior compared with TEE monitoring, allowing prompt detection of complications; (ii) TTE evaluation of PVL is reliable, exhaustive in most of cases and shows good correlation with pre-discharge assessment.

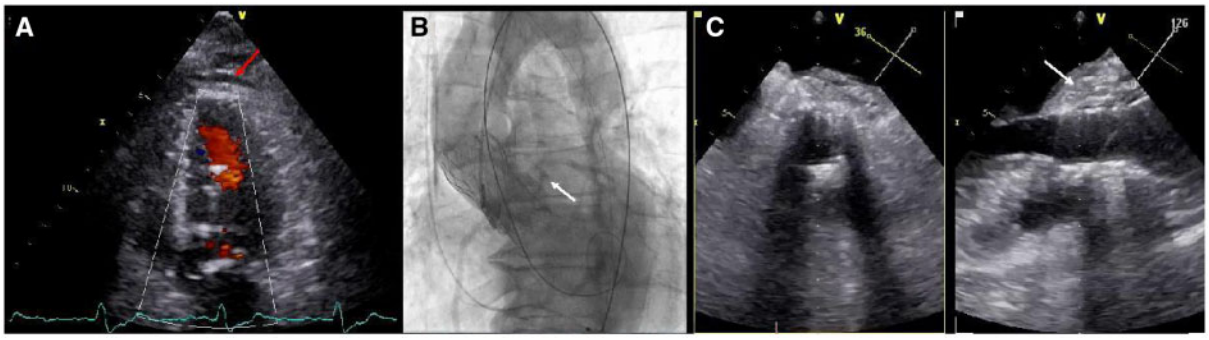

Figure 4 (*A*) TTE four-chamber view with colour Doppler, showing the absence of significant PVL and the presence of mild pericardial effusion (red arrow). (*B*) Angiographic appearance of contrast medium effusion within the aortic annulus (white arrow). (*C*) TEE simultaneous biplane view of aortic root, showing the presence of peri-aortic thickening, diagnostic for peri-aortic haematoma (white arrow).

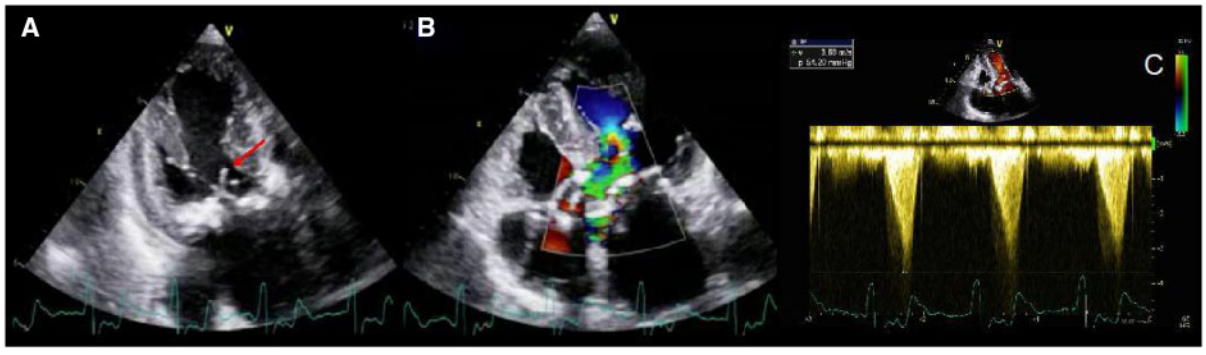

Figure 5 (*A*) TTE three-chamber view showing systolic anterior motion of anterior mitral leaflet (red arrow). (*B*) Colour Doppler shows flow acceleration in LVOT. (*C*) Continuous wave Doppler analysis confirms outflow obstruction with significant late systolic peak gradient.

In our 9-year experience, TTE monitoring, with TEE backup, looks to provide a enough imaging tool for intra-procedural TAVR monitoring. Such a minimalist approach did not prevent a rapid switch to TEE under general anaesthesia if a complication was even suspected, without delay. Although there is a world-wide trend towards simplified procedures, in recent large-scale TAVR experience (France TAVI) general anaesthesia and TEE guidance were still used in 51.7% and 31.2% of procedures, respectively.[22]

In our study, 30-day all-cause mortality (2.1%) was lower than that reported in previous trials where TEE was used as a routine monitoring tool, such as Partner II (3.9%),[23] which involved patients with similar characteristics (mean STS 5.8) or in previous experiences without TEE monitoring (5%) in intermediate-risk patients.[11] A large France database collecting TAVR procedures during the period 2007–2015, also showed higher 30-days mortality (5%).[24] Moreover, TTE alone, provided a definitive diagnosis of complication in eight cases (35%) of our complicated TAVR procedures without need for switch to TEE. The need for urgent cardiac surgery was similar to that reported in a real-word European multicentre registry (0.7%).[25]

In addition, our data highlight that the PVL evaluation by TTE is feasible and reliable in most cases despite patients are supine and acoustic window result suboptimal. The information provided by a multimodality multi-parametric integrative approach, combining echocardiographic, angiographic, and invasive haemodynamic data ensure intra-procedural final result assessment. Indeed, pre-discharge TTE evaluation, confirming in most cases the data acquired in the cath-lab, validates this strategy.

The American Society of Echocardiography recommends intra-procedural TEE imaging during TAVR.[19,26] Accordingly, a comprehensive TEE should be performed before THV deployment, in order to confirm annular sizing, evaluate the aortic valve complex and to provide additional information for stiff wire positioning, balloon aortic valvuloplasty monitoring, and valve positioning before implantation. By considering all these procedural aspects seen above, intra-procedural TEE undoubtedly offers the significant advantage of accurate real-time imaging and ability to verify procedural results.[3,15,20] It is also often advocated the ability to anticipate procedural complications but is not just an exclusive right of TEE.

Accurate pre-procedural planning and fine risk assessment should be based on a multimodality imaging (MSCT, TTE, and TEE) evaluation. Indeed, a continuous TEE guidance, by an experienced operator could not be probably able to anticipate predictable complications, if a proper pre-procedural risk profile assessment has not be adequately identified previously. In the contest of a minimalist approach, pre-procedural comprehensive TEE evaluation could be performed in echo-lab instead of in cath-lab, and the procedural steps can be effectively and safely monitored by a fluoroscopic and invasive haemodynamic integrative approach, in a setting of expert operators. Indeed, our single centre experience, confirms that the progress and the ongoing improvement in TAVR devices and delivery system combined with the growing operator experience, technical easing and in careful pre-procedural planning have significantly reduced the incidence of peri-procedural complications, allowing for more smoothly and simplified interventions under conscious sedation. In our study, TEE was undoubtedly essential in identifying the precise mechanism of complications in most cases and the switch from TTE resulted never delayed. Furthermore, 3D-TEE was fundamental in all cases of urgent TAVR without previous MSCT evaluation. It provided aortic root and annular measurements essential for prosthesis sizing, with successful subsequent prosthetic valve implantation.

Moreover, the main weakness of TEE approach remains the need for general anaesthesia and endotracheal intubation. In addition, the interaction between continuous TEE and fluoroscopy monitoring may be sometime critical, as the TEE probe may obscure in several procedural steps, fluoroscopy imaging of the aortic valve/annulus, thus a compromise in term of fluoroscopic angles or echocardiographic windows may be required.

As far a concern PVL assessment colour-Doppler TTE and TEE provide several information about the presence, location, and severity of AR by multi-windows 2D and 3D imaging approaches. Because PVL jets are often multiple, irregular, and eccentric, the imaging and grading of PVL by echocardiography is often challenging. Hence, a multi-windows, multi-parametric, integrative approach is essential to accurately assess the severity of PVL. Other modalities such as cineangiography and invasive haemodynamic, may also be useful to complement or corroborate echocardiography for the grading of PVL during the procedure. In our experience, in most of cases of discordance between imaging modalities, cineangiography lead to underestimate PVL grade, since this modality is known to be dependent on observer's experience as well as on numerous technical factors. However, echocardiographic underestimation of PVL compared with angiographic data can also occur mainly because of suboptimal acoustic window. In these cases, TEE could be considered mandatory and/or useful to better define the grade of PVL. However, as shown in our study, final PVL grading and its intra-procedural management was usually based on multi-parametric integrated data. Moreover, the increase of both mild and moderate-to-severe PVL percentage with the concomitant decrease of moderate degree cases, according to the pre-discharge evaluation, is not surprising and could be explained on the base that: (i) initially moderate PVL may improve after immediate implantation, as THV nitinol structure continue expansion adjustment, rusting in final mild PVL; (ii) fine distinction between moderate and moderate-to-severe PVL, could result difficult in cath-lab settings, in case of suboptimal supine echocardiographic window, multiple regurgitant jets, and no angiographic and/or haemodynamic data supporting one rather than the other PVL degree; (iii) haemodynamic condition during TAVR procedure may are different from the one displayed in echo-lab, because patients are under conscious sedation with blood pressure continuously monitored and controlled by in-vein therapy administration for hypertension avoidance; (iv) intrinsic difference of PVL evaluation modalities, being the intra-procedural multi-parametric (angio, echo, and invasive haemodynamics) and the pre-discharge based only on echo assessment.

This new scenario leads to an obvious dilemma, whether continuous intra-procedural TEE monitoring is still always necessary or not. Although no direct comparison between these two approaches has been made, Greif *et al.*[11] reported a combined safety endpoint by VARC criteria of 12.8% and a 30-day mortality rate of 5% in an intermediate-risk group of patients treated by minimalist approach. However, the minimalist approach should be advised in experienced centres only, as mortality was higher in one study involving patients with intermediate risk undergoing TAVR without TEE monitoring, compared with rates in Partner II.[23] Conversely other studies from experienced, high volumes centres suggest that intra-procedural TEE may not be necessary.[9,11,12,27,28] Finally, recent experiences showed a modest agreement between intra-operative TEE and post-operative TTE for PVL assessment.[20] Our findings contribute to the discussion about under/overestimation of leaks with different methods.

Alternative imaging modalities compatible with conscious sedation like intra-cardiac echocardiography (ICE), or newer 3D ICE exist, but the usefulness of these narrow sector volumetric images for TAVR require further investigation. Moreover, the acoustic shadowing from both calcium and the prosthetic valve stent will remain a significant limitation, together with the potentially increased cost.

Conclusion

Omitting TEE as a continuous imaging tool during TAVR seems not to affect procedural success with acceptable 30-day and 1-year all-cause and cardiac mortality. The lack of invasive imaging may be compensated by increasing operator experience, improved valve technology and deliverability, shorter procedural times rather and minimum use of general anaesthesia. However, the importance of imaging guidance likely depends on individual patient peri-procedural risk: patients with higher risk and complex anatomy benefiting the most from imaging.

Probably this approach may be feasible only in tertiary care centres with high procedural volume and highly experienced, where a close interaction between skilful interventional cardiologists and dedicated echocardiographers, expert in percutaneous procedure monitoring, is needed.

Conflict of interest: none declared.

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